BCS Health & Care Executive

Review of *How standards will support interoperability*

Introduction

This document provides comments from the BCS Health & Care Executive on *How standards will support interoperability* (the 'strategy')[1].

Overall we are pleased to see the strategy document and related work as improving interoperability in health and care is essential. There are many encouraging signs of progress and parts of the strategy are particularly welcome.

Although the strategy is not drafted as a standards document, we have reviewed it as if it were and the rest of this document is a table of issues that we have identified. For each issue, we have provided a comment that explains it and then, wherever possible, provided a separate suggestion for improvement.

[As the strategy was a draft for consultation, it has not been reviewed thoroughly for drafting or other editorial issues. However a few that came to our attention while considering the more substantial issues are noted].

Version 1.0 (as submitted to FCI but with minor editorial changes)

[1] https://facultyofclinicalinformatics.org.uk/blog/faculty-of-clinical-informatics-news-1/post/how-standards-will-support-interoperability-90

Contents

Subject	*Section/Page*	*Comment*	*Suggested change/action*
Strategy scope			
1 Medical device interoperability		Medical device interoperability is not mentioned at all but both medical imaging equipment and other digital medical devices need to be explicitly in the scope of an interoperability strategy for health and care.	See more detailed comments below.
2 Medical imaging		DICOM and related IHE profiles are not referenced anywhere in the document.	Add to document.
3 Medical devices		Many digital medical devices including patient monitors, infusion devices and point of care testing instruments need (or have the capability) to hold basic patient information. Newer digital medical devices have networking capabilities and this will be increasingly common because the cost of including the necessary hardware in the device is so low. However, even if a device can be networked, basic patient information often has to be rekeyed from an IT system as there is no operational link between them. To give some simple examples: patient name, NHS number or other id and date of birth are entered into ECG machines and ultrasound scanners. There is also a need for information to flow from the devices as (some of) it should be held in patients' records. Often such information is transferred on paper (e.g. ECG traces) or	Confirm strategy will cover digital medical devices and other electronic equipment, such as fitness trackers, that may hold health-related data. Coverage needs to include patients' own devices as well as equipment which belongs to health and social care providers. Some providers' equipment may be portable and/or not on their premises. In such cases, information exchange will usually take place over a public network rather than an internal NHS or other secure network.

Subject	*Section/Page*	*Comment*	*Suggested change/action*
		rekeyed from medical devices (e.g. blood pressure).	
4 Clinical and business requirements		The document does not state what clinical and business requirements are in scope.	It may well be that adopting a generic and technology-driven approach rather than a patient-centric one will meet a wide range of use cases. However, assurance that the strategy satisfies specific clinical and business requirements (both existing and foreseeable) would be easier if they were outlined. See also next (and related) comment.

5 Settings, locations and flows		Related to the issue of clinical and business requirements is the scope of the strategy in relation to settings, locations and flows.
		
		To meet the stated vision, the strategy needs to allow for all possible types of patient or service users in the English NHS and social care system who, at any point (before, during or afterwards), are recipients of services from other sources. There are many examples including people in cross-border flows between the four home countries, visitors to and from other jurisdictions, etc., etc..
			The strategy needs to cover (or demonstrate that there are no unintended exclusions for) incoming and outgoing information for patients and service users such as the following (of which one or more may apply to any individual):
			• from parts of the UK other than England;
			• from outside the UK;
			• who have been treated in the:
			  ○ independent/private sector:
			  ▪ hospitals;
			  ▪ GPs, dentists and other health professionals including pharmacists, optometrists, etc.;
			  ○ third sector (charities and voluntary organisations);
			  ○ military;
			  ○ prison health system;
			• who have self-care records and/or their own digital medical devices.
			[The list above is not intended to be exhaustive or definitive].

Subject	*Section/Page*	*Comment*	*Suggested change/action*
			In addition the strategy needs to allow for: • patients retrieving and updating their own records; • the related needs of patients' carers; • migrants, refugees and 'undocumented' people; and • children including those in social care (the division of responsibilities between different organisations and government departments is a challenge but does not mean that information should not be available where it is needed for clinical or other purposes such as child protection).
6 Standards beyond scope		The focus is on interoperability. However the document also discusses the end-to-end model, the standards directory, standards roadmap and other topics that could apply to areas in addition to interoperability. Other standards in the directory or roadmap may not be relevant to interoperability at all. In other words, work outlined by this strategy could be taken as covering all other standards areas by extension. In contrast, another interpretation is that this document is part of an overriding standards strategy.	Clarify which activities are in the scope of the strategy and what is just background information.
7 Human-interpretable information		One implication of the Vision statement at the very start of the document is that human access to a remote system is not excluded. This seems to be confirmed in 2(3) "….while machine-readable, complete semantic operability is a useful goal, sometimes just enabling clinicians to be able to see the data is good enough".	It follows not only that UX and UI need to be taken into consideration but also that standards are needed to ensure some consistency during access to diverse remote systems.

Subject	*Section/Page*	*Comment*	*Suggested change/action*
Strategic approach			
8 Model care record		The challenges associated with creating a model care record together with the uncertainties about both ISO 13606 and OpenEHR have no doubt been addressed in submissions from other parties. These issues are therefore not considered further here. There is an alternative approach, and that is to accept that there will always be multiple models in existence. The question then becomes what can be done in that case.	Processes for publicizing, comparing and mapping between models need to be established. Once those are in place, there should be a requirement either to use existing models or, if none of them is being used in a particular instance, to explain why not. Work being done in other domains, in which multiple models and sources of data exist, could inform the development of the proposed processes. For example, CODATA[2], the Committee for Data of the International Science Council, have identified a need to establish a standardised approach for the management of metadata across disparate domains, where there is a mix of modelling approaches used for the representation of data. They have commissioned the development by the Data Documentation Initiative of the Cross-Domain Integration (DDI-CDI) metadata standard[3]. Although the future of DDI-CDI is uncertain, it is clear that harmonisation and comparison of data at a metadata level will be needed in order to accommodate the inevitable heterogeneity of data.
9 Processes, pathways and guidelines		The strategy is concerned almost exclusively with interoperability and standardisation of data in care records.	Consider adding some discussion of standardising processes, pathways and guidelines. Interoperability of those could also be considered.

[2] https://codata.org
[3] https://ddialliance.org/Specification/ddi-cdi

Subject	*Section/Page*	*Comment*	*Suggested change/action*
		Healthcare data does not exist within a vacuum. On the contrary, it is derived from and informs a collection of processes, and the dynamics of this data life-cycle are intrinsic to the need of systems interoperability. Data quality is, by definition, assessed by reference to the use to which data is to be put; therefore, the ability to characterise business process is essential.	
10 Commercial attractiveness	Section 5 page 18	It is unclear whether Section 5 *Make it commercially attractive* contains the intended text particularly as it has subsections numbered 3.1 and 3.2 in it. Although there are some useful statements elsewhere in the document that should encourage suppliers, as currently drafted this Section gives the impression that it is about managing and controlling suppliers rather than incentivizing them.	Redraft section.
Strategy implementation			
11 Priorities, sequencing and duration		As stated in other comments, the document is not a strategy as such. That is not a problem in itself, and outline plans can follow. However the document does not provide sufficient detail on relative priorities or sequencing of activities. In addition the overall timescale that is envisaged is not stated.	Include outline information.

Subject	*Section/Page*	*Comment*	*Suggested change/action*
		Without at least some of this information, it is difficult to assess how implementable the strategy is.	
12 Risks		A balanced strategy needs to consider risks as well as benefits. However there is little coverage of risks.	Add a section on risk to the document. (See also other comments with specific issues). There are several main areas. For example: • the strategy may be technically flawed or not supported by key stakeholders; • once agreed, the strategy may not be achievable if there is a lack of funding or timescales are unrealistic; and • operational risks once the strategy is implemented. For instance, remote systems not being available could be a patient safety risk.
13 System procurement		Although there is some implicit coverage of procurement, the strategy does not address it sufficiently (or explicitly). The document discusses some of the challenges that (care) providers and suppliers face in connection with standards. The document also describes some solutions, including the Standards Directory and Standards Roadmap. However, even if providers know the standards required for a system being procured, they often have difficulties (sometimes failing completely) in ensuring that suppliers meet the requirements.	Provide specific wording for each standard both for: • requests for proposals or similar documents; and • contractual documents. This will assist both providers (who should not have to do work again that has already been done by other organisations) and suppliers who will have better documents from providers to deal with.

Subject	*Section/Page*	*Comment*	*Suggested change/action*
		There are two main reasons: • The documents, such as RFPs (requests for proposals), issued by providers during the earlier stages of procurements do not specify requirements adequately. For example a procurement document might ask a question like "Does the system support FHIR?". That is (obviously) not specific enough and elicits little useful information in supplier responses. • The related problem is that final contracts are often no better. For example a clause might say "The system shall support FHIR".	
14 Scope of Standards Directory		During procurements systems need to be fully specified and that process includes all applicable standards, not just those for achieving interoperability. Presumably the Directory covers all standards that apply to systems and not just those for interoperability. What is not clear is whether, when meeting "a particular use case, setting or care provision", the needs of stakeholders during procurements have been taken into account.	Confirm whether procurements are a use case.

Subject	*Section/Page*	*Comment*	*Suggested change/action*
Governance, openness and transparency			
15 Approval of standards	(Section 3.4 Standards Roadmap) Page 16)	The role of DAPB is mentioned in passing but is not discussed. It may be that its functioning is visible from within the NHS, but from the outside it operates as a 'black box'. At the time of writing none of the following is in the public domain: terms of reference, membership list, meeting papers or even minutes. There may be good reasons for this and is not a criticism. However there is not an open and transparent processes for approving standards in which all key stakeholders are involved.	An open and transparent process, involving key stakeholders (especially from front-line provider organisations and suppliers both of which often have major difficulties with meeting requirements for data collections in particular), is needed either before DAPB makes a final decision or as a replacement.
16 Availability of standards		Many of the standards that are relevant to health and care systems are produced by *de jure* bodies such as ISO, IEC, CEN and CENELEC. In the vast majority of cases such standards are currently not free of charge (whether or not this will or should change is not for comment here). In provider organisations, it is difficult for the individuals who need access to the standards to obtain them. That's not just because of the cost of each standard; many have extensive references to further standards which also need to be accessible.	Just as several Government departments and universities have done, arrange long term funding for access, for all relevant staff (irrespective of seniority) in NHS organisations, to applicable standards for which there is normally a charge. Ensure such access includes IEC and/or CENELEC standards for (digital) medical devices. Assist trade bodies with similar negotiations for supplier access.

Subject	*Section/Page*	*Comment*	*Suggested change/action*
		There is a similar problem for suppliers, particularly the smaller ones.	
Technical considerations			
17 Patient safety		The strategy may well improve patient safety overall but, as with any changes, it will introduce new risks from technical issues. These need to be considered, along with potential benefits, to form a balanced strategy.	From 2(1): "patients' information is fragmented and held on distributed systems in many different formats and structures, but where it can be discovered and accessed when needed by clinicians across the system". Some of the risks that therefore need to be considered are: one or more remote IT systems being temporarily unavailable, poor data quality or undetected errors in patient records in remote IT systems, expiry of access permissions, data longevity variations such that parts of patients' records are archived and/or become permanently unavailable over different timescales, etc..
18 Security		There is very little discussion of security (although there is a passing mention to OAuth 2.0).	Provide additional information as this is a critical area for obvious reasons.
19 Clinical governance and audit		The vision is that clinicians could be accessing information from multiple systems. In some cases there will be sematic interoperability but in others there will be remote access to systems or a combination of both. Creating audit trails of what clinicians did and were presented with (on screen) becomes a significant challenge in such circumstances. There are potentially serious clinical governance and clinical audit issues, not to	The strategy needs to address this topic (ISO 27789 may be of assistance).

Subject	*Section/Page*	*Comment*	*Suggested change/action*
		mention potential medico-legal problems in the event of clinical accidents, if it is not possible to establish what information was available to and seen by clinicians at a particular point because of inadequate audit trails.	
20 Data quality		Data quality is critical to interoperability but there is little discussion of it. The forthcoming data strategy may be concerned with the issue of data quality generally. However in the current strategy the issues of data quality have to be considered in the specific context of interoperability.	This strategy needs to address data quality in the context of interoperability (see also following comment). Ensure that addressing the topic is not delayed or side-lined because of the forthcoming data strategy.
21 Data strategy	(Page 4)	It is unclear how the data strategy on its own can "ensure data is available in time" particularly "to make better clinical decisions" when that needs an interoperability strategy as well.	The risk of overlap or, potentially more seriously, omissions between the two strategies needs to be managed. On a related point, the data strategy needs to ensure there is an effective programme of data governance and best practice in data management. These are essential for data quality (see previous comment).
22 Dependencies on other standards		The document does not address in any detail dependencies on other standards required to achieve interoperability. These include not only technical standards for clinical safety, various aspects of security, etc. but also management system standards (for business continuity, information security, and quality for example).	Clarify how these dependencies will be identified, addressed and communicated.

Subject	*Section/Page*	*Comment*	*Suggested change/action*
23 Event-based architectures	Enabling Increased use of event-based architectures	"The NHS is significantly underutilising this architectural style" needs explanation as the statement in its current form is debatable.	Clarify/elaborate.
24 Current use of NHS numbers	Addressing the under-use of NHS Number Page 12	The NHS number has been mandated in some way or another since the mid to late 1990s. Despite this, it has not been used or implemented in the NHS as required by the Centre. It is not clear whether the reasons for this are understood or have even been assessed recently. It follows that there are risks that the changes listed in the strategy will not be applied in practice and/or the changes won't have the desired effect. There are also risks of certain patients being allocated more than one NHS number or other unintended consequences.	If it has not already been done, consider research into why the NHS number is still not used as required (see also next comment).
25 NHS number changes	Addressing the under-use of NHS Number Page 12	Without going into detail here (and subject to further consideration), it is uncertain that the changes listed are entirely appropriate in their current form. This applies particularly to edge cases including unusual patient flows (see specific comment elsewhere on flows for examples) and system unavailability.	The steps outlined should be subject to a detailed consultation and a formal risk assessment. Perform a safety case exercise.
Terminology			
26 Use of terms		There are issues with: • use of multiple terms which may or may not mean the same as each other	

Subject	*Section/Page*	*Comment*	*Suggested change/action*
		• terms not being used consistently in the main document • terms not being used in accordance with accepted practice elsewhere • etc.	
27 Definitions		Many of the definitions in the glossary are not recognized. In addition their source is not stated.	Bodies such as ISO and IEC have successfully addressed problems with definitions. They: • avoid creating new definitions where possible; • identify the sources of definitions that are used in a particular standard; • indicate whether a definition from elsewhere has been adapted; and • provide databases of terms and definitions. The same principles should be adopted for the strategy. A standardised list of definitions for informatics (standards) in the NHS should be compiled. The Standards Knowledge Management Tool[4] (SKMT) which is a "health informatics document registry and glossary" from the Joint Initiative for Global Standards Harmonization may be of assistance. The IEC and ISO terminological databases for use in standardization are at: https://www.electropedia.org https://www.iso.org/obp (select "Terms & Definitions")

[4] http://www.skmtglossary.org

Subject	*Section/Page*	*Comment*	*Suggested change/action*
Document status and structure			
28 Purpose		The document's purpose is not explicitly stated (and cannot be inferred adequately).	Add a section on purpose.
29 Strategy requirements		The document, while worthwhile (as previously stated), does not: • specify timescales in most cases; • quantify funds; or • have an outline plan. In addition it does not give any detail of how any of these will be determined. Overall the document is more of a policy statement or white paper and, as such, not a fully developed strategy. That is not necessarily a problem and the document itself does not really claim it is a strategy. However the information provided during the consultation process suggests otherwise.	Either add necessary information consistent with a strategy or clarify the nature of the document. In this connection (see separate comment) a section on the purpose of the document would help.
30 Provenance		The document itself does not identify its source (although the FCI consultation information states it emanates from NHS England and specifically the Transformation Directorate).	Provide provenance information. As a minor related point, elaborate on "NHS England is currently working on a target data architecture" (page 4) to avoid uncertainty over which team (if different) is responsible for that and the relationship to the Standards and Interoperability work.
Drafting issues			
31 General			

Subject	***Section/Page***	***Comment***	***Suggested change/action***
Organisation and flow	-	The organisation and flow of the document could be improved. There is also a fair amount of repetition that could be removed. Examples of issues: • *Why this matters* consists of over two and a half pages with no subheadings. • The 14 points at the beginning of Section 2 look like part of the vision that applies to the whole strategy not just the *Architectural Approach*.	Restructure document and break into smaller sections. For example there are obvious subsections on benefits and the data strategy in *Why this matters*.
Executive summary		A document of this length would benefit from an executive summary.	Add executive summary.
Use of the word "we". (see also comment on provenance).	-	The word "we" is used often (99 times) but without saying anywhere who that is. Frequently it refers to those responsible for the document's content. In other instances its meaning is broader as in, for example, "we can transfer money quickly from one bank account to another" (page 2). Elsewhere it would be better not to use the word at all, for example "By ensuring interoperability … we can avoid delays".	Review all use of the word. Where necessary replace or redraft as necessary e.g. "everyone can transfer money quickly from one bank account to another" and "Ensuring interoperability … can avoid delays".
Reserved words/phrases	-	It is not always immediately obvious when the document is using terms in a reserved way.	Capitalize terms that are specific to the domain and/or not being used generically, for example: "Information Standard" (for those approved by DAPB), "International Standard" (from *de jure* organisations).

Subject	*Section/Page*	*Comment*	*Suggested change/action*
Nature of consultation	Section 2 Pages 9-11	One definition of consult[5] is "To seek another's approval of a course already decided on". On pages 9, 10, 11 all of which belong to Section 2 *Architectural approach* the phrase "we propose" is used for a series of bullet points. This seems to be inviting feedback but the phrasing is only used in Section 2 whereas "engage*" is used elsewhere. It is not clear whether this is just a variation in drafting or the differences are significant.	Clarify any differences or improve consistency.
Meeting requirements of standards	-	The terms complies/compliant on the one hand and conform/conformance on the other appear to be used interchangeably.	As it's the standards world ("always more than one to choose from"), there are options but one of the accepted conventions should be chosen.
32 Editorial			
	A shared understanding Page 7	Minor typos: firstly the list of "five key standards…" is followed by a list of six and secondly "Dm+d" should not have a capital letter.	Change first to "six key standards…" (or remove FHIR which is in a different category anyway) and second to "dm+d"
	Figure 1 Page 8	It is unclear what this figure is intended to convey but, whatever it is, the content is – at best – unexpected. Too many issues to list – this is a selection: • practitioners appear to originate patient information which then flows to the patients themselves; • patient information flow appears to be unidirectional (upwards); and	Delete figure, redraw, or clarify.

[5] http://www.thedevilsdictionary.com/c.html#CONSU

Subject	*Section/Page*	*Comment*	*Suggested change/action*
		• patient information is only shown as shared between settings and practitioners are excluded.	
	Section 3 Page 12	"Core Information Standard" is referred to but with no reference or qualification.	State the 'standard' emanates from PRSB and provide a link to it on the PRSB website. Add note that it is not currently an "information standard" that has been approved by DAPB.
	Glossary Page 21 (see also comments on terminology and definitions)	There are numerous issues with the glossary but documenting them individually would be excessively time consuming. In summary: • the definition of some terms is one or more of: inconsistent with usage in the main body of the document, unclear, circular; and • some terms are not used in the main body of the document at all, for example "business patterns".	Review and revise all definitions of terms used in the document and remove unused terms.
	Clinical information standards Page 22	• The purpose of this list and the criteria for inclusion are unclear. • No reference is made in the main body of the document to this list. • It is not stated (unless it has changed recently) that dm+d covers a very restricted range of devices. • Minor but the entry for dm+d reads more like an advertisement than a statement of fact.	• Delete section or insert explanation for, and reference to, it in main text. • State criteria for inclusion • Unless it has changed, clarify dm+d does not cover all devices (in the sense the term is commonly used in a medical context).