A New Approach to Interoperable Information Standards for Health and Social Care: Normalizing Culture, Contracts and Co-design

Philip Scott[1,2], **Michael Berger**[3], **Iain Carpenter**[2], **Lorraine Foley**[2]

[1] Centre for Healthcare Modelling and Informatics, University of Portsmouth, UK

[2] Professional Record Standards Body for health and social care, London, UK

[3] Department of Psychology, Royal Holloway, University of London, UK

Abstract

Background: In recognition of the limitations of technology-led standards for practitioner implementation of electronic care records, the Professional Record Standards Body for health and social care (PRSB) was established in the UK in 2013. The remit of PRSB is to develop and assure standards for the content and structure of records across all care sectors, based upon professionally-led and patient-guided requirements as endorsed by the professional bodies of the constituent health and social care disciplines. This new initiative is a very different approach from previous national information projects and faces challenges including organizational culture, operational procurement requirements and the logistics of collaborative design.
Objective: This paper describes the progress of PRSB and the practical issues it faces to achieve deep stakeholder engagement and widespread adoption of its standards and guidance. The goal is to offer a sustainable approach that builds on the strengths of work to date, learns from past experience of what works and what fails, and draws upon theoretical models of transformational change.
Methods: We conceptualize the PRSB strategy in terms of organizational change frameworks, evaluate it against models of success factors in health information technology and employ Normalization Process Theory (NPT) to articulate the activity stages required for realization of its goals.
Results: We present an NPT model of how PRSB standards can become embedded in routine practice for care practitioners, patients/citizens, government agencies and information technology providers. We suggest some critical success factors for cultural change, moving the supplier market and sustaining a genuine co-design approach.
Conclusions: It is abundantly clear that interoperability involves far more than just technology. Improving information sharing between care practitioners and with patients and citizens requires the innovative professionally-led and patient-guided approach that PRSB has pioneered. It is necessary to formally evaluate the impacts of implementation, both to build a compelling evidence base and to generate a virtuous cycle of iterative maintenance and general adoption.

Keywords

Electronic health records; Organizational change; Culture; Contracts; Collaboration;

Correspondence to:

Dr Philip Scott
University of Portsmouth
Address: Lion Terrace, Portsmouth PO1 3HE, UK.
E-mail: Philip.scott@port.ac.uk

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1 Introduction

Based upon earlier work by the Health Informatics Unit of the Royal College of Physicians [1, 2], a Joint Working Group set up by the Department of Health Informatics Directorate recommended that an institution should be established, provisionally called the "Professional Records Standards Development Body" (PRSDB), to take forward the work of developing and assuring professional guidance for patient record content and structure across all care disciplines in the UK.

The Professional Record Standards Body for health and social care (PRSB) was formed in 2013 as a Community Interest Company. Its stated objects in its Articles

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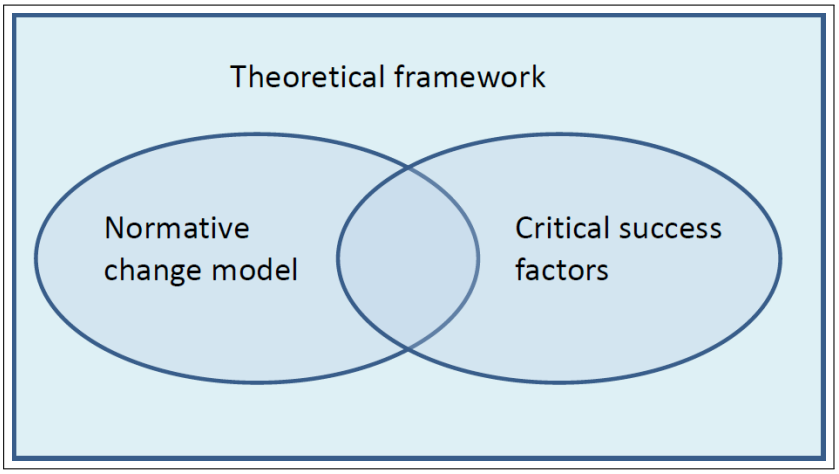

Figure 1: Relationship between conceptual perspectives.

of Association were: "to ensure that the requirements of those who provide and receive care can be fully expressed in the structure and content of health and social care records." PRSB's founding members were a core group of Royal Colleges and other professional bodies. Importantly, PRSB also includes patient representative groups so that the needs of citizens and family carers are taken into account alongside the views of clinicians and other care providers.

During 2015, PRSB was commissioned by the Health and Social Care Information Centre (HSCIC) to undertake five projects:

- Produce information models for a defined subset of the discharge summary from hospital to general practitioner.
- Advise on a forthcoming national programme on diagnostics.
- Provide guidance on secure use of email for healthcare communications.
- Produce a roadmap for development of standards for communicating medication information.
- Create a methodology for clinical user testing of professional record standards.

We have previously reported the initial progress made with a proof-of-concept project to derive formal information models and conformant technical artefacts from the professionally defined record standards [3]. In this paper we address the questions of stakeholder engagement and practitioner adoption of PRSB standards and guidance, reflecting on experience gained in the five projects listed above and from wider consultation across the four nations of the United Kingdom.

The objective of this report is to describe the progress of PRSB and the practical issues it faces to achieve deep stakeholder engagement and widespread adoption of its standards and guidance. The goal is to offer a sustainable approach that builds on the strengths of work to date, learns from past experience of what works and what fails, and draws upon relevant theoretical models of transformational change.

We strongly endorse the view that interoperability is far more than just technology. In a forthcoming paper [4], we propose a systemic model that aims to capture the complexity of devising, deploying and maintaining record systems dependent on people for the provision of information. This is based on the argument that consideration needs simultaneously to be given to the political and economic context, the service ecologies, and to professionals and service users as active processors of information, not simply passive consumers. Information about care is created to be understood and utilized by others. In the record, it is a form of indirect or mediated communication affected by multiple factors – psychological and social – as well as technology and the other influences that contribute to the fidelity and utility of the record. We argue for creating and sustaining information-centered service cultures in which records and information quality are integral to practice and not just another burden on the practitioner.

2 Methods

2.1 Approach

There are numerous conceptual models that could be applied to the PRSB scenario, depending on the objectives and desired output of the modelling exercise. In this case, the goal is to embed a new way of working as routine practice for care professionals and the health information technology (HIT) supplier market, so some form of transformation framework is needed to describe and explain. Such frameworks seem to operate at two distinct levels. Firstly, there are normative models of the necessary steps to manage change. This kind of model is typically an eponymous distillation of 'management wisdom'; a "how-to" guide, or catalogue of critical success

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factors. At the second level are theoretical models of how and why a change is succeeding or failing. This order of conceptualization is, by its nature, more usually derived from philosophical, sociological or psychological theory. Figure 1 attempts to illustrate the relationship between these conceptual levels.

2.2 Normative Models of Organizational Change

In this section, we briefly outline some common features from three well-known normative models of organizational change: those of Kanter [5], Kotter [6, 7, 8] and Fernandez & Rainey [9]. Table 1 (extending Table 4 in [10]) summarizes the key steps in each of these frameworks.

The basic ideas of each of these models are clearly very similar. Obvious common factors are: establishing the need, building a shared vision, assembling a coalition of support, planning, resourcing, communication, institutionalization and continuous development. We use these common principles to consider the progress made by PRSB and its future strategy.

Parallels can be inferred from general information technology acceptance models such as TAM [11] and UTAUT [12]. Similar themes can be found in specific recommendations for successful information technology adoption in healthcare [13, 14, 15] and in a recent 'blueprint' for acceptance of healthcare information sharing [16].

2.3 Theoretical Frameworks for Effecting Change

Several theoretical frameworks have been proposed to inform the design, development and evaluation of transformational change [17]. One way to differentiate between these frameworks is their level of abstraction: there are micro-, meso- and macro-system perspectives to consider [18]. Some focus on individual psychology, while others are primarily sociological. A common thread across such frameworks is the recognition that changing individual and organizational behaviour is complex, with diverse interacting contextual factors, so the actual mechanisms to effect change are not necessarily obvious or straightforward. Here we consider two widely used frameworks: Theory of Change and normalization process theory (NPT). They operate at different levels, but the contrast is instructive.

Theory of Change emerged from the field of international development projects [19, 20]. It is a way of conceptualizing change to deconstruct, describe and justify the theory behind the supposed working of a specific initiative. A Theory of Change approach expects extensive discussion with stakeholders to absorb multiple viewpoints. It begins from the long-term goals and maps back to the necessary pre-conditions, causal pathways, interventions, assumptions, rationale and measurable indicators. Theory of Change will analyse the context (political, organizational, social and environmental), the actors (both implementers and 'subjects' of the change), the assumptions (about the participants or the mechanism or effectiveness of the proposed interventions and indicators) and the justification (reason to believe that the intervention will work as expected). It uses a graphical model with explanatory narrative to visualize how the various elements of the situation will interact, where intervention can be made and what indicators can be measured. This is "a working model against which to test hypotheses and assumptions about what actions will best bring about the intended outcomes" [21]. In summary, Theory of Change is an abstract methodology to arrive at a concrete explanation rather than a pre-defined explanation in itself.

By contrast, NPT does seek to provide a substantive explanation of how practices become part of everyday life. The purpose of NPT is to help explain the "dynamic processes" involved in the implementation of "complex interventions and technological or organizational innovations" [22]. It recognizes that collective behaviour is not simply the sum of individual choices, but is constrained or promoted by social factors. NPT is formally defined in three propositions [23]. Firstly, that practices become routinely embedded through the implementation work done individually and collectively. Secondly, that implementation work involves four mechanisms: coherence, cognitive participation, collective action and reflexive monitoring. Thirdly, that the sustainability of the practice needs continuing action from its participants. While the first and third propositions may – at least, once they are articulated – seem like stating the obvious, the four constructs in the second proposition offer meaningful empirically-derived insights into the mechanism of adoption of new practices [24]. NPT has been used in several health-related studies [22, 25].

For the kind of change that PRSB is working to bring about, NPT fits well. We are not yet modelling specific interventions and indicators, as in Theory of Change, but are looking at the general stages of the approach becoming routine practice (which is in itself one of the common normative principles of organizational change noted above).

3 Results

3.1 Organizational Change Principles

In Table 2, we summarize how PRSB has implemented the common principles of organizational change identified in 2.2 and highlight where further work is needed.

3.2 Normalization Process Theory

In this section we consider how PRSB work done so far fits with the four constructs of NPT. There are some overlaps between the four NPT constructs and the com-

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Table 1: Comparison of normative change models (adapted from [10]).

Kanter	**Kotter**	**Fernandez & Rainey**
Analyse the organisation and its need to change.		Ensure the need.
Create a vision and common direction.		
Separate from the past.		
Create a sense of urgency.	Establish a sense of urgency.	
Support a strong leader role.		
Line up political sponsorship.	Create a guiding coalition.	Build internal support for change and overcome resistance.
		Ensure top-management support and commitment.
		Build external support.
Craft an implementation plan.		Provide a plan.
Develop enabling structures.	Empower broad-based action.	Provide resources.
Communicate, involve people and be honest.	Communicate the change vision.	
Reinforce and institutionalize change.	Anchor new approaches in the culture.	Institutionalize change.
	Institutionalize success through formal policies, systems, and structures.	
	Consolidate gains and produce more change.	Pursue comprehensive change.
	Generate short-term wins.	

mon normative principles outlined above. The difference in perspective is between normative (*what* should happen – the principles) and normalization (*how* it works – the theory). This is necessarily a subjective assessment. It is mostly retrospective but does offer some prospective hypotheses about next steps. The definitions of the four constructs are given in [23].

Coherence in NPT means the "sense-making" work that is done. Formally it is "work that defines and organizes a practice as a cognitive ensemble", held together by a set of meanings and competencies. This involves differentiation from other activities and a shared sense of purpose [24]. The work of PRSB has involved helping stakeholders to understand the distinction between its work and national IT programmes in each of the four UK nations and how it relates to existing standards bodies, both international (for example, IHTSDO and HL7) and national (such as the NHS Standardisation Committee for Care Information [26]). This has been a gradual and continuing process going back over a decade. The demise of the National Programme for IT in the NHS in England led to a general realization that a more consensus-based approach and practitioner leadership were needed. In particular, the work of formally establishing PRSB as a legal entity required numerous discussions and compelled stakeholders to become sufficiently clear about what this new "thing" meant and what value it added. The regular participants in the PRSB Advisory Board who represent the constituent professional bodies do seem to have attained this coherence. However, there remains variation and further sense-making work to do to reach a point where every individual volunteer and professional member body understands what contribution they are invited and expected to make as distinct from their 'day job' role. For example, some of the royal colleges have specialist health informatics groups with considerable expertise and a recognized structure. However, other professional bodies simply happen to have volunteer members with an interest in informatics, with little real organizational support for their activities.

The formal NPT definition of **cognitive participation** is work that "defines and organizes the actors" and is "shaped by factors that promote or inhibit" participation. This mechanism entails activity to develop engagement and ownership, resulting in a community of practice. Again, the formal constitution of PRSB required tasks of initiation and enrolment that delineated the founder member bodies and their individual representatives. This was shaped by aspects such as the relative enthusiasm of each member body, the personal background and seniority of the nominated representatives. The depth of informed debate at PRSB Advisory Board meetings certainly demonstrates cognitive participation, which was very evident in the initial surveys of the medical profession and has been demonstrated by continuing engagement of practitioners and patient groups in substantive project work.

Collective action is about enacting or operationalizing a practice. It includes the facilitation of participant interactions, their trust in the new practice and how the distribution of specialist skill-sets is affected. Crucially, it also involves "contextual integration" – the "fit" with existing structures, processes and social context. The standards development work of PRSB has highlighted the need for new and expanded skill sets: there are clear differences in informatics maturity and capacity level between member bodies. Interaction within multi-disciplinary project groups has demonstrated the need for a 'common language' and glossary of concepts and processes to support

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Table 2: PRSB application of common normative change principles.

Principle	Actions taken
Establish the need for change.	First iteration of medical record headings began with a series of three on-line polls (1,000, 1,500 and 3,000 responders to a single question) found overwhelming support for the concept. A longer questionnaire to doctors and patients explored detailed response to draft 36 medical record headings: overwhelming interest (>3,000 responders in 2 weeks). Consultation by Joint Working Group of Department of Health.
Build a shared vision.	The message accompanying the questionnaire was that (1) professional definition of requirements was needed so that they could be fit for purpose and (2) wide participation and consensus is better than clinical representatives on standards committees. Wrote to the president of every medical royal college and major specialist society to nominate a representative to lead specialty contribution and actively engaged patient groups. Series of well-attended workshops and online questionnaire consultations on draft record headings. Direct contact with every specialty representative who had concerns to explore the concerns and to ensure they were addressed.
Assemble a coalition of support	First iteration of medical record headings endorsed by the Academy of Medical Royal Colleges meeting and welcomed by a very wide range of organisations including medical defence organizations, the NHS Litigation authority and the NHS Ombudsman. PRSB establishment phase built support from member bodies and government agencies. Initial explanatory email followed up with telephone calls to President or Chief Executive, and several face to face meetings. Supporting coalition grown over time with high level meetings with Department of Health, HSCIC and NHS England, resulting in recognition in IT strategy. Regular and growing involvement of Scotland, Wales and Northern Ireland, including four nation reports at every advisory board meeting. Active engagement of patient advocacy organizations.
Plan and resource.	Negotiations and project commissions from national agencies. Growing capacity in executive leadership, clinical assurance, technical oversight and project management.
Communicate.	Communications advisor appointed, with emphasis on Plain English and jargon-free content. Informal communication via member bodies and more formally through website, events, webinars, Chief Clinical Information Officer network. Recognized as immediate high priority, with new website in development.
Embed as routine practice.	The current challenges addressed in this paper using NPT.
Sustain continuous development.	

effective co-operation. There is still work to do to influence the culture of national agencies to integrate fully with the PRSB approach. Historically, especially in England, there has been a highly top-down style of managing information systems and standards [27], which is at odds with the essentially collective ethos of PRSB. A related example is the PRSB wish to base conformance validation on a 'comply or explain' basis, not simply mechanical compliance as currently practiced. Implementation of PRSB standards is at an early stage: one dependency is changing the commercial environment from supply-led to demand-led. There are already requirements in English NHS standard contracts to deploy PRSB standards but these are so far only weakly enforceable. As trust develops – 'relational integration' in NPT terms – we aspire to generate demand from frontline practitioners and patients to influence local procurement decisions and therefore move the supplier market. PRSB has formed an open vendor forum and recent discussions have demonstrated a realization among certain suppliers that having PRSB as a clinical design authority for interoperability standards would be commercially valuable.

Reflexive monitoring is the work of formal and informal evaluation that reflects the depth of cognitive participation and collective actions. NPT describes both individual and communal appraisal. A semi-formal lessons learned review was performed at the conclusion of the 2015 work programme. PRSB has recently undertaken a corporate strategy development as part of its 'gearing up' to meet demand from service commissioners. These exercises offered helpful critical reflection by stakeholders about the exact nature of PRSB's contribution and ways of working. The very articulation and iterative clarification of organizational practices serves to embed them (at least internally). However, a particular gap is formalized evaluation of implementing PRSB standards to create a dynamic feedback loop of user experience.

In summary, Figure 2 outlines a retrospective view of how the NPT constructs have been applied and Figure 3 shows a prospective view of further work anticipated.

4 Discussion

4.1 Building practitioner and patient demand

The case for nationally defined and agreed standards is now accepted as overwhelmingly obvious, but there is a danger of over-claiming and appearing either not credible or not relevant to real people on the ground trying to change systems and processes. PRSB therefore has to work at two levels to make change happen. National influence must continue so that the central strategy, di-

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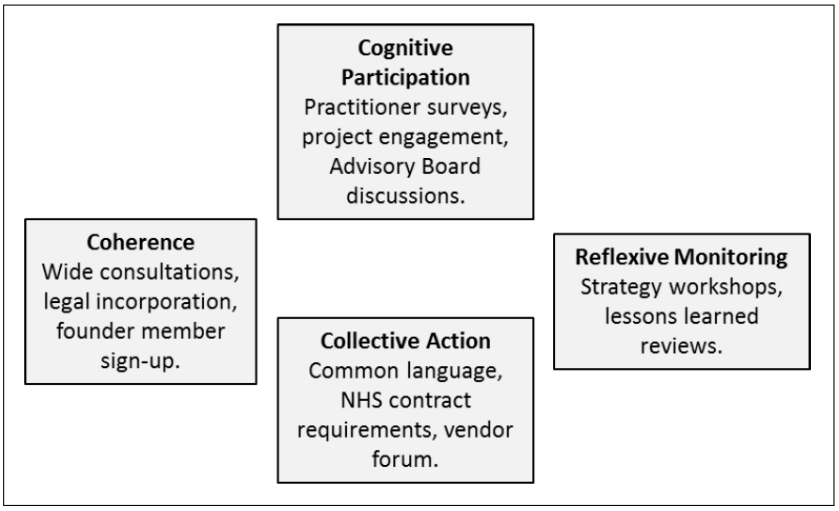

Figure 2: Current progress shown as NPT constructs.

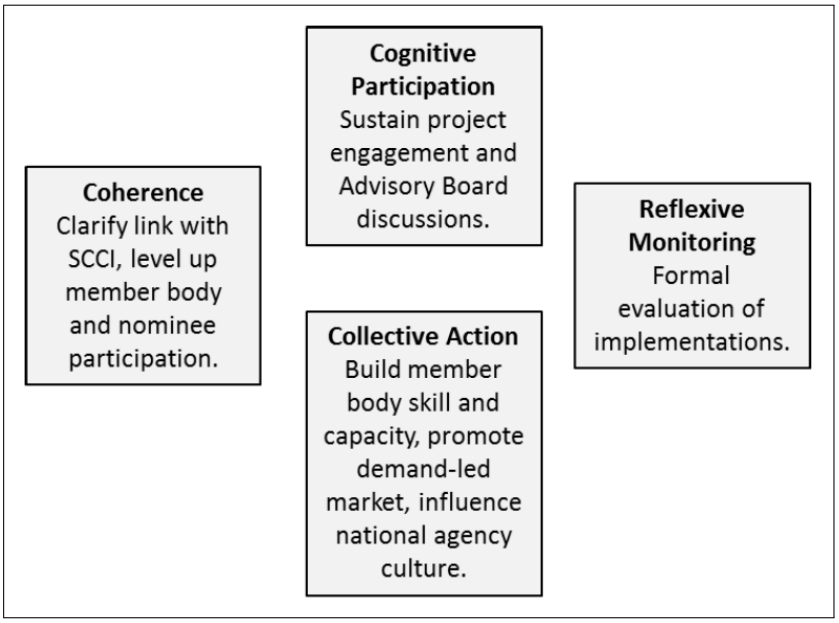

Figure 3: Further work to normalise the work of PRSB.

rection and incentives are established and reinforced by those with the power – in policy, service commissioning and regulation. Local engagement and persuasion is also needed, so that practitioners, executives, local commissioners, Chief Clinical Information Officers (CCIOs) and Chief Information Officers (CIOs) feel not only instructed to make the change to comply with national policy but empowered and enthused and accountable for making the change because they understand the benefits and importance to their patients and the whole care system.

4.2 Political and practitioner diversity

Due to the devolution of health policy, varied approaches are needed for the four UK nations. For example, whereas England has an extensive national infrastructure to manage information policy and programme execution, the other UK nations (who have similar ambitions around health and social care integration and patient access to records) typically lack such levels of resource and recognition by central government. There are also striking divergences in the political complexion of the current administrations that manifest in the financial models of funding and managing health services.

The kind of practitioners who are drawn to participation in information standards development are often at the 'geeky' end of the spectrum [28]. While such expertise is necessary and valuable, this creates a risk of over-engineering proposed solutions (as was found with HL7 version 3, for instance) and alienating the more 'average' care provider. The PRSB methodology of wide-ranging stakeholder consultation should mitigate this risk.

4.3 Role of professionals and professional bodies

The role of the professional bodies is key in setting the expectation of the respective groups in adhering to commonly agreed standards. There is concern from the regulatory authorities that the professional bodies and indeed the professionals themselves have on occasion been remarkably silent about recent scandals in care provision. A similar lack of leadership or complete engagement is also observable in respect of information standards. There is a need for narratives and case studies from respected peers to persuade the professionals and their societies to become the leaders and owners of this agenda. Practitioners are very interested in the concept of bringing their combined might together to influence IT vendors and tell them what is required. This is the kind of pressure that has real potential to change the market.

4.4 Limitations

As noted above, this is necessarily a subjective assessment and is inevitably biased by personal participation in the formation and execution of the work of PRSB.

5 Conclusion

PRSB offers a unique opportunity to demonstrate that interoperability a field that is led by practitioners and citizens rather than technologists. Substantial progress has been made but significant challenges remain. NPT offers a helpful theoretical lens to analyze the situation and focus attention on how to continue influencing institutional culture and contracting processes and sustain deep engagement from professional bodies in co-design practices. It is necessary to formally evaluate the impacts of implementation, both to build a compelling evidence base and to generate a virtuous cycle of iterative maintenance and general adoption.

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