CHC PCCC Deliverables Consolidated Report

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Editor: Dipak Kalra

Table of Contents

1. Executive Summary

Working towards one of Connected Health Cities main aims of stimulating economic growth across the North of England, CHC has been engaging with numerous companies. The CHC Hub launched a consortium for companies active in the health ICT sector, the Pre-Competitive Collaborative Consortium (PCCC), in November 2017. This consortium ran until March 2019, when it closed in its present form. A lighter-touch continuation strategy is being explored.

The objective of the PCCC was to tackle common (pan-industry and NHS-wide) problems in health technology research, innovation, procurement, delivery and sustainability, focusing on the north of England as the co-creation environment for possible solutions. The PCCC was a collaboration between industry, the health service and academia, serving as a trusted eco-system for the public-private sharing of insights into better opportunities for the deployment of eHealth, pHealth and mHealth products and services, and how to overcome the barriers to sustainable adoption, interoperability and scale-up.

When considering the challenges of getting novel ICT products and services adopted across the NHS, there was consensus amongst the PCCC industry members, confirmed by the experience of NHS colleagues, that the consortium should focus on two complementary activities to tackle two recognized problems.

Sustainability. Working with NHS and academic change champions to define and promote the success factors that embed innovations within NHS culture and workflows, so that initial ICT pilots are more likely to be sustained as procurements and result in definitive adoption of the innovation.

Transferability. Working with early adopter sites to capture marketable metrics of value: a kind of Kite Mark of trustworthiness and relevant benefit indicators that would help convince subsequent NHS organisations to take on the ICT innovation rather than to insist on undertaking their own pilot, starting from scratch.

Starting with small group meetings and discussions in 2017, multi-stakeholder workshops were held during 2018 in both of these areas, leading to recommendations for the design and evaluations for future ICT-driven innovation pilots. The results of the work done on these two deliverable threads are reported in this document, to capture the learning and insights gained from these PCCC events and public-private interactions.

Recommendations for the design, negotiation, implementation and evaluation of a pilot ICT-driven care innovation, to maximise the likelihood of sustainability as an adopted product, are presented in Section 4. Further work is suggested to enrich and to validate these success factors.

A first candidate set of indicators (metrics) for a Kite Mark assessment of the benefits of a piloted ICT innovation are presented in Section 5. These need further refinement in consultation with NHS decision makers.

Wider multi-stakeholder engagement and prototyping are needed to refine and finalise these results, and to turn them into operational guidance that can be promoted. Consultation will be undertaken during 2019 with the NHSA and the four regional AHSNs on the best ways to achieve this.

2. Background

2.1 The Connected Health Cities Programme (CHC)

Health North: Connected Health Cities (CHC), was a three-year (2016-2019) Department of Health funded health and care project delivered by the Northern Health Science Alliance (NHSA), through the NHSA'S membership of Universities, Hospitals and Academic Health Science Networks. The CHC mission aimed to safely demonstrate innovations in care delivery that lead to improved health for citizens, more effective health and care services, growth of clinical research capabilities and stimulation of the North of England's economy.

With a population of ~15 million people across the 4 northern city regions involved, CHC aimed to improve the efficiency of using patient and population data, to deliver real improvements to local communities. Through advanced data-analytics CHC aims to deliver actionable healthcare information, that improves the way service users access and experience health services.

The CHC pilot projects were allocated a budget of £20m allocated across the North's health research ecosystem to develop new methodologies of health care delivery, across a designated set of care pathways. It partnered with NHS healthcare provider organisations and charities, local authorities, universities, patient and public associations and companies producing healthcare products and services. The project has been managed by the CHC Coordinating Centre based in Manchester, with the care pathways being distributed across four different northern regions; the North West Coast, Greater Manchester, the North East and North Cumbria and Yorkshire and Humber. More information about the CHC, its care pathway projects and its work to foster innovation can be found here: https://www.connectedhealthcities.org

CHC engaged with industry through multiple avenues, including directly through the care pathway projects and in the form of a Pre-Competitive, Collaborative Consortium.

2.2 The CHC Pre-Competitive Collaborative Consortium (PCCC)

The health ICT industry is a vital partner to support CHC in achieving its mission. CHC launched an industry consortium for the health ICT sector, the PCCC, in November 2017. Through the combined efforts of CHC's large stakeholder expertise, clinical recognition and industry input the consortium was carefully crafted, prior to its launch, to ensure it would deliver valuable and relevant insights to all its members and bring benefits to the NHS.

The objective of the PCCC was to tackle common (pan-industry and NHS-wide) problems in health technology research, innovation, procurement, delivery and sustainability, focusing on the north of England as the co-creation environment for possible solutions. The PCCC was a collaboration between industry, health service and academia, serving as a trusted eco-system for the public-private sharing of insights into better opportunities for the deployment of eHealth, pHealth and mHealth products and services, and how to overcome the barriers to sustainable adoption and scale-up.

The PCCC reached a membership of 21 ICT companies, ranging from micro SMEs through to large multi-Internationals, formalised through signed Heads of Terms. It was governed by a Management Board (comprised of equal representation from industry members and all four regions of the CHC, chaired by the CHC Hub director), which met regularly to propose priority issues to be tackled and to oversee governance arrangements. More information about the PCCC, its industry members, objectives and activities can be found here: https://www.connectedhealthcities.org/partnerships/industry-opportunities/

The PCCC prioritised two work streams tackling two key industry challenges to successful innovation.

- Sustainability: Championing change and adoption of innovation

Working with NHS and academic change champions to define and promote the success factors that embed innovations within NHS culture and workflows, so that initial ICT pilots are more likely to be sustained as procurements and result in definitive adoption of the innovation.

- **Transferability: Evidencing the benefits of innovation**
  Proposing marketable metrics of value: a kind of kite-mark of trustworthy and relevant benefit indicators that would help convince subsequent NHS organisations to take on the ICT innovation rather than to insist on undertaking their own pilot starting from scratch. The kite mark indicator areas cover health outcomes, financial, technical maturity and policy alignment.

The PCCC ran until March 2019, when it closed in its present form. A lighter-touch continuation strategy is being explored. It was the wish of its industry members that further work be undertaken to evolve the progress made in both work streams, which this report consolidates as of the end of 2018.

3. Rationale for the two PCCC deliverable projects

When considering the challenges of getting novel ICT products and services adopted across the NHS, there was consensus amongst the PCCC industry members, confirmed by the experience of NHS colleagues, on two areas.

The first of these is local sustainability. Companies indicated that it can be challenging to progress from *ad hoc* conversations with individual clinicians or ICT managers to an NHS organisational agreement for a fully-fledged pilot of an innovation. This is recognised to be an almost inevitable challenge because of the multi-faceted nature of innovations being delivered within the complex NHS socio-technical environment. A senior level NHS change champion who could win the support of colleagues, help to overcome resistance and would promote and support the pilot, was recognised to be a critical success factor for the establishment of a pilot. However, the experience of almost every company has been the failure to sustain their pilot if the change champion leaves or shifts focus onto new priorities, or when a perceived natural period of evaluation has elapsed. ICT pilots usually seem to be pre-destined from scratch to have a short-term life. The additional elements of the pilot that would be needed to embed the innovation more holistically within the NHS organisation seem often to be missing. These sustainability elements include widening the change champion group from a single innovator to multi-professional endorsement including senior management, deriving evidence of clinical and organisational value including business benefit, and ensuring alignment with local and national NHS organisational strategic goals. Companies often undertake pilots at best on a cost recovery basis and sometimes at a loss, and the lack of sustainability is therefore expensive as well as failing to stimulate their market.

The second major challenge faced by companies is the lack of willingness of an NHS organisation to accept findings from a pilot conducted elsewhere in the NHS. There is frequently insistence upon a new fully-fledged local pilot, which might often re-discover the same findings as a previous one, which again loses the company money and might be yet another non-sustained pilot that fails to arrive at a procurement contract. Although this is partly because each NHS organisation believes itself to be unique, it is also because the initial pilots fail to generate evidence that can be considered relevant, trustworthy and acceptable by downstream sites, that would avoid the need for a pilot study to be repeated.

Apart from negative consequences for companies, these challenges prevent or delay the NHS from benefiting from opportunities for innovations in healthcare delivery, and therefore effectively disadvantage patients as well.

In order to address these two complementary challenges of sustainability and transferability, the PCCC organised a series of events, including multi-stakeholder workshops, during 2017 and 2018. The two challenges were examined in detail and recommended practices were identified that could be adopted by industry, and by NHS organisations, to help make pilots more effective. Figure 1 below illustrates how these two deliverable projects were integrated within the overall Connected Health Cities methodology, to benefit from its multi-stakeholder expertise and its commitment to patient care pathway innovation enabled via ICT.
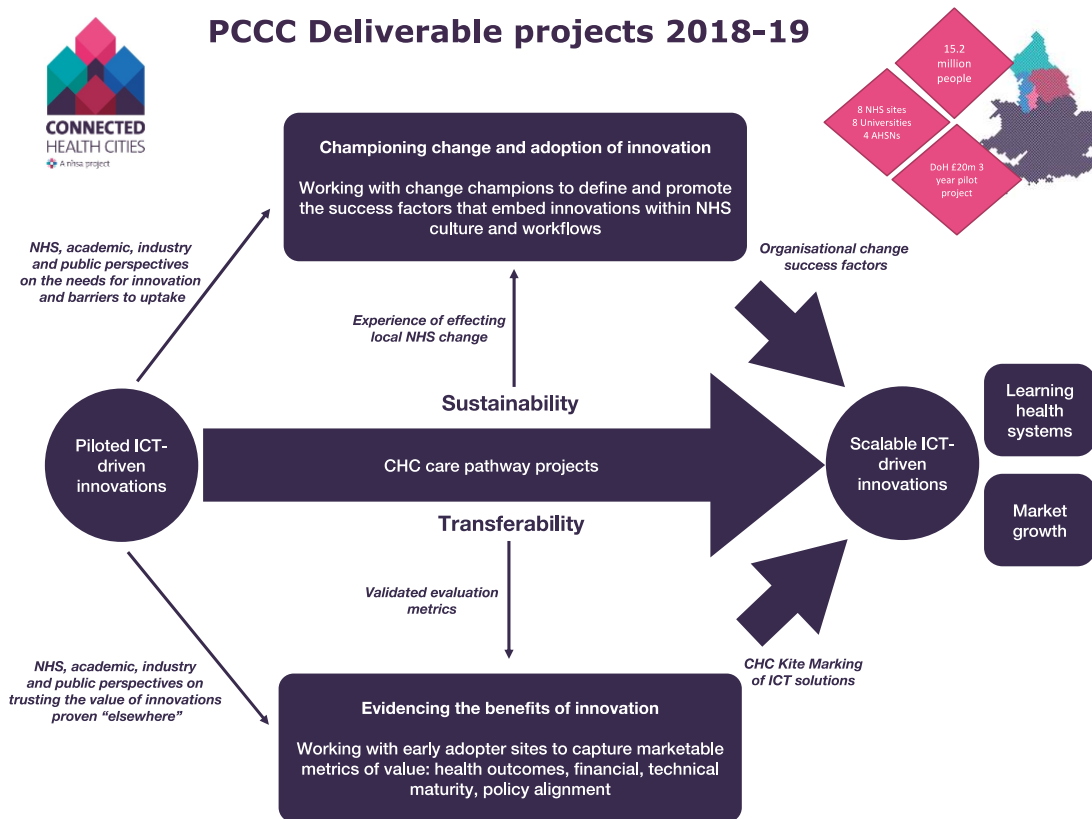
Figure 1: relationship of the two PCCC deliverable projects to the overall CHC methodology

Section 4 of this report summarises the results of interactive workshops with "change champions", to define series of sustainability success factors (good practices) to be taken into account when designing an ICT innovation pilot.

Section 5 presents four main categories of success indicator, with candidate metrics, that could be formally assessed as part of a pilot evaluation. If these can be assessed objectively and independently, or independently verified, it is hoped that these could be packaged as a kind of Kite Mark. A Kite Mark and its detailed indicator scores could be furnished by a company as trustworthy evidence of NHS organisational benefit derived from their ICT product or service.

4. Sustained adoption of innovation

4.1 Overview

This work stream and deliverable benefitted from working with NHS change champions from the CHC care pathways to define and help promote the success factors that embed innovations within NHS culture and workflows. Building on the outputs from a Knowledge to Practice workshop of NHS and academics held in February 2018, a full public-private Change Champions workshop was held in May 2018, attended by around 50 participants. Useful good practice points were distilled from this event, covering the following ten principles.

- Focus on the NHS problem
- Align with NHS strategy and local priorities
- Take NHS and local capacity into consideration
- Consider the impact on clinicians
- Find a route of entry
- Obtain the necessary approvals
- Build and leverage the right relationships
- Present or generate relevant evidence of value
- Incorporate recognised success factors
- Work with AHSNs and the NHSA

Each of these ten is summarised below, with more detailed points arising during the workshops at the end of this chapter. Whilst these issues and success factors are not new, this consolidation highlights the ones that our multi-stakeholder community felt to be the most important and the least likely to have been addressed in pilots they have come across. They are proposed as the most important success factors to be taken into account when conceiving, negotiating, establishing and evaluating a pilot ICT-driven care innovation.

4.2 Summary of recommendations to companies, for sustainable ICT innovation pilots

Focus on the NHS problem

It is important that the innovation is clearly connected to an organisational effectiveness or healthcare delivery problem or unmet healthcare need that the NHS organisation demonstrably has. The benefits to clinicians, patients and potentially to other organisational stakeholders must be clearly specified. At least some benefits should be achievable in the short to medium term.

Align with NHS strategy and local priorities

It is vital to first identify how the innovation aligns with the strategy of the target NHS site and its capacity in change management and other necessary skills, before making contact. It should also be apparent how the innovation enables the NHS organisation to better align with NHS strategy and potentially to better meet its targets. It is more difficult to gain acceptance of an innovation that improves patient care unless this can be linked to cost savings or targets or NHS strategy.

Take NHS and local capacity into consideration

NHS organisations are resource limited, capacity limited and have limits on the extent of change and disruption that can be accommodated at any one time. Investigate what the site would need to have in place in order to adopt the innovation, including any gaps in infrastructure or capacity, or any extra short-term resource that may be required to support transitional adoption. Clearly emphasise any existing inefficient or expensive practices that could be rapidly discontinued by adopting the innovation

Consider the impact on clinicians

It is difficult to get the balance right between innovations that are disruptive enough and have enough impact to make a tangible difference, and innovations that can easily fit into existing practice through introducing sequential small steps. Consider the impact on clinical staff including workload, cognitive strain, integration with existing workload and with existing ICT systems.

Find a route of entry

It is usually helpful to identify a change champion who would greatly support the adoption of the innovation and would orchestrate the necessary acceptance and changes. However, clinical change champions will usually only be effective within their own clinical areas, and may eventually leave or shift focus to other priorities.

Obtain the necessary approvals

It is important to identify if a new product would be classified as a healthcare intervention and may need formal approval (such as MHRA approval), which should be obtained before engaging with healthcare sites.

Build and leverage the right relationships

The adoption of an innovation and it successful sustainability requires the engagement of many healthcare provider stakeholders who need to be brought on board as early as possible. This usually includes clinicians, but may include operational managers, ICT and other decision-makers. It may additionally be helpful to secure buy in from national opinion leaders such as clinicians and CCIOs.

Present or generate relevant evidence of value

The USP of the company and the product should have evidence for how its innovation will meet an unmet need. Evidence the financial benefits as well as other organisational benefits for adopting the innovation. Use pilots and testbeds as a vital opportunity to generate any additional evidence that will be needed for sustained adoption.

Incorporate recognised success factors

Organisational change is very difficult in complex organisations, and historically successful implementations have allocated up to 80% of the total adoption budget to user support and internal communications. Once a pilot is underway, or even beforehand, try to identify the source of continuing post-pilot funding.

Work with AHSNs and the NHSA

Work with AHSNs, who are important for SMEs as they already have established relationships with NHS organisations and have resources to encourage NHS innovation.

4.3 Detailed recommendations for sustainable ICT innovation pilots

Focus on the NHS problem

Advice to companies:

- The case for the innovation should be clearly communicated: it is crucial to convey the problem statement, the specific healthcare need and opportunity and the benefits to clinicians and patients.
- Show the value of the product to the healthcare site / department specifically as well as its wider health care value. It is important to identify in advance who is most important to show that value to.
- Ensure that the solution has currency now and will offer at least some direct benefits in the short to medium term.
- Typical questions that CIOs will ask are: How does the product suit our needs; what value would it bring; and how does that value fit into my organisation?
- Make the case (with evidence) for the benefits of adopting a potentially disruptive or intrusive technology.
- Analytical solutions such as dashboards may be driven by what is possible to derive from available data, and not necessarily what is needed by personnel to make better decisions / take action.

Advice to clinicians:

- There must be a clear demand for the solution, from enough stakeholders in the organisation to be persuasive internally. It is not sufficient that one clinician recognises the need.
- Undertake some form of risk stratification to demonstrate the number of patients or care scenarios who may benefit from the innovation, and the impact of that benefit.

Align with NHS strategy and local priorities

Advice to companies:

- Do not approach a healthcare site to get buy in until you have identified how your innovation aligns with strategy of the site and their capacity in change management resources and skills.
- Understand how decisions are made within the NHS (including how business cases need to be framed), and by whom, which is very different from the private sector.
- The NHS focus around meeting targets restricts healthcare sites to innovation in confined areas. This can limit the scale of local engagement for a different innovation.
- Be clear about how the product (and its value) fit with the specific site's strategy and also with the NHS wider strategy.
- It can be a source of irritation to the provider when suppliers don't know how their products align with the specific healthcare site's strategy.
- Pitches should be realistic and grounded in relation to the specific NHS health care site requirements and likely budget.
- Is the business case relevant to the specific financial director or individual decision maker(s)?
- Think how the site and the wider NHS can save money through your innovation.
- When care providers are incentivised to follow "best practice", then it is virtually impossible to introduce anything that goes beyond that "best practice".
- Healthcare sites are not directly rewarded for improving clinical outcomes or for improving the patient experience and overall benefit to society, but have other immediate reward incentives, to which the proposed innovation has to relate.
- Service delivery demands mean in reality the hospital is looking at the front door, like A&E times, and doesn't have time for other areas of transformation.
- The solution should fit into a care pathway so that reimbursement is also possible.
- How does the product help with providing information that NHS organisations need to provide, e.g. to support national audits?

Take NHS and local capacity into consideration

Advice to companies:

- Understand where the pressures are within the NHS, both locally and nationally. There is limited time and resource allocated within healthcare sites for innovation activities that do not help with those pressure points.
- Take into account the variations across the NHS in the ability of staff and organisations to make good use of novel technology products.
- Investigate what the site would need to have operational in order to adopt the innovation, and any local capacity changes and infrastructure gaps that may need to be closed before deployment.
- Showcase how to make the product adoptable within the specific NHS site, considering the challenges it is facing (a bespoke prospectus).
- Consider how the product will be implemented into the health service, and if extra resource will be required to support a transitional adoption stage. Work out in advance how the innovative products will fit within the current structure and infrastructure at the specific site, such as the effort and time needed for integration with existing EHR/EPR software. Consider the staff skills and training implications of using the digital innovation, which may require the organisation to invest in.
- If something new is going to be implemented, is there "something old" that will be removed and how will this be done?
- The NHS works on annual planning cycles and so getting your product into plans / investment agreements will take time.
- The individuals you are likely to engage with in the NHS are likely to be very strained for time.

Consider the impact on clinicians

Advice to companies:

- There is a tension between the need to fit innovations into existing clinical practice by making relatively few changes ("small steps") and the need for innovations to change clinical practice (to be sufficiently disruptive to make a difference). It is important that an innovation facilitates at least some early wins – that can be used as driver for motivation among clinical staff.
- Interventions that help to organise a process or pathway that was previously unstructured are more easily adopted in clinical practice.
- Consider the impact on clinical staff from adopting the innovation: activity workload, cognitive strain, integration with clinician workflows, empowerment and collaboration with the ICT or being undermined.
- Make clear to clinicians what the incentives are for them to adopt the innovation, particularly given their time limitations.
- Take into account if the innovation will affect current job roles, which may greatly impact its acceptability.
- It is extremely hard to remunerate clinicians, so their time requirement must be minimised – even in a pilot or trial.
- When submitting funding bids companies should have an understanding of the need to fund clinical time.

Find a route of entry

Advice to companies:

- A key step to supporting the successful adoption of innovations is the success of the conversation, communications & engaging relevant roles and people who will be affected by the change.

- Identifying a change champion within a specific health care organisation would greatly support the chances of the innovation being adopted.
- Clinical change champions will only be relevant in their own clinical areas and not in other areas.
- When one clinician is the driver of change, the implementation of the innovation might easily break down when that individual leaves the unit, unless a willing protégé is available or wider enthusiasm has been secured by then.
  Advice to CIOs/CCIOs:
- Work out and disseminate (internally and externally) how companies should best engage your and your organisation's interest, to gain an opportunity to show what the company can offer.
- Guide and support your organisation's potential early adopters of innovation in how to handle a company contact or to take forward an innovation they come across.
- Develop a clear framework to triage novel digital interventions. Implement fail-fast systems that value extensive testing and incremental development to determine whether an idea has any value
- **Advice to clinicians**:
- When a clinician is approached by a company and gets interested in using a product, they should have a discussion with the relevant CIO/CCIO as soon as possible to agree a suitable strategy e.g. whether this could be tested inside a "sandbox" (i.e. separate from the operational systems).

Obtain the necessary approvals

Advice to companies:
- It is important to identify if a product would be classified as a healthcare intervention or a data capture / workflow tool.
- The implementation of digital innovations can be slowed down by the need for necessary approvals, such as MHRA approval, for interventions that are classified as a medical device. This is sometimes a grey area, e.g. a smartphone app requiring MHRA approval but the same functionality built into a hospital EPR not requiring approval.
- Sometimes the need for MHRA approval can be waived in pilot settings.
- Allow time and capacity for paperwork/approvals/bureaucracy for data access, if this is needed to develop or customise the innovation or to establish the evidence.

Build and leverage the right relationships

Advice to companies:
- The adoption of digital innovation is always going to be complex and require collaboration. It takes time to develop relationships.
- Not enough discussion with operational managers or clinicians means technology is not going to be well adopted.
- Over time build relationships and open communication channels with decision makers and champion adopters, admitting any limitations and challenges.
- SMEs, especially, need to become well equipped to be relationship managers and agile contract providers.
- Getting national opinion leaders (clinicians, CCIOs) behind the innovation is great way to gain a buy in.
- Ensure to target the right clinicians if trying to incorporate innovation. For instance, research clinicians tend to have some more flexible time and are therefore more likely to engage. They can see the unmet needs and help with finding funding.
- Each healthcare site must see a value in the supplier relationship: look for opportunities for co-creation and to share risk.
- Different individuals will have different risks they may be willing to take, influencing the approaches they would consider.
  Advice to CIOs/CCIOs:

- There is a lack of clarity around how industry should engage with clinicians and also how clinicians want industry to engage with the NHS. There are no established routes for clinicians who have identified unmet needs to find and liaise with businesses. There is no best practice to this process and where to go from here is not clear.
- Signpost how industry should engage with the relevant clinicians and avoid gaining only a small-scale (short lived) pilot? This applies especially if a company has limited resource to fully investigate the strategic specific healthcare site requirements.

Present or generate relevant evidence of value

Advice to companies:

- Present the evidence base supporting the product. The USP of the company and product should target an unmet need, which should be identified as early as possible in the engagement life cycle.
- For many digital interventions, the key "active ingredient" is poorly defined. Broad, ill-defined terms such "mHealth", "telehealth", and "app" merely describe a delivery mechanism but do not capture the essence of the intervention. A business case needs to present the solution more precisely.
- Digital interventions deliver information to enable their users to make better decisions. It is increasingly recognised that that will only work if the information provided is "actionable", which must be demonstrated.
- Companies have the tendency to oversell their products without clearly identifying the USP over and above competing products that are available in the market. Show how your product is the most suitable (in comparison to other similar products) for the needs of that specific healthcare site.
- Define and evidence the financial benefits for adopting the innovation e.g. cost savings.
- Consider evaluating the value flow through the whole organisation, not just the user department.
- Solutions must be sufficiently disruptive to achieve an impact, but not so disruptive that they are perceived as too challenging to adopt.
- Using a common tool may better enable multi-disciplinary working – an important benefit to try and demonstrate.
- Evidence based practice is highly valued by everyone, and the existence (or lack of) evidence is often raised in discussions about the need to implement innovations. However for many areas of clinical practice there is a fundamental paucity of evidence – for instance because it is not possible to conduct RCTs.
- Evidence of effectiveness is less important in testbeds – because 'innovation' is in itself the objective.
- **Advice to clinicians:**
- Clinicians may make conflicting claims about evidence in their field: it is important to validate personal opinions around evidence.
- If there is as yet insufficient evidence for a product, consider supporting the generation of evidence. It may be better to pitch for an initial pilot budget for evidence base generation rather than for definitive adoption without the evidence base. Be realistic about the time and effort required for this and if possible obtain grant funding.
- When looking for existing evidence around an innovation, it is worthwhile to not just look at the published academic evidence but also look for case studies.
Advice to CIOs/CCIOs:
- Even if introducing changes to one specific part of the health system, system wide effects on other parts of the organisation must be considered e.g. an instant biopsy seemed an attractive option to speed up operative decision making, but required a permanently available pathologist: i.e. it had a knock-on effect in routine practice.
- There may be a need for health economic evaluation to ascertain the return on investment in early phases of development/deployment of an intervention.

Incorporate recognised success factors

Advice to companies:

- Change is never only/just about the technology - and in fact the technology may well not be the main issue or be the focus of most of the resource. Successful historic implementations have ~80% of adoption funds allocated to user support and communication.
- Organisational changes are a real minefield. Enumerate the anticipated barriers in advance and plan mitigation strategies.
- Where possible try to future proof the innovations as much as possible and relay this to the healthcare site.
- Fail fast and iterate the product quickly where a healthcare site may not have flexibility and if it proves difficult to allow for change within an innovation roadmap.
- Funding is a clear issue as industry cannot be expected to donate their innovation for free but there are limited funds within the NHS. Joint funding applications seem like a logical solution.
- Identify as quickly as possible a source of continued funding post-pilot (a resource to maintain the innovation).
- Create a sense of local ownership of the innovation at implementation sites.

Work with AHSNs and the NHSA

Advice to companies:

- The AHSNs are really important for SMEs to leverage as they have the relationships already established.
- The AHSNs remit is to encourage adoption at scale and pace and to support the evaluation and funding of these projects.
- Undertaking research is in the NHS constitution, however it is not currently checked to see if all healthcare sites are enforcing the constitution.
- The clinical digital council are assessing what the standards should be by combining real world evidence and clinical evidence.

Advice to AHSNs and the NHSA:

- Decide if it is the responsibility of industry to understand the NHS, or the NHS (e.g. via AHSNs) to signpost industry to the right parts of the NHS.
- Provide an external "matching service" which can support NHS access to companies and vice versa.
- Engage with NHS stakeholders to share with industry what the right innovations and timings might be. Establish a co-creation space for NHS problem holders to co-create solutions with industry or to identify what solutions are required.
- Explore how company interests can be aligned to provide co-produced, more complete, solutions. Facilitate companies to collaborate together to support each other in "breaking into" the NHS.
- A list of funders and calls (who would fund such innovations or have a previous track record) would be useful to encourage cross-collaboration as a first step for interested teams.

4.3 Suggested areas for further work

These are aspects of sustainability that could benefit from more in-depth exploration, possibly via multi-stakeholder workshops.

Examine the characteristics of evidence-based interventions in health care

- How are innovation priorities set: is evidence always relevant?
- How to determine and convey the opportunity cost of adoption?
- What are the benefits to NHS organisations from improved patient outcomes?
- How to deal effectively with regulatory barriers to entry?

Define success strategies for the adoption of innovation enablers in healthcare

- How do digital interventions add value to care delivery?
- How best to specify the essence of the intervention?
- How can companies engage with the right decision makers or decision influencers?
- How are annual planning cycles derived?
- Is budget planning based on risk-adjusted forecasting or cost based planning?
- How to identify a source of continued funding post-pilot?

How should companies deal with limited success?

- What to do if a product fails to gain interest?
- How to handle a pilot that is fading out or a pilot that completes but does not go well?
- What to do next if there is no measurable evidence of value from a pilot?

5. Transferability: Evidencing the benefits of innovation

5.1 Overview

This work stream and deliverable benefitted from working with multiple CHC stakeholders to determine what evaluation results early adopter sites of an ICT innovation should capture in order to provide marketable metrics of product/service value. Four main categories of transfer metrics were identified: health outcomes, financial, technical maturity, policy alignment. A small group workshop in September 2018 explored the scope and appropriate level of complexity these metrics should take. Further consultation with industry members took place later in 2018 via TCs and email exchanges.

For three of the four categories, the following factors may need to be taken into account.

Health benefit

- Identify what impact the innovation/project has on health e.g. faster diagnosis, improved treatment or better treatment decisions, patient safety, patient independence, helping with capacity management within the healthcare system e.g. reduce hospital admissions.
- Incorporate real world evidence if this is possible.
- Model the innovation and its impact for the local demographics.
- Identify if there are savings elsewhere within the healthcare system.
- Undertake both a qualitative and a quantitative assessment.
- Ongoing assessment – adopt a measured approach to maintaining and improving services
- How to embed the product within the NHS organisation

Financial benefit

- Value in mapping out the early route to market stage, very beneficial to know:
  - Who the customer is, who the buyer is, how the NHS will gain, who the point of contact is would increase understanding of the optimum health economic model?
- Metrics to incorporate:
  - Time until organisation see financial return, Savings applied to specific departments within the NHS compared to where the product is implemented, Support & evidence for the commissioning group to purchase if innovation is to be used across different departments/ whole health care site. What evidence exists around this?
- Value of personal buy in & support for the products – don't underestimate!
- If company gains interest in product & support from NHS – what next – how will money be saved and how will patient care be improved? - structure with validated data points
- Does it financially make sense for a company to gain the Kite Mark?
- Funding considered for implementation of product on the ground at healthcare site?

Technology & Maturity

- What level has project been developed to? What is the trial size? Has it been modelled for local demographic?
- Is there an independent impact evaluation?
- Is there funding available for; production & scaling.
- Proving impact is equally as important as retrospective investigation of lack of performance
- Security – data & privacy – risk assessment incorporated to identify the boundaries around this?
- Can overlay of job fears from implementing a new product be avoided – sustain the quality of the current work
- More formalised strength to stress testing required
- Compliance with the Medical Devices Directive (93/42/EEC) etc

5.2 Kite Mark indicator tables

Health benefit

Indicator (what is being measured?)	Method (how is it being measured?)	Value to be demonstrated
Cost	Provide at least one commercial use case that proves that the solution offered is commercially viable and scalable.	Demonstrate cost savings via a real-world use case. The commercial use case should focus on the short-term costs savings rather than on reduced risk as it is more appealing to the financial departments within health bodies who are allocated short-term budgets. The cost savings figure should be endorsed by and referenced by at least one "in post" UK Health or Social Care commissioner.
Effective	The solution needs clinical evidence from a reputable institution that demonstrates the solution improves the health outcomes that it set out to achieve. Evidence that the innovation been through clinical trial and received positive feedback. Evidence that the innovation been tested and shown to be beneficial to patients with the relevant condition.	A technology company may show the evidence in cooperation with a non-academic clinical or social care organisation, as long as the methods are sound and endorse by reputable reviewers. A peer-reviewed research paper that illustrates improved health outcomes such as: Better management of chronic conditions, reduced hospital readmissions, reduced burden on caregivers, happier more/informed /empowered patients, better understanding of a disease (research paper), etc..
Secure	For the NHS, the security aspects of the solution would at least have to be assessed using the NHS Data Security and Protection Toolkit online self-assessment tool. Be able to provide a SLA and DPIA on demand. Ideally the solution should be ISO 27001 certified from an accredited certifier. The solution or product must show evidence of whether it is a medical device not and of what level of medical device it is. If it is a medical device then easy access to the technical file and Declaration of Conformity must be provided.	Gain vital trust with the caregiver, patient and health bodies. Gain access to markets
Transparent	The solution should be registered with the ICO. The solution should be transparent to the end-user of its purpose. The Terms of Service and Privacy Policy should clearly explain how patient data is	An ORCHA Score should be provided, if appropriate Evidence of Satisfied end-users Good product reviews on review sites

	processed. The number of users who have complained about the lack of transparency with the solution's data use policy. How many complaints did the solution receive from the Information Commissioners Office (ICO)? The number of users who have registered and used the device? If the solution uses (electronic) consent, the number of users who have signed consent to use the solution. (If electronic consent is used, the consent form should be easy to read and transparent.)	
Trustworthy	Good NHS Data Security & Protection Toolkit score. Security certified. Cyberessentials as a minimum as per Cabinet Office. Easy to understand privacy policy. Definitely no use of data for commercial purposes above and beyond intended use of tool. Needs to be clearly stated in Conditions of Use. Publicised real-world use cases.	Gain trust and credibility Gain access to markets Increased brand awareness
Intuitive	Accessibility across cognitive (learning disabilities, post CVA, dementia, TBI), vision, hearing and physical impairments ideally. A statement about conformity and target population would be best practice. W3C rating clearly shown if appropriate. High-retention rate using the solution over a long duration. Solution is used by a wide demographic (young, middle-aged, elderly). Good reviews on user-friendliness on the product/solution on highly-regarded and trusted review sites.	Gain traction and maintain a good user base.

Standardised	Specified format for the data that is stored (so it can be quickly inferred if it is proprietary or not). Does the solution use open healthcare standards (e.g. HL7 FHIR)? Signing up to and aligning with NHSD Open Platforms approach, ideally, or at least having it on the roadmap. Evidence of how easy it is to integrate with existing healthcare systems.	High interoperability with existing healthcare systems.
Feedback / User involvement	Does the innovation have user feedback as part of its design and/or development phase? Integrated user feedback tools within the live product as an addition to this. Having a standard procedure for responses to feedback at a minimum. Does the innovation continue to have user involvement in testing? Has the innovation been positively evaluated or validated by a clinical, or other relevant expert (e.g. sports scientist - note this may be the developer if they have demonstrated the necessary qualification to validate the app. Has the innovation attempted to validate any guidance with academic expertise Is the advice or guidance within the innovation frequently reviewed?	

Financial benefit

Indicator (what is being measured?)	Method (how is it being measured?)	Value to be demonstrated
Financial savings to the health and care system	Cash releasing benefits profiles for individual product / service benefits as outlined in the benefits plan the deployment business case (£)	Releases cash for use by organisations in the health and care system for re-investment. However, savings in one organisation are often realised in another, making it difficult for organisations to sign up without a system wide ' benefit share' approach.
Return on Investment (RoI) – Supplier	Net Profit / Total Investment * 100 (%) – by year	Demonstrates the commercial value to the supplier organisation

Return on Investment (RoI) – Health and care organisation	Cash releasing savings / total cost of deploying and running innovation* 100 (%) – by year	Demonstrates the financial benefit to the deploying organisation
Ability to achieve external investment	External investment received (£): • Supplier – e.g. seedcorn or scale up funding, 'state aid' or EU support • Health and care organisation – e.g. NHS Test Bed, OLS funding	Demonstrates independent case for investment in innovation, proving a level of external validation of the scalability of the solution
Level of commercial opportunity	Based on target pricing for the innovation, volume pricing and specific NHS discounts, market demand estimates for the innovation nationally and internationally	Demonstrates the likely commercial return for any investor

Technology & Maturity

Indicator (what is being measured?)	Method (how is it being measured?)	Value to be demonstrated
Quality of research methodology	Has research method been validated using internal processes or external review? Is it based on recognised model? Are the outputs clear and measurable?	Provide a better evidence base for adoption and demonstration of the value of the implementation
Demonstration of alignment with national policy and guidance, e.g. FHIR, NHS Digital policy, LHCRE, ITIL, ISO27001, etc.	Proof of incorporation of policy into design and links with policy bodies, e.g. meetings, external validation, use of correct tools. Does the innovation have a CE Mark with MHRA/ FDA etc. Has the innovation achieved any other "scores" from other reviews or accrediting bodies or individuals?	Demonstrates that solution will be compliant with standards, reducing barriers to adoption and proof of market need
Application/Service utilisation	Proof of utilisation by target user groups, e.g. audit logs, numbers of records created, calls, CPU and storage, etc.	Demonstrates that solution has been adopted and used, and that it functions as described. Also can demonstrate scalability.
User satisfaction	Qualitative response from user groups	Provides evidence that user groups believe solution works and delivers value.
Evidence of provable health economic model for cost benefits and defining value proposition for commissioners	Health economic model for use based on recognised model, with clear evidence based on testing and implementation against the model.	Meets needs of commissioners and other purchasers to be cost effective vs existing methods/services.

| Assessment for marking/ accreditation | Does the innovation state it is currently undergoing assessment for CE marking by the MHRA or other UK based notified body: Amtac Certification Services Ltd (0473), BSI Healthcare (0086), Lloyd's Register Quality Assurance Ltd (0088), SGS United Kingdom Ltd (0120), UL International (UK) Ltd (0843 | |

Policy alignment

Indicator (what is being measured?)	Method (how is it being measured?)	Value to be demonstrated
Conformance to DHSC specified standards for interoperability, data protection and information security	1. Vendor self-declaration of those standards which are relevant and have been adopted 2. An independent interoperability interface conformance test report 3. A reference implementation that demonstrates use of the relevant interoperability standard(s) 4. Vendors need to verify which standards are applicable to their products and services. It will be easier if an external QA process exists to demonstrate conformance.	• Trusts should benefit through easier interfacing with existing components • Trusts can demonstrate conformance to DHSC policy
Openness of the interfaces	1. The Vendor can supply interface specifications that would allow complementary products and services to connect to their product 2. Ideally there is at least one example demonstrating a third party product can interface with the vendor product	• Trusts have confidence of building a coherent informatics capability, rather than multiple silos
Non-proprietary storage of data	1. The Vendor can specify the data storage format and secure API to access (a) patient level data (b) trust provided configuration data, if applicable	• Trusts are confident of avoiding vendor lock-in

5.3 Suggested next steps

The set of indicators are, at present, candidates needing greater clarity about what would constitute convincing evidence to an NHS decision maker presented with a set of evaluation results – as a Kite Mark – arising from a pilot conducted elsewhere in the NHS.

It is suggested to use a mixed method combining multi-stakeholder workshop consensus with a Delphi survey to prioritise these and propose a first draft Kite Mark evaluation assessment, for feedback from NHS decision makers. This could eventually be operationalised as an evaluation framework for pilots, potentially to be performed under independent academic supervision from the north of England universities.

6. Conclusion

Both sets of results, presented in Sections 4 and 5, are interim findings from the co-creation workshops and other multi-stakeholder engagements undertaken via the PCCC. Further work is needed to mature Section 4 into a good practice guideline for the design and implementation of any ICT innovation pilot in the NHS. Section 5 needs further consultation on the most appropriate indicators to provide convincing evidence of benefit and trustworthiness of an ICT product or service, to help to break the cycle of repeated pilots.

The experience of working on both of these deliverable projects brought ICT companies (small and large) alongside NHS clinicians, service managers, ICT leads and procurement decision makers, accompanied by academics in health informatics and in health service evaluation, and also importantly, patient and public representatives. This combination of stakeholders worked together very well in a spirit of trying to help enable the NHS to deliver better care within its existing resources and capacity, through smarter working and leveraging novel digital solutions. Although this report has focused on written outputs, such as good practice points and possible Kite Mark indicators, the added value (and for some participants the main value) of the PCCC has been to enrich the mutual understanding of each other's potential contribution to this shared aspiration, and the barriers and pain points they each struggle with.

An important facet of pursuing any further work on these interim deliverable results will be to ensure that this rich combination of stakeholders is again engaged in co-creation, in a neutral and mutually respecting way, since this appears to be the only approach that will ensure the end results can bring value to all.