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Tony Cornford and Valentina Lichtner
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Digitalization of medicines: artefact, architecture and time

Tony Cornford, Associate Professor in Information Systems, Department of Management, London School of Economics and Political Science, London, UK, t.cornford@lse.ac.uk

Valentina Lichtner, Lecturer in Information Management, Leeds University Business School, University of Leeds, Leeds, UK, v.lichtner@leeds.ac.uk

> *Digitalization: "The encoding of analogue information into a digital format and the possible subsequent reconfigurations of the socio-technical context of production and consumption of the associated products and services".[1]*

This edition includes two papers reporting research from a five year study of electronic prescribing in English hospitals.[2 3] These papers each address a significant safety and quality issue drawing data from the wider study. These issues are the level of coordination and integration that electronic prescribing systems achieve,[3] and the emergence of 'workarounds' as managers and clinical users adapt electronic prescribing systems' capabilities to their needs and working environment.[2] . The risks to patient safety posed by these systems, their implementation and use, are further explored in a third associated paper published elsewhere.[4]

Workarounds were found to be either 'informal' or 'formalised' practices, the former derived from user innovations, the latter promoted and endorsed by management. Both types involved the use of other 'intermediary systems', such as paper or other software.[2] While workarounds can create new risks and are an opportunity for safety issues to emerge, the study does acknowledge the positive role of workarounds in permitting poor usability of systems to be addressed, as 'intentional strategies to help users gradually get used to a new system', and as a means to support local innovation and tailoring.

The issue of integration of information is a common theme that crosses both studies. Workarounds, arguably, serve to better integrate information into work practices while the interfacing of multiple digital systems can provide a more coherent and timely flow of information. The research reports that even integrated hospital-wide systems were found not to interface well with external systems.[3] It is important to note that the systems considered for integration with electronic prescribing in these studies are not necessarily medicines' systems (e.g. in pharmacy) – they include also administration, imaging, laboratory, or specialty systems and the systems are not differentiated in terms of the data they hold – whether about medicines, or patients, or other operational data.

For the organisation, the choice between the *integration* provided by integrated hospital-wide EHR packages or *interfacing* ('knitting together' different standalone software – sometimes described as a 'best of breed approach') was found to pose a complex set of trade offs among a 'range of considerations, of which patients safety is only one'. [3]

These studies provide valuable and detailed accounts of the state of the art in electronic prescribing in England. They also offer an opportunity to reconsider how we conceptualise the role of digital technology in improving the way medicines are used. To do so, we identify three interlinked contemporary themes to add to or recast those emerging from these papers and described above. The three additional themes are: (1) considering the medicine itself as a 'digital artefact'; (2) the significance of time in medicines use; and (3) the architectures of the digital systems supporting medicines use. Taken together these may invite a change in scope and focus of the discussion of electronic prescribing – to move from task orientation (prescribing, administration, discharge) to an institution-wide or

even system-wide perspective that emphasise data and communications infrastructures in support of new services and processes specifically for 'digital medicines'.

Medicines as digital artefacts

> *Digital Artefacts: Editable, interactive, reprogrammable, and distributable resources. Their value and utility is contingent on shifting webs of functional relations with other artefacts across contexts and organizations.[5]*

When considering the implementation and use of digital systems such as electronic prescribing, it is easy to focus on the task at hand and forget the physical artefacts these systems represent and combine with - in this case, medicines. Medicines are products with multiple physical and digital realizations and representations, representations that are potentially editable, interactive, reprogrammable and distributable. Thus any given medicine will exist in many different databases, including manufacturing and supply chain, research and clinical trials, regulation and licensing, institutional stock handling, protocols and guidelines, electronic prescribing, dispensing and administration, as well as in patient records and other registries. However, the digital artefact, as a summation of such representations, has not so far shaped how we have thought to date about electronic prescribing and other medicines related systems. Each partial digital representation has been taken more or less as separate and relating to a particular task, place and time.

More focus on the medicine as a data rich digital artefact may lead to increased awareness that medicines are different one from another in many dimensions, including their storage, transport, legal and regulatory status, protocols of use, and in the ways that they 'match' the patient's needs. Recognition of this may yield new capabilities for safer use of medicines. The logic of the current generation of electronic prescribing systems, as

studied in the papers considered here, is that all medicines can be accommodated within the constraints of limited pre-set functionality and on the basis of a given database. Thus, a primary motivation for 'workarounds', as suggested by Cresswell et al [2] is the recognition that a particular medicine does not 'fit' the system's assumptions.

Medicines in time and space

Medicines are artefacts with a complex time dimension. Safe use of medicines is fundamentally related to their being made available at the right time and right place. Thinking of medicines as digital artefacts can offer powerful means to control time and place – to position medicines at the time and place when they are needed (e.g. in the warehouse, in the automated dispensing machine, on the drug round, ready for patient discharge), and to monitor the timeliness of activities (e.g. dispensing, transport, administration). This can serve in process improvements and potentially cash saving efficiencies, including in the management of logistics and supply chains [6]. The ability to better account for temporality of the artefact may also lead to the design and implementation of better software with interfaces and decision support that confidently draws on temporal data. Of course, such capabilities will also offer new potential to create errors of time and place – to mis-locate medicines or to mis-specify time controls.

Time and place dimensions are also apparent in electronic prescribing systems implementation and support processes, as evident from the studies considered here. System roll-out and user adoption takes time; it takes place in time and across locations as work processes adapt and change (including workarounds); implementation should not be conceived as a one-off task, but as an adjusting and evolving process over time, that is directed in part by data on medicines accumulated during system use. Thus the medicine

as a digital artefact can 'know' its own history and use this data to help innovate behaviours.

Architectures and infrastructures

Cresswell et al [3] suggest that to achieve even minimal integration of electronic prescribing with other hospital systems, the hospitals they studied faced a bald choice between adopting a single integrated bundle of inflexible software and functionality, or taking on the task of interfacing their chosen electronic prescribing software with other systems. Future generations of electronic prescribing software may need a new architecture to help institution's get beyond this dilemma. Achieving the safety and efficiency benefits from viewing medicines as digital artefacts will require common, shared, networked, services in support of integrated working – a digital medicines infrastructure. How might we get there?

We know from recent research that the way digital infrastructures emerge and develop is different from how our current generation of electronic prescribing systems and electronic patient records have been developed. The packaged software and commercial off-the-shelf solutions used for electronic prescribing today are for the most part based on proprietary code and limited, task-focused, requirements analysis. Digital infrastructures, in contrast, evolve as they respond to and meet multiple needs.[5] The resulting architecture focuses on providing shared services, and their cultivation and evolution (see Box 1).

Box 1. Six core concepts of digital infrastructure, adapted from [5]

1. **Shared**: a digital infrastructure is shared by the members of a community.

2. **Evolving**: a digital infrastructure is not designed or created in a singe act, but evolves continually as it expands in scale and is adapted for new purposes.

3. **Open**: a digital infrastructure is available for new users and new uses.

4. **Standardized**: a digital infrastructure needs agreed common standards to ensure its functional integrity and allow it to scale up.

5. **Heterogeneous**: a digital infrastructure consists of different elements: technology, users, organizations, governance.

6. **Installed base**: a digital infrastructure will build on, expand and integrate previous systems and services.

We are today in the earliest phases of developing the standards and resources that open up the option of a digital medicines infrastructure at the hospital scale and upon which multiple services might be built. Why, for example, should a hospital not be able to deploy services that allow a prescriber to look at the stock of a medicine, its price, its use for other patients/patient groups, current research and so on. Such a case looks beyond separate software driven islands for procurement, prescribing, dispensing, administration, discharge, research, audit and so on, and moves towards a core digital artefact, served by a new infrastructure that allows multiple task-oriented software applications to support safe and context relevant work practices reflecting a rich detail of specific medicines.

At one level such an infrastructure is just a step or two on from the 'interfacing' model that Cresswell et al. introduce.[3] However, infrastructures have another essential and valuable quality – that of *generativity,* "a system's capacity to produce unanticipated change through unfiltered contributions from broad and varied audiences."[7]

In providing services that support the flexible and open sharing and mixing of digital artefacts (medicines but also patients, samples, tests, population data, demand data, etc.) the opportunity for 'contributions' from the broader community is reinvigorated. Today, as Cresswell et al. note [2], the users of electronic prescribing software have few opportunities to take their own ideas and make them work. By separating the *infrastructure layer*, where digital artefacts and associated services are made available to share, from the users' *applications layer* , this engine of innovation – including innovation in safety - may be restarted.

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