The Integrated Support and Assurance Process (ISAP): an introduction to assuring novel and complex contracts

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2. Introduction

2.1. Overview

The NHS Five Year Forward View, published in October 2014, set out an ambitious vision for transforming NHS services. Local health communities will be supported to develop new care delivery options as they seek to better integrate primary and specialist care, physical and mental health services, and health and social care. NHS England and NHS Improvement have jointly recognised that these new care models and contracts may mean:

- The contract form and the calculation of the financial value of the contract envelope are novel;
- The organisational forms of the bidding organisations may be complex, as providers seek legal entities that allow for greater collaboration between partners; and
- Other incumbent NHS providers can be significantly affected by a single procurement for a new care model.

Recent reviews of the collapse of the Cambridgeshire and Peterborough CCG contract with Uniting Care Partnership in December 2015[1] identified that parts of the system worked in silos, and that there was not a full and shared understanding of the contract risks by the commissioner, the providers or the regulatory bodies. CCGs, participating providers and their respective governing bodies and boards should ensure that they are familiar with the recommendations in these reviews before embarking on a novel or complex contract.

This process has identified seven key lessons, and four questions that need to be answered before embarking on new care models and contracts.

Seven lessons:

1. The service design needs to be right from the outset;
2. Cost information from legacy providers must be transparent;
3. Commercial skills and awareness will be needed;

[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

4. Clarity on the role of external advisers is needed to ensure sufficient expertise is provided, there is appropriate synthesis and the proposal under consideration is consistent with the advice received;

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

6. Contract implementation should be delayed if issues are unresolved; and

7. NHS Improvement and NHS England should scrutinise the arrangements for these novel and 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 risk?
- Have the consequences for other providers been thought through?
- Does the proposed service model merit considering adjustments to the regulatory approach?

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

The dual purpose of the ISAP is to guide the work of local commissioners and providers in creating successful and safe schemes and provide a means of assurance that this has happened. The process depends on:

- Competent local executives designing complex contracts along with providers successfully implementing services under those contracts;
- 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.

The ISAP provides a coordinated approach to reviewing the procurement and transactions related to complex contracts. NHS England and NHS Improvement want to support commissioners and providers to identify, understand and manage

the risks in developing such contracts. The ISAP will enable all parties to learn from previous failures and implement best 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[2] and will continue to be refined.

2.2. Purpose of the document

This document describes the integrated NHS England and NHS Improvement process for supporting commissioners and providers looking to complete procurements for complex contracts. It is an initial introduction to and overview of the process. We will publish full guidance later this year providing more detail on the submissions and evidence expected from commissioners and providers at each checkpoint in the process. The process and requirements are likely to continue to evolve as the ISAP is piloted.

3. Objectives of the ISAP

The ISAP refers to a set of activities that begin when a clinical commissioning group or a commissioning function of NHS England (collectively referred to as commissioners) starts to develop a strategy which involves the commissioning of a complex contract through to the subsequent award, and mobilisation of, services under the contract. The intention is for NHS England and NHS Improvement to provide a 'system view' of the proposals, which focuses on what is required to support the successful delivery of complex contracts. Applying the ISAP will help mitigate but not eliminate risk, which is inevitable if the opportunity is to be acted upon. It is also 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.

The objectives of the ISAP are to:

- Ensure the proposals represent a good solution in the interests of patients and the public;
- Ensure a system view has been taken of the potential consequences of contract award;

[2] *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

- Enable the risks of the complex contract to be identified, understood and mitigated as far as possible; and
- Deliver efficiency and reduce duplication in the work of NHS England and NHS Improvement, increasing the speed of the national due diligence for complex contracts.

4. Application of the ISAP

4.1. Alignment with existing processes

The ISAP has been developed based on lessons learnt from the failure of the contract with Uniting Care Partnership in 2015 and is aligned with:

- NHS England's processes, including those for major service redesign and the CCG Improvement and Assessment Framework[3]; and
- 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 set out in its guidance on transactions.

NHS Improvement's transaction guidance currently applies only to NHS foundation trusts. In line with the Single Oversight Framework[4], which sets out that 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 at checkpoint 2. If a transaction review is required for NHS foundation trusts or NHS trusts it will be conducted as part of the ISAP (see section 5.3 for more detail). The requirement for a provider risk rating from NHS Improvement as part of the ISAP will be determined by applying the transaction guidance. Therefore, foundation trusts and NHS trusts should read this introduction document, and the full guidance document that will be published later this year, in conjunction with NHS Improvement's transaction review guidance and Single Oversight Framework.

CQC expects all providers to be able to demonstrate that they will be capable of providing safe, effective, caring, responsive and well-led services, in line with the requirements of CQC registration. New providers will need to make sure they have registered with CQC before they can begin to deliver regulated activities, and existing providers are likely to need to apply to vary the conditions of their registration.

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[3] *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

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

4.2. When will the ISAP apply?

The ISAP is intended to support all novel or complex procurements by commissioners. Specifically, if contract forms, risk sharing arrangements or calculations of the contract value are taking a previously unused approach, or if potential providers are creating legal entities involving new organisational forms, the ISAP will apply.

This includes, but is not limited to, the commissioning of systemically significant new care models, such as multispecialty community providers (MCP), primary and acute care systems (PACS) and any Accountable Care Networks that result in significant change in whole health systems. Because of their smaller scale, it is not envisaged that the ISAP will apply to some other varieties of new care model, such as Enhanced Care in Care Homes.

Examples of other contracts, beyond new care models, that will be captured by ISAP include contracts aiming to integrate a range of services, such as for elderly or cancer patients. Similarly, contracts with population based budgets or significant levels of payment conditional on outcomes would also need to go through the ISAP.

The examples above are not exhaustive. **If there is any doubt, commissioners should engage with their regional NHS England teams as early as possible** to reach a shared view on whether the procurement or other arrangement would benefit from going through the ISAP.

4.3. Who will the ISAP apply to?

The ISAP will apply to commissioners procuring complex contracts.

The ISAP tests relating to providers will apply to any preferred bidder in such a procurement. The ISAP will be testing whether commissioners have adequately assessed as part of the procurement the ability of the preferred bidder to take on the risks associated with the proposed contract. This is intended to ensure that the risk profile of all preferred bidders, be they NHS foundation trusts, NHS trusts or independent sector providers, is factored into commissioner decisions and is scrutinised through the ISAP.

Table 1 shows how the guidance applies.

Table 1: What does this mean for you?

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

5. Details of the ISAP

5.1. Development of the ISAP

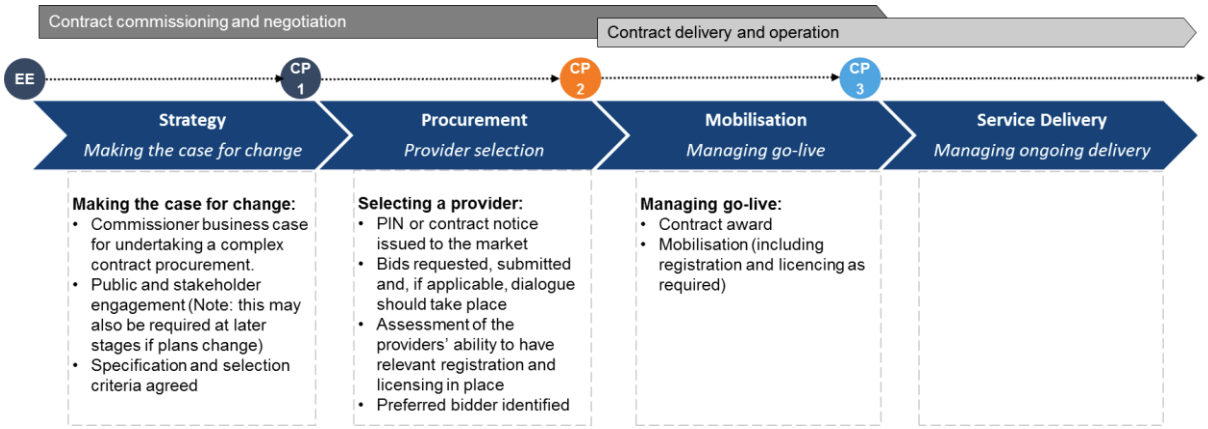
One of the key objectives of the ISAP is to provide a framework to support commissioners and providers contemplating a complex contract, helping them navigate the potential risks by engaging at several points as the proposal develops.

The ISAP has been developed, drawing on expertise from across NHS England and NHS Improvement, around the key stages of a major procurement and contract lifecycle and 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), further details about which are provided in section 5.3. At each stage, NHS England and NHS Improvement will 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 team to carry out the ISAP checkpoints for each complex contract. This approach should enable both organisations to deliver their distinct organisational remit while minimising the duplication of due diligence across the procurement lifecycle.

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

Figure 1: Procurement lifecycle and the ISAP checkpoints



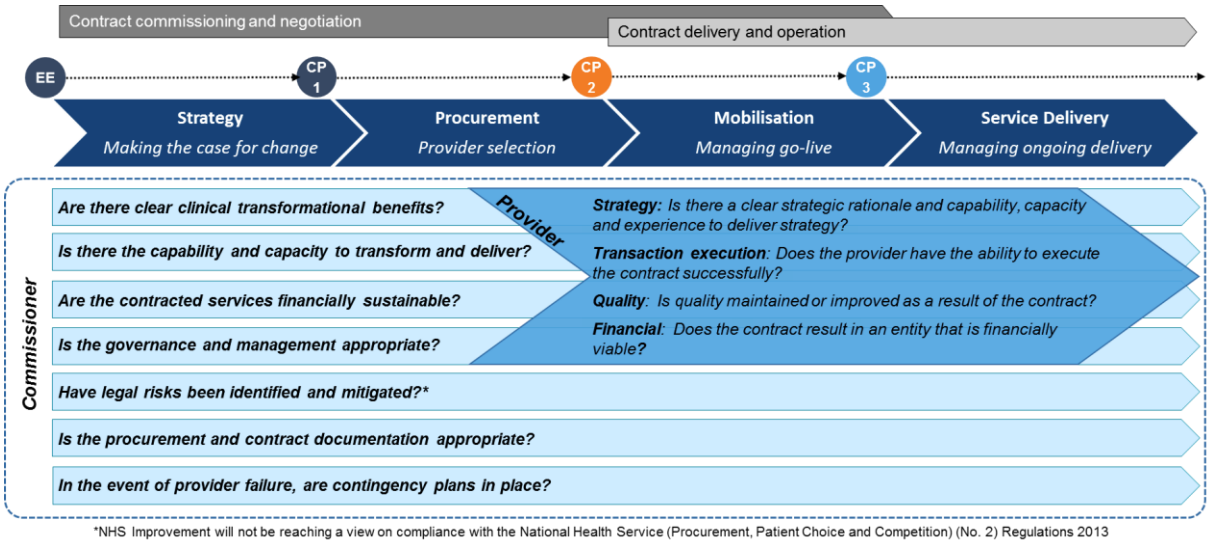
We expect the following checkpoints to occur:

- An Early Engagement (EE) meeting takes place, while a commissioner is developing a strategy which involves the commissioning of a complex contract (see section 5.2);
- Checkpoint 1 (CP1) takes place just before formal procurement or other commissioning process;
- 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 foundation trusts and NHS trusts where the thresholds for transaction reviews are met, and NHS England will be responsible for assuring the procurement aspect of that checkpoint); and
- Checkpoint 3 (CP3) takes place just before service commencement.

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

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 and NHS Improvement's assurance regimes. KLOEs are structured as questions, which will establish the risk profile and other relevant parameters of the complex contract at each checkpoint. This concept is outlined in figure 2, which shows the areas of focus for both commissioners and providers. A description of each KLOE is provided in Table 4 within Annex 1. At each checkpoint the KLOEs will form the basis of NHS England and NHS Improvement's assessment.

Figure 2: The 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 checkpoints 1 to 3 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.

5.2. Early engagement

Commissioners who are considering an arrangement involving a complex contract should engage with their NHS England regional team early on – ideally as soon as they decide to develop a strategy to commission one.

Engaging early allows discussions to take place with commissioners to understand when the ISAP checkpoints will occur. It also enables us to assist with understanding the expected content of checkpoint submissions and type of supporting documentation. First contact should be with the relevant NHS England regional team who will co-ordinate an early engagement meeting, including NHS Improvement colleagues, to determine if the proposed contract should go through the ISAP and, if so, the timing of the process. The early engagement meeting will also review the scope of the services and/or the size of the transaction.

5.3. Checkpoint objectives

It is acknowledged that each new complex contract will be unique and, as such, will be considered on an individual basis. Table 2 below provides guidance to help commissioners and providers understand what will be considered at each stage along the procurement lifecycle, including example questions that form the KLOEs for each of the ISAP checkpoints.

Table 2: Checkpoint descriptions and example questions

Checkpoint	Example questions
Early Engagement	**Key consideration: Does ISAP apply and what is the anticipated procurement lifecycle?** **For the commissioners:** • Does the contract trigger the ISAP? • Has the case for change been articulated? • Has there been appropriate patient engagement or is this planned? • What services are included and are they representative of a complex contract? • What is the proposed size of the complex contract? • Has all possible growth in services over the life of the contract been considered? Do planned consultations cover this? • Where multiple commissioning agencies are involved (e.g. multiple CCGs, NHS England direct commissioners, Local Authorities), are all parties in support of the collective approach? • What process is intended to be used to procure the services and how will quality, value for money and provider capability be tested? • What is the timetable for the ISAP? • Has the commissioner considered the ISAP and designed the procurement process accordingly? **Relating to providers:** • No questions will be asked of providers at early engagement, as it happens before formal procurement and the preferred bidder will not yet have been identified.
Checkpoint 1: Readiness	**Key consideration: Does the proposal represent the correct strategic solution for the local health economy and has the necessary preparatory work been completed for the proposed procurement?** **For commissioners:** • Are the plans in line with the NHS Five Year Forward View and applicable frameworks? • What benefits is the complex contract expected to achieve for care quality and sustainability and how will they be achieved? Is it a good option for patients and the local health economy? • Have the necessary preparations and documents for procurement been completed, including evaluation criteria and methodology? • Has appropriate engagement with providers, other commissioners and stakeholders taken place including impact

Checkpoint	Example questions
	assessment and identification of reasonable mitigations? • Has all possible growth in services over the life of the contract been included in the documentation and been consulted on? • Has a robust procurement plan been developed and sufficient resources allocated to deliver it? • Have any potential subcontracting arrangements been considered and is there a process to consider foreseeable changes to subcontracting? • Where an area's Sustainability and Transformation Plan (STP) plan is well developed, are the procurement plans aligned to it? Where it is less well developed, is the strategic intent a good fit to challenges in the local health economy? • Where the planning footprint for service configuration is larger than the STP footprint (such as for specialised services) have the plans been tested for congruence with plans at that multi-STP level and issues resolved? • What impact do the plans have on the potential viability of commissioners and other providers and how will this be managed? • What are the commissioner's plans for monitoring performance and managing the complex contract? • Has the commissioner considered the impact of the complex contract on patient choice and competition, and how will potential risks be mitigated? **Relating to providers:** • No questions will be asked of providers at checkpoint 1, as it takes place before formal procurement and the preferred bidder will not yet have been identified. • However, it is important that the commissioner can show that it has completed appropriate engagement with providers before starting on the procurement. • In addition, NHS Improvement will input into the assessment of whether or not the proposed approach is a good solution for the local health economy given the potential impact on providers. • NHSI will also contribute to the assessment of whether the proposed risk allocation is likely to be acceptable to providers.
Checkpoint 2: Selection	**Key considerations: Has the procurement process been robust? Are the contract and preferred bidder(s)* appropriate for the complex contract? Is the financial envelope appropriate for services being bought?** **For commissioners:** • Are the contract terms and financial values clear and understood

Checkpoint	Example questions
	by all parties? • Is suitably scoped and integrated advice on commercial, legal, procurement and other matters available, and effectively utilised, including appropriate scrutiny by governing bodies? • Have standard form documents been followed with any derogations being only those that are permissible? • Has the commissioner robustly evaluated that the provider has the appropriate capability to provide the contract and capacity to manage risks? • Does the provider have a robust financial plan, and is the risk allocation in the proposed contract appropriate so that the provider is able to withstand those risks, considering its organisational form? If relevant, have sufficient parent company guarantees been secured? • What impact does the contract have on the potential viability of commissioners and other providers? Are reasonable mitigations in place to address the risks identified? • Can the commissioner demonstrate how its statutory duties will be discharged going forward? • Are there appropriate arrangements and plans in place to manage the contract? • Is there an effective process for dispute resolution in the contract? • Are there appropriate plans to ensure clinical service continuity through any transition? • How do payment and contract terms ensure the quality and outcomes sought are delivered? • In the event of provider difficulty or failure, what are the contingency plans to ensure alternative provision and maintain continuity of care? • Are IT systems and clinical record access appropriate? • Has the detailed scrutiny and challenge by the governing bodies been concluded with appropriate rigour based on suitable documentation? **Relating to the preferred provider(s)*:** • Is the provider's overall strategy well-reasoned and can the board articulate how the contract supports its delivery? • Has there been a detailed options appraisal, and is there a clear rationale for the option the provider has selected? • Does the provider have capability, capacity and experience to deliver the strategy and minimise execution risk of the complex contract? • Is the provider able to identify and quantify contract risks

Checkpoint	Example questions
	appropriately, including any risks associated with competition rules? Is its approach to due diligence robust and is there evidence that key risks have been recorded? • Is there a robust and comprehensive plan for delivery of the contract, including integration and realisation of other benefits? • What is CQC's view of the provider and the impact of the planned contract? • Does the provider's plan demonstrate clear arrangements for the quality of care that is to be delivered, including who is accountable for its delivery? • Does the provider's plan demonstrate financial viability post contract? • If relevant, does the preferred bidder have in place appropriate assurances with their proposed sub-contractors? • Has appropriate scrutiny and challenge by the provider's board been concluded?
Checkpoint 3: Go-live**	**Key consideration: Is it safe for the service to go-live?** **For commissioners:** • Has anything material changed since checkpoint 2? • Are appropriate licensing and registration in place? • Are IT systems and clinical record access appropriate? • Are governance arrangements in place? • Has the CQC been contacted for the latest information which may not be captured in the published reports? • Are there appropriate plans and capability in place to manage the contract? **Relating to the provider(s)*:** • Has the board effectively mitigated key risks and established effective processes for the continued management of these risks post transaction? • Is there a robust and comprehensive plan for delivery of the contract, including integration and realisation of other benefits? • Is the integration plan sufficiently supported by clear lines of accountability, governance processes, delivery milestones and dedicated resource? • Has the provider met all regulatory and legal requirements (including Monitor licence and CQC registration), and is it planning the contract with reference to good practice guidance? • If relevant, are sub-contractual arrangements in place and suitably robust, and is risk appropriately shared?

Checkpoint	Example questions
	• Is the necessary workforce in place? • Is the necessary estate secured and set-up?

* All references to the preferred bidder or provider should be understood to encompass situations of multiple providers.
** In development, for illustrative purposes only.

5.4. Early engagement and checkpoint 1 submissions

The indicative submissions expected for Early Engagement and Checkpoint 1 are included in Table 3. This list is not exhaustive and submission expectations will continue to be refined as the ISAP is piloted. Details of submission expectations for Checkpoint 2 and 3 will be set out in the guidance document that will be published later this year.

Table 3: Early engagement and Checkpoint 1 example submissions

Stage	Indicative submissions
Early engagement	• An articulation of the scope and scale of the care model; • Level of patient engagement • The approximate contract value • The strategic rationale with particular regard to STP alignment and alignment to any relevant care model frameworks; • The extent of local clinical and non-clinical engagement in the care model development; • The risks that are known at this stage and how they have been, or will be, mitigated; and • An explanation of the intended procurement process, timeline and how the ISAP has been factored into its construction.
Checkpoint 1	Submissions will build on the early engagement meeting with additional supporting evidence expected as follows: • The quantified benefits to the local health economy and impact on population health; • Why the complex contract is the most appropriate solution for the local health economy; • Detail regarding the procurement management arrangements: timetable, Senior Responsible Officers, available resource and readiness for large-scale procurement process, legal support, bidder eligibility, evaluation criteria and details of public engagement/consultation. • Issues and risks that have been identified by stakeholders and how those have been addressed or mitigated before procurement; • Capability of commissioner leadership and impact of procurement on commissioner viability;

Stage	Indicative submissions
	• The financial model for the service scope over the lifetime of the contract. This financial model should convey the rationale for the procurement, its role in delivering a sustainable local health economy and the impact that changes in activity driven by the service scope will have on incumbent providers; • The contract value and calculation of the financial envelope, including an explanation of how expanding the service scope, adjusting the geographical footprint or demographic and non-demographic growth might change the financial envelope; • Details of any risk/gain-sharing arrangements applicable to the contract; and • Anticipated transformation/transitional funding requirements, and how they are to be provided.

5.5. Checkpoint duration and outcomes

Figure 3: Summary of checkpoint duration and outcomes

				
Duration	1 week	1 month	2-3 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; and • areas of good practice and/or areas which should be addressed before proceeding to the next stage.		

Checkpoints 1 and 3 are anticipated to take about one month. Checkpoint 2 is anticipated to take up to three months; this time requirement 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 of submission of all necessary documentation by the commissioner, and provider where relevant, through to NHS England and NHS Improvement providing the outcome shown in Figure 3. Early contact is encouraged 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 are assessing whether risks have been identified, understood and mitigated as far as possible. NHS England and NHS Improvement will rate the commissioner, and where relevant the provider, 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 evidence the success characteristics set out for each checkpoint. These ratings are detailed in Figure 4.

Figure 4: Definition of ratings

Rating	Definition	Proposed outcome
Green	Meets or exceeds expectations	Outcome a) recommendation to 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 activities to undertake before proceeding
Red	Does not meet expectations	Outcome c) recommendation not to proceed without fundamental revision

A recommendation to proceed 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.

NHS Improvement will not, as part of the ISAP, reach a view about compliance of a commissioner with the Procurement, Patient Choice and Competition Regulations.[5] Therefore a recommendation to proceed with a procurement process should not be taken as NHS Improvement certifying that the procurement is compliant with those regulations or that the process will not be the subject of a complaint to NHS Improvement under those regulations.

[5] The National Health Service (Procurement, Patient Choice and Competition) (No 2) Regulations 2013.

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

6. Governance arrangements

At each checkpoint, submissions from commissioners must first be assured by their respective governing body or board. Decision makers, generally the whole of the 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 that it is making fully informed decisions, both through the written information it receives from internal and external sources and through the opportunities it has 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 from providers assurance that all submissions have been agreed by their board. This should include why it has elected to bid for the contract, how it fits into its overall strategy and why this approach is a good option for patients and the local health economy.

At each ISAP checkpoint, a panel will be convened by the NHS England regional director to review and challenge the submission. The panel membership is expected to include a combination of a medical director, NHS England and NHS Improvement regional and regulatory representation and relevant subject matter experts in 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 is recommended that 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.

At checkpoint 2, once the NHS England and NHS Improvement integrated panel has reviewed the submission, they will make recommendations to the respective governance forums of each organisation.

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 must be one for local commissioners, and the ISAP should not and cannot remove this decision to the national bodies. However, the view of the national bodies should form a key consideration for local commissioners. NHS England will expect commissioners to action the additional activities indicated in the checkpoint outcome prior to the decision to proceed. In addition, NHS Improvement will expect NHS foundation trusts and NHS trusts to pause and adapt their involvement in a transaction if NHS Improvement's 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, in order to streamline the submission process, CQC is committed to supporting the ISAP, and will provide advice and information at appropriate points in the process. Commissioners will be expected to engage with CQC to obtain relevant information about the quality of providers, and to have considered the regulatory implications of proposed changes.

7. Feedback

The intention of the ISAP is that NHS England and NHS Improvement act in a cooperative and effective way to provide a 'system view' of the proposals, when exercising existing NHS England and NHS Improvement functions and processes. As such, although we do not need to consult on the ISAP, we have drawn on input from representative stakeholders including commissioner and provider representatives as well as other arm's length bodies such as the CQC in developing the approach set out in this document.

If you have any feedback on the ISAP principles set out in this document, please send this to england.finance@nhs.net by 18 November 2016. All feedback received will be carefully considered as part of the development of the full guidance that will be published later this year.

8. Next Steps

Guidance for commissioners and providers contemplating a novel or complex contract will be published by the end of 2016, detailing the full requirements at each checkpoint and outlining indicators of best practice.

However, as set out in Section 5.2, commissioners who believe the ISAP could apply to a complex contract or other arrangement they are planning should engage with us at an early stage – ideally, as soon as they decide to develop a strategy which involves the commissioning of 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.

Annex 1: Key Lines of Enquiry (KLOEs)

As set out in Section 5, the ISAP will consider KLOEs which are the collective term for the areas of focus for NHS England and NHS Improvement's assurance regimes. A description of the KLOEs is included within Table 4 below.

Table 4: KLOEs

KLOE	Areas of focus
For commissioners	
Are there clear clinical transformational benefits?	Focus should be on whether the care model can deliver the clinical transformational benefits envisaged for patients and populations. For example, during the procurement phase focus will be on whether the procurement documentation is consistent with the stated objectives, benefits and/or delivery model in the case for change.
Is there the capability and capacity to transform and deliver?	Focus should be on whether the commissioner and/or provider's structure, financial capacity, governance and capability to transform will be able to deliver the care model. For example, during procurement focus may be on whether the commissioner has requested, or the provider has clearly articulated, the accountabilities, roles and responsibilities during the transition of services. Alternatively, during the mobilisation phase, focus may be on whether the ongoing management of the contract is robust or able to enforce its intentions.
Are the contracted services financially sustainable?	Focus should be on whether the complex contract is financially sustainable. For example, during the procurement phase the focus may be on whether the provider is financially robust and assumed risk transfer is therefore realistic.
Is the governance and management appropriate?	Focus should be on whether the governance and management by the commissioner is sufficient to deliver the procurement and complex contract successfully. For example, during the strategy phase there may be focus on whether the commissioner has adequately identified and rectified gaps in capacity and capability.
Have legal risks been identified and mitigated?	Focus should be on whether the procurement is compliant with procurement law and whether other legal risks have been considered. For example, during the mobilisation phase the process should confirm that contract variations agreed post contract signature do not make fundamental changes to the contract which could lead to a breach of procurement laws.

KLOE	Areas of focus
Is the procurement and contract documentation appropriate?	Focus should be on whether the complex contract documentation adequately documents the agreement between commissioner and provider. For example, during the mobilisation phase contract variations would not be expected to weaken the levers available to enforce the contract.
In the event of provider failure, are contingency plans in place?	Focus should be on whether contingency plans ensure the alternative provision of patients' services and maintain continuity of care in a way that is financially efficient for the taxpayer – and that these plans are suitably reflected in the contractual terms.
Relating to providers	
Strategy	Is there a clear strategic rationale for the complex contract and does the board have the capability, capacity and experience to deliver the strategy?
Transaction execution	Does the provider have the ability to execute the complex contract successfully?
Quality	Is quality maintained or improved as a result of the complex contract?
Financial	Does the complex contract result in an entity that is financially viable?