Research Protocol

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Overview

• Drugs going digital: how we understand this
• How we research it: method and language (a ‘protocol’)
• Some reflections and future work
Introducing Digital Drugs...

• Our concern is with the changing nature of medical drugs (medicines) as they become encrusted with digital features and embedded in new data ecosystems.

• We ask how, where and for whom the digitalisation of the chain of supply and consumption of medical drugs (medicines) may create or add value, and the new or changed work practices and business models that develop.
Background

• Drugs and digitalisation

- Active molecule, material delivery systems, informational resources for legitimation and use
- Their use set within complex and elaborated work practices and institutional arrangements
- The new Digital Drugs are just more so
- Dependent on and substantially constituted by multiple digital representations and connections, with use and effectiveness strongly mediated through digital means.
Background

- A healthcare ‘imperative’

  - Our healthcare is built on using medicines - a primary means of providing care and a primary source of cost
  - Current expectations of new drugs, and of **better ways to use the ones we have; more effect for less cost**
  - A over a decade of digitization of drug-use data and related ICT systems e.g. electronic prescribing with decision support, robotic dispensing, prescription transmission, adherence technologies
  - More opportunities ahead: EHRs at scale, pharmacovigilance, $10 genome, stratified and personalised medicines etc.
Theoretical Propositions (Hypotheses)

1. digitalisation is changing the *materiality* of the drug
2. digitalisation is changing the *value* of the drug
3. digitalisation is changing the *assemblages* that occur around and involving the drug
4. the drug is (or becoming, or returning to be?) an ‘*incomplete product*’; the drug is (or is becoming) entangled with the digital, as a ‘digital hybrid’
Theoretical influences

• *Changing as a sociomaterial process* (Petrakaki, Cornford et al. 2010)
• *Digital materiality* enmeshed within work practices (e.g. (Leonardi 2010, Yoo 2012))
• *Assemblages* - a question of emergence (emergent properties, generativity) in open systems – “the always-emergent conditions of the present” (Marcus and Saka 2006, De Landa 2002).
• *Digital business models* and their narrative and performative roles in mobilizing and explaining change (Christensen, Grossman et al. 2009)
Conceptual foundations

- **Digitization**: information that moves from analog to digital form (data) or when new digital data sources become available.

- **Datafication**: the process of accumulation of these data and their multiple repurposing (as in, but not restricted to, Big Data); volume, velocity, variety.

- **Digitalization**: the wider sociotechnical changing associated to both (the subsequent reconfigurations of the socio-technical context of production and consumption of the associated products and services) – *a socio-digital reconfiguring?*

- **Agency migration**: the changing in how agency is (re)distributed as digitalisation occurs.
How do we study this?
Study design: follow-the-drug in a multi-episode study

• A focus on value, practices and business models
• 5 Episodes studies of the phenomenon of digitalisation of medicines
• 3 Exemplars chosen drugs followed across the five studies (tracer approach)
Why Episodes?

• to reflect that drugs become digital incrementally and cumulatively through multiple transitions occurring in different places and times
• resonates with the temporal/historical nature of processes of digitalisation
• reminds us that studies of change (before-after studies) are but snapshots in a longer timeframe – a longer becoming
• to distinguish our study design from the more traditional case study research (Yin 2003)
The term protocol originated in Medieval Latin where it referred to the first (proto) paper sheet glued (kolla) to the top of the minutes of public transactions and that outlined the contents of the resulting volume. As chronicled in the OED, the semantic field of the term has since undergone considerable extension, leading to the present-day scientific and clinical meanings that include the list of the successive steps of an experiment, the outline of a planned examination, or the agreed-upon schedule of chemotherapeutic drugs and dosages. The term thus has multiple meanings referring simultaneously to a legal authority, since its content is binding on the participating parties; a convention, for it is the result of a transaction between participants; a public, because as a communal document it is open to inspection by interested individuals or, at least, overseeing agencies and organizations; a prescription, since it dictates both the activities that have to be undertaken by participants and how they should be performed; and, finally, a description, insofar as it acts as a record of what has been done (see also Lynch, 2002).

What’s next? Maps and mapping
Maps and mapping


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Maps and mapping

1. Patient sees prescriber
2. Need for repeat medication identified
3. Repeat medication authorised
4. Patient decides to re-order medication
5. Request for repeat submitted
6. Check whether repeat allowable (administrative check)
7. Prescription produced
8. Prescription presented for signature
9. Check whether repeat appropriate
10. Prescription signed
11. Prescription returned to practice staff
12. Medication review, and prescription issued / given
   (if prescription not given to patient, it is then returned to practice staff)
13. Prescription collected / given to patient or representative
14. Prescription received by pharmacy
15. Professional check
16. Patient medication record checked
17. Prescription checked with prescriber / prescriber records — as necessary
18. Items dispensed / accuracy check
19. Medication put out for collection
20. Medication received by patient
21. Medication used
Maps and mapping

“... facilitate the management and navigation through major public policy issues. These maps have benefits for policy analysts and decision-makers similar to those of geographic maps. They provide patterned abstractions of policy landscapes that permit the decision-makers and their advisors to consider which roads to take within the wider policy context.

...”.

Conclusion

- Next steps: access to sites, research in the field...
- Analysis – mapping and modelling ...
Conclusions

• The process of developing the protocol: collaborative, informative and generative

• Asking questions to ourselves, provoked clarification of concepts

• Inspired writing and contributed to the LSE Research Festival poster
LSE Research Festival Exhibition
21 May 2015, 5.30-8.30pm
Lower ground floor, New Academic Building, LSE
Digital Drugs: noun, pl.
drugs that are dependent on and substantially constituted by multiple digital representations and connections, and whose use and effectiveness is strongly mediated through digital means.

Medicines and Drugs are hybrids, part active molecule, part delivery system, part packaging and instructions, and embody protocols of use and afford work practices. They are also becoming in part digital – they are digitizing their agency as artefacts (devices, objects) and of chemical action in biological milieu. But it is also a story of digital materiality and digital agency.

As a hybrid digital artefact a drug is constituted within, and an expression of, multiple digital representations and inter-connections. From the in-silico science of drug discovery, and testing procedures of randomised control trials, a drug is embodied as digital data.

And the digital sedimentations continue once a drug becomes a licensed product and moves to manufacture and then use. The people and groups who work with and use drugs (e.g. of us) are drawn in to the digital sphere and shape new practices of medicines use, individually and system wide.

In this way digitalization implies new and novel architectures of value creation, realization and capture – new business models. These are expressed in reconfigurations of the socio-technical and economic context of medicines within healthcare; as value propositions, as products and increasingly as services, as therapeutic agents, as the locus of innovation and as new forms of regulation.

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Conclusions

• How do we understand digitalisation?
• How do we study it?
References 1

References 2

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