An independent review into the cessation of maternity services provided by One to One Midwives

Final Report

August 2022

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Final report, post factual accuracy checks, legal checks and professional standards review.

Niche Health and Social Care Consulting is an independent management consultancy that specialises in supporting health care providers with all issues of safety, governance, and quality, including undertaking independent investigations following very serious incidents.

Our Report has been written in line with the terms of reference issued by NHS England in August 2020, for an independent investigation into the issues and sequence of events which led to the cessation of community maternity services provided by One to One Midwives. This is a limited scope review and has been drafted for the purposes as set out in those terms of reference alone and is not to be relied upon for any other purpose.

Events which may occur outside of the timescale of this review will render our report out-of-date. Our report has not been written in line with any UK or other (overseas) auditing standards, we have not verified or otherwise audited the information we have received for the purposes of this review and therefore cannot fully attest to the reliability or accuracy of that data or information which has been supplied by respective organisations.

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Foreword

Pregnancy, childbirth and new parenthood is, arguably, the most important time in a woman's life and that of her partner, family and support network. This is a time where women should feel supported and empowered to make decisions about their care. It is known that relational continuity during the antenatal, birth and postnatal phases of a woman's journey, leads to better outcomes for both parent and child.

NHS maternity units have, over the years, seen significant reconfigurations in order to systematise, make-safe and meet growing population demands. However, this has not always resulted in more 'choice' for women as NHS maternity services have been increasingly cost and resource pressured. There have been a number of policy initiatives in recent years that have sought to redress this imbalance. This report seeks to show the laudable attempts to translate policy into practice within the then operating context of the NHS.

Other attempts to assimilate independent, outsourced providers into the NHS have been implementable, for example mobile scanning, private pathology services, ophthalmology services, and indeed General Practice. However, in our view, assimilation of these types of services has not been as emotive and close to the heart of the NHS as maternity services and this is reflected in the media when care failings occur.

One to One Midwives was one of a small number of similar businesses over the last ten years which aimed to bridge the gap between greater choice and the NHS maternity offer; none of these businesses, to date, have survived. In line with the terms of reference for this review, this report seeks to understand some of the many complicated barriers between strategy and implementation and how better design and planning, as well as full engagement between all stakeholders, was essential to ensure the ideals of Better Births were met.

The review found that in the case of One to One Midwives, the challenges to this enhanced way of delivering maternity care proved to be numerous and ultimately insurmountable. For this (and other) independent maternity ventures to have longevity and provide real alternatives to women accessing services, there needs to be a radical rethink of how to operationalise such strategic plans. Buy-in to the service model and promotion at a senior level did not mean, on this occasion, that the new service could be successfully implemented by operational teams delivering care to women. A safe and effective care pathway with supportive and flexible joint working relationships could not be established as there was a fundamental difference in maternity care philosophy between One to One and NHS obstetric-led maternity services. Seeking assurance over quality and safety around the One to One service became increasingly problematic due to non-standard approaches and also unanticipated out-of-area growth.

There is a need for policy makers and commissioners to have a greater understanding and recognition of potential challenges by policy makers and commissioners, including the less tangible aspects such as culture and philosophy, to consider how these can be addressed before vital resources are committed to implementation. During the course of this review, the Ockenden reports[1] were published which set out a broad range of improvement measures for all NHS Maternity Services. This signals the intention that NHS providers are now being tasked to deliver on the strategic objectives of increased choice and more tailored maternity care to provide safer, better services in the future. Delivering this ambition will still require the motivation towards innovation and increasing collaboration.

Niche Health and Social Care Consulting, 2022.

[1] First report of the independent review into maternity services at the Shrewsbury and Telford Hospital NHS Trust | Ockenden Maternity Review, OCKENDEN REPORT - FINAL (ockendenmaternityreview.org.uk)

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1. Executive summary

Overview

1.1. This report has been commissioned by NHS England under the Serious Incident Framework (SIF) to review, using appreciative methods, the cessation of the independent One to One Midwives service. The index incident for this case relates to the sudden loss of service continuity for over 1,800 women who were receiving active care from One to One Midwives. This incident was, at the time, managed accordingly by the NHS to ensure the rapid repatriation of these women into NHS care. The review team have not been made aware of any additional incidents which were caused as the result of the index incident.

1.2. The expectation that a woman is able to make an informed choice about her care during pregnancy is embedded in every document from *Changing Childbirth* published in 1993 through to Maternity Matters[2] in 2007 and the National Maternity Review, Better Births[3] in 2016. The chronology of events relating to One to One Midwives provides a rich picture of the risks and considerable challenges involved in the implementation of this vision.

1.3. One to One Midwives ('One to One') aimed to support the delivery of national policy objectives to offer greater choice to all women, through a midwifery-led, community-based, case loading model. This aimed to provide a named midwife to care for a woman throughout all stages of her pregnancy from antenatal care through to birth and postnatal care. One to One were a strong advocate for home births. For women who chose or whose clinical presentation required them to go to a local NHS obstetric unit for their care during pregnancy, the intention was that shared care arrangements would be in place and the One to One named midwife would coordinate a woman's care and continue to provide support.

Summary points

1.4. Attempts to fuse together NHS and private sector provision under national initiatives has typically been fraught with challenges due to differences in philosophy, respective cultures, ways of working, legislative and regulatory environments. Despite attempts by stakeholders at a local, regional and national level to make the case loading model work, over the 10-year period of One to One's involvement with the NHS these barriers proved insurmountable.

1.5. One to One believed in 'Patient Choice'[4] and that this was not being met within NHS services because the NHS had a low threshold for risk and the focus was on making the patient fit the service rather than the service fit the patient. However, the NHS perception, based on interviews undertaken, was that this philosophy was not safe and that One to One were not appropriately managing the risks involved and ensuring an informed choice.

1.6. However, women often reported that they found the service empowering and convenient and in the majority of cases we found that women had a good experience.

1.7. Our review found a pervasive 'them and us' culture between One to One and NHS Trust maternity teams. The NMC Code sets out guidance on the professional standards required for midwifery practice, but we heard concerns from One to One about the rigidity with which NHS maternity services applied them with regard to

[2] Maternity Matters (ioe.ac.uk)
[3] national-maternity-review-report.pdf (england.nhs.uk)
[4] https://www.gov.uk/government/publications/the-nhs-choice-framework

choice and continuity of care. Furthermore, NHS maternity services told us of occasions when they had concerns on the interpretation of the standards by One to One. It was also driven by financial considerations for both One to One and NHS providers. There was a perception that a private sector provider was not part of the 'NHS family' and would drain funding from the NHS.

1.8. Maternity care often has a political element (unit closures, place of birth, access to local services), arguably not experienced in quite the same way by other NHS service lines. The last two decades have shown that when failures in maternity services occur, they are taken into the nation's heart and draw significant media attention, although this is clearly not without a proper basis. The Morecambe Bay maternity failures[5] between 2004 and 2013, and the Shrewsbury and Telford cases of deaths and brain damage between 2000 and 2019 (leading latterly to the Ockenden review[6]) show the consequences of closed cultures, poor practices, poor governance and poor operational execution of services; many of the issues that Better Births in 2016 was aiming to address.

1.9. Problematic relationships between One to One and NHS stakeholders were evident from the outset and conduct which sometimes lacked professionalism was apparent on all sides through the lifespan of One to One. These issues were not tackled directly. Had these tensions been acknowledged and addressed at an early stage, it might have been possible to develop mature working relationships, mutual trust and respect to enable the implementation of the case loading model.

1.10. Engagement as part of the introduction of the One to One model into an established system had not been sufficient to obtain the buy-in of stakeholders. Shared care arrangements could not subsequently be agreed with One to One. Our view is that the cultural barriers, some of which were caused by the philosophical impediment to the integration of NHS and private sector maternity services, could not be set aside to collaborate effectively on an initiative which offered significant benefits to many women and babies.

1.11. The service was perceived as unsafe by NHS stakeholders, and this became entrenched within the narrative and was based upon a lack of understanding of the model and informal soundings in the system rather than on substantive evidence. Quality concerns were frequently raised by NHS providers, but these were often shown to be unfounded. The lack of agreed shared care pathways was a considerable risk to the safety of both One to One and NHS Trust services. This required genuine commitment, collaboration and compromise on both sides and not enough had been done to lay the groundwork for this radical shift.

1.12. One to One clearly faced ongoing staffing challenges, due to the difficulties in resourcing a continuity of carer model which required midwives to be on call to the women on their caseload as their needs required. This model was challenging for staff in terms of their work/life balance and became unsustainable. Moves towards team-based models for continuity were not acceptable to commissioners.

1.13. We could not ascertain definitively through our work that the services provided by One to One were any less safe than those provided by NHS providers. We found that tolerances in relation to high-risk pregnancies were not properly articulated and acted upon by One to One. The profile of the issues arising was magnified for One to One due to the high level of scrutiny that was applied through the Care Quality Commission (CQC) and NHS England-led quality surveillance. However, this increased surveillance was clearly implemented because of ongoing safety fears

[5] The Report of the Morecambe Bay Investigation (publishing.service.gov.uk)
[6] Ockenden Maternity Review | Independent review of maternity care at Shrewsbury and Telford Hospitals NHS Trust

(however poorly articulated), and this is the absolute role of both NHSE and the CQC.

1.14. Routine proactive commissioning oversight of safety and quality was, on the whole, lacking and there was a reliance on other system quality surveillance mechanisms. Contract management did not provide an effective forum for quality oversight and was too localised; there was a distinct absence of systematic intelligence on and insight into incidents, complaints and audit. This considerably weakened commissioners' assurance on quality and safety and contributed to a lack of confidence in One to One's service.

1.15. The pilot and subsequent proposal from One to One did not give the required assurance on safety and quality, nor the operational and financial viability of the case loading model; however, the model was allowed to progress. The transition from pilot to award of contract was rushed and did not allow sufficient time for commissioners to properly evaluate the model and its implications through robust due diligence. Our review found that, despite very senior interventions to progress the objectives of Better Births, there was little progress made to remove the blockages and impediments to the viability of the model.

1.16. Innovation and the development of alternative models for maternity services required the NHS to work differently, with flexibility and pace to encourage diversity in the marketplace and collaboration between the NHS and the independent sector. Commissioners used a practical procurement route to introduce One to One's service quickly to the system, but this was set within the context of weakness in governance processes. The resulting uncontrolled growth through self-referrals introduced risk to women and babies as oversight was not coordinated.

1.17. As a small business, One to One struggled to replicate NHS governance requirements through its structures, policies and procedures; there were limited points of reference for this new service. Governance documentation was produced reactively and was not of a good standard. This further weakened confidence in the service.

1.18. Performance dashboard reporting was disproportionate and overly resource-intensive for commissioners and One to One. A more pragmatic approach was required with a relatively small, start-up business.

1.19. Due diligence on the safety and effectiveness of One to One's services and their financial position was inadequate. There were weaknesses in One to One's financial planning; they did not produce robust financial projections with any informed analysis to assess the various scenarios which might arise.

1.20. The contract was allowed to run on despite the serious risks emerging and implications of the company's precarious financial position. There were several early opportunities to take stock and potentially pause the further expansion of the service which were not taken. Within this context, the decision to award the co-commissioned contract in 2016 appears imprudent.

1.21. A dysfunctional tariff system and the sustainability of the business became the dominant topic of debate for several years; this was a distraction from the focus that should have been applied by One to One on quality and safety.

1.22. There was an acknowledgement in the system that the One to One model was unworkable. One to One had national attention and direct relationships with key influential figures involved in the National Maternity Review to whom they directly escalated their concerns. However, this did not lead to resolution as, to this type of private provider, the NHS seemed 'hidebound' with restrictions and regulation.

1.23. The debt and tariff issues were key contributory factors to One to One's demise and required a prompt response by commissioners and NHS Improvement (NHSI). Locally, commissioners felt unable to act despite a clear destabilisation of the system and risks to the safety of women as a result. The NHSI audit recommendations for changes to the pricing model were not acted upon, and subsequent tariff reform proposals came too late for One to One.

1.24. There were clear efforts made and much senior resource expended to develop contractual solutions to allow One to One to continue to operate on a financially sustainable footing. NHS England and NHS Improvement (NHSE/I) and predecessor organisations acted in a supportive role to commissioners locally to try to find solutions. There was positive collaboration between Clinical Commissioning Groups (CCGs), NHSE regional leads and the national Choice Team, NHS Trusts and One to One to explore the principles of a prime provider/sub-contracting model. These proposals were not able to be implemented by NHS Trusts due to perceived risks and financial disincentives.

1.25. One to One believed they were part of a significant shift in commissioning and that their model was shaping market development, arguably, this should have been a fair assumption. This illustrates the issue of national policy not translating effectively into workable practice as even through their direct relationships with key figures involved in the National Maternity Review, progress was not forthcoming.

1.26. Solutions needed to be found which were able to be implemented locally with the appropriate governance upwards through the NHS system as required. Our review found that greater collaboration and pragmatism were required at all levels from strategic inception to care delivery. Far greater translational work was required to ensure that the objectives of Better Births could be implemented at a local level.

1.27. The National Maternity Review has led to some NHS Trusts developing alternative models for maternity services, including continuity of carer models. However, in the 10 years prior to this, One to One had been a pioneer in the North West, and undertook the groundwork involved in establishing a community-based, case loading model. The contribution of One to One in laying the foundations for the future development of this model within the NHS should be acknowledged, and the learning identified taken forward to encourage further controlled innovation for the benefit of women and babies.

1.28. Although predating the publication of the second Ockenden Review (2022)[7], Better Births was taking all maternity services in the same direction; it may still be some time before continuity of care is consistently available across the country. There may therefore be a need to commission bespoke services in the future and the learning from this review should be key in helping to underpin how this might work.

More recent developments

1.29. Subsequent to the timeline covered for the terms of reference for this review, there have been some significant developments to enhance focus on safe maternity care. The first Ockenden Report published in December 2020, made some key recommendations following a review of maternity services at Shrewsbury and Telford Hospitals NHS Trust. The report found that despite considerable progress having been made in improving maternity safety, there remained too much variation in experience and outcomes for women.

1.30. The report's findings were focussed on the immediate learning for NHS maternity units. Several aspects were discussed around shared care, governance, risk

[77] OCKENDEN REPORT - FINAL (ockendenmaternityreview.org.uk)

management and oversight of serious incidents, which echo the findings of our review and are just as pertinent for community-based providers. Key weaknesses found were:

- the ongoing risk assessment of women, joint decision-making and informed consent concerning place of birth;
- evidence of midwives practising without the appropriate level of competency and a failure to escalate when necessary;
- poor consultant oversight for high-risk women;
- problems with the monitoring of fetal wellbeing;
- a lack of antenatal multidisciplinary team planning for women with high-risk factors and a frequent failure to recognise a woman's deterioration; and
- the robustness of serious incident investigations.

1.31. The report's recommendations for immediate and essential action are set out below.

Ockenden Report – Immediate and Essential Actions
1. Safety in maternity units across England must be strengthened by increasing partnerships between Trusts and within local networks. Neighbouring Trusts must work collaboratively to ensure that local investigations into Serious Incidents (SIs) have regional and Local Maternity System (LMS) oversight.
2. Maternity services must ensure that women and their families are listened to with their voices heard.
3. Staff who work together must train together.
4. There must be robust pathways in place for managing women with complex pregnancies.
5. Staff must ensure that women undergo a risk assessment at each contact throughout the pregnancy pathway.
6. All maternity services must appoint a dedicated Lead Midwife and Lead Obstetrician, both with demonstrated expertise, to focus on and champion best practice in fetal monitoring.
7. All Trusts must ensure women have ready access to accurate information to enable their informed choice of intended place of birth and mode of birth, including maternal choice for caesarean delivery.

1.32. NHSE/I acted promptly to implement clear and robust oversight of the implementation of the Ockenden recommendations. Immediately following the publication of the report, NHSE/I wrote to all NHS Trusts and commissioners to confirm requirements and highlight the priorities for immediate action[8]. NHSE/I also developed an assurance assessment tool for Trust Boards for completion by January 2021 and submission to Local Maternity Systems through to NHSE regions and up to the National Maternity Transformation Board. The deadline for completion of the tool was extended to mid-February 2021 due to the impact of the Covid-19 pandemic.

1.33. In March 2021, a paper to NHSE/I's Public Board provided an update on progress. Key actions reported were:

[8] NHS England » Ockenden review of maternity services

- the Board assurance tool for local, regional and national oversight had been completed by all Trusts providing maternity services;
- the national governance structure had been strengthened to include early intervention and support through the Maternity National Safety Champions, the Maternity Quality and Safety Assurance Committee, Local Maternity Systems and the National Maternity Safety and Surveillance Concerns Group (established in 2020).
- a safety culture development programme for leaders across maternity services had been commissioned;
- investment had been made in increasing workforce capacity to allow teams to train together to improve multidisciplinary team working;
- a survey of midwife numbers and requirements with Health Education England had been completed and an obstetric workforce tool was under development; and
- a digital tool had been developed so that women and their families can record their wishes and consent.

1.34. Additional investment of £95m has been made available in 2021/22 to support these work programmes and further developments, including the introduction of new roles: a regional obstetrician, a Deputy Chief Midwife, Maternity Improvement Advisors, and an Independent Senior Advocate to ensure consistency in services across the country.

2. Key findings and recommendations

2.1. Our recommendations for improvement and learning based on the detailed findings in this report are set out below under each key theme; we have focussed on the most important findings. We have also developed a case study which has been shared with NHSE/I (under separate cover) to support implementation of the learning from this review.

2.2. As a summary, we set out below a set of eight core recommendations which capture the recommendations made under each key theme.

Core recommendations

1. Proposals for new maternity service models should be comprehensively tested before commitment to implementation through robust pilot evaluation and business case scrutiny, including consideration of procurement route.
2. Commissioners should consider whether maternity services can be improved through offering choice but should only contract with providers which can demonstrate the ability to meet local service specifications, quality standards and contractual terms required for the safe delivery of high risk services.
3. Engagement work with relevant stakeholders should be prioritised to assess the potential barriers to effective joint working before the introduction of a new maternity model into an established NHS system.
4. Governance of maternity services including - due diligence, contract award and management, finance, quality and operational oversight - involving smaller providers, especially from the independent and voluntary sectors, must be improved at a system and local level. This must be proportionate and must include involvement of the provider in Local Maternity System arrangements for oversight.
5. Service specifications for new service models for maternity services must be tested with all stakeholders involved in shared care arrangements; service specifications and annual reviews must include scrutiny by an external obstetrician and an external midwife.
6. The Care Quality Commission and NHS Resolution should consider the findings from this review to determine whether any changes are needed to their maternity inspection and assessment processes.
7. The NHS National Maternity Team should consider the learning from the case study in terms of the future development and implementation of any new or prospective national maternity policy
8. Maternity services' commissioners, national policy makers, Local Maternity Systems, Integrated Care Boards and regulators should read the findings of this review to support future commissioning, policy and contract decisions.

Theme 1: Quality and safety

2.3. One to One's quality governance arrangements were not sufficiently defined to allow a full picture to be gained of governance structures and processes. There was evidence of appropriate governance groups operating below Board level with senior representation; however, it was unclear how the Board scrutinised and gained assurance on safety and quality issues as a collective. There was no independent representation for quality governance on any existing governance forums.

2.4. We were told that over time, there were many changes in roles and responsibilities for governance below Director level, which were not conducive to the establishment of solid and consistent governance arrangements.

2.5. Repeated concerns were raised by the CQC regarding fundamental weaknesses in One to One's quality governance arrangements, including the robustness of policies and procedures, risk management, clinical audit and medicines management.

2.6. A suite of policies and procedures was maintained but we found weaknesses in the governance arrangements over policy development. We were told that there was a lack of a structured and robust approach to the development of clinical policies which were frequently developed in a rushed, reactive way in response to requests from commissioners and the CQC.

2.7. Multiple weaknesses were identified by the CQC around clinical audit processes and the CQC were not assured that processes were effective in providing assurance on safe care and treatment. We found that information on audit outcomes was insufficient for learning purposes.

2.8. The quarterly Quality Reports produced by One to One were concise and well presented. They provided a good basis for further development for internal and external assurance purposes. The safety section of the reports required strengthening by a focus on themes, learning and actions from audit, incidents and complaints. In addition, workforce metrics should have been included as a key aspect of safety.

2.9. Based on the evidence available to our review, we were not assured that One to One had systematic, robust quality governance processes in place to ensure the safe care and treatment of all women. If One to One had been able to demonstrate a good standard of internal quality governance to commissioners and NHS providers, this might have strengthened confidence in their service and willingness to collaborate.

2.10. One to One staff were very conscious of the need for women to make an informed choice and for the documentation on that choice to be explicitly recorded. However, there was clear evidence of concerns in this regard which were confirmed by our review of clinical case notes.

2.11. Women not deciding the place of birth until late in their pregnancy or during labour created tensions with the local maternity providers who often only became aware of a woman when she transferred to them in labour. The safety of women and babies was also compromised by this practice.

2.12. One to One accepted women of all risk profiles for care as the core ethos of the company was to offer more choice to all women. This was identified as a concern by local maternity providers when high-risk women transferred to them, and by the CQC who raised concerns about the training of midwives to care for high-risk women.

2.13. There were unacceptable risks to the safety of care and treatment, due to the absence of formal shared care agreements and robust information sharing protocols between One to One and NHS Trusts.

2.14. Over its lifetime, One to One faced ongoing staffing challenges due to the difficulties in staffing a continuity of carer case loading model which was challenging for staff in terms of their workload and work/life balance. Recruitment and retention of staff was identified as a high risk on One to One's risk register. There were gaps in the skills of midwives and evidence of a significant proportion of midwives being relatively recently qualified. This was identified as a concern by the CQC.

2.15. Attempts were made to address some of the staffing and financial challenges such as the use of a team-based model rather than full case loading, recruitment of an in-house obstetrician and a move to self-managed regional teams. However, these operational changes were not acceptable to commissioners who had commissioned a full case loading model.

2.16. Our review of clinical records found that there was an over-reliance on the use of tick boxes in the notes which does not provide sufficient evidence of the discussions with women to support decision-making. There was no evidence that appropriate handover documentation was shared with local NHS Trusts and GPs. There was insufficient evidence to determine whether the electronic notes were made contemporaneously.

2.17. The key themes arising from our review of incidents were poor communication between One to One and NHS providers and the lack of shared care arrangements, inappropriate risk management and delays in transferring women to obstetric care.

2.18. The absence of an identified single lead commissioner to coordinate the management of and assurance for all incidents involving One to One was a significant risk management issue, given the issues experienced around shared care. Prior to 2017, this lack of oversight and leadership resulted in there being no coherent, evidence-based assessment of and opinion on the safety of the service.

2.19. Our analysis of 137 incidents highlights clear inconsistencies in the level of reporting of incidents between CCGs. Our review of 17 incidents provided by commissioners found examples of incidents not being closed off or being closed without the appropriate evidence to support this action. There were also some significant delays between the reporting and discussion of incidents at the CCG Serious Incident Review Group (SIRG). Furthermore, there was insufficient depth of exploration of the factors involved in incidents and limited assurance on associated learning.

2.20. There were weaknesses in the approach by the SIRG, for example, the group did not use a Closure Checklist and there was a lack of constructive feedback and support to One to One to improve the quality of investigations, reports and embed the learning.

2.21. The lack of a coherent, verified data set about incidents involving One to One's care, combined with failings in system oversight, allowed for the continuation of a belief by NHS stakeholders that One to One was not clinically safe. This perception was not properly tested.

2.22. One to One did not report its financial position as a serious incident, despite there being significant implications for the safety and quality of their services.

Recommendations

1. As part of due diligence, commissioners should assess the governance arrangements in place with independent sector providers to ensure they will meet their expectations for delivery of NHS-funded services.
2. Proportionality should be exercised for small businesses in terms of how commissioners and regulators assess governance arrangements in the independent sector.
3. Commissioners should consider a contractual requirement for an independent clinical representative on the Board of small, family-run businesses providing NHS-funded services.
4. A single governance forum for safety and quality with appropriate senior clinical representation and standardised performance reporting should be a

core requirement for independent sector providers so that commissioners can link into this forum for more robust assurance.

5. NHSE/I (and their successor body) should consider the guidance for commissioners regarding the overview, management, and assurance of incidents where there are complex care pathways with multiple providers, to ensure that there is clear accountability for oversight of all serious incidents. This should include reference to incidents where a service is being provided under non-contracted activity arrangements.
6. The regional teams of NHSE/I (and their successor body) should provide guidance to commissioners on the circumstances under which financial pressures on an organisation should be a reportable incident.
7. Commissioners should review serious incident management processes to ensure these are robust in terms of identifying and managing incidents that involve care from more than one provider.
8. Commissioners should consider implementing the serious incident Closure Checklist to support the review of investigations and reports, and to be assured that they meet the required standard. The Checklist can then be shared with providers to support their learning.
9. Commissioners should invite providers to attend the Serious Incident Review Groups when their serious incident reports are reviewed.
10. Commissioners should consider how they can be assured that they have oversight of low level incidents recorded by providers to allow the identification of trends and themes.

Theme 2: Implementation of national policy

2.23. Over the 10-year relationship between One to One and the NHS, national policy did not provide a sufficiently developed framework to allow an independent sector maternity provider to thrive within the NHS infrastructure. There was no evidence that national policy was taken through a design stage to test the feasibility of a shared care arrangement between an NHS and independent sector provider to understand some of the risks and challenges that might emerge.

2.24. Key recommendations made by Better Births[9] were not implemented and we did not find any evidence of consideration of national funding to pump prime investment by providers in the case loading model.

2.25. Responsibility for delivery of national policy rested with Local Maternity Systems. These partnerships only came into being after the publication of Better Births in 2016. Before this, there was no dedicated structure for oversight of delivery of national policy objectives.

2.26. Many of the recommendations from Better Births came too late to allow the One to One scenario to be recalibrated as the service was well established and the tariff and relationship problems were already entrenched in local systems

2.27. Policies on Choice, Any Qualified Provider (AQP) and the Who Pays guidance (see section 10; paragraphs 10.11 onwards) were not aligned and conducive to the successful delivery of the One to One model. Furthermore, they were technically complex and in some areas could be subject to different interpretations. One to One and some commissioners disagreed on whether the guidance in place following

[9] national-maternity-review-report.pdf (england.nhs.uk)

award of the contract in 2011, meant that self-referrals would be authorised and paid for. The maternity pathway payment challenges had not been worked through. Better Births acknowledged the financial disincentives and recommended reform of the system, but this did not happen during the lifetime of One to One.

2.28. Locally, commissioning focus on implementing Better Births varied as there were other significant priorities driven by financial challenges. Birth rates were reducing, and the sustainability of some maternity units was uncertain. Prior to 2016, progress by NHS Trusts in developing alternative models to provide greater choice and continuity of care was slow and significant interest in the case loading model only became apparent in 2019.

2.29. As national policy evolved, it was recognised that the full case loading model was of particular value for women with more complex needs. However, the model was implemented for all women in the areas in which One to One operated without considering this aspect.

2.30. Recent evaluation of the implementation of national policy notes good progress on continuity of care which had mainly been driven by the redesign of services offered by NHS Trusts rather than the involvement of the independent sector. However, it identified gaps in provision for women in some vulnerable groups.

Recommendations

1. Future proposals for new models to support the delivery of national maternity policy should be comprehensively tested from a clinical, operational, and financial perspective, with scrutiny of the business case and the implementation plan before commitment to and roll-out of the service.
2. Local Maternity Systems should be tasked with direct responsibility for monitoring progress on such initiatives. These forums should provide a single point of oversight for service developments, pilots and evaluation. We note that the recommendations on governance from the Ockenden Report strengthen the role of Local Maternity Systems in this regard.
3. Pilot evaluation should consider the impact on the wider system and include system-wide engagement and deliberation with all stakeholders involved. The potential risks of the cultural barriers involved in bringing the independent sector into an established NHS infrastructure should be assessed.
4. For new, innovative service models of significance to national policy, specific funding should be considered to pilot and pump prime investment in a new service to stimulate greater market interest.
5. Mainstreaming of a new service should be at a prudent pace to allow full consideration of issues and risks raised as well as re-evaluation at milestone points.
6. In line with national policy, commissioners should consider how to encourage innovative proposals for maternity care which are focused on plugging the gaps in provision which still exist, for example, access to continuity of care for women from vulnerable groups.

Theme 3: Due diligence

2.31. Wirral Primary Care Trust were proactive in attempting to drive innovation to improve services locally and it was reasonable to test an unproven service model through a preliminary pilot. However, the pilot was not comprehensive and therefore did not provide proof of concept.

2.32. There was a fundamental failure in governance processes around the development of the pilot before any decision to commission the service. The transition from pilot to award of contract was rushed and did not allow sufficient time for commissioners to properly evaluate the model and its implications.

2.33. The One to One model was the only option considered and we found no evidence of their proposal being scrutinised from a quality, safety or financial perspective. Horizon scanning was limited and there was a missed opportunity to learn from the experience of the Albany Midwifery Practice, which operated in London between 1997 and 2009 (see paragraph 9.27), and which had similarities with One to One.

2.34. There was an absence of commercial challenge or demonstration of understanding of the potential risks to a new start-up business, for example, access to external finance, cash-flow, initial set-up costs and therefore a need for commitment and guaranteed activity levels. There was no evidence that the potential serious impact of high insurance premiums was debated.

2.35. One to One's contract was allowed to run on from 2011 to 2016 without any significant review of how the service was working from an operational or financial perspective. This was despite alerts raised since 2012 by One to One and NHS providers about financial viability, safety and integrated working.

2.36. There were some examples of comprehensive due diligence being undertaken by commissioners and NHS Trusts involved with One to One. The exercises undertaken in Greater Manchester and Cheshire were examples of good practice; however, these reports do not appear to have been considered before subsequent extensions and awards of contracts to One to One.

2.37. Ad hoc quality and safety reviews were undertaken as a reactive response to concerns raised in the system, rather than as part of standard due diligence before award of contracts. The Mersey Internal Audit Agency review in October 2018 was the only formal financial due diligence undertaken by commissioners; this did not provide additional insight and came too late to allow proactive intervention.

2.38. We conclude that due diligence on the safety, quality, operational and financial aspects of One to One's service was inadequate before contracts were awarded and extended. The lack of private sector commercial experience in predominantly clinically led Primary Care Trusts and CCGs at the time, was likely to have been a key contributing factor to the absence of such scrutiny. If robust due diligence had been applied, this would have highlighted the significant risks of entering into a contract with a start-up company with a weak balance sheet position, wholly reliant on the rapid growth of activity through NHS contracts.

Recommendations

1. Proof of concept through pilot testing and consultation should be comprehensive and consider all pathway components that are intended to be commissioned before introduction into an established system.
2. A comprehensive pilot evaluation should be undertaken as a fundamental step in the commissioning process, at a pace which allows all stakeholders to contribute to feedback. This should set out the learning and challenges experienced, potential risks and implications for future commissioning, and should allow recalibration of options and retesting if appropriate.
3. Commissioners should produce a business case for assurance and decision-making purposes for innovative and potentially high-risk service developments. This needs to be completely independent of proposals from

providers offering their services and include a thorough evaluation of the market.

4. A tailored approach to due diligence should be applied to small private sector providers who have a limited track record of working within the NHS. This should be undertaken on an 'open book' basis and include review of policies and procedures as well as financial forecasts and assumptions.
5. As part of due diligence, commissioners should evaluate the extent of support that might be required by start-up businesses to understand the broad-ranging compliance requirements of the NHS regulatory and contractual infrastructure.
6. Comprehensive audit, from both a financial and quality perspective, should be undertaken before all key contracting decisions and on a regular basis as part of formal annual reviews of contract performance.
7. Due diligence should be undertaken with the appropriate clinical and commercial expertise, and this should be sourced externally if the skills are not available in-house or if independence is required.
8. A checklist should be developed to set out the areas of safety and quality which should be reviewed as part of routine annual due diligence of independent sector providers. This should include as a minimum: reviews of policies and procedures, staffing levels, incidents, complaints and claims, surveys of staff and service users, risk registers, performance reports and feedback from other stakeholder organisations (for example, NHS Trusts, GPs and other service providers).

Theme 4: Procurement and contracting

2.39. The AQP approach was previously a commonly used procurement solution to allow commissioners to contract with NHS and independent sector providers. This was a pragmatic approach to allow One to One to start providing its services.

2.40. The approach was a proportionate way to explore market interest and move at pace to establish the new service. However, it was not appropriate for a high-risk, complex service; it led to an uncontrolled growth in self-referrals and non-contracted activity with consequent risk to women and babies.

2.41. Without formal contracts (non-contracted activity), commissioners could not put appropriate governance in place; in addition, cover under the Clinical Negligence Scheme for Trusts was a risk. One to One did not comply with the intentions of the guidance on non-contracted activity at the time and the growth of the service across the country contributed to this weakness in governance. A co-commissioned contract across Cheshire and Merseyside was a positive step in regaining control of the expansion of the market.

2.42. A weakness generally with the AQP approach was the introduction of independent sector providers without assurance that they were set up to comply with complex NHS regulatory and contractual frameworks. This proved to be a major challenge for One to One who found the NHS system inflexible, disproportionate and impracticable. Following the pilot, the company was not able to flourish within the NHS infrastructure.

2.43. There were three failed procurements involving One to One. This was not value for money to the public purse. For the first two procurements, this outcome could have been foreseen as One to One were the only provider expressing a serious interest. The procurement in 2019 was abandoned to allow local NHS providers to deal with the operational consequences of the One to One service cessation.

2.44. The decisions to award a new contract in 2016 and the extension of the contract in December 2018, at the height of commissioners' financial viability concerns, were questionable. There were missed opportunities to re-assess and potentially plan for an earlier exit from the contract, particularly before the award of the three-year co-commissioned contract in 2016.

2.45. It was reasonable for commissioners to plan to re-procure the service in 2019 following the end of the term of One to One's contract. There was increasing market interest in providing alternative models following national planning guidance and commissioners needed to find a way to manage the substantial risks that had arisen under the One to One contract.

2.46. We noted some positive learning points in the revisions made to NHS Wirral CCG's procurement policy which acknowledge some of the challenges experienced on the One to One contracts.

Recommendations

1. Comprehensive due diligence should be undertaken with the appropriate commercial expertise before decisions to award and extend contracts.
2. Commissioners and independent sector providers should work in an 'open book' way, particularly for start-up businesses offering new services, to ensure a full understanding of the cost base and allow scrutiny of the assumptions underpinning business plans.
3. Commissioners should consider direct award approaches for services where there is only one provider expressing serious interest, where this flexibility is permitted by procurement policies, to minimise procurement costs.
4. Steps should be taken to ensure new providers to the NHS understand the technical requirements of contracts. Formal confirmation that they are set up to comply with requirements should be sought as part of pre-contract conditions.
5. Commissioners should include a reference to their position on non-contracted activity in their procurement/contract management policies. This should be replicated in service specifications.
6. Governance arrangements around material changes to service specification requirements should be clarified in commissioners' relevant procurement/ contracting policies and the Scheme of Delegation.

Theme 5: Service specification development

2.47. The service specifications did not change significantly over time and reflected the national drivers for maternity care, the specific requirements for the community-based case loading model, NICE guidance, local policies and interdependencies with other services.

2.48. There is clear evidence of learning in the development of the service specifications to reflect national policy for the case loading model, provide more definition on implementation and ensure a safer service for women.

2.49. There was no formal annual review of how the service specification was working in terms of compliance with specification requirements and from an operational and practical perspective.

2.50. The service specifications did not adequately define how shared care protocols should be developed. The absence of such agreements was a major risk to the safety of women and babies. The service specifications were not sufficiently robust

in setting out responsibilities in this regard. There was no recognition that NHS Trusts equally needed to agree and comply with joint working protocols to ensure safe services for women nor how commissioners might support and facilitate this.

2.51. Commissioners accepted One to One's assurances that this work was progressing. This issue was not addressed and there was no coordinated approach across Cheshire and Merseyside. One to One had to work to each NHS provider's individual requirements rather than working to a standard template which was inefficient from a practical perspective.

2.52. It is evident that the service specifications were informed by and tailored to the service provided by One to One. We found limited references to independent clinical input, other than with GPs for the specification for the co-commissioned contract in 2016. We did not find evidence of engagement with NHS Trust teams (obstetric and community midwifery providers) or with other independent operators such as The Albany Midwifery Practice and Neighbourhood Midwives. We have not therefore been able to fully conclude on the appropriateness of clinical input to the service design.

2.53. The experience of women and families was captured to some degree in all of the specifications, and it was reasonable to propose a survey approach. There was a stronger focus on this in the first specification issued to One to One and some useful metrics on response times were included in the West Cheshire specification. One to One provided feedback in Quality Reports from its surveys of service users; however, the specifications were generally not prescriptive enough in terms of what was required from these surveys. There was no indication of how commissioners would monitor improvement in service user experience.

Recommendations

1. Independent clinical review should be a standard component of service specification development. For new service models involving integrated care pathways and significant potential clinical risk, full engagement should be undertaken with relevant professionals to inform the specification.
2. We recommend formal annual reviews of the delivery of the service specification and contract as good practice to highlight risks and emerging challenges.
3. Amendments to service specifications should be fully documented and tracked to enable discussion at contract meetings.
4. Specifications should be explicit on the requirements of all stakeholders relating to the development of shared care protocols.

Theme 6: Contract and performance management

2.54. Contract monitoring meetings were held between commissioners and One to One throughout the duration of the contracts at an appropriate frequency for the size of the contract and risks involved.

2.55. The standard NHS contracting and performance management regime was resource-intensive and costly for a small provider to manage and led to a reactive approach from One to One which created additional risk. There was a disproportionate effort by all concerned on the management of the relatively small contracts.

2.56. There was a good level of debate to gain an understanding of One to One's business model and evidence of positive collaborative working. However, the agenda became focussed on the sustainability of One to One's business, rather than on rigorous monitoring against the contract quality requirements.

2.57. Significant issues were not escalated to an appropriate level early enough or not escalated at all. One to One became frustrated that their concerns were not able to be dealt with through the contract meetings and resorted to direct escalation to senior levels within CCGs, NHS England and NHS Improvement (formerly Monitor). This led to disjointedness in the communication channels and tensions in relationships.

2.58. There was no evidence of structured, routine commissioning oversight of safety and quality at contract meetings. We found minimal systematic reporting and discussion on core quality topics such as incidents and complaints. There was no robust reporting from One to One on these areas, nor on audits undertaken and associated themes, actions and learning. This considerably weakened commissioners' assurance over quality and safety and their confidence in the service.

2.59. Scrutiny of One to One's performance at contract meetings was generally reactive in response to other system quality surveillance mechanisms. One to One felt that they were being 'micro-managed' by the various assurance processes in place.

2.60. The set-up of the co-commissioned contract across Cheshire and Merseyside was disjointed. The co-commissioned contract meetings did not work effectively; the content of the meetings was predominantly on issues raised by the lead commissioner and the number of attendees was a hindrance to gaining an appropriate level of assurance for each commissioner. This was a poor use of limited commissioning team resource.

2.61. Routine collaboration between all commissioners involved with One to One was not evident. Importantly, there was no mechanism between commissioners across Cheshire and Merseyside and Essex to share intelligence. The lack of visibility of One to One's operations as a whole compounded commissioners' concerns about potential safety risks.

2.62. Commissioners had different perspectives on their involvement in the challenges between One to One and NHS providers. The absence of a formal collaborative forum was a missed opportunity to work in a structured and coordinated fashion for quality assurance and risk management purposes.

2.63. Until the latter stages of the contract, links were not made at contract meetings between the commercial challenges facing One to One and the associated risks to the quality and safety of services. There was generally a lack of senior finance and quality representation at the meetings and a lack of commercial experience, which is likely to have contributed to this.

2.64. The metrics used in the performance dashboard were appropriate to the service and focussed on risks. However, there were some key metrics missing relating to continuity of care, safe staffing and the risk profiles of women.

2.65. There was positive collaboration between One to One and commissioners to try to establish a sound basis for the dashboard. However, the dashboard evolved in an unmanageable way and became an onerous monitoring framework. Co-commissioners did not work together to develop a single best practice template.

2.66. The dashboard did not settle into a routine, consistent framework to allow any meaningful interpretation of trends. Review of performance frequently led to debate about the applicability of the metrics rather than any value added insight. There was an absence of exception reporting and commentary to provide direction to key areas of focus. Data quality was not tested.

2.67. There was minimal evidence that use of the performance monitoring framework triggered actions to deliver measurable improvements in the services provided. A key contributing factor was the fragmented nature of performance reporting, due to the need for insight from NHS providers involved in shared care to inform the interpretation of the metrics.

Recommendations

1. Commissioners should establish mechanisms for routine quality assurance on all contracts, to include reporting on incidents, complaints, claims and audit and periodic quality assurance visits. Commissioners should make use of a provider's internal quality governance processes for this purpose.
2. For new, innovative services, experienced commissioning and quality leads should be involved in developing the quality assurance framework required and in signing off performance dashboards and ensuring they continue to reflect requirements and do not become onerous.
3. For shared care arrangements, commissioners should obtain insight on performance from all providers involved through respective contractual quality performance meetings, to triangulate evidence from these multiple sources for greater insight and intelligence.
4. As part of the development of joint working protocols for shared care, responsibilities for performance reporting on key shared metrics should be documented.
5. Terms of reference should be set out for contract meetings with defined responsibilities for areas of oversight, escalation protocols and delegated authority for decision-making. Issues logs and risk registers should be used routinely for escalation purposes.
6. Co-commissioners should work in a coordinated way to develop performance reporting frameworks and manage challenges arising under the contract which have the potential to destabilise local systems. The requirement for formal collaboration agreements should be set out in local contract management policies.
7. Co-commissioners' pre-meetings or other collaborative forums should be formalised so that common themes can be discussed, and queries raised at the formal contract meetings, without the need for attendance of multiple representatives from each commissioner.
8. Commissioners' contract management policies should be reviewed to consider tailoring the requirements for smaller, independent sector providers, for example, by strengthening requirements for annual service reviews and audit,

as well as highlighting the commercial risks to consider on contracts with such providers.

9. Performance management frameworks should be designed to reduce the burden of data collection and reporting while allowing a focus on risk. This should include highlights and exception reporting, a basket of critical performance metrics for routine monitoring purposes, and 'deep dives' into particular areas on a cyclical basis.
10. Data quality audits should be a core requirement of service specifications and the Data Quality Improvement Plan under the contract used to support this area of work.

Theme 7: Tariff arrangements

2.68. A local tariff was appropriate for the One to One contract due to its cost base not reflecting an acute model. However, the local tariffs paid to One to One before the advent of the maternity pathway payment system in 2013/14 were significantly higher than those indicated by the pathway tariffs. In addition, a double payment was implied for transfers of care.

2.69. The introduction of the maternity pathway payment system was well intentioned in seeking to put the correct incentives in place for providers to innovate and offer choice in maternity care. However, with a fixed financial envelope for maternity services, the introduction of an independent provider into the market meant that income to existing NHS Trusts would be eroded.

2.70. Administrative systems were not set up to manage the invoicing arrangements for provider to provider charging. This led to much manual validation and effort by all providers, particularly as One to One disputed many of the charges made for care by NHS Trusts. Commissioners did not use their audit powers to test invoicing between NHS Trusts and One to One.

2.71. There was a fundamental flaw in the tariff system as provider to provider charges were made using the episodic tariff. This removed the incentive for Trusts to reduce clinical interventions where appropriate.

2.72. Financial agreements were not in place between One to One and NHS Trusts for provider to provider charges. There was no financial incentive for NHS Trusts to engage on this as it would potentially reduce their income. The lack of financial agreements was contrary to Monitor guidance but there was no intervention to ensure compliance with this. The service specifications for One to One did not refer to the financial complexities of the tariff and the need for agreements on provider to provider charges.

2.73. The lack of financial compromise between One to One and NHS Trusts became an insurmountable problem, exacerbated difficult relationships and led to the destabilisation of local systems. It created risk to women and babies due to the impact on joint working relationships. Commissioners felt that they were not able to get involved in finding a solution as it was, in their view, an issue between providers.

2.74. The maternity pathway tariffs were based on an NHS hospital model so were not representative of the cost base or the activities undertaken by a community-based midwifery-led model. There was no evidence of work being undertaken to assess the appropriateness of the tariff for the service offered by One to One. The case loading, midwifery-led community model called out for a tailored approach and potentially a continued local tariff.

2.75. The deficiencies in the tariff model were not addressed during the lifetime of One to One. The audit undertaken by NHS Improvement in October 2017 made some important recommendations to address the fundamental issues involved but its conclusions were not progressed further.

2.76. Alternative pricing models for community-based services have taken time to develop. The recent proposed changes to the maternity tariff to remove provider to provider charging through a blended payment model were too late for One to One.

Recommendations

1. In the absence of national developments on tariffs for community-based models of care, local bespoke tariffs should be applied, based on a robust assessment of the cost base of providers.
2. Robust testing of tariff arrangements should be undertaken to understand the impact on commissioners and providers where joint working with the independent sector is proposed and different tariffs may need to be applied.
3. Notwithstanding formal structural accountabilities and responsibilities, commissioners and NHSE/I (and their successor body) need to maintain oversight of material issues relating to tariff, which might impact on the stability of their local systems and create risk to the safety and quality of services.
4. Commissioners should use their audit powers under contracts with all providers to investigate any significant concerns about billing arrangements.
5. NHSE/I (and their successor body) should maintain oversight of its requirements relating to previous tariff guidance issued and provide clarity where previous national guidance might be inconsistent with current guidance or where tariff rules appear unfair.
6. The maternity tariff guidance should be supplemented with more detailed guidelines on how to agree tariffs for provider to provider charges, as the current guidance leaves this open to interpretation.
7. The blended payment model introduced in 2019/20 should be tested for maternity services between an NHS acute and NHS community-based maternity provider as part of the system.

Theme 8: Financial viability

2.77. Since its establishment, the company was in a precarious financial position. Initial losses were not recouped, and the business model continued to be loss-making due to provider to provider charges and the level of overheads.

2.78. The company's financial sustainability was dependent on the rapid growth of NHS-funded activity to cover start-up losses and fixed costs. The significant erosion of margins which resulted with the introduction of the maternity pathway tariff exacerbated this position. The minimum activity levels required by One to One to achieve financial viability in Cheshire and Merseyside did not appear realistic within the short timescale required for financial recovery.

2.79. The AQP approach with a zero-based activity contract, was a key contributory factor to One to One's financial demise, as considerable start-up costs and overheads were incurred which were not covered by the volumes of activity generated. In addition, non-contracted activity was not paid for, which was in line with commissioners' interpretation of the guidance at the time.

2.80. Self-referrals led to a loss of control over activity and income by One to One, so growth did not progress in a planned way. Inadequate financial controls were in place to ensure payment for non-contracted activity undertaken.

2.81. It is evident that the level of interventions and charges by NHS Trusts were much higher than anticipated by One to One. The bulk of the problem was on the antenatal pathway where the majority of the income received through the pathway payment was used to pay for the associated provider to provider charges. One to One had not adequately planned for the various scenarios that might arise before the start of the co-commissioned contract in 2016, following which these charges increased exponentially.

2.82. As a result, the level of overheads incurred was not manageable and the level of insurance premiums were unsustainable for the business model. The basis for Clinical Negligence Scheme for Trusts (CNST) insurance premiums remains unclear and a methodology based on number of births was not appropriate for One to One.

2.83. Even if existing debt had been written off, the charging system would have continued with a consequent continued accumulation of costs and debt. Without any change to the payment mechanism, the One to One business model was not financially viable.

2.84. One to One believed that through their relationships at senior levels and the commitment to Better Births, that a solution to their financial challenges might be found. This was not the case, particularly, given the multiple complexities involved and the need for a rapid solution.

2.85. Before the cessation of the business, there was no resolution to the fundamental problem of an unworkable payment system. Various proposals were made by One to One to try to influence commissioners to change their approach to the tariff and a prime provider model was supported by NHSE/I. These did not progress as there were risks and financial disincentives to NHS Trusts.

Recommendations

1. Relatively small independent sector providers, particularly start-up businesses working exclusively in the NHS, should work transparently on their business plans with commissioners so that the commercial challenges are understood by all parties.
2. Business plans should be rigorously stress tested to ensure assumptions in areas of risk are appropriate and that the business plan has a buffer for contingencies and unexpected variations in key assumptions.
3. Commissioners should consider adding a section on non-contracted activity to their contract management policy and service specifications, so that the rules to be followed are clear to new providers.
4. Commissioners should consider applying a tailored approach to oversight of small contracts to avoid a disproportionate bureaucratic burden and level of cost to providers of the resources and the systems required for performance reporting and quality assurance.
5. Increased commissioning flexibilities should be considered for small contracts, for example, local tariff arrangements between providers, block contracts and guaranteed activity levels.
6. A prime provider model should be further investigated for services to be provided jointly between NHS and independent sector providers.

7. NHS Resolution should set out a transparent methodology for calculating premiums for community-based maternity care providers, this should be based on an appropriate risk assessment.
8. Small companies without any other sources of finance or a portfolio of services should ensure the sustainability of their business plans, particularly, that they should be prudent and be based on a realistic scenario.

Theme 9: Culture, relationships and behaviours

2.86. Our review found a pervasive 'them and us' culture between One to One and NHS Trust maternity teams. The relationship problems with NHS providers were evident from the outset and were exacerbated as One to One became more established within the system. Relationships deteriorated further as the issue of provider to provider charges took hold across Cheshire and Merseyside in particular.

2.87. The onus was placed on One to One to put joint working protocols in place as this was extremely challenging in the face of the unwillingness to engage by NHS providers. This approach transferred a disproportionate amount of risk to One to One and to NHS Trusts, particularly as both continued to operate without agreed joint working and cross-charging agreements. As a consequence, this created additional risk to the safety of women and babies.

2.88. The impression gained is that NHS Trust teams were under pressure to resolve the issues and work with One to One due to safety concerns and to respond to commissioning priorities, but mutual trust between the respective teams was lacking. Some commissioners were unwilling to get involved in brokering solutions between One to One and NHS Trusts as they viewed the challenges as regulatory and for resolution between providers; as a result, their oversight was with a relatively light touch and did not accelerate progress.

2.89. There was a lack of flexibility and compromise on all sides and One to One's approach of escalating issues to the most senior national level further weakened local relationships. Hierarchical and rigid NHS structures and policies acted as a barrier to effective joint working.

2.90. GPs were clearly reluctant to engage with One to One and this had a significant impact on the activity levels that One to One were able to achieve. Although commissioners encouraged GPs to work with One to One, there was not enough focus on understanding the factors which were influencing their position.

2.91. There were various communication and access issues for One to One with other associated services such as Health Visiting, Local Authority Safeguarding and Perinatal Mental Health.

Recommendations

1. Potential cultural barriers to joint working in maternity care between acute and community providers should be tackled as part of engagement work before introducing a new model into an established NHS system.
2. Service specifications should be agreed by all stakeholders involved in shared care pathways. Interfaces with other services should be defined and fully documented as part of an agreed shared service specification rather than being a development requirement of the specification.
3. Engagement should continue regularly with wider stakeholders to obtain comprehensive and honest feedback on implementation and to inform any changes to a service specification.

4. Commissioner support should continue to broker shared care arrangements and maintain oversight of relationships across the system.
5. Professional integrity issues need to be investigated as a priority by commissioners and professional bodies when concerns are raised either informally or formally.

Theme 10: System oversight

2.92. System oversight presented a complex landscape, the component parts of which were not always aligned. It was fragmented and difficult for any individual part of the system to gain a single view of One to One and therefore be assured on the safety of their services. System oversight was also weakened by the lack of structured, proactive oversight of quality and safety at a local level through CCGs and sub-regional groups.

2.93. System oversight was fragmented despite the national profile of this service. There was no clear route for accountability and oversight of this new model from local commissioners and local maternity systems through to NHSE at a regional level and the National Maternity Transformation Board.

2.94. Relationships were not continuous as there were many changes to NHS structures over this period. We were told that the move from Primary Care Trusts to CCGs, in particular, resulted in a loss of knowledge with regard to the commissioning and monitoring of maternity services.

2.95. Some CCGs felt somewhat constrained in the influence they could have over NHS Trusts and were therefore reluctant to get involved in the relationships between One to One and NHS providers. Notwithstanding formal structural accountabilities and responsibilities, there was a reasonable justification for commissioners to act decisively on these risks well before the implementation of the larger co-commissioned contract in 2016.

2.96. There was an absence of prompt intervention on the risk factors relating to One to One at a system level. As the core issues of shared care agreements and tariff barriers were not resolved, relationships were irreversibly damaged, and One to One's financial position became irrecoverable.

2.97. It was important to commissioners for the One to One model to succeed, to offer more choice in maternity services. There were clear efforts and positive collaboration at all levels of the system to support One to One; however, proposed solutions were not able to be implemented due to the risks perceived by NHS Trusts and were developed too late to provide resolution.

2.98. There was an acknowledgement in the system that the One to One model was unworkable. One to One had national attention and direct relationships with key influential figures involved in the National Maternity Review to whom they directly escalated their concerns, however this did not lead to resolution as, to this type of private provider, the NHS seemed 'hidebound' with restrictions and regulation.

2.99. Risk Summits were initiated due to concerns about quality and safety, but these issues were side-lined due to a focus on contractual issues. Consideration and assessment of the quality and safety issues were addressed through the completion of a Quality Risk Profile Tool, but this was not reviewed prior to One to One being stepped down from the Risk Summit process in December 2016.

2.100. The Quality Risk Profile Tool offered a structured mechanism for self-assessment against key safety and quality criteria. This was not used on an ongoing basis and was a missed opportunity to provide core assurance to commissioners and the CQC. Although One to One were described as being under "*enhanced surveillance*", it was not clear what additional surveillance was being undertaken.

2.101. Financial issues were not addressed as part of the heightened quality surveillance processes. This was a weakness, as the financial issues were inextricably linked to whether One to One were able to provide safe, high quality services. The CQC did not use their powers to assess the financial viability of One to One when there had been clear system intelligence of financial issues for several years.

2.102. There were various allegations by One to One of organisational bullying and intimidation. We would have expected to see a coordinated approach to the management of these allegations.

2.103. One to One did not hold a provider licence; although exempt from licence conditions on the basis of size, there was evidence of uncertainty as to whether their intrapartum care should be classified as a Commissioner Requested Service. This was a missed opportunity to enhance the financial oversight of One to One at an early stage.

2.104. The lack of financial agreements between NHS Trusts and One to One was contrary to Monitor guidance but neither Monitor, nor subsequently NHSI, intervened to ensure their guidance was reasonably applied. The NHSI audit of provider to provider charges in late 2017 made recommendations for a different payment mechanism to be applied for the One to One scenario but this was not progressed further at the time.

2.105. There were weaknesses in CQC oversight. The repeated identification of recurring themes indicated that inspectors did not receive assurance about actions taken to address concerns from previous inspections. The CQC did not complete an inspection of One to One after January 2017.

2.106. There was a lack of structured commissioner oversight of the action plans developed by One to One to address the issues identified in the CQC inspection reports.

2.107. The role of Local Maternity Systems in overseeing delivery of the Maternity Transformation Programme has recently been strengthened. Before 2016, arrangements for oversight of transformational change in maternity services were less clear. One to One were engaged with the Local Maternity Systems; however, relationships deteriorated significantly as One to One escalated their particular issues directly to senior levels.

2.108. The Local Supervising Authority worked consistently alongside stakeholders as part of quality surveillance processes and there was clear evidence of support provided to One to One. Generally, there were no significant concerns recorded by the Local Supervising Authority Midwifery Officers until March 2015.

2.109. Perinatal loss data submitted to the Strategic Clinical Network and benchmarking were not reliable. One to One understood their perinatal death rate to be low, but we are unable to confirm this as the calculation methodology does not take account of all births where One to One provided an element of care.

Recommendations

1. For further innovative developments in maternity services, testing should be undertaken at a design and feasibility stage before commitments are made to implementation. This would assist in building a common understanding, between policy leaders and local NHS teams tasked with implementation, of the challenges to be overcome.
2. Where financial challenges are identified during the quality surveillance and Risk Summit processes, consideration should be given to appropriate financial representation in the meetings; this is important as safety and quality considerations are often inextricably linked to financial challenges.
3. The Care Quality Commission should review its approach to consider the impact that financial instability might have on a small company's ability to provide safe care.

4. The Care Quality Commission should consider how they publicly share information about actions taken to address any issues from previous regulation activity, ensuring this is easy to understand, accessible and provides evidence of how they have held organisations to account for people's care.
5. The regional teams of NHSE/I (and their successor body) should ensure that a clear description of the Quality Surveillance Group and Risk Summit processes is shared with providers who are subject to them. This information should include the triggers for each level of surveillance.
6. The regional teams of NHSE/I (and their successor body) should review processes and timescales for Quality Surveillance Group and Risk Summit processes, to ensure that they are transparent and that agendas are shared in advance so that providers are aware of the issues to be discussed and have sufficient time to prepare for the meetings.
7. For new and/or high risk services, commissioners should consider the use of tools such as the Quality Risk Profile Tool, particularly for independent sector providers and start-up businesses whose arrangements do not mirror those of NHS providers. This should be undertaken as part of a periodic (annual or six-monthly) assurance process for an appropriate period until sufficient assurance is gained through routine monitoring mechanisms.
8. A robust methodology for determining the stillbirth rate by provider needs to be developed that takes into account shared care arrangements between providers of maternity care.

3. Introduction and objectives

Overview

3.1. One to One Midwives ('One to One') was an independent sector provider established in 2010 to provide maternity services to NHS-funded clients through a midwifery-led, community-based, 'case loading' model. This aimed to provide a named midwife to care for a woman throughout all stages of her pregnancy from antenatal care through to birth and postnatal care. One to One were a strong advocate for home births.

3.2. The company operated mainly in Cheshire and Merseyside, and North East Essex. The company's head office was in Nantwich, Cheshire, and they had bases in the Wirral, Warrington, Crewe, Liverpool, Colchester and Bradford. The trading company, One to One (North West) Ltd, went into voluntary administration in August 2019 as their business model became unsustainable. Incident management plans were implemented to manage the safe transfer of women to the care of local NHS acute providers.

3.3. NHS England commissioned Niche to undertake an independent collaborative review into the issues and sequence of events which led to the cessation of community maternity services provided by One to One. The terms of reference for this review are provided in full in Appendix 11. We provide a guide with reference to sections of our report to show how the terms of reference have been delivered in Appendix 12.

Our approach to the review

3.4. In order to deliver the project scope we undertook:

- engagement with women and families through a survey, interviews, and email feedback;
- a detailed review of 42 sets of clinical case notes ('sample case note audit');
- a desktop review of key documents including meeting papers and minutes, briefing papers, incident reports, corporate information, policies and procedures, contracts, national publications, and email communications; and
- over 75 interviews via videoconference with current and former staff of One to One, NHS Trusts, Clinical Commissioning Groups (CCGs), NHS England, NHS Improvement (NHSI), the Care Quality Commission (CQC) and other stakeholders with knowledge of the issues involved.

3.5. We have referenced key documents in footnotes to the report and listed other key information sources in Appendix 10. Our review has considered a 10-year timeline and the amount of documentation made available over this period was extensive. We have focussed on the documentation necessary to provide an informed view of the timeline of events and nature of discussions. There were a considerable number of email communications and we have focussed only upon those matters which are significant within the context of the scope of this investigation. This report does not provide a detailed review of all communications or all events which have occurred within the chronology.

3.6. Where possible, we have supplemented the research undertaken through our interviews with documented evidence. Where we have placed reliance on minutes from meetings, we highlight that these may not be a full record of the discussions which took place.

Investigation team

3.7. Summary credentials for the investigation team are provided below:

Kate Jury (BA Hons), Partner, Governance and Assurance. Kate is a governance specialist and has worked with over 300 NHS clients in the capacity of healthcare governance, reviews and investigations and has written national guidance on the subject.

Elizabeth Donovan (LLB), Senior Consultant and Project Lead. Elizabeth has worked for over 20 years in health and social care settings and has extensive experience of investigating patient safety incidents. She was Head of Investigations for a large NHS Trust prior to joining Niche.

Michelle Carberry (BA, ACA), Senior Consultant. Michelle is a qualified Chartered Accountant with over 30 years' experience of finance, performance and governance improvement projects in the health and care sector.

Marie McDonald (RN, RM, MA, Health Management), Clinical Lead. Marie is a qualified midwife and started her career as Head of Midwifery at University Hospital Lewisham. Since 2002, she has held senior clinical roles at Guys and St Thomas' NHS Foundation Trust including as Head of Midwifery, Clinical Director for Women's Services and from 2014 to 2019 as Director of Quality and Assurance. Marie has been a member of the Nursing and Midwifery Council and a Board Member for the Royal College of Midwives (2011-1016). Marie has been involved in various projects with the Royal College of Midwives and the National Health Service Litigation Authority.

How to use this report

3.8. Our report is set out as follows:

Section 4 - Timeline of events

Section 5 - What we heard from women

Section 6 - Quality and safety

Section 7 - Incident management

Section 8 - National maternity policy

Section 9 - Innovation and start-up

Section 10 - Procurement and contracting

Section 11 - Service specifications

Section 12 - Due diligence

Section 13 - Contract and performance management

Section 14 - Tariff arrangements

Section 15 - Financial viability

Section 16 - Culture, relationships and behaviours

Section 17 - System oversight

Section 18 - Service cessation

Section 19 - Summary of contributing factors

3.9. Appendices are set out in a separate document to accompany this report.

Quality control

3.10. Interested parties are given the opportunity to provide factual inaccuracy responses to a draft investigation report, and individuals have been provided with a right to reply through their representative organisations. These are carefully documented along with any changes which result from feedback. No party has the right to amend or dictate our work in any way, regardless of bill-payer.

3.11. At Niche we have a rigorous approach to quality standards. We are an ISO 9001:2015 certified organisation and have developed our own internal single operating process for undertaking independent investigations. Our final reports are quality assured through a Professional Standards Review process (PSR) and approved by an additional senior team member to ensure that they have fully met the terms of reference for review. This report has been extensively peer reviewed within Niche by experienced professionals prior to distribution.

4. Timeline of events

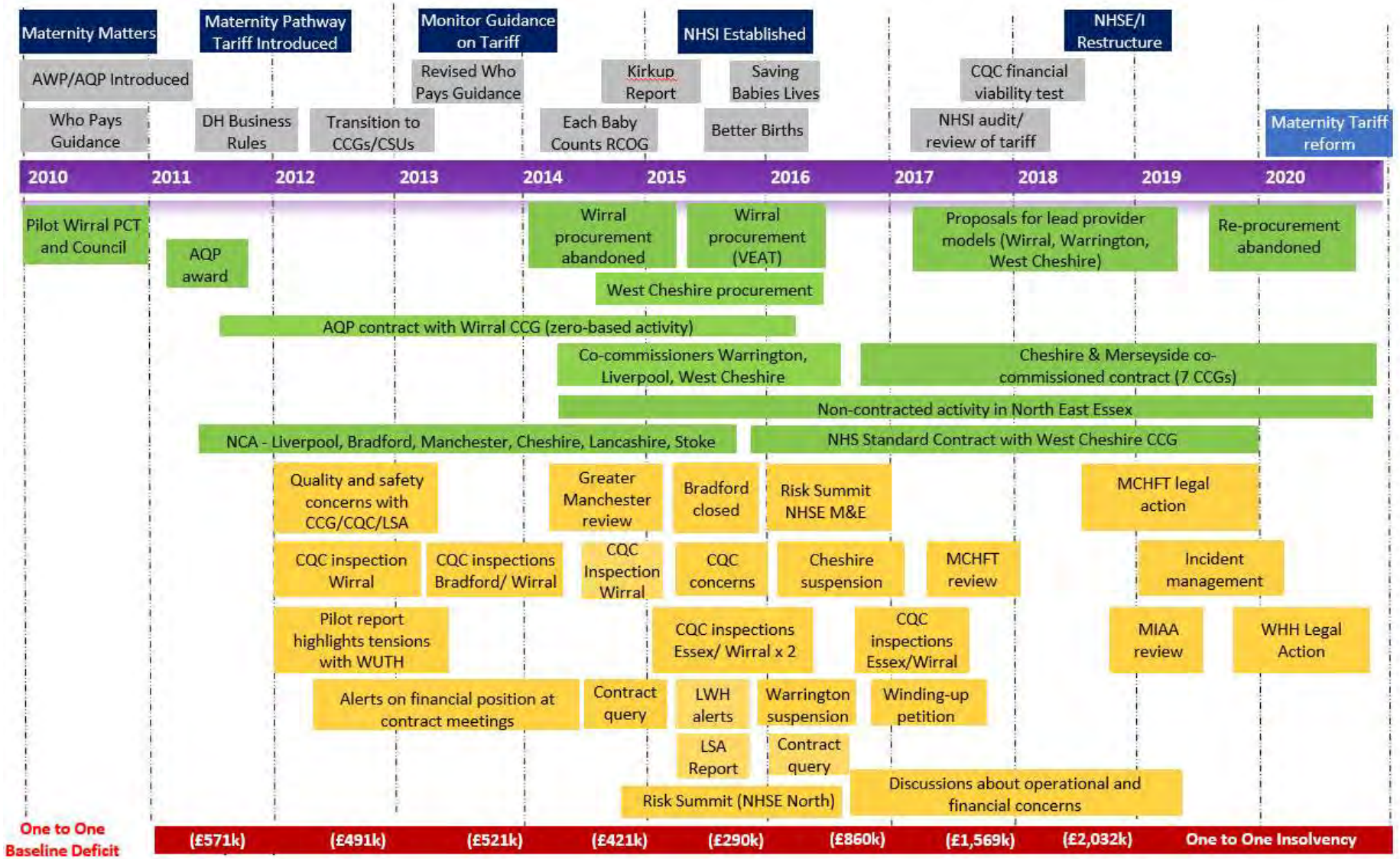
Overview

4.1. In this section, we provide a summary chronology to aid understanding of the sequence of events from the initial concept and set-up of One to One's service through to its demise in 2019. Detailed chronologies are provided in Appendix 5 and cover:

- the inception of the One to One Midwives concept and the establishment of One to One (North West) Limited as a trading company;
- One to One's initial engagement with NHS commissioners, procurement and contracting;
- the subsequent delivery of NHS-funded maternity services;
- quality and performance oversight;
- One to One's financial position; and
- associated national policy and guidance of relevance to the provision of these services.

4.2. The following chart provides a diagrammatic representation of the timeline of key events.

Timeline overview



Summary chronology

Part One: Inception and pilot (pre-April 2011)

4.3. The One to One community-based case loading model for maternity services was developed by two independent midwives operating in the North West. The intention was that this service would be for NHS-funded clients and would operate alongside existing NHS provision to improve local choice for women. The model was consistent with the aspirations of national policy set out in Maternity Matters (2007).

4.4. One to One Midwives ('One to One') was established as a trading company and incorporated as One to One (North West) Limited to provide the service to NHS-funded clients. The company was loss-making from the start; it had no track record or guaranteed income to access external sources of funds and was therefore reliant on self-financing to establish the business. One to One approached several commissioners across the UK and sought to raise the business's profile.

4.5. In June 2010, One to One obtained agreement to pilot a version of the model on the Wirral; this was for antenatal and postnatal care only. Wirral Primary Care Trust (Wirral PCT) had undertaken a review of maternity services and were interested in developing more local choice. The pilot was funded jointly with Public Health as it focussed on the needs of a vulnerable cohort of women in a deprived area of the Wirral. The pilot was awarded under the Any Willing Provider (AWP) framework which was introduced in 2009 and sought to encourage diversity in the provision of services.

Part Two: Contract with Wirral CCG and national growth (from 2011/12 to 2013/14)

4.6. The pilot had attracted much interest from women. One to One were awarded a contract by NHS Wirral PCT for all elements of the maternity pathway to be provided in the community setting (antenatal, intrapartum/home births and postnatal care) from November 2011 to March 2014. The specification was for all women regardless of risk profile. The initial risk assessment would inform a mutually agreed care plan between the woman and the midwife. The specification required shared care arrangements for obstetric advice and hospital births with the local NHS Trust.

4.7. One to One expanded across the country and women self-referred; however, contracts were not put in place for this activity. One to One also set up an office base in Bradford. The AQP approach encouraged growth, but One to One did not follow the national 'Who Pays' guidance which required contracts to be put in place for routine, non-elective activity. GPs were reluctant to refer to the service and some CCGs refused to pay for non-contracted activity. Liverpool and West Cheshire CCGs agreed to pay for activity under the Wirral contract from April 2013 and a re-procurement was planned.

4.8. During 2012/13, significant tensions were emerging between One to One and Wirral University Teaching Hospital (WUTH) due to the latter's concerns about loss of maternity income and safety issues. This culminated in Trust staff writing to the CCG, the Care Quality Commission (CQC) and Local Supervising Authority Midwifery Officer (LSAMO); however, the investigations undertaken found no significant issues with One to One's processes. Local Trusts continued to voice concerns about One to One's standards but CQC inspections found no compliance breaches. Issues were emerging on the adequacy of joint care protocols and pathways with NHS Trusts.

4.9. The Maternity Pathway Tariff was introduced with 'lead provider' arrangements which created significant complexities due to arrangements for cross-charging for shared care between NHS Trusts and One to One. One to One built up a significant

level of debt due to the provider to provider charges, which they disputed as they did not agree with Trusts' activity coding and the level of their clinical interventions.

4.10. Signs were emerging of One to One's precarious financial position. Heavy initial losses due to start-up costs and punitive insurance premiums were compounded by insufficient levels of activity and the provider to provider charges. One to One wanted to agree local charging arrangements with Trusts, as set out in Monitor guidance, but Trusts were unwilling to engage on this. One to One planned to employ an in-house obstetrician to reduce the costs associated with women attending local NHS maternity services.

Part Three: Business expansion and quality oversight (2014/15)

4.11. Liverpool, Warrington and West Cheshire CCGs became co-commissioners on the Wirral contract from April 2014. One to One expanded into North East Essex following approval by the CCG on a non-contracted activity (NCA) basis. Greater Manchester commissioners withdrew their support for One to One following a quality review.

4.12. One to One tried to further develop their services through investment in 'pop-up' shops and a pregnancy advice centre; they employed a part-time Consultant Obstetrician. One to One obtained insurance cover under the Clinical Negligence Scheme for Trusts (CNST) and reported an improving financial position; however, their initial losses had not been recouped.

4.13. The Wirral-led contract was extended to the end of March 2015; a re-procurement process was unsuccessful with commissioners citing concerns over the specification. Three local NHS Trusts had submitted an interest in bidding as a consortium but did not pursue this. One to One was concerned that the specification was for women with a low risk pregnancy only, given that the current service was available to all women. West Cheshire CCG undertook a separate procurement exercise in 2014/15.

4.14. Scrutiny on quality and safety increased over this period. A commissioner-led review identified some concerns on data quality, documentation, joint working with NHS providers, adherence to national guidance and midwife supervision. Wirral CCG issued a contract query notice following the review, which was resolved to their satisfaction. Commissioners realised they did not have oversight of all serious incidents involving One to One. The CQC inspection found consistent themes.

4.15. NHS England Quality Surveillance and Risk Summit meetings began in July 2014 to discuss similar issues. The risk profile of women being cared for by One to One remained a key area of concern. This high level scrutiny of One to One continued until the Risk Summit meetings were stepped down in March 2015. These meetings provided clarity on the legal right to choice, CNST cover and the rules for non-contracted activity.

4.16. Completion of the maternity performance reporting dashboard was challenging for One to One as there were issues with data validation and in sourcing data when a woman's care had transferred to an NHS provider. The way some of the metrics were presented did not appropriately reflect One to One's low activity volumes.

4.17. Significant challenges continued in terms of relationships with NHS providers. One to One tried to set up formal joint working agreements but NHS Trusts on the whole were reluctant to engage.

4.18. The review found six adverse outcomes for women and/or their babies in 2014/15. The findings from the investigations into these incidents identified issues with record keeping, information sharing between One to One and NHS providers, and poor

risk assessments by One to One. One of the incidents identified that a midwife lacked basic midwifery skills and the experience required to provide care.

Part Four: Fragile relationships, financial viability and CQC concerns (2015/16)

4.19. The Wirral CCG-led contract continued with Liverpool and Warrington CCGs as co-commissioners. West Cheshire CCG awarded a contract to One to One in September 2015 for an initial three-year term; this was for all women regardless of risk profile, working under shared care arrangements with obstetric providers.

4.20. Services continued in Essex under non-contracted activity (NCA) arrangements. One to One's Bradford office closed in October 2015 as services were not being paid for by commissioners. Other CCGs in the North West were not willing to engage One to One's services under NCA following clarification that NHS Litigation Authority (NHSLA)[10] cover would apply only to contracted activity.

4.21. Wirral CCG started a further procurement process; this was delayed and still in progress at the end of the year. One to One's financial viability was the key challenge to the procurement. One to One were again concerned that the specification was for women with low risk pregnancies only when their ethos and operating model were based on supporting all women. One to One also expressed the concern that the company would not survive on the basis of a low risk specification as this would not generate a financially viable level of activity.

4.22. The CQC continued to respond to concerns about One to One and completed three inspections in the North West during 2015/16. The CQC was not assured that the service was safe. The service was not deemed compliant with Regulation 12[11] regarding management of medication and Regulation 17[12] regarding governance. Their report in June 2016, however, found evidence of improvement.

4.23. An inspection in Essex in February 2016 resulted in a letter being sent to One to One by the CQC Head of Hospital Inspections highlighting a number of issues. There was particular concern about One to One's risk management policy ('Midwives Mitigating Risk'). The CQC was not confident that One to One midwives were being supported to act in line with best practice. One to One was disappointed that the inspection had not considered service outcomes.

4.24. The Risk Summit process in the North was drawing to a close with a Quality Risk Tool being developed to assess whether there were any quality or risk issues to be actioned. An oversight meeting was called by NHS England Midlands and East; several CCGs in Essex were not assured that shared care pathways were in place and had safety and quality concerns.

4.25. One to One was able to report incidents on the Strategic Executive Information System (StEIS)[13] from 2015. We identified 20 incidents reported in 2015/16 where some aspect of care had been provided by One to One. Three of these incidents were reported by One to One with the remaining incidents reported by NHS Trusts. The main themes in the incident reports were poor communication/documentation between One to One and other services required by women and risk management.

[10] https://www.gov.uk/government/organisations/nhs-litigation-authority
[11] https://www.cqc.org.uk/.../regulation-12-safe-care-treatment
[12] https://www.cqc.org.uk/.../regulation-17-good-governance

[13] Strategic Executive Information System (StEIS) A system which enables electronic logging, tracking and reporting of Serious Incidents between Trusts and Commissioners

Part Five: Co-commissioned contract and financial challenges (from 2016/17 to 2018/19)

4.26. The co-commissioned contract was extended pending completion of the procurement. The procurement did not generate sufficient interest; only One to One submitted a tender and they failed the financial qualification criteria. A new contract was awarded to One to One using a technical notice for circumstances where there is a single supplier of services. This was a co-commissioned contract for seven CCGs in Cheshire and Merseyside (C&M) for an initial term of three years to May 2019. The specification covered women in all risk categories for antenatal and postnatal care and low risk for home births. The West Cheshire contract continued until the CCG joined the C&M co-commissioned contract in April 2019.

4.27. Commissioners had ongoing quality and financial concerns. Wirral CCG served a contract performance notice and Warrington and South Cheshire CCGs issued service suspensions. A winding-up petition and debt recovery procedures were initiated by local Trusts. Early in 2018/19, North East Essex CCG also considered ceasing One to One's services.

4.28. These actions together with associated quality reviews were damaging to One to One's activity but further investigation by commissioners found no significant safety concerns. Serious incident investigations continued to highlight communication and collaboration issues between One to One and NHS providers.

4.29. During 2017, the CQC completed inspections in the North West and Essex. Some of the issues identified included lack of partnership working with local maternity providers, governance issues around policies and corporate risk management, weaknesses in medicines management and the employment of newly qualified midwives.

4.30. Tensions increased around the winding-up petition due to the risk to continuity of care and financial exposure for the NHS. One to One offered financial settlements to some Trusts with regard to the provider to provider charges and these offers were declined. NHSI intervened to encourage a settlement with WUTH; the situation with other Trusts remained unresolved.

4.31. Challenges continued on joint working protocols and information sharing with NHS Trusts. Trusts would not consider local agreements with One to One on cross-charging or tariff sharing. Proposals for a prime provider/sub-contracting model stalled due to the additional perceived risks to Trusts. NHS England recognised that the national maternity tariff would not work for the One to One model and a different solution was needed.

4.32. Relationships with the C&M Women and Children's Partnership were strained as One to One did not feel involved in its work programme. One to One escalated to NHS England its serious concerns about the unprofessional behaviour of NHS Trust maternity teams and their unwillingness to engage. The Partnership escalated its own concerns about potential reputational damage to the system due to One to One's actions.

4.33. One to One continued to warn of immediate financial viability issues; the published accounts cast doubt on the business as a 'going concern'. Commissioners requested financial forecasts and exit plans, and contract scrutiny increased. An external review of One to One's financial position in 2018 confirmed that activity needed to increase, and the tariff issue needed to be resolved for viability. A national solution on payment reform did not materialise.

4.34. From March 2019, NHS England led incident meetings with the CCGs to plan for business continuity in the event of One to One's failure.

4.35. Commissioners started to plan for the end of the One to One contract in March 2020 and served notice in March 2019 in line with the contract terms. A service review would inform next steps and a potential re-procurement.

Part Six: Business cessation (2019/20)

4.36. Following the contract termination notice, commissioners and NHS England agreed that referrals to One to One would continue until March 2020 and appropriate communications would be put in place with women to manage any transfers of care.

4.37. A procurement was planned for a new service from April 2020. One to One challenged the need to re-procure as their financial position meant they would not pre-qualify, and some Trusts had started to develop a case loading model; this meant that One to One would not be the only potential provider. One to One felt that the decisions taken were designed deliberately to exclude them from the market. Commissioners were obliged to follow procurement rules and NHS contracting guidance and therefore could not offer further contract extensions.

4.38. Stakeholders recognised the period of uncertainty facing One to One and its staff and the potential risk to continuity of women's care should the company be unable to continue. This risk was heightened by pending legal action for the recovery of debt by Mid-Cheshire Hospitals NHS Foundation Trust, as well as pre-legal actions by Liverpool Women's Hospital, Warrington and Halton Hospitals, and Wirral University Teaching Hospital. Significant legal costs had been incurred by all parties.

4.39. The Wirral contract meeting was used as a forum to plan for business continuity and develop communications plans. No significant quality or safety concerns were raised as part of contract monitoring during this period.

4.40. One to One informed Wirral CCG that they would cease trading on 31 July 2019. The company went into administration due to insolvency on 1 August 2019 with estimated debt to NHS Trusts of £2.4m. The procurement process was cancelled to allow commissioners and providers to activate contingency plans for women's care.

4.41. Two local Trusts in C&M expressed significant concerns about the due diligence undertaken by commissioners before decisions to contract with One to One and frustration at the consequences for women and local Trusts.

4.42. Commissioners agreed to vary into local NHS Trust contracts the new service specification developed during the cancelled procurement, for delivery from April 2020.

5. What we heard from women

Introduction

5.1. In this section we present the feedback we obtained from women about their experiences of maternity care provided by One to One. This is raw, qualitative information and does not seek to draw a conclusion on whether care was 'good' or 'bad' as there is no counterfactual data available. Feedback does outline the very broad spectrum of experiences of the care provided by One to One, as well as the diversity of expectations and preferences of women and their families.

5.2. We reached out to women through the Maternity Voices Network asking them to share their experience of One to One with the review team, and the invitation to participate was shared by women on social media. 395 women and families contacted us.

5.3. 317 women completed the survey. The remaining 78 women told us about their experience either by email or through unstructured interviews in which they were given the opportunity to tell their story in their own words.

5.4. We also received feedback from groups that represented women in the areas where the service from One to One was not commissioned, including Yorkshire and Manchester.

5.5. The survey was structured into eight sections covering background, referrals, antenatal care, intrapartum care and postnatal care (see Appendix 2). There was an additional section for feedback from partners and other family members. Each section contained structured questions that sought to capture details of the care provided. Women were able to provide further narrative comments on their experience about the care provided.

5.6. In Appendix 2, we have presented a graphical analysis of the survey results and we have referred below to any key observations from this analysis.

Key findings

5.7. We summarise below the key themes from our engagement with women about their experience of One to One with reference to each stage of the maternity pathway. We have also highlighted particular quotes from women to illustrate the depth of insight provided by the additional narrative comments received (we have not corrected any grammatical errors found in these quotes).

Referrals

5.8. Women described hearing about One to One as an option for their care from a number of sources including friends and family, social media and their GP. We note from the survey that 57% of respondents heard about One to One from friends and family, whilst only 9% were told about One to One by their GP.

5.9. The main reasons given for why women chose One to One, or transferred their care to One to One, were:

- continuity of midwife;
- flexibility of antenatal appointments at home;
- the option of a home birth;
- a personalised approach with involvement in decision-making about their care; and
- the extended postnatal care offered.

5.10. Some of the other factors that informed women's decisions included an unsatisfactory experience with another provider during a previous pregnancy and birth and the positive stories that the woman had heard about One to One from friends and family.

5.11. Some women transferred their care to One to One from another provider because they were not happy with the care from NHS maternity services. They gave a number of reasons for this which included:

- seeing a different midwife at each appointment;
- a bad experience during a previous pregnancy;
- an NHS provider not being able to support a home birth;
- a need for more person-centered care which they did not believe the NHS offered; and
- feeling that NHS providers did not always treat them with respect or supported them to make decisions about their care.

Why did you choose One to One?

"Initially because I needed the guarantee of a homebirth, but then it also became apparent it was a gold standard service far better than any local NHS were offering, and equivalent to what Independent Midwives offer. Continuity of care, flexibility of appointments, inclusion of husband in appointments, scans in a non-clinical office, homebirth, birth pool, hypnobirthing course, 6 weeks postnatal visits."

"I saw a couple of friends reviews of the service and they were amazing and so positive. I wanted a home birth and one to one seemed like the perfect choice once I had researched them a little more."

Why did you transfer your care to One to One?

"I found seeing a different NHS midwife at every appointment stressful and impersonal, the staff were good but One to One were a much better fit for me and really enhanced the experience of expecting my first baby. There was no question that I would use One to One again when I was pregnant with my second child and I am so disappointed that One to One won't be there if we have any more children, it is a great loss to midwifery."

"A friend told me of the service, and I initially switched because I wasn't impressed by the lack of contact, I'd had and my scan at the […NHS provider] wasn't a very special experience either. I visited […One to One] and immediately felt welcome and could see this was a more personal service. I was a nervous first-time mum and needed more than the NHS were giving me."

Antenatal care

5.12. One to One provided all of their antenatal appointments in a woman's home. They had a flexible approach to appointments and were able to offer them at times that suited the woman and her family, including evenings and weekends. Furthermore, women described there being no time pressure at the appointment. They appreciated the time spent with them and felt that this allowed their midwife to talk them through their care options.

5.13. This approach was supportive of women with work commitments. Families with small children described how it allowed the younger members of the family to be

involved in the pregnancy. Some women felt that family relationships benefitted from this inclusive approach.

5.14. Continuity of care was valued by women as they did not have to repeat their medical history at appointments. This was particularly important for women with other medical conditions that may have impacted on their pregnancy.

5.15. One to One also gave women access to classes including parenting, hypnobirthing, baby massage and baby yoga. These value added aspects of One to One's service were appreciated by the women who accessed them.

5.16. Whilst the majority of women were happy with the antenatal care they received, some women identified issues or concerns, for example:

- One respondent stated that when she was supported during her second pregnancy the service was *"a bit disjointed,"* and they described not having the same feeling of continuity.
- One woman stated: *"it was right to stop it. Rogue inexperienced midwives with pressure about home births, all because if you deliver at hospital, the hospital gets paid, and they won't."*
- When a named midwife left One to One, women referred to delays in another midwife being allocated to them. One woman told us that her midwife changed four times while under the care of One to One. Communication between them failed to ensure the correct care and scan appointments were not well organised. Her baby was not well at birth and the woman attributed this to failings in the care provided.
- Three women identified that response times could have been better to calls and texts. Other concerns included lost test results and cancelling and/or being late for appointments. Some women felt that their midwife was irritated when they contacted them outside of core working hours.
- Some clinical concerns were raised including, in one case, a failure to identify pre-eclampsia. Two women commented that One to One were not sensitive and supportive when scans identified a problem with their baby. These women described how the attitude of the One to One staff added to their distress at what was already a difficult time for them.

Women's concerns about staffing arrangements

"The only issue we had was lateness to appointment but that generally was down to midwife having been at a birth. They were quite short staffed, and the staff suffered for it."

"1st time round in 2014 they were amazing and can't fault the care. 2nd time round in 2019 my scan dates got changed and moved to different venues several times, and the 2nd scan was done by someone who was very inexperienced which led to high anxiety about the scan results."

"I had twins, and the midwife I had wasn't prepared or experienced in that. Kept telling me I could make it to 40 weeks despite the research I had done say it 37 weeks is full term for twins"

Intrapartum care

5.17. One to One offered women the option of a home birth. This was one of the reasons that many women gave for choosing One to One.

5.18. The majority of women who completed the survey told us that they were provided with sufficient information to make a choice about the place of birth.

5.19. 22 women provided comments about how they were supported to make the decision about the place of birth. Of these, more than half said that One to One provided them with the information they needed to make the decision.

5.20. However, one woman described One to One as *"… horribly pushy and telling me all sorts of hospital related horror stories. The midwife led unit were wonderful and gave me great unbiased information."*

5.21. One woman said that they had the information they needed to make the decision about the place of birth, but this information was provided by their local NHS provider.

5.22. In response to the question: **'If you birthed at home were you supported by your named midwife?'**, 86 respondents provided their birth stories and additional comments. In addition, this question provided the opportunity for women who were supported by One to One while in labour to comment on the care they received. The following feedback was received:

- 26 women described feeling supported by One to One and believed that the advice given about care and treatment, and transfer to the local NHS maternity provider whilst in labour, was effective.
- Two women did not feel the advice, care and treatment provided by One to One was supportive or helpful.
- Four comments referred to the attitude of staff at the local NHS maternity provider towards One to One midwives.
- In two cases the hospital would not allow the One to One midwife to provide a handover; one comment referred to the hospital staff as *"rude."* However, feedback from women evidenced variation in the attitude of local NHS providers towards One to One. Some women described their One to One midwife being allowed to support their hospital birth as a Doula[14].

Local NHS maternity providers and One to One

"After that I was taken back to the ward without my baby or husband and the midwife taking me was telling me about her adversity to One to One."

"...I was told by my family that the staff at the hospital were very rude to the midwife and refused her handover"

"I felt there was a negative attitude towards the One to One midwives from the midwives at the hospital (not all) which was completely unnecessary since everyone in that position of midwife were working towards the same goal. I feel there should have been some bridging between the two and training provided to help the two organisations work together more harmoniously."

5.23. Women who experienced a home birth identified a 'sense of calm' from being supported in their own home by a midwife who knew them. The following comment typifies the views expressed by the women, *"The calming support, everything was taken care if for me. It was relaxed. I didn't feel like it was over medicalised. I felt I was in control of the birth and had expert support at every stage"*

5.24. Women described feeling supported, informed, and respected. Some women described feeling in control: "*There was not much interfering, they made all the essential checks but in-between me and my partner were left to birth how we*

[14] a woman, typically without formal obstetric training, who is employed to provide guidance and support to a pregnant woman during labour

wanted to. I knew they were there if I needed them and I did call upon them a couple of times, but there wasn't too much interfering".

5.25. One woman stated: *"They used terminology that was not fear based rather than cold medical terms. Surges not contractions, how comfortable are you instead of is it painful."*

5.26. Some women were unhappy with the care and advice they received during labour and birth, for example:

- One woman told us that she made a complaint to One to One because the on-call midwife would not come out to see her when she believed she was in labour.
- Some women expressed feeling pressurised into having a home birth. They referred to being encouraged to remain at home until it was too late to go to the local hospital to give birth.
- One woman described being left to heal naturally following a 'tear.' She told us she was not sure this was the correct procedure.
- Another respondent described being left in pain while she waited for another midwife to apply sutures.
- Three women identified issues with the availability of pain relief. One woman was concerned that the only pain relief available was gas and air[15].
- A woman with signs of meconium was told not to rush to hospital; the baby was subsequently admitted to intensive care.
- One woman described feeling discriminated against as she had been under the care of the local authority.

Postnatal care

5.27. One to One provided up to six weeks' postnatal care. This included support with breastfeeding from MAMA's[16]. Women were grateful for the support they received for breastfeeding, particularly those who had previously been less successful in establishing and maintaining breastfeeding.

5.28. One respondent stated: "*My little boy ended up in hospital for 5 days due to weight loss. One to one maintained a good relationship with us, making sure they kept coming out to weigh him which put it minds at ease. Also as mentioned above, the breastfeeding support. That was so vital to me as I wanted to breastfeed so much but had lots of difficulties, but the MAMA helped me through it and I fed for 13 months"*

5.29. Some women said their support continued beyond six weeks to support them with ongoing needs, e.g., the baby was unwell, or the woman was experiencing mental health issues. One woman described how One to One had supported her family with an NHS investigation for a year after the birth.

5.30. A small number of women told us that they were not happy with the postnatal care provided by One to One. One woman transferred her postnatal care to the NHS community midwives, and they were described as *"head and shoulders above One to One".* Conversely, a woman who had experience of both NHS and One to One postnatal care described the NHS care as *"awful."*

[15] 'Gas and Air' is a commonly-used pain killer in labour that can help take the edge off labour pain.
[16] Midwifery assistant

5.31. The majority of respondents (89%) said that a prompt referral was made to an appropriate healthcare provider during the postnatal period when required.

5.32. Ten women made comments regarding babies born with a Tongue Tie[17]; nine of the ten were happy with the support provided by One to One.

5.33. One woman commented that her GP and the health visitor appeared to have issues with One to One and she could not understand what these were.

Summary points

5.34. The majority of women described a positive experience with One to One. They told us that they felt empowered by the service to make decisions about their pregnancy and birth.

5.35. The most valued aspect of One to One's service that women valued was continuity of care. Women described being able to develop a trusting relationship with their midwife. This gave them confidence in their midwife and the information she was sharing with them. Women valued being able to access advice and support from a midwife 24/7 should they have any concerns or worries about their pregnancy.

5.36. Other areas of good practice and key reasons why women chose One to One for their care were:

- flexibility of antenatal appointments at home;
- the option of a home birth;
- a personalised approach with involvement in decision-making about their care; and
- the extended postnatal care offered, particularly support with breastfeeding.

5.37. However, women raised several issues of concern and identified areas where they believed the service could be improved:

- The interface between One to One and local providers did not work effectively, and women described an unwillingness by NHS providers to work with One to One.
- Some women commented on the inexperience of One to One's midwives and identified failings in clinical care.
- Some women did feel pressured to have a home birth and were uncomfortable with this.
- Continuity of care did not always operate as intended, weaknesses in communication and changes in a woman's lead midwife led to a disjointed experience in some cases.
- Operational challenges were recognised by women, for example response times and appointment cancellations.

[17] Tongue-tie (ankyloglossia) is where the strip of skin connecting the baby's tongue to the bottom of their mouth is shorter than usual.

Some final words from the women we engaged with

"The personalised care; the experience and kindness of the midwives; the additional MAMA service; the 100% support for your birth choice and advocating for you; the positivity they provided to treat each woman and each pregnancy individually- not labelling someone or pushing them into a particular birth type because of a previous pregnancy or specific pregnancy circumstance; flexibility and frequency of appointments; more modern approach and training than a lot of the dates NHS guidance."

"Choice informed and unbiased literature was given to you if you weren't sure on the decision to make. The same midwife from 4 weeks pregnant to 6 weeks after birth. I had the same midwife for both pregnancies. The support I received after my first was needed and she would pop round if she had time to check in up to twice a day and she was always at the end of a text. My second pregnancy I was extremely sick, and she was very supportive and understanding. My whole pregnancy experience was amazing."

"Awful […] only interested in homebirth."

"One to one took chances, they were not safe midwives. Maverick in their approach, has no idea about high risks pregnancy and always had a bad attitude about having to use the local hospital."

"Amazing, my midwife was very highly trained. She dealt with my daughters' tongue tie the night she was born. She gave me the confidence to breast feed the way I wanted too. She was my advocate with pushy relatives."

"…my named midwife and was fabulous, made me feel so safe, positive about my birth and so supportive throughout, discussing all situations that could have happened and making sure we had all plans for all scenarios, as I was having twins."

"One to One were fantastic at equipping me, as a father to be, with everything I needed to feel fully informed and prepared for the birth of our first child. The Hypnobirthing course was incredibly valuable. The overall experience of having our first child in the comfort and security of our own home was quite frankly the best we could possibly have imagined. With the closure of One to One Midwives it feels like midwifery in the UK has taken a step back and I hope for a future where continuity of carer and home birth is met to the exemplary gold standard set by One to One."

"I formed a real bond with my midwife. She was my midwife through an earlier miscarriage the year before and the subsequent pregnancy of my daughter in 2019. She was a fantastic support and almost a friend. I am so saddened by the fact that any future pregnancy I may have will not be supported by one to one midwives."

"We were heartbroken when one to one was closed and it made me anxious about having another child having to go into hospital. I loved the care we received and would recommend it to anyone and would love to see it again. I would even pay for it if I could."

6. Quality and safety

Introduction

6.1. In this section, we consider the quality aspects of One to One's services in terms of safety and clinical effectiveness. Quality concerns were raised during the lifetime of One to One and our review seeks to understand the nature of these concerns, their significance and how they were addressed by One to One. We also undertook a review of 42 sets of clinical case notes to inform our findings (see also Appendix 3).

6.2. The experience of One to One's services by women and their families is considered further in Section 5. System oversight of the safety and quality of One to One's services is covered in Section 17 of the report.

Key findings

The One to One model

6.3. The One to One case loading model required community-based midwives to carry a caseload of women providing care 24 hours a day, 7 days a week, for 52 weeks of the year. Midwives worked within a 'buddy system' which involved midwives working in pairs to provide support and cover for each other if required. The intention was that the primary, named midwife attended the majority of routine antenatal and postnatal appointments, supported women during labour at home and was present at home births where women chose a home birth.

6.4. One to One offered women an unlimited number of antenatal visits at home, scans in the community, flexible appointment times (8.00am–8.00pm) and triage visits, including monitoring through cardiotocography (CTG) at home in the antenatal period. Postnatal care was provided up to six weeks following birth. One to One also provided weekend parent education sessions including hypnobirthing.

Emerging clinical risks

6.5. Most of the perceived clinical risks emerged at an early stage and remained as concerns throughout the lifetime of One to One. The key safety and quality concerns raised by stakeholders about the One to One service related to:

- quality governance;
- advice and informed choice;
- shared care;
- record keeping;
- staffing;
- medicines management;
- compliance with best practice guidance; and
- incident management (see Section 7).

6.6. From the outset safety concerns were repeatedly raised, predominantly by NHS maternity services providers. This contributed to a lack of trust and respect between One to One and NHS providers which inhibited the seamless approach to care that was essential for safety. The general perception by NHS providers was that One to One delivered lower standards of care to women. However, on the whole, this was not substantiated upon investigation by quality surveillance mechanisms.

Quality governance

Governance arrangements

6.7. The information provided on governance structures for One to One was limited and arrangements were somewhat unclear. One to One was a small business and not subject to the legal corporate governance code requirements of UK listed companies and NHS organisations. We would therefore expect less formality in terms of structures but nevertheless clear, documented governance arrangements and processes.

6.8. From a legal perspective, the company was required to have one Director and there was no requirement to constitute a Board. A Board was formed to perform statutory duties such as the submission of annual accounts, but there was no evidence that a Board was routinely convened as a forum to consider the safety and quality governance aspects of the service.

6.9. From company set-up in 2010 until mid-2013, the Chief Executive was the sole Director of the company and was accountable for oversight of all aspects of governance. Further director appointments were made in September 2013. A non-executive Director was appointed as Chair of the Board and finance lead (resigned in March 2018) and a Commercial Director was employed (resigned in May 2015). In June 2014, a Clinical Director was appointed (resigned in January 2016). There was no independent representation for quality governance on the Board.

6.10. The Desktop Review completed in February 2015 as part of the Risk Summit process was not able to provide assurance that there were appropriate risk management and quality monitoring arrangements in place. The Review commented that risk and governance information was reported to the Clinical Director only and not onwards to other Board members (in 2015 there were four Directors in post). It was unclear whether the Review was referring to the Clinical Director and Chief Executive or the Clinical Director who was recruited to a separate post from June 2014.

6.11. Based on the information provided to our review, the governance structures in place below Board level included:

- Quality Meetings – a monthly meeting to discuss performance and review of the Quality Report;
- a Clinical Governance Meeting;
- the Audit Group; and
- the Practice Point Development Group (standard operating procedures).

6.12. We did not have sight of any terms of reference or papers for these meetings, so we are unable to comment on the specific remits of these groups and the frequency of the meetings. It was also unclear whether the Quality Meetings were separate to the Clinical Governance Meetings, but we found references to both forums. We also found references to other quality forums which appear to have been different names used for the Quality Meetings, but we were unable to confirm this.

6.13. One to One also held weekly Senior Leadership Team meetings which focussed more on broader financial, contractual and operational performance issues.

6.14. One to One referred to the Quality Meetings in contract meetings with commissioners. In 2017, One to One offered to share extracts of the meeting notes with North East Essex CCG to provide assurance around performance reporting. Wirral CCG also proposed attending these meetings to gain assurance about quality and processes. There was no evidence that these suggestions were followed through by One to One or the CCGs.

6.15. We were told at interview that One to One staff who attended the Quality Meetings felt that these were unduly long and stressful, with an emphasis on individual performance monitoring rather than governance aspects.

6.16. Quality governance concerns were raised following CQC inspections completed in 2014, 2015 and 2016:

- In 2014, the CQC noted poor attendance at One to One's Audit Group, Clinical Governance Forum and Practice Point Development Group and the minutes lacked the detail to effectively disseminate information across the wider organisation.
- Feedback in 2015 noted some improvement in governance arrangements but the CQC were "*not given enough assurance that the organisation provided a safe environment for mothers and unborn babies.*" Following this inspection, the CQC required One to One to ensure that there was a robust system in place for good governance.
- The 2015 inspection highlighted that there were weaknesses in the processes for review of quality performance. A quality performance dashboard was used by One to One at monthly Quality Meetings, but the inspectors found that the meeting minutes did not refer to the dashboard.
- In 2016, an inspection in Essex identified that the governance processes in place did not provide consistent information for the senior team.

6.17. The organisation chart provided from February 2011 indicated that initially there were clear senior clinical leadership roles covering all aspects of governance. The Clinical Leadership Team was set up as follows:

- The Chief Executive and Clinical Director was accountable and responsible for all aspects of clinical governance.
- The Clinical Lead for Midwifery was responsible for promoting normality within the service and implementing systems and procedures to ensure that the service adhered to best practice.
- The Clinical Lead for Governance was responsible for risk management systems, development of policies and procedures and quality standards.
- The Clinical Lead for Training and Development was responsible for continuing professional development training programmes for staff to ensure professional skills were maintained and appropriate to their area of work.

6.18. A subsequent organisation chart showed a less defined structure with regard to clinical governance roles. This chart was not dated, but we understand it was provided as part of tender documentation in 2015. It indicates a Clinical Director role separate from the Chief Executive, and a Quality and Governance Lead below this level. There was a Quality and Governance Lead and Risk Manager reporting into the Clinical Director. The structure indicated that clinical governance responsibilities were focussed on two individuals, the Chief Executive and Clinical Director, rather than with the previous clinical leadership team of four senior members of staff.

6.19. The Clinical Director resigned in January 2016, and it is unclear how the clinical governance duties of the role were absorbed into the organisation at an appropriate level of seniority.

6.20. We were told that over time, there were many changes in roles and responsibilities for governance below Director level, which were not conducive to the establishment of solid and consistent governance arrangements.

Clinical policies

6.21. We had access to some policies provided by One to One to commissioners as part of procurement processes. The policies are listed in the following table to illustrate aspects of governance around these policies.

Table 1: Clinical policies

Name	Start date	Author	Ratified by	Review Date
Record Keeping	Oct 2011	Clinical Governance Lead	Not identified	Oct 2014
Informed Consent	Feb 2012	Chief Executive	Governance Forum	Feb 2014
Safeguarding Children	Feb 2013	Clinical Governance Lead and Safeguarding lead	Not identified	Oct 2016
Domestic Violence	Oct 2016	Not identified	Not identified	Oct 2018
Transfer and Discharge	Nov 2014	Not identified	Senior leadership team	Nov 2017
Serious Incident Policy	Aug 2014	Clinical Governance Lead	Not identified	Aug 2017
Clinical Incident Reporting	July 2015	Clinical Governance Lead	Not identified	July 2018
Infection Control Policy	Nov 2015	Chief Executive	Senior Leadership Team	Nov 2016

6.22. Our observations are:

- We have not seen the most up-to-date versions of clinical policies, so we are unable to establish whether policies were reviewed at the review dates indicated.
- We did not see reference to HR/staffing policies and a complaints policy.
- A risk management policy is not separately identified but we note that One to One developed a standard operating procedure called Midwives Mitigating Risk (this is referred to further below).
- Policy development and approval was inconsistent. Some policies do not indicate the author, and many do not indicate any review or ratification by appropriate senior clinical expertise.
- There is no indication that policies were centrally managed, for example, the Clinical Governance Meeting was not indicated as the forum for approval of policies.
- Policies were generally planned for review every two or three years; annual review may have been more appropriate for a new service establishing itself within a complex system.
- There was no evidence of independent clinical review of One to One's policies or procedures.

6.23. It was unclear how staff had access to core policies. We were told that staff routinely used standard operating procedures called 'Practice Points', NICE guidance and Royal College guidance which were available on their iPad devices.

Compliance with guidance

6.24. One to One's standard operating procedures were known as Practice Points. Midwives had access to these via Apps on their iPads, as well as to guidance from NICE and the relevant Royal Colleges. A CQC report in 2017 for the Birkenhead location found that care and treatment were being provided in line with the Practice Points which reflected national guidance from NICE and Royal Colleges.

6.25. We were able to review some of the Practice Point documents provided for our review, but they were not up to date as they were completed in 2012. They did reference NICE guidance and Royal College of Obstetricians and Gynaecologists guidelines.

6.26. The Risk Summit Desktop Review in February 2015 described One to One as having a "*rolling log of gap analysis*" for compliance with NICE guidance; we understand this to mean a log of areas where One to One were not compliant with NICE requirements. The Desktop Review was unable to ascertain responsibility within One to One for addressing non-compliance. We did not see evidence of commissioners requesting routine assurance on audit against relevant standards.

6.27. We were told at interview that One to One reviewed and revised a number of their policies in 2016 in order to meet the requirements of NICE guidance. However, the CQC inspection in the North in 2017 once again identified an issue with NICE compliance.

6.28. Furthermore, we were told in interviews that the process for developing policies and procedures to comply with national best practice and guidance was undertaken as and when required by regulators and/or commissioners in a reactive way and often in a hurried manner. Interviews did not describe a structured, robust approach to the review and revision of clinical policies to ensure compliance with national guidance.

6.29. One to One's Midwives Mitigating Risk (MMR) document was a standard operating procedure. It was written in February 2016 and ratified by the Clinical Management Team. It was due for review in February 2019. It was available to midwives electronically on the One to One shared drive.

6.30. The document defined the risk levels within the care pathway (standard, intermediate and intensive) and set out the procedures to be followed. It defined when women would require care from senior clinicians within One to One or a referral to the local NHS maternity provider.

6.31. The document identified the Nursing and Midwifery Council (NMC) codes and NICE guidance that midwives were expected to follow. It also refers to the 'Fresh Eyes' approach which was a requirement for a midwife's caseload to be reviewed by a locality coordinator on a monthly basis to ensure that a woman is on the correct pathway as per the guidance in the MMR document.

6.32. One to One were required to comply with the standards for maternity services set by the Clinical Negligence Scheme for Trusts (CNST) as part of the conditions for cover under the scheme.

6.33. One to One's adherence to best practice standards (NICE and CNST standards) was called into question by NHS Trusts and was one of the reasons why they were unwilling to agree care pathways with One to One. This was identified in CQC reports, serious incident reports and in contract monitoring meetings.

Clinical audit

6.34. In 2014 the CQC identified issues with One to One' s clinical audit processes, namely:

- several planned audits were overdue;
- it was difficult to see how learning from audits was shared;
- some audits lacked a methodology, for example, the case note audit did not specify the standards case notes were being audited against; and
- attendance at the Audit Group was described as poor, with the notes from the meeting lacking the detail needed for dissemination across the organisation.

6.35. The Desktop Review in 2015 noted that One to One had an overly ambitious audit programme and questioned its ability to meet its own expectations. The Desktop Review recommended that One to One identify critical issues that required audit and concentrate on these.

6.36. When the service in Essex was inspected in 2016 by the CQC, One to One was advised to improve its audit processes. This was mirrored by recommendations from an inspection completed in the North in the same year for One to One to develop a comprehensive focussed audit and monitoring strategy.

6.37. One to One reported on audits in the Quality Reports but in the main these did not contain sufficient information about the findings from audits. The Quarter 3 2018/19 Quality Report did contain information about an audit completed that highlighted a lack of continuity, unanswered telephone calls and a lack of advice for women. This was not questioned by commissioners and there was no evidence of any audits being shared with commissioners

Corporate risk management

6.38. The Quality Surveillance Group held in the North West in November 2014 identified that One to One's organisational risk management arrangements were out-of-date. The Desktop Review completed in February 2015 was not assured that there were appropriate risk management processes in place.

6.39. One to One maintained a corporate risk register. The CQC identified issues with One to One's organisational risk register in 2014. They found that the risk register did not clearly articulate all risks, their causes and consequences. Furthermore, completion dates were sometimes identified as 'ASAP' or 'ongoing'.

6.40. There were further concerns when the CQC completed an inspection in the North in 2017. The risk register had been reviewed and there was an action plan in place. Five of the identified risks remained static and had been rolled over from the previous register. This included the recruitment and retention of midwives. This risk had increased from moderate to high, but the action plan remained unchanged. Two of the new risks identified did not have an action plan documented, despite one of them being rated as high.

Quality reporting

6.41. One to One produced an annual Quality Report known as a 'Quality Account', which was shared with commissioners. The production of a Quality Account was a requirement of the contract and this report sought to comply with these requirements. One to One also produced quarterly Quality Reports for internal purposes which appear to have been shared with commissioners from the end of 2017/18 as One to One had advised that they contained a greater detail on incidents and learning.

6.42. We have reviewed the Quality Accounts from 2011 to 2017/18 and the quarterly Quality Reports from Quarter 4 2017/18. The two sets of documents taken together provide a considerable level of insight and intelligence relating to One to One's services. However, each in isolation does not provide a comprehensive view.

6.43. Our observations on the annual Quality Accounts are as follows:

- There is a significant amount of narrative in the documents explaining the model of care, the quality framework and how the service is evaluated from a safety, quality and experience perspective. This was helpful for commissioners to inform their understanding of the service and how performance should be monitored, but it did not need to be repeated every year.
- The reports generally present positive messages without giving sufficient balance with regard to areas identified for development and the actions to be taken to address them. However, we found the tone comparable to Quality Accounts produced by NHS Trusts.
- They contained a comprehensive presentation of key performance metrics against national performance. It was helpful to see a national comparison but there was no comparison of trends year-on-year to understand whether performance was improving or deteriorating and there was no separate analysis for the North West and North East Essex.
- Client feedback through surveys was very comprehensively presented and included direct feedback from women on their birth stories.
- The section on safety was weak; significant gaps were incident reporting, complaints analysis and workforce metrics relating to safety such as caseloads, staff turnover and absence.
- The reports referred to clinical audits undertaken and planned but gave little explanation of the findings of audits, areas identified for improvement and associated actions taken.
- Ways of working with system partners were described and some partners provided feedback on One to One, but there were important omissions as there was no feedback from NHS Trusts and General Practice.
- The reports presented statements of generic priorities for the following year, but links were not made between reports year-on-year through monitoring of an associated action plan.
- The report format was not consistent over time and would have benefitted from a standard structure. However, it was clear that the report improved in terms of additional content year-on-year, for example, with dedicated sections on training and supervision, employee satisfaction and safeguarding.

6.44. The quarterly Quality Reports were concise and well presented. They generally reflected information contained in the Quality Accounts but were more focussed on specific deliverables and on providing more insight from incidents, evidence of learning and actions taken. Our other observations on these reports are:

- A good level of detail was provided in a tabular format on incidents with helpful commentary, learning points and actions taken. Apart from serious incidents, this analysis included a focus on specific areas and themes such as Transfers from Home Birth, Neonatal transfers and 'Births Before Arrival.'
- Some of the actions from learning were not specific enough, for example, "*to be discussed at team meeting*," and needed to indicate further follow-up, for example, through audit.

- The reports did not provide a summary of performance against key metrics (as this was provided in the Quality Account) with trends and analysis of exceptions.
- Some gaps remained in terms of learning and actions taken from the findings of clinical audit and review of complaints. We only found reference to these in one of the quarterly reports.
- There was reference to the number of entries on the risk register but no indication of the nature of the risks themselves.
- The later reports started to comment on workforce metrics in terms of leavers and sickness absence, but these were absolute numbers and trends could not be observed as these metrics had not been reported on previously.
- There was an excellent section in one of the reports on exceptions relating to screening metrics; this was presented separately for each locality and provided a full explanation of exceptions. We understand that this information was collated from the out-sourced diagnostics provider.

Safety risks

6.45. In this section, we provide an overview of One to One's approach to informed choice, shared care arrangements with NHS Trusts, medicines management and staffing, as these were some of the key safety risks raised through NHS quality surveillance over the lifetime of One to One. We have examined safety with reference to incident management in Section 7 of the report.

Informed choice

6.46. It is good practice to provide each woman with information about her clinical options and for the midwife to explore the pros and cons for each option with her. This should include a discussion about the risks of each option, based on the woman's maternity history and her current pregnancy. This should allow the woman to have the pregnancy and birth that she wants, in the safest environment. Good practice is to review options throughout the pregnancy and birth and change plans if required.

6.47. One to One accepted woman of all risk profiles for care as the core ethos of the company was to offer more choice to all women. One to One staff confirmed verbally during the Desk Top Review visit in 2015 that if a woman exercised her choice to access their services, then regardless of risk, One to One would provide midwifery care. This approach was challenged in situations where NICE guidance recommended that women with identified risk factors should receive antenatal/postnatal care and give birth in an obstetric unit.

6.48. In these circumstances, although the midwives working for One to One would inform the woman of the risks associated with different care options , if a woman decided to refuse care from other providers, then this was viewed as informed choice by One to One.

6.49. It was clear from interviews that One to One staff were very conscious of the need for women to make an informed choice and for the documentation on that choice to be explicitly recorded. However, there were times when assurance over this was weak. This was confirmed by the audit of clinical records undertaken as part of our review. The clinical notes have a series of tick boxes to identify information shared with women, but there is limited narrative to identify the discussions they had with the woman.

6.50. It is also good practice to support a woman to identify the place of birth before 20 weeks' gestation. The One to One Practice Point for a normal birth clearly states that a woman should not be pressured to decide her place of birth, discussions

should be ongoing throughout the pregnancy and the decision might be made while the woman is in labour.

6.51. There was clear evidence that One to One was not expecting women to identify the place of birth until late in their pregnancy. Information about women under the care of One to One at the point of business cessation indicated that approximately a third of women had not identified the place of birth at 30 weeks' gestation. In fact, there were a number of women at 40 weeks plus who had yet to identify the place of birth.

6.52. In December 2018, West Cheshire CCG noted that One to One should focus on supporting women to choose the safest place for the birth, rather than focussing on choosing a home birth.

Shared care

6.53. The One to One model of care was midwife-led with some women opting to give birth at home, but a large proportion opting to give birth in the local NHS obstetric unit. For some women, their clinical presentation required obstetric advice or other elements of their care to be provided by an obstetric-led service. As a result, One to One and NHS Trusts were dependent on each other to ensure that safe and effective shared care arrangements were in place.

6.54. Under the contract service specifications, there was a requirement for One to One to put shared care pathways in place with NHS Trusts and other care providers involved in the maternity care pathway. These shared care pathways were needed for obstetric advice for women with other medical conditions such as diabetes and epilepsy, for women who chose or were advised to give birth in an NHS obstetric unit and for emergency situations during pregnancy and labour.

6.55. Developing shared care pathways proved to be a major challenge for One to One and NHS Trusts. There is evidence from both sides that attempts were made to put formal shared care pathways in place. One to One was working with a large number of Trusts, across Cheshire and Merseyside (C&M) and in Essex, each with their own policies and procedures. One to One needed to develop pathways with each individual Trust which was particularly onerous for a small organisation.

6.56. Another barrier to the development of agreed shared care pathways was the different philosophical views of both parties to pregnancy and childbirth. One to One believed themselves to be focussed on the needs of women and that the care provided by NHS obstetric-led units was being driven by inflexible policies and procedures. NHS Trusts did not consider the One to One approach to be clinically safe.

6.57. Examples of some of the attempts made to develop effective shared care arrangements were:

- The local NHS Trust in North East Essex was asked by the CCG to put in place a service level agreement for shared care pathways as a matter of urgency in September 2014. Although the CCG understood that an agreement was in place, we did not have sight of a signed document. When the CCG asked for this to be updated in 2017, the action was not progressed further.
- An NHS Trust in the North West concluded that they did not have the clinical resource to develop care pathways with One to One. They stated that this would require them to consult on, communicate with and train the One to One staff on the Trust's 100+ clinical policies, guidelines and pathways.
- Following Wirral CCG's amendment to the service specification requiring One to One to use the obstetric teams of local NHS Trusts for obstetric advice, One to

One developed draft specifications for joint obstetric care arrangements with NHS Trusts. We found no evidence that these were formalised.

- In 2017, Warrington Hospital was considering a formal arrangement to provide obstetric services across the C&M footprint as part of the pathway for all women booked with One to One; other NHS Trusts were also interested in this model. This did not come to fruition, reportedly due to resource constraints for Warrington Hospital.
- One to One highlighted the misunderstanding over shared use of their community hubs; One to One invited Trusts to make use of these facilities to encourage shared care, support continuity and improve relationships. Commissioners had understood that One to One were expecting payment for use of these facilities.

6.58. Although we found evidence of some Trusts working with One to One to develop agreements, we did not have sight of any formal signed agreements. Despite some evidence of a willingness to cooperate and agree shared care pathways for the safety of women, the differences in clinical perspectives and practical challenges could not be resolved. This meant that both One to One and NHS Trusts were operating with a level of risk to women and their babies.

6.59. In practice, relationships between One to One and NHS Trusts at an operational level were difficult. There were reports of a lack of professional courtesy from Trust midwives towards One to One and at times behaviours were described as bullying and intimidating. This resulted in One to One midwifes being reluctant to support women who needed to be seen by NHS Trust obstetric services.

6.60. Information-sharing issues were problematic. The Desk Top Review in 2015 found that One to One did not have robust information-sharing processes in place with local NHS maternity units. CQC reports found that communication with local maternity providers was poor in 2016 and 2017. This was because up-to-date information about a woman's care was not always available in her handheld notes. The review we completed of clinical notes was unable to establish if SBARs ((the Situation, Background, Assessment, Recommendation forms – see further below) were shared with local maternity providers when a woman transferred to them.

6.61. One to One completed their documentation on a bespoke electronic system that could not be accessed by NHS providers. In addition, NHS Trusts did not all use the same systems, which compounded the difficulties.

6.62. One to One's handheld notes did not always contain sufficient information to inform clinical decision-making if a woman attended an NHS obstetric unit without the support of a One to One midwife. In the event of an emergency admission, the absence of the appropriate standard handover documentation (the Situation, Background, Assessment, Recommendation (SBAR) form) meant that the NHS obstetric team would not have access to comprehensive clinical notes or information on any risk factors. Some Trusts reported that often the first time they became aware of a woman was when she transferred to them in labour.

6.63. One to One frequently stated that they did not receive information from NHS Trusts about incident investigations and sufficient backing information for invoices on the treatment provided by NHS Trusts.

6.64. We were told that One to One received minimal support from commissioners or Local Maternity Systems to progress shared care arrangements. The CCGs' expectation was that women with complex issues should receive obstetric advice and care from the local Trust. The CCGs were not prepared to endorse the part-time Consultant Obstetrician employed by One to One; it would therefore have

been reasonable to expect them to have supported the development of arrangements between One to One and the Trusts.

Medicines management

6.65. Concerns were raised about One to One's management of medication in four of the CQC inspections (Wirral 2015, Essex 2016 and both the Wirral and Essex inspections in 2017). The inspection in 2015 identified that One to One did not have a Home Office licence for the provision of Schedule 2 Controlled Drugs[18]. One to One chose not to apply for a licence and as a result, women in the North did not have access to opioid-based pain relief. This resulted in women transferring to NHS Trusts during labour to manage their pain. These were reported as incidents by the NHS Trusts involved. The issues around One to One's management of Schedule 2 Controlled Drugs were resolved by them ceasing to support women to access opioid pain relief from their GP.

6.66. The 2015 inspection also identified gaps in both processes and policies to ensure the safe management, storage and use of medicines (specifically Entonox). Issues with One to One's medication policies had not been addressed by the time of the inspections in Wirral and Essex in 2017. The report for the Essex inspection identified the need for an up-to-date policy on controlled drugs and medicines for the third stage of labour. We have no evidence that the CQC followed up on their recommendations relating to these issues.

Staffing and caseloads

6.67. One to One faced persistent staffing challenges, due mainly to the difficulties in staffing a continuity of carer case loading model. Better Births describes this model as consistency in the midwife or clinical team that provides care for a woman through the three stages of pregnancy and birth, such that there is a named midwife who takes responsibility for coordinating the women's care.

6.68. One to One employed midwifes to be available to the women on their caseload 24/7 and 365 days a year. This model was challenging for staff in terms of their workload and work/life balance. There was clear evidence of these emerging difficulties:

- In 2015 the CQC raised concerns about the sustainability of the model based on concerns raised by staff.
- The staff survey in 2017/18 identified that 50% of staff felt able to meet all conflicting demands on their time while at work. 52% felt there were enough staff to allow them to do their job properly. 78% stated they regularly worked unpaid overtime to complete their work. Three staff said that their teams were understaffed.
- The survey provided evidence that staff did not feel valued and there was poor communication between the senior leadership team and the staff. At interview we were told that new staff could feel unsupported. One midwife reported being given a caseload and an 'A to Z' without any form of induction to the organisation or the locality.
- We were told by some midwives of the challenges of the One to One model, for example, in balancing the demands of the job against their family and private life. The One to One model was one that required a personal commitment and belief in the philosophy.

[18] https://www.nice.org.uk/guidance/ng46/evidence/full-guideline-pdf-2427186353

6.69. These issues resulted in a high turnover of staff. The CQC identified that recruitment and retention of staff was on the organisation's risk register and in January 2017 it was identified as a high risk.

6.70. The following table provides an indication of One to One's staffing profile, from the information available to the review at key points in time.

Table 2: One to One's staffing profile, October 2012 and May 2018

Staff group	October 2012	May 2018
Senior management	5	9
Midwives	9	68
Midwifery assistants		13
Administration	4	20
Total	**18**	**110**
Approximate bookings per month	*53*	*250*

Note: these are number of staff in post (not full-time equivalents)

6.71. One to One's team in October 2012 consisted of 18 staff: a Clinical Director, three Clinical Leads, a Midwifery Team Leader, six experienced midwives and three newly qualified midwives, and four administrative staff. The level of activity under the Wirral contract at this time was approximately 53 bookings per month and seven home births per month.

6.72. By 2018, bookings had increased to a level of 250 per month, a fivefold increase. Midwifery staff had increased from 9 to 81, a ninefold increase. Administrative and senior management staff had increased from 9 to 29, a threefold increase.

6.73. One to One's planned ratio of midwives to women was an average of 1:35. This was in line with the recommendations of implementation guidance for Better Births[19] issued in December 2017 which referred to the Birthrate Plus®[20] assessment of staffing requirements for home birth models and an average caseload of 1:36. A CQC report for Neighbourhood Midwives in April 2017 also referenced a 1:35 ratio as appropriate.

6.74. Based on a simple calculation from the table above, in 2018, the ratio for One to One midwives was approximately 1:44 (excluding midwifery assistants). This indicates that midwife caseloads may have been higher than planned in 2018. At this point, One to One could have been operating on a team-based model, as reported to West Cheshire CCG in 2017, which would have allowed them to have larger caseload numbers. However, we note that the CCG challenged the use of a team-based model as this did not reflect the requirements of the service specification and One to One stated that they reverted to a full case loading model.

6.75. One to One had a good relationship with Edge Hill University and provided placements for student midwives. Recruitment often came from newly qualified midwives who lacked the experience needed for the level of independent practice required by the One to One model. This was raised in the Wirral contract meeting in October 2014. Concerns about the employment of newly qualified midwives were also noted in both of the CQC inspections completed in Essex.

[19] https://www.england.nhs.uk/wp-content/uploads/2017/12/implementing-better-births.pdf
[20] Birthrate Plus® Methodology - Birthrate Plus®

6.76. There were concerns about the quality of the NHS England commissioned screening services provided by One to One. We were told that this was due to the fact that midwives were not initially trained to perform Newborn and Infant Physical Examinations and it took a considerable period of time to obtain placements for this training.

6.77. The experience profile of the midwives employed by One to One, according to their staff survey of 2018, is shown in the table below. We were unable to identify the number of respondents to the survey. A third of the midwife workforce at this point consisted of midwives with less than one year's experience and 57% had less than two years' experience.

Table 3: Experience profile of One to One midwives, 2018

Experience	% of 2018 survey respondents
Less than a year	33
1 – 2 years	24
3 – 5 years	33

6.78. In 2015 the Local Supervising Authority Midwifery Officer raised concerns about midwife supervision numbers. One to One had three supervisors but the ratio of supervisors to midwives was unclear as staffing numbers were not provided at this time. One to One were considering a full-time supervisor rather than several midwives undertaking the role. Supervisors were not remunerated for taking on the additional responsibilities of the role other than to have dedicated time. Resources to provide supervision may have been a challenge for One to One due to the size of their operation; however, this was not substantiated in One to One's description of their model in February 2014. This stated that One to One had a ratio of 1:9 (supervisors to midwives); this compared favourably with the recommended LSA ratio of 1:15.

6.79. The Quality Risk Profile (QRP) Tool completed by NHS England North in October 2015 required Wirral CCG to obtain assurance on the completion of annual competency assessments for One to One Midwives and their continued professional registration with the Nursing and Midwifery Council. As part of the QRP submission to provide assurance that staff were fit for practice, One to One described:

- induction, orientation, and a full year of Preceptorship for all newly qualified midwives;
- staff learning passports with annual mandatory updates;
- fortnightly rolling training programmes which included emergency skills drills;
- reflective practice monthly group meetings; and
- instant access to evidence-based guidance on iPads.

6.80. As part of the QRP oversight process, Wirral CCG were required to routinely monitor the following staffing metrics:

- turnover and vacancy rates;
- sickness rates;
- use of agency staff;
- percentage of staff completing appraisal/professional development reviews; and
- midwife revalidation.

6.81. We did not find any evidence of any routine monitoring of these metrics through the performance dashboard or other information provided to contract meetings and it was unclear whether this was followed up subsequently through QRP oversight. We have commented further on the use of this tool in Section 17 on system oversight.

6.82. Better Births recommended that a midwifery team should have an identified obstetrician for advice. One to One accessed the support of NHS obstetric units for women with more complex needs or who were assessed as of a higher risk profile. From summer 2014, One to One employed a part-time Consultant Obstetrician who was a former Clinical Director of an NHS Trust and championed the One to One model. The Consultant Obstetrician provided non-urgent obstetric advice to women and midwives. One to One's intention was to provide better continuity for women and the Consultant Obstetrician would advise women if there was a need to go to a hospital obstetric service. One to One also aimed to generate cost savings as a result, by avoiding provider to provider charges for NHS obstetric advice.

6.83. An NHS Trust due diligence paper stated that the contractual arrangements were that the Consultant Obstetrician could complete medical examinations, order investigations and review the care of individual women. The obstetrician was contracted for 12 hours a week across all locations. He was also employed in the NHS at the time.

6.84. One to One were informed in January 2015, that commissioners did not support this model for obstetric input and were told that this should cease, and referrals be made to local NHS obstetric units. The service specification was subsequently amended to formalise this. One to One ceased clinics but retained the support of the Consultant Obstetrician for advice on complex care and additional quality assurance. The obstetric clinics continued in Essex, and we were told that commissioners did not raise any objections to this although we found a reference to concerns about the obstetric support only being available at the weekends.

6.85. One to One moved to self-managed teams in North East Essex, referencing the Buurtzorg model[21]. We understand from interviews that the 'self-managed teams' model was also being implemented in the North West. This resulted in team members taking on non-clinical responsibilities such as finance, recruitment and HR for their team, in addition to their clinical duties. The 2018 staff survey identified that staff found this difficult, and this was supported by the interviews completed by our review. We were also told that newly qualified staff found it a challenge to work within the model, and at times lacked the commitment required.

6.86. At the second Essex inspection in 2017, the CQC were concerned that there was no longer a Registered Manager for Essex or a dedicated Clinical Manager, as One to One had moved to a 'self-managed teams' model with remote central management. They were also concerned about staff supervision and lone working.

Case note review: key findings

6.87. We completed a review of 42 sets of One to One's clinical notes, covering a period from 2015 to 2019. Of these notes 23 sets were complete, meaning that both the handheld and electronic notes were present, and 19 were in the form of electronic notes only. The full review is provided in Appendix 3. Our key findings are shared below.

6.88. There is some evidence that women with underlying health conditions were managed well, with shared care in place.

[21] The Buurtzorg Model - Buurtzorg International

6.89. There was no narrative record of the discussion leading to informed choice decisions in any of the notes we reviewed. These were recorded using a tick box menu of discussion points and reference to NICE guidance.

6.90. There was only one record of One to One requesting the notes for a previous pregnancy outcome.

6.91. Where women had transferred their care from another provider to One to One, no information was recorded at the booking appointment about previous care and no clinical assessments were available. This is of concern, as many women transferred in their second or third trimester.

6.92. SBAR information was not recorded in the handheld notes, therefore information about triage assessment was not available if a woman attended hospital alone. Furthermore, the midwives did not always make direct contact with the local Trust when a woman attended the hospital alone.

6.93. Fresh Eyes reviews were introduced as part of the Midwives Mitigating Risk policy in February 2016. The requirement was for each midwife's caseload to be subject to monthly review by the locality coordinator or a lead midwife to ensure that the woman was on the appropriate care pathway. Fresh Eyes had been completed for seven of the 35 sets of notes that were eligible for our review. They were not completed by a lead midwife or locality coordinator as we would have expected; instead, they were completed by a buddy midwife. They were not comprehensive. The outcomes were that the care was appropriate. Only one set of notes made a substantive comment about care.

6.94. We found that details of conversations about the choice of place of birth were not recorded. There was a reliance on tick boxes to demonstrate that discussions had occurred but limited narrative of the discussions.

6.95. There were safeguarding records for the one woman in the review with a history of mental health issues and drug use. There were plans in place for two women identified with low level mental health needs.

6.96. Controlled drugs were not available to the women we reviewed; there was no evidence of conversation with women about access to pain relief in labour.

6.97. Observations were not recorded on Maternal Early Obstetric Warning Scoring System (MEOWS) charts where relevant.

6.98. Postnatal information was not included in the handheld record for either mother or baby.

Summary points

6.99. One to One's quality governance arrangements were not sufficiently defined to allow a full picture to be gained of governance structures and processes. There was evidence of appropriate governance groups operating below Board level with senior representation, but it was unclear how the Board scrutinised and gained assurance on safety and quality issues as a collective. In addition, there was no independent representation for quality governance on the Board or any of the existing clinical governance forums in place.

6.100. Governance meetings appeared to cover the core dimensions of quality governance – clinical governance, quality performance review, audit and policies and procedures. However, without sight of terms of reference and papers for these meetings, their remit was unclear.

6.101. Initially there were clearly identified clinical lead roles through a clinical leadership team of four senior staff. By 2015, the structure was less well defined, with clinical leadership provided through the Chief Executive and a Clinical Director.

6.102. We were told that over time, there were many changes in roles and responsibilities for governance below Director level which were not conducive to the establishment of solid and consistent governance arrangements.

6.103. Repeated concerns were raised by the CQC regarding fundamental weaknesses in One to One's quality governance arrangements, including the robustness of policies and procedures, risk management, clinical audit and medicines management.

6.104. A suite of policies and procedures were maintained but we found weaknesses in the governance arrangements over policy development and ratification. There was no evidence of independent clinical review of One to One's policies or procedures. In addition, we were told that there was a lack of a structured and robust approach to the development of clinical policies which were frequently developed in a rushed, reactive way in response to requests from commissioners and the CQC.

6.105. Multiple weaknesses were identified by the CQC around clinical audit processes and the CQC were not assured that processes were effective in providing assurance on safe care and treatment. Our review of Quality Reports found that information on audit outcomes was insufficient for learning purposes.

6.106. The quarterly Quality Reports produced by One to One were concise and well presented. They generally reflected information contained in the Quality Accounts but were more focussed on specific deliverables and on providing detailed insight from incidents, evidence of learning and actions taken.

6.107. The Quality Reports required more work on structure and presentation of trends in performance, learning themes and actions, but they provided a good basis for further development for internal and external assurance purposes. The safety section of the reports required strengthening by a focus on themes, learning and actions from audit, incidents and complaints. In addition, workforce metrics should have been included as a key aspect of safety.

6.108. Based on the evidence available to our review, we were not assured that One to One had systematic, robust quality governance processes in place to ensure the safe care and treatment of all women. If One to One had been able to demonstrate a good standard of internal quality governance to commissioners and NHS providers, this might have strengthened confidence in their service and willingness to collaborate.

6.109. One to One staff were very conscious of the need for women to make an informed choice and for the documentation on that choice to be explicitly recorded. However, there was clear evidence of concerns in this regard which were confirmed by our review of clinical case notes.

6.110. Women not deciding the place of birth until late in their pregnancy or during labour created tensions with the local maternity providers who often only became aware of a woman when she transferred to them in labour. The safety of women and babies was also compromised by this practice.

6.111. One to One accepted woman of all risk profiles for care as the core ethos of the company was to offer more choice to all women. This was identified as a concern by local maternity providers, when high-risk women transferred to them, and by the CQC who raised concerns in inspections in 2016 and 2017 about the training of midwives to care for high-risk women.

6.112. There were unacceptable risks to the safety of care and treatment due to the absence of formal shared care agreements and robust information-sharing protocols between One to One and NHS Trusts. Despite some evidence of a willingness to cooperate and agree shared care pathways for the safety of women, the differences in clinical perspectives and practical challenges could not be resolved. More proactive support from commissioners might have facilitated the earlier implementation of shared care agreements.

6.113. Over its lifetime, One to One faced ongoing staffing challenges due to the difficulties in staffing a continuity of carer model which required midwives to be available for their caseload 24/7 and 365 days a year. This model was challenging for staff in terms of their workload and work/life balance. Recruitment and retention of staff was identified as a high risk on One to One's risk register.

6.114. There were gaps in the skills of midwives and evidence of a significant proportion of midwives being relatively recently qualified. This was identified as a concern by the CQC in the inspections in the North in 2016 and 2017, and in Essex in 2017.

6.115. Attempts were made to address some of the staffing and financial challenges, such as use of a team-based model rather than full case loading, recruitment of an in-house obstetrician and a move to self-managed regional teams. However, these operational changes were not acceptable to commissioners who had commissioned a full case loading model.

6.116. Our review of clinical records found that there was an over-reliance on the use of tick boxes in the notes which does not provide sufficient evidence of the discussions with women to support decision-making. There was no evidence that SBARs were shared with local Trusts and GPs. There was insufficient evidence to determine whether electronic notes were made contemporaneously or later when the midwife returned to the office.

What could have been done differently?

- Although One to One was a small business where less formality in governance structures would be expected, it would have been reasonable to expect a single forum for quality governance with membership from Directors, clinical leads, governance, and quality managers.
- It would have been prudent for One to One to have considered appointing a non-executive member of the Board to give a degree of independence to the oversight of quality and safety.
- More rigour should have been applied by One to One to the development of policies and procedures and their approach to risk management, including independent review.
- One to One should have developed a single Quality Report both for ongoing internal use and to feed into an annual Quality Account for commissioners. It would have been reasonable to share a redesigned report on a quarterly basis with commissioners to provide much greater insight and assurance at contract meetings.
- One to One should have put more robust supervision processes in place to ensure that the requirements of Fresh Eyes were being adhered to.

Recommendations

1. As part of due diligence, commissioners should assess the governance arrangements in place with independent sector providers to ensure they will meet their expectations for delivery of NHS-funded services.
2. Proportionality should be exercised for small businesses in terms of how commissioners and regulators assess governance arrangements in the independent sector.
3. Commissioners should consider a contractual requirement for an independent clinical representative on the Board of small, family-run businesses providing NHS-funded services.
4. A single governance forum for safety and quality with appropriate senior clinical representation and standardised performance reporting should be a core requirement for independent sector providers so that commissioners can link into this forum for more robust assurance.

7. Incident management

Introduction

7.1. We have reviewed the management of incidents against the requirements of the NHS England Serious Incident Framework 2015 (SIF)[22]. This framework is designed to inform staff providing and commissioning NHS-funded services who may be involved in identifying, investigating or managing a serious incident.

7.2. We have reviewed the data provided for our review to summarise the themes and outcomes from incidents involving One to One. We asked NHS Trusts and CCGs to share with us all incidents reported where some aspect of care had been provided by One to One. Not all the NHS Trusts and CCGs provided incident information, therefore our analysis is limited to the information provided for our review.

Key findings

Serious Incident Framework

7.3. The Serious Incident Framework (SIF) 2015 sets out the process for the management of incidents by healthcare providers and commissioners. We highlight that the SIF provides best practice guidance and is not mandated. It identifies process and procedure to ensure that serious incidents (SIs) are identified correctly, investigated thoroughly and learned from, to prevent the likelihood of similar incidents occurring again. The guidance applies to all NHS providers including independent operators providing NHS-funded care.

7.4. Serious Incidents (SIs) are defined as including "acts or omissions in care that result in unexpected avoidable death, unexpected or avoidable injury resulting in serious harm, abuse, Never Events, incidents that prevent (or threaten to prevent) an organisation's ability to deliver the acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare service."

7.5. Healthcare organisations are required to identify and report incidents and consider whether the incident meets the criteria for further investigation. Investigations are completed at one of three levels:

- Level 1 is a concise internal investigation and report completed by the local team.
- Level 2 is a comprehensive internal investigation completed by someone from the organisation who is external to the service/area where the incident occurred.
- Level 3 is an independent external investigation commissioned by NHS England when the integrity of the investigation is likely to be challenged or it might be difficult for the organisation to conduct an objective investigation.

7.6. One to One's quarterly Quality Report contained information about the number of clinical and non-clinical incidents that did not require investigation. We would have expected to have seen discussion of these incidents with commissioners. A good understanding of the learning from low/moderate level incidents can support the identification of trends and themes and learning from these can improve clinical practice and lead to a reduction in the number of incidents that result in harm and require investigation.

[22] https://www.england.nhs.uk/patient-safety/serious-incident-framework/

Analysis of incidents involving One to One

7.7. We asked the CCGs who were party to the co-commissioned contract, West Cheshire CCG, North East Essex CCG and NHS Trusts in Cheshire and Merseyside and Essex, to share all SIs reported and investigated involving care provided by One to One. A total of 137 incidents were shared with us over the period from 2013 to 2019 and these are summarised in Appendix 4. There are some limitations to the analysis as there were gaps in the information provided which made it difficult to identify the incident type, the reason for reporting and contributing factors in all cases.

7.8. We also note that this is unlikely to be the complete dataset of incidents as we have not received any information for 2010/11 or 2011/12 and not all the CCGs and NHS Trusts shared information with us. The following table shows the number of incidents, by organisation, from our analysis of the information provided. 103 (75%) of the incidents were reported on StEIS. It should be noted that these are all incidents where an element of care was provided by One to One.

Table 4: Incident numbers provided by organisation

Organisation	No. of incidents	Reported on StEIS
Calderdale CCG	2	2
Colchester Hospital	1	1
Countess of Chester Hospital	2	2
Liverpool CCG	3	3
Liverpool Women's Hospital	3	3
Mid-Cheshire Hospitals	3	3
North East Essex CCG	10	6
North Manchester CCG	1	1
South Cheshire CCG	88	61
St Helens and Knowsley Teaching Hospitals	1	1
Trafford CCG	1	1
Vale Royal CCG	3	2
Wakefield CCG	1	1
Warrington CCG	2	2
Wirral CCG	5	5
Wirral University Teaching Hospital	4	4
Cheshire & Merseyside (unspecified)	2	2
Not specified	5	3
Total	**137**	**103**

7.9. There is a clear anomaly in that South Cheshire CCG reported 59% of the total incidents on StEIS. As this type of analysis was not undertaken to provide a single view for commissioners, there is no evidence that this line of enquiry was investigated either by One to One or commissioners.

7.10. The following table provides an indication of the number of incidents reported by year and by type of incident, based on an indicative categorisation from the information available.

Table 5: Incidents by indicative category and year

Incident type	2013	2014	2015	2016	2017	2018	2019	Total	%
3rd degree tear				1		1		2	1%
Baby death		1				1		2	1%
Clinical care			1	4	9	12	6	32	23%
Emergency c-section				1				1	1%
Intrauterine death	2	2	2		4	1		11	8%
Maternal haemorrhage			1	4		5	2	12	9%
Neonatal death	1	2				2		5	4%
NICU admission	2	7	5	2	2	5	3	26	19%
Postnatal baby admission			1					1	1%
Retained placenta			1	2	1			4	3%
Safeguarding					4	2		6	4%
Sepsis					1			1	1%
Stillbirth			1					1	1%
Unplanned caesarean							2	2	1%
Other care issue			7	7	6	4	2	26	19%
Not indicated			2	3				5	4%
Total	**5**	**12**	**21**	**24**	**27**	**33**	**15**	**137**	**100%**

7.11. Our observations on the analysis above are:

- There were 11 intrauterine deaths over the period; in five of these cases problems with communication and shared care were cited. There were seven neonatal and baby deaths, but limited information was provided on the contributory factors to these.
- Almost a fifth of incidents related to an admission to a Neonatal Intensive Care Unit following a birth. There were multiple contributing factors, including weaknesses in clinical care, risk management, transfers in labour, record keeping and communication around shared care.
- There were 16 cases involving maternal haemorrhage/retained placenta; no detail was provided for 11 of these cases so key themes could not be identified. Two cases involved transfers during labour.
- Almost a quarter of incidents involved a problem with clinical care that we have been able to identify from the information provided. These problems included delayed transfers to obstetric care, transfers during labour and weaknesses in shared care arrangements having a direct impact on clinical care.
- Almost a fifth of incidents (25) indicated other quality of care issues. 11 of these incidents referred to issues with communication and shared care arrangements between One to One and NHS Trusts. The key other themes were risk management and communication issues with women and GPs.
- There was an increasing number of incidents over the time period (noting that One to One operated for only part of 2019). It should be noted that One to One were not able to report on StEIS prior to 2015. The inability to report to StEIS could mean a low benchmark from which to compare the subsequent increase in incidents from 2015.
- The very small numbers of deaths/stillbirths do not provide any meaningful analysis.

7.12. We highlight that the quality of the information provided does not indicate responsibility or otherwise for any failures in the care given to women; the incidents represent those where an element of care was provided by One to One. Given the deficiencies in the data, there is a need for caution in drawing firm conclusions from this analysis.

7.13. This type of analysis was not undertaken routinely by One to One or commissioners to provide trends and thematic analysis to inform joint review of serious incidents and root cause analysis investigations and to support learning.

One to One's approach to incident management

7.14. One to One's approach to incident management is articulated in their Clinical Incident Reporting Policy. This clearly identifies the incidents that need to be reported and the processes for doing this. The policy then outlines the processes to be followed to manage the incident, dependent on the severity. The policy is in line with the SIF.

7.15. One to One would appear to have had a robust process in place for reporting and managing incidents. They reported low level incidents in their Quality Reports and completed investigations into serious incidents, as discussed further below.

Commissioner oversight of incidents

7.16. There is a requirement for commissioners to hold initial discussions with a provider about all incidents that might meet the threshold for further investigation and agree to the appropriate level of investigation. They are further required to review the quality of the investigations and reports against the requirements of the SIF, support providers to develop action plans and monitor the implementation of these. Commissioners are responsible for closing the incident on the Strategic Executive Information System[23] (StEIS) once they are assured that action plans have been completed and learning from the incident is embedded in the organisation.

7.17. The SIF acknowledges that in a complex landscape with multiple commissioners and providers spanning local and regional geographical boundaries, a flexible approach may be required, with commissioners working collaboratively to agree how best to manage SIs. The SIF guidance suggests the identification of a 'single lead commissioner' (usually the commissioner with the greatest contract value) to lead the oversight of serious incident management for a provider organisation. This should be formally agreed through a collaborative agreement.

7.18. This allows the provider to report and engage with one single commissioner who can liaise with other commissioners. This approach supports continuity in the management, oversight and assurance of SIs, and at the same time minimises the risks of ambiguity and of SIs being overlooked. Furthermore, the approach reduces duplication where there is confusion about accountability and/or responsibility for the general management of the SI process.

7.19. Prior to 2017 we have not been able to identify a collaborative approach to the oversight and assurance of serious incidents involving care provided by One to One. It is evident from the information provided by Wirral CCG that from 2017 onwards there was a collaborative approach taken through Wirral CCG's Serious Incident Review Group (SIRG). The meetings reviewed SIs reported to them and to co-commissioners to the contract; the SIRG did not consider incidents arising in North East Essex.

7.20. The Wirral CCG SIRG was chaired by a GP, who was also the Chair of NHS Wirral CCG. The meeting was well attended by senior staff from the CCG including the Director of Quality and Safety, safeguarding leads, the quality manager and representatives from Wirral University Teaching Hospital (WUTH). It is to be noted that One to One did not attend any of the SIRG meetings where their SIs were

[23] The system which enables electronic logging, tracking and reporting of Serious Incidents between Trusts and Commissioners

discussed. It would have been good practice for One to One to be invited to attend these meetings.

7.21. We would have expected the SIRG to have used the SIF Closure Checklist to provide an assessment of each phase of the investigation, including setup, gathering and mapping, analysing information, and generating solutions. We have been provided with the minutes of the SIRG meetings in 2017 and 2018 where One to One incidents were discussed. These notes are, in the main, brief in nature and would have benefitted from references to the Checklist. This would also have allowed the SIRG to provide constructive, objective feedback to One to One on the quality of their investigations, reports and recommendations.

7.22. When initially approached, Wirral CCG as lead commissioner provided details of 11 SI investigations and reports between 2015 and 2019 which had been reported on StEIS by One to One. The CCG subsequently identified a further six incidents that were reported during this time period. We understand that the additional investigations and reports were identified by Wirral CCG in September 2019 upon further interrogation of StEIS following One to One's cessation. Of the total 17 incidents, eight occurred prior to 2017 and were not subject to the oversight and assurance of the Wirral CCG SIRG. The table below therefore provides a summary of discussions at the SIRG about the nine incidents reported between 2017 and 2019 and our comments.

Table 6: Incidents discussed at Wirral CCG SIRG, 2018 – 2019

Date of report	Date discussed at SIRG	Host CCG	Actions noted in SIRG minutes	Niche comments
27 April 2017	7 June 2017	Warrington	Completed action plan requested.	A completed action plan was provided but it was noted that there were actions for other providers that were not addressed or completed.
3 Jan 2018	10 Jan 2018	Wirral	Report noted 'for comment'. Wirral CCG corporate officer to provide feedback.	The minutes do not identify who the feedback is to be provided to – the CCG, One to One or the North West Ambulance Service (NWAS),
15 Feb 2018	7 March 2018	Warrington	Concerns about working hours for midwives. Corporate officer to feed back to Warrington CCG.	It is unclear why this incident was discussed again on 20 Nov 2018 and 10 Jan 2019 before it was agreed it could be closed on receipt of an action plan.
	20 Nov 2018		Concerns to be fed back to One to One. Concerns about rest time for midwives to be raised at next Quality Surveillance Group meeting and with the next scheduled meeting with One to One.	The meeting noted that One to One was under enhanced Quality Surveillance.
	10 Jan 2019		Additional information received from One to One.	The action plan had items identified as ongoing.

			Close on receipt of action plan.	
12 Oct 2017	7 Mar 2018	Wirral	The CCG had concerns about shared care pathways. Quality Meeting to be arranged between the CCG and One to One.	The CCG did not share the minutes of Quality Meetings with One to One for the purposes of our review, so we are unable to comment on the discussions held and the reason for the delay in this report being discussed.
25 Oct 2018	20 Nov 2018	Wirral	NWAS had not been included in the investigation. One to One to revise the report and resubmit as meeting not assured.	No evidence that the report was revised and resubmitted.
31 Oct 2017	12 Dec 2018	Wirral	Director of Quality and Safety to liaise with *[South Cheshire]* CCG to check that they were sighted on this incident and if they were to close it.	No evidence of the discussion, no feedback provided. It is not clear from the minutes why there was a delay in this report being discussed in SIRG.
24 Oct 2017	12 Dec 2018	Wirral	To close once completed action plan submitted.	One of the actions on the plan was identified as ongoing. It is not clear from the minutes why there was a delay in this report being discussed in SIRG.
12 Oct 2018	6 Mar 2019	Liverpool	Root cause analysis (RCA) and supporting documents to be shared with Liverpool CCG and to be brought back to the meeting.	At this meeting the agenda item was changed to One to One Ongoing Incidents update rather than a reference to the individual incident. This may have been due to the heightened scrutiny at this point in time due to One to One's financial position. It is not clear why there was a delay in this report being discussed in SIRG. There is no evidence that this RCA was brought back to the meeting for further discussion.
8 April 2019	3 July 2019	West Cheshire	To be closed once updated action plan received. Discuss with the CCG.	It is not clear from the minutes why there was a delay in this report being discussed in SIRG. No evidence an updated action plan was provided or discussion with the CCG took place.

7.23. Other observations on the information shared with us on the incidents identified by Wirral CCG are as follows:

- In 2015, the relevant CCG SIRG agreed to close an incident as they were assured that the action plan was complete and a letter to this affect had been sent to One to One. The incident remained open on StEIS.
- An email from North East Essex CCG to Wirral CCG in 2015 covered two incidents and stated that the investigation had been managed through their SI process and could be closed on StEIS, but they did not provide any supporting evidence.
- A further incident in 2015 had been discussed at the relevant CCG SIRG meeting but there were outstanding actions and the incident remained open. There was no evidence of further discussions about this incident.
- In 2016, the relevant CCG was not able to provide assurance about the completion of an action plan following an incident. The CCG view was that as One to One was "*no longer in business*" the outstanding actions about relationships with the local NHS Trust were no longer relevant and the incident could be closed on StEIS. One to One were operating at this time, so this incident may relate to a CCG who had ceased to use One to One's services.
- North East Essex CCG sent an email to Wirral CCG stating that the investigation for an incident in 2017 had been managed through their SI process and could be closed on StEIS, but they did not provide any supporting evidence.
- In 2017 and 2018 there were nine incidents reported to StEIS by One to One for which the Wirral CCG SIRG was responsible for oversight and assurance. We would have expected this meeting to also have had oversight of all incidents reported to StEIS by NHS Trusts where an element of care was provided by One to One. We have not been provided with evidence that this was the case.
- Investigations had commenced but were not concluded into two incidents reported in May 2019; One to One ceased trading in July 2019. As both incidents resulted in the transfer of mother or baby to an NHS provider, we would question why the CCG did not request that the provider conclude the investigation.
- We would have anticipated further discussion at subsequent meetings for some incidents, to follow up actions before they were closed. Of the incidents discussed at the SIRG shown in the table above, only one was discussed at more than one meeting, after which it was then considered appropriate to close it.
- For some of the incidents in the table above, there is a significant delay between the date of the incident's occurrence and its discussion at the SIRG.

7.24. There was no evidence of structured, routine commissioning oversight of safety and quality in contract meetings through incident reporting and monitoring. Incident themes and associated actions and learning were not visible. One to One provided their quarterly Quality Reports to this meeting from May 2015, which included details of incidents, but discussion was limited and unstructured. These reports were not reviewed routinely for the purpose of obtaining assurance on incidents. From February 2017 onwards hospital-reported incidents were included on the agenda for the co-commissioned contract meeting; however, there was limited discussion of such incidents at the meeting.

7.25. The SIF requires commissioners to share information about incidents with members of their local Quality Surveillance Group (QSG), for example, where the SI indicates

an issue or problem that has or may have significant implications for the wider healthcare system, or where an incident may cause widespread public concern. The QSGs did receive information on incidents which led to the Risk Summit processes.

7.26. Over the lifetime of One to One, concerns about the number of incidents by commissioners and NHS providers triggered single item Quality Surveillance meetings, Risk Summits and Care Quality Commission (CQC) inspections. Despite this, no arrangements were put in place for a single commissioner to accept responsibility for the oversight, management and assurance of One to One incidents.

Concerns raised

7.27. Throughout the lifetime of One to One, there were persistent echoes of concerns expressed by NHS providers and commissioners about the safety of One to One's clinical care and incidents; they shared these concerns with NHS England and the CQC. Examples of this are:

- In June 2012, WUTH raised concerns with commissioners about the clinical care provided by One to One. They provided details of 18 incidents that they identified relating to care provided by One to One. The issues raised included weaknesses in the 'buddy' system, missing notes, and a claim that women were being pressured into having a home birth. These concerns were investigated and determined to be unfounded.
- In November 2014, at the single item Quality Surveillance Group convened by NHS England North, it was reported that One to One had an SI rate (as a proportion of the number of births) of 2% compared with a rate of 0.2% for a large NHS provider
- In February 2016, Mid-Essex Hospitals NHS Trust reported that it was reviewing 21 incidents involving care provided by One to One, seven of which they considered might meet the threshold for an SI.
- In 2018, the Strategic Clinical Network (SCN) raised concerns about One to One's stillbirth rate. They commented that stillbirths reported by NHS providers may have related to care provided by One to One but were not attributed to them because they were not the lead provider for the birth.

7.28. We noted that One to One did not at any point report the factors which led to their significantly deteriorating financial position as an SI, yet this was a key driver of the loss of confidence in the service by stakeholders, particularly across Cheshire and Merseyside. The ramifications of this for the safety and quality of care were evident. Equally, commissioners did not report this situation as a serious incident.

Incident reporting

7.29. There were inconsistencies in One to One's reporting of incidents. Based on the information provided for our review, it was challenging to map out a clear narrative on the reporting of incidents.

7.30. To corroborate the information provided by CCGs and NHS Trusts on incidents, we cross-referenced it to the information provided to support the Risk Summits, CQC inspections and the quarterly Quality Reports compiled by One to One. This highlighted discrepancies in reporting between commissioners, NHS Trusts and One to One. Some of the factors we are aware of which may have contributed to these inconsistencies in reporting were:

- One to One were reporting incidents to multiple commissioners, depending on the area where the incident occurred. This was a significant administrative

burden and required conversations with many commissioners with different approaches.

- Prior to 2015, when One to One were providing care as non-contracted activity to some CCGs, it was not clear from the evidence provided to the review what incident reporting arrangements were in place.
- We have not been able to establish the incident reporting system used by One to One in the early years, although from 2015 they used the Ulysses system[24]. One to One was not able to report on StEIS prior to 2015.
- Where care was shared by One to One and an NHS Trust, it could be unclear who was responsible for reporting the incident and completing the investigation.
- There were challenges in interpreting data on incidents because a woman could receive care from more than one lead provider on a pathway, but the incident would be attributed to the lead provider at the time of the incident.

7.31. The CQC inspection report in June 2016 noted that One to One did not meet their duty to report incidents to the CQC. They were only reporting incidents within a narrow definition in that they were reporting incidents that they considered likely to threaten their CQC registration, rather than reporting all serious incidents. Commissioners were reporting all One to One incidents to the CQC.

7.32. The most comprehensive record of incidents was provided in One to One's quarterly Quality Reports. A good level of detail was provided on incidents, with helpful commentary, learning points and actions taken. Apart from serious incidents, this analysis included a focus on particular areas and themes such as Transfers from Home Birth, Neonatal transfers and 'Births Before Arrival'. Some of the actions from learning were not specific enough, for example, "*to be discussed at team meeting*", and would have benefitted from further follow-up, for example, through audit.

Investigating and learning from incidents

7.33. The lack of robust exploration of and learning from incidents by One to One was identified by the CQC in several reports:

- In 2014, they identified that learning from incidents was only addressed in meetings which did not require mandatory attendance by staff, and attendance was generally poor. Furthermore, there was a reliance on sharing information electronically. This provided limited assurance that staff had a good understanding of the learning and had embedded it in their clinical practice.
- In the same report, the regulator noted that although root cause analysis (RCA) was carried out, One to One did not appear to consider all possible contributory care and service delivery factors; also, that the investigations were limited and did not explore the cause of the incident.
- In 2015, the inspection team were not assured that incidents were being reviewed independently in line with good practice.
- In 2016, the inspection team reported that when reviewing six sets of notes to identify learning from incidents, all but one had documented the same statement with no specific detail on what had been discussed.
- In 2017, staff were asked about Duty of Candour and were not able to provide assurance that they had a full understanding of it or the process around it.

[24] https://www.ulysses.co.uk/]

7.34. We have completed a review of the SI reports completed by One to One which were shared with us, and we support the comments and findings of the CQC. Furthermore, the actions identified from investigations were repetitious which would indicate that an organisation was not learning from incidents.

7.35. In reading the investigation reports that originated with One to One, it would appear that the reports were completed in draft then shared with the NHS provider concerned who would comment by responding to questions from One to One. It is our view that this is not in the spirit of joint working and does not support joint learning from incidents. We would have expected the reports to demonstrate a collaborative approach with both providers developing the terms of reference, gathering and analysing information together, to reach mutually agreed conclusions and recommendations.

7.36. One to One investigations were completed by the Risk Manager and Clinical Governance Manager. We were told that these staff were trained in RCA techniques but were not provided with evidence to support this.

Summary points

7.37. Based on our analysis of information provided to the review for 137 incidents involving One to One, the key themes arising were:

- poor communication and shared care arrangements between One to One and NHS providers; and
- inappropriate risk management and delays in transferring women to obstetric care.

7.38. One to One had a Clinical Incident Reporting Policy that was based on the SIF and contained the relevant information about the identification and management of incidents.

7.39. The absence of an identified single lead commissioner to coordinate the management of and assurance for all incidents involving One to One was a significant risk management issue. Prior to 2017, this lack of oversight and leadership resulted in there being no coherent, evidence-based assessment of and opinion on the safety of the service. There was no collaborative agreement to identify a lead commissioner for SIs in line with the SIF recommendations, although we recognise this guidance is not mandated

7.40. Wirral CCG's Serious Incident Review Group (SIRG) did not appear to have oversight of all incidents reported by NHS Trusts where an element of care was provided by One to One. This was a key weakness given the issues experienced around shared care.

7.41. Our analysis of the 137 incident details provided to the review highlights clear inconsistencies in the level of reporting of incidents between CCGs which has not been queried by One to One or commissioners.

7.42. Our review of 17 incidents provided by the lead commissioner to the contract over the period from 2015 to 2019 found examples of incidents not being closed off or being closed without the appropriate evidence to support this action. There were also some significant delays between the reporting and discussion of incidents at the Serious Incident Review Group. Furthermore, there was insufficient depth of exploration of the factors involved in incidents and limited assurance on associated learning.

7.43. There were weaknesses in the approach by the SIRG, for example, the group did not use a Closure Checklist and there was also a lack of constructive feedback and

support to One to One to improve the quality of investigations and reports and embed the learning.

7.44. The lack of a coherent, verified data set about incidents involving One to One's care, combined with failings in system oversight, allowed for the continuation of a belief by NHS stakeholders that One to One was not clinically safe. This perception was not properly tested.

7.45. One to One did not report its financial position as a serious incident, despite there being significant implications for the safety and quality of their services.

7.46. There was limited evidence that One to One worked collaboratively with NHS Trusts on shared investigations.

7.47. The most comprehensive information on incidents was provided in One to One's Quality Reports; however, these were not reviewed in any depth by commissioners for assurance purposes on incidents.

What could have been done differently?

- Wirral CCG as the lead commissioner should have considered the complexities when shared care pathways were in place and should have put in place a robust process for identifying and managing all incidents involving an element of care from One to One, in line with the requirements of the national Serious Incident Framework.
- This single point of oversight of all incidents involving One to One, including those reported by NHS Trusts, would have allowed commissioners to exercise greater control over emerging risks and to identify trends and themes.
- Wirral CCG as the lead commissioner should have developed a process for the review of low level incidents, to identify trends and themes. This could have been achieved through a quarterly Quality and Safety meeting.
- Wirral CCG could have had a more robust approach to Serious Incident Review Group (SIRG) processes, by using the Closure Checklist and by inviting One to One and Trusts to the group to discuss their reports.
- It would have been reasonable to have reported One to One's financial position as a serious incident, given the implications for the safety of services.
- One to One should have produced comprehensive analysis of all incidents in its Quality Reports, to show overall numbers of incidents, incident types and key contributory factors identified following investigation. Inconsistencies in reporting levels should have been investigated to understand the reasons for this.
- Quality Reports contained a good depth of information and commissioners should have worked with One to One on a summary report using this source data for the purposes of incident oversight.

Recommendations

1. NHS England should consider the guidance for commissioners with regard to the overview, management and assurance of incidents where there are complex care pathways with multiple providers, to ensure that there is clear accountability for oversight of all serious incidents. This should include reference to incidents where a service is being provided under non-contracted activity arrangements.
2. NHS England regions should provide guidance to commissioners on the circumstances under which financial pressures on an organisation should be a reportable incident.
3. Commissioners should review serious incident management processes to ensure these are robust in terms of identifying and managing incidents that involve care from more than one provider.
4. Commissioners should consider implementing the serious incident Closure Checklist to support the review of investigations and reports and to be assured that they meet the required standard. The Checklist can then be shared with providers to support their learning.
5. Commissioners should invite providers to attend the Serious Incident Review Groups when their serious incident reports are reviewed.
6. Commissioners should consider how they can be assured that they have oversight of low-level incidents recorded by providers to allow the identification of trends and themes.

8. National maternity policy

Introduction

8.1. In this section, we consider the national policy initiatives for maternity services and other national drivers which had an impact on One to One's development. We assess how policy was translated into implementation locally and the significance of One to One's case loading model as part of this strategy.

Key findings

Policy development

8.2. The expectation that a woman is able to make an informed choice about her care during pregnancy is embedded in every document from Changing Childbirth published in 1993 through to Maternity Matters[25] in 2007 and Better Births[26] in 2016. How this was to be achieved in practice was not defined and the One to One story provides a rich picture of the risks and considerable challenges involved.

8.3. Maternity Matters was published by the Department of Health (DH) in 2007. This national framework for maternity services aimed to improve choice, access and continuity of care for women. The policy aims were that all women should have choice on where they gave birth and should be supported by the same midwife throughout their pregnancy.

8.4. The policy was explicit on the need for the national tariff system, Payment by Results (PbR), to correctly incentivise high quality and innovative maternity services. It stated: "*PbR will support the choices women make during their pregnancy and the scope of PbR will, over time, increase in order to take choice into account.*" It encouraged commissioners to consider local pricing models, ensuring costing was robust and other contract mechanisms to reduce hospital interventions to encourage normality in birth.

8.5. Encouraging innovation and choice has been a long-standing feature of NHS reform and the Any Qualified Provider (AQP)[27] initiative played a role in this, particularly in encouraging the independent sector to enter the NHS market. The Health and Social Care Act, 2012, brought in wide-ranging changes of significance to patient choice and the use of independent sector provision. The NHS Procurement, Patient Choice and Competition Regulations, 2013,[28] gave further impetus to this agenda. However, there was no legal right to choice for maternity care under the NHS Constitution.

8.6. In 2014, the House of Commons Committee of Public Accounts published a review of maternity services[29]. It found serious shortcomings in the performance of maternity services and the implementation of the national strategy with confusion on policy objectives and accountability for delivery. Specific shortcomings were:

- inadequate data to inform policy – the Maternity Services Data Set was subsequently introduced in November 2015;
- lack of evidence of the affordability of policy objectives, and clinical negligence costs were too high – "nearly a fifth of trusts' spending on maternity services, is for clinical negligence cover, equivalent to £700 per birth";

[25] Maternity Matters (ioe.ac.uk)
[26] national-maternity-review-report.pdf (england.nhs.uk)
[27] https://www.networks.nhs.uk/nhs-networks/ahp-networks/documents/AQP%20guidance.pdf
[28] The National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 (legislation.gov.uk)
[29] https://publications.parliament.uk/pa/cm201314/cmselect/cmpubacc/776/776.pdf

- research suggested that only a quarter of women wanted to give birth in a hospital with consultant-led care, but 87% of women gave birth in hospitals in 2012, five years after the introduction of the policy; and
- Local maternity networks required more development.

8.7. There was recognition of the need to accelerate transformation in maternity services which led to the National Maternity Review. Better Births was published in February 2016 and set out a strategy for:

- personalised care;
- continuity of carer;
- safer care;
- better postnatal and perinatal mental health care;
- multi-professional working;
- working across boundaries; and
- a fairer payment system.

8.8. It set out the following recommendations:

- a lead midwife for all appointments; midwife to provide antenatal, intrapartum, and postnatal care;
- booking by 28 weeks; and
- a ratio of one midwife to 36 women (less for complex cases) in teams of no more than 8, working as self-organised teams.

8.9. Better Births still found the data collection requirements for maternity services too cumbersome and made recommendations to streamline quality reporting and make it more insightful: "*A smaller number of more relevant indicators would promote greater focus on collecting information that matters and on improving accuracy and completeness of data collection*."

8.10. The Review also recommended that the DH consider a different insurance model for maternity services to avoid lengthy legal processes for women and families and to reduce costs to the NHS.

8.11. Local Maternity Systems were tasked with the operational delivery locally of the workstreams under the National Maternity Transformation Programme following Better Births, with oversight by a National Transformation Board.

8.12. Better Births recommended a phased approach to adopting its recommendations, via early adopter sites for proof of concept, followed by a national roll-out phase. It anticipated that funding would be available for early adopter sites and stated: "*the review recognises that this requires a step change across maternity services. It is likely to be challenging and is likely to require two to three years to put into widespread practice*."

8.13. The Review had been undertaken following the introduction of the new maternity pathway payment mechanism in 2013/14. It highlighted feedback from commissioners and providers that the maternity tariff system was not fit for purpose.

8.14. The Better Births report recognised the sorts of problems that had been experienced by One to One in terms of financial disincentives to joint working due to the payment system. It recommended further reform of the payment system "*so that it is fair, incentivises efficiency and pays providers appropriately for the services they provide, recognising different cost structures, supporting organisations to work*

together." The NHS Five Year Forward View[30] also recommended a review of the payment system to support choice and make it easier for groups of midwives to set up their own NHS-funded midwifery services.

8.15. There have been many accompanying documents published to provide further impetus to national strategy. These reiterated the key themes of the core policy documents, for example:

- In September 2010, the DH published Midwifery 2020: Delivering expectations[31]. This set out the anticipated role of midwives in contributing to high quality and cost-effective maternity services. It stated that a midwife should be the lead professional for uncomplicated pregnancies and act as the care coordinator in other cases.
- In July 2012, NHS England issued Commissioning Maternity Services: A Resource Pack to support Clinical Commissioning Groups.[32]
- In March 2016, NHS England published Saving Babies' Lives[33], a resource to support providers and commissioners to reduce stillbirths.
- In October 2016, the Department of Health published Safer Maternity Care[34]. This was an action plan to support the national maternity transformation programme. Its objectives were to halve the rates of stillbirths, neonatal deaths, brain injuries that occur during or soon after birth and maternal deaths by 2030. Its workstreams included: supporting local transformation, promoting good practice for safer care, increased choice, increased access to perinatal mental health, transforming the workforce, sharing data, harnessing technology, reforming the payment system, and improving prevention. Leadership was to be provided by the Maternity Clinical Networks.
- In December 2017, implementation guidance for Local Maternity Systems was issued by NHS England called 'Implementing Better Births: Continuity of Carer'. It set out two models that would meet the principles of Better Births:
- team continuity, whereby each woman has an individual midwife, who is responsible for coordinating her care, and who works in a team of four to eight;
- full case loading, whereby each midwife is allocated a certain number of women and arranges their working life around the needs of the caseload.

8.16. The document stated that full case loading would be more appropriate for specific cohorts of women who would benefit from individual continuity, for example, women with complex medical or social needs.

8.17. In April 2018, the Maternity Safety Support Programme (MSSP)[35] was launched to help maternity services achieve sustained improvement across the five CQC assessment domains. This was supported by a team of Maternity Safety Champions.

8.18. The National Maternity Review did lead to NHS Trusts developing alternative models for maternity services as the implementation of Better Births became part of the NHS Planning Guidance and in 2018/19[36] set a target for continuity of carer of 20% across the full maternity pathway.

[30] NHS England » NHS Five Year Forward View
[31] Layout 1 (publishing.service.gov.uk)
[32] Commisioning Maternity Services – the scope for doing things differently (esydave.com)
[33] saving-babies-lives-car-bundl.pdf (england.nhs.uk)
[34] Safer maternity care - GOV.UK (www.gov.uk)
[35] NHS England » Maternity and Neonatal Safety Improvement Programme
[36] https://www.england.nhs.uk/wp-content/uploads/2018/02/planning-guidance-18-19.pdf

8.19. Significant progress has been reported since the issue of Better Births. A recent evaluation[37] of the implementation of Better Births was published by NHSE/I in March 2020. It reported good progress in reducing perinatal and maternal mortality, with the 20% target reduction in stillbirths having been achieved ahead of schedule. The associated national survey reported a steady improvement in women's experience of maternity care and growing confidence in the safety of services. Many more women had access to continuity of care and Local Maternity Systems had played a key role in delivering these improvements.

8.20. One of the areas noted for improvement was access to the continuity of care model to women in the most vulnerable groups – Black, Asian and ethnic minority families, and those from the most deprived areas. It is interesting to note that the One to One pilot was focussed on supporting a particular cohort of women with economic and social vulnerabilities on the Wirral, but the service then expanded through self-referral rather than as a result of commissioning for particular needs.

Local context

8.21. Following the publication of Maternity Matters, Wirral Primary Care Trust (PCT) undertook an independent review of local maternity services and were keen to develop services locally to improve choices for women. Existing maternity services were provided by the local acute Trust who were approached by the PCT about delivering some maternity services in the community; the PCT made some additional investment in ultrasound equipment for this purpose. However, this did not progress as the Trust did not want to develop a community-based model at the time. The PCT were subsequently approached by One to One and the Birkenhead pilot was taken forward in 2010.

8.22. In Liverpool, the CCG's plans over the period from 2013 to 2018 were articulated in the Healthy Liverpool[38] strategy which focussed on a reconfiguration of acute services, including Liverpool Women's Hospital (LWH), to support women with complex needs. One to One became known to Liverpool commissioners through non-contracted activity (NCA) as awareness of the service grew through 'word of mouth' from neighbouring Wirral. In the context of approximately 8,000 births per annum, One to One's activity in the area at the time was not significant. The CCG became a co-commissioner on the Wirral-led contract from April 2014.

8.23. West Cheshire commissioners undertook a review of maternity services in 2012/13 to look at the needs of women locally to obtain a better understanding of options to give women choice and continuity of carer. There was a low home birth rate and no midwifery-led service in the area at the time. The CCG was aware of the better outcomes achieved through continuity of carer. The CCG became co-commissioners on the Wirral-led contract from April 2014 and subsequently undertook a procurement exercise resulting in a separate contract being awarded to One to One in September 2015. The CCG re-joined the co-commissioned contract in early 2019 at the request of NHS England.

8.24. In South Cheshire and Vale Royal, One to One started operating under NCA in 2012 through self-referrals. In early 2014, the local NHS Trust expressed concerns to the CCGs about the fragmented model emerging and the use of independent midwifery services in general. The Trust was also concerned about the economic viability of its maternity unit at Leighton Hospital as a consequence. The CCGs were keen for a formal arrangement to be put in place between the Trust and One to One for the better management of women. However, in 2015, the CCGs stopped

[37] https://www.england.nhs.uk/wp-content/uploads/2020/03/better-births-four-years-on-progress-report.pdf
[38] prospectus-for-change.pdf (liverpoolccg.nhs.uk)

paying One to One for NCA on the basis that the CCGs had not commissioned this service. Subsequently in 2016, under direction from NHS England, South Cheshire and Vale Royal CCGs changed direction and were seeking a formal contractual arrangement with One to One. The CCGs joined the Wirral-led co-commissioned contract in Cheshire and Merseyside.

8.25. Since October 2015, the CCGs and NHS Trusts across Cheshire and Merseyside (C&M) have formally worked together on the implementation of the commissioning strategy for maternity services through the Cheshire and Merseyside Women's and Children's Services Partnership. The Partnership was set up as a Vanguard under the NHS England Five Year Forward View[39] to work alongside the Maternity Clinical Network and Local Maternity System leads, to support the delivery of improved maternity services. The strategy was known as 'Improving Me'.[40]

8.26. In 2016 the Partnership became an Early Adopter site under the Maternity Choice and Personalisation Care Pioneer Programme to deliver the aspirations of Better Births. An external review was undertaken in 2016 on the sustainability of maternity units across the footprint; this had recommended a reduction in the number of maternity units.

8.27. Work continued through the partnership, for example, on Personal Maternity Care Budgets through a pilot with LWH in 2016. However, buy-in to the development of more community-based options for women and a continuity of care model by NHS Trusts was slow to progress and only came to fruition in 2019 (following the NHS Planning Guidance requirements) with the work on the specification for the planned procurement across C&M, shortly before the cessation of One to One.

8.28. In North East Essex, an external review was undertaken in 2013/14. This recommended that the CCG look at models offering more choice and continuity of care. One to One's service was approved as a model to support local choice and services were provided on an NCA basis. Following Better Births in 2016, the Local Maternity System set out its strategy for maternity services to 2020/21. The providers at this time for North East Essex were Colchester Hospital University Foundation Trust (CHUFT) and One to One. One to One were a member of the LMS Board overseeing the programme of work. No major restructuring of maternity services or changes in funding were planned in the region; NHS Trusts were given block contracts. The focus was on engagement with local service users to understand how maternity services could be better tailored to give local choice. One to One remained an integral part of the plans for North East Essex and led on the continuity of care workstream jointly with CHUFT.

8.29. One to One undertook non-contracted activity in other areas of the country such as Greater Manchester and Yorkshire but commissioners took action to prohibit One to One from operating in their areas, either due to quality concerns or as they had not been directly commissioned. In Greater Manchester, following a comprehensive review of One to One, the conclusion was that they did not offer a service which complied with their specification for maternity services.

Implementation challenges

8.30. One to One were one of the few providers to offer the case loading model and were therefore important to the delivery of the aspirations of national policy at a local level. The company had the support of the Chair of the National Maternity Review.

[39] North West Coast Strategic Clinical Networks and Senate: Improving women's and children's services across Cheshire and Merseyside (nwcscnsenate.nhs.uk)
[40] Home - Improving me

One to One had started up in the North of England and provided an opportunity to begin to address the gaps in provision identified and offer improved local choice.

8.31. One to One's service was intended to be complementary to existing NHS provision and the vision was to develop a seamless approach with local NHS Trusts to ensure safe and effective care. Implementation of this vision, however, brought challenges which had not been anticipated in national policy. These are discussed in detail throughout this report but are summarised below:

- National policies aimed to increase locally commissioned choice options, but maternity care was not a legal right to choice. Maternity Matters stated that women could choose a provider outside their local area if the provider had capacity. This led to some confusion and misinterpretation of national policy by One to One and women who believed they had a right to choice.
- Demand for One to One's services grew predominantly through self-referrals and non-contracted activity (NCA). Demand was therefore not controlled, and this created a significant governance risk for commissioners. Some commissioners had no awareness of One to One's activity in their areas, had not commissioned the service and therefore had no safety and quality oversight processes in place.
- As there was no legal right to choice for maternity care, some commissioners adhered strictly to the 'Who Pays' guidance and did not pay for significant amounts of activity creating financial pressures for One to One.
- Relationships between One to One and local NHS Trusts were fraught with difficulties. This meant that the integrated, seamless approach required for women did not materialise and created more clinical risk.
- One to One's model was not financially viable within the constraints of the national tariff mechanism. NHS Trust charges to One to One under the lead provider model were unaffordable and were a key contributory factor to the company's demise.

Summary points

8.32. Over the 10-year relationship between One to One and the NHS, national policy did not provide a sufficiently developed framework to allow an independent sector provider to thrive within the NHS infrastructure. Whilst the One to One model was based on continuity of carer, it was inevitable that some women would require either planned or unplanned care from an obstetrics provider. There was no evidence that national policy was taken through a design stage to test the feasibility of a shared care arrangement between an NHS and independent sector provider, to understand some of the risks and challenges that might emerge.

8.33. Key recommendations made by Better Births were not implemented and we did not find any evidence of consideration of national funding to pump prime the case loading model.

8.34. Responsibility for delivery of national policy rested with Local Maternity Systems, for example, the C&M Women's and Children's Partnership. These partnerships of commissioners and providers came into being after the publication of Better Births. Before this, there was no dedicated structure for oversight of delivery of national policy objectives for maternity.

8.35. Many of the recommendations from Better Births came too late to allow the One to One scenario to be recalibrated, as the service was well established, and the tariff and relationship problems were already entrenched in local systems.

8.36. As national policy evolved, it was recognised that the full case loading model was of particular value for women with more complex needs. However, the model was implemented for all women in the areas in which One to One operated without considering this aspect.

8.37. Policies on Choice, Any Qualified Provider and the 'Who Pays' guidance were not aligned and conducive to the successful delivery of the One to One model. The technical complexities involved in interpreting the operational requirements from these policies were therefore understandably challenging for all stakeholders involved. Policies on Choice, AQP and the Who Pays guidance were technically complex and in some areas could be subject to different interpretations. One to One and some commissioners disagreed on whether the guidance in place following award of the contract in 2011, meant that self-referrals would be authorised and paid for.

8.38. The challenges of the maternity pathway payment system had not been worked through in terms of the impact on a community-based provider as well as on NHS Trusts. Better Births acknowledged the financial disincentives and recommended reform of the system, but this did not happen during the lifetime of One to One.

8.39. Locally, commissioning focus on implementing Better Births varied as there were other more significant priorities driven by financial challenges. Birth rates were reducing, and the sustainability of some maternity units was uncertain. Some CCGs undertook reviews of maternity services, some of which were as a result of the awareness of One to One and what their model could offer. Prior to 2016, progress by NHS Trusts in developing alternative models to provide greater choice and continuity of care was slow, and significant interest only became apparent in 2019.

8.40. Recent evaluation of the implementation of national policy notes good progress on continuity of carer, mainly driven by the redesign of services offered by NHS Trusts rather than the involvement of the independent sector. However, it identified gaps in provision for women in some vulnerable groups.

What could have been done differently?

- The continuity of care model should have been tested as part of a design and feasibility stage to the development of national policy. This should have been undertaken as part of the work of the National Maternity Transformation programme before local implementation was encouraged.
- A comprehensive evaluation of the One to One model should have been undertaken in 2016 following the publication of Better Births. Other options for improving maternity services should have been considered at this point, for example, full case loading, integrated team continuity models, community hubs. This might have strengthened procurement options and opened the market up to more providers.
- National funding should have been considered to trial continuity of care models in different regions up to fixed levels of activity only. It might have been possible for funding under the National Maternity Transformation Programme to cover local testing of alternative models of maternity care.

Recommendations

1. Future proposals for new models to support the delivery of national maternity policy should be comprehensively tested from a clinical, operational, and

financial perspective, with scrutiny of the business case and the implementation plan before commitment to and roll-out of the service.

2. Local Maternity Systems should be tasked with direct responsibility for monitoring progress on such initiatives. These forums should provide a single point of oversight for service developments, pilots and evaluation. We note that the recommendations on governance from the Ockenden Report strengthen the role of Local Maternity Systems in this regard.
3. Pilot evaluation should consider the impact on the wider system and include system-wide engagement and deliberation with all stakeholders involved. The potential risks of the cultural barriers involved in bringing the independent sector into an established NHS infrastructure should be assessed.
4. For new, innovative service models of significance to the delivery of national policy, specific funding should be considered to pilot and pump prime investment in a new service to stimulate greater market interest.
5. Mainstreaming of a new service should be at a prudent pace to allow full consideration of issues and risks raised as well as re-evaluation at milestone points.
6. In line with national policy, commissioners should consider how to encourage innovative proposals for maternity care which are focused on plugging the gaps in the provision which still exist, for example, access to continuity of care for women from vulnerable groups.

9. Innovation and start-up

Introduction

9.1. This section describes the beginnings of the One to One concept for maternity care and how the business was set up and promoted. We examine how an initial pilot of the model was developed, evaluated and implemented on the Wirral.

9.2. We consider the extent of broader horizon scanning undertaken at the time and whether due diligence was appropriate before a contract was awarded.

Key findings

One to One start-up

9.3. Two independent midwives working in the Merseyside area started to develop the concept of a community-based model for maternity care. This would provide continuity of care through a named midwife and the option of a home birth where safe to do so; this was known as a 'case loading model'. The aim was to provide a service which would be complementary to and run alongside existing NHS maternity services to improve choice for women. The concept was aligned to the vision for national maternity policy at the time (Maternity Matters, 2007).

9.4. The two midwives became Directors of a company to take the concept to market, called One to One Maternity Services Ltd. The company was a vehicle for marketing and development with no income and limited sources of finance. The Directors approached external investors and received some interest, but there were no formal commitments, mainly due to the challenges in finding an affordable insurance solution for independent midwives.

9.5. One of the existing Directors went on to set up One to One Midwives (North West) Ltd as a trading company to provide the case loading midwifery service to NHS-funded clients. The company did not provide private services.

9.6. Approaches were made to NHS commissioners across the country, including in Sheffield, the Midlands and Manchester, to explore interest in commissioning the case loading service.

Wirral pilot

9.7. During 2007/08, Wirral Primary Care Trust (PCT) undertook an independent review of local maternity services in response to Maternity Matters and as a result, were keen to develop services to improve local choice for women. The local NHS Trust had no plans to offer a community-based midwifery service at the time.

9.8. The Directors of One to One approached the lead commissioner for maternity services at Wirral PCT who was receptive to the case loading model concept.

9.9. In June 2010, a pilot scheme for 70 women was agreed by Wirral PCT. It covered the antenatal and postnatal elements of the pathway only, as One to One's insurance did not cover intrapartum care. Women transferred to the local NHS obstetric unit for the birth, with the intention that they were accompanied by their One to One midwife. The local NHS Trust raised concerns about the clinical risks of the model and the impact on their income due to the loss of activity to One to One.

9.10. The pilot was funded jointly by the PCT and the local authority Public Health for £100k, based on the One to One proposal for 70 women. Public Health contributed as the pilot focussed on the needs of women with difficult health and social issues such as poor mental health and problematic lifestyle choices, in Birkenhead, a deprived area on the Wirral.

9.11. A contract was put in place for the pilot under Any Willing Provider (AWP) arrangements for nine months with an option to extend. AWP was a national initiative introduced in 2009/10 to encourage innovation and more patient choice, including through the use of the independent sector. The service specification was clear that home and hospital births were to be provided by the local NHS Trust, due One to One's insurance limitations. The specification included performance metrics for monitoring purposes.

9.12. The One to One pilot continued in Birkenhead until October 2011 and had expanded to approximately 200 women. We were told that the PCT and local authority funded the additional activity on a local tariff basis.

9.13. The pilot was for a specific group of identified women and therefore did not address referral pathways and the implications in terms of buy-in from GPs and self-referrals, potentially from neighbouring geographic areas.

9.14. We reviewed the pilot proposal paper presented to Wirral PCT's Professional Executive Committee (PEC) in June 2010. The PEC membership consisted predominantly of GP clinical representatives, other clinicians and the Executive team. There was no specialist procurement or contracting representation. This paper demonstrated strong alignment with commissioning strategy for maternity services. It stated that feedback from women and clinicians indicated a need for such provision. However, there were some weaknesses observed, as follows:

- This was not a commissioning business case; there was no options appraisal, financial evaluation or risk analysis. The paper relied on a proposal prepared by One to One which was not specific to the pilot and was based on a service for antenatal and postnatal care for the broader population with a caseload of one midwife to 70 women, excluding intrapartum care.
- The PCT had offered funding of £100k for 70 women. The accompanying 'new investment assessment form' does not indicate source of funding and return on investment. One to One's proposal had indicated significant annual cost savings (a range of £0.6m to £1m) based on avoided hospital activity for 1,000 women. These calculations did not reflect the additional cost of One to One's services and therefore the net saving to the PCT.
- One to One's paper highlighted that Care Quality Commission (CQC) registration would not be in place in advance of the pilot, based on typical timescales, and proposed that initial bookings and risk assessments would take place in women's homes as an interim measure. Based on our understanding of the CQC's requirements for midwifery services, it appears that One to One did not have appropriate registration for the first four months of the pilot and this was not raised by commissioners when planning for the pilot.
- Targeting women with difficult health and social care needs implies potential complications and risks in pregnancy. The paper is somewhat contradictory in this regard as it stated that women with complex health needs would be excluded from the pilot and referred to the local NHS Trust.
- There was no explanation for setting the nine-month period of the pilot which meant that in most cases, continuity of care from antenatal to postnatal stage was not feasible.
- There was no evidence of engagement undertaken by commissioners to obtain views from local women and clinicians about the service model. The extent of engagement with local obstetric services is unclear, although the paper does state that the local NHS Trust was not taking forward an alternative community-based option.

- The paper stated that the service would not affect the dynamics and infrastructure of the existing NHS system but would in fact relieve pressure on acute Trust services. There is no evidence in the paper to support this statement or describe the pressures that existing services were experiencing. One to One's proposal was based on savings through reductions in acute Trust activity (admissions, outpatient appointments and sonography). Local system dynamics were subsequently a major barrier to successful implementation.
- The pilot service was to be offered as a local choice for women through Wirral GP practices. There was no detail as to how implementation with GPs would be overseen, how referrals would be managed by commissioners and there was no reference to self-referrals. One to One's proposal had set out how they would market the services to GPs and that self-referrals would be accepted.
- The paper does not indicate any input from a PCT finance representative or consideration of financial, procurement and contracting risks. No risks had been identified in the PCT's covering paper and there was no evidence of commercial advice having been sought.

9.15. The pilot was initially planned for a cohort of 20 women and was approved for 70 women. The report refers to 200 women being cared for. We have not seen any evidence that there was any management of referrals to the pilot scheme or whether the increased numbers were funded retrospectively. Expansion of the scope of the pilot in terms of numbers appears imprudent before the model was fully tested for the initial cohort proposed.

9.16. We have seen no information to indicate that any performance metrics were monitored on a routine basis during the pilot.

9.17. There was no evidence of a formal pilot evaluation to understand whether the model had worked as intended, from a quality, safety or financial viability perspective. This could have highlighted the risks involved in attempting to put in place a model which required commitment from GPs and other NHS Trust maternity units. This was a missed opportunity to thoroughly assess and consult on the introduction of a new independent sector provider into an established NHS system.

First contract award

9.18. One to One produced a proposal to provide a full case loading model in February 2011. This was to provide a full maternity pathway. The proposal contained no information on costs, pricing model or the insurance position. Further pilot testing was not undertaken to cover the full maternity pathway before the award of the contract for the full pathway.

9.19. Following the end of the pilot in October 2011, One to One were awarded their first contract by Wirral PCT to run from November 2011 until March 2014 under the Any Qualified Provider (AQP)[41] framework with no guaranteed activity levels. We have not seen any documents approving this decision to allow comment on associated PCT governance.

9.20. The PCT had a reputation at the time for being at the forefront of innovative commissioning development and were viewed positively for their pro-activity in trying to establish a new service to offer more local choice to Wirral women. However, the transition from a pilot exercise to award of contract did not allow sufficient time for comprehensive evaluation and a commissioning business case

[41] Main heading (networks.nhs.uk)

was not produced for decision-making purposes. This was described to us as "*wild west commissioning*".

9.21. We noted that in September 2011, the Department of Health provided some AQP guidance for commissioners which referred to other potential models for consideration where continuity of care and integration was important, for example, personal health budgets or a lead contractor/sub-contractor approach. These alternative models had not been considered by commissioners as part of a business case.

9.22. Insurance for intrapartum care proved to be a significant problem for One to One as they were not initially part of the Clinical Negligence Scheme for Trusts (CNST) (they became a member of this scheme from October 2013). One to One referred to a service level agreement (SLA) having been developed with Liverpool Women's Hospital to allow them access to the scheme which was not progressed. Private insurance arrangements were put in place by One to One (including for intrapartum care) in November 2011, but these were punitively expensive: an annual premium of £650k was quoted in the contract meeting of November 2012 which was more than half of One to One's income under the contract.

9.23. A generic policy wording document was included in the procurement papers which indicated cover for medical negligence, but we did not see the master schedule showing the specific cover for One to One or an insurance certificate. It is unclear therefore whether commissioners were aware of the level of premium before awarding the contract. AQP guidance to commissioners stated that the Department of Health (DH) was considering an indemnity arrangement to cover clinical negligence risks for the independent sector. One to One liaised directly with the DH on this issue.

9.24. The local NHS Trust had highlighted barriers to effective working with One to One due to perceived clinical and financial risks. In November 2012, a helpful review was undertaken by the Medical Director and the Commissioning Lead for Maternity Services of Wirral CCG following a 'letter of concern' sent to the CCG, CQC and the Local Supervising Authority Midwifery Officers (LSAMO) by the obstetric team at Wirral University Teaching Hospital. This work included confidential discussion with women whose care had allegedly been compromised and a review of 18 cases. The LSAMO was involved in the review. The report, 'Investigation of Concerns Regarding the One to One Maternity Service', found that:

- the incidents did not meet the criteria for investigation through StEIS reporting;
- One to One's actions relating to the incidents were appropriate, proportionate, and timely;
- four out of the five women interviewed expressed very high levels of satisfaction with the service. The woman who said she would not use the service again stated that it was a good model of care for low risk pregnancies.

9.25. The report highlighted that the impact of introducing the One to One service to the existing NHS infrastructure should have been evaluated beforehand and plans to mitigate the risks put in place at an early stage:

"*Significant issues arose during the pilot of 'embedding' a new provider with a significantly different care model into the complex and highly interconnected maternal and infant health and social care services already in place in Wirral. These were worked through during the pilot, and by the time the standard contract was agreed, the majority of areas of concern had been addressed and compliance with local multi-agency pathways, protocols and standards was incorporated into the service specification.*"

"*However, the tensions that had arisen in the relationship between the local acute trust provider of maternity services, […] and the One to One midwives had not been resolved.*"

9.26. There was no evidence of further horizon scanning other than discussion with the local NHS Trust. More meaningful engagement across the wider system of NHS providers, for example, with NHS Trusts providing community midwifery services and existing independent midwifery services, might have identified other options to consider and risks to be assessed.

9.27. The experience of The Albany Midwifery Practice was particularly pertinent. It was set up in 1994 by a group of independent midwives in South East London to provide a continuity of care model. They obtained NHS funding and in 1996 they were sub-contracted by King's College Hospital. The midwives provided care for women regardless of any perceived obstetric, medical or social risk and were integrated with the Trust to collaborate with other health professionals as needed. In 2009, the Practice closed due to safety concerns.

9.28. There is no evidence that NHS governance and performance management requirements under an NHS contract were tested out with One to One before awarding the first contract. We were told by One to One that as requirements emerged, they had to reactively put policies and procedures in place.

Summary points

9.29. It was reasonable for Wirral PCT to explore and test an unproven service model through a preliminary pilot. However, the pilot was not comprehensive and therefore did not provide proof of concept. The PCT were proactive in attempting to drive innovation to improve services locally. However, there was a fundamental failure in governance processes around the development of the pilot before any formal procurement was undertaken.

9.30. Based on the evidence provided to our review, neither the pilot nor the subsequent proposal from One to One gave the required assurance on safety and quality, nor the operational and financial viability of the case loading model. The transition from pilot to award of contract was rushed and did not allow sufficient time for commissioners to properly evaluate the model and its implications.

9.31. The One to One model was the only option considered and we found no evidence of One to One's proposal being scrutinised from a clinical or financial perspective. A comprehensive commissioning business case with a full options appraisal was not produced.

9.32. There was an absence of commercial challenge or demonstration of understanding of the potential risks to a new start-up business, for example, access to external finance, cash-flow, initial set-up costs and a consequent need for commitment and guaranteed activity levels.

9.33. There was no evidence that the potential serious impact of high insurance premiums was debated and escalated or that CNST cover was followed up by commissioners for AQP awards.

9.34. One to One found NHS compliance requirements onerous and they required investment in systems, processes and resources which did not appear to have been debated. The NHS infrastructure was relatively unfamiliar to One to One and they had to work hard to get up to speed with requirements. As a consequence, One to One responded to governance requirements in a reactive, unplanned way.

9.35. Horizon scanning was limited and there was a missed opportunity to learn from the experience of the Albany Midwifery Practice which had similarities with One to One.

9.36. We conclude that due diligence by commissioners was inadequate at this stage and the lack of private sector commercial experience in predominantly clinically led PCTs at the time was likely to have been a key contributing factor to the absence of such scrutiny.

What could have been done differently?

- A more comprehensive pilot should have been undertaken, given the intention to award a contract for the full maternity pathway. This might have highlighted the complexities involved in transfers of care and associated payment arrangements, as well as the relationship and practical challenges.
- Appropriate enquiries should have been made regarding CQC requirements for One to One prior to the pilot.
- Wider consultation with NHS providers before the award of a contract for more than 2.5 years would have been a more prudent approach. The consequent system problems arising might have been anticipated if NHS Trusts had been involved in the specification development. The lack of engagement may have adversely impacted on subsequent relationships between NHS Trusts and One to One.
- Broader horizon scanning should have been undertaken, particularly to understand the experience of The Albany Midwifery Practice and other NHS community midwifery provision.
- A comprehensive business case should have been produced following the pilot to set out a range of potential options for debate and scrutiny by the relevant approving committee. A robust business case would have provided an opportunity for the commissioning rationale to be challenged and for risks to be assessed at the appropriate level.
- Insurance arrangements should have been scrutinised further as these rendered the business model unviable at this early stage.

Recommendations

1. Proof of concept through pilot testing and consultation should be comprehensive and consider all pathway components that are intended to be commissioned before introduction into an established system.
2. A comprehensive pilot evaluation should be undertaken as a fundamental step, at a pace which allows all stakeholders to contribute to feedback. This should set out the learning and challenges experienced, potential risks and implications for future commissioning, and should allow recalibration of options and retesting if appropriate.
3. Commissioners should produce a business case for scrutiny and decision-making purposes for potentially high-risk service developments. This needs to be completely independent of proposals from providers offering their services and include a thorough evaluation of the market.
4. Commissioners should evaluate the extent of support that might be required by independent sector providers, particularly start-up businesses with no NHS track record, to understand the broad-ranging compliance requirements of NHS policy, regulatory and contractual governance.

10. Procurement and contracting

Introduction

10.1. In this section, we set out the procurement and contracting routes used to commission One to One's services and consider the appropriateness of these approaches and associated governance. We also refer to due diligence aspects which are considered further in Section 12.

Key findings

Any Qualified Provider

10.2. In November 2011, One to One were awarded their first contract by Wirral PCT under an Any Willing Provider (AWP) framework until March 2014. The NHS Standard Community Services Contract was put in place. AWP was a national initiative to encourage innovation through competition to offer greater patient choice, particularly through the use of the independent sector. It was first introduced in 2009 and from 2011 was known as Any Qualified Provider (AQP)[42]. Guidance set out a range of suitable services, broadly covering community-based and mental health services. Antenatal education and breastfeeding support were potential areas for inclusion from 2013/14. Commissioners could choose other services if there was a clear case to do so. Interest in AQP waned from around 2014 onwards and has since only been used for low risk services such as audiology, non-obstetric ultrasound, podiatry and eye care.

10.3. The framework involved a qualification process for applicants and a standard service specification and pricing model. It is unclear whether the opportunity was advertised. AQP provided a quick and cost-effective way to bring One to One into the market compared to a full competitive tender process. As One to One were essentially the only feasible provider of the case loading model at this time, it was a proportionate approach and would potentially allow other providers onto the framework in future.

10.4. In September 2011, the Department of Health (DH) provided some AQP guidance[43] for commissioners of relevance to the review. It stated: "*Where the AQP model is used, providers will have a contractual obligation to co-operate so that patient care is safe, transfers are coordinated properly, and patient experience is good.*" Providers on the framework were required to work within local health system referral pathways and protocols. These aspects were incorporated in the service specification at a high level but with limited guidance on how this would be implemented in practice.

10.5. The DH was also considering how an indemnity arrangement to cover clinical negligence risks could be made available under AQP awards to the independent sector.

10.6. The Royal College of Midwives (RCM) opposed the introduction of AQP for midwifery services (Midwives, Volume 15, Issue 2 of 2012[44]). While recognising the benefits of increasing choice for women, the RCM expressed concerns about a market-driven service. It envisaged lower quality and a less integrated model as existing NHS providers would be reluctant to support competitors. The issues raised by the RCM proved to be real barriers to the success of the One to One service.

[42] Operational Guidance to the NHS : extending patient choice of provider - GOV.UK (www.gov.uk)
[43] Any Qualified Provider: your questions answered | Modernisation of health and care (mas.org.uk)
[44] https://www.rcm.org.uk/publications/?publicationtype=midwivesmagazine&fromDate=2012-01-01t00&toDate=2012-12-31t00&page=1

10.7. Under an AQP contract, there were no guaranteed activity levels; it was for One to One to market their services including through a national directory of services (known as Choose and Book at the time). Access to Choose and Book proved to be problematic at the time for One to One, so this was delayed. One to One therefore sought to develop their business to generate income which led to subsequent problems with non-contracted activity.

Non-contracted activity (NCA)

10.8. As One to One promoted its service model, interest grew in neighbouring areas to the Wirral and across the country. Women self-referred to the service which resulted in significant non-contracted activity (NCA) initially in Liverpool and West Cheshire. One to One expanded through NCA across the country including in Lancashire, Greater Manchester, Warrington, Stoke-on-Trent, Halton, St Helens, Yorkshire and Essex. GP referrals were minimal.

10.9. Activity was not able to be managed by commissioners; we were told that in some cases they only became aware that One to One was providing a service in their area when they received an invoice for activity undertaken.

10.10. One to One undertook NCA on the understanding that this was permitted under AQP, with the Wirral agreement as an implied contract. We were also told that as part of its marketing strategy, One to One were willing to take on women in other areas despite the risk of non-payment, as this demonstrated to commissioners a need for the service in their areas.

10.11. However, national guidance on NCA set out certain conditions under which NCA could be undertaken. There have been two versions of NCA guidance published: Who Pays? Establishing the Responsible Commissioner, DH, 2007[45], and Who Pays? Determining responsibility for payments to providers, NHSE, 2013[46]. The 2007 guidance was in place when One to One's contract was initiated and stated:

- NCA was not an alternative to contracting formally and applied mainly to emergency treatment in a hospital or elective care on an exceptional basis.
- A patient referral was regarded as authorisation to treat. It did not specify whether this covered GP referrals only or self-referrals and was therefore unclear in this regard.
- There was no specific reference to the validity of implied contracts under this guidance.
- Recommended good practice was for providers to identify NCA at the point of booking and inform responsible commissioners of any claims for payment over £10k.

10.12. One to One's interpretation of this guidance was that self-referrals would be funded in other areas. Initially, One to One did not establish agreement to NCA. One to One stated as part of the Risk Summit process in 2015 that they approached commissioners but received no response; no evidence was provided to validate this statement. As a result, many commissioners adhered to the guidance and did not pay for NCA. In Liverpool and West Cheshire alone, One to One estimated lost income of £250k. The Wirral contract accepted self-referrals but the specification

[45] https://webarchive.nationalarchives.gov.uk/ukgwa/20130107105354/http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=148730&Rendition=Web

[46] https://www.england.nhs.uk/wp-content/uploads/2014/05/who-pays.pdf

covered Wirral women only. We have seen no evidence that this was queried by One to One or raised by commissioners as an argument for non-payment of NCA.

10.13. The 2013 guidance made some clarifications which were pertinent to One to One's situation:

- Where there was no legal right to choice, GP referral would constitute authority for commissioners to pay for the activity. There was no legal right to choice for maternity services under the NHS Constitution.
- For self-referrals, the provider must seek prior approval from the responsible commissioner, otherwise commissioners were under no obligation to pay for the activity.

10.14. However, the over-riding principle in both sets of guidance was that formal contracts should be in place for routine activity. Despite the potential for misinterpretation, One to One did not adhere to the intention of the Who Pays guidance in not seeking prior approval for NCA.

10.15. We were told that, generally, commissioners accepted NCA from a GP referral. GPs, however, were reluctant to engage with One to One and their referrals were insignificant in number, despite One to One's marketing efforts with general practice.

10.16. In 2015, following confirmation by the NHS Litigation Authority (NHSLA) that indemnity cover under CNST was only available to providers if an NHS contract was in place, commissioners and One to One withdrew from NCA. There was no clarification as to whether cover would apply to an implied contract arrangement.

10.17. North East Essex (NEE) CCG continued to approve NCA based on the Wirral contract; a direct contract was not put in place over the duration of the arrangement with One to One between 2014 and 2019. NEE CCG and NHS England Midlands and East received strongly worded legal advice in April 2016 regarding the risks of running NCA for routine activity without a service specification. The legal position on insurance was also highlighted as a major risk to the CCG in terms of liability for payment of claims and a risk to the public purse with potential reputational damage. The CCG's view was that a contract was in place under AQP rules through the Wirral contract and confirmed that One to One had CNST cover.

10.18. We noted a reference made in the Essex contract meeting in November 2017 to financial challenges between One to One and the local NHS Trust. An options appraisal had been prepared for a potential procurement of the case loading service, but this was put on hold pending the resolution of the debt issue.

10.19. The other CCGs in Essex were not willing to continue to offer One to One as a choice for women under NCA. Some CCGs prevented One to One from operating in their area due to quality concerns, for example, in Greater Manchester and Bradford.

10.20. In Cheshire and Merseyside, One to One sought a larger co-commissioned contract. In the interim, Liverpool and West Cheshire CCGs agreed to fund NCA in their areas using the Wirral agreement as an implied contract during 2013/14.

Procurements in Cheshire and Merseyside

10.21. Liverpool, Warrington and West Cheshire CCGs became co-commissioners on the Wirral contract from April 2014; an NHS Standard Contract was put in place until March 2015 pending a procurement exercise. The evidence provided to our review did not provide any details on the governance processes undertaken by the co-commissioners before their decision to enter into this contract. As the term was for

one year only and it did not permit any extension, it did not consider continuity for new referrals.

10.22. The procurement process was initiated in September 2014 and was led by the specialist procurement team of the North West Commissioning Support Unit (CSU). This was planned as a co-commissioned contract for Wirral, Warrington and Liverpool CCGs for three to four years.

10.23. West Cheshire CCG undertook their own separate procurement process with a specification tailored to their own requirements around the management of risk. We were told that the CCG also wanted to directly manage the contract rather than through a co-commissioned arrangement where the level of focus for West Cheshire would be diluted.

10.24. One to One and two local acute Trusts – Liverpool Women's Hospital (LWH) and Wirral University Teaching Hospital (WUTH) – expressed an interest in the Wirral CCG procurement. One to One queried the specification being for low risk women only as the current service was available to all women. One to One were also concerned that they would fail the financial pre-qualification tests.

10.25. The pre-qualification questionnaire (PQQ) completed by One to One and WUTH was a standard template and contained the necessary financial safeguards, including:

- a provision to request clarifications on financial information and potentially the need for a financial guarantor. One to One stated that their provider of diagnostics services would act in this capacity, if required;
- a Dun & Bradstreet[47] report which would determine a pass/fail assessment. We noted that One to One did not provide a reference needed to allow this report to be run (a DUNS number) but provided the 2014/15 published accounts; and
- insurance confirmation – One to One's submission stated that CNST cover was in place through the NHS Litigation Authority (NHSLA) until March 2016. We confirmed that CNST cover was in place since October 2013 by reference to the NHSLA (now NHS Resolution) website.

10.26. WUTH stated that LWH, WUTH, and Warrington and Halton Hospitals (WHH) were intending to form a consortium. Four PQQ responses were reportedly received, but we have not seen the submissions from LWH and WHH or further evidence that a consortium model was under serious consideration.

10.27. In April 2015, the procurement was abandoned due to various concerns around the specification and the Governing Body approved a further procurement process. The associated paper stated that the specification required update for NHS planning guidance, the Kirkup investigation[48] and new NICE guidance. It recommended an extension of the One to One contract but did not reference the ongoing concerns, for example, the Risk Summit process, the Greater Manchester review and financial viability risks. There was a missed opportunity at this point to consider withdrawal from the One to One contract before escalation of these issues.

10.28. As a new contract had not been put in place for the co-commissioners, there were discussions of their obligations regarding NCA and the indemnity position following the NHSLA advice in February 2015 that a contract needed to be in place.

10.29. In April 2015, a new procurement was initiated with an indicative contract value of £5m per annum. Wirral CCG was the coordinating commissioner for seven other

[47] A Dun & Bradstreet rating is an overall evaluation of the financial strength and creditworthiness of a company
[48] The Report of the Morecambe Bay Investigation (publishing.service.gov.uk)

CCGs across Cheshire and Merseyside. The process was managed by the Midlands and Lancashire CSU. One to One, LWH and WUTH again expressed an interest.

10.30. A Wirral CCG paper in August 2015 stated that lessons had been learned from the previous procurement and more clarity would be provided on the type of service required, payment mechanism, activity expectations and care pathways. Wider consultation had been undertaken with service users and a GP survey was undertaken to inform the specification. The Governing Body were assured on the robustness of the re-tendering process. We have reviewed the specifications (see Section 11) and noted some improvements made.

10.31. One to One were still concerned about the financial qualification tests. Wirral CCG sought legal advice regarding One to One's position. An update in April 2016 to the CCG's Clinical Operational Group stated that four providers had passed the pre-qualification stage. One to One failed the financial tests but were taken forward with the support of a guarantor which failed to materialise. Only One to One submitted a tender. The options put forward were:

- to continue to term with the existing contract (extended to March 2017) with no new referrals from April 2016; or
- to award a contract with a specification for low risk women only, using a Voluntary Ex-Ante Transparency (VEAT) notice. This approach is used as a procurement route when it is believed that there is a sole supplier able to provide a service and allows a period for other potential providers to challenge the award.

10.32. The paper acknowledged the financial risks to One to One including the low risk specification, growing debt and the winding-up petition issued by WUTH in 2016. It did not refer to any quality concerns. The debt relating to provider to provider charges and impact on One to One's cash-flow was deemed "*not the concern of the CCG.*" The paper stated that contingency arrangements were in place with WUTH should One to One's service cease to operate although no further details were provided.

10.33. The CCG agreed to the VEAT notice and the option to move to a low risk service specification. The minutes of this meeting do not indicate any significant debate around the serious issues raised by the briefing paper; we noted that the Chief Finance Officer did not attend. The VEAT notice was issued in July 2016 for a three-year contract with a potential one-year extension. No challenges were received from other providers.

10.34. The contract was awarded to One to One by Wirral CCG from June 2016 (for a period of three years) with a revised service specification which included high-risk women (excluding high obstetric risk) rather than the previously agreed specification for low risk women. It is not clear from the documentation provided what prompted the change to the specification and the governance arrangements for co-commissioners around this significant amendment.

10.35. West Cheshire CCG undertook a separate procurement exercise during 2014/15 with a service specification for all women regardless of risk profile. Liverpool Women's Hospital, UK Birth Centres and One to One passed the pre-qualification stage. Financial standing was a core element of the standard pre-qualification questions and the summary report in April 2015 on the procurement outcome, produced by the North West Commissioning Support Unit, stated that One to One had passed this element. There is no detail provided in the paper to show how this conclusion was reached. Based on balance sheet information for the previous three years in the published accounts, One to One were in an extremely weak financial

position. Only One to One submitted a tender and it received high scores from all the evaluation panel members. A contract was awarded to One to One from September 2015. There was a service mobilisation phase but there is no evidence that due diligence was undertaken during this period.

10.36. This contract was extended for one year to August 2019 and it was noted in a paper to the Finance, Performance and Commissioning Committee in November 2018 that the CCG had no quality concerns regarding One to One's service. The Committee approved the contract extension on the proviso that contingency plans would be put in place should One to One be unable to continue to trade.

10.37. The paper signalled the CCG's intention to commission a prime provider model at a future date for the delivery and potential sub-contracting of the case loading model. West Cheshire CCG put in place appropriate arrangements for the exit of the contract with One to One and initiated a procurement for a prime provider model during 2018/19 but this was withdrawn. The CCG joined the Wirral-led contract as a co-commissioner from April 2019. We were informed that this was at the request of NHS England to encourage collaboration across Cheshire and Merseyside and mitigate financial risks.

10.38. In December 2018, the commissioning CCGs agreed to extend the contract until March 2020 on the basis that a service review would be undertaken with a potential procurement to follow. This decision was made at the height of the financial concerns around One to One with pending legal action by Mid Cheshire Hospitals NHS Foundation Trust.

10.39. On 29 March 2019, Wirral CCG wrote to One to One to serve notice on the current contract which was due to end in March 2020. The letter advised that the contract could not be subject to a further extension which was in line with the CCG's contract management policy. One to One were disappointed that the contract was not able to be extended and viewed a re-procurement process as unnecessary.

10.40. The termination date for new referrals was 1 July 2019 to allow for women's pregnancies to complete before the end date of the contract. However, NHS England subsequently requested that referrals continue until the end of the contract and that an individual management plan be put in place for each woman. This approach was debated as it was seen as a potentially risky strategy by commissioners in terms of how to communicate to women regarding potential transfers of care.

10.41. In June 2019, a further procurement was planned for a community midwifery service. The annual contract value was £5m over three years from April 2020, with a potential two-year extension. Wirral CCG coordinated the procurement on behalf of eight CCGs in Cheshire and Merseyside (Wirral, Liverpool, South Cheshire, Southport and Formby, South Sefton, Vale Royal, Warrington and West Cheshire). There was greater market interest, from six NHS Trusts and One to One.

10.42. One to One were concerned about the financial viability test to be imposed in terms of a turnover cap for this procurement. We were told that no records were maintained of discussions from the engagement event.

10.43. The Invitation to Tender was issued in July 2019 just prior to the announcement of One to One's voluntary administration. The procurement was abandoned due to the impact of the service cessation. The CCGs subsequently agreed to vary the revised specification into local NHS Trust contracts from April 2020.

10.44. We noted in the 2019 procurement approach some areas of good practice which demonstrate learning from the commissioning of the One to One service:

- More extensive engagement was undertaken to inform the service specification, including from the Clinical Leads within the C&M Local Maternity System, an independent Obstetrician, a GP with interest in Maternity, Quality and Safety, Commissioning and Finance leads within the collaborating CCGs and the Wirral Maternity Voices Partnership.
- The qualification questionnaire was more robust in terms of financial information to be provided, including a cash-flow forecast and bank letter; a minimum turnover value was required.
- The services were clearly defined as 'Commissioner Requested Services'[49] which means that NHSI provides additional financial oversight of the provider and can intervene if there are concerns about financial sustainability to protect service continuity.
- The tender submission questions were comprehensive and specifically reference the requirements of a continuity of care model including clinical governance, informed choice, management of risk, capacity, staff policies, operational management, performance monitoring and IT infrastructure. There is a clear focus on integrated working, information sharing and transfers of care. A detailed staffing model was required to allow evaluation of skill mix and staffing ratios.

10.45. We found some specific governance weaknesses relating to the 2014/15 contract and the subsequent co-commissioned contract from July 2016:

- The 2014/15 contract was for one year only and did not specify how continuity of care would be managed after March 2015 for referrals already received.
- This contract was subsequently extended to March 2017 without a procurement process which was not permitted in the contract terms; however, this did not conflict with CCG policy (as described above). New referrals could be taken until the end of May 2016.
- The co-commissioned contract was awarded from June 2016 rather than from April; contractual arrangements were therefore unclear for April and May 2016.
- We noted that the 2016 contract was not signed by all co-commissioners at the start date; other commissioners gradually came on board during the first year of the contract so were working under an implied contract only.

Procurement policy

10.46. We have considered the procurement events in the context of Wirral CCG's 2015 procurement policy. This policy was consistent with the requirements of the NHS Procurement, Patient Choice and Competition Regulations (PCCR), 2013[50]. We did not have access to an earlier version of the procurement policy. The following extracts are pertinent:

"*it is for commissioners to decide if and when to introduce choice and competition when it is in the interests of patients, beyond the rights set out in the NHS Constitution;*"

"*Where commissioners want to test an idea or consider whether there is a solution to a particular issue and/or develop a product, they may want to conduct a trial or pilot scheme with a provider. The CCG will decide whether to competitively procure a trial service or use an existing contract(s) in line with this policy.*"

[49] NHS England » CRS policy – Information for commissioners
[50] Procurement, patient choice and competition regulations: guidance - GOV.UK (www.gov.uk)

"*The main procurement route options that the CCG will consider are: […] Considering the use of 'framework' type agreements to facilitate local patient choice of provider (Any Qualified Providers); Single Tender Action. […] Appoint a specific provider without putting that service out to open competition where there is a clear justification and the CCG can demonstrate that their decision meets the requirements of the PCCR.*"

10.47. There were several contract extensions and a subsequent contract award where One to One was the only interested provider. The policy indicates that the decisions made relating to the pilot and subsequent contract awards were in line with the 2015 policy.

10.48. We also reviewed the procurement policy introduced in August 2018 which contains some clarifications that demonstrate learning from the One to One situation:

"*[The CCG] may award a new contract for the provision of health and social care services to a single provider without advertising an intention to seek offers from providers in relation to that contract, where the CCG Governing Body is satisfied that the services to which the contract relates are capable of being provided only by that provider.*"

"*When considering a single tender action ensure appropriate steps have been taken to identify other capable providers*"

"*Where it can be demonstrated that an existing healthcare or social care service is fit for purpose, offers best value for money, and continues to fit with the strategic direction of WHCC [Wirral Health and Care Commissioning] it may consider retaining the existing provider on expiry of its existing contract without competition. Where this cannot be demonstrated an appropriate procurement process should be undertaken.*"

10.49. There is a helpful section in this policy on the advantages and disadvantages of different contracting models. This recognises the risks involved in an AQP approach and some of the issues raised by One to One, namely:

- the inability to control volumes and costs;
- lack of commitment increasing the risk to the provider, resulting in higher unit costs;
- the conflict arising with block contract arrangements elsewhere in the system; and
- non-contracted activity.

Summary points

10.50. The Any Qualified Provider (AQP) approach was a pragmatic procurement solution to allow One to One to start providing its services. However, it created a governance risk due to the unstructured and uncontrolled growth in self-referrals to One to One.

10.51. The approach was consistent with commissioning objectives to encourage more local choice in maternity services, and it was a proportionate way to explore market interest and move at pace to establish the new service. A full tender would not have been justified in value for money terms, given the limited market interest at the time.

10.52. AQP permitted a local tariff which was helpful as there was no national tariff for community midwifery at the time.

10.53. AQP led to an expansion of non-contracted activity which was not challenged until it was too late. Non-contracted activity created unnecessary risk to women and

babies due to the lack of coordinated governance over this activity. Without formal contracts, commissioners could not put appropriate governance in place; in addition, CNST cover was a risk. One to One did not comply with the intentions of the guidance on non-contracted activity at the time and the growth of the service across the country contributed to this weakness in governance.

10.54. Whilst One to One may have not have actively marketed their service, they did have a presence on social media, an example of this was through Facebook, as referenced in One to One's 2013/14 Quality Account. An unintended consequence of this social media presence was to stimulate interest in One to One in areas where it did not have an existing presence.

10.55. As the service was presented as a local choice option and accepted self-referrals, NCA might have been anticipated as awareness of One to One spread. A co-commissioned contract across C&M was a positive step in regaining control of the expansion of the market.

10.56. A weakness experienced generally with the AQP approach was the introduction of the independent sector into a complex NHS infrastructure without providing support to ensure they would be able to comply with NHS regulatory and contractual frameworks. This issue proved to be a major challenge for One to One who found the NHS system inflexible, disproportionate and impracticable. Following the pilot, the company was not able to flourish within the NHS environment.

10.57. There were three failed procurements over the period of commissioners' involvement with One to One. This was not value for money to the public purse. For the first two procurements, this outcome could have been foreseen as One to One were the only interested provider. The procurement in 2019 was abandoned to allow local NHS providers to deal with the operational consequences of the One to One service cessation. Commissioners did not appear to consider a direct award approach for the situation where One to One was the only interested provider. Direct awards are in line with the NHS Procurement, Patient Choice and Competition Regulations (Regulation 5)[51].

10.58. We found some governance weaknesses around the contracts awarded. In particular, we were not able to establish the decision-making process for the change to the service specification for the 2016 contract to include women with high-risk profiles.

10.59. The lack of challenge from NHS providers on the VEAT notice in 2016 was perhaps surprising given their evident concerns, the proposed length of the contract, and the potential for NHS providers to develop their own community-based options within this timeframe. NHS providers did start to develop new models to align with Better Births in readiness for the 2019 procurement. It was noted at the Wirral contract meeting in August 2016 that if the specification had included obstetric support, NHS providers might have challenged the notice. Commissioners recognised the potential damage this could have done to already strained relationships between One to One and NHS providers.

10.60. One to One's contract was allowed to continue from 2011 to 2016 without any significant review of how the service was working from an operational or financial perspective. This was despite alerts raised since 2012 by One to One and NHS providers about financial viability and integrated working. There was insufficient due diligence on the financial position of One to One and the operational viability of its

[51] The National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 (legislation.gov.uk)

business model before key decisions were made. We comment further on due diligence in Section 12.

10.61. Against this backdrop, the decisions to award a new contract in 2016 and the extension of the contract in December 2018, at the height of commissioners' financial viability concerns, were questionable. There were missed opportunities to re-assess and potentially plan for an earlier exit from the contract, particularly before the award of the three-year co-commissioned contract in 2016.

10.62. It was reasonable for commissioners to plan to re-procure the service in 2019 following the end of the term of One to One's contract. There was increasing market interest in providing a community-based model following national planning guidance and commissioners needed to find a way to manage the substantial risks that had arisen under the One to One contract.

10.63. We noted some positive learning points in the revisions made to Wirral CCG's procurement policy which acknowledge some of the challenges experienced with the One to One contract.

What could have been done differently?

- The appropriateness of the Any Qualified Provider procurement route should have been subject to further scrutiny as it encouraged One to One to market their services which paved the way for self-referrals, a loss of control of activity and the associated governance risks.
- Given the differences in interpretation of the Who Pays guidance, commissioners should have proactively addressed this issue earlier and put in writing to One to One their policies on non-contracted activity (NCA). Further clarification should have been sought by those CCGs who operated under NCA, particularly regarding the status of implied contracts and the insurance position under CNST.
- Insurance arrangements under CNST for One to One should have been followed up before award of the first contract, particularly as the Department of Health were considering arrangements for independent sector providers.
- The costs of abandoned procurement processes could have been avoided by undertaking more extensive engagement to establish the level of genuine market interest. Commissioners could have considered a direct award approach, given this flexibility was permitted by their procurement policies.
- Given the lack of consensus and wider contention on the risk profile of women able to access the service, the decisions made on changes to the specification should have been made at an appropriate level of seniority in the CCG governance structure and documented accordingly.
- It would have been prudent to have taken stock before the award of the larger co-commissioned contract across Cheshire and Merseyside in 2016 and to have planned for a controlled exit of the existing contract, given the serious financial viability concerns and clear destabilisation of local systems.

Recommendations

1. Comprehensive due diligence should be undertaken with the appropriate commercial expertise before decisions to award and extend contracts.
2. Commissioners and independent sector providers should work in an 'open book' way, particularly for start-up businesses offering new services, to ensure

a full understanding of the cost base and allow scrutiny of the assumptions underpinning business plans.

3. Commissioners should consider direct award approaches for services where there is only one provider expressing a serious interest, where this flexibility is permitted by procurement policies, to minimise procurement costs.
4. Steps should be taken to ensure new providers to the NHS understand the technical requirements of contracts. Formal confirmation that they are set up to comply with requirements should be sought as part of pre-contract conditions.
5. Commissioners should include a reference to their position on non-contracted activity in their procurement/contract management policies. This should be replicated in service specifications.
6. Governance arrangements around material changes to service specification requirements should be clarified in commissioners' relevant procurement/contracting policies and the Scheme of Delegation.

11. Service specifications

Introduction

11.1. In this section, we summarise the service specifications issued to One to One under its contracts. We comment on clinical input to the service specifications and how the experience of women and their families was captured. We identify the main changes between the versions issued to understand whether learning is demonstrated.

Key findings

11.2. The following table sets out the key elements of the service specifications. There were three specifications issued under the Wirral-led contracts and two specifications for West Cheshire CCG. Under the co-commissioned contract, West Cheshire CCG retained their own service specification.

Table 7: Summary of contract specifications

Contract	Key elements
Wirral CCG Nov 2011 – Mar 2014	• AQP, zero-based activity contract on a local pathway tariff. • Covers antenatal/postnatal care and home births for women of all risk profiles, Wirral only. • Emphasises integrated working and safe and effective shared care arrangements with hospital maternity services and GPs: "*relationships [should be] developed as specified and as circumstances dictate*." • Includes "*high risk antenatal care, including management from acute trust for high risk conditions*." The specification does not identify responsibility for obstetric advice during the care pathway but is clear that this is a midwifery-led model. • Adherence to safe staffing ratios and clinical supervision requirements. • Quality and performance monitoring metrics comprehensive and appropriate to case loading model, including unplanned admissions/attendances to secondary care. • Monitoring of service user experience through surveys of women, their carers/partners and improving response rates, complaints/compliments, barriers to access. • References national guidance to be followed for NCA. • Sub-contractors to be approved by commissioners. • Intrapartum care classified as an Essential Service so subject to Monitor oversight. • Contract required annual review and written record of review.
Wirral CCG (co-commissioned) Apr 2014 – Mar 2015	• Zero-based activity contract, annual value based on forecast activity – £1.9m (Wirral £1.25m, West Cheshire £0.2m, Warrington £0.13m, Liverpool £0.33m). There were some casting errors on tables (not impacting on the contract value) and activity volumes were not shown for Wirral.

	• Covers antenatal/postnatal care and home births for women of all risk profiles for co-commissioners only. • Maternity pathway payment tariff applied. • CQUIN for continuity of care performance (2.5% of contract value) to reach 85% by Quarter 4. • Additional clarification provided on transfers of obstetric care to other providers and communication required with GPs and other providers and information to be shared. • Sub-contracts require agreement of commissioners. • The document does not specifically require that obstetric advice is provided by NHS obstetric units. • Midwifery performance dashboard comprehensive with targets and defined ranges for performance ratings. • Complaints/compliments reporting and general reference to reporting feedback from local surveys as part of a quarterly report. • Participation in NHS Friends and Family Test. • Not categorised as an Essential Service.
West Cheshire CCG Sep 2015 – Aug 2018	• Zero-based activity contract for three years with a potential one-year extension. • Covers antenatal/postnatal care and home births for women of all risk profiles in West Cheshire. Non-contract activity was not permitted under this contract. • Emphasis on shared care arrangements with obstetric services for more complex care, ensuring adherence to locally agreed pathways, policies, and protocols. The specification did not state that obstetric care should be via an NHS Trust. • Midwife as lead professional for low risk women and care coordinator for all women. Target of 80% for continuity of care. • 12-month preceptorship required for newly qualified midwives. • Clarifies protocols for when a woman chooses to deviate from national guidance based on her informed preference and importance of written record of decision-making. • Shared learning to be undertaken on incidents involving transfer of care between providers with the CCG to attend a joint meeting. • Monitoring of complaints. • Evidence to be provided of routine collection of service user feedback and that this intelligence is used to inform service developments. • The specification was updated in December 2016 following the National Maternity Review. Key additions were: – clarity on the difference between a named midwife/buddy model and a team-based approach;

	– the care to be provided by each organisation on a shared care pathway was to be agreed by all parties and reflected in the woman's care plan; agreements to be put in place with the local NHS provider; – the provider should have established care pathways with the local NHS obstetric unit as required during the antenatal pathway; – comprehensive requirements on risk assessment and determinants of care pathway selection and states that midwife-led care can continue with Obstetrician agreement; – prior CCG approval required for women who choose a home birth but whose risk profile means this is not recommended; with monitoring at the contract meeting bi-monthly; – quarterly audit of response times for face-to-face and telephone contacts; – quarterly reporting on levels of satisfaction and views of women, their families, and referrers.
Wirral CCG (co-commissioned) Jun 2016 – May 2019	• Initial estimated contract value £2.8m for seven CCGs across Cheshire and Merseyside. • Maternity pathway tariff applied, and link provided to national tariff guidance. • Updated to reflect the National Maternity Review. • Robust and formal arrangements required for obstetric care. Specification requires referral to an NHS Consultant Obstetrician where appropriate. • Clear requirements relating to risk assessment and protocols for women who are not low risk. Midwife-led care can continue with an Obstetrician's agreement. • Clear inclusion/exclusion criteria for the case loading midwifery-led service and home births for women of different risk profiles. • Clarifies the risk definitions as NICE definitions only applied to intrapartum care and would restrict women who would benefit from continuity of midwife-led care in the antenatal period. • Requirement for established care pathways with obstetric units for shared care, "The provider will work in collaboration with Wirral CCG and other partners to develop services and system wide pathways…." • Prior CCG approval required for women who choose a home birth but whose risk profile means this is not clinically recommended. The use of this escalation route was to be monitored at contract meetings. • Referral pathways to stop smoking services and perinatal mental health included in the specification. • 12-month preceptorship required for newly qualified midwives.

	• Additional quality assurance programme including monthly quality review visits, shadowing of midwives by local commissioners, monthly exception reporting on use of escalation policy, commissioners to attend at least two joint One to One/NHS provider meetings per annum.

11.3. The specifications were similar for all contracts in terms of core content on the service requirements for a midwifery-led, community-based, case loading model. The specifications from 2016 onwards for the Wirral and West Cheshire contracts provide greater clarity on:

- the requirements for risk assessment and the risk criteria to assess the suitability of the case loading model and a home birth for a woman;
- the requirement to work with local NHS obstetric providers for obstetric advice and care;
- protocols for when a woman chooses to exercise an informed choice which deviates from clinical guidance and advice;
- communication and information to be shared with NHS providers and GPs on transfers of care and discharge;
- the role of the midwife as care coordinator when care is shared between providers; and
- preceptorship requirements for newly qualified midwives.

11.4. There were also improvements in terms of enhanced quality monitoring and oversight of joint working with NHS providers. For example, for West Cheshire CCG, joint meetings were required to learn from incidents involving shared care; and for Wirral CCG the additional quality assurance programme included CCG attendance at joint meetings.

11.5. Before the National Maternity Review recommendations in 2016, we did not see any evidence of a formal review of the service specification for the Wirral contract; the contract required an annual documented review. North East Essex CCG also worked to this specification under an implied contract; we saw no evidence of their review of the Wirral specification.

11.6. A review might have reconsidered the appropriateness of the full case loading service for all women. Implementation guidance to support Better Births issued to Local Maternity Systems in December 2017[52] highlighted two models to deliver continuity of care:

- team continuity, whereby each woman has an individual midwife, who is responsible for coordinating her care, and who works in a team of four to eight; and
- full case loading, whereby each midwife is allocated a certain number of women and arranges their working life around the needs of the caseload.

11.7. The guidance stated that full case loading would be more appropriate for specific cohorts of women who would benefit from individual continuity, for example, women with complex medical or social needs. The original pilot for One to One was in fact conceived for a cohort of women with complex needs, but the subsequent roll-out applied the full case loading model to all women. Some stakeholders referred to the

[52] Implementing Better Births: Continuity of Carer, NHS England, December 2017

fact that the One to One model was originally intended for women with complex needs only. There is no evidence that a team-based continuity of care model was considered when developing the specifications.

11.8. Although a specification requirement and subject to much discussion at contract meetings, robust shared care agreements with Trusts were not in place, which created risk for women and compounded the problems around provider to provider charges. We found no signed formal agreements for joint working between One to One and NHS Trusts.

11.9. The specifications provide generic statements of the need for collaborative working but do not define responsibility for ensuring operational arrangements and agreed shared care protocols are in place, timescales, or how commissioners would monitor and support. In practice, the interpretation by all stakeholders was that this was One to One's responsibility. The challenges experienced in implementing formal agreements are not reflected in the later service specifications, despite commissioners being aware of the significant risks this created to the safety of services.

11.10. The specifications did not refer to the circumstances under which a One to One midwife should accompany a woman to a hospital appointment or hospital birth; this was a particular area of difficulty experienced by One to One midwives and the women they cared for.

11.11. The specifications referenced the application of the maternity pathway payment mechanism from 2014/15. Given the significant financial issues that arose due to this tariff system, the later specifications would have been improved by making specific reference to the lead provider model and what this entailed. Monitor set out how the payment system should be implemented in 'The maternity pathway payment system: Supplementary guidance'[53] of August 2014. The guidance said that sub-contracts should be in place between providers. This should have been considered as a service specification requirement for both One to One and the NHS providers involved.

11.12. The West Cheshire CCG specification stated that the contract was not to be used for non-contracted activity (NCA). If an annual review had been undertaken, the first specification for Wirral could have been amended to mitigate the risks that arose due to NCA by including a similar statement in the exclusion criteria.

11.13. We found minimal debate around the implications of changes made to the service specifications for the Wirral-led contract. One to One did not query at contract meetings how some of the practical challenges were expected to be addressed. One to One also felt that some of the changes to the specifications limited their scope of practice and were made for the benefit of NHS obstetric providers, for example, the requirement to refer to the local NHS Trust for obstetric input. Examples of risks which we would have expected to have led to more debate include:

- the introduction of the maternity pathway payment mechanism and the implications of provider to provider charging in 2013/14;
- implementation of the reporting requirements under the maternity services data set in 2015/16;
- the more detailed requirements and protocols around the management of higher risk women; and

[53] Maternity pathway payment system: guidance for NHS providers and commissioners - GOV.UK (www.gov.uk)

- the practicalities of putting in place shared care pathways with NHS Trusts given their reluctance to engage with One to One.

11.14. We found a greater depth of discussion in the West Cheshire meetings at the end of 2016 on the refreshed specification and the CCG provided support to facilitate the development of shared care pathways.

11.15. The specification developed by Wirral CCG for the AQP contract from November 2011 was strong on the requirements for the monitoring of service user experience. Subsequent specifications were less specific in this area; for example, the Wirral CCG 2014/15 contract referred to a "*quarterly trend report on complaints and local surveys*"*;* and the 2016 specification referred to monitoring of numbers of complaints and Friends and Family Test scores only.

11.16. The first West Cheshire specification required monitoring of complaints and "*Evidence of routine collection of service user feedback and that this intelligence is used to inform service developments.*" The amendments to the specification in December 2016 required quarterly monitoring of service user satisfaction and quarterly audit of response times for face-to-face and telephone contacts.

11.17. We noted from contract meetings that active monitoring in these areas was limited but One to One did provide comprehensive reporting on service user feedback, through surveys undertaken, which was reported in their quarterly Quality Reports.

11.18. It was evident that the original service specifications were co-produced with One to One as the content reflects the One to One service model proposal. We did not find any reference to other clinical input to, and review of, the service specifications.

11.19. AQP guidance required commissioners to work with clinicians locally to "*design better and more integrated pathways of care*". We did not see evidence of commissioners working with local clinicians, other than with One to One, on the specification for the new service model in advance of its implementation.

11.20. A Wirral CCG paper in August 2015 referred to wider consultation having been undertaken in the development of the specification with service users and through a GP survey.

Summary points

11.21. The service specifications did not change significantly over time. They reflected the national drivers for maternity care, the specific requirements for the community-based case loading model, NICE guidance, local policies and interdependencies with other services.

11.22. There is clear evidence of learning in the development of the service specifications to reflect national policy for the case loading model, provide more definition on implementation and ensure a safer service for women.

11.23. There was no formal annual review of how the service specification was working in terms of compliance with specification requirements and from an operational and practical perspective.

11.24. The service specifications did not adequately define how shared care protocols should be developed. The absence of such agreements was a major risk to the safety of women and babies. The service specifications were not sufficiently robust in setting out responsibilities in this regard. In practice, the onus was placed on One to One to engage with NHS providers and resolve the challenges around joint working. There was no recognition in the specification that NHS Trusts equally needed to agree and comply with joint working protocols to ensure safe services for women nor how commissioners might support and facilitate this.

11.25. Commissioners accepted One to One's assurances that this work was progressing. This issue was not addressed and there was no coordinated across Cheshire and Merseyside. One to One had to work to each NHS provider's individual requirements rather than working to a standard template which was inefficient.

11.26. It is evident that the service specifications were informed by and tailored to the service provided by One to One. We found limited references to independent clinical input, other than with GPs for the specification for the co-commissioned contract in 2016. We did not find evidence of engagement with NHS Trust teams (obstetric and community midwifery providers) or with other independent operators such as The Albany Midwifery Practice and Neighbourhood Midwives. We have not therefore been able to fully conclude on the appropriateness of clinical input to the service design.

11.27. The experience of women and their families was captured to some degree in all of the specifications and it was reasonable to propose a survey approach. There was a stronger focus on this in the first specification issued to One to One and some useful metrics on response times were included in the West Cheshire specification. One to One provided feedback in its Quality Reports from its surveys of service users, but the specifications were generally not prescriptive enough in terms of what was required from these surveys. There was no indication of how commissioners would monitor improvement in service user experience (although we note this was referred to as a metric for development in the first specification issued by Wirral PCT).

What could have been done differently?

- As this was an untested service model with significant potential clinical risks, independent clinical input should have been obtained to assess the robustness of the service specifications. Views should have been obtained from both NHS and other independent sector providers, as well as from relevant maternity networks and perhaps the Royal College of Midwives.
- The specifications should have been reviewed formally on an annual basis to assess compliance with requirements and to understand the operational and practical challenges involved.
- A specification review might have reconsidered the appropriateness of the full case loading service for all women and considered a team-based model.
- Discussion and agreement to changes made to service specifications should have been recorded at contract meetings.
- The specifications should have recognised the challenges involved in developing shared care arrangements with NHS Trusts and provided more detail on how these would be developed, overseen and signed off.

Recommendations

1. Independent clinical review should be a standard component of service specification development. For new service models involving integrated care pathways and significant potential clinical risk, full engagement should be undertaken with relevant professionals to inform the specification.
2. We recommend formal annual reviews of the delivery of the service specification and contract as good practice to highlight risks and emerging challenges.

3. Amendments to service specifications should be fully documented and tracked to enable discussion at contract meetings.
4. Specifications should be explicit on the requirements of all stakeholders relating to the development of shared care protocols.

12. Due diligence

Introduction

12.1. In this section, we consider in more detail the extent and robustness of due diligence undertaken by commissioners before key decisions to enter into or extend contracts with One to One. We examine both the financial and commercial elements, as well as any steps taken to gain assurance through due diligence on the quality and safety aspects of the service before key decisions were made.

Key findings

12.2. There was limited information available on the due diligence undertaken by commissioners as part of the initial AQP procurement. A pre-qualification questionnaire (PQQ) was used but we have not had sight of the completed document from One to One to understand how governance arrangements and financial standing were tested. The 2011 contract issued references several aspects of due diligence:

- A business continuity plan was required as intrapartum care was categorised as an Essential Service.[54] One to One's plan covered operational continuity such as IT failure, buildings/utilities, and public health risks. It did not cover common risks facing a start-up business such as recruitment, cash-flow, and funding. This was a missed opportunity to consider the commercial risks facing One to One.
- The exit arrangements section was not populated so did not provide assurance on a smooth transition of services upon contract cessation.
- The contract states that a full review of the service should be undertaken with the first year of the contract, which was a further opportunity to understand emerging challenges. We have no evidence that this took place formally.
- Documents to be relied upon included a bank reference, insurance certificate, care pathways and signed sub-contracts. Sub-contracts were listed with Liverpool Women's Hospital (LWH) for safeguarding support, the Royal Liverpool Hospital for pathology services and a private sector provider for scanning. There was evidence of these documents being followed up by the procurement team. We did not find an agreement with LWH for safeguarding support and found only unsigned versions of other sub-contracts.
- We found an unsigned service level agreement between One to One and LWH for an integrated maternity service with a service specification dated July 2011. Due to the passage of time, LWH were unable to corroborate this document.

12.3. This contract, due to end in March 2014, was subsequently extended with Liverpool, Warrington and West Cheshire CCGs as co-commissioners. We found no evidence that the host commissioner and co-commissioners undertook further due diligence before extension of the contract.

12.4. West Cheshire CCG started a separate procurement process in 2014 and in May 2015 recommended the award of a contract to One to One. One to One were the only bidder. The procurement documentation indicates that One to One had passed the financial pre-qualification but does not indicate the financial criteria required. One to One would not have passed the standard NHS procurement financial tests based on its accounts at this point in time.

[54] A service classed as an Essential Service/Commissioner Requested Service attracts additional financial oversight by the regulator (Monitor/NHSI) who has powers to intervene if there are financial viability concerns to protect service continuity.

12.5. An example of good practice was the due diligence undertaken in June 2014 in Greater Manchester (GM) following three reported serious incidents. Trafford CCG undertook a quality review on behalf of GM commissioners which included scrutiny of policies, staff numbers and previous CQC inspection reports. The review identified concerns with policies, safeguarding training, partnership working and communication with local NHS providers. It concluded that the service did not meet the standards expected and the service specification was not aligned to GM's requirements. GM CCGs did not endorse One to One operating in their area. We found no evidence that this work was considered by other commissioners before awarding/extending contracts with One to One.

12.6. Some aspects of due diligence were covered through other processes, such as the Risk Summits and reviews undertaken by Wirral and Warrington CCGs. However, the scope of these exercises was not as comprehensive.

12.7. There were clear quality and financial viability concerns prior to the procurement and award of the co-commissioned contract in June 2016. One to One had repeatedly raised financial viability issues at contract meetings since 2012. In November 2012, One to One stated that without further support from commissioners in terms of guaranteed activity levels, the company would go into liquidation.

12.8. Furthermore, Wirral CCG had issued contract queries in May 2014 and March 2016, and Warrington CCG issued a service suspension in April 2016 due to safety and quality concerns. In April 2016, before the main co-commissioned contract had commenced, Wirral CCG had started to assess their financial exposure in the event of One to One ceasing to trade.

12.9. West Cheshire CCG requested One to One's financial forecasts at the contract meeting in February 2016, but we found no record of these being followed up and scrutinised.

12.10. There was a request for a financial plan by Wirral CCG at contract meeting in April 2016. This was to give "*a sense of how long they can keep going*". This was not followed up in the action log of the contract meeting but One to One provided the information in a letter to Wirral CCG which was also copied to Liverpool and Warrington CCGs. This was a detailed analysis setting out all of the current financial challenges facing One to One and the assumptions underpinning the financial forecasts. We found no evidence that these plans were scrutinised with the appropriate financial expertise. This was a missed opportunity for commissioners to work on an 'open book' basis with One to One to thoroughly understand the drivers of their financial performance.

12.11. The Wirral-led contract ran on until the larger co-commissioned contract across Cheshire and Mersey was awarded in June 2016. Although governance arrangements were in place to approve these decisions, we found no evidence of appropriate due diligence by commissioners to support these decisions.

12.12. We found no reference to commissioners considering the experience of other community midwifery providers:

- The Albany Midwifery Practice provided a continuity of care model under a sub-contract to King's College Hospital and was closed due to safety concerns in 2009; this had been subject to much publicity and controversy.
- Neighbourhood Midwives were established in 2012 and commissioned from 2016 by Waltham Forest CCG. They operated a continuity of care model with a primary and secondary midwife within small self-managed teams. The business ceased in January 2019 due to financial reasons. The company's adverse

financial position is clear from its publicly available financial accounts from 2016 onwards. The Director's report references ongoing financial challenges and a tariff system that was not designed for small, independent providers.

- Bridgewater Community Healthcare NHS Foundation Trust provided community midwifery services in the North West. One to One raised at both the Wirral and West Cheshire CCG contract meetings that they had experienced similar issues on provider to provider charging. Bridgewater did not provide intrapartum care and experienced similar challenges on the reporting of continuity of carer performance for shared care arrangements with acute Trusts.

12.13. As well as the continuing concerns by NHS providers about the quality and safety of One to One's services, there were multiple alerts from NHS Trusts regarding One to One's financial position and evidence of them undertaking their own due diligence:

- In April 2015, Wirral University Teaching Hospital (WUTH) escalated the increasing debt due from One to One. This led to WUTH notifying Wirral CCG in April 2016 of their intention to apply for a winding-up order against One to One. The petition was supported by LWH, St Helens and Knowsley Teaching Hospitals NHS Trust (STHK) and Countess of Chester Hospital (COCH).
- In October 2015, LWH had obtained a Dun & Bradstreet[55] analysis for One to One and had severe concerns about the company's ability to continue trading. LWH informed Liverpool CCG and asked them to underwrite the debt owed to the Trust by One to One. The CCG's position was that this was an issue between providers, and they would not intervene.
- The situation was escalated in April 2016 by a letter from the Chief Executive of LWH to the Accountable Officer of Liverpool CCG which stated the intention to begin legal proceedings to recover the debt. One to One had ceased making the payments on account agreed in 2015 due to financial challenges. LWH pointed out that to avoid any risk to women, they were obliged to care for those presenting at the hospital. As the CCG held the contract with One to One, the Trust felt that it was necessary for commissioners to act.
- In July 2017, a comprehensive due diligence paper was produced by Mid Cheshire Hospitals NHS Foundation Trust (MCHFT) for their Board, covering finance, quality, safety, patient and staff experience aspects. The paper reviewed the options for collaborative working and considered the risks presented. The Trust had access to One to One's policies and procedures for this review. The paper also examined Companies House information. One to One owed the Trust approximately £70k for provider to provider charges.
- In April 2019, the Audit Committee Chair of LWH wrote to the Audit Committee Chair of Wirral CCG with serious concerns. The letter stated: "*It is surprising that a CCG would continue to commission from an organisation in this financial position.*" "*Secondly, it is a matter of concern that Wirral CCG continues to commission services from One to One, in full knowledge that pathway payments being made are not being passed on to NHS providers in line with payment rules. Whilst the Trust has continually been told that this is a 'provider to provider issue,' for the CCG to continue with this approach to payment, knowing that appropriate payments are not being made to NHS trusts, is not acceptable.*" The CCG's view was this was an issue between the Trust and One to One and was not able to intervene.

[55] A Dun & Bradstreet rating is an overall evaluation of the financial strength and creditworthiness of a company

12.14. The same financial warnings were given by One to One to commissioners in January 2018, at which point commissioners asked for financial information for assurance (cash-flow statement and statement of liquidity signed by a qualified accountant). We saw no evidence that this was provided or followed up.

12.15. We found no evidence that commissioners sought to understand the extent of the financial issues by examining the company's financial accounts on the Companies House website. The Companies Act requires Directors to present accounts which give a 'true and fair view' and a Director's opinion is required regarding 'going concern' status for the next 12 months only. One to One (North West) Ltd had the small companies' exemption[56] from audit and submitted abbreviated accounts only. Legal disclosure requirements were limited; however, with appropriate expertise, it was possible to assess One to One's liquidity and balance sheet position; our analysis is provided in Section 15.

12.16. Commissioners escalated their concerns to NHS England over the financial position of One to One in January 2018. This was prompted by the lack of progress on the sub-contracting model with WUTH which had been proposed by NHSI, and One to One's consequent warnings about their cash-flow. Wirral CCG had also been informed that MCHFT were planning legal action for recovery of debt. One of the co-commissioning CCGs highlighted the Companies House information on One to One and described this as *"enlightening"*.

12.17. This resulted in Wirral CCG commissioning a financial viability review by Mersey Internal Audit Agency (MIAA). The review confirmed the weak financial position of the company and highlighted that that the provider to provider charging arrangements needed to be addressed. The contract meeting records the view that the report had not covered the intended scope. We were told that the review did not provide any additional insight to commissioners by this point.

12.18. In November 2018, NHS England's regional Director of Commissioning Operations produced a helpful briefing for the NHS Chief Executive on One to One's history and current position. However, this was reactive to the alerts during 2018 regarding One to One's financial viability with a view to contingency planning.

Summary points

12.19. Financial and commercial due diligence of One to One's business model by commissioners was inadequate prior to the award and extension of contracts. If robust due diligence had been applied before the award of the first contract, this would have highlighted the significant risks of entering into a contract with a start-up company with a weak balance sheet position, wholly reliant on the rapid growth of activity through NHS contracts.

12.20. There was minimal evidence that NHS stakeholders considered how a start-up business might be funded and of the need to have formal commitments to grow. The lack of guaranteed activity levels under the AQP contract prevented One to One from accessing finance for investment in infrastructure and growth. It took several years for a larger co-commissioned contract to be agreed but this did not offer any guaranteed activity levels and the company remained loss-making.

12.21. We did not find any examples of appropriate due diligence by commissioners on the safety and quality aspects of the service before decisions to award/extend the contract. This was despite awareness of heightened system scrutiny over quality and safety, the WUTH winding-up petition (2015/16) and the service suspensions by Warrington CCG (March 2016) and South Cheshire CCG (July 2016).

[56] https://www.gov.uk/audit-exemptions-for-private-limited-companies

12.22. One to One's contract was allowed to run on without due diligence on how the service was working from an operational or financial perspective from 2011 to 2016. This was despite alerts raised since 2012 by One to One and NHS providers about financial viability and integrated working. These alerts did not trigger appropriate action and risks were not mitigated.

12.23. One to One's published accounts should have raised questions for commissioners before entering into further contractual commitments. Commissioners did not obtain and scrutinise this publicly available information.

12.24. The standard due diligence undertaken under NHS procurement processes is designed for organisations who are already set up within an NHS infrastructure. The framework for assessment is not designed to understand how private sector organisations operate and is therefore inadequate for assurance purposes.

12.25. There were some examples of due diligence being undertaken by other NHS stakeholders working with One to One. The exercises undertaken in Greater Manchester and Cheshire were examples of good practice in this regard. However, these reports do not appear to have been considered before subsequent extensions and awards of contracts to One to One.

12.26. The MIAA report completed in October 2018 was the only documented example of financial due diligence undertaken by local commissioners. NHS England also undertook due diligence at the end of 2018. Both reviews came too late to be able to inform commissioning plans at earlier points in time when there were possible opportunities to intervene.

What could have been done differently?

- Comprehensive due diligence covering clinical safety, quality, operational and finance domains should have been undertaken with the appropriate expertise before decisions were made to work with One to One. This needed to be a tailored approach to obtain a full understanding of One to One's business plan and financing arrangements as a start-up business.
- As One to One was a new business with no track record, it would have been more prudent to undertake a review of financial forecasts and underpinning assumptions, directly and on an 'open book' basis with One to One.
- Operational due diligence was also required to understand how a start-up business, with limited NHS experience, would be set up to comply with the requirements of the NHS governance infrastructure.
- Due diligence should also have been undertaken at key decision points by commissioners during the lifetime of the service. The good practice examples of work undertaken by other stakeholders to assess quality and safety could have been used as a model to follow for annual review.
- Audit of One to One's financial projections should have been undertaken before the award and extensions of contracts, and routinely as the service evolved. As the company had only NHS income sources, it should not have presented any commercial risk to One to One to work with commissioners transparently.
- Commissioners should have considered using external commercial expertise to support due diligence. The financial viability review commissioned in 2018 was helpful in terms of an independent assessment of One to One's position but should have been undertaken much earlier.

Recommendations

1. A tailored approach to due diligence should be applied to small private sector providers who have a limited track record of working within the NHS. This should be undertaken on an ‘open book’ basis and include review of policies and procedures as well as financial forecasts and assumptions.
2. Comprehensive audit, from both a financial and quality perspective, should be undertaken before all key contracting decisions and on a regular basis as part of formal annual reviews of contract performance.
3. Due diligence should be undertaken with the appropriate clinical and commercial expertise, and this should be sourced externally if the skills are not available in-house or if independence is required.
4. A checklist should be developed to set out the areas of safety and quality which should be reviewed as part of routine annual due diligence of independent sector providers. This should include as a minimum: reviews of policies and procedures, staffing levels, incidents, complaints and claims, surveys of staff and service users, risk registers, performance reports and feedback from other stakeholder organisations (for example, NHS Trusts, GPs and other service providers).

13. Contract and performance management

Introduction

13.1. In this section, we consider the effectiveness of contract management arrangements and whether risks were appropriately escalated and acted upon. We consider the approach to quality assurance and the performance management framework applied under the contracts.

Key findings

Contract monitoring

13.2. Formal monitoring of the contracts led by Wirral CCG and West Cheshire was in place during the life of the One to One contracts. In addition, North East Essex CCG held routine monitoring meetings between 2014 and 2019, though the relationship was based on non-contracted activity and an implied contract.

Wirral CCG-led contracts

13.3. For the contracts led by Wirral CCG (and the former PCT), we have reviewed contract monitoring meeting papers from April 2012. We did not find terms of reference for these meetings. Wirral CCG's Contract Management Policy for the period 2017 – 2019 provides some guidance for the management of contract meetings and we refer to this where relevant.

13.4. Meetings were set up on a monthly basis with attendance by the commissioning lead for maternity services with contracting and finance representation. A member of the senior management team attended from One to One. There was no representation from the lead commissioner's quality team until early in 2016/17.

13.5. The contract meetings generally followed a structured agenda covering performance, activity, finance and contract transactional issues. The performance update reviewed performance against the metrics specified in the contract, summarised on a maternity performance dashboard. The finance section monitored activity volumes and CCG spend against plan, submissions required for payment purposes and the Commissioning for Quality and Innovation (CQUIN) scheme each year. The contract update dealt with the formal requirements and the schedules to the contract.

13.6. The meetings were generally held to the agreed frequency. Initially this was monthly and as commissioners became more confident in the level of assurance provided, these became bi-monthly or quarterly. In 2018, the meetings reverted back to monthly due to One to One's deteriorating financial position.

13.7. Minutes were recorded and agreed at each meeting. The quality of minutes was variable. One to One did not feel that the minutes accurately reflected discussions but did not raise this formally as a concern.

13.8. We found no evidence of a formal contract review during the lifetime of the contracts with One to One. For existing contracts, this is a requirement of the CCG's Commissioning Decisions Policy and Procedure[57] which was first issued in January 2016. The document provides a useful review checklist for this purpose.

[57] final-whcc-commissioning-decision-policy-081118.pdf (wirralccg.nhs.uk)

2012 – 2013

13.9. The approximate value of the contract with Wirral PCT in this year was £1.4m.

13.10. Papers were not included with the agendas provided for our review; however, the minutes indicate that the maternity dashboard tended to be tabled at each meeting rather than in advance. There were no issues logs or risk registers maintained. However, we noted that actions from previous meetings were picked up in the minutes.

13.11. There was much discussion in the first year of the contract relating to the set-up of One to One within the NHS system and the development of One to One's business with other CCGs. Emerging system challenges were raised, for example, working with other organisations in the system and referral volumes from GPs; however, these issues were not put on a risk register or issues log for escalation. A risk management report from One to One was suggested as a standard agenda item in 2012 but this was not actioned.

13.12. There was a good level of discussion and challenge on the performance metrics in the maternity dashboard. As understanding of the application of the metrics to One to One's model developed, the indicators and targets were discussed appropriately and amended to ensure the necessary insight.

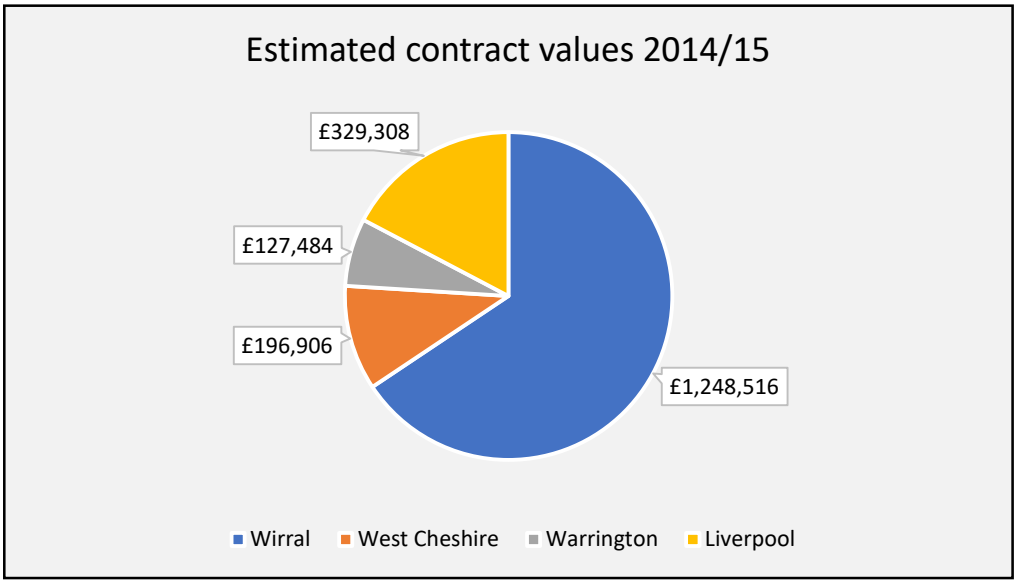
13.13. There was no separate agenda item for quality assurance. We found minimal systematic reporting and oversight on quality topics such as incidents, complaints and safeguarding. We found no evidence of separate meetings for quality oversight to address this gap. Quality concerns and complaints were discussed on an ad hoc basis as they arose. These issues were typically raised by One to One and indirectly by NHS Trusts and other system stakeholders, rather than through structured commissioning oversight.

13.14. We found that some potentially significant issues were not followed up appropriately or escalated outside of the contract meeting in these earlier years of the contract:

- In September 2012, the meeting discussed the clinical concerns raised by the 'letter of concern' from the obstetric team at Wirral University Teaching Hospital (WUTH) in June 2012. The contract meeting confirmed that there were no clinical concerns but made no reference to the ongoing associated system scrutiny that this led to and the impact on One to One's business.
- One to One frequently raised the issue of non-contracted activity and payment for this work in Cheshire and Merseyside (C&M). This had been escalated to the Strategic Health Authority. This was not recorded or escalated as a risk to One to One or to the safety and quality of services.
- In November 2012, One to One raised serious financial concerns due to the lack of guaranteed activity levels and continuing problems with GP engagement. There is no evidence of the recording of this risk or escalation outside of the meeting. The GP referrals issue is marked as resolved in the minutes of the next meeting; however, this issue continued as a major challenge for One to One.

2013 – 2016

13.15. Liverpool, Warrington and West Cheshire CCGs formally joined the Wirral-led contract from April 2014. Prior to this the three CCGs operated on a non-contracted activity (NCA) basis. Based on the contract plan, the approximate value of the contract with the four CCGs in 2014/15 was £1.9m. The split between the CCGs is illustrated below. Wirral CCG held 66% of the contract value. Liverpool CCG was the next largest commissioner with 17% of the contract value.



13.16. Representatives from the co-commissioners attended the meetings and One to One held separate, regular meetings with the commissioning lead from West Cheshire CCG. Some approved non-contracted activity continued in C&M and other commissioners were invited to attend. There was a separate agenda item for co-commissioners' updates. There was no evidence of a terms of reference for contract meetings.

13.17. The meetings followed a similar format and content as previously. From August 2014, there were separate maternity dashboards for Wirral, Liverpool, Warrington and West Cheshire and a combined version for co-commissioners. These were circulated in advance with the agenda.

13.18. The level of scrutiny remained focussed on activity performance and the maternity dashboard for Wirral CCG. The discussion continued to demonstrate positive joint working relationships with commissioners. A comprehensive action log was maintained from March 2014.

13.19. There was still no structured CCG assurance over risks, incidents, claims and complaints and this was not queried or requested by commissioners for this meeting. One to One offered to provide their quarterly Quality Report to cover these aspects. The report was not provided until May 2015 (for Quarter 4 of 2014/15); commissioners did not request previous reports for assurance. Safeguarding became an agenda item in December 2015 for the first time and Wirral CCG's Safeguarding Lead attended the meeting routinely.

13.20. The agenda did include updates from the various external quality scrutiny processes ongoing, particularly during 2014/15, for example, the 'table top' review undertaken by Wirral CCG, CQC inspections and Local Supervising Authority visit reports. The focus, however, was on the processes themselves rather than the findings, key themes arising and actions taken.

13.21. Wirral CCG issued a contract query notice following the 'table top' exercise in May 2014. The matter was discussed at the contract meeting in June 2014. One to One were concerned about the use of a formal mechanism to raise queries and asked for more information on the points raised. Commissioners were of the view that sufficient feedback had been provided after the exercise and were reluctant to discuss further. Commissioners stated that One to One's original response "*was not helpful and came across as defensive*" and asked for a revised response.

13.22. The discussion on the contract query also highlighted that information on incidents which occurred in different localities to the Wirral was not being shared with Wirral CCG as the coordinating commissioner.

13.23. The contract query was closed in September 2014 as commissioners were satisfied with the information provided. The action plan was closed a year later. In some areas of the action plan commissioners accepted verbal reassurance that processes were being put in place rather than evidence that processes had been embedded. There was no indication of any subsequent audit of the implementation of the actions required.

13.24. We found some examples of unclear governance, lack of escalation or risks and inadequate follow-up of actions from these contract meetings, for example:

- In February 2014, One to One raised an issue about GP practice staff making negative comments in a public setting about the safety of One to One's service. This was discussed outside of the contract meeting, but we found no further reference to the action taken by commissioners on this issue.
- In August 2014, One to One advised of their plans to provide obstetric advice. A contract variation was prepared for this in October 2014. However, upon being taken through Wirral CCG's governance arrangements, the proposal was not approved. One to One were notified of this decision at the contract meeting in January 2015, six months after the original proposal. One to One were frustrated as they had understood that this had already been agreed at the contract meeting. Commissioners acknowledged that there were flaws in their decision-making process: "*it was the Clinical Leads from the CCG who made the decision not to approve this service and [x] felt that the process for approvals may need to be looked at.*"
- The contract specification required formal arrangements to be in place around joint working with other providers. This was first raised in August 2014 by One to One as they were working on agreements with each provider. The response at the contract meeting was "*this would be good to have in place*." There was no evidence of this issue being followed up or escalated at this time.
- Data validation for the maternity dashboard was appropriately raised as discrepancies had arisen during the 'table top' exercise in May 2014. It was suggested that audit could be undertaken. However, it is unclear how this was taken forward as the action was closed in November 2014 without any indication of how assurance had been put in place.
- In March 2015, One to One reported an issue with an NHS Trust refusing to accept women booked under One to One, unless an emergency, and women having to be referred to other hospitals as a result. We found no evidence of further curiosity around this issue to understand the reasons why this potentially risky scenario had occurred, and no record of this being escalated.
- Provider to provider charges issues were raised frequently at the contract meetings in 2015/16 by One to One. At the contract meeting, there was a reluctance to get involved: "*Wirral CCG are unable to get involved with inter-[provider]* pathways *but do have an interest in whether this is resolved.*" One to One highlighted that there was no incentive for a Trust to put a financial agreement in place and they had escalated this to Monitor as their guidance recommended such agreements should be put in place. At the contract meeting in May 2016, it was suggested that these issues might be addressed by the Maternity Transformation Programme and that the requirement for agreements could be incorporated in NHS Trust contracts. There was no follow-up action indicated of this.

- One to One made several requests for additional payments in advance to support their cash-flow. Serious financial viability concerns were raised by One to One in April 2016 and there was a request for a financial plan to give "*a sense of how long they can keep going*". There was no evidence that these serious financial risks were escalated to an appropriate level of seniority or that the financial plans were scrutinised appropriately.
- Midwife caseloads were discussed in 2015 as the staff survey had indicated problems with workloads and One to One were experiencing recruitment challenges. One to One were asked for caseload information by area but this was not pursued: "*[x] asked whether One to One were able to report locally on the average number of caseloads each midwife has in each area but [x] felt that this wouldn't be of any benefit but agreed to ensure that commissioners were assured on a regular basis that midwives haven't exceeded their caseloads.*" The issue was closed and One to One planned to reduce caseloads by limiting annual leave. There was no reference to national guidance on caseloads in this discussion and no evidence that this issue was recognised as a risk to both women and midwives.
- Continuing issues with GP engagement were highlighted throughout 2015. It was reported that in West Cheshire, leaflets had been provided for inclusion in maternity packs and they were removed prior to the pack being given to women. A more positive experience was noted in Essex. Although there was significant discussion on this issue, there was no follow-up to understand what steps had been taken in Essex and how CCGs could support further as part of their role in managing referrals.
- Warrington CCG issued a service suspension in March 2016. This was referred to in the April 2016 contract meeting as a quality review had highlighted no clinical concerns. This suspension had a significant impact on One to One's income and One to One considered the action taken to be disproportionate. We found no formal reference to this contract sanction and no discussion about the reasons for the suspension.

13.25. Some actions were not closed off after a substantial period of time, for example:

- One to One had been asking for support on Choose and Book to help referral volumes since 2012. This was noted as resolved in the action notes to the contract meeting in December 2015.
- An action on a safeguarding self-assessment initiated in June 2014 was not closed until a year later and resulted in a new self-assessment having to be completed by One to One.
- A request for the activity baseline from a CCG in October 2014 was still an outstanding action in May 2015, by which time it was no longer needed.
- A request for CCG assistance regarding the format and content of Quality Accounts for One to One in April 2015 was still outstanding and closed in December 2015 without having been actioned.

13.26. There was a tendency in action logs to close actions upon completion of a process without providing the necessary evidence of resolution of issues or assurance. For example, meetings were arranged to discuss issues without an outcome being logged and reports were to be provided without logging that these were provided.

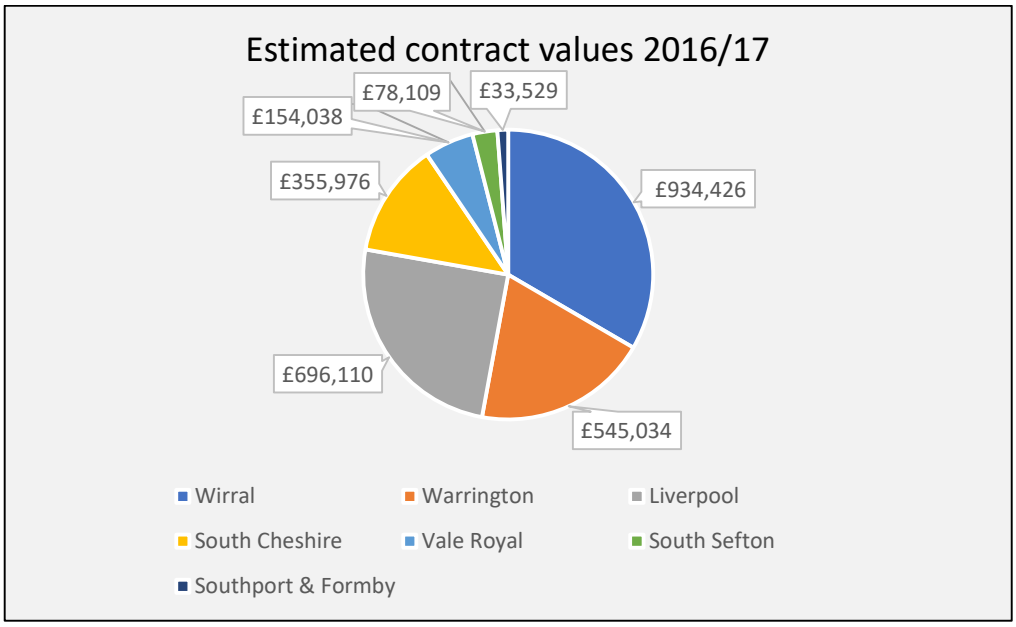
13.27. A Quality Update was included as a separate agenda item from March 2016 which coincided with a period of heightened quality scrutiny. The CQC were considering regulatory action following an inspection in Essex due to concerns around One to One's risk management policy. Wirral CCG issued a contract query in March 2016

as a result, and One to One was asked to provide a remedial action plan and participate in a quality surveillance visit. The visit did not identify any safety risks and an action plan was to be monitored through monthly contract meetings. A Quality Manager attended the meetings from this point to oversee this. The contract query was closed in May 2016.

13.28. The quality section of the agenda subsequently covered the quality assurance programme, safeguarding and an update on the CQUIN scheme. The CQUIN payment was agreed for One to One each year without any particular issues. Typically, the schemes covered breastfeeding, stopping smoking and a more ambitious target performance for continuity of care by a named midwife.

2016 – 2019

13.29. One to One were awarded a co-commissioned contract across Cheshire and Merseyside (C&M) in August 2016. The approximate value of the contract with the seven CCGs in 2016/17 was £2.8m. The split between the CCGs is illustrated below. Wirral CCG held 33% of the contract value. Liverpool CCG was the next largest commissioner with 25% of the contract value. When the co-commissioned contract was re-tendered in 2019, the estimated contract value was £5m.



13.30. The agenda for contract meetings broadly followed the same structure as under the previous contract with an item for co-commissioners' updates.

13.31. Other co-commissioners joined the contract over the next year. The service specification was noted as finalised in the September 2016. The contract was not signed before the service commencement date by co-commissioners. Wirral CCG performed the coordinating commissioner role which consisted mainly of the administrative and transactional contract management tasks involved.

13.32. The NHS England Model Collaborative Commissioning Agreement[58] was put in place for the seven CCGs and NHS England, although we did not see a version that was signed by all commissioners. The use of this framework was not mandatory. An underlying principle of the agreement was to "*share information and best practice, and work collaboratively to identify solutions, eliminate duplication of effort, mitigate risk and reduce cost.*"

[58] NHS England » Model Collaborative Commissioning Agreement: Single Contract Option

13.33. The key element of this agreement was the establishment of a Collaborative Forum for commissioners to discuss aspects of the contract, including concerns about the safety of service users, quality, concerns raised by external regulatory bodies, market management and service design. We found no evidence that this meeting was formally convened at any time. Issues of concern from co-commissioners on the One to One contract were discussed within the contract meetings on an ad hoc basis. We were told that commissioners held pre-meetings before the contract meeting with One to One but these were not formal minuted meetings, so we are unable to comment on the frequency of these or the nature of the discussions held.

13.34. The various co-commissioners started attending contract meetings during 2016/17; South Sefton CCG from September 2016, South Cheshire and Vale Royal CCGs from November 2016. There was no representative from Southport and Formby CCG but the CCG operated jointly with South Sefton CCG. There was a representative from NHS England's Public Health team who commissioned screening programmes.

13.35. Despite the intention to work collaboratively, we found several areas where the approach to commissioning seemed disjointed. For example:

- Separate quality assurance meetings were held between co-commissioners and One to One during 2018/19, however, no structured feedback was provided through the contract meetings for co-commissioner assurance. For example, a Quality Manager from Wirral CCG had undertaken a "*year-end quality review*." This was noted in the May 2018 contract meeting, but no report was provided; quality assurance meetings were also noted in the same meeting with Liverpool, South Cheshire, and Vale Royal CCGs.
- The inconsistency and resource-intensive nature of the different approaches to quality assurance was highlighted in June 2018 and January 2019; Wirral CCG suggested that the way forward was for joint quality meetings. There is no evidence that this had been considered previously. Quarterly meetings were subsequently planned to review active caseloads; however, given the timing, it is unclear if the intention behind these meetings was contingency planning or routine assurance. This was a sensible suggestion but came too late to have any impact on routine quality assurance arrangements.
- In November 2016, it was reported that in West Cheshire a GP Lead had been identified which had had a positive impact on referrals. Wirral CCG agreed to investigate this, but this was not referenced again. Warrington CCG did not consider this a priority. A coordinated approach to GP engagement across C&M might have proved more fruitful in influencing GP behaviours.
- Despite being a specification requirement, CCGs did not consistently oversee the implementation of shared care arrangements between One to One and their local NHS providers.
- Communication mechanisms for transfers of care from One to One to NHS providers varied across C&M. In September 2016, it was noted that East Cheshire CCG had provided a template letter that One to One should issue to women upon transfer to hospital care. Other commissioners wanted the handover to be undertaken through a conversation with the woman and the providers involved

13.36. The membership of the contract meeting from the various commissioners was inconsistent in terms of roles and level of seniority, and attendance varied. This is demonstrated by the titles of attendees over time which included:

- Commissioning Support Manager, Lead Commissioner (Maternity, Children and Families), Commissioning Manager;
- Head of Clinical Quality, Associate Director of Quality and Safeguarding, Clinical Quality and Safety Programme Manager, Head of Clinical Services, Quality Manager, Associate Director of Quality and Patient Experience;
- Senior Programme Manager (Children and Maternity);
- Safeguarding Lead for Children;
- Deputy Chief Nurse;
- Chief Performance Officer;
- Senior Contracts Manager, Contract Manager, Head of Delivery and Contracts;
- Contracts Accountant,
- GP Lead.

13.37. We noted that attendees were below Director level for all CCGs. We found no reference to a terms of reference for the meeting to provide clarity on escalation and delegated authority for the meeting. Wirral CCG's Contract Management Policy 2017 – 2019 required escalation of quality concerns to the Director of Quality and Patient Safety and of other performance issues to the Director of Commissioning or another CCG Director. The policy also refers to the requirement for a contract owner as the 'go to' person for the contract; it is unclear from records if there was a nominated individual performing this role as a conduit for escalation. One to One felt that the level of seniority of the membership of the contract meetings was not sufficient given the risks and issues arising. This resulted in One to One escalating issues directly to the most senior level of the lead CCG and at times to NHS England, NHS Improvement (formerly Monitor), and the Chair of the National Maternity Review to aid resolution.

13.38. Some CCGs sent several representatives covering contract management, commissioning and quality areas, which led to large numbers of attendees; for example, by mid-2018, the meeting consisted of between 25 and 30 people. There were significant numbers of apologies sent at many meetings but there was typically at least one representative from each CCG.

13.39. There was a notable increase and then a fall-off in attendance during 2018/19; the reasons for this are not noted in the minutes. The Director of Quality and Patient Safety for Wirral CCG started to attend these meetings from June 2018. At the June 2018 meeting, there was discussion of the financial sustainability of One to One and the MIAA financial review. The Director of Quality and Patient Safety also suggested that a review from a clinical perspective would also be appropriate and that it would be timely to complete a review of the service specification

13.40. A quality assurance programme had started in September 2016 in response to heightened concerns and the agenda continued to cover this topic and safeguarding. The quality assurance programme was closed in November 2017. The quality section then became a discussion led primarily by One to One on any incidents arising and root cause analysis (RCA) reports being produced.

13.41. In February 2017, commissioners referred to a similar quality assurance programme being undertaken concurrently with NHS providers of maternity services

by the same team. However, we found no evidence of feedback from these processes to improve joint working with One to One.

13.42. There remained a significant gap in terms of systematic quality assurance on incidents, claims and complaints. We would have expected to see routine reporting in these areas which identified themes, actions and learning, as well as feedback from commissioners on the timeliness and quality of RCA reports. We were not able to gauge from the contract meetings whether the number and types of incidents were a cause for concern. One to One had highlighted that this detail was available in their Quality Reports, but these were not routinely requested or referred to in any depth by commissioners. One to One's Quality Reports were an organisation-wide document and provided information on:

- client satisfaction (Friends and Family Test and birth stories);
- total referrals and bookings;
- birth and continuity of care statistics;
- training and development;
- safeguarding;
- audits undertaken;
- incidents by type and details of each incident, with some commentary on themes identified and learning;
- details of transfers for hospital birth;
- details of transfers to hospital for neonatal care; and
- complaints information.

13.43. These reports were not at CCG level and there were areas which required development as described in Section 6.

13.44. The safeguarding dashboard was provided to the contract meeting for the first time in February 2017. Prior to this point, there was no routine reporting in this area, but the contract meetings were attended by a safeguarding representative, and this was a standard agenda item.

13.45. We found no record of routine annual contract compliance audits being undertaken by commissioners as part of the contract monitoring process as required by Wirral CCG's contract management policy. Commissioners had powers under the NHS standard contract (General Condition 15) to audit service providers at any time.

13.46. CQC oversight was referred to by One to One under other business arising. It remained unclear from the meeting minutes whether the CCGs attended the CQC meetings; the associated action relating to this was closed without resolution in November 2016 and the issue was raised again in February 2018. CCG attendance at these meetings would have offered an opportunity to strengthen commissioning oversight and understanding of the issues raised by the CQC.

13.47. Some of the key discussions at contract meetings during this period are summarised below:

- The 2016 service specification required CCG approval for women who chose a home birth but whose risk profile meant that this was not clinically recommended. The use of this escalation route was to be monitored at contract meetings, but we found no evidence of such monitoring.
- One to One had provided an exit strategy at the time of the winding-up petition and this was noted by commissioners as a comprehensive document. In the

September 2016 contract meeting, potential insolvency was discussed. Commissioners asked for confirmation that insurance cover for claims would continue following an insolvency situation. The NHS Litigation Authority had reportedly advised that it would be the CCG's obligation to provide cover. This issue was noted in the action log for escalation within Wirral CCG; however, it was marked as closed without indicating how the issue had been resolved.

- Wirral CCG appropriately contacted all other CCGs in C&M and Essex who were working under NCA so that they could put contingency arrangements in place in view of the winding-up petition.
- Hospital-reported incidents were an agenda item from February 2017; these were to be monitored by each commissioner and any issues brought to the contract meeting. This was a positive step to focus on the effectiveness of shared care arrangements. We did not, however, find any systematic reporting on such incidents or evidence of considering the differing perspectives of One to One and NHS providers on incident themes.
- Communication arrangements between One to One, GPs and NHS Trusts were raised in February 2017 as faxes continued to be used with GPs and some Trusts. This issue was ongoing in August 2018 and the Local Medical Council were asked to action this with Primary Care.
- In May 2017, Warrington Hospital was considering providing obstetric services across the C&M footprint as part of a single pathway with One to One. Other Trusts were also interested in this model. This had not progressed significantly, but commissioners were concerned that they had not been aware of this development. There was no record of this being escalated despite there being clear system and choice implications.
- In August 2017, One to One noted that their Essex base had been deregistered and the service was being run as a hub from the North West base. There was no discussion about why this action had been taken and the potential impact on staff and care of women.
- From 2017/18 onwards, a significant proportion of the agenda discussion was taken up by the proposal for a sub-contract model with WUTH. This took the focus away from quality assurance and issues arising in other areas of C&M.
- Reference was made in February 2018 to direct communication by One to One to the Accountable Officer of Wirral CCG regarding their financial position and the lack of progress on the sub-contract model with WUTH. This letter had not been shared at the contract meeting.
- There was a reference in the same meeting to the CCG having shared contingency plans relating to One to One's financial position; we did not see these contingency plans, so we are unable to comment on these. No response had been received from One to One relating to these, but this is not referred to in the action log.
- An example of rigorous, appropriate challenge was in March 2018 regarding midwife caseloads and enquiries as to guidance on ratios used. The CCGs requested a presentation from One to One at the next meeting as the response provided at the contract meeting did not give the required assurance.
- In March 2018, the frequency of meetings was re-assessed as they were being held monthly due to the financial concerns. The minutes stated: "*As assurance has now been provided [x] agreed to discuss with the CCG Directors whether they would be happy for these meetings to be moved to bi-monthly. All those present were happy for the meetings to be held bi-monthly….*" Wirral CCG had

escalated their concerns to NHSE/I at this point as they had not in fact gained assurance on this issue. This indicated a disconnect in communication between the business of the contract meetings and actions being taken by executives outside of the contract meeting.

- A risk register was introduced from March 2018; no entries were recorded. Wirral CCG's contract management policy introduced in 2017 indicated that risk registers should be used in contract meetings. We noted that the legal action proposed by Mid Cheshire Hospitals NHS Foundation Trust in May 2018 was not put on the risk register. We observed only two items being placed on the risk register: the financial risk relating to One to One in July 2018 and the insourcing of diagnostics by One to One in December 2018. We noted that the financial risk relating to One to One due to the winding-up petition by WUTH was recorded on Wirral CCG's corporate risk register in July 2016.
- In June 2018, the minutes indicate heightened discussion around hospital-reported incidents. One to One were asked to follow up on the detail and this was recorded in the action log, but the cluster of incidents referred to were not considered for the risk register.
- In June 2018, there was recognition that the status of One to One with regards to quality surveillance had been confusing. The following clarification was provided: "*[One to One] are at enhanced surveillance but routine for monitoring.*" Wirral CCG's contract management policy, introduced in 2017, set out the process for escalation of quality concerns to potentially trigger enhanced quality surveillance through the Cheshire and Merseyside Quality Surveillance Group. This implied that routine monitoring should continue alongside enhanced quality surveillance. It was agreed to include quality surveillance levels on the agenda for the next meeting, but this was not discussed again. Our interpretation is that this discussion reflected the fact that routine quality oversight had been lacking at the contract meeting with too much reliance placed on external quality surveillance.
- From July 2018, attendance at these meetings fell and discussion became more focused on the financial issues with very few queries on performance. Warrington CCG stopped sending their financial summaries and although this was queried no response was recorded. There was clearly heightened concern over One to One's financial position and caseload numbers were included on the performance dashboard with a view to contingency planning.
- In December 2018, One to One noted that West Cheshire CCG were planning to procure a new service. This was not recorded on the risk register despite the ongoing financial viability concerns and this contract representing 25% of One to One's annual income.
- In January 2019, commissioners, including NHS England, acted promptly to put quality assurance arrangements around One to One's scanning service which had been taken in-house; One to One had not notified commissioners in advance to the change in arrangements.
- Commissioners suggested quality meetings/calls on a quarterly basis with One to One to examine caseloads and risks in January 2019; this appears to have been driven by the financial concerns at this time.
- In May 2019, it was noted that activity data had not been submitted to the system since September 2018; there was no explanation as to why this had not been identified earlier.

13.48. There were some further examples of actions not being completed in a timely fashion or closed off appropriately:

- An analysis of GP referrals to be undertaken by Wirral CCG's Business Intelligence team was requested in November 2016 and was still outstanding a year later, by which time it was no longer required.
- An action in February 2017 on sharing clinical pathways was closed as completed in August 2017, without evidence that these had been provided.
- An action opened in August 2016 relating to carbon monoxide monitoring was closed in November 2017.
- Work to review the maternity dashboard to determine which indicators were within One to One's control was requested in June 2018 and had not been completed six months later.
- The contract required Quality Accounts to be produced and One to One had asked for support on this in 2015. In December 2018, Wirral CCG offered to help One to One to align their existing Quality Reports with the Quality Accounts requirements. This action remained outstanding in May 2019 although it was noted that Wirral CCG were happy with the content of One to One's report.

13.49. Following the notice of contract termination in March 2019, contract meetings were split into two parts from April 2019. Part A covered business continuity and communication arrangements following the contract termination notice in March. Part B was for routine contract monitoring. This was a sensible approach which prioritised the needs of women and their families and One to One's staff, given the sensitivities involved around the contract termination notice. The communication plan was shared with NHS Trusts on an embargoed basis only. Meetings ceased in July 2019.

West Cheshire CCG contract 2015 – 2019

13.50. West Cheshire CCG awarded a separate contract to One to One from September 2015. The contract value was £0.2m but we noted that the plan was adjusted to almost £0.4m for 2015/16. Activity increased significantly over time and the estimated value of this contract in 2020/21 was £1.2m.

13.51. We were told that as an associate on the Wirral contract, the CCG had struggled to get enough focus on West Cheshire in contract meetings to be sufficiently assured on quality issues. The CCG also wanted to directly support and improve the relationship between One to One, the local NHS Trust and GPs.

13.52. We were provided with papers from March 2016 to March 2019 for contract meetings (referred to as Quality and Performance Meetings). Meetings were held monthly initially and moved to quarterly in 2017. The core attendees were:

- Head of Quality and Safety;
- Director of Commissioning (from June 2016);
- Head of Contracts;
- Maternity Commissioning Manager;
- Starting Well Commissioning Lead;
- GP Lead for Maternity;
- Incidents Coordinator; and
- One to One representatives.

13.53. The involvement of a GP Lead for maternity strengthened the quality of debate and follow-up of actions regarding General Practice. The CCG's Director of Quality and Safeguarding attended from November 2017 onwards.

13.54. The agenda was structured around immediate quality issues and risks as well as routine review of the maternity performance dashboard. The typical agenda in 2016 covered: CQC inspection update, individual reported incidents arising, shared care pathways, financial update and financial viability, the winding-up petition and contingency planning.

13.55. Recognising that this contract was put in place at a time of heightened scrutiny and financial risks regarding One to One, it was proportionate to focus on the areas highlighted in the agendas during 2016. However, the agenda into did not settle into a recognised, routine format to cover the core requirements of assurance on quality and safety and monitoring of financial performance.

13.56. A comprehensive action log was maintained, and this was well managed in terms of closure of actions and following up on evidence for assurance. Actions were not dated, which made it difficult to see for how long actions had been outstanding. There was no risk register for escalation outside of the contract meeting.

13.57. We found the level of discussion and scrutiny at contract meetings to be relatively effective in terms of providing an understanding of the immediate risks and requesting the appropriate assurance on these. There was a clear focus on risk management rather than on the interpretation of the dashboard performance metrics and the transactional aspects of the contract.

13.58. We noted a decrease in the quality of debate and scrutiny from March 2018; a contributory factor may have been that the GP Lead for maternity and the Maternity Commissioning Manager had left the CCG and had been consistent attendees at the meeting. In addition, the focus at this time was on the financial viability of One to One. We observed a tendency to rely on verbal reassurance and broad statements on policy and practice from One to One which were not debated.

13.59. The performance dashboard was not scrutinised in detail at every meeting; queries were taken by email and exceptions discussed at the meeting. The Director of Quality and Safeguarding queried this approach in November 2017 but feedback was that the exception basis was working well. This seemed a proportionate approach during a period when other issues needed to be prioritised.

13.60. We did not see evidence of any routine quality oversight in terms of reporting on incidents, complaints and claims and associated learning. Individual incidents arising were discussed, including those raised by GPs, and actions followed up. There was minimal discussion of safeguarding issues and this was only included as an agenda item in late 2018.

13.61. The CCG did not routinely request or scrutinise One to One's quarterly Quality Report for assurance. We found a reference to the Quality Report in April 2016. The report was included in the papers of the March 2019 meeting. One to One had invited commissioners to their internal quality meetings but there is no record of the CCG attending these meetings.

13.62. There was a gap in terms of routine monitoring of activity and costs against plan. In January 2018 the CCG reported a significant overspend to date of £216k. There was no significant discussion of the reasons for this; One to One suggested a block contract which was not taken further. One to One provided data at the CCG's request on referrals and activity but these were infrequent.

13.63. There was a full discussion on the revised service specification for 2017/18 and this demonstrated effective joint working to update the specification and performance

metrics. For example, metrics were included to monitor safe staffing ratios and thresholds were set for the continuity of care target. Additional staffing metrics were included as One to One had highlighted issues with recruitment and retention. The requirement for shared clinical pathways was included in the Quality Schedule.

13.64. Continuity of care was a CQUIN target in 2016/17 and closely monitored on a quarterly basis for each element of the maternity pathway. This was an appropriate focus, given that this was a key element of One to One's value proposition. There was a governance issue regarding payment of the 2016/17 CQUIN as the CCG had made the payment despite One to One not meeting the target due to the operational challenges experienced. This payment was clawed back.

13.65. There was a further issue on the CQUIN for smoking status in 2017/18. The Director of Quality was concerned that One to One had not been held to account appropriately on CQUIN and acknowledged that a contributory factor was the lack of support from the quality team at this meeting. One to One provided a comprehensive report in May 2018 demonstrating achievement of the 2017/18 CQUIN target. The CQUIN proposed for 2018/19 was a target on the home birth rate. It was agreed that the CQUIN needed to be about women giving birth in their place of choice when safe to do so.

13.66. The CCG demonstrated an awareness of externalities in terms of issues impacting on their assurance and oversight of One to One and the implications of One to One's financial challenges for the safety of services. For example:

- The meeting discussed serious incidents in different CCG areas. The CCG had become aware of an incident in South Cheshire area and recognised the need for clarity on their responsibility for alerting CCGs operating under non-contracted activity about incidents in their areas.
- The CCG monitored progress on the Remedial Action Plan in response to Wirral CCG's contract query in 2016.
- In 2017, the CCG followed up One to One's action plans on quality assurance over screening and immunisation services and in response to the NHS England publication Saving Babies Lives[59].
- The CCG intended to extend the contract for one year from August 2018. It was noted that this was dependent on the outcome of the independent financial review being undertaken by Mersey Internal Audit Agency commissioned by Wirral CCG.
- In discussion about One to One's intention to raise the issue of block contracts with NHS Trusts, the Director of Quality and Safeguarding expressed concern about the potential destabilising impact of this action on clinical relationships. The CCG recognised it had a role to play in supporting these relationships to ensure the safety of services. In November 2018, the CCG's Finance and Performance Committee had recognised the potential overpayment involved in holding a block contract with Countess of Chester Hospital at a time of decreasing birth numbers while funding activity through One to One. The CCGs planned a procurement for a prime provider model aimed to resolve this issue.

13.67. The CCG was clearly supportive of One to One and demonstrated flexibility and compromise in relation to performance reporting requirements. They took proactive steps and facilitated meetings to find solutions to the ongoing issues such as GP

[59] saving-babies-lives-car-bundl.pdf (england.nhs.uk)

referrals, shared care pathways and settlement of the debt with the local NHS provider. Examples of this are described below:

- Over the six-month period to February 2016, out of 110 referrals only three were from GPs. In response, the CCG arranged for One to One to attend Practice Managers' meetings and developed a shared care leaflet with contributions from both One to One and Countess of Chester Hospital (COCH). The CCG's GP Lead supported the promotion of One to One with General Practice. Activity increased substantially by almost 50% in 2016/17 and continued to increase in 2017/18 and 2018/19.
- Formalisation of shared care arrangements and agreement on provider to provider charges with COCH remained the key barrier to progress. In March 2016, One to One reported that an information sharing agreement had been signed and that clinical pathways had been agreed. The CCG stressed the need for the signed hard copy evidence of the agreed pathways, and this was followed up directly by the CCG representative who also facilitated joint meetings. Despite the CCG's prioritisation of this issue, progress was slow. A draft agreement written by One to One was included in the contract meeting papers in September 2017 and there was evidence of joint working with COCH in the document comments. In November 2017, it was recorded that COCH had asked the CCG to approve the agreement, however, we found no evidence that this agreement was finalised; the action was marked as complete in June 2018.
- Despite efforts to facilitate by the CCG, there was limited progress on a financial agreement with COCH on provider to provider charges. In November 2017, it was noted that payment of outstanding debt to COCH had been agreed for 2016/17 and was being validated for 2017/18. It was recognised that NHSI would need to provide direction on this issue. Our understanding is that this is a reference to the review of tariff and coding audit which was undertaken by NHSI in October 2017 and did not result in any immediate action on financial arrangements.
- The CCG asked the Chief Nurse of NHS England North for an external review of One to One's risk management policy and shared care pathways to support their development. Peer review by NHS providers was suggested by NHS England but this did not provide the required independence. NHS England were unwilling to support an independent review and advised that the issue would be addressed by the "*collaborative commissioning group*." Our understanding is that this was referring to the Wirral-led co-commissioners. This action was closed in August 2017 without any clear resolution. We found no evidence that this was followed through by NHS England with Wirral CCG and co-commissioners.
- Pathways into perinatal mental health services were discussed as One to One were having difficulties in accessing these services via COCH. The CCG was involved in a review of these services and agreed to share progress and outcomes at the Maternity Network meetings.
- In June 2017, the CCG suggested shared antenatal clinics between One to One and COCH to build improved relationships and effective shared care. One to One did not support this idea as they felt this would impact on continuity of care; it was not progressed further.
- In November 2017, a sub-contract model with COCH was proposed. This was discussed further with the CCG but was not taken forward. We understand that this was due to concerns by COCH around risks and a potential VAT cost.

- There were several discussions relating to One to One's attendance at Starting Well meetings and the Maternity Network meetings. One to One found the numerous meetings to be a poor use of time as the agendas covered areas which did not involve One to One.

13.68. There were some instances of issues raised which might have been subject to further scrutiny or which should have been escalated:

- With regards to the winding-up petition, in April 2016, the CCG suggested using the Centre for Effective Dispute Resolution to support resolution. One to One said that the coding issues involved would be too complex for this approach and this was not taken further. The CCG also suggested an external, independent audit on coding, but this was not taken forward as an action; separately One to One had raised the issue with NHSI who did undertake an audit in October 2017.
- The CCG took appropriate action to request exit plans and caseload information should the winding-up petition succeed. The CCG requested sight of One to One's financial forecasts and this action was marked as complete in May 2016 but there was no discussion about the financial projections evident in the contract meeting.
- One to One reported that a local NHS Trust providing community midwifery services had experienced similar issues on provider to provider charges. The CCG suggested that One to One contact the Trust to investigate further; this was not followed up.
- One to One reported to the contract meeting that its concerns about collusion occurring between a neighbouring Trust and CCG on provider to provider charges had been raised with NHSI (formerly Monitor). The minutes state: "*Monitor has agreed that the Trust's behaviour was inappropriate, although they will not commence an investigation into this issue as funding is not available to support a single investigation and that this issue is likely to be addressed once pioneers start to resolve payment issues.*" This appeared to be a serious allegation which required further investigation and escalation.
- In June 2016, One to One advised that one of their contingency plans was to set up a new company should the winding-up petition be successful. As One to One's financial viability remained in question, the company set-up was discussed again in June 2017 with a view to continuing the business model. The CCG agreed to consider this option following appropriate assessment of the new company on safety. The propriety of this proposal in the context of One to One ceasing to trade does not appear to have been questioned and was treated as a request for a new sub-contractor to One to One. One to One did not in fact pursue this further.
- In January 2017, there was a query about One to One moving to a team based-approach with one named midwife and three named buddies. Commissioners' view was that this model was no different to that offered by COCH and therefore did not give additional choice. In June 2017, the CCG confirmed that the team model was not appropriate to the service specification. There was no further explanation noted regarding the model offered by COCH.
- In December 2018, the CCG queried whether there had been a change in practice by One to One as COCH had reported an increased level of interventions. One to One advised that this was due to national guidance but did not specify how this had changed. The CCG did not enquire further about this, despite the potential implications for the care of women.

North East Essex 2016 – 2019

13.69. Activity in North East Essex remained on a non-contract activity (NCA) basis over the period from April 2014 to July 2019; annual spend was approximately £0.5m. North East Essex CCG held routine contract monitoring meetings from April 2016 onwards. Evidence of monitoring of the service provided by One to One in North East Essex under NCA prior to April 2016 has not been shared with this review.

13.70. We reviewed the documentation provided for Contract and Performance Meetings from April 2016 to June 2019. Terms of reference for these meetings were agreed by the group in September 2016.

13.71. The meeting's responsibilities were to:

- provide assurance, shared governance, strategic direction and leadership for the performance and management of the contract;
- oversee incident management and reporting;
- ensure that there were mutual working relationships between local providers and relevant clinical services;
- define the acceptable risk profile and risk thresholds for the service;
- ensure that all provider and commissioner risks were documented in a risk register for the Children and Maternity Programme Board, including actions to mitigate risk; and
- receive and review performance exception reports and responses to national directives.

13.72. Members were required to attend a minimum of 50% of meetings a year. Representation at the meeting was relatively consistent and in line with the defined membership over the three-year period. The Chair for the meeting was initially the CCG's Director of Nursing and Quality who chaired the first four meetings held in 2016; from November 2016, this responsibility transferred to the Deputy Director of Nursing and Quality. The meeting membership including the CCG's Business Manager for Children's and Maternity Services, Head of Contracts and the Designated Nurse for Safeguarding. One to One was initially represented by the regional Clinical Lead and Operations Manager; however, from January 2017, One to One representation was from the team based in the North West and by 2018 this was often via teleconference.

13.73. The terms of reference did not specify the frequency of the meetings. Based on the papers provided, meeting frequency was approximately bi-monthly (six meetings) in 2016/17 and then reverted to a quarterly basis from 2017/18 onwards. Meetings were held in May and June 2019 due to increasing concerns about One to One's financial viability and the CCG's intentions to go out to procurement for the service.

13.74. The meetings generally followed a structured agenda which included review of the performance dashboard, safeguarding, contract activity and review of One to One's quarterly Quality Reports. One to One provided a separate safeguarding dashboard.

13.75. There was no evidence that activity and finance performance was monitored against plan and there was no finance representation at the meeting.

13.76. One to One provided a commentary on performance exceptions as part of its Quality Reports which were provided from December 2016 onwards. Exception reports were required by the CCG for persistent underperformance against key performance indicators (KPIs). There were some instances of Quality Reports not being provided in advance of meetings and repeated conversations on the same

issues. In addition, as these reports were for One to One as an organisation as a whole, the CCG requested more clarity on the aspects which related to their area in December 2018.

13.77. There were a number of ad hoc items on the agenda such as patient choice being restricted because Mid Essex Hospitals Trust would not accept One to One women who wished to give birth there. Other items included communication with Colchester Hospital University NHS Foundation Trust (CHUFT) and antenatal and newborn screening. Communication and integrated working arrangements with CHUFT remained as standing items on the agenda.

13.78. An action log was routinely maintained and reflected the discussions at the meetings. It was reviewed and updated at each meeting. The action log was well set out and signposted the reader to relevant discussion in the meeting minutes. There were some longstanding open actions which had not been closed off by the final meeting in July 2019. An action ('RAG'-rated as red) had been on the log since July 2017 which referred to the challenges in agreeing joint working arrangements with other providers. The action was to confirm an agreement was in place with the local Health Visiting service. It also referenced the need to review the agreement in place with CHUFT as the agreement in place was three years old (we were not provided with a signed version of the previous agreement with CHUFT).

13.79. An issues log was routinely maintained and items were added to the log from September 2016. The issues logged centred around communication and relationships between One to One and the local Trust:

- In November 2016, communication and the behaviour of midwives and staff at other organisations towards One to One staff was highlighted, with the potential negative impact on women's care and potential reputational damage for One to One. The CCG was to take the matter to the Director of Nursing meeting.
- In January 2017, an update referred to cultural issues between 'frontline staff'. Each incident was to be raised with the Trust.
- In May 2017, the issue of communication between One to One and CHUFT was discussed, and it was agreed to update the issues log to reflect the need for regular multidisciplinary team (MDT) meetings between the organisations. An update in July 2017 noted that One to One reported an improving situation and that this issue should be de-escalated on the log.

13.80. There were examples of some key issues being discussed and not entered on the issues log nor referred to in future meetings, for example, in September 2016 the CCG Safeguarding Lead asked for One to One's safeguarding plans relating to female genital mutilation; in November 2016 the Contract Manager identified formal concerns about medicines management. The issue log remained on the agenda until May 2018, without any further updates.

13.81. Risk management was not included as an agenda item for the contract meeting, although the terms of reference required the meeting to report risks through the risk register to the Children and Maternity Programme Board. A risk register was not maintained at the contract meeting.

13.82. Discussions at contract meetings demonstrated appropriate debate and scrutiny on safety and quality performance issues:

- During 2016/17, there was an ongoing dialogue regarding a service level agreement for joint working with CHUFT; a version completed in 2015 had been revised but required signing. In September 2016, One to One reported experiencing issues accessing consultant appointments at the Trust for women under their care.

- Service level agreements for joint care pathways with CHUFT and local Health Visiting services remained as key discussion points throughout the duration of the involvement of One to One in North East Essex as signed agreements were not in place. One to One said that here had been a delay in developing pathways due to internal staff changes. In May 2018, the CCG requested copies of the agreements for partnership working but this action remained outstanding.
- One to One and the local Trust were to reinstate monthly MDT meetings. One to One was to provide evidence of this by March 2019.
- There were various other challenges reported on joint working, for example, in July 2018, One to One raised a concern about the local Trust not complying with national policy on serious incidents, and the CCG raised this with the Trust.
- In February 2019, One to One raised issues regarding hip scanning for babies and asked the CCG to support the agreement of care pathways. The CCG wanted to know why this issue had not been raised with them earlier. The CCG were to discuss this with the Trust.
- The Antenatal and Newborn Screening quality assurance action plan 2017/18 for Essex was discussed. There were concerns about the status of the action plan and the Newborn and Infant Physical Examination (NIPE) pathway. One to One reported that the issue was not being able to get direct referrals into a paediatrician and the tariff to be applied. The CCG said that the local Trust should work with One-to-One to put a pathway in place and said that financial issues should not delay this. The CCG requested further assurance on this as it had been raised at the Quality Surveillance Group.
- In May 2016, incidents were discussed under the exception reporting item on the agenda. In November 2017 it was agreed that One to One would provide an incident overview report for the meeting in lieu of the Quality Report. This was to be provided by the end of the month and quarterly thereafter.
- The CQC report for the inspection in Essex in February 2016 was discussed in September 2016. One to One did not believe that the report was a fair representation and did not accept the findings. Notwithstanding this, the CCG found that the action plan to address the findings was of a good standard.
- In November 2016, it was noted that One to One's Regional Lead had resigned and was not to be replaced. One to One were planning to implement the Buurtzong[60] model of self-managed teams, although some functions would remain centralised in the North West.
- At the end of 2016, One to One reported staffing challenges. One to One reported that they were operating at full capacity in November 2017 but were reluctant to employ more midwives until a contract was put in place with the CCG.
- The One to One action plan for the CQC inspection visit completed in January 2017 was discussed in the November contract meeting. The CCG was concerned that some of the completion dates had passed and asked for it to be updated. Verbal assurance was provided by One to One and the CCG requested that this was confirmed in writing.
- In March 2018, the CCG provided an update on procurement plans for the service. CHUFT were not opting for a lead provider model. The intention was for a block contract arrangement, with an activity ceiling linked to a guaranteed

[60] https://www.england.nhs.uk/6cs/wp-content/uploads/sites/25/2015/04/implementing-buurtzorg-principles.pdf

income level. One to One were concerned that this would restrict choice and limit growth in North East Essex.

- In May 2018, there were some queries on incident reporting contained in Quality Reports and the identification of lessons learned. The meeting was told that the lessons learned reported were not specific to Essex but for the whole organisation. The meeting was provided with verbal assurance that any lessons learned would have been identified through the One to One governance processes.
- One to One advised that they were planning to attend the Local Maternity System Board meetings at the start of 2018/19. Work was being completed locally by the Heads of Midwifery to refresh the maternity dashboard. One to One were not included in this and the CCG were to raise this with the Heads of Midwifery.

Performance management framework

13.83. We have reviewed in detail the performance dashboards used over the period of the One to One contracts. The following table summarises the key activity and performance metrics applied under each grouping in the dashboard, and we note any key differences observed for West Cheshire and North East Essex CCGs.

Table 8: One to One performance dashboard metrics

Activity
• booking numbers • timing of booking from referral and stage of pregnancy • antenatal transfers from other providers • active caseload numbers (from 2017/18) • continuity of care (named midwife) metrics (from 2016/17) • total births and home births planned and achieved • type of delivery – normal, instrumental, and caesarean • referrals to Health Visiting services • teenage pregnancies and referrals to the Family Nurse Partnership service • additional birth metrics on multiple deliveries, live deliveries and age profile, water births, caesareans (emergency/elective), vaginal birth after caesarean, inductions of labour for North East Essex CCG • In 2018/19, the West Cheshire CCG included: • percentage of women booked on a standard, intermediate and intensive pathway • antenatal continuity – all appointments • antenatal continuity – routine appointments • intrapartum continuity • postnatal continuity
Morbidity and risk management
Most of these metrics were introduced in 2014/15 and continued to be monitored unless otherwise noted. • Percentage of urgent call-outs achieved within one hour (from 2016/17)

• Number of eclampsias for home births • Number of post-partum hysterectomies (from 2014/15 to 2015/16) • Number of post-partum haemorrhages (from 2014/15 to 2015/16) • Meconium aspirations • Hypoxic encephalopathy • Shoulder dystocia • 3rd and 4th degree tears • Neonate admissions within 28 days due to feeding problems • Neonate admissions within 24 hours • Mother and babies admitted intrapartum • Apgar scores • Low birth rate babies • Maternal sepsis for North East Essex CCG • Stillbirths for North East Essex CCG • Clinical reported incidents and serious incidents for North East Essex CCG
Breastfeeding
• Initiation rate (split for home births from 2017/18) • Breastfeeding at 10–14 days (from 2013/14) • Referrals to peer support services (2012/13 only)
Substance/alcohol misuse
• Number of women identified with misuse problems • Numbers referred to drugs/alcohol services • Alcohol units and identified drug use (from 2018/19)
Mental health
• Number of women with mental health problems • Newly identified and pre-existing problems • Women on a perinatal mental health pathway (from 2013/14)
Smoking
• Number/percentage of women smoking at booking and delivery • Smoking status at discharge (in 2018/19) • Additional validation metrics (in 2018/19) • Ex-smoker metrics (in 2015/16 only) • Several metrics on referrals to stop smoking services
Learning disabilities
• Number of new referrals of women with a learning disability (in 2012/13 only as it had been a national requirement)
Obesity

• Number/percentage of women with a body mass index (BMI) of over 30 and 35 (additional metrics for BMIs of over 40 and 50+ for North East Essex CCG).

Sexual health and contraception
• Percentage of women advised and provided with contraception of choice on discharge • Percentage of women aged 15–24 tested for chlamydia during care episode
Social factors/multi-agency working
• Number of families with a Children in Need plan • Number of families with a Child Protection plan (until 2017/18) • Number of families with 'Common Assessment Framework/Team around the Child' plan (until 2017/18) • Number of families with identified domestic abuse (until 2017/18) • Number of referrals to a Multi-Agency Risk Assessment Conference (until 2017/18) • Number of families with safeguarding issues (2013/14 only) • Number of meetings attended relating to Children in Need and 'Team around the Child'
Workforce
• Supervisor to midwife ratio (not populated) • Midwifery caseload (North East Essex CCG from 2015/16 but not populated) • Safeguarding training (North East Essex CCG from 2015/16 but not populated)
Feedback
• Number of complaints received (until 2017/18) • Number of 'thank you' letters received (until 2017/18) • Complaints responded to within required timescales (until 2017/18) • Quarterly trend report on incidents, claims, complaints, surveys (2014/15 only) • Friends and Family Test scores (2014/15 and 2015/16 only). The West Cheshire CCG dashboard included Friends and Family Test metrics until 2018/19.

13.84. We have considered the performance dashboards used in the context of the good practice guidance set out by the National Audit Office: 'Performance measurement: Good practice criteria and maturity model' of 2016[61] (see Appendix 6). Our key observations are set out below.

13.85. Routine performance monitoring was undertaken at contract meetings using a dashboard of metrics relevant to the service. All metrics were reported monthly, and there were separate dashboards for each co-commissioner as well as an organisational level dashboard for One to One.

[61] https://www.nao.org.uk/wp-content/uploads/2016/11/

13.86. We noted that the West Cheshire CCG dashboard was not aligned in some areas with the dashboards used for the Wirral-led contracts. One to One did not report any issues with producing the two versions of the dashboard and were advised that a regional dashboard would be developed for consistency. There were still two different versions of the dashboard in 2018/19.

13.87. The dashboards used by North East Essex CCG contained several additional and more detailed measures as indicated in the table above. These were predominantly around birth outcomes for which the information would need to be accessed from the local acute Trust involved in a woman's care. Many of these measures were highly relevant to the assessment of the safety of a woman's care but were not used on the dashboards for Cheshire and Merseyside.

13.88. There was a significant administrative burden involved in collating, reporting and reviewing the metrics for each individual commissioning area. The number of metrics included on the dashboard was considerable and ranged from 42 in 2012/13, to 81 in 2014/15, and 71 in 2018/19.

13.89. The basket of metrics for 2014/15 was expanded considerably to 81 (from 34 in the previous year). This increase was due to:

- the inclusion of a section on morbidity and risk management which was an important addition to provide greater focus on areas of risk and safety;
- additional metrics on complaints and the Friends and Family Test;
- additions for absolute numbers as well as percentage measures. One to One sometimes provided comments within the dashboard to contextualise some of the percentage metrics which in isolation might have been misleading when they related to small numbers.

13.90. There were continual amendments to the metrics used each year as these were refined to reflect a growing understanding of the service and how it was integrated with hospital-based services. Metrics were frequently changed between percentage measures or absolute numbers. Reporting of some metrics was sporadic, for example, on staffing metrics, complaints/feedback, smoking status, social factors and multi-agency working.

13.91. Some important metrics which were integral to One to One's service model such as caseload numbers and continuity of care were only introduced from 2017/18.

13.92. There was a significant gap in reporting on workforce metrics such as caseload ratios, safe staffing, sickness/absence, staff turnover and vacancies. Such measures were important for assurance on the safety of the service.

13.93. There was no reporting of the numbers and stages of women transferring to hospital services, which was an important omission given the risk on shared care pathways.

13.94. The dashboard for the co-commissioned contracts did not contain information on the risk profiles of women on the caseload. From 2018/19, West Cheshire CCG monitored the percentage of women booked on a standard, intermediate and intensive pathway.

13.95. The Wirral 2016 service specification required CCG approval for women who chose a home birth but whose risk profile meant that this was not clinically recommended. The use of this escalation route was to be monitored at contract meetings. This would have been a helpful metric to monitor through the performance dashboard.

13.96. The dashboard did not appear proportionate and balanced in some years, for example, there was a particularly heavy focus on substance misuse and smoking metrics in some years; this may have been due to national requirements.

Complaints and feedback were heavily monitored in 2014/15 and limited to numbers of complaints and 'thank you' letters in other years. Complaint response times were not consistently monitored.

13.97. In 2014/15, the dashboard referenced a quarterly trend report on incidents, claims, complaints and surveys. There was no routine reporting in these areas.

13.98. Targets and thresholds were defined to allow a 'RAG' rating approach to many of the metrics. We found no documentation to evidence how the targets had been set, but there was no evidence of any significant disagreement on the targets and thresholds at contract meetings. Targets were set mainly for metrics over which One to One had some direct influence, including:

- timeliness of booking;
- timely referral to Health Visiting services;
- home birth rates;
- normal vaginal deliveries;
- named midwife in attendance at birth/providing continuity;
- discharge summaries;
- the majority of the morbidity and risk metrics; and
- breastfeeding.

13.99. For many of the metrics, One to One frequently reported 100% achievement, 'zero' or very low numbers on most of the morbidity and risk management indicators, substance misuse, teenage pregnancies and those relating to safeguarding. This implies that the metrics were not suitable for routine monitoring. Reporting on an exception or less frequent basis would have been more appropriate and proportionate.

13.100. Wirral CCG's Contract Management Policy required a smaller basket of high-risk performance metrics to be identified for which persistent underperformance would be escalated. This was not implemented for the One to One contracts.

13.101. There were frequent discussions on the definition and applicability of some of the metrics to One to One's model, particularly as shared care with an NHS obstetric unit was a key feature of the model. Metrics which focussed on the outcome for women were important as even if a woman transferred to an NHS provider for the birth, the earlier interventions by One to One needed to be understood. One to One frequently experienced difficulties in obtaining information from NHS providers to whom a woman's care had transferred, due to the lack of robust communication and information sharing arrangements.

13.102. There was recognition by commissioners that responsibility for some of the metrics, particularly the morbidity section, was unclear in terms of whether the information should come from One to One or the obstetric provider. However, processes were not set up to obtain routine reporting or feedback from NHS providers on shared care metrics so One to One continued to report on these metrics, despite the risks to the accuracy of the information.

13.103. In the West Cheshire CCG contract meeting in July 2016, the challenges relating to shared care metrics were acknowledged: "Due to shared care arrangements it is difficult to obtain a dashboard that is truly reflective of One to One performance. For example; […] reported that instrumental delivery and CSections are nothing to do with One to One as these are hospital procedures. It was felt that there is a need to explore a way of reporting shared care but that this work is a medium/long term aim."

13.104. There was no graphical presentation of trends, making it difficult to establish any patterns for subsequent scrutiny.

13.105. A 'Highlights Report' approach was not used for performance monitoring and there was no routine commentary on exceptions and variances to direct commissioners to areas which required their particular attention. Exception reporting and commentary was requested from May 2019 which was towards the end of One to One's contract.

13.106. There were some instances of missing data in the dashboards, typically due to the introduction of revised metrics for which systems needed to be set up to collect the data. Many of the metrics required information to be extracted from individual clinical records. Data was generally submitted on a timely basis and the dashboards included in the agenda papers in advance of meetings.

13.107. We found some instances of commissioners querying the accuracy of data and examples of data errors. In One to One's Quality Report for 2011/12, there is a reference to challenges with data collection and the planned roll-out of a bespoke electronic system from Spring 2013 to improve data collection processes. In 2014, following Wirral CCG's contract query and a quality assurance exercise, a significant inaccuracy was identified in the number of births reported. At the contract meeting, a validation process by the Commissioning Manager and One to One was to be undertaken but there was no further reference to this issue. There was no systematic approach, such as audit, to obtaining assurance on the quality of the data submitted in the dashboards.

13.108. Separate dashboards were also completed for metrics relating to Safeguarding Adults and Children. The same dashboard format and content was used by all commissioners. It is unclear when these were initiated, but we were provided with a sample of them from 2016/17. Some of the metrics on these dashboards duplicated those on the maternity performance dashboards.

13.109. The recommendations of Better Births regarding performance management for maternity services were not implemented during the lifetime of One to One. The Review found that the data collection requirements for maternity services remained too cumbersome, and made recommendations to streamline quality reporting and make it more insightful:

"*A smaller number of more relevant indicators would promote greater focus on collecting information that matters and on improving accuracy and completeness of data collection.*"

"*NHS England should convene, as a matter of urgency, a group to draw up a nationally recommended set of quality indicators which could be used locally and regionally. The group should also take the opportunity to review overall data collection with a view to supporting the refocusing of effort on collecting the most useful data and feeding into the ongoing evolution of the Maternity and Children's Minimum Data Set […].*"

Summary points

13.110. Commissioners applied a standard NHS contracting and performance management regime to One to One. This was resource-intensive and costly for a small provider to manage and led to a reactive approach from One to One which created additional risk. There was a disproportionate effort by all concerned on the management of the relatively small contracts. This was a general weakness experienced by commissioners and providers under the Any Qualified Provider approach.

13.111. Contract monitoring meetings were held between commissioners and One to One (in the North and in Essex) throughout the duration of the contracts at an appropriate frequency for the size of the contract and risks involved.

13.112. There was a good level of debate to gain an understanding of One to One's business model and evidence of positive collaborative working. However, the agenda became increasingly focussed on the development of One to One's business, problems with joint working agreements, and financial sustainability, rather than on rigorous monitoring against the contract quality requirements.

13.113. Significant issues which required attention at a director level were not escalated early enough or not escalated at all and remained on the contract meeting agendas for considerable periods of time without resolution. Risk registers were not used routinely as an escalation mechanism. One to One became frustrated that their concerns were not able to be dealt with through the contract meetings and resorted to direct escalation to senior levels within CCGs, NHS England and NHSI (formerly Monitor). This led to disjointedness in the communication channels between the CCG senior team and the contract meeting, and tensions in relationships.

13.114. There was no evidence of structured, routine commissioning oversight of safety and quality at contract meetings. We found minimal systematic reporting and discussion on core quality topics such as incidents and complaints. There was no robust reporting from One to One on these areas, or on audits undertaken and associated themes, actions and learning. This considerably weakened commissioners' oversight of quality and safety and contributed to a lack of confidence in One to One's assurance processes.

13.115. There was a significant level of scrutiny of One to One's performance at contract meetings, but this was generally reactive following other system quality surveillance mechanisms, rather than as a result of proactive systematic quality assurance. One to One found that they were providing responses to the same queries from the CQC, the Local Supervising Authority Midwifery Officer, NHS England and CCGs. This was described by One to One as "*micro-management*".

13.116. At periods of heightened concern, commissioners did not make effective use of audit to assess One to One's services and contract compliance either routinely or on an unannounced basis.

13.117. There was some lack of administrative rigour and weaknesses in governance. In particular, there were no clear mechanisms for the recording and escalation of risks. There were examples of generic verbal reassurance being accepted from One to One without follow-up of evidence for assurance. We did not find specific terms of reference for the contract meetings.

13.118. The set-up of the co-commissioned contract across Cheshire and Merseyside was disjointed, with commissioners joining over an extended period of time so that the service specification was not agreed before commencement of the contract. The co-commissioned contract meetings did not work effectively; the content of the meetings was predominantly on issues raised by the lead commissioner. The number of attendees at meetings was unwieldy and a hindrance, given time constraints, to gaining an appropriate level of assurance for each commissioner. This was a poor use of limited commissioning team resource.

13.119. The lack of visibility of One to One's operations as a whole compounded commissioners' concerns about potential quality and safety risks. Routine collaboration between commissioners involved with One to One across the country was not evident. Importantly, there was no mechanism between commissioners across Cheshire and Merseyside and Essex to share intelligence on quality and safety, including serious incidents.

13.120. Commissioners had different perspectives on their involvement in the challenges between One to One and NHS providers. The absence of a formal collaborative forum was a missed opportunity to work in a structured and coordinated fashion for quality assurance and risk management purposes. Commissioner pre-meetings were not formal and therefore did not feed into the contract meeting in a structured way. Joint quality assurance meetings were proposed in January 2019 only as part of exit planning from the contract.

13.121. There were examples of sensible suggestions by CCGs and One to One, to try to resolve the shared care arrangements and financial challenges, which were not pursued. There was a degree of inflexibility and inaction demonstrated by both parties to some of the suggestions made

13.122. Until the latter stages of the contract, links were not made at contract meetings between the commercial challenges facing One to One and the associated risks to the quality and safety of services. There was generally a lack of senior finance and quality representation at the meetings and a lack of commercial experience, which is likely to have contributed to this situation.

13.123. A performance dashboard was developed to monitor activity and key metrics were agreed under the contract. However, review of the dashboard frequently resulted in debate about the applicability of the metrics used rather than any value-added insight on performance.

13.124. There was positive collaboration between One to One and commissioners to try to establish a sound basis for the performance dashboard; significant time and effort were expended on this task. However, this contributed to the multiple changes and a gradual evolution of the dashboard in an unmanageable way over time, creating an increasingly onerous framework which was not proportionate to the size of the contracts. The dashboard did not settle into a routine, consistent framework to allow any meaningful interpretation of trends.

13.125. The metrics used in the dashboard were appropriate to the service and focussed on key areas of risk. There were some key metrics missing for the majority of the reporting period, relating to continuity of care, safe staffing and the risk profiles of women. One to One were obliged to populate several versions of the dashboard for different commissioners. Commissioners did not work together to develop a single best practice version for the One to One model.

13.126. The performance framework used was somewhat effective in highlighting areas of underperformance; however, frequently explanations for under-performance related to women's choice or aspects that were not within One to One's direct control. One to One often reported 100% compliance and/or low numbers against many of the metrics so they were not particularly insightful and did not warrant monitoring on a monthly basis. There was an absence of exception reporting and commentary to direct commissioners to key areas of focus.

13.127. A key weakness was the lack of a systematic approach to obtaining assurance on the quality of the data submitted in the dashboards. The Data Quality Improvement Plan section of the contract was not used.

13.128. We noted little of significance to indicate that the performance monitoring framework used was effective in terms of triggering actions to deliver measurable improvements in the services provided. A key contributing factor was the fragmented nature of performance reporting, due to the lack of insight from NHS providers under shared care arrangements to inform the interpretation of the metrics.

13.129. The National Maternity Review found that the data collection requirements for maternity services remained too cumbersome and made recommendations to make performance reporting more practical. The recommendations of Better Births were not implemented during the lifetime of One to One and a regional performance dashboard was not developed.

What could have been done differently?

- Greater focus was needed on establishing a structured, proactive approach to the oversight of safety and quality as the absolute priority for performance management of the new service; this required the input of senior commissioning and quality team leads at the beginning of the relationship with One to One.
- This could have involved commissioners joining One to One's internal quality meetings and through the further development of the provider's quarterly Quality Reports to provide the required assurance.
- The contract meetings required greater rigour in terms of governance. There was a need for greater focus on the high-risk issues emerging and escalation of these outside of the meetings to an appropriate level of seniority.
- A formal collaborative forum between co-commissioners could have provided an opportunity for joint learning on how the contract was working in other areas, and for planning a joint approach to addressing system issues such as GP referrals and shared care.
- The requirement for shared care agreements was a clear example of an issue for which a coordinated approach to oversight by all commissioners could have been adopted, as One to One was not able to compel NHS Trusts to comply with this requirement. Commissioners could have also supported the development of standard templates for the development of shared care protocols.
- Commissioners should have considered ways to reduce the bureaucracy and costs involved in applying a standard NHS contract and performance management framework to a small, independent sector provider.
- Both commissioners and One to One should have taken a step back from defining the detail of the metrics in the performance dashboard and allowing the number of metrics to expand to an unworkable level. The performance framework required a comprehensive reassessment to plan and design a reporting dashboard which was manageable and meaningful to all.
- It would have been helpful for shared learning if commissioners in Cheshire and Merseyside and North East Essex had worked together to develop a single best practice dashboard.
- A smaller basket of priority metrics for routine monitoring should have been agreed before the start of each contract year, so that there was sufficient time in contract meetings to discuss the fundamental issues around safety and quality emerging from incidents and complaints. Other lower priority metrics could have been reviewed on a less frequent basis and only if there was an underperformance trend observed or significant numbers involved.
- Areas of risk could have been reviewed on a cyclical basis to make better use of time in contract meetings.
- Areas of underperformance relating to shared care arrangements with NHS providers should have been prioritised as a key risk, given the concerns

across the system in this area. This required commissioners to obtain insight through both One to One contract meetings and quality performance meetings with NHS providers.

- Commissioners should have made greater use of peer review and audit to investigate concerns, for example, in relation to policies and procedures and invoicing for provider to provider charges, and to gain assurance on action plan implementation to avoid relying on verbal reassurance.
- Data quality audits should have been undertaken routinely by One to One with evidence provided to commissioners for scrutiny and assurance.

Recommendations

1. Commissioners should establish mechanisms for routine quality assurance on all contracts, to include reporting on incidents, complaints, claims and audit and periodic quality assurance visits. Commissioners should make use of a provider's internal quality governance processes for this purpose.
2. For new, innovative services, experienced commissioning and quality leads should be involved in developing the quality assurance framework required and in signing off performance dashboards and ensuring they continue to reflect requirements and do not become onerous.
3. For shared care arrangements, commissioners should obtain insight on performance from all providers involved through respective contractual quality performance meetings, to triangulate evidence from these multiple sources for greater insight and intelligence.
4. As part of the development of joint working protocols for shared care, responsibilities for performance reporting on key shared metrics should be documented.
5. Terms of reference should be set out for contract meetings with defined responsibilities for areas of oversight, escalation protocols and delegated authority for decision-making. Issues logs and risk registers should be used routinely for escalation purposes.
6. Co-commissioners should work in a coordinated way to develop performance reporting frameworks and manage challenges arising under the contract which have the potential to destabilise local systems. The requirement for formal collaboration agreements should be set out in local contract management policies.
7. Co-commissioners' pre-meetings or other collaborative forums should be formalised so that common themes can be discussed, and queries raised at the formal contract meetings, without the need for attendance of multiple representatives from each commissioner.
8. Commissioners' contract management policies should be reviewed to consider tailoring the requirements for smaller, independent sector providers, for example, by strengthening requirements for annual service reviews and audit, as well as highlighting the commercial risks to consider on contracts with such providers.
9. Performance management frameworks should be designed to reduce the burden of data collection and reporting while allowing a focus on risk. This should include highlights and exception reporting, a basket of critical

performance metrics for routine monitoring purposes, and ‘deep dives’ into particular areas on a cyclical basis.

10. Data quality audits should be a core requirement of service specifications and the Data Quality Improvement Plan under the contract used to support this area of work.

14. Tariff arrangements

Introduction

14.1. In this section, we consider the tariff arrangements that were in place in the contracts with One to One and in particular the impact of the national maternity pathway payment system. This was a significant development introduced during One to One's contract term and which had serious consequences for the company's financial viability.

Key findings

Development of the maternity tariff

14.2. The national Payment by Results (PbR) tariff system was in place when One to One first entered the market. This meant payment to NHS Trusts based on a standard tariff for an 'episode' of care, for example, an antenatal appointment or a birth. This system meant that the more clinical interventions undertaken, the more a hospital was paid. There was, therefore, an inherent disincentive for NHS Trusts to develop alternative models which reduced medical interventions. There was no tariff for community-based midwifery care.

14.3. Maternity Matters had recognised that PbR did not "*incentivise normality*" and was contrary to the personalisation of care. It supported the introduction of tariffs for midwifery-led clinics, community appointments and home births. It encouraged locally agreed prices, specifically for home births where costs were significantly different compared to a hospital birth. The policy also suggested that commissioners should use other contract mechanisms with obstetric providers, for example, performance targets to encourage normality in birth.

14.4. The maternity pathway payment mechanism was introduced in 2012/13 for testing. 2013/14 was a transition year and the tariff was fully implemented in 2014/15. It consisted of tariffs for each element of the maternity pathway – antenatal, birth and postnatal. There were three levels of payment on the antenatal and postnatal pathways for different levels of risk and complexity. There were two levels for the birth payment for 'with' and 'without' complications/co-morbidities. Home births were paid for on the same basis as a hospital birth and there were no separate pathway tariffs for midwifery-led care in the community. We noted that a home birth tariff was introduced from 2019/20.

14.5. Women chose their lead provider for each element of the pathway and commissioners paid the lead provider responsible for each stage, for example, a woman might choose One to One as lead provider for antenatal and postnatal care and an NHS Trust as lead provider for the birth. The lead provider retained full responsibility for a woman's care even if a woman required or chose intervention from a different provider partway through a pathway. Department of Health (DH) tariff guidance[62] set out the proportions of the antenatal pathway tariff to be paid by the lead provider to a second provider on transfer of care during the pathway based on gestational weeks.

14.6. This led to complex billing arrangements known as provider to provider charges which were applied between NHS Trusts as well as between NHS Trusts and One to One. The standard non-mandatory PbR episodic tariffs applied for provider to provider charges. These provided tariffs for recharges as follows:

- an admitted patient and outpatient procedure;

[62] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216443/dh_132715.pdf

- an outpatient attendance;
- a community antenatal and postnatal visit; and
- a community antenatal assessment visit.

14.7. Initial guidance in 2012/13 by the DH set out specific episodic tariffs for booking appointments, antenatal and postnatal checks. The charge proposed for an antenatal check under the 2012/13 guidance was £28–£47. These tariffs were not taken forward in subsequent guidance. In the PbR tariff for 2014/15, an outpatient attendance ranged between £66 and £138 for a consultant or midwife-led appointment which was the only tariff available for an antenatal check-up. There was a clear disparity between these costs; we have not been able to establish the basis for the lower charges proposed in the 2012/13 guidance.

14.8. There were considerable administrative requirements involved. Legal information sharing arrangements had to be put in place between providers to share patient-level information. There was a delay in the introduction of the national maternity dataset to support the system. It was planned to be in place by October 2013 and was finally introduced in November 2015; however, there were still issues with the identification of the lead provider from the dataset. In the interim, Monitor[63] advised providers and commissioners to set up local arrangements: "*to help identify the lead provider and resolve billing and invoicing issues.*" Some commissioners used their Commissioning Support Units to manage the data flows and validate charges.

14.9. The pathway tariffs set out were calculated based on the existing global funding for maternity services. In areas where plurality of provision might develop, as in the One to One scenario, Trusts would potentially lose income as the total funding pot would be shared between more providers as women exercised choice. We were told by NHS Trusts that it was recognised that there would be 'winners and losers' under the new system as women exercised choice. In addition, as the One to One model would manage women with lower risk, the case mix of NHS Trusts would move towards greater complexity and higher costs.

14.10. This system was intended to incentivise NHS Trusts to innovate and develop their own maternity services, but this was slow to happen, as demonstrated by the limited interest in the procurements undertaken in Cheshire and Merseyside (C&M). It was not until the procurement in 2019 when NHS Trusts expressed an interest in a community-based case loading model.

14.11. Better Births published in 2016 recommended further reform of the payment system to take account of community-based models: "so that it is fair, incentivises efficiency and pays providers appropriately for the services they provide, recognising different cost structures, supporting organisations to work together." It recommended that NHSI undertake a comprehensive bottom-up costing exercise with a view to potentially introducing different prices for home births, midwifery-led units and obstetric units.

14.12. Better Births also recommended implementation of Personal Maternity Care Budgets to support personalisation and choice. A trial commenced in C&M as a pilot with Liverpool Women's Hospital (LWH) in 2016.

14.13. There have been no other significant developments on the national tariff since the introduction of the maternity pathway payment mechanism in 2013/14, despite the recommendations for reform in national policy and acknowledgement nationally and locally of the provider to provider charges issues which had impacted on One to

[63] Maternity pathway payment system: guidance for NHS providers and commissioners - GOV.UK (www.gov.uk)

One. The Monitor guidance of 2014/15 has not been updated and still applied in 2019/20.

14.14. The Healthcare Financial Management Association had undertaken a survey on the maternity payment pathway approach to inform NHSI's pricing team of issues experienced by providers to inform tariff setting for 2019/20[64]. The briefing produced in July 2017 found that all respondents experienced problems with provider to provider charges from an operational and administrative perspective. Provider to provider charges were not capped so could be more than the pathway payment received by the lead provider. There were many disputes as a result and this was exacerbated when an independent provider was involved. Locally some work-arounds had been implemented. One respondent had agreed a block arrangement between a midwifery-led unit and an obstetric unit. One respondent had agreed that the birth provider received the whole tariff and agreed a standard level of reimbursement with the community provider. There is no evidence that these options had been considered at the time for the One to One scenario.

14.15. A blended payment model was launched by NHSI for some services in 2019/20 and this was to be rolled out as an option in 2020/21 for maternity[65]. The key objective of the model was to minimise provider to provider payments. The model moves away from an activity-based tariff system and involves a fixed payment supplemented by variable quality incentive and optional risk sharing elements. The fixed payment would be based on agreed activity and unit prices for each provider based on the costs of delivering the activity. The agreed activity and payment would exclude invoicing by other providers to the lead provider. Between NHS providers within a Local Maternity System the impact would be neutral. We have not seen an example of how this would work with an independent sector provider as part of the local system. The proposals were paused due to the impact of the Covid-19 pandemic.

Contract pricing

14.16. The Wirral pilot was for a fixed price of £100k for the antenatal and postnatal care of 70 women. We were told there was no particular methodology to the pricing. Where care was transferred to the NHS provider, the Trust was funded through normal PbR tariff so during the pilot there was potentially a small element of double payment by commissioners.

14.17. One to One's first core contract from November 2011 was based on a local tariff using a pathway approach. This was a fee of £2,200 for antenatal and postnatal care (combined) and £2,100 for a home birth. For comparison, the maternity pathway tariffs introduced in 2013/14 were as follows:

- antenatal and postnatal combined – £1,317 (standard), £2,026 (intermediate) and £3,682 (intensive);
- birth – £1,477 (without complications) and £2,161 (with complications).

14.18. The local tariff applied was therefore at the high end of these ranges. We have not been able to establish the rationale used for the local tariff; One to One believed this was based on what was paid to NHS Trusts at the time. The tariff applied to the One to One contract appears incongruous with the concept that high-risk pregnancies would be managed by an NHS obstetric service with midwifery support only by One to One.

[64] https://www.hfma.org.uk/docs/default-source/publications/Briefings/maternity-reimbursement-survey-report-2017.pdf?sfvrsn=944d92e4_0
[65] 20-21 Guidance on blended payments (england.nhs.uk)

14.19. Based on our understanding of the payment system, for transfers of antenatal/postnatal care to NHS providers, a double payment by commissioners was implied as Trusts were funded through the PbR tariff for their activity at this point. We saw no evidence that the double payment scenario was considered before award of this contract. There was a reference to the issue in the February 2012 contract meeting and One to One agreed to highlight transfers of care in the activity data they provided. We found no further reference to this issue or any evidence of charges to One to One for their clinical input. It is uncertain whether this was addressed before the issue was resolved by the implementation of the maternity pathway payment system in 2013/14.

14.20. From 2014/15 onwards, the maternity pathway tariffs were applied in One to One's contracts. One to One had been receiving higher pathway payments under the local tariff so there was an additional financial pressure due to this. One to One were allocated a one-off transitional payment of approximately £168k in recognition of this.

14.21. National tariffs for maternity are based on NHS Trust reference costs and maternity activity. The tariffs did not therefore accurately reflect the operating model and costs of a community-based, case loading midwifery-led service providing home births. Particular differences in the cost base of note are:

- One to One did not provide obstetric services which are a standard component of maternity care provided by an NHS Trust.
- Insurance premiums for an NHS Trust are significantly higher as they manage the care of women with a higher risk profile.
- As a community-based service, infrastructure costs for One to One would be significantly lower than for an NHS Trust.
- The recommended midwife caseload under a case loading model is one midwife to 35 women. We were told that a hospital-based service typically had ratios of 1:98 women.

14.22. During the lifetime of One to One, despite recommendations in national policy, the tariff was not reviewed in terms of its relevance to a community-based midwifery-led model. Without such review, it is not possible to conclude whether the tariffs paid to One to One since 2014/15 were appropriate.

Provider to provider charges

14.23. We have described above the mechanics of provider to provider charges which were a significant contributing factor to One to One's demise. The charges started to be applied from April 2014. There had been a transitional arrangement in C&M in 2013/14 so no charges were made. One to One said they were unaware of such an arrangement and therefore chased LWH for approximately £12k of debt in 2013/14 which led to LWH seeking recovery of its charges for that year which were significantly higher.

14.24. One to One disputed much of the debt to NHS Trusts for the following reasons:

- Robust clinical pathways were not established and the clinical interventions which respective providers should anticipate when a woman transferred services during a pathway were not agreed.
- One to One's view was that many interventions undertaken by NHS providers were unnecessary or duplicated their input. For example, we were told that a woman might need to attend an obstetric unit for a consultant appointment, and the woman would then be booked for follow-up appointments without this being communicated to or agreed with One to One as the lead provider. The following

quote illustrates One to One's perspective: "*It's a bit like you've got a car and you've got a bit of a problem with it, you think you've got a squeak, so you take it into the garage, they have a quick look at it, and it comes back out. They say it just needs a bit of oil on this, and by the way, we've washed your car for you, and we've hoovered it all out, but it doesn't cost you anything, and you think that's great, and that's because they're invoicing somebody else for it. There's no need for it to be washed, no need for it to be valeted, and actually nobody gave them the authority to do that.*"

- There were no agreements in place on provider to provider charges and Trusts were unwilling to enter into such agreements as there was no financial incentive for them to do so. One to One suggested a capping arrangement and cited an example of charges of £11k being invoiced for one woman's antenatal care.
- Women who at booking with One to One were on a low risk antenatal pathway may have been subsequently assessed by an NHS obstetric unit as higher risk on contact with their services. Under the rules, this would lead to a higher level of charge under the episodic tariff to One to One than they had received payment for under the pathway tariff. This issue was raised at a Wirral contract meeting but there was no evidence that action was taken to address this issue.
- There were a significant number of coding queries due to the complexities of the episodic tariff and high variability in charges between Trusts. NHS Trusts told us that the charging system was standard for all providers based on professional clinical coding which was routinely audited.
- One to One undertook detailed validation work against their clinical records, which led to a high level of queried and disputed items, including duplicated billing and billing for activity they had not undertaken. A common issue raised by One to One was that NHS providers would invoice for an inpatient admission rather than an outpatient attendance. The queries were described to us as follows: "*We were being invoiced for women that weren't ours, we were being invoiced for inpatient stuff when it was obviously outpatient stuff. We were being invoiced when we didn't really know what we were being invoiced for [...] there are some fairly fundamental things that were totally wrong with the whole process.*"
- We were told that backing data to support invoices was frequently not provided or provided very late. An example was given of a year's charges without backing data which needed much work to follow up. Trusts also requested prompt validation due to the 'flex and freeze' process which allowed three months for finalisation of invoicing.
- A key problem for validation of invoices was the lack of access to clinical notes held by NHS providers. In addition, One to One had limited resource to investigate queries; we understand this was the responsibility of a member of the finance team with the support of a midwife.
- The unpredictability and delay in billing by Trusts made it difficult for One to One to plan. One to One requested that a 'flex/freeze' approach be applied to provider to provider charges so that billing would be finalised within a certain time. One to One discussed this with NHSI who agreed to this in principle going forwards, but not in relation to historic debt. One to One felt that this showed bias towards protecting the position of NHS Trusts.
- Importantly, the Monitor guidance of 2014 required sub-contracts to be put in place between a lead provider and other providers to set out the obligations under the pathway mechanism and for the prices payable to be agreed. NHS

providers were unwilling to put sub-contracts in place with One to One relating to financial arrangements.

14.25. The situation was summarised as follows by one of the stakeholders interviewed: "I think maybe it got down to, this is a tariff for this outpatient appointment or this, and that didn't necessarily fit in with the pathway tariff. That would strip away 30–40% of the tariff and then arguably that would become untenable really. If there was a more working agreement around it, I am sure all parties could have got a better output really."

"*I accept Trusts have books to balance as well, they are not going to give away income, so I think, money for me was always the root of the issue really, more so than what would benefit the patient which is the sad thing about it.*"

14.26. In response to One to One's concerns, in October 2017, NHSI undertook an audit of provider to provider charges at two Trusts as part of an exercise to make recommendations on a payment mechanism to promote integrated care between One to One and NHS Trusts. There were some fundamental findings which demonstrated flaws in the system for provider to provider charging with One to One. We were provided with a draft, undated paper. The key points are summarised as follows:

- One to One were being charged an inpatient tariff for an outpatient attendance in a significant proportion (around 70%) of cases. This was rationalised by Trusts as follows "inpatient tariffs are appropriate, even when women do not stay overnight or for a full day, due to the nature of the clinical services provided."
- The charges made for the care of women admitted to hospital, based on clinical coding, exceeded the antenatal tariff payment made to One to One. A single inpatient attendance absorbed about half of the antenatal tariff for a woman who was low risk.
- NHSI compared the most common tariffs used to invoice One to One with Trust reference costs. This indicated that the tariffs charged were much higher than reference costs and therefore could significantly exceed the unit cost for Trusts to provide the services.
- NHSI found that Trusts were following the published guidance on tariff and were appropriately following their clinical protocols for the care and treatment of women. However, an issue was that One to One were not being advised of follow-up attendances and joint care plans were not being developed to coordinate care for women.
- NHSI referred to invoices received by One to One for women who had not booked with them. NHSI confirmed that One to One should not be responsible for paying these charges and it was the Trust's responsibility to identify the lead provider.
- Several examples were found of a Trust continuing to invoice One to One for attendances when the woman had already transferred to the Trust as lead provider for their care.
- Where One to One was disputing charges as they had no record of attendance, NHSI agreed that Trusts should inform One to One of all attendances and the outcome, either on the woman's care record or through a record of attendance or discharge note. However, NHSI did not support non-payment of these invoices and would have expected both parties to have agreed a mechanism for validation of historic attendances.

- NHSI did not find an issue with duplicated invoicing. Invoices for the same woman's care on the same day were mainly due to multiple same-day attendances at a clinic. NHSI stated that better care coordination would avoid this issue. One to One disputed these invoices as they viewed this as fragmented care for a woman.

14.27. The paper concluded that there was scope to develop a payment mechanism that more closely aligned charges to the costs of care. It recommended that NHS Trusts should no longer charge PbR tariff to One to One for each attendance. It recommended that commissioners should split the antenatal maternity tariff payment between One to One and Trusts. The tariff should be based on costs rather than PbR tariffs.

14.28. The paper reiterated the requirement for shared clinical protocols and information sharing arrangements. Given the potential for escalation of costs for the investigation of reduced fetal movement, it recommended a joint clinical protocol and revised pricing based on costs and the woman's ongoing risk profile.

14.29. The paper set out a commitment to take the recommendations forward for testing:

"*NHSI and NHSE will support the Trusts, One to One and commissioners to reach an agreement setting out details about how the recommended payment arrangement will work and setting a time period for testing the arrangement to understand its financial impact.*"

We did not find any evidence of the conclusions of this audit being taken any further.

14.30. We noted, perhaps in recognition of the system problems experienced, that the 2019/20 maternity tariff guidance[66] stated that providers should agree prices for provider to provider charging and these should be "*proportionate and fair.*"

Summary points

14.31. A local tariff was appropriate for the One to One contract due to its cost base not reflecting an acute model. However, the local tariffs paid to One to One before the advent of the maternity pathway system in 2013/14 were significantly higher than those indicated by the pathway tariffs. In addition, a double payment was implied for transfers of care, and we have no evidence that this was addressed. Due diligence around the implications of setting a local tariff for the contract was therefore inadequate.

14.32. The introduction of the maternity pathway payment system was well intentioned in seeking to put the correct incentives in place for providers to innovate and offer choice in maternity care. However, with a fixed financial envelope for maternity services, the introduction of an independent provider into the market meant that income to existing NHS Trusts would be eroded. The provider to provider charging mechanism allowed Trusts to counterbalance this.

14.33. There were some teething problems upon implementation of the tariff as administrative systems were not set up to manage the complex invoicing arrangements between providers under the lead provider model. This led to much manual validation and administrative effort by One to One and NHS providers. This increased as disputes arose on the charges. Commissioners did not request the support of the Commissioning Support Unit to validate charges or to use their contractual audit powers to test invoicing between NHS Trusts and One to One.

[66] NHS England » Past national tariffs: documents and policies

14.34. There was a fundamental flaw in the tariff system as provider to provider charges were made using the episodic tariff. It removed the objective to incentivise Trusts to reduce clinical interventions where appropriate. We saw no evidence that commissioners acknowledged this issue or considered using other contract levers such as local performance metrics with NHS Trusts to remove this unintended consequence.

14.35. Sub-contracts were not in place between One to One and NHS providers to agree financial arrangements for provider to provider charges. NHS Trusts were unwilling to engage on this. One Trust said that they would not agree to a financial arrangement which would result in different prices for provider to provider charging for maternity services. Another Trust suggested in 2019 that One to One should have a local tariff for work undertaken to avoid the provider to provider charges, rather than apply the maternity pathway tariffs. For smaller Trusts, in our view, a key factor was that this was generally because any compromise on charges would have led to lost income. The lack of financial agreements was contrary to Monitor guidance but neither Monitor nor local commissioners intervened to ensure compliance with this guidance. Local commissioners viewed the mounting debt as a provider issue.

14.36. It was a commissioning decision to apply the national maternity pathway tariff to the One to One contract without due consideration of the impact of provider to provider charging. The lack of financial compromise between One to One and NHS Trusts contributed to what became an insurmountable problem, compounded difficult relationships and led to the destabilisation of the local system, in Cheshire and Merseyside in particular. It created risk to women and babies due to the impact on working relationships between One to One and NHS providers. Commissioners felt that they were not able to get involved in finding a solution as it was in their view an issue between providers.

14.37. The service specifications for One to One did not refer to the financial complexities and the need for agreements on provider to provider charges with reference to the relevant Monitor guidance. In our view, this should have been raised during the shadow tariff year (2013/14) by commissioners working with One to One and NHS providers.

14.38. The maternity pathway tariffs were based on an NHS hospital model so were not representative of the cost base or the activities undertaken by a community-based midwifery-led model. We have no evidence that any work was undertaken locally to assess the appropriateness of the tariff for the service offered by One to One. The case loading, midwifery-led community model called out for a tailored approach and potentially a continued local tariff. A commitment by commissioners and One to One to work together to understand costs on a transparent basis was necessary.

14.39. The deficiencies in the model were not addressed during the lifetime of One to One. Positive soundings from NHSE/I about re-examining the tariff due to the issues experienced by One to One did not materialise into concrete action; this was described to us as "*jam tomorrow*". The audit undertaken by NHSI in October 2017 was important and its conclusions were not taken forward.

14.40. Alternative pricing models for community-based services have taken time to develop. The recent proposed changes to the maternity tariff to remove provider to provider charging through a blended payment model were too late for One to One.

What could have been done differently?

- The recommendations of national policy relating to the development of tariffs which were appropriate for community-based maternity care required much greater impetus with accountability for delivery through NHS Improvement (formerly Monitor).
- The maternity pathway payment mechanism and how this would work with an independent sector provider should have been assessed as part of the National Maternity Review in 2015/16.
- The basis for the local tariff applied should have been scrutinised through appropriate commissioner governance channels, as the rates appeared high and inconsistent with the rates paid to NHS Trusts at the time. A reimbursement mechanism should have been considered, to avoid double payment by commissioners for activity before the advent of the maternity pathway payment mechanism.
- Given the destabilisation of the local system and the risks to the safety of services caused by the disagreements on provider to provider charges, commissioners should have taken a lead on resolving this issue with the support of NHSI (formerly Monitor).
- Work should have been undertaken with One to One to fully understand their costs to develop a bespoke tariff for a community-based case loading service, to avoid the complications due to the application of the national maternity pathway tariffs.
- Commissioners should have considered other contract mechanisms with NHS obstetric providers to encourage choice and avoid the financial incentive for Trusts to care for more women under a hospital-based model of maternity care.
- Commissioners should have undertaken audits to validate charges between NHS Trusts and One to One and considered using the Commissioning Support Unit for this work.
- The disparity between the tariffs for provider to provider charges in the initial guidance from the Department of Health with the subsequent Payment by Results tariffs, should have been investigated to understand why these lower rates were not taken forward.
- The valid concern raised by One to One regarding being paid on a low risk antenatal pathway and subsequently receiving a charge from an NHS Trust for a high-risk pathway was an anomaly in the tariff rules which should have been investigated.
- NHSI (formerly Monitor) should have intervened to ensure its guidance of 2014 was implemented regarding the requirement for formal financial agreements between providers for provider to provider charging.
- The important NHSI audit in 2017 of the charging between One to One and NHS Trusts should have been used as a basis to develop an interim tariff solution, pending national tariff reform.

Recommendations

1. In the absence of national developments on tariffs for community-based models of care, local bespoke tariffs should be applied, based on a robust assessment of the cost base of providers.
2. Robust testing of tariff arrangements should be undertaken to understand the impact on commissioners and providers where joint working with the independent sector is proposed and different tariffs may need to be applied.
3. Notwithstanding formal structural accountabilities and responsibilities, commissioners and NHSE/I (and their successor bodies) need to maintain oversight of material issues which might impact on the stability of their local systems and create risk to the safety and quality of services.
4. Commissioners should use their audit powers under contracts with all providers, to investigate any significant concerns about billing arrangements.
5. NHSE/I (and their successor body) should maintain oversight of its requirements relating to previous tariff guidance issued and provide clarity where previous national guidance might be inconsistent with current guidance or where tariff rules appear unfair.
6. The maternity tariff guidance should be supplemented with more detailed guidelines on how to agree tariffs for provider to provider charges, as the current guidance leaves this open to interpretation.
7. The blended payment model introduced in 2019/20 should be tested for maternity services between an NHS acute and NHS community-based maternity provider as part of the system.

15. Financial viability

Introduction

15.1. In this section, we provide an analysis of the financial position of One to One over the life of the business and explain the key drivers of the financial pressures experienced by One to One which taken together were ultimately the cause of the company's failure to thrive within the NHS infrastructure and led to its closure.

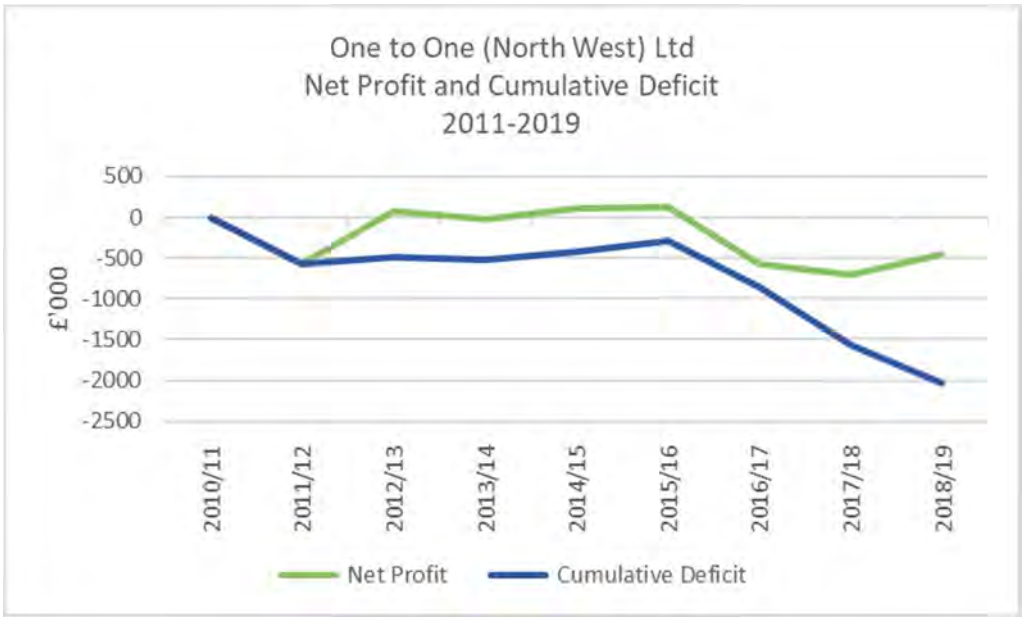
15.2. The main sources of information for the financial analysis are the published financial accounts and the Administrator's reports available through Companies House[67].

Key findings

Financial review

15.3. One to One was a start-up business with limited external financing and a reliance on personal funding by family shareholders. A trading company (One to One (North West) Limited) was established in 2010. NHS contracts were the company's sole income source as the company was set up to provide an NHS-funded community-based case loading model. The company did not undertake private work.

15.4. The analysis below, from the published annual accounts, shows the financial results and balance sheet position of One to One (North West) Ltd over the nine-year period. The summary graph illustrates clearly that One to One was not financially viable over its lifetime. One to One did not generate enough income and profit to recover from its initial start-up losses. Once the co-commissioned contract started in 2015/16, the level of provider to provider charges resulted in a rapidly deteriorating deficit position.



[67] ONE TO ONE (NORTH WEST) LIMITED - Overview (free company information from Companies House) (company-information.service.gov.uk)

One to One North West Ltd - Trading Performance Analysis 2011-2019

Year	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19
					£'000				
Balance Sheet									
Fixed Assets	3	51	76	112	155	136	129	66	80
Current Assets	98	404	1057	389	803	893	593	767	869
Total Assets	**101**	**455**	**1133**	**501**	**958**	**1030**	**722**	**833**	**949**
Creditors due <1 year	103	932	1345	793	1155	1039	1346	2109	2756
Net Current Liabilities	-5	-527	-288	-404	-352	-146	-753	-1342	-1887
Creditors due >1 year	0	95	85	35	30	87	42	98	31
Total Net Assets	**-2**	**-571**	**-297**	**-327**	**-227**	**-96**	**-666**	**-1374**	**-1838**
Working Capital Ratio	**0.95**	**0.43**	**0.79**	**0.49**	**0.70**	**0.86**	**0.44**	**0.36**	**0.32**
Profit & Loss Account									
Turnover							4086	4960	6080
Operating Costs							2833	3622	4430
Gross Profit							1253	1338	1650
Gross Profit %							***31%***	***27%***	***27%***
Overheads							1822	2047	2113
Net Profit	**-2**	**-569**	**81**	**-30**	**100**	**130**	**-569**	**-709**	**-463**
Cumulative Deficit	-2	**-571**	**-491**	**-521**	**-421**	**-290**	**-860**	**-1569**	**-2032**

Notes to the analysis:
1. Full profit and loss account information is not available in the published accounts due to the small companies' exemption and legal requirement to submit abbreviated accounts only.
2. Full accounts were available in the Administrator's Report[68] of 13 September 2019.

15.5. Our key comments on the company's trading performance are:

- One to One suffered significant liquidity problems as illustrated by the negative net assets and poor working capital ratio throughout the company's life.
- The company did not generate sufficient income in the early years to recover from the loss (over £0.5m) incurred in the first full year of trading in 2011/12. Start-up costs included a £650k premium for private insurance to cover intrapartum care.
- The short-term creditors were predominantly debt relating to provider to provider charges from NHS Trusts. One to One did not make any significant headway in reducing this debt and it increased exponentially under the co-commissioned contract across Cheshire and Merseyside.
- We noted from the accounts that there were significant injections of cash from shareholders, a Director's loan and commercial loans secured on the business; however, these provided limited respite from the underlying financial problems. One to One's Director provided personal guarantees in respect of company borrowings and was significantly impacted from a personal finance perspective.

15.6. One to One's cost base was semi-fixed in terms of employed midwives, which meant a certain volume of activity needed to be met to cover these costs. Over the three years to March 2019, the profit and loss information shows gross margins of between 27% and 31%. We confirmed with One to One that their operating costs included the full impact of provider to provider charges, including the disputed amounts. This means that at a gross margin level, the company was managing to make a profit and covering its operating costs despite the level of provider to provider charges. However, these margins were insufficient to support the level of overheads incurred.

15.7. Based on the last three years' information, the level of overheads tipped the company into a significant loss-making position. Overheads were running at approximately £2m per annum of which 50% related to head office staff costs. We

[68] ONE TO ONE (NORTH WEST) LIMITED - Filing history (free information from Companies House) (company-information.service.gov.uk)

were told that One to One recognised that overheads had become too high due to the need for a certain infrastructure to grow, for example, IT systems, the base in Essex and disproportionate expenditure on marketing and business development.

15.8. The balance sheet position had improved by the end of March 2016 following a capital injection. However, One to One required a higher level of turnover to reach future viability. One to One reported the challenges experienced in trying to increase activity – predominantly the lack of GP referrals, combined with reputational damage caused by the actions of NHS Trusts, disproportionate system scrutiny and the winding-up petition in April 2016. This led to lost business, with more women transferring to NHS providers as they were reportedly being told that One to One might no longer be financially viable.

15.9. Financial performance deteriorated significantly from 2016/17 and over the duration of the co-commissioned contract in Cheshire and Merseyside. Debts and losses accumulated year on year until company cessation. The main financial pressures described to us during the review that were material to the cumulative loss-making position are discussed further below.

15.10. Set-up costs were significant and included investment in premises, systems and legal fees. An office base was set up in Bradford in 2013 but One to One received no payment for activity undertaken in this area.

15.11. Private insurance premiums to cover intrapartum care were very high. The first premium of approximately £650k was more than half of One to One's income in 2011/12. For comparison, One to One's first premium under the NHS Clinical Negligence Scheme for Trusts (CNST)[69] was almost half of this amount (see further below). Insurance costs under CNST were a continued pressure for One to One who were admitted to the scheme from October 2013. We were told that the NHS Litigation Authority (NHSLA) did not have a valid basis for setting insurance premiums for a community midwifery model:

"*The NHSLA didn't really know what to do with us because it was a new model to them. Initially they said 'we're going to charge you at exactly the same rate we charge Trusts'. […] We said why is that right, because predominantly we deal with lower risk women rather than higher risk women.*"

15.12. This uncertainty is reflected in the variability of the premiums paid which we summarise in the table below from information provided by One to One. The detailed paper provided evidenced their engagement with the NHSLA to try to establish a valid basis for insurance for their care model.

Table 9: Analysis of CNST insurance premiums

Year	Original Premium	Rebate	Revised Premium	Premium change	Actual no. of births	Premium/ birth	Premium/ birth change
	£	£	£	%		£	%
2013/14	165,000		165,000		119	1,387	
2014/15	346,500	(214,765)	131,735	-20%	272	484	-65%
2015/16	346,500	(168,658)	177,842	35%	394	451	-7%
2016/17	370,239	(162,164)	208,075	17%	365	570	26%
2017/18	244,489		244,489	18%	385	635	11%
2018/19	419,376		419,376	72%	365	1,149	81%
Average	**315,351**		**224,420**		**317**	**779**	

[69] Clinical Negligence Scheme for Trusts - NHS Resolution

15.13. The initial premium of £165k was based on planned births of 330 at a price per birth of £500. For comparison, the premium paid by Neighbourhood Midwives was £84k in 2017/18. As a broad indication of activity levels, Neighbourhood Midwives cared for 342 women over the period Nov 2016 to Jan 2019 (25 months) with a 45% home birth rate, which approximates to 164 births. Their premium equates to £512 per birth, which is in line with One to One's premiums.

15.14. One to One received some significant rebates on the insurance premiums paid. The premium was rebased to reflect actual birth numbers and One to One highlighted that they were not caring for women with high obstetric risk and did not birth the majority of their women; it was therefore unfair to apply the same premium per birth as for an NHS obstetric provider.

15.15. Over the six-year period of membership, the average annual premium was £315k which gave an average of £779 per birth based on actual activity. One to One accepted subsequent premium increases as being in line with those applied to NHS Trusts, until 2018/19 when the premium increased by 72% to £419k. One to One made a part-payment based on their birth activity and the balance remained in dispute.

15.16. One to One did not receive payment for non-contracted activity (NCA) over the period from 2013 to 2016 and estimated £250k in lost income for activity undertaken in Liverpool and West Cheshire. We were told of other significant lost income in Yorkshire and Manchester and although this was not specifically quantified, an estimate of an additional £100k was cited for invoices raised and not paid.

15.17. From 2014/15 onwards, the maternity pathway tariffs were applied in One to One's contracts. As One to One had been receiving higher pathway payments under the local tariff, there was a significant adverse impact on income. For example, One to One's local tariff for a combined antenatal/postnatal pathway was £2,200 compared to £2,026 for intermediate level under the national tariff. This was a reduction of 8%. For the standard level pathway, the national tariff was £1,317, a reduction of 40%. One to One estimated that 50% of their activity was at the intermediate level. Similarly, there was an almost 30% reduction in the fee for a birth without complications.

15.18. Provider to provider charges from NHS Trusts for obstetric support or when a woman had chosen or was obliged for clinical reasons to transfer her care to an NHS Trust created significant debt. As One to One were a midwife-led service, they had to refer to NHS obstetric units for women with more complex needs. One to One had employed a Consultant Obstetrician to mitigate the impact of these charges, but Wirral CCG did not support this arrangement and asked One to One not to commence these clinics. In early 2019, One to One's further proposal to offer obstetric support was again declined, with the view expressed that this might further weaken fragile relationships with NHS providers. An independent review undertaken by Mersey Internal Audit Agency in 2018 which estimated that provider to provider charges were over 25% of the antenatal tariff received, compared to One to One's planning assumption of 12%.

15.19. We were told that the caseload midwives were working to was not sustainable, with midwives working to a **maximum** of 1 midwife to 32 women rather than to an **average** of 1:32 which was the level required for the model to be viable. For the average to be achieved, midwives would have had to increase their caseloads. Workload pressures were discussed regularly at contract meetings from 2015 onwards.

15.20. One to One reported significantly increased diagnostics costs for scans in the third trimester due to the impact of national policy (Saving Babies' Lives[70]) in 2017/18 as they were not funded through tariff. Diagnostics services were provided by an external company and One to One planned to bring diagnostics in-house to generate savings of approximately £173k per annum.

15.21. Significant legal costs were incurred over the period from 2016 to 2018, approximately £65k relating to claims before CNST cover was in place and £196k due to the winding-up petition.

15.22. One to One went into voluntary administration due to insolvency in July 2019. At this point, the company had realisable assets of £292k and creditors of £3.21m. £2.8m of these creditors were amounts owing to the NHS. A summary of creditors as set out in the Administrator's Report of 21 February 2020[71] is shown below.

Table 10: Summary of One to One's creditors, February 2020

One to One Creditors - February 2020	£	% of Total Debt
Preferential:		
Merseyside Loan and Equity Fund	35,256	
Small Business Loans Ltd	15,265	
Holiday pay arrears	10,176	
Total Preferential Creditors	**60,697**	**2%**
Unsecured NHS Creditors		
Warrington & Halton Hospitals NHSFT	838,928	26%
East Suffolk & North Essex NHSFT	519,981	16%
Liverpool Women's Hospital NHSFT	438,397	14%
NHS Litigation Authority	376,928	12%
Wirral University Teaching Hospital NHSFT	188,174	6%
Mid Cheshire Hospitals NHSFT	166,044	5%
Mid Essex Hospital Services NHSFT	114,843	4%
Countess of Chester NHSFT	106,915	3%
Southport & Ormskirk NHST	18,624	1%
St Helens & Knowsley Teaching Hospitals NHSFT	17,910	1%
Other NHS Trusts	6,048	0.2%
Total NHS Creditors	**2,792,793**	**87%**
Other trade creditors	70,301	2%
Employee claims	155,491	5%
HMRC	92,153	3%
Director's Loan	38,865	1%
TOTAL CREDITORS	**3,210,299**	**100%**

15.23. Other associated companies in One to One's group also went into administration with losses of almost £200k. This included amounts due for employee claims, tax and social security creditors, rent and other unspecified creditors of £108k in One to One Maternity Services Ltd, a dormant company set up for business development purposes.

[70] saving-babies-lives-car-bundl.pdf (england.nhs.uk)

[71] application-pdf

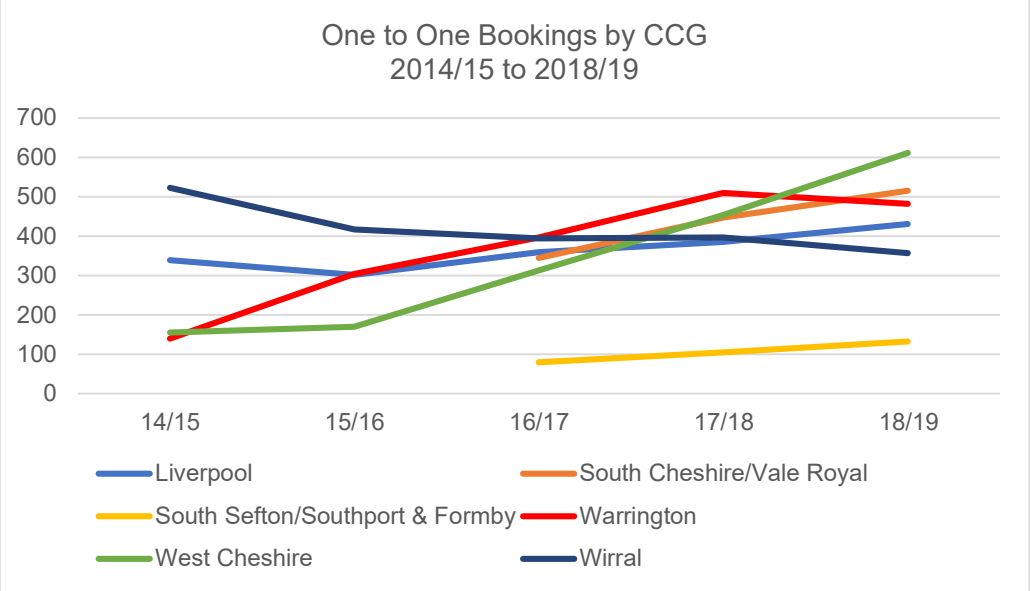
Activity levels

15.24. One of the key challenges for One to One was the need to increase activity levels to cover the fixed cost base and generate sufficient margin to recover from the accumulated deficit position. The table and graph below show the trends in bookings over the period from 2014/15 to 2018/19 from the performance dashboards included in contract meeting papers.

Table 11: One to One bookings, 2014/15 to 2018/19

CCG	14/15	15/16	16/17	17/18	18/19
Liverpool	339	302	359	385	431
North East Essex	355	337	300	416	574
South Cheshire/Vale Royal			345	447	516
South Sefton/Southport & Formby			80	105	133
Warrington	140	304	397	510	482
West Cheshire	156	170	313	454	612
Wirral	523	417	394	397	357
Total	**1,513**	**1,530**	**2,188**	**2,714**	**3,105**

Note: Some month 12 dashboards for West Cheshire CCG and North East Essex CCG were not available so the activity is an estimate based on year-to-date data at months 10 and 11.



15.25. Key observations from the analysis are:

- Bookings doubled over the period to a total of approximately 3,100 in 2018/19. Average bookings per month in 2018/19 were 259 across Cheshire and Merseyside and North East Essex.
- A large element of the increase was due to the award of the co-commissioned contract across Cheshire and Merseyside in 2016/17.
- For the Wirral, bookings decreased by 32% over the period, with a sharp drop in 2015/16. This is consistent with the impact of the reputational damage reported by One to One at this time.
- Bookings in Warrington and West Cheshire showed the largest increases over the period.

- In Liverpool and North East Essex, bookings increased by 27% and 62% respectively.

15.26. One to One's proposal in 2017/18 for a minimum guaranteed activity level to assure financial viability required a minimum average monthly booking level across Cheshire and Merseyside of 310 (3,720 per year). Across Cheshire and Merseyside only, the average bookings per month in 2018/19 were 211 (2,532 per year). Based on 2018/19 figures, there remained a considerable stretch for One to One to meet the target activity for financial viability across Cheshire and Merseyside; bookings were only 68% of the required target in 2018/19.

Financial viability assessment

15.27. Wirral CCG commissioned MIAA to undertake a review of One to One's financial viability in 2018. The key findings of this review were:

- viability was feasible if activity levels were maintained;
- provider to provider charges were double the anticipated value. Without local compromise or a national directive on the application of the maternity pathway payment model, the provider charges issue would continue, even if existing debt were written off; and
- the financial pressures were due to non-recurrent issues.

15.28. We have undertaken some further scenario analysis based on the information available from the published accounts, the Administrator's Report and the MIAA report, to test the impact of some of the financial pressures experienced by One to One. Two scenarios are presented below.

Scenario 1

15.29. The assumptions for this scenario are:

- CNST arrangements could have been put in place before award of the first contract, so the scenario replaces the private insurance premium in 2012/13 with the average CNST premium incurred of £315k; the CNST premium is also reduced by £100k in 2018/19 in view of the disproportionate uplift.
- 50% of the estimated income not paid through NCA is assumed recovered on the basis that this should have been agreed in advance with commissioners.
- 20% of provider to provider charges are reimbursed to One to One as a prudent assumption. One to One's management accounts show that 33% of these charges were recovered in 2017/18.
- Legal costs relating to the winding-up petition in 2016 are removed as this could have been avoided with earlier action.
- Diagnostics are brought in-house with a consequent saving of £86k in 2018/19 as detailed in the MIAA report.
- A 5% increase in income over the period 2016 to 2019 is assumed by avoidance of reputational damage to One to One and improved referrals by GPs. As an indication, this would equate to approximately 200 additional bookings each year on an antenatal pathway. (For comparison, Wirral, Warrington and Liverpool CCGs each had an average of 423 bookings per year.)

15.30. As illustrated in the table below, under these assumptions which in our view are relatively conservative, One to One becomes financially viable. The profit generated would bring the group of associated companies to an almost break-even position.

Table 12: Scenario 1

Scenario 1 - Minimum cost savings and 5% increase in income

Year	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19
					£'000				
Net Profit/Loss	-2	-569	81	-30	100	130	-569	-709	-463
Scenario adjustments:									
1. Reduce insurance premiums			335						100
2. Payment for NCA				125	50				
3. Provider to provider charges								422	129
4. Legal fees re winding up							59	137	
5. Diagnostics insourcing									86
6. Income increase - 5%							204	248	304
Revised Net/Profit Loss	**-2**	**-569**	**416**	**95**	**150**	**130**	**-306**	**98**	**156**
Revised Cumulative Deficit	**-2**	**-571**	**-155**	**-60**	**90**	**220**	**-86**	**12**	**169**

Scenario 2

15.31. The assumptions under this scenario incorporate a higher level of cost savings and therefore improved financial viability:

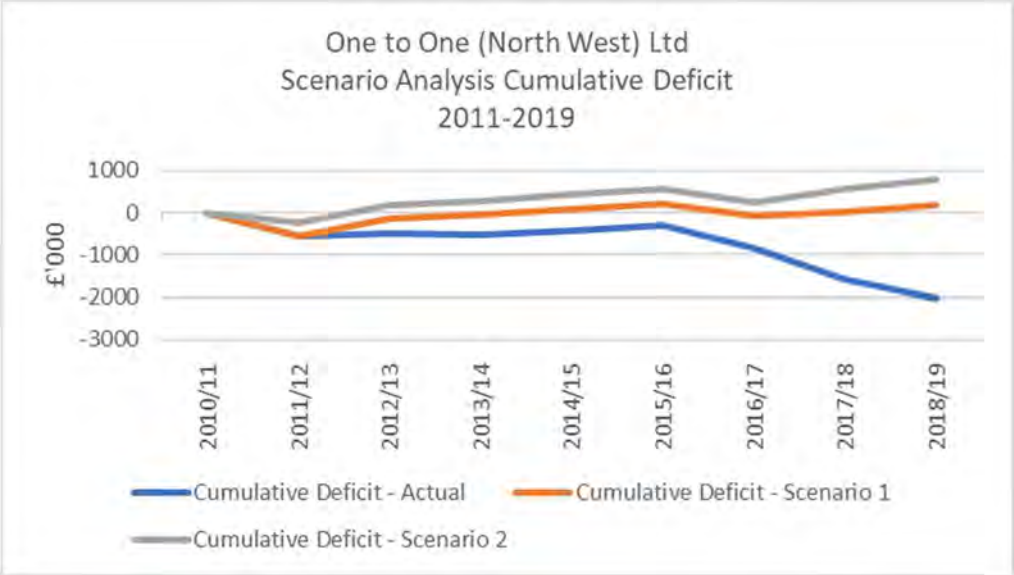
- CNST membership is put in place from April 2011 with associated premium savings against private insurance.
- 30% of provider to provider charges are reimbursed to One to One.
- Additional overhead savings of 5% in 2018/19.

Table 13: Scenario 2

Scenario 2 - Maximum cost savings and 5% increase in income

Year	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19
					£'000				
Net Profit/Loss	-2	-569	81	-30	100	130	-569	-709	-463
Scenario adjustments:									
1. Reduce insurance premiums		335	335						100
2. Payment for NCA				125	50				
3. Provider to provider charges								633	194
4. Legal fees re winding up							59	137	
5. Diagnostics insourcing									86
6. Overhead reduction									106
7. Income increase - 5%							204	248	204
Revised Net/Profit Loss	**-2**	**-234**	**416**	**95**	**150**	**130**	**-306**	**309**	**227**
Revised Cumulative Deficit	**-2**	**-236**	**180**	**275**	**425**	**555**	**249**	**558**	**785**

15.32. We summarise the two scenarios compared with the actual financial performance of One to One in the following graph.



15.33. The service model as it stood was not financially viable. However, the scenario analysis indicates that if actions had been taken to resolve underlying issues that were outside of One to One's control, particularly CNST insurance and agreements on provider to provider charges, the service model is likely to have been financially sustainable.

15.34. A company providing a similar case loading model in the community was Neighbourhood Midwives. The business ceased in January 2019 due to financial reasons. The company's adverse financial position is clear from its publicly available financial accounts from 2016 onwards. These reference ongoing financial challenges and a tariff system that was not designed for small, independent providers. In their 2018 accounts, they stated that they were working on a new payment system with their local Trust and NHS England. This situation appears comparable with the One to One experience and provides further evidence that the community case loading model was not financially viable under the existing tariff system.

15.35. There were various attempts to look at ways of establishing a financially sustainable model. During 2017, NHS England and NHS Improvement (formerly Monitor) and CCGs worked alongside One to One and Wirral University Teaching Hospital (WUTH) to develop a prime provider model. The intention was for the model to be developed across Cheshire and Merseyside by the Local Maternity System. This involved the NHS Trust sub-contracting the case loading service to One to One. This was considered by WUTH, Warrington and Halton Hospitals and Countess of Chester Hospital (COCH). However, there were some fundamental challenges with this model which appeared disadvantageous to NHS Trusts:

- The model transferred all the contractual delivery risk to the NHS Trust; this was significant given the context of obstetric teams having safety and quality concerns about One to One's practice.
- The additional income the Trust received through tariff would fund the sub-contracted service and the Trust would need to agree a tariff arrangement with the sub-contractor. Depending on the financial arrangement with One to One, the NHS Trust might ultimately be financially disadvantaged as they would lose income from provider to provider charges.

- If a Trust's services were under a block contract, as was the case for several providers, the Trust would not receive any additional income for taking on this sub-contract but would incur additional cost.

15.36. The model did not progress; the reasons given were that WUTH would need to go through a procurement process and One to One would not pass the financial pre-qualification criteria; COCH also cited a potential VAT cost through the sub-contract. WUTH was also of the view that it was offering improved choice through its Midwifery Led Unit. West Cheshire CCG remained supportive of this model as the most favourable way forward for the commissioning of this service. There was recognition that it was difficult for One to One to replicate the governance infrastructure of an NHS Trust within the bounds of affordability and the prime provider model might help to resolve this issue.

15.37. As part of the development of the prime provider model, One to One suggested a local tariff arrangement with a 'top slice' approach, whereby they would receive a proportion of the tariff within the pathway payment and the remainder would then be available to fund provider to provider charges. The proposal made assumptions on guaranteed activity levels across Cheshire and Merseyside. It demonstrated financial viability from both One to One's and WUTH's perspective. There is no evidence that the assumptions underpinning this model were tested by commissioners. Our analysis above indicates that the activity levels required were not realistic within a short time frame.

15.38. One to One challenged commissioners on the validity of provider to provider charges where block contracts were in place with NHS Trusts. One to One understood that NHS providers were paid for their activity as part of the block and if NHS Trusts billed One to One for their activity, this amounted to a double payment. The Trusts we spoke to did not consider the additional One to One activity to be included in their prior year baseline activity plans for the block contracts and continued to apply the tariff rules. However, we were told that in Essex, the acute Trust was on a block contract and stopped invoicing One to One when this issue was highlighted. We noted a significant creditor in the Administrator's Report for this Trust. One to One believed this was invoiced only upon notice of One to One's administration in the belief that it would not be challenged by the administrators.

15.39. Commissioners generally concurred with the view that activity plans in block contracts did not include One to One activity. However, West Cheshire CCG noted in a paper to the Finance, Performance and Commissioning Committee in November 2018 that as birth rates were falling, there was a potential issue as they were paying the block contract as well as for the increasing activity with One to One. We also noted that Wirral CCG updated its procurement policy in 2018 to reflect the potential conflict between a local tariff under AQP contracts and block contracts.

15.40. There was no further discussion on the block contract issue. The MIAA report indicated that One to One had suggested that where block contracts were in place, the tariff paid to One to One should be reduced as provider to provider charges would not be applied. This was a reasonable suggestion but would have resulted in lost income to NHS Trusts through provider to provider charges.

Financial governance

15.41. The Mersey Internal Audit Agency report commissioned by Wirral CCG in 2018 provides an independent view of financial governance and control at One to One. The following key points were made.

15.42. There was reasonable evidence that One to One was well managed with financial governance arrangements appropriate to the size and nature of the business.

15.43. One to One faced considerable challenges in reconciling and validating the charges made by NHS Trusts. One to One diligently undertook the work to do this, evidence of which was provided in the report, but this was made challenging by the lack of supporting information provided for some charges. We were told that it was also difficult for NHS finance teams to access the patient-level information requested by One to One to understand the clinical decisions in order to validate the charges.

15.44. One to One's cash management was adequate but there were weaknesses in cash-flow planning. In our view, cash-flow forecasting would have been very difficult without clear visibility on the charges to be made by NHS providers which would be unpredictable per se, due to the exercising of choice by women.

15.45. One to One employed a management accountant and accessed experienced, senior financial expertise through a Non-Executive Director who was also a Board member of an NHS acute Trust. It was evident through interviews that One to One's senior team had a good grasp of the complexities of the tariff system and associated payment policies. Their Chief Executive attended national tariff working groups.

15.46. All required statutory returns to Companies House were made, including annual accounts, over the period from incorporation to entering voluntary administration due to insolvency on 1 August 2019. There were some instances of late returns which were promptly rectified.

15.47. The Director's Reports in the accounts gave annual assurances over the life of the company that One to One was a 'going concern'. One to One sought technical advice on these statements and legal advice in relation to the disputed debt. The statements were made on the basis that much of the debt was disputed and the statement required was looking forward for only one year. The Administrator's Report[72] of September 2019 states that legal advice was that One to One had a 50% chance of successfully defending the legal action on provider to provider charges initiated by an NHS Trust in 2019.

15.48. The statements referred to reliance on the support of NHS Trust creditors. We were told by NHS Trusts that they were not willing to provide this support and were seeking to recover the debt, as evidenced by some Trusts taking debt recovery and legal action.

15.49. With regards to non-NHS creditors, a letter from One to One to the Chief Executive of the NHS in June 2016 regarding the winding-up petition stated that although NHS Trusts had contacted One to One's suppliers, these suppliers did not support the petition.

15.50. Statements were made in the Director's reports in 2016 and 2017 regarding development of an operating model with a local acute Trust and a revised cross-charging approach being examined by NHS England as part of the rationale for the 'going concern' judgement. Evidence from meetings with NHS England and CCGs

[72]https://find-and-update.company-information.service.gov.uk/company/07252080/filing-history

indicate that these statements were based on exploratory conversations with no firm commitments made by commissioners. These issues remained unresolved.

15.51. The technical solvency of the company was not formally tested over the company's life until voluntary administration in 2019, as the winding-up petition in 2016 did not progress. However, it is our opinion that the economic substance of the accounts gave significant cause for concern based on the net current liability position of the company over many years, adverse key financial ratios (liquidity and net profit margin) and an inability to pay creditors on normal due dates.

15.52. The Administrator's Report stated that investigations into potential wrongful trading are ongoing following creditor concerns; however, progress has stalled due to the impact of the Covid-19 pandemic.

Summary points

15.53. From its establishment, the company was in a precarious financial position. Initial losses were not recouped by subsequent contracts and the business model continued to be loss-making due to provider to provider charges and the level of overheads.

15.54. The company's financial sustainability was dependent on the rapid growth of NHS-funded activity to cover start-up losses and fixed costs. The significant erosion of margins which resulted with the introduction of the national maternity pathway tariff compounded the need to rapidly generate increased activity. The minimum guaranteed activity levels required by One to One to achieve financial viability in Cheshire and Merseyside did not appear realistic within the short timescale required for financial recovery.

15.55. The Any Qualified Provider (AQP) approach was a key contributory factor to One to One's financial demise, as considerable start-up costs and overheads were incurred which were not covered by the volumes of activity generated under the AQP contract. In addition, non-contracted activity (NCA) was frequently not paid for, which was in line with commissioning guidance at the time.

15.56. Self-referrals and NCA led to a loss of control over activity and income by One to One, so growth did not progress in a planned way. Inadequate financial controls were in place to ensure payment for activity undertaken.

15.57. It is evident that the level of interventions and charges by NHS Trusts were much higher than anticipated, leading to a significant erosion of One to One's margins. The bulk of the problem was on the antenatal pathway where the majority of the income received through the pathway payment, was used to pay for the associated provider to provider charges. One to One had not adequately planned for the various scenarios that might arise before the start of the co-commissioned contract in 2016, following which these charges increased exponentially.

15.58. As a result, the level of overheads incurred was not manageable and the level of insurance premiums were unsustainable for the business model. The basis for the insurance premiums charged under CNST remains unclear and a methodology based on number of births was not appropriate for One to One's model.

15.59. Before the cessation of the business, there was no resolution to the fundamental problem of an inconsistent and unworkable payment system between One to One and NHS Trusts. One to One believed that a solution to the issue would be found at a national level but this was unfounded. There were various proposals made by One to One to try to influence commissioners to change their approach to the tariff, and a prime provider model was supported by NHSE/I. These proposals did not progress as there were financial disincentives to NHS Trusts.

15.60. Even if existing debt had been written off, the charging system would have continued with a consequent continued accumulation of costs and debt. Without any change to the payment mechanism, the One to One business model was not financially viable.

What could have been done differently?

- Before making decisions to invest in staff and infrastructure for growth, One to One should have paused to take stock and undertake robust business planning, following the Wirral pilot and before the commencement of the maternity pathway payment mechanism.
- One to One should have obtained independent, expert validation of its business plans with stress testing on key assumptions to understand the risks.
- Given One to One's limited experience of working within the NHS regulatory and contractual framework, greater prudence should have been exercised before expanding the business through non-contracted activity. One to One should have contacted commissioners upon receiving self-referrals, to obtain permission to operate in their areas so that they would be paid for the activity.
- Greater use of pilot testing should have been made by One to One and commissioners in areas where One to One did not hold a contract to avoid uncontrolled growth through self-referrals.
- Commissioners should have undertaken robust scrutiny of One to One's business plan as part of the initial pilot evaluation and before subsequent contract awards. One to One should have shared their financial projections and scenario analysis on an 'open book' basis with commissioners, to demonstrate the level of activity that was required for financial viability.
- As a start-up business, One to One might have reconsidered acceptance of zero-based activity contracts, as the fixed cost base meant mitigation of this risk was not possible without significant damage to the business and its reputation.
- One to One should have requested more support from commissioners following the pilot, to make sure that the costs and practical implications of contractual requirements and quality oversight in the NHS were understood. One to One should have thoroughly assessed the costs to a start-up business of establishing an infrastructure to ensure compliance with NHS requirements.
- A more transparent discussion on the potential conflicts in the system due to block contracts would have been helpful, as One to One perceived the lack of debate on this issue as protectionism of NHS providers.
- While recognising that there were initial barriers to the proposal for a prime provider model, this should have been tested further with the top-sliced local tariff approach which might have been more financially feasible for NHS Trusts.
- Commissioners should have escalated earlier the issues which could not be addressed and resolved locally. NHSE/I regionally should have supported local commissioners to seek solutions to address the insurance position, tariff arrangements and provider to provider charging.

Recommendations

1. Relatively small independent sector providers, particularly start-up businesses working exclusively in the NHS, should work transparently on their business plans with commissioners so that the commercial challenges are understood by all parties.
2. Business plans should be rigorously stress tested to ensure assumptions in areas of risk are appropriate and that the business plan has a buffer for contingencies and unexpected variations in key assumptions.
3. Commissioners should consider adding a section on non-contracted activity to their contract management policy and service specifications, so that the rules to be followed are clear to new providers.
4. Commissioners should consider applying a tailored approach to oversight of small contracts to avoid a disproportionate bureaucratic burden and level of cost to providers of the resources and the systems required for performance reporting and quality assurance.
5. Increased commissioning flexibilities should be considered for small contracts, for example, local tariff arrangements between providers, block contracts and guaranteed activity levels.
6. A prime provider model should be further investigated for services to be provided jointly between NHS and independent sector providers.
7. The NHS Litigation Authority (NHSLA) should set out a transparent methodology for calculating premiums for community-based maternity care providers, this should be based on an appropriate risk assessment.

16. Culture, relationships and behaviours

Introduction

16.1. In this section, we set out our findings on One to One's relationships with other NHS providers. We have explored the nature of relationships with maternity services provided by NHS Trusts and also considered how One to One liaised with General Practice.

16.2. We have considered differences in cultures and practice as well as operational working relationships. This has informed our understanding of how these relationships impacted on the ability of One to One to deliver safe and effective care to women and babies.

Key findings

NHS Trusts

16.3. Throughout the lifespan of the service, NHS providers and One to One described a culture of poor communication, lack of trust and unprofessional behaviour which was evident on both sides. On occasions, women and their partners were exposed to this behaviour, often at a stressful time, such as an emergency transfer into hospital.

16.4. Feedback on the Wirral pilot in late 2012 referred to problems experienced in relation to integration with other services. The report highlighted that the impact on existing services and infrastructure had not been considered by commissioners before the introduction of One to One. The local acute Trust involved in the pilot, Wirral University Teaching Hospital (WUTH) raised concerns about safeguarding incidents, the potential clinical risks of the model and the impact on their income due to activity that would be lost to One to One. Monthly meetings were held between senior midwives from One to One and WUTH to try to resolve issues which had arisen around joint working.

16.5. As early as in 2012, there were serious allegations about One to One's practices which were escalated throughout the system by NHS providers. In June 2012, representatives of the maternity service at WUTH contacted Wirral PCT with a list of their concerns on quality and safety issues. This letter was also sent anonymously to the CQC and the Local Supervising Authority Midwifery Officer (LSAMO). It contained potentially inflammatory and unsubstantiated comments about One to One which had been shared with the local MP and media. Wirral PCT's subsequent review made some recommendations to strengthen risk assessment and documentation but found that One to One had appropriately investigated incidents and women had expressed a high level of satisfaction with the service.

16.6. A meeting was held in August 2012 with Liverpool Women's Hospital (LWH) to discuss the management of high-risk women. LWH expressed concerns about One to One's view of women's 'right to choice', rather than the midwife exercising clinical judgement. LWH's view was that all high-risk women should be seen by an obstetrician.

16.7. The CQC, LSAMO and commissioners had no significant concerns at this time. One to One perceived the criticisms of their practice by local Trusts as bullying behaviour. One to One raised the issue with the LSAMO in August 2012. We found no evidence of a formal complaint or allegation of bullying by One to One regarding these criticisms.

16.8. Effective collaboration was critical to the successful implementation of the One to One model, but relationship issues continued to frustrate attempts to work together,

establish agreed joint working protocols and appropriate documentation. For example:

- An issue was raised in April 2012 around safeguarding and social services not recognising One to One as a woman's care provider and their information being shared with the NHS Trust rather than directly with One to One.
- In May 2013, an issue over serious incident reporting was raised by WUTH. One to One said that a more formal process needed to be in place and raised a complaint about claims by the Trust that they were not providing the information required.
- In February 2014, a senior manager from a Trust in Cheshire and Merseyside (C&M) contacted commissioners about the impact of independent midwifery generally and the risks it created in terms of a fragmented care model for women, differences in the approach to risk assessment and lack of joint care pathways. The view was expressed that commissioners did not fully appreciate the operational challenges involved in collaborative working between One to One and NHS providers.
- In September 2014, it was reported that there was resistance from the local Trust in North East Essex (NEE) to One to One operating in their area. One to One planned to hold workshops for the local maternity community to build relationships. NEE CCG asked the Trust to put a service level agreement in place as a priority.
- In October 2014, Mid Cheshire Hospitals NHS Foundation Trust raised concerns with commissioners (CCG and NHS England) and were advised to liaise with the Care Quality Commission (CQC). The Trust remained nervous about working with One to One and requested their clinical pathway documentation for due diligence before they would sign a service level agreement. The Commercial Director of One to One referred the Trust to NICE guidance as well as assurance already given to commissioners and was reluctant to share One to One's policies.
- NHS providers reported their concerns directly to the CQC on several occasions, which led to additional inspections and further deterioration in relationships; however, many of the claims made were unsubstantiated when subjected to further investigation. We found no evidence that NHS providers escalated their concerns through appropriate internal governance routes or local midwifery forums.
- NHS providers also made referrals of One to One staff to the Nursing and Midwifery Council, but these were not pursued.

16.9. There were instances of NHS providers appearing willing to engage with One to One to work through relationship and joint working challenges, for example:

- Following the pilot, monthly meetings were held between senior midwives from One to One and WUTH to try to resolve issues which had arisen around joint working and care pathways.
- Upon the introduction of One to One's services in Essex in July 2014, the local NHS Trust had several meetings with One to One and following the request by NEE CCG to prioritise an agreement, we were told that a partnership working agreement was signed by the NHS Trust.
- Countess of Chester Hospital NHS Foundation Trust (COCH) had been working with One to One during 2016 on information sharing and clinical pathway agreements, but this was put on hold pending the outcome of the winding-up

petition in 2016 which COCH supported. Work continued on the shared care agreement and although we did not find a final signed version in the documentation, there was clear collaborative working on this document. In the September 2018 contract meeting, continued, positive joint working was reported by the CCG and One to One. Progress was made with COCH, with the oversight of the CCG.

- WUTH worked with One to One to develop the proposal for a lead contractor model which had been put forward by NHS England as a potential solution moving forwards.
- As part of the procurement led by Wirral CCG in 2014/15, an NHS Trust stated that they had a positive relationship with One to One: "*Engagement with a private provider of midwifery care is excellent given that there is regular engagement/communication and there is a real desire to work together especially with those women identified as high risk*."

16.10. However, these examples of attempts to work together do not concur with our overall findings on relationships between One to One and NHS Trusts. Where attempts were made to establish effective joint working, these tended to be commissioner-driven or under national direction, rather than initiated voluntarily by NHS Trusts. Some Trusts reported feeling pressured to agree joint working agreements with One to One and as debt relating to provider to provider charges took hold, relationships with NHS Trusts deteriorated further.

16.11. Our findings on teamwork and respect between professionals are consistent with the National Maternity Review. A summary provided by the Royal College of Midwives in February 2016[73] stated:

"*Midwives and obstetricians highlighted the need to improve working relationships between their professions and with other groups but mentioned issues of communication, handovers and disagreements about how to handle specific situations as barriers to achieving this. Everyone has the interests of the woman and baby as their priority but had different perspectives on how to secure the best possible care for them.*"

16.12. The origins and drivers of the relationship challenges were multifaceted. There were significant differences in culture and maternity care practice. One to One's philosophy centred around viewing pregnancy as a normal physiological event and aimed to put women in control and reduce unnecessary interventions during antenatal care and birth. The NHS model has been termed 'medicalised' as it follows standard policies and procedures and is 'consultant-led'.

16.13. The cultural issues were compounded by differences in language and terminology. For example, One to One replaced the word 'contractions' with 'surges' and they did not identify women's progress in labour in terms of 'stages'. One to One did not typically use standard NHS terminology in their policies and procedures and their staff did not all have titles that were recognised by NHS providers, for example, One to One did not have a Head of Midwifery.

16.14. NHS providers were worried about the safety of One to One's approach as they were managing women with higher risk profiles than NHS providers believed had been intended by commissioners. Their view appeared to be borne out by the number of incidents reported and their experience of the subsequent management of women who transferred into their care. NHS Trusts told us that women not known

[73] Electronic letterhead - to be sent as a PDF document (rcm.org.uk)

to their services would present at their obstetric units, some requiring urgent medical attention.

16.15. One to One were able to offer women choice and improved continuity of care through their model which was not generally offered by NHS providers. This was welcomed by commissioners and national policy influencers who wished to accelerate delivery of policy aspirations. However, One to One were viewed locally by NHS providers as a small pilot exercise rather than representing a genuine shift in the commissioning of maternity services which required their engagement.

16.16. Some NHS providers believed that One to One were commissioned to make savings by reducing acute activity as this was central to their service proposition. There was no financial incentive for Trusts to work with One to One; they were concerned about the potential loss of income and some about the longer term viability of their obstetric units. We were told that generally, hospital maternity units were loss-making due to the high costs of indemnity insurance through CNST.

16.17. NHS Trusts rigidly followed the rules for provider to provider charges under the lead provider arrangements and as set out in the national Payment by Results (PbR) maternity tariff framework. One to One disputed the majority of these charges and challenged the clinical decisions made. Significant outstanding debt resulted, which NHS Trusts tried to recover, taking legal recourse in some instances.

16.18. One to One were not viewed by NHS providers as part of the 'NHS family' as they were a private sector organisation taking funds outside of the NHS system. This view is inconsistent with the NHS perception of General Practice who are fully integrated into the system but are also independent practitioners operating a business but funded by the NHS.

16.19. We were also told of a perception that NHS midwifery teams did not view community midwives as equal in professional standing to midwives working in obstetric units.

16.20. These differing perspectives and perceptions resulted in behaviours which led to significant operational challenges. Some NHS Trusts did not allow One to One to accompany their women to appointments and births in their maternity units. We were told that One to One staff felt intimidated and were afraid to seek advice or take their women for care at some NHS maternity units, creating a stressful situation for staff and risks to women and babies.

16.21. We were told by NHS stakeholders that relationships with One to One were frustrating and that it was extremely difficult to work with members of their team at times. We were told that: "*unfortunately some of the people involved in it had burnt their bridges with the local providers, so no matter how hard they tried, they were never going to build those relationships with those providers*".

16.22. We were also told that as One to One was a small business with individuals exposed to significant personal financial risk, this changed the focus of conversations to financial sustainability rather than the quality of the service, and therefore the dynamics of relationships were not aligned.

16.23. We have seen no evidence of any formal, signed agreements for joint working between One to One and NHS Trusts; we are aware that One to One developed proforma agreements, but these were not adopted. Some Trusts reported feeling pressured to commit to these agreements, for example, in North East Essex.

16.24. The lack of agreement on provider to provider charging between NHS Trusts and One to One also increased risk to women, due to the financial impact on One to One's business model. We were told that at times, midwives felt challenged on their clinical decisions to refer a woman to an NHS provider due to the costs that would

be incurred. Disputes arose mainly from inadequate supporting documentation and evidence of clinical justification for interventions. An example of how One to One described this problem is given below:

'[…] I've been referred in because I'm diabetic and I need my care plan'. The obstetrician would say, 'here's your care plan, I want to see you next week and the week after and the week after'. Where actually, we're saying, we only needed the obstetrician to go over the care plan and make sure it's okay, the midwife is a qualified person doing this job, she can monitor along with the woman who has been diabetic all her life and understands her own diabetes, we can do it, and if something arises, you would refer her in."

16.25. One to One and NHS providers repeatedly escalated the same concerns to commissioners around relationships, perceptions of unprofessional behaviour and provider to provider charges. Commissioners were reluctant to get involved with providers to broker solutions; their attendance at some meetings did not accelerate progress and their general view was that these were issues to be resolved between providers.

16.26. Commissioners placed the onus on One to One to put local joint working protocols in place with the NHS system. This was challenging for One to One, a relatively small operation, faced with the reluctance of NHS providers to accept One to One as part of the system. The challenges were compounded by the need for shared pathways with a large number of NHS providers, each with different policies and procedures.

16.27. Heads of Midwifery meetings were an important forum for relationship building. However, One to One did not feel welcome at these meetings. We were told that behaviours on both sides were unprofessional and antagonistic at times. Relationships within the Local Maternity System with One to One were described to us as follows: "*There was active antipathy towards them, which I don't think they always did their best to overcome. Sometimes anger and annoyance were responded to by anger and annoyance back.*"

16.28. Some NHS-employed midwives went on to work for One to One. We were told that midwives who had previously worked harmoniously with colleagues in an acute provider were subsequently viewed differently as an employee of One to One. We heard from One to One staff who continue to feel ostracised by colleagues they are now working alongside in NHS services, even after the cessation of One to One.

General Practice

16.29. Although the majority of women self-referred to One to One's services, GP referrals were important to One to One as commissioners would generally pay for non-contracted activity that resulted from a GP referral. However, we were told that in many cases, the need to ask a woman to obtain a GP referral before booking with One to One was a hindrance to the effectiveness of the service model. One to One had also raised concerns about the lack of direct communication from GPs to One to One about women's care.

16.30. Only one GP practice based on the Wirral engaged with the One to One pilot; we were told that this was for political reasons. The pilot was promoted by the practice in the NHS Commissioning Board's publication in 2012, Commissioning Maternity Services: A Resource Pack to support Clinical Commissioning Groups.[74] It referred to "*GPs reporting better communication and collaboration with the midwives*". It also recognised that more work was needed on the pathway into health visiting services.

[74] Commisioning Maternity Services – the scope for doing things differently (esydave.com)

Our impression was that the positive message regarding GP engagement with the model set out in the case study in the document was not borne out by reality.

16.31. A GP survey undertaken on the Wirral in 2012 to obtain views on the service highlighted their concerns about the high number of home births and whether women were being pressurised into having a home birth. We were also told that other contributory factors were that One to One were not known by GPs, wariness of a private sector company, and safety concerns. In addition, some practices had their own community midwives. In February 2014, it was reported that concerns were expressed by staff at a Wirral GP practice, in a public forum, about the safety of One to One's service. A contract meeting records the following example of the barriers experienced:

"*an issue that has arisen regarding a lady who self-referred to One to One and then attended her GP practice for an appointment. When with her GP she was advised that if she did not change maternity provider she would be de-registered from the practice.*"

16.32. In West Cheshire, we were told that GPs were initially wary of the service from a safety and governance perspective. The CCG focussed on engagement with GPs and they became more assured as activity grew in West Cheshire and they received positive feedback from women.

16.33. Relationships with GPs in North East Essex (NEE) were initially positive. During 2015, One to One reported that activity in Essex was higher than in the North West and believed this was due to greater acceptance of the service by GPs who were offering choice. We were told that relationships deteriorated when One to One removed the local management team and managed the service from the North West from the end of 2016, following which there were increasing concerns over quality.

16.34. One to One expressed their concerns from 2012 onwards about low levels of GP referrals despite their efforts to engage:

- A One to One survey in April 2013, indicated that in 89% of cases, women were not being offered choice by their GP and only five out of sixty practices on the Wirral had responded to One to One's approaches.
- In August 2014, Warrington CCG expressed a view that the difficulties in engaging with GPs were influenced by national policy which did not advocate the need for pregnant women to see their GPs. It was suggested that the local Maternity Network Meetings might facilitate an improved understanding of One to One's service, but One to One stated that their attendance had not been encouraged.
- In January 2015, NEE CCG sent a communication to GPs outlining maternity choices, including One to One. During 2015, One to One reported that activity in Essex was higher than in the North West and believed that this was due to greater acceptance of the service by GPs who were offering choice.
- In February 2016, One to One reported that in West Cheshire, out of 110 referrals over a six-month period, there were only three GP referrals. Subsequently, activity improved in West Cheshire and the CCG and GP Lead for Maternity were proactive in supporting relationship development with GPs.

16.35. Commissioners sent communications to GPs to highlight that One to One were part of the choice offer to women, but these seemed to have limited impact. It was reported in 2015 that in one area, leaflets had been provided to GPs for inclusion in maternity packs and they were removed prior to the pack being given to women.

Other services

16.36. Maternity services have important interfaces with other NHS services such as health visiting and perinatal mental health services, and with local authority Safeguarding teams. There were several examples of dysfunction in these interfaces discussed at contract meetings.

16.37. Commissioners recognised that further work would be needed to integrate the community case loading model with Health Visiting services. However, we did not find evidence of any focussed work involving One to One in this area. One to One gave examples of some of the problems arising when health visitors did not contact them directly about a woman's care at a contract meeting in October 2014. West Cheshire CCG asked One to One to attend the Starting Well meeting in West Cheshire which covered Health Visiting and Family Nurse Partnership services. Timeliness of referrals to Health Visiting services was a metric monitored on the performance dashboard for One to One; there was no significant underperformance noted on this metric.

16.38. In January 2015, an agreement was set up between One to One and Anglia Community Enterprise who provided the health visiting service in Essex, but this was only signed by One to One. In the North West, a memorandum of understanding was put in place between One to One and Virgin Care for Health Visiting services in early 2019.

Summary points

16.39. Attempts to fuse together NHS and private sector provision under national initiatives has typically been fraught with challenges due to differences in respective cultures, ways of working, legislative and regulatory environments. Innovation and the development of alternative models for maternity services required the NHS to work differently, with flexibility and pace to encourage diversity in the marketplace and collaboration between the NHS and the independent sector.

16.40. One to One believed they were part of a significant shift in commissioning and shaping market development rather than responding to it. However, the national support they anticipated was not forthcoming when problems started to emerge in working relationships, particularly with NHS Trusts.

16.41. Our review found a pervasive 'them and us' culture between One to One and NHS Trust maternity teams. The relationship problems with NHS providers were evident from the outset and were exacerbated as One to One became more established within the system. Relationships deteriorated further as the issue of provider to provider charges took hold across Cheshire and Merseyside in particular.

16.42. The onus was placed on One to One to put joint working protocols in place, as this was extremely challenging in the face of the unwillingness to engage by NHS providers. This approach transferred a disproportionate amount of risk to One to One and to NHS Trusts, particularly as both continued to operate without agreed joint working and cross-charging agreements. As a consequence, this created additional risk to the safety of women and babies.

16.43. The impression gained is that NHS Trust teams were under pressure to resolve the issues and work with One to One due to safety concerns, but mutual trust between the respective teams was lacking. Commissioners were unwilling to get involved in brokering solutions, so their oversight was with a relatively light touch and did not accelerate progress.

16.44. We did not find any evidence that commissioners sought to understand or act on the clear cultural issues that existed between the NHS and One to One. Better Births recognised that the culture within maternity services was a matter that

commissioners should consider: "*Commissioners should take an interest in the culture of the maternity services that they are commissioning for their communities, as this will be a key determinant of quality and outcomes.'*

16.45. There was a lack of flexibility and compromise on all sides; this was needed in the interest of putting women and their families first. Hierarchical and rigid NHS structures and policies acted as a barrier to effective joint working. One to One's focus was its absolute commitment to its founding principles of providing greater choice to all women, and the sustainability of a business which had grown from a small family company, to employ approximately 120 people, caring for almost 2000 women.

16.46. One to One's approach of escalating issues to a national level further weakened local relationships. If relationships had been positive and productive, shared care pathways would have been easier to agree and implement, and provider to provider charges would have been better understood by all parties.

16.47. GPs were clearly reluctant to engage with One to One and this had a significant impact on the promotion of the service as a choice option and on the activity levels that One to One were able to achieve. Positive comments about relationships with GPs on the Wirral in 2012 were not borne out by reality. Although commissioners took some steps to encourage GPs to work with One to One and ensure women were offered choice, there was not enough focus on understanding the multiple factors which were influencing the acceptance of One to One by GPs and their particular concerns. In addition, this issue was not appropriately escalated outside of the Wirral contract meetings.

16.48. Pathways with other associated services such as Health Visiting, Local Authority Safeguarding and Perinatal Mental Health services were not a particular area of focus for the development of the model. There were various communication and access issues for One to One with these services.

What could have been done differently?

- Locally commissioners should have considered their system management role and how to facilitate relationship building and mutual trust between One to One, other NHS providers and GPs. This was important due to the implications for the safety of women and babies.
- Commissioners might have considered local incentive schemes through contractual arrangements with NHS Trusts and General Practice to encourage the offer of choice and collaborative working.
- Full engagement should have been undertaken with all stakeholders involved in shared care arrangements at the testing stage of the new service model, including interfaces with Health Visiting, Safeguarding and Perinatal Mental Health services.
- One to One should have formalised complaints about unprofessional behaviour and referred these to commissioners and appropriate authorities.

Recommendations

1. Potential cultural barriers to joint working in maternity care between acute and community providers should be tackled as part of engagement work before introducing a new model into an established NHS system.
2. Service specifications should be agreed by all stakeholders involved in shared care pathways. Interfaces with other services should be defined and fully documented as part of an agreed shared service specification rather than being a development requirement of the specification.
3. Engagement should continue regularly with wider stakeholders to obtain comprehensive and honest feedback on implementation and to inform any changes to a service specification.
4. Commissioner support should continue to broker shared care arrangements and maintain oversight of relationships across the system.
5. Professional integrity issues need to be investigated as a priority by commissioners and professional bodies when concerns are raised either informally or formally.

17. System oversight

Introduction

17.1. In this section, we consider the effectiveness of system oversight of the developments with One to One in terms of the mechanisms and approaches used by local commissioners, NHS England and NHS Improvement (formerly Monitor), the CQC and the Local Supervising Authority. The focus is on how risks were escalated and managed, and whether actions taken were appropriate.

17.2. We have considered the oversight framework in the round, including the influence of national imperatives, to assess how well this functioned as a collective infrastructure and the challenges experienced.

Key findings

Local oversight

17.3. Contractual and quality oversight by CCGs is considered fully in Section 13. The key factors which impacted on the effectiveness of local system oversight, including our observations on the human factors involved, are presented below.

17.4. At key decision points, due diligence on the safety of One to One's services and their financial position was inadequate. Importantly, before the award of the first contract, this lack of rigour triggered a set of circumstances which allowed the uncontrolled expansion of One to One without the appropriate governance arrangements being put in place.

17.5. Scrutiny of One to One's service became reactive in response to concerns raised by NHS providers and other system quality surveillance mechanisms such as the Risk Summit processes.

17.6. An absence of proactive, structured, routine oversight of safety and quality weakened commissioners' and wider stakeholders' assurance and confidence in the service. Significant risks were not escalated to an appropriate level of seniority at an early stage. One to One began alerting commissioners at contract meetings to its financial problems in November 2012 and to the tariff issues in April 2013.

17.7. We were told that the move from Primary Care Trusts to CCGs in 2013/14 resulted in a loss of knowledge with regard to the commissioning and monitoring of maternity services.

17.8. The lack of visibility of One to One's operations as a whole limited the effectiveness of commissioner oversight prior to 2016/17. The co-commissioned contract across Cheshire and Merseyside was a positive step to move to a more centralised and coordinated view. A common view expressed was the disproportionate effort put into managing a small contract. The challenges of managing the risks involved with an independent sector provider working within an established system with multiple NHS stakeholders were, in our view, underestimated.

17.9. The collaborative contracting agreement which underpinned the co-commissioned contract across Cheshire & Merseyside from 2016, refers to 'market management' as one of the key functions of the co-commissioned arrangement. We found little evidence of joint working between commissioners in terms of maintaining local strategic coherence and the stability of maternity services following the introduction of One to One into the market. Prior to 2018, co-commissioners did not effectively share intelligence and act together promptly on the serious risks that had emerged and which had not been addressed,

17.10. Wirral CCG as lead commissioner in Cheshire and Merseyside, was under considerable pressure from NHS Trusts and One to One to resolve the tariff issues.

NHS Trusts felt that this obligation fell on CCGs as they had made the decisions to contract with One to One on the basis of the national maternity tariff. There were examples of strongly worded communications from NHS Trusts questioning the CCGs' decisions in this regard. One Trust asked their CCG to underwrite the outstanding debt.

17.11. The lack of escalation from contract meetings of the increasing debt issue due to provider to provider charges implied that senior CCG officers may not have been aware of this emerging risk at an early stage. For example:

- The first record we have found of the issue being raised at contract meetings was in April 2015. There was no record of any action on this issue or escalation from this meeting.
- It was recorded in September 2015 that One to One sought direct support from Monitor on this issue, thereby potentially bypassing communication channels with commissioners. Monitor declined to intervene at this point.

17.12. The debt issues continued to be raised at contract meetings in 2015/16 until it was referred to in the Risk Summit process and NHS England North escalated the issue to the national team in February 2016. We found no evidence of further action from the national team at this point. At the same time, Wirral CCG stated that they could not get involved in provider to provider pathways but "*do have an interest in whether this is resolved.*"

17.13. Some CCGs felt somewhat constrained in the influence they could have over NHS Trusts as NHS Improvement (formerly Monitor) was responsible for their oversight. They were therefore reluctant to get involved in the relationships between One to One and NHS providers to broker solutions and accelerate progress on the major barriers to joint working. However, there was a clear destabilising effect on local systems and risks to the safety of women and babies. Notwithstanding formal structural accountabilities and responsibilities, there was a reasonable justification for commissioners to act decisively on these risks well before the implementation of the larger co-commissioned contract in 2016.

17.14. From 2017, there were many efforts and much senior resource expended, to develop contractual solutions to allow One to One to continue to operate on a financially sustainable footing. NHS England and NHS Improvement acted in a supportive role to commissioners locally to try to find solutions. There was positive collaboration between CCGs, NHS England (NHSE) regional leads, the national Choice Team, NHS Trusts and One to One to explore the principles of a prime provider/sub-contracting model. These proposals were not able to be implemented by NHS Trusts due to perceived risks and financial disincentives. The Chair of the National Maternity Review commented in a letter to the NHS Chief Executive that CCGs' enthusiasm was not matched by that of local NHS Trusts.

17.15. It was clear from interviews and documentation that stakeholders in NHS systems locally came to a shared view that the One to One model would not work. This was recognised in an email in August 2017 from Wirral CCG, NHSE and NHS Improvement (NHSI) to all CCGs and NHS Trusts in Cheshire and Merseyside regarding the prime provider model. This acknowledged that One to One was not viable and that a new financial model was needed. When the prime provider model was not able to be implemented, it was inevitable that the contract would need to be terminated and the service potentially re-procured.

17.16. However, commissioners locally (CCGs and NHSE North), and in particular Wirral CCG as the lead commissioner, were in a difficult situation as there was evidence of other factors which were inhibiting their ability to take earlier action. These are explained further below.

17.17. One to One's service model was aligned to the objectives of national maternity policy in offering more choice and control to women. One to One had national attention and direct relationships with key influential figures involved in the National Maternity Review.

17.18. The model was therefore attractive to commissioners as a way to implement policy locally in the absence of alternative models being offered by NHS providers. Women wanted this type of service, as demonstrated by the rapid growth in self-referrals. It was therefore important to commissioners for the service to succeed.

17.19. One to One believed they were part of a significant shift in commissioning and that their model was shaping market development and arguably, this should have been a fair assumption. Their relationship with national influencers enabled One to One to enhance their profile and bring national attention to the challenges they were experiencing in local systems. Despite very senior interventions to progress the objectives of Better Births, there was little progress made to remove the blockages and impediments to the viability of the model.

17.20. As One to One became more frustrated that their concerns were not able to be resolved locally, the Chief Executive increasingly resorted to direct escalation to senior levels within CCGs, NHS England and NHSI as well as to the senior figures involved in national maternity policy. For example:

- In April 2015, One to One wrote to the Chief Nurse of NHSE North. They complained that the Risk Summit process had been unfairly applied to them and that this amounted to organisational bullying. Furthermore, they said that they were being intimidated by some of the CCGs.
- In March 2016, One to One wrote to the Director of Nursing at NHS England Midlands and East to make a formal complaint regarding perceived bullying and anti-competitive behaviour by Mid Essex CCG. The CCG were concerned about One to One's integration into the local health system and no longer supported One to One operating in their area.
- In June 2016, the Chief Executive of One to One wrote directly to the NHS Chief Executive asking for support regarding the winding-up petition. The letter provided a full history of events, questioned the motivations of NHS Trusts, and referred to their behaviour as "*bullying in nature.*"
- In September 2016, One to One were disappointed at the decision to award the Cheshire and Merseyside Pioneer Pilot Site to Liverpool Women's Hospital as this would restrict their ability to offer services to women requesting a personal budget in Liverpool. One to One escalated this to the NHSE/I national team stating: "*I am frustrated that yet again I am having to challenge decisions being made at a regional level when they will have a direct impact on our sustainability as a service and instead of inviting One to One to be part of the pilot you still resist this which further supports my belief that One to One are purposely being excluded.*"

17.21. At contract meetings, there were several examples of One to One referring to commitments made and discussions held at national level, for example, at the Maternity and Payment by Results working groups. This created the impression that One to One had advanced knowledge of national developments and were supported at a senior level.

17.22. The position was articulated in an email to NHS England in January 2018 regarding a letter received from One to One: *"The letter is suggesting that this is all due to NHS commissioners and has been copied to [NHS England North Regional Director], although I suspect others have seen it too. I am heading into a position*

where we may have to suspend the contract if we have no assurance on viability – which may mean metaphorically (or maybe literally) donning some Kevlar hats and jackets."

17.23. In May 2018, the Chair of the National Maternity Review wrote to the NHS Chief Executive and the NHS England senior team summarising the One to One position. The letter was supportive of One to One and recognised their importance in delivering the continuity model. The letter stated that it was unfair to re-procure and sought the NHS Chief Executive's intervention and a solution due to the potential adverse impact on national strategy.

17.24. Several communications followed involving the Chief Nurse of NHS England, the Programme Director for the National Maternity Transformation Programme, the Chief Nurse of NHSE North and Wirral CCG. The outcome was to commission the Mersey Internal Audit Agency financial viability review; however, this report did not make any key recommendations beyond the need for the tariff system to be reviewed, which was already recognised. Following this, in October 2018 a briefing was produced for the NHS Chief Executive by the Director of Commissioning Operations for Cheshire and Merseyside.

17.25. One to One's actions led to heightened tensions as they were perceived by CCGs and NHSE regional team members as antagonistic and not contributing to a positive solution that commissioners had hoped to find. From 2018 onwards, no further proactive work was undertaken by commissioners with One to One to look at other solutions, as it appeared that relationships had been irreversibly damaged by this point.

17.26. On 15 March 2019, NHS England called an incident coordination meeting with the Cheshire and Merseyside CCGs in view of the business continuity risks involving One to One. It succinctly summarised the situation that: "*One to One had relationships with national leads who wanted the case loading model to succeed, however, when issues have arisen on tariff, this had been left to local commissioners to manage.*"

NHS England quality surveillance

17.27. Regional system oversight was put in place through a series of single item Quality Surveillance Meetings and formal Risk Summits. The detailed tables in Appendix 7 provide a record of the quality surveillance processes that were in place with One to One.

17.28. The Wirral CCG Contract Management Policy 2017/19 provides a description of the process for managing quality concerns. Although this postdates the Quality Surveillance Group (QSG) meetings and formal Risk Summit we have no reason to believe that the process in place at the time was any different.

17.29. The triggers for a single item QSG meeting are described as:

- lack of confidence in the provider's ability to improve;
- serious patient safety concerns;
- serious contract breaches/contractual notices;
- issues outside of the provider's control;
- persistent failures to meet CQC standards.

17.30. The triggers for a Risk Summit are described as:

- serious failings within the provider;
- a need to act rapidly to protect patients and/or staff;

- a single material event.

17.31. NHS England Cheshire and Merseyside triggered the QSG when safety concerns were raised with them about One to One by NHS providers. Concerns were also raised about One to One's use of non-contracted activity (NCA). It was appropriate for these concerns to trigger the single item QSG. This meeting collated information about One to One from a number of sources including commissioners, NHS Trusts and the CQC.

17.32. The findings from the single item QSG resulted in the Risk Summit process being initiated. While the circumstances did not meet the individual criteria described as triggers for the process, it was a reasonable course of action based on the cumulative issues and concerns about One to One being expressed across the North, not just within the Cheshire and Merseyside area.

17.33. Financial issues were not addressed as part of the heightened quality surveillance processes. In January 2015 it was proposed that a separate meeting be held to address these issues but there was no evidence that this meeting took place. The Risk Summit's understanding of the financial issues was unclear. The Risk Summits did not refer directly to the provider to provider charging issue and a letter purporting to address the financial issues appears to confuse the two issues of debt relating to NCA and debt relating to provider to provider charges. Financial concerns were not followed up by NHS Midlands and East when potential insolvency was identified in April 2016. In December 2016, when the Risk Summit was stepped down, it was stated that assurance had been gained on One to One's financial position. This was not credible, given the information available in their published accounts and given that the tariff issues had not been resolved. We noted that there was no financial representation as part of the Risk Summit.

NHS Improvement (formerly Monitor)

17.34. NHS Improvement (formerly Monitor) as the health sector regulator is responsible for promoting the interests of patients by ensuring the whole sector works effectively. Its key role is oversight of NHS Trusts and of independent sector providers through a provider licence. Other statutory duties include:

- setting prices for NHS-funded care;
- enabling integrated care;
- safeguarding patient choice and preventing anti-competitive behaviour which is against the interests of patients; and
- supporting commissioners to protect essential health care services for patients if a provider gets into financial difficulties.

17.35. Our observations regarding NHSI/Monitor's involvement with the One to One scenario in the context of these duties are set out below.

17.36. Monitor's provider licence requirements for non-NHS providers were introduced in April 2014[75]. One to One's level of turnover was below the threshold for the requirement to have a licence. This meant that One to One would not be subject to the additional financial oversight by Monitor imposed by licence conditions.

17.37. However, we noted that One to One's services for intrapartum care were stated as Essential Services (now called Commissioner Requested Services), in its contract which ran from November 2011 to March 2014. In subsequent contracts they were

[75] The new NHS provider licence (publishing.service.gov.uk)

not classified as such. Commissioner Requested Services require a provider licence.

17.38. Commissioner Requested Services[76] are those services which NHS England or CCGs consider would need to continue if a provider became financially unsustainable because removal of the services would cause harm to patients, and there are no alternative providers. Such services attract additional financial oversight by NHSI (and formerly by Monitor) who have powers to intervene if there are financial viability concerns to protect service continuity.

17.39. We were told that One to One did not hold a provider licence for Commissioner Requested Services. We found no evidence that One to One applied for a licence or that this was queried. Additionally, we found no evidence of debate on the change to the service status after March 2014.

17.40. One to One were therefore not subject to the 'continuity of service' conditions which required Monitor to assess the risks to service continuity should the provider get into financial difficulties and set out how the service would be protected.

17.41. We noted that, in November 2017, as part of the discussions on solutions to the challenges for One to One, NHSI considered adopting an Essential Services approach for financial oversight of One to One; this was not taken forward.

17.42. Monitor undertook a review of maternity tariff issues raised by commissioners and providers following its mandatory introduction and issued The Maternity Pathway Payment System: Supplementary Guidance, March 2014. This examined the provider to provider charges arrangements under the lead provider model and recommended that:

"*Where maternity care is routinely shared by two providers, the lead provider should establish a sub-contract between itself and the other provider*"

"*The prices payable [...] will be agreed between them, but NHS England has published non-mandatory episodic prices as a guide*".

17.43. The lack of financial agreements between NHS Trusts and One to One was contrary to this guidance but neither Monitor (nor subsequently NHSI) intervened to ensure this guidance was reasonably applied. The guidance remained in place during the lifetime of One to One.

17.44. There were several examples of Monitor/NHSI's direct involvement with One to One and attempts to address their concerns:

- One to One sought Monitor's support directly to investigate the problems with the tariff in September 2015. Monitor declined to intervene at this point.
- At the West Cheshire CCG contract meeting in May 2016, One to One advised that they had raised with Monitor the issue of cross-charging and the concern of collusion occurring between a neighbouring Trust and CCG. One to One stated: "*Monitor has agreed that the Trust's behaviour was inappropriate, although they will not commence an investigation into this issue as funding is not available to support a single investigation and that this issue is likely to be addressed once pioneers start to resolve payment issues.*" We were not able to substantiate this response from Monitor in the documentation provided for our review.
- NHSI intervened to encourage the NHS Trusts involved to come to a settlement with One to One over the winding-up petition in July 2016 to avoid legal action.

[76] 150319_DH_Licence_exemptions_guidance_for_providers_RD.pdf (publishing.service.gov.uk)

This intervention directly followed One to One's letter to the NHS Chief Executive in June 2016 (see paragraph 17.20).

- In 2017, NHSI's Choice Team led the work on developing a prime provider/sub-contracting model as a potential solution.
- In response to One to One's concerns, in October 2017, NHSI undertook an audit of provider to provider charges with a view to making recommendations on a payment mechanism to promote integrated care. There were some fundamental findings which demonstrated flaws in the system for provider to provider charging with One to One. The work recommended that a mechanism should be developed that more closely aligned tariffs to the costs of care. This was not progressed further at this time.
- In February 2018, One to One contacted NHSI to raise the issue that NHS Trusts on block contracts were potentially being paid twice for the same activity. NHSI advised that this was a local issue for CCGs to resolve.

Care Quality Commission (CQC)

17.45. One to One were registered with the Care Quality Commission (CQC) and subject to routine and unannounced inspections. From the information available on the CQC website, the locations registered are summarised below.

Table 14: CQC registration

Dates registered	Location	Inspected
Feb 2010 (archived Nov 2013)	Birkenhead Medical Building	Yes
Oct 2013 (archived Feb 2014)	Thursby House, Wirral	No
No information provided (archived Aug 2019)	Bidston and St James' Children's Centre, Wirral	Yes
Dec 2013 (archived Oct 2015)	Carlisle Business Centre, Bradford	Yes
July 2013 (archived Oct 2013)	Pall Mall Medical, Manchester	No
March 2015 (archived Aug 2017)	Abbey Field Medical Centre, Colchester	Yes

17.46. One to One's locations were registered to carry out the following regulated services:

- maternity and midwifery services;
- treatment of disease, disorder, or injury; and
- diagnostic and screening procedures.

17.47. Based on our understanding of the CQC's requirements for midwifery services, it appeared that One to One did not have appropriate registration for the first four months of the pilot. The requirements state that services by midwives are exempt if **all** the following circumstances are met:

- they are acting on their own behalf – self-employed rather than acting for a partnership or organisation;
- they are providing non-NHS care, not under contract for an NHS service; and
- they are providing services to their patients only in the patient's home – not as part of a hospital- or clinic-based service.

17.48. We were unable to establish through our interview with the CQC how One to One were initially assessed for registration.

17.49. In 2016, West Cheshire CCG highlighted a CQC registration issue and requested clarity on why Bidston and St James' Children's Centre was named in the report and not One to One Midwives Ltd. One to One confirmed that this was due to it being the registered address of the company. It was noted that Bidston and St James' Children's Centre is a separate organisation and that this could cause confusion as to which organisation had been inspected. The previous CQC inspection outcome had been misreported by the Liverpool Echo based on this confusion.

17.50. Each of the CQC inspection teams included an inspector with a background in maternity.

17.51. The two inspections completed in 2017 were at the One to One bases on the Wirral and in Essex. There were some members of the inspection teams common to both inspections. This allowed the teams to consider any commonality of issues and to view One to One as a whole.

17.52. The CQC inspections included speaking with women, their families and staff, looking at guidelines, case notes and audit reports, plus incidents, investigation reports and action plans.

17.53. The methodology used by the CQC changed in April 2015. Four inspections were completed using the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 methodology and five inspections using the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 methodology.

17.54. The reports prior to 2014 were brief; they identified that standards were met, with little narrative or identification of areas for improvement. With the change of methodology, the reports became more detailed and constructive from 2014 onwards, in identifying both areas of good practice and matters of concern.

17.55. The inspections from 2015 onwards asked five key questions about the service being inspected:

- Are they safe?
- Are they effective?
- Are they caring?
- Are they responsive to people's needs?
- Are they well led?

17.56. Each of these questions is answered in a narrative format. The report then goes on to identify actions in terms of 'must dos' and 'should dos' for the service to complete to address the issues identified.

17.57. The CQC did not rate One to One against each of these questions. We have been told that the rating of services came in over a period of time after the regulations were changed and as such were not applied to the One to One inspections.

17.58. The programme of inspections and a summary of key findings is shown in the detailed table in Appendix 8. There were nine inspections over the period from 2012 to 2017. Two inspections were undertaken at One to One's Wirral base at the Birkenhead Medical Building and four at Bidston and St James' Children's Centre. Two inspections were undertaken in Essex and one in Bradford.

17.59. The first two inspections completed by the CQC of the One to One service in the North did not identify any concerns. The remaining seven inspections and reports identified some key themes:

- documentation and record keeping;
- shared care pathways and communication with local NHS providers;
- governance;
- clinical risk management;
- policies and compliance with NICE guidance; and
- staffing issues.

17.60. It is to be noted that these themes can also be found in the serious incidents reported and investigated relating to care provided by One to One (see Section 7).

17.61. Documentation and recording keeping were identified in the inspections completed in November 2015, February 2016 and both inspections completed in 2017. A recurring theme was the discrepancies between handheld records and the electronic clinical records. Handheld notes were not comprehensive and not always contemporaneous. As a result, women could transfer to a local provider in an emergency with an incomplete clinical record.

17.62. Issues with governance were identified by all of the inspections. One to One was issued with a notice of breach of Regulation 10 following the inspection completed in 2014. The inspection identified several issues including poor attendance at meetings and a reporting structure that was not conducive to risks being shared with the senior leadership team and Board. It also described the poor management of audits. There were a number of planned audits overdue, it was difficult to see how the learning from audits was shared and there was no methodology for some audits.

17.63. There were also concerns about the reporting and investigation of serious incidents, and the sharing of learning across the organisation. Concerns about learning from incidents were a feature of the inspections completed in Essex in February 2016 and the Wirral in January 2017.

17.64. Several CQC reports identified that One to One's management of its risk register was poor, with action plans not being reviewed and revised even when a risk had been escalated to high.

17.65. The CQC expressed concerns about One to One's management of clinical risk, especially for women with high-risk pregnancies. The Wirral inspection in November/December 2015 did not gain assurance on this. The CQC required assurance that all women received care and support from the professionals qualified to provide best practice. The inspection completed in Essex in February 2016 reviewed seven risk assessments completed by One to One and concluded that six of them were not sufficiently detailed or clear. A breach of Regulation 12 was also identified because there had not been an appropriate escalation of risk for women with complex social histories. There remained concerns about the management of risk and in 2017 the Wirral inspection identified that One to One needed to ensure continued compliance with Regulation 12.

17.66. Inspections completed in June 2014, April 2015, February 2016 and January 2017 identified that One to One did not have up-to-date policies that were compliant with best practice and NICE guidance. In 2014 the CQC were concerned that One to One was not following NICE guidance. Concerns remained in January 2017.

17.67. The CQC identified several issues and challenges relating to One to One and staffing:

- The inspection in November 2015 identified that concerns remained about how well high-risk pregnancies were monitored during pregnancy because staff stated they had not received specialist training to support women with underlying conditions such as epilepsy and diabetes. This was echoed in the February 2016 inspection. The January 2017 inspection also found the need for additional training for midwives on the care of women with complex obstetric and medical conditions.
- The inspections in April 2015 and February 2016 identified issues with midwives acting outside of or deviating from their scope of practice.
- In April 2015 midwives described to the CQC the challenges of working within this model of care and suggested that they did not believe it was sustainable. The February 2016 inspection questioned whether One to One Midwives was in breach of the European Working Time Directive. The report completed in January 2017 highlighted the need to monitor and review the working hours of midwives when attending a home birth.
- The inspections completed in January 2017 highlighted the need for all One to One staff to complete annual mandatory training and have annual appraisals. The Essex inspection also expressed concern about the lack of a registered manager and clinical manager on site to support the staff. Concerns were expressed about the culture of the team in Essex.

17.68. One to One described regular meetings with an officer from the CQC but notes pertaining to these meetings were not available to the review. One to One staff described the relationship with the CQC as good and collaborative, with safety a priority.

17.69. Although the CQC visits were frequent and the reports clearly set out concerns and identified areas for improvement, we have not been able to identify how the actions required following each inspection were tested by the next inspection. The CQC advised that inspection reports were not the only method used to follow up concerns raised during inspections. Evidence of other meetings between the CQC and One to One was not shared with this review.

17.70. We had access to a limited number of action plans developed based on CQC reports. The two action plans reviewed were for the North East Essex service. There is no assurance provided on the completion of each action or how it was embedded into practice. The tone of the responses from One to One to some of the issues raised is that of exasperation. Frustration is clearly expressed in some of the communications between One to One and commissioners about aspects they feel were overlooked by the inspection team.

17.71. Follow up on highlighted issues was absent from subsequent inspections. Some examples were:

- An inspection in April 2015 identified that One to One did not hold a Home Office licence to hold pethidine. This resulted in the withdrawal of offering this means of analgesia to women giving birth at home. A subsequent report noted that GPs were prescribing pethidine, but midwives were failing to ensure appropriate means of disposal were in place. This may have been included in an action plan, but this was not shared with us, and the subsequent inspection did not address this issue. The NICE guidance on intrapartum care (2014) states "*Ensure pethidine, diamorphine or other opioids are available in all birth settings.*"

- The Desk Top Review of One to One in February 2015 identified several actions arising from findings. In a letter to the Chief Executive in March 2015 the Chief Nurse of NHSE North stated that the quality assurance review did not find significant assurance that the concerns raised at the outset of the process were being mitigated; such as the failure to ensure adequate communication with hospital services or compliance with NICE guidance. The Chief Nurse NHSE North wrote that the CQC had indicated that they would undertake a comprehensive review under the new inspection methodology in Quarter 2 of 2015/16 and that the quality summit convened at the end of this inspection would allow judgement regarding assurance to be made. The Risk Summit was stepped back to be replaced by heightened surveillance by the CCGs and Quality Surveillance Group arrangements. In the Desk Top Review, governance arrangements were identified as requiring additional evidence, particularly in terms of structure and a claims policy. Neither were identified as followed up in the CQC inspection of April 2015.
- In the inspection of June 2014, several issues were noted, such as the lack of adequate information about possible complications of home birth, that an updated policy for Serious Incidents was due before the end of June 2014 and that the complaints policy gave inaccurate information on who to contact. None of these issues were followed up at the next inspection in February 2015. The inspection report noted that governance systems were inadequate and was an outstanding action.

17.72. In the absence of documentary evidence of other methods used by the CQC to seek assurance about how One to One had addressed the concerns from previous inspections, we conclude that the CQC's oversight of One to One lacked rigour. Most of the inspections completed were reactive, as a result of concerns expressed either by local providers or by the regional teams of NHS England. The reports that we have reviewed do not demonstrate any 'follow through' on the findings from previous reports, review of resultant action plans or evidence that findings had been addressed. At the very least, we would have expected to see reference to the progress that One to One made to resolve issues identified as regulatory breaches.

17.73. The CQC was involved in regional quality surveillance through the Risk Summits and the NHS England Midlands and East 'Information Gathering Meetings'. They responded to the concerns raised by NHS England Midlands and East by completing an inspection in North East Essex. However, in the main their role was advisory, and there was no documentary evidence that the CQC acted as a result of their involvement in the meetings.

17.74. There was a missed opportunity to compare the themes emerging from CQC inspections with the themes from serious incidents. Had this been completed, the system would have been aware that there were reoccurring themes that were not being effectively addressed by One to One or commissioners.

17.75. The CQC has always been required to consider financial viability issues under Regulation 13[77] as part of the registration of providers, but there has been a recognised lack of clarity on how this aspect was assessed. The regulation requires that:

"*the service provider must take all reasonable steps to carry on the regulated activity in such a manner as to ensure the financial viability of the carrying on of that activity.*"

[77] Regulation 13: Financial position | Care Quality Commission (cqc.org.uk)

"*The provider must have the financial resources needed to provide and continue to provide the services as described in the statement of purpose to the required standards.*"

17.76. The CQC has powers to refuse registration and take enforcement action for continuing failure to meet this requirement.

17.77. We were unable to establish through our discussions with the CQC how One to One had been evaluated and the evidence provided as part of their initial registration and subsequent registration of new locations. We are unable therefore to conclude on the robustness of the CQC's approach at registration. In addition, we did not see any documentary evidence that the CQC pursued the financial viability concerns as part of its inspection programme with One to One.

17.78. In February 2018, the CQCs clarified their requirements in terms of the evidence to be provided relating to financial viability[78]. This requires a statement of assurance from an accredited financial specialist such as an accountancy firm or bank as to whether the provider is able to operate the proposed service to the required fundamental standards in a way that ensures it is financially viable. This requirement applies to existing providers seeking to make changes to their registration or when the CQC has intelligence that suggests that a provider does not have the required financial standing. The CQC referred to a letter sent to One to One in March 2018; however, this was not provided to the review. We did not therefore see documentary evidence that the CQC used these new powers to assess One to One when there was clear system intelligence of financial issues; we were told that the CQC had been aware of these for several years.

17.79. The CQC were involved in the conversations in 2018 about the financial stability of One to One and options to address this issue. In May 2018, the CQC concluded that at that stage, they were not aware of any concerns regarding patient safety and therefore were unable to take any further action. We would question this conclusion as One to One's worsening financial position did have significant potential to adversely impact clinical care.

Local Maternity Systems

17.80. Local Maternity Systems (LMS), partnerships of commissioners, providers and other stakeholders, are tasked with the operational delivery of the workstreams under the National Maternity Transformation Programme with oversight by a National Transformation Board.

17.81. Before 2016, arrangements for oversight of transformational change in maternity services were less clear. In 2014, the House of Commons Committee of Public Accounts published a review of maternity services[79] which found serious shortcomings in the oversight of implementation of the national strategy and the need to develop Local Maternity Systems.

17.82. The Cheshire and Merseyside (C&M) Women and Children's Partnership was the LMS for the region. One to One were engaged with the C&M Partnership as they were a key contributor to the delivery of the workstream for 'continuity of care'. One to One were able to discuss their service developments in this forum, including the proposals developed for joint working with local Trusts.

17.83. Initially the C&M Partnership was supportive of One to One in facilitating their involvement in the system. However, One to One persistently challenged decisions made by the Partnership, for example, the award of the pilot for personal maternity

[78] https://www.cqc.org.uk/news/providers/new-guidance-assessing-financial-viability-providers-applying-registration
[79] https://publications.parliament.uk/pa/cm201314/cmselect/cmpubacc/776/776.pdf

care budgets to a local NHS provider in 2017 and the use of community hubs in 2018. One to One felt that they were being deliberately excluded from developments which would impact on their sustainability as a business.

17.84. In September 2017, One to One expressed serious concerns to the C&M Partnership about barriers to collaborative working by local Trusts. One to One felt these issues needed escalating to a national level: "*Women are being denied care, choice of provider, and frightened into transferring their care. Trying to establish shared governance pathways is almost impossible, while the Trust representatives say the right words at MDT/CCG meetings and agree to work in partnership, in reality it's not happening. My concerns also extend to our midwives as they face unprofessional behaviour interacting with trusts. Some midwives feel very intimidated and may be reluctant to accompany their women not only for antenatal consultations but when transferring care for clinical concerns.*"

17.85. Partnership representatives became increasingly frustrated with One to One's behaviours as they continued to escalate their issues directly to senior figures at a national level; relationships deteriorated significantly as a result. The Partnership itself expressed concern at the reputational damage One to One might cause due to their communications directly to a national level. Their concerns were expressed as follows: "*But what I also think we should be frank about is how much we have tried to help One to One but that they have caused so much trouble we don't have the time, energy or resource to continue engaging with them.*"

17.86. These issues were escalated to the Chief Officer of Wirral CCG and NHSE's Chief Nurse for C&M. We did not find evidence of any further actions taken to investigate these concerns or who took responsibility for this.

17.87. In North East Essex, One to One were a member of the LMS Board overseeing the programme of work to deliver the national programme. One to One remained an integral part of the plans and led on the continuity of care workstream jointly with the local acute Trust, Colchester Hospital University Foundation Trust. However, in 2017, One to One expressed concern about the lack of momentum in the LMS in Essex.

Strategic Clinical Network

17.88. One to One reported intrauterine deaths and stillbirths to the North West Coast Strategic Clinical Network (the 'Network') as part of the Quality Improvement Programme for Maternity and Perinatal Mental Health. This network was a voluntary group, intended to share learning and to support provider reviews of services to look for trends and themes from which learning could then be shared across the Network. Maternity providers reported perinatal deaths to the Network using the Perinatal Mortality Review Tool.

17.89. As with serious incidents, it was a challenge to identify intrauterine deaths and stillbirths reported that involved an element of care provided by One to One. In November 2018 the MBRRACE-UK[80] Project Team Leader responded to a query from the Network regarding the reporting of deaths. They stated that "*perinatal deaths where the baby was delivered under the care of One to One are reported to us under an arrangement between them and the local hospitals. These deaths are attributed to One to One, not the reporting trust […]. ALL perinatal deaths are reported by care provider at the time of delivery, regardless of who delivered the antenatal care, or where the baby died.*"

[80] MBRRACE-UK: Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries. https://www.npeu.ox.ac.uk/mbrrace-uk

17.90. As we have previously identified, reporting protocols recorded an incident against the provider at which the woman gave birth. The calculation of the stillbirth rate reported in the dashboard therefore only reflected births carried out by One to One, in other words, home births. It did not include births for women receiving antenatal care from One to One and who subsequently gave birth with another provider. Intrauterine deaths and neonatal deaths following a transfer of care to an NHS Trust were recorded against the NHS provider.

17.91. The Network reported challenges with One to One and some other providers about the reliability of the data being submitted to them. They sought to understand the full picture and bring together the stillbirths reported by One to One and those reported by NHS Trusts where a woman had been transferred to their care by One to One, usually in labour.

17.92. In the period from May 2017 to April 2018 One to One reported to the Network 498 births with a 2.51% stillbirth rate (12 stillbirths). However, between January to December 2018, One to One reported 273 births with three stillbirths, a 10.99% stillbirth rate. This compared with an average of 7.06% across the Lancashire and South Cumbria region and 5.64% across the C&M region. Using a percentage metric on small absolute numbers meant that the stillbirth rate for One to One was not meaningful or comparable to benchmarks. The relevance of this metric was therefore doubtful given that One to One's annual reported birth rate to the Network in the calendar year 2018 was approximately 10% or less of any of the NHS providers. This is another example of a national metric not being suited to a small provider.

17.93. Concerns regarding the lack of scrutiny on care provided by One to One where an intrauterine death or neonatal death ultimately occurred were raised by a user representative to the Network. At this time the maternity dashboard for the Network showed One to One as having a 7.44% stillbirth rate per 1,000 births.

17.94. In addition to reviewing data from providers about the birth rates and stillbirths, the Network also received learning templates from maternity providers. These standard templates were completed by maternity providers and shared with the Network and Maternity Clinical Experts Group to support providers to reflect on the learning and change their practice accordingly.

17.95. In January 2019 the Network received two learning templates from Wirral with similar themes around communication and transfer of care by One to One midwives to NHS Trusts.

17.96. Concerns were raised by a Network representative that NHS Trust stillbirth and 'cooled baby'[81] statistics did not identify if the antenatal care had been given by another provider. They queried how outcomes of other providers were monitored.

17.97. In response to the concerns raised by the Network about One to One's stillbirth rate, the Director of Nursing for NHS England in Cheshire and Merseyside requested an explanation of the workings behind the figures. Following this they wrote to Wirral and West Cheshire CCGs to request a discussion to explore the concerns raised in more detail.

17.98. A summary of serious incidents involving care provided by One to One between January 2017 and January 2019 was compiled by Wirral CCG in a report to support this call. Twelve serious incidents had been reported – nine by One to One and three by NHS Trusts. Eleven were maternity/obstetric incidents that met the serious

[81] https://www.nice.org.uk/guidance/ipg347/resources/controlled-cooling-to-treat-newborn-babies-with-brain-injury-caused-by-oxygen-shortage-during-birth-pdf-314509357

incident criteria for baby only and one related to both mother and baby. Eight had resulted in the unexpected or potentially avoidable death of a baby. Three resulted in unexpected/unavoidable injury causing serious harm. One related to an unexpected/potentially avoidable injury requiring treatment to prevent death or serious harm. The reports reviewed identified the following:

- Five highlighted communication between One to One and the NHS Trust as a contributing factor to the incident. Recommendations were made to improve communication.
- Two highlighted sub-standard documentation which adversely impacted on outcomes and gaps in care.
- One identified issues with the internal escalation processes to the senior team within One to One.
- Two referred to weaknesses in external escalation processes between the ambulance service and the NHS Trust emergency team.
- Issues with the triage system used by One to One were referred to in two cases.
- There was a reference to organisational policies and procedures not being followed. It was unclear whether this was with reference to One to One, NHS Trusts or both.

17.99. The report contained a detailed table of the incidents. When cross-referenced with incidents seen by the review team, there are three which had not been reported elsewhere, including a neonatal death, a poor outcome and an admission to a neonatal unit.

17.100. At the follow-up meeting between the NHS England's Director of Nursing for Cheshire and Merseyside and the Wirral CCG Quality Team, several actions were agreed. These included a requirement for the CCGs to check StEIS[82] for further incidents and a request to all maternity providers for up-to-date information on stillbirths to January 2019. Wirral CCG were to complete a review of the three stillbirths to determine the context of the deaths, the learning and if there was any cause for concern about the clinical care provided by One to One. A follow-up meeting was scheduled.

17.101. In February 2019 the Network referenced that Saving Babies' Lives Version 2[83] was imminent and requested data (for April 2018 to January 2019) relating to:

- registerable births per calendar month;
- stillbirths after 24 weeks' gestation;
- stillbirths that occurred at or after 37 weeks' gestation; and
- intrapartum stillbirths that occurred at any point of gestation.

17.102. One to One had already provided data up to June 2018. One to One informed the Network that the data was not "*working its way through the Maternity Dashboard hence my informatics lead has nothing to pull*". A dashboard working group was being established to address the issue in due course.

17.103. No further action was taken about this before One to One ceased trading in July 2019.

[82] Strategic Executive Information System (StEIS) A system which enables electronic logging, tracking and reporting of Serious Incidents between Trusts and Commissioners
[83] https://www.england.nhs.uk/wp-content/uploads/2019/03/Saving-Babies-Lives-Care-Bundle-Version-Two-Updated-Final-Version.pdf

Local Supervising Authority (LSA)

17.104. Local Supervisory Authorities (LSAs) were responsible for ensuring that the statutory supervision of midwives was undertaken according to standards set by the Nursing and Midwifery Council (NMC).[84] [85] LSAs were established in each geographic region. Each LSA had a Midwifery Officer (LSAMO) to oversee the supervision of midwives and ensure that any concerns related to midwifery practice were fully investigated.

17.105. The role of the LSAMO was to carry out the functions of the LSA and to develop an audit standard of supervision within the LSA boundary. They reported to the NMC and did not represent the interests of the CCGs or providers of maternity services. Locally the LSAMO reported to the Regional Director of Nursing. The LSAMO could suspend a midwife from practice in situations of concern. The LSAMO was required to submit an annual report to the NMC on the activity within their LSA which included numbers of Supervisors of Midwives, incidents investigated and referrals to Fitness to Practice.

17.106. Supervision of midwives was a statutory role and all maternity services, including One to One, had Supervisors of Midwives (SoMs) to support midwives and women. The aim was to have a ratio of one SoM to 15 midwives with at least one annual meeting between each midwife and the SoM. SoMs also had a role in investigating serious incidents and to determine whether action was required, for example, further training, or whether fitness to practice was a matter of concern.

17.107. In 2012, the NMC revised its Midwives Rules and standards for midwives with a view to mitigating the risks inherent in the LSAMO's dual role for support as well as regulation. It strengthened the requirements on the LSA to investigate, report and share information on incidents and complaints.

17.108. A report was produced by the Parliamentary and Health Services Ombudsman in December 2013[86] following an investigation into maternity incidents at University Hospitals of Morecambe Bay NHS Foundation Trust. This highlighted the deficiencies and perceived conflicts in the arrangements for midwifery supervision and regulation at a local level to identify poor midwifery practice. The report recommended that midwifery supervision and regulation should be separated and that the NMC should be in direct control of regulatory activity. These recommendations were reaffirmed by a further review by the Kings Fund in 2015[87] which highlighted the need for providers of midwifery services to ensure the right clinical governance processes are in place.

17.109. The Morecambe Bay Investigation of 2015[88] found that "the Local Supervising Authority system for midwives was ineffectual at detecting manifest problems, not only in individual failures of care but also with the systems to investigate them."

17.110. The associated recommendations were approved in a policy document by the Department of Health and Social Care in January 2016. Legislative changes were required, and a task force set up to progress this. In April 2017 a new model of clinical supervision was unveiled by the Chief Nursing Officer for England. The model is known as A-EQUIP which stands for advocating and educating for quality

[84] https://www.england.nhs.uk/wp-content/uploads/2016/03/lsa-midwfry-sprvsion-sngl-operatin-mod.pdf
[85] https://www.nmc.org.uk/
[86] https://www.ombudsman.org.uk/sites/default/files/Midwifery%20supervision%20and%20regulation_%20recommendations%20for%20change.pdf
[87] https://www.kingsfund.org.uk/blog/2015/02/making-sure-health-professionals-are-supported-untangling-supervision-and-regulation
[88] The Report of the Morecambe Bay Investigation (publishing.service.gov.uk)

improvement. Seven pilot sites were established to begin training midwives as Professional Midwifery Advocates (PMAs) who are employed by maternity services to offer support and guidance to midwives, with a ratio of up to 20 per PMA. One to One were one of the pilot sites, although the review has seen limited information pertaining to how this worked in practice.

17.111. During the years up to 31 March 2017 when LSAs were disbanded, there was evidence of the LSAMO's involvement with One to One through the annual audit reports:

- In August 2012, One to One met with the North West LSAMO to discuss the issues around joint working and professional conduct, following the letter sent to the LSAMO by members of the obstetric team at Wirral University Teaching Hospital raising their safety concerns. One to One raised the issue of bullying behaviour from local NHS maternity providers. The LSAMO had no concerns at this time on safety and had been involved in a recent review of 18 cases undertaken by Wirral PCT. The LSAMO advised that any issues would be picked up by the annual midwifery audit in November 2012.
- We found no evidence of a formal complaint or allegation of bullying by One to One regarding these criticisms and it is unclear whether there was further discussion or follow-up by the LSAMO.
- The LSAMO provided feedback to the Quality Surveillance Group meetings in 2014 and were involved in the Risk Summits. The LSAMO reported that they had completed an audit in November 2014 which showed that all LSA standards were being met.
- In 2015, the LSA identified several issues with the care being provided to women. Five midwives had left One to One without working their notice. The LSA had been notified of six incidents. Investigations were being completed into two of these. A theme was that inexperienced midwives were not calling for help in a timely manner. The opinion was that under the LSA's decision tool framework, the level of incidents was high given the small caseloads. The CQC was not aware of the incidents discussed and these should have been reported to them. One to One commented that they would be challenging aspects of this, as they were being treated inappropriately as an NHS acute Trust. The LSAMO UK Forum had determined that consistent use of a decision tool would lead to efficiency as smaller issues that did not require a full investigation could be exposed at an early stage and addressed. Its use was encouraged to help the SoM to assess whether the midwife followed professional standards of practice and would lead to shared learning even in cases where no action was required.
- A CQC report published in April 2015 referenced the LSAMO's concerns about newly qualified midwives being expected to work alone. A recommendation was that One to One should work closely with the LSAMO regarding the number of supervision investigations and practice reviews being triggered at the time.
- One to One met with the Chief Nurse NHSE North and the Local Supervising Authority Midwifery Officer (LSAMO) in May 2015 to discuss the Risk Summit process and to follow up on concerns around scope of practice and adherence to NICE guidance. The LSAMO had started working with One to One to review care pathways for high-risk women and to ensure learning from incidents was embedded within midwifery practice. The Desk Top Review team included one LSAMO.
- In June 2015, One to One reported positive feedback following an LSA visit. An area of challenge was supervision numbers; One to One had three supervisors but the ratio of SoM to midwives was unclear as staffing numbers were not

provided at this time. The LSA was to investigate a cross-regional role. One to One were considering a full-time supervisor rather than several midwives undertaking the role. Supervisors were not remunerated for taking on the additional responsibilities of the role other than to have dedicated time. Resources to provide supervision may have been a challenge for One to One due to the size of their operation; however, this was not substantiated in One to One's description of their model in February 2014. This stated that One to One had a ratio of 1:9 (SoM to midwives); this compared favourably with the recommended LSA ratio of 1:15.

- We found no further references to the involvement of the LSAMO in the documentation provided for our review after this date.

Other maternity services stakeholders

17.112. We were provided with feedback from the women who were members of the Maternity Services Liaison Committee (MSLC) in Bradford and Airedale, to support this review. The intention of this forum was to bring together health care professionals, commissioners and the women who used the service, to help shape the maternity care provided for them, during the implementation of Changing Childbirth.

17.113. One to One was providing a service in the Bradford and Airedale area under non-contracted activity. The women in the area advocated and campaigned loudly for One to One to be given a contract to continue to provide this service. They described experiencing considerable resistance from the local CCGs and Trusts. The CCGs chose not to contract with One to One.

17.114. A strong view was expressed by a former member of the MSLC that One to One had been subject to unfair treatment and a disproportionate level of system scrutiny. This had resulted in the service not being commissioned and available to women in Yorkshire. Their view was that much of the enhanced scrutiny was due to unfounded concerns expressed to commissioners and regulators in a deliberate attempt to undermine the One to One model. This was because One to One were a "*disrupter*" in an established NHS provider market and a threat to the stability of the established NHS providers of maternity services. This created a real dichotomy as women wanted to access this new service, but they were prevented from doing so due to what was essentially viewed as NHS protectionism.

Summary points

17.115. System oversight presented a complex landscape, the component parts of which were not always aligned. It was fragmented and difficult for any individual part of the system to gain a single view of One to One and therefore be assured on the safety of their services. System oversight was also weakened by the lack of structured, proactive oversight of quality and safety at a local level through CCGs and sub-regional groups.

17.116. System oversight was fragmented despite the national profile of this service. There was no clear route for accountability and oversight of this new model from local commissioners and local maternity systems through to NHS England at a regional level and the National Maternity Transformation Board.

17.117. Relationships were not continuous as there were many changes to NHS structures over this period.

17.118. Some CCGs felt somewhat constrained in the influence they could have over NHS Trusts and were therefore reluctant to get involved in the relationships between One to One and NHS providers. Notwithstanding formal structural accountabilities and responsibilities, there was a reasonable justification for commissioners to act

decisively on these risks well before the implementation of the larger co-commissioned contract in 2016.

17.119. There was an absence of prompt intervention on the risk factors relating to One to One at system level. As the core issues of shared care agreements and tariff barriers were not resolved, relationships were irreversibly damaged and One to One's financial position became irrecoverable.

17.120. It was important to commissioners for the One to One model to succeed to offer more choice in maternity services. There were clear efforts and positive collaboration at all levels of the system to support One to One, but proposed solutions were not able to be implemented due to the risks perceived by NHS Trusts and were developed too late to provide resolution. The audit undertaken by NHSI was an important piece of work which was not acted upon.

17.121. There was an acknowledgement in the system that the One to One model was unworkable. One to One had national attention and direct relationships with key influential figures involved in the National Maternity Review. One to One directly escalated their concerns and allegations about unfair treatment to senior levels. One to One's actions led to heightened tensions as they were perceived by local teams as antagonistic and not contributing to a positive resolution of the issues.

17.122. The Risk Summits were initiated due to concerns about quality and safety. These issues were side-lined due to a focus on contractual issues. Consideration and assessment of the quality and safety issues was addressed through the completion of a Quality Risk Profile Tool. This tool was completed twice in October and November 2015 but was not reviewed prior to One to One being stepped down from the Risk Summit process in December 2016.

17.123. The Quality Risk Profile Tool offered a structured mechanism for self-assessment against key safety and quality criteria. This was not used on an ongoing basis and was a missed opportunity to provide core assurance to commissioners and the CQC. Although One to One were described as being under 'enhanced surveillance', it was not clear what additional surveillance was being undertaken.

17.124. Financial issues were not addressed as part of the heightened quality surveillance processes. This was a weakness as the financial issues were inextricably linked to whether One to One were able to provide safe, high quality services. There was no financial representation at the Risk Summit meetings. The CQC did not use their powers to assess the financial viability of One to One when there had been clear system intelligence of financial issues for several years.

17.125. There were various allegations by One to One of organisational bullying and intimidation. These allegations were made at contract meetings and as part of the Risk Summit process, and were raised with the LSAMO, and through a formal complaint in 2016 to NHS England Midlands and East, and to the NHS England National Team. We would have expected to see a coordinated approach to the management of these allegations.

17.126. One to One did not hold a provider licence; although exempt from licence conditions on the basis of size, there was evidence of uncertainty as to whether their intrapartum care should be classified as a Commissioner Requested Service. This was suggested again by NHSI in 2017. Their services were classified as such in the contract from 2011 to 2014 and therefore a licence should have been in place. This was a missed opportunity to enhance the financial oversight of One to One at an early stage.

17.127. The lack of financial agreements between NHS Trusts and One to One was contrary to Monitor guidance but neither Monitor (nor subsequently NHSI)

intervened to ensure their guidance was reasonably applied. The NHSI audit of provider to provider charges in late 2017 made recommendations for a different payment mechanism to be applied for the One to One scenario but this was not progressed further at the time.

17.128. The CQC had not completed an inspection of One to One since January 2017 and it would have been prudent for an inspection to be completed, to provide assurance that safety was not being compromised.

17.129. The CQC provided information to and attended the QSGs, Risk Summits and Information Gathering Meetings. Furthermore, they were party to the conversations with NHS England North and commissioners about One to One in 2018.

17.130. The CQC identified some reoccurring themes in the inspections they completed. The repeated identification of themes indicates that when an inspection was carried out, inspectors did not receive assurance about actions taken to address concerns from previous inspections. The CQC advised that inspection reports were not the only method used to follow up concerns raised during inspections. Evidence of other meetings between the CQC and One to One was not shared with this review.

17.131. There was a lack of commissioner oversight of the action plans developed by One to One to address the issues identified in the CQC inspection reports. Although action plans were discussed at some contract meetings, we have not seen a systematic approach to this.

17.132. There is no evidence available to this review that suggests that where One to One were found to be in breach of regulations, the next inspection reviewed any actions taken by One to One with regard to this.

17.133. The role of Local Maternity Systems in the oversight of delivery of the Maternity Transformation Programme has recently been strengthened. Before 2016, arrangements for oversight of transformational change in maternity services were less clear. One to One were engaged with the Local Maternity Systems in view of their contribution to the development of maternity services locally. However, relationships deteriorated significantly as One to One escalated their particular issues directly to senior levels.

17.134. One to One were operating at a time when the role of the LSA was under significant scrutiny and the findings of various reviews found deficiencies in the arrangements and risks that safety concerns would not be identified through these processes. However, the LSAMOs worked consistently alongside stakeholders as part of quality surveillance processes and there was clear evidence of support provided to One to One. Generally, there were no significant concerns recorded by the LSAMOs until March 2015.

17.135. Perinatal loss data and benchmarking was not reliable. One to One understood their perinatal death rate to be low compared to the national average, but we are unable to confirm this as calculation methodology does not take account of all births where One to One provided an element of care. One to One confirmed that once a woman was admitted to an NHS Trust, their ability to participate in her care-giving was limited and they could not provide information on clinical decision-making by the NHS Trusts to whom women transferred. Equally, staff from the NHS Trust teams expressed concern that their statistics were negatively impacted by sub-optimal care by One to One that was beyond their influence. Efforts to resolve this through improved communication were constantly at an impasse.

What could have been done differently?

- Testing should have been undertaken of the case loading model with shared care arrangements between NHS and independent providers, as part of a design and feasibility stage to the development of national policy before commitments were made to implementation. This would have assisted in building a common understanding, between policy leaders and local NHS teams tasked with implementation, of the challenges to be overcome.
- The coordination of intelligence across the fragmented area over which One to One operated should have been prioritised. This could have been achieved by the better application of the quality surveillance processes.
- Financial considerations should have been considered alongside safety and quality issues as part of enhanced quality surveillance processes. It would have been prudent to include senior finance representation at Risk Summit meetings.
- It would have been prudent for NHS England North to have required the Quality Risk Profile Tool to be reviewed prior to stepping down One to One from the Risk Summit process.
- The Quality Risk Profile Tool should have been used on an ongoing basis following its introduction in 2015 as a structured approach for internal and external assurance on safety and quality. It would also have been reasonable to expect NHS England at a local level to have continued to review the quality of One to One's service through the annual completion of the Quality Risk Profile Tool, to provide assurance that the quality issues were being resolved and that there were controls in place to reduce the risk of repeated occurrence.
- Oversight of the bullying allegations by One to One should have been coordinated through the Risk Summit process and quality governance processes.
- CQC oversight could have been enhanced, particularly by clearly articulating the actions taken by One to One to address the issues identified in previous inspections. The CQC should also have considered an inspection of One to One in the North in early 2018.
- More effective monitoring of the action plans from the CQC inspections should have been undertaken at contract monitoring meetings.
- NHS England, the CQC and commissioners should have focussed more on obtaining substantive evidence of actions taken by One to One, with less reliance on verbal assurance.
- A robust review of One to One's policies against national guidance and best practice should have been undertaken by commissioners, with independent expertise as required.
- The methodology for benchmarking stillbirth rates should have been challenged and an alternative approach developed to take into account shared care arrangements.

Recommendations

1. For further innovative developments in maternity services, testing should be undertaken at a design and feasibility stage before commitments are made to implementation. This would assist in building a common understanding, between policy leaders and local NHS teams tasked with implementation, of the challenges to be overcome.
2. Where financial challenges are identified during the quality surveillance and Risk Summit processes, consideration should be given to appropriate financial representation in the meetings; this is important as safety and quality considerations are often inextricably linked to financial challenges.
3. The Care Quality Commission should review its approach to consider the impact financial instability might have on a small company's ability to provide safe care.
4. The Care Quality Commission should consider how they publicly share information about actions taken to address any issues from previous regulation activity, ensuring this is easy to understand, accessible and provides evidence of how they have held organisations to account for people's care. Regional teams of NHSE/I (and their successor body) should ensure that a clear description of the Quality Surveillance Group and Risk Summit processes is shared with providers who are subject to them. This information should include the triggers for each level of surveillance.
5. Regional teams of NHSE/I (and their successor body) should review processes and timescales for Quality Surveillance Group and Risk Summit processes, to ensure that they are transparent and that agendas are shared in advance so that providers are aware of the issues to be discussed and have sufficient time to prepare for the meetings.
6. Commissioners should consider the use of tools such as the Quality Risk Profile Tool for independent sector providers, particularly start-up businesses whose arrangements do not mirror those of NHS providers. This should be undertaken as part of a periodic (annual or six-monthly) assurance process for an appropriate period until sufficient assurance is gained through routine monitoring mechanisms.
7. A robust methodology for determining the stillbirth rate by provider needs to be developed that takes into account shared care arrangements between providers of maternity care.

18. Service cessation

Introduction

18.1. In this section, we summarise the impact of the cessation of the One to One service in terms of operational management and estimated financial exposure and remedial costs.

18.2. We have presented as a summary diagram the key factors which contributed to the service cessation, based on the findings of our review.

Key findings

18.3. Following notice of One to One's intention to cease trading on 31 July 2019, incident management plans were implemented to manage the safe transfer of women to the care of local NHS acute providers. Contingency plans for this eventuality had been developed over the previous months due to growing concerns about financial viability. Implementation of the plan was coordinated centrally from Arrowe Park Hospital (WUTH) for women in Cheshire and Merseyside as well as in North East Essex. The plan was successfully implemented and the incident response closed within two weeks on 14 August 2019.

18.4. The main activities and issues involved in transferring the care of women were as follows:

- contacting women under the care of One to One; more than 1,800 women were identified, contacted and provided with an alternative provider;
- triage of women to ensure any clinical or safeguarding cases were prioritised; an NHS England debriefing document of October 2019 noted that a significant amount of work was involved in checking safeguarding cases as One to One's system was not up to date;
- setting up communication and referral arrangements, including a dedicated Helpline; women had to be rebooked as there was no access to One to One's electronic records and scans;
- determining workforce capacity within NHS providers to deal with the increased workload and additional funding;
- ensuring that clinical waste and medications had been removed from clinic sites;
- management of outstanding incidents and complaints; and
- communication with other stakeholders and the media.

18.5. The following table provides an estimate of the total costs to the NHS system of the service cessation, based on information provided for the review; we estimate a maximum exposure of up to £3.4m in terms of financial impact.

Table 15: Estimate of remedial costs to the NHS

Cost category	£
NHS Trust Creditors	2,415,864
Additional contract payment to WUTH	300,000
NHSLA insurance premiums unpaid	376,928
Wirral CCG - advance payments not recoverable	36,172
Cheshire & Merseyside - transfers to other providers	279,203
Helpline	15,490
Records storage	2,122
Total	**3,425,779**

18.6. 71% of the total cost relates to NHS Trust creditors for provider to provider charges as per the Administrator's Report of February 2020. The total exposure needs to be considered in the context of the following points:

- A significant proportion of this debt was disputed by One to One and it is therefore uncertain how much of this debt would be validated. However, it remains a financial exposure to NHS Trusts on the assumption that this has been accounted for in their income and has not been written off.
- At least one Trust we spoke to wrote off provider to provider debt in previous years, so the creditor figure is understated in this regard.
- A Wirral CCG Board paper of February 2020 indicated that an additional payment of £300k would be paid to WUTH for the additional activity resulting in 2019/20. We did not receive any information regarding additional contract payments to other providers being required. This may be due to block contracts being in place.
- Some NHS Trusts provided an updated analysis of the debt; taken together, this would add an additional £122k to the analysis above.
- East Suffolk and North Essex NHS Foundation Trust (incorporating the former Colchester Hospital University NHS Foundation Trust) did not process invoices to the value of £116k due to One to One, to set against the £520k debt recorded as due to the Trust.
- We have received no information on any advance payments made and not recovered by other CCGs.
- We received no information on the operational costs of the cessation for the North East Essex system.

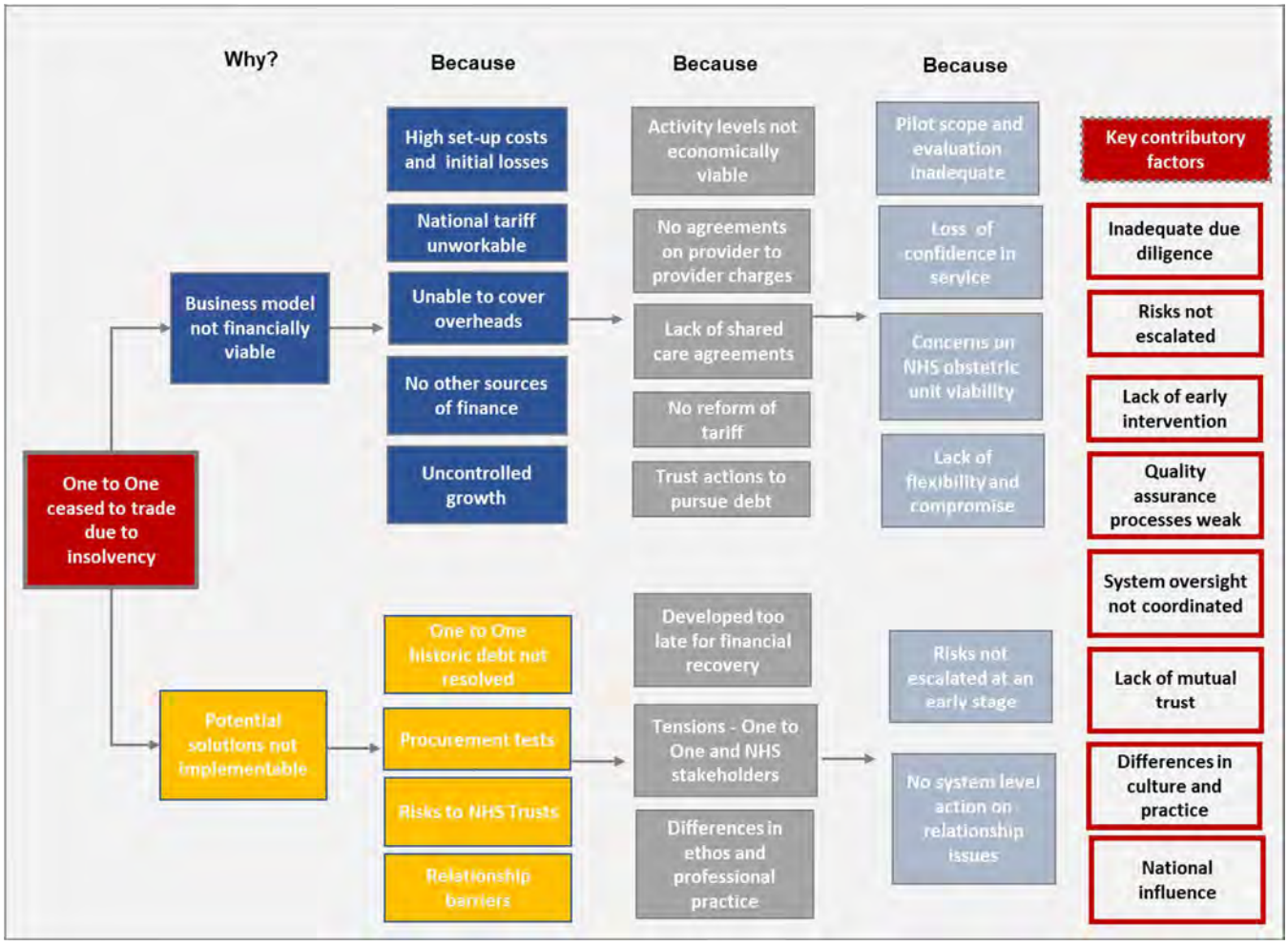
18.7. The NHS England briefing noted that liability for claims in North East Essex remained a risk as the position regarding non-contracted activity remained unclear. We noted that this had been a point of discussion in 2015.

Summary of contributing factors

18.8. There were multiple and complex contributing factors including weaknesses in governance, accountability, planning and implementation of the new service, combined with an unworkable national tariff system. This created an unfeasible scenario which required clear and decisive strategic leadership.

18.9. Based on the findings of our review, we have summarised in the diagram overleaf the key factors which contributed to the demise of One to One.

Key contributory factors



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