Developing a conformance methodology for clinically-defined medical record headings: A preliminary report

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Abstract

Background: The Professional Records Standards Body for health and social care (PRSB) was formed in 2013 to develop and assure professional standards for the content and structure of patient records across all care disciplines in the UK. Although the PRSB work is aimed at Electronic Health Record (EHR) adoption and interoperability to support continuity of care, the current technical guidance is limited and ambiguous.

Objectives: This project was initiated as a proof-of-concept to demonstrate whether, and if so, how, conformance methods can be developed based on the professional standards. Methods: An expert group was convened, comprising clinical and technical representatives. A constrained data set was defined for an outpatient letter, using the subset of outpatient headings that are also present in the epSOS patient summary. A mind map was produced for the main sections and sub-sections. An openEHR archetype model was produced as the basis for creating HL7 and IHE implementation artefacts.

Results: Several issues about data definition and representation were identified when attempting to map the outpatient headings to the epSOS patient summary, partly due to the difference between process and static viewpoints. Mind maps have been a simple and helpful way to visualize the logical information model and expose and resolve disagreements about which headings are purely for human navigation and which, if any, have intrinsic meaning.

Conclusions: Conformance testing is feasible but non-trivial. In contrast to traditional standards-development timescales, PRSB needs an agile standards development process with EHR vendor and integrator collaboration to ensure implementability and widespread adoption. This will require significant clinical and technical resources.

Keywords

Medical records; Electronic health records; HL7; IHE; OpenEHR; Archetype; CDA; FHIR Conformance; Testing

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1 Introduction

1.1 Clinical Leadership

Health and social care information technology projects have typically been technically-led not clinically-led and this has frequently been identified as a significant risk factor [1, 2]. By analogy, the development of information standards is as much at risk from lack of clinical leadership as the design and deployment of software.

In an attempt to bring clinical leadership to the production of standards for patient records, in 2002 the Health Informatics Unit of the Royal College of Physicians

(RCP) began investigating variations in current record-keeping practice [3, 4]. This work led to a joint project on generic medical record keeping standards commissioned by NHS Connecting for Health and led by the RCP, with involvement throughout from other professional bodies and patients, resulting in the first version of standards for the content and structure of patient records, published in 2008. That project was followed in 2010-12 by a Joint Working Group set up by the Department of Health Informatics Directorate (the first successor body to NHS Connecting for Health), to resolve the governance of multi-professional standards. The Joint Working Group made a series of recommendations, including the observation that "Technical standards alone do not ensure the ability for information systems to transfer interpretable health data around the NHS" [5]. It was also recommended that a new group should be formed, provisionally called the "Professional Records Standards Development Body" (PRSDB), to continue and extend the work of developing and assuring professional guidance for patient record content and structure across all care disciplines in the UK.

The Professional Records Standards Body for health and social care (PRSB) was formed in 2013 as a Community Interest Company. Its stated objects in its Articles 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." The founder members were: National Voices (an umbrella patient group organisation), the Royal College of Physicians, the Allied Health Professions Federation, the Royal College of Nursing, the Royal College of General Practitioners, the Royal College of Pathologists, the Royal College of Surgeons of England, the Royal College of Psychiatrists, the Royal College of Paediatrics and Child Health, the Academy of Medical Royal Colleges, the Association of Directors of Adult Social Services and the British Computer Society (BCS). PRSB also has representation from the Health and Social Care Information Centre (HSCIC), the Scottish Government, NHS Wales and the Northern Ireland Department of Health, Social Services and Public Safety.

One of the early standards endorsed by the PRSB was the 2013 version of the standards for the content and structure of patient records [6].

1.2 Technical Conformance

The end goal of PRSB is computable but user-friendly semantic interoperability. The PRSB business plan for 2014-15 contained a work programme which included an intention to: "Develop [an] internal proposal on whether and how PRSB should offer an IT application certification service". The feasibility of a certification scheme is based on the fundamental assumption that PRSB standards are sufficiently well-defined to form the basis of a testing mechanism of some kind. However, the existing guidance on the structure and content of patient records [6] is deliberately written from the perspective of a clinical user not a technical implementer. The way that headings and sub-headings are described is typically fairly loose, mostly based on examples rather than precise definitions (Figure 1). Even the amplified text in the technical annexes tends to be illustrative rather than normative (Figure 2). In fact, the RCP web page for the technical annexes specifically states that they are not intended to pro-

Medications and medical devices

Subheading	Clinical description
Medication name	May be generic name or brand name (as appropriate).
Medication form	Eg capsule, drops, tablet, lotion etc.
Route	Medication administration description (oral, IM, IV, etc): may include method of administration (eg, by infusion, via nebuliser, via NG tube) and/or site of use (eg, 'to wound', 'to left eye', etc).
Dose	This is a record of the total amount of the active ingredient(s) to be given at each administration. It should include, eg, units of measurement, number of tablets, volume/concentration of liquid, number of drops, etc.
Medication frequency	Frequency of taking or administration of the therapeutic agent or medication.
Additional instructions	Allows for: • requirements for adherence support, eg, compliance aids, prompts and packaging requirements • additional information about specific medicines, eg, where specific brand required • patient requirements, eg, unable to swallow tablets.
Do not discontinue warning	To be used on a case-by-case basis if it is vital not to discontinue a medicine in a specific patient scenario.
Reason for medication	Reason for medication being prescribed, where known.

Figure 1: Example of record heading definitions.

vide a technical specification for implementing the headings in EHRs [7].

In January 2014, PRSB asked the BCS to initiate a project to address the viability of a conformance scheme. The aims of this project were found to coincide with the interests and objectives of the EU-funded Semantic HealthNet thematic network [8], which offered to partly fund the work.

2 Methods

2.1 Scope

The purpose of this project was to determine whether, and if so how, selected PRSB standards could be verifiably implemented as conformant technical artefacts. This was explicitly limited to a proof-of-concept and excluded any operational deployment. The example instance selected was the outpatient clinic letter, from hospital consultant to general practitioner (GP), based on outpatient record headings in [6] and the example template [9]. The scope was restricted to data items contained within the definition of the extended data set for the epSOS patient summary ([10], section 6.2, pp 43–50), with the addition of information structurally required for a minimally functional letter (for example, outpatient clinic details). The epSOS constraint was applied for two reasons: firstly, to compare the definition and interpretation of the epSOS patient summary content (a specific use case) with the generic record headings; and secondly to limit the number of data items to a tractable size.

The project set out to consider implementation using a plurality of technical standards and methodologies: HL7 CDA and/or FHIR, IHE profiles and/or XDS metadata and openEHR archetypes. We aimed to utilize the SNOMED CT concepts developed for high-level record headings [11] and sought to coordinate with other HSCIC work on the Clinical Documentation and Generic Record Standard (CDGRS) [12].

The project objectives were to determine: (1) what methodology to adopt to produce implementation-agnostic conformance criteria from the PRSB documentation; (2) which artefacts to produce for each technical standard; (3) what specific conformance tests to use for each technical artefact; and (4) what conformance claims could be reliably asserted. It is intended that the eventual conformance specification be adopted by EuroRec for promotion within EHR quality labelling schemes across Europe.

2.2 Approach

An expert group was convened, comprising clinical and technical representatives. The technical members of the project team included leaders from openEHR, HL7 UK, IHE-UK, EuroRec and the HSCIC. We adopted an iterative approach to seek consensus on how to model the PRSB standards, anticipating that each stage of refinement would produce a set of assumptions and clarifications for resolution by discussion between the domain experts and with the clinical advisors. For two reasons, we decided that the most flexible approach was to start by producing an implementation-agnostic representation (sometimes called an abstract information model). Firstly, this would enable the structure and content requirements to be presented and debated with clinical advisors more simply and accessibly than could be achieved using any kind of technical diagram (even simple UML). Secondly, it de-coupled the information structure from any particular implementation formalism and could therefore enable traceability from a single authoritative definition of structure and content through to multiple realisations in disparate technical representations. (At this stage, the traceability would be by human inspection. This could

Dose	This is a record of the total amount of the active ingredient(s) to be given at each administration. It should include, eg, units of measurement, number of tablets, volume/concentration of liquid, number of drops, etc.	Medication dose is an attribute of medication record. This is a record of the total amount of the active ingredient(s) to be given at each administration. In 'dose based prescribing', where a VTM is used, strength is expressed as a separate attribute, whereas in 'product based prescribing', it is usually included as part of a VMP or AMP. dm+d: where strength is expressed as part of a VMP or AMP. SNOMED CT: used where a VTM is used and strength is expressed separately. Allow for mass per unit volume format, to allow for liquid preparations. Where prescribing co-name drugs (eg co-trimoxazole), a strength must be specified for each active ingredient. Also see NHS dose syntax. NHS dose syntax could be used, but has not yet been through clinical assurance, and would need to be, for it to be recommended for use.

Figure 2: Example of technical annex explanations.

become a computational validation, subject to the availability of suitable tooling.) Being generic across the selected technical standards, this agnostic form would also underpin interoperability testing for transformations between the standards.

3 Results

3.1 Data Set Constraints

The first step was to constrain the outpatient headings to the data elements in the epSOS patient summary. Many of the elements from the two sources were transparently equivalent, but there were several significant differences of viewpoint or meaning. For the purposes of our proof-of-concept, we noted the issues and made pragmatic consensus decisions that would enable us to progress with our generic model. The notable issues are addressed in section 4.1.

3.2 Implementation-Agnostic Model

The abstract model was produced as a mind map, showing headings as sections and sub-headings as subsections (Figure 3). After several iterations to clarify questions of interpretation and process, we settled on a high-level structure that was sufficient for our purpose. Pragmatic decisions were made about whether sections were mandatory, required or optional and when there was ambiguity about whether a sub-heading was a section (simply a record organizer for human purposes) or a semantic unit. The abstract model only showed sections, not semantic content. The principal output was not the model itself but the process needed to derive it.

3.3 openEHR Archetype Model

Our openEHR designer produced a set of openEHR archetypes and templates, re-using components including detailed medication models based on UK GP2GP, NHS Scotland messaging models [13] and the detailed RCP medication technical annex [14]. These were combined with other archetypes drawn from the international openEHR repository [15] and a set of new higher-level archetypes aligned with the PRSB headings.

The key issue here was that detailed sub-headings were often insufficiently defined to support interoperability and the elements within artefacts may not match headings precisely.

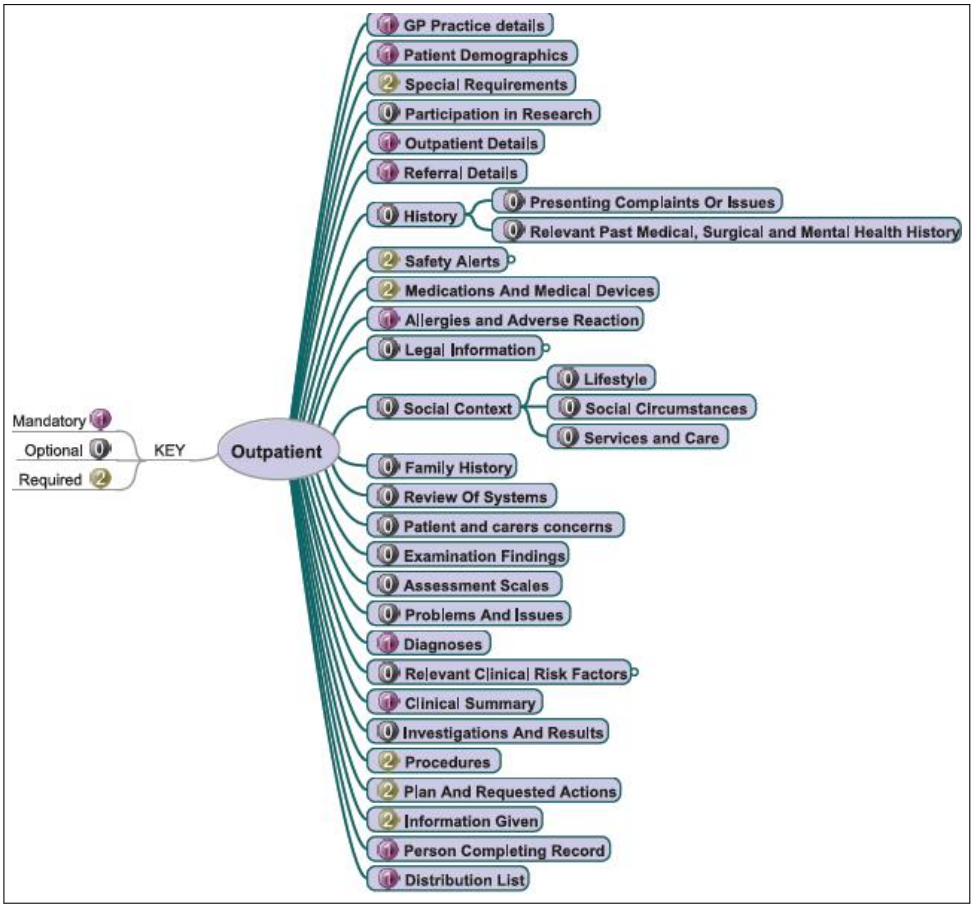

Figure 3: Top-level view of abstract model with selected sections expanded.

3.4 HL7 Artefacts

We investigated the feasibility of representing the outpatient letter with PRSB headings in FHIR resources, using the current FHIR Draft Standard for Trial Use (DSTU) as baseline. This was done through element-by-element analysis of the archetype model, to see whether each of the approximately 500 data elements could be represented in terms of the core resources of the current FHIR DSTU; if it could be so represented, the path in the relevant FHIR resource was recorded in a spreadsheet, against the archetype element.

Complex exchanges are represented in FHIR as Atom-Feed Bundles, which are flat structures of resources represented in XML or JSON, with references between the resources. There are various ways in FHIR to convey clinical documents; the main native FHIR representation is as a Composition resource which holds a hierarchy of sections and sub-sections, which in turn refer to other resources. The referenced resources may be in the same bundle or separate.

Therefore in representing a document which conforms to the PRSB clinical headings in FHIR, the entire structure of PRSB headings and sub-headings is represented in sections and sub-sections of one Composition resource, with references out to other resources to hold the detailed clinical information. This makes the FHIR bundle easier to understand and analyse than the comparable deep nested structures in HL7 Version 3 or CDA. None of the paths in the FHIR representation of the archetype model are very long.

For a purely human-readable document (analogous to a CDA level 0 or 1) the FHIR resources representing detailed clinical information could be resources with only Narrative content, bound together by the sections and sub-sections (headings) in the Composition resource; this would constitute the 'low road' to a PRSB-conformant FHIR bundle. However, we have mainly investigated the 'high road' where the resources also represent the clinical information in coded form. In this case, the resources should still contain human-readable narrative; a sender may choose to generate some of this narrative automatically from the coded data. The FHIR technical analysis is ongoing. The main results so far are as follows:

- There is no difficulty in defining a Composition Resource whose sections and sub-sections reflect the PRSB headings, because the section and sub-section structure of a FHIR Composition resource is entirely flexible. But this has not yet been done in detail; nor has a specifically profiled Composition resource been developed.

- For certain kinds of information in the outpatient letter (such as referrals), the appropriate FHIR resource does not yet exist in the current DSTU. The recommended FHIR approach to this issue (which is to define what you need as an extension of the 'Other' resource) seems very inelegant and unsustainable, and was not investigated. Some of the required resources are being addressed in the current new DSTU under development.

- In cases where the required information does fit in an existing core FHIR resource, generally the level of fit with the Archetype model at the element level was fairly good.

- Nevertheless, at a detailed level we have found many instances of either awkward partial fits (where the FHIR and Archetype definitions are similar but not identical), or of data elements in the archetype model but not represented in the core FHIR resources.

- These instances point to a need to profile and extend the FHIR resources in order to get a good fit with UK and PRSB requirements, however this is an expected stage in national FHIR adoption.

The analysis of the archetype model in terms of CDA (using the UK NPfIT defined profiles and templates) has just been started but no results are ready to report at the time of writing.

3.5 IHE Metadata Definitions

In parallel to this project, IHE-UK had decided to produce generic metadata definitions for a broad range of clinical documentation. This was initially targeted at XDS implementations, but over time it has taken a broader perspective to consider metadata requirements for other platforms. The primary objective of this work is to identify the elements of metadata required to satisfy searches of an electronic patient record for clinical documents relevant to a patient's care, such as specialty, document type, author, following normal patterns of usage in the UK. The possibility of including details of PRSB sub-headings within the metadata is being considered, which might allow simple and efficient location of documents which contain particular information, such as a patient's current medication or problem lists.

3.6 EuroRec Proposals

The EUROREC Institute (EuroRec) is an independent not-for-profit organisation, promoting in Europe the use of high quality Electronic Health Record systems (EHRs). One of its main missions is to support, as a European certification body, EHR quality labelling and defining functional and other criteria.

Inherent within this mission is the promotion of the adoption of relevant standards to achieve greater interoperability across all health systems. Semantic interoperability is recognized to be especially challenging. Its

success lies in the co-creation of standards between professional bodies and health informatics SDOs that provide a useful and usable level of clinical domain coverage and granularity. It is also important to achieve a balance between a tight enough specification for robust computability and a flexible enough approach that recognises the individuality of patients and the inherent and appropriate variability in clinical practice between settings and countries. Through projects like SemanticHealthNet, EuroRec is highlighting the importance of this multistakeholder engagement and helping to understand how this co-creation can best be supported. The work reported in this paper is indeed an example of this, in which clinical professionals from the PRSB are working with the informatics experts to co-create a specification that can be used for conformance testing.

EuroRec will subsequently include these criteria within its portfolio of EHR quality labeling statements, and use them in its future certification programmes across Europe. EuroRec will work with the BCS and other bodies involved in this work to promote and deliver such certification in the UK.

3.7 Conformance Methodology

Based on iterative discussions, we determined that the following steps were needed to derive an abstract information model from the clinical record headings. These steps probably seem like stating the obvious to experienced information modellers, but we found the need to make the process explicit to help clinicians understand why the extant professional guidance was not in itself sufficient to develop technical conformance criteria.

- Decide whether headings and sub-headings are "sections" or "entries" (using EN ISO 13606 terminology).
- Assert the optionality (mandatory, optional, required) and cardinality (for example, one-to-many, one-to-one) of each element, and hence minimal conformance to the model.
- Infer the formal definition of the headings and subheadings; in some cases this required re-labelling (e.g. "GP details") or re-grouping (e.g. "Social context").
- Identify patterns of data that can be handled similarly (e.g. "Referral details" and "Outpatient details").
- Specify single precise data definitions and particular forms of data representation (e.g. what can be free text and what must follow a defined structure or use a particular terminology or value set).
- Disentangle the various perspectives in the professional guidance, for example whether the description is static (e.g. "GP details") or process-based (e.g. "History"). The variance in perspectives sometimes embeds use case constraints into a supposedly generic standard and complicates its interpretation.
- Clarify inconsistencies between structural hierarchies, such as the typical message structure convention of separating administrative ('header') from clinical ('payload') content.

We have also drafted conformance level definitions, but these are under review at the time of writing so are excluded from this report. The general principles are comparable to the CDA R2 constraint levels [16].

4 Discussion

4.1 Comparison of epSOS Patient Summary with Generic Patient Record Headings

The use cases of these two documents are different, so it is not surprising that there are variances in data element content and interpretation. However, some of the differences are notable and suggest that modification or clarification is needed in one or other data set. All the data items in the epSOS "Patient Data" section were readily mapped, apart from "Insurance number" which is not currently applicable in the UK health system. In total, 33/42 data items in the Patient Summary were mapped to the RCP headings and nine items were judged out of scope. Apart from document author, none of the items in the Summary Data (actually metadata) part of the epSOS data set were mapped as the RCP scope excludes metadata.

We found one example of data present in the epSOS Patient Summary not found in the RCP headings:"Vaccinations" – this is a recognized gap in the existing headings guidance.

For some other items it is unclear whether they are the same in the two data sets:

- "Autonomy/Invalidity" in epSOS might be part of "Special Requirements" or "Social Context" in the RCP headings.
- "Expected date of delivery" in epSOS might be part of "Relevant past medical, surgical and mental health history" in the RCP headings.

The structure of data in the Medication Summary part of the epSOS "Patient Clinical Data" section is very different to "Medications and medical devices" in the RCP headings, but we decided that as sections they could be treated as synonymous for the purposes of this project.

4.2 Mind-Mapping as a Design Tool

Mind maps have been a simple and helpful way to visualize the abstract information model and expose disagreements about which headings are purely for human

navigation and which, if any, have intrinsic meaning. This is valuable both for non-technical designers to grasp definitions and conceptual relationships between elements of the model, and for designers from diverse standards backgrounds to agree a common understanding.

5 Conformance Testing

The timescale of the project has not permitted actual conformance testing. We have determined the process that would be necessary to produce testable specifications for certain implementation artefacts (CDA templates and FHIR profiles) that can be traceably derived from an abstract information model. Standard CDA conformance testing methods such as Schematron [17] could be applied to the derived artefacts.

The project has made the working assumption that clinical headings and subheadings are fixed at a point in time (though subject to an agile maintenance cycle) and expressed in abstract information models and specific use case profiles (e.g. "Outpatient letter" is a particular use of the generic headings in the "Outpatient record") comprising a set of constrained information components. We propose that conformance assessment should not be rigid and solely mechanistic, but reviewed on a "comply or explain" basis [18] that allows for constrained adaptation by region or discipline (that still requires "core" content, however defined) and varying levels of adherence.

5.1 Implications for PRSB Processes and Resources

One of the major benefits of this project has been the increased understanding of the importance of clinical and technical partnership. Clinical meaning can be difficult to define with sufficient precision to create unambiguous computable artefacts. An example can be afforded by the long history of debates on the definition of "diagnosis" as differentiated from "symptom" or "problem". The dialogue can be not dissimilar to that had by a group of US and UK citizens when the two natural English-speaking populations have a subtly different understanding of a word that is common to both dialects. Without the dialogue, misinterpretation by one of the other is very real risk. This clinical/technical discussion is critical to ensure the realisation of the shared objective of creating an electronic record that meets the requirements of patients and clinicians.

The first generation of implementations in EHRs and integration services will face numerous questions and issues to resolve. We believe that implementers will not be satisfied, and may lose interest, if resolution only progresses in the glacial timescales of traditional standards-development organizations. We argue that PRSB needs an agile standards development process with EHR vendor and integrator collaboration, and a technical/clinical partnership that maintains a continuing dialogue with the professions and patients, to ensure implementability and widespread adoption. This will require significant clinical and technical resources.

5.2 Adoption and Wider Applicability

The focus of this project has been implementation of the professional guidance in EHRs and communications. This begs the question of human adoption of the guidance and its fundamental usability regardless of how it is technically represented or transmitted. Work to date has attempted to address this by distinguishing "core" headings from the larger superset, however the practicality of this has yet to be demonstrated in real world implementation.

If a conformance scheme seems viable following industry consultation, our aim is to help to lay the groundwork for a collaborative European partnership (that takes a global perspective) between EuroRec (dealing with functional and non-functional requirements), HL7 Europe (dealing with CDA templates, FHIR profiles and other artefacts), IHE Europe (dealing with profiles and metadata definitions), the openEHR Foundation (dealing with archetypes)), the PRSB (providing patient and care professional perspective), and other relevant participants.

Our aspiration is to converge with the EU eHealth Network strategy and the Semantic HealthNet recommendations. Through other modelling activities, in the domain of heart failure, that project has already begun to highlight the challenges of developing a mutual understanding between clinicians and health informatics standards developers, for representing clinical information to a suitable granularity and precision that meets both sets of needs. The work reported here will be adding further evidence of these challenges and of ways in which they may be tackled.

We recommend that as this work progresses it should consider whether a broader contextual model of care concepts such as ISO 13940 (ContSys) could help to unify definitions and clarify viewpoint discrepancies.

5.3 Evaluation and Further Work

We have achieved our first objective, to determine a methodology to produce implementation-agnostic conformance criteria from the PRSB documentation (see 3.7 above). The second objective, to select artefacts to produce for each technical standard, is also complete (see 3.3 and 3.4). We have not yet fully addressed the question of specific conformance tests to use for each technical artefact and therefore what conformance claims could be reliably asserted. We also need to finalize our analysis of FHIR and CDA artefact creation and the definition of conformance levels.

6 Conclusions

Clinical leadership in the design of professional information standards is highly desirable to ensure that EHRs and communications are safe, effective and efficient. The partnership between clinicians and implementers from varying standards backgrounds in this project has demonstrated that the goal of traceably conformant systems and communications is in principle achievable, but non-trivial. Realization of this vision will require substantial investment, a pragmatic culture and a sufficient resource base of skilled clinicians and informatics specialists that can translate between disparate worldviews.

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