Chapter 2: Innovation, implementation and evaluation in healthcare

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1. Innovation in Health Systems

“...(R)ather than asking how research evidence can be made more influential, academics should aim to understand what influences and constitutes policy” (Oliver et al., 2014:1).

In this chapter we will consider the nature of change in health systems, and how small innovations in technology or service delivery complement large changes in policy or program design to improve outcomes of care. We provide guidance to health systems evaluators and researchers to help you deploy your scientific skills to design, implement, and scale up innovation in healthcare technology or service delivery, and assess their impact on health care and health outcomes. We hope you as evaluators and researchers will use some of these ideas to influence decision-making in health systems, in order to improve the health care experience of patients, communities and providers, health outcomes and health system efficiency.

The majority of health innovation ideas do not progress into viable products, services or changes in healthcare delivery and the failures occur at every stage. Few of those that are successfully developed and pilot tested are implemented effectively and even fewer scale to their full potential and are institutionalized into common practice. The best studied area of innovation is drug development, but the process of developing a new drug takes on average 14 years and 2 billion US $, and yet fewer than 5 percent of these reach scale and are sustained (NIH, 2014). The proportion of successes is simply not known for technologies, health service delivery or policy changes but given the relatively low investment in their early stage development, compared to the investment in drug development, there is reason to think that the success rate might be even lower.

Even if you have a good idea and a good innovation that is supported by empirical science that is simply not enough; the health system is complex and good innovations alone will not be effective in real world settings. Successful development, implementation and scale up of health innovations is a multi-stage process that requires appraisal at every stage and it is a team sport that requires active exchange and collaboration among all stakeholders at every stage. Successful uptake of innovations appears to depend on the interests of the critical stakeholders including the innovators, end users and the decision makers. Scale up is influenced by the broader context including the social and physical environment, the health system, and the regulatory, political and economic environment. Successful scale up is also strongly dependant on the maturity of the innovation at the point when it is offered to the health system decision makers for consideration. All too often, the maturity of an innovation is overoptimistically assessed, a usually by the innovators themselves, who are naturally confident in their idea. This assessment of the maturity would be more realistic if based upon acceptability of the innovation to other stakeholders, the evaluation results up to that stage and characteristics of the innovation itself including its disruptiveness.

We propose an approach to innovation which explicitly encourages this collaborative judgment of the maturity of an innovation and consciously undertakes specific work to ensure that it is ready for ‘prime time’ when it enters widespread use.
Our suggested approach to innovation and its spread into the health system consists of several stages: development, pilot testing, implementation, scaling up and institutionalization. The approach is accompanied at each stage by very careful evaluation, in order to identify potential problems that the innovation will face and facilitate remedies before large investments are made in a potentially flawed solution.

*Is there ‘a’ health system?*

We often speak of our countries’ as each having a health system, bringing to mind a large, coherent, rationally designed and managed organization. In such a health system we might well assume that most change is implemented through major policy initiatives led by national, provincial and local government health departments. But healthcare systems are not tightly coordinated or well integrated machines. It would be more accurate to think of health systems as consisting of multiple separate and uncoordinated elements in a spontaneously and rapidly evolving eco-system, each element with a unique history and well established ways of doing things. These parts intersect, overlap, collaborate and compete against a background of changing patterns of disease, demography and care delivery. In this constant and often contradictory flux, widely varying responses to change in need, demand, social forces, pattern of illness are implemented, some as policy, but many more simply as ad-hoc decisions on delivery of care in reaction one or other currently high profile problem.

Governments are only one of the many groups trying to shape the health system in their own interests. Others include professional organisations, producers and sellers of drugs and technologies, non-profit governance organizations running hospitals or long term care homes, advocacy groups for specific patient and disease issues, and last, but not least, citizens and their families, as individuals, interest groups and communities. These end-users of health care may favour different approaches to care, with dramatically different priorities and proposals for structuring health systems, depending on whether they are young or old, urban or rural, recent migrants or long established, wealthy or poor (and even how poor) and depending on whether or not they are ill, and if so, with what conditions.

It is important for Health services researchers to understand that such complex systems are not easy to improve, and that well intended changes to one aspect of care may produce unintended consequences for another part of the health system. With complex patterns of needs, and complex structures for responding to these needs, how do health systems decision-makers decide what care to provide, to provide, to whom, and how? Whether to prioritize health services for children, or the elderly, on chronic or acute infectious illnesses, on equity, access or coverage of the population, on quality of care or continuity? Let alone the many other questions arising, such as whether primary care should be delivered by nurses, physicians, some other category of health worker entirely or inter-professional teams?

Many issues influence health systems decision-making, and scientific evidence is only one element. This evidence might include a randomized trial or systematic review on what intervention works best to deal with a particular health or health care problem, or new survey data on the rapidly rising prevalence of a particular health problem or of a problem with equity, cost, quality or access. It might be focus group data describing the perceptions of a particular group of users of care, or case studies of successful quality improvement initiatives. These kinds of evidence can influence decision making in different ways. Sometimes the evidence is used as a post hoc justification for a decision that has already been taken. This rhetorical use of evidence may ignore contradictory evidence. Evidence may also be used substantively, as a coherent and comprehensive overview of options and evidence leads directly to a decision that is supported by the prior evidence. While this substantive use of evidence may sometimes be very influential, especially when supported by prominent, positive media coverage, more
often the evidence is one part of the impetus towards action, or towards choosing among options for action.

**How do healthcare systems evolve?**

Innovation and change in health systems can be at large or at small scale. Large scale policies have a profound influence on health care systems, determining their overall structure, funding, activities, eligible users and the health conditions they focus on. While these broad outlines determine the context in which care is provided, it may not necessarily determine the detailed daily operation, which are a result of the multitudes of small delivery processes chosen to implement each major policy. We propose that influencing these details of how care is provided, irrespective of the broader system context, is where our readers’ skills and efforts may have the most impact.

Whereas national or provincial policymakers covering large jurisdictions need to have bold policies visible to those who elect them, lower levels of their organisations and smaller jurisdictions tend to focus on smaller, more local, operational choices rather than large scale policies. For health decision makers in such a position, it is important to continuously develop innovations that are carefully focussed on their priorities, so that they can spread and scale up the best of the interventions that improve the delivery of care, incrementally. As these small (and thus low risk) innovations accumulate, as successful innovations are evaluated, and distinguished from failures, which are dropped, the multiple small improvements in several aspect of care can accumulate to make a large impact on the overall outcomes of patients.

National government focus on making changes to law, like Obamacare, the Canada Health Act of 1967, or the South African Ministry of Health’s commitment in 1995 to a National Health Insurance System. These result in policies which have enormous impact on how the health systems of those countries are structured, and thus on what their health systems can and cannot do. For example, Canada’s Health Act focussed on physician centred acute care rather than chronic care, and did not require reimbursement of care provided by other professionals such as dentists and physiotherapists. The Act offered little funding support for long term or home care, and funded hospitals but not than community based services (aside from family physician care) or ambulatory pharmaceutical provision for the elderly. Even though these choices are federal, they have strongly shaped the structure and functioning of the provincial health systems. Thus, many major features of health care in all provinces are similar, even though there is complete constitutional autonomy of provincial health departments in relation to how care is delivered. This autonomy and strong central influence means that there has been little coordination or learning of lessons from each other as provinces have individually tried to adapt their structure to the changing needs of an aging population, and to control the costs of intensive, hospital based care within the requirements of the Canada Health Act.

In South Africa, with a similar national/provincial structure, and greater socio-economic and epidemiological challenges, including both HIV/AIDS and chronic disease, the commitment to a National Health Insurance System has focussed debate and senior decision-maker attention on how to fund care, with the consequence that strategic innovation in national policies and programs and public pronouncements has tended to focus on infrastructure and financing, rather than on detailed development, implementation and evaluation of delivery mechanisms. As in Canada, this has left the implementation of care delivery in the hands of provincial health departments, rather than the national government, with autonomy allowing locally relevant innovation. Although there is more communication and learning between provinces in South Africa than in Canada, there is similar influence of the national health policy priorities and structures on provincial priorities in care delivery, and similarly slow progress in designing large scale policies to deal with priority problems and demographic and disease challenges,
such as chronic disease and HIV/AIDS at provincial level. In most countries, irrespective of level of income, strategic innovations in the form of high stakes national policy decisions with huge impact on the structure of healthcare occur infrequently, but occupy most of the attention of decision makers and the public,

Smaller scale innovation opportunities arise much more frequently. These arise most often where incremental changes in specific health care delivery mechanisms are need in response to a locally recognised problem, without major change in policy. Of course, innovation opportunities may also arise when detailed implementation plans for large-scale responses to growing health problems (e.g. chronic diseases, HIV/AIDS). The high level policy responses to these priority health problems rarely includes the detailed design of service delivery, leaving opportunities for health systems researchers to use creativity and scientific evidence in ways that are potentially less constrained by political requirements or rhetorical commitments than would be the case with the overarching policy. These seemingly “minor details” are fruitful work opportunities for Health Systems Researchers. Small innovations and improvements in healthcare may also arise in response to newly available (or, in low and middle income countries, newly affordable) technical innovations in prevention, diagnosis and treatment. When these technical innovations and combined with carefully designed changes in organization and delivery of care, they can, if they are well evaluated, successfully implemented and scaled up, become the basis for improved health systems, whether in high, low or middle income settings.

An incremental approach to health system improvement might be especially appropriate for constrained economies in this economically depressed stage of globalisation, where economic concentration and weakened social solidarity leads to shrinking states and public budgets. In spite of this apparent association with economic recession and spending constraints, this ‘low’ road to healthcare improvement can tap into the new knowledge generated by health service and systems researchers, in potentially advantageous ways. Technical innovations in prevention, diagnosis and treatment, in conjunction with finely tuned changes in organization and delivery of care, can, if well designed, be the basis for improved health systems, whether in high, low or middle income settings.

When deeply integrated into existing health systems, incremental innovations can result in unexpected positive consequences. When we designed a new training system for nurses in primary care clinics in South Africa to improve their ability to diagnose Tuberculosis (TB), we hoped only to improve the reliability with which tuberculosis would be diagnosed and referred for treatment. We had also a vague hope that this would demonstrate their capacities as clinicians, and open up a larger and more effective role for such nurses in publicly funded primary care in South Africa. Fifteen years later, over 20 thousand nurses are making use of a wide range of newly acquired skills to diagnose and treat not only Tuberculosis but a full range of minor acute and major chronic illnesses including hypertension, asthma and AIDS, using evidence based guidelines, all arising from the expansion of an incremental improvement- the development of effective and efficient in- service, on-site training systems. This success suggests that as primary care becomes an ever more important part of the health system, iterative improvements in organising care, delegating functions, sharing care and referring patients for specialized treatment can lead to improved coverage, quality and impact of care. This success is an argument for health service research to focus on implementation of incremental improvements to existing programs of primary care, using strategies that will be easily scaled up in existing local health systems without disruption.

The combination of incremental innovation with health services research, especially implementation research can help existing health systems evolve to deal with changing health and demographic trends while improving health outcomes, promoting equity and containing expenditure increases. Incremental innovation promotes simplification of care, and thus
improves access to effective treatments or preventive interventions. In large part, the fall in child mortality throughout the developing countries since the 1960’s has been due to the delivery by alternative, non-physician providers of simple and highly effective treatment or preventive interventions such as immunizations. It is easy to forget that smallpox was a world scourge, eliminated by a simple new vaccination technology, the bifurcated needle, and delivered through an equally simple but well organized effort to isolate cases and immunize protective perimeters of populations around them. Similar effects have arisen from the development of effective treatments for chronic diseases including hypertension and diabetes, tuberculosis and HIV/AIDS, where innovations in treatment have been delivered alongside refinements and simplifications of care systems so that access, adherence and quality of care improve, and combine to reduce morbidity and mortality form these conditions.

2. The role of researchers in incremental innovation

Innovation is a long and complex process and thus highly unpredictable; health systems researchers can help ensure that as an innovation is developed, implemented, spread and scaled up to cover entire jurisdictions, that it is evaluated carefully at each stage, and that the lessons learned from that evaluation inform either early abandonment if it is clearly not an effective innovation, or improvement, to ensure that a successful innovation can be most easily implemented and can achieve its maximum impact. This continuous attention to evaluation and iterative improvement (or appropriate abandonment) reduces the unpredictability of innovation.

Health systems research offers many insights during the complicated process of innovation: HSR helps understand the problem that needs to be solved, ensures that the proposed innovations are acceptable to those who will be affected by their implementation, that the chosen innovation achieves its expected benefits, and that it does not create any unexpected harms or costs, either within the part of the system in which it is implemented, nor in other parts through unexpected links. Researchers provide information and evidence which can assist decision makers in several ways:

- defining the priority problem to be addressed;
- designing and choosing among options for the innovation;
- developing and testing implementation and scale up strategies;
- determining the impact of real world implementation on health and healthcare delivery;
- recognising areas for improvement in future iterations.

We will discuss methods and timing of evaluation in incremental innovation. Evaluation is crucial, because it ensures that each of these innovations is indeed an improvement, and not simply added work and cost with no benefit, or, even worse, no benefit and extra harms and/or costs. If an evaluation shows that the innovation is not effective, then it is possible to stop the innovation, not implement or scale up widely, and rethink, with modifications to the innovation based on flaws recognized in the evaluation process. This iterative cycle of innovation, implementation, evaluation, improvement, and so on to another round of innovation, is a key approach to making a difference with health systems and services research.

With the complexity of the health system described above, it is best for health systems researchers to collaborate closely with other stakeholders to succeed in tactical healthcare improvement, either in an actual team (within an organisation like a ministry of health or a non-governmental organisation) or in a virtual team (if different stakeholders from different organizations are working together on an initiative). This collaboration goes through several steps as discussed below.
3. The stages of innovation: from problem to scale up

The most commonly cited ethical principle that healthcare students are taught in medical schools is 'First, do no harm', which for our purposes might be interpreted as ‘be very aware of the potential risks associated with any health systems innovation as well as the potential benefits’. The way in which we can best try to ensure that is to proceed with caution, moving step-by-step through the following stages:

1. Problem: identify priority problems that are susceptible to tactical solutions
2. Solution: develop one or a few potential solutions to the point where they can be tested in a small, real world pilot or identify plausible solutions developed elsewhere and adapt them to local conditions
3. Pilot test: if it tests well then prepare for larger implementation, if it needs improvement, adapt and pilot test again, if it seems not to be improvable, abandon
4. Implement: in similar settings to pilot, but at larger scale and under real world conditions. Evaluate and decide on spread to different problems and settings, and/or on scale up to jurisdiction/s
5. Scale up: based on evaluation of implementation stage, adapt the innovation and supporting systems to allow massive growth, and test whether it can be adapted to solve different problems, or the same problem in different settings. Evaluate jurisdiction wide scale up, especially whether effectiveness has been maintained, with rigorous, often randomized longer term evaluations of results and implications for other parts of health system.

An innovation’s ability to progress through these stages is contingent on several factors (Gupta, 2015). It is dependent on the characteristics of the innovation itself and the interests of the key stakeholders including:

- innovators (usually researchers) who are involved in developing the innovation;
- end users (the practice community and innovation users) from the health system unit;
- decision makers (government and non-government policy makers) who have policy jurisdiction within the health system unit.

It is also dependent on the broader context including:

- the social and physical environment,
- the health system unit where the innovation will be integrated (i.e. organization, clinic, hospital, community, province etc.); and
- the regulatory, political and economic environment.

It is important to identify barriers early in the innovation process and accept that some innovations simply may not be able to overcome important barriers and perhaps, there will be a need to go back to earlier stages and re-design the innovation, or in some cases abandon the project all together. Innovations are commonly rushed through stages and even skip essential stages all together. They may be implemented or scaled up prematurely without evaluations to verify that they are mature enough to advance forward.

Open and thoughtful (rather than rhetorical) discussion is needed between multiple stakeholders, including health innovators, decision makers and end users on potential barriers to scale up as they come into view, allowing for innovations to be sequentially adapted before meeting these problems in the “real world” setting. Collective problem solving among stakeholders is an essential element of deliberation, which “allows individuals with different
backgrounds, interests and values to listen, understand, potentially persuade and ultimately come to more reasoned, informed and public-spirited decisions” (Abelson 2003:241).

It is helpful to be constantly aware of what stage the innovation is at and to identify what barriers have to be overcome in order to move forward in the process of implementation and scale up. Awareness from the beginning of the whole process leading to the end stages increases the ability to pre-empt barriers, and the likelihood of achieving successful scale up and spread of an innovation. This approach to staging of innovation may be most usefully applied to discrete innovations and to multicomponent interventions, rather than paradigmatic innovations (Edwards 2010). Paradigmatic innovations are often attempted as solutions to difficult strategic problems, and as discussed above, these may be easier to solve in a piece by piece fashion.

Discrete innovations are well defined such as scale up of zinc in early childhood (Larson et al. 2012), scale up of ART (Harries et al. 2009) or the use of new technology for diagnosis and treatment of TB (Meyer-Rath et al. 2012). Multicomponent interventions involve several interacting program elements to produce a composite set of innovations that are targeted at multiple system levels. Examples include multilevel initiatives to decrease childhood obesity (deSilva-Sanigorski et al. 2010) or scale up of post abortion care services in two countries (Billings et al. 2007). Paradigmatic innovations require a shift in the way we understand health problems and the potential solutions to address them. An example of this is China’s quality of care reforms to modify their family planning programs to be in line with the international agenda which required a systems wide approach, and partnerships between international groups and all levels of governments in China, including those that extend outside of public health (Kaufman et al. 2006).

**Stage 1: Identify the problem to be solved**

If a problem is widely discussed, its characteristics understood and magnitude well measured, its priority agreed upon by the full range of stakeholders, including those with the health problem, their communities, the professions and organizations providing care and health care funders and decision makers it is likely that health systems research skills can help to address it. It is easier to tackle if the problem has a high public profile and a solution is required by new laws (or at least, not prevented by any), or is enabled by a newly available technology or healthcare delivery change.

Difficult problems have more multifactorial origins, are deeply rooted in cultural, social or economic stresses, have more polarization, stigmatization, or conflicting interest groups. Perhaps a chain of simple innovations can help, building up over time, with each small step addressing one small part, and achieving gradually widening support. Often some of these stages require new laws, new financial commitments and complicated political support. These difficult, strategic problems are often the most important problems in health systems, the result of inequitable social situations, but taken as a whole, such problems are hard to solve in one step. We suggest that you try to work on a mixture of simpler and more complex problems, preferably related to each other so that the learning you achieve from one helps you to understand and possibly help with others.

**Stage 2: Find or develop a solution**

New innovation development should only progress if it is clear that there are no existing solutions to the problem. Do a literature search to check whether this problem has been addressed elsewhere, and, if so, how. Ask your networks if they know of existing solutions. If not, start thinking about the innovations needed to solve this problem. Use an approach called user centred design. Consider if the innovation should be aimed at clinicians, managers, a
team, multiple units or facilities, jurisdictions or end users, and which ones? Does it focus on individual awareness, knowledge, motivation, attitudes, engagement, skills, behaviour or work processes? Is it a drug, a technology or a process change? Diagram how you think an innovation will work. Gather feedback from end users and managers to test your assumptions about what is needed and to direct the design. Develop one or a few local innovations- keep them simple, adaptable by end users and compatible with the existing culture, health system and workflow.

Rapidly test alternative ideas with enthusiastic users, starting with simple pictures of the solution, moving to physical mock-ups and/or role-plays of the innovation in use. Go through several cycles of prototyping, feedback, adaptation until ready for pilot testing.

**Stage 3: Pilot test**

Test a real version of the innovation with a few local enthusiasts, who are ordinary end users (patients, communities, providers) in a real setting. Evaluate convincingly, using transparent qualitative and quantitative measures: is it acceptable to all stakeholders, does it work, is it simple, does it integrate into the system easily, is it better than the alternatives, at what cost? If not, abandon, or improve the innovation. After improvements, test again. When there are no major uncertainties, get ready for implementation.

**Stage 4: Implement**

In similar settings to pilot, but at larger scale, under real world conditions and with comparative effectiveness evaluation built in. Consider contracting out for implementation and consider recruiting independent evaluation team. In any case, build an implementation and evaluation team with buy in from end users, including patients, providers and communities, local respected champions, decision makers from several levels and strong administrative support; also advisers with KT knowledge. Ensure shared implementation decision making between stakeholders, communications of progress and an agreed performance measurement framework based on logic model from previous stages.

Evaluation should be pragmatic, realist and participatory. Effectiveness should be measured both in processes (how has healthcare delivery changed) and in outcomes (how has health or other end user relevant outcomes changed). Designs should include rigorous, preferably randomized trials, with mixed methods (including trial, qualitative and economic) evaluation including satisfaction, user experience, uptake, quality, effectiveness, and economic measures and observations. Look for unintended consequences and system impacts especially opportunity costs of implementation and e.g. internal diversion of resources and performance decline in other areas of function of involved delivery organizations. Report on social, cultural, geographic and health system effects on innovation; consider regulatory legal and financial barriers and potential solutions. Report on external validity/generalizability as well as effectiveness, benefits and harms in different subgroups, and recommend whether the innovation is ready for spread to different settings, problems user groups, (spread) and/or whether it is ready for scale up (expansion of innovation to other but similar settings dealing with the same or similar problem. If not, make explicit whether adaptation is possible, and if so, along what lines, or if a new direction is preferred.

**Stage 5: Scale up**

Assuming the evaluation from the implementation stage is positive and recommends scale up adapt the innovation as suggested and choose new problems or settings, if extensions is to be addressed first; or identify an expansion path (similar settings, same problem, minimal adaptation) if the decision is that the innovation is able to scale, but not extend to different
settings or problems. Adaptation is based on rethinking the logic model, to see which elements can and need to be changed to match the different situation or problem. Consider the core and adaptable elements, and how to adapt the latter for the different settings or problems while maintaining sufficient fidelity to the original successfully implemented innovation to continue to be effective. Scale up may require changes in the physical, health system or legal/regulatory/financial context in which the intervention is to be implemented, possible changes include to the delivery mechanisms, capacity development, funding any of which may need to be further developed to assist in scaling up a successful innovation to similar settings on a jurisdiction-wide or multi-jurisdiction scale.

The stage of scale up needs to be evaluated as well, as thoroughly and rigorously as the implementation stage itself was evaluated. This is because, inevitably, the initial implementation, like the pilot much earlier, is led by the most committed to the innovation, implemented in the site most likely to succeed, and reviewed through the most optimistic lens, by decision makers whose reputation is built on announcements of successful pilot projects being widely implemented. It becomes all the more important that the long term commitments on a massive scale that accompany a decision to scale up, with or without spread beyond the area and problem initially targeted, are based on a rigorous objective and possibly independent evaluation of whether or not the expected gains are actually forthcoming. A reliable evaluation of the initial efforts at spread and scale-up provides the ability to correct course in order to maximise the positive and minimise unexpected negative consequences, and the reassurance to all stakeholders, prior to setting the innovation into the system, irreversibly for the foreseeable future that the innovation deserves to be scaled-up and spread. This evaluation at scale must also consider implications of the scale up efforts on other innovations or other parts of the health system.

4. Conclusion

Health systems are complicated and improving them in ways that achieve wide and positive impact depends on understanding the particular problem which you want to solve very carefully. This may mean breaking down bigger problems into manageable pieces and developing innovations for each one, rather than trying to solve deep problems all at once. A new idea will not necessarily work, and even if it does so at a small scale, innovation is not self-implementing. Each innovation needs to be tested and only if it is successful should it pass on to the next stage. A large part of successful innovation is knowing when something has failed, and not trying to scale it. If an innovation appears to be successful as a prototype in pilot studies, it should be tested in a larger scale, using rigorous evaluation tools; with this information, if positive, it is worth trying to adapt the innovation to try and spread it as a solution to other problems, or the same problem in other settings; and also to scale it up widely across jurisdictions. Even at this stage it remains important to evaluate, to see if the earlier successes are maintained at scale.

Annex: The Nose-to-Tail Tool

The Nose-to-Tail tool is intended to help stakeholders identify the stage of maturity of an innovation, facilitate deliberative discussions on the key considerations for each major stakeholder group and the major contextual barriers that the innovation faces. It should help to identify potential problems and facilitate early modification, before large investments are made in a potentially flawed solution.
References


