NHS
Herefordshire and Worcestershire
Clinical Commissioning Group

Quality Impact Assessment Policy

Document Reference Information

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Directorate responsible:	Nursing and Quality
Directorate lead:	Chief Nurse
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Target audience:	All CCG employees. All staff who work for partner organisations who support related commissioning functions or commission services on behalf of Herefordshire & Worcestershire CCG.

Version Control Record

Version	Description of change(s)	Reason for change	Author	Date
V3	Amendments of flowcharts to reflect revised process and greater clarity for the rationale and content of QIAs	Introduction of verto and need for more consistent guidance for authors who need to complete a QIA	Rachael Skinner	December 2017
V4	Addition of Safeguarding Children Impact Assessment and clarity for when to repeat a QIA	Response to consultation with Lay members and Quality Team of the CCGs	Rachael Skinner	March 2018
V5	Amendment to approval flow chart in Appendix 1 to reflect change in how authors make initial notification to the Quality Team.	Awareness of change in expected functionality of Verto	Rachael Skinner	January 2019

Contents

1 Introduction

1.1 The Worcestershire Clinical Commissioning Groups (NHS Redditch and Bromsgrove Clinical Commissioning Group, NHS Wyre Forest Clinical Commissioning Group and NHS South Worcestershire Clinical Commissioning Group) are committed to ensuring that a consistent approach is taken to inform commissioning decisions, business cases, financial recovery plans and any other business plans, including a robust evaluation for their impact on healthcare quality.

1.2 Healthcare systems are increasingly complex with a growing number of interdependencies, some of which sit outside of the traditional range of NHS funded services. The gap between healthcare demand and available capacity has contributed to a significant challenge for the NHS and accountable organisations are required to make increasingly difficult decisions about the viability and range of local services. Significant changes are required to address the recognised variance between healthcare demand and capacity, to improve the health of our local population through better prevention of health need and to enable services to work in an effective and efficient way. Achieving this will require some significant changes in local service pathways. Service changes require robust planning and implementation to ensure that the potential for unintended harmful impact on patient safety, clinical effectiveness or patient experience is not realised.

2 Purpose

2.1 The purpose of this policy is to set out the principles, responsibilities, process and format to be followed to ensure that changes, initiated as a consequence of commissioning decisions made by the endorsing organisations, are fully assessed for their impact. Impact assessment must consider the positive impact expected on healthcare quality, ensure that any known or expected negative impact on quality is robustly assessed and understood and ensure that any potential unintended negative consequences are identified and mitigated.

3 Definitions

Quality	Quality can be defined as embracing three key components: **Patient Safety** –the potential for avoidable harm to patients, as a consequence of being in receipt of healthcare, is minimised. This may include ensuring that the environment is clean and safe at all times and that systems are in place to support the avoidance of harmful events. **Effectiveness of care** – the most appropriate and effective treatments, interventions, support and services will be provided, in a timely manner, to those patients who will benefit. This results in positive clinical outcomes for patients. **Patient Experience** – the patient's experience will be at the centre of the organisation's approach to quality and any experience that may have a harmful consequence (for example, anxiety) is minimised or avoided.
Quality Impact Assessment	A Quality Impact Assessment (QIA) is a process of identifying the anticipated, actual or potential impact of a strategy, policy, plan or proposed plan, service change or intervention, on the areas of quality (patient safety, effectiveness, patient experience),to ensure any necessary

mitigating action to affect a reduction in residual risk, is outlined, implemented and evaluated in a robust way.

4 Scope

4.1. The policy relates only to the process of undertaking and approving Quality Impact Assessments that are to be undertaken when developing commissioning projects, QIPP plans, commissioning organisation Cost Improvement Plans, business cases, service redesign, strategies and any other plans for change initiated by the Clinical Commissioning Groups. This includes any new or reviewed service specification that, when implemented, may result in a change in service delivery.

4.2. This policy applies to all staff members that lead or seek assurance about service developments and re-design programmes, QIPP and financial recovery programmes and any other developments that result in healthcare service change initiated following a commissioning decision.

4.3. The process for gaining assurance of the quality impact of Cost Improvement Plans for commissioned provider organisations is not covered within the scope of this policy.

5 Training/Competencies if required

5.1 No specific training is required to complete a Quality Impact Assessment. The Quality Team of the Clinical Commissioning Groups will respond to individual requests to provide advice and guidance to support QIA completion and can deliver team training if required.

6 Responsibilities and Duties

The roles and responsibilities for Quality Impact Assessments are set out below:

Chief Officer	Chief Operating Officer has ultimate responsibility for the quality assurance of commissioning decisions across the organisation.
Chief Nurse / Director of Quality	The CCG Chief Nurse is responsible for ensuring that Quality Impact Assessments are effectively considered and undertaken as part of discussions and decisions about business cases relating to financial recovery, service transformation or other business plans affecting service delivery change. The Chief Nurse will be responsible for the approval of submitted QIAs and for the escalation of QIAs for Financial Recovery Board decision where any mitigated risk remains at a score of 8 or above. The CCG Chief Nurse is also responsible for seeking assurance that providers have robust systems in place to undertake QIAs for all Cost Improvement Plans.
Executive Governing Body members	Executive and Governing Body Board members are responsible for ensuring that financial and operational initiatives (e.g. business cases, service re-design, strategies and other business plans) have

been evaluated for their impact on quality and have assured themselves that minimum standards will not be compromised. Executive leads will also be responsible for assuring themselves and others that the impact on quality and patient safety is monitored appropriately throughout the introduction of service change, via scheme highlight reports and the risk log, in order to ensure that emerging unintended impact is identified and mitigated or escalated to the appropriate Governing Body.

Staff and members of the CCG

Any individual with lead responsibility for completing or preparing a policy, strategy, business case, service re-design, commissioning or other plan is the responsible author for a Quality Impact Assessment (QIA). The QIA author is responsible for ensuring that the QIA is completed, recorded, approved and reviewed in accordance with this policy and any related operational procedure guidance.

7 Why, when and how often should a quality impact assessment be undertaken?

7.1. Why should a QIA be undertaken?

Completion of the QIA is a continuous and dynamic process to help decision makers fully think through and understand the consequences and potential impact of financial and operational initiatives. They support evidence of fair and proportionate reasoning and a robust process for making challenging decisions about local healthcare services. They provide assurance that actual or potential risks to patients have been sufficiently considered and mitigated, particularly for decisions that may be considered contentious. A QIA will also support the avoidance of false assurance regarding a scheme that may have been underpinned by anecdotal or subjective opinion. Undertaking a QIA often requires a close collaboration between scheme leads and clinicians and this supports a framework for engagement and strengthens the rationale for the implementation of a scheme.

7.2. When should a QIA be undertaken?

Quality Impact Assessments must be initiated as part of the development and proposal stage of all commissioning decisions, financial recovery plans, business cases, service redesign, strategies and any other plans for change that have a direct or indirect impact on patient care. QIAs must be initiated as part of the development and proposal stage of developing plans in order that necessary mitigation can be agreed as essential components of project implementation plans. QIA approval must be in place before a scheme commences implementation. The approval process is outlined in **appendix 1.** Quality Impact Assessments should be reviewed and updated as part of other on-going evaluation of a scheme during implementation. Where the components of a scheme change and delivery is modified due to the emergence of new evidence or performance data, an updated Quality Impact Assessment should be undertaken.

7.3. How often should a quality impact assessment be undertaken?

QIAs should be reviewed on a regular basis by the project lead, as part of reviewing the actual impact throughout the project initial implementation as well as during formal

evaluation. Following initial Chief Nurse approval, emerging and unexpected issues and changes in risk scores (where implementation clarifies that an estimated risk score is actually less or more significant than anticipated) should be captured within the Verto risk log and project documentation and the Quality Team notified. The frequency of quality impact review will be proportionate to the level of risk identified and the expected response time of the project outcome. Review will be a minimum of monthly during the initial scheme implementation phase and will be documented in scheme highlight reports (within the mandated Quality Impact Update section).

A summary of quality impact over the course of the implementation of a scheme will be documented at the point of formal scheme evaluation Consideration of the impact of a scheme on healthcare quality is as important as the intended financial and key performance outcomes.

The Quality Team will, 12 months after the approval of a QIA, review scheme highlight reports and the scheme risk log in Verto, to consider and then provide assurance that on-going impact is being safely managed.

8 What should be considered when undertaking a quality impact assessment?

The QIA template for completion can be found in Verto and outlines the areas to be considered under the three domains of quality. A copy of the template can be found in **appendix 2**. Consideration must also be given to aspects of safeguarding when making a judgement about impact and risk. Where there is the potential for an impact on children a 'safeguarding children impact assessment' must be completed and submitted to the Worcestershire Safeguarding Children Board (**appendix 5**).Further guidance and the current template can be found on the Local Safeguarding Children Board (Worcestershire) website. A 'how to' guide for completing a QIA is included within Verto and can be found in **appendix 3**.

QIA authors are requested to consider the realistic timescales required for enabling project assurance and approval processes to be completed, prior to project initiation.

9 Process for raising concerns

Where the Chief Nurse does not have assurance that mitigating actions are sufficient to reduce an identified risk, the QIA will not be approved and a recommendation will be made for the risk mitigation or the overall scheme to be modified or for the scheme implementation to be considered by the Executive Team. CCG Patient and Public Involvement representation will be included in the QIA Approval Review Panel to ensure transparency and represent the patient voice.

There may be occasions where a service transformation or change is required, informed by a commissioning decision, where the risk of not intervening is as great or greater than the quality impact of the proposed change. Where risks identified within a QIA for a scheme that has been approved for implementation, are scored at 8 or above and cannot be mitigated further, the nature of the risk must be clearly documented on the CCG Risk Register by the scheme lead. New risks added to the register and progress for mitigating risks that are scored at 15 or above, will be reported to the CCG Quality, Performance and Resource Committee.

Where patient safety, clinical effectiveness or patient experience concerns are identified within the implementation of a scheme, either through the planned monitoring of outcomes or via another route such as staff or patient feedback, they should be escalated for review with the Quality Team in the first instance.

10 Monitoring

The implementation of this policy will be monitored by the Quality Team and Associate Director of Nursing and Quality on behalf of the Chief Nurse. The completeness and accuracy of Quality Impact Assessments will be monitored in line with the process detailed in appendix 1.

11 Equality Impact Assessment

In applying this policy the Clinical Commissioning Groups for Worcestershire will have due regard for the need to eliminate unlawful discrimination and promote equality of opportunity, particularly in regard to the protected characteristics under the Equality Act 2010. All Quality Impact Assessments will be accompanied by a Equality Impact Assessment to ensure that changes to services as a result of commissioning decisions do have result in intended or unintended discrimination.

12 References

National Quality Board (2013) How to: Quality Impact Assess provider Cost Improvement Plans.

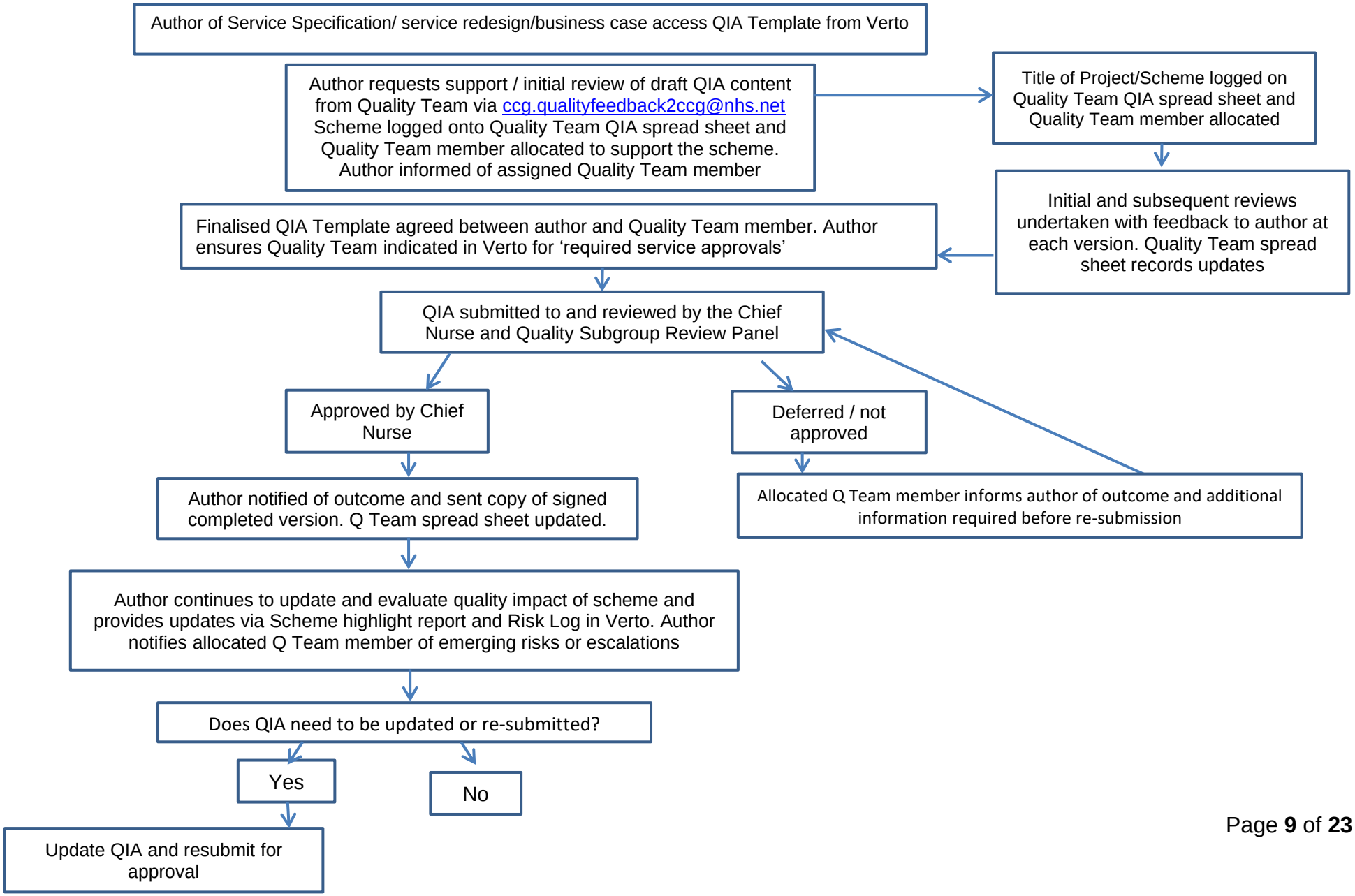
NHS Providers (2015) Good Practice in Quality Impact Assessment. Foundation Trust Network.

13 Associated Documentation

The Quality Impact Assessment template is provided in appendix 2.

The Safeguarding children impact assessment template is provided in appendix 5.

Appendix 1 - Quality Impact Assessment Approval and Review Process



Appendix 2 - Quality Impact Assessment (QIA)

An impact assessment is a continuous process to ensure that possible or actual business plans or changes to NHS service delivery are assessed and the potential unintended consequences on quality are considered, with necessary mitigating actions outlined in a uniformed way. It is a continuous process to help decision makers consider the consequences of financial and operational initiatives (e.g. Commissioning decisions, business cases, transformation projects and other business and financial plans). Impact Assessments must be undertaken as part of the development and proposal and planning stages of initiatives and should also be reviewed regularly by the project lead, as part of reviewing and reporting of the actual impact throughout the implementation stage, during implementation and through follow up monitoring.

Scheme Name :			
Project Lead and author of Quality Impact Assessment		Date final version of Impact Assessment agreed	
Clinical Lead involved in informing the Impact Assessment:		Other forums and engagement groups involved in informing the Impact Assessment:	

Version control		
Version	**Date**	**Summary of changes made**
Version 1		
Version 2		
Version 3		

Summary of scheme overview, scope and proposed service changes	
Scheme Quality Assurance	
In what forum will agreed key quality indicators be reported and monitored? Who is the responsible Chair?	
How frequently will indicators be reviewed?	
Quality indicators – please list, against each one of the three headings below, the quality indicators that will be used to inform monitoring of the impact of the scheme.	
Patient safety and potentially avoidable harm	

Clinical effectiveness including clinical outcomes	
Patient experience	

Please list all potential individual risks under the headings below and include how the risks will be mitigated to reduce likelihood of occurrence									
Risk	**Outline of Risk**	**Probability(P):** **1.Rare** **2.Unlikely** **3.Possible** **4.Likely** **5.Certain**	**Consequence (C);** **1.Insignificant** **2.Minor** **3.Moderate** **4.Major** **5.Catastrophic**	**Score;** **P x C**	**Mitigation from these risks**	**Probability(P):** **1.Rare** **2.Unlikely** **3.Possible** **4.Likely** **5.Certain**	**Consequence(C);** **1.Insignificant** **2.Minor** **3.Moderate** **4.Major** **5.Catastrophic**	**Score;** **P x C**	**Progress against the mitigation**
Patient Safety Risks *(add further lines below as required)*									
1									
2									
3									
Clinical Effectiveness Risks *(add further lines below as required)*									
1									
2									

3									
Patient Experience Risks *(add further lines below as required)*									
1									
2									
3									

Nursing and Quality Team Reviews

Name	Job Title	Date	Outcome

Chief Nurse Sign off:

Name	**Signature**	**Date**
Lisa Levy		

Appendix 3 - Undertaking a Quality Impact Assessment

Getting started

The Project Lead is responsible for liaising with the lead clinician and others for completion of the QIA. The impact assessment will be more effective if it is commenced at the start of initial discussions about the scheme and is completed by collating the contributions of more than one person. Consider bringing a small group together to include at least one clinician, a member of the CCG Quality Team and a patient representative to initiate the QIA. This will provide a wider perspective and breadth of knowledge than trying to complete it as a lone author.

It is important to use valuable data available to both inform the impact assessment and act as a benchmark from which to evaluate scheme implementation. Teams across the CCGs will hold helpful information that may be used to benchmark the pathway that is being considered for re-design. Helpful indicators to monitor the quality impact of change may include:

- Serious Incidents and incident trends
- Complaints data
- Available clinical outcomes
- Patient stories
- Patient survey feedback (including Friends and Family Test)
- Soft intelligence via available clinical or patient forums
- Adherence to available NICE guidance
- External inspection outcomes and ratings
- Service concern feedback from General Practice to locality teams or the Quality Team.

Identifying potential areas of impact

The QIA must include the assessment of areas of potential impact for patient safety (exposure to avoidable harm), clinically effective outcomes, patient experience.

Most schemes should and will enable quality benefits to be evidenced as a direct or indirect result of the scheme implementation. This may include:

- Care closer to home
- Improved care continuity due to reductions in handovers between teams
- Care delivered by trusted or familiar primary care clinicians
- Reduced exposure to the risks associated with acute care including healthcare acquired infections, medicine errors
- More timely access to secondary care for those with the most acute needs
- Reductions in unwarranted variation
- Reduced rates of adverse events which may include condition specific mortality, re-admission rates, delayed diagnosis

All areas of potential benefit may also become areas of risk if they are not realised because the implementation of change is not appropriately managed. Intended scheme outcomes may be delayed or never realised due to specific challenges (for example, recruiting staff with sufficient competency to key posts). Action to resolve or mitigate areas of potential negative impact should be detailed within the mitigation section of the QIA for each area identified. Action can then be built into scheme initiation plans or specifications that will actively reduce the potential for any negative impact identified. This detail must be included even where action has already been taken as it will provide evidence that consideration has been given to known risks. Where risk scores remain high as no effective mitigation is available, contact the Quality Team to discuss your concerns at the earliest opportunity. For more information on possible areas of impact, and for examples of how impact areas may be mitigated, see the guidance in **Appendix 4** (also available in Verto).

Approval process

The full process to approval is outlined in **Appendix 1** (Quality Impact and Risk Assessment Process). The amount of time it takes to complete a QIA varies depending on the complexity of the scheme. The QIA Review Panel meets monthly and so authors are strongly advised to allow sufficient time to complete and make required amendments to the QIA prior to the intended start date of the scheme. The key elements against which the policy/strategy/service development needs to be assessed are detailed on the QIA template (**see Appendix 2**)

Appendix 4 – Guidance for Completing Quality Impact Assessment

	Considerations	Possible outcome	Options for mitigation
Patient safety	Will clinical risk assessment be compromised due to barriers of access to patient medical history?	Treatment decisions omit to consider contra-indications which result in harm.	Specification will outline requirements for access to patient information systems.
	Will transitions to new providers result in gaps in SOPs that may contribute to harm?	Patients present late and in a state of deterioration to clinicians	Referral forms will request specific information to enable safe clinical decision making.
	Are there aspects of expected self-care that patients may not adhere to that have harm implications?	Those who are less able to communicate their needs have poorer access to services	Self-care expectations and the implications of non-compliance must be clearly detailed in an accessible format.
	Is there a risk that patients with high clinical need will not access the service if they are less able to articulate their needs?	Harm caused due to delay in identifying deterioration	Clear plans for when to escalate changes back to clinician communicated to patients and referrers at initial assessment
	Has the criteria for the frequency of clinical review changed where there is the potential for harm to not be detected or for there to be a delay in detection?	Harm caused due to gaps in provision or misunderstanding about pathways	Required clinician competency will be detailed within specification
	Has the role or the expectation of the competency of the clinician delivering the intervention changed where there is the potential for harm to not be detected/ detected late?	Delayed or missed diagnosis	Specifications will outline the need for clear SOPs to ensure safe pathways between providers/ teams

	Considerations	Possible outcome	Options for mitigation
Clinical Effectiveness	Will the change in service result in lack of continuity across the MDT pathway, resulting in risk of duplication/ cross-over or gaps?	Treatment outcome relies on aspects of self-care that are not adhered to resulting in reduced effectiveness.	Clear expectations included in specification regarding need for provider partners to work together effectively.
	Will guidance be more or less likely to be implemented/ adhered to?	Clinicians fail to adhere to guidance resulting in reduced effectiveness.	Communication and engagement will be prioritised- public, clinicians, media
	Are there aspects of expected self-care that patients may not adhere to?	MDT functioning is impaired resulting in disjointed care	Adherence will result in greater consistency in access
	May changes in service threshold result in an increase in acuity of patient need that impacts on services in other ways (ie longer length of stay, more complex intervention required)?	Greater acuity of need/ late presentation of high clinical need	KPIs will be applied to new services to enable impact to be clearly understood following implementation. This will permit emerging unintended consequences to be identified early and addressed as required.
			Service concern alerts to CCGs will enable feedback to inform evaluation post implementation
			Clinical consultation will inform impact awareness

	Considerations	Possible outcome	Options for mitigation
Patient experience	Will people be required to travel to alternative or unfamiliar places to access treatment? Will the change in service require a change in expectation or perceived 'loss'? Will familiar patient/ clinician relationships be affected? Will those requiring public transport be adversely affected?	Inconvenience Loss of confidence due to change in relationship/ unfamiliar clinicians Reduced confidence in health care may lead to reduced engagement (eg DNAs) Reduced confidence may lead to risk to reputation or heightened media interest.	Clear communication strategies with the public will be agreed. Clinicians will be briefed and supported to communicate a clear message about changes to patients at the point of referral, in a consistent manner. Patient safety benefits will be highlighted so that the rationale for changes in proposed venue is clearly understood. Liaise with partners to ensure travel arrangements are considered and options are communicated as part of the engagement strategy.

Appendix 5 - Safeguarding Children Impact Assessment

Safeguarding Children Impact Assessment

A recent Case Review in West Mercia found that *"re-organisations of services by individual agencies are not planned in a multi-agency way, which means that there may be unintended consequences that can lead to confusion amongst partner agencies, resulting in poor accountability and decision making, which ultimately does not safeguard children".*

Name	
Agency	

Section 1

Please give description of development/proposal/policy etc.	
What is the aim or purpose?	

Is there a direct or indirect impact upon children? **Yes**

If **yes,** please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; positive or negative; competing / conflicting impact between different groups of ch&yp)	
If **no,** please describe why there is considered to be no impact/significant impact on children	

Section 2

Impact requires further consideration / assessment.

- Further information / evidence
- Consultation

Review of the effectiveness of policing model and implementation will take place informed by the HMIC Vulnerability PEEL Effectiveness Inspection 2016, findings from which have not yet been published, and the National Vulnerability Strategy, and in line with College of Policing good practice and HMIC recommendations.

Has there been a consultation with children / young people?

If **yes** nature and outcome of consultation (may be drawing on previous consultations/views)	
If **no** reason for not consulting with children and young people	.

Assessment signed off by (Strategic Lead for the scheme):	
Signature:	
Date:	