Summary of the Document

This paper summarises how the Success Regime (and subsequent Sustainability and Transformation Planning) has monitored and assessed risk in various options for the future, a process that has been different from the ‘risk register’ approach for managing current services.

Summary of Conclusion:

System and population risks and challenges have been assessed in the Success Regime process and proposed clinical strategy and service options have been reviewed against those risks in reviews of impact, ranging from health and fairness to population travel requirements and ability to attract staff.

It is equally important that risks to individual patients (and patient groups & categories) are considered and mitigations planned or simulated when service change is considered (just as they are under constant review for existing services). The clinical groups considering service change options have looked intensively at these issues using all avenues of evidence, policy, expert advice and debate against a quality framework of safety, outcomes and experience (captured in quality impact assessment).

Consultation has demonstrated that public and professionals nonetheless want more information on both risk and possible mitigations, especially for individuals in the particular circumstances of their needs and location. Whatever options are preferred in the decision making process, implementation planning will need further scenario planning and consistent joint work with communities to understand and plan for the agreed important risks and issues.

Some themes about perceived risk have emerged in the consultation process, including everything to do with maternity (and an emphasis on the hazards and risks of labour), travel times and potential lost opportunities for particular early treatment and care options alongside acknowledgement of the severe system risks associated with recruitment and capacity in the system.
Appendix 5

Healthcare for the Future in West, North & East Cumbria
Approach to Risk Explanatory Paper
February 2017
Our approach to Risk

Introduction

1. An important feature of the Public Consultation response was regular feedback from the public (and some professionals) that no consistent assessment of risk had been done, and that a documented risk assessment was not available in expected format.

2. During the development of the options published in the Healthcare for the Future consultation document, risk was considered and assessed in a number of ways and, of course, risk assessment is a routine part of day-to-day service provision within the NHS.

3. The term “risk assessment” can be used to describe how impacts have been considered and assessed in various ways, including

   - Benefits: are services as existing or proposed capable of consistently delivering the expected outcomes for patients?
   - Safety: are the potential hazards of services as existing or proposed understood and any risks of harm from those being approached with appropriate mitigations?
   - Patient experience: are services as existing or proposed likely to improve or compromise dimensions such as waiting times, communications, environmental factors and other context circumstances
   - Equality impact: are services as existing or proposed likely to be fair to potential recipients as individuals or populations?
   - Health needs: do individuals or populations have needs that services as existing or proposed can contribute to?
   - Cost: are finances under control and what are the possible issues related to loss of control?

4. The first three of these factors: outcomes, safety and experience, are brought together under the umbrella of “quality” and the process of developing options for Healthcare for the Future included quality impact assessment. During and after consultation, the quality impact assessments have been updated, alongside other impact assessments such as equality, health, travel and finance.

5. As part of good governance, NHS organisations will identify significant risks and use standard processes to assess existing services (be they financial, safety, logistical or however defined) to enable any risks to be prioritised. Usually this would include classification of the likelihood of the risk being expressed and the impact if it is expressed. Using a simple scoring system, risks can then be prioritised. (i.e. priority given to those risks which combine high likelihood with high impact). Mitigation and contingency plans would be made for priority risks. These assessments would be maintained in a risk register.

6. These processes will be familiar in many industries and in standard programme and project management.
7. This paper summarises how the Success Regime (and subsequent Sustainability and Transformation Planning) has monitored and assessed risk in various options for the future, a process that has been different from the ‘risk register’ approach for managing current services.

Making judgements of risk for Healthcare for the Future

8. Pooling knowledge of the risks the NHS and its partners in West, North and East Cumbria were facing gave the Regime an overview of the highest priority ‘challenges’ the system was facing. Each of these challenges came from high likelihood, high impact risks.

8.1 Without clear strategy and balanced investment for health promotion, prevention and clinical services, the overall health of the population will not be as good as other comparable parts of the country. It is not.

8.2 Without the right staff, important services cannot be maintained or consistently delivered. Locally the NHS finds it very difficult to attract and retain the doctors, nurses, paramedics and other staff that are needed.

8.3 Without appropriate community services and other relevant mitigations, too many people are admitted to hospital or stay too long in hospital which wastes resources and can impair likelihood of best possible outcomes.

8.4 Without delivering the right efficiencies and effective strategies the NHS cannot manage within the resources allocated to it. The resulting over-spend, the financial gap, had been growing and affects the ability to mitigate other risks.

8.5 Without the right strategies, the right staff, the right balance of services and the right investments, the overall quality of services would suffer and the Care Quality Commission (which inspects and regulates health and social care services) would declare some services to be inadequate or in need of improvement. This is exactly what was happening.

9. These risks are nationally recognised and summarised as the health and wellbeing gap, the care and quality gap and the funding and efficiency gap.

10. The mitigation of these risks was known to be difficult because of some important local features, including: the significant & growing proportion of older people, the dispersed and rural communities separated by relatively large distances, the distance from specialised service centres and the history of service delivery patterns.

11. In considering the overall mitigation of these population and system based risks and the locally relevant challenges, the Success Regime planned a process that included:

11.1. Review of the current state of services (including the views of CQC and other regulators)

11.2. Review of past plans and strategies to understand the successes and failures of implementation of previous mitigations (including the 2014 RCOG review of Maternity)

11.3. Review the national and international evidence base, national policy and guidance.
11.4. Asking for expert advice (from local clinicians & leaders, national respected leaders in their fields, the regional and specialist services, the Strategic Clinical Networks, the Clinical Senate and national clinical leads)

11.5. Asking patient representatives, community leaders and other local stakeholders

12. Based on advice and evidence, in March 2016 the Success Regime published a clinical strategy and the process outlined above was then further iterated in a range of specific service and clinical areas where some of the risks (for example recruitment, as in Paediatrics) or mitigation advice (for example the identification of specific service gaps, as in hyper-acute stroke care) had been highlighted.

13. This further work led to a variety of options for change and these were tested, first against:
   - their ability to mitigate risks of missing essential standards for quality;
   - their ability to be delivered in light of risks like recruitment;
   - their ability to mitigate the financial risks;

and then the short-listed options were examined again (jointly with wider stakeholders) against their ability to mitigate the health & wellbeing gap, the care and quality gap, the funding and efficiency gap and to test their ease of delivery. This process is described in detail in the Pre-consultation business case.

14. Each option was subject to an iterative process of quality impact (with a particular emphasis on clinical outcomes and safety), equality and health impact and the Success Regime programmed additional work on travel impact.

15. The safety and outcome work was reviewed by the North West Clinical Senate.

16. Some of the proposals involved substantial developments or variations in the provision of services and were therefore subject to a formal public consultation process.

17. At this point, the focus of scrutiny of risk assessment shifted from system risks as identified in paragraph 8 above to individual risks for specifically defined individuals, that is from a population assessment of risk to a patient based assessment of risk (not exclusively, of course. Patient risks were central to the process outlined above and system risks were much debated in the consultation process).

18. Inevitably this changed the dialogue from mitigating a system risk (“You need to have a hyper-acute stroke unit and the most likely way of implementing such a development is one of these options...”) to the perceived lack of mitigation of a personal risk (“Someone who lives in Seascale cannot get to a stroke unit in Carlisle quickly enough to benefit from all possible therapy options”). This dialogue was particularly intense in discussing the hazards associated with intra-partum care (women in labour).

19. It was very apparent in the consultation, and reflecting upon the responses, that there was a mismatch of expectations between some consultees and the Success Regime. Some members of the public and a few professionals expected to see and hear about ‘risk assessment’ in particular formats (both the [likelihood] x [impact] = score and the
statistical evaluation of the evidence) whereas the expert opinion and advice, whilst based particularly on the evaluation of evidence and experience, most often was in the form of qualitative review.

**Weighing up risk – why we have most often quoted risk assessments qualitatively rather than quantitatively**

20. There are four principle reasons:

20.1. The sum of evidence, guidance and policy has gaps and applicability problems that require expert opinion rather than simple quantification

20.2. System and population risk mitigation inevitably requires trade-offs that require opinion and may not be amenable to quantification

20.3. Prior to decisions on the principle of options, detailed implementation planning cannot be done and therefore detailed risk quantification for individuals and all population subgroups is not possible (clearly, due diligence requires some scenario planning and the clinical groups have debated these issues at length)

20.4. Risk quantification is different for individuals (where the impact is always hugely important) than it is for populations and so the mitigations are different. This process was to decide system mitigations for population scale risks – it acknowledges the detail for some individuals still requires mitigation and contingency planning.

21. For example, in the consultation document, in the discussion of risk and impact, the maternity option 1 (a consultant and midwife led unit at both hospitals) is acknowledged to be better for access but more difficult for achieving clinical standards; it would enable consultant care in Whitehaven but risks future unsustainability because of problems in another service (paediatrics). Furthermore (in the discussion of option 2) it was clear that for system risks such as ability to meet standards and deliverability the proposal had merit, resolving obvious transport problems for individuals would need to be done.

22. One helpful part of the consultation process was to test the quantification (of evidence) that had been done. Here the issue of debate was the interpretation of the same evidence. So, for example, is extra travel time for mothers in labour dangerous? Our expert advice was that most of the hazards did not have statistically significant impacts for populations of women who lived within 4 hours of the unit where birth was planned – and indeed it was difficult to interpret the applicability of the studies done elsewhere to the specific services planned for Cumbria. In summary, the view was that all the proposed options where capable of delivering equivalent outcomes and none were unsafe (and indeed the options may be capable of improving some different risks – e.g. of stillbirth). Some responders were unimpressed with this summary and quoted the same evidence as showing, in particular circumstances, individual standards couldn’t be met and individual mothers and babies had excess risk. It appeared to be no comfort to hear that our scenario planning indicated those circumstances were extremely unlikely. (The challenge to our expert advice led to review and confirmation of the opinion)
Specific individual risks and mitigations for our preferred options

Maternity

23. The attached appendix details the hazards and risks and the overall mitigations associated with the all maternity options (NB the preferred option was option 2)

24. Whichever option is chosen, clearly more assurance is required on the perceived risks associated with travel – considered from the expert analysis of evidence to be unlikely with respect to overall outcome but from the public views, clearly high impact on mother and family experience (for progressively larger numbers in options 2 and 3).

Children

25. Two risks were widely identified for the preferred option 1 (and each increased in perceived likelihood with options 2 & 3):

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigation</th>
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<tbody>
<tr>
<td>Children’s condition might deteriorate during increased travel or transfer times</td>
<td>No evidence was found that the impact of this risk was likely to be significant, like maternity the perception created fearfulness. Scenario planning and standard operating procedures for urgent care and ambulance staff would help.</td>
</tr>
<tr>
<td>There might be increased demand to stabilise and treat children prior to transfer</td>
<td>This risk mitigation falls particularly on A&amp;E staff at WCH, and other urgent care staff and ambulance staff. Training, standard operating procedures and innovations in telehealth should all be employed. Option 1 would have an on-call paediatrician out of hours.</td>
</tr>
</tbody>
</table>

26. Whichever option is chosen, clearly more assurance is required on the perceived risks and loss of experience associated with travel.

Community Hospitals

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigation</th>
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</table>
| (System risk) The reduction in total beds in an already ‘pressured’ system would create more problems for the acute hospital sites and access for local services to local people | 1. There are clear opportunities to reduce patients with ‘delayed transfers of care’ (ICCs etc.) and the beds available for acute care and rehabilitation would increase  
2. The clinical strategy assumes ability to prevent admissions and reduce length of stay, increasing flow through the acute system and reducing the need |
Increased travel / loss of local access for vulnerable older people | Local planning (as per the Maryport Alliance alternative proposal option 2) and co-production of a population based health system reduces dependency on beds and creates a large net increase in locally accessed care

### Emergency and acute services

<table>
<thead>
<tr>
<th>Risk</th>
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</thead>
<tbody>
<tr>
<td>Patients with severe and complex conditions may lose opportunity for key treatments in the ‘golden hour’ and during travel and/or transfer times</td>
<td>Mitigations again fall to urgent care staff in and out of hospital, including in the ambulance service. Training, telehealth, standard operating procedures and community partnerships (like first responder schemes) will all contribute.</td>
</tr>
</tbody>
</table>

### Hyper-acute stroke

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Patients with stroke may lose opportunity for key treatments in the ‘golden hour’ and during travel and/or transfer times</td>
<td>Mitigations again fall to urgent care staff in and out of hospital, including in the ambulance service. Training, telehealth, standard operating procedures and community awareness to avoid delays in seeking treatment will all contribute.</td>
</tr>
</tbody>
</table>

### Emergency surgery, trauma and orthopaedics

<table>
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</tbody>
</table>
Conclusion

27. System and population risks and challenges have been assessed in the Success Regime process and proposed clinical strategy and service options have been reviewed against those risks in reviews of impact, ranging from health and fairness to population travel requirements and ability to attract staff.

28. It is equally important that risks to individual patients (and patient groups & categories) are considered and mitigations planned or simulated when service change is considered (just as they are under constant review for existing services). The clinical groups considering service change options have looked intensively at these issues using all avenues of evidence, policy, expert advice and debate against a quality framework of safety, outcomes and experience (captured in quality impact assessment).

29. Consultation has demonstrated that public and professionals nonetheless want more information on both risk and possible mitigations, especially for individuals in the particular circumstances of their needs and location. Whatever options are preferred in the decision making process, implementation planning will need further scenario planning and consistent joint work with communities to understand and plan for the agreed important risks and issues.

30. Some themes about perceived risk have emerged in the consultation process, including everything to do with maternity (and an emphasis on the hazards and risks of labour), travel times and potential lost opportunities for particular early treatment and care options alongside acknowledgement of the severe system risks associated with recruitment and capacity in the system.
## APPENDIX: Maternity Options: Summary of Principle Hazards, Risks and Mitigations

<table>
<thead>
<tr>
<th>Known Hazards</th>
<th>Identified Risks if no change agreed</th>
<th>Mitigations offered by the proposed options</th>
<th>Other considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>“pre-pregnancy” advice and care not accessed or not well provided</td>
<td>There is a possible lack of emphasis on strategy to manage public health hazards' associated with many problems (from failure to conceive to subsequent still birth and birth defects) and constant emphasis on ‘place of birth’ could distract individuals, commissioners and providers of services</td>
<td>For all options: Ending uncertainty about how services might be configured for place of birth is urgent and should allow progress to be made on wider health &amp; pregnancy issues.</td>
<td>The “Integrated Care Community” (ICC) way of working outlined in the Success Regime clinical strategy will deliver better strategies to tackle public health and inequalities</td>
</tr>
<tr>
<td>Antenatal care not accessed or not well provided</td>
<td>Again, the huge emphasis on ‘place of birth’ and possible associated risks may downplay the huge importance of good antenatal care – which is commenced early in pregnancy – in the prevention of complications and reduction in bad outcomes</td>
<td>For all options: A full antenatal service is offered, including consultant clinics at WCH – and all services are part of a regional network that includes very specialist advice and care (e.g. genetic issues, unusual pregnancy complications or baby health issues) accessed in Newcastle. The intention to implement the Maternity hub concept in line with ‘Better Births’ Better births implementation will also concentrate on continuity of carer throughout the pregnancy.</td>
<td>Again, the ICC and ‘Better Births’ philosophy brings in GPs, community midwives, public health specialists and community leaders to deliver better antenatal care alongside public health strategy and a range of children’s services</td>
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<table>
<thead>
<tr>
<th></th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
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</thead>
<tbody>
<tr>
<td>CLU both sites</td>
<td>MLU at WCH, CLU+MLU at CIC</td>
<td>Consolidation at CIC</td>
<td></td>
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<tr>
<td>Unplanned or unexpected birth away from professional care</td>
<td>Longstanding doubts about future of services may cause confusion about intended or best place for birth, leading to delay and not getting to desired unit on time</td>
<td>For all options: Ending uncertainty about how services will be configured for place of birth is urgent and will allow planning. Better births implementation includes a renewed emphasis on birth plans, including planning to get to place of birth. Although some births will have to book delivery at CIC or Newcastle, the large majority of women can book at a consultant unit of their choice, including at WCH</td>
<td>Absolute clarity on place of birth will support individual planning for labour. The publicity and debate about maternity has raised awareness of this issue. Unplanned delivery ‘out of hospital’ (Born Before Arrival) is rare but interest in the issue should reduce incidence.</td>
</tr>
<tr>
<td>Complications occur during labour*</td>
<td>1 Both current units are small and relatively isolated and the Kirkup report on Morecambe Bay identified clear risks associated with training, culture and behaviour by and between professionals</td>
<td>For all options: single team working (across the different sites) will support exchange of ideas, expertise and leadership amongst the midwives and consultants Risk assessment during pregnancy will engage both CIC and Newcastle as possible planned venues for care during labour (for complex and anticipated ‘high risk’ pregnancy)</td>
<td>A single bigger unit will allow development of MLU care and CLU care on one site with clearer leadership and single ethos. The process of considering options (which itself built upon the review by the Royal College of Obstetricians &amp; Gynaecologists) has led to stronger connections with the regional maternity network, itself a safeguard against relative isolation and supports the development of local teams and clinicians.</td>
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<tr>
<td>Complications occur during labour (cont.)</td>
<td>2 Both current units are small and find it difficult to recruit and retain sufficient staff creating problems of continuity and cover (more locums and agency staff)</td>
<td>A clear decision removes uncertainty</td>
<td>Increased autonomy and expertise will be attractive to some staff</td>
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<td></td>
<td>Potential risks needing support are identified early and care is planned at CIC or Newcastle so fuller paediatric cover is available (NB of course this is a strong feature of current services)</td>
<td>Only women with anticipated lower risks will be booked at stand-alone MLU. Dedicated transport will be available and a specialist retrieval system will operate for babies who need additional care after birth</td>
<td>Arrangements for all supporting speciality services are easier to arrange for one-site working. Proximity to Newcastle makes some specialist jobs easier to recruit into</td>
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<tr>
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<td>3 Both units are small and – particularly at WCH - have regular difficulties maintaining staffing for necessary supporting specialities such as paediatrics and anaesthetics</td>
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<td></td>
<td>4 There is sometimes a need to transfer mothers during labour (including occasionally to Newcastle) and if no change is agreed there is the possibility of unplanned movements of mothers and even relatively short-notice unit closures as staffing issues persist</td>
<td>The reduced uncertainty over the future allows for better planning, more innovative staffing models and more stability reducing the risks of unplanned service discontinuity</td>
<td>More mothers will transfer in early labour as MLU care indicates need for consultant cover (usually because of pain relief issues and delay in progression of labour). Dedicated transport will be available</td>
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There is one further hazard worthy of fuller discussion: clearly the wellbeing of the mother (and baby) can be affected by both unfounded anxieties and concerns alongside all the real and rational worries associated with pregnancy. This becomes a risk at every stage in the framework above and the consultation process has shown it is a particular concern at the time of labour (although obviously exists at every stage and continues after birth). The mitigations for these wellbeing risks cover all of the technical issues discussed above (from teamwork and continuity in ante-natal care, transport to place of birth to access to pain relief) but the necessary mitigations are clearly wider and raise all of the important developments highlighted in ‘Better Births’. There is little doubt that mother and family experience can and should be improved.

The change process itself is a cause for concern and fearfulness. Mothers, midwives and many others have emphasised the need to work on a better vision of how “21st century” maternity care could be and seeing that better future is a required mitigation to the worries of what might happen to existing services.

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1 There are many general issues for good health (like exercise, smoking, obesity, excess alcohol etc) that can impact on chances of a healthy pregnancy and some very specific ones like folic acid supplements to prevent some birth defects. See [https://cks.nice.org.uk/pre-conception-advice-and-management](https://cks.nice.org.uk/pre-conception-advice-and-management)

2 See [https://www.nice.org.uk/guidance/cg62](https://www.nice.org.uk/guidance/cg62)