

Evaluating the introduction of innovations into routine health and social care: balancing rigour and resources

- Increasingly in the NHS there is a drive to identify and apply innovations that will demonstrate better value for money and improve the quality of care delivered.
- Innovation without adequate evaluation can lead to misattribution of effects and worse, the wider adoption of technologies and practices without proven benefits.
- Prospective pathways for undertaking rigorous experimental evaluation are well defined but with innovation implementation the opportunity, time and resource needed to employ these can be limited.
- We call for a rigorous and incremental approach to evaluation that addresses the “what, why, how, where and for whom” of innovation implementation.
- Evaluation should enable understanding of the process of implementation, the influence of contextual factors as well as quantification of effects.
- Adopting a prospective approach will facilitate more informed decisions in relation to continuation or wider spread.

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Background

Increasingly in the NHS there is a drive for faster roll out of 'transformational' innovations including products/technologies and ways of working that aim to demonstrate better value for money and improve the quality of service and outcomes experienced by patients.

In 2011, *Innovation Health and Wealth*¹ heralded that identifying and applying innovative approaches to delivering healthcare was integral to the long term future of the NHS. It asserted that doing this consistently and comprehensively would dramatically improve the quality of care and services for patients and strengthen its role as a wealth creator for the UK economy.

The commitment to accelerate innovation uptake in the NHS has continued with the *Five Year Forward View*.² Twenty nine 'Vanguard' sites have been announced to drive the development of new models of care forward.³ These sites are to act as test beds for multicomponent innovations in service delivery that will aim to move specialist care out of hospitals into the community (multispecialty community providers), integrate primary and acute care systems (PACS), or enhance the delivery and experience of care for older people living in care homes. The Vanguard programme is supported by a £200million transformation fund, which is in addition to the impetus for integration between health and social care and novel service delivery in primary care driven by resources available via the Better Care Fund and Prime Minister's Challenge Fund.

The sheer scale of the transformation proposed in the Five Year Forward View serves as a timely reminder that innovation without adequate evaluation will compromise informed decision making in relation to continuation or wider spread. If the NHS is to capitalise on this quest to establish better (more efficient) ways of working, we have to know which innovations work best, why, how, in what circumstances and at what cost. There is some recognition that previous roll out and testing of innovations has been suboptimal.² An intensive evaluation programme that will seek evidence on 'what works' to inform wider spread is promised for the Vanguards but detail is currently lacking on what this will actually entail.⁴

Innovation without adequate evaluation can lead to misattribution of effects and worse, the wider adoption of technologies, practices and ways of working without proven benefits over existing alternatives. For example, the advocacy of the 3MillionLives initiative put those commissioning health services under pressure to rapidly invest in telehealth technologies despite known uncertainties relating to complexity, costs and benefits⁵ and before lessons could be learned from the Department of Health funded Whole Systems Demonstrator project.^{6,7} Some unnecessary and costly investment in unproven technology could have been avoided had a more considered and incremental approach to deployment been undertaken.⁸

Clarity is therefore needed on approaches that will increase transparency, reproducibility, and ensure sufficient rigour.

The new models of care proposed by Vanguard are complex innovations that represent a mix of intervention, process, workforce and system changes.⁹ The interrelationship between these and the contextual setting within which they are introduced is what determines the extent of 'successful' implementation. In this context, evaluation can be complicated especially when conducted in the face of policy driven change. Indeed evaluation can be used as a strategy to strengthen the legitimacy of decisions or policies.^{10 11}

We have not identified any established evaluative pathway specifically focussed on the introduction of untested innovations in health and social care; although planning guides for innovation adoption are available.¹² There are also a number of general evaluation 'how to' guides that are written for service audiences - *Evaluation: what to consider* from the Health Foundation for example.¹³ The NIHR School for Public Health Research is currently funding a project that aims to identify and appraise existing guidance on evaluation. The aim is to then develop practical, evidence-based evaluation guidance relevant to public health interventions. Although public health focussed, many of the methods and tools identified are likely to be of interest to other NHS audiences. Although this work is ongoing, we already know enough in terms of existing frameworks, theories, evaluative methods and implementation research generally to propose a set of key issues that should be considered by those embarking on innovation implementation.

Box 1 lists 12 questions that those seeking to introduce innovations should always consider before they start. We believe that these questions are relevant to evaluation at any scale or level of resource and expertise, from experimental evaluations of 'complex interventions' through to service-led small-scale evaluation. The questions focus attention on the "Why, How, What and Who" of innovation implementation and we use these to frame this paper.

Box 1**12 questions those seeking to introduce innovations should consider before they start****Why?**

1. Why are you introducing this innovation?
2. What is the problem that the innovation is aiming to address?
3. What perceived benefits are there over any practice alternatives?

How?

4. How do you think the innovation will work/realise its effect?
5. How will you assess whether the innovation has been successfully implemented?
6. How will the innovation affect the delivery of other services or existing practices – will there be unintended consequences?

What?

7. What resources are available to support both implementation and evaluation?
8. What data needs to be measured; what is available/easily collectable?
9. What costs are associated with implementation, and how will you capture them?
10. What will you do to understand the ways in which context influences implementation?

Who?

11. Who else is likely to be innovating in this way - are there opportunities for pooling resources, collaboration and or shared learning?
12. Who will be interested and how will you report what you did?

If innovation is the solution what's the problem?

Key to any evaluation of an innovation is 'problem' specification. Rather than assume a benefit over existing practices, it is important to establish a clear role and need for innovation. What is the rationale? Does it add to or replace existing practices? Is there a clear and measureable gap in current performance or practice that the innovation could address? The 'systems fit' of the innovation and the availability of other practice alternatives should be considered. If a need cannot be established, then implementation should not proceed. A clear a priori rationale for the innovation will enable evaluation to be focused.

Given the plethora of policy initiatives, it is important to understand what is driving the implementation of the innovation since this may influence the focus, pace and resource available for the evaluation.¹¹ It is also important to identify the political drivers for evaluation at this stage, since this will influence both design and rigour.

If a clear need can be established, those implementing innovations should then seek to undertake as rigorous an evaluation as possible. There is always a tension between robust evaluation and 'good enough' evidence,^{14 15} and so inevitably there will be a trade-off between what evidence is desirable and what is possible.

How will it work?

A criticism of the evaluation of policy innovations has been the absence of clearly articulated theory to explain how and why an innovation would be expected to deliver benefits over existing practices¹⁰. Theory provides a lens through which we can predict, identify and describe the key features that influence the implementation of any innovation. Its use reinforces the complex and non-linear nature of implementation and emphasises the inter-relationship between aspects of the innovation, the recipients and the context. There are no shortage of frameworks and theories that have been or can be applied to implementation activity,^{16 17} and a few in particular are increasingly favoured in the research literature.¹⁸⁻²¹

With innovation implementation, we can use theory to build a logic model to establish the key determinants of success, to plan initial implementation and to offer a more efficient and meaningful method to generalise and predict outcomes and the potential for successful replication in other settings. This involves ensuring that there is clarity about the innovation itself - what it consists of, what it does and how it is expected to work - together with clarity over the wider system, processes and contextual features that will be need to be addressed if its causal mechanism is to function as planned.²² Evaluation must then be designed to find out whether the innovation actually achieves the intended outcomes, and if not, why not.

What is the scale and nature of the evaluation?

Alongside theory, empirical and experiential evidence are also required to provide information through evaluation.²³ All three evidence types are essential and when combined enable understanding of the process of implementation, the influence of likely contextual factors as well as quantification of effects.

Prospective pathways for undertaking rigorous outcome and process evaluation of complex and large-scale interventions are well defined.²⁴⁻²⁶ However with innovation implementation, be it driven by policy or local initiative, the opportunity, time and resource needed to employ rigorous experimental evaluation of this type can be limited. It also requires significant academic expertise and time to design and conduct these evaluations effectively. There are also recognised weaknesses within the existing MRC guidelines, notably a lack of focus on the initial development, piloting and refinement of intervention components and on the influence of context

An IDEAL alternative

The IDEAL framework has been developed to provide a systematic and incremental pathway to aid the transfer of surgical innovations into practice.²⁷ It presents a five phase approach to innovation implementation encompassing: Idea, Development, Exploration, Assessment, and Long term study. Although broadly following the MRC framework in its latter phases, IDEAL better recognises the planned and unplanned nature of innovation and the need to adapt methods to the innovation process rather than doing the opposite.

This framework could offer an alternative pathway for prospectively evaluating the impact of the type of ‘combinatorial’ innovations likely to feature in the Vanguard sites. Some products, processes and ways of working are likely to be planned from the outset but others may emerge by accident or occur through the unintended consequences of planned innovation, and this is part of the design of the Vanguard initiative. The telehealth experience highlights that the planned and unplanned introduction of untested innovations is not specific to surgery. The Developmental/Exploratory end of the IDEAL pathway recognises that the innovations can evolve and be adapted over time.

In the Developmental/Exploratory phase, small scale iterative evaluations that test whether a particular innovation is likely to succeed in a particular setting and that allow for refinement before more rigorous testing are preferred.²⁸ Implementing innovations incrementally at a pace that enables greater system integration, understanding of causal mechanisms and the influence of contextual factors may offer a better chance of success. It is at this end of the evaluative pathway that innovation implementation should therefore be focussed.

A range of evaluative approaches can be employed but some (Bayesian approaches for example^{29 30}) require significant statistical expertise not found in all academic institutions and rarely within the health service itself. As such, with an initial focus on iterative change, those that traditionally feature in quality improvement initiatives may be most appropriate.³¹ The plan-do-study-act (PDSA) method and statistical process control (SPC) are now widely used as part of efforts to improve the quality and safety of care,³²⁻³⁵ within a range of approaches such as continuous quality improvement (CQI), Six Sigma, and total quality management (TQM), as well as the widely-adopted Institute for Healthcare Improvement (IHI) ‘Model for Improvement’.³⁶

Common to all these approaches is the generation of real time data driven learning and decision making within an overall framework for change. This makes them ideally suited to addressing questions such as should we do this again? Should we pursue this further? These approaches can be used by staff with relatively little training compared to that required for full academic evaluation. But training is an essential prerequisite if well documented shortcomings in planning, execution, analysis and reporting are to be avoided.^{32 34 35} There are also renewed calls for a theory of change to be explicit in QI: *“more informed use of theory can strengthen improvement programmes and facilitate the evaluation of their effectiveness.”*²²

Well conducted, small scale exploratory evaluations can only ever give tentative indications of benefit and can be prone to misinterpretation, misattribution and bias. These therefore should always represent the starting point. Further corroboration, explanation and evaluation for promising innovations should be sought along the prospective pathway. And beyond this phase, plans for wider spread or indeed ‘whole system’ adoption of any innovation should be accompanied by robust and independent comparative evaluation. At this point, the MRC Framework for Complex Interventions recommends that prospective quasi experimental designs such as controlled before-after, stepped wedge and interrupted time series should be considered.^{37 38} Such designs are likely to require significant resource and academic input in order to ensure rigour.

Costs

Implementation of any innovation is not without cost or consequences. As with all change, there will be opportunity costs as innovation activity competes with other health-care services for finite health-care resources. Therefore, appropriate measurement of costs is a crucial element of any evaluative pathway. Economic evaluation has long been neglected in both implementation research and quality improvement initiatives generally.^{39 40} But early economic assessment may help to identify and eliminate cost-ineffective innovations - especially important if judgements are to be made as to whether implementation is likely to be beneficial.

As with evaluation, consideration of costs needs to be rigorous as possible within the resources available. Rudimentary cost benefit analyses such as Return on Investment are often presented as part of NHS business cases but their use can be undermined by a failure to adequately capture and incorporate all the relevant costs and benefits. At the IDEAL exploratory/ developmental phase, resource use and costs associated with implementation of innovation should be captured from a clearly stated perspective. Beyond this phase, an explicit attempt to assess opportunity cost should be made and this will involve some form of cost effectiveness or cost utility analysis. Given current financial constraints are a driver of innovation 'at scale and pace' initial interest should be focussed on technical rather than allocative efficiency. The Health Economics theme of the NIHR Yorkshire and Humber CLAHRC are exploring a range of economic frameworks that could be used to generate timely, "fit-for-purpose" evidence for local decision makers.⁴¹

Context

Empirical evidence on its own is not sufficient to make judgements as to whether an innovation is worth pursuing further. With any observed effect we need to understand whether these occurred as intended or whether they were the result of unintended consequences. Understanding the influence of context and experience of the implementation of the innovation is therefore as important as outcome evaluation (see Box 2). What is the innovation like to use? What has been learned about the its application in a specific context and setting?²³ Contextual factors of influence include both individual and system readiness to change but can also include factors beyond the organisation in the wider economic, social and political environment.⁹

Box 2

The NIHR CLAHRC for Greater Manchester has conducted an evaluation of the NHS England (Greater Manchester) primary care demonstrator communities; six bespoke projects that aimed to increase access in general practice. Although each site differed in scope, size and ambitions, three core innovation themes were common to all: integration, access and technology. The evaluation combined quantitative assessment of outcomes with a process evaluation to understand and explore the processes and context involved in planning and implementing the Demonstrator projects. The evaluation was designed to enable real time learning so that sites could adapt and refine their approaches 'as they go' in order to maximise their potential impact.

Bringing evidence together

Linking different sources of context, process and outcome data to make sense of how and why the innovation achieved the results it did can be challenging even for experienced research teams. This is especially true for small scale exploratory evaluations as any 'difference' between innovation implementation and what was deemed baseline practice needs careful interpretation and cautious attribution of effects. Any synthesis should therefore reflect on the nature of the comparator employed, the influence of contextual factors and include a reasonable range of changes that may (or may not) have resulted from the implementation.

The MRC has published new guidance on process evaluation and its use within outcomes evaluation designs.⁴² The guidance focuses on planning and conducting theory driven evaluations of implementation processes, likely mechanisms of impact, and the influence of contextual factors. The guidance recommends that plans are made for integration of these different data sources from the outset and that this is reflected in the evaluation design. For example, seeking the perspectives of stakeholders in qualitative work, purposively sampled according to characteristics which are anticipated to influence implementation and outcomes.

One factor often neglected in evaluation is patient experience; even in national implementation programmes measurement can be poor.⁴³ The MRC guidance acknowledges that there are "substantial definitional and empirical uncertainties relating to PPI" and therefore refers readers to existing guidance on PPI in research.⁴²

Who will be interested?

Attempts should be made to identify whether evaluation of this, or similar, innovations have already taken place. However, it is worth acknowledging that this is easier said than done. In general, there is no comprehensive source of information about innovations that we have been able to identify.

IDEAL recommends that all surgical innovations are prospectively registered, and that it is unethical not to do so.²⁷ NHS England already has structures in place to enable prospective registration of innovations.⁴⁴ although the extent to which it's use is mandated is unclear. This site will act as a repository for expression of interests in response to the recent call for 'Real world testing of combinatorial innovations'.⁴

Alongside prospective registration of innovations, we echo the call of others that a system for prospective registration of evaluations should also be instituted.⁴⁵ Prospective registration will aid transparency by providing a permanent record of evaluations, regardless of whether they are eventually published or not, and whether they are formally written as research protocols. It helps safeguard against reporting biases and will provide a documentary record of how an innovation was adopted, adapted and ultimately applied in a given context. Registration should include details on how and by whom any evaluation is to be conducted.

As with other types of research,⁴⁶ the implementation and evaluation of innovations should be adequately reported (regardless of 'success' or 'failure') otherwise time and resources invested could be wasted. Insights and contextual information which could inform wider spread and learning should therefore be systematically captured in a generalisable format. Reporting guidelines exist but all are much less adopted and adhered to than they should be.⁴⁷

The SQUIRE guidelines⁴⁸ may represent the most appropriate framework for reporting innovation implementation. Although initially designed for quality improvement, SQUIRE demands reporting of the influence of factors relating to local context. Such detail will assist others to determine whether an innovation may be worth pursuing in their own setting and what contextual factors need to be taken into consideration. A revised SQUIRE guideline will be published later this year that aims to encourage reporting of not just what happened but more nuanced reporting of what happened over time, and what the meaning was of the outcomes and events that were observed.⁴⁹

Conclusions

Increasingly in the NHS there is a drive to identify and apply innovations that will demonstrate better value for money and improve the quality of care delivered. Innovation without adequate evaluation can lead to misattribution of effects and worse, the wider adoption of technologies and practices without proven benefits.

Prospective pathways for undertaking rigorous experimental evaluation are well defined but with innovation implementation the opportunity, time and resources needed to employ these can be limited. However, the same underpinning principles can and should also apply to innovation planning, implementation and evaluation.

We advocate a systematic and incremental approach to evaluation, based on a number of key issues:

- Why: If innovation is the solution what's the problem?
- How: How will the innovation 'work'?
- What: What is the scale and nature of the evaluation?
- Who: Who will be interested?

We argue that evaluation should include theoretical, empirical and experiential evidence, which when combined enable understanding of the process of implementation, the influence of likely contextual factors as well as quantification of effects. Prospective, iterative evaluations that aim to assess the context, process and outcome of implementation should be encouraged.

An adapted IDEAL framework offers a pathway for prospective longitudinal evaluation of the Vanguard test bed sites and similar complex and emergent innovations. Adopting this common analytical framework will ensure evaluation is built in from the outset, cross-site comparison and learning can be facilitated and that any decisions relating to continuation or wider spread are transparent and evidence informed.

Appendix 1
Definition of terms

Innovation	<p>Innovation Health and Wealth¹ defined innovation as “an idea, service or product, new to the NHS or applied in a way that is new to the NHS, which significantly improves the quality of health and care wherever it is applied”</p> <p>Service innovation can be defined as “a novel set of behaviours, routines, and ways of working that are discontinuous from previous practice, directed at improving health outcomes, administrative efficiency, cost effectiveness or users’ experience and that are implemented by planned and coordinated actions”⁹</p>
Implementation	<p>“active and planned efforts to mainstream an innovation within an organisation”⁹</p>
Evaluation	<p>The process of determining the impact/outcomes and process of the implementation of an innovation</p>

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