DESIGN THINKING IN DATA-INTENSIVE HEALTHCARE IMPROVEMENT: LESSONS FROM A PERIOPERATIVE CASE STUDY

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ABSTRACT

Healthcare generates vast quantities of 'routinely collected' data that is recognised as a valuable substrate to drive improvement. Realising this benefit however, requires the sequential distillation of new knowledge before analytical findings are used to inform real-world change. This dichotomy requires the combination of techniques from data science (to derive meaningful knowledge) and improvement (to deliver change). Recognising this transdisciplinary need and the complexity of modern healthcare, we developed an improvement project to incorporate a 'systems approach' into the analysis of pseudonymised perioperative data for the purpose of redesigning the systems that deliver surgical care to older patients. This required the development of novel mixed-methods workflows combining tools used to realise a systems approach in practice and to support meaningful analysis, and to translate these findings towards 'better' care systems. This paper recounts the incorporation of these tools into 'data-intensive improvement' and reflects on the relevance of design thinking to improve the conduct of the necessary data science to achieve our ultimate aim, using data to improve services for older surgical patients.

Keywords: Systems Engineering (SE), Design process, Big data, Healthcare Improvement

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1 INTRODUCTION

1.1 Healthcare data as a substrate for improvement

Healthcare is increasingly digitised, with vast repositories of 'routinely-collected' healthcare data advocated as vital for medical research and service improvement (Goldacre, 2022). Routinely collected healthcare data exists in a multitude of forms and is a clear example of 'big data', being of such a *'high volume, velocity, and variety to require specific technology and analytical methods for its transformation into value'* (De Mauro et al., 2016). Such value might be improved efficiency, drug discovery, precision diagnostics, or new methodological insights (Rumsfeld et al., 2016).

However, it is apparent that data alone cannot directly improve health outcomes, with any route between stored data and 'better' care requiring the sequential distillation of new knowledge and subsequent action (Figure 1). The first of these involves the curation and analysis of large datasets to yield new knowledge through data science; a combination of computational and statistical methods of relevance to researchers from multiple disciplines (Stoudt et al., 2021). Methods for directly improving healthcare through practical action are described in both the quality improvement (QI) and implementation science (IS) literatures. Combining these two has conceptual overlap with models of the design process such as the 'double diamond' (Ball, 2019). Under the schematic shown in figure 1, the analysis limb could reflect the refinement of the problem space, with the action limb mapping to the 'deliver' phase.

Despite the widespread use of QI and the breadth of available data, use of data in QI remains primarily descriptive; tracking compliance with process and balancing measures (Shah, 2019). This is at odds with the fact that advanced analytical techniques (such as network analysis) can clearly yield insights of relevance to system redesign (Kohler and Ercole, 2020).

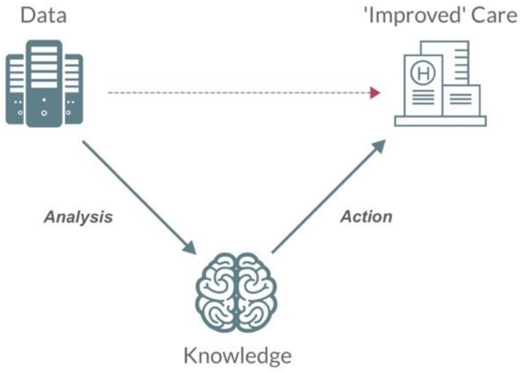

Figure 1: Conceptual model of how improving care using healthcare data requires an analytical process (to distil meaningful knowledge from data) coupled to a series of actions to effect change in the real world. Direct improvement from data is impossible (red line).

Part of the challenge is that data science and healthcare improvement arise from distinct epistemological and ontological foundations. To bring the benefits of big data analytics to real-world change, an overarching framework is required. This paper presents systems design, embedded within a wider systems approach as one such approach.

1.2 A systems approach to data-intensive improvement

1.2.1 Potential of a systems approach

Healthcare is frequently conceptualised as a complex system with traditional biomedical research disciplines such as epidemiology advocating for the use of tools derived from systems thinking to aid in interrogating and intervening in complex causal problems (Rutter et al., 2017). Additionally there is growing recognition of the potential for big data to support analytical methods derived from engineering (Committee on engineering and the healthcare system, 2005), the need for greater transparency in the assumptions and conduct of data analysis, and the real-world potential of a systems approach to intervene in healthcare (Komashie et al., 2021).

The V-diagram is a well-established device for graphically representing a systems development lifecycle. Combining this model with the analytical and action stages of translating healthcare data

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into improved care (Figure 2) provides face validity for the use of systems engineering in structuring data-driven healthcare improvement.

In 2017 the UK's Royal Academy of Engineering led a collaboration with the Royal College of Physicians and the Academy of Medical Sciences to define what a systems approach to healthcare may look like, drawing on the expertise of systems engineers, healthcare professionals, operational researchers, and healthcare improvers (Clarkson et al., 2017). The final report, *Engineering Better Care*, envisages a systems approach as being one that sequentially addresses the core domains of people, systems, risk, and *design* through a series of iterative questions.

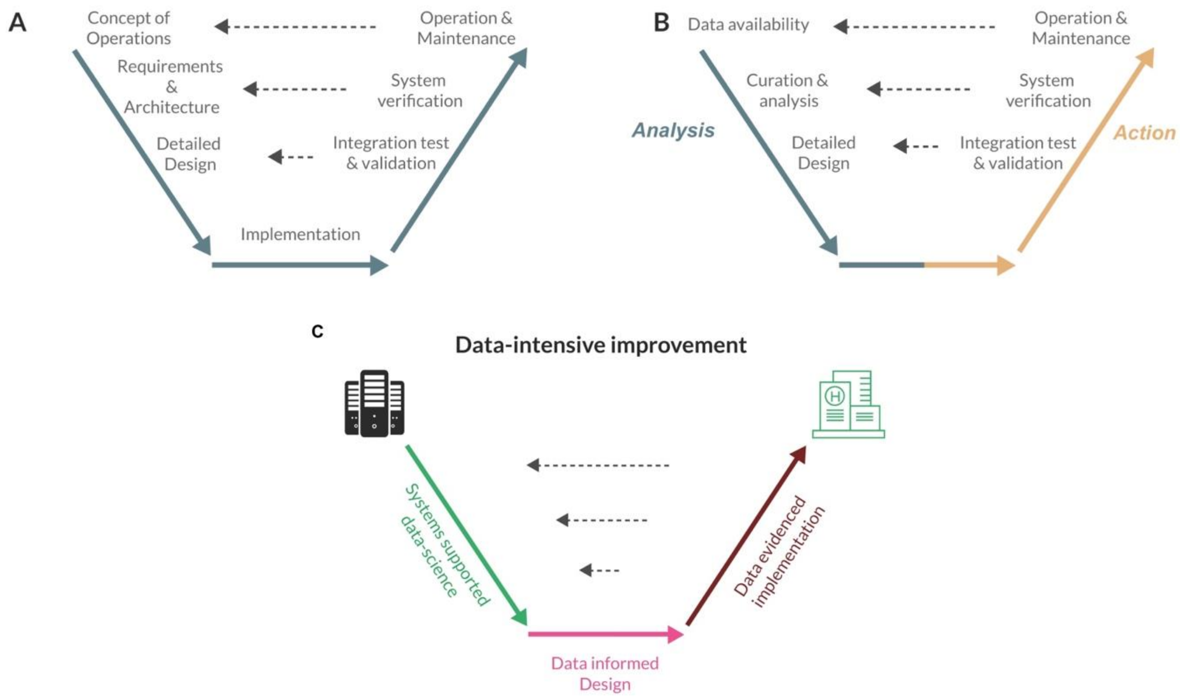

Figure 2: Conceptual mapping of the systems engineering 'V' diagram (A) to the potential stages of translating data into improved healthcare (B). In B the descending analytical limb involves increasingly granular data analysis to inform the design of an intervention that is subsequently implemented and validated in practice. C demonstrates a conceptual schematic for data-intensive improvement structured using the V-diagram

1.2.2 A case study

To explore the utility of a systems approach to scaffold the translation of healthcare data into improved care, we conducted a prospective case study of a novel perioperative improvement initiative supported by the analysis of a large pseudonymised Electronic Health Record (EHR) dataset.

The 'Designing Improved Surgical Care for Older people' (DISCO) project sought to use insights gained from the statistical analysis of EHR data to identify problems (that impact patient outcome) that might be addressed by appropriately designed intervention. Data science and implementation workflows were specifically tailored to address the key EBC questions and stages.

The DISCO project focussed on the inpatient stay of individuals aged 60 or over undergoing surgery, seeking to identify and understand problems that may negatively impact on patient outcome (Figure 3). Recognising that acting on either 'false positive' or 'false negative' statistical results could result in fundamental flaws in solution design, a decision was made to ground statistical analysis in the discipline of 'causal inference', a cross-disciplinary framework to yield robust estimates of the causal effect of specific variables on a designated outcome (Hernan and Robins, 2020). This involved the co-design of a causal diagram (a ‘directed acyclic graph’ DAG) with a cross-section of professionals to provide a transparent and robust underpinning to subsequent statistical analysis.

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Early stages of the project, involving process mapping, stakeholder identification, and a modified Delphi process (of 33 distinct professional roles across two hospital sites) to define the core metrics required to adequately analyse and map the problem space of the perioperative system, has been previously published (Stubbs, et al., 2022a). Further details are available in the doctoral thesis summarising this work (Stubbs, 2023). Similarly, results from earlier analysis of related EHR data (Stubbs et al., 2020) is being used to inform the design of a complex intervention relating to the care of a cohort of frail neurosurgical patients, within a national initiative (Stubbs, et al., 2022b).

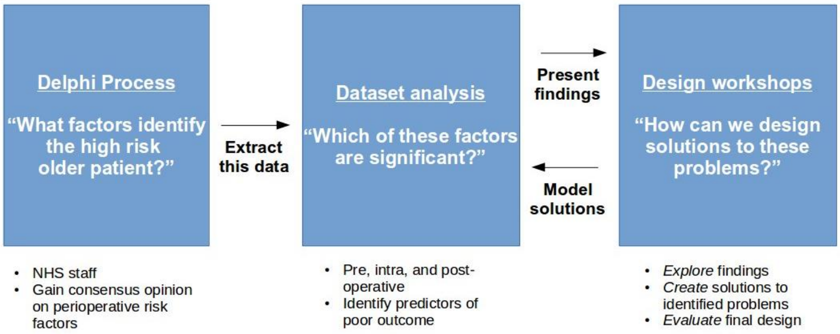

Figure 3: Core stages of the designing improved surgical care for older people project.

1.3 What is the role of design in data-intensive healthcare improvement?

Work on the DISCO project suggests that systems tools can support the conduct of meaningful data science and completion of core steps, before aiding in the design of a suitable information, whilst the corroboration of intervention (in the form of a quasi-experimental study) is a key part of national guidance (Skivington et al., 2021).

The importance of the *'design'* component of a systems approach emerged repeatedly throughout DISCO. The importance of design thinking in healthcare has been noted by other authors (Crowe et al., 2022), and a key advantage of the EBC systems approach over competing healthcare improvement methodologies is its explicit focus on design (Clarkson et al., 2017). Indeed, the data science workflow established for DISCO prospectively used tools from design thinking (Table 1) to transparently communicate and justify analytical decisions, in an effort to increase transparency at points in the analytical process which could contribute to significant variation in analytical results (Huntington-Klein et al., 2021).

Although quantitative analysis is often lauded as providing 'objective' evidence, in reality the subjectivity of statistical analysis has been long noted (Berger and Berry, 1988). Indeed, comparative studies, using identical datasets, has demonstrated that analytical choices can yield opposite results (Breznau et al., 2021), some of which may be down to researcher decisions that are poorly communicated (Huntington-Klein et al., 2021). This challenge to the objectivity of quantitative data poses significant difficulties for a hypothetico-deductive model of healthcare. However, can it be accommodated by a design-led systems approach to healthcare improvement? More broadly, what is the role of design in data-intensive healthcare improvement?

2 METHODS

2.1 Research framework and approach

This work is based on experiential reflection (Kolb, 1983) on the conduct of a data-intensive improvement initiative relating to the care of older, medically complex, patients undergoing surgery. The case study is a recognised research technique (Fitzgerald, 1999) and permits the practical investigation of under explored elements linking 'data' and 'improvement'. This reflection sought to understand the importance of design thinking and methods at key points in the design and development of the dataset for the DISCO project. It summarises the role of design in analytical phases of the data-science workflow, specifically the curation of required data and the design of novel covariates. Further reflections are available elsewhere (Stubbs, 2023).

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2.2 Case study rationale

Surgical risk increases with chronological age due to both patient factors (such as frailty) (Lin et al., 2016) and system factors (such as staffing) (National Confidential Enquiry into Perioperative Outcome & Death, 2010). Recognising this, we instigated a local perioperative quality improvement programme in a digitally mature healthcare trust in the East of England. This project specifically sought to establish a data infrastructure to support the identification of key problems relating to adverse patient outcome, verify this using statistical means, and use these findings to re-design surgical pathways with the aim of minimising patient risk (Figure 3).

2.3 Data storage and approvals

Pseudonymised healthcare data was obtained following regulatory approval and stored in an approved storage location by Cambridge University Hospitals NHS Foundation Trust (CUH). The DISCO project was jointly sponsored by CUH and the University of Cambridge. Ethical approval was gained from the London and Surrey Borders NHS Research Ethics Committee (approval reference: 19/LO/1648) in October 2019.

2.4 Specific methods

2.4.1 The data science workflow

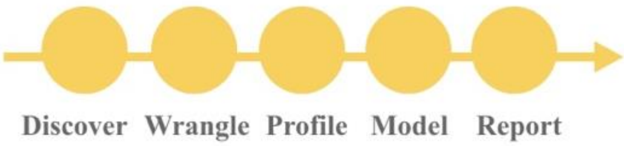

Figure 4: A data science workflow as derived by Kandel. (Kandel et al., 2012)

Completion of a data science task relies on a series of five, often iterative, stages (Figure 4, Kandel et al., 2012). The *'discover'* phase involves identifying relevant data sources before these are *'wrangled'* into a format suitable for analysis, *'profiled'* to ensure veracity and then used to conduct a specific piece of analytical modelling. Finally, these results must be reported to relevant individuals (for action)

Table 1. Systems tools incorporated into the various phases of the DISCO data science workflow and their summary use.

Tool	Use	Data science 'phase'
Process mapping	Mapping system processes Identifying data sources in EHR	Discover Wrangle
Card Sorting	Identifying core variables for statistical modelling	Discover Model
Participatory diagramming	Refining process maps Causal diagrams	Discover Model/Report
Personae	Incorporating statistical results into co-design workshops	Report
Bow-tie diagrams	Visualisation of project risks	Discover/Wrangle/Report
Needs assessment	Design of novel covariates Design of complex interventions	Discover/Wrangle Report
Morphological charts	Mapping of potential data sources against concepts for measurement Mapping of problems to potential solutions	Discover/Wrangle Report

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2.4.2 Design and systems thinking to support a data science workflow

DISCO incorporated techniques used to realise a systems approach in practice at each stage of its data science workflow (Table 1). Techniques were drawn from the toolkit used to operationalise Engineering Better Care in practice ('*The Improving Improvement toolkit*') (Clarkson, 2020).

3 RESULTS

3.1 Dataset design

Use of healthcare data for secondary purposes (such as research) is governed by key legislation (such as the Data Protection Act (Data Protection Act 2018) with required approvals dependent on analytical aims (NHS Health Research Authority, 2022). Importantly, data does not exist in a readily accessible format for this secondary use, it must be obtained (either through a research study) or extracted and curated from routinely collated sources.

The DISCO project required a dataset that would be broad enough to sufficiently map the perioperative system while fulfilling governance requirements on minimising data use and maintaining privacy. These are clearly competing requirements and can be represented by the needs of specific individuals or organisations (figure 5).

As a ...	... I need ...	... so that ...
Researcher	A dataset of sufficient breadth and accuracy	I can use it to answer relevant research or Improvement questions
	A dataset that captures patient and population relevant outcomes	I can use it to answer relevant research or Improvement questions
	A dataset that maintains anonymity	I maintain patient trust and comply with necessary governance legislation
	To understand what important data might be missing from my dataset	I can seek to improve it and to understand how this may affect my analysis
	For the data to be stored in a secure location with adequate computational power	I can conduct necessary analyses
Governance Lead	To understand what the dataset is for (research or improvement)	I can advise on appropriate approvals and governance structure
	Any dataset to be kept securely and maintain patient anonymity	The organisation complies with necessary legislation
		Patient trust is maintained
	To understand what data sources researchers may require	I can advise on their appropriateness
Patient	My data to remain secure	My privacy is maintained

Figure 5. Illustrative needs of key parties in the development of a dataset for healthcare improvement using routinely collected healthcare data. Needs captured using a template from the 'Improving Improvement toolkit' (www.iitoolkit.com) - used with permission.

The development and delivery of the dataset for analysis consisted of numerous interlinked and iterative steps including; defining the necessary dimensions of the dataset, obtaining electronic surrogates for these data fields, and the choice of a physical storage platform. Each of these could be viewed as individual design steps or as part of an overarching process (Figure 6).

3.2 Dataset dimensions

Our combination of process mapping, stakeholder identification, and a modified Delphi (Stubbs, et al., 2022a) expressly sought stakeholder opinions to broaden the dimensions of included data beyond that readily obtainable from the literature. Process maps were used to model both where specific information may be stored within the EHR (Figure 7) as well as tracing patient journeys to identify key stakeholders for representation on the Delphi panel. The views of these 33 stakeholder groups were then harnessed to provide a divergent view on dataset dimensions (Stubbs, et al., 2022a).

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The process identified novel suggestions (suggesting benefit of divergent thought) and helped converge on core components of what the final dataset should contain. This convergence was aided by efforts to identify duplicated concepts amongst the results of the Delphi (using card sorting) and begin mapping these to available data resources within the source EHR.

3.3 Designing variables

Having defined the desired core data fields, the delivery of these into a real dataset required their mapping to available information sources within the EHR. Electronic health records have complex structures, guided by international standards (International Organisation for Standardisation (ISO), 2015). Identification was made more complex due to the nature of many of the suggestions that emerged from our earlier Delphi. For instance, variables such as *'Age'* were readily identified in structured data fields, while more abstract concepts such as *'multidisciplinary working'* clearly required the development of complex electronic surrogates. Indeed, even common variables such as medical history proved complex to accurately define.

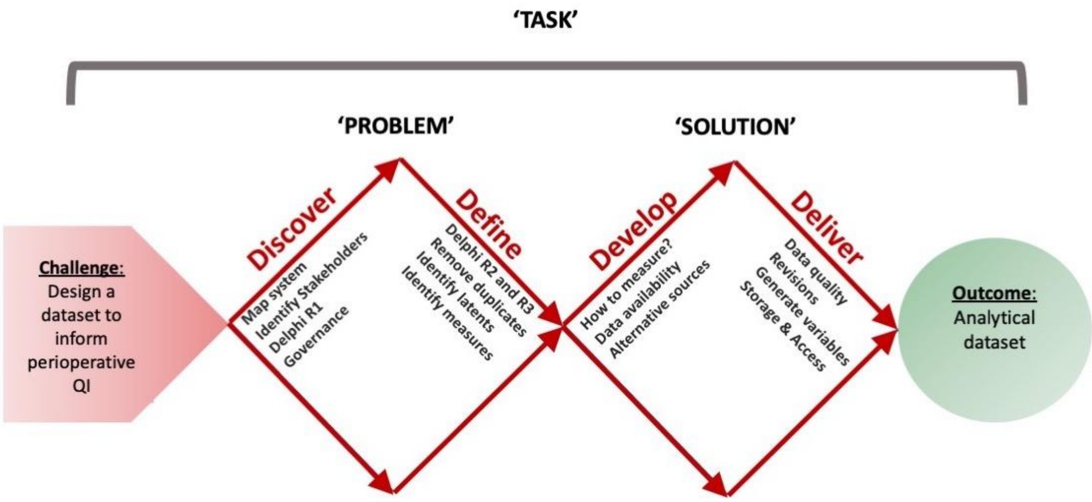

Figure 6: Work done to deliver an analytical dataset containing pseudonymised healthcare data mapped to the phases of the Design Council's 'double diamond' model (Ball, 2019). In reality, the delivery of this dataset formed one specific 'task' within a wider data science workflow. For practical improvement dataset must be subsequently curated and assessed.

Of the 409 consensus variables considered from the Delphi, only 271 (66%) could be mapped directly (n = 225) or indirectly as a calculated proxy (n = 46) to an available electronic source. Further challenges emerged when defining past medical history ('comorbidities') as data were imperfectly recorded in pre-specified locations. This created the potential for either a complex challenge of 'missing data' or a pragmatic solution to address this deficiency by 'foraging' for information in other available electronic sources.

We took the decision to use process mapping with key stakeholders, informed by cross-referencing with relevant local or national care standards, to transparently communicate how our final dataset would codify someone as having a specific health condition. This is shown in Figure 7, highlighting how information relating to comorbidity is captured as part of normal care and informing our choice of which information sources could be sequentially interrogated to deliver a final database field in the form of a composite reference.

Although originally chosen as a method to communicate to readers why specific analytical decisions were made, the diagram in figure 7 demonstrates the importance of avoiding fixation in designing specific variables. An exclusive focus on determining prior health status based on codified diagnoses in the problem list would exclude valuable information obtainable from medication records (e.g. a prescription of insulin would indicate that someone had a history of diabetes).

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4 DISCUSSION

4.1 Major findings

Opaque analytical decisions have been suggested to be involved in widely divergent results from similar quantitative analyses (Huntington-Klein et al., 2021). Our design-informed approach enables the assessment of decisions made throughout the analytical process in a transparent manner. Through the conduct of a real-world effort at data-intensive healthcare improvement we have demonstrated the importance of design thinking in facilitating the data science tasks required to obtain new knowledge from stored healthcare data. This suggests that the role of design in healthcare improvement goes beyond the design of an intervention itself, but is a discipline that could yield valuable assistance, as part of a broader systems approach, to understanding, structuring, and analysing EHR data.

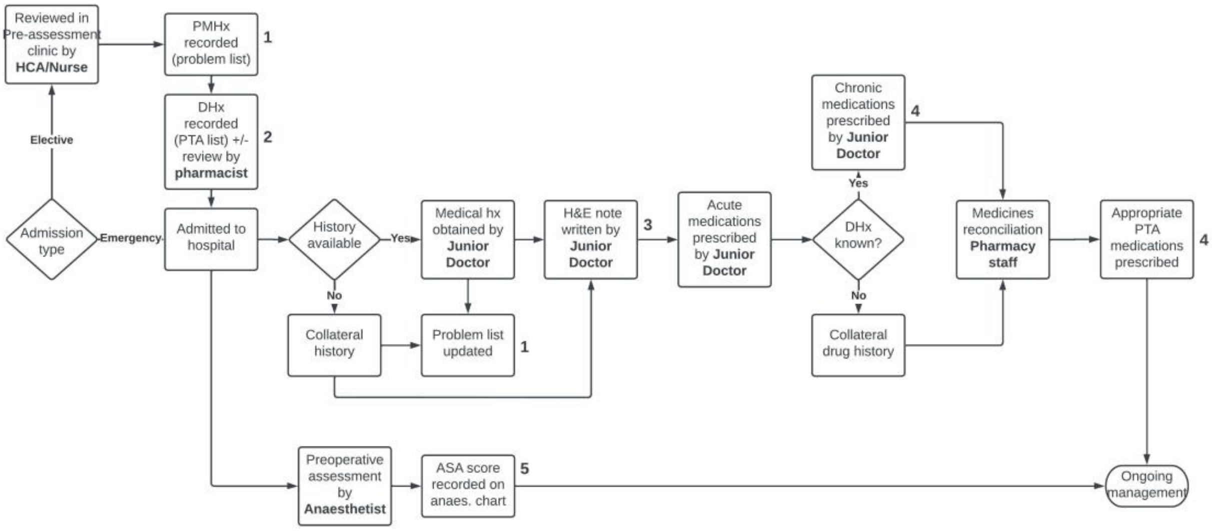

Figure 7: Early process map showing the capture of information on prior health conditions when a patient is admitted for surgery. 5 major data sources exist: a historic 'problem list' (1), a historic drug list (2), an unstructured 'history and examination' note (3), and inpatient medications (4). A corroborating source of information is the anaesthetic record (point 5).

Work outside of healthcare has previously shown how datasets can be used to support the broader design process, identifying problems or prioritising interventions (Kun et al., 2018). This is consistent with the emphasis on design in guidance on developing 'complex' interventions (Skivington et al., 2021).
The specific examples recounted here allow the conceptualisation of the stages of a data science workflow as design challenges, with divergent thinking crucial to avoid a fixation on solely using a 'perceived' gold-standard data source (the problem list), that may be unreliable due to the care processes which captures this information (Hripcsak and Albers, 2013). The development of an electronic metric such as this, or indeed an entire dataset, has resonance not only with the design council's 'double diamond' model of the design process but can also be traced to the seven stages of design proposed by Simon (Simon, 1969). Such divergent thought allowed stakeholder insights to broaden the dimensions of our analytical dataset beyond those achievable using the literature (Stubbs, et al., 2022a).

4.2 Strengths

One of the major strengths of this work is that the observations have emerged from the practical application of a systems approach to real world data, that is being analysed with the express intention of identifying problems and designing subsequent interventions. This has allowed the research team to reflect on our own reliance on tools from systems and design thinking to complete necessary steps in the manipulation and interpretation of healthcare data. This recognition is timely, given that analytical variations can have significant effects on final results (Huntington-Klein et al., 2021).
Data and data science techniques more broadly have been shown to be of benefit to designers, with dataset analysis being used to aid in problem space refinement or development (Kun *et al.*, 2018). What we demonstrate is the reciprocal relevance of design thinking and the design process to the technical conduct of data science and statistical testing. This posits the role of healthcare design as broader than the development of interventions or solutions that in themselves influence patient care or safety

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(Clarkson et al., 2004). Indeed, there is close mirroring of concepts, if not terminology, between the statistical and design literature. Statisticians use sensitivity testing to assess the resilience or appropriateness of their chosen modelling techniques (Qian and Mahdi, 2020), in a manner analogous to prototyping (Simon, 1969). Similarly, the assumptions that underlie individual statistical techniques could be viewed as requirements that any final analysis must fulfil if it is to be fit for purpose.

4.3 Limitations and future research

Despite their grounding in real world efforts at improvement, we recognise our findings are derived from reflections on a single setting case study. Validation should address two aims. Firstly, to refine the combinations of techniques which we have employed at different phases and secondly to verify the objective benefit (if any) of using design thinking to support the practical conduct of health data science. One consideration would be against what outcome 'benefit' should be judged. From a researcher perspective, if improved statistical fit was achieved via workflows such as ours this is a clear benefit. However, benefits should also be considered from the perspective of the user of the statistical results, including whether these techniques improve reader understanding and insight.

5 CONCLUSIONS

Through practical application of a systems approach to the use of healthcare data we identify the importance of design thinking in data science modelling. Design thinking encouraged divergent thought in tasks such as variable definition and database construction. We highlight the need for future validation and the need to investigate whether such techniques improve statistical performance and application.

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