To implement, or not to implement?

Ammenwerth [1] rightly highlights the disparity between aspirations and evidence. Political expectations and commercial assertions about the benefits of health information technology are typically derived anecdotally or ideologically rather than from scientifically reliable evidence [2]. Clearly, this cannot mean that ambitious innovation in health informatics should be stopped. It is neither reasonable nor necessary for every application to be rigorously tested in every possible socio-technical context before being 'licensed' for use in the real world.

On the other hand, caution is required when information systems are used to make changes in processes of care. As with innovations in direct care, there are both optimistic and pessimistic approaches [3, 4]. The optimistic school of thought argues that promising interventions lacking definitive evidence may be judiciously implemented, subject to concurrent evaluation of quality, cost and context. This would seem to be a plausible analogy for a health informatics innovation – as long as there is a well-reasoned business case that articulates the rationale for expecting the intervention to deliver net benefits, and the methods by which the impact will be assessed [5].

There are several broader contextual factors that influence implementation practice. Unlike direct care, health information technology (apart from medical devices in the European Union) is an unregulated domain. There is no country that requires minimum qualifications or training for individuals to become health informatics practitioners. There is no legislation or regulation, other than the EU Medical Device Directive, that controls who can develop or sell what health IT products. There are best practice methodologies for project management and change management, but their adoption and the effectiveness of their implementation is subject to organizational policy and competence. Ammenwerth notes that individual health informatics professionals have ethical duties in the conduct of their work, but the relative anarchy of the domain hinders consistent adoption of good practice.

Evaluation methodology

The first challenge that Ammenwerth identifies is the quality of evaluation studies. Arguably, most health informatics deployments would qualify as "complex interventions" [6]: they involve "several interacting components", are sensitive to local contextual factors, difficult to assess using experimental methods and often characterised by an opaque causal relationship between the intervention and the outcomes [7]. The UK Medical Research Council's guidance on complex interventions has much to offer health informatics studies, such as the potential of cluster randomised trials (where the aim is to determine effectiveness, controlling for context [8]) and the need for theory-based process evaluation that exposes the mechanisms of change and their interaction with context and outcomes [9]. The widely adopted 'Theory of Change' is a specific approach to unpack the assumptions, rationale, pre-conditions, indicators and impacts of a change programme [10], and seems to offer a promising method for health informatics deployments. Perhaps the GEP-HI guideline [11] should be expanded to incorporate principles from these sources.

A further weakness of many health informatics studies, that Ammenwerth does not directly highlight but which is implicit in section 4.5, is the virtual absence of measurement studies to validate instruments and outcome measures [12, 13]. Without such standardisation, the reliable application of meta-analysis in health informatics remains an elusive goal.

As a final observation, it might be suggested that a 'lite' method could be proposed for projects that lack formal evaluation funding. This should become part of the business case development process, building on the 'benefits realisation' plan in project management terminology [14] How can the

programme funders know their anticipated business benefits have happened (and not been outweighed by unintended consequences) unless they have some clear method of assessment? Health informatics as a discipline would benefit enormously if the implementation experience of every project were captured and shared. This need not be an onerous or expensive add-on to project costs, but proportionate to the expected return on investment. This is currently lost evidence, and we are poorer for that loss [15].

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