The Integrated Support and Assurance Process (ISAP): guidance on assuring novel and complex contracts

Part A: Introduction

Published by NHS England and NHS Improvement

August 2017

First published: **Friday 5 November 2016**

Revised version published: **Wednesday 16 August 2017**

Prepared by: **NHS England and NHS Improvement**

This document is for: Commissioners, NHS trusts, NHS foundation trusts and independent providers.

Publication Gateway Reference: **07096**

The current version of the document will always be made available on the NHS England website.

Version 2.0

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact **0300 311 22 33** or email **england.contactus@nhs.net.**

Contents

1. Introduction

1.1. Overview

Local health communities are developing new care models to better integrate primary and specialist care, physical and mental health services, and health and social care. *The NHS Five Year Forward View* set this ambition in 2014, and *Next Steps on the Five Year Forward View* reiterated it in March 2017. NHS England and NHS Improvement recognise that the contractual arrangements through which some new care models will be implemented may mean:

- The contract structure, form, content or the calculation of the financial value of the contract envelope are 'novel';
- The bidder's organisational forms may be complex, as providers form legal entities and arrangements that allow for greater collaboration between partners; and
- A single procurement for a new care model can significantly affect incumbent NHS providers.

Recent reviews of the collapse of NHS Cambridgeshire and Peterborough Clinical Commissioning Group's contract with UnitingCare Partnership in December 2015[1] found that parts of the system worked in silos, while commissioners, providers and regulatory bodies did not have a full shared understanding of the contract risks. Clinical commissioning groups (CCGs), participating providers and their respective governing bodies and boards should ensure they are familiar with these reviews' recommendations before embarking on novel and complex contract structures (called 'complex contracts' in this guidance). This process identified seven key lessons, and four questions that need to be answered.

Seven lessons:

1. The service design needs to be right from the outset;
2. Cost information that legacy providers share with commissioners must be transparent;

[1] *NHS England Review Of Uniting Care Contract* (April 2016) at https://www.england.nhs.uk/mids-east/wp-content/uploads/sites/7/2016/04/uniting-care-mar16.pdf
Uniting Care Partnership (UCP) Procurement Review (23 September 2016) at https://www.england.nhs.uk/mids-east/wp-content/uploads/sites/7/2016/09/ucp-proc-review-report.pdf
The Public Accounts Committee report on *Uniting Care Contract (November 2016) at* https://www.parliament.uk/business/committees/committees-a-z/commons-select/public-accounts-committee/news-parliament-2015/unitingcare-partnership-contract-report-published-16-17/

3. Commercial skills and awareness will be needed;

4. Commissioners need to be clear on the role of external advisors and ensure that sufficient expertise is provided. The advice from different external advisers needs to be corroborated and the proposal should be consistent with the advice given;

5. Appropriate terms should be agreed at the start of the procurement process;

6. Contract award and/or commencement of service delivery should be delayed if issues are unresolved; and

7. NHS Improvement and NHS England should scrutinise the arrangements for these complex contracts through an integrated process.

Key questions:

- Will the service model produce net benefits?
- Are the provider and commissioner capable of managing the contract and the risk allocated to them?
- Have the consequences for other providers been thought through?
- Does the proposed service model merit considering adjustments to the regulatory approach, including the approach to failure?

NHS England and NHS Improvement established a group in August 2016 to design a consistent, streamlined process for supporting and assuring procurements for complex contracts. This group designed the Integrated Support and Assurance Process (ISAP) described in this document.

NHS England and NHS Improvement want to support commissioners and providers to identify, understand and manage the risks in developing such contracts[2]. The ISAP provides a co-ordinated approach to reviewing the procurement and transactions related to complex contracts. It will enable all parties to learn from previous successes and failures and implement best practice.

The ISAP has two purposes: to support the work of local commissioners and providers in creating successful and safe schemes, and to provide a means of assurance that this has happened. It depends on:

[2] References to procurement in this document refer to the process for selecting an appropriate newly contracted delivery model and the provider to be involved, whether that entails a competitive bidding process or not.

- Competent local executives designing complex contracts and arrangements, along with providers successfully implementing services under those arrangements;
- Well-informed commissioner governing bodies and provider boards holding them to account and shaping the solution; and
- An integrated process carried out by NHS England and NHS Improvement providing final assurance that the complex contract arrangements have been robustly constructed according to defined good practice.

This document reflects our current guidance. The ISAP has been built on existing processes – for example, NHS Improvement's approach to reviewing transactions for NHS foundation trusts[3] – and will continue to be refined.

1.2. Purpose of the document

This document describes the integrated NHS England and NHS Improvement process for supporting commissioners and providers looking to procure and bid for complex contracts. It replaces the introductory document published in November 2016.

The document contains guidance for engaging with the ISAP and provides detail on the submissions and evidence expected from commissioners and providers at each stage in the process. The process and requirements are likely to continue to evolve as the ISAP is developed.

This guidance has three parts:

1. **Part A**: Introduction to the ISAP for commissioners and providers looking to procure, or bid for, a complex contract;
2. **Part B:** The questions that will be asked and the submissions from commissioners expected at each stage of the ISAP; and
3. **Part C:** Guidance for NHS trusts and foundation trusts looking to bid for a complex contract. This may also help independent providers bidding for such contracts.

[3] *Supporting NHS providers: guidance on transactions for NHS foundation trusts,* updated March 2015 at www.gov.uk/government/publications/supporting-nhs-providers-considering-transactions-and-mergers

2. ISAP's objectives

The ISAP refers to a set of activities that begin when a CCG or a commissioning function of NHS England (collectively referred to as commissioners) starts to develop a strategy involving the procurement of a complex contract. It also covers the subsequent contract award and mobilisation of services under the contract. The intention is that NHS England and NHS Improvement provide a 'system view' of the proposals, focusing on what is required to support the successful delivery of complex contracts. Applying the ISAP will help mitigate but not eliminate the risk that is inevitable if a complex contract is to be utilised. It is not about creating barriers to implementation.

Within the ISAP, NHS England and NHS Improvement will be responsible for the activities consistent with their respective functions, and will collaborate on the ISAP activities performed by each other.

ISAP's objectives are to:

- Ensure the proposals represent a good solution in the interests of patients and the public;
- Take a system view of the potential consequences of the contract award;
- Enable the risks of the complex contract to be identified, understood and mitigated as far as possible; and
- Improve efficiency and reduce duplication in the work of NHS England and NHS Improvement, increasing the speed of the national assurance for complex contracts.

3. Applying ISAP

3.1. Alignment with existing processes

The ISAP draws on, among other things, lessons learned from the failure of the contract with UnitingCare Partnership in 2015. It is aligned with:

- NHS England's processes, including those for major service redesign and the CCG Improvement and Assessment Framework[4]; and

[4] *CCG improvement and assessment framework 2016/17* (31 March 2016) is available at: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/03/ccg-iaf-mar16.pdf

- NHS Improvement's processes for evaluating the risk impact of transactions. NHS Improvement is not implementing a new process, and therefore will apply the thresholds in its existing guidance on transactions.

NHS Improvement's transaction guidance currently applies only to NHS foundation trusts. In line with the Single Oversight Framework,[5] which says foundation trusts and NHS trusts will be treated similarly unless there is sound reason not to, NHS trusts will also be subject to NHS Improvement's transaction review process. If a transaction review is required for NHS foundation trusts or NHS trusts it will be conducted as part of the ISAP (see Part C for more detail). Applying the transaction guidance will meet the requirement for a provider risk rating from NHS Improvement as part of the ISAP. NHS trusts and foundation trusts should therefore read this document alongside NHS Improvement's transaction review guidance and Single Oversight Framework.

The Care Quality Commission (CQC) expects all providers to be able to demonstrate that they will be capable of providing safe, effective, caring, responsive and well-led services, as CQC registration requires. New providers will need to register with CQC before they can begin to deliver regulated activities; existing providers are likely to have to apply to vary the conditions of their registration.

Some complex contracts may include such a significant scope of services that the CCG's ongoing role will change. For example, a commissioner may take a more strategic role, establishing different relationships with neighbouring CCGs, the local authority and providers, and enable these bodies to carry out commissioning activities on its behalf. NHS England will look for assurance from CCGs that their future arrangements are robust and viable and that they continue to deliver their statutory functions effectively, in line with the existing CCG Improvement and Assessment Framework.

3.2. When will ISAP apply?

Commissioners should always ensure that the risk in any contract is assessed in a systematic and structured way. The ISAP principles are intended to support all complex procurements by commissioners, and applying the ISAP ensures assessment of contracts that could introduce higher levels of risk into the local health system. Specifically, if proposed contract forms, risk sharing arrangements or calculations of the contract value will take an approach previously unused in that locality, or if potential providers are likely to propose the creation of legal entities involving new organisational forms, it will be considered whether to apply the ISAP.

[5] *Single Oversight Framework* is available at: https://improvement.nhs.uk/resources/single-oversight-framework/

Examples of complex contracting arrangements include, but are not limited to, commissioning systemically significant new care models, such as multispecialty community providers (MCPs), primary and acute care systems (PACS) and any accountable care collaborations that result in significant changes in local health systems. It is not envisaged that the ISAP will apply to some smaller-scale new care models, such as enhanced health in care homes.

Examples of other complex contracts, beyond new care models, that the ISAP may capture include contracts aiming to integrate services along a care pathway, such as for older people or cancer patients, or those that include complex delivery and reimbursement mechanisms for specialised services. Contracts with population-based budgets or significant levels of payment conditional on outcomes may also need to go through the ISAP.

The ultimate decision on whether the ISAP should apply to a complex contract is at NHS England's and NHS Improvement's discretion. **Commissioners should engage with their regional NHS England teams as early as possible** to establish whether the procurement or other arrangement would benefit from going through the ISAP.

Once it is established that the contract proposal is complex, the decision on whether the ISAP will apply will be influenced by the factors in Table 1. These assist in assessing the level of risk inherent in any contract.

Table 1: Factors to consider when determining whether the ISAP applies

	ISAP is more likely to apply	Judgement is balanced	ISAP is less likely to apply
Relative contract value[6]	Over 40% of one or more of the commissioners' allocations is committed to the new contract	Between 10% and 40% of one or more of the commissioners' allocations is committed to the new contract	Less than 10% of each of the commissioners' allocations is committed to the new contract
Contract length	The contract is longer than the current allocation period set by NHS England	The contract is longer than two years but no longer than the current allocation period set by NHS England	The contract is no longer than two years

[6] This factor does not apply when considering specialised services.

	ISAP is more likely to apply	Judgement is balanced	ISAP is less likely to apply
Commissioner quality	There are well established and evidenced shortcomings regarding one or more of the commissioners' financial or operational performance	Financial or operational performance of one or more of the commissioners raises some concerns	Financial and operational performance of all commissioners is strong
Degree of performance-based income	Performance-based income is greater than 4% of total contract value	Performance-based income is between 2.5% and 4% of total contract value	Performance-based income is less than 2.5% of total contract value

Crucially, for the ISAP to apply, the commissioner must be proposing a procurement that would establish new contracting arrangements for existing services, or the re-procuring of a complex contract. Therefore, an alliance agreement or other arrangement aiming to integrate local health services, that does not require a procurement, does not need to go through the ISAP.[7]

If NHS England and NHS Improvement decide that the ISAP need not apply to a proposed contract, commissioners will still benefit from using elements of the structure and considering the principles in this guidance.

3.3. Who will ISAP apply to?

The ISAP will apply to commissioners procuring complex contracts and those developing a strategy that may involve commissioning a complex contract.

The ISAP also applies to any providers selected as preferred bidder following the procurement. The ISAP will test whether commissioners adequately assessed, as part of the procurement, the preferred bidder's ability to take on the risks associated with the proposed contract. This is intended to ensure all preferred bidders' risk profiles – whether NHS foundation trusts, NHS trusts or independent sector providers – are factored into commissioners' decisions and scrutinised through the ISAP.

[7] NHS Providers that are planning to enter such arrangements should consult with NHS Improvement as a separate transaction review may be required.

NHS England and NHS Improvement established the ISAP to assure and support CCGs, NHS providers and the effective operation of the health system. Some new care model contracts subject to the ISAP will include social care and public health services, for which local authorities are responsible. The ISAP is not designed to consider local authorities' decisions or assure the providers of local authority services. However, the ISAP applies to the entire procurement, and where local authority services are in scope it will seek assurances that any additional risks are properly assessed and managed. Inevitably, the steps commissioners are required to take and any recommendations from NHS England and NHS Improvement in the ISAP will affect local authorities' decisions as joint commissioners and potentially as providers. There will be discretion for local authorities to submit evidence and be involved in discussions with the panel as part of the ISAP.

Each CCG and local authority is accountable for its decisions when carrying out its statutory functions and the ISAP is not a substitute for their governance and assurance processes, although it is anticipated that CCGs and local authorities will find the ISAP supportive when they jointly commission a complex new care model spanning health and care.

Table 2 shows how the guidance applies to commissioners and providers.

Table 2: What does this mean for commissioners and providers?

Type	Application of guidance
Commissioners	The ISAP will apply to commissioners procuring complex contracts and those developing a strategy that may involve commissioning a complex contract.
Providers	The commissioner's assessment (during the procurement process) of the preferred provider's ability, whether a trust or independent provider, to take on the risks associated with the complex contract will be assessed through the ISAP. NHS trusts and foundation trusts will be subject to NHS Improvement's transaction review process, which for complex contracts will now be incorporated into the ISAP.

It is important that commissioners familiarise themselves with the ISAP's requirements (see Part B) and it is expected that they will design their procurement process to collect sufficient information from bidders to satisfy any considerations relating to potential providers.

4. How ISAP works

4.1. Checkpoints

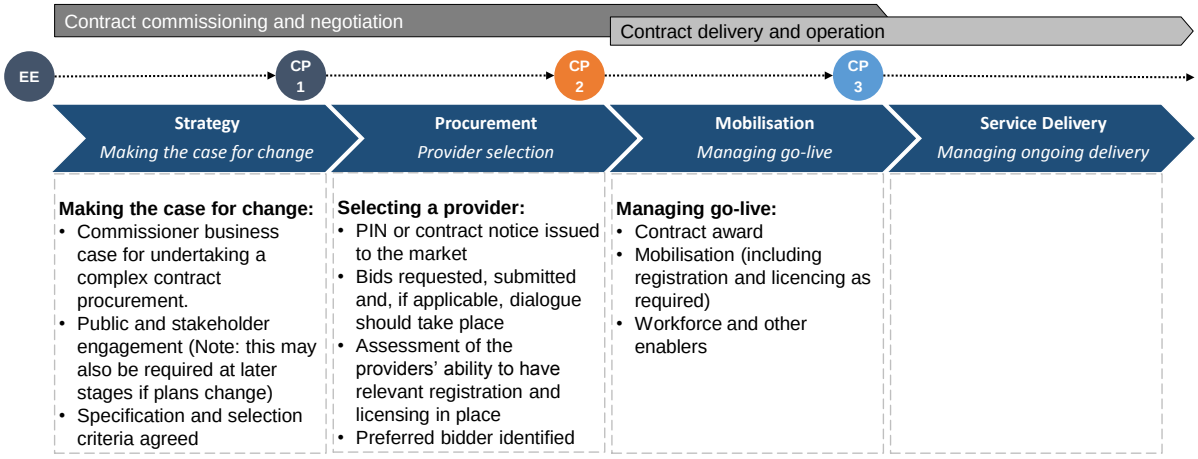
The ISAP provides a framework to help commissioners and providers contemplating a complex contract navigate the potential risks by engaging at relevant points as the proposal develops.

The ISAP may be applied in a similar way where the proposal does not ultimately involve a competitive procurement exercise. The ISAP has a series of checkpoints (see Figure 1), which NHS England and NHS Improvement will use to support the commissioner and provider(s) to identify, understand and mitigate as far as possible the risks of a complex contract.

The ISAP combines the oversight work of NHS England and NHS Improvement using an integrated panel to carry out the ISAP checkpoints. This approach is designed to enable both organisations to fulfil their distinct remits while minimising the duplication of assurance across the procurement lifecycle.

Importantly, this process requires that local governing bodies and boards provide an effective first line of assurance. Therefore, commissioners and providers should ensure their governing body/board is kept fully informed and given the opportunity to scrutinise, test and challenge the proposals in depth at each stage, including having first-hand access to advisers' conclusions and recommendations.

Figure 1: Procurement lifecycle and the ISAP checkpoints



The checkpoints[8] are:

- An early engagement (EE) meeting takes place while a commissioner is developing a strategy that involves commissioning a complex contract and typically before a formal market engagement exercise, if relevant, begins;

[8] See parts B and C of this guidance for more detail

- Checkpoint 1 (CP1) takes place just before formal competitive procurement or other selection process begins;
- Checkpoint 2 (CP2) takes place when a preferred bidder has been identified, but before the contract is signed. (NHS Improvement will be responsible for performing the transaction review on NHS trusts and foundation trusts where the thresholds for transaction reviews are met; NHS England will be responsible for assuring CP2's procurement aspect); and
- Checkpoint 3 (CP3) takes place just before the service begins.

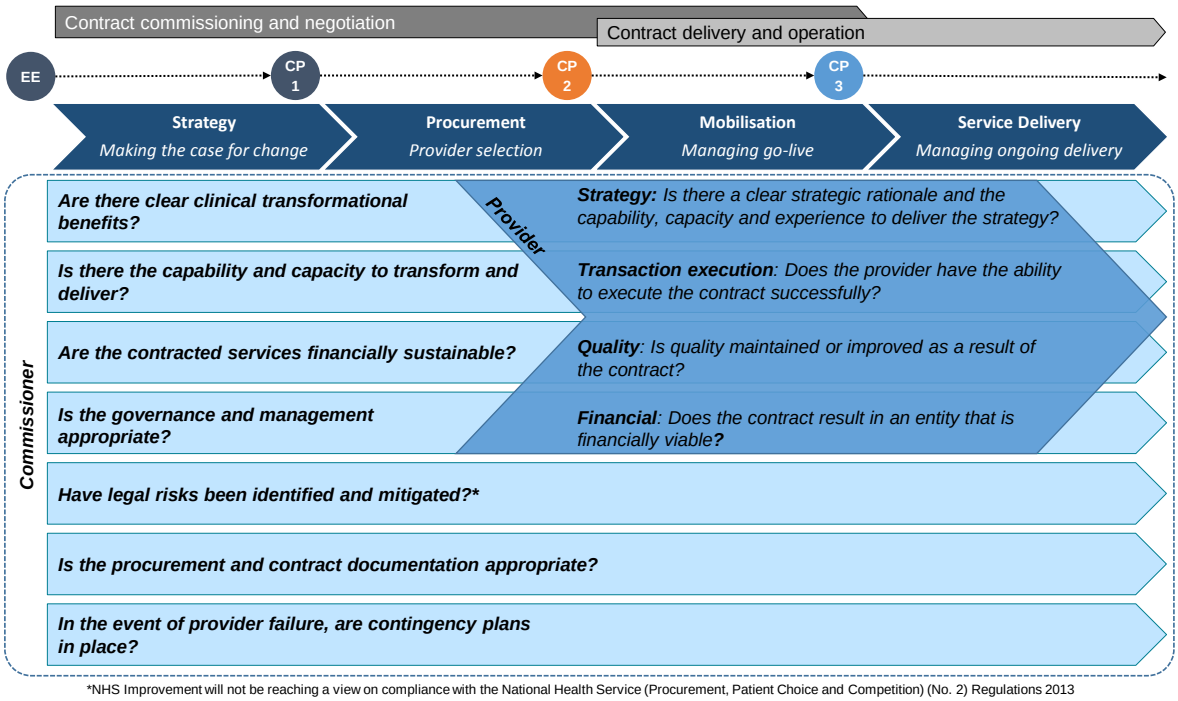
Feedback and outcomes will be provided at the end of each checkpoint. They will include recommended next steps and, as appropriate, commissioner and provider risk ratings.

4.2. Key lines of enquiries

To do this, the ISAP will consider Key Lines of Enquiry (KLOEs), which is the collective term for the areas of focus for NHS England's and NHS Improvement's assurance regimes. KLOEs are structured as questions that will establish the risk profile and other parameters of the complex contract at each checkpoint. They will form the basis of NHS England's and NHS Improvement's assessments.

Figure 2 shows the areas of focus for commissioners and providers. Parts B and C of this guidance provide a description of each KLOE.

Figure 2: ISAP KLOEs across the procurement lifecycle



*NHS Improvement will not be reaching a view on compliance with the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013

The KLOEs at each checkpoint will assess the commissioner's and (where relevant) the provider's identification, understanding and mitigation, as far as possible, of the risks during each phase of the procurement lifecycle. They are designed mainly to provide a self-assurance checklist. Each checkpoint is therefore focused on working with commissioners to ensure they have completed their self-assurance to a satisfactory standard and not overlooked critical issues. For example, the ISAP panel will ask whether commissioners sought legal advice on specific topics and adjusted their approach accordingly. The ISAP panel will not review or quality-assure the legal advice, but will seek assurance it has been followed.

4.3. Duration and outcomes

Figure 3: Summary of checkpoint duration and outcomes

				
Duration	1 week	1 month	3 months	1 month
Outcome	Outcome letter which confirms: • whether the ISAP applies, and if applicable • timelines for checkpoints.	Outcome letters, which outline: • rating • proposed outcome • areas of good practice and/or areas that should be addressed before the next stage.		

Checkpoints 1 and 3 will take about one month and Checkpoint 2 up to three months. This reflects the usual timescales for an NHS Improvement transaction review and may be shorter when this is not required. The timings are from the date the commissioner (and provider, where relevant) submits all necessary documentation to NHS England and NHS Improvement. The endpoint of Checkpoint 2 is an NHS England and NHS Improvement joint panel. This will be followed by NHS England and NHS Improvement internal governance procedures.

We encourage early engagement so we can work with applicants in scheduling these checkpoints to allow a smooth transition into the next stage of the procurement and contract lifecycle.

When the complex contract is reviewed, we assess whether risks have been identified, understood and mitigated as far as possible. NHS England and NHS Improvement will rate the proposals against a three-point colour rating. The colour rating depends on the extent to which the commissioner, and where relevant the provider, has adhered to good practice guidance and can demonstrate the success characteristics described for each checkpoint in parts B and C of this guidance. These ISAP ratings are detailed in Figure 4.

Figure 4: Definition of ISAP ratings

ISAP Rating	Definition[9]	Proposed outcome
Green	Meets or exceeds expectations	Outcome (a): No material concerns have arisen from the assurance process and the commissioner (and provider where relevant) may proceed
Amber	Partially meets expectations and there is confidence in management's capacity to deliver green performance within a reasonable timeframe subject to improvements in some elements	Outcome (b): recommendation of further activities to undertake, some of which may need to be completed before proceeding
Red	Does not meet expectations	Outcome (c) recommendation not to proceed without fundamental revision or significant further input by one or more parties.

In order for a procurement to achieve an overall ISAP rating of green or amber at Checkpoint 2, an NHS trust or foundation trust must receive an appropriate provider risk rating in accordance with NHS Improvement's transaction guidance.

A green rating should not be taken as confirmation from NHS England or NHS Improvement that the commissioner(s) and provider(s) have complied with all their relevant legal obligations, or that there are no risks, legal or otherwise, associated with the procurement, contract award or service delivery. Commissioners and providers are responsible for ensuring their actions are lawful and that they have satisfied their statutory and other legal obligations. Similarly, any rating at Checkpoint 3 will not of itself have any bearing on the rights and obligations of the

[9] The expectations relate to the areas of focus and KLOEs described in Part B of this guidance.

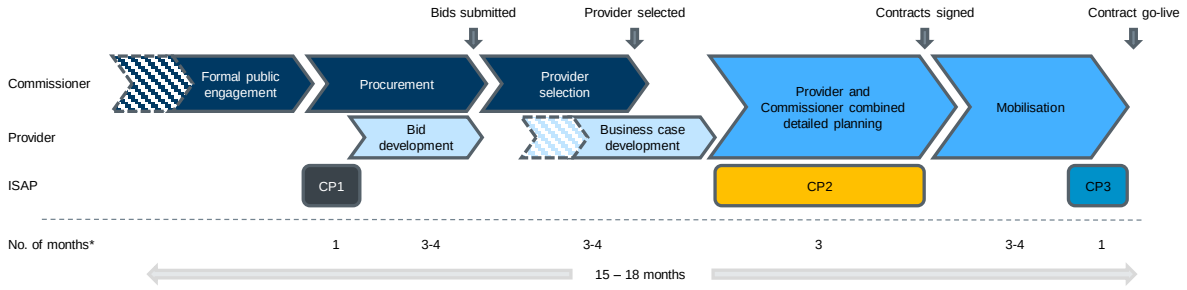
commissioner(s) and provider(s) under contracts already entered into: all parties will need to take their own legal advice in this regard.

NHS Improvement will not reach a view about a commissioner's compliance with the Procurement, Patient Choice and Competition Regulations[10] or the Public Contracts Regulations[11] as part of the ISAP. Therefore, a green rating should not be taken as NHS Improvement certifying that the procurement complies with those regulations or that the process will not be the subject of a referral to NHS Improvement under those regulations. The parties will, at all stages, need to take their own legal advice as regards compliance with the Procurement, Patient Choice and Competition Regulations and the Public Contracts Regulations 2015.

Following the award of a complex contract, regulatory implications for existing providers may require amendments to their registration conditions. Equally, new legal entities need to register to deliver regulated activities to begin to deliver services against the contract. Applicants should be aware that the CQC registration process can take 12 weeks from the submission of application forms, and this should be included in the mobilisation timescales.

The minimum expected timeline for the procurement of a complex contract is anticipated to be 15 – 18 months and is shown below in figure 5. The development of the full strategy – including the ISAP early engagement meeting, precedes the timeline below and assumes that both commissioner and providers continue to progress their preparations without significant issues. The bid development phase can extend this timeline depending on requirements from commissioner, providers and regulators. The timeline below gives an indication of how the checkpoints will fit into a typical competitive procurement process.

Figure 5: Indicative timeline for procuring a complex contract



[10] The National Health Service (Procurement, Patient Choice and Competition) (No 2) Regulations 2013.
[11] The Public Contracts Regulations 2015

5. Governance arrangements

At each checkpoint, sources of evidence submitted by commissioners and providers must first be assured by their respective governing body or board. Decision-makers – generally the whole governing body/board except members with a conflict of interest – should be provided with full information in an accessible way.

The governing body/board should ensure it is making fully informed decisions, both through the written information it receives from internal and external sources and through its opportunities to challenge and test this information. In particular, the governing body/board and/or relevant committees should consider having advisors present their findings and articulate the risks and implications.

Similarly, it is expected that commissioners will seek assurance from independent providers that all sources of submitted evidence have been agreed by their boards. This should include reasons as to why this approach is a good option for patients and the local health economy, and why the provider chose to bid for the contract.

At each ISAP checkpoint, the NHS England regional director will convene a panel to review and challenge the sources of evidence submitted. The panel membership is expected to include NHS England and NHS Improvement regional and regulatory representatives and relevant experts in clinical, finance, commissioning development and other areas as required, depending on the type, scope and stage of procurement.

If the panel identifies major risks to the provider or the commissioner, such that it recommends the procurement is not started, the contract is not awarded or the process is significantly delayed, the panel will inform (and consult as appropriate) NHS England's executive team and/or NHS Improvement's Provider Regulation Committee.

After the end of Checkpoint 2, once the panel has reviewed the sources of evidence submitted, it will make recommendations to the governance forums of NHS England and NHS Improvement. Throughout, NHS England and NHS Improvement will work together to fulfil the objectives of the ISAP, and will be responsible for activities consistent with the respective functions of the organisations.

The decision about whether to procure and award a contract, and then to allow service delivery to begin, must be one for local commissioners, and the ISAP will not transfer this decision to the national bodies. However, the view of the national bodies should be a key consideration for local commissioners. NHS England will expect commissioners to carry out any extra activities indicated in the checkpoint outcome before they move onto the next stage. In addition, NHS Improvement will expect NHS foundation trusts and NHS trusts to pause and adapt their involvement in a transaction if its Provider Regulation Committee issues a red transaction risk rating, in accordance with NHS Improvement's transaction guidance.

As the regulator of care quality, CQC is independent from the process and does not form part of the panel during the ISAP checkpoints. However, to streamline the process, CQC is committed to supporting the ISAP, and will provide advice and information at appropriate points. Commissioners will be expected to obtain information about the quality of providers held by CQC, and to consider the regulatory implications of proposed changes. Providers should engage early with CQC about new or changing registration requirements.

6. Feedback

The intention of the ISAP is that NHS England and NHS Improvement act in a co-operative and effective way to provide a 'system view' of the proposals, when exercising their existing functions and processes. As such, although consultation on the ISAP is not needed, comments have been drawn from representative stakeholders including commissioners and providers, as well as arm's length bodies such as CQC in developing the approach set out in this document.

If you have any comments on the ISAP principles in this document, please send them to england.finance@nhs.net. All feedback received will be carefully considered as part of the ISAP's ongoing development.

7. Next steps

Where commissioners believe the ISAP could apply to a complex contract or other arrangement that they are planning, they should engage with NHS England at an early stage – ideally as soon as they decide to develop a strategy that involves commissioning a complex contract. To do this they should contact their NHS England regional teams. If this strategy has already been developed and is underway, commissioners should contact their regional teams immediately.

NHS providers are encouraged to contact NHS Improvement at an early stage if they are contemplating collaborative arrangements with other providers, forming a joint venture or new organisational form in response to a commissioner's plans to procure a complex contract. NHS Improvement can advise on any potential competition issues and help providers in engaging with the Competition and Markets Authority (if it becomes necessary). The best time to engage with NHS Improvement is likely to be at the preferred bidder stage when providers are able to explain how any collaboration or new organisational form will work, although NHS Improvement can also help providers think through potential issues at an earlier stage.