Report Appendices – *An independent review into the cessation of maternity services provided by One to One Midwives*

Date of issue: August 2022

Not for normal distribution / contains sensitive information

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HEALTH & SOCIAL CARE CONSULTING

Contents

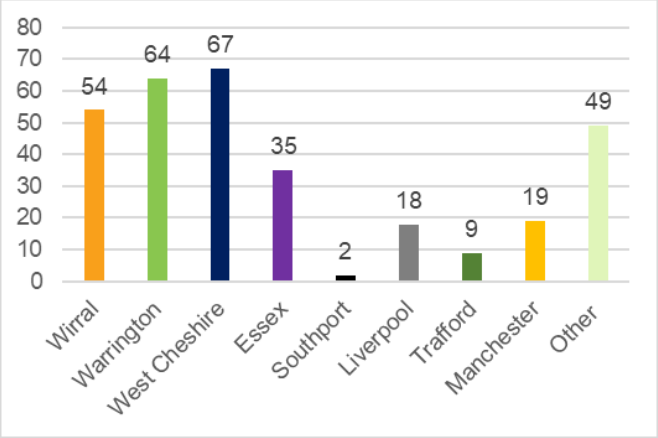
Appendix 1 – Glossary of terms

AQP	Any Qualified Provider
AWP	Any Willing Provider
C&M	Cheshire and Merseyside
CCG	Clinical Commissioning Group
CHUFT	Colchester Hospital University NHS Foundation Trust
CNST	Clinical Negligence Scheme for Trusts
COCH	Countess of Chester Hospital NHS Foundation Trust
CQUIN	Commissioning for Quality and Innovation
CSU	Commissioning Support Unit
CPN	Contract Performance Notice
DCO	Director of Commissioning Operations
DH	Department of Health
DHSC	Department of Health and Social Care
GM	Greater Manchester
GROW	Gestation Related Optimal Weight
HOMS	Heads of Midwifery
LMS	Local Maternity System
LSA	Local Supervising Authority
LSAMO	Local Supervising Authority Midwifery Officer
LWH	Liverpool Women's Hospital
MCHFT	Mid Cheshire Hospitals NHS Foundation Trust
MEOWS	Maternal Early Obstetric Warning System
MIAA	Mersey Internal Audit Agency
MMR	Midwives Mitigating Risk
NCA	Non-contracted Activity
NEE	North East Essex
NHSE	NHS England
NHSFT	NHS Foundation Trust
NHSLA	NHS Litigation Authority
NHSI	NHS Improvement
NHSR	NHS Resolution
NICU	Neonatal Intensive Care Unit
NIPE	Newborn and Infant Physical Examination
NMC	Nursing and Midwifery Council
PbR	Payment by Results
PCT	Primary Care Trust
PHE	Public Health England
PQQ	Pre-Qualification Questionnaire
QSG	Quality Surveillance Group
RAG	Red, Amber, Green

RAP	Remedial Action Plan
RCA	Root Cause Analysis
RCOG	Royal College of Obstetricians and Gynaecologists
RCM	Royal College of Midwives
SBAR	Situation, Background, Assessment, Recommendation
SCN	Strategic Clinical Network
SHA	Strategic Health Authority
SI	Serious Incident
SLA	Service Level Agreement
SUS	Secondary Uses Service
VEAT	Voluntary Ex Ante Transparency Notice
WHH	Warrington and Halton Hospitals NHS Foundation Trust
WUTH	Wirral University Hospital NHS Foundation Trust

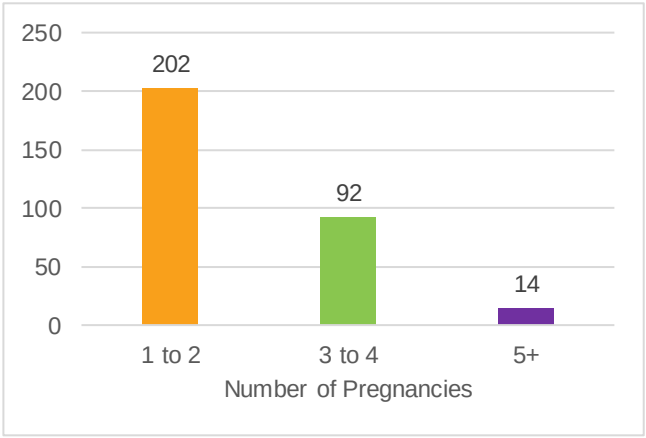
Appendix 2 – Survey analysis

Where did you live when you were under the care of One to One?



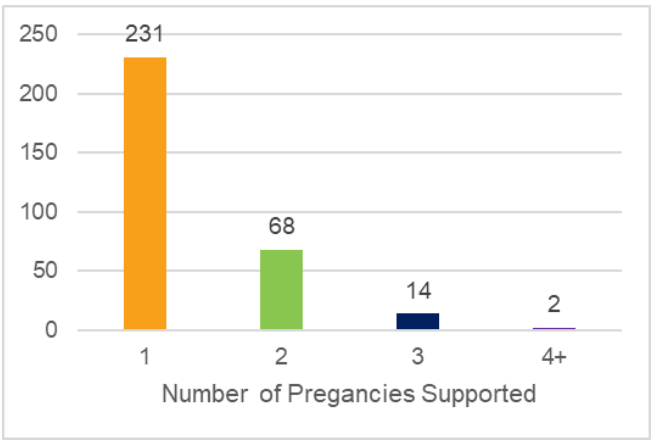
Number of responses 317

How many pregnancies have you had?



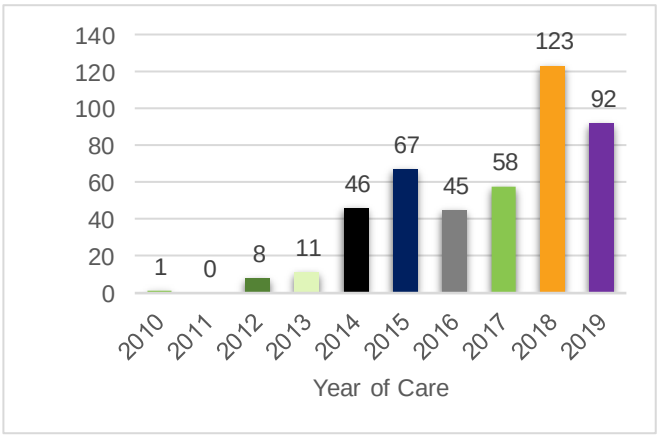
Number of responses 308

How many pregnancies did you have supported by One to One?



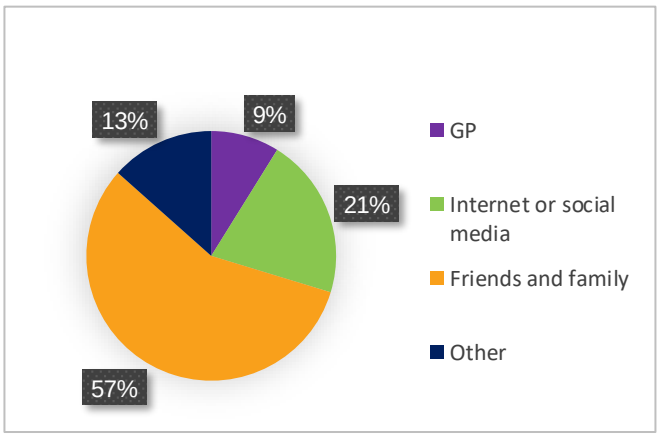
Number of responses 315

What year were you under the care of One to One?



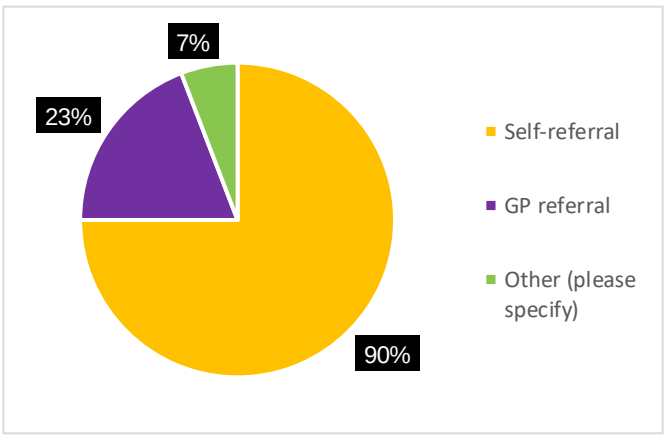
Number of responses 451

How did you hear about One to One?



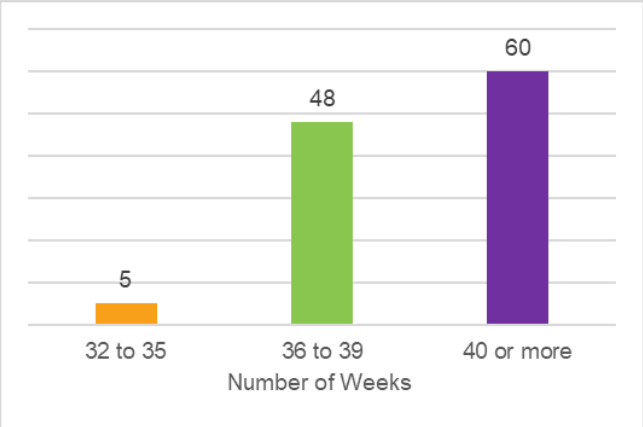
Number of responses 350

How were you referred to One to One?



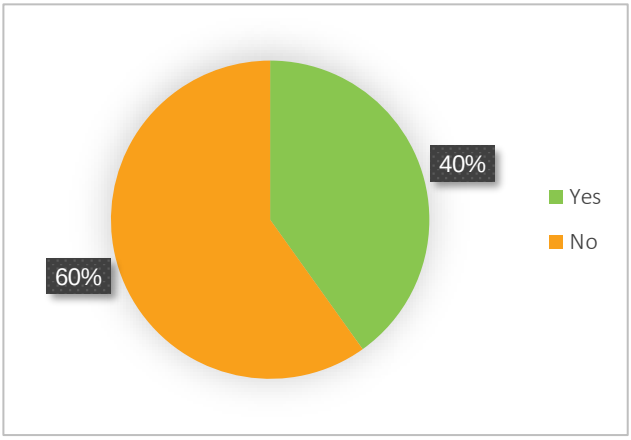
Number of responses 324

How many weeks pregnant were you when One to One became responsible for your antenatal care?



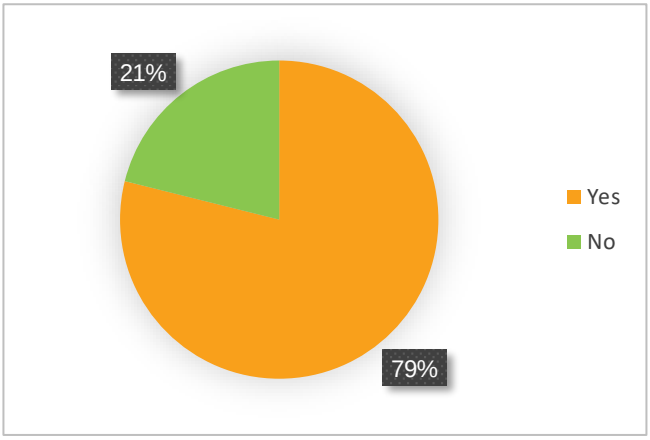
Number of responses 113

Did you experience any health issues requiring treatment during your pregnancy?



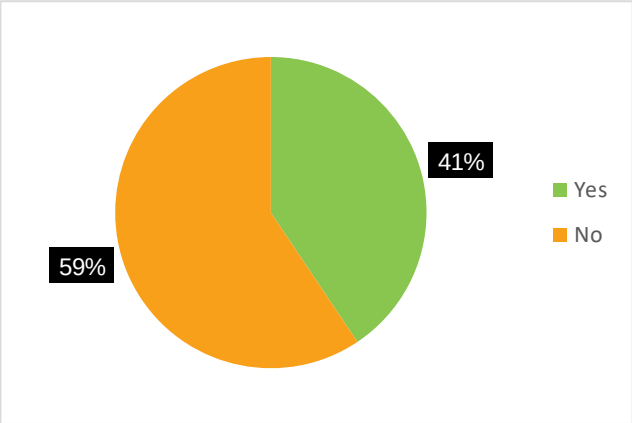
Number of response 314

Did One to One support you to get the additional treatment you required?



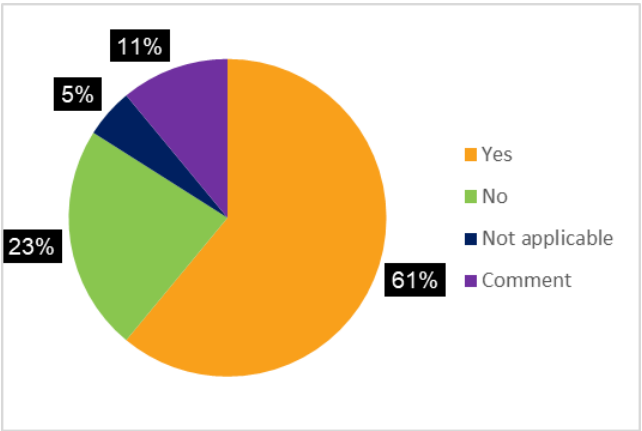
Number of responses 289

Was there any evident tension between health and social care providers and One to One?



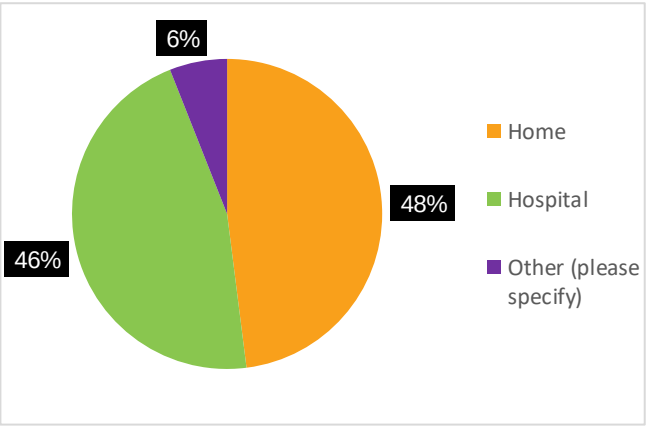
Number of responses 293

Did One to One support your birth?



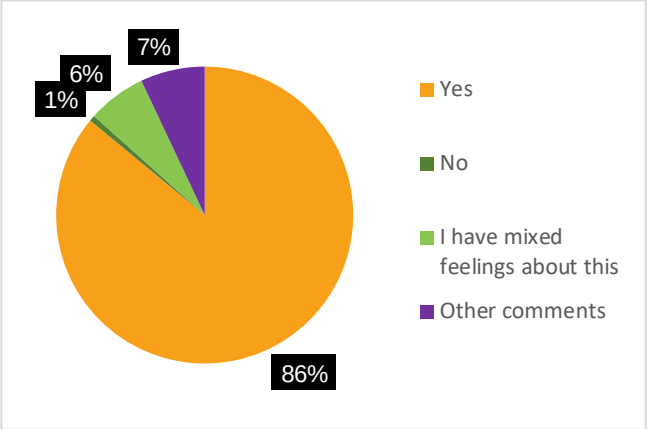
Number of responses 315

Where did you give birth?



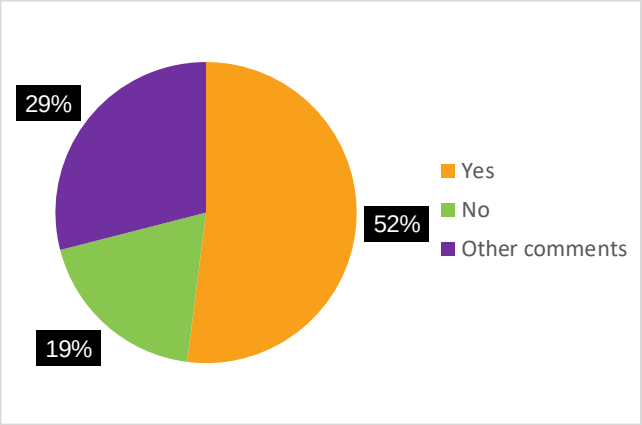
Number of responses 314

Did you feel you had sufficient information to make the decision about your place of birth?



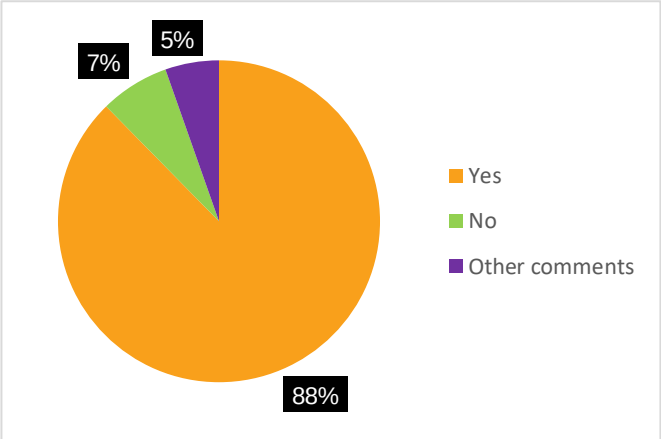
Number of responses 314

Did your named midwife support your birth?



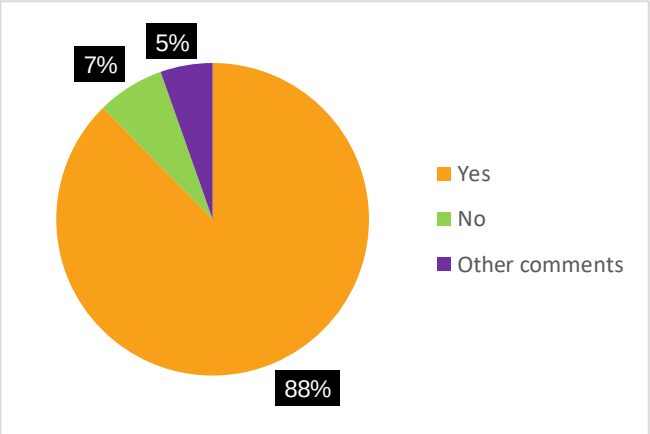
Number of responses 287

Did you receive your postnatal care from One to One?



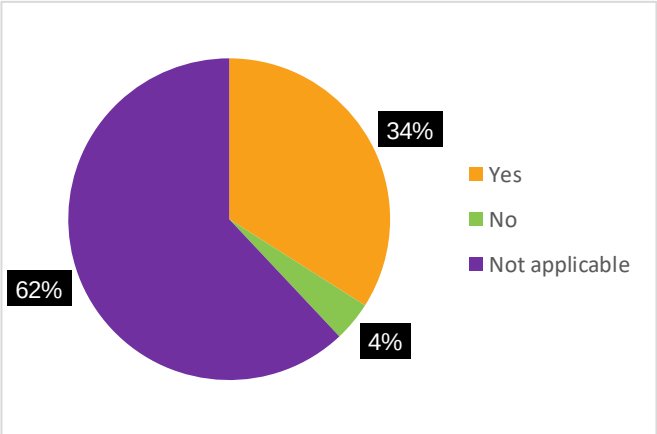
Number of responses 313

Did you require care from other services?



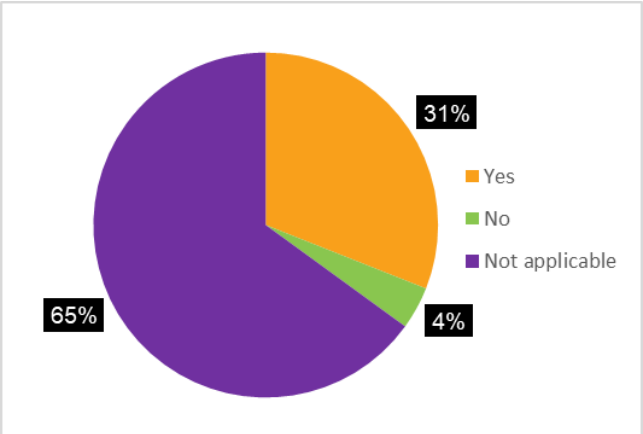
Number of responses 315

Was your need for care from another provider identified promptly by One to One?



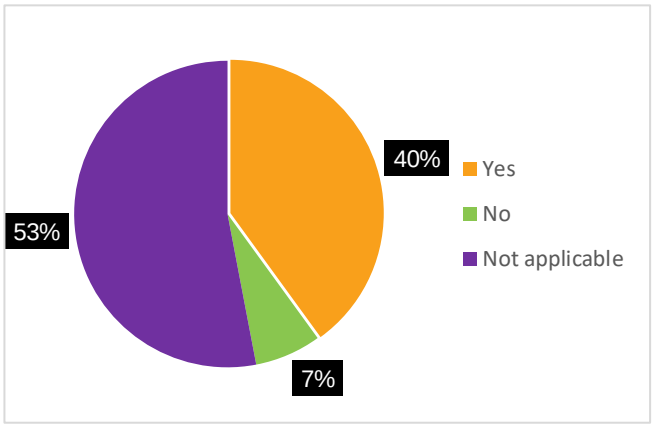
Number of responses 286

Was the referral to another provider made promptly?



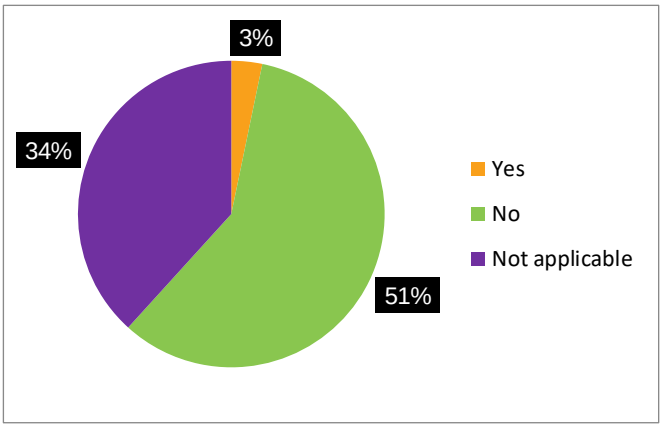
Number of responses 398

Did One to One liaise effectively with the other provider?



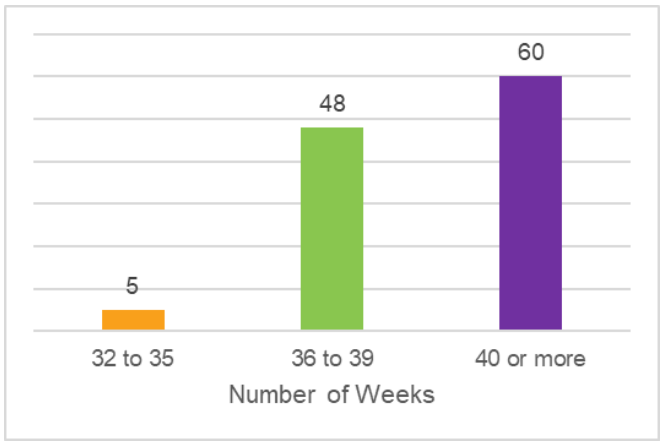
Number of responses 311

Did you experience any problems? E.g., not sharing notes, tests being repeated.



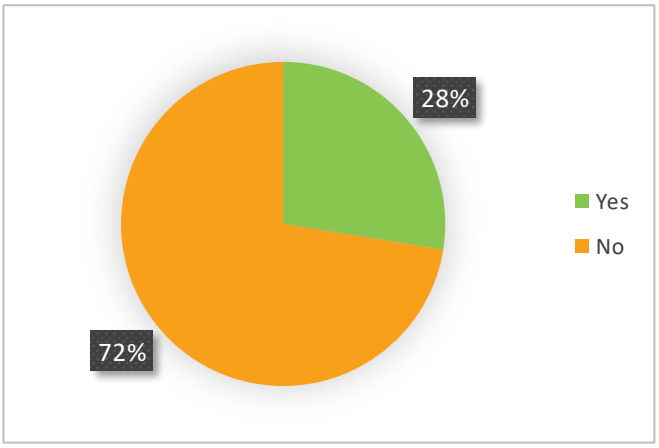
Number of responses 315

How many weeks pregnant were you when your baby was born?



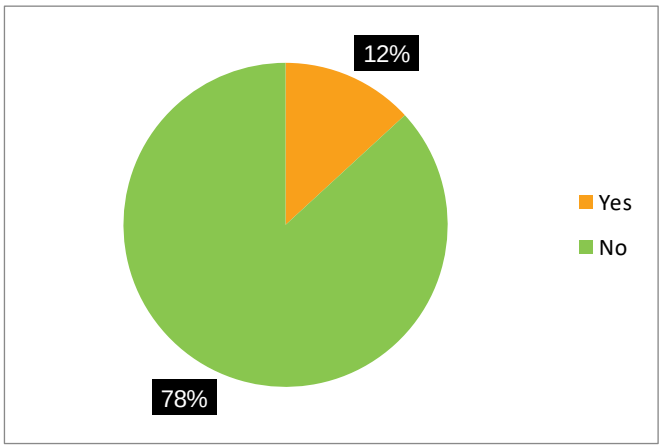
Number of responses 113

Did your baby experience any difficulties during or immediately after the birth?



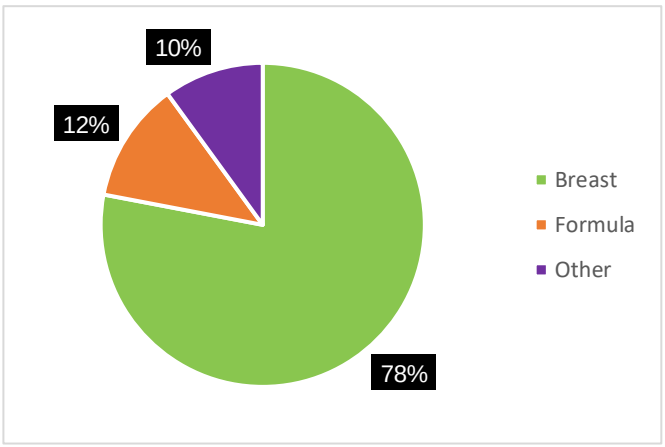
Number of responses 216

Did your baby require a hospital admission?



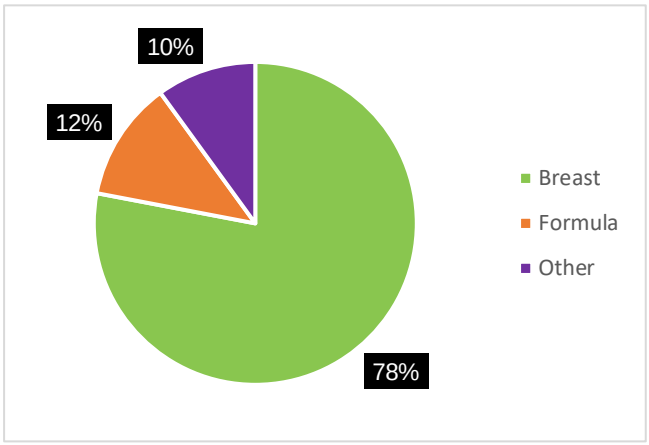
Number of responses 312

How did you feed your baby?



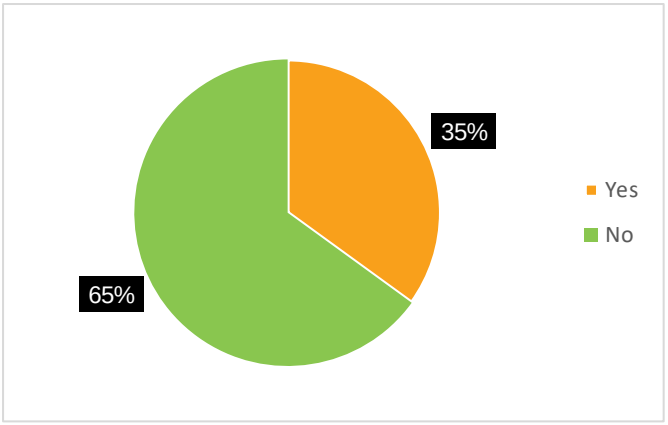
Number of responses 314

Did you receive the help you needed with feeding your baby?



Number of responses 313

Did your baby have any difficulties in the first weeks of life?



Number of response 314

Appendix 3 – Review of clinical case notes

Methodology

We completed a review of clinical records completed by One to One Midwives Limited. We undertook this review to inform our assessment of the quality of care provided by One to One with a particular focus on record-keeping, advice given to women and interactions between care providers.

The key questions we were seeking to answer were:

1. Did One to One complete a booking with women that identified:
    - previous medical history; and
    - previous pregnancy history – including if a woman could be safely cared for under a caseloading system?
2. How did One to One determine through risk assessment processes, whether their service was appropriate for women referred to them?
    - Did One to One identify potential risks for women including other issues such as mental health and substance/alcohol misuse.?
    - Where any of these issues were identified, did One to One take appropriate action?
    - How did One to One share information with women about their care and treatment options to support them to make an informed choice about their care?
    - Did One to One share information about the women under their care with other maternity providers when women had planned and unplanned contacts with their local NHS provider?
3. Did One to One apply its clinical policies in the management of risk and to inform clinical decision-making? In 2015, One to One developed a Midwives Mitigating Risk Policy and introduced the 'Fresh Eyes'[1] approach. The review sought to understand if Fresh Eyes was being used in line with the policy.
4. Did One to One provide women with information about their medication options? The CQC had raised concerns around the management of medication. This was regarding the management of controlled drugs without the requisite Home Office licence. This resulted in One to One offering limited pain management options to women.
5. Did One to One's clinical record keeping meet the expected professional standards?

In 2020 the clinical records, both handheld and electronic were transferred to the custody of Wirral University Teaching Hospital NHSFT (WUTH) from the Administrators of One to One (North West) Ltd. We asked WUTH for the clinical notes for the period from 2015 to 2019. This was to allow for the assessment of the impact of actions taken by One to One in response to the CQC inspections completed in 2015 and 2016, and compliance with the clinical requirements of the service specification under the contract with Wirral CCG from 2016 to 2019 (see also Annex A).

WUTH shared 42 sets of notes. We reviewed 33 complete sets of records (both handheld and electronic) which were provided. We did not review the

[1] Fresh Eyes reviews were introduced by One to One following the CQC inspection in Essex in March 2015. One to One described the implementation of monthly Fresh Eyes Reviews whereby individual caseloads would be reviewed by the Lead Midwife or locality midwife to identify women with risk factors and provide an oversight role to support midwives in making appropriate and timely referrals.'

remaining 9 sets of electronic notes only as we did not consider that they gave a full picture of the care and treatment provided.

The review questions were set out under the following sections:

- antenatal period;
- Continuous Fetal Heart Monitoring with CTG – if applicable;
- medication;
- labour care;
- postnatal care; and
- general record keeping

See Annex B for full details of the review.

Summary of key findings

Risk assessment and management

Individual care plans were evidenced in 30 of 33 cases. However, care plans for high risk women referenced NICE guidance but did not always specify aspects of the guidance relevant to the individual woman's risk.

In the sample of 33 cases, nine were identified with pre-existing health conditions. They all had care plans in place to manage the associated risks.

There were a limited number of safeguarding notes in the sample reviewed. These were for 11 women with a history of mental health issues or who were currently experiencing mental health issues.

We observed a mixed approach by One to One towards women with mental health issues, for example:

- A woman with a history of previous drug use, obsessive compulsive disorder and postnatal depression declined support at booking and self-referred to services via her GP in the postnatal period. Safeguarding notes were available for this case indicating that there had been discussions to determine if ongoing referral for additional support was needed.
- A woman who experienced anxiety following induction of labour for her first baby declined mental health support at booking. Her risk status was noted to be 'green' despite the potential for this to happen again. However, following a Fresh Eyes review her risk status was elevated from 'green' to 'amber'.
- Another woman was identified as 'amber' risk due to a history of anxiety and depression for two years for which she had been under the care of her GP. She had a home birth, and the midwife noted a plan to visit only twice in the postnatal period which would not afford much opportunity to observe for evidence of her anxiety returning.

There was a broad variation in the number of risk assessments completed for each of the cases reviewed.

The CQC action plan of August 2016 stated*: "Ensure that women in their care are robustly risk assessed at booking also at each contact and an accurate record is made of risk assessments to determine if One to One (North West) Limited can meet or continue to meet their needs. Action: Monthly through the*

Fresh Eyes review of caseload. Risk assessment review is part of the record keeping audit."

It was difficult to determine how robustly risk assessments were completed. The electronic notes list a number of assessment topics on the tab labelled '*risk assessment'.* What follows is a tick list of issues for discussion during antenatal appointments. This would indicate that a discussion had taken place regarding a risk but did not allow recording of the detail of the discussion. There are also examples of the narrative notes stating that a risk assessment had been completed but there was no corresponding risk assessment in the relevant section of the notes.

There is evidence of risk assessments and discussions with all but one of the women in the review sample as summarised in the table below. For 75% of the sample (24 cases) more than one risk assessment was undertaken and logged on the relevant tab in the electronic notes.

Number of risk assessments completed	Number of cases
1	8
2	5
3	11
4	3
5	-
6	-
7	2
At every antenatal visit	3
Total cases	**32**

Evidence of ongoing risk discussions was available in 78% of relevant cases (24 cases out of 31). There were two cases where no ongoing discussion could be identified, four where it was noted as not applicable, and one where the woman was identified as receiving advice about risk from the consultant obstetrician at an NHS maternity provider.

Twelve of the cases reviewed identified a high risk labour. Of these cases ten went to an NHS maternity provider for all their intrapartum care. One woman was supported at home by One to One while in labour and transferred to the NHS maternity provider for the birth. One woman whose pregnancy was identified as high risk because her body mass index was greater than 35, chose a home birth and was supported by One to One.

The maternal early warning observation (MEOWS) charts were identified by the CQC in 2016 as a safety measure required to be implemented by One to One. The review observed very few MEOWS charts.

There was evidence in all the cases we reviewed of discussions with women about the One to One model of care and how it worked. Discussions about

informed choice were completed in 66% (22 out of 33) cases. We found some variability in the records of the information provided to women when making an informed choice about their care and treatment options. In the main, the narrative would reference a discussion about the relevant NICE guidance but there was no information about the associated discussion itself. The review was not therefore able to conclude that this met the requirement to provide women with detailed information about the care and treatment options.

Out of the 32 births in the sample 9 were home births; the remainder were at an NHS obstetric or midwife led unit. There were two caesareans in the sample. The home birth cases were all assessed as low risk with one initially high risk for breech but then cephalic presentation[2].

There were discussions about the place of birth in 31 of the 33 sets of notes reviewed. However, in six cases discussion of the risks and benefits of place of birth were not evidenced. Documentation regarding choice of place of birth did not include the details of every conversation. There were boxes to tick that demonstrated a discussion had taken place but usually the free text component stated that the advice given was according to NICE guidance without explicit details being documented. The handheld records usually included additional information on subjects such as healthy eating, hypnobirthing etc.

There were relatively few occasions observed in the notes where women declined care from One to One. An example was one woman who declined perineal repair; in this instance the midwife documented the discussion comprehensively.

Shared care and information sharing

Some of the women who received their care from One to One also received care from NHS maternity providers. This applied for:

- planned care where the women required a shared care pathway or had chosen a hospital birth; and
- unplanned care when a women attended an obstetric unit after being triaged by One to One in the antenatal period or transferred to the obstetric unit while in labour.

Reliance on handwritten notes resulted in limited clinical information generally being available to the NHS providers. The sample reviewed contained examples of shared care with an obstetric unit for high risk women. On two occasions, there were references to advice being sought from One to One's Consultant Obstetrician but there were no handwritten notes by the consultant in the clinical record to provide detail about the advice provided.

One to One midwife would need to triage a woman between planned antenatal visits, for example if she reported reduced movements. Should a woman need to attend an obstetric unit following triage the expectation was

[2] Cephalic presentation | definition of cephalic presentation by Medical dictionary (thefreedictionary.com)

that the One to One midwife would either accompany the woman or make direct contact with the NHS provider. However, in the sample reviewed there were no examples of either the One to One midwife accompanying a woman or making direct contact with the NHS provider.

There was also an expectation that the One to One midwife would complete an SBAR (Situation, Background, Assessment and Recommendation) for the woman to share with the NHS provider. The SBAR was recorded in the triage tab of the electronic record. There was evidence of SBARs being completed in the electronic notes for women who attended an NHS maternity provider. However, there was no evidence to demonstrate that a paper copy of the SBAR was given to the woman to take with her or that this was shared with the NHS maternity provider or GP.

Some triage appointments with women were completed by telephone rather than face to face with advice to go to the NHS provider. Following these telephone assessments, the One to One midwife did not always make direct contact with the NHS provider to provide an SBAR. In addition, the outcomes of triage assessments resulting in a woman attending an NHS provider or being admitted were not always recorded.

There was one transfer during labour, and the woman was not accompanied by the One to One midwife.

Of 20 applicable cases, only four records evidenced that the GP had been informed of a transfer to another provider from One to One. We could only evidence 3 cases where records had followed to the new provider within 24 hours.

Some women transferred their antenatal care to One to One having initially booked with an NHS Provider. In the sample reviewed there were women who transferred their care in the second or third trimester by which point they had received significant care from another provider. We found that there was no narrative information in the booking section about the clinical care or assessments provided by the NHS Provider. We would have expected One to One to have taken a narrative history from the woman and then requested her clinical record from the NHS provider. There was no evidence in the records review to indicate that such a request was made. However, we noted that the results of previous investigations were available in the clinical records.

Clinical policies

Fresh Eyes reviews were introduced following the CQC inspection in Essex in March 2015. The report into this inspection noted that the One to One midwives were identifying risk factors but not always escalating these in line with their Midwives Mitigating Risks (MMR) guidance. In response to this, One to One implemented Fresh Eyes reviews whereby individual caseloads would be reviewed by the lead midwife or locality midwife to assess compliance with the MMR pathways.

The objective of this process was to: *"identify women with risk factors and provide an oversight role to support midwives in making appropriate and timely referrals."*

Of 33 sets of notes reviewed Fresh Eyes reviews had been completed in seven cases. The reviews were documented in the electronic notes.

The reviews were completed by a 'buddy' midwife rather than the lead midwife or locality midwife as required by the policy (we note that the midwife who undertook the review may not have identified themselves as the lead or locality midwife). For the reviews undertaken, the conclusion tended to be that the care being delivered was appropriate, or there was a suggestion made to complete investigation results. In only one case was a significant comment made about the care.

For women with high risk pregnancies, the Fresh Eyes reviews were undertaken by a Consultant Midwife rather than the Consultant Obstetrician.

Medication management

NICE guidance for intrapartum care for women and babies[3], published in 2014 and updated in 2017, states that pethidine, diamorphine, or other opioids should be available in all birth settings. The One to One Medicines Management Policy stated that One to One midwives did not carry opiates therefore women requesting this would have to transfer to their local NHS provider.

One to One did not hold a Home Office licence for Controlled Drugs. There was no evidence that this information was provided to women when planning a home birth. The review confirmed that Controlled Drugs were not available to women during labour. There was no documentation regarding how to access such analgesia for home births.

There is evidence that One to One reviewed allergies with woman in 25 sets of the clinical records reviewed. This information was available on the medication tab of the electronic record.

Clinical record keeping

For each woman there were two parallel sets of clinical records - handheld and electronic notes:

- Handheld notes – these were handwritten. They were limited to antenatal and postnatal care only. These records were available to the local NHS maternity provider should a woman attend for planned or unplanned care. Should the NHS provider require additional information, they would have to make direct contact with One to One, who would access the electronic notes and provide the information requested.
- Electronic record - One to One used an electronic clinical record keeping system called HERA[4]; this was a bespoke IT system and did not interface with NHS maternity services'

[3] www.nice.org.uk/guidance/cg190/chapter/Recommendations#pain-relief-in-labour-nonregional
[4] Hera was a bespoke system and there is no further information available to this review about it.

systems. The electronic notes recorded care provided through the continuum of pregnancy and childbirth. The midwives entered data on the electronic notes using individual iPads.

The handheld notes provided limited information about the care provided to women, whereas the electronic record was a full record of care. One to One told the CQC during one inspection that the expectation was that midwives would print out the electronic notes following each appointment and put a copy of the information in the woman's handheld notes. We saw no evidence of this practice in the handheld records reviewed.

The review identified that 17 of the 33 cases reviewed demonstrated that Nursing and Midwifery Council professional standards[5] had been met with regards to record-keeping. Compliance with these standards was better for home births, 7 cases out of 9 (78%). For births taking place in other locations, compliance was found in 10 cases of 22 reviewed (45%).

Within the sample, we found that incomplete documentation was common:

- Details of discussion leading to informed choice decisions were not documented beyond references to NICE and ticking boxes on a menu of discussion points.
- Observations were not recorded on MEOWS charts, where relevant.
- There was no information about controlled drugs for women considering home births.
- Postnatal information was not included in the handheld record for mother or baby.
- Handheld notes did not contain information following triage events should a woman need to attend an NHS maternity provider alone. SBAR information was not available in the handheld notes.

Conclusions

Based on the findings of our limited review of 33 sets of records:

- When completing a booking One to One did identify the woman's previous medical and pregnancy history. They considered whether a woman could be safely cared for under a caseloading system. They did not however decline to support women identified as more suitable for care by an obstetric led provider.
- There was evidence in the sample that One to One identified women with other issues such as, e.g., mental health and substance/alcohol misuse issues, and take the appropriate action to support these women.
- There was evidence that One to One shared information with women about their care and treatment options to support them to make an informed choice. However, we were not sufficiently assured on how the information provided was explored effectively with women. This was because of the reliance the use of tick boxes to identify the information shared, e.g., NICE guidance, but without any narrative of discussions held.

[5] www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf

- The information shared by One to One with other providers for women who chose or required care from NHS maternity units was found to be limited. This was due to the reliance on handheld notes which may not have been up to date or contain sufficient information.
- Furthermore, there was no evidence in the sample reviewed that One to One made direct contact with the NHS maternity provider or shared an SBAR when a woman attended for unplanned care.
- The review has not provided sufficient assurance that One to One implemented the Fresh Eyes approach appropriately to inform clinical decision making and mitigate risk. There was limited evidence of its use (seven out of 35 cases reviewed). Furthermore, the reviews were more akin to a peer review because they were completed by a 'buddy midwife' rather than a lead midwife or locality midwife. The intention of Fresh Eyes had been to mitigate risk by an experienced midwife completing the reviews.
- One to One did not hold a Home Office licence for Controlled Drugs. As a result, they were not able to comply with NICE guidance regarding the pain relief available to women in labour. The cases reviewed confirmed this. Woman were offered Entonox[6], hypnobirthing techniques, waterbirths and massage to help them manage their pain.
- One to One' record-keeping met professional standard requirements in 51% of the records reviewed. Compliance was better for home births at 78%; compliance where births took place in other settings was lower at 45%.
- Postnatal records were not available in any of the cases reviewed.

Annex A – Service Specification

The service specification under the contract with Wirral CCG from June 2016 to May 2019 required a risk assessment to be undertaken at booking by the midwife, using the woman's previous medical history (including mental health) and pregnancy history. This assessment would determine whether the woman could be safely cared for under the caseloading model or be required transfer to an obstetric unit or a shared care arrangement.

The specification for women whose pregnancies required obstetric care required that:

- One to One should have established care pathways with obstetric led providers for women who required shared care either from booking or at a any point during pregnancy.
- Shared care was defined as when a pregnant woman chooses to have her antenatal care provided via the caseloading model, but care also needs to be provided by other organisations such as, NHS obstetric services, mental health services and social services. The degree of shared care was to be agreed by all parties.
- Women who were identified with an 'exclusion risk' should be transferred to an obstetric led service of her choice after booking. The specification states as *"whilst the pregnant woman may have chosen to be cared for by the caseloading provider, if the initial assessment at booking identifies that they are not suitable for care by this provider […] and all care and ongoing management must be transferred immediately and in full to the NHS obstetric unit of her choice."*

[6] Entonox (known as 'Gas and Air') A mixture of half oxygen and half nitrous oxide that is used for pain relief

- The specification acknowledged that some women may refuse to accept clinical advice and wish for a home birth at their own risk. The specification required One to One to seek approval prior to the birth for those women, from the relevant CCG. This was to ensure appropriate measures were in place for care planning along with the informed consent of women.

For reference, the risk factors set out in the service specification for consideration as inclusion/exclusion criteria are set out in the tables below. These set out the circumstances under which shared care or obstetric care only would be suitable and when a home birth plan should be discontinued. The factors for a woman to be designated as low risk when she went into labour are also shown below.

Suitable for inclusion into caseloading and for shared obstetric care	**Exclusion risk – to be transferred to obstetric led service**	**Discontinue home birth plan**
Complex social factors BMI > 35 BMI <18 Physical disabilities Substance misuse Alcohol misuse Mental health Hepatitis B Hepatitis C Inherited disorder Previous 3rd or 4th degree tear Grand multiparity – more than 5 previous births Previous shoulder dystocia Previous Caesarean section Previous instrumental delivery Previous (x2) post-partum hemorrhage of >1000mls 3 or more consecutive miscarriages Stillbirth Neonatal death Intrauterine growth restriction Low birth weight <2.5kg High birth weight >4.5kg Fetal congenital abnormality Twins HIV positive Rhesus isoimmunization Haematological disease	Epilepsy requiring anti-convulsant Previous uterine surgery Hypertension with existing medication and routine medical input Respiratory disease requiring regular medication Cystic fibrosis – any condition that requires ongoing medical input Puerperal psychosis Pre-term birth <34 weeks (if pregnancy progresses beyond 37 weeks – for shared care) Fetal loss 12-24 weeks Placenta accreta Multiple pregnancy >2 Renal disease requiring ongoing medical input Diabetes/endocrine disorders – known insulin dependent Cardiac disease Cancer Thromboembolic disease Autoimmune disease – lupus Thrombophilia / clotting disorder Previous fetal anomaly that required fetal medicine	Gestational diabetes Breech presentation Any other malpresentation Pre-eclampsia / eclampsia
Low risk labour factors		
Had an uncomplicated pregnancy Is between 37-42 weeks gestation Has a BMI <35 at the start of pregnancy Is aged between 16-40 years Has hemoglobin levels of 9gms or above The baby has developed normally and is presenting as head down The membranes rupture and liquor is clear The presence of strong, regular contractions		

Annex B - Review Questions

The questions set out in our review template were as follows:

Antenatal period

1. Have risk factors been identified?
2. Has the named midwife been identified?
3. Has a lead professional been identified for women with complex pregnancies?
4. Is there evidence of information and discussion regarding place of birth options?
5. Is there documented evidence that social circumstances have been discussed?
6. Is there evidence of communication with social service/safeguarding leads?
7. Has the ethnic origin been documented?
8. Has the woman's previous medical history been documented, including mental health?
9. Has the woman's previous obstetric history been documented?
10. Is there documented evidence that family history has been discussed?
11. Have allergies been identified?
12. Is smoking status recorded?
13. Is occupation noted?
14. If a current mental health problem, or risk has been identified, is there documented evidence that this has been communicated to mental health services, GP, Health Visitor, Interpretation services where appropriate?
15. When mental health issues have been identified, has a plan been made, and potential problems in the puerperium been acknowledged?
16. Is there documented evidence that written information has been given and discussed regarding - screening tests (Down's, ultrasound, blood tests), including consent obtained, place of birth options, Vitamin K prophylaxis, fetal monitoring in labour?
17. If the woman has declined initial screening, is there evidence of another offer of screening?
18. Is there documented evidence if appropriate that written information has been given and discussed regarding - induction of labour, general anaesthetic, vaginal birth after caesarean, perineal repair, external cephalic version (ECV), women who decline blood and blood products?
19. Are all blood results recorded appropriately?
20. Has the Body Mass Index been calculated and documented?
21. Was initial contact made within 48 hours of receipt of an initial referral?
22. Was the initial assessment of need and risk completed by 8 completed weeks gestation?
23. Was a comprehensive assessment of health and social care needs undertaken within 7 days of the initial referral?
24. Was a comprehensive assessment of health and social care needs undertaken by 12 weeks and 6 days of pregnancy?
25. Were females under 16 years referred to the local Family Nurse Partnership following booking?
26. Is there documented evidence of a plan of care?
27. For women with a previous Caesarean section is there documented evidence of a discussion regarding: mode of delivery, place of birth, individual plan, plan for pre-term labour, plan for fetal heart monitoring?
28. If breech presenting at 36 weeks is there evidence of discussion regarding ECV?

29. Has the plan for infant feeding been documented?
30. If labour has not commenced by 40 weeks, is there documented evidence that induction of labour has been discussed?
31. If labour has not commenced by 40 weeks, has a membrane sweep been offered at 41 weeks?
32. If this is a multiple pregnancy, is there documented evidence of discussion regarding the following: the risks and benefits of different modes of delivery, place of birth, timing of birth, individual birth plan?
33. If there is a pre-existing / familial reason for antenatal thromboprophylaxis has the appropriate risk assessment been performed and medical prescription obtained?
34. For women with Type 1 diabetes: Was care given in a joint clinic (midwife/obstetrician/diabetic physician/dietitian)? Is there documented evidence that the timetable of antenatal care has been discussed? Is there documented evidence of advice regarding changes in awareness of hypo or hyperglycaemia?
35. In the event of an emergency transfer in pregnancy is there evidence of an appropriate verbal and written handover being provided?

Continuous Fetal Heart Monitoring with CTG – if applicable

1. Is there documented evidence of indication for use of CTG monitoring (if applicable)?
2. Is there documented evidence in the recording of: the woman's name, date and time of commencement, chronological time is the same as on the CTG monitor, case note number, indication for the CTG, woman's pulse rate at commencement and intermittently through the recording, staff name and signature, fetal movements, maternal position, name of staff member who reviewed CTG – documented evidence of method used, plan of care following CTG, storage in the case notes?

Medication

1. Is there a record of all medications prescribed and given throughout pregnancy, labour and puerperium?
2. Are the woman's details noted?
3. Are allergies noted?
4. Is the prescription legible with signature and printed name?
5. Is there documented evidence of administration as prescribed?
6. Is there a VTE risk assessment documented?

Labour care

1. Has the woman completed a birth plan?
2. Is there documented evidence that the birth plan has been discussed?
3. Have initial observations been recorded?
4. Was the woman admitted for a planned hospital birth?
5. Was the woman admitted for an elective Caesarean section?
6. Is there documented evidence that fetal monitoring in labour has been discussed?
7. Is there evidence of discussion regarding the plan of care in labour?
8. Has a review of history taken place and the labour assessed as high or low risk?
9. Has the fetal heart been auscultated and recorded on arrival to woman in labour?
10. Has the fetal heart rate been auscultated and recorded for one minute at 15 minute intervals following a surge?
11. If electronic fetal heart monitoring was used, has the indication been documented?
12. Has the frequency, strength and length of contractions been recorded every 30 minutes?

13. Has the maternal pulse been recorded hourly, unless indicated to be more frequent (60-100bpm)?
14. Has the maternal blood pressure been recorded 4 hourly, unless indicated to be more frequent (diastolic < 90, systolic <150)?
15. Has the maternal temperature been recorded 4 hourly, unless indicated to be more frequent (36.2-37.5)?
16. Has an initial abdominal palpation been recorded?
17. Has a vaginal examination been offered if doubt exists re presenting part on palpation?
18. Has abdominal palpation been undertaken and recorded at 4 hourly intervals?
19. Has vaginal examination been performed for a clinical indication or maternal request?
20. Has vaginal examination been preceded by an abdominal palpation?
21. Has vaginal discharge been recorded?
22. Has the woman passed urine at least 2-3 hourly?
23. Have the woman's emotional and psychological needs been considered?
24. Has the colour of liquor been noted?
25. What analgesia has been offered?
26. Has the woman been encouraged to adopt different positions?
27. Has every effort been made to ensure the woman was mobile in labour?
28. If there was delay in the first stage of labour, was this identified?
29. If there was delay was the labour ward lead midwife?
30. In second stage was the fetal heart auscultated and recorded at 5 minute intervals been contractions?
31. In second stage was a vaginal examination performed with consent?
32. If there was a delay in the second stage of labour who was informed?
33. For the third stage of labour was the perineum management discussed in advance?
34. For the third stage of labour was consent obtained prior to administration of Syntocinon or Syntometrine?
35. Has the method of delivery of the placenta and membranes been recorded?
36. If perineal trauma occurred was consent obtained prior to suturing
37. Was a systematic assessment of perineal and vaginal trauma recorded?
38. Effective analgesia been administered?
39. Anal syphincter integrity reviewed?
40. Record of repair of the perineum, including type of suture used?
41. Swab count correct?
42. Appropriate referral made for third degree tear?
43. Have all the drugs that were administered been recorded?
44. Has the birth outcome been recorded?
45. If a urinary catheter was required has the insertion date and time been recorded?
46. Is the consent form for any procedure stored with the records?
47. Have the maternal observations following labour been recorded?
48. Has the woman passed at least 200mls of urine following the birth?
49. Is the labour summary complete?

50. In the event of an emergency transfer in labour is there evidence of an appropriate verbal and written handover being provided?

Postnatal care

1. Is there documented evidence of the initial examination by the midwife?
2. Is there documented evidence of skin to skin contact?
3. Is there documented evidence of the first feed?
4. Is there documented evidence the first feed being given within one hour of birth?
5. Is there documented evidence of the quality of the feed/amount of formula taken?
6. Is there documented evidence of the baby's temperature at birth?
7. Is there documented evidence of the baby's weight, length and head circumference?
8. Is there documented evidence of Vitamin K: parental consent, being administrated, route of administration?
9. Is there documented evidence of a plan of care for mother and baby?
10. Is there documented evidence of a feeding plan?
11. Is there documented evidence of the woman being given appropriate instruction on sterilization of feeding equipment / reconstitution of feeds?
12. Is there documented evidence of the woman being offered an opportunity to discuss the birth?
13. Is there documented evidence of a fully NIPE?
14. Is there documented evidence of the baby's red book being given to the parents to discuss?
15. Is there documented evidence of action taken in response to indications of neonatal jaundice?
16. Is there documented evidence of support from appropriate healthcare professionals if an adverse outcome occurs?
17. Is there documented evidence of support for parents who have communication or language support needs?
18. In the event of an emergency transfer in the postnatal period is there evidence of an appropriate verbal and written handover being provided?
19. Has a discharge summary been provided to the GP and health visitor?

General Record Keeping

1. Is there evidence of documentation that full disclosure of known risks has been discussed with the Named Midwife / Buddy Midwife when a woman has chosen not to follow clinical advice based on national guidance?
2. Is there evidence that the woman understands the potential consequences of the choices made in terms of personal safety to her / and her baby?
3. Is there evidence of the woman's GP being informed of transfer of care to another provider within 24 hours?
4. Is all documentation legible in a manner that the text cannot be erased?
5. Is all handwritten documentation in black ink?
6. Are all records recorded contemporaneously?
7. If records are not recorded contemporaneously is there a written explanation with date and time of entry?

8. Are loose pages clearly marked with the woman's name, date of birth and identification number?
9. Are all entries dated and timed using a 24 hour clock?
10. Are all entries signed?
11. Is the name printed and the qualification stated by each health professional making an entry?
12. Is all information in chronological order?
13. Have all handovers of care been clearly identified?
14. If abbreviations have been used have, they been previously explained?
15. Are all errors crossed once, dated, timed, and signed with the words 'written in error' entered?
16. Are all records factual, free from jargon, meaningless phrases, irrelevant speculation and subjective statements?
17. Are all documents/loose papers filed in chronological order securely?
18. Are all ultrasound scan reports secured in the notes?
19. Are all blood results reported in the notes?
20. Is there any evidence of records from previous pregnancies being filed with this pregnancy?
21. Are any scraps of paper e.g., used for noting timing of events, secured in the notes?
22. If care has been transferred to another provider is there evidence that all records were forwarded to the receiving provider within 24 hours including bank holidays and weekends via a secure source?

Appendix 4 – Analysis of serious incidents

The tables below provide a summary analysis of the information provided for 137 incidents.

	Year	CCG/Provider	Reported on StEIS	Incident type	Theme	Key findings from investigations
1	2013	Calderdale CCG	Yes	Intrauterine death	Communication/shared care problems	Communication – delay in informing that woman had transferred care. Risks – how they were communicated to the woman
2	2013	Calderdale CCG	Yes	Intrauterine death	Communication	Communication – midwives triaged woman via text messages
3	2013	Wirral CCG	Yes	NICU admission	Delayed transfer to obstetric care	Communication and delay in transfer
4	2013	Liverpool CCG	Yes	NICU admission	Record keeping	Record keeping
5	2013	North Manchester CCG	Yes	Neonatal death	No information provided	
6	2014	LWH	Yes	NICU admission	No information provided	
7	2014	Trafford CCG	Yes	Baby death	Communication/shared care problems	Communication with NHS provider
8	2014	Cheshire & Merseyside	Yes	Intrauterine death	No information provided	
9	2014	COCH	Yes	NICU admission	No information provided	
10	2014	COCH	Yes	Neonatal death	Clinical care	Hypertension not well-managed
11	2014	Wakefield CCG	Yes	NICU admission	No information provided	
12	2014	Liverpool CCG	Yes	NICU admission	Record keeping	Discrepancy in types of growth-monitoring charts, record keeping
13	2014	WUTH	Yes	Intrauterine death	Record keeping	Record keeping
14	2014	LWH	Yes	NICU admission	Communication/shared care problems	Failure in communication by LWH
15	2014	Cheshire & Merseyside	Yes	NICU admission	Clinical care	Inexperienced midwife
16	2014	Liverpool CCG	Yes	Neonatal death	No information provided	Planned home birth
17	2014	Not specified	Yes	NICU admission	Clinical care	Home birth, undiagnosed breech
18	2015	MCHFT	Yes	Other care issue	Communication/shared care problems	Non-compliance with Trust policy
19	2015	Not specified	Unclear	Other care issue	Communication with GP	GP unaware of birth
20	2015	MCHFT	Yes	Not indicated	No information provided	
21	2015	Vale Royal CCG	Yes	Maternal haemorrhage	No information provided	Retained placenta
22	2015	South Cheshire CCG	Yes	Clinical care	Clinical care	Home birth - incorrect suturing by One to One midwife
23	2015	South Cheshire CCG	Yes	NICU admission	Clinical care	NIPE assessment not completed within prescribed timescale
24	2015	South Cheshire CCG	Yes	Retained placenta	No information provided	Home birth - any haemorrhage?
25	2015	North East Essex CCG	Yes	Intrauterine death	No information provided	
26	2015	Not specified	Yes	NICU admission	No information provided	
27	2015	North East Essex CCG	Yes	Postnatal baby admission	No information provided	
28	2015	North East Essex CCG	Yes	Not indicated	No information provided	Home birth
29	2015	North East Essex CCG	Yes	Other care issue	Risk management	Lack of information about a woman with risk factors
30	2015	CHUFT	Yes	Intrauterine death	No information provided	
31	2015	Not specified	Yes	NICU admission	Communication	Communication with NHS provider
32	2015	North East Essex CCG	Yes	Other care issue	Risk management	Woman not aware of risks of her birth plan
33	2015	STHK	Yes	Stillbirth	No information provided	
34	2015	South Cheshire CCG	No	NICU admission	No information provided	
35	2015	South Cheshire CCG	No	Other care issue	No information provided	Baby jaundiced
36	2015	South Cheshire CCG	No	Other care issue	Risk management	Baby hips problems – late referral
37	2015	Not specified	No	Other care issue	Midwife availability	One to One midwife had not attended when woman reported reduced movements
38	2015	North East Essex CCG	No	NICU admission	No information provided	
39	2016	South Cheshire CCG	No	Other care issue	Compliance with policy	Hearing screening not offered
40	2016	South Cheshire CCG	No	Retained placenta	No information provided	Home birth
41	2016	South Cheshire CCG	No	Other care issue	Communication/shared care problems	Communication – One to One asked the NHS provider to triage a woman
42	2016	South Cheshire CCG	No	Maternal haemorrhage	No information provided	
43	2016	South Cheshire CCG	No	Maternal haemorrhage	No information provided	Home birth, retained placenta
44	2016	South Cheshire CCG	No	Other care issue	Risk management	Woman not suitable for planned home birth due to history of high blood pressure, transferred to NHS provider, obstructed labour
45	2016	South Cheshire CCG	No	Other care issue	Risk management	Woman reported inappropriate advice given by One to One midwife – RCA found this was not the case
46	2016	South Cheshire CCG	No	Other care issue	Record keeping	Transfer to NHS provider, incomplete documentation, escalation process not followed, no handover in labour
47	2016	South Cheshire CCG	No	Maternal haemorrhage	Communication	Poor communication
48	2016	South Cheshire CCG	No	Not indicated	Transfer in labour	Woman transferred in labour
49	2016	South Cheshire CCG	No	NICU admission	Transfer in labour	Woman transferred in labour.
50	2016	South Cheshire CCG	No	Not indicated	Transfer in labour	Transfer in labour
51	2016	South Cheshire CCG	No	Emergency c-section	Transfer in labour	Transfer in labour
52	2016	South Cheshire CCG	No	NICU admission	Communication/shared care problems	Poor multi-agency working, not following latest NICE guidance
53	2016	South Cheshire CCG	No	Maternal haemorrhage	No information provided	Bi-corneal uterus
54	2016	South Cheshire CCG	No	Clinical care	No information provided	Mother required iron transfusion at 36 weeks
55	2016	South Cheshire CCG	No	Clinical care	Risk management	Reduced movements, sent to NHS provider for triage
56	2016	South Cheshire CCG	No	Retained placenta	No information provided	Home birth
57	2016	South Cheshire CCG	No	Clinical care	Delayed transfer to obstetric care	Woman in labour. Late transfer to NHS provider unsuccessful
58	2016	South Cheshire CCG	No	Not indicated	No information provided	Planned home birth – gave birth with NHS provider
59	2016	South Cheshire CCG	No	3rd degree tear	No information provided	Third degree tear
60	2016	Vale Royal CCG	No	Other care issue	Communication with GP	Did not share information with GP about ovarian cyst
61	2016	South Cheshire CCG	No	Other care issue	Communication/shared care problems	Poor planning and communication with the NHS provider
62	2016	South Cheshire CCG	No	Clinical care	Delayed transfer to obstetric care	Transfer to NHS provider – delay in first stage of labour
63	2017	Warrington CCG	Yes	Safeguarding	No information provided	Harm to baby
64	2017	South Cheshire CCG	Yes	Clinical care	Transfer in labour	Mother admitted in labour – low weight baby and query regarding Down's syndrome
65	2017	South Cheshire CCG	Yes	NICU admission	Transfer in labour	Transfer in labour
66	2017	North East Essex CCG	Yes	Intrauterine death	Communication/shared care problems	Woman experienced negativity towards One to One from NHS Provider staff and attended hospital without informing One to One. Transfer to NHS provider at 31 weeks.
67	2017	South Cheshire CCG	Yes	Safeguarding	Communication	Poor communication
68	2017	South Cheshire CCG	Yes	Safeguarding	No information provided	
69	2017	South Cheshire CCG	Yes	Clinical care	Clinical care	High Body Mass Index, no plan. No antenatal visits 17-30 weeks
70	2017	South Cheshire CCG	Yes	Other care issue	Communication/shared care problems	Woman transferred in labour. NHS provider unaware of woman
71	2017	South Cheshire CCG	Yes	Other care issue	Communication/shared care problems	NHS provider suggested One to One Midwife over-influencing the woman
72	2017	South Cheshire CCG	Yes	Other care issue	Communication/shared care problems	Woman told NHS provider she was unhappy with care from One to One. Declined to transfer care
73	2017	South Cheshire CCG	Yes	Other care issue	Communication/shared care problems	One to One requested NHS provider complete ultrasound scan ('small for date'). Care remained with One to One.
74	2017	South Cheshire CCG	No	Sepsis	No information provided	Mother admitted with sepsis, safeguarding
75	2017	South Cheshire CCG	Yes	Clinical care	Transfer in labour	Transfer into NHS provider in labour – long latent phase

	Year	CCG/Provider	Reported on StEIS	Incident type	Theme	Key findings from investigations
76	2017	South Cheshire CCG	Yes	Clinical care	Transfer in labour	Transfer into NHS provider in labour - hypertensive
77	2017	LWH	Yes	Intrauterine death	Communication/shared care problems	Communication issues between One to One and the NHS provider; One to One midwife not aware SBAR needed for transfers. Lack of ownership of ongoing plan of care as no shared care pathways
78	2017	South Cheshire CCG	Yes	Clinical care	Communication/shared care problems	
79	2017	South Cheshire CCG	Yes	Other care issue	Communication with woman	One to One used text messages to communicate with woman and to triage
80	2017	Wirral CCG	Yes	Intrauterine death	No information provided	
81	2017	South Cheshire CCG	Yes	Other care issue	Communication/shared care problems	One to One made request to NHS provider for external cephalic version at 38 weeks
82	2017	South Cheshire CCG	Yes	NICU admission	Delayed transfer to obstetric care	Delay in Mama identifying the issues and arranging the transfer.
83	2017	Warrington CCG	Yes	Intrauterine death	Communication/shared care problems	Friction identified between One to One and the NHS provider.
84	2017	South Cheshire CCG	Yes	Safeguarding	Communication	Communication identified as an issue
85	2017	South Cheshire CCG	Yes	Clinical care	Communication/shared care problems	Hospital birth – no plan for this with NHS provider
86	2017	South Cheshire CCG	Yes	Retained placenta	No information provided	Home birth
87	2017	South Cheshire CCG	Yes	Clinical care	Delayed transfer to obstetric care	High risk pregnancy, first appt with consultant at 26 weeks
88	2017	South Cheshire CCG	Yes	Clinical care	Delayed transfer to obstetric care	Planned home birth – delayed in transfer to NHS provider
89	2017	South Cheshire CCG	Yes	Clinical care	Risk management	High risk of deep vein thrombosis, mental health issues
90	2018	MCHFT	Yes	Neonatal death	No information provided	
91	2018	South Cheshire CCG	Yes	Clinical care	Delayed transfer to obstetric care	Referral at 33 weeks to NHS provider of woman with epilepsy
92	2018	South Cheshire CCG	Yes	Safeguarding	Communication	Lack of communication about safeguarding issue
93	2018	Vale Royal CCG	Yes	Other care issue	Communication with GP	Communication issue, GP concern that One to One not getting medical records
94	2018	South Cheshire CCG	Yes	Clinical care	Delayed transfer to obsetric care	Late referral for intrauterine growth restriction following ultrasound scan
95	2018	WUTH	Yes	NICU admission	Communication, record keeping and risk management	One to One did not recognise that this was a high risk pregnancy, One to One documentation substandard. NHS provider did not share information about non-attendance with One to One
96	2018	South Cheshire CCG	Yes	Safeguarding	Communication/shared care problems	Communication for postnatal care
97	2018	South Cheshire CCG	Yes	Other care issue	Communication with woman	Woman concerned about One to One measurement of fundal height
98	2018	South Cheshire CCG	Yes	Clinical care	Midwife availability	One to One not able to provide timely clinical care
99	2018	South Cheshire CCG	Yes	Other care issue	Communication/shared care problems	No communication when transferred to NHS provider
100	2018	South Cheshire CCG	Yes	Clinical care	Midwife availability	Planned home birth. Transfer to NHS provider in own car because no One to One midwife available or contactable and 3 hour wait for ambulance
101	2018	South Cheshire CCG	Yes	NICU admission	No information provided	Home birth
102	2018	South Cheshire CCG	Yes	Clinical care	No information provided	Malpresentation – admitted to NHS provider for a caesarean section
103	2018	Wirral CCG	Yes	NICU admission	No information provided	Planned induction of labour
104	2018	WUTH	Yes	NICU admission	Risk management	One to One providing care to woman with significant risks who would not engage with the NHS provider. Not clear how she was 'encouraged' to engage with them.
105	2018	South Cheshire CCG	Yes	Clinical care	Transfer in labour	Planned home birth. Transfer to NHS provider pushing
106	2018	South Cheshire CCG	Yes	Other care issue	Communication/shared care problems	Poor communication about clinical presentation with NHS provider
107	2018	South Cheshire CCG	Yes	Intrauterine death	No information provided	
108	2018	South Cheshire CCG	Yes	NICU admission	Transfer in labour	Transfer to NHS provider at 9cm.
109	2018	South Cheshire CCG	Yes	Clinical care	Midwife competency	Documentation error and lack of knowledge – new starter. No communication with NHS provider for a hospital birth
110	2018	South Cheshire CCG	Yes	Clinical care	Transfer in labour	Planned home birth, failure to progress, transfer to NHS provider
111	2018	South Cheshire CCG	Yes	Clinical care	Communication/shared care problems	Eclamptic fit at home, twin pregnancy, no communication with NHS provider
112	2018	North East Essex CCG	No	Baby death	No information provided	
113	2018	North East Essex CCG	No	Maternal haemorrhage	No information provided	
114	2018	North East Essex CCG	No	Maternal haemorrhage	No information provided	
115	2018	South Cheshire CCG	Yes	Clinical care	Communication/shared care problems	Transfer to NHS provider, no advance directive for Jehovah's witness
116	2018	South Cheshire CCG	Yes	Clinical care	Transfer in labour	Transfer to NHS provider - breech
117	2018	WUTH	Yes	Neonatal death	No information provided	
118	2018	South Cheshire CCG	Yes	Maternal haemorrhage	No information provided	
119	2018	South Cheshire CCG	Yes	Maternal haemorrhage	Transfer in labour	Planned home birth. Transfer to NHS provider in labour, 3rd degree tear and maternal haemorrhage
120	2018	South Cheshire CCG	Yes	Clinical care	Transfer in labour	Transfer to NHS provider for pain relief
121	2018	South Cheshire CCG	Yes	3rd degree tear	No information provided	3rd degree tear, home birth
122	2018	South Cheshire CCG	Yes	Maternal haemorrhage	Transfer in labour	Transfer at 9 cm
123	2019	South Cheshire CCG	Yes	NICU Admission	Risk management	Home birth unplanned
124	2019	South Cheshire CCG	Yes	NICU admission	No information provided	
125	2019	South Cheshire CCG	Yes	Other care issue	Communication/shared care problems	Woman transferred to NHS provider herself, no SBAR
126	2019	South Cheshire CCG	Yes	Unplanned casearean	Don't know	Transfer to NHS provider, Caesarean section
127	2019	South Cheshire CCG	Yes	Clinical care	Transfer in labour	Transfer to NHS provider for pain relief
128	2019	South Cheshire CCG	Yes	Clinical care	Communication/shared care problems	Planned hospital birth but One to One would not assess before transfer to NHS provider.
129	2019	South Cheshire CCG	Yes	Clinical care	Communication/shared care problems	Communication with NHS provider. Planned hospital birth.
130	2019	South Cheshire CCG	Yes	Clinical care	Communication/shared care problems	Woman not seen in anaesthetic clinic
131	2019	South Cheshire CCG	Yes	Maternal haemorrhage	Risk management	Known placenta praevia. Advice given by One to One inappropriate. Admitted to NHS provider. 3rd degree tear, maternal haemorrhage
132	2019	Wirral CCG	Yes	NICU admission	RCA not completed	RCA not completed because One to One notes not available
133	2019	Wirral CCG	Yes	Maternal haemorrhage	RCA not completed	Unplanned home birth, 3rd degree tear and maternal haemorrhage. RCA not completed because One to One notes not available
134	2019	South Cheshire CCG	Yes	Unplanned casearean	Transfer in labour	Transferred to NHS provider in labour, caesarean section
135	2019	South Cheshire CCG	Yes	Other care issue	Communication/shared care problems	Woman attended NHS provider, no referral from One to One
136	2019	South Cheshire CCG	Yes	Clinical care	Communication	Use of text messages
137	2019	South Cheshire CCG	Yes	Clinical care	Midwife availability	Woman in labour could not make contact with One to One. Admitted to NHS provider and gave birth in hospital

Appendix 5 – Detailed chronology of events

We set out overleaf a detailed chronology of key events from the inception of One to One through to the company's cessation.

For ease of understanding, the chronology is in a tabular format so that the commentary on the commissioning, contracting and finance elements is kept distinct from the quality and safety aspects. Given the complexity and length of the timeline, we have divided it into 6 constituent parts as follows:

Part One:	Pre-April 2011	Inception and pilot
Part Two:	2011/12 - 2013/14	Contract with Wirral CCG and national growth
Part Three:	2014/15	Business expansion and quality oversight
Part Four:	2015/16	Fragile relationships, financial viability and CQC concerns
Part Five:	2016/17 - 2018/19	Co-commissioned contract and financial challenges
Part Six:	2019-20	Business cessation

Chronology Part One

Pre-April 2011 Inception and pilot

Commissioning, Contracting and Finance	Quality and Safety
2007/08	
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 (the case loading model). The aim was to provide a complimentary service to existing NHS provision to improve choice for women. In September 2007, national guidance on the responsibility for payment for a patient's care was issued by the Department of Health (DH), 'Who Pays? Establishing the Responsible Commissioner, 2007'. This would have significant implications for One to One's business growth.	'Maternity Matters' was published by the Department of Health in 2007). This was a national framework for maternity services to improve choice, access and continuity of care for women. The policy stated that women could choose a provider outside their local area if the provider had capacity. Wirral Primary Care Trust (PCT) undertook an independent review of local maternity services in response to Maternity Matters and were keen to develop services locally to improve choices for women. Existing maternity services were provided by the local acute Trust, Wirral University Teaching Hospital (WUTH) who were approached by the PCT about delivering maternity services in the community; the PCT made an additional investment in ultrasound equipment for this purpose. However, the Trust was not offering a community-based model at the time.
2008/09	
The two midwives became directors of a company set up to take the concept to market called One to One Maternity Services Ltd. Approaches were made to CCGs across the country including in Sheffield, the Midlands and Manchester. The company was a vehicle for marketing and development and had no income and limited sources of finance. It ran up a loss of £30k this year mainly due to expenditure on salaries, training and travel. The Directors approached external investors and received some interest but there were no formal commitments due to the challenges in finding an insurance solution for independent midwives.	
2009/10	
The financial position of the company deteriorated due to the lack of alternative sources of finance and concrete interest by the NHS. The company posted a loss of £108k and remained dormant. There was a	In 2009, the Albany Midwifery Practice was closed due to safety concerns; this had been subject to much publicity and controversy. They had been sub-contracted by King's College Hospital NHS Trust in

disagreement on strategy between the two Directors with one remaining a silent partner in the dormant company. The remaining Director went on to establish a trading company (see further below).

The Any Willing Provider (AWP) policy was introduced in 2009 as a contracting framework to encourage commissioning of a wider range of providers including the independent sector, to offer more choice. The guidance set out a range of services for which the approach might be suitable, broadly covering community-based and mental health services. AWP could be used for other services if there was a clear case to do so, for example improved access and quality.

1997 to provide a continuity of carer model for an agreed number of women per year.

2010/11	
In May 2010, One to One Midwives ('One to One') was established as a trading company and incorporated as One to One (North West) Limited to provide a case loading midwifery service to NHS-funded clients. The company did not provide privately funded services. One to One approached the lead commissioner for maternity services at Wirral PCT who was receptive to the concept proposed. In June 2010, a pilot scheme for 70 women was agreed with Wirral PCT. This was to be funded jointly by the PCT and local authority by a single block payment of £100k. The contract was under AWP arrangements for 9 months with an option to extend. It covered the antenatal and postnatal elements of the pathway only as One to One's insurance did not cover intrapartum care.	The pilot proposal was presented to Wirral PCT's Professional Executive Committee. The paper stated that feedback from women and clinicians indicated a need for such provision. Women transferred to the local NHS obstetric unit for the birth with the intention that the woman was accompanied by their One to One midwife. WUTH raised concerns about the potential clinical risks of the model and the impact on their income due to activity lost to One to One. The Local Authority's Public Health department contributed to the funding because the pilot focused on the needs of women with particular challenges such as poor mental health and problematic lifestyle choices in Birkenhead, a relatively deprived area on the Wirral. In September 2010, the DH published 'Midwifery 2020: Delivering expectations'[7]. This set out the anticipated role of midwives

[7] https://www.gov.uk/government/publications/midwifery-2020-delivering-expectations

One to One presented a proposal to Wirral PCT to provide a full case loading model in February 2011.

The pilot continued this year and into the next.

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 co-ordinator in other cases.

In early 2011, WUTH raised a number of safeguarding issues; seven cases were of particular concern. These were subsequently investigated (see Part 2).

Chronology Part Two

2011/12 to 2013/14 Contract with Wirral CCG and national growth

Commissioning, Contracting and Finance	Quality and Safety
2011/12	
April - October 2011	
The accounts for One to One (North West) Ltd. showed a small loss of £2k for the year to 31 May 2011.	In May 2011, an initial meeting took place between One to One and WUTH to discuss communication, joint working pathways and incident reporting. One to One reported having requested such meetings since the beginning of the pilot. Tensions had arisen in the relationship between One to One and WUTH due to the Trust's clinical concerns following the series of incidents in 2010/11 (see Part 1). Further meetings continued until Autumn 2011 when they paused. One to One reported that relationships deteriorated due to *"unprofessional communication from the [WUTH] team".* In July, WUTH's Designated Nurse for Safeguarding Children undertook an independent review of the safeguarding cases and advised that during the audit, One to One were unable to provide case notes for six of the cases. Further investigation found that some case notes had been subsumed in WUTH's records as there had been joint care arrangements.
The DH issued guidance in September 2011 on the application of AWP frameworks. The AWP policy changed, essentially in name only, to Any Qualified Provider (AQP). Antenatal education and breastfeeding support were suggested areas for inclusion under the latest guidance. The One to One pilot continued in Birkenhead until October 2011. This had expanded to approximately 200 women. The PCT and local authority funded the additional activity.	
November 2011 - March 2012	
In November, One to One were awarded their first contract by Wirral PCT under the AQP framework until March 2014. A local tariff was applied: £2,200 for antenatal and postnatal care and £2,100 for a home birth. Under an AQP contract, there were no guaranteed activity levels; it was for	The contract specification covered women registered with a Wirral GP only, all risk profiles and all elements of the maternity pathway. When a woman chose or required a hospital birth, the specification stated that clinical responsibility for their care would rest with the hospital midwife. The specification emphasised the need for

One to One to market their services. AQP providers were included on a national directory of services (Choose and Book at the time) to support this. As One to One promoted its service model, interest grew in neighbouring areas to the Wirral. Women self-referred to the service which resulted in non-contract activity (NCA), notably in Liverpool and West Cheshire. One to One undertook this activity on the understanding that NCA could be undertaken on this basis of the Wirral contract under the AQP framework. However, One to One did not seek agreement to this from Liverpool and West Cheshire commissioners. As a result, the PCTs did not pay for this activity as it had not been commissioned by them; they adhered to the Who Pays Guidance of 2007 which stated that NCA would not be funded for routine elective care as a contract should be put in place. One to One estimated lost income of approximately £250k for this activity. Commissioners in Warrington and Cheshire expressed an interest in becoming co-commissioners on the contract.	the development of safe and effective shared care arrangements with hospital maternity services and GPs. Following the pause in joint meetings due to strained relationships between One to One and WUTH, the monthly meetings were restarted from January 2012 between senior midwives to try to resolve the issues which had arisen around joint working. At the meeting in January, One to One provided a report which gave *"evidence of the unprofessional behaviour of WUTH midwives towards One to One midwives and clients".* One to One had reported the incidents to the WUTH risk management team and through the supervision of midwives' process. At the February meeting, there was further discussion on the implications of the report for the care of women. One to One understood that there would be a full review through senior management and local supervision and that an update would be provided at the next meeting in March. One to One advised that they did not receive any update. One to One produced a Quality Report for 2011/12. The section on Clinical Audit stated that One to One *"has used audit effectively to confirm that our processes work and that we are successful in achieving our outcomes, in identifying areas for improvement and for implementing change".* It references challenges with data collection and the planned roll-out of a bespoke electronic system (HERA) in Spring 2013 to improve processes. There was no information about patient safety incidents in the Quality Report.
2012/13	
April 2012	
The DH introduced the Maternity Pathway Tariff for shadow testing. It set out three stages for payment purposes – antenatal, delivery and postnatal care. There were 3 levels of payment on the antenatal and postnatal pathways to recognise different levels of risk and complexity. There were two levels for the birth payment for 'with' and 'without'	The Royal College of Midwives (RCM) opposed the use of AQP for midwifery services (Midwives, Issue 2 of April 2012). The RCM recognised the benefits of increasing choice for women, however, expressed concerns about quality and outcomes as a result of a market driven service. It envisaged less integrated care

complications/co-morbidities. Home births were at the same tariff as a hospital birth. It introduced the concept of a women choosing their 'lead provider' for each stage of the pathway. Commissioners would make one payment to the lead provider responsible for each stage. This could mean separate payments to different lead providers. For example, a woman might choose One to One for antenatal and postnatal care and their local NHS obstetric unit for the birth. These arrangements meant that should a woman change provider during the pathway, the lead provider who has been paid for that pathway stage would need to pay the receiving provider for their interventions (for example scans, tests and appointments). These were known as provider to provider charges and were applied on the basis of standard national non-mandatory tariffs. One to One accepted self-referrals from women in a number of other areas, including Lancashire, Greater Manchester, Stoke, St Helens and Bradford.	as NHS providers would be reluctant to support competitors. The contract meeting in April 2012 referred to a GP survey undertaken to obtain views on the service. There were some concerns about the high number of home births and whether women were being pressured into having a home birth. An issue was raised about social services not recognising One to One as a woman's care provider and their information being shared with the NHS Trust rather than with One to One. One to One undertook a CQC self-assessment in April 2012 and invited WUTH and the Local Supervising Authority Midwifery Officer (LSAMO) to engage with this.
May 2012	
In May, One to One expressed concerns at the lack of GP referrals despite their attempts to engage with practices. The accounts for the year to 31 May 2012 for One to One (North West) Ltd. showed a cumulative loss of almost £0.6m and creditors of almost £1m. There had been a commercial loan of £0.2m to support the business. The Director's Report refers to liquidity problems and reliance on creditors. One to One put its debtors out to a factoring company for recovery. These were invoices to NHS Trusts under provider to provider charging arrangements.	
June 2012	
	In June, WUTH contacted the Wirral PCT Chair with their concerns on several quality and safety issues relating to One to One – referred to as a 'letter of concern'. The

	letter was from the Head of Midwifery, the Obstetric Clinical Service Lead and the Supervisor of Midwives from WUTH. It was unclear whether the WUTH Executive Team were sighted on this letter. Details of 18 safeguarding and quality concerns since May 2011 were provided. The Trust's understanding was that One to One's remit was to care for low risk women only. The letter stated that One to One had been operating outside their sphere of practice by undertaking newborn examinations, without the appropriate training (this was subsequently found to be unsubstantiated). This letter was sent anonymously to the CQC and the LSAMO. The CQC requested an immediate response which One to One provided. The LSAMO had no concerns and advised that any issues would be picked up by their annual audit in November. The issues had also been raised with the North West Strategic Health Authority's (SHA) Assistant Director of Children and Maternity.
July 2012	
In July 2012, NHSE published 'Commissioning Maternity Services. A Resource Pack to support Clinical Commissioning Groups.'	One to One were informed of the 'letter of concern' from WUTH by Wirral PCT. One to One were disappointed that the "hard work" that had been undertaken to build relationships had been undermined. One to One suspended the monthly meetings pending resolution of the issues outlined in the letter. The Chief Executive of One to One requested a meeting with the Chief Executive Officer of WUTH to escalate the concerns around unprofessional conduct. It is unclear if this meeting took place.
August 2012	
	In August 2012, One to One met with the North West LSAMO to discuss the issues around joint working and professional conduct. One to One raised the issue of bullying behaviour from local NHS maternity providers. They were concerned about the impact of the actions of NHS providers on GP referrals and One to One's reputation. A meeting was held in August 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. One to One's notes of this meeting were more positive and referred to plans for developing joint working and attendance at a *'great day'* at LWH to present to the obstetricians.
September 2012	
At the contract meeting, One to One raised the Liverpool NCA activity which had not been paid for. One to One had been escalating this to the SHA since January 2012 without resolution. One to One planned to stop their marketing activity in Liverpool as a result. One to One reported that the NHS Litigation Authority (NHSLA) rules for insurance cover were due to change and any provider could become a member on the condition that they had an NHS contract.	At the end of September, there was an unannounced inspection by the CQC and an external regional Supervisor of Midwives at One to One's registered office in Birkenhead. The inspection report in October found that One to One met all required standards; detailed records were available for women and there was evidence of learning from incidents. There were no recommendations for improvement. The response document to the letter sent to the CQC by WUTH in June was scrutinised and the PCT responded to WUTH's comments. It contained potentially unfounded comments by WUTH staff and a Unison representative which had been shared with the local MP and media.
October 2012	
	An internal CCG report produced by the Commissioning Lead for Maternity Services in October 2012 summarised the concerns that had arisen and describes the actions that had been taken by the CQC and LSAMO. It included the CQC response document. A further report in October, "Investigation of Concerns Regarding the One to One Maternity Service" was produced by the Commissioning Lead for Maternity Services and the Medical Director of Wirral PCT. This further articulated the problems that had arisen during the pilot and the first year of the contract. It made some recommendations to strengthen risk assessment and documentation. It found that One to One had appropriately investigated the incidents (none of which

	met the threshold for reportable incidents) and that women had expressed a high level of satisfaction with the service. The report highlighted that the impact on existing services and infrastructure had not been considered by commissioners before the introduction of One to One. West Cheshire PCT undertook a review of maternity services and approached Wirral PCT with regards to joining the contract. One to One's team in October 2012 consisted of a Clinical Director, three Clinical Leads, a Midwifery Team Leader, six experienced midwives and three newly qualified midwives as well as four administrative staff. One to One's planned ratio of midwives to women was 1:35.
November 2012 – March 2013	
At the contract meeting, One to One alerted commissioners to its financial problems stating that without further support from commissioners in terms of guaranteed activity levels, the company would go into liquidation. One to One estimated that they needed 72 bookings and 14 births per month to be financially viable. Bookings were running at about 53 per month and home births at about 7 per month. One to One had managed to obtain private insurance but the premiums were unsustainable at £650k per annum. In addition, other PCTs were refusing to pay for NCA including in Bradford and Manchester. One to One asked for its March contract payment in advance to help with these pressures. In January, One to One received legal advice on the legal right to choice and non-payment of invoices for NCA. The advice suggested that One to One may have a legal justification to pursue non-payment of NCA but this was subject to the interpretation of the Who Pays guidance in place at the time, and it was unclear which version applied. The paper highlighted the inconsistency between this guidance and national maternity policy.	

In February, the former Lead Commissioner for Maternity Services at NHS Wirral joined One to One as Commercial Director.	
2013/14	
April – May 2013	
The Maternity Pathway Tariff became mandatory from 1 April. At the contract meeting, One to One raised concerns about the fairness of provider to provider charges when a woman transfers to hospital and is funded at a higher level of complexity than under the payment initially received. One to One sought support from the CCG but were told that they could not express a preference for a particular provider. Liverpool and West Cheshire CCGs agreed to fund activity under the Wirral contract from April 2013. In May, One to One made a further request for a payment in advance. The accounts for the year to 31 May 2013 for One to One (North West) Ltd. showed a profit for the year of £81k and a cumulative loss of almost £0.5m. Liquidity had improved, creditors had increased to £1.3m but this was counterbalanced by £0.8m of debtors. There was an additional cash injection of £0.2m in share capital. The creditors on One to One's balance sheet related mainly to provider to provider charges from NHS Trusts.	At the April contract meeting, One to One referred to a survey they had undertaken which indicated that in 89% of cases, women were not being offered choice by their GP. Problems continued with low GP referrals and only 5 out of 60 practices had responded to One to One's approaches. One to One reported some improved engagement later in the year. In May, 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 they raised a complaint about claims by WUTH that they were not providing the information required.
June – September 2013	
In July 2013, One to One appointed an experienced accountant (a former Partner at KPMG) as a Non-Executive Director.	In July, Neighbourhood Midwives was set up as an employee-owned social enterprise. It was commissioned to provide a case loading model in North East London by Waltham Forest CCG. One to One (North West) Ltd. had started operating under NCA in Vale Royal and South Cheshire. In July, One to One sent communication protocols to the local NHS Trust covering safeguarding, incident reporting and transfers for intrapartum

The national 'Who Pays' guidance was refreshed in August 2013. This reiterated the 2007 guidance that formal contracts should be put in place where activity is significant. It clarified that there was no legal 'right to choice' for maternity services under the NHS Constitution.	care. The Trust had not contributed to these documents.
October 2013	
One to One expressed their need for a longer term contract to give assurance to investors and to support their planned investment in new offices and a birthing centre in Birkenhead. The CCG advised that a procurement process would be required. There were still concerns about non-payment of NCA and One to One referred to a letter from Monitor which stated that self-referrals should be paid for. The CCG reiterated that the Who Pays Guidance did not permit this, and prior approval was required from commissioners. One to One became a member of the Clinical Negligence Scheme for Trusts (CNST).	At the contract meeting in October, it was reported that regular audits were now carried out on home births. The general findings were that women felt more in control, would repeat the experience and did not feel pressured into a home birth. In October, the CQC undertook an unannounced inspection in Birkenhead following concerns raised by a local NHS provider. The report found all standards had been met.
November – December 2013	
In November 2013, Wirral CCG agreed to extend the contract for the period from December 2013 to March 2015 pending a planned re-procurement.	In December 2013, the CQC undertook an inspection of One to One in Bradford due to concerns raised by the local acute Trust. The subsequent report (January 2014) found all standards had been met. It noted that One to One should consider the impact on the acute Trust of booking women with them in their third trimester as there was a potential for the acute Trust to have to manage emergencies with women who had not booked with them. There was a CNST requirement for women to book in their first trimester.
January 2014	
Wirral CCG raised concerns about One to One's marketing on Facebook which implied that services were available to women outside the area but did not state that a GP referral or prior CCG approval was needed. One to One	In January, the House of Commons Committee of Published Accounts published its review 'Maternity Services in England'.[8] It found serious shortcomings in the DH's assurance on the performance of

[8] https://publications.parliament.uk/pa/cm201314/cmselect/cmpubacc/776/776.pdf

confirmed that they were not adhering to the Who Pays guidance in this regard.	maternity services and delivery of the national strategy (Maternity Matters, 2007).
February 2014	
In February, a senior manager from an NHS provider contacted Wirral CCG about the impact of independent midwifery generally, highlighting the risks of a fragmented care model, differences in risk assessment and lack of care pathways. The letter also raised the potential adverse impact on the financial viability of their local obstetric unit. Commissioners remained keen to develop formal arrangements for collaborative working with One to One. The view was expressed that the CCGs did not fully appreciate the operational challenges involved in this.	One to One informed Wirral CCG that they were planning to bring obstetric cover in-house. This was to promote continuity of care with obstetricians that shared the One to One approach to maternity care and deliver cost savings. Concerns were expressed by a member of staff from a Wirral GP practice in a public forum, about the safety of the One to One service. One to One reported that they were having quarterly meetings with WUTH and meetings with the Countess of Chester Hospital (COCH), but that LWH had not responded to requests for meetings.
March 2014	
In March, there was further discussion about advance payments with One to One stating that *"they did not have the same access to public funds like acute hospital maternity wards."* Monitor undertook a review of maternity tariff issues raised by commissioners and providers nationally, 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".* NHS Trusts were charging One to One using the recommended national tariff, but sub-contracts were not in place. At the same time, NCA was increasing in other areas of the country, for example in Essex and Bradford.	In March, there was a discussion about performance information on maternal morbidity. One to One were not able to provide this data for women transferring to acute Trusts for the birth due to not having any subsequent involvement. Commissioners asked for numbers of women transferred into hospital from One to One who had suffered post-partum haemorrhage or hysterectomy. It was expected that this information would come from the acute provider who would indicate who had provided the antenatal care. Wirral and West Cheshire CCGs planned a workshop event with One to One on learning from incidents. Our review found that in 2013/14 there were ten incidents reported that included three intrauterine deaths and three neonatal deaths. There were four incidents of babies being transferred to the neonatal unit, two of which were hospital births and two were born at home. One of the cases was de-escalated from a Serious Incident (SI). Concerns relating to midwifery practice within One to One were present in five of the investigations. The concerns identified by the investigations included safeguarding, communication, lack of a formal contract, non-contracted activity

Wirral CCG confirmed a competitive procurement process would be undertaken for a case loading model as the current contract would expire in March 2015. West Cheshire CCG planned a separate tender exercise to adopt their own service specification. One to One's financial position at the end of 2013/14 (accounts to March 2014) remained broadly similar with a cumulative loss of £0.5m. Creditors had fallen to £0.8m and the Directors Report stated there was increased confidence in an improving position and that working capital was sufficient.	and patient care not being appropriately managed by a midwife.

Chronology Part Three

2014/15 Business expansion and quality oversight

Commissioning, Contracting and Finance	Quality and Safety
2014/15	
April 2014	
Wirral, Liverpool, Warrington and West Cheshire CCGs as co-commissioners, put in place a standard NHS contract with One to One from April 2014 for one year; the approximate annual value was £1.9m. Representatives from each commissioner attended the monthly contract meetings. All CCGs apart from Liverpool agreed to make payments on planned activity. Liverpool CCG paid on actual activity. The NHS Litigation Authority confirmed CNST cover for One to One from 1 April 2014. Scanning was sub-contracted to an external company. Blood tests were subcontracted to the Royal Liverpool Hospital.	In April, North East Essex (NEE) CCG approved a proposal for One to One to provide services to approximately 200 women. One to One was seeking to formalise its relationship with NEE. The proposal was positive about One to One's service outcomes and expressed the view that introducing the model would not destabilise the existing local maternity system. The proposal received clinical endorsement by the CCG. The local NHS provider, Colchester Hospital University Foundation Trust (CHUFT) were made aware of the discussions and had a number of meetings with One to One.
May 2014	
LWH received a letter from One to One chasing £12k of debt for provider to provider charges made by One to One. At the time there was a local agreement to defer the provider to provider charges system and LWH informed One to One of this. One to One stated they had not been informed of this and insisted on recouping payment. As a result, LWH billed for their charges which were much more significant.	Wirral CGG and co-commissioners completed a Desk Top review with One to One for quality assurance. A number of areas were identified as requiring improvement including, communication on safeguarding issues, deviation from national guidance, documentation and midwife supervision. An incident involving a perinatal death was raised as an example of where midwife supervision appeared inadequate. One to One provided assurances that the Root Cause Analysis (RCA) report which had been shared with West Cheshire CCG addressed the queries raised. Wirral CCG did not have oversight of all serious incidents and RCA reports, and this would need to be put in place going forwards. Wirral CCG issued a contract query notice following the review. One to One were concerned about the use of a formal mechanism to raise concerns.
June 2014	
One to One appointed a Clinical Director in June 2014.	In the contract meeting in June, One to One's data quality was questioned due to a

	significant inaccuracy identified in the number of births at the Desk Top review. The Commissioning Support Unit (CSU) would be collating the data for reporting and a validation process was to be taken forward by the Commissioning Manager and One to One's Commercial Director. One to One was providing services in Greater Manchester (GM) through NCA at this time. In June 2014, following three reported serious incidents, Trafford CCG commissioned a quality review which identified concerns with the standard of policies, safeguarding training, partnership working and communication with the local maternity providers. One to One's service specification was not consistent with requirements for GM. The GM CCGs did not endorse One to One operating in their area. In June, the CQC undertook an unannounced inspection in Birkenhead in response to concerns from some NHS providers. The subsequent report (September 2014) commented on many aspects of governance and assurance, for example, RCA reports did not consider all contributory and service delivery factors, midwifes did not routinely apply learning from incidents and lacked awareness of NICE guidance; the risk register did not have action leads or completion dates. In addition, it highlighted weaknesses in joint working arrangements with local Trusts and tensions in relationships.
July 2014	
One to One started to provide services in North East Essex (NEE) under the Wirral arrangements as an implied contract. Lead provider arrangements applied with payment for activity in arrears.	In July, NHS England (NHSE)North convened a single item Quality Surveillance Meeting. The issues identified were that One to One was providing a service in areas where it had no contract, and that NHSE North was unable to quantify and manage the level of risk associated with the service. The outcome of this meeting was for NHSE North to gather more intelligence about One to One and to call a further meeting in November 2014. Four complaints were received by One to One in July, mainly relating to communication with other providers.

August 2014

NHSE North West contacted the NHSLA to understand the criteria for an NHS commissioned service, such as One to One, to be considered for insurance cover for clinical negligence, including scenarios for NCA with no GP referral.

In August, NEE completed a review of maternity services and recommended further examination of One to One's service model.

In the Wirral contract meeting, Warrington CCG expressed a view that the difficulties in engaging with GPs were potentially 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 may be helpful to improve understanding of One to One's services. One to One stated that they had attempted to join these groups but that their attendance had not been encouraged.

One to One started to employ a part-time Consultant Obstetrician to provide face-to-face and remote support to midwives. The associated risks were discussed at the contract meeting.

September 2014

In September, One to One said they were developing agreements for joint working with NHS providers. One to One had approached Trusts in Cheshire and Merseyside (C&M) and some reported feeling pressured to adopt the agreements. NEE asked CHUFT to put in place an agreement as a matter of urgency.

South Cheshire and Vale Royal CCG were interested in joining the contract but were not accepted at this point as the contract was due to expire at the end of the year.

In September, Wirral, Liverpool and Warrington CCGs commenced a procurement process for a case loading service with a view to a co-commissioned contract from April 2015. A provider engagement event was attended by One to One and two local acute Trusts (LWH and WUTH). Queries from providers were focused on the specification for low risk women only and impact on financial viability, as well as concerns over financial pre-qualification tests.

In September, it was reported that there was resistance from CHUFT to One to One operating in their area. One to One planned to hold workshops for the local maternity community to build relationships.

In September, Wirral CCG undertook a site visit to One to One. They were assured by their observations and the contract query was closed with ongoing oversight through the action plan.

The Royal College of Obstetricians and Gynaecologists (RCOG) initiated the 'Every Baby Counts' programme. This was a national quality improvement programme to reduce the number of babies who die or suffer harm as a result of incidents during labour. Notifiable cases to the RCOG were births over 37 weeks that included one or more of intrapartum stillbirth, early neonatal death, severe brain injury and avoidable term admission to NICU. It was the responsibility of the care provider to report this information.

October 2014

The pre-qualification questionnaire was completed by One to One and WUTH. The WUTH submission stated that LWH), WUTH and Warrington and Halton Hospitals NHSFT (WHH) were intending to form a consortium to provide the service. This did not progress further.

One to One requested an explanation of 'flex and freeze' dates under Payment by Results. One to One were unclear on the data to be submitted under the NHS Digital Secondary Uses Service (SUS).

In October, concerns were raised at the contract meeting about the competency of newly qualified midwives employed by One to One and assurance was requested.

One to One provided examples of problems created by GPs and health visitors not contacting One to One directly regarding women in their care.

In October, Mid Cheshire Hospitals NHSFT (MCHFT) raised concerns with commissioners (CCG and NHSE level) having become aware of the incidents reported by Trafford CCG. The Trust was advised to raise any further concerns with the CQC. The Trust remained nervous about working with One to One and requested their clinical pathway documentation for due diligence. The Commercial Director of One to One referred the Trust to NICE guidance and the assurance already provided to commissioners and was reluctant to share their policies.

November – December 2014

In November, One to One reported improving activity levels in Liverpool and West Cheshire and stated at the contract meeting that they were operating at a break-even level. One to One were planning to open 'pop-up' shops in Liverpool, Birkenhead and Crewe.

The Maternity Service Dataset was introduced in November for the submission of activity data to NHS Digital. This had been delayed since April 2014. One to One reported challenges in providing all the data as they did not have the information in cases when care was transferred to another maternity provider.

NHSE North held another 'single item' Quality Surveillance Meeting on One to One due to concerns raised. This meeting was chaired by the Chief Nurse NHSE North and was attended by representatives from NHSE South Yorkshire and NHSE Midlands and East. Information was shared about One to One activity in each area and the concerns that they and NHS providers had about the service. The conclusion was that a Risk Summit would be called to give One to One the opportunity to respond.

The Risk Summit was held on 12 November 2014. One to One was invited to attend the second part of the meeting with two days' notice. The letter identified four main

concerns: poor communication and no agreed pathways with local maternity providers; services provided to high risk women; compliance with NICE guidance; and the level of serious incidents compared with other organisations. In addition, the meeting was to address One to One working in areas without a contract, NHSLA cover and professional competency issues for midwives working at One to One.

At November's contract meeting, One to One stated that their incident rate was running at 2% against a national average of 0.2%. One to One believed this was due to *"being tagged into a number of incidents, i.e., should a baby need to attend hospital within a period of time following birth even though the reason they are attending is nothing to do with One to One."*

The December 2014 planning guidance to the Five Year Forward View referred to working with the Royal College of Midwives (RCM) *"to develop plans so that, from 2016/17 tariff based funding will support choice rather than constrain. As a result, it will make it easier for groups of midwives to set up as their own NHS funded midwifery service"*

January 2015

In January, North East Essex CCG sent a communication to GPs outlining maternity choices, including One to One.

In the Wirral CCG led contract meeting, commissioners advised that they did not support the in-house obstetrician model.

In January, a briefing was produced for Wirral CCG's Governing Body (approved in April) proposing that the procurement be abandoned due to various concerns around the specification. The CCG required this to be updated for NHS planning guidance, the ongoing Kirkup investigation into maternity services[9] and new NICE guidance. Issues were also raised around the legal obligations on commissioners and the indemnity position of providers relating to NCA. One to One's contract was extended to March 2017 as a consequence.

An agreement was set up between One to One and Anglian Community Interest Company, who provided the Health Visiting service in Essex; it was not signed.

NHSE North West held a further Risk Summit. The key topics discussed were the need for clarity about contracting and choice; the settlement of outstanding invoices; NHSLA cover and quality assurance. It was agreed in the meeting that NHSE North would complete a Desk Top review to seek quality assurance on the care provided by One to One.

In January, the contract meeting was informed that there had been a number of referrals regarding One to One staff to the Nursing and Midwifery Council. No further details were provided on this issue.

[9] The Report of the Morecambe Bay Investigation (publishing.service.gov.uk)

February 2015

In February, in response to NHSE's previous query, the NHSLA confirmed that cover for clinical negligence would apply to a service if there was an NHS contract in place.

The Desk Top review was completed in February 2015. It identified non-compliance with NICE guidance and poor relationships with providers. There were concerns that the risk assessments of women were not based on clinical criteria but on practical considerations such as caseload capacity and travel time to the woman's home. A woman declining care from an alternative provider after being provided with information about their risk was viewed by One to One as exercising informed choice.

One to One had not previously had access to the Strategic Executive Information System (StEIS) for reporting incidents. This was now in place.

In February, NHS England North wrote to the regional Director of Commissioning Operations and CCGs to confirm that women had no legal right to choice beyond the local CCG offer and that NCA could only be used in exceptional circumstances.

March 2015

LWH issued a standard letter to all providers advising that following the transitional year, the Trust would be invoicing for provider to provider charges. The letter set out the backing data that would be provided for invoices.

One to One advised of a new pregnancy advice centre which they had opened in Warrington. They hoped to undertake scans at this location and had advised the local Trust of the centre.

One to One's accounts for the year to March 2015 showed a profit of £100k, with cumulative losses reducing to £0.4m. Creditors had increased to approximately £1.2m, counterbalanced by £0.8m of debtors.

The Desk Top review findings were presented to a third Risk Summit. The review was unable to provide assurance in the following areas: emergency and planned shared care pathways; the risk assessment completed with women when they booked with One to One and midwives routinely being expected to work outside their scope of practice, e.g., inexperienced midwives attending home births alone. The meeting was attended by the Consultant Obstetrician employed by One to One who provided verbal reassurance about the issues raised and on the care of high risk women.

At the end of March, the prior Chief Nurse North left their post and provided the incoming Chief Nurse with a summary of the Quality Surveillance Group and Risk Summit process to date. This letter concluded that the process had not provided the level of assurance required with regards to relationships and communication between One to One and local NHS providers, the management of high risk women and midwives working

outside their scope of experience. However, it was not felt that the Quality Surveillance Group (QSG) and Risk Summit forums were the appropriate way to address these issues. A more in depth scrutiny of patient records and patient and staff interviews were needed. Risk Summit members (CCGs and the CQC) were identified as best placed to do this, to avoid disproportionate scrutiny of One to One.

One to One was to remain under enhanced surveillance until the additional assurance activities had been completed. The proviso was that should new information come to light, any stakeholder could request the Risk Summit to be reconvened.

Wirral CCG provided the activity and finance report for the year to the contract meeting in March for final reconciliation and baselining for the following year. No reports were presented from other co-commissioners, and they were unable to advise on their plans for the following year at the meeting.

In the Wirral contract meeting in March, One to One queried the representativeness of the maternity performance dashboard in some areas as it reported in percentages and their activity numbers were low. They were also concerned that their dashboard was seen by other maternity providers at the regional QSG.

One to One were asked to start producing Quality Accounts.

The One to One staff survey was discussed. Caseloads were reported to be 40 with plans to reduce them to 35 but midwives' annual leave would need to be reduced. Midwives reported poor communication from senior management and there were concerns about appraisal rates.

A report by the LSAMO was presented in March 2015. One to One commented that they would be challenging aspects of this as they were being treated inappropriately as an NHS acute Trust.

An issue had arisen with MCHFT who were not accepting women who had booked with One to One except in cases of emergency. Women who wanted to give birth in hospital were being referred to neighbouring hospitals.

Wirral CCG issued a contract query to One to One in March 2015 due to the heightened quality concerns.

We identified six adverse outcomes for women and/or their babies in this year. 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 completed by One to One. One of the incidents identified that the One to One midwife lacked basic midwifery skills and the experience required to provide care.

Chronology Part Four
2015/16 Fragile relationships, financial viability and CQC concerns

Commissioning, Contracting and Finance	Performance, Quality and Safety
2015/16	
April 2015	

Wirral CCG's Governing Body agreed to abandon the procurement due to the need to update the specification. One to One's contract had been extended to March 2017 as a consequence.

Wirral, Liverpool and Warrington CCGs confirmed their intention to undertake a further procurement exercise. Referrals under the current contract would cease in March 2016. The new contract would not cover NCA.

One to One requested monthly payments to support their cash-flow.

One to One reported that activity in Essex was higher than in the North West and believed this was due to greater acceptance by GPs in offering choice.

Following clarification on the need for contracts for NHSLA cover in March, other CCGs were withdrawing from NCA. East Cheshire CCG had asked for referrals to cease. One to One said that the CCG was undertaking a review and did not want to continue on an NCA basis. One to One said that some commissioners in the North West were considering the Individual Funding Request[10] route, however this was unlikely to be approved.

One to One had written to several other CCGs in the North West to request zero-based activity contracts (Southport and Formby, South Sefton, Halton and Vale Royal CCGs).

WUTH escalated to commissioners the non-payment of provider to provider charges. One to One said that no backing had been provided to substantiate coding, some items were duplicated and some related to women who were not under their care.

One to One reported capacity pressures in Liverpool at the contract meeting and difficulties in recruiting as NHS providers were also recruiting.

A complaint had been received about sub-optimal care and highlighted the continued absence of joint working on incident investigations. Concerns about One to One had been raised by LWH but upon further investigation, they were not substantiated.

West Cheshire CCG recognised One to One's contribution to their maternity network winning a regional award for innovation in maternity services.

There was further discussion about One to One providing in-house obstetric cover. The CCG did not approve this which was frustrating for One to One as their impression was that this had been approved at a previous contract meeting. The response was that CCG Clinical Leads had made this decision.

In April, there was an unannounced CQC inspection of One to One at Bidston and St James Children's Centre in Birkenhead due to concerns raised.

On 13 April One to One wrote to the Chief Nurse NHSE North. They complained that the Risk Summit process had been unfairly applied to them and that this amounted to organisational bullying. The need for the Risk Summits had not been adequately explained to them. Furthermore, they said that they were being intimidated by some of the CCGs.

[10] An Individual Funding Request (IFR) is a request to fund, for an individual patient, an intervention or treatment that falls outside existing contracts and commissioning arrangements.

One to One asked commissioners to help with the Choose and Book system (now known as NHS E-Referrals)[11] to increase their antenatal and postnatal activity.

May 2015

In May, the Commercial Director (former Commissioning Lead for Maternity at Wirral CCG) resigned from One to One.

One to One met with the Chief Nurse North and the LSAMO on 1 May 2015. The process that was followed prior to calling the Risk Summit was explained to One to One.

One to One were concerned that information was not shared with them in advance of the Risk Summit. The Chief Nurse North acknowledged that the Risk Summit process needed to be more open and transparent. One to One felt that the process had not concluded in a satisfactory way, and it was having a negative impact on their reputation.

One to One stated that they had received an apology from the former Chief Nurse North regarding how the Risk Summit had been implemented as it addressed historical issues which had been resolved and some concerns raised were based on anecdotal evidence.

The meeting discussed NHSE's concerns about care being provided under NCA without oversight of quality or risk. One to One said that they would no longer provide care without an agreement being in place.

Scope of practice and adherence to NICE Guidance was discussed due to concerns regarding the number of Serious Incident RCA investigations where it appeared that midwives were working outside their scope of practice. It was reported that 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 in practice.

[11] https://www.england.nhs.uk/2014/05/choose-and-book/

June 2015	
	At the contract meeting, One to One reported positive feedback following a Local Supervising Authority (LSA)visit. An area of challenge was supervision numbers; One to One had 3 supervisors. The LSA was to look into a cross-regional role. One to One were considering a full time supervisor post. In June 2015, the CQC informed One to One that they would be issuing a warning notice with regard to compliance with Regulation 17 on governance: *"providers must securely maintain accurate, complete and detailed records in respect of each person using the services and records relating to the employment of staff and the overall management of the regulated activity."*
July 2015	
LWH sent NHS Improvement (NHSI) a briefing about the arrangements they had put in place for provider to provider charges with NHS providers and One to One.	One to One received a draft CQC report for the April inspection. One to One disagreed with the report's findings; they felt it had many inaccuracies and that sections had been taken from the Risk Summit. One to One planned to make a formal complaint about the inspecting officer's lack of professionalism. One to One wrote to Wirral CCG on 29 July and stated that the inspection completed in June 2014 had found them to be non-compliant with Regulation 17 and that this had been addressed through an action plan. They believed the unannounced visit in April 2015 had been to review the action plan. However, this unannounced visit was due to serious concerns raised by a senior nurse. The action plan was not reviewed, and they had received a further warning for continued non-compliance with Regulation 17. One to One was to develop another action plan to be reviewed in a comprehensive inspection in December 2015. One to One were frustrated that they had developed two action plans in response to CQC concerns that had not been reviewed. One to One informed the CCG that they were working with the Chief Nurse North on a Quality Risk Profile Tool that would

	provide assurance on quality and identify risks.
August 2015	
A procurement process commenced for Wirral, Liverpool and Warrington CCGs for a three year contract to start in April 2016 with an option to extend for one year. The current contract was extended to March 2017 to ensure continuity of care for women already under the service. A paper to Wirral CCG's Governing Body provided an update on the procurement which was being managed by the North West Commissioning Support Unit (CSU). The CCG and CSU had reviewed lessons learned from the previously aborted tender process and the tender documents would provide clarity on the type of service required, payment mechanism, activity expectations and care pathways. The Governing Body were assured on the robustness of the process. There was a provider engagement day at the end of August, which was attended by One to One, WUTH and LWH. The indicative contract value was £5m per annum across Wirral, Liverpool and Warrington CCGs. The service specification was for low risk women only. For women assessed as higher than low risk, shared care arrangements would be required for antenatal and postnatal services. Concern was raised that the specification was for women with low risk pregnancies only, as the existing service was for all women. Approximately 50% of women fell into the intermediate pathway at the time. A query was raised about the financial criteria for the procurement as One to One would be unlikely to qualify. Wirral CCG said that legal advice would be required. Other queries raised were staffing ratios and the potential for duplicated care. One to One wrote to the Director of Finance of LWH regarding the issues around reaching agreements on shared care and financial arrangements with reference to the Monitor guidance. The letter expressed	The draft service specification for the Wirral CCG led procurement was produced and shared with the co-commissioners for their comments. A summary of the service specification was shared with all Wirral GPs, and they were invited to comment.

concern about the behaviours of Trust staff and the tone of correspondence received.

September 2015

A contract with West Cheshire CCG commenced in September for a three year term with a potential one year extension. The specification was for all women regardless of risk profile.

One to One sought Monitor's support on the provider to provider charges as WUTH's charges tended to be higher than for other Trusts. Monitor declined to intervene.

One to One advised that activity was below plan; they continued to make efforts through E-Referrals and by visiting GP practices. GPs in the North West remained negative towards the service.

The safeguarding plan for One to One was discussed at the NEE contract meeting in September 2015. One to One was to be invited to local safeguarding meetings.

October – November 2015

LWH wrote to Liverpool CCG to alert them to the weak financial position of One to One and asking that the existing debt of £65k owed to the Trust at this point be underwritten by the CCG.

The CQC published their report into the inspection completed in April 2015. Six patient safety incidents had been reported to the CQC by the CCG. The inspectors identified that One to One had systems in place to report and investigate patient safety incidents, however they were not assured that all incidents were being identified, managed effectively and reviewed independently in line with good practice. This was a breach of Regulation 17. They reported that the number of incidents was disproportionate to the number of births.

The report identified that midwives may have been operating outside the widest accepted view of normal midwifery scope of practice. The LSA expressed concerns about lone working for newly qualified midwives. The midwives interviewed were concerned about the sustainability of the way they were being asked to work, i.e., responsive to the needs of women 24/7.

The report also identified a breach of Regulation 12, management of medication.

The NHSE Quality Risk Profile Tool was completed. This had been developed with One to One, NHSE North's regional Directors of Commissioning Operations,

CCG's and the CQC. The risk matrix allocated a score between 1-25 from low through to extreme risk. The average risk score for One to One was 9 (medium risk group). Intelligence was gathered to populate the tool from CCGs, CQC, Healthwatch, the Trust Development Agency, Monitor, the Nursing and Medical Directorates of NHSE, Primary Care Commissioning NHSE and Public Health England.

Later in the month, the tool was reviewed, and the meeting concluded that the profile demonstrated an improving position in a number of areas. The tool was a draft position only and would need to be updated for outstanding information such as CQC inspection feedback.

In November there was a further Quality Review meeting, and the Quality Risk Profile Tool was finalised.

December 2015

At the Wirral CCG contract meeting, it was noted that One to One activity for Wirral CCG remained below plan and consideration was given to reducing monthly payments. Antenatal activity was £113k below plan, postnatal £17k under plan and births £9k below plan. Most of the antenatal activity was at the intermediate level. One to One thought that the main reason for the reduced activity was the CQC report. Co-commissioners did not provide their activity information.

It was noted that Warrington CCG was considering a block contract with WUTH to manage financial challenges.

The provider to provider charges were noted as a continuing problem with WUTH who were following Payment by Results (PbR) rules for charges.

In December, the CQC completed a planned two day inspection at Bidston and St James Children's Centre in Birkenhead. The report for this inspection was not published until June 2016.

There were quarterly meetings between Wirral CCG's Safeguarding Lead and One to One. One to One were in the process of appointing a lead for safeguarding. It was noted that there had been a one-off 'dip' in safeguarding training compliance, but there were no concerns at the time.

One to One's Quality Report for quarter 2 was circulated on the day of the contract meeting. The Wirral CCG Safeguarding Lead found no areas for concern. The report identified *"a couple"* of stillbirths but there were no clinical concerns about the care provided by One to One.

One to One provided feedback on an RCA report and the findings which identified issues with communication between One to One and the local NHS maternity provider and documentation.

The meeting queried One to One's practice of not asking the women to

identify her chosen place of birth until she was in labour. One to One said that the options were discussed with women throughout their pregnancy and only about 10% of women leave the decision until they are in labour.

One to One shared their Quality Improvement Strategy 2015-18 at the contract meeting. It referred to reducing midwife caseloads from 40 to 32. Commissioners asked for this document to be revised as it was about One to One's philosophy rather than a document about quality improvement.

January – February 2016

The Clinical Director of One to One resigned at the end of January and was due compensation for loss of office (£16k).

Better Births recommended a complete review of the payment system to incentivise choice, for implementation in 2018/19. It highlighted that the NHS Five Year Forward View also recommended a review of the payment system to make it easier for groups of midwives to set up their own NHS-funded midwifery services.

At the February contract meeting with West Cheshire CCG, One to One offered obstetrician cover at no additional cost.

One to One referred to redundancies of non-clinical staff to make savings. West Cheshire CCG requested One to One's financial forecasts.

One to One was experiencing challenges in getting referrals from GPs in West Cheshire – out of 110 referrals over the last 6 months, there were only 3 GP referrals.

One to One raised advance payments with West Cheshire CCG saying that NHSE had issued guidance that advance payments should be made. The CCG said their guidance from NHSE contradicted this and no advance payments would be made.

One to One acknowledged their obligation to pay provider to provider charges to WUTH and LWH but queried the amounts and consistency of charges as well as the

Better Births[12], the National Maternity Review led by Baroness Cumberlege was published this month. Better Births had been commissioned by NHSE to consider how maternity services could meet the aspirations of the Five Year Forward View[13] and embed the learning from the Kirkup Report[14]. The vision of the report for maternity services involved personalised care, continuity of care, safer care, better postnatal and perinatal mental health care, multi-disciplinary working, working across boundaries and a fairer payment system.

In February, there was a CQC inspection at One to One's base in Colchester, Essex. The report into this inspection was published in July 2016.

One to One informed West Cheshire CCG at the February contract meeting that joint clinical pathways had been agreed with COCH.

In February 2016, One to One produced a policy and procedure document called Midwives Mitigating Risk (MMR) which set out how risks were assessed, and the care pathway managed for women booking into their care.

[12] national-maternity-review-report.pdf (england.nhs.uk)
[13] NHS England » NHS Five Year Forward View
[14] The Report of the Morecambe Bay Investigation (publishing.service.gov.uk)

quality of information provided to allow validation. One to One suggested a capped fee arrangement and cited a recent example of a woman attending hospital 17 times for which One to One incurred a charge of £11k. NHSE and Monitor had not been able to support resolution of the issue and One to One stated that legal action may be necessary. Wirral CCG stated that they could not get involved in provider to provider pathways but *"do have an interest in whether this is resolved."*

NHSE North escalated the provider to provider debt issue to the national team.

March 2016

The Wirral CCG led contract meetings reverted to a monthly basis to enable greater scrutiny.

One to One raised GP referrals again in the Wirral contract meeting, noting that in Liverpool there was a high proportion of women who transfer their care into One to One as they did not know about the service until later in their pregnancy. The impact of E-referrals had been minimal as the issue was women knowing that the service existed and being offered choice.

The underspend on the Wirral contract for the year was £216k so no payment was made in March 16. Monthly payments with quarterly reconciliation adjustments would apply going forward.

One to One wrote to the Director of Nursing at NHSE Midlands and East to make a formal complaint regarding perceived bullying and anti-competitive behaviour by Mid Essex CCG. One to One had been working with the CCG to establish the service in this area but the CCG was concerned about One to One's integration into the local health system. The CCG had produced a position statement which did not support One to One operating in their area. The CCG then decided to operate with One to One for low risk women only with a cap on activity levels which One to One found overly restrictive. One to One

Saving Babies' Lives[15] was published by NHSE which provided guidance to reduce stillbirths. The key elements were reducing smoking, fetal growth surveillance, increased awareness of fetal movements and effective monitoring of the fetal heart during labour. Reducing stillbirth rates was a priority in the NHS Plan for 2015/16.

Guidance called Spotlight on Maternity[16] was also published by the DH in March, to encourage NHS Trusts to contribute to the national ambition for maternity services.

On 9 March, the CQC Head of Hospital Inspections wrote to One to One to advise of possible urgent regulatory action following the inspection undertaken in Essex in February. The CQC was unclear if the Midwives Mitigating Risk document (produced in February 2016) was policy, guidance, a pathway or if they were adopting NICE or RCOG[17] recommendations. The CQC's view was that it did not clearly identify risk and they were concerned about the potential for delays in referrals to an obstetrician.

The CQC expressed concerns that fetal monitoring was not being completed in line with NICE Clinical Guideline 190[18].

[15] saving-babies-lives-car-bundl.pdf (england.nhs.uk)
[16] https://www.england.nhs.uk/.../16/2015/11/spotlight-on-maternity-gui...
[17] https://www.rcog.org.uk
[18] https://www.rcog.org.uk/en/guidelines-research-services/guidelines/...

shared this communication with the Chair of the National Maternity Review and NHS England's national team.

For the year to March 2016, One to One made a profit of £130k. Cumulative losses had reduced to £0.3m. Creditors of £1m were counterbalanced by debtors of £0.8m. The accounts refer to disputes with NHS Trusts on provider to provider charges and the adverse impact on profitability and cash-flow. The accounts stated that until an appropriate basis for provider to provider charges is agreed, the issue is a major risk to the future profitability and sustainability of the business.

They were not assured that midwives were following best practice.

One to One responded to this letter on 11 March. They were disappointed that the CQC did not consider the outcomes for the service. The MMR was developed following concerns from NHS providers, and they believed it gave clear guidance. One to One asked for an external review of the MMR to provide assurance that it was safe and effective.

The CQC letter was discussed in the Wirral contract meeting and in March 2016, Wirral CCG issued a contract performance notice requiring One to One to provide a remedial action plan within three working days and to participate in a quality visit planned for 24 March.

In March NHSE Midlands and East convened an 'information gathering meeting'. This meeting was similar to the Single Issue Quality Surveillance meetings held in the North. The meeting was chaired by the Director of Nursing NHSE Midlands and East. Representatives from the Essex CCGs and the CQC attended the meeting. The Chief Nurse NHSE North sent apologies to the meeting. There were two main areas for discussion – safety and NCA).

The meeting confirmed that One to One was operating under NCA in North East and Mid Essex and were pursuing NCA in West and South Essex. South Cheshire and Leeds CCGs had terminated One to One's activity.

The meeting received feedback from the North Risk Summit. There were ongoing concerns about the number of incidents involving high risk women.

Mid Essex CCG advised that clinical pathways were not in place with their local NHS provider. There was also an ongoing dispute about sharing of the pathway payment. There were quality and safety concerns and Mid- Essex CCG wished to suspend the service. Their concerns were around the number of incidents reported, inexperienced midwives and poor handovers. The resignation of several midwives from One to One had resulted in a number of

women being referred to the local NHS provider late in pregnancy. There were also concerns about One to One only having access to advice from their obstetrician at weekends.

North East Essex CCG advised that an agreement was in place for clinical pathways with the local NHS provider. However, the CCG advised of concerns about One to One's staffing and supervision processes, governance arrangements, and safeguarding. The LSA had identified a number of issues with the care being provided to women. Five midwives had left One to One without working their notice. Since May 2015, the LSA had been notified of 6 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 LSA's opinion was that under their 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.

The actions from the meeting were for the incidents to be shared with the CQC; the Chief Nurse North was to share the Quality Risk Profile Tool and action plan from the North Risk Summit. Mid Essex CCG was to call an urgent meeting with the local NHS provider to ensure an agreement for pathways and quality monitoring was in place. If this was not achievable the service was to be suspended until they could be put in place. The CQC was to complete a further inspection.

Chronology Part Five

2016/17 to 2018/19 Co-commissioned contract and financial challenges

Commissioning, Contracting and Finance	Quality and Safety

2016/17

April 2016

On 13 April, WUTH notified Wirral CCG of their intention to apply for a winding-up order against One to One for *"repeated failure to pay debts to the Trust in excess of £93,000."* Their email indicated that LWH were likely to follow suit.

On 19 April 2016, there was an update on the procurement to Wirral CCG's Clinical Operational Group. The paper stated that four providers had passed the pre-qualification stage. One to One had failed the financial criteria but had been put forward as they had offered a financial guarantor; this did not materialise. Only One to One submitted a tender. The options put forward were to either continue to term with the existing contract which had been extended to March 2017 or award a contract with a specification for low risk women only, using a Voluntary Ex Ante Transparency (VEAT) notice following legal advice. This approach is used when it is believed that there is a sole supplier able to provide a service. The process allows a period for other potential providers to challenge this. No challenges were received.

The paper referenced other financial risks. If the specification was for low risk women only, this would exacerbate the financial challenges for One to One. 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."* However, the winding-up order if successful would mean that the CCG would be unlikely to recover advance payments made to One to One. A further request for an advance payment plan by One to One was declined.

The paper stated that contingency arrangements were in place with WUTH should One to One's service cease to operate. It was agreed to move to a low risk service specification.

At the Wirral contract meeting on 20 April, it was noted that One to One were providing

Following the contract query issued by Wirral CCG in March 2016, One to One asked to be notified in advance of the issues involved to prepare their response for the planned meeting.

On 6 April, Warrington CCG issued a service suspension notice following an incident in Halton and the letter from the CQC following the Essex inspection in February 2016. A quality review was undertaken by two midwives from Warrington hospital who found no concerns with clinical care and areas of good practice were fed back to their team.

A meeting between Wirral, Liverpool and Warrington CCGs and One to One was held to discuss a Remedial Action Plan (RAP) following the contract query. Concerns were not sufficient to warrant a service suspension. No immediate safety risks were identified following a review of 88 women; they were being appropriately assessed for risk and were on a shared care pathway if necessary. A RAP was produced to address process improvements and a quality assurance programme was to be put in place.

The Chief Nurse NHSE North wrote to One to One regarding completion of the Quality Risk Profile as part of the Risk Summit process to determine if the risk level could be reduced.

NHSE North West's regional quality surveillance meeting on 18 April discussed One to One. One to One's financial position was reported to be volatile. Commissioners had quality and risk concerns due to two serious incidents, the CQC letter of February 2016 and One to One's risk management processes.

The contractual and regulatory actions taken against One to One resulted in interest from the NHS Chief Executive, the Chair of the National Maternity Review

services in South Cheshire under NCA but had received no payment for five months. West Lancashire CCG were interested in becoming an associate to the contract.

One to One highlighted significant financial challenges. They expected to lose £40k in income due to the Warrington suspension. One to One was operating at 50% of capacity (90% was the target). Reducing referrals combined with fixed overheads and urgent cash-flow issues were all impacting on the viability of the business.

One to One asked for clarification on responsibility for the risk assessment of women referred into their care under a low risk specification. The CCG responded that PbR maternity tariff rules would be followed and One to One would be paid as the lead provider.

A financial plan was requested from One to One to give *"a sense of how long [sic] can they keep going".* One to One advised that the forecasts would be dependent on activity. One to One were unable to obtain overdraft/loan facilities on a zero-based activity contract and had no access to national funds for investment in systems which they had financed themselves. The financial forecasts demonstrated various scenarios.

and the NHSE Quality Team. One to One had made a complaint to the CQC and NHSE regarding their perception of a disproportionate level of scrutiny.

There was positive feedback in the Wirral contract monitoring meeting on One to One's Quality Report and compliance with targets under the Commissioning for Quality and Innovation scheme (CQUIN) for Quarter 3 was confirmed.

One to One were interested in getting involved in the NHSE Pioneer Sites under the Maternity Transformation Programme.

A RAP update on 26 April showed One to One to be compliant with requirements. One of the actions was *"To work collaboratively with Wirral, Liverpool and Warrington acute providers in MDT [multi-disciplinary team] meetings to develop and agree pathways and policies with One to One".*

West Cheshire CCG requested assurance regarding One to One's risk management policy (MMR) at the April contract meeting. The CCG offered support with pathways and risk management and suggested an independent review. The Chief Nurse of NHSE North asked for a peer review approach.

May 2016

In May, One to One asked Wirral, Liverpool, Warrington and West Cheshire CCGs for forward commitments to support their defence of the winding-up petition. The petition was supported by LWH, St. Helens and Knowsley Teaching Hospitals NHS Trust (STHK) and COCH. One to One had reviewed the WUTH alleged debt of £93k and found £12k of duplications in one month alone. LWH's alleged debt was £132k, STHK £11k and COCH £21k. Wirral CCG said they would attempt to exert influence but had no authority to direct their local Trusts.

Mediation took place relating to the winding-up petition, no agreement was reached. One to One contacted the Chief Executives of the Trusts and NHSE for support. LWH and WUTH declined settlements offered.

On 11 May, One to One were awarded a new contract subject to the VEAT notice. This was

On 9 May, Warrington CCG lifted the service suspension having reviewed various policy and strategy documents relating to governance, risk and training as well as a forecast profit and loss account for 2016/17.

Wirral CCG closed the contract query on 13 May and quality risks would continue to be monitored through the contract meetings.

COCH was willing to develop information sharing and clinical pathway agreements, but this was put on hold pending the outcome of the winding-up petition.

One to One highlighted to West Cheshire CCG that the maternity performance dashboard did not cater for shared care arrangements.

for a term of three years from June 2016 with an option to extend for one year. This was with a revised service specification for antenatal and postnatal care for all women and home births for low risk pregnancies only. Wirral CCG would be the co-ordinating commissioner for 7 other CCGs across C&M.

At the contract meeting on 18 May, West Cheshire CCG suggested the Centre for Effective Dispute Resolution as a way forward on the winding-up petition. The CCG offered to escalate the need for a financial agreement with COCH but One to One said the Trust was unwilling to sign any financial agreement. The CCG suggested an independent audit on coding. The CCG requested an exit plan should the winding-up order succeed. The CCG prepared its own business continuity plan.

At the West Cheshire contract meeting, 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. Monitor were unwilling to intervene.

One to One advised that having raised the tariff issue with Monitor, they had been directed to collaboration agreements, but Trusts were unwilling to engage. It was hoped that the Maternity Pioneer sites would address this.

At the Wirral contract meeting, it was noted that the GP only referral restriction had been retracted in South Cheshire and self-referrals were now permitted.

Warrington hospital had offered to provide obstetric care to One to One clients across the area outside of the hospital setting.

At the Wirral contract meeting in May, One to One suggested review of the specification by the RCM for independent validation which was accepted.

The quality programme was discussed, and this would include quality visits to discuss the maternity dashboard, the 'Fresh Eyes Review', exception reporting on the use of the escalation policy, risk assessment documentation. The programme would also include joint meetings with acute providers.

Challenges in agreeing information sharing protocols with Warrington hospital were reported.

One to One shared the exit strategy which had been provided to West Cheshire CCG. This was deemed very comprehensive, and commissioners recognised the need to work on their own exit strategy.

At the Essex contract meeting, One to One referred to issues with sharing information with CCGs as they did not have an 'nhs.net' secure email account.

The NHSLA confirmed to NEE CCG that One to One had insurance cover through the Clinical Negligence Scheme for Trusts (CNST) for 2016/17.

At a CQC meeting with One to One on 16 May, there was reference to commissioners' responsibilities for oversight of collaborative working.

June 2016

A collaborative contracting agreement was put in place for co-commissioners.

One to One's Chief Executive wrote to the Chief Executive of the NHS England regarding the winding-up petition and providing a summary of the history behind this and the provider to provider charging issues. The letter questioned the motives of NHS Trusts for taking this action given that NHS organisations were also in a financially challenged position and referred to the behaviour as *"bullying in nature."* The letter

At the Wirral contract meeting, One to One stated that Trusts were not acknowledging their incident notifications. One to One were asked to send incident reports to the CCGs for monitoring on Datix.

It was noted at the meeting that South Sefton and West Lancashire CCG did not have routine quality oversight meetings with One to One for the NCA activity.

The C&M Women and Children's Partnership met in June and discussed planning across the footprint, including the

also highlighted the potential redundancies and the Chief Executive of One to One's significant personal financial risk.

There were further discussions about the possibility of One to One being wound up at the June meeting with West Cheshire CCG. The CCG advised that Transfer of Undertakings (Protection of Employment) regulations would not apply to a company ceasing to trade due to insolvency.

One to One informed West Cheshire CCG that similar issues had been experienced on provider to provider charges by Bridgewater Community Healthcare NHSFT who provided community midwifery services.

One to One set up a new company (My Midwife and Me Ltd) and applied for CQC registration.

South Cheshire and Vale Royal CCGs asked to be associates to the West Cheshire or Wirral contract. One to One advised that ongoing NCA activity in South Cheshire, South Sefton and West Lancashire was through GP referral or CCG prior approval.

One to One reported no GP referrals for Quarter 1 2016/17 in West Cheshire.

One to One raised concerns about inconsistent approaches by commissioners to funding for screening programmes.

One to One stated that they had signed a service level agreement with the local Trust in Essex.

One to One took out a lease on premises in Ellesmere Port.

Maternity Pioneer project. One to One were disappointed at the decision for LWH to be the Pioneer site for personal maternity budgets. One to One said they had not been invited to the meeting where this was discussed.

The Maternity Transformation Programme Board was established to drive forward the implementation of Better Births through Clinical Networks and Local Maternity Systems (set up for Sustainability and Transformation Partnership footprints). C&M was selected as an early adopter under the Maternity Choice and Personalisation Pioneers programme. The C&M Women's and Children's Services Partnership was set up as the Local Maternity System to deliver the programme.

The CQC inspection report following the Wirral visit in November 2015 was published on 27 June. Integrated working and pathways with NHS providers remained a key risk.

At the West Cheshire contract meeting, the CQC report was discussed. Some items had not been resolved from the previous inspection and there were continuing themes on managing risk and consent.

July 2016

The hearing for the winding-up petition was on 21 July. NHSI had intervened to encourage an out of court settlement, but WUTH and LWH proceeded with the hearing. STHK and COCH did not send any representation. LWH offered a settlement to One to One of £90k for debt up to the end of June 2016. One to One had offered £60k to both LWH and WUTH.

The VEAT notice was issued on 29 July.

One to One continued to experience a general underperformance on activity. Warrington CCG had issued a leaflet on patient choice and an increase in GP

South Cheshire CCG suspended referrals for home births due to safety and quality concerns following the death of a baby. One to One had reviewed the incident and found no clinical concerns. The service suspension was reported in the media as women were making complaints about not being able to have a home birth. Wirral CCG had spoken to the Director of Nursing at South Cheshire CCG who had no concerns about the care provided by One to One.

One to One suggested that WUTH did not always follow NICE guidelines and Wirral

referrals had been observed. Liverpool and Wirral CCGs were considering similar actions to encourage activity.	CCG requested evidence of this. One to One did not provide any further details and retracted their statement. Commissioners had been working on a press statement about continuity of care should the winding-up petition succeed. The CQC were requesting an action plan in response to the inspection in November 2015. Key actions were to update the risk register to reflect caring for high risk women, implementation of 'Fresh Eyes'; and development of an early warning tool for use in a home birth setting. The CQC report following the Essex inspection in February 2016 was published in July and an action plan produced.
August 2016	
In August, NHSI intervened again and a settlement amount of £60k (68% of the debt) was agreed with WUTH and paid immediately. The situation with LWH and COCH remained unresolved. One to One said work was being undertaken with NHSI to review historical invoices. One to One also referred to work being undertaken by NHSI on the tariff and pathways and there was a suggestion of a tariff sharing arrangement.	One to One reported to the Wirral contract meeting in August that all 12 incidents which had occurred over a 12 month period in South Cheshire had been reviewed by the CCG and no clinical concerns were found. Wirral CCG asked for a review of incidents which were below the threshold for serious incident reporting.
September 2016	
It was a requirement of the contract for One to One to be on Choose and Book (NHS E-Referrals) by September 2016.	The CQC were planning to do a comprehensive inspection in November. One to One queried the approach as the CQC had agreed to inspect Neighbourhood Midwives under the new community standards approach rather than being inspected as an acute Trust. It was noted that the Wirral and West Cheshire performance dashboards were inconsistent, and it would be preferable to have a single version. A regional dashboard was being developed. Public Health England reported on a quality assurance review of One to One on Antenatal and Newborn Screening Programmes. Concerns were: *"that those babies who have a screen positive result following Newborn and Infant Physical Examination (NIPE) are referred to the General Practitioner rather than immediate*

	referral into secondary care for diagnostics…. The pathway for referral to paediatric ophthalmology was unclear."
October 2016	
By October, there was a £66k underperformance on antenatal activity under the Wirral contract. GP referrals remained the key challenge. In West Cheshire there had been a positive impact on referrals (up by 15%) once a GP lead had been identified. Warrington CCG advised that due to financial challenges they were looking to reduce referrals to make savings. In NEE, One to One was marketing the service and new midwives were due to join the team. One to One made a request for advance payment.	The DH published Safer Maternity Care[19]. This was an action plan to support the national maternity transformation programme. Its objectives were to halve the rates of stillbirths, neonatal deaths and brain injuries that occur during or soon after birth and maternal deaths by 2030. Leadership would be provided by the Maternity Clinical Networks.
November - December 2016	
The new C&M co-commissioned contract was ready for issue in November. Public Health England (PHE) put in place a separate contract for NHSE screening programmes. PHE confirmed that there was no tariff attached to newborn hearing screening. This was an additional cost of between £15-£60 per test for which One to One was not reimbursed. NEE CCG raised the lack of management presence in Essex. One to One explained it was implementing the Buurtzorg model[20] of self-managing teams.	In November, the West Cheshire service specification was revised, and agreement of shared clinical pathways was a requirement of the contract quality schedule. NEE CCG needed to agree a format with One to One for reporting activity. The agreement with CHUFT had been revised but not yet signed, One to One declined support from the CCG with this. In December 2016, NHSE North stepped down the Risk Summit process. It was assured by *"an improving position in a number of areas of the Quality Risk Profile …. Assurance had been gained with the financial position of the organisation."*
January – February 2017	
	A CQC inspection was undertaken in January. One to One was inspected as a community service. West Cheshire CCG raised the 'continuity of carer' performance metric. One to One had experienced difficulties in retaining midwives due to the on-call requirements and stated that they were operating a team model, and a target of 75% was feasible. The CCG queried how the model was different to what was offered by COCH.

[19] Safer maternity care - GOV.UK (www.gov.uk)
[20] https://www.england.nhs.uk/6cs/wp-content/uploads/sites/25/2015/04/implementing-buurtzorg-principles.pdf

In February, there was a proposal by NHSE/I for a prime provider model with WUTH sub-contracting activity to One to One. This was set out in a letter to all Trusts and CCGs across C&M as there was the potential for this to be replicated across the footprint. The model was to be developed as part of the Maternity Pioneers programme. One to One had also proposed a top-slice tariff approach as part of this model.

At the Essex contract meeting, One to One confirmed that they were holding monthly meetings with CHUFT. The CQC action plan was noted, and verbal assurance provided on progress.

At the Wirral contract meeting in February, there was a reference to quality reviews of maternity services being undertaken at Warrington and Arrowe Park hospitals.

One to One said that their quality team was on a *"learning curve"* due to a safeguarding issue in Warrington which was subject to an investigation.

March 2017

In March, a proposal was developed by One to One for a joint venture with Warrington hospital. It was shared with the C&M Women and Children's Partnership in the hope that its implementation would be supported. It proposed a block contract arrangement to provide certainty, no financial details were provided.

There was a £127k underperformance on the Wirral contract for 2016/17. One to One were deemed compliant with CQUIN requirements. There was a small underperformance on CQUIN for West Cheshire in 2016/17 but the CCG agreed to pay this in view of the problems experienced by One to One.

For the year to March 2017, One to One's turnover was just over £4m with a gross profit of £1.3m. However, the level of overheads incurred gave a significant overall loss of £0.6m with a cumulative negative balance sheet position of almost £0.7m. Liquidity showed a sharp deterioration with creditors of approximately £1.3m. The accounts refer to a *"turbulent year"* and stated that the losses were due to disputes with NHS Trusts over their charges which had impacted on One to One's activity and reputation. There were material uncertainties on the ability of the company to continue to trade.

In March, One to One confirmed that care pathways were in place with COCH.

2017/18

April 2017

In April 2017, the Warrington joint venture was discussed at the C&M Women and Children's Partnership as a potential pilot. The pilot was agreed by NHSI.

The CQC published its report following an inspection in the Wirral in January. Midwives were concerned about a lack of work/life balance which was a high impact

risk on the risk register. One to One reported a staff turnover rate of 19%. Issues with NHS Trusts continued and there were reports of negativity towards One to One.

The CQC published its report following an inspection in Essex in January. One to One produced an action plan in response.

May - June 2017

In May, One to One estimated that 34% of their income was lost due to provider to provider charges. One to One reported attending a meeting about tariff where the consensus was that there needed to be a local tariff between providers, but this needed NHSI direction.

One to One were asked about My Midwife and Me Ltd. This company had been set up when the winding-up petition was in progress and was used as a vehicle to obtain insurance for independent midwives. One to One suggested that this company could be used for the sub-contract arrangement.

Plans for the joint venture with Warrington hospital had not yet progressed due to capacity issues.

A query was raised at the Wirral contract meeting in May as to whether the case loading model was applied in all areas. One to One said a team led model had been used in some areas but they had reverted to a case loading model.

One to One was considering midwife led units as their set-up for home births was not sustainable. One to One were discussing use of hospital premises.

No progress was reported in May on a joint pathway agreement with COCH and they were unwilling to progress the midwife led unit concept with One to One.

The 'named midwife' CQUIN performance target with West Cheshire was deemed challenging by One to One due to transfers of care.

July 2017

In July 2017, MCHFT commenced debt collection proceedings. Other NHS providers also started to chase debt.

One to One asked the C&M Partnership Lead how to approach Halton, St Helens and Knowsley CCGs as potential associates to the C&M contract as there was increasing demand in these areas.

The MCHFT due diligence paper indicated that One to One owed the Trust approximately £70k. The Trust had run a credit report on One to One up to March 2015 and the company was rated 'red' with metrics indicating cash-flow problems and an inability to meet its short term obligations. Without any financial forecasts, the Trust was unable to assess the financial sustainability of the company.

The Healthcare Financial Management Association had undertaken a survey on the maternity payment pathway approach to

One to One stated at the Essex meeting that they were to be the North of England Pioneers for personal budgets for maternity care. This did not materialise.

A due diligence paper was prepared by MCHFT in July 2017 for their Board providing a detailed analysis of One to One from a quality, safety and financial risk perspective. The purpose of the paper was to inform the options for collaborative working with One to One as recommended in CQC reports and as directed by NHSE and local commissioners. The overarching conclusion was that One to One's ethos and attitude to risk, standards, documentation and governance was not aligned with that of the Trust.

MCHFT's Board approved an option to continue current arrangements which involved communication protocols around emergency care and place of birth and to

inform NHSI's pricing team of issues experienced by providers to inform tariff setting for 2019/20[21]. 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 as lead provider. There were many disputes as a result, and this was exacerbated when a private provider was involved.

implement care pathways for 'low risk' women only.

The due diligence paper identified 38 incidents which had been reported had involved the Trust and One to One over the previous 2 years. 6 of these were judged as moderate/major harm (19 no harm and 13 low harm). The incidents highlighted areas of One to One's practice which did not adhere to national guidance. The paper listed in detail their concerns about One to One's practice and joint working challenges.

August 2017

A joint email in August 2017 from Wirral CCG and NHSE/I to C&M CCGs and Trusts acknowledged that One to One was not viable and a new financial model was needed to avoid protracted disputes. It set out the proposal for WUTH to act as prime provider and sub-contract to One to One. There was the potential to replicate this model across C&M. A new payment structure would be developed to remove all future provider to provider recharges. One to One was to be asked to settle historic debt. The aim was for the key terms of the pilot to be agreed by 30 September and implemented by the end of the year.

A paper was drafted for NEE CCG's Operational Executive Committee to recommend putting a formal contract in place with One to One. It is unclear if this paper was considered.

Hospital reported incidents were now a standing item on the contract meeting agenda and this was queried by One to One.

An apology from the CQC to One to One was recorded at the meeting regarding their mistake on NICE guidelines.

September 2017

In September, West Cheshire CCG advised that the sub-contract model would not be feasible with COCH due to VAT implications.

One to One produced a proposal for the prime provider model across C&M which incorporated minimum guaranteed activity levels for its current operating model and staffing numbers to be sustainable. One to One proposed a top slice approach to cover NHS Trust costs.

The actions relating to shared care pathways with COCH were included in the contractual Service Development and Improvement Plan.

In September, One to One expressed concerns to the C&M Partnership about poor communication and collaboration with MCHFT.

An incident in Essex involving One to One, had been escalated to the Nursing and Midwifery Council (NMC) which was reported in the local press.

[21] https://www.hfma.org.uk/docs/default-source/publications/Briefings/maternity-reimbursement-survey-report-2017.pdf?sfvrsn=944d92e4_0

One to One were concerned about the lack of momentum in the Local Maternity System in Essex.

One to One's Chief Executive forwarded an internal email to the C&M Women and Children's Partnership. This raised serious concerns about governance and 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."

These issues were escalated to the Chief Officer of Wirral CCG and NHSE's Chief Nurse for C&M.

One to One expressed their disappointment to the C&M Women and Children's Partnership as LWH were chosen as the C&M Pioneer Site. They felt that the impact on other providers had not been assessed and that they had not been given an opportunity to express an interest. This was refuted by the Partnership who believed they had supported One to One. There was an acknowledgement of tensions in the system, which could have been addressed by a joint piece of work; however, with regard to the Pioneer pilot, One to One was not a signed up partner at the time the submissions were made. One to One had understood the pilot was for personal maternity care budgets only and requested a copy of the scope of the pilot which was not received. One to One's concerns were escalated to Liverpool CCG and NHSE/I:

"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."
October 2017	
In October, NHSI undertook an audit of provider to provider charges at two Trusts as part of an exercise to recommend 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. The paper concluded that there was scope to develop a payment mechanism that more closely aligned charges to the costs of care. The paper set out a commitment by NHSI and NHSE to take the recommendations forward for testing.	In October, the C&M Partnership's concerns were escalated to NHSE regarding their reputational damage due to One to One's actions.
November 2017	
In November, One to One met with NHSI to discuss payment structures, cross charging and guaranteed activity levels for the prime provider model. NHSI's representative from the Choice Team highlighted that agreement to the activity levels required was the main barrier to progress on the prime provider model. Wirral CCG were in a position to potentially guarantee activity at current levels only. NHSI were to continue to work with WUTH and One to One to determine the financial viability, scalability and sustainability of the proposed model, including consideration of the tariff proposals. NHSI also considered adopting an 'Essential Services' approach for financial oversight of One to One to review ongoing financial sustainability and business continuity. One to One did not expect the PbR national working group to resolve the provider to provider charges issue. West Cheshire CCG agreed to look into a sub-contract model with their local acute Trust. At the NEE contract meeting, financial challenges were reported between One to One and CHUFT due to debt issues. An options appraisal paper was being prepared	One to One asked for more detail on the 'continuity of carer' target for the prime provider model as they believed that WUTH were not held to account on this metric. Performance on 'named midwife' for home births on the Wirral contract had been at 0% over the last 2 months. It was noted that this was integral to One to One's value proposition. One to One were hoping to see more stability in their team and referred to the high number of transfers into their service (30%) as women were not aware of the service. 98% continuity of carer was being achieved on antenatal care. Joint care pathways were reported as near agreement with Warrington hospital. There were issues with regard to One to One providing 'Baby Boxes' as they did not feel the scheme was aligned to their values. There was an email exchange between the C&M Women's and Children's Partnership and Wirral CCG stating *"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,*

by the CCG for a procurement of a case loading service.

energy or resource to continue engaging with them. [X] got threatened with ejection from the last HOMs meeting for her behaviour."

In November, the RCM published 'Can Continuity Work for Us', a resource pack for midwives[22]. It provided guidance to calculate staffing requirements for a case loading model, based on a ratio of 1 midwife to 35 women e.g., 8 midwives could provide care for 280 women a year.

One to One attended the Local Maternity System meeting in November for C&M. NHSE provided feedback on the local maternity plan which required more work on targets and trajectories.

December 2017

In December 2017, implementation guidance was issued by NHSE called 'Implementing Better Births: Continuity of Carer'.[23] It set out two models that would meet the principles of Better Births: a team continuity model and full case loading. The document stated that full case loading would be more appropriate for specific cohorts of women who would benefit from individual continuity, e.g., women with complex medical or social needs.

On 16 December, One to One contacted the Chief Officer of Wirral CCG and the Director of Finance at WUTH to request a meeting to accelerate progress with the prime provider model. A proposal was attached for minimum guaranteed activity levels under the pilot. The email referred to the workstreams stalling due to a lack of *"Executive decision".* One to One requested urgent action as disputes with Trusts were escalating. The email stated:

"I appreciate that my timeframes might be ambitious, but these are based on a real urgency due to our cash flow requirements and the pressure that is being applied from the system in meeting the provider payments."

The Chief Officer of Wirral CCG responded on 22 December that they were supportive of the prime provider work, but it was being led by WUTH rather than being commissioned by the CCG. Once an agreement had been

[22] RCM_Guide_20171221.qxp_Layout 1
[23] https://www.rcm.org.uk/media/2267/can-continuity-work-for-us.pdf

reached between One to One and the Trust with a *"sustainable clinical and financial delivery model",* the CCG would terminate their contract with One to One as they would then work under a sub-contract to WUTH.

Wirral CCG was therefore not able to agree minimum activity levels, particularly on behalf of other CCGs, as this would be for WUTH to determine, as well as the associated payment arrangements. Commissioners' involvement would be through performance oversight of the WUTH contract and targets for increasing home births and midwifery led care.

Wirral CCG was concerned about the cash-flow issues highlighted by One to One. The CCG asked for details of the current caseload with a view to making contingency arrangements. One to One were caring for approximately 2,500 women across England at this point.

Wirral CCG received an email from South Cheshire/Vale Royal CCG highlighting the potential legal action by MCHFT and stating that Companies House information on One to One was *"enlightening".*

January 2018

The Chief Officer of Wirral CCG contacted co-commissioners and key stakeholders at NHSE/I to advise of One to One's potential imminent viability challenges and the need to have contingency plans:

"We have received intelligence that One to One Midwives have significant cash flow issues and may be unviable in the next few weeks."

A series of emails followed between the CCG, NHSE/I and One to One. An email from Wirral CCG to NHSE advised that One to One could provide no assurance on the viability of the service. The email also stated: *"The letter is suggesting that this is all due to NHS commissioners and has been copied to [NHSE 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. I think that we*

may need that QSG[24] when we have gathered more information."

NHSE responded that a Risk Summit would be required.

One to One wrote to Wirral CCG on 15 January to explain that they had raised the financial viability issues to try to accelerate progress on the prime provider model; the Chief Executive regretted bringing this issue to the fore. The letter confirmed that One to One would continue to trade, however the financial challenges remained the same and the service was not sustainable in its current form.

Wirral CCG responded that this information did not provide sufficient assurance and asked for a cashflow statement and statement of liquidity certified by an accountant within 48 hours.

Wirral CCG informed NHSE/I that financial due diligence was being undertaken and a contingency plan was being developed with WUTH. It was acknowledged that the central issue was provider to provider charges.

In January, One to One met with MCHFT to try to agree a solution to the debt issue and avoid legal action being taken. A subsequent update to Wirral CCG stated: "*agreement was reached in the meeting for a different compromise offer which both parties accepted. Subsequently to the meeting, One to One withdrew this compromise offer. My understanding is the One to One representative in the meeting (fielded by the company) apparently didn't have the authority to make such agreements. Therefore, it is extremely frustrating for Mid Cheshire for One to One to now be offering options which have already been disregarded. The Trust is in the process of responding to the letter but is also extremely frustrated about the amount of management time this whole interaction with One to One is taking up."*

On 22 January, Wirral CCG received a letter from a manager at MCHFT pointing out financial viability issues inherent in One to One's service model due to their case loading ratio of 1 midwife to 34 women. The Trust's caseload ratio for community midwifery (not a case loading model) was 1:98. As One to

[24] Quality Surveillance Group

One offered services to women of all risk profiles, their financial challenges were exacerbated by the provider to provider charges. The letter stated that the model was originally set up for vulnerable women requiring more intensive midwifery support and in this case One to One's ratios would be appropriate. The Trust's team who provided this type of service had a ratio of 1 midwife to 40 women. Wirral CCG decided not to respond to this email. An internal communication stated:

"*I feel a sense of deja vu when WUTH as a provider was trying to control the activities/governance/finance of the same provider. In this instance NHSI/NHSE intervened as it was perceived nationally that it was bullying by a large provider."*

On 24 January, NHSI contacted the Chief Nurse North to advise that One to One had contacted the Director of Finance at LWH suggesting that the prime provider model pilot was going ahead with WUTH and that it had been agreed that provider to provider charges within C&M would be put on hold until a framework had been developed for cross-charges. The NHSI officer stated that the WUTH pilot was at a very early stage and no such agreement had been reached. The email stated that this was not something that NHSI would have requested Trusts to do, and the North Region Finance Director agreed with this standpoint.

The Chief Officer of Wirral CCG contacted the Chief Nurse for NHSE North also refuting the statements by One to One: "*This is not right. It has not come from WUTH or NHS Wirral CCG, or from the wider LMS [Local Maternity System]. We were clear on our call the provider to provider recharges were a matter for NHSI. This is clearly an untruth that One to One are spreading and it can only have come from them."*

On 29 January, MCHFT sent a pre-legal action letter to One to One for the prompt recovery of debt (£113k) otherwise the Trust would issue a court order for insolvency. The letter was copied to Wirral CCG. One to One paid almost £60k of the debt and offered a settlement for the remainder but this was declined as the Trust said this would not solve the underlying issues and any new care

model developments would not impact on historic debt.

February 2018

At a pre-meeting before the Wirral contract meeting, co-commissioners discussed the financial issues and contingency arrangements regarding One to One.

One to One proposed a prime provider pilot which included a risk pool approach to minimise the provider to provider recharging. The pilot development with WUTH was now uncertain as there were procurement issues to consider for the sub-contract.

There had been a significant increase in scanning costs due to the Saving Babies' Lives programme for which there was no additional funding from NHSE. This was a cost pressure of about £110k per annum for One to One.

Warrington CCG was concerned about the debt with their local Trust. One to One had discussed this with the Trust and said that coding was to be examined.

In February, the CQC introduced a new financial viability test. This could be triggered when concerns were raised around an existing provider's financial position.

One to One contacted NHSI to ask about Trusts on block contracts potentially being paid twice for the same activity. NHSI contacted Wirral CCG to advise that this was a local issue for CCGs to resolve.

On 9 February at a Heads of Midwifery (HOMS) meeting, One to One raised the difficulties they experienced in supporting women who birth at hospital as the One to One midwife did not accompany women.

At the Wirral contract meeting in February, One to One asked about the planned single directory of services covering the local maternity system. It was pointed out that One to One were not commissioned to provide services across the whole area.

One to One had hoped for access to a pop-up clinic in a Children's Centre in the Wirral as part of the Local Maternity System (LMS) programme. One to One was concerned that the CCG had not involved them in this.

Liverpool CCG asked for issues relating to LWH to be escalated to them directly rather than via the Trust. One to One said work on pathways was progressing with LWH but it was difficult to arrange meetings with the Trust.

March 2018

The Non-Executive Director of One to One who provided financial expertise resigned in March 2018.

For the year to March 2018, turnover grew by over 20% to almost £5m with a gross profit of £1.3m. However, overheads increased to give an overall loss of £0.7m. The cumulative deficit had almost doubled in a year to £1.6m. Liquidity was poor with a further increase in debt to £2.1m (from £1.3m the previous year). The accounts refer to:

"another turbulent and challenging 12 months" and escalating disputes with NHS Trusts and a cost efficiency programme. The accounts also refer to engagement with "NHSE and the Maternity Transformation

The CCGs requested exception reporting from One to One. Discussion highlighted that many of the performance metrics used were not relevant for One to One.

There remained an underperformance on having a named midwife at a home birth; One to One wanted to amend the metric to include a named 'buddy'.

Following a serious incident, Liverpool CCG requested a monthly meeting with One to One to go through their active caseload and risk factors. One to One challenged whether this level of oversight was applied to other providers and the CCG response was that this would not be the case. One to One believed they had

Team to propose a pilot for payment reform to be supported at national level for the implementation at local level". The Director's Report stated that resolution of this issue was critical to ability of the business to continue to trade during 2018/19.

Wirral CCG refreshed its procurement policy in March 2018; it recognised some of the risks experienced with One to One.

provided all the information required and such meetings were not necessary.

A presentation on caseload management was requested for the next meeting. One to One also offered to share their quarterly Quality Report.

2018/19

April 2018

In April, NEE CCG became aware of concerns about provider to provider charges from CHUFT. One to One believed that CHUFT were double booking and receiving double payment for interventions.

MCHFT initiated further legal action to recover provider to provider debt (£63k at this point). At the Wirral contract meeting, One to One stated that that this was not a winding-up order however this was a legal technicality only. MCHFT had gone down a court order route to secure the debt as payable to avoid One to One issuing a court injunction.

NEE CCG were concerned that One to One midwives were not attending CHUFT when women were transferred. One to One reported that planned meetings were often cancelled by CHUFT. The review of care pathways with the Trust was two years overdue.

The screening coordinator for NHSE Midlands and East, contacted North East Essex CCG to advise that they had not been receiving accurate performance information from One to One since 2015. In addition, there had been no update provided on the action plan from a Screening Quality Assurance Service visit in September 2017.

The following concerns were expressed at a quality assurance meeting for North East Essex: governance and safety of antenatal and newborn screening services; remote management of the One to One service as the management team was based in the North West. The outcome of this meeting was that a decision would be made as to One to One's continued operation in NEE.

In April 2018, the national Maternity Safety Support Programme (MSSP) was launched. This was supported by a team of Maternity Safety Champions.

May 2018

In May, it was confirmed that the WUTH prime provider pilot would not go ahead because One to One would not pass the pre-qualification financial criteria for a procurement process which WUTH would need to undertake for the sub-contract. WUTH also believed they had improved choice through their Midwifery Led Unit.

At the Wirral contract meeting in May, One to One gave a presentation for quality assurance purposes, on the case loading model, the processes in place and training for midwives.

One to One had met with Liverpool CCG to discuss quality issues and the CCG

On 25 May, the Chair of the National Maternity Review wrote to the NHS Chief Executive and the NHSE senior team summarising One to One's position. The letter was supportive of One to One and recognised their importance as one of only two providers with NHS contracts to deliver the continuity model.

The letter stated that it was unfair to reprocure as One to One would fail the financial tests and that Trusts were not obliged to tender for the sub-contract. The letter sought the NHS Chief Executive's intervention and a solution due to the impact on the national strategy.

Various emails followed involving the Chief Nurse of NHSE, the Programme Director for the National Maternity Transformation Programme, the Chief Nurse North and Wirral CCG regarding a briefing which was anticipated with the NHSE Chief Executive.

A meeting was convened on 29 May at the request of the Chief Nurse North. NHSE and Wirral CCG remained focused on seeking a solution that would support One to One. One to One provided the meeting with activity information and a summary of the challenges faced.

In 2017/18 there were 2,718 women booked with One to One (2016/17 2,495) with 34% of women booking part way through their pregnancy resulting in part-pathway payments.

One to One employed 110 staff - 68 midwives, 13 midwifery assistants, 9 senior management and 20 support staff.

The key outcome from the meeting was that Mersey Internal Audit Agency (MIAA) were to undertake an audit of One to One to gain a better understanding of their financial position. At the Wirral contract meeting in May, the scope of the MIAA work was confirmed – financial viability, cash-flow, payment mechanisms, provider to provider charges and governance.

The CQC also expressed concerns about One to One's financial viability.

On 30 May, One to One emailed NHSE's Chief Nurse North to advise that LWH were considering legal action for recovery of debt.

wanted to re-establish regular tri-partite meetings with LWH.

A meeting was held with MCHFT on a shared care model; there were concerns about differences between the service specification and NICE guidance on birth planning.

At the Local Maternity System meeting in May, it was noted that six maternity providers in C&M were rated as 'requires improvement' by the CQC.

June 2018

Wirral CCG estimated their financial exposure should One to One to cease to operate which was £78k for up-front payments and £255k to cover the cost of moving provider. WUTH estimated a cost of £235k to manage the transfer of patients involved.

LWH contacted Liverpool CCG on 27 June to provide an update on the debt issue and requested their support. The letter stated that One to One had not made any payments for activity since April 2017. One to One had informed the Trust that payments were on hold pending the roll-out of the prime provider model and that amounts due were covered by their block contract. These claims by One to One were disputed by LWH and NHSE/I locally. LWH stated that the prime provider model was not financially viable for NHS Trusts.

LWH was concerned that services were still commissioned from One to One. LWH highlighted that the debt was almost £1m across C&M and that One to One was at high risk of financial failure. LWH planned to take legal action for its £240k share of the debt. Liverpool CCG declined to get involved in the situation as in their view it was a provider issue, and they did not have the authority to intervene in payment disputes. The CCG stated:

"However, this situation does require us to look at the risk that this significant financial dispute raises in relation to the viability of One to One as a provider. As a result, we will be asking One to One to inform us of all the Liverpool women on their caseload on a month to month basis so that if they are no-longer able to provide a service, these women can safely transfer to another provider."

In June, Wirral CCG offered to work with One to One on the maternity dashboard to review the indicators which needed the input of an acute provider which One to One were unable to report on in isolation.

Hospital reported incidents were reviewed. More information was requested about the stillbirth rate as there were four stillbirths reported in Quarter 4 2017/18 which was significantly higher than the national average. This was subsequently confirmed as the number for the whole year.

An information governance breach by One to One was reported by Liverpool CCG.

Good progress was reported on the pathway work with Warrington hospital.

The CCG recognised that there had been confusion around the enhanced surveillance process for One to One and this would be clarified at the contract meeting going forwards.

Commissioners were given an open invitation to One to One's internal quality meetings.

July 2018

At the Wirral contract meeting, One to One stated that they had regular meetings with NHSE/I regarding their financial position. They had requested that a 'Flex and Freeze' reconciliation approach be applied for provider to provider charges due to the time lag involved in validating the charges.

The performance dashboard in July showed an underperformance on many indicators. Explanations for these were mainly women's choice and dependence on acute providers. Some indicators showed low numbers in absolute terms, so the percentage performance reported was arguably misleading.

The MIAA work was anticipated to be completed by the end of August 2018.

An update call was held between NHSE, NHSI and Wirral CCG on 20 July. All but one of the CCGs in C&M wanted to extend the One to One contract for a further year and a re-procurement would follow. This would be dependent on the outcome of the MIAA work due to be completed by the end of July.

Regarding the disputed debt, it was acknowledged that some invoices were not correct. NHSE had asked One to One to pay the validated invoices.

There was recognition that within the current tariff rules and payment system it was difficult to provide a solution to the One to One scenario.

There was a discussion regarding whether the national tariff update would improve One to One's position, but this was unlikely to be a sustainable solution. One to One had asked the LMS for C&M to apply to be an early adopter site for payment system reform.

A quality review meeting held with Liverpool CCG, LWH and One to One on 20 July discussed patient transfers and communications with Primary Care. Faxes were to be replaced by use of NHS mail.

August - September 2018

At the September contract meeting, One to One advised that they planned to bring diagnostics in house; the service had been outsourced to Diagnostics Healthcare Ltd.

One to One asked CCGs about block contracts with NHS Trusts. They were querying these arrangements as their understanding was that Trusts were paid under a block contract so were receiving payment twice by charging One to One for obstetric care.

One to One sent a letter to LWH on 26 September disputing the debt since April 2017 as the Trust had a block contract in place. One to One was also unwilling to pay the debt prior to this as they stated that the Trust had not been willing to put an agreement in place with One to One as advised in national guidance. They requested a credit of £273k after taking account of a coding validation exercise which identified £33k as due to LWH.

In September, the CQC contacted PHE regarding the licence required by One to One to undertake ultrasound scanning which required their approval. The plan would also require the CCGs approval.

South Cheshire CCG was meeting monthly with One to One to review women on a medium to high risk pathway. A communications protocol was being developed for liaison with Health Visiting.

In September, an incident was raised by Liverpool CCG relating to the pathway into Health Visiting. One to One responded that they provide the mobile number of the woman's midwife on the referral form so that the Health Visitor can contact them. This had previously worked well.

One to One attended the C&M Women's and Children's Services Partnership meeting.

October 2018

In October, One to One sent requests to all NHS providers to confirm within 4 weeks the level of outstanding debt due.

In October, the MIAA draft report confirmed that One to One could only be viable if activity increased and provider to provider charges were resolved. Wirral CCG was not satisfied with the report as it had gone off scope; the specification was to look at the financial viability of One to One and whether they would meet the requirements of a procurement process, not to provide the suggestions for improvement which were in the report.

A prescribing incident was raised relating to a South Cheshire patient. One to One believed this was specific to Leighton hospital as joint processes worked well elsewhere.

There was an update from the LMS meeting. The Directory of Services issue had not yet been resolved. GPs were to be issued with cards to hand out to women to offer choice. 'Pop-up' centres were being commissioned with additional funding; both WUTH and COCH had expressed an interest.

In October, the C&M Partnership declined One to One's proposal to develop a community hub. One to One stated that the Partnership had misunderstood their intention as their plan was to use their existing hub for collaborative working with other providers; they were not requesting funding. One to One also noted their frustration that a transparent procurement process had not been undertaken for the 'pop-up' birth centre in Seacombe. This meant that women under their care would not have access to the centre as WUTH were required to ensure continuity of care through the birth centre. One to One intended to raise this issue at regional and national level. The Partnership contacted NHSE's Chief Nurse North to advise that in their view One to One were promoting the rental of their facilities to providers rather than intending to collaborate.

November 2018

There was an action from the Wirral contract meeting in November to consider whether there were other services which faced a similar scenario to One to One on provider to provider charges. Ophthalmology was cited but CCGs had not been involved in resolving the issues in this service.

West Cheshire CCG considered procurement options for the whole maternity pathway with a potential sub-contract model to One to One. WUTH and LWH responded that they would not be expressing an interest. No response had been received from COCH. The One to One contract was due to expire in September

2019; it represented 25% of One to One's annual income.

In November, One to One wrote to Wirral and West Cheshire CCGs asking for a contract extension and challenged the need for re-procurements. West Cheshire CCG replied that commissioners were acting in accordance with procurement rules.

December 2018

No further comments were received on the MIAA report by December 2018, and this was finalised.

In December, it was confirmed that the Wirral CCG led contract would be extended until March 2020 to allow a service specification and re-procurement to take place. No new referrals were to be accepted after 1 June 2019.

It was noted that Warrington CCG was reluctant to share their activity and finance information with the contract meeting, but no explanation was given for this.

Liverpool CCG said that they would not continue as mediators between LWH and One to One on pathways and provider charges issues. One to One had not received a response from LWH regarding their latest request for a meeting.

At the contract meeting in December, Wirral CCG offered to support the development of One to One's Quality Report to ensure it met commissioners' requirements.

Following the move to in-house scanning, there had been some equipment delays. No significant issues were identified for patient care as a consequence of this; the issue was added to the CCG's risk register.

The maternity performance dashboard was amended in several areas to tailor this more appropriately to One to One.

One to One disagreed with commissioners over reporting an incident in South Cheshire as an SI.

The Directory of Services link had been provided for One to One's details.

January 2019

MCHFT had written to One to One to suggest mediation on the outstanding debt. One to One expected that other Trusts would be waiting for the outcome of this meeting before determining their own course of action. No settlement was agreed and One to One expected this would have to go down a legal route. Legal costs for the Trust were estimated as £110k for the action. One to One costs would be for a similar amount.

Neighbourhood Midwives, an independent provider of a case loading service in London, closed due to financial difficulties.

One to One confirmed there had been no change to their financial position and they had written to Wirral CCG asking for consideration of a local tariff.

At the Wirral contract meeting in January, scanning arrangements were discussed again. Diagnostics Healthcare, the scanning provider, had withdrawn their services from One to One. One to One provided reassurance that there were no backlogs. Capacity and demand were being monitored through weekly calls with PHE.

The monthly meetings with each CCG to review caseloads were proving to be too resource intensive; One to One asked if these could be managed collectively.

One to One expressed an interest in being involved in the development of the community hubs in the Wirral for shared care. Proposals were not expected to progress until Summer 2020.

The review of the service specification was on hold pending work on the Long Term Plan which had been published in January.

In January, there was a presentation on continuity of carer at the C&M Heads of Midwifery (HOMs) meeting. Several providers had not yet submitted the data including One to One. The data was required as part of the Maternity Transformation Programme submission.

One to One received positive feedback on the completion of an RCA report.

February 2019

One to One made a proposal to provide an online obstetric advice service. Commissioners were unwilling to take this forward as this might further destabilise relationships with NHS Trusts and result in One to One managing women of higher obstetric risk than was intended. An existing national programme (Consultant Connect) would be used for this type of service.

The activity and finance plan for 2019/20 for Wirral CCG showed a £34k decrease in income for One to One due to a fall in birth numbers.

West Cheshire CCG were planning for a £350k overperformance on the contract for 2018/19. One to One reported a significant increase in bookings. The CCG also advised that there had been a significant increase in intensive tariffs.

A memorandum of understanding was put in place between One to One and Virgin Care for Health Visiting services.

A midwife representative from NHSE observed the Wirral contract meeting in February.

Positive feedback was received on One to One's Quality Report. One to One noted that there had been no problems recently in working with acute Trusts on RCAs; there were some challenges in engaging with the North West Ambulance Service.

Scanning was back up to full capacity and the meetings with PHE were now monthly.

In February, One to One were asked for data by the C&M Partnership for the routine submission to NHSE for the Pioneer programme. One to One referred to the resource needed to collate the data and did not want to provide the data on continuity of care due to the issues with transfers of care:

"*Our core issue is that we don't have the support of providers to accompany labouring women booked with us into a hospital setting and to remain the lead provider of care for the intrapartum period. This means that around 70% of our caseload are forced to transfer care to a hospital provider if they either choose or need to be transferred into a hospital environment for the intrapartum element of their care pathway."*

One to One had already escalated this to NHSE who provided a revised definition. One to One were frustrated that the data submission had been made showing their performance as 0% without referencing

that the revised definition was awaited. The Partnership highlighted that One to One had submitted 100% performance which was inconsistent with that previously reported of 77-78%.

March 2019

It was confirmed in March that West Cheshire CCG would join the co-commissioned contract from 1 April 2019.

A new Director of Operations represented One to One at contract meetings.

One to One were served notice of compulsory strike off by Companies House. This was due to late submission of the annual accounts for the previous year to March 2018. The action was withdrawn and One to One submitted their accounts in April 2019.

On 15 March, NHSE called an incident coordination meeting with the C&M CCGs in view of the business continuity risks involving One to One. It was noted 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.

The options presented were contract termination, allowing the contract to run to term or a re-procurement. Termination of the contract would require a provider insolvency event to be established and this would likely lead to a legal challenge as the debt was disputed. Continuing the contract until expiry and re-procurement was the chosen option as it best met the requirements for national policy delivery.

NHSE said that testing of business continuity arrangements with respect to One to One had been undertaken 18 months previously. Commissioners were asked to confidentially assess the level of risk to their Trusts and caseloads and test their business continuity plans. There was a follow-up meeting on 22 March.

On 29 March, Wirral CCG wrote to One to One to confirm the contract arrangements until March 2020. It advised that the contract could not be subject to a further extension and therefore the letter also served as notice on the current contract. The termination date

At the March contract meeting, Wirral CCG queried the lack of quality exceptions reported over the last two months. One to One confirmed that this was because none had occurred.

Liverpool CCG asked for the routine meetings with One to One to be reinstated.

PHE calls regarding screening were no longer required; there would be a final assurance review at the end of March.

Liverpool CCG queried the underperformance on referrals to Health Visiting and % of patients booked on or before 12+6 weeks gestation.

At the West Cheshire meeting in March, the CCG raised an incident which COCH had not communicated to One to One; it was the patient who had informed One to One. This was to be raised at the next maternity network meeting.

There was learning from a previous serious incident for both One to One and COCH; one issue identified was One to One's access to a local laboratory in Warrington.

At the C&M HOMS meeting in March, NHS Trusts queried the data submissions from One to One. It was confirmed that NHSE was looking into the template ambiguities which affected other providers, not just One to One. One to One explained that they had not been able to submit data for continuity of care pending clarification on the template. A view was expressed that One to One had refused to submit the data.

Saving Babies Lives Version 2 was published by NHSE as part of the Maternity Transformation Programme. The focus was on reducing smoking, risk assessment for fetal growth, increased awareness of fetal movement, fetal heart monitoring and reducing pre-term births.

for new referrals was 1 July 2019. Commissioners were intending to undertake a service review which may result in a further procurement process.

For the year to March 2019, turnover grew by 23% to almost £6m with a gross profit of £1.7m. Overheads increased to give an overall loss of £0.5m. The cumulative deficit was over £2m. Liquidity worsened with a further increase in debt to £2.8m (from £2.1m the previous year).

There was greater emphasis on continuity of care. Its requirements were included in the NHS Standard Contract for 2019/20.

Chronology Part Six

2019/20 Business Cessation

Commissioning, Contracting and Finance	Quality and Safety
2019/20	
April 2019	

From April 2019, contract meetings were split into two parts. Part A would cover business continuity and communication arrangements following the contract notice in March. Part B was for routine contract monitoring.

One to One sent apologies for both parts of the meeting. In an email to Wirral CCG on 18 April, the Chief Executive highlighted the serious implications for One to One of the contract termination notice and was preparing a response. One to One queried why a termination notice had been issued rather than a re-procurement. In addition, they repeated the challenges around contractual agreements with providers on pricing:

"Trusts raised multiple invoices at once, for example, they had received 6 months charges from a Trust without backing data for validation.

Trusts were receiving payment twice for obstetric services under block contracts and that it was not possible for CCGs to understand whether One to One activity was included in activity plans. One to One were not paying outstanding debt as they would legally dispute this due to the block contract issue.

Trusts were using advantageous coding to inflate charges, for example using an admission instead of an attendance."

An internal NHSI email to prepare the response to One to One stated that:

"Whilst this may be described as a provider to provider issue, it is argued that no independent organisation could sustain such over-charging and therefore the One to One service facing financial difficulty was entirely predictable. These provider charges could not be afforded in tariff envelope."

A response to this email stated that: *"It should also be noted that maternity services*

The date for cessation of referrals had been discussed with NHSE North's Director of Commissioning Operations who asked that referrals continue to the end of the contract with an individual management plan for each woman under the care of One to One. The CCGs wanted to assess the risks of this in terms of continuity of care and financial implications. Women would need to be informed up front that they may need to be transferred to the care of an NHS Trust at a later date.

South Cheshire CCG raised concerns regarding the stability of One to One until March 2020, and safety for their patients, given the potential impact of the contract termination on the business. One to One managed over 500 bookings per year in South Cheshire.

The communications plan noted that One to One had been shortlisted for the national MaMa awards to be judged in May. It also referenced the media article advising of the closure of Neighbourhood Midwives in January 2019.

In Part B of the contract meeting in April, the quality review by PHE of One to One's screening service was discussed. The issue regarding safe storage and transfer of images had been addressed. Otherwise, there were only minor issues, and no risks were identified.

West Cheshire CCG were not assured by the quarter 2 performance on screening as One to One were the only provider not rated green. A quality assurance visit was planned regarding this, and it was noted on the risk register.

South Cheshire CCG was impressed by the work done by One to One and supportive of the service stating: *"they are [a] really good quality service who*

within NHS providers are typically loss making."

A response was prepared by NHSE/I and Wirral CCG. It confirmed the technical requirement to undertake a reprocurement. It also referred to the deficiencies in One to One's proposed payment reform approach.

The letter advised that that not all Trusts were on block contracts and that baselines were based on the previous year's forecast outturn based on PbR activity only, therefore excluding One to One activity. In addition, it confirmed that Trusts were appropriately applying the national rules for provider to provider charges.

Communication between Wirral CCG and NHSE/I noted that the payment reform proposals set out by One to One had been presented several times over recent years and had been rejected. It would effectively take funding from other NHS providers and could mean commissioners paying for minimum activity that may not materialise. The modelling was deemed not sufficiently robust.

On 15 April, the Director of Finance of Warrington and Halton Hospitals NHSFT (WHH) expressed frustration at the level of debt with One to One and emailed Wirral CCG with their concerns. They queried if the One to One contract was going to be renewed/extended, whether appropriate regulations and due diligence had been applied. They also challenged whether arrangements with One to One were compliant with the principles of HM Treasury's publication 'Managing Public Money' on value for money.[25]

On 16 April, the Chair of the Audit Committee of LWH wrote to the Chair of the Audit Committee of Wirral CCG. The letter *has a large percentage of the indicators on green."*

It was agreed that meetings/calls would resume quarterly with CCGs to review caseloads. Notes of these meetings were to be provided to the contract meeting.

One to One had introduced Badgernet, a maternity clinical management system used widely in the NHS for submitting the maternity minimum dataset requirements.

In April, there were further communications between the Chair of the Heads of Midwifery forum in C&M and NHSE about One to One's data submissions on continuity of carer. NHSE's understanding was that they were commissioned for low risk pregnancies only and therefore 100% could be correct. The Chair advised NHSE that they managed more complex cases and therefore there would be some transfers to Trusts with consequent impact on the metric reported. NHSE asked One to One to look into this issue. The concern was that One to One were recording continuity of care for all women even if obstetric care had transferred to an NHS provider.

[25] "Ensuring that the organisation's procurement, projects and processes are systematically evaluated to provide confidence about suitability, effectiveness, prudence, quality, good value judged for the Exchequer as a whole, not just for the accounting officer's organisation." https://www.gov.uk/government/publications/managing-public-money

reiterated LWH's serious concerns over One to One's financial viability due to their net liability position and non-payment of provider to provider charges: *"It is surprising that a CCG would continue to commission from an organisation in this financial position."* The letter referred to LWH's suggestion that One to One should be paid for work undertaken rather than the pathway tariff to avoid the provider to provider charges issue: *"During contract negotiations, it was suggested by LWH that pathway payments to One to One ceased, and that they were paid just for work undertaken. It is unclear why this was refused by the CCG."*

Wirral CCG had been working with NHSE to develop a communications plan for the contract termination. One to One had restricted communications to their senior leadership team and emphasised the need for this information not to be leaked to staff. Communications were to be limited to Director of Nursing level at NHS Trusts and embargoed. The intention was to issue the communication on 3 May and include a joint statement with One to One.

The draft plan set out the intentions for a re-procurement exercise for a new service from April 2020 with a specification to comply with Better Births. Press statements were drafted to explain the need for a re-procurement and included a statement for the scenario under which One to One were unable to continue in business.

The agreed actions from the meeting were to: request caseload information from One to One, examine the financial impact of referrals terminating either in July 2019 or March 2020, share the communication plan with One to One and start conversations with NHS Trusts.

In Part B of the meeting, an underperformance of £35k was noted on the Wirral contract for 2018/19 which was in line with trends previously reported. No finance summaries were received from other commissioners. Liverpool CCG highlighted an over-performance of £150k.

Wirral CCG requested that the contract meeting was more focused and proposed continued monthly monitoring in relation to

finance and business continuity with quarterly monitoring on quality performance.

May 2019

One to One attended Parts A and B of the contract meeting in May. All discussions took place in the Part B meeting.

One to One provided papers on staff numbers and caseload by CCG and stage of pregnancy (total 1,417 women).

One to One advised that a court date was likely between June and September in relation to the debt recovery by MCHFT. This legal action had cost One to One over £100k which was more than the debt involved.

One to One's Chief Executive stated that there was a total of approximately £1m of disputed debt relating to provider to provider charges and this would require resolution with CCGs and NHSE involvement.

One to One challenged the need to reprocure and wanted a rolling contract as for acute providers. One to One recognised that their financial position meant they would not qualify for the procurement. Their view was that NHS Trusts might express an interest with the objective of removing One to One from the market and some had set up services replicating the case loading model. The CCG confirmed their intention to reprocure in line with fair procurement principles given there would be other market interest; One to One would not be the sole potential supplier.

At this point, One to One employed 130 staff and had around 3,000 women on active caseloads.

Commissioners received One to One's proposal for a pilot for payment reform. No response had been received from the LMS to whom it had been presented. A response from the CCG would be brought to the next contract meeting.

One to One wanted referrals to continue to the end of the contract. It was agreed that referrals would continue to March 2020, and appropriate communications would be put in place.

At the May contract meeting, there were no significant issues raised on the maternity performance dashboards for April. It was noted that a 'RAG' rating appeared to be incorrect on breastfeeding initiation as One to One had achieved 50% but were rated red.

There was a query from Warrington CCG regarding missing data in the maternity dataset since September which One to One were to investigate.

There was a discussion about TUPE and West Cheshire CCG advised that it may apply to One to One staff given activity levels. One to One were to seek advice on this.

One to One were planning to express an interest in the forthcoming procurement. One to One asked if there had been an update from NHSI about payment reform. The CCG advised that the procurement would be based on national tariff guidance at the time.

On 30 May, the Chief Executive of WHH wrote to One to One regarding unpaid invoices which exceeded £0.8m, requesting a meeting and that the debt was paid by the end of June; otherwise, the Trust would cease to take referrals from One to One.

June 2019

On 3 June, One to One received a letter from solicitors requesting payment of almost £1.4m within 21 days after which court action would be taken. The debt related to WUTH (£177k), LWH (383k) and WHH (£819k) to April 2019.

At the meeting on 5 June, One to One said they would legally dispute the debt with WHH. A teleconference was held on 10 June with NHSE/I to discuss the current situation in Warrington.

An email from WHH to Warrington CCG on 5 June stated that the Trust would be happy to continue to work with One to One if there was no financial risk involved.

On 10 June, a request for expressions of interest was issued for the procurement. A market engagement event was planned for 28 June.

Wirral CCG was coordinating the procurement of a Community Midwifery Service for Wirral, Liverpool, South Cheshire, Southport and Formby, South Sefton, Vale Royal, Warrington and West Cheshire CCGs.

A contract variation was issued to One to One to bring the contract into line with provisions of the NHS Standard Contract for 2019/20. Amendments of significance were to:

At the June contract meeting, feedback from the PHE quality assurance visit on screening did not identify any issues. A revisit was planned for October 2019.

The key areas of underperformance in May were referrals to Health Visiting, patients booked before 12+6 weeks gestation, normal vaginal deliveries (all births), same midwife for antenatal and postnatal care and planned Caesarean section rate. It was noted that the exceptions related to small numbers and late transfers into the service due to patient choice.

The Quality Report for Quarter 4 was reviewed. The response rate to the Friends and Family Test was over 32% compared to a national average of 15%. The induction of labour rate remained high at over 34% which was for obstetric reasons rather than choice. Training had been provided to the North West Ambulance Service. The ratio of experienced to newly qualified midwives was requested. Wirral CCG gave positive feedback on this report.

An incident which involved safe storage of scan results on the HERA system was discussed. Investment was needed in other systems and One to One were not in a position to do this.

"ensure that high quality, integrated and co-ordinated care for the Service User is delivered across all pathways spanning more than one provider";

"fully implement the Saving Babies' Lives Care Bundle by no later than 31 March 2020";

"to use all reasonable endeavours to achieve the Continuity of Carer Standard by 31 March 2020".

On 21 June, 6 NHS Trusts and One to One submitted expressions of interest in the procurement and the market engagement event took place at the end of June.

On 24 June, an email between NHSE leads and Wirral CCG raised the risks to business continuity of the MCHFT legal action and the WHH decision to stop accepting referrals from One to One. NHSE North was to lead on business continuity and communications plans for the North West region and NHSE East of England were to lead for Essex. The national team were to prepare a briefing for the Regional Directors and the Chief Executive of NHSE.

Three hospital reported incidents had occurred in West Cheshire over the preceding 3 months. There were no themes identified. The hospital had not involved One to One in an RCA investigation for a post-partum haemorrhage. The Trust reported that the communication from the One to One midwife involved had been unacceptable. West Cheshire CCG stated that in their view One to One followed the correct protocol for serious incident reporting.

In June, Wirral CCG noted the referral of One to One's Chief Executive to the Nursing and Midwifery Council. The CCG saw no need to pursue this as there was no obvious breach of professional standards and the situation was being managed by the contract. The briefing said it was the NMC's responsibility to pursue if they so required.

July 2019

On 16 July, One to One held a meeting with their accountants, solicitors and a firm of corporate recovery specialists. The decision was made by One to One that the Company was insolvent as other Trusts were likely to pursue their debt and the contract was unlikely to be renewed.

The draft briefing prepared by NHSE's national team was shared in mid-July. It highlighted approximately £300k of debt that One to One owed to NHS Resolution (NHSR) (formerly NHSLA) relating to unpaid CNST insurance premiums from 2018 when premiums had increased. NHSR had not withdrawn cover and had agreed to put the £300k debt on hold, providing One to One continued to pay current premiums due.

On 12 July, an email exchange between WHH, Warrington CCG and NHSE/I highlighted concerns the Trust had had for some time based on One to One's published accounts. Debt was £830k and

increasing at a rate of £20k per month (the Trust owed One to One £223k). The Trust had considered legal action with two other Trusts, but this was a lengthy and costly process. The Trust would be ceasing to take referrals from One to One from 31 August.

The email also noted that the top-slice model repeatedly referred to by One to One simply allocated a share of maternity income to One to One was therefore disadvantageous to the Trust.

On 24 July, Wirral CCG received legal advice on the application of the contractual provision regarding a potential insolvency event. This clarified the steps to be taken should commissioners be seeking to terminate the contract under this provision. The advice was shared with NHSE. Wirral CCG noted that the advice did not cover the outstanding NHSR insurance premium issue.

On 25 July, the Invitation to Tender was issued for the procurement. The estimated contract value was £5m with a term of 3 years and option to extend for 2 years.

On 29 July, One to One filed an intention to appoint an Administrator and informed Wirral CCG that they would cease trading from 17:00 on the 31 July 2019. There was a total of 1,664 women across Cheshire Merseyside and North East Essex requiring antenatal and postnatal care.

One to One informed staff and 89 redundancies were involved. Staff were advised of the steps to be taken to transfer patient care and records. Approximately £7,000 was incurred in fees by One to One for pre-administration costs. The total estimate of costs to be incurred for the administration was £79,505 plus expenses (£7k) which would be paid before any distribution to other creditors.

On 30 July, requests were received for an extension/suspension of the procurement process from NHS Trusts due to the developments with One to One. The deadline was extended to mid-September.

August 2019

On 1 August, One to One entered administration due to insolvency. The

company had realisable assets of £292k and creditors of £3.21m. Significant creditors and potential liabilities were as follows: NHS Trusts £2.7m; £377k to the NHSR for CNST cover; employee claims of £150k for redundancy and compensatory notice; and tax and National Insurance liabilities of £92k.

In August, Wirral CCG considered One to One's associated company, My Midwife and Me Ltd and established that the company did not hold an NHS contract; the CCG understood the company was for private midwifery services. The CCG wanted controls to be put in place to prevent GP referrals to this company.

On 2 August, Wirral CCG expressed concern with the draft external communications as it focused on the failure of the business model rather than the national tariff. The CCG understood NHSE were supporting this view by amending the wording.

CCGs agreed to cancel the procurement exercise on 8 August, given the additional demands on Trusts to manage the impact of the cessation of One to One.

MCHFT provided an update to its Board to advise of One to One's cessation and the status of their court action for the recovery of debt (£181k at this point). The action would be halted until the end of the administration. The debt had already been provided for in their accounts. £166k of legal costs had been incurred to date.

September – October 2019

An Administrator's Report was published on 13 September providing full details of assets and liabilities. It stated that solicitors suggested that One to One had a 50% chance of successfully defending the action being taken by NHS Trusts on debt relating to provider to provider charges. However, One to One was unable to afford the legal fees involved.

Wirral CCG responded to LWH on 25 September explaining the approach with NHSE/I to the major incident response regarding One to One.

In September at the C&M Programme Board, it was reported that the system response to the collapse of One to One had been excellent in terms of offering care for women and families. However, it had impacted on capacity in the system and compliance with Birthrate Plus activity and capacity planning recommendations.

"Whilst the abrupt nature of the company's failure did require other NHS providers to step in and provide care without sufficient prior warning it also required the whole system, including commissioners, to find placements for around 1,800 women in a collaborative manner. Whilst the situation was "unplanned" it was not unexpected, and preparations were in place for a system wide response…."

[Refers to investigation] …. This will clearly afford an opportunity for you to share the "rigorous records" you have in respect of the concerns you have raised with NHS Liverpool CCG, as your local commissioner. Aside from a letter from the Chair of the Liverpool Women's Hospital NHS Foundation Trust to the Chair of the NHS Wirral CCG Audit Committee, we can find no written record of you sharing the concerns you cite with NHS Wirral CCG directly."

November – December 2019

In November, the Chief Executive of COCH contacted NHSE/I to provide an update on the Trust's meeting on 5 November with the Administrators for One to One. The email confirmed that all One to One's associated companies had ceased trading other than My Midwife and Me Ltd which offered insurance cover to independent midwives. There had been discussion about action for wrongful trading, but the advice was this was only viable if the Directors had substantial personal wealth given the cost of such action. The Department of Trade and Industry would determine at a later date whether the Directors would be disqualified.

A paper to Wirral CCG's Quality, Finance and Performance Committee in November presented the procurement options. The specification had been updated following the market engagement event held in June and from feedback from clinical leads in the C&M LMS, an independent obstetrician, a GP with interest in maternity and Maternity Voices.

On 18 November, C&M commissioners met and agreed to vary local NHS Trust contracts with the agreed specification. Wirral CCG noted that this was the only

A West Cheshire CCG paper dated 1 November reported that they had no quality concerns with One to One.

viable option in the absence of any other market interest. The CCG also stated that WUTH would be held to account for delivery of the specification requirements, including national policy objectives

In December 2019, NHSE/I published a consultation document on the national maternity tariff for 2020/21. It proposed that the payment approach for maternity services should either be a blended payment, involving fixed, risk share and outcomes elements, or the maternity pathway payment. The plan was to introduce a blended payment model as the default method from 2021/22.

January – August 2020

In February, the Administrators published a progress report. It stated that some creditors had raised concerns regarding 'wrongful trading'. The Administrators had already complied with their obligations by making the relevant submission to the authorities. Progress on this issue was subsequently delayed due to the COVID-19 situation.

Secured creditors had been paid in full and it was anticipated that there would be sufficient funds to pay employee claims. The position for unsecured creditors such as NHS Trusts was uncertain.

In July, the company moved into a Creditors' Voluntary Liquidation with a cash balance of approximately £124k for distribution to unsecured creditors.

Appendix 6 – National Audit Office (NAO) Performance measurement framework

We have extracted below the key elements of the NAO best practice framework for performance measurement as set out in its document 'Performance measurement: Good practice criteria and maturity model' of 2016.[26]

Performance information needs to be:	
Accurate:	providing a fair picture of performance, with sufficient accuracy for the intended purpose
Valid:	recorded and used in compliance with relevant requirements, including the correct application of any rules or definitions
Complete:	with processes to monitor for, and act on, incomplete, missing or invalid data

To be effective, the framework requires good performance measures. These are ones that are:

Relevant to the purpose of the performance framework and to what the organisation is aiming to achieve

Able to avoid perverse incentives and should not encourage unwanted or wasteful behaviour

Attributable: the activity measured must be capable of being influenced by actions that can be attributed to the organisation; with clarity about where accountability lies

Well defined: with a clear, unambiguous definition so that data will be collected consistently, and the measure is easy to understand and use

Timely: producing data quickly and frequently enough for the intended purposes, and informing timely decision-making

Reliable: reflecting stable and consistent data collection processes across collection points and over time

Comparable with either past periods or similar programmes elsewhere

Verifiable with clear documentation behind it, so that the processes that produce the measure can be validated

[26] https://www.nao.org.uk/wp-content/uploads/2016/11/

Appendix 7 – Record of quality surveillance processes

This section summarises in note form, the key points of debate arising from the various quality surveillance processes undertaken as extracted from the minutes of meetings.

Quality surveillance – NHSE North

Event and date	Details
Single item Quality Surveillance Group (QSG) 28 July 2014	Chaired by the Regional Chief Nurse for NHSE North, this was an initial meeting during which concerns about One to One were discussed. Wirral CCG and the Local Area team reported that contract review mechanisms were in place and quality issues identified were being managed via these arrangements. The main concern was about One to One operating in areas without a contract in place, and there being no means of clearly identifying and addressing the level of risk associated with the service or of gaining assurance regarding actions taken to address risks. The outcome of this meeting was for NHSE North to gather more intelligence about One to One and to call a further meeting in November 2014.
Single item QSG 3 November 2014	Chaired by the Deputy Director of Nursing and Quality Assurance for NHSE North and attended by representatives from NHSE South Yorkshire and NHSE Midlands and East. Information was shared about One to One's activity in each area and the concerns that they and NHS providers had about the service. The meeting was provided with an update from the CQC. One to One was not compliant with Outcome 16 (Assessing and monitoring the quality of service provision[27]) and was under review. The NHS Litigation Authority (NHSLA) had advised that One to One would only be covered under CNST if formal arrangements were in place with CCGs. The conclusion was that a Risk Summit would be called to allow One to One to participate and respond to concerns relating to: • poor communication and lack of agreed pathways with NHS providers; • the service being provided to high risk women; • compliance with NICE guidance; • the rate of serious incidents compared with other providers; • contracts not being in place in some areas and the impact on quality assurance and NHSLA cover for non-contracted activity (NCA); and • professional issues for One to One midwives and whether they were always working within their scope of practice. One to One were invited to the meeting by letter of 10 November (two days' notice). An agenda for the meeting was not provided.
Risk Summit pre-meeting 12 November 2014	Feedback was received from the QSG meeting on 3 November from the Local Supervising Authority Midwifery Officer (LSAMO), NHSE Regional and Area Teams, CCGs, the NHSE national team, the CQC and Monitor.
Risk Summit meeting	This was chaired by the Chief Nurse NHSE North. Attendees were: Deputy Director of Nursing Quality Assurance, NHSE North

[27] https://services.cqc.org.uk/sites/default/files/gac_-_dec_2011_update.pdf

12 November 2014	Director of Operations and Delivery, Wirral CCG Director of Commissioning, NHSE North LSAMO North West Head of Maternity and Children's Services, NHSE North Deputy Director of Nursing and Patient Experience, Merseyside Area Team Assistant Director of Nursing and Patient Safety, West Yorkshire Area Team Deputy Director of Nursing, Quality and Safety, Lancashire Area Team Director of Nursing and Quality, Cheshire, Warrington and Wirral Area Team Deputy Director of Nursing and Quality, Greater Manchester Area Team Director of Nursing and Quality, Greater Manchester Area Team Associate Director of Corporate Services, Trafford CCG Director of Provider Management, Stockport CCG Inspection Manager, CQC Commercial Director, One to One Chief Executive Officer, One to One Clinical Director, One to One The Chief Nurse for NHSE North wanted to address the following high level issues: • the core values of One to One and how they were disseminated and embedded within the service and with staff; • how the organisation ensured governance and quality assurance was embedded within the service; • staff turnover; • skill mix and percentage of newly qualified staff; and • preceptorship and supervision provisions within the service (excluding statutory supervision). *Feedback* The LSAMO reported that they had completed an audit which showed all LSA standards were being met. Wirral CCG reported that One to One's quality surveillance was a concern for the CCGs. There were concerns about the management and quality of care for high risk patients and communication with some NHS providers about pathways. In areas where there were no contracts in place, there were concerns about quality standards and compliance with quality performance requirements. Trafford CCG had completed a review on behalf of the Manchester CCGs. One to One would not pass a pre-tender procurement stage due to its standard of documentation and service arrangements in place. The Area Teams provided feedback on incidents reported on StEIS, focusing on high risk women. The Wirral service specification was unlikely to reflect requirements in other areas. There was a lack of knowledge of the performance indicators in use to assure quality and safety. GPs were reporting aggressive marketing tactics. The national update advised that the NHS Constitution sets out choice of location for birth but there was no legal right to a choice of provider in maternity services. It was for a CCG to make local choice available. 'Who Pays' guidance also stated there was no legal choice of provider. This had been communicated to One to One and Monitor. NHSE North raised the lack of pathways and communication with providers, particularly in emergency situations and regarding newborn assessments. Issues were not being raised promptly and concern about the rate of incidents reported on StEIS. *One to One response*

	One to One said that their core values were – 'women centred', professional and safety. They appreciated that they were the first independent provider of midwifery services and the challenges that this posed for them in the NHS landscape. One to One said that they did not market the service outside of their area, but women came to them. They stated that the NHS Commissioning Board had told them they could go where there was demand. GPs were informed when a woman booked with them, had given birth and were discharged. Women were given an information sheet to give to their GP on booking with One to One. GP referrals were not provided for women who transferred to them from another provider. One to One confirmed they had a safeguarding lead. Risk assessments were undertaken at booking, high risk patients were referred to an NHS obstetric provider, but some women did not want to move to an obstetric provider. One to One attended appointments at hospital with women and shared copies of the women's clinical notes with the NHS provider. One to One had appointed an obstetrician, working with intermediate risk women. Two midwives attended the birth for high risk women. There was no routine communication with NHS providers about low risk women in labour. *Summary of the meeting* One to One had not described how they gained assurance about quality and safety. This would be the key focus of the next meeting. One to One were required to provide information to demonstrate: • a service model that meets all quality standards and compliance with NICE guidance; • evidence of agreed communication with NHS providers; and • evidence of risk assessment and documentation relating to high-risk women who choose to ignore location of birth advice. *Actions from the meeting* Serious incident process - Deputy Director of Quality Assurance NHSE North to lead Contract interpretation – Director of Commissioning NHSE North to lead NHSLA letter – Chief Nurse to lead Discussion with Greater Manchester CCGs – Chief Nurse to lead One to One was to provide: • details of assurance and governance processes; and • workforce information in all areas One to One cover. Another meeting was to be arranged in four weeks.
Risk Summit 21 January 2015	Chaired by the Chief Nurse NHSE North. The meeting was attended by representatives from NHS England, the CQC, NHSE North, NHSE Yorkshire, a representative for the 12 Greater Manchester CCGs, NHSE Greater Manchester and Lancashire, NHSE Merseyside and One to One. The minutes did not identify the job titles for the attendees. The agenda was to be flexible to allow a focus on contractual issues. It was agreed that One to One's financial issues would be discussed in a separate meeting. A Desk Top review was to be completed on 6 February; the terms of reference would be shared with One to One in advance,

	One to One confirmed that they now had access to the Strategic Executive Information System (StEIS). The NHSLA had been approached for an opinion on CNST cover for One to One. A presentation was given on the arrangements under which One to One could provide a service: • an NHS Standard Contract with the commissioner; • as an appointed sub-contractor to a lead provider with an NHS Standard Contract; and • exceptionally through NCA with the CCG's permission One to One said this was the first time they had been given clarity about this matter. The Chief Nurse was to send a letter to the Directors of Commissioning Operations (DCOs) to share this information with the CCGs. One to One confirmed that they were providing services in Essex with the full support of the CCGs. *Actions from the meeting* • A Desk Top review was to be undertaken. • The response from the NHSLA was to be shared. • The Chief Nurse was to write to DCOs. • A request was to be made to the CQC for a comprehensive review of One to One using their revised methodology[28] as part of the assurance process for the Risk Summit. • A further meeting was to be arranged regarding finances. The next meeting was planned for early March
Desk Top review 6 February 2015	The Desk Top Review was completed by the Clinical Quality Director, NHSE/I for North East and Yorkshire. The objectives were to: • focus on specific quality information and the implementation of organisational and national guidance and best practice to contribute to quality and safety assurance processes; and • gather assurance evidence to contribute to the Risk Summit for triangulation with other quality and safety information. The review had 13 lines of enquiry in the terms of reference which were discussed. Key findings from the review are set out below. Risk management and incident reporting - One to One did not report on the National Reporting and Learning System (NRLS) but could now report on StEIS. One to One's Risk Management Strategy set out the process for reporting incidents. Identification of SIs/Never Events - incident reporting information appeared to reflect national principles and requirements for reporting externally to commissioners. The process for reporting was established and facilitated via iPads. One to One appeared to be a consistent reporter of all incidents meeting the SI criteria Lessons learned - there was no evidence these were identified through incident reporting or other processes. The trigger list identifying reportable incidents in One to One's Risk Management Strategy was not mirrored in the Quarterly Quality Report (Oct 2014- Dec 2014). The review suggested improvements to the terminology used for incident types for consistency.

[28] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 methodology

	Governance - the One to One Quality Report identified one ongoing claim. Assurance was needed on the management of claims. Risk Management Strategy - this did not detail the reporting structure which appeared fragmented and unclear. Risk and governance responsibility rested with the Clinical Director. The Board and CEO appeared to have no reporting structure beneath it. Risk management training and education - this was defined in the Risk Management Strategy and Training Matrix. Audit arrangements - the documents provided for review did not provide sufficient assurance. The number of planned audits was considered ambitious by the review panel, and they questioned One to One's ability to meet its own expectations. Critical topics that should have been subject to audit, e.g., compliance with NICE guidance, were not included. One to One maintained a rolling log/gap analysis. It was unclear who was responsible for risks when compliance was not achieved. Audits were reported via the Quality Review Group meeting with the CCG, monthly 'practice point' meetings and the risk register. There was limited assurance on escalation of risk. Emergency and planned care pathways with other providers - One to One reported challenges in engaging with other providers but that this had not impacted on the care provided to women. The Quarterly Quality Report (Oct 2014- Dec 2014) identified that all of the communication requirements in the Risk Management Policy were met. Risk assessment of women - One to One would not refuse a woman based on risk. There were concerns that risk assessments were not based on clinical criteria. A woman declining care from an acute provider after being provided with information about their risk was viewed by One to One as exercising informed choice. A question remained whether One to One would decline care in the best interests of the woman and baby. The circumstances under which One to One would not accept a woman were if: • they had no caseload capacity; • a woman lived more than 30 minutes radius from the midwife; or • it was believed that a woman would refuse a midwife entry in labour or during delivery. One to One only offered midwifery care so this presented challenges with pregnancies that were not low risk. The review suggested that One to One was offering care to women where it may be argued that it was not in her best interests. The Quarterly Quality Report (Oct 2014- Dec 2014) referred to One to One not asking women to choose their place of birth until the day they were in labour. One to One were asked if there was access to 'Fresh Eyes' reviews[29]. One to One were incorporating these reviews into their systems and processes. Safeguarding training - this was a risk identified in the Quality Report. Plans for compliance by December 2014 were not met; a priority plan was in place for compliance by April 2015. Safe staffing and recruitment - the 'buddy' arrangement for high risk women was discussed. Midwives with the right skills were 'matched' with women. Edge Hill University placed student midwives with One to One; there were concerns that newly qualified midwives were not adequately supported. One to One were unable to identify how it would manage a Professional Alert.

[29] Fresh Eyes reviews were introduced by One to One following the CQC inspection in Essex in March 2015. One to One described the implementation of monthly Fresh Eyes Reviews whereby individual caseloads would be reviewed by the Lead Midwife or locality midwife to identify women with risk factors and provide an oversight role to support midwives in making appropriate and timely referrals.'

	The review identified non-compliance with NICE guidance and poor relationships with NHS providers. The Desk Top Review had not been able to provide assurance against the terms of reference on appropriate risk management and quality monitoring of the service. The panel asked One to One to provide a wide range of information following the visit as it had not been provided on the day. The recommendation was to complete an in-depth clinical case note review alongside patient and staff interviews.
Risk Summit 24 March 2015	Chaired by Chief Nurse NHSE North Attendees - there were representatives from: NHSE, the CQC, LSA, Stockport CCG, Manchester CCG, Trafford CCG, One to One and the Commissioning Support Unit (attendees were not identified by job title). The meeting noted that the original request for a Risk Summit had been because of contractual concerns. These had been resolved with the advice from the Head of Patient Choice at NHSE. Issues about outstanding funds were being led by the Director of Assurance and Delivery NHSE North (we understand 'funds' refers to payment for NCA from CCGs). The NHSLA was clear that if a contract was in place, CNST cover would apply. The request for a CQC inspection had been agreed. The Desk Top Review findings were presented. The report had been sent to One to One for factual accuracy checking, but feedback had not yet been received. The review was unable to provide assurance to the meeting in the following areas: emergency and planned shared care pathways with local NHS providers; risk assessment of women at booking stage; and midwives routinely being expected to work outside their scope of practice, e.g., inexperienced midwives attending home births alone. One to One's Consultant Obstetrician felt several changes had been made since the Desk Top review and provided verbal reassurance about the issues raised and on the care of high risk women. The Consultant provided clinics for high risk women. If high risk women refused to see the Consultant, the midwife would ask for clinical advice. The Consultant said that in the past they had declined to provide care and advised that the woman go to an NHS obstetric provider. As a consultant who had worked in the NHS, he could confirm that One to One's processes were aligned with those of NHS providers, and they were confident about the escalation process. The Consultant felt the panel did not have a sufficient understanding of One to One's model. There were significant issues due to NHS providers not working effectively with One to One. One to One advised that their midwives were subject to abuse from hospital staff on the phone and that there was constant resistance form certain NHS Trusts. One to One told the meeting that Trafford, Salford and East Cheshire CCGs were happy for referrals to be made to One to One. South Manchester commissioners had asked for a care plan for woman under One to One's care. Trusts in Greater Manchester had received One to One's policies but not commented as yet. One to One were advised to raise problems in engaging with providers with the relevant CCG and then to the sub-regional QSG. The CQC advised that new processes and outcomes were to be considered and independent providers would be benchmarked annually. It was not identified who they would be benchmarked against. The development of a clinical dashboard with the CCG was discussed. An inspection was planned for quarter two. All Greater Manchester CCGs had been briefed. *Summary*

	• Factual accuracy checks on the Desk Top Review report to be completed and report recirculated. • Letter to be sent to CCGs to advise that the Risk Summit had received a level of assurance. • CCGs to be asked to advise NHS providers about the One to One service. • One to One were reminded that NHS obstetric units should be informed of all women in labour. • Abuse should be reported to the CCG. It was agreed that more in-depth scrutiny of patient records and patient and staff interviews may provide the required level of assurance, but it was noted that individual Risk Summit member organisations were most appropriately placed to scrutinise to this level. This would avoid any unnecessary or disproportionate scrutiny of One to One. The CQC confirmed plans for an in-depth inspection and the Risk Summit agreed to 'step back' the formal meeting process and allow these additional assurance activities to take place, following which the members and process would reconvene. It was confirmed that One to One would remain on a heightened level of surveillance during this time and until the Risk Summit process had concluded. It was agreed that, should new information or additional concerns come to light, any stakeholder could request the formal Risk Summit meeting to be reconvened at any point.
Letter 31 March 2015	From the former Chief Nurse NHSE North to the incoming Chief Nurse NHSE North and the Regional Director NHSE North. This was a summary of the QSG and Risk Summit process to date. This letter concluded that the process had not provided the level of assurance required in the following areas: relationships and communication between One to One and local NHS providers, the management of high risk women and midwives working outside their scope of experience. However, it was not felt that the QSG and Risk Summit forums were the appropriate way to address these issues. More in depth scrutiny of activities and records should be undertaken by CCGs and the CQC as they had the authority and mandate to do this. The letter confirmed that there was no legal right to choice in maternity services and the 'local choice offer'' was dependent on what services were commissioned by CCGs. Referrals and transfers could be made at any point on the pathway, within the local choice offer. The expectation was that One to One should have an NHS contract or sub-contract approved by the responsible commissioner. Exceptional non-emergency treatment may be delivered by a non-contracted provider subject to the CCG's prior permission. CCGs must put in place local referral protocols and pathways to ensure: • GPs understand and apply the protocols; • contracted providers have the same understanding that women can transfer only between locally contracted providers; and • women are aware of the local choice offer. *Payment pathways* There should be a lead provider for each part of the pathway recognising that there could be a different provider for each stage. A single payment is made to the lead provider for the stage. They are responsible for reimbursing other providers providing care within the stage. *Non-contracted activity* NCA was not a routine alternative to formal contracting and should only be used in exceptional circumstances for small, unpredictable volumes of patient activity.

	GPs should refer outside of the local choice offer exceptionally and with the CCG's permission. Non-authorised providers should get CCG permission before accepting and treating a woman. *NHSLA cover* Litigation for non-contracted activity - the NHSLA would not cover activity undertaken that did not have an NHS contract. *Desk Top exercise* This did not provide significant assurance that all risks identified at the beginning of the quality surveillance process have been mitigated. The Risk Summit took a level of assurance from the personal reassurances of the One to One Consultant Obstetrician. One to One's Consultant Obstetrician is not routinely involved in completing RCAs. Compliance with NICE guidance was not confirmed. Assurance was not gained that: • there was adequate communication with hospital services, especially in emergency situations; • there was adequate communication about high risk women to ensure that they are appropriately and fully informed of risks, benefits and alternatives by midwives deemed to be competent to provide the information, and therefore make informed decisions; and • midwives were not routinely expected or encouraged to work outside their scope of practice The reported poor behaviour of hospital staff towards One to One staff was a commissioning issue and should be reported to the CCG, to manage through incident reporting and whistle blowing. This was deemed more appropriate than reporting staff to the Nursing and Midwifery Council (NMC). CCGs were to be asked to evidence robust quality assurance processes to the local QSG meetings.
Letter 13 April 2015	One to One to the Chief Nurse North (we did not have sight of the letter; the detail below is from the Chief Nurse's response). One to One raised several concerns: • they were unfairly subject to the Risk Summit process; • use of the process amounted to organisational bullying; • they experienced intimidation by individual CCGs; and • there had been a lack of explanation regarding the need for a Risk Summit.
Meeting 1 May 2015	The Chief Nurse NHSE North met with One to One and the LSMAO. Minutes for this meeting have not been shared with this review but the meeting is summarised in the letter of 6 May 2015 below.
Letter 6 May 2015	From the Chief Nurse NHSE North to One to One. This was a response to a complaint letter from One to One. It set out the outcomes from the meeting of 1 May 2015, under broad headings: *Risk Summit* One to One thought that assurance had been provided that all issues had been resolved and was available through routine processes – the CQC inspection June 2014, quality review by the 12 CCGs in Greater Manchester, LSA audit and contractual CCG processes. The Chief Nurse responded that the decision to hold a Risk Summit had come from concerns raised by a number of CCGs in the North via their local QSG; these had been escalated to the Regional QSG for their consideration. Two single item QSGs had been called. One to One stated that findings and soft intelligence were shared with commissioners, regulators, professional bodies and QSG

	members to enable an assessment of perceived risks and decide if they warranted further investigation and action. The Chief Nurse explained that the need for a Risk Summit is determined when assurance is not gained, and the reported risks are still an active concern if patient safety seriously compromised. The Risk Summit was used to meet with One to One and share the collective concerns raised about activity in non-commissioned areas. This led to the Desk Top review and further meeting. One to One were concerned that information was not shared with them in advance of the first Risk Summit and their comments about the findings were not considered. One to One felt that the Risk Summit was not concluded in a satisfactory way, and this was impacting on them negatively from a reputational perspective. The Chief Nurse acknowledged that the Risk Summit process needed to be more open and transparent and was looking at the tools used to assess risk and the triggers to the Risk Summit process. One to One were waiting for the CQC report; the Chief Nurse NHSE North was to follow this up with the CQC. *NCA and NHSLA cover* There were concerns that without an agreed contract there was a lack of quality surveillance and governance, no agreed pathways, no financial governance around payments and no NHSLA cover for any potential litigation around clinical negligence. One to One disputed that they had not contacted CCGs before providing a service in their area, they said that some CCGs did not respond to their approach. The CCGs' perspective was that in the absence of their response and confirmation, an NCA agreement was not in place. One to One said that now they had clarity about NCA and patient choice they were no longer routinely undertaking NCA without prior approval. *Scope of practice and NICE guidance* Serious Incidents (SIs) were routinely considered as a quality indicator and risk factor. Incident reporting from One to One appeared to be higher than from other maternity services. There was recognition that One to One was a discrete service that might make benchmarking difficult. Analysis of SIs had indicated midwives might be working outside their scope of practice and NICE guidance. High risk women were specifically a concern with the One to One model. Work had started to review pathways of care for high risk women and to ensure learning from clinical incidents was embedded into practice. *Communication* One to One complained about a lack of response to their letters by the previous Chief Nurse for NHSE North. It was noted that these concerns may have now been addressed in the Risk Summit process. One to One had a complaint lodged with Monitor regarding the application of the Competition and Choice regulations; this was to be managed separately. *Next Steps* • The Chief Nurse NHSE North was to liaise with the CQC about timescales for publication of inspection report. • The Chief Nurse NHSE North was to ensure the factual accuracy of the last Risk Summit letter. • The LSA was to work with One to One about scope of practice and LSA processes. • The Chief Nurse NHSE North was to review the triggers for Risk Summit escalation. • The Chief Nurse NHSE North was to act as lead for One to One on behalf for NHSE.
Quality Risk Profile Tool Meeting	Chair Chief Nurse NHSE North Attendees: Six representatives from NHSE

29 October 2015	One representative from Wirral CCG Two representatives from West Cheshire CCG One representative from Stockport CCG One representative from Central Manchester CCG One representative from Trafford CCG Three representatives from One to One Midwives *Job titles not identified* The Chief Nurse had met with One to One to discuss the Quality Risk Profile Tool (QRP) and it was agreed that one approach would be taken across the North, involving all stakeholders. NHSE had worked with One to One to populate a QRP and this was discussed in the meeting. It was acknowledged that this was a picture at a point in time and other information was needed before final completion and agreement of risks. Information outstanding included the findings from the planned CQC inspection.
Letter 2 February 2016	From the Chief Nurse NHSE North to the regional Directors of Commissioning Operations (DCOs). Further to the previous letter on 25 March 2015 regarding the dispute between One to One, CCGs and NHS Trusts about NCA debt, the Director of Assurance and Delivery North proposed a *"pragmatic approach".* She believed some CCGs had attempted to resolve the issue without success, so it had been escalated to the national team. The letter stated that the Chief Nurse North had no authority to direct CCGs or providers but was asking the DCOs to tell her what their position was in terms of actions and communications with One to One to try and resolve the dispute.
Risk Summit Progress update letter 15 April 2016	From the Chief Nurse NHSE North to One to One. There were a number of factors preventing the completion of Quality Risk Profile tool: • A CQC inspection in the North had been completed but the report had not been published. • The CQC had completed an unannounced inspection in Essex, the report had not yet been published. • One to One's financial position was volatile and added to the potential quality risk for the overall service. Therefore, it had been agreed with local commissioners that it was not possible to step down the Risk Summit level of surveillance being applied to One to One.
Regional Quality Surveillance meeting 18 April 2016	This is referenced in the letter from the Chief Nurse dated 15 April 2016. The meeting discussed the Quality Risk Profile tool for One to One. *Note: there was no additional information provided for our review about this meeting, e.g., notes or minutes.*
Letter 9 December 2016	From the Chief Nurse NHSE North to One to One. This stated that assurance had been gained on an improving position in number of areas of the Quality Risk Profile. Assurance had been gained about financial position. One to One was stepped down from Risk Summit status.

Quality surveillance – NHSE Midlands and East

Event date	Details
Information gathering meeting 8 February 2016	Chair - Director of Nursing, NHSE Midlands and East Attendees: Deputy Director of Nursing, NHSE Midlands and East Director of Nursing and Quality, Mid Essex CCG Deputy Director of Nursing and Quality Assurance, NHSE Midlands and East Director of Nursing and Clinical Quality, North East Essex CCG Two representatives from the CQC (no job titles) One representative identified as NHSE (no job title) Apologies were received from the Chief Nurse NHSE North and two others whose job titles were not identified. Concerns about potential risks, quality and patient safety resulted in the information gathering meeting. The main concerns were about safety and use of NCA. Mid Essex CCG were following legal advice and had notified One to One that they would not allow women to self-refer to the service using NCA. One to One was operating in Mid Essex and North East Essex (NEE). There was awareness of activity in West and South Essex, but this was not confirmed. One to One had contacted Monitor for advice about contract procurement and notice periods. Previous advice from Monitor stated that: • CQC registration was required; • staff should be appropriately qualified; • the terms of the NHS Standard Contract would apply; • One to One should be willing to be paid on PbR at tariff with no guaranteed activity levels; and • arrangements should be in place to integrate with local maternity services. The meeting received feedback from the NHSE Risk Summits in the North. Concerns remained about high risk women and home births. It was reported that there had been 21 SIs in the North (including eight baby deaths). It was reported that there were contracts in place with Wirral, Liverpool, Halton and West Cheshire CCGs. South Cheshire and Leeds CCGs had recently terminated activity in their area; they had been advised to release withheld NCA payments to One to One. The Chief Nurse NHSE North had been working with One to One and would be able to provide additional information. The meeting received feedback from the two Essex CCGs where it was confirmed One to One was operating. Mid Essex CCG reported that there was no service level agreement (SLA) between their local NHS Trust and One to One. The Trust were in dispute with One to One about sharing of the pathway payment. There were no shared records between the two and poor handovers when escalation required. Women who required a consultant appointment were being seen at the local hospital by a consultant who also worked for One to One at weekends. 21 incidents were being reviewed by the Trust - six or seven potential SIs. One to One staffing was not up to establishment, there were three midwives in post. Staff had left One to One and this had resulted in patients being referred to the Trust. Midwives were inexperienced. Mid Essex CCG wanted to suspend One to One's services due to quality and safety concerns. North East Essex CCG reported that an SLA was in place with the local acute Trust and Anglian Community Enterprise (a provider of community services), with agreed pathways. There were concerns about staffing, safeguarding and the supervision of midwives. The service had improved since receiving support from the local NHS provider.

<table>
<tr><td></td><td>The LSA was concerned about staff turnover. From May 2015 to date, there had been six incidents against which LSA Decision Making Tool had been applied. Two full investigations were completed (a baby died in both incidents). The LSA advised that given One to One's small caseloads, six cases appeared to be high. A consistent theme was inexperienced midwives not calling for help.

The CQC advised that One to One was registered at Abbeyfields Medical Centre. The CQC was unaware of any SIs reported which was a regulatory requirement. The CQC was to investigate this further.

Actions

NHSE Midlands and East were to share SIs with the CQC.

One to One were to be treated on an equal footing with NHS providers.

NHSE North was to share the Quality Risk Profile Tool and the outcomes from the Risk Summit action plan.

Mid Essex CCG was to meet with One to One and their local NHS Trust to put in place pathways for low risk women. If this was not possible, the service would be suspended.

Obstetric cover with local providers should be provided via an SLA.

The Deputy Director of Nursing for NHSE Midlands and East was to check service availability was equitable across the East region.

The CQC was to complete an inspection.</td></tr>
<tr><td>Confidential summary

3 February 2016</td><td>Summary of One to One incidents - November 2013 to December 2015 (Essex)

<table><tr><td>Maternity/obstetric incident meeting SI criteria: mother and baby</td><td>6</td></tr><tr><td>Maternity incident</td><td>3</td></tr><tr><td>Maternity Services - Unexpected admission to neonatal intensive care unit</td><td>7</td></tr><tr><td>Maternity Services - Unexpected neonatal death</td><td>1</td></tr><tr><td>Maternity service</td><td>1</td></tr><tr><td>Intrauterine death</td><td>2</td></tr><tr><td>Other</td><td>1</td></tr><tr><td>13 babies alive
8 deaths (intrauterine and neo-natal)</td><td>21</td></tr></table>
This was prepared to support the next Information Gathering Meeting.</td></tr>
<tr><td>Information gathering meeting

1 March 2016</td><td>Chaired by the Deputy Director of Nursing, NHSE Midlands and East
Attendees:
Director of Nursing & Quality, Mid Essex CCG
Director of Nursing & Quality, West Essex CCG
West Essex Contract lead and Children's commissioner
Director of Nursing & Clinical Quality, North East Essex CCG

This meeting discussed contracts and incidents; the key points of discussion are listed below for each CCG.

North East Essex</td></tr>
</table>

	• The pathway agreement with the local Trust; there was no subcontracting agreement in place. • NCA activity. • Quality monitoring agreements were not in place; the local NHS Trust was not responsible for One to One's quality. • No incidents had been reported. • The CCG was working with One to One's new operations manager. Mid Essex • Progress very slow on pathway agreements; the local NHS Trust would not agree to any form of contract. • One to One was concerned about being restricted to low risk women and negotiations were ongoing. • A potential SI was identified. One to One were reluctant to investigate at this point as they were preparing for a CQC visit. There was no evidence that the incident had been reported. West Essex • Only 5 women had chosen to use the service. There was no agreement with the local acute hospital. • Risk findings had been shared with the CCG. • No incidents had been reported.
Information gathering meeting 15 March 2016	There is a reference to this meeting in the minutes for the meeting held on 30 March 2016 however no minutes were provided for our review.
Information gathering meeting 30 March 2016	Chaired by the Deputy Director of Nursing, NHSE Midlands and East Attendees: A representative for the Director of Nursing NHSE North A representative for NHS England Midlands and East Acting Director of Nursing Mid Essex CCG Two representatives from Mid Essex CCG. Director of Nursing and Quality, West Essex CCG. West Essex Contract lead and Children's Commissioner. Two representatives from the CQC. Apologies received from the Director of Nursing NHSE North and the Director of Nursing and Clinical Quality North East Essex CCG *CQC update* The North and East CQC inspection reports were to be shared with the national team for consideration as a single organisation. A management review meeting was to be held the following week to determine actions. The CQC is required to share any details of enforcement action with NHSE who will share with the CCGs. *Update from NHSE North* High risk work undertaken by One to One under the contract was to be ceased. One to One was dealing with a Regulation 28[30] letter due to poor records at point of transfer. *Update North East Essex CCG* The plan was to continue engaging with One to One under NCA and the SLA in place with CHUFT. The Director of Nursing for NHSE Midlands and East requested this to be

[30] Paragraph 7 of Schedule 5, Coroners and Justice Act 2009, provides coroners with the duty to make reports to a person, organisation, local authority or government department or agency where the coroner believes that action should be taken to prevent future deaths.

	put in writing. Once confirmed this would be shared with Mid and West Essex CCGs. Incidents were being logged by the local NHS provider *Update Mid Essex CCG* The pathway SLA was being reviewed. A contract was required to be signed by 16 April 2016 or the CCG would not allow any further bookings and NCA would cease. High risk patients were being transferred to local providers. One to One were disputing that obstetric cover must be close to the area of booking. Incidents were being reviewed and discussed by the CCG and One to One. None were recorded as serious incidents. *Update West Essex CCG* The local NHS provider did not want an SLA with One to One. Activity would be discontinued. Seven incidents relating to transfer without appropriate records had been reported. *Actions* A joint CCG meeting was planned for 6 April 2016. Mid Essex CCG was to provide commissioning intentions in writing and NHSE was to share this with the other CCGs. The CQC was to share enforcement plans with the CCGs.
NHSE Midlands and East meeting 11 April 2016	Chaired by the Director of Nursing, NHSE Midlands and East Attendees: Deputy Director of Nursing, NHSE Midlands and East Accountable Officer, North East Essex CCG Director of Nursing and Quality, North East Essex CCG Contract manager, North East Essex CCG Unidentified member of staff from North East Essex CCG The Director of Nursing for NHSE Midlands and East shared legal advice obtained regarding contracting. One to One was known to the legal team because CCGs had previously sought advice about the legal right to 'choice' in maternity services. The advice given was: • Choice was being met because acute providers offered home births, midwife led, and consultant led care. There was no need to commission an alternative. • CCGs can only commission using an NHS Standard contract. There was an implied contract if women were self-referring to One to One and the CCG was paying for these services. • NCA was for exceptional circumstances only and was high risk without a service specification as the CCG had no control over what the provider was doing. This was described as *"grossly irresponsible."* • Indemnity insurance - if One to One was not covered this would fall to the CCG and their CNST cover in the event of harm. There was a risk of reputational damage to the CCG. • There was a risk of not meeting the legal obligation of Duty of Care by continuing to use NCA particularly as the CCGs were aware of the CQC inspection outcomes and number of incidents. Ideally the CQC needed to take enforcement action. • The alternative was to cease the activity and not pay because One to One was not a commissioned service. • It was also noted that an SLA was not a valid legal instrument between an NHS Trust and a private provider. *NEE CCG update* NEE CCG were considering an Any Qualified Provider procurement process. NCA was based on the Wirral contract, with the Wirral service specification. One to One had informed the CCG that the CQC had withdrawn its concerns.

	One to One had advised that they had CNST insurance cover. The CCG had concerns about the quality of maternity care at CHUFT. An assurance paper was to go to the relevant CCG committee in May 2016. 52 incidents had been logged in NEE. (It was unclear if these were reported by One to One, Colchester Hospital University NHSFT (CHUFT) or if these included all maternity incidents). The information was to be shared with the LSA for their decision tool approach. Actions - NHSE Midlands and East was to receive the assurance paper and service specification. Confirmation was requested that a signed contract was in place in the North and that appropriate insurance was in place.
Information gathering meeting 12 April 2016	Chaired by the Director of Nursing, NHSE Midlands and East Attendees: Two unnamed representatives from the CQC Deputy Director of Nursing, NHSE East Assistant Chief Operating Officer, NHSE North Unnamed member of staff from NHSE Midlands and East Acting Director of Nursing, Mid Essex CCG Two unnamed representatives from Mid Essex CCG Director of Nursing and Quality, West Essex CCG Contract lead and Children's Commissioner, West Essex CCG Apologies were received from the Director of Nursing and Clinical Quality, North East Essex CCG *CQC update* The CQC met with One to One on 30 March 2016. One to One had informed North East Essex and West Essex CCGs that there were no warnings or concerns. An internal CQC meeting was to be held the following week to consider further information and decide actions. Inspection reports from the North and East were to be shared with the national team on 29 April to provide an organisation view. One to One stated that they had not been able to share the information requested by the CQC as they did not have an NHS.net email account. The Director of Nursing for West Essex CCG advised that One to One had been sharing information with them about incidents from an NHS.net account and would share the details. *North update* The meeting was advised of potential insolvency issues and other quality issues. *North East Essex update* The CCG had received legal advice about NCA which highlighted concerns about the lack of a local specification and insurance. An assurance paper had been taken to their Board (it was unclear which Board this was referring to). Assurance was to be provided about the contract in the North West with One to One. A risk was that in the North West, they were intending to contract for low risk activity only. It was confirmed that the incidents previously identified were logged by CHUFT. *Mid Essex update* The CCG had been informed by One to One that they would be ceasing to operate in this area. The CCG were reviewing the pathway for women who remained under the service. High risk patients were being transferred to the acute Trust. Incidents were reviewed by an independent midwife and discussed by the CCG and One to One. None had been logged as SIs at this point. The incidents were to be shared with the LSA officer. *West Essex update*

	The acute Trust did not want to continue activity with One to One. Care was agreed for five current patients and then the service would be discontinued. Seven incidents related to transfers without appropriate records.
Information gathering meeting 26 April 2016	Chaired by the Director of Nursing, NHSE South Attendees: Representative from the CQC Deputy Director of Nursing, NHSE Midlands and East Representative from NHSE Midlands and East Director of Nursing & Clinical Quality, North East Essex CCG Two representatives from Mid Essex CCG (job titles not given) Director of Nursing & Quality, West Essex CCG. Contract lead and Children's Commissioner, West Essex CCG The CQC were planning a meeting with One to One in London. There was an issue with record keeping (hand held records not reflecting electronic records). North East Essex – the caseload was 178 under NCA based on the Wirral contract. Mid Essex – the caseload was 76 and still included women of a high risk profile. West Essex - the service was to be discontinued. NHSE Midlands and East had requested confirmation of the contract and specification that NCA was linked to and evidence of indemnity insurance. *Actions* NEE and West Essex CCGs were to share the Wirral contract and copy of One to One's CNST insurance cover. NEE CCG were to share their assurance paper. CQC enforcement action plans were to be shared with CCGs by the Directors of Commissioning Operations. The transfer of high risk women to NHS obstetric care was to continue in Mid Essex. An SLA was to be put in place for low risk women to complete their pathway. The CCG was to deal with an associated complaint from One to One. West Essex CCG were to include NEE CCG in any discussions about incidents.
Quality Surveillance Group (QSG) Report 23 May 2018	This was a one page summary report to the Essex Quality Surveillance Group meeting setting out the reasons for raising the QSG: • There had been significant concerns about quality of antenatal and newborn screening services. • Performance metrics had not been validated raising concerns about the monitoring of women under One to One's care. • The management team was now based in the North and there had been poor attendance at the local transformation programme Board. • Pathways were not clear when women were referred to CHUFT. • Following the screening visit to services in the North, timescales for high priority actions in the action plan had been breached. • Concerns raised in 2015 and the cessation of services by Mid and West Essex CCGs due to pathway concerns. Consideration was to be given as to whether the One to One service should continue to be offered in NEE.

Appendix 8 – Summary of CQC inspections

Inspection Details	Details and findings
1. Birkenhead Medical Building Date of inspection: 28 September and 1 October 2012 Report date: October 2012	Unannounced inspection after information had been sent to the CQC by other organisations. The report found that all standards had been met.
2. Birkenhead Medical Building Date of inspection: 9 October 2013 Report date: November 2013	Unannounced inspection following concerns raised by a local NHS provider. The report found all standards had been met.
3. Carlisle Business Centre, Bradford Date of inspection: 17 December 2013 Report date: January 2014	Unannounced inspection. The CQC had received information of concern from a local NHS provider about the care and treatment being provided to women. The report found all standards had been met but noted that One to One should consider the impact on the local acute Trust of booking women with them during their third trimester because there was the potential for the local Trust to have to manage emergencies with women not booked with them. There was a CNST requirement for women to book in their first trimester.
4. Bidston and St James Children's Centre, Birkenhead Date of inspection: 27 June 2014 Report date: September 2014	An unannounced inspection in response to concerns from local NHS providers, about care provided to women and quality checking systems. The report concluded that One to One did not meet the required standard for 'assessing and monitoring of service provision', Regulation 12, Health and Social Care Act 2008 (Regulated Activities) Regulations 2010[31]. The inspectors reached this conclusion due to the following factors: • An over reliance on electronic communication as a method of sharing learning. • No systematic approach to the management of safety alerts. • Poor management of audits. There were several planned audits overdue, and it was difficult to see how the learning from audits was shared. There was no methodology for some audits, e.g., against what standards a case note audit was performed. • The complaints procedure contained inaccurate information and complaints were not being responded to within the required timescales. • Action from a self-assessment against the Essential Standards for Quality and Safety to review the Serious Incident Policy by June 2014, had not been completed although it was in progress. • Governance arrangements were in place, but attendance at the Audit Group, Clinical Governance Forum and Practice Points Development Group were described as poor and the minutes of the meeting lacked the detail needed to disseminate information across the wider organisation. • RCA investigations were completed into incidents, but they did not consider possible contributory care and service delivery factors. The inspectors

[31] Regulation 12: Safe care and treatment | Care Quality Commission (cqc.org.uk)

	concluded that the investigations were limited and did not explore the cause of the incident. • A gap in processes for monitoring NICE compliance. One to One advised that they used 'practice points' based on NICE guidance, and that all midwives had access to these as well as NICE and Royal College guidance. • A lack of robust documentation, records of decision making and investigation of clinical incidents. • The risk register did not clearly articulate all risks in terms of condition, cause and consequence, and completion dates were identified as 'as soon as possible' or ongoing. One to One were required to provide the CQC with a report addressing these concerns by 2 October 2014. They were to notify the CQC when compliance actions were complete and the CQC were to check that action had been taken to meet the standards and report on their judgements.
5. Bidston and St James Children's Centre, Birkenhead Date of inspection: 13 Apr 2015 Report date: October 2015	This was an unannounced, focused inspection due to concerns raised by local NHS providers about the care provided by One to One. It noted that One to One had shown some improvement in governance since June 2014 but there was insufficient assurance that the organisation provided a safe environment for mothers and unborn babies. One to One were found to be in breach of Regulation 12, Safe Care and Treatment[32]. Procedures for medicines management did not always protect patients from risks. One to One were required to submit a report to the CQC about what actions it would take to meet the requirements. The inspection found: • Woman always had access to support in a timely. • One to One was managing risks appropriately and safely in line with their statement of purpose. • There were joint pathways in place with the local acute Trusts. • There were gaps in processes and policies to ensure the safe management, storage and use of medicines. • Risk assessments for women were not always carried out in a timely manner. • Due to lack of comparable data, it was not possible determine if the staffing establishment was sufficient for the number of women under their care. • The model of working was not sustainable, based on comments from the midwives interviewed. • One to One was acting outside the 'accepted view of midwifery practice' regarding Cartography. The report identified five 'must do' actions: • Ensure that there was an appropriate Home Office license for the provision of Schedule 2 Controlled Drugs. • Put processes and policies in place to ensure the safe use of medicines in the service. • Review practices to ensure midwives were working within the widest acceptable view of midwifery practice such as in the use of Cartography. • Take steps to ensure that a robust system is in place for good governance.

[32] Regulation 12: Safe care and treatment | Care Quality Commission (cqc.org.uk)

	• Ensure risks are clearly identified and they are managed effectively and safely. In addition, the report identified three 'should do' actions: • Review access to a second midwife. • Work closely with partners such as the LSAMO regarding the number of supervision investigations and practice reviews being triggered. • Ensure that the interface between risk, governance and supervision remains robust and managers lead on feeding back 'lessons learnt' to midwives and staff.
6. Bidston and St James Children's Centre, Birkenhead Date of inspection: 30 November and 1 December 2015 Report date: June 2016	This was an unannounced inspection due to concerns raised and a follow up to the inspection in 2014. Medicines management issues from the previous inspection had been addressed. The CQC were not assured that risk was being managed effectively to provide a safe environment for high risk pregnancies. There was no evidence that midwives had the training to support women with underlying conditions such as epilepsy and diabetes. It was also not clear how One to One managed women who developed complications and refused to seek medical interventions and/or hospital support when the midwives identified it was required. There was no evidence of joint pathways with local providers. One to One was not reporting incidents to the CQC in line with Regulation 18[33] of the CQC (Registration) Regulations 2009. Other risks identified included: • handover of care when the lead midwife was not available; and • how care was agreed with women with complex needs with a risk of a poor outcome, who chose to deviate from NICE guidance. The report identified some 'must do' actions: • Develop robust risk registers, policies, procedures and guidelines for working with women with high-risk pregnancies. • Ensure records provide evidence that expectant mothers have received detailed information about their care and treatment to enable them to give informed consent. • Ensure evidence of informed consent is available. • Ensure all expectant mothers receive care and support from professionals best qualified to provide best practice care and guidance • Use an early warning tool to help identify when a woman's condition is deteriorating when in labour. • Develop and introduce detailed and clear child protection and safeguarding policies which address the different aspects of teenage pregnancies. • Develop and introduce policies and guidelines in relation to female genital mutilation. The 'should do' actions were: • Ensure risk assessments and action plans have review and completion dates. • Develop a comprehensive outcome focused audit and monitoring strategy.

[33] Regulation 18: Notification of other incidents | Care Quality Commission (cqc.org.uk)

	• Develop benchmarks and implement a range of local and national audits, which will measure performance against set targets and drive improvement. • Consider completing audits of electronic and paper records to ensure all required information is readily accessible in both formats. • Consider having multidisciplinary skills and drills training and competency assessment-based learning. • Ensure all concerns and complaints are recorded. • Consider providing specific information about raising complaints and concerns on One to One's website.
7. Abbey Field Medical Centre, Colchester Date of inspection: 29 February 2016 Report date: July 2016	This inspection was completed because of concerns raised with by NHSE Midlands and East. It identified a high number of SIs; the inspector was not assured that One to One was reporting incidents to the CQC in line with the regulations. Local NHS Trusts had reported 74 incidents involving care provided by One to One. There was a lack of risk assessment and onward referral to a service best placed to manage identified risks. Six of the seven risk assessments reviewed lacked detail and it was not clear that best practice guidance had been discussed with women. Record keeping was poor; there was insufficient detail about how women were supported to make choices about their care. There was a lack of formalised emergency care pathways. Arrangements were not in place for the shared care of high risk women, although there were ongoing discussions. This hindered the sharing of information. The report identified the following 'must do' actions: • Ensure that serious untoward incidents are captured, documented, robustly investigated, and where required reported to the CQC under the statutory notification regulations. • Review the risk management practices and supporting documentation to ensure these accurately reflect evidence-based practice and provide unambiguous guidance to staff. • Ensure that women are robustly risk assessed at booking and on each contact and an accurate record is made of risk assessments to determine if One to One can meet or continue to meet their needs. • For women who require referrals to specialist obstetric and or hospital led care, One to One must ensure that timely referrals are made and accurately documented. • Ensure that women have access to obstetric referral within the locality in which they intend to give birth. • Ensure that staff follow evidenced based practice including best practice guidance contained within their own policies and supporting documentation. • Ensure staff make accurate records of information given and discussed with women about risks and benefits associated with a chosen birth option to ensure they have sufficiently detailed information about the risks to enable them to make informed choices and or consent to treatment. • Ensure that there are contracts and SLAs in place between One to One and all commissioners, community, and acute providers in Essex to ensure that women receive appropriate care. • Ensure that all acute hospitals are notified about women in their locality who are booked with One to One.

	'Should do' actions were: • Review of risk management documentation to provide streamlined, clear and up to date guidance for staff on how One to One expects staff to manage risks. • Review the audit processes for the service to ensure that all outcomes to demonstrate safe maternity care are provided. • Look at staff contracts, job descriptions and working hours to ensure these comply with the European Working Time Directive. One to One were also found to be in breach of Regulation 12 HSCA (RA) Regulations 2014 (safe care and treatment)[34] because there had not been appropriate escalation of risk for some women with complex social histories. One to One were also found to be in breach of Regulation 17 HSCA (RA) Regulations 2014 (good governance)[35] because handheld records were not always contemporaneous as electronic records One to One's policies did not always adhere to national guidance on managing high risk, multidisciplinary working was variable and communication with local hospitals was insufficient. Mental health issues were not always addressed in accordance with national guidance. Midwives were identifying risk factors but not always escalating these risk factors in line with One to One's Midwives Mitigating Risks guidance. The CQC was not assured that staff were sufficiently skilled to identify and effectively manage women for whom pregnancy became increasingly high risk or for whom a low risk pregnancy suddenly required obstetric intervention. Governance systems did not always provide consistent information for the senior team. Key performance indicators reported nationally were inconsistent for Essex. Policies and procedures did not always provide clear guidance for staff and did not always reflect the national guidance they referenced. For example, emergency procedures for shoulder dystocia, post-partum haemorrhage and antepartum haemorrhage were not based on national best practice guidance. Staff did not always follow the guidance provided, deviating from best practice and, in some cases, midwives' scope of practice. Improvements were needed to ensure the culture of the service enabled the teams to work well with other stakeholders and commissioners The performance dashboard did not include the reasons for unplanned hospital admissions such as retained placenta, additional pain control, or maternal collapse. Some monitoring was not in line with national best practice requirements. Incidents were not being reported to the CQC as statutory notifications where required.
8. Bidston and St James Children's Centre, Birkenhead Date of inspection: 16 and 17 January 2017 Report date: April 2017	The report does not identify if this was a planned or unplanned inspection. This report identified continuing concerns about poor contemporaneous record keeping, discrepancies between handheld and electronic clinical records, and the lack of postnatal record keeping. There was limited assurance that information would be available to other organisations who did not have access to One to One's electronic notes.

[34] Regulation 12: Safe care and treatment | Care Quality Commission (cqc.org.uk)
[35] Regulation 17: Good governance | Care Quality Commission (cqc.org.uk)

	One to One had not implemented the full 'GROW'[36] package of care since the last inspection in 2015; 60% of midwives had been trained on the approach. Women were not being offered pethidine or opioid based pain relief. Shared care pathways with NHS providers were not in place for high risk pregnancies; inspectors were told eight agreements were in draft. Staff reported mixed relationships with local NHS providers. Not all NICE guidance was followed, e.g., the inclusion list for home births. There were ongoing concerns about the risk register. Nine identified risks were reviewed and had associated action plans, but five were static and had been carried forward from the previous inspection. Retention of midwives had been increased from moderate to high risk, but the action to address this was unchanged. Two of the three newly identified risks did not have an action plans, despite one being identified as high. The inspection identified the following 'must do' actions: • Ensure that all records of completed risk assessments, informed consent and decline of care by women are recorded fully and are clear and easily accessible to other care providers. • Ensure that all national guidelines and inclusion and exclusion criteria pathways are strictly adhered to by staff. • Ensure NICE guidelines are followed for the administration of Syntoncinon for the delivery of the placenta. • All staff to complete all annual mandatory training and receive an annual appraisal. • Undertake formal risk assessments for carrying medical gases in midwives' cars and ensure that cylinders are transported in secure bags. • Complete formal risk assessments for the use of birthing pools. • Keep the risk register fully up to date, including review of static risks and include a named lead for each risk. • All staff to complete the GROW training package and full implementation of the GROW package. 'Should do' actions were: • Ensure that paper handheld notes are accurate, complete and contemporaneous records are kept in relation to care and treatment. • Ensure that all electronic records are printed and made available when women end their pregnancy. • Ensure all postnatal records are accurately documented in women's handheld notes and are easily accessible to other care providers. • Ensure all staff follow the correct cleaning process following the use of a birthing pool. • Ensure all clinical areas are clean and well maintained in order to minimise the risk of infection. • Ensure that the "lead" carer (especially in the case of shared care and a high risk pregnancy) is clearly documented in the front of the handheld notes.

[36] The Gestation Related Optimal Weight (GROW) package is a set of customised charts to improve the antenatal detection of fetal growth problems, to avoid un-necessary investigations and to reduce anxiety by reassuring mothers when growth is normal according to the Perinatal Institute.

	• Continue to develop collaborative working relationships, agree, and sign agreements with local trusts and CCGs. • Continue to develop shared pathways and governance with local NHS Trusts. • Ensure all policies are up to date. • Continue to develop consistency across organisations and especially proportionate responses to incidents. • Improve attendance from senior management at the monthly quality assurance meetings. • Ensure staff are trained in providing care for women with complex obstetric and medical conditions. • Postnatal discharges that are received by telephone from the local trust to be recorded in an official discharge record book • Monitor the competencies of staff such as caring for women using a birthing pool and suturing; provide adequate training and regular updates to ensure staff skills are maintained. • Monitor and review the working hours of midwives attending home births. • Staff to receive appropriate training and understand their individual responsibilities in relation to Duty of Candour. The CQC continued to require One to One to provide assurance about the steps it was taking to comply with the requirements of Regulation 12[37] and Regulation 17[38].
9. Abbey Field Medical Centre, Colchester Date of inspection: 19 January and 6 February 2017 Report date: April 2017	The primary concern raised by this inspection was the lack of a Registered Manager and clinical manager in the location. This heightened concerns raised in the report about lack of meetings with midwives, lone-working arrangements, medicines management, skill mix, lack of infection control audits, record keeping and midwives not using an early warning system such as the Maternal Early Obstetric Warning System (MEOWS). There were also continuing concerns about the risk register. It did not identify who was responsible for each presented risk and action plans had not been updated following risk register reviews. This inspection identified the following 'must do' actions: • Ensure the safety of staff during through 'lone working' arrangements during work time. • Have an up-to-date policy in place for medicines management, in relation to controlled drugs and medicines for the third stage of labour and communicate this information to staff. • Ensure that accurate, complete and contemporaneous records are kept. The records should clearly identify the pathway of risk for women. Postnatal records should be accurately documented and easily assessable to other care providers. • Ensure that staff have regular one-to-one meetings with a line manager. • Ensure that local management and supervision arrangements are reviewed. 'Should do' actions were:

[37] Regulation 12 HSCA (RA) Regulations 2014
Safe care and treatment Regulation 12 (2) (b) Safe Care and Treatment.
[38] Regulation 17 HSCA (RA) Regulations 2014
Good governance Regulation 17 (2) (b) Good Governance

	• Complete a risk assessment for the transportation of Entonox and ensure that midwives are transporting Entonox in line with national safety recommendations. • Complete a risk assessment for staff entering closed and empty buildings and update their policies and procedures accordingly. • All staff to complete their annual mandatory training. • Ensure there are systems in place to monitor cleanliness and hygiene. • Keep the risk register up to date, including review of static risks and include a named lead for each risk. • Implement a MEOWS system. • Complete a needs assessment for the local community to which One to One provides a service. • Make sure that all patient information leaflets contain review dates. • Review the culture of midwives working at the Essex location. • Ensure that all staff are trained in providing care for patients with complex obstetric and medical conditions. • Ensure that staff have knowledge of Fraser[39] competence guidelines.

[39] https://learning.nspcc.org.uk/child-protection-system/gillick-competence-fraser-guidelines

Appendix 9 – List of interviewees

We undertook interviews as part of the review with the individuals listed in the following table. We have listed the job titles provided by interviewees with a reference to current and former roles where these were given.

Job title and organisation
Chief Officer, Wirral CCG and Chair of the Cheshire and Merseyside Women's and Children's Partnership, former Chief Officer of Halton CCG
Director of Nursing, Greater Manchester Health and Social Care Partnership, former Director of Commissioning Operations for Greater Manchester
Clinical Network Programme Manager, North West Coast Strategic Clinical Network
Head of Finance, NHSI Cheshire and Merseyside
Member of the Maternity Voices Partnerships (national and local, Greater Manchester)
Director of Nursing, NHSE Cheshire and Merseyside, former Deputy Chief Nurse for NHSE North, former Director of Commissioning Operations for Cheshire and Merseyside
Head of Performance and Contracts, Warrington CCG
Head of Midwifery, Mid Cheshire Hospitals NHSFT
Programme Manager, Cheshire and Merseyside Women's and Children's Partnership
Assistant Director of Finance, Wirral University Hospital NHSFT
Former Clinical Governance Lead and Head of Midwifery, One to One (North West) Ltd
Regional Chief Midwife North East and Yorkshire, NHSE, former Associate Chief Nurse (Midwifery) at Warrington and Halton Hospitals NHSFT and former Chair of Cheshire and Merseyside Heads of Midwifery
Acting Chief Nurse, Trafford CCG
Former Finance Lead, One to One (North West) Ltd.
Finance Manager, Wirral University Hospital NHSFT
Former midwife, One to One (North West) Ltd.
Chair of the National Maternity Review
Inspector, Merseyside, Cheshire and Warrington Area Team, Care Quality Commission
Financial Planning Accountant, Warrington and Halton Hospitals NHSFT
Director of Finance, Mid Cheshire Hospitals NHSFT, former Director of Finance Wirral PCT
Former Director, One to One Maternity Services Ltd.
Former Commercial Director, One to One (North West) Ltd., former Head of Commissioning for Community Services, Wirral PCT
Interim Head of Midwifery, Countess of Chester Hospital NHSFT
Former midwife, One to One (North West) Ltd.
Former Non-Executive Director, One to One (North West) Ltd.
Former Midwife, One to One (North West) Ltd.
Former midwife, One to One (North West) Ltd. (former patient)
Director of Finance, Liverpool Women's NHSFT
Former MAMA (midwifery assistant), One to One (North West) Ltd (former patient)

Deputy Director of Finance, Liverpool Women's NHSFT
Former Director of Finance, Wirral University Teaching Hospitals NHSFT
Medical Director, Trafford CCG
Chief Nurse, NHSE North
Quality Lead, Trafford CCG
Director of Commissioning, Warrington CCG
Programme Director, Greater Manchester Elective Care Reform Programme, former Director of Commissioning, West Cheshire CCG
Programme Director, Cheshire and Merseyside Women's and Children's Partnership
Head of Safeguarding, Liverpool Women's NHSFT
Associate Director of Business Intelligence, Cheshire CCG, former Head of Contracts and Performance, West Cheshire CCG
Senior Lawyer, Nursing and Midwifery Council
Former Clinical Director, One to One (North West) Ltd.
Former midwife, One to One (North West) Ltd. (former patient)
Assistant Director of Finance, Liverpool University Hospitals NHSFT, former Deputy Director of Finance, Wirral University Hospitals NHSFT
Deputy Director of Nursing, North East Essex CCG
Chief Nurse, NHSE Midlands and East, former Director of Nursing, Colchester Hospital University NHSFT
Clinical Quality Director, NHSE/I North East and Yorkshire
Former Chief Executive Officer, One to One Midwives (North West) Ltd.
Former Chief Executive, Warrington and Halton Hospitals NHSFT
Head of Contracts and former Senior Contracts Officer, Liverpool CCG
Chief Operating Officer, Liverpool Women's NHSFT
Director of Quality and Safety, Wirral CCG, former Head of Locality, Wirral PCT and Head of Performance, Wirral CCG
Governance Lead Warrington and Halton Hospitals NHSFT and former Head of Governance, One to One (North West) Ltd.
Director of Finance and Contracting, Cheshire CCG (formerly South Cheshire and Vale Royal CCGs)
Former Recruitment Lead for One to One (North West) Ltd.
Assistant Director of Provider Policy, NHSE/I, former Senior Manager, Competition Team NHSI/Monitor
Regulation Advisor, Nursing and Midwifery Council
Head of Contracts, North East Essex CCG
Clinical Network Programme Manager, North West Coast Strategic Clinical Network
Head of Hospital Inspection, Care Quality Commission
Deputy Director Personalised Care Group, NHSE, formerly Head of Choice Team
Programme Director, Maternity Transformation Programme

Lead Midwife, Warrington and Halton Hospitals NHSFT and former Lead Midwife, One to One (North West) Ltd.
Director of Commissioning Operations, NHSE Cheshire and Merseyside
Former Director of Quality and Safeguarding, West Cheshire CCG

Appendix 10 – Key information sources

The review has involved of an extensive list of documentation including emails and attachments, meeting papers and minutes, corporate documentation and national publications. Where possible we have provided direct links to these documents in the footnotes to our report. Other references are listed below. This list may not include all documents to which we have referred for the purposes of our work.

Information sources

Changing Childbirth, Department of Health, 1993

Maternity Matters: choice, access and continuity of care in a safe service, Department of Health, 2007

Who Pays? Establishing the Responsible Commissioner, Department of Health, September 2007

Midwifery 2020: Delivering Expectations, Department of Health, September 2010

Community Caseloading Midwifery Service Business Case, One to One, February 2011

NHS Standard Community Services Contract (Multilateral), 2011/12, Wirral Primary Care Trust and One to One (Northwest) Ltd.

Any Qualified Provider: your questions answered, Department of Health, September 2011

Maternity Services Pathway Payment System, A Simple Guide, Department of Health, Royal College of Midwives, Royal College of Obstetricians and Gynaecologists, and Healthcare Financial Management Association, 2012/13

Investigation of Concerns Regarding the One to One Maternity Service, Wirral PCT, November 2012

Quality Review of One to One North West Ltd Report, Trafford CCG, June 2014

Midwifery Led Service Specification - December 2013 – April 2015, Wirral CCG, November 2013

Substantive guidance on the Procurement, Patient Choice and Competition Regulations, Monitor, December 2013

The maternity pathway payment system: Supplementary guidance, Monitor and NHS England, August 2014

NHS Standard Contract 2014/15, Wirral CCG and One to One

2015/16 National Tariff Payment System: A consultation notice, Monitor and NHS England, November 2014

One to One Desk Top Review Report, NHS England, February 2015

NHS Standard Contract 2015/16, West Cheshire CCG and One to One (North West) Ltd.

Service Specification, Alternative Provider of Maternity Services – caseloading model, 1 September 2015 to 31 August 2018, West Cheshire CCG

NHS Standard Contract and service specification, Wirral CCG/co-commissioners and One to One North West Ltd, 2016/17

Risk register extract, Wirral CCG, August 2016

One to One contract financial analysis 2013/14 to 2019/20, Wirral CCG, July 2021

Service Specification, Case Loading Community Midwifery led service, 1 June 2016 – 31 March 2019, Wirral CCG

Service Specification, Alternative Provider of Maternity Services – caseloading model, West Cheshire CCG, December 2016

Report to the Operational Executive Committee, North East Essex CCG, August 2017 (draft paper)

Contract Management Policy, Wirral CCG, 2017-19

Due Diligence One to One (North West) Ltd, Mid Cheshire Hospitals NHSFT, May 2017

Proposal for Minimum Guaranteed Activity, One to One, September 2017

One to One Midwives Report, NHSI, draft, undated (produced in October 2017)

Commissioning Decisions Policy and Procedure, Wirral Health and Care Commissioning, June 2018

Financial Viability Review: One to One (North West) Ltd, Mersey Internal Audit Agency, October 2018

Briefing Note: One to One Midwifery, NHSE Cheshire and Merseyside, November 2018

2020/21 National Tariff Payment System, NHS England and NHS Improvement

2020/21 National Tariff Payment System – Guidance on blended payments, NHS England and NHS Improvement

2020/21 National Tariff Payment System – a consultation notice, Guidance on the maternity pathway payment, NHSE and NHSI, December 2019

National Tariff Payment System: non-mandatory currencies and prices, NHSE/I, 2019/20

One to One Debrief, NHS England (Cheshire and Merseyside), 2019

Service Specification, Community Midwifery led service, Wirral CCG, 1 April 2020 – 31 March 2021

Emails and papers provided by the Chief Officer of Wirral CCG relating to One to One

Emails and papers provided by the former management team of One to One

Emails and papers provided by CCGs in Cheshire and Merseyside and North East Essex

Emails and papers provided by NHS Trusts in Cheshire and Merseyside and North East Essex

Contract management meeting papers for Wirral PCT/CCG led contracts

Contract management meeting papers for West Cheshire CCG contracts

Contract management meeting papers for North East Essex CCG, 6 May 2016 to 19 March 2019.

Quality surveillance and risk summit papers for NHSE North, 28 July 2014 to 15 April 2016.

Information Gathering Meeting minutes for NHSE Midlands and East, 8 February 2016 to 26 April 2016.

Maternity performance dashboards for Wirral CCG and West Cheshire CCG contracts 2012/13 to 2018/19

Quality Accounts, One to One, 2011/12 to 2017/18

Quality Reports, One to One, 2017/18 and 2018/19

Factsheets, Trust and Health Authority Claims Data, NHS Litigation Authority, 2015-2019

Cheshire and Merseyside Screening and Immunisation Programmes: Key Performance Indicators Reports, NHS England (Public Health), October 2017, October 2018 and October 2019

Serious Incident details (137 records) for the period from 2013 to 2019, provided by Cheshire and Merseyside CCGs.

Clinical case notes (42 sets) over the period from 2015 to 2019, provided by Wirral University Teaching Hospital NHSFT.

Appendix 11 – Terms of reference

Terms of Reference for Independent Investigations in accordance with Appendix 3 of NHS England's Serious Incident Framework 2015

The following Terms of Reference 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 Liverpool, have been produced by NHS England and Improvement in consultation and with the agreement of Wirral Clinical Commissioning Group.

These Terms of Reference have been developed in collaboration with the investigative supplier, key stakeholders and identified affected patients/families.

Purpose of the investigation/commission

To commission an independent investigation with recognised subject matter expertise to; examine the design, procurement and operation of the One to One Midwives contract, (from inception to the last contract award July 2019) to review the clinical outcomes delivered under the contract and to scrutinise and assess the events that led to the contract termination by One to One Midwives and the cessation of the service.

Involvement of the affected patients/ family members

- Ensure that identified women and families affected by the closure of the service are; fully informed of the investigation, the investigative process and understand how they can contribute to the process.
- Engage with appropriate Stakeholders, and NHS Partners such as the national Maternity Transformation Programme, the Clinical Network Reducing Stillbirth Group, Maternity Voices and accessible representatives of One to One Midwives.

Initial Investigation key lines of enquiry

1. Consider the longer-term viability and sustainability of the service taking into account the strategic influence of national drivers, policy and initiatives at the time of initiation.
2. Identify any areas of best practice and determine any opportunities for learning to influence future service design.
3. Determine the level of horizon scanning, comparison with other similar service models and efficacy of due diligence checks undertaken prior to contract award.
4. Review the available data and determine the rates, in relation to the reporting of deaths and poor outcomes for mothers and babies following, or as a result of care by One to One Midwives (including women who initially booked with One to One Midwives, and or received antenatal care but who subsequently did not receive all of their intrapartum care from the service).
5. Consider the nature, level and type of incident reporting by One to One Midwives, cross-referencing with serious incident data recorded by other Providers relating to the transfer of patients from the service.
6. Determine the effectiveness of incident reporting oversight and monitoring by the CCG, commenting on gaps in information exchange and escalations.
7. Consider the quality of informed advice provided to women booking with One to One Midwives and review the arrangements for obstetric advice.
8. In the absence of CQC regulatory oversight, determine the nature of safety and quality concerns and comment on required indicators of quality and how this was monitored by the CCG.

9. Consider and critically analyse the sequence of events which led to contract's termination, including accountability and risk management factors in doing so, identify any gaps, deficiencies or omissions in the service specification.
10. Identify any issues in respect of; capacity or resources (including external provision and Provider relationships) that impacted on One to One Midwives' ability to provide the contracted services.
11. Consider the relationship with NHS Providers to determine whether this affected the care delivered by One to One Midwives.
12. Determine the level of expert input into the design and procurement of the service.
13. Consider the commercial and relevant clinical expertise in designing the contractual terms and service requirements, including how patient experience was captured and reflected in the contract.
14. Consider the level and appropriateness of commercial expertise available to interrogate and test the business model offered by One to One Midwives.
15. Determine the effectiveness of the CCG's performance measurement framework, assessing against recognised models such as NAO Performance measurement: Good practice criteria and maturity model.
16. Consider and determine the effectiveness of oversight arrangements of the contract, and any assessment of whether the anticipated benefits would merit continued support of the innovative approach to service provision.
17. Consider the level and quality of data submission by One to One Midwives to SCN database for transparency and variation.
18. Consider any presenting risk in the system and identify how this was escalated and acted upon by CCG and NHS England.
19. Consider emerging clinical and cumulative financial risks presenting during the contract term.
20. Determine the scale of remedial cost to the CCG on cessation of the service taking into account contract variations.
21. Consider if there were effective and appropriate arrangements in place for the escalation of concerns (clinical and financial risk).
22. Assess whether the actions carried out in response to concerns being raised were appropriate and correct.
23. Determine whether complexity of need and available expertise and resource impacted on service delivery and costs.
24. Consider the staffing profile of midwives employed by One to One Midwives, determine whether the skills and expertise to work under the model was sufficient to provide safe and effective care.
25. Determine and test the robustness of overall governance, review and assurance processes of the Commissioner in relation to One to One Midwives.
26. Make recommendations on the lessons to be learned for NHS England and NHS Improvement and the wider NHS to secure the delivery of high-quality maternity care.

Deliverables

- Provide a final written and publishable report to; NHS England and NHS Improvement as soon as practicable given the scope of the investigation and completion of required governance processes.

- Based on investigative findings and identified lessons, make system specific outcome focused recommendations to inform future commissioning arrangements, service design and oversight.
- Deliver an action planning event for key Stakeholders to share the report's findings and to provide an opportunity to explore and fully understand the intention behind all recommendations.
- Support the commissioners (where required) in developing a structured plan for review of implementation of recommendations. This should be a proposal for measurable change and be comprehensible to those with a legitimate interest.

Appendix 12 – Delivery of the terms of reference

The following table maps relevant sections of our report to the key lines of enquiry required by the terms of reference.

Requirement	Report reference
1. Consider the longer-term viability and sustainability of the service taking into account the strategic influence of national drivers, policy and initiatives at the time of initiation.	Sections 8 and 15
2. Identify any areas of best practice and determine any opportunities for learning to influence future service design.	Learning points referenced in all sections
3. Determine the level of horizon scanning, comparison with other similar service models and efficacy of due diligence checks undertaken prior to contract award.	Section 12
4. Review the available data and determine the rates, in relation to the reporting of deaths and poor outcomes for mothers and babies following, or as a result of care by One to One Midwives (including women who initially booked with One to One Midwives, and or received antenatal care but who subsequently did not receive all of their intrapartum care from the service).	Section 17
5. Consider the nature, level and type of incident reporting by One to One Midwives, cross-referencing with serious incident data recorded by other Providers relating to the transfer of patients from the service.	Section 7
6. Determine the effectiveness of incident reporting oversight and monitoring by the CCG, commenting on gaps in information exchange and escalations.	Section 7
7. Consider the quality of informed advice provided to women booking with One to One Midwives and review the arrangements for obstetric advice.	Sections 5, 6 and Appendix 3
8. In the absence of CQC regulatory oversight, determine the nature of safety and quality concerns and comment on required indicators of quality and how this was monitored by the CCG.	Sections 6, 7 and 13
9. Consider and critically analyse the sequence of events which led to contract's termination, including accountability and risk management factors in doing so, identify any gaps, deficiencies or omissions in the service specification.	Sections 4, 9, 10, 11 and 13
10. Identify any issues in respect of; capacity or resources (including external provision and Provider relationships) that impacted on One to One Midwives' ability to provide the contracted services.	Section 6, 15, 16
11. Consider the relationship with NHS Providers to determine whether this affected the care delivered by One to One Midwives.	Sections 5, 16
12. Determine the level of expert input into the design and procurement of the service.	Sections 9, 10 and 11
13. Consider the commercial and relevant clinical expertise in designing the contractual terms and service requirements, including how patient experience was captured and reflected in the contract.	Section 11
14. Consider the level and appropriateness of commercial expertise available to interrogate and test the business model offered by One to One Midwives.	Sections 12 and 15

15. Determine the effectiveness of the CCG's performance measurement framework, assessing against recognised models such as NAO Performance measurement: Good practice criteria and maturity model.	Section 13
16. Consider and determine the effectiveness of oversight arrangements of the contract, and any assessment of whether the anticipated benefits would merit continued support of the innovative approach to service provision.	Sections 6, 13 and 17
17. Consider the level and quality of data submission by One to One Midwives to SCN database for transparency and variation.	Section 17
18. Consider any presenting risk in the system and identify how this was escalated and acted upon by CCG and NHS England.	Sections 13, 14 and 17
19. Consider emerging clinical and cumulative financial risks presenting during the contract term.	Sections 6, 13 and 14
20. Determine the scale of remedial cost to the CCG on cessation of the service taking into account contract variations.	Section 18
21. Consider if there were effective and appropriate arrangements in place for the escalation of concerns (clinical and financial risk).	Sections 13 and 17
22. Assess whether the actions carried out in response to concerns being raised were appropriate and correct.	Sections 13 and 17
23. Determine whether complexity of need and available expertise and resource impacted on service delivery and costs.	Section 6 and 15
24. Consider the staffing profile of midwives employed by One to One Midwives, determine whether the skills and expertise to work under the model was sufficient to provide safe and effective care.	Section 6
25. Determine and test the robustness of overall governance, review and assurance processes of the Commissioner in relation to One to One Midwives.	Sections 6, 7, 13 and 17
26. Make recommendations on the lessons to be learned for NHS England and NHS Improvement and the wider NHS to secure the delivery of high-quality maternity care.	Learning points referenced in all sections

insight
integrity
impact

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