On Designing an Algorithmically Enhanced NHS: Towards a Conceptual Model for the Successful Implementation of Algorithmic Clinical Decision Support Software in the National Health Service

Jessica Morley

Exeter College

University of Oxford

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What you are holding in your hands, or reading on your screen, is my magnus optum. It is, by far, the most significant piece of solo work I have ever produced. Yet, because it is a product of *me* it, would not exist without the people who shaped me into the person I am, developed my ability to think, or gave me material to think about. I owe all those responsible for this shaping, developing, and giving, a debt greater than I could ever repay in a few sentences on a page. It is, however, at least, a place to start.

First, I must thank my never-endingly patient (and probably slightly exasperated) family. When I first embarked on the adventure that is an Oxford higher education as an undergrad in 2009, I plunged my parents (Sue and Michael Morley) head-first into a world of which they had no knowledge or experience. Despite this, I still expected them to be able to understand and calm every single one of the many (many many many) worries and 'what ifs' that abounded in my mind as soon as I entered the uncertain world of academia. Whilst my exact worries and 'what ifs' changed as I moved from BA, to MSc, and finally to PhD, my expectation of my parents did not. Over the course of eight (non-consecutive) years, they have answered the phone to me (at all times of the day and night), walked around the park with me, and rescued me from Oxford more times than I could possibly count, never once complaining or ceasing to be encouraging. This is of course after years of helping with homework, coming with me to debate competitions, turning up to watch me play hockey (extremely badly, although with an excellent pink stick), telling teachers where to go when my lack of interest in speaking made them underestimate how loud it was inside my head, and so much more. Without the safety net this unwavering support provided me with, I would be – but this thesis would not be - finished. Any qualifications or accolade that may come from this thesis is as much theirs as it is mine.

My grandparents and my brothers must also share some of the credit. It is to my grandad (Redvers Brandling), author of numerous children's books and assembly books for schools, I owe my love of writing stories – after all, what is a thesis except a very long story? I also owe him my ability to wink, do the thumbs up, and play the piano, but these are rather irrelevant facts. It will forever sadden me that he died six months before I completed this thesis, but his final words of encouragement "don't forget to enjoy yourself, pet" have been a great motivator in finishing. On the other hand, it is to my gran (Thelma Brandling) I owe my understanding of the power of 'going for a walk', of the need to keep looking for a swan when all you see are coots, and of the importance of

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how to write a convincing argument. I shall forever be grateful for every tutorial, every essay crisis, and every stroke of red pen. Of course, coming back to Oxford later, led me to my supervisor Professor Luciano Floridi who, from the first time we met when I was a part-time MSc student, has been endlessly encouraging, supporting me to apply for the PhD and throughout the process of completing it, as well as to write and publish as much as possible. Nobody has had a greater influence on my ability to think, or on my enjoyment of academic life. Professor Floridi has not, however, acted alone, he has been joined by my co-supervisor, and deputy director of the Digital Governance Lab, Professor Mariarosaria Taddeo. If Professor Floridi has taught me to 'think big,' then Professor Taddeo has taught me to 'think deep', with an unparalleled ability to ask the exact question necessary to sharpen the question recipient's argument. It is not just for their academic support that I must thank Professors Floridi and Taddeo, but also their friendship, kindness, and frequent reminders to have fun away from my keyboard. Professor Floridi, and the person to whom he is married – Professor Kia Nobre -, also played a very significant role in putting me back together when I was broken, which is something I will never forget.

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All these individuals have had a huge and undeniable impact on me as a person and so on the content of this thesis. However, the words within the following pages are mine and mine alone, they do not represent the opinions of any of those named, including my interview participants, and any remaining mistakes remain my sole responsibility.

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List of Abbreviations

Abbreviation	Definition
ACDSS	Algorithmic Clinical Decision Support Software
BNF	British National Formulary
CCG	Clinical Commissioning Group
CCIO	Chief Clinical Information Officer
CDSS	Clinical Decision Support Software
CPG	Clinical Practice Guideline
CQC	Care Quality Commission
DHSC	Department of Health and Social Care
EBM	Evidence Based Medicine
EHR	Electronic Health Record
EMIS	Egton Medical Information Systems (one of the main electronic health record providers for GPs in the NHS)
HSCIC	Health and Social Care Information Centre (later rebranded as NHS Digital and now subsumed into NHS England)
ICO	Information Commissioner's Office
ICS	Integrated Care System
ITPOSMO	Information, Technology, Processes, Objectives and Values, Staffing and Skills, Management Systems and Structures, and Other Resources
LHS	Learning Healthcare System
MHRA	Medicines and Healthcare products Regulatory Agency
NASSS	Non-Adoption, Abandonment, Scale-up, Spread and Sustainability
NHS	National Health Service
NHSD	NHS Digital
NHSE	NHS England
NHSX	(This is not an abbreviation, it refers to the temporary 'digital, data, and technology' office of the NHS established when Matt Hancock was the Secretary of State for Health and Care)
NICE	National Institute for Clinical Excellence
NPfIT	National Programme for Information Technology
P4 Medicine	Predictive, Personalised, Preventative, and Participatory Medicine
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
STS	Science and Technology Studies
TPP	The Phoenix Partnership one of the main electronic health record providers for GPs in the NHS)
TRE	Trusted Research Environment

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Abstract

Established in 1948, the National Health Service (NHS) has lasted 75 years. It is, however, under considerable strain: facing chronic staff shortages; record numbers of emergency attendances; an ambulance wait-time crisis; and more. Increasingly, policymakers are of the view that the solution to these problems is to rely more heavily on one of the NHS's greatest resources: its data. It is hoped that by combining the NHS's data riches with the latest techniques in artificial intelligence (AI), that the means to make the NHS more effective, more efficient, and more consistent, can be identified and acted upon via the implementation of Algorithmic Clinical Decision Support Software (ACDSS). Yet, getting this implementation right will be both technically and ethically difficult. It will require a careful re-design of the NHS's information infrastructure to ensure the implementation of ACDSS results in intended positive emergence (benefits), and not unintended negative emergence (harms and risks). This then is the purpose of my thesis. I seek to help policymakers with this re-design process by answering the research question 'What are the information infrastructure requirements for the successful implementation of ACDSS in the NHS?'. I adopt a mixed-methods, theory-informed, and interpretive approach, and weave the results into a narrative policy synthesis. I start with an analysis of why current attempts to implement ACDSS into the NHS's information infrastructure are failing and what needs to change to increase the chances of success; anticipate what might happen if these changes are not made; identify the exact requirements for bringing forth the changes; explain why the likelihood of these requirements being met by current policy is limited; and conclude by explaining how the likelihood of policy meeting the identified requirements can be increased by designing the ACDSS's supporting information infrastructure around the core concepts of 'utility, usability, efficacy, and trustworthiness'.

Preface

In autumn of 2012, as a new graduate, I began working as an analyst for my local NHS Clinical Commissioning Group. What was initially supposed to be six weeks of work turned into six years, and by 2018 – via a long and rather convoluted route – I found myself working at the Department of Health and Social Care as a 'tech advisor' specialising in AI. This was not a job that I had actively sought, rather it was a job that had somewhat incongruously found me. I say incongruously because I was by no means an AI afficionado. What I was a relatively young and tech literate civil servant who could (with an enormous amount of help from Stack Overflow) write a line of analytic code. In an institution that largely relies on the skills of policy generalists this surprisingly unique capability marked me out as an 'expert' and so, in the wake of embarrassing system failures such as the illegal data sharing agreement between Google DeepMind and the NHS Royal Free Hospital, I was increasingly pulled into policy work related to AI. Although this was undeniably interesting, I began to feel uncomfortable about the decisions I was being asked to make or to support. I remember, for example, being asked to 're-design' the regulatory framework to support AI within six months. I did not think that I had sufficient understanding of the complexities associated with AI to be making these types of decisions, nor did I feel as though there was sufficient knowledge and skills within the wider Department. I felt that this knowledge deficit left the Department vulnerable to manipulation by those with more technical skills but different agendas, such as the technology companies producing AI tools. Ultimately, I feared that this lack of understanding, coupled with a fervent ministerial desire to rush the implementation of AI into the healthcare system, would result in inappropriate or potentially harmful decisions being made. Such potentially ill-informed decision-making would, I believed, result in one of two potential outcomes: a) a loss of faith in the ability of the NHS to implement AI, and a consequential complete abandonment of the umbrella technology; or b) rushed implementation of some – but not necessarily the most useful – 'AI', resulting in patient and/or system harm and consequential loss of trust in the umbrella technology. Both outcomes would, as I saw it, be damaging, resulting in inexcusable harms, wasted public funds, and significant opportunity costs. Thus, it was a desire to help the NHS avoid the negative impacts of these two potentially devastating outcomes that drew me back to academia.

Starting with my MSc at the Oxford Internet Institute, I began to explore in more depth the nuanced and multi-layered ethical, legal, and social implications of 'data-driven healthcare' writ large. From the implications of the tendency of policymakers to frame patient-facing data-driven tools as 'empowering' (Morley & Floridi, 2020b); to the trust implications of the NHS partnering with private

technology companies (Morley et al., 2019); to the considerable ethical concerns arising from the use of AI in healthcare (Morley, Machado, Burr, et al., 2020; Morley & Floridi, 2020a); to the poor quality evidence surrounding digital health tools ('apps') (Morley, Floridi, & Goldacre, 2020); to the challenges of governing 'group' level impacts of data-driven technologies (Morley & Floridi, 2021); to the impact of the 'infosphere' on health outcomes and inequalities (Morley, Cowls, Taddeo, et al., 2020), I began to develop a much deeper understanding of the many challenges faced by policymakers wanting to get data-driven healthcare, and in particular AI, *right* (Morley et al., 2022; Morley & Joshi, 2019a). Then, in March 2020, in the second year of my MSc, the COVID-19 pandemic arrived.

As the pandemic unfolded, my involvement in research into the factors associated with COVID-19 infection and death (e.g., Nab et al., 2023; The OpenSAFELY Collaborative et al., 2022; Williamson et al., 2020), the impacts of infection (e.g., Walker et al., 2021), as well as the effectiveness and safety of both preventative measures and treatments (e.g., Curtis et al., 2022; Green et al., 2023; Hulme et al., 2022), that went on to inform key national policies (such as the NHS shielding list, and the prioritisation of the NHS vaccine roll-out), provided me with two reminders. First, I was reminded of the life-saving potential of 'algorithmic clinical decision support software', such as the use of complex computational models to determine and advise on who is most at risk of specific diseases and how a variety of demographic and clinical factors influence the effectiveness of treatments in different individuals. Second, I was reminded that developing such models in 'the lab' is one thing but deploying them in clinical systems is another, and the NHS does not yet know how to ensure that the translation of complex clinical decision models from research into practice is smooth (e.g., Campbell & Campbell, 2020; Mahase, 2021; Patel, 2021). In short, it became abundantly clear to me that the NHS was not yet able to benefit from the significant potential of Algorithmic Clinical Decision Support Software (ACDSS), in part because it is not yet known by NHS policymakers (my primary audience) how to manage the various technical, ethical, social, and regulatory complexities to ensure successful implementation. It was my desire to help NHS policymakers overcome this hurdle, and so benefit from the potential of ACDSS whilst avoiding the potential risks (so-called the 'dual advantage' by Floridi et al., 2018), that motivated me to write this thesis.

Motivated by this desire to help the NHS capitalise on the dual advantage of ACDSS, and inspired by the theory of systems engineering which argues that it is the design of the underpinning architecture (or information infrastructure) that is responsible for determining the success of a desired system (in this instance the desired ACDSS-enabled NLHS), the aim for my thesis became:

Aim: To design the information infrastructure that will enable the NHS to capitalise on the dual advantage of ACDSS.

Then drawing upon the theory of the logic of design as a conceptual logic of requirements developed by my supervisor, Professor Luciano Floridi (Floridi, 2017b), which sees the elicitation of requirements (scope, function, features, purpose) as the cornerstone of design, my overarching research question became:

ORQ: What are the information infrastructure requirements for the successful implementation of ACDSS in the NHS?

Or, with an expanded definition of information infrastructure (Sittig & Singh, 2010):

ORQ: What are the hardware and software; clinical content (raw data); human computer interface; people; workflow and communication; internal organisational policies; external rules, regulations, and pressures; and system measurements and monitoring requirements for the successful implementation of ACDSS in the NHS?

I chose to base this question on the 'theory of the logic of design as a conceptual logic of requirements' because, as I explain in Chapter One, Government technology implementation projects (including NHS technology projects) often fail when a typical command-and-control or planned approach to implementation is taken. I reasoned, therefore, that if I were to adopt a similarly planned and inflexible approach to the identification of the necessary information infrastructure requirements for ACDSS implementation, I too may fail to help the NHS achieve success. In contrast, I reasoned that if I were to adopt a more creative, more ontological, more flexible, and more contextually aware, design-based approach – specifically intended to overcome the pitfalls of planned implementation approaches – I may be more able to help the NHS achieve success.

Of course, this reasoning raised the question: what does success mean in this context? To answer this, I conducted a brief overview of the existing literature (presented in Chapter Two). By focusing purely on the high-level themes of factors influencing technology implementation identified by existing literature on change management in the NHS (e.g., (Allock et al., 2015b; Asthana et al., 2019a; Begun & Dooley, 2003; Chandler et al., 2016; Ferlie et al., 2012; Macfarlane et al., 2013a; T. Scott, 2003a)); technology adoption (in general and in the NHS specifically) (e.g., (Benson, 2019; F. D. Davis, 1989; Greenhalgh & Stones, 2010a; Johnson et al., 2014a; Mishuris et al., 2019; Venkatesh & Davis, 2000; Wainwright & Waring, 2007a; Ward, 2013)); acceptance and adoption of AI in

healthcare (e.g., (Bak et al., 2022; Bates et al., 2003; Brannigan & Dayhoff, 1986; S. M. Carter et al., 2020; Cortez, 2018; Fritzsche et al., 2023; Goodman, 2020; Iqbal & Biller-Andorno, 2022; X. Liu et al., 2022; R. A. Miller, 1985; Perc et al., 2019; W. B. Schwartz, 1970; Shortliffe & Sepúlveda, 2018a; Vourgidis et al., 2019a)); implementation of AI into healthcare (e.g., (P.-H. C. Chen et al., 2019; Fujimori et al., 2022; Jill Hopkins et al., 2020; Richesson et al., 2020; Semenov et al., 2020; Westerbeek et al., 2022; Wiens et al., 2019a; Yoo et al., 2022)); and evaluation of individual ACDSS products (e.g., (Balestrieri et al., 2020; Bates et al., 2003; Cox et al., 2020, 2020; Delvaux, Piessens, et al., 2020; Downing et al., 2019; Gold et al., 2022; Heselmans et al., 2020; Kharbanda et al., 2018; D. Mann et al., 2020; McDonald et al., 2022; Neugebauer et al., 2020; Palen et al., 2019; Peralta et al., 2020; Rieckert et al., 2020; Rubin et al., 2021; Webster et al., 2021; Yao et al., 2021)), I was able to determine that successful, in the context of the research question, means 'technically feasible, ethically justifiable, socially acceptable, and legally compliant.' In full, the overarching research question can, therefore, be read as:

> ORQ: What are the hardware and software; clinical content (raw data); human computer interface; people; workflow and communication; internal organisational policies; external rules, regulations, and pressures; and system measurements and monitoring requirements for the technically feasible, socially acceptable, ethically justifiable, and legally compliant implementation of ACDSS in the NHS?

This fully defined research question, then led me to position my thesis within the Science and Technology Studies (STS) paradigm. I decided this was the most appropriate paradigm because STS research focuses on understanding how the development, deployment, use (i.e., implementation), and consequences of specific technologies is influenced by historical, social, cultural, and contextual factors. In other words, STS research covers all the components within the definition of successful (technical, ethical, social, and legal), and its multidisciplinary approach is well-suited to the broad definition of information infrastructure.

It was important to establish this positioning because it helped to guide my selection of research methods. Specifically, I chose to adopt a mixed-methods, theory-informed, ethnographic, and interpretive methodology, combining the results of (1) a systematised realist review of the existing literature; (2) a series of semi-structured interviews with key stakeholders from across the health and care system; and (3) a rhetorical analysis of current relevant policy documents. I then combined the results from the analysis of these three data sources into a narrative policy synthesis that – over a series

of five empirical chapters (described in more detail below) – builds up a conceptual model that answers the overarching research question.

I chose this methodology for two reasons. First, because the mixed approach reflects the multidisciplinary nature of the STS paradigm; realist review is explicitly designed to identify and explain the mechanisms that determine whether or not complex policy programmes work; semi-structured interviews contextualise the findings from the realist review, making them specific to the NHS, and answering questions of 'why' in addition to the 'what' and how' questions answered by the realist review; and rhetorical policy analysis highlights the fact that policies are not simple documents translating evidence into action, but ideological documents infused with values, representations, and meanings that are produced in specific contexts by specific groups of individuals. Second, because it is a version of a methodology that is frequently used by NHS policymakers to develop health policy (although not always health technology policy) and should, therefore be familiar to my primary audience. It is, for example, fairly typical for NHS policymakers to commission a theoretical review of a specific policy problem - via a think tank, consultancy, or academic policy research unit funded by the National Institute for Health Research -, synthesise the results of this review to generate evidence of what is needed to solve the policy problem; contextualise the findings through stakeholder engagement methods such as online consultation, policy roundtables, focus groups, and sometimes interviews; and eventually translate these results into policy recommendations. Indeed, this is a methodology that I have used myself to both develop health policy 'in house' (for example, the NHS cloud and data offshoring policy, or the NHS code of conduct for data-driven health and care technologies) and to develop policy recommendations for the Government as an independent advisor (for example, *Better, Broader, Safer: Using Health Data for Research and Analysis* (Goldacre & Morley, 2022)). It is my hope, therefore, that as NHS policymakers have found this approach valid for the development of policy in the past, they will also find it a valid approach for informing the development of ACDSS policy.

I shall explain all this further in the forthcoming chapters, albeit in passive voice to put distance between myself and the findings, but first a brief overview of what to expect.

In Chapter 1, the introductory and conceptual chapter, I argue that the NHS must change its modus operandi to cope with 21st century challenges. I stress that the implementation of ACDSS may help achieve this shift, by enabling the NHS to become a national 'learning healthcare system' (henceforth ACDSS-enabled NHLS), while acknowledging that implementation is neither straightforward nor without risk and noting that attempts to 'transform' the NHS through technology

in the past have failed. Therefore, as I explain above, I argue that to avoid another failure, policymakers will need to carefully design the implementation of ACDSS, identifying the conceptual requirements for 'success' and using these requirements to plan forwards – rather than working backwards or trying to take a command-and-control approach. This leads to the introduction of my overarching research question (see above).

In Chapter 2, the literature review chapter, I offer a brief overview of the existing literature for the dual purpose of (1) defining successful in the context of my overarching research question (see above); and (2) problematising previous attempts to answer similar questions, to explain what can be learned from previous attempts and what can be improved.

In Chapter 3, the methodology chapter, I provide more detail on the method and methodology described above, providing a detailed justification for each of the selected methods and a thorough description of how I used each method in practice to produce the results in the subsequent empirical chapters.

In Chapter 4, the first empirical chapter, I analyse what is wrong with the current design of the NHS's information infrastructure that is resulting in attempts to implement ACDSS failing (i.e., resulting in unintended negative emergence, technology abandonment, and loss of trust), and what changes to the information infrastructure are needed to ensure future implementation success. I base the analysis on the '**N**on-Adoption, **A**bandonment, **S**cale-up, **S**pread, and **S**ustainability' (NASSS) Framework (Greenhalgh et al., 2017a), as this is framework is well known to my primary audience and used frequently as an internal tool by the Department of Health and Social Care. I argue that current attempts to implement ACDSS are hindered by the underestimation and mismanagement of complexity in a series of seven domains from 'condition' to 'adaptation over time.' To make this argument clearer, I compare the level of complexity present in each of the domains for traditional passive clinical decision support software (i.e., expert systems or computerised decision-trees) and ACDSS. I conclude that if success is to be achieved, then changes must be made to ensure this complexity is reduced, better managed, and made more successful.

In Chapter 5, the second empirical chapter, I analyse what the consequences could be if the complexity currently present in the NHS's information infrastructure is not reduced or better managed before ACDSS is implemented. I do this by developing a detailed description of three 'anticipated' scenarios that – if not proactively mitigated by the careful re-design of the NHS's information infrastructure – could result in a fundamental re-engineering of the NHS and its underpinning values. The three scenarios are: (1) the patient is displaced from the centre of care; (2) the fundamentals of

care are disrupted; and (3) the NHS ceases to be for all. I conclude that if the NHS wants to ensure successful implementation of ACDSS, the requirements for designing-out harms must be identified as well as the requirements for achieving positive outcomes.

In Chapter 6, the third empirical chapter, I identify the ideal vision (benefit-enhancing) and ideal delivery (risk-mitigating) information infrastructure requirements in the following categories (derived from the ITPOSMO Framework (Heeks, 2002) – also well-known to policymakers): **I**nformation, **T**echnology, **P**rocess, **O**bjectives and Values, **S**taffing and Skills, and **M**anagement systems and structures. I then examine whether, given current policy developments, it is likely that these requirements will be met and, therefore, whether it is likely that the NHS will be able to capitalise on the dual advantage of ACDSS. I conclude that there is a significant sociotechnical gap between the ideal requirements and the requirements covered by current policy and, therefore, it is currently unlikely that the NHS will be able to achieve successful ACDSS implementation unless this gap is closed.

In Chapter 7, the fourth empirical chapter, I explain that the first step to closing this sociotechnical gap is understanding why it exists. I attribute the existence of the sociotechnical gap to several assumptions underpinning current policy developments related to the scale of the implementation challenge, the art of the possible, the relationship between information and action, and the role of regulation in supporting innovation. I then identify the source of these assumptions. Specifically, I argue that the assumptions stem from the influence of the technical epistemic community on the development of policy. I conclude the chapter by stating that if the sociotechnical gap is to be closed, and the implementation of ACDSS is to be successful, then the negative influence of this community's assumptions on the development of policy must be negated at source through the identification of a unifying function.

In Chapter 8, the final empirical chapter, I develop the conceptual model for the successful implementation of ACDSS into the NHS. Inspired by the middle-out approach to systems engineering, I do this in stages. Working from the top down, I first identify the conceptual function requirements that can negate the influence of the technical epistemic community's assumptions on the development of policy at source: utility, usability, efficacy, and trustworthiness. Then, working from the bottom up, I identify the form requirements that can operationalise the ideal vision (benefit-enhancing) and delivery (risk-mitigating) requirements in keeping with the function requirements. In so doing I illustrate how function maps to form via concept. Finally, I combine the results of these two analyses

with the analyses from Chapters One, Two, and Six to produce a hierarchical conceptual model for the successful implementation of ACDSS into the NHS, that can be read as follows:

1. To become a Learning Healthcare System, the NHS requires the implementation of ACDSS. This in turn requires:
2. Supporting information infrastructure that ensures the implementation of ACDSS is technically feasible, ethically justifiable, socially acceptable, and legally compliant. This in turn requires:
3. An information infrastructure design that is intended to support the function "maximise the utility, usability, efficacy, and trustworthiness of existing NHS information for the purpose of meeting clearly identifiable information needs". This in turn requires:
4. An information infrastructure design intended to provide the system with epistemic certainty, robust information exchange, validated outcomes, protected values, autonomous staff, and meaningful accountability. This in turn requires:
5. An information infrastructure design intended to deliver consistently good data quality; sufficient data quantity; reliable data interpretability; UX focused EHR design; privacy enhancing data access; seamless system integration; protection from vendor lock-in; clearly stated clinical objectives; mindful model development; rigorous technical validation; rigorous clinical evaluation; careful local calibration; ongoing impact evaluation; commitment to collective provision; commitment to patient centricity; commitment to quality care; protection of clinician epistemic authority; valued informatics workforce; data-literate leaders; fit for purpose Information Governance; regulated medical devices; clinician and patient protection; and auditability. This in turn requires:
6. Policy that is focused on EHR design templates; model-to-data ACDSS development approaches; interoperability standards; audit and feedback; modularity and local customisability; data-work; NHS ACDSS-ready data assets; clinicians as originators of demand; value pluralism; patient and public involvement and engagement; qualitative health information; provably trustworthy relationships; a technical buddy system; the status of NHS analysts as clinical not clerical; the clinician's right to override; HTA and NSC review of ACDSS; model development and feature selection guidance; 'in silico' and 'in socio' model testing; roving data science teams; oversight of ACDSS integration and use' data governance

simplification and clarification; regulation of ACDSS as SaMD; process accountability regarding liability, discrimination, and consumer protection; and public documentation.

Finally, in Chapter 9, the concluding chapter, I surmise that whilst the existence of this conceptual model for the successful implementation of ACDSS into the NHS, represents a not-insignificant step forwards towards the aim of enabling the NHS to capitalise on the dual advantage of ACDSS, there are limitations that must be acknowledged, and future work will be required to overcome these limitations. Specifically, (a) the final model is still comprised only of necessary, not sufficient requirements, but sufficient requirements will be needed to increase the chances of successful ACDSS implementation; (b) the final model remains at the middle-level of abstraction and is, therefore, still open to interpretation; (c) design is an iterative process and the final model has not been iterated following independent evaluation and feedback, and may therefore be overly influenced by my own personal experiences and positionality; (d) the final model does not address whether an ACDSS-enabled NLHS will genuinely help the NHS deal with its pressing resource challenges, or whether it will simply divert resources away from more useful or valuable policy interventions; and (e) there is evidence to suggest that the NHS may not have the capacity, or the willing, to tackle change of this scale at this time. To overcome these limitations future work will be needed to identify the sufficient requirements following robust stakeholder engagement to subject the model to external independent scrutiny, iteration, and validation; to combine the model with the results of research at a lower level of abstraction, for example research focused on identifying best practice for specific algorithm design; and to pilot the model to assess its overall chances of success. Ensuring this further work happens is vital because it will improve the quality of the research overall, and because the NHS is too important to not insist that every single suggested solution, policy recommendation, or decision is subject to intense scrutiny from all angels.

It is my sincere hope that in providing this comprehensive breakdown of the current problems with the NHS's information infrastructure, why they exist, what the requirements for a re-designed information infrastructure are, why these requirements matter, how they can be operationalised, and the implications of the suggested changes, my thesis meets its aim and that I am genuinely able to help the NHS design the information infrastructure that will enable it to capitalise on the dual advantage of ACDSS.

1. Complex systems that cannot be controlled, must be designed

1.1 Background: A beloved institution in trouble

In 1946, as Britain began to recover from the impact of the Second World War, Clement Attlee's new Labour Government passed the National Health Service (NHS) Act, and so set out its intentions to establish a publicly funded "comprehensive health service to secure the prevention, diagnosis, and treatment of illness." Two years later, on July 5th 1948, the new NHS was established, designed to: meet the needs of everyone; be free at the point of delivery; and based on clinical need rather than the ability to pay (Rivett & The Nuffield Trust, 2019). This arrival of the NHS did more than revolutionise healthcare provision in the UK: it provided the British Government with a set of moral objectives to which all subsequent Governments have subscribed (P. Bradshaw, 1998); provided the British public with a set of societal values related to fairness and equality (Appleby & Abbasi, 2018); and founded the UK's largest employer (Akenroye, 2012). Its importance cannot, therefore, be overstated. The NHS is, without a doubt, a beloved institution which British citizens are proud of and continue to strive to protect (Heath, 2018). It is also, by most metrics, a 'success' (Charlesworth & Bloor, 2018).

Over the past 75 years, life expectancy in the UK has increased from 68 to 80; infant mortality has fallen from 34/ 1000 live births to less than 3/1000 (Majeed et al., 2018); the amount of care provided in an evidence-based manner has increased significantly (Appleby & Abbasi, 2018); and the proportion of national wealth spent on healthcare has doubled (Charlesworth & Bloor, 2018). Crucially, all of this has been achieved in keeping with the same underlying values set out at the foundation of the NHS (Young, 2017). However, as positive as these achievements have been for the individual citizens of the UK, and for the ideology of state-funded healthcare, they have also begun to pose problems for the performance and economic viability of the NHS.

Although the NHS has never ceased to strive to improve the quality of its care, it is increasingly evident that the higher expectations of 21st century patients, increased complexity of care associated with chronic conditions and multi-morbidities, and the rising costs of healthcare technology, have combined to result in diminishing returns (Augustsson et al., 2020). Even before COVID-19 (the greatest challenge the NHS has ever faced), the net deficit of the NHS was more than £910 million (The Kings Fund, 2021) and it was visibly beginning to struggle to deliver on its goal of providing free, adequate, and equally accessible healthcare for all (The Lancet Oncology, 2018). Indeed, by the early 2000s, the UK was lagging behind other European countries in crucial areas such as child health and

cancer survival (Majeed et al., 2018), and was experiencing a steady decline in performance in areas ranging from emergency care to mental health provision (R. Murray, 2021). As such, prior to 2020, the NHS was already subject to multiple policy initiatives designed to increase productivity and cut costs (Allock et al., 2015b), leading Bevan, in 2010, to conclude that "the scale and pace of change now required by the NHS is probably greater than that achieved previously by any other healthcare system globally."

Attempts to constrain overall expenditure, and improve organisational efficiency, have included multiple re-organisations; the introduction of payments for prescriptions; charges for optical and dental services (Rivett & The Nuffield Trust, 2019); payment for performance schemes aimed at GPs (K. Ahmed et al., 2021); increasing spend on preventative care and public health (Hunter, 2019); and offering patients the option of paying for expensive or inaccessible treatments or services themselves (O'Dowd, 2012). Although, some of these policy interventions have resulted in minor improvements in care, efficiency, or cost reduction, by and large they have proven insufficient. For example, the increased use of performance targets has only led to improved care in very specific areas, and payments for performance initiatives have proven to be subject to gaming (Tomson, 2009). This poor track record of success is particularly concerning now as, post-2020, the scale of the challenges facing the NHS are greater than ever.

Never having had a chance to 'pause and recover' from either COVID-19 or the UK's exit from the European Union, the NHS is now facing chronic staff shortages (Alderwick et al., 2021); record numbers of emergency attendances; ambulance wait-time crises; hospital waiting lists of more than 1.3 million; and the highest-ever volume of GP appointments (R. Murray, 2021). Unfortunately for policymakers, the lacklustre response to previous policy interventions makes it clear that they will be unable to rely on tried-and-tested methods to help the NHS overcome these challenges. It is increasingly evident that they will have to try something else to – as Balicer & Cohen-Stavi (2020) suggest – completely change the *modus operandi* of the NHS.

1.2 Embracing complexity

Achieving this perceived-to-be-necessary shift in the operating model of the NHS is unlikely, however, to be a straightforward task. As multiple change management theorists (e.g., Ashburner et al., 1996; Bamford & Daniel, 2005; Breckenridge et al., 2019; Goff et al., 2021; Macfarlane et al., 2013; Scott, 2003) have highlighted, the 'standard' approach, favoured by policymakers in the Department of Health and Social Care over (at least) the last twenty-five plus years, of top-down, chain-logic strategies,

narrowly defined policies, hierarchies, and standardisation, is unlikely to work (Braithwaite et al., 2020). Such an approach belies the inherent complexity of the NHS. It assumes that the relationship between policy intent ('cause') and policy outcome ('effect') is linear and predictable. The reality is that the relationship between policy intent and policy outcome is often *unpredictable* and *non-linear,* impacted by multiple variables which are rarely known in advance (Atun, 2012). At least this is the argument put forward by increasingly influential champions of complexity theory. Proponents of these lines of thought argue that achieving long-term change in the NHS will *only* be possible if a more dynamic approach is taken: one that recognises and, indeed, *uses* to its advantage the self-organising and dynamic nature of the NHS, *leaning into* rather than *away from* its complexity.

This means viewing the NHS not as a brand, nor as an organisation, nor a series of disconnected component parts, but as a *system*: "A set of elements or parts that is coherently organised and interconnected in a pattern or structure that produces a characteristic set of behaviours, often classified as its 'function' or 'purpose' (D. H. Meadows & Wright, 2008, p. 188)" Viewing the NHS as a system encourages a shift in perspective; a zooming out from a focus on basic 'numbers' (e.g., number of people on a waiting list) and allegedly simple 'tweaks' that might shift these numbers slightly (Meadows, 1999). Viewing the NHS from the systems perspective, encourages policymakers to: (a) identify individual system components; (b) identify the interconnections between these components; and (c) ask 'what if' questions about how changes in these components and interconnections might alter behaviour by, for example, reducing the amount of delay in an exchange or creating a new balancing feedback loop (Meadows & Wright, 2008). In short, systems thinking presents policymakers with an alternative – and potentially more effective – way of identifying how to bring about long-lasting change.

In the past, identifying the relevant system components and – crucially – their interconnections has proven difficult. This is because, as Meadows & Wright (2008) highlight, many of the interconnections in systems (and in the NHS in particular) operate through flows of information and for many years information flows within the NHS were largely invisible or unobservable. Of course, basic medical information was written in textbooks, doctors wrote paper notes locked away in filing cabinets to act as an aide memoire if they ever saw that patient again, consultants passed information about specific patient's care in hurried conversations on busy hospital wards, and young parents asked pharmacists for advice on how to administer specific medications to their children. However, these brief, often ad-hoc, information exchanges were rarely recorded, aggregated, or linked with other sources of information – such as information about a patient's diet or genetic make-up. Consequently,

clear examples of 'system failure,' such as the Alder Hey Organ (D. Hall, 2001), Bristol Hospital Heart (Quick, 1999), serial killer Harold Shipman (Smith, 2002), and infected blood scandals (Mitchell, 2019), went unnoticed and unrectified for years, and sometimes decades. To summarise, the invisibility of information flows within the NHS made it difficult – if not impossible – for policymakers to identify the most effective leverage points in the system or where to intervene to bring about desirable change. Digitisation, or more specifically, datafication, has changed this and created new opportunities to observe the system in its entirety in far more granular detail.

1.3 New opportunities for learning

The NHS is widely considered as one of the most 'data rich' healthcare systems in the world. By 1996, 96% of all NHS GP practices had a computer and had begun digitising their records (Stein, 2022). Now, almost every single interaction with the NHS is recorded in some capacity: the diagnoses, treatments, tests and outcomes for almost every citizen in the country (Goldacre & Morley, 2022). This near constant logging of activity, generates billions of clinical and administrative (e.g., staffing levels, bed availability, waiting list length, resource availability) data points every week (Castle-Clarke, 2018). These medical and managerial records contain almost unfathomable depth and potential, and have only been further augmented by the advent of wearables and development of self-tracking behaviours (Raza et al., 2022).

Although not necessarily revealing in their raw form, when collated, curated, and analysed, these 'data riches' provide researchers and policymakers an unparalleled view of the healthcare system and its functioning. By making existing information flows visible, and creating new flows between the NHS 'frontline' and central policymakers, NHS records provide the means of "identifying the most effective intervention or 'leverage' points which can help the system: proactively anticipate future demands; tackle instances of unwarranted variation in care; pinpoint, in real-time, specific opportunities to improve quality, safety, and cost-effectiveness of care; model waiting lists; determine optimum locations for new services; extract the underlying causes of disease and poor healthcare outcomes; effectively evaluate whether new interventions or reorganisations have achieved their clinical or logistic objectives; monitor – and, where necessary, intervene in – the volume of activity passing through services to ensure value from clinical contracts; and more" (Goldacre et al., 2020, p. 1; Tillmann et al., 2015). In short, if 'information holds systems together and plays a great role in determining how they operate,' then – in cybernetic terms – the datafication of the NHS's information

has provided policymakers with the means of controlling its performance (Meadows & Wright, 2008; Wiener, 1948).

Referencing cybernetics makes it clear that the idea of leveraging the information flows within a system to change its operations and performance is not entirely new. It is not even an idea that is completely novel to the NHS. In the 1970s, the (then) Ministry of Health in England established a 'policy for computing' branch which, by 1972, had published a report entitled *Using Computers to Improve Health Services* (Alderson, 1976). However, for most of the preceding seven decades, the NHS has been missing the key ingredients needed to fully capitalise on the opportunities presented by the more effective leveraging of information flows within the system. As already highlighted, most of the NHS's information flows have only been fully digitised in the last twenty years, and until relatively recently the necessary *science* has also been missing.

Science in this context refers to both data science and medical science. To cover data science first, traditional medical and healthcare services research relied upon classic medical statistical techniques, such as multiple linear regression, logistic regression, and survival modelling. Although perfectly adequate for traditional research, such techniques have struggled to cope with the volume of data now generated by the healthcare service; are often inflexible and require hypotheses to be defined *a priori;* and cannot always be used for causal analysis (C. H. Lee & Yoon, 2017). These, and other key features of traditional statistical methods, have limited their usefulness for *insight-generating* analysis, i.e., these techniques have not proven sufficient for identifying means of bringing about significant change in the system's operation and performance. Insights of this nature have, instead, only recently become more plausible with the development of advanced data science techniques including those falling under the umbrella headings of Artificial Intelligence (AI), and Machine Learning (ML) (e.g., Abidi & Abidi, 2019; Awaysheh et al., 2019; Buch et al., 2018; Davenport & Kalakota, 2019; Kanbar et al., 2022; Liu & Demosthenes, 2022; Loh et al., 2022; Ngiam & Khor, 2019; Reddy et al., 2019; Toh et al., 2019; Watson et al., 2019).

Medical science has seen a similar transition from a largely deductive approach which sought to abstract away from complexity – for example, excluding or not accounting for differences in outcomes associated with biological sex or ethnicity (Hussain-Gambles, 2003; K. A. Liu & DiPietro Mager, 2016) – to a more inductive complexity-informed approach. Specifically, systems biology which developed from the early 2000s thinking of David Galas and Leroy Hood (Bengoechea, 2012), views biology – and by extension medicine – as an informational science that aims to tackle the complexity of the human body and how it operates by: (1) quantifying both 'biological' information

(for example a person's genome) and 'environmental' information (for example, air quality or food intake); (2) integrating the resulting 'biological' and 'environmental' datasets; and (3) modelling how the different components (variables) from each of these datasets interact to produce different outcomes (for example, the development of disease) (Hood & Flores, 2012). In so doing, systems biology aims to use computational techniques to 'demystify wellness and disease' and, as Bengoechea, (2012) says, make medicine more:

- Personalised: based on the genetic and other personal data of individuals.
- Predictive: 'personal data' is used to calculate the risk of a specific individual developing a specific disease.
- Preventive: lifestyle or therapeutic interventions are 'prescribed' to an individual to reduce their risk.
- Participatory**:** individuals are required to collect, and share, data, to be involved in decision-making, and to act on the advice of clinicians.

It is the combination of these developments (datafication, AI, and systems biology) that has both reinvigorated, and made more plausible, the idea that the key to bringing about a successful change in the NHS's *modus operandi* might lie in its information flows. Specifically, this combination of developments has given rise to the concept of the 'learning healthcare system' (Banerjee et al., 2018; Deeny & Steventon, 2015; McLachlan et al., 2019; Melder et al., 2020; Scobie & Castle-Clarke, 2020; Torkamani et al., 2017).

The relatively new but increasingly popular concept of the learning healthcare system (LHS) centres on the importance of informational feedback loops where: (1) 'real-world' data is recorded in clinic when a patient is 'treated' or 'diagnosed' (Torkamani et al., 2017); (2) this data is used to train computational models that lead to new understandings of disease and, in particular, its underlying causes (systems medicine); (3) this new understanding is translated into tools used in the clinic to help clinicians advise patients on how to prevent disease (Hunter, 2019) ; (4) the outcomes of these preventive interventions are recorded and fed back both into new computational models and into the wider system for the development of, for example, new clinical guidelines. Via these feedback loops, the NHS can 'learn' how to most efficiently produce the best outcomes and so become more efficient, more effective, and more sustainable (Blasimme & Vayena, 2016), as well as more evidence-based,

less wasteful, and less harmful (Braithwaite et al., 2020). With promises as appealing as these it is perhaps not surprising that, over the past decade, this idea has come to be a focal point of NHS strategy.

1.4 Policy Promises

Whilst information has featured in NHS strategy documents since the 1970s, it was typically presented as a separate category to strategies focusing directly on the provision of care service, improving outcomes, or the workforce. Most often bracketed within strategies focusing on 'Information Technology,' information (or data) was typically presented as an exhaust product, something to be managed and controlled rather than something to be *used* as a key enabler of change. This changed with the publication of *Personalised Health and Care 2020* in 2014 which explicitly stated that the NHS intended to "use data and technology to transform outcomes for patients and citizens" (Department of Health and Social Care, 2014, p. 1). This was followed in 2018 by *The future of healthcare: our vision for digital, data and technology in health and care* (Department of Health and Social Care, 2018)*;* the *NHS Long Term Plan* (NHS England, 2019) in 2019; and both *Data Saves Lives: reshaping health and social care with data* (Department of Health and Social Care, 2022e); *A plan for digital health and social care* (Department of Health and Social Care & NHS England, 2022) in 2022. Although, the exact content of each of these document differs slightly, all clearly express an ambition to use data, research and innovation, and information technology to help the NHS become more proactive, more outcomes focused, and more cost efficient (Alderwick & Dixon, 2019). Indeed, these ambitions have only become more explicit with time, as the following quotations from strategy documents published since 2021 illustrate:

> **Saving and Improving Lives: The Future of UK Clinical Research Delivery**
> "Our vision is for the UK to have the most advanced and data-enabled clinical research environment in the world – where we capitalize on our unique data assets to deliver improvements to the health and care of patients across the UK and beyond" (Department of Health and Social Care, 2021c, p. 19)

> **The Future of Artificial Intelligence for Health and Social Care (Draft NHS AI Strategy)**
> "By 2030, the UK has a learning health and care system delivering better outcomes for the public, enabled by the effective use of safe, ethical, and effective AI, setting an example to the world" (NHS England, 2022b, p. 1)

> **Life Sciences Vision**
> [We will] |seize opportunities to support the NHS and patients through innovative NHS data partnerships that fundamentally drive improvements in health outcomes and/or reduce health inequalities" (Department for Business, Energy, and Industrial Strategy & Office for Life Sciences, 2021, p. 24)

> **Health and Social Care Integration: Joining up Care for People, Places, and Populations**
> "The NHS App will offer a personalised experience for users and encourage them to engage in tailored preventative activity (screening, immunisations, and vaccinations, and health checks.)" (Department of Health and Social Care, 2022b, p. 46)

In short, it is increasingly clear that the NHS hopes information – and its role in creating a learning healthcare system - could be the key to achieving the triple aim of: improved outcomes; improved experience of care; and reduced per capita costs (Wyatt et al., 2020a). What is often less clear is the exact *mechanism(s)* these strategies intend to use to alter NHS information flows and so intervene in the system. Most references to technology, 'information exchange,' or 'data sharing' in Government and NHS strategy documents are high-level and abstract focusing on the *what* and not necessarily the *how*. To identify the *how* then, it is necessary to look to the academic and clinical research literature for examples of knowledge (or information) translation tools that can bring together the three elements (data, AI, and systems biology) underpinning policymakers hope in the LHS concept.

The literature reveals that multiple such tools exist and are in use in the NHS system currently, including: new data infrastructures, 'apps', ICT-based interventions, educational interventions, audit and feedback, the introduction of guidelines or protocols, and the reward and punishment of staff (Bai et al., 2020; S. Green et al., 2022), but by far the most common and the most effective are tools falling under the heading of Clinical Decision Support Software' (CDSS) (e.g., Brown et al., 2015; Eberhardt et al., 2012; Mahadevaiah et al., 2020; Osheroff et al., 2012; Ostropolets et al., 2020; Sarkar & Samal, 2020; Sim et al., 2001).

1.5 CDSS: Hope and hype

Clinical Decision Support Software[1] (CDSS) is a generic term for a wide range of computerised information systems designed to aid clinical decision-making in real-time (Sutton et al., 2020). Although the exact form in which the aid is presented varies (for example it may be an alert, a reminder, a pop-up, a suggestion (Austrian et al., 2021; B. Brown et al., 2015)) the basic process remains the same: (1) a healthcare professional provides the CDSS with the characteristics of an individual patient; (2) the software matches these characteristics to those stored in a clinical knowledge base; and (3) the software uses this information to present the clinician with a range of patient-specific information that

[1] It is worth noting that in the literature – policy, academic, and grey – the terms Clinical Decision Support *Software* and Clinical Decision Support *System* are used interchangeably. Software is used throughout this thesis to differentiate from the use of the word 'system' to describe the overarching healthcare system and systems thinking.

might include a diagnosis, a warning, a prognosis, or a recommended treatment (Reddy et al., 2019; Sim et al., 2001a). The general idea is that by providing the right information, at the right time, in the right format, through the right channel (Eberhardt et al., 2012; Freimuth et al., 2017; Osheroff et al., 2012), CDSS can be used to reduce the amount of uncertainty faced by clinicians when making decisions (Heckman et al., 2020; Kazandjian & Lipitz-Snyderman, 2011). It is hoped that in doing so, the use of CDSS can result in higher-quality decision-making which, in turn, can make clinical care more evidence-based, more cost-effective, safer (reducing errors), more consistent, and more efficient (Cox et al., 2020; Reddy et al., 2019; Reisman, 1996a).

The foundations for this idea were laid in the 1950s when the first systematic review comparing clinical decisions made by humans to those made by statistical models was published. It found that, when it came to forecasting outcomes, statistical models were more accurate than humans (Longoni et al., 2019; Meehl, 1954), thus initiating the interest in CDSS. This interest in – and subsequent demand for – CDSS has only increased with time as the volume of available information, data, and evidence has increased (as described above) and exceeded the cognitive capacity of most clinicians (Cox et al., 2020; Eberhardt et al., 2012; Johnson et al., 2014a; Reddy et al., 2019). This imbalance between complexity (volume of information) and cognitive capacity is referred to as cognitive overload and is believed to be one of the main causes of information error (the overuse, underuse, or misuse of information) in the NHS (Sood & McNeil, 2017).

Hope that CDSS might reduce cognitive overload (Parikh, Teeple, et al., 2019), and thus improve the quality of care, has driven NHS interest in CDSS since the early 1990s (Haines & Donald, 1998). Consequently, there are currently several CDSS tools in use by the healthcare system. For example, the NHS's national programme for IT, originally scoped in 1998 (Robertson et al., 2010), included the 2001 role out of PRODIGY, a decision support system for GPs which embodied NHS guidelines for prescribing (Heathfield, 1999). It was decommissioned in 2007 (when the contract expired) but replaced with NHS Clinical Knowledge Summaries, part of the NHS National Library of Health (Richards, 2009). Similarly, NHS Pathways, a CDSS for telephone and digital triage, was rolled out across the NHS in 2005 (NHS Digital, 2022), and the NHS Health Check, which was introduced in 2009, makes use of a number of decision support tools.

This interest is understandable, potentially even commendable. Evaluations of CDSS use conducted outside of the NHS have shown that when implemented well, CDSS can reduce prescribing of antibiotics, improve management of transplant patients, improve compliance with guidelines for treating complex long-term conditions, reduce the ordering of unnecessary tests, and reduce the risk

of inappropriate prescribing in elderly patients (Austrian et al., 2021). Furthermore, research shows that CDSS is potentially available to help with a far wider range of problems, including: assessing stomach pain in primary care (Rubin et al., 2021); managing chronic disease (Chen, Howard, et al., 2022; P. Jia et al., 2019; Mainous et al., 2018; Souza-Pereira et al., 2020); checking for drug allergies, medication errors, and adverse drug events (Hajesmaeel Gohari et al., 2021; Légat et al., 2018; Whitehead et al., 2019); handling breathlessness and respiratory illnesses (D. Mann et al., 2020; Sunjaya, Martin, et al., 2022); managing infection and infection risk (Dunn et al., 2021; Neugebauer et al., 2020); improving the management of cardiovascular risk out of hospital (Gold et al., 2022; Webster et al., 2021); and more. There are, however, significant limitations with these types of CDSS.

Initially, CDSS were standalone systems (mostly known as expert systems) that required clinicians to manually enter patient information, before reading and interpreting the results; from 1967 CDSS were slowly integrated into clinical information management systems; and by the late 1980s CDSS could be separated (and thus deployed separately) from the underlying clinical knowledge base – providing data scientists with considerably more flexibility (Mahadevaiah et al., 2020). Yet, the functional scope of these CDSS examples has remained limited, restricted to 'if this, then that' type of logic (Cafri et al., 2018; Challen et al., 2019), capable only of simple actions such as suggesting when to initiate disease screening (based on very basic demographic information), order diagnostic tests, or prescribe appropriate treatment (Cox et al., 2020, p. 42). CDSS of this nature is primarily 'passive' (requiring clinicians to actively seek out its advice) and 'presentational' (presenting information that is almost always already known) (Eberhardt et al., 2012). In most cases CDSS of this nature is a computerised form of a clinical guideline i.e. "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Woolf et al., 1999). It cannot be customised to the local population, or the specific patient; cannot adapt or 'learn' over time in response to changes in clinical knowledge; is not easily integrated within existing Electronic Health Record (EHR) systems and so highly inefficient in terms of staff time (Amarasingham et al., 2014); cannot provide causal insights; cannot be easily combined; and each outcome of interest must be trained on its own, using a static dataset, drastically limiting flexibility and thus usability (P. Arora et al., 2019). In short, this type of CDSS cannot meaningfully contribute to the development of a LHS (Boxwala et al., 2011), it primarily *preserves* existing information flows rather than creating new flows or generating new feedback loops.

Turning the NHS into a LHS will instead rely on the use of, what Eberhardt et al., (2012) term 'Algorithmic Clinical Decision Support Software' (henceforth ACDSS)[2] to create an ACDSS-enabled National Learning Healthcare System (henceforth ACDSS-enabled NLHS or 'the system'). Unlike *passive* and *presentational* CDSS, ACDSS is typically *active* and *inferential,* capable of actively alerting clinicians to information they do not already know, providing new knowledge and creating new information flows. This information may be requested by the clinician, for example via a 'conversation' with a chatbot, or a clinical notes summary, but is more likely to be 'pushed' to the clinician without their active request for example via a 'pop-up', an alarm, or some other notification or reminder (Kim, 2018). Rather than having been pre-programmed from already codified and formalised knowledge, as in the case with passive CDSS, the information generated by ACDSS is inferred and generated in real-time, by the ACDSS 'asking' questions such as "if this patient's physiological and medical conditions are similar to the majority of other patients with the same category of disease, then the most effective treatment will probably be A" (Sloane & J. Silva, 2020, p. 561) or "what are the chances that a patient with these symptoms has disease B? or disease C" (Baalen et al., 2021, p. 5). This kind of 'epistemological reasoning' is made possible by the processing of input data, for example that within an Electronic Health Record (Baalen et al., 2021), by a trained algorithm, for example, random forest, support vector machine, Naïve Bayesian classifier, Neural Network, Decision Tree, or Ensemble model, housed within the backend of a software application (Nwanosike et al., 2022; Vasudeva Rao et al., 2022). These models reason by comparing the specific patient's data to data or knowledge that already exists within its knowledge base (Baalen et al., 2021) which the model may have 'acquired' through clinical knowledge graphs, text sources (such as academic publications or textbooks), international guides, local policies, as well as raw data (M. Moor et al., 2023). This reasoning can then support a wide range of functions including diagnosis, outcome prediction, treatment planning, prescribing and management of medications, preventative care, chronic disease management, image interpretation (contouring, segmentation, and pathology detection), and many others (Mahadevaiah et al., 2020). For instance, in a hospital, an alert might look something like "Warning: This patient is about to go into shock. Her circulation has destabilized in the last 15 minutes <link to data summary>. Recommended next steps: <link to checklist>" (M. Moor et al., 2023, p. 261). Table 1 below, informed

[2] Eberhardt et al (2012) use the exact phrase 'Algorithmic Clinical Decision Support System' and the abbreviation of ACDSS. The phrase is far less consistent, however, than 'CDSS.' Different authors, different hospital systems, and others, all use slightly different variations. Other phrases used, include 'algorithm-based clinical decision support,' 'automated clinical decision support software', 'intelligent clinical decision support,' and 'real-time clinical decision support.' Others may not even use the phrase 'decision support' but refer instead to the more specific function such as 'medical calculator,' or 'diagnostic algorithm', 'algorithmic decision-making', 'risk prediction tool', or 'risk stratification algorithm.' All phrases refer to a form of algorithmic-based system that is capable of inferring likely diagnoses, expected treatment response, and more from existing clinical data (Eberhardt et al., 2012).

by Sutton and colleagues., (2020) (who differentiate between knowledge-based and non-knowledge-based CDSS) and Arora and colleagues (2019), summarises the difference between the two types of CDSS.

CDSS	**ACDSS**
Knowledge engine = Pre-programmed knowledge base (e.g., computerised clinical guidelines) following basic generic pattern rules if this, then that. Cannot handle non-linear relationships. Typically based on a system of one model per outcome.	Knowledge engine = Complex algorithms learned on data (e.g., neural networks) capable of completing more multi-layered, conditional reasoning, accounting for very large numbers of clinical and non-clinical parameters so one model can model multiple outcomes. Can handle non-linear relationships.
One-way knowledge extraction centre = extracting the relevant rule from the knowledge engine. Personalised only on the basis of basic demographic information.	Two-way knowledge reasoning centre = inferring relevant advice by 'asking and answering' questions, inferring risk, completing case-based reasoning tasks, or modelling 'what if' scenarios. Highly personalised advice based on multiple clinical and non-clinical parameters.
Interface = presenting information to clinicians for example in a basic warning, or alert, with little or no description or contextualisation. No causal inference.	Interface = presenting information to clinicians in a well-reasoned and argued form with necessary description e.g., patient X has is exhibiting X symptoms, patients like X had X% increased risk of developing disease Y, patients like X responded best to treatment Z to prevent the risk of developing disease Y. Explicit causal inference.

Table 1. Table comparing CDSS with ACDSS.

ACDSS (Eberhardt et al., 2012) of this nature has a number of advantages. ACDSS can, for example, cope with complex non-linear associations and so extract causal inferences (Buch et al., 2018) leading to novel insights about the causes of disease and the best way to treat it (Blease et al., 2019); can be continually updated with new information and adapted to local populations (i.e. it *can learn*)(Johnson et al., 2014a; Sim et al., 2001a); and is flexible enough to cope with large multi-dimensional datasets, and complexity (P. Arora et al., 2019; Muralitharan et al., 2021). These capabilities make the predictions (or 'decisions') made by ACDSS considerably more specific, personalised, and accurate – ultimately, it is hoped, leading to better patient outcomes (Grote & Berens, 2020; Levy-Fix et al., 2019a). Reddy, and colleagues (2019), for example, describe a study which showed that ACDSS was capable of recommending alternative (more suitable) treatment pathways and inferring a patient's health status even when there were vital measurements missing from the patient's record, and it was able to refine its recommendations as new information (for example new evidence) was received. Such capabilities, enable ACDSS to deliver on the following four dreams of data-driven healthcare (or an LHS) identified by Stevens and colleagues (2022, pp. 6–9):

- **The dream of being seen** where, when a patient enters a hospital, the clinicians already know that they are coming, are familiar with their medical history, and have access to the best available evidence (in real-time) to tailor their treatments specifically to that patient.
- **The dream of timeliness** where, when a clinician is treating a patient, they have access to a health risk warning system that can inform them of the diseases that patient might be likely to develop and how the clinician might be able to intervene.
- **The dream of connectedness** where data scientists can connect qualitative data about patient experience to quantitative data collected in the clinic or by wearables in one structured place and use this diverse data to help uncover new insights, information, and truths which is fed back to clinicians.
- **The dream of being in control** where the chief executive of a hospital, or of the NHS, needs to decide on the investment in particular services or treatments, can open a dashboard and get a comprehensive overview of the healthcare needs of the population they are responsible for managing.

These dreams effectively summarise how, by improving the availability and *use* of data, knowledge, and evidence, ACDSS can create a new causal feedback loop leading to the desired better-quality decision-making (Ostropolets et al., 2020).

It seems, therefore, that ACDSS holds great promise for the NHS. Research shows that it can be used to predict clinical deterioration (Muralitharan et al., 2021); aid the diagnosis of mental health conditions (Benrimoh et al., 2018); drug-drug interactions (Vo et al., 2023); cardiogenic shock (Aleman et al., 2021); and the development of sepsis in neonates (Persad et al., 2021), as well as inform complex neurosurgery decisions (Buchlak, Esmaili, Leveque, Farrokhi, et al., 2020) and enable the practice of pharmacogenomics[3] (Borden et al., 2021). These potential benefits are, however, yet to be realised.

Although ACDSS has shown considerable clinical utility in the lab, it has not yet replaced the use of conventional, or passive, CDSS in clinical practice (Nwanosike et al., 2022). A systematic review conducted by Lee and colleagues (2020) of predictive models embedded into EHR systems (i.e., ACDSS) found no examples from the NHS or the UK, and of those found elsewhere (most notably in the US), only 10% of the implemented models used machine learning or deep learning algorithms (Baxter & Lee, 2021). Similarly, whilst Corbin and colleagues (2023) describe DEPLOYR - a technical framework for deploying researcher created ACDSS directly into the EHR of a hospital – this was only within the context of a clinical academic centre (Stanford Medical School and Standard Health Care Hospital). Finally, a study by Honeyford and colleagues (2023) of digital sepsis alerts in use in NHS hospitals, found that whilst the majority of NHS hospital trusts have an electronic health record

[3] The branch of genetics concerned with the way in which an individual's genetic attributes affect the likely response to therapeutic drugs.

system, and are using digital sepsis alerts (CDSS), none have yet connected the two to make use of data-driven or ML-driven sepsis alerts (AICDSS). These examples, highlight the fact that ACDSS implementation outside of academia, and particularly within the NHS, has been beset with multiple technical, ethical, regulatory, and cultural difficulties (Davenport & Kalakota, 2019; Eberhardt et al., 2012; Johnson et al., 2014a). Consequently, there is currently little to no evidence that ACDSS relying on EHR (or similar) data inputs[4], can improve clinical decision-making outside of the research context (Ben-Israel et al., 2020; Vasey et al., 2021). Or as Robert Wachter, author of the NHS Wachter Review *Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England (Wachter, 2016),* remarked, when it comes to the use of AI in healthcare (including ACDSS) "there is [currently] more hope than reality and more hype than evidence" (Banerjee et al., 2018; Emanuel & Wachter, 2019).

Seneviratne and colleagues (2020 p.45) refer to this gap between the 'hype' and 'reality' of ACDSS as the 'implementation gap' and describe the current lifecycle of a healthcare algorithm as: train on historical data → publish a good receiver-operator curve → collect dust in the 'model graveyard.' Yet, if the NHS's information flows are to be effectively leveraged to help the system improve its performance and outcomes, then this implementation gap must be closed. What is concerning to policymakers, clinicians, and data scientists alike, is that the NHS does not have the best track record when it comes to technological transformation.

1.6 ACDSS: Doomed to fail?

As Scobie and Castle-Clarke (2020, p. 2) put it "the NHS has a chequered history of digital development." Computers were first introduced to the NHS in the 1960s. Interest in the idea that increased used 'information technology' could improve NHS performance first spiked in the 1990s and, in December 1992, the NHS Executive launched the first comprehensive Information Management and Technology Strategy for the NHS *Getting Better with Information* (Bond & Kirkham, 1999). This was followed by *Information for Health* in 1998; *Delivering 21st Century IT Support for the NHS* in 2002; *Information and Technology for Better Care* in 2015; *The future of healthcare: our vision for digital, data, and technology in health and care* in 2018; and *Data Saves Lives* in 2022. Some of these strategies, and their associated technology implementation projects, have led to moderate successes, including the

[4] There is considerably more evidence that AI-based image recognition software used to support radiologists can work and deliver benefits in a clinical setting. Indeed, in August 2023, the National Institute for Clinical Excellence (NICE) approved 9 AI tools to 'contour' CT or MRI scans to help plan radiotherapy treatments, potentially saving between 3 and 80 minutes per plan. However, these types of AI technologies fall outside the definition of ACDSS in this context (NICE, 2023).

introduction of: the NHS Number; primary care EHRs; the NHS Spine; E-Prescribing; E-Booking; NHS Mail (C. Price et al., 2019); and the NHS App. However, there are many more examples of failed large-scale NHS technology implementation projects, resulting in unintended consequences (unintended emergence); missed delivery targets (i.e., missed intended emergence); frustrated staff; moral harm (e.g., loss of public trust); wasted public funds; and technology abandonment (Cameron et al., 2016; J. Chapman, 2002; Greenhalgh et al., 2020; Kittay, 2011) (henceforth 'failure'). The examples of the National Programme for Information Technology (NPfIT); the collaboration between DeepMind and the Royal Free; and the ill-fated Care.Data Programme all provide examples of this history of failure.

1.6.1. National Programme for IT

The National Programme for Information Technology (NPfIT) was launched by Tony Blair's Labour Government in 2002. Described as the 'world's largest civil IT programme,' it had an initial budget of £6.2billion (Justinia, 2017). Initially intended to run for two years, and nine months from April 2003, NPfIT was supposed to bring NHS information infrastructure into the 21st century, by enabling the joining up of information systems and datasets for use in direct care, so that patient outcomes could be improved and more sustainable business models could be developed (Sood & McNeil, 2017). Policymakers hoped that by 2006 the NHS would be largely paperless, with almost all administrative tasks from booking appointments to transferring prescriptions from GPs to local pharmacies being completed electronically, and that patients would only have to 'tell their story once' because all previously recorded information would be available to any clinician anywhere with the touch of a button (Greenhalgh & Keen, 2013). These hopes were never realised, however. From the start the programme was dogged by delays, resistance from frontline clinicians, and spiralling costs. In short, the programme was not trusted by doctors given that it appeared to have no impact on patient safety and private contractors (notably BT) failed to deliver either on time or within budget (Justinia, 2017). By May 2011, more than five years after the programme was supposed to have concluded, the National Audit Office (NAO) suggested that completion of the still-promised upgrades to the NHS's information infrastructure would cost the taxpayer more than £11.4 billion, leading the head of the NAO to refer to it as 'yet another example of a department fundamentally underestimating the scale and complexity of a major IT-enabled change programme' and recommending that it be shut down (Cranfield et al., 2015; National Audit Office, 2011). This prompted the Cabinet Office's Major Projects Authority to conduct an official review into the project. This review concluded in September

2011, finding that the NPfiT was not 'fit to provide the modern IT services that the NHS needed' and so dismantled the programme (Department of Health and Social Care, 2011).

1.6.2 Care.Data

'Care.Data' was a project launched by the Health and Social Care Information Centre (HSCIC – later known as NHS Digital and now merged with NHS England) in 2013. The intention was to extract data from all GP records and hospitals, link it, de-identify it by removing names and addresses, and store it centrally inside a 'safe haven' so it could be made available for researchers and commissioners responsible for planning health services (NHS England, 2013). The HSCIC had a legal basis for doing this, set out in the Health and Social Care Act 2012, and it already extracted GP records via the General Practice Extraction Service (GPES) for various purposes including monitoring NHS activity (Laurie et al., 2015). However, this legal basis proved insufficient for the HSCIC to gain the trust and confidence of patients, citizens and healthcare professionals (Sterckx et al., 2016; van Staa et al., 2016). The 'information and engagement' strategy of delivering leaflets to all households in England failed to adequately inform the public; hundreds of people claimed not to have seen the leaflet; and it did not set out how data would be protected, nor who would have access to it under what conditions (Hays & Daker-White, 2015). Furthermore, privacy campaigners accurately pointed out that policymakers were overstating the ability of the HSCIC to make the data 'anonymous' through de-identification processes, and alerted the public to the fact that their data would still be vulnerable to re-identification – especially as technology developed (Presser et al., 2015). In short, the programme failed to gain the necessary 'social licence' to go ahead (P. Carter et al., 2015; Woolley et al., 2016) and was shut down in July 2016 (Limb, 2016).

1.6.3 'Streams:' DeepMind and the NHS Royal Free Hospital

Streams was an app designed by Google's London-based subsidiary DeepMind, in partnership with the NHS Royal Free Hospital, to present clinicians with key information that would make it easier for them to recognise the early signs of Acute Kidney Injury and so intervene – i.e., it was designed as a presentational form of CDSS. To enable DeepMind to develop the app, the Royal Free transferred 1.6million patient records to the Google affiliate. As the hospital believed that because the app was to be used for 'direct care purposes' patient consent was not needed (Rumbold & Pierscionek, 2017), it failed to publicly disclose any of the details of this arrangement (Powles & Hodson, 2017). This was viewed as being a significant infringement of patient rights, and thus damaging to patient autonomy,

leading to the details of the partnership being investigated by the Information Commissioner's Office (ICO). Following its investigation, the ICO ruled that the Royal Free had failed to comply with data protection law – specifically it failed to comply with the common law duty of confidence – as patients would not have expected their data to be used by the hospital in that manner (The Royal Free, 2017). Although this ruling did not result in the project begin shut down – though it was required to establish a legal basis under the Data Protection Act – it did lead to a significant 'trust deficit' and is viewed as having significantly set back the development of CDSS – especially ACDSS – in the NHS (H. Shah, 2017).

In some respects, the fact that many of the most technically ambitious NHS programmes have failed is unsurprising. All technical transformation projects are risky as the associated costs and disruption are typically much easier to demonstrate than the benefits (Boddy et al., 2009), and as Greenhalgh and Papoutsi (2019, p. 1) stress, intervening in a system as complex as the NHS is hard; it takes hard work; involves diverting staff from other potentially more important clinical tasks; requires the shifting of cultural and professional norms; and making changes that might lack support. However, there are also systemic issues with the inflexible way in which central policymakers (for example those inside the Department of Health and Social Care, NHS England, and other central bodies) plan, commission, and fund NHS transformation projects.

Previous research has shown that choices regarding which technologies to invest in are made by centralised largely unscrutinised teams on the basis of flawed assumptions, forecasts and expectations that are overly optimistic', and perceived benefits that are not directly relevant to the needs of frontline staff (Black, 1989; Collingridge & Margetts, 1994). In addition, evaluations of failed projects have found a tendency for policymakers to considerably underestimate the sociotechnical challenges associated with the design, implementation, and evaluation of any new health information technology (G. Martin et al., 2020; Ojiako et al., 2010). Finally, a history of 'repeated mistakes' reveals a propensity to ignore the lessons of failed projects past. For example, in 2020 NHS Digital launched the General Practice Data for Planning and Research programme. It had the same aims as Care.Data and made many of the same mistakes, such as inadequately engaging with the public and not putting in place sufficiently robust data protection mechanisms. Consequently, it was subject to significant negative press and was, ultimately, placed on indefinite 'pause' in mid-2021 after its announcement resulted in the number of people 'opting out' of their NHS data being used for planning and research more than doubling (de Zulueta, 2021; Goldacre & Morley, 2022). Unless these repeated patterns are

interrupted it seems likely that any attempts to increase the adoption and spread of ACDSS in the NHS are also doomed to fail.

This prescient warning, combined with the fact that currently very little is known about how to incorporate ACDSS into the healthcare system without causing significant harm via unintended consequences (Amarasingham et al., 2014; Bai et al., 2020), has prompted pushback against its use and calls for a 're-examination' of the role of ACDSS in clinical care (Kouri et al., 2022). Such pushback is particularly strong amongst members of the technical and clinical communities who believe that current confidence in the potential of ACDSS is unfounded. These individuals argue that the enthusiasm for ACDSS's potential expressed in NHS strategy documents is based on a blinkered attitude that ignores the scale of the implementation challenge – particularly with regard to potential trade-offs, competing interests, and complex value judgements (Cohen et al., 2020a; James, 2014; Vegter, 2018). Members of this camp believe that ACDSS will ultimately fail to meet expectations and that the NHS is, therefore, precariously balanced on the precipice of the 'trough of disillusionment' which has resulted in previous 'AI winters' (Bainbridge, 2019). Panch and colleagues (2019) suggest that as these sceptical voices grow louder, the NHS may be forced to significantly downgrade its enthusiasm regarding the potential of 'algorithmically enhanced care.'

Abandoning ship is potentially the least reputationally damaging option and it would at least protect against further waste of public funds. However, it would also result in patients and the NHS incurring significant opportunity costs (D. S. Watson et al., 2019), and could pose a threat to the NHS's commitment to improving lives. 'Innovation' is explicitly identified as a tool for improving healthcare in the NHS constitution (Akenroye, 2012). As Jones and colleagues (2017, p. 49) argue, there is ample evidence to suggest that the underuse of health data is implicated in the deaths of many thousands of people and potentially £billions in financial burdens to society. Or as Goodman (2020, p. 29) put it, "if health information technology could improve health, then, *ceteris peribus,* this [entails] a duty to use it for this purpose," stressing that "it would be irresponsible to acquire information in a clinic, research study, or public health surveillance effort and not use it support one of the others." From this perspective, giving up on the demonstrable potential benefits of ACDSS just because getting its implementation *right* is difficult, would be just as ethically problematic and wasteful as continuing to throw good money after bad.

It is clear, therefore, that the NHS needs to find a way of resolving this tension between incorporating the benefits and mitigating the potential harms of ACDSS: simultaneously avoiding the misuse and underuse of this potentially life-saving (and system-improving) technology (Floridi et al.,

2018). Or, to put it another way, the NHS needs to find a way of ensuring its transition towards an ACDSS-enabled NLHS results in positive intended emergence (i.e., new capabilities, activities, outcomes) and avoids negative unintended emergence (i.e., unintended consequences, undesirable transformative effects)(Cameron et al., 2016). Finding an approach to the implementation of ACDSS that achieves this goal would confer on the NHS what Floridi and colleagues (2018) refer to as the 'dual advantage:' enabling the NHS to identify and leverage socially acceptable benefits of ACDSS (intended emergence) whilst also enabling it to avoid or at least minimise costly mistakes and so prevent repeating the errors of the past (unintended emergence). Thus, the motivating question for this thesis is:

> Motivating Question: How can the NHS be enabled to capitalise on the dual advantage of ACDSS?

1.7 From command and control to design

The first step in developing a new approach to anything is recognising the limitations of previously tried and tested approaches. As already described, most previous attempts to implement 'data-driven' technologies into the NHS have been led by central policymaking teams with little outside influence (Collingridge & Margetts, 1994). This is typical of an inflexible 'command and control' approach to *planned* implementation (J. Chapman, 2002; Collingridge & Margetts, 1994; Escobar, 2013) where decision making power is concentrated among a small number of experts who are assumed to have diagnosed the implementation problem correctly and to have developed the right solution (Escobar, 2013; Mulgan & Leadbeater, 2013).

This kind of tightly controlled approach to planned implementation is borne out of the reductionist paradigm. It assumes that implementation problems exist within a bounded rationality, that the health system and its component parts are objectively observable, and that the implementation steps can be understood in a relatively straightforward mechanical and linear fashion (Atun, 2012; J. Chapman, 2002). This simplified approach can work in situations where the end goal is the optimisation of an existing process or system, for example when an existing technology is simply being upgraded or directly switched, or when the technology is designed to fix an old and well-known problem (The Design Council & The Point People, 2020; Winograd & Flores, 1986). However, in situations where these conditions are not met, where what is required is *transformational change* and solutions are needed to more open problems such as 'how to ensure the use of a new technology is suited to particular purposes and values,' then a reductionist *planned* approach can mean that the most important aspects of a problem are missed or overlooked. As has already been shown, when the NHS

encounters technology implementation projects of this nature, the result is often failure. In short, when the implementation of a specific technology case is intended to bring an entirely new system into being, such as the creation of an ACDSS-enabled NLHS, then a reductionist approach is just not pragmatic (Ferraro et al., 2015). This is especially true when – as in this case - the new system is embedded within an existing larger system (the health and care system), and accompanied by smaller essential enabling systems (Cameron et al., 2016). In other words, reductionist planned approaches to implementation are least likely to work when dealing with transformations in complex systems composed of many "interrelated, interconnected, and interwoven entities and relationships" (Cameron et al., 2016, p. 50).

Developing an implementation approach that will work in these more challenging circumstances requires the acceptance of a fundamental truth: complex systems cannot be *controlled* or willed into being, but they can be *designed* (Meadows & Wright, 2008). This is why design, or "delivery science" (R. C. Li et al., 2020), is seen as being key to the successful implementation of 'innovation' in the public sector (Bason, 2017). In contrast to command-and-control approaches to implementation, design-based approaches are less planned, more propositional and ontological, less concerned about what *is* and more concerned with imagining what *if* (Escobar, 2013; Hopkins, 2019; The Design Council & The Point People, 2020). This is because 'designers' are exploratory by nature: they bring together methods and insights from a variety of disciplines including anthropology, data science and, crucially, systems thinking (Rowan et al., 2017) to develop a deeper and more nuanced understanding of the implementation problem (Bason, 2017). In developing this deeper understanding, design-based approaches to implementation, make it easier for policymakers to identify weak spots in the existing system's supporting architecture that can be targeted by policy to bring about change. By doing this, policymakers can reduce the gap between what is written in policy and what is implemented in practice and so significantly increase the chances of implementation success (Cameron et al., 2016; McBride et al., 2020; D. H. Meadows & Wright, 2008). In other words, the creation of a new system (i.e., the creation of a NLHS via the implementation of ACDSS), is more likely to be successful if the system's architecture is carefully designed (Cameron et al., 2016). This is because if those responsible for developing the system, develop it according to an agreed architecture, then the described and exhibited system (i.e., the policy ambition and the technology implemented) will be aligned (Weilkiens et al., 2022).

This power of system architecture design lies in its ability to use logic to reduce complexity and make complex systems more manageable, by (1) identifying the system's components,

connections, and constraints (*form)*[5]; (2) identifying the system stakeholders' needs (desired system *function);* and (3) demonstrating (via an architectural *concept* such as a model*)* how different configurations of the systems components, connections, and constraints affect the ability of the system to satisfy the system stakeholders' needs (i.e. how different system architecture designs influence the likely success of the system) (Cameron et al., 2016; Gacek et al., 1995; Zachman, 1987). So effective is this process believed to be that Gacek and colleagues (1995) argue that completing it should be a precondition for any system design projects that wishes to be successful.

It is perhaps this faith in architecture design that inspired Panch and colleagues (2019) to suggest that if policymakers do not wish to downgrade their enthusiasm for AI in healthcare (ACDSS in this context) then they should focus their whole attention on the only other viable option: developing (in this case designing) the necessary [information] infrastructure. Information Infrastructure is, after all, the architecture of cyber-physical systems (Weilkiens et al., 2022) (e.g., ACDSS-enabled NLHS), and has been recognised as an object of design since at least 1996 (Karasti, 2014; Neuman & Star, 1996).

1.8 Defining information infrastructure

At first associating something as 'boring' as information infrastructure (Star, 1999) with something as creative as design (Barbero, 2017) might seem incongruous. However, it should be remembered that whilst in the case of new water or electricity systems, infrastructure might be purely technical, comprised of pipes and wires and little else, information infrastructure is both technical and semantic (Karasti, 2014). Information (or data) is not a purely technical concept – it is not just undifferentiated 'bits' transported across a network – it is relational, contextual, and inherently social (Karasti, 2014). Its infrastructure, therefore, is not solely comprised of protocols, databases, and python code. Information infrastructure is instead always comprised of multiple interacting informational, technical, procedural, sociocultural, ethical, and regulatory components (Ngiam & Khor, 2019a).

To be more specific, information infrastructure embedded within complex healthcare systems (such as the NHS) is – according to Sittig and Singh (2010, pp. 4–6) – comprised of eight distinct components:

[5] *Form* is what the system is, *function* is what the system does (Cameron et al., 2016)

1. Hardware and software computing infrastructure e.g., Electronic Health Record systems (EHR) used by NHS hospitals, GP surgeries, and other NHS organisations, including EHR systems provided by TPP, EMIS, or Cerner.
2. Clinical Content e.g., the structured and unstructured information (data) recorded and stored in the system, such as lists of symptoms, diagnoses, prescriptions, images.
3. Human Computer Interface e.g., the interface clinicians use to enter information into an EHR, or – crucially in this context – to access ACDSS.
4. People e.g., ACDSS developers, clinicians, patients, and other stakeholders
5. Workflow and communication e.g., when does ACDSS fire during a clinical consultation, how is it acted upon, how is it interpreted, how are the results communicated to patients.
6. Internal organisational policies, procedures, and cultures e.g., the protocols governing the development of ACDSS from data collection through to ongoing monitoring, organisational and system values.
7. External rules, regulations, and pressures e.g., data protection regulation, medical device regulation, consumer protection regulation, discrimination regulation.
8. System measurement and monitoring e.g., Key performance indicators, indicators of success.

As explained above, the design of each of these components, and their interactions, can have a significant effect on the overall success of the system the information infrastructure brings into being. Successful information infrastructure design should result in a system (ACDSS-enabled NLHS) that benefits from positive intended emergence and avoids negative unintended emergence (i.e., a system that capitalises on the dual advantage). In contrast, failed information infrastructure design might result in a system (ACDSS-enabled NLHS) that suffers from negative unintended emergence and rarely – if ever – benefits from positive intended emergence (i.e., is unable to capitalise on the dual advantage). In short, the design of the NHS's information infrastructure, supporting the implementation of ACDSS, will likely have a significant impact on the success of the resultant ACDSS-enabled NLHS and whether the NHS is able to capitalise on the dual advantage. Thus, getting the design of the NHS's information infrastructure *right* is essential. The aim of this thesis is, therefore:

> Aim: To design the information infrastructure that will enable the NHS to capitalise on the dual advantage of ACDSS.

The question then becomes, how exactly to do this?

1.9 It's All About the Requirements

System architecture design or, in this case 'infrastructuring' (The Design Council & The Point People, 2020) is a poietic science: it does not seek to create a model of the past, but rather seeks to help policymakers (the primary audience of this thesis): (1) *understand* the past and the present; (2) develop the ideal model for a system; and (3) use policy to realise the system according to the model – or at least as close to it as possible (Floridi, 2017b). This process is *conceptual,* as – as explained above architecture (or information infrastructure in this case) is the *concept* mapping *form* to *function* (Cameron et al., 2016)- and starts by asking questions about the abstract properties, principles, mechanisms, or dynamics characterising the system in question (Buchanan, 2019; Floridi, 2017b). The success of the process is, therefore, largely dependent on the first question asked (Winhall & Leadbeater, 2020). The first question defines the boundaries of the process. Closed questions are unnecessarily restrictive, they simply ask 'what can be built?' constraining imagination and creativity, and resulting in outputs that are too restrictive: *product* rather than *purpose* focused (Escobar, 2018; The Design Council & The Point People, 2020; Winograd & Flores, 1986). Fruitful design processes thus start with open questions (Winhall & Leadbeater, 2020) that reveal greater possibilities about 'what can be?' and create space for the simultaneous defence of some existing system practices or properties, the transformation of others, and the invention of entirely new practices or properties (Escobar, 2013). The resulting outputs should then be as non-prescriptive as possible, protecting the autonomy of the system, whilst still clearly establishing the direction of change and setting boundaries that may not be crossed by any implementation strategy (J. Chapman, 2002). This necessitates asking questions that encourage integrative thinking and abductive reasoning – discovering *what* can be and then identifying *how* this can be realised (Barbero, 2017; Morley, Floridi, Kinsey, et al., 2020; The Design Council & The Point People, 2020).

According to Floridi (2017) this inferential step between the *what* and the *how* is at the core of the conceptual logic of design, and it is begun by focusing the questioning process on the elicitation of the necessary requirements (scope, features, purpose, functionality) that the system must have to satisfy the specific purpose. These requirements can then be 'operationalised' through an iterative process involving the determining of specific functions (remembering that *function* maps to *form* via *concept)*, the allocation of resources (without specifying how they must be deployed) and granting the necessary permissions (the policy decisions) (J. Chapman, 2002). In this way, the conceptual logic of design is translated into the conceptual logic of requirements, adapting the well-known 'double

diamond' design process used for product design and applying it to purpose design (Floridi, 2017b; Rowan et al., 2017; Sanders & Stappers, 2008).

Exactly how this can be achieved in this context is discussed later in Chapter 3. For now, it suffices to say that, informed by Cameron and colleagues (2016), Greenhalgh and colleagues (2019), McBride and colleagues (2020) and Meadows and Wright (2008) it involves the following steps: (1) understanding the NHS information infrastructure *as-is* and identifying the leverage points to bring about change through policy intervention*;* (2) identifying the undesirable consequences (i.e., unintended emergence/risks) that could result from weaknesses in the information infrastructure design; (3) identifying the ideal information infrastructure vision and delivery requirements that can enable successful ACDSS implementation and the requirements covered by policy; (4) analysing the assumptions and theories influencing the ideal information infrastructure requirements and those covered by policy, why they differ, and the consequences of these differences; (5) identifying the policy requirements to overcome the differences between the ideal requirements and those covered by policy, to realise the form of the ideal requirements (i.e., operationalise the requirements); and (6) bringing together these function, vision, delivery, and form requirements into a conceptual model for the successful implementation of ACDSS into the NHS that will enable the resultant ACDSS-enabled NLHS to capitalise on the dual advantage. Thus, the overarching research question for this thesis becomes:

> ORQ: What are the information infrastructure requirements for the successful implementation of ACDSS in the NHS?

Or with the expanded definition of information infrastructure (see above (Sittig & Singh, 2010)):

> ORQ: What are the hardware and software; clinical content (raw data); human computer interface; people; workflow and communication; internal organisational policies; external rules, regulations, and pressures; and system measurements and monitoring requirements for the technically feasible, socially acceptable, ethically justifiable, and legally compliant development, deployment, and use of ACDSS in the NHS?

Most of this thesis (Chapters Four – Eight) will, therefore, be dedicated to answering this question following the steps outlined above. In brief, Chapter Four aligns with step 1 above and explores the weaknesses (disorganised complexity) associated with the NHS's current information infrastructure; Chapter Five aligns with step 2 and identifies the potential re-ontologising (or fundamentally re-engineering) consequences that might occur if the design of the information infrastructure design does not adequately mitigate the risks (unintended emergence) of ACDSS implementation; Chapter Six aligns with step 3 and identifies the ideal information infrastructure vision (benefit-enabling) and

delivery (risk-mitigating) requirements and compares these to the requirements covered by current relevant policy; Chapter Seven aligns with step 4 and explores why the current ideal vision and delivery requirements differ considerably from those covered by current policy, and how these might be overcome; Chapter Eight aligns with steps 5 and 6, and identifies the policy requirements for operationalising the ideal requirements in accordance with a unified function designed to close the gap between the ideal requirements and those covered by policy before combining all the requirements into a conceptual model for the successful implementation of ACDSS into the NHS; and Chapter Nine concludes the thesis, summarising the main findings, limitations, and next steps.

More detailed signposting is provided at the end of Chapter Three. However, it is first necessary to refine the scope of the overarching research question by (1) defining successful; and (2) identifying what is already known (both the known knowns and known unknowns) about the requirements for the successful implementation of ACDSS. These are the tasks of the next chapter – the literature review.

2. Identifying the known knowns and known unknowns of ACDSS implementation

2.1 Introduction

The previous introductory chapter made it clear that the challenges the NHS is facing as it passes its 75th birthday are so significant that individual policy tweaks are unlikely to be sufficient. Instead, to cope with the pressures of caring for 21st century patients in an increasingly resource-constricted context, the NHS will need to change its MO, relying more heavily on its information flows to become a national learning healthcare system (NLHS). However, the previous chapter also made clear that making this transition will be far from straightforward. To transition from NHS to NLHS, the NHS will need to implement ACDSS (and so become an ACDSS-enabled NLHS). Yet, despite considerable policy enthusiasm for the potential of ACDSS to help the NHS achieve this transition, exactly how to implement ACDSS successfully, and avoid repeating the mistakes of past technology implementation failures, remains unknown. Insights from systems engineering (or 'architecting') and the logic of design as a conceptual logic of requirements, suggest that one way to help the NHS overcome this hurdle or implementation gap, is to identify the information infrastructure requirements necessary for the successful implementation of ACDSS. It is hoped that, as the design of a system's architecture (in this case the information infrastructure) has a significant influence on the overarching success of the resultant system (i.e., the desired ACDSS-enabled NLHS), carefully designing the NHS's information infrastructure into which ACDSS will be implemented, will enable the NHS to capitalise on the 'dual advantage' of ACDSS: maximising the benefits of desirable intended emergence, and proactively mitigating the risks of undesirable unintended emergence. Hence, the overarching research question for this thesis is:

> ORQ: What are the information infrastructure requirements for the success implementation of ACDSS into the NHS?

It is not yet possible, however, to identify how best to answer this question as the scope is not entirely clear. This is because whilst the definition of information infrastructure has been identified (the combination of eight components including hardware and software as well as external rules and regulations), the definition of successful has not. Nor has it been clarified what is already known (both

the known knowns and known unknowns) about the requirements for the successful implementation of ACDSS and, therefore, it is unknown what this thesis should seek to learn from previous studies and what it should seek to improve. It is the purpose of this chapter to fill in these gaps and so refine the scope of the overarching research question.

To complete this task, this chapter provides a brief thematic overview of the existing literature. The purpose is not to provide a detailed analysis of any of the specific findings within the extant literature or to translate these into specific information infrastructure requirements – this type of detailed literature analysis will come later (see Chapters Four to Eight) once the scope of the research question has been clarified. Instead, the sole focus of this chapter is to complete this necessary *a priori* task by:

1. Identifying categories of success factors that the requirements must cover (and thus must be included in the definition of success); and
2. Identifying key guiding principles for the elicitation of requirements process.

Specifically, it does this via a two-stage analysis process. First, it provides a high-level thematic overview of the known technology implementation success factors that may also impact ACDSS implementation success drawn from literature on change management in the NHS; technology adoption, scale-up, and spread; acceptance and adoption of AI in healthcare; implementation of AI into healthcare; and evaluation of individual examples of ACDSS. Second, it problematises the studies that produced these findings from the perspective of the aim of this thesis (to design the information infrastructure that will enable the NHS to capitalise on the dual advantage of ACDSS) so that in answering the overarching research question, this thesis can focus on making necessary improvements to the existing literature rather than unnecessarily reinventing the wheel. Once it has completed these two tasks, the chapter concludes with a fully defined overarching research question for this thesis and an explanation of its scope.

2.2 Categories of success

The question, 'What are the information infrastructure requirements for the successful implementation of ACDSS in the NHS? is a multidisciplinary question, and as Wyatt et al., (2020) state the specific social science literature on 'big data' tends to pay little heed to routine health data - only really touching on wearables data. It is not possible, therefore, to identify one single body of literature from which to draw out the known success factors. Instead, it is necessary to look for attempts to

answer parts of the question rooted in disciplines as wide ranging as: social psychology, anthropology and sociology, philosophy, organisational sociology, information systems (Shaw et al., 2017), medical sociology, communication studies, marketing and economics, development studies, health promotion, complexity studies, and more (Greenhalgh et al., 2004a). What follows is a brief overview of this wide-ranging literature, starting with literature at a high-level of abstraction[6] (LoA) on change management in the NHS and ending with literature at a low-level of abstraction on evaluating individual ACDSS studies.

2.1.1 Achieving change in the NHS

As alluded to in Chapter One, over its more than 75-year lifespan the NHS has been subject to almost continuous top-down pressure to adapt to changes in the demographic make-up of the population it serves, to political and cultural changes, to changes in medicine, and to technological change (Ashburner et al., 1996b). It is no surprise, therefore, that much of the published literature operating at the highest level of abstraction is focused on analysing examples of successful and failed transformation initiatives in order to identify the mechanisms that are most effective at producing the intended outcomes (Best et al., 2012). In essence, this body of literature – which primarily draws from organisational sociology and social psychology – frames achieving large-scale change in the NHS as a management problem and attempts to identify the macro, meso, and micro factors (and the interactions between them (Begun & Dooley, 2003; Chandler et al., 2016)) that facilitate or hinder the institution's ability to adapt to changes in strategic intent (Pettigrew et al., 1988).

The resultant list of macro, meso, and micro 'success' factors identified by this body of literature is long, but the range of factors is relatively contained. Indeed most of this literature was published between the late 1980s and the early 2010s suggesting that thematic saturation was reached. Allock and colleagues (2015), for example, identify seven factors that are essential if change is to be successfully achieved in the NHS: committed and respected leadership; a culture hospitable to, and supportive of, change; management practices that ensure execution and implementation; data and analytics that measure and communicate impact; resources and support for change; an enabling environment that supports and drives change; and the ability of the workforce to identify and solve problems. Adding to this, Asthana and collagues (2019), outline the factors that influence the NHS's

[6] A level of abstraction represents an interface, or a particular vantage point, from which aspects of a system are observable (and therefore analysable), while other aspects are opaque or invisible. LoAs are common in computer science, where systems are described at different LoAs (computational, hardware, user-centred, etc.). Although not always, LoAs can be both combined into complex sets, and hierarchical (Floridi, 2008; Milano et al., 2020).

ability to adopt new e-health innovations including: incentives and regulatory requirements; commissioning targets and financial pressures; and the impact on the values, priorities and routines of staff. Scott (2003) and Ferlie and colleagues (2012) add a critical perspective to such lists, noting that different organisations within the NHS often exhibit varying degrees of adaptability. Respectively, they attribute this variation to 'cultural lag' where – in some parts of the NHS – there is a considerable dissonance between the prevailing culture of the organisation and the culture of wider society, and differences in organisational power relations. Finally, Ham and colleagues (2003) add the importance of training to improve staff receptiveness to change, particularly when said change involves the implementation of new technical systems. All these 'success factors' for change reappear elsewhere in the literature. For example, Redfern & Christian (2003) also stress the importance of there being a supportive organisational culture that is open to change; Breckenridge and colleagues (2019) reiterate the value of committed leadership; Martin and colleagues (2013) focus again on the importance of value alignment; and Sermed Mezher and Muhammad Sajid (2019) flag again the necessity of tying the change to clear targets. Such overlaps mean that the very long list of success factors extracted from this body of literature can be summarised for ease (see Table 2) as: committed and inspiring leadership; culture receptive to change; adequate resource and incentivisation; alignment with stakeholder values; properly trained staff; demonstrable impact.

Success Factor	**References**
Committed and Inspiring Leadership	(Allock et al., 2015b; Breckenridge et al., 2019; Ferlie et al., 2012; Ham et al., 2003; G. P. Martin et al., 2013)
Culture receptive to change	(Allock et al., 2015b; Breckenridge et al., 2019; Hamilton et al., 2007; G. P. Martin et al., 2013; Redfern & Christian, 2003; T. Scott, 2003a)
Adequate resource and incentivisation	(Allock et al., 2015b; Asthana et al., 2019a; G. P. Martin et al., 2013)
Alignment with stakeholder values	(Asthana et al., 2019a; Hamilton et al., 2007; G. P. Martin et al., 2013; Sermed Mezher & Muhammad Sajid, 2019)
Properly trained staff	(Ham et al., 2003; Hamilton et al., 2007)
Demonstrable impact	(Allock et al., 2015b; Asthana et al., 2019a; Breckenridge et al., 2019; Hamilton et al., 2007; Sermed Mezher & Muhammad Sajid, 2019)

Table 2. Success factors extracted from literature on change management in the NHS.

2.1.2 Technology adoption, scale-up and, spread

The next body of relevant published literature spreads out from Rogers' original (1962) (Rogers, 2003) diffusion of innovation theory which, for example, Wainwright & Waring, (2007), apply to four different case studies looking at the uptake of new information systems within NHS General Practices.

It is a sprawling body of literature, covering everything from comprehensive theories of social practice such as Latour's Actor Network Theory (Cresswell et al., 2010a), Giddens' structuration theory (Giddens, 1984), social construction of technology theory (Klein & Kleinman, 2002; Pinch & Bijker, 1984), and normalisation process theory (Shaw et al., 2017), through to hyper-specific metrics designed to predict the likelihood of a specific NHS organisation adopting a specific innovation, such as 'The Innovation Readiness Score' (Benson, 2019). Although very different in approach, all these theories and metrics attempt to answer the question: 'how do we begin to theorise what happens at macro, meso, and micro levels when government tries to modernise a health service with the help of big IT?' (Greenhalgh & Stones, 2010b). Mishuris and colleagues (2019), for instance, surveyed clinicians in two primary care institutions after they had been using a specific example of CDSS for six months, and used the results to evaluate whether Normalisation Process Theory could be used to explain the barriers and enablers to implementation of CDSS in primary care settings. This generalisability perhaps explains why it is this body of literature that the NHS itself has shown greatest interest in, with the UK Department of Health commissioning a systematic review on the topic in 2002 as part of its NHS Service Delivery and Organisation Programme (Greenhalgh et al., 2004a).

The range of potential contributing factors that can be extracted from these theories of social practice and individual 'technology readiness metrics' is vast including: digital literacy, usefulness, ease of use, motivation to change behaviour, anticipated benefits, perceived effort, social norms, and user optimism in technology. To try to reduce this complexity, scholars have also combined various variations of these different factors into models that can be more readily applied to specific cases. These models include the Technology Acceptance Model (TAM) (Davis, 1989), extended TAM (Venkatesh & Davis, 2000), the unified theory of acceptance and use of technology (Venkatesh et al., 2003), and conceptual Population-Intervention-Environment Transfer Model of Transferability (Schloemer & Schröder-Bäck, 2018a).

Most of these theory-based models of adoption have, at some point, been used to explain the success or failure of different technology implementation projects in the NHS. For example, Johnson and colleagues (2014) use the Technology Acceptance Model to identify the technological, organisational and behavioural factors affecting clinician acceptance of traditional CDSS. Despite this, no one model has emerged as dominant in the literature – particularly from the perspective of helping to design successful technology implementation projects. Indeed, it is felt that further work is needed to refine and test these different models before they can be used to develop predictive hypotheses about what may increase the chances of success, particularly in the context of complex information

technologies, such as ACDSS (Ward, 2013). However, this does not mean that the individual factors recognised as being important for success in different context should not be extracted and summarised as below (see Table 3).

Success Factor	**References**
Openness to innovation	(Benson, 2019; Greenhalgh et al., 2004a; Johnson et al., 2014a; Pinch & Bijker, 1984; Ward, 2013)
Digital literacy and confidence	(Benson, 2019; Schloemer & Schröder-Bäck, 2018a)
Innovation coherence	(Benson, 2019; Johnson et al., 2014a; Mishuris et al., 2019)
Usefulness	(Benson, 2019; F. D. Davis, 1989; Ji et al., 2021; Rogers, 2003; Schloemer & Schröder-Bäck, 2018a; Venkatesh & Davis, 2000; Ward, 2013)
Ease of use	(Benson, 2019; F. D. Davis, 1989; Venkatesh & Davis, 2000; Wang et al., 2023)
Capability to change	(Benson, 2019; Giddens, 1984; Schloemer & Schröder-Bäck, 2018b)
Sensitivity to context (internal and external)	(Cresswell et al., 2010b; Giddens, 1984; Greenhalgh et al., 2004a; Greenhalgh & Stones, 2010a; Johnson et al., 2014a; Klein & Kleinman, 2002; Pinch & Bijker, 1984; Schloemer & Schröder-Bäck, 2018b; J. Shaw et al., 2017; Venkatesh & Davis, 2000)
Individual actors with agency	(Giddens, 1984; Greenhalgh et al., 2004a; Greenhalgh & Stones, 2010a; Klein & Kleinman, 2002; Mishuris et al., 2019; Pinch & Bijker, 1984; Schloemer & Schröder-Bäck, 2018b; J. Shaw et al., 2017)
Clear links with outcomes	(Greenhalgh & Stones, 2010a; Mishuris et al., 2019; Rogers, 2003; Schloemer & Schröder-Bäck, 2018b)
Alignment with values	(Greenhalgh & Stones, 2010a; Rogers, 2003)
Relevant skills	(Greenhalgh & Stones, 2010a; Johnson et al., 2014a; Klein & Kleinman, 2002; Mishuris et al., 2019; Schloemer & Schröder-Bäck, 2018b; J. Shaw et al., 2017; Wainwright & Waring, 2007a)
Adequate resources	(Klein & Kleinman, 2002; Rogers, 2003; Schloemer & Schröder-Bäck, 2018b; Venkatesh & Davis, 2000; Wainwright & Waring, 2007a)

Table 3. Success factors extracted from literature on technology adoption, scale-up, and spread.

2.1.3 Acceptance of AI in healthcare

Arriving at the middle LoA, the literature focuses on factors associated with the acceptance of AI in healthcare in general. In particular, the literature leans heavily on the significant role appropriate governance – both soft (ethical governance) and hard (regulatory governance) (Floridi, 2018a) – plays in the healthcare system's willingness to adopt any new technology and argues that it will play an equally important role in the willingness of the system to accept AI.

To start with soft governance, there has been a burgeoning of publications focusing on the ethical implications of using AI (including ACDSS) in healthcare (e.g., Zhang & Zhang, 2023). This is to be expected given medicine's overall mandate of 'do no harm' (MacKinnon, 1988; Manchikanti &

Hirsch, 2015) and the proliferation of normative documents (Schiff et al., 2020) addressing the ethics of AI including ethics codes, guidelines and frameworks from private companies and public bodies alike (e.g., Greene et al., 2019; Hagendorff, 2020; Jobin et al., 2019; Terzis, 2020)). Beyond such analyses of high-level ethics principles (typically beneficence, non-maleficence, autonomy, justice and explainability (Floridi & Cowls, 2019), most of this sub-section of the published literature consists of theoretical discussions about the potential impact of AI on key tenets of care and the importance of ensuring these tenets are protected to ensure acceptability. Specifically, by identifying ethical challenges related to data, process, and management (Xafis & Labude, 2019) this literature highlights the implications for consent (Andorno, 2004b; Brill et al., 2019a; Findley et al., 2020); shared decision-making and the protection of patient values (e.g., Dalton-Brown, 2020; Jotterand, 2005; McDougall, 2019; Panch et al., 2019; Vayena et al., 2018); patient safety (especially the risks of misdiagnosis) (e.g., Gianfrancesco et al., 2018; Hague, 2019); empathy (e.g.,Kerasidou, 2020); 'fair' resource allocation (e.g., Garattini et al., 2019; Holmboe & Bernabeo, 2014; Nordling, 2019; Schönberger, 2019); the nature of the patient-clinician relationship (e.g., Boers et al., 2020; Cabitza et al., 2017; Char et al., 2018; de Boer & Kudina, 2021); and, of course, privacy (Abouelmehdi et al., 2017; Bartoletti, 2019a; Mooney, 2023; W. N. Price & Cohen, 2019; Xafis et al., 2019).

Next to the literature focusing on hard governance measures (Floridi, 2018a), there is a relatively long history of published work analysing the legal implications of using ACDSS. Given the multifaceted nature of ACDSS, it is unsurprising that this literature, which dates back to 1970 (Brannigan & Dayhoff, 1986; R. A. Miller, 1985; W. B. Schwartz, 1970), touches upon a wide range of legal fields, from legal philosophy, human rights, and tort law, to contract, product, and medical device law (Cortez, 2018; Perc et al., 2019). As there have not yet been any (known) cases of, for example, a patient being harmed as the result of a misdiagnosis by an ACDSS, most of the literature in this domain is speculative in nature – focused on identifying how the use of ACDSS might challenge the way in which existing legislation is traditionally applied. For example, Favaretto and colleagues (2019) and Fosch-Villaronga and colleagues, (2022) are quick to point out that interpretations of anti-discrimination law will need updating as, in the context of AI (ACDSS), core notions such as motive and intention will no longer apply. In short, papers of this nature seek to highlight the current 'regulatory gap' (S. M. Carter et al., 2020; Iqbal & Biller-Andorno, 2022) and to answer the question 'what are the appropriate legal standards for ACDSS (Moses, 2016; Rhem, 2021)?

Currently, the literature is struggling to answer this question as most papers are either highly generic, for example focusing on the principle components of a proportionate governance framework

for ACDSS (Liao et al., 2022; Morley & Joshi, 2019b; Reddy et al., 2020; Sethi & Laurie, 2013), or very specific, such as the challenge posed by the increasingly blurred lines between frontline care and research (Braun et al., 2020) or the challenge posed by the updating nature of self-learning algorithms for existing static product-based medical device law (see for example Becker et al., 2019; Fraser et al., 2018; Gerke, Minssen, et al., 2020; Hwang et al., 2019; Lee et al., 2020; Smith et al., 2003). This 'extremism' limits the generalisability of the conclusions or findings of papers of this nature, particularly as they tend to be only applicable to one narrow jurisdiction, for example Germany in the case of Molnár-Gábor's (2020) analysis of product liability and ACDSS or the United States in TerKonda & Fish's (2023) analysis of the pressure placed on state regulation by ACDSS. Additionally, the literature is struggling to keep pace with changes in context and regulation. For example, Yang & Thompson(2015), Gerke and colleagues (2020), Carroll & Richardson (2016) and McCarthy & Lawford (2015) provide detailed analysis of how the European Union Medical Device Directive (MDD) could be applied to the development of AI, but the MDD was replaced by the Medical Device Regulation (MDR) in 2020 and, whilst the transition takes place, it is difficult for the literature to assess its impact (Čartolovni et al., 2022; Lukas et al., 2021; McInerney et al., 2021). In the case of the NHS, this is further complicated by the fact that British law is likely to increasingly diverge from European law, as evidenced by the consultation recently published by the UK Medicines and Healthcare products Regulatory Agency (MHRA) (MHRA, 2021a). Finally, this body of literature lacks balance, with considerably more attention paid to issues of medical malpractice liability (e.g., Cohen et al., 2014; Price et al., 2019; Prictor et al., 2020; Tobia et al., 2021; Vayena et al., 2018) and confidentiality (e.g., Mészáros & Ho, 2018; Mourby, 2020; Rumbold & Pierscionek, 2017; Sorbie, 2020) than any other issues such as commercial exploitation of 'public' healthcare data (Aboy et al., 2019). For the purposes of this chapter, these limitations of the hard governance literature, and those of the soft governance literature above, are of little import. What matters is that the existing literature is very clear on the role that ethical and regulatory clarity will play in willingness of the healthcare system to adopt AI and, therefore, in the success of ACDSS implementation (see Table 4).

Macro Success Factor	Specific Success Factor	References
Ethical Clarity	Protection of autonomy (including right not to know, and right to give consent)	(Andorno, 2004b; Boers et al., 2020; Brill et al., 2019b; Buck et al., 2022; Dalton-Brown, 2020; Findley et al., 2020; Garattini et al., 2019; McDougall, 2019; Mourby, 2020; Sorbie, 2020; Wang et al., 2023; Xafis et al., 2019; Zhang & Zhang, 2023)
	Justice	(Boers et al., 2020; Char et al., 2018; Favaretto et al., 2019b; Garattini et al., 2019; Gianfrancesco et al., 2018; Hague, 2019; Holmboe & Bernabeo, 2014; Nordling, 2019; Panch, Mattie, & Atun, 2019; Perc et al., 2019; Schönberger, 2019; A. E. Smith et al., 2003; Vayena et al., 2018)
	Explainability	(Braun et al., 2020; Čartolovni et al., 2022; Chang Ho Yoon et al., 2022; C.-F. Liu et al., 2022)
	Empathy	(Cabitza et al., 2017; Čartolovni et al., 2022; A. Kerasidou, 2020a)
	Protection of privacy	(Abouelmehdi et al., 2017; Bartoletti, 2019a; Braun et al., 2020; Char et al., 2018; Garattini et al., 2019; Gerke et al., 2020b; Mészáros & Ho, 2018; Mooney, 2023; Mourby, 2020; W. N. Price & Cohen, 2019; Sorbie, 2020; Vayena et al., 2018; Xafis et al., 2019)
	Protection of skills	(Cabitza et al., 2017; Rhem, 2021)
Regulatory Clarity	Clear medical device regulations	(Becker et al., 2019; Brannigan & Dayhoff, 1986; Carroll & Richardson, 2016; S. M. Carter et al., 2020; Čartolovni et al., 2022; Fraser et al., 2018; Hwang et al., 2019a; Lukas et al., 2021; McCarthy & Lawford, 2015; McInerney et al., 2021; Reddy et al., 2020; Rumbold & Pierscionek, 2017; A. E. Smith et al., 2003; Yang & Thompson, 2015)
	Clear medical liability guidance	(Braun et al., 2020; Čartolovni et al., 2022; Gerke et al., 2020b; Molnár-Gábor, 2020a; W. N. Price et al., 2019; Prictor et al., 2020; Schönberger, 2019; Tobia et al., 2021)
	Clear IP law	(Aboy et al., 2019)

Table 4. Success factors extracted from literature on the acceptability of AI in healthcare and the role played by governance.

2.1.4 AI implementation frameworks

Staying at the meso LoA, but moving away from literature considering the generic factors influencing acceptability and willingness to adopt AI in the healthcare system, to a body of literature focused on the more specific analysis of barriers and enablers to AI implementation. This literature is largely qualitative, and tends to split into two categories: interview (e.g., Landers et al., 2023; Richesson et al., 2020), focus group (e.g. Westerbeek et al., 2022) and case-based studies investigating generalisable barriers to, and enablers of, the successful implementation of AI in healthcare; and high-level evaluation frameworks,

Starting with the interview and focus group studies, these draw heavily on the implementation science theories and adoption and spread models described above, such as the Unified Theory of Acceptance and Use of Technology model (Fujimori et al., 2022) or the Coping Mechanism User Adoption model (Nitiéma, 2023). Consequently, and unsurprisingly, the factors identified by this literature are very high-level and overlap significantly with the general success factors for adoption identified by the theoretical literature, such as perceived usefulness of and trustworthiness of AI (e.g., Abujaber et al., 2022; Choudhury, 2022; Tran et al., 2019), involvement of clinicians in the design of any AI-based tool (e.g., Kanbar et al., 2022; Padley et al., 2020; Prausnitz et al., 2023), user confidence, (W. Chen, O'Bryan, et al., 2022), and rigorous performance evaluation (Buck et al., 2022; Harris et al., 2022; Kilsdonk et al., 2017; Olaye & Seixas, 2023; Tsopra et al., 2021). The only point of differentiation, is that this literature sometimes highlights more specific technical barriers, for example interoperability issues (e.g., Semenov et al., 2020; Yoo et al., 2022).

Moving to the literature focused on the development of evaluation frameworks for AI which, perhaps unsurprisingly, overlap significantly (at least in a thematic sense) with the literature highlighting the importance of hard governance measures for successful implementation described above. For example, in their paper focused on developing a 'roadmap for responsible machine learning for healthcare' Wiens and colleagues (2019) conclude that what is needed more than anything else is regulatory incentives. Similarly, Seneviratne et al. (2020) in their paper on 'bridging the implementation gap of machine learning in healthcare', and Tran and colleagues (2019) in their paper describing a 'framework for applied AI in healthcare', both stay at the ethical principles LoA noting the importance of safety, trust and ethics as well as the importance of a robust regulatory strategy. Other papers, notably Chen and colleagues' (2019) 'how to develop machine learning models for healthcare;' He and colleagues' (2019) 'practical implementation of AI technologies in medicine;' Hopkins and colleagues' (2020) 'from AI algorithms to clinical application;' and Shah and colleagues'

(2019) 'translational perspective' on AI and machine learning in clinical development, focus on listing the steps involved in developing and training a machine learning model from defining the problem to training the workforce to use the model. Lastly, there are papers which take a product development approach and seek to outline what is involved at each stage from 'idea formation' through to 'post-market surveillance' (e.g., Crossnohere et al., 2022; Higgins & Madai, 2020; Sendak et al., 2020).

As with the literature on change management in the NHS, the resulting list of potential success factors from this literature is seemingly never-ending, but it can be summarised (see Table 5):

Success Factor	**References**
Problem and solution alignment	(Abujaber et al., 2022; P.-H. C. Chen et al., 2019; W. Chen, O'Bryan, et al., 2022; Choudhury, 2022; Fujimori et al., 2022; X. He et al., 2023; Higgins & Madai, 2020; Kilsdonk et al., 2017; Nitiéma, 2023; Prausnitz et al., 2023; M. P. Sendak et al., 2020; Seneviratne et al., 2020a; Tran et al., 2019; Tsopra et al., 2021; Westerbeek et al., 2022)
Clear communication between clinical and technical teams	(J. He et al., 2019a; Padley et al., 2020)
Interoperable & curated datasets	(P.-H. C. Chen et al., 2019; Harris et al., 2022; J. He et al., 2019a; Jill Hopkins et al., 2020; Richesson et al., 2020; Semenov et al., 2020; Tran et al., 2019; Tsopra et al., 2021; Wiens et al., 2019a; Yoo et al., 2022)
Validated performance	(Crossnohere et al., 2022; de Hond et al., 2022, 2022; Jill Hopkins et al., 2020; M. P. Sendak et al., 2020; Seneviratne et al., 2020a; Tsopra et al., 2021)
Evidence of efficacy/impact /safety	(Ammenwerth et al., 2013; Buck et al., 2022; P.-H. C. Chen et al., 2019; Choudhury, 2022; Fujimori et al., 2022; J. He et al., 2019a; Higgins & Madai, 2020; Jill Hopkins et al., 2020; Kanbar et al., 2022; M. P. Sendak et al., 2020; P. Shah et al., 2019; Tsopra et al., 2021)
Post-market surveillance	(de Hond et al., 2022; J. He et al., 2019a; Higgins & Madai, 2020; Jill Hopkins et al., 2020; Kanbar et al., 2022; M. P. Sendak et al., 2020)

Table 5. Success factors extracted from literature regarding AI implementation frameworks.

2.1.5 Example ACDSS Trials, Implementations and Evaluations

Finally, at the lowest, or micro LoA, there is large and ever-growing body of literature charting the technical development of ACDSS and evaluating specific ACDSS products either in clinical trials or – more rarely – in situ.

First, the literature that charts the technical development of CDSS over time starts with traditional logic-based 'expert-systems' models in the late 1950s and early 1960s (Reisman, 1996b); moves through the emergence of 'evidence-adaptive' CDSS designed to improve adherence to official guidelines in the 2000s (De Clercq et al., 2004; Sim et al., 2001b); through the development of probabilistic CDSS based on Bayesian networks (Kyrimi et al., 2020, 2021); to the use of deep learning (Miotto et al., 2018) and machine learning techniques such as random forest and neural networks

(ACDSS) (Harerimana et al., 2018; Levy-Fix et al., 2019b); and now to the use of generative AI or foundation models (Ghosheh et al., 2022; Kather et al., 2022; Korngiebel & Mooney, 2021; E. Loh, 2023; M. Moor et al., 2023). Mostly the published literature in this domain serves as useful technical background. However, it does serve to highlight the fact that success factors vary depending on the type of CDSS (i.e., CDSS or ACDSS) and the type of model used within an ACDSS (e.g., Neural Net, Foundation model, etc.). For example, for traditional passive CDSS speed of response and ease of use matter the most for successful adoption and acceptability (Bates et al., 2003), whereas for inferential, machine learning driven ACDSS factors that influence clinician and patient trust are more important (Vourgidis et al., 2019a) for example explainability, reliability and validity (C.-F. Liu et al., 2022; Shortliffe & Sepúlveda, 2018a; Terry et al., 2022).

Next, is literature describing the results of specific ACDSS trials or in-situ evaluations. In theory, this literature should reveal what factors determine whether ACDSS itself is successful (i.e., accurate, reliable, or effective). However, the quality of this literature is so mixed, it primarily acts as further technical background emphasising the range of potential uses of ACDSS, and acting as a reminder that there is – yet – little agreement regarding the success factors of any part of the ACDSS implementation pipeline.

To start with the positive, this literature[7] reveals that trials involving ACDSS have been conducted for the diagnosis, treatment, and prevention of depression and other mental health conditions (Balestrieri et al., 2020; Benrimoh et al., 2018); acute respiratory infections (D. Mann et al., 2020); atrial fibrillation (Cox et al., 2020; Nemis-White et al., 2021); sepsis (Downing et al., 2019); cardiovascular disease (Gold et al., 2022; Webster et al., 2021; Yao et al., 2021); diabetes (Heselmans et al., 2020); hypertension (Kharbanda et al., 2018); chronic kidney disease (Peralta et al., 2020); HPV (Wilkinson et al., 2019); gastrointestinal issues (Rubin et al., 2021); and urinary tract infections (Neugebauer et al., 2020). In addition, the extended literature, shows the potential administrative or management uses of ACDSS including the ordering of routine tests or images (Delvaux, Vaes, et al., 2020; Palen et al., 2019) or polypharmacy reviews (McDonald et al., 2022; Rieckert et al., 2020). This literature, therefore, reiterates the many potential benefits that the system may be able to capitalise on if implementation is successful.

[7] These examples were found by searching PubMed, Web of Science, and Google Scholar for articles involving the evaluation of Clinical Decision Support Software in the last five years. Selection criteria included: evaluation conducted in a clinical setting, ACDSS design vs. passive CDSS, and 'quantitative' evaluation i.e., trial, or similar rather than qualitative user-experience or interview-based evaluation.

Moving to the less positive. Whilst there is clear agreement in this body of literature that technically and clinically evaluating the performance of any models destined to be used in frontline care (including in ACDSS) is vitally important for successful implementation, there is almost no agreement regarding what constitutes successful ACDSS evaluation, nor what contributes to a successful evaluation. There is not, for example, even a clearly agreed 'gold standard' of trial design, with Downing et al., (2019), Kharbanda et al., (2018), Neugebauer et al., (2020) and Rubin et al. (2021) reporting results from single-arm trials; McDonald et al., (2022), Balestrieri et al., (2020), Cox et al., (2020) Delvaux et al., (2020). Gold et al., (2022) Heselmans et al., (2020), Nemis-White et al., (2021), Palen et al., (2019), Peralta et al., (2020), Rieckert et al., (2020) Webster et al., (2021), Yao et al., (2021) and Mann et al., (2020)all reporting results from cluster randomised trials; and only Adusumalli et al., (2021) Wilkinson et al., (2019) reporting the results of large multi-centre randomised controlled trials (the traditional 'gold standard'). This very large heterogeneity in study design, and lack of detail provided on ACDSS design makes it nearly impossible to evaluate why ACDSS worked in some instances but not in others. Even systematic reviews focused on identifying success-enabling features of CDSS or ACDSS from published trials, have not managed to extract anything more detailed than 'standalone CDSS is more popular than web-based CDSS' (Hak et al., 2022).

Given the limitations of these two sub-categories of literature (technical history and individual evaluations) for the purpose of determining success factors, it is difficult to extract any exact summary factors beyond the macro success factors highlighted below in Table 6.

Macro Success Factor	**References**
Alignment between use case, technical model design, and implementation strategy	Multiple
Clinical evaluation of performance	Multiple

Table 6. Success factors extracted from literature describing example ACDSS trials, implementations, and evaluations.

2.3 Successful: technically feasible, socially acceptable, ethically justifiable, legally compliant

The above overview of the factors known to impact the success of NHS change programmes, generic technology implementation projects, and even specific ACDSS projects, has revealed a list of 31 factors that might potentially impact the success of ACDSS implementation into the NHS. Clearly a definition of success, for the overarching research question, that listed each of these factors individually would be impractical. It would also be unlikely to help policymakers distinguish between 'what is interesting' and 'what is necessary' (P. L. Miller & Sittig, 1990) when it comes to information infrastructure design, and therefore would not help this thesis meet its aim. It is, therefore, necessary

to condense this vast list of potentially relevant success factors into a smaller number of thematic categories of success. Table 7 does this, revealing that all 31 factors can be categorised as either technical, sociocultural, ethical, or regulatory/legal. From this, it can be concluded that, according to the extant literature, the definition of ACDSS implementation success is 'technically feasible, socially acceptable, ethically justifiable, or legally compliant.'

Category	**Success Factors**
Technical	• Alignment between use case, technical model design, and implementation strategy. • Interoperable and curated data sets • Protection of privacy
Sociocultural	• Problem and solution alignment • Clear communication between clinical and technical teams • Protection of skills • Openness to innovation • Digital literacy and confidence • Innovation coherence • Usefulness • Ease of use • Capability to change • Sensitivity to context • Individual actors with agency • Clear links with outcomes • Adequate resources • Committed and inspiring leadership • Culture receptive to change • Training provided to staff
Ethical	• Protection of autonomy (including right not to know, and right to give consent) • Justice • Explainability • Empathy • Alignment with values (staff and stakeholders)
Regulatory/ Legal	• Clinical evaluation of performance • Validated performance • Evidence of efficacy/impact/safety • Post-market surveillance • Clear medical device regulations • Clear liability guidance • Clear IP law

Table 7. Thematic analysis of the known technology implementation success factors extracted from the extant relevant literature.

When this definition of success is combined with the previously provided definition of information infrastructure (see section 1.8), it becomes clear that, when fully defined, the overarching research question reads:

> ORQ: What are the hardware and software; clinical content (raw data); human computer interface; people; workflow and communication; internal organisational policies; external rules, regulations, and pressures; and system measurements and monitoring, requirements for the technically feasible, socially acceptable, ethically justifiable, and legally compliant implementation of ACDSS in the NHS?

This full definition already makes the scope of the research question clearer, highlighting what categories of success the identified information infrastructure requirements must cover. However, to ensure it is completely clear, before the most appropriate methodology for answering the overarching research question can be determined, it is first necessary to (1) explain the limitations of these elicited success factors from the perspective of this thesis's aim; and (2) use this limitations analysis (or problematisation) to identify some key guiding principles for the elicitation of requirements process. This is the task of the next section.

2.3 Defining the scope

From this brief overview of the extant literature, it is clear that numerous attempts have been made to identify at least some of the generalisable success factors that might also increase the chances of ACDSS implementation success into the NHS. It is not, therefore, because of a complete gap in the literature that, as discussed in Chapter One, NHS policymakers do not yet have a clear answer on how to successfully implement ACDSS into the NHS. Indeed, much of the literature is highly relevant and may reappear later in this thesis. Nor is it solely because most of the more specific literature (e.g., existing implementation frameworks) comes from outside the NHS, which – given how frequently the importance of contextual awareness is raised in the existing literature – may undermine its applicability. This limitation could be overcome by, for example, conducting an evaluation of one of the existing frameworks in an NHS context. Instead, the reason why the existing literature has not yet enabled NHS policymakers to develop a comprehensive idea of how to implement ACDSS successfully and so enable the NHS to capitalise on the dual advantage of ACDSS, is because of a lack of synthesis and translational insight.

Each of the above identified known implementation success factors came from a different body of literature focused at either a very high LoA of principles, hypothetical possibilities and general frameworks (A. Arora, 2020; Bhattacherjee & Hikmet, 2008) or at a very low technical specifications LoA (Sendak et al., 2020). Consequently, throughout the existing literature, there is little to no

consideration given to either horizontal (for example between ethical implications, regulation, technical design, and social acceptance) or vertical (between the two LoAs) interactions (La Fors et al., 2019; Pollock & Williams, 2010; Ward, 2013) between the different success factors. There is also little to no consideration given to the prioritisation or hierarchy within the factors, and in most cases the success factors are only the *what* not the *how,* which limits their translational and predictive or 'design' power (Ward, 2013). This may be why there is very little evidence in the literature of any of the theories, models, or frameworks, from which the success factors are lifted, being applied to inform the development of more effective policy and strategy from the beginning. It is far more common for the various theories, models, and frameworks, to be applied to case studies retrospectively or to be purely abstract. In other words, the existing literature tells policymakers that to ensure successful implementation it may be necessary to consider everything from digital literacy, to privacy, to the protection of patients' autonomy, but not how to translate these high-level concepts into practical policy actions for specific purposes, nor how to consider the potential trade-offs that might need to be made. In short, at face value the insights into the potential success factors for ACDSS implementation, drawn from the existing literature, do not fulfil all the criteria to count as requirements (scope, function, features, purpose). As such whilst the success factors, in their 'raw' form, provide a foundation for thinking about how ACDSS might be successfully implemented into the NHS, there is still considerable epistemological uncertainty regarding how the desired ACDSS-enabled NLHS could or should be brought into being through practical action (Mittelstadt et al., 2015).

This epistemological uncertainty has left policymakers in an information vacuum: there remain too many 'unknowns' about the specific mechanisms involved in the translation process from ideation to implementation (Cohen et al., 2020b; Melder et al., 2020; M. Sendak, Elish, et al., 2020a). With so little known about 'what matters most' (Tsoukas, 2017) when it comes to the successful implementation of ACDSS, it is unsurprising that the efforts made by policymakers to-date feel reactive, ad-hoc, and fragmented (Char et al., 2020a; May, 2013a). Indeed, AI practitioners and other key stakeholders perceive current policies designed to increase the adoption and use of ACDSS, such as the Draft National Strategy for AI in Health and Social Care (NHSX, 2021), as not reflecting the realities of the real world (Tsoukas, 2017). There is a view that such early efforts – whilst commendable – rely too heavily on reductionist assumptions that a one-size-fits-all inflexible 'blueprint' for the implementation of ACDSS can be developed. Such assumptions fail to acknowledge the fact that success can depend on complex interactions between key personalities, implicit social norms, hierarchies of power and accountability mechanisms, healthcare policies, government regulation

embedded culture, technical infrastructure, the wider psycho-social environment, and more (Dullabh et al., 2022; S. Green et al., 2022; Poland et al., 2005). In other words, the identifiable success factors may be useful for planned approaches to implementation, but, in their current disconnected and somewhat impractical form, are insufficient for designed implementation which – as has already been established – is what is needed to achieve success. As a consequence, there is growing concern that whilst the transformative potential of ACDSS for the NHS is well recognised (Maddox et al., 2019; Norgeot et al., 2019; Wyatt et al., 2020a), the implementation gap between expectation and reality is growing ever wider (Gillan et al., 2019).

With this critique in mind, if this thesis is to achieve its aim, and help NHS policymakers close the implementation gap and so enable the NHS to capitalise on the benefits of the dual advantage, then its overarching research question must be seen as a problematisation of current approaches: an attempt to know how and to what extent it might be possible to think differently instead of what is already known and in so doing, challenge any identified assumptions of current approaches to implementing ACDSS in the NHS (Davis, 1971; Sandberg & Alvesson, 2011). To ensure this thesis achieves this goal of thinking differently about both new and existing knowledge, then the process of eliciting information infrastructure requirements must be guided by the following principles:

- Requirements must be considered not in isolation, but as part of a hierarchic whole so that the complexity associated with interactions between the different requirements, and any necessary trade-offs, can be dealt with (Best et al., 2012; Currie, 2012; Kerr et al., 2018; Shachak et al., 2019) and potential emergent effects can be identified (R. C. Li et al., 2020)..
- Requirements must not view context and technology as separate, but rather as inherently intertwined (Greenhalgh & Stones, 2010a; Uotinen, 2010).
- Requirements must be detailed, theory-informed, and must have both back-propagation explanatory power and forward-propagation explanatory power (Greenhalgh et al., 2004a).
- Requirements must move between the micro, meso, and macro scale (Greenhalgh et al., 2008) to draw out all parts of the system: how its parts work (the humanisation problem); how the whole works (control problem); and how it interacts within its containing system (environmentalisation) (Silverman et al., 2015).
- Requirements must not consider any aspect of implementation, including design, development, deployment, and use, as separate from social influence and effect (Crawford and Calo 2016).

- Requirements must be considered from the perspective of multiple stakeholders including individual professionals and patients; healthcare groups; individual organisations providing NHS services; and the wider healthcare system (Jill Hopkins et al., 2020).
- Requirements must have both a *what* and a *how* element , so it can be established how likely it is that they will be met and, therefore, how likely success is (Kashyap et al., 2021).
- Requirements must be bounded and linked to a specific purpose i.e., intended to solve a specific problem, or enable a specific feature. If there are limitations to any of the requirements, these must be clearly stated.
- Requirements must be informed by the middle-out approach to systems engineering, considering both top-down system needs and bottom-up system wants (Asthana et al., 2019a; Eason et al., 2013; Greenhalgh & Keen, 2013; Sheikh et al., 2021).
- Requirements must be extracted and synthesised from a variety of 'evaluation' perspectives from reporting, regulatory, functional, and economic through to ethical and clinical (Hardt & Chin, 2020; Hochheiser & Valdez, 2020; McCradden, Stephenson, et al., 2020)

In short, to ensure the elicited information requirements are not of limited utility for policymakers (the primary audience of this thesis), the process for their elicitation must be informed by a conjunctive approach to theorising (Tsoukas, 2017). The process must focus on connecting concepts traditionally used in a disjointed manner, so that the whole policy system – including its hidden agendas, and crucially, its effects on the successful implementation of ACDSS – can be described and understood (Haynes, 2008; M. C. Shaw & Stahl, 2011).

With this having been established, the guiding principles can now be combined with (1) the description of clinical data (e.g., EHR)-based ACDSS provided in Chapter One; (2) the fully defined research question, and (3) the definition of the logic of design as the logic of necessary (not sufficient) conceptual requirements met through policy, to produce the scope outlined in Table 8.

In Scope	Out of Scope

• ACDSS that is primarily based on structured clinical data such as EHR data rather than imaging data, that is intended to be used by clinicians at the point of care.
• Technical, ethical, social, and regulatory requirements, relevant to the NHS in England and related to:
  o Hardware and software supporting the development, deployment, and use of ACDSS.
  o Clinical content (i.e., raw daw) supporting the development, deployment, and use of ACDSS.
  o ACDSS Human computer interface.
  o The people involved in the development deployment, and use of ACDSS i.e., the main stakeholders ACDSS developers, clinicians, patients, commissioners, central policymakers, and regulators.
  o Internal organisational policies i.e., strategies, standards, guidance, produced by and for local NHS organisations such as GP surgeries, NHS Hospitals, NHS Trusts, and more.
  o External rules, regulations, and pressures i.e., strategies, policies, standards, regulations, produced by all UK Government departments and arms-length bodies with jurisdiction over data policy, AI policy, and NHS policy in England.
  o System measurements and monitoring i.e., the processes for developing, evaluating, and monitoring ACDSS.
• Policy related to the above requirements produced by UK Government departments and arms-length bodies with jurisdiction over data policy, AI policy, NHS policy[8], that is currently still applicable (i.e., produced by the current Conservative Government which came into power in 2015).
	• Technical, ethical, social, and regulatory requirements related to the listed information infrastructure domains but irrelevant to the NHS e.g., requirements related to the use of ACDSS for medical insurance purposes.
	• Technical, ethical, social, and regulatory requirements related to the listed information infrastructure domains and the NHS but focused solely on image-recognition uses of AI.
	• Technical, ethical, social, and regulatory requirements related to the listed information infrastructure domains and the NHS but focused solely on consumer-facing AI e.g., wellness apps.
	• Policy related to the outlined requirements, but produced outside of the UK e.g., policy produced by the EU (such as the EU AI Act), or the US (such as medical device regulations produced by the FDA).
	• Policy related to the outlined requirements, but applicable only to the devolved administrations e.g., policy related only to NHS Scotland or NHS Wales.
	• Policies, standards, strategies, or guidance documents related to the requirements, and potentially to the NHS, but produced by organisations outside of the UK Government and its arms-length bodies e.g., policy produced by the Association of the British Pharmaceutical Industry, the British Standards Institute, or the Royal College or General Practitioners.

Table 8. Outlining the scope of the overarching research question.

Exactly how this thesis will seek to answer the overarching research question, within this scope, is the topic of the next chapter.

[8] Department of Health and Social Care; Office for Life Sciences; Office for AI; Cabinet Office; Department of Culture, Media, and Sport; Department for Science, Innovation, and Technology; Information Commissioner's Office; NHS England, NHS Digital, Health Education England, National Institute for Clinical Excellence, Care Quality Commission; Medicines and Healthcare products Regulatory Agency; Health Research Authority; National Data Guardian.

3. How to design NHS information infrastructure for the 21st century

3.1 Methodological approach

Combined, the preceding two chapters have reached two conclusions which are important to highlight before proceeding.

First, it is now clear that if the NHS is to succeed in its attempts to implement ACDSS, and this thesis is to meet its aim of enabling the NHS to benefit from the dual advantage of ACDSS, then it will be necessary for policymakers to look beyond command-and-control approaches to implementation in favour of a design-based approach. Design-based approaches are less planned, more propositional and ontological, less concerned about what *is* and more concerned with imagining what *if* (Escobar, 2013; Hopkins, 2019; The Design Council & The Point People, 2020). Such approaches are much better suited, therefore, to bringing into being new realities (i.e., an ACDSS-enabled NLHS) - especially when something as complex as the NHS's information infrastructure is involved. In practice, this necessitates focusing on the logic of design as a conceptual logic of necessary requirements and so this thesis seeks to answer the overarching research question: "What are the information infrastructure requirements for the successful implementation of ACDSS in the NHS?" With 'implementation' covering the development, deployment, and use of ACDSS; 'successful' being defined as ethically justifiable, technically feasible, socially acceptable, and legally compliant; and information infrastructure meaning hardware and software, clinical content, human computer interface, people, workflow and communication, internal organisational policies, external rules and regulations, and system measurements and monitoring. It is hoped that by eliciting these information infrastructure requirements for the successful implementation of ACDSS into the NHS, this thesis can help policymakers enable the NHS to capitalise on the dual advantage of ACDSS as it becomes an ACDSS-enabled NLHS.

Second, it is also clear that whilst the existing literature on the topic of implementing AI in general, and ACDSS specifically, into the NHS has provided foundational insights into some of the high-level success factors for implementation, it has some significant limitations from a policy-informing and design perspective. For instance, the fragmented and often 'extreme' (either extremely general or extremely specific) nature of the extant literature has left policymakers dealing with epistemic uncertainty about the exact *mechanisms* involved in the translation process from ideation to implementation (Cohen et al., 2020b; Melder et al., 2020; M. Sendak, Elish, et al., 2020a). Ultimately,

this limits the utility of the existing body of literature for supporting the development of an overarching policy framework intended to enable the successful implementation of ACDSS (Gama et al., 2022; Ljubicic et al., 2020; Thompson & Morgan, 2020). If this thesis is to avoid falling foul of the 'Is-Ought' problem (Spielthenner, 2017) and provide insights of higher utility for NHS policymakers (the primary audience), then it must provide a pragmatic (Ferraro et al., 2015) answer to the overarching research question. This will require problematising current approaches to implementation: it must try to disrupt the reproduction and continuation of current institutionalised lines of reasoning that see technical implementation challenges as requiring purely technical solutions and challenge the assumptions underlying existing implementation theories (Sandberg & Alvesson, 2011b). Specifically, it must seek to produce a complexity-informed implementation theory[9] (Greenhalgh & Papoutsi, 2018), informed by a deeper understanding of how the multiple social, cultural, technical, and ethical factors interrelate to produce different outcomes (Bhavnani & Sitapati, 2019; Chaudoir et al., 2013; Kaminskas & Darulis, 2007), and so capable of explaining how and why ACDSS might succeed or fail in different settings (Cresswell et al., 2010a; R. C. Li et al., 2020).

These conclusions help to clarify the scope and nature of the research problem that this thesis is attempting to solve: a prerequisite for selecting the appropriate research methods (Noor, 2008a). More specifically as explained in section 2.3, these conclusions help clarify that the process for the elicitation of requirements must be informed by a conjunctive approach to theorising (Tsoukas, 2017) (the nature of the problem) and must cover the scope outlined in Table 8. It is crucial, therefore, that methods are selected which are capable of connecting concepts traditionally used in a disjointed manner, so that the whole policy system – including its hidden agendas, and crucially, its effects on the successful implementation of ACDSS – can be described and understood (Haynes, 2008; M. C. Shaw & Stahl, 2011). It is only by selecting methods that have these capabilities, that it can be ensured that the technical, sociocultural, ethical, regulatory, and legal requirements essential for successful implementation are given equal consideration (Kaminskas & Darulis, 2007; Ngiam & Khor, 2019b). It is, therefore, only by selecting methods with these capabilities, that this thesis can meet its aim of helping policymakers capitalise on the opportunities presented by ACDSS whilst safeguarding against harmful unintended consequences (O'Doherty et al., 2016b). i.e., help policymakers enable the NHS

[9] Implementation science is the systematic study of how to encourage and promote the uptake of research findings and other evidence-based practices into routine practice and, in so doing, improve the quality and effectiveness of health services and care (Car et al., 2019). Complexity science adds the social element to this by focusing on how the interconnections between agents in a system result in emergent, dynamic, and sometimes unpredictable, systems-level behaviours. Combined, the two approaches provide a comprehensive framework for understanding how we can achieve better, more effective, evidence-based care. (Braithwaite et al., 2018)

to capitalise on the dual advantage. Thus, although research on topics related to health informatics is typically rooted in experimental and quantitative methods, the most appropriate methods in this instance are interpretive methods; specifically ethnographic and realist methods (e.g., Ackerman et al., 2015; Greenhalgh & Swinglehurst, 2011; Pollock & Williams, 2010; Star, 1999), situated within the sociotechnical systems (STS) research paradigm .

Research within the STS paradigm attempts to understand the contribution of ethical, legal and sociocultural factors on the performance of technical systems by connecting them to system behaviours and then to artefact design with the explicit aim of *designing* new, safer and more effective technical systems (Coiera, 2007). It is, argue Strang & Sun (2019), the ideal paradigm for examining the complexity hidden under 'simple' theories related to 'big data analytics' problems in healthcare. This is particularly true when ethnographic methods, intended to highlight how the development and implementation of healthcare technologies are enmeshed in socio-political, historical, and political agendas, are used (Lipworth & Axler, 2016; Lock & Nguyen, 2018; Fischer, 2007). Crucially, given the problematising nature of the research question, ethnographic methods are deliberately designed to challenge seemingly 'concrete' or dominant theories about implementation – to remind researchers and policymakers that theory is not static but something undergoing near continuous development (S. Ackerman et al., 2015; Holman Jones, 2016). For these reasons, and the fact that – as mentioned in the introduction – the exploratory nature of designers mean they bring together methods from a variety of disciplines (Rowan et al., 2017), this thesis makes use of a mixed (Ritchie et al., 2018), ethnographic methodology combining semi-structured interviews, realist review, and rhetorical policy analysis. This type of approach, which makes considerable use of 'conceptual blending' (Cranfield et al., 2015), has already been shown to be fruitful (see e.g., (Govia, 2020)) and is described in more detail in the next section.

3.2 Methodology: data collection

3.2.1 Realist review

The purpose of a realist review is to identify and explain the mechanisms that determine whether or not complex policy programmes work, with the intention of providing more effective policy recommendations (Best et al., 2012). More specifically, as explained by Pawson (2002) and Pawson

anc colleagues (2005) a realist review involves conducting a systematised[10] literature search (Grant & Booth, 2009) with the explicit purpose of answering the question "what it is about this programme that works for whom and in what circumstances? (Pawson et al., 2005a, p. 345): by searching the literature for insights into the theories, assumptions, expectations, and rationalizations underpinning the belief amongst policymakers (and other stakeholders), that specific interventions will work as intended. The ultimate intention is, therefore, to problematise these identified theories (and more) to build new and refined theory. It is a method that, therefore, aligns perfectly with the aims of this thesis, the problematising nature of the overarching research question, and its scope.

The exact steps involved in a realist review, and how each step aligns with different chapters in this thesis, are summarised in Table 9. In detail:

1. The scope of the review was clarified in Chapters One and Two which specify the research question, the policy aims (i.e., the creation of an ACDSS-enabled NLHS), the key themes that need to be explored (known success factors, definitions of success and information infrastructure), and the scope of the overarching research question (see Table 9).
2. Search terms were identified from the success factors identified in the literature review in Chapter Two, as well as the definitions of success and information infrastructure used in the overarching research question, and the terms used by Kim, (2018). The full list of terms is provided in Table 10. These terms were used to search Scopus, Web of Science and PubMed systematically, and then Google Scholar was used to check for any gaps. The initial searches were conducted in September 2021 and were repeated on the first of every month from September 2021 to August 2023 to ensure the review was kept up to date with the most recent literature.
3. Inclusion and exclusion criteria were established in accordance with the scope of the overarching research question (see Table 8). Articles included needed to be written in English; be focused on the use of AI in healthcare, ACDSS, or digital health or on the governance

[10] According to Grant & Booth (2009, p. 95) a systematic review "seeks to systematically search for, appraise and synthesise research evidence adhering to strict guidelines on the conduct of a review". Search aims to be exhaustive and involve the quantitative assessment of the quality of the literature. The analysis typically covers what is known in terms of recommendations for clinical practice, what remains unknown, uncertainty about findings, and recommendations for future research. A systematised literature search includes "elements of a systematic review process whilst stopping short of a full systematic review." It includes a comprehensive search strategy but does not necessarily comply with the full guidelines on the conduct of a systematic review. Analysis is narrative, commenting on what is known, any uncertainty, and limitations of the methodology. Ideally a systematic review would be conducted for a realist review, but this requires a bigger team – including at least two literature reviewers, and is therefore, not necessarily suited to sole-authored thesis projects. This limitation is recognised in the conclusion chapter (Chapter 9).

considerations of AI; set within the NHS or in a context comparable with the NHS e.g., within a European or US context; concerned with technical, ethical, social, or legal requirements for ACDSS implementation success; and concerned with one or more of the information infrastructure domains included within the definition of information infrastructure. These are deliberately generous inclusion criteria and do cover articles not written exclusively about the NHS to ensure the full scope of the overreaching research question was covered, and nothing was missed. There is currently a limited amount written exclusively about the use of AI in the NHS, or even exclusively about the NHS's information infrastructure. It would, therefore, have been restrictive to include only NHS-specific articles. Furthermore, as the purpose of a realist review is to reveal assumptions and identify ideal policy requirements, it was important to capture a wide range of views about what is necessary for success from different perspectives and apply these to the context of the NHS, rather than restrict to what is already agreed about the NHS. Accordingly, the exclusion criteria were relatively narrow. Articles were excluded if there were not written in English; not available through the University of Oxford; concerned with requirements not identified as being relevant to success; focused only on AI for image recognition; focused only on consumer-facing uses of AI; or set within a context not comparable to the UK. Several different frameworks were used to extract data from the included articles for different purposes. These are detailed in subsequent chapters (specifically Chapters Four to Eight) and a rationale is given for each framework or coding method used.

4. The initial searches returned 3,584 results before duplicates were removed; 478 duplicates were removed, leaving 3,106 titles to be reviewed; 1,989 articles were removed after the title and abstract screening; 556 results were removed for being unavailable; 561 articles were read in full; 426 articles were excluded; 135 articles were included; 36 articles were added following new literature alerts between September 2021 and August 2023; and 42 additional articles were added by reference following in the previously included articles. This resulted in a total included list of 213 articles (see Figure 1, Appendix A). These articles were then thematically analysed according to the process outlined in section 3.3.
5. The results from the analysis were discussed with interviewees, triangulated, contextualised, iterated, and refined.

Steps in realist review
1. Clarify the scope: a. Specify the research question and the policy aims (see Chapter One) b. List the key themes to be explored (see Chapter Two) 2. Search for evidence a. Search the literature: first to understand the literature as a whole and then become progressively more focused (see Table 10) 3. Review primary studies and extract data: a. Develop an appraisal checklist including inclusion and exclusion criteria (see Table 11) b. Develop a framework used to guide data extraction and thematic analysis (see individual chapters) 4. Synthesise the evidence and draw conclusions (see section 3.3) 5. Disseminate and evaluate: a. Test the recommendations and sufficient conceptual model with key stakeholders and identify the best means for operationalising the policy recommendations to ensure the desired level of specificity is achieved (See Chapter 8).

Table 9. Steps involved in a realist review (informed by Pawson et al., 2005) and how each step aligns with different chapters in this thesis

Realist review structured search terms	
NHS & UK &	History; Innovation; "Information Technology;" Politics; Patient Data; "Artificial Intelligence;" Regulation | Legislation; Rhetoric; Values | Ethics; "Electronic Health Record;" Informatics; "Information Systems;" "Variation in Care;" "Performance Monitoring;" "Quality Improvement;" Efficiency; Sustainability: "Change Management
"Clinical Decision Support Software"	_
"Clinical Practice Guidelines"	_
"Artificial Intelligence" &	"P4 Medicine;" "Preventative Medicine:;" "Participatory Medicine;" NHS & Complexity
"Artificial Intelligence" & "Clinical Decision Support Software" &	Adoption; Implementation; Safety; Efficacy; Evaluation; Validation; Ethics; Trust; Governance; Autonomy; Policy; NHS; Impact; "Evidence Based Medicine"
"P4 Medicine"	_
"Precision Medicine" &	Governance; Regulation; Ethics; Policy; NHS; "Clinical Decision Support Software"
"Predictive Analytics" | "Risk Prediction" &	Health; Ethics; Implementation
"Medical Device" &	Software; "Artificial Intelligence;" "Clinical Decision Support Software"
"Information Technology" & Health &	Acceptance; Adoption; Diffusion; Implementation
Health & Policy &	Data; "Data Ethics;" "Data Sharing;" "Data Access;" "Data Governance"
"Complexity Science" & Health &	"Artificial Intelligence;" Innovation; Information
"Implementation Science" & Health	"Artificial Intelligence;" Innovation; Information

Table 10. Search terms used to search Scopus, Web of Science, and PubMed for relevant literature

Inclusion Criteria	Exclusion Criteria
• Written in English. • Focused on the specific requirements of AI/Digital/ACDSS in health OR focused on the requirements for successful Governance of AI. • Set within a relevant context (i.e., within the UK, or within a relatively comparable context e.g., EU, or American healthcare systems). • Set at a middle level of abstraction (i.e., not too high-level to not be implementable, nor too specific to not be generalisable) • Concerning ethical, technical, regulatory, or sociocultural requirements for ACDSS implementation. • Concerning the information infrastructure elements listed in the definition.	• Not available in English. • Not available via the University of Oxford. • Focused on generic translational medicine or implementation frameworks and not specifically relevant to AI/ACDSS/Digital Health. • Related only to AI for image recognition. • Set within a context that is non-comparable to the UK e.g., China, India, Africa. • Purely theoretical. • Poor quality. • Focused exclusively on a specific use case e.g., AI in surgical decision making.

Table 11. Inclusion and Exclusion criteria used for screening literature included in the Realist Review

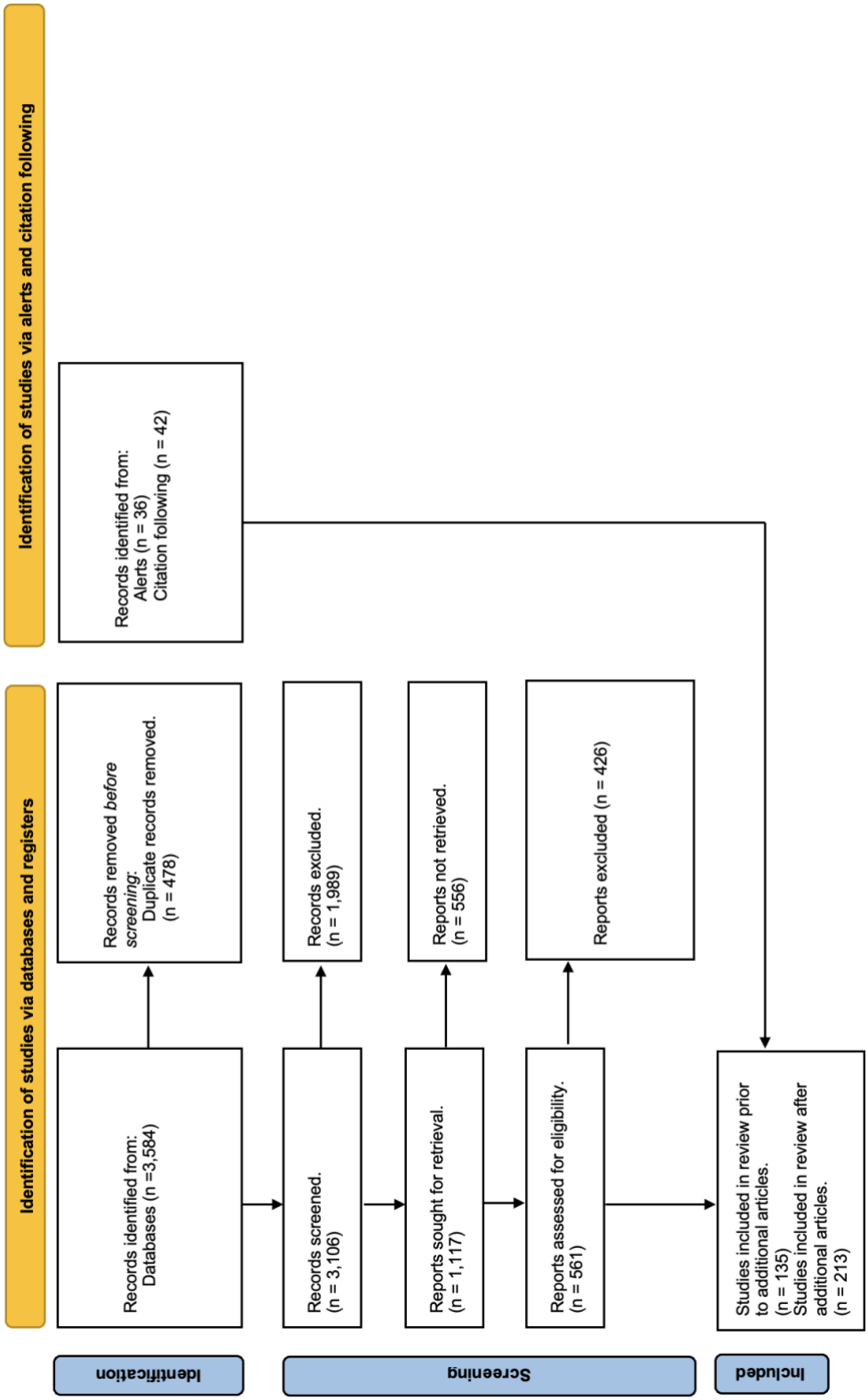

Figure 1. PRISMA Flow diagram for Realist Review (Page et al., 2021)

3.2.2 Semi-structured interviews

As stated above the purpose of a realist review is to provide insight into the theories, assumptions, expectations, and rationalisations underpinning the belief amongst policymakers (and other stakeholders), that specific interventions will work as intended. This it does well. However, the insights provided by the literature included in a realist review tend to be narrow in scope and less dimensionally rich (Ulucanlar et al., 2013) than is necessary for a problematising and complexity-informed research project. Typically, literature identified as part of a realist review will provide a top-level summary of the headline views of key stakeholders, but will not explain *why* these views are held; how they vary between different groups of stakeholders and in different contexts; or whether there are any nuances in the assumptions held depending on the unique beliefs or values of influential individuals (Birkbak et al., 2015). Perhaps, most importantly, because there is a limited amount of literature written exclusively about the NHS, not all the articles included in the realist review are directly relevant to an NHS-context. The realist review cannot, therefore, give insight into any NHS-specific variables, it can only provide insights that *might* be applicable to the NHS. If not countered, these limitations can result in the 'wrong' (or at least too generic or not directly applicable) conclusions being drawn and presented as universal 'truths' (O Riordan, 2014). The purpose of interviews, therefore, is to gather more detailed, more dimensionally rich, more nuanced, and more contextually specific insight into the beliefs, rationalisations, and assumptions of key information infrastructure stakeholders across the NHS and to contextualise the findings of the realist review.

In-depth semi-structured interviews were, therefore, conducted with a wide range of stakeholders from across the health and care system in the UK, and the EU, and the US for the purpose of challenging assumptions. Participants were recruited via social media (Twitter & LinkedIn) as well as via specific online forums (NHS-R community forum, NHS-Python community forum, NHS-Futures AI Lab Forum). Recruitment took place during September 2022 and continued until a reasonably representative sample of stakeholders had been recruited. Initially 85 participants were recruited, of which 73 were interviewed, representing as many groups of stakeholders as possible from NHS data analysts and commissioners to software engineers, clinicians, and technologists (see Table 12). The interviews took place online over a six-week period beginning in October 2022. Interviewees were provided with an interview topic guide (see Appendix B) and were given the opportunity to veto any topics that they were uncomfortable discussing (see Table 13), otherwise interviews were largely participant led with open questions being used to encourage participants to speak in their own words about their experiences, observations, opinions, and beliefs (Harmon & Kale, 2015).

Recordings of, and detailed notes from, the interviews were thematically analysed alongside the results from the realist review, as described in section 3.3. Appendix C provides a high-level example of this thematic analysis. To protect the anonymity of interviewees, several of whom were senior stakeholders within the NHS, interviewees are not quoted in the text. Instead, throughout the text, individual anonymised interviewees are cited where they raised an important thematic point that is relevant to that specific discussion. This, and other ethical considerations of the interviews, are highlighted in Table 13.

Interviewee categorisation and proportional representation	
Pharma	1
AI ethicist	1
Compliance Officer	1
Privacy Campaigner	1
Healthtech Investor	1
Clinical Entrepreneur	1
Research Charity Manager	1
Communications Expert	1
NHS Financial Manager	1
UX Designer	2
NHS Commissioner	2
Clinical Informatician	2
Software Engineer	3
Student	3
Pharmacist	3
Data Scientist	5
Policymaker	7
Patient	7
NHS Analyst	7
Clinical Academic	7
Technologist	8
Clinician	8
Total	**73**

Table 12. Full categorisation of stakeholders interviewed and proportional representation.

Semi-structured interview ethical considerations
All researchers have a duty of care to their participants, as well as to themselves, and must always consider the implications of their research once it is 'out' in the world. The plans for this thesis were reviewed and approved by the Oxford Internet Institute's Departmental Research Ethics Committee, and the main steps that were taken to ensure interview participants were well cared for are summarised below: • All interviewees were presented with a full interview participant sheet before they confirmed their interview slot. This included confirmation that interviewees would not be paid to participate. • All interviewees were asked to give consent to participating and being audio-recorded, either in writing ahead of the interview, or verbally at the start of the interview. Regardless of method of consent, all received the same consent form. • All interviewees were interviewed as individuals and not as representatives of their employer. • All interviewees were given a topic guide (see Appendix B) before the interview and given the opportunity to veto any topics they did not want to discuss. This was also reiterated during the interviews. • All interviewees were told they could 'pass' on any questions and could pause or stop the interview at any time. • The interviews did not deliberately tackle sensitive areas but if the interviews strayed into more sensitive areas (for example, some patients mentioned specific conditions). This information was not included in any of the analysis. • As all interviews were conducted online the interview setting was of less concern than it might be in other contexts, but all interviews were conducted in private spaces out of earshot of others to ensure participants did not feel as though they were under surveillance at any point. • All interviewees were reminded that they could remove consent at any point during the research process. • All interviewees were given full details of the interviewer's positionality before any interviews began to ensure complete transparency and to build trust. This also presented an opportunity to smooth through any potential concerns regarding differential power dynamics, making clear the research was being conducted as part of a DPhil project and that there were no 'right or wrong' answers. • To protect the anonymity of interviewees, several of whom were senior stakeholders within the NHS, interviewees are not quoted in the text. Instead, throughout the text, individual anonymised interviewees are cited where they raised an important thematic point that is relevant to that specific discussion. • All the opinions expressed in the text, and any mistakes, are solely attributable to the author. Use of the insights from individual interviewees embedded throughout the text does not imply endorsement or agreement by the interviewees.

Table 13. Ethical considerations of semi-structured interviews

3.2.3 Rhetorical policy analysis

As explained in Chapter One, the aim of this thesis is to enable the NHS to capitalise on the dual advantage of ACDSS by determining the necessary requirements for its successful implementation. These requirements are, as also explained in Chapter One, supposed to be (1) pragmatic; and (2) expressed as policy recommendations. Policy (writ large) is, after all, responsible for providing funding, technological infrastructure, establishing data standards, mandating interoperability, setting out privacy protection regulations, dictating quality outcome metrics, and much more (Whitsel et al., 2019). It is, therefore, essential to assess whether the requirements elicited from the realist review and further developed and contextualised via the semi-structured interviews, are likely to be met by current policy and if not, why not, so that the requirements can be further refined and made more pragmatic. This is why, it is also important to analyse existing policy documents, including white and green papers, strategy, legislative, guidance, and other documents, alongside the realist review and semi-structured interviews. Specifically, rhetorical policy analysis is needed because, rhetoric highlights the fact that policies are not 'simple' documents translating evidence into action, but rather unequivocally ideological documents infused with values, representations, and meanings that are produced in specific contexts by specific 'networks' of relationships (Janes & Corbett, 2009; L. Jones & Exworthy, 2015; Shore & Wright, 1997). In short, paying attention to rhetoric emphasises both the content of particular policy documents and also "how and why certain policies come to be developed in particular contexts, by who, for whom, based on what assumptions, and with what effect" (Blackmore & Lauder, 2005, p. 97; Browne et al., 2019, p. 1033). This kind of analysis shows how the representation of a particular problem has a considerable influence on the design of the solutions introduced (Burau et al., 2021) and, in this context, the likelihood that specific information infrastructure requirements will be met and so the likelihood that ACDSS implementation will be successful.

With this in mind, gov.uk as well as the websites for all relevant NHS arm's length bodies (NHS England, NHS Digital, NHS Improvement, NICE, MHRA, CQC) were searched for results related to data policy; digital policy; technology policy; NHS policy; Health policy; and public health policy to identify policies and policy documents relevant to the identified information infrastructure requirements. Searches were conducted in June 2023. Specifically, the following search strategy was used:

1. On gov.uk each of the content types (news, guidance and regulation, research and statistics, policy papers and consultations) were searched by topic, sub-topic, document type, and

organisation as per Table 13 for any relevant documents published between May 2015 and the present (the period of the current Conservative Government's control as per the scope)

2. gov.uk was also searched by keyword to check for any missing documents. Keywords used were: "Artificial Intelligence"; "Digital Health"; "Health Data"; "NHS"; "Health Technology".
3. The websites of each of the relevant health arm's length bodies were then also searched by the same keywords: MHRA; CQC; HEE; HRA; NHS Digital; NHS England; NICE; NDG. This is necessary as not all relevant policy content produced by these bodies is published on gov.uk. The same time period was used to constrain the search, for consistency purposes.
4. Finally, the website (https://search-material.parliament.uk/) for searching Parliamentary materials was used to search for relevant legislative documents, as well as any relevant documents from select committee hearings or all parliamentary groups. Here, the same key words were searched, and filtered by content type: legislation, parliamentary committees, parliamentary proceedings, research briefings. The same time period was used to constrain the search, for consistency purposes.

Results were screened according to the inclusion and exclusion criteria listed in Table 14. In total, 113 relevant documents were read in full and 62 were included in the analysis: 35 policy papers, 24 guidance documents, and 3 consultation documents. The full list is provided in Appendix D. Each of these documents was analysed thematically and rhetorically to assess the overlap between identified ideal requirements and requirements covered by policy. Further details are provided in in Chapter 7.

Topic	Health and Social Care	Business and Industry	Education, Training and Skills	Government	Society and Culture
Sub-Topics	• Medicines, medical devices • National Health Service • Public Health • Research and innovation in health and social care • Technology in health and social care	• Industrial Strategy • Science and innovation	• Further and higher education, skills, and vocational training	• Cyber security • Data • Government technology and digital services	• Digital inclusion and accessibility in society • Equality, rights, and citizenship • Online safety
Document Types	• Policy papers • Consultations (open) • Consultations (closed) • Calls for evidence (open) • Calls for evidence (closed)				
Organisation	• Cabinet Office • CQC • Central Digital and Data Office • Centre for data ethics and innovation • Competition and Markets Authority • Council for Science and Technology • Department for Culture, Media, and Sport • Department for Science, Innovation and Technology • Department of Health and Social Care • Government Analysis Function • Government Communications Headquarters • Government Data Quality Hub • Government Digital Service • Government Equalities Office • Government Office for Science • Government Statistical Service • Health Education England • Health Research Authority • Information Commissioner's Office • Medicines and Healthcare products Regulatory Agency • National Cyber Security Centre • National Data Guardian • National Institute Clinical Excellence • NHS Digital • NHS England • Office for AI • Office for Life Sciences • Office for National Statistics				

Table 14. Topic, sub-topic, document type, and organisation tags used to search gov.uk for relevant policy documents

Inclusion Criteria	Exclusion Criteria
• Related to healthcare, digital, data, or artificial intelligence policy • Published since 2015 • Published by or related to a relevant UK Government Department or NHS body.	• Related to policy outside of the healthcare, digital, data, or artificial intelligence domains. • Published prior to 2015. • Published by an outside agency, or non-UK Government Department.

Table 15. Inclusion and Exclusion Criteria for Policy Searches

3.3 Methodology: data analysis

As stated in the opening of this chapter. The starting point for the selection of appropriate research methods is the nature of the research problem (Noor, 2008b). This is why ethnographic and interpretivist research methods (realist review, semi-structured interviews, and rhetorical policy analysis) were selected because they are known to be able to handle complexity, to be useful for connecting multiple ethical, legal, and sociocultural factors, and to align well with the overarching design-based approach of this thesis. These same criteria were used to assess the suitability of different overarching analytical methods, resulting in the selection of the constant comparative method of thematic analysis for the analysis of the realist review articles and the semi-structured interviews, which was then combined with the rhetorical analysis used to analyse the policy documents (described above)

The constant comparative method of analysis, closely entwined with the process of grounded theory development pioneered by Glaser and Strauss (1967, 2017), is a systematic analytical technique intended to 'discover' themes, concepts, linkages and – ultimately theories – from the data (Ritchie et al., 2013). The process does not start with a preconceived theory that needs to be proven, but moves through a series of four stages to build new theory in response to a research question (Pace, 2012, p. 7):

1. Open Coding: breaking the data down into significant concepts.
2. Theoretical Coding: reassembling the significant concepts in a way that highlights the linkages and connections with each other.
3. Selective Coding: narrowing the analysis down to only those concepts and relationships that have explanatory power for the specific research problem.
4. Theoretical Sorting: combining the insights into an outline and writing up the emerging theory.

This comprehensive and rigorous process ensures that each unit of analysis (in the case of this thesis the realist review, semi-structured interviews, and rhetorical policy analysis) is given equal attention. This, in turn, ensures that all linkages, contradictions, assumptions, and interactions between concepts

are highlighted so that a rich description is produced, capable of providing a full explanation of the phenomenon under investigation (Gale et al., 2013). This analytical approach is well suited to the research problem tackled by this thesis for two reasons: first because it leans into rather than abstracts away from complexity; and second – and perhaps most importantly – it aligns well with design-based research approaches.

As explained in Chapter One, design is a poietic science: it does not seek to create a model of the past, but rather seeks to: (1) understand the past and the present; (2) develop the ideal model for a system; and (3) use policy to realise the system according to the model – or at least as close to it as possible (Floridi, 2017b). This process is conceptual (essential as form maps to function via concept (Cameron et al., 2016)), and starts by asking questions about the abstract properties, principles, mechanisms, or dynamics characterising the system in question (Buchanan, 2019; Floridi, 2017b). This is exactly the process enabled by the constant comparative method of grounded theory, which stresses the 'interactive, iterative, and non-linear linkages' between theory, data, and design (Lewis & Nicholls, 2013).

To guide this process, and slowly, but sequentially, build up an answer to the overarching research question, the overarching research was broken down into a series of sub-research questions, with one question aligned to one phase of the logic of design as shown in Table 15.

Phase of Design	**Sub-Research Question**
Originate: The thinking phase in which one realises that something new needs to be built to satisfy a particular purpose. It is the "needing" moment.	RQA: (i) Why is the current NHS information infrastructure design resulting in ACDSS implementation failure? What changes are required to increase the likelihood of implementation success? (ii) What would be the consequences if these changes were not made, or if the wrong changes were made?
Focus: The phase in which one defines the system's requirements (scope, features, purpose, functionality) that the system must have to satisfy the purpose. It is the "vision" moment.	RQB: (i) What are the ideal NHS information infrastructure requirements to enable the successful implementation of ACDSS? How likely is it that these requirements will be met by current policy? (ii) What underpinning assumptions and contextual factors might limit the likelihood of the ideal requirements being met by current policy?
Design: The phase in which one models the system's requirements. It is the "shaping" moment.	RQC: What is the unifying function of the desired ACDSS-enabled NLHS? How might policy successfully operationalise the ideal requirements to meet this function?

Table 16. Sub-research questions aligned with the individual phases of the logic of design.

By following the constant comparison process in answer to these questions, and combining the results with the rhetorical policy analysis used to answer RQB(ii), the results were first grouped into five top-level themes (one per empirical chapter): information infrastructure problems undermining the likely success of ACDSS implementation in the NHS (Chapter Four); risks of ACDSS implementation (negative unintended emergence) in the NHS (Chapter Five); requirements for successful implementation in the NHS (Chapter Six); assumptions underpinning requirement suggestions and policy developments in the NHS (Chapter Seven); and suggestions for operationalising the requirements in the NHS (Chapter Eight). How these themes were applied to the realist review articles and semi-structured interviews is highlighted in Appendices A and C. Second, within each of these top-level themes, further analysis was conducted to identify 24 mid-level analytical codes and more than 50 sub-level analytical codes. Exactly how these different mid and sub-level analytical codes were derived is explained within the method section of each of the five following empirical chapters. For now, it suffices to say that once derived, the codes were applied to key sections, arguments, or principles in each of the relevant data sources (remembering that the policy analysis is only relevant to codes within RQB) so that the resulting insights could be synthesised into a comprehensive theory (represented as a conceptual model) for the successful implementation of ACDSS into the NHS. This synthesis process is explained more fully in the next section.

3.4 Methodology: synthesis

The results of the analysis process described above were brought together into a narrative policy synthesis split across five empirical chapters summarised in Table 17 below. A form of interpretive synthesis, narrative synthesis involves the selection, chronicling, and ordering of evidence into a comprehensive account involving discussion of 'complex dynamic processes, and offering explanations that emphasise the sequential and contingent character of phenomena' (Dixon-Woods et al., 2005, p. 47). Its use in the context of this thesis is relevant and helpful because it is believed to be the type of synthesis most suited to the generation of middle-range theories tasked with making intractable policy problems more amenable (Browne et al., 2019; Dixon-Woods et al., 2005). It was, therefore, used to integrate the insights from the analysis of all data sources (realist review, semi-structured interviews, rhetorical policy analysis), with relevant components of existing theories, and so produce a comprehensive explanation of all the information infrastructure concepts that may influence the likely success of ACDSS implementation (May, 2013b). The final design results were

brought together in a conceptual model, demonstrating how information infrastructure form is mapped to function via concept.

More than a simple descriptive summary of the data (Breckenridge et al., 2019), the conceptual model is presented as an 'ordered set of assertions' about the behaviour of the NHS's information infrastructure and the impact of its design on the success (or failure) of ACDSS in a range of specific instances (Kislov et al., 2019, p. 2). In keeping with the practice of grounded theory and with the aims of design, this model is not intended to be viewed as a high-level generalisable truth (Pace, 2012), but as a plausible and modifiable hypothesis about the key requirements for successful ACDSS implementation derived from comprehensive, systematic, and theory-laden process (Breckenridge et al., 2019). It is hoped that this single-voiced conceptual theory will have more explanatory and predictive power regarding the likely success of planned ACDSS implementation projects than existing frameworks, given that it considers all relevant stakeholders as well as the wider sociocultural impacts (Kazanjian & Green, 2002) and links together many previously disparate concepts. Ultimately, it is hoped that this conceptual model – summarised briefly in Table 17 below - will help ensure this thesis meets its aim, by providing NHS policymakers with an *aide memoire* (Greenhalgh et al., 2004b) that will help them develop an NHS information infrastructure that will enable the NHS to capitalise on the dual advantage of ACDSS. However, before the results that led to the development of this model can be discussed in full, it is first necessary to caveat the strength of the results by reviewing the limitations. This is the topic of the final preliminary section, presented after Table 17.

Chapter	Purpose & Data Sources	Central Argument
4	Answer RQA(i): Why is the current NHS information infrastructure design resulting in ACDSS implementation failure? What changes are required to increase the likelihood of implementation success? Contribute to the completion of the 'Originate' phase of the logic of design. Data sources: realist review and semi-structured interviews.	The current NHS information infrastructure design is fraught with disorganised complexity. Disorganised complexity is associated with a higher likelihood of the system experiencing negative unintended emergence, and a lower likelihood of the system experiencing positive intended emergence because of ACDSS implementation. Therefore, current ACDSS implementation efforts are failing. To reduce this likelihood of implementation failure and increase the likelihood of implementation success, therefore, the NHS's information infrastructure must be re-designed to organise the inherent complexity. Organising the complexity inherent in the NHS's information infrastructure will reduce the chances of the system experiencing negative unintended emergence (risks) and increase the chances of the system experiencing positive intended emergence (benefits) because of ACDSS implementation, and so enable the NHS to capitalise on the dual advantage of ACDSS implementation.
5	Answer RQA part (ii): What would be the consequences if these changes were not made, or if the wrong changes were made?	The level of disorganised complexity currently plaguing the NHS's information infrastructure is significantly increasing the likelihood that ACDSS implementation will result in negative unintended emergence. Specifically, it is increasing the possibility that ACDSS

	Contribute to the completion of the 'Originate' phase of the logic of design. Data sources: realist review and semi-structured interviews.	implementation may result in negative re-ontologising (or fundamentally re-engineering) emergence that could completely transform the NHS's core values and result in (1) the patient being displaced from the centre of care; (2) the fundamentals of care being disrupted; and (3) the NHS ceasing to be for all. To mitigate these risks, the NHS's information infrastructure must be re-designed, not to reduce the level of complexity but to organise it. Organisation involves identifying common abstractions or requirements that can both design in the benefits (positive intended emergence i.e., creation of ACDSS-enabled NLHS), and design out the risks (negative unintended emergence i.e., re-ontologising of the NHS's core values).
6	Answer RQB(i): What are the ideal NHS information infrastructure requirements to enable the successful implementation of ACDSS? How likely is it that these requirements will be met by current policy? Contribute to the completion of the 'Focus' phase of the logic of design. Data sources: realist review and semi-structured interviews, rhetorical policy analysis.	To ensure the NHS can capitalise on the dual advantage of ACDSS, its information infrastructure must be re-designed around a series of ideal vision (benefit-enabling) and ideal delivery (risk-mitigating) requirements that will organise (i.e., make more predictable and more manageable) its inherent complexity. If met, these requirements will provide the system (i.e., the desired ACDSS-enabled NLHS) with epistemic certainty, robust information exchange, validated outcomes, protected values, autonomous staff, and meaningful accountability, and enable the NHS to capitalise on the dual advantage of ACDSS. However, very few of the ideal vision or delivery requirements are covered by current policy developments. Indeed, there is a significant sociotechnical gap between the ideal requirements and those covered by current policy. If the NHS is to capitalise on the dual advantage of ACDSS, it is imperative that this sociotechnical be closed. First, it is necessary to identify why the gap exists.
7	Answer RQB(ii): What underpinning assumptions and contextual factors might limit the likelihood of the ideal requirements being met by current policy? Contribute to the completion of the 'Focus' phase of the logic of design. Data sources: realist review and semi-structured interviews, rhetorical policy analysis.	The sociotechnical gap between the ideal vision and delivery information infrastructure requirements and the requirements covered by current policy is significant but not insurmountable. The gap exists because the ideal information infrastructure requirements and the requirements covered by policy are underpinned by different assumptions. The requirements covered by policy are underpinned by assumptions of technical determinism, first order change, rationality, the innovation-stifling power of regulation. The ideal requirements are underpinned by assumptions of sociotechnical complexity, second order change, non-rationality, and the innovation-promoting power of regulation. The two sets of assumptions are so different because they belong to different communities. The ideal requirements are influenced by the scientific epistemic community (comprised primarily of clinicians, social scientists, and research software engineers). The requirements covered by policy are influenced by the technical epistemic community (comprised primarily of third-party private technology and ACDSS developers). The two communities do not agree on the function of the desired ACDSS-enabled NLHS and so they do not agree on the form requirements of the supporting information infrastructure. To close the sociotechnical gap, therefore, it will first be necessary to identify a unifying function that meets the needs of all stakeholders (including members of both communities) and negates the negative influence of the technical epistemic community's assumptions on the development of policy at source.
8	Answer RQC: What is the unifying function of the desired ACDSS-enabled NLHS? How might policy	To negate the negative influence of the technical epistemic community's assumptions on the development of policy at source, the NHS's information infrastructure and subsequent

	successfully operationalise the ideal requirements to meet this function? Complete the 'Design' phase of the logic of design. Data sources: realist review and semi-structured interviews.	implementation of ACDSS must be designed around the function of maximising the utility, usability, efficacy, and trustworthiness of existing NHS information for the purpose of meeting specific information needs, rather than diffuse information wants. The ideal vision and delivery requirements must then be operationalised, through policy, in a way that ensures the information infrastructure form meets this function, and provides the system (ACDSS-enabled NLHS) with epistemic certainty, robust information exchange, validated outcomes, protected values, autonomous staff, and meaningful accountability for the purpose of maximising the utility, usability, efficacy and trustworthiness of existing NHS information to meet specific information needs. This requires policy focused on EHR design templates; model-to-data ACDSS development approaches; interoperability standards; audit and feedback; modularity and local customisability; data-work; NHS ACDSS-ready data assets; clinicians as originators of demand; value pluralism; patient and public involvement and engagement; qualitative health information; provably trustworthy relationships; a technical buddy system; the status of NHS analysts as clinical not clerical; the clinician's right to override; HTA and NSC review of ACDSS; model development and feature selection guidance; 'in silico' and 'in socio' model testing; roving data science teams; oversight of ACDSS integration and use' data governance simplification and clarification; regulation of ACDSS as SaMD; process accountability regarding liability, discrimination, and consumer protection; and public documentation.

Table 17. Overview of chapters including their purpose, method, and central argument

3.5 Limitations

All research has its limitations, and this thesis is no exception. In particular, the use of qualitative and especially ethnographic methods can impose limits related to transparency (J. Smith & Firth, 2011), rigour, and generalisability (S. Ackerman et al., 2015). Although impossible to completely eradicate these limitations, there are ways to ensure this type of qualitative research is as credible and defensible as possible. Chang (2016), for example, notes that it is crucial to take a systematised approach to the research process and provide a detailed discussion of this in the outputs to ensure trustworthiness of data sources, the research process, and the researcher efforts. More specifically Gilson et al. (2011) state that rigorous qualitative investigation involves the following steps:

- An active process of questioning and checking during the research, ensuring to ask how and why as well as what questions.
- A constant process of conceptualising ideas and theory to deepen the understanding of the research problem.
- Evidence-based interpretive judgments provided alongside clear justifications for the conclusions drawn and acknowledgement of any contradictory evidence.

- Researcher reflexivity and making clear when the researcher's own assumptions have influenced an interpretation.

Following this advice, all chapters contain a detailed description of the specific analysis method used to derive the results in that specific chapter, as well as the rationale for choosing that method. This is in addition to the general methodology described in this chapter. Furthermore, throughout, the narrative synthesis draws on existing theories where appropriate – augmenting the findings of the realist review with specific theoretical insights wherever possible and providing support to the insights provided by the semi-structured interviews. In particular, the analysis of why the current design of the NHS's information infrastructure is resulting in ACDSS implementation failure, draws on the NASSS framework developed by Greenhalgh et al. (2017) which itself is based on Strong Structuration Theory (Greenhalgh & Stones, 2010b) and Normalisation Process Theory (Sooklal et al., 2011); and the analysis of why the requirements covered by policy differ to the ideal requirements draws on neo-institutional theory, normalisation process theory and Goffman's dramaturgical theory (Macfarlane et al., 2013b). Finally, the concluding chapter, Chapter 9, provides a detailed reflection examining any instances where the results may have been influenced by my own assumptions.

It is also possible that as the logic of design is a logic of necessary conditions (requirements) but not sufficient conditions (requirements), the resultant conceptual model and policy recommendations may not be comprehensive enough to achieve the overall aim of improving the system within which ACDSS is developed, deployed, and used by the NHS. This is especially possible since this thesis does not cover the verification and validation stages of the logic of design. To ensure this limitation does not undermine the value of the research presented in this thesis, the boundaries or limits of the resulting conceptual model and policy recommendations are made clear in Chapter 9, as are the specific steps that would be needed to validate and verify the conceptual model. Furthermore, to ensure the research was conducted in keeping with the aim of helping the NHS to capitalise on the dual advantage of ACDSS, an expert panel of 'critical friends' representing key stakeholders was established to regularly review and feedback on the outputs of the research to help ensure its final output is helpful and not a hinderance or irrelevant.

Now that these limitations have been established, it is now time to move on to the empirical part of this thesis, starting with Chapter Four which, as made clear in Table 17, attempts to answer RQA(i).

4. ACDSS and the NHS: it's (more than) complicated

4.1 Introduction

4.1.1Avoiding abandonment

In Chapter One it was explained that fruitful design processes start with open questions and abductive reasoning to reveal possibilities about 'what can be?' (Winhall & Leadbeater, 2020) and so get to the inferential task at the core of the logic of design: moving from the *what* to the *how* of new system creation. Although this is primarily a creative task, concerned with imagining future potential rather than fixing the problems of the old (The Design Council & The Point People, 2020), this does not mean that the old or present system can be ignored entirely. Indeed, Chapman (2002) argues convincingly that it is the Government's tendency to do this that results in repeated 'system design failures.' According to Meadows and Wright (2008), this is because avoiding the history of a particular system encourages the 'designer' to define the problem (i.e. the *what*) not by the system's current behaviour and intended purpose, but by the designers preferred and predetermined solution (i.e., the *how*). Avoiding this particular source of failure requires designers to be patient and to start with observing the current system, watching how it works and asking: 'What's wrong?', 'What needs to change?', 'Why are these changes not happening immediately?', as well as 'How did the system get here?', and 'What will be the consequences if no changes or the wrong changes are made?' (Escobar, 2013; D. H. Meadows & Wright, 2008). Starting with observations of this nature, forces the designer to focus on facts and not theories and helps mitigate the risk of falling too quickly for common misconceptions or overly simplistic understandings (Meadows & Wright, 2008).

This is why – as highlighted in Chapter Three - the first phase of design, is the "Originate" phase during which observations make clear that something new needs to be built in order to satisfy a particular purpose (Floridi, 2017b). In this specific instance, the new thing that needs to be imagined is the NHS's information infrastructure so that the NHS can be enabled to capitalise on the 'dual advantage' of ACDSS. Hence, RQA which is linked to the Originate phase is:

> RQA: Why is the current NHS information infrastructure design resulting in ACDSS implementation failure? What changes are required to increase the likelihood of implementation success? (ii) What would be the consequences if these changes were not made, or if the wrong changes were made?

To return to the insights from Chapter One once again, complexity and systems theory both suggest that the answers to this question are unlikely to be 'simple'. Indeed, it is much more likely that misunderstood and under-estimated complexity (particularly *disorganised* complexity (Weaver, 1948)) is at the heart of why the current NHS information infrastructure design is resulting in ACDSS implementation attempts failing. At least this is the central proposition of the Non-Adoption, Abandonment, Scale-up, Spread and Sustainability (NASSS) Framework developed by Greenhalgh et al., (2017), which is commonly used by policymakers inside the Department of Health and Social Care to understand why NHS technology projects are failing or have failed in the past. This Framework, which is discussed in more detail below, is, therefore, ideal for analysing why the current NHS information infrastructure design is resulting in ACDSS implementation failure.

4.2 Method

Based on Diffusion of Innovation Theory (Menachemi et al., 2004; Sendak, D'Arcy, et al., 2020), Actor Network Theory, and Strong Structuration Theory (Greenhalgh & Stones, 2010a), the NASSS Framework posits that risk of technology implementation failure, and the presence of sociotechnical complexity in the underpinning infrastructure, are directly correlated (Greenhalgh et al., 2017a). In other words, the creators of the Framework argue that as infrastructural complexity increases – and becomes more disorganised – so does the risk of implementation failure, or to relate the theory back to the research question: when infrastructure is failing to support implementation, it is likely that the design is fraught with disorganised and ill-managed complexity (Weaver, 1948). The Framework is therefore designed to provide policymakers with a structured and evidence-based approach to the identification of infrastructural complexity so that the complexity might be reduced or better managed (i.e., changed to enhance the chances of implementation success). It does this by: 1) identifying seven sources (referred to as domains in the Framework) of complexity; and 2) providing a series of top-level questions (centred on uncertainties, interdependencies, and possible unintended consequences) that can be used to estimate the level of complexity present in each of the seven domains (Greenhalgh et al., 2020).

The seven domains included in the Framework are: the condition or illness; the technology; the value proposition; the adopter system (comprising professional staff, patient, and lay caregivers); the organisation(s), the wider (institutional and societal) context; and the interaction and mutual adaptation between all these domains over time (Greenhalgh et al., 2017a). Whilst to-date it has primarily been used as a post-hoc evaluation tool (e.g., Abimbola et al., 2019; Greenhalgh et al., 2018)

for case study analysis, the Framework can also be used as a forward-looking design tool. This is, in fact, the preferred use of the Framework by the authors, who stress that it provides the most benefit when used at the *earliest possible* opportunity in any technology implementation programme (Greenhalgh et al., 2020). Thus, what follows is a narrative synthesis of the findings from both the realist review and the semi-structured interviews described in Chapter Two analysed using the NASSS Complexity Assessment Tool (NASSS-CAT) and themed by the seven domains.

To ensure that the analysis is as comprehensive as possible and thus as clear as possible about what needs to be done to increase the chances of successful implementation (Escobar, 2013), a comparison is woven throughout between 'traditional' (or passive) CDSS and ACDSS. This helps to answer the question why traditional CDSS implementation has been relatively successful, and CDSS has been in use since the 1980s, but why the breakthroughs in both clinical care and operational efficiency promised by the wider adoption and use of ACDSSS are still largely unrealised (N. R. Adam et al., 2017; Norgeot et al., 2019). In turn, this helps to focus the concluding analysis on the specific and unique infrastructural challenges posed by ACDSS rather than the challenges posed by digital technologies in general which, as the Literature Review revealed in Chapter Two, are discussed extensively elsewhere (Shaw et al., 2019).

4.3. Results and discussion: identifying the sources of infrastructural complexity

4.3.1 Condition

Complexity in the 'condition' domain relates to: a) uncertainties about the illness or condition the technology in question is targeting; and b) the sociocultural factors that might prevent or hinder individuals with the condition from benefitting from the technology. A condition is considered simple if it is clearly defined; associated with a well-known population; affects different people in approximately the same way; manageable within a single healthcare setting; rarely associated with co-morbidities; and affected by sociocultural factors (such as poverty) in clearly quantifiable ways. In addition, 'simplicity' rests on the assumption that the population with the condition, and/or how the condition is treated is unlikely to change significantly within the next three to five years (Greenhalgh et al., 2020).

Since traditional or passive CDSS is intended to provide generalisable advice, it meets many of these criteria by default. NICE guidelines, NHS pathways, and the British National Formulary (described in Chapter 1) all largely assume that the clinician consulting them for 'support' are dealing

with an 'average' person who will present with average symptoms, has no co-morbid conditions, and will respond to treatment in an expected manner – regardless of their sociocultural context.

In contrast, ACDSS is designed with the specific intention of accounting for complexity. As explained in Chapter One, it is this very feature upon which many of the hopes of NHS policymakers rest. ACDSS is designed to be able to handle the prediction, diagnosis, prognosis, and treatment planning of multiple heterogenous conditions based on inferences involving thousands of interacting variables, many of which have non-linear relationships, and interpret how the development, presentation, and outcome of disease might vary according to multiple demographic and clinical factors (Castaneda et al., 2015). Furthermore, ACDSS is specifically intended to help accelerate the process of 'translating' new medical knowledge into frontline clinical care by updating its 'advice' in as close to real-time as possible (Toh et al., 2019). Thus, whilst it is not guaranteed that the way in which ACDSS recommends that specific conditions are treated will change within the 3–5-year timeframe, it is unlikely that the recommendations will remain entirely static (I13, Interview, 19 October 2022). This process is potentially further complicated if reinforcement or other types of unsupervised machine learning are used in the ACDSS's underlying model. This may mean that updates to ACDSS recommendations are non-transparent or non-explainable to the clinicians using the software for support (Amann et al., 2020). This could potentially undermine trust and theoretically create liability issues if the clinician disagrees with the recommendations made by the ACDSS (Cohen et al., 2014; C.-F. Liu et al., 2022).

4.3.2 Technology

In the technology domain simplicity or complexity is determined by the absence or presence of uncertainty related to what the technology is; where it is has come from; its performance and dependability; its usability and acceptability; whether or not the technology needs to be integrated into existing systems; whether it is likely to require major changes to organisational tasks and routines; and whether the technology is likely to change significantly within the next 3-5 years.

Passive CDSS is trusted, well governed, well used, and felt to be demonstrably effective and safe. It has been implemented in the NHS for more than forty years and it is produced by organisations or companies that are known entities, registered as providers of CDSS, and considered to be within the 'NHS family.' The number of companies involved in the production is also relatively small, with one pharmacist interviewee noting that they could name all the companies involved if necessary (I61, Interview, 11 November 2022). In addition, the development pipeline for CDSS is well-understood,

human-led, and generally very transparent. The BNF, for example, is a joint publication of the British Medical Association (BMA) and the Royal Pharmaceutical Society. It is published under the authority of a Joint Formulary Committee which comprises representatives of the two professional bodies, the UK Health Departments, the Medicines and Healthcare products Regulatory Agency (MHRA), and a national guideline producer. The advice it provides is drawn from clinical literature and so reflects an evaluation of the evidence from diverse sources, whilst also taking account of authoritative national guidelines and emerging safety concerns, and the information contained within it is regularly reviewed. Similarly, NICE Guidelines are based on published evidence, the recommendations are put together by experts, users of the healthcare service, carers, and the public, and each guideline is developed according to a transparent and well-documented process[11]. Even NHS Digital's NHS Pathways Service, which sits on the boundary between passive CDSS and ACDSS, is well controlled. The service is owned by the Department of Health and Social Care and maintained by a clinical authoring team who are all registered practicing clinicians. Detailed information about the safety and efficacy of the advice provided by NHS Pathways is also available online[12].

Finally, passive CDSS is typically deployed within self-contained web-based applications, that do not require live access to patient data and – as explained in Chapter One – clinicians choose to access at a point in their workflow that suits them. As such, it rarely (if ever) needs to be integrated into existing clinical systems and requires no major changes to the workflow of end-users. Passive CDSS can, therefore, be perceived to be a relatively simple technology that poses little challenge to the NHS's information infrastructure from an integration, interoperability, privacy, or transparency perspective. The same cannot be said for ACDSS.

First, in stark contrast to CDSS, the development pipeline for ACDSS, comprised as it is of many stages and players, is not well understood and lacks transparency. It was stressed, for example, by several interviewees that there is no list of software pop-ups currently in use by the NHS, the companies who produce them are unknown, and – unlike with CDSS – the regulators (in this instance the MHRA) do not keep a register of ACDSS in use (I27, Interview, 26 October 2022; I61, Interview, 11 November 2022; I70, Interview, 21 November 2022). This lack of scruatability, or certainty, regarding the development pipeline introduces further complexity from an epistemic perspective, because with no-known process in place for assessing and assuring the validity of the knowledge

[11] See for example: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/how-we-develop-nice-guidelines
[12] See for example: https://digital.nhs.uk/services/nhs-pathways/clinical-safety-and-governance

provided by ACDSS to clinicians, there is no guarantee of its accuracy (Challen et al., 2019). The complexity of this particular problem becomes especially pronounced, when it is considered that a) ACDSS is intended to generate new knowledge that may not be known to the clinician (making it less likely that they would question it even if it appeared wrong) (Cohen et al., 2014; Prictor et al., 2020); and b) ACDSS relies heavily on access to large volumes of patient data (initially for training purposes and then for the purpose of making inferences about specific patients) (Kanbar et al., 2022), which is itself extremely difficult to understand and work with.

All NHS data is technically administrative data, collected for managing NHS business as usual, not for research (including model development) purposes. It is, therefore, subject to contextual differences in what is recorded (Martin et al., 2015) and - as oft commented on by interviewees (I2, Interview, 17 October 2022; I4, Interview, 17 October 2022; I13, Interview, 19 October 2022; I21, Interview, 21 October 2022) – hugely variable in terms of accuracy, format, and detail (Leyens et al., 2017) which can undermine its trustworthiness. Clinical coding, for instance, is influenced significantly by what codes are available, what order they are presented from drop-down menus within EHR systems, and whether GPs (or other healthcare providers) are paid to code for particular conditions. This leads to biases in NHS data that are difficult to detect and, in the case of new conditions or conditions that fall outside of 'paid pathways', gaps in the data that even data science techniques designed to deal with missingness cannot necessarily overcome. These problems are further exacerbated – or at least increased in scale - by the fact that NHS data is multi-modal and noisy. EHRs alone contain numeric, free text, coded, and imaging data. Training algorithmic models used in ACDSS to find patterns among this data can lead to more accurate diagnosis, prediction, and overall better performance, but it can also do the reverse if not carefully handled as it can be difficult for models to differentiate true signals from the noise (Xiao et al., 2018).

Second, ACDSS needs to be integrated with existing clinical systems – most notably EHRs – so that it can use the information contained within for inference and personalisation purposes. Achieving this is extremely complex (I1, Interview, 17 October 2022; I16, Interview, 20 October 2022; I23, Interview, 24 October 2022). Whilst in primary care there are only two main EHR providers (TPP and EMIS) within secondary care there are many more – indeed many hospitals have more than one EHR for example, the EHR used in the Intensive Care Unit might not be the same EHR used within the Emergency or Cardiothoracic Departments. All are separately set-up, installed, many are difficult to update and often embedded within legacy systems that are sometimes no longer fit for purpose for the day job let alone capable of supporting the use of ACDSS. In the most extreme cases,

one EHR is tied to only one condition or one type of 'scan' and is only accessible from one computer inside a particular hospital. As a consequence of these interoperability and legacy issues, ACDSS is often deployed in a non-integrated, and seemingly random and ad-hoc fashion, working with one system but not another, requiring multiple logins and sometimes requiring manual input when the tool cannot access the necessary raw data (I16,Interview, 20 October 2022). Ultimately, this can make ACDSS tools feel burdensome rather than helpful to healthcare professionals. In the worst-case-scenario pushing clinicians, or other healthcare providers, to use such poorly integrated systems can result in the development of unsafe workarounds that put patients at risk (I58, Interview, 10 November 2022).

Finally, as several interviewees were keen to highlight, the experience of currently implemented ACDSS is extremely poor: there are often too many 'pop-ups' in use at once; their utility is unclear; they are difficult to use and difficult to interpret; and are largely perceived as a source of irritation (I27, Interview, 26 October 2022; I56, Interview, 10 November 2022). As with the integration and usability issues, this problem is more than just a 'simple' case of poor user experience design. Instead, there is considerable concern among healthcare professionals about the patient safety risks associated with so-called 'alert fatigue' (Bowman, 2013; Jankovic & Chen, 2020; Olakotan & Mohd Yusof, 2021; U. Sarkar & Samal, 2020). The concern is that healthcare professionals will become desensitised to the many alerts, pop-ups, or alarms being triggered multiple times a day and so either ignore the one potentially-fatal-if-ignored warning – a problem that is sometimes referred to as 'alert fatigue' (Bowman, 2013; Goff et al., 2021; Johnson et al., 2014a).

Combined, these factors, demonstrate the extent to which almost everything about the origins of ACDSS, its performance, dependability, usability, acceptability, interdependencies, and its impact on workflows is uncertain. This uncertainty is currently acting as a significant hinderance to the successful implementation of ACDSS.

4.3.3 Value proposition

The value proposition domain of the NASSS Framework focuses on the costs and benefits of the technology in question, specifically the balance between the two. Complexity in this domain is high when there is significant uncertainty surrounding the technology's value to patients, clinicians, the healthcare system at large or the specific healthcare organisation in question, and to specific groups of stakeholders – noting that value can be negative for some groups even if it is positive for others.

Once again, passive CDSS has the edge in this domain. The relative simplicity of its development pipeline and its self-contained nature (i.e., the fact that it does not need to be integrated into clinical systems) means that its development cost is relatively low. In addition, as explained in Chapter One, passive CDSS typically represents electronic or digitised Clinical Practice Guidelines (CPGs) which, as the primary mechanism for communicating standard of care expectations throughout the NHS (Guerra-Farfan et al., 2022), have been subject to rigorous safety and efficacy evaluations for decades (e.g., Grimshaw & Russell, 1993). Consequently, since the early 1990s, there has been relatively robust evidence that CPGs can improve the quality of care; improve patient outcomes; improve the quality of decisions made by clinicians; and improve the efficiency and cost effectiveness of care (Grimshaw & Russell, 1993; Shapiro et al., 1993; Woolf et al., 1999). Therefore, whilst there are lingering concerns about bias and conflicts of interest in the production of CPGs, and limitations regarding their ability to handle multimorbidity and rapidly changing medical science (Guerra-Farfan et al., 2022), there is today a reasonable degree of certainty that – when used independently and implemented with the intention of improving compliance with CPGs – passive CDSS use corresponds to significant improvements in patient outcomes (Tomasone et al., 2020) and benefits to the healthcare system at large.

The picture is, perhaps predictably, murkier for ACDSS. The more complex development pipeline (see 4.2.2) means it is considerably more expensive to produce (Lewkowicz et al., 2020). More concerningly, its relative 'newness' in an NHS context means that there is no agreed process for subjecting ACDSS to rigorous evaluation and identifying whether (and how it works), no serious research surrounding its use and integration, and so no answers to questions such as 'where did this pop-up come from?', 'where did it get the content or advice from?' 'who is this designed for' – all questions that are essential to building clinician trust in the use of any new technology (I8, Interview, 17 October 2022; I9, Interview, 17 October 2023; I27, Interview, 26 October 2022; I29, Interview, 27 October 2022). As a consequence of this lack of standardisation or systematisation, studies evaluating the efficacy (or benefits of) ACDSS are extremely heterogeneous in terms of study objectives, study designs, study populations, and the quality of reported results (Légat et al., 2018). This means that, despite the significant increase in the number of published studies evaluating the impact of ACDSS more than quadrupling since 2010, the quality of the evidence they contain has not improved (J. Kwan, 2020): it is moderate at best, and poor at worst (Ciapponi et al., 2021; Klarenbeek et al., 2020), full of spin and exaggerated claims (Andaur Navarro et al., 2023; Ge et al., 2023).

There are, for example, very few trial-based studies, even fewer randomised controlled trials (Park & Han, 2018; Plana et al., 2022), and when trials are published these tend to be 'one-off' studies evaluating the efficacy of *one* very specific type of ACDSS in one very specific setting (e.g., (Adusumalli et al., 2021; Cox et al., 2020; Gold et al., 2022; Mainous et al., 2018; D. Mann et al., 2020; McDonald et al., 2022; Peralta et al., 2020; Yao et al., 2021). Furthermore, systematic reviews and meta-analyses of these kinds of studies often reveal them to be limited or flawed (Plana et al., 2022): based on small populations, with small effect sizes, and limited significance (W. Chen, Howard, et al., 2022); potentially biased (Nwanosike et al., 2022); or inconsistent between studies (Sunjaya, Ansari, et al., 2022; Whitehead et al., 2019). Most problematically from a value proposition perspective, published evaluation studies rarely report the impact on patient outcomes, most often conducting studies in 'lab-only' settings (Buchlak, Esmaili, Leveque, Bennett, et al., 2020; Nwanosike et al., 2022) and focusing on 'technical' performance measures such as the Area Under the Curve (AUC) value (Ge et al., 2023). A systematic review conducted by Aleman and colleagues (2021), for example, found that just 2.2% of included studies evaluated patient outcomes. Finally, a number of concerns have been raised about the integrity or reproducibility of published studies. Coiera and Tong (2021), for instance, conducted a review to assesses the frequency, fidelity, and impact of replication studies in the relevant literature, and found a replication rate of just 3 in a thousand studies.

These concerns about the quality of the evidence supporting the claims made by ACDSS developers, are considerably undermining confidence in the value of ACDSS for the NHS. Particularly, as the lack of consistency makes comparison between studies extremely difficult (Ge et al., 2023), meaning that there is no agreement in the published literature regarding the conditions under which ACDSS implementation is 'beneficial' (J. L. Kwan et al., 2020). This limits the generalisability of the available evaluation studies, especially as almost none are conducted in an NHS setting or even in the UK: most are conducted in contextually very different healthcare systems in the US (e.g., Downing et al., 2019; Macheel et al., 2020; Mainous et al., 2018); Canada (e.g., Kharbanda et al., 2018; Nemis-White et al., 2021); Europe (e.g., Heselmans et al., 2020; Neugebauer et al., 2020); or Australia (Webster et al., 2021)[13].

It is not surprising, therefore, that certainty in the ability of ACDSS to deliver value, to healthcare in general, and to the NHS specifically is declining (Crigger et al., 2022; Vasey et al., 2021). Indeed, it is felt by many across the system – particularly those with clinical backgrounds – that the

[13] Note that these references are included for illustrative purposes, they are not drawn from the Realist Review

demonstrable lack of rigour surrounding the evaluation of ACDSS is leaving the NHS exposed to risk from snake oil[14]. Ultimately, this uncertainty regarding the potential benefit to patients, to clinicians, and to the NHS at large is making it harder for individual NHS organisations to justify the necessary investment in ACDSS, especially when it is considered that the number of lives saved or improved by the use of ACDSS might – at first – be relatively small (I30, Interview, 28 October 2022). A study by Kwan and colleagues (2020), for example, found that in over 100 trials reporting data from over 1 million patients, use of [A]CDSS increased the average proportion of patients receiving desired care by just 5.8%. This type of result might be worthwhile but, as highlighted by a health economist interviewee, unlikely to be seen as cost effective (I30, Interview, 28 October 2022)..

This is because, whilst the NHS can sometimes justify the purchase of expensive treatments, technologies, or screening programmes that are more experimental or only beneficial to a very small number of individuals (either currently or – in the case of rare diseases – permanently), this is harder when: a) there is no clear mechanism for evaluating cost-effectiveness of software (there is for medical technologies, screening programmes, and drugs (Akehurst, 2003)); and b) when resources are as constrained as they are currently and there is no obvious source of additional funding available for implementing ACDSS (I47, Interview, 4 November 2022; I67, Interview, 21 November 2022).

Overall, it can be concluded that there is considerable uncertainty surrounding the value proposition of ACDSS, lessening its chances of success.

4.3.4 Adopters

The fourth category of the NASSS framework assesses whether the people directly involved with the technology, in this case health care professionals using ACDSS tools to diagnose or treat patients, understand what it is for, think it is worth trying, feel able to use it and are motivated to give it a go. More specifically, this domain centres around the degree to which policymakers (or other would-be implementers) can be *certain* that patients and medical professionals will adopt the technology in question.

Given that passive CDSS is already in use, any questions regarding whether it will be adopted can largely be considered moot. Although, this was not guaranteed when CDSS first became available: literature from the early 1990s reveals a degree of healthy skepticism (Allaërt & Dusserre, 1992; Broverman et al., 1996; Grimshaw & Russell, 1993; Shapiro et al., 1993). Despite this initial reluctance,

[14] A phrase commonly used to describe the deceptive marketing of healthcare products leading to healthcare fraud.

positive user experience, demonstrable benefits to patients and the healthcare system, and increased prominence of evidence-based medicine have resulted in relatively sustainable adoption and diffusion of CDSS. These positive experiences with CDSS go some way to explaining why there is considerable enthusiasm for the use of ACDSS in the NHS from across the system, with some patients expressing a view that ACDSS will result in better outcomes for patients, more efficient health systems, and better value for taxpayers, and healthcare providers (particularly pharmacists) viewing ACDSS as a hugely significant untapped opportunity (I57, Interview, 10 November 2022; I59, Interview, 11 November 2022). This enthusiasm is not, however, a guarantee that adoption is certain. There are just as many individuals across the system who are highly dismissive of the concept of ACDSS, believing the noted enthusiasm to be derived from poorly evidenced hype, and outrageous claims by technology companies.

Some of this growing scepticism, or uncertainty regarding the likelihood of ACDSS adoption, can be attributed to the fact that – as explained in the value proposition domain – the quality of evidence supporting claims that ACDSS is safe and effective is currently poor. Good quality evidence of efficacy is almost always a prerequisite for adoption of any technology in the healthcare sector and this is likely to be especially true for ML-based technologies (Abujaber et al., 2022). Thus, until the evidence base improves, there is likely to be continued uncertainty about whether clinical staff will be willing to adopt and use ACDSS (Nitiéma, 2023), particularly when the current user experience of ACDSS is so poor. Indeed, one interviewee noted that staff in their hospital were only using one particular instance of ACDSS to identify patients in need of blood thinning medication because they were contractually obligated to do so, and the nurses were often doing the calculations manually first and then giving the answer to the ACDSS because they did not trust the ACDSS generated answer and felt it did not take into account the full range of factors that it should (I56, Interview, 10 November 2022). Such examples explain why there is also uncertainty among the clinical and technical communities regarding claims that ACDSS will reduce either the logistical or cognitive burdens currently facing NHS frontline staff. Some interviewees even expressed the exact opposite view: that the introduction of ACDSS would only increase burden (I4, Interview, 17 October 2022).

It is, for two reasons, relatively easy to understand why this belief that ACDSS might increase rather than decrease workload persists throughout the NHS community. The first reason is that informatics, or data science, are not included in standard medical training either at university or as part of continuing professional development (Scobie & Castle-Clarke, 2020). Consequently, clinicians receive very little training in the use, interpretation, and validation of algorithmic models in general,

and ACDSS specifically. Add to this the fact that many of the most accurate or 'high-performing' models used by ACDSS (for example neural networks or random forest) are considered to be 'black boxes,' impossible to interpret or 'explain' to patients (Ding et al., 2022; N. Price, 2018), and it is clear why some clinicians feel as though ACDSS would only add to cognitive burden by undermining their epistemic authority (Grote & Berens, 2020).

The second reason is that whilst it is reasonable to assume that ACDSS use will improve diagnostic accuracy and treatment precision, it cannot be assumed that its use will improve treatment efficiency (or the rate at which patients can be seen) as this depends almost entirely on demand, staffing, and the allocation of resources (Braillon et al., 2015; Brall & Schröder-Bäck, 2016). Thus, as although there is a general feeling of positivity surrounding the underpinning science of ACDSS, there is considerable uncertainty regarding its usefulness or benefits in clinical practice and so it is felt that getting clinicians on board will likely be challenging (I1, Interview, 17 October 2022; I5, Interview, 17 October 2022; I48, Interview, 7 November 2022; I52, Interview, 8 November 2022).

These concerns could perhaps be overlooked or overcome if clinicians were certain about either the motivations of policymakers for pushing the introduction of ACDSS and/or the demand from patients for its introduction. However, there is no such certainty. There is, in fact, feeling among some clinicians that policymakers are only pushing the introduction of ACDSS for 'performance management' and 'surveillance' purposes. Individuals with this view do not perceive ACDSS as a tool primarily designed to support clinicians, but as a tool designed to police and control them; to force through new ways of working and identify – before sanctioning - non-compliant performers. Furthermore, there is considerable doubt surrounding the social acceptability of ACDSS use from a patient and public perspective. This is because, despite some initial studies evaluating public attitudes and perceptions towards medical AI having been conducted (Wu et al., 2023), there are several unknowns concerning patient and public attitudes towards the use of AI in the healthcare sector. It is not known, for example, if there are any social redlines regarding the use of AI more generally (or ACDSS more specifically); if patients will expect to provide informed consent before ACDSS is used in the provision of their care (if this is even practically possible) (Kraft et al., 2018; Townend, 2018); or how the current 'trust deficit' regarding the use of NHS data for research and analysis might hinder the deployment and use of ACDSS (H. Shah, 2017). These unknowns mean that just as there is uncertainty about whether and how frontline clinicians will adopt ACDSS, there is also uncertainty about whether and how patients and the public will adopt ACDSS, further limiting the likelihood of success.

4.3.5 Organisation(s)

Moving on from the previous domain's focus on individuals and groups, the fifth domain of the NASSS Framework focuses on organisational complexity. Specifically, the questions posed by the Complexity Assessment Tool in this domain are intended to assess the readiness of a specific organisation (or cluster of organisations) to adopt the technology under review. Complexity is high when the organisation has limited capacity, for example when resources are limited or strained, when organisational routines or processes will need to be reconsidered to accommodate the use of the technology, and when it is not yet clear how the technology will be procured.

As has already been discussed, passive CDSS sits separately to existing clinical systems and is 'external' to the workflow – clinicians actively seek its input and so its use poses no 'interruptive' threat to the existing clinical thought process. Similarly, as highlighted, passive CDSS is relatively cheap to develop and implement and so its introduction places little additional strain on already-stretched resources. Again, as stressed above, the same cannot be said for ACDSS; the integration of which into existing technical infrastructure and workflows is fraught with difficulty, complexity, and unknowns. What is important to add here is that the complexity in each of these sub-domains (technology, culture, workflows) is magnified by the size, scale, and variability of the NHS itself (I20, Interview, 21 October 2022; I23, Interview, 24 October 2022).

Although, from the outside, the NHS appears to be a single cohesive organisation, the reality is more complex. In England there are more than 6,500 GP practices, all run as independent businesses, 42 'Integrated Care Systems', 219 NHS trusts, and 1,129 hospitals. Each of these organisations has its own culture, and each uses multiple operating systems, electronic health record systems, financial systems, and more (I25, Interview, 25 October 2022). In addition, the way in which care is organised is constantly changing. Finally, as Ljubicic and colleagues (2020) write, unlike in some industries where processes can be fully standardised, healthcare is characterised by high variability from case to case, and speciality-specific processes further increase the variability and heterogeneity. This constant state of flux, and organisational complexity means that the options available to ACDSS when it comes to recommending treatment pathways, for instance, are constantly changing and subject to local variability. To successfully spread across the NHS, therefore, ACDSS must simultaneously be generalisable to benefit from economies of scale, and locally customisable to be accurate. This tends to mean that even when the use of information technologies is mandated centrally by policymakers, procurement is done at a regional or even local level (I32, Interview, 28 October 2022). Consequently,

providers of ACDSS often find themselves having to repeat processes of procurement, and implementation– never benefiting from previously successful implementations, and never knowing how long their solution might be used by any one NHS organisation (I5, Interview, 17 October 2022; I39, Interview, 31 October 2022; I58, Interview, 10 November 2022). For technologists trying to develop ACDSS tools for the NHS, this organizational complexity appears to be the biggest source of frustration and is perceived as being the highest hurdle to successful implementation with ACDSS developers being completely unsure of how to find the front door through which they can sell.

More than just a problem for procurement and sales, interviewees explained that constant restructurings and organisational spaghetti are also the root cause of more insidious forms of complexity in this domain (I27, interview, 26 October 2022). It was noted by that NHS data has become siloed, stored in multiple databases owned and controlled by different NHS organisations. Rather than being incentivised to see these different databases as individual components of an overarching public good, individual NHS organisations are – by the near constant threat of impermanence – incentivised to view sole ownership of a particular database as a competitive advantage (Goldacre & Morley, 2022). Outside national emergencies, such as the COVID-19 pandemic, there is no legal requirement for NHS organisations to agree to share the data they control with other NHS organisations. Indeed, it is more common for NHS organisations to use Information Governance requirements (or hoops) to justify withholding data or preventing outside access. Not only does this additional layer of complexity make it incredibly difficult to ascertain who is responsible for data integrity, attribution and distribution (Booth, 2003), it also makes it exceedingly difficult to provide access to the volumes of data necessary to train the models used by ACDSS and, once deployed, to ensure it has access to all the data it needs to make decisions. In short, this messy and complex situation is likely further impeding attempts to implement ACDSS.

4.3.6 External context

The penultimate domain of the NASSS Framework focuses on the wider national and local context of the technology, particularly the regulatory, commercial, economic, and cultural contexts. The degree of complexity present in this domain is inversely correlated with ethical, legal, regulatory, and sociocultural clarity. When it is clear to the NHS and to technology partners what each party is obligated to do from a contractual, regulatory, legal, sociocultural, and ethical perspective, then complexity is low, and implementation is likely to be successful. In contrast, when the obligations in

each of these areas are either unknown or unclear to either or both parties, then complexity is high, and implementation is likely to falter or fail.

As stressed above, passive CDSS is typically produced by those within the NHS – or at least within the NHS's wider network – the content is regularly reviewed by qualified clinicians and is clearly regulated. In addition, passive CDSS is not perceived to pose any threat from an accountability or liability perspective: passive CDSS is simply providing already known information at the point of care and so functions in much the same way a textbook might. Finally, the use of passive CDSS rarely raises complex data management concerns. It can be argued therefore that, even if there were complexities when passive CDSS were first introduced and there remain some ethical concerns regarding the content of practice guidelines (Franco et al., 2020), the obligations of those using and designing passive CDSS are relatively well-known and so complexity is low. These obligations are far less clear for those developing, deploying, and using ACDSS as the pace of its evolution has far outstripped that of the necessary regulatory, legal, and ethical frameworks (Bourne, 2015). This is particularly clear when the issues of accountability and liability; commercial partnerships; data protection; data use; and discrimination are considered.

To start with accountability and liability, it is currently unclear who should be held accountable when (a) things go wrong, for example if ACDSS misdiagnoses a patient or recommends an inappropriate treatment; and (b) if a clinician decides to override the recommendations of an ACDSS and harm comes to the patient as a result (Goodman, 2016; A. Kerasidou, 2021; Prictor et al., 2020). There are two reasons for this lack of clarity. The first is that, despite the fact that this issue has been debated since at least 1985 (R. A. Miller, 1985), there is currently no case law or precedent for how such cases will be handled (Cohen et al., 2014; Smith & Fotheringham, 2022). The second, according to interviewees, is the sheer number of organisations, individuals, companies, and 'actors' involved in the development of an ACDSS tool (I16, Interview, 20 October 2022). When in the past cases of mistreatment or medical negligence may have involved one clinician, the hospital or GP practice they worked at, and potentially a drug manufacturer, similar cases revolving around the use of ACDSS tools may involve the algorithm developer, the data provider, the organisation that procured the ACDSS, the organisation that installed it, and the clinician who used it. It is clear from interviewees across the system, that this current lack of clarity is acting as a major barrier to the adoption (and success) of ACDSS tools with some worrying that its use might land them in the Coroner's Court (I16, Interview, 20 October 2022).

Moving to the complexity surrounding commercial partnerships. Several interviewees were keen to stress that the NHS has failed to hire people with 21st century skills, and currently has a lack of technical, data science, and informatics skills in-house (I20, Interview, 21 October 2022). Whilst there is a large analytics workforce, this is mostly comprised of 'operational' analysts with little computational skills, who mostly rely on 'point-and-click' tools working with aggregate statistics rather than with raw patient data for the purpose of developing models that may eventually become embedded in an ACDSS tool. Consequently, most of the organisations and individuals working on the development of ACDSS come from outside the NHS. Although some are public sector universities or research charities, many are commercial software companies. This causes complexity in several ways. First, as Bagenal and Naylor (2018) correctly highlight, there are no clear guidelines on how NHS trusts should share data with commercial companies, nor how data should be valued when said commercial companies might develop commercially valuable IP from NHS data. At a local level this situation leaves NHS legal teams at a disadvantage and makes them anxious about adopting ACDSS for fear of retribution. At a national level, this lack of clarity risks harming public trust and devaluing a key national asset (Bagenal & Naylor, 2018). Second, collaborations with private companies can raise value-based concerns, when individuals across the system feel as though these types of interactions directly conflict with the positioning of the NHS as a public good. It is felt that this is currently stopping potentially productive partnerships from happening.

Finally, there are the complexities surrounding data and information governance. The NHS data governance framework in its entirety is complex, duplicative, overlapping, and difficult to navigate (Goldacre & Morley, 2022). Furthermore, it is increasingly clear that the resulting confusion is preventing good things from happening, for example causing significant delays to high-quality data science research, whilst ineffectively preventing bad things from happening (Goldacre & Morley, 2022), such as data leakage or use of data considered inappropriate by patients or publics (Oxford, 2022). The associated problems are exacerbated in the context of ACDSS as 'health data' is often treated differently by data protection legislation to other categories of 'personal data' creating issues when it is necessary to link two or more 'types' of data which is often essential if the true benefits of ACDSS are to be realised (Butterworth, 2018). There are also fundamental issues that the current data governance framework does not address, including: who owns health data, who is responsible for it, who can use it (Panch, Mattie, & Celi, 2019b), and, crucially, how to balance the need to protect individual patient privacy with the need to capitalise on the public benefits that can be derived from broader use of NHS data (Sexton et al., 2017; Stockdale et al., 2019). However, the greatest source of

uncertainty stems from the fact that the way in which data is governed, including the permissions needed, differs entirely depending on whether the data use in question is classified as direct care, research, or service evaluation, yet the development and use of ACDSS collapses these boundaries (Braun et al., 2021). As highlighted in Chapter One by the example of the failed partnership between Google DeepMind and the NHS Royal Free Hospital, this confusion exposes both NHS organisations and third parties to considerable reputational risk (Ballantyne & Schaefer, 2020).

Overall, this complexity relating to the external regulatory, ethical, and legal context surrounding ACDSS is likely significantly hampering implementation attempts.

4.3.7 Adaptation over time

The final domain of the NASSS Framework is adaptation over time. This domain covers complexity arising from the technology itself changing over time, as well as the service or condition it supports changing over time.

Of course, it is very unlikely that any digital or software-based technology will remain static and completely unchanging. This goes against the very nature of software development which is, purposefully, iterative, and agile. Passive CDSS is, for example, subject to regular content reviews and updates, and its user experience has greatly improved over time. However, these updates are not automated., they occur via transparent human-led processes that are often relatively slow (in fact sometimes the lack of speed is detrimental (Guerra-Farfan et al., 2022)). In other words, there are no surprises involved in the adaptation of passive CDSSS. Additionally passive CDSS is not, as has been stressed, connected to live clinical systems. It also provides generic advice and does not draw from live patient data. As such, changes in data structures or the demographics of the population being treated have little to no impact on the overarching performance of passive CDSS. Consequently, there is almost no risk that the accuracy of CDSS might degrade over time, at least not to the extent that this would cause concern from a patient safety perspective. This is not true for ACDSS which is significantly impacted by complexity associated with model adaptability, dataset shift, scalability, and temporarility (W. N. Price, 2018).

It is the very fact that Machine Learning models can adapt in real-time to changes in input that make their use in ACDSS appealing. Medical knowledge is, for example, almost constantly being updated as new research is published. In addition, the data upon which ACDSS is both trained and deployed is almost constantly shifting due to changes in patient populations and developments in clinical and operational practices (Kelly et al., 2019). Finally, diseases themselves are always progressing

and changing over time in nondeterministic ways (Miotto et al., 2018). It is the ability of ACDSS to respond to these changes, ensuring that clinicians are being advised according to the latest research in a way that is both targeted to the specific population and personalised to the specific patient, that makes them key enablers of the learning health system concept. However, issues arise when this adaptation process happens automatically (or autonomously) inside a black box with little human oversight. In the absence of clear processes to monitor or scrutinise these adaptations, clinicians and regulators feel as though they cannot trust the validity, efficacy, or safety of the updated software (W. N. Price, 2018). This means that ACDSS requires significant aftercare implying that the complexity of its implementation does not lessen over time

It is, in fact, possible that the complexity surrounding the implementation of ACDSS will only increase over time, as the value proposition; underpinning technology; adopter attitudes; regulatory, legal, sociocultural, economic, and ethical context; and organisational readiness and structure are all likely to change significantly over the next 3-5 years.

4.4 Conclusion

By breaking down the complexity of the NHS's current information infrastructure in a way that highlights the number of variables, uncertainties, and interconnections involved, the preceding narrative analysis of the NASSS Framework (summarised in Table 18), makes clear why realising ACDSS's promised benefits is proving more challenging than policymakers originally envisioned (Grote & Berens, 2020). The level of disorganised complexity present in each of the domains is so significant, it is not surprising that the current attempts to implement ACDSS tools across the NHS are failing. If the current levels of complexity are left as disorganised then the outcomes of any initiatives designed to implement ACDSS into the NHS are likely to remain unsuccessful (Greenhalgh et al., 2018). Indeed, if policymakers continue to rely on magical thinking – or the idea that ACDSS can *simply* be implemented into the NHS's information infrastructure with little difficulty (Dixon-Woods et al., 2011) - then Reddy and colleague's 2019 prediction that 'the large-scale use of ACDSS is *at least* ten years away', might be proven right.

NASS Domain	Passive CDSS	ACDSS
Condition	Designed on the assumption that conditions can be diagnosed and treated in a largely 'one-size-fits-all' manner and where there are potentially complicating variables, these have linear relationships with outcomes.	Designed to handle the fact that development of disease (i.e., the presence or absence of a condition) is dependent upon several complex biological, genetic, and social factors that interact in non-linear ways, meaning that a personalised approach to diagnosis and treatment is necessary.
Technology	Deployed as self-contained applications, often on the web, do not require integration with clinical systems and rarely vulnerable to inaccuracies or deficiencies in underlying databases.	Deployed within clinical systems, extremely vulnerable to issues with legacy systems and lack of interoperability, entirely reliant on access to raw patient data presenting risks associated with the accuracy and completeness of NHS patient records and introducing considerable patient privacy issues that need to be handled.
Value Proposition	Clear evidence base, clear processes in place for demonstrating evidence of clinical efficacy and cost effectiveness.	Confused and limited evidence base, no clear process for demonstrating evidence of clinical efficacy or cost effectiveness.
Adopters	High degree of certainty that they will be adopted, many are already in use, patients have accepted their use in care and clinicians are willing to adopt and use them.	No guarantee that they will be adopted, whilst there is surface-level willingness this is conditional and there are currently many barriers preventing these conditions from being met, including lack of evidence and poor positioning.
Organisation(s)	Sit outside existing clinical systems and are used when convenient by the clinician so changing workflows and differences between organisations matter little, few on offer and often procured centrally so restructures have minimal impact	Embedded in clinical workflows and existing clinical systems, re-organisation of demands has significant impacts on ability to integrate. Mostly developed and sold by private companies so restructurings have significant negative impacts.
External Context	Clear regulation, minimally affected by economic challenges and limited cultural complexity.	Significant uncertainty in the current regulatory context both in terms of liability and accountability, as well as data protection law; significantly affected by economic challenges; pose considerable cultural challenges especially with regards to interactions between private companies and the 'public' NHS.
Adaptation over time	Adapts slowly over time via a transparent and well-governed process. Not affected by changes in underlying data or population make-up.	Can adapt in real-time, potentially in a black-box fashion, via an ungoverned process. Significantly affected by changes in underlying data and population make-up.

Table 18. Summarising the different levels of complexity present in the information infrastructure supporting CDSS vs. ACDSS.

If the hopes resting on the successful implementation of ACDSS were based purely on mythology (boyd & Crawford, 2012), innovation bias (Greenhalgh, 2013), and a belief in the power of magic bullets (Janes & Corbett, 2009), then an excessively long lead time might be no bad thing. In fact proponents of the precautionary principle might argue in favour of a more drawn out implementation process (Andorno, 2004a) (more on the limitations of this in the next chapter). However, as explained in Chapter One, the fact that there is evidence supporting the potential life-saving benefits of well-designed and well-implemented ACDSS places an ethical and constitutional imperative on the NHS to take all necessary actions to ensure these benefits can be realised as soon as possible (Akenroye, 2012). This should be motivation enough for policymakers who might otherwise rest on their laurels. However, a desire to accelerate the rate of successful implementation of ACDSS is not the only reason to tackle the inhibiting disorganised complexity currently present in the NHS's Information Infrastructure.

A second, and arguably more important, reason for reducing and better managing the extant infrastructural complexity is that complexity is primarily associated with unpredictability. Or to put it differently, the longer the NHS continues to attempt to implement ACDSS on top of an infrastructure fraught with disorganised complexity, the greater the risk posed by negative unintended emergence. This is why RQA also asks "what would be the consequences if these changes [to the information infrastructure] were not made, or if the wrong changes are made?" Answering this question is the task of the next chapter.

5. Be Careful What You Wish For

5.1 Introduction

5.1.1 The emergence of a dilemma

By using the NASSS Framework (Greenhalgh et al., 2020) to analyse why the current NHS information infrastructure design is resulting in ACDSS implementation failure, the previous chapter revealed that ACDSS implementation is currently being significantly hindered by mis-managed and disorganised complexity. There are several reasons why this relationship between disorganised complexity and implementation failure exists. For one, disorganised complexity greatly limits the effectiveness (and success rate) of tightly planned and 'project managed' implementation efforts, often forcing policymakers and planners to rely more on unstructured and ad-hoc decision-making (J. Chapman, 2002). However, the primary reason why unmanaged complexity causes issues for technology implementation projects is negative unintended emergence (or undesirable emergence).

Although sometimes critiqued for being rather loosely defined (Kivelson & Kivelson, 2016), emergence is the term used to describe the outcomes of interactions between individual components of a complex system. In well-designed systems, emergence is positive and intended (i.e., it is desirable). The design of the system organises complexity and brings previously disconnected system components together to produce a new desirable function that delivers benefits to the system at large. In the case of ACDSS implementation into the NHS, desirable emergence would be the creation of the ACDSS-enabled NLHS, and the benefits would be all the benefits of ACDSS use described in Chapter One, for example, improved efficiency, improved outcomes, and more. In contrast, non-designed systems, or poorly designed systems, characterised by disorganised complexity often suffer from the risks (or unintended consequences) associated with negative unintended emergence (i.e., undesirable emergence). Emergence of this nature often results in system behaviour that cannot be explained, predicted, or controlled by simply observing the behaviour of the individual component parts (Chandler et al., 2016). The consequences of this type of negative or undesirable emergence can be severe (Cameron et al., 2016) because of the potential negative impacts on individual patients, groups of patients, and the overall performance of the system. In other words, the risks of negative unintended emergence associated with disorganised complexity are high. Therefore, if this thesis is to achieve its aim of designing the information infrastructure to enable the NHS to benefit from the dual advantage of ACDSS, it must consider how the information infrastructure can be designed to ensure the benefits of positive intended emergence of ACDSS implementation are maximised, whilst the risks

of negative unintended emergence are proactively mitigated. Coming up with such an information infrastructure design is, however, challenging if the exact risks that need to be mitigated cannot be predicted.

This catch-22 of needing to proactively mitigate risks associated with negative unintended emergence, the exact nature of which cannot be predicted, is one of the reasons why policymakers have thus far struggled to develop an information infrastructure that achieves this seemingly impossible task. There are generalisable and well-known strategies for mitigating unpredictable risks associated with upfront tasks such as technology roll-out (e.g., modular implementation strategies, agile approaches to project management, generous timescales Barnett et al., 2011; McLachlan et al., 2019; Thompson & Morgan, 2020). However, there are no such well-known strategies for mitigating unpredictable risks (or harms) associated with technology *use*, i.e., technology impact, which can build up over time (Chandler et al., 2016). Indeed, there are some who would argue that the types of interactions that might occur between different components of the NHS's information infrastructure following the implementation of ACDSS may be so numerous and unpredictable, and uncontrollable (Marinescu, 2017) that the belief that the risks of negative unintended emergence can be designed-out (or proactively mitigated) (Sanders & Stappers, 2008) is completely unrealistic (D. H. Meadows & Wright, 2008).

This is certainly the argument put forward by those who fervently believe in the existence (and insurmountable nature) of the "Dilemma of Control" – also known as the "Collingridge Dilemma." According to the Dilemma, attempts to control any form of emerging technology are fraught with difficulty and prone to failure because during the early stages of development - when a technology might be controllable - not enough is known about its potentially harmful social consequences to warrant controlling its development, but by the time the consequences become apparent, it is 'too late' to intervene and control has become costly and slow (Collingridge, 1982, p. 19). There is, of course, a degree of observable truth in both horns of this Dilemma in the context of ACDSS (Genus & Stirling, 2018): predicting the potential harms caused by ACDSS is proving very challenging (as illustrated above), and intervening once a medical technology becomes embedded is also often inordinately costly, slow, and complex (see for example, recent attempts to start regulating software – including apps – as a medical device (Baines et al., 2022; MHRA, 2022a; Palmieri et al., 2021)). However, believing that this Dilemma cannot be overcome, or that no other scenarios exist between the two extremes of early and late intervention, would be a mistake. Following this line of reasoning would likely lead to overly deterministic (Le Dantec & Do, 2009) and laissez-faire attitudes among policymakers, resulting in a

normative circle where ACDSS becomes uncontrollable because no attempts are made to control it (Genus & Stirling, 2018). This would clearly be an untenable situation as it would expose individual patients, clinicians, groups, and the healthcare system to untold harm, and prevent the NHS from being able to capitalise on the dual advantage. It is, therefore, essential that whilst identifying the information infrastructural requirements for success, this thesis also considers how to overcome this Dilemma.

5.1.2. Overcoming the dilemma

Although Collingridge is known for having acknowledged the existence of the Dilemma, he did not believe that it could not be overcome. Indeed, he strongly believed that the Dilemma's societal and epistemological status should not be regarded as a 'universal, historically invariant proposition' (Liebert & Schmidt, 2010) and put forward two distinct strategies for overcoming it.

The first strategy for overcoming the Dilemma, according to Collingridge, is (what can be considered) the 'Epistemological Strategy.' This strategy, which can be seen as having been derived from the classic concept of Technology Assessment (Brey, 2012), centres on efforts to generate more quantitative knowledge about the potential harms caused by a technology whilst it is still in the R&D phase and *before* it is implemented. In other words, one option might be to recommend that all ACDSS implementation efforts be paused until the extant disorganised complexity in the NHS's information infrastructure is made more organised and therefore more manageable (Weaver, 1948). That is to wait until any potential harms or risks are more observable, more known, more predictable, and so more controllable. This is the option preferred by proponents of the Precautionary Principle (S. Clarke, 2005) which operates on a better safe than sorry basis and aims to minimise potentially serious or irreversible risks under conditions of uncertainty by restricting technological development until cause and effect relationships become clearer (Som et al., 2004). Whilst the Principle was originally developed in the context of environmental policy, its use has been greatly expanded over the past two decades. Indeed, Sikma and colleagues (2020) recently applied it directly to the development of ACDSS, arguing that whilst the development of ACDSS continues to be surrounded by 'ambiguities, complexities, and uncertainties,' the precautionary principle seems to be applicable until desirable limits to the implementation of ACDSS have been unilaterally agreed.

In some respects, this is a reasonable strategy. As Tannert and colleagues (2007) argue, in situations (such as the implementation of ACDSS) where the decision regarding the implementation of a particular technology might have implications for the lives of others, the decision to pause

development in favour of the pursuance of scientific certainty regarding potential risks, might be seen as an ethical duty. However, in other respects, this precautionary approach is significantly limited. First, and most prosaically, the Precautionary Principle itself has been criticised for being a relatively ill-defined concept that violates several of the adequacy conditions of a usable decision-rule (Hansson, 1997; Stefánsson, 2019). Despite, for example, multiple versions of the Principle having been developed, none (consistently) dictate: the threat threshold for triggering the Principle; the level of precaution that should be applied in any given circumstance; the burden of proof technology developers should have to meet to demonstrate 'safety' (Marchant, 2003). Second, pausing implementation efforts until uncertainty regarding potential risks has been sufficiently reduced, assumes that there is only objective epistemological uncertainty to be dealt with. This is not the case in the context of NHS ACDSS implementation where the presence of disorganised complexity and consequential negative unintended emergence is more associated with ontological uncertainty, i.e., uncertainty that is associated with stochastic and nonlinear behaviour that cannot necessarily be reduced by deterministic reasoning (Tannert et al., 2007). Third, this precautionary approach also implies that it is possible to reach a 'risk-free' scenario and that it is only in a 'risk-free' environment that the benefits of ACDSS might be realised (Stefánsson, 2019). This ignores the reality that no human action is entirely risk-free, and that the practice of medicine itself is entirely predicated on the belief that it is possible to make rational cost-benefit decisions in situations where (as explained in Chapter One) there is an ethical duty to act in order to save lives even if some harm does occur (Termeulen, 2005). Finally, even if it were possible to pause implementation efforts until all uncertainties and emergent tendencies of the NHS information infrastructure had been removed– which is unlikely as all systems tend to retain 'echoes' of their past behaviour even after undergoing significant change (Chandler et al., 2016) - this might not be desirable. Retaining a degree of unintended emergent functionality can, for example, be advantageous in situations where (like in the NHS) it might be necessary for a system to respond rapidly to changes in the environment without collapsing (Steels, 1991). Thus, it seems unlikely that precaution (and thus the Epistemological Strategy) is the right response to the conundrum posed by the need to take proactive mitigating measures against risk, and the seeming impossibility of accurately predicting the harms that need to be protected against.

The second strategy, put forward by Collingridge, is far less defined, but can be thought of as the 'Normative Strategy' in the sense that it aims to reverse the normative circle described previously so that control of emerging technologies becomes more feasible because 'we' have developed technologies that can be controlled. In other words, the Normative Strategy focuses less on

overcoming the Dilemma, and more on ensuring it does not materialise in the first place (Liebert & Schmidt, 2010). The fact that this strategy relies less on the ability of policymakers to *predict* the emergence of harms (which has been shown to be almost impossible in the context of disorganised complexity and negative unintended emergence) and more on ensuring there are mechanisms in place to assess possible consequences as the technology develops and adapt plans accordingly (J. H. Moor, 2005), makes it the more plausible and suitable strategy in the context of this thesis. It is a strategy that, in today's interpretation, clearly overlaps with Social Shaping of Technology theory and Value Sensitive Design theory, which both assert that the impact of a technology is shaped through almost constant negotiation between social, technical, and economic factors (Le Dantec & Do, 2009), and informs Responsible Research and Innovation (RRI) approaches to technology development which stress the importance of reflexivity and stakeholder engagement (Genus & Stirling, 2018). It is this strategy, therefore, that this thesis uses to answer the second half of RQA: 'What would be the consequences if the [necessary]changes [to the NHS's Information Infrastructure] were not made or if the wrong changes were made?' Exactly how it does this, is the topic of the next section.

5.2 Method

To answer the Question 'What would be the consequences if the [necessary]changes [to the NHS's Information Infrastructure] were not made or if the wrong changes were made?" and so identify the requirements for designing-out risk of harm associated with negative unintended emergence, it is necessary to shift from predictive (or 'foresight') ethical analysis towards anticipatory ethics. Predictive ethical analysis is typically risk-based (Genus & Stirling, 2018), akin to 'cost-benefit' analysis (S. Clarke, 2005), and – whilst sometimes disguised as being 'abstract' – based on deterministic or probabilistic laws drawn from science, economics, and public administration (B. Adam & Groves, 2011). This type of analysis often excessively focuses on 'the immediate horizon point' and so struggles to keep up with the rate at which new potential harms emerge as technologies develop (Hester et al., 2015). Anticipatory ethics is instead focused on the future (i.e., not the immediate horizon) (Shilton, 2015) and involves the study of diverging futures and socio-technical imaginaries (Genus & Stirling, 2018). Based on deliberative democracy, procedural theory, participatory governance, and distributed responsibility, anticipatory ethical analysis ultimately aims to enable a wide group of stakeholders to reflect on what types of futures are possible and - of those - what types are socially desirable (Floridi & Taddeo, 2016; Hester et al., 2015; Morley & Floridi, 2021).

There is no singularly agreed upon method for conducting an anticipatory ethics analysis (Shilton, 2015) but one common method, and the method used here, is the 'technical-ethical scenarios' method developed by Boenink and colleagues (2010). By asking what could happen and producing narrative descriptions of future possibilities (Brey, 2012; Nanayakkara et al., 2020), the scenario method is deliberately intended to help policymakers anticipate ethical controversies (so that they can proactively mitigate harms) regarding emerging technologies (Brey, 2012). Thus, what follows is a narrative analysis, of a range of potential 'technical-ethical scenarios' that could arise from the implementation of ACDSS into the NHS, if the right requirements for designing-out these potential harms associated with negative unintended emergence are not identified. The scenarios were developed by:

1. Analysing the NHS Constitution. This is the foundational policy of the NHS. It sets out the principles and values of the NHS in England. The Secretary of State for Health, all English NHS bodies, private and voluntary sector providers supplying NHS services, and local authorities in the exercise of their public health functions are required by law to take account of this Constitution in their decisions and actions (Department of Health and Social Care, 2021d).
2. Conducting a thematic analysis of the semi-Structured interviews in line with the main aims of the NHS Constitution (i.e., to put the patient at the centre of care; to build trusting relationships between patients and healthcare providers; and to treat everyone equally). Following the approach outlined in Chapter 3.
3. Combining the results from the analysis of the NHS Constitution and the semi-structured Interviews with existing theory related to bioethics and healthcare services provision.
4. Applying the theory to specific ACDSS-related issues and concerns identified in the realist review.

By taking this approach, the intention is to provide an analysis that does more than simply reiterate commonly rehearsed concerns regarding transparency, privacy, accountability, fairness, and explainability. The aim is to consider the potential broader societal harms that may result from negative unintended emergence associated with the implementation of ACDSS (O'Doherty et al., 2016a) and, in so doing, highlight the potential for ACDSS to re-ontologise (fundamentally re-engineer the intrinsic nature of) the ways in which healthcare is delivered in the NHS (Floridi, 2017a). The hope is

that this will help ensure, that when it comes to identifying the requirements for designing-out harms, these requirements consider complex and nuanced ethical issues such as the effects of ACDSS implementation on fiduciary relationships (Mittelstadt & Floridi, 2016); changes in people's perception of their responsibility in managing their own body (Verbeek, 2009); disruption to the harmonious relationship between 'patient, disease, and clinician' (Antoniou et al., 2010); shifts in power dynamics (Vegter, 2018); changes in the meaning of formally stable concepts such as health and illness (Rubeis, 2023); and the implications for trust-based relationships between the body, culture, and society (Lock & Nguyen, 2018). The scenarios discussed are as follows: A) the patient is displaced from the centre of care; B) the fundamentals of care are disrupted; and C) the NHS ceases to be for all. These are not mutually exclusive and are presented in order of scale from the individual to the systematic, rather than in order of significance or importance. After each of the scenarios has been described, the analysis concludes that, whilst the scenarios may seem extreme or overly negative, it is essential that the 'risks' are taken seriously if policymakers are to avoid a situation in which the NHS becomes a healthcare system that suits the algorithms but is not socially desirable or even acceptable (Robbins, 2020).

5.3 Results and discussion: avoidable re-ontologising scenarios

5.3.1. Scenario A: The patient is displaced from the centre of care

A key founding principle of the NHS Constitution is 'The patient will be at the heart of everything the NHS does.' This is supported by the values 'working together for patients,' and 'respect and dignity;' and underpinned by the patient right to 'receive care and treatment that is appropriate to them, meets their needs, and reflects their preferences.' From a philosophical standpoint this pragmatic principle is derived from the ethical principle 'autonomy' which, sometimes controversially (Stirrat, 2005), is considered the *primus inter pares* or the 'first among equals' when sat alongside the other bioethics principles Justice, Beneficence, and Non-Maleficence (Gillon, 2003). In other words, 'respect for autonomy' is prioritised in medical ethics and thus so too is the principle of 'patient centricity' in the NHS's Constitution.

Differing definitions and conceptualisations of autonomy (Racine et al., 2021; J. Wilson, 2007) as well as changing attitudes towards medical paternalism, mean that the exact way in which this principle has been operationalised in the NHS has changed over time (Chin, 2002). However, since the early 1990s its operationalisation through: the practice of Evidence Based Medicine as defined by Sackett and colleagues (1996); valuing 'patient stories' (i.e., listening and valuing the embodied experience of illness) (Hawkins & Lindsay, 2006); informed choice or consent (Stirrat, 2005); and

shared decision-making (Bravo et al., 2015), has been consistent with a libertarian view of autonomy (i.e., exercising a choice free from external constraint) (Slowther, 2007). In practice this means that patients are provided with a full and comprehensive description of the problems requiring intervention followed by an authoritative – but judgement free – statement of the benefits and risks of the various treatment options (including doing nothing). This explanation and problem statement should then inform a two-way conversation about which treatment plan the patient would like to pursue – taking into account their values and preferences (McDougall, 2019). Or, as Whitney and colleagues (2008, p. 703) summarised: "Optimal decision-making results from expert identification of the medically reasonable alternatives and the determination of the presence or absence of uncertainty in the clinical situation, as well as thoughtful probing of the patient's preferences when they are relevant.'

Although, like the concept of autonomy itself, this operationalisation of the NHS's commitment to patient centricity has been criticised (see e.g., Aggarwal et al., 2014), it has shown to be relatively successful and valuable from a patient trust and experience perspective (Kraetschmer et al., 2004; Schattner et al., 2006). The first anticipated scenario then, is that the implementation of ACDSS into the NHS displaces the patient from the centre of care.

There are three drivers behind this scenario all of which share the common theme of separating 'valid knowledge about the body' from the person to whom the body belongs in a way that undermines individual autonomy (Rubeis, 2023). These drivers are: (i) changing what counts as evidence of illness; (ii) changing what counts as good patient behaviour; and (ii) undermining the right not to know. Each of these drivers will now be discussed in turn.

5.3.1.1 Changing what 'counts' as evidence of illness

To start with evidence of the presence of illness, relying on ACDSS to make all decisions regarding diagnosis and prognosis, could narrow the scope of the clinical gaze so that it only looks upon, and thus only considers relevant, facets of a person's health that can be recorded as facts in an EHR (Holmes et al., 2006). This assumes that the presence or absence of a specific SNOMED code (standardised clinical terminology used by the NHS to record symptoms, diagnoses, and treatments) can, for example, confirm or dismiss a specific condition. In other words, relying on ACDSS may mean that where once patient-led reports of the haptic 'sensations' they felt in their bodies would have been considered valid and relevant knowledge of the body, now the only knowledge considered 'valid' is that which is 'quantifiable and observable' (i.e., positivistic) (Chin-Yee & Upshur, 2019). Humanistic knowledge (such as a person's lived experience (Deeny & Steventon, 2015) or their subjective feeling

of wellbeing (Molnár-Gábor, 2020b) or common sense knowledge (R. D. Schwartz, 1989), may be deemed irrelevant and ignorable. Longoni and colleagues (2019) refer to this effect as "uniqueness neglect" and stress that it can reduce the extent to which patients are viewed as holistic individuals (Heyen & Salloch, 2021). Overall, this process of ontic occlusion (Mittelstadt & Floridi, 2016) might make healthcare less embodied (Nettleton et al., 2007), more restrictive than caring (Kerr et al., 2018) and more paternalistic than patient-centric (Chin-Yee & Upshur, 2018; the Precise4Q consortium et al., 2020). In short the 'analogue' patient would be replaced with their data self, a digitised representation that may not match the patient's perception of themselves, undermining integrity of self (Cheney-Lippold, 2019), potentially causing psychological harm, and ultimately, as a number of interviewees commented, worsening the patient experience (I2, Interview, 17 October 2022; I11, Interview, 18 October 2022; I22, Interview, 21 October 2022; I51, personal Interview, 8 November 2022).

Over time this disconnect between physical patients and their data selves being treated, could make it near impossible for most individuals to meet the criteria of a good patient further displacing the patient from the centre of care and potentially exacerbating inequality.

5.3.1.2 Changing what 'counts' as good patient behaviour

The idea of the good patient is a normative concept closely tied to Parsons' sick role (Parsons, 1975). According to Parsons, illness is not merely a natural state of a person when they are unwell, but an institutionalised role which must be accepted if a person is to be considered treatable or worthy by the institutionalised healthcare system. To accept the role, individuals must meet three criteria: (1) the illness must have arisen from forces beyond the individual's control; (2) the individual must be incapable of or exempt from ordinary daily obligations and expectations; and (3) the individual must willingly seek help from an institutionalised healthcare provider and fully commit to following their advice to get well. Good patients, therefore, are those that willingly accept the sick role. Good patients, accept the diminished *autonomy* brought about by illness, respect the authority of their clinician, and play an active role in their recovery (Sointu, 2017). Bad patients on the other hand refuse to take on the sick role, are often considered to be wilfully ill, do not respect the authority of their clinicians, and demonstrate a limited willingness to get well or prevent ill health (Sointu, 2017; Stimson, 1974). Self-responsibility (both forward and backward looking) is, therefore, central to the idea of good and bad patients: individuals are perceived as being in charge to ensure that a desired outcome is achieved and looking backwards to appropriate blame and possibly redress, when a failure has occurred (Wardrope,

2015). Good patients take up this mantle willingly and, in return, accrue health cultural capital which is a critical ingredient in patient-centric healthcare transactions (Dubbin et al., 2013). Bad patients eschew the responsibilities of the sick role, have little health cultural capital, are seen as less-worthy (Higashi et al., 2013), and consequently receive care that involves less reassurance, listening, and empathy i.e., less patient-centric (Sointu, 2017).

This process of categorising patients has always been (and will always be) problematic. However, the health habitus it covers in the purely analogue world is relatively confined in both space and time (T. Lewis, 2006). Good physical patients may be required to abstain from drinking or smoking to excess, to finish a course of antibiotics as prescribed, and to vaccinate their children – all activities that fall neatly within the health or medical domain. The predictive and personalisation focus of ACDSS, however, may dissolve or liquify the boundaries that protect other aspects of a person's life from the controlling influence of medical 'biopower' (Rubeis, 2023). By focusing on the future, and the personalised insights that can be derived from the analysis of large volumes of aggregated data including clinical data, genomic data, and phenotypic data (e.g., wearables data), ACDSS use may make the concepts of health and illness more fluid, so that health is not merely the absence of disease or a state of wellbeing but something to be assessed from the angle of future developments, something that is always endangered and something that requires constant attention (Rubeis, 2023). Taking care of one's health, and being a good patient, may become a full-time duty even for those who consider themselves to be healthy (Rubeis, 2023). In other words, the increased visibility of the processes of the future self - afforded by the use of ACDSS – may result in an increase in responsibility (Baistow, 1994; Vezyridis & Timmons, 2015) where the good patient norm obligates people not only to strive to maintain their health but also to see themselves as incomplete (or 'sick') and in need of continuous improvement (Catlaw & Sandberg, 2018; Juengst & McGowan, 2018).

Once cast in the permanent sick role of 'not ill yet' data patients may be required to submit passively to the administrations of, not their clinician, but to the advice of the ACDSS which is required to do little more than determine how far away the patient is from a particular normal baseline (I8, Interview, 17 October 2022). Whilst developers of ACDSS may wish to give the impression that these baselines and recommendations speak for themselves (Rubeis, 2023) based on science, objectivity (McLaughlin, 2016), and highly personalised references, the reality may be more opaque or unclear (Morley & Floridi, 2020b). It may be that the baselines are based on chance, poor science, hype, politics, and economics (Morley & Floridi, 2020b)(Andaur Navarro et al., 2023). Furthermore, the underlying data making up the data patient may be wrong – unbeknownst to the physical patient-

leading to inaccurate or potentially even harmful suggestions, the advice itself may be antithetical to the patients' values, and it may be impossible for the patient to act on (T. Lewis, 2006) because their options are constrained by socioeconomic factors that are likely to affect some groups more than others (de Freitas & Martin, 2015; I2, Interview, 17 October 2022). In short, rather than improving care, ACDSS, it is felt, may become a tool for commercial interests and political agenda's intended to serve the interests of those other than the patient (Owens et al., 2017; Vogt et al., 2016), and leave patients feeling tyrannised by averages (I4, Interview, 17 October 2022; I11, Interview, 18 October 2022).

This potential tyranny (Lock & Nguyen, 2018) would result in patients no longer being viewed as individual human entities (a core feature of patient-centred care) (Dubbin et al., 2013) and is why Owens and colleagues (2017) believe that there is reason to be highly sceptical about the claims of digital health tools (including ACDSS) offering the healthcare system and individuals genuine opportunities for health improvement. Instead, they argue that digital health tools (ACDSS in this context) could exacerbate existing health inequalities (I32, Interview, 28 October 2022), by creating a situation in which people become trapped in a quasi-contract where they will be expected to achieve unrealistic expectations of 'wellness' (Juengst & McGowan, 2018), and labelled as irresponsible citizens (bad patients) when they fail (Juengst et al., 2012). As well as this resulting in a very large number of people being categorised as bad patients and less deserving of care, it may also act as a disincentive to those wishing to exert their 'right not to know.'

5.3.1.3 Undermining the right not to know

The connection between patient-centred care, autonomy, informed consent, and shared decision-making can make it appear that the primary right that is being upheld is the patient's right to be involved in their care. However, this is only part of a broader whole. More broadly, patient centred care is about upholding the "moral philosophy that patients are unique human entities" and recognising the "multidimensionality of the human experience of health and illness" (Dubbin et al., 2013, p. 113). Recognising the uniqueness of individual patients, requires an acknowledgement of the fact that there is a complex relationship between social factors, rationality, and an individual's desire to be involved in making choices (Walach & Loughlin, 2018). There will, therefore, never be a one-size fits all model for the balance between agency and patiency in doctor-patient relationships, as this will always be dependent on the specific nature of the decision and the current circumstances of the individual in question (Whitney et al., 2008). Thus, taking a meta-rights approach, if patient-centred

care gives patients the right to know about their future health risks and the options available to them, it makes sense that patients should also be given the right not to exercise this right (Basu, 1984).

This right not to know is well recognised in the context of genetic screening. Indeed, in the German legal literature, this right is a central component of the "right to informational self-determination". In general, there is an awareness that just as the principle 'do no harm' or non-maleficence applies to physical integrity so too does it apply to psychological integrity (Andorno, 2004c). If the scenario arises where patients are blamed or considered bad for not acting on preventive health advice about future relative risks, upholding this right in the context of ACDSS implementation may become challenging. In many ways P4 medicine – a key driver behind the desire to implement ACDSS – can be considered a new form of continual algorithmic screening process unprecedented in intensity and scope (S. Green & Vogt, 2016). Trained on large datasets from multiple sources, and running even when the patient is not present in a clinical setting, ACDSS may be used to screen individuals for many diseases and risk factors at once (Vogt et al., 2019). Not only might individual patients feel as though they have no opportunity to provide meaningful informed consent (Stirrat, 2005) to this continual background screening process, but they may also feel as though they have no choice but to absorb the generated knowledge to ensure their cultural health capital remains in credit. There is pronounced concern from across the system that this may result in phycological harm from information overload and health anxiety – particularly in situations where either the patient cannot act on the information provided or where they feel as though the process is akin to unethical profiling or harm from overdiagnosis (Chiolero et al., 2015) and the feeling of being surveilled (I4, Interview, 17 October 2022; I7, Interview, 17 October 2022; I8, Interview, 17 October 2022).

5.3.2. Scenario B: The fundamentals of care are disrupted

The third principle of the NHS Constitution is the NHS aspires to the highest standards of excellence and professionalism. This is supported by the values commitment to quality care and compassion (Department of Health and Social Care, 2021d), and echoed in the fundamental standards (the standards below which care must never fall) set out by the NHS regulator the Care Quality Commission (CQC) (CQC, 2022). Whilst it may seem that quality care is a rather subjective concept that is hard to define and is likely variable, there is in fact an established framework for its operationalisation in the NHS: The Fundamentals of Care Framework (FCF). Although the FCF was originally developed for nursing, its applicability is far broader. According to the FCF, fundamental care is about protecting a person's physical and psychosocial wellbeing by ensuring their essential

needs are met through the development of positive and trusting relationships (Feo et al., 2018; Kitson et al., 2013). In essence, the FCF and the NHS Constitution make the point that trust-based relationships, between professionals and patients, and between differently skilled professionals (Bainbridge, 2019; Heath, 2018), are at the heart of the NHS's commitment to excellence.

Placing trusted relationships at the centre of the NHS's commitment to excellence is further justified on the basis that medical advances lose their value if patients do not trust their care providers, the care system (Bhuyan et al., 2016), or the innovations used in their care (Asthana et al., 2019a). In short, trust plays a vital role in mediating therapeutic processes and has a measurable direct impact on patient satisfaction which, in turn, has an indirect but significant positive effect on patient outcomes (Vourgidis et al., 2019b). Whilst in the past, this trust was largely assumed (G. Bevan, 2008), today it is known to be conditional (Calnan & Rowe, 2008). Trust is earned through quality interactions, full of kindness, courage, thoughtfulness (Heath, 2018), and empathy as well as a comprehensive Governance framework (Benbow, 2018). Combined these two elements earn trust by demonstrating to patients the trustworthiness of the NHS's commitments to quality care, clinical competence, and truthfulness (C. Jones et al., 2021). This creates an environment in which patients feel safe, trusting the expertise of the healthcare professionals they encounter, and basing their decisions on the advice they receive (N.-F. Wagner, 2019).

The introduction of ACDSS into the NHS has the potential to disrupt these mechanisms of trust in a way that may undermine the quality of the trust-based relationships (M. Sendak, Elish, et al., 2020b). Thus, the second anticipated scenario is that the foundation of care is disrupted. Again, there are three primary drivers behind this scenario: changing power dynamics; devaluing the ethics of care (Foster & Young, 2012); and the challenges of accountability (A. Kerasidou, 2021). Each of these drivers will now be discussed in detail.

5.3.2.1 Changing power dynamics

Trusted relationships between patients and clinicians develop when an appropriate balance in power between the two agents is achieved. Patients gain power by bringing essential contextual and 'lived-experience' knowledge into the consultation (Molnár-Gábor, 2020b)– knowledge that is necessary if the clinician is to be enabled to properly practice EBM (see above) (Sackett et al., 1996). Clinicians gain power through 'epistemological freedom' i.e., the freedom to make choices with regards to clinical reasoning, such as deciding which information is relevant to a diagnosis and how to interpret specific information supplied by the patient (Baalen et al., 2021). Clinicians are warned against abusing this

power, by the well-known oath "do no harm" which reminds clinicians not to use their authority and expertise inappropriately, and to be faithful to the trust placed in them (Sharpe, 1997). This duty is then grounded in a clinician's fiduciary responsibility to use their power and knowledge to the benefit of others i.e., to listen to the patient's contextual information and act in their best interests. Legally, this responsibility holds clinicians to the highest standards of conduct, acting as a learned intermediary when advising patients on decisions regarding diagnostic and therapeutic approaches, and protecting them from harm (Drazen, 2002). These duties are most obviously applied to the prescribing process (Goetz & Growdon, 2008). However, they also apply when clinicians protect patients from psychological harm (for example, knowing about a risk factor that cannot be mitigated) or the harms of overdiagnosis (Vogt et al., 2019). Clinicians, for example, help patients understand the differences between *relative* and *absolute* risk. This intermediation is often necessary as bodies are complex, psychology subtle, and causality is very rarely clear-cut. By taking seriously these responsibilities, clinicians ensure that both their autonomy over the decisions they make, and the autonomy of the patient is protected, and a trusted relationship can develop (Brill et al., 2019b). The implementation of ACDSS may disrupt this careful balance of power and so disrupt the trust that should exist between clinicians and patients.

As Kerasidou (2021) highlights, ACDSS is intended to increase the reasoning and decision-making capacities of clinicians. In other words, ACDSS is intended to increase the power of clinicians by increasing their epistemological resources and freedom. It is entirely possible, however, that the implementation of ACDSS may achieve the exact opposite: decreasing the epistemological freedom of clinicians, undermining their authority, diminishing their power, and so altering the conditions under which trusted relationships between clinicians and patients develop. This may happen because in outsourcing (at least some of) the clinical and technical skills required for diagnosis, prognosis, and treatment decisions to ACDSS (A. Kerasidou, 2020b), it may become encoded with human agency (Beer, 2017). This encoding of agency, would transform ACDSS from being merely 'a tool' into another morally relevant agent capable of generating new knowledge and of (non-transparently) shaping existing knowledge (for example, choosing to present one treatment option as the preferred option with little explanation) (A. Kerasidou, 2020b) and in so doing, giving ACDSS more epistemological freedom than the clinician. Over time, this may result in a shift of medical authority – the collective medical mind - from clinicians to the algorithms embedded within ACDSS so that it is ACDSS that acts as the central node in all medical decision-making processes (Blasimme & Vayena, 2019). Ultimately, this might place algorithmic limitations on the thought processes of clinicians,

eroding their independent decision-making capacity (Beer, 2017) and, as interviewees were keen to stress, potentially leaving clinicians 'de-skilled' and overly reliant on the outputs of ACDSS (I6, Interview, 17 October 2022; I11, Interview, 18 October 2022; I22, Interview, 21 October 2022).

There are potentially two further concerns about this transference of agency and power happening outside of an algorithmic equivalent of a fiduciary responsibility (Blasimme & Vayena, 2019) that have important implications for trusted relationships. The first is that, whist clinicians are likely to use a very extensive set of epistemic criteria (including adequacy, plausibility, coherency), pragmatic criteria, and qualitative criteria (such as patient preferences or feelings as discussed in the previous scenario), to assess the relevance and usefulness of a particular piece of knowledge in a specific situation, ACDSS may use a much narrower set of epistemic criteria (e.g., statistical accuracy) (Baalen et al., 2021). There is potential for this type of unthinking 'parroting' of knowledge to be perceived as being paternalistic (Grote & Berens, 2020) and for it to result in 'e-iatrogenesis' – or patient harm resulting from a mismatch between the insight or advice of the ACDSS and the real-life of the patient (Bouaud et al., 2015) (I41, Interview, 31 October 2022; I60, Interview, 11 November 2022). The second is that, whilst ACDSS may be able to learn how to replicate one very specific part of a medical decision-making process (e.g., the diagnosis), it is possible that it will not be able to learn how to replicate the entire cognitive workflow of clinicians which includes, for example, thinking about the synchronisation of clinical staff, equipment, tools, and facilities to complete the full 'care pathway' for any newly diagnosed patient (Nemeth et al., 2005; Rezaei-Yazdi & Buckingham, 2018). This lack of complex understanding, which is a major concern for the clinical community, may result in a very poor experience of care for some patients, for example being diagnosed long before they can access treatment (something that may cause significant psychological harm), resulting in considerable loss of trust (I1, Interview, 17 October 2022).

Combined, these shifts in power and responsibility from clinicians to ACDSS have the potential to drastically reduce the role of the clinicians in the clinical encounter from a trusted agent, seen as the central node in a caring healthcare system to little more than a data worker whose technical, analytical, and emotional labour is used solely to 'train machines' (Fiske et al., 2019; Green et al., 2022; I7, Interview, 17 October 2022). Not only is it felt that this process might be exploitative, but it is also unclear if patients would know how to, or would even desire to, develop a trusted relationship with a clinician in such a reduced and intermediated role.

5.3.2.2 Devaluing the ethics of care

Since the 1970s, there have been several attempts by policymakers to make the NHS in England more accountable to the public through the introduction of performance metrics, audits, inspections, and other means of surveillance and monitoring (G. Bevan, 2008). In many ways the introduction of these myriad 'performance management' tools can be seen as an attempt by policymakers to outwardly demonstrate or prove the trustworthiness of individual clinicians to individual members of the public (patients) (Calnan & Rowe, 2008). Such attempts at proving trustworthiness are grounded in the ethics of justice, the basis of which is verifiable and reliable decision-making based on universal rules and principles and positivistic rationality (Botes, 2000). In essence, surveillance policies try to demonstrate trustworthiness by quantifying the extent to which NHS providers are offering competent and equal treatment options (Ruthledge & Wesley, 2001). However, since the 1980s and the development of feminist theory, it has been widely acknowledged that patients do not in fact desire or ask for proof of trustworthiness. Instead, patients prefer for clinicians to earn trust by providing quality services and positive experience of care (Calnan & Rowe, 2008). To put it more simply, for patients, trustworthiness – and so trusted relationships – is personal. Attempts to make trustworthiness a more abstract and de-contextualised concept (Tong, 1998) can have the opposite effect of undermining and lessening trustworthiness (Checkland, 2004), and creating both unnecessary and potentially harmful distance between patients and clinicians (Mittelstadt & Floridi, 2016). Trustworthiness from the patient perspective is, therefore, grounded in the ethics of care rather than the ethics of justice (Morrell, 2006).

The ethics of care places more emphasis on the quality of the patient-clinician interaction than abstract disembodied performance data (Calnan & Rowe, 2008). It is, therefore, a relational ethic (Foster & Young, 2012) that emphasises the importance of each individual patient experience (Garbutt & Davies, 2011). The ethics of care recognises that positive patient experiences, and therefore earned trustworthiness, are not based solely on quantitative efficiency factors such as wait times. Instead, positive experiences and trustworthiness depend heavily on fundamental caring values, including empathy and compassion (A. Kerasidou, 2020b). Whilst hard to measure, and not equally present in all practising clinicians, these values – alongside others such as courage and thoughtfulness – are performed as social practices in the clinical encounter (Leget, 2013) and play an essential role in maintaining trust in clinicians and healthcare (Heath, 2018). In short, by maintaining the autonomy, self-esteem, and dignity of both parties (Kittay, 2011; Pettersen, 2011), the values at the heart of the ethics of care help protect the good provided by trusted relationships between clinicians and patients (Mittelstadt & Floridi, 2016). This is why Carper, (1979, p. 14; Leininger, 1977, p. 2) states "caring acts

and decisions make the crucial difference in effective curing consequences [….] it is caring that is the most essential and critical ingredient to any curative process." The mediation of the relationship between clinician and patient by ACDSS may reduce these human aspects of caring (Blasimme & Vayena, 2019; Esmaeilzadeh, 2020), worsening the experience of care and undermining trustworthiness.

The potential for the use of ACDSS to demote the importance of caring in the clinical encounter stems from the fact that no matter how realistically empathetic an ACDSS may present information, even in the form of a conversation (Howick et al., 2021), it will never truly replicate such quintessentially human values, because algorithms have no concept of their meaning, relevance, or importance. There is, therefore, a considerable possibility that the greater use of ACDSS in healthcare could result in the side-lining of these values and a fundamental shift in the way healthcare is practised (Halligan, 2008). The caring, relational, or contractual model of the clinician-patient relationship may be replaced by the engineering model. In the engineering model, the sole purpose of a clinician is to completely and dispassionately present facts to the patient in a way that is devoid of any considerations of ethics or values (Carper, 1979). This reduces humans, full of haptic sensations and emotions, to mere objects of science and reduces decisions from what ought to be to nothing more than what is possible (Carper, 1979). This is a major concern for healthcare practitioners and patients alike who see ACDSS tools as little more than 'pattern recognition machines' incapable of providing the types of care that results in positive outcomes. This type of healthcare may be efficient and cost-effective, but – as several interviewees noted - it is unlikely to be trustworthy or caring.

5. 3.2.3 The challenge of accountability

The fact that clinical governance – or the continuous surveillance of the clinical encounter (described above) (Checkland, 2004) – does not necessarily result in increased trust in the relationship between clinicians and patients, makes it clear that the relationship between trust and accountability is not always straightforward (Bovens, Goodin, Schillemans, & Greiling, 2014). This is, at least in part, because there are in multiple different models and forms of accountability in the healthcare system (Emanuel, 1996). Whilst the professional model of clinical governance (horizontal accountability) might not engender trust, and indeed might be counterproductive, the process model of system governance (vertical accountability) (Genovese et al., 2017) - i.e., the domain of system regulation and control – is seen as a trust-securing mechanism (Gille et al., 2021). Process accountability is less concerned with the individual patient experience, and more concerned with the existence and monitoring of systems that ensure all agents (including algorithmic and external human agents) are

operating effectively and safely (Allen, 2000; H. Davies, 1999; Russo et al., 2023). This type of accountability is an *a priori* requirement for individuals looking to partake in healthcare-related activities (Gille et al., 2021). In other words, patients require assurance of the existence of process accountability before they will even enter a clinical 'relationship.' Process accountability is the foundation upon which trusted relationships rest. As already discussed in the previous chapter (section 4.2.6) the implementation of ACDSS into the NHS raises significant questions related to process accountability – such as who is liable for ACDSS-mediated missed or misdiagnoses. These questions highlight the potential for ACDSS implementation to considerably disrupt the loci, domains, and procedures of process accountability (Emanuel, 1996) and, in so doing, destabilise the foundations of the essential trusted relationships.

What matters most here is not the specific processes that are disrupted, but the overarching uncertainty that may be introduced by the introduction of new organisations, institutions, and social practices (for example private technology companies) into the previously relatively closed system of healthcare delivery (Chataway et al., 2012). This introduction of new parties, new loci of accountability, or new agents may redistribute and diffuse responsibility for multiple processes related to effectiveness and safety (Morley, Machado, Burr, et al., 2020; Turilli & Floridi, 2009). This redistribution of responsibility has the potential to break already fragile foundations of trust and, as noted by clinicians and patients alike, amplify pre-existing reservations about ACDSS (Braun et al., 2021). Over time, this breakdown of the foundations of trust has the potential to result in an overarching de-legitimisation (Allen, 2000) of the healthcare system from the public's perspective.

5.3.3. Scenario C: The NHS ceases to be 'for all'

The first principle of the NHS Constitution, and the principle upon which many believe the NHS was founded, is "the NHS provides a comprehensive service, available to all" (R. Bradshaw & Bradshaw, 1995). This is supported by the value 'everyone counts' (Department of Health and Social Care, 2021d). This is a principle of both equality "[the NHS] is available to all irrespective of gender, race, disability, age, sexual orientation, religion, belief, gender reassignment, pregnancy, and maternity or marital or civil partnership status" and equity "[the NHS has a duty to] pay particular attention to groups or sections of society where improvements in health and life expectancy are not keeping pace with the rest of the population." In short, the principle and its supporting value, commit the NHS to providing equal access to care for people of equal clinical need (Powell & Exworthy, 2003), to ensure that every person who seeks medical attention from the NHS is offered an equal standard of care, including

equal treatment options (Ruthledge & Wesley, 2001). Whilst in reality issues related to implicit bias, stereotyping and prejudice (Chapman et al., 2013) mean that this principle is often more of an aim than a statement of fact, it remains a principle of great cultural significance and a benchmark against which the success of the healthcare system can be judged (R. Bradshaw & Bradshaw, 1995). For this reason, one of the great hopes of ACDSS implementation is that its use will both reduce the impacts of human prejudice (thus improving equality) and improve the targeting of interventions (thus improving equity). There is, however, no guarantee that ACDSS implementation will result in these positive outcomes. Instead, it is felt to be entirely possible that the implementation of ACDSS will *worsen* health inequalities (Geneviève et al., 2020; Gray et al., 2017). The third and final anticipated scenario is, therefore, that the NHS ceases to be for all. The two primary drivers behind this scenario (bias and the inverse care law) will now be discussed in more detail.

5.3.3.1 Baked in bias

Bias is sometimes necessary in clinical settings. It is, for example, often necessary to account for differences in biological sex or ethnicity for the purpose of making precise diagnoses or for effectively targeting treatment (Cirillo et al., 2020). In other words, this type of deliberate bias is desirable and not of concern from the perspective of ensuring the NHS continues to provide equal care for equal need. Problems for this principle instead arise from unintentional or undesirable bias (Challen et al., 2019; Cirillo et al., 2020). This type of bias is associated with unnecessary discrimination and stems from the fact that (as briefly mentioned in section 4.2.2) clinical data is often messy and incomplete in non-random ways (Wiens et al., 2019a). In short, undesirable bias associated with ACDSS can arise from the well-known "rubbish in, rubbish out" problem and has the potential to both exacerbate existing inequalities related to social bias (Schönberger, 2019) and create new inequalities related to epistemological bias (S. S.-J. Lee, 2021).

Social bias is the better recognised issue, and springs from non-random missingness in historical clinical datasets. Historical structural issues, for example inequal access to healthcare, unwillingness to deal with hormonal complexities in clinical trials, and variable trust in the healthcare system amongst different communities, have resulted in the under-representation of women, and minority groups (including ethnic and gender minorities) (Geneviève et al., 2020). This can mean that training datasets for ACDSS are non-representative of the population on which the ACDSS may be used in the future, increasing the likelihood that the (for example) diagnostic accuracy of the ACDSS

may be highly variable – and so unequal – an issue known as selection or feature bias (Paulus & Kent, 2020; Yusuf et al., 2020).

Epistemological bias receives less coverage, at least in popular media, partly because it is a more technical issue and partly because it is more insidious. Like social bias, epistemological bias arises from structural issues, but unlike social bias epistemological bias does not arise from who is recorded in clinical data, but rather what is recorded in clinical data (S. S.-J. Lee, 2021). The functionality and design of data entry systems, for instance EHRs, dictate what is recorded, as does the organisation of the care system itself, and the reimbursement system (for instance services that generate payments to GPs are more likely to be recorded accurately than those that do not) (Verheij et al., 2018). This can mean that certain causes of diseases, and the effects of specific treatments are better recorded than others. For example, it is far more likely that medical, and even genomic, causes of disease will be recorded than causes related to the social determinants of health such as a person's income (Challen et al., 2019). These problems can be magnified by additional layers of structural design and structural inequality. For example, health clinics that predominantly serve populations in lower socioeconomic groups may be less likely to have an EHR and may instead rely on written notes and scanning – resulting in far less comprehensive recording. Issues that fall on the boundary between healthcare and social care (for example, certain types of mental health issues) are also much less likely to be recorded. Since most ACDSS models are probabilistic, build on inductive learning, and are not equipped to differentiate between correlation and causation these biases can lead to spurious correlations that may be socially unacceptable (Schönberger, 2019). For example, if people of a particular ethnicity live in a certain area that is known to have high-levels of pollution, and this group is also more likely to be diagnosed with lung cancer, but the pollution levels are not recorded it may be assumed by the ACDSS that the predictive variable is their ethnicity. Individuals within this group may then be advised to take ineffective preventative action and blamed for their own ill health if they become unwell (Morley & Floridi, 2020b).

As one GP interviewee stressed, the potential harms of these biases may be amplified, if the system continues to perpetuate the myth of the objective algorithm and fails to acknowledge the potential for bias to be "baked into ACDSS" without anyone noticing (I58, Interview, 10 November 2022). A lack of monitoring of the effects of such baking in could mean that biases (and so their related inequalities) worsen over time – a phenomenon known as latent bias. ACDSS that was 'fair' at the point of deployment might later become biased if it is deployed in a different context than it was trained for; if it learns from uncorrected biases in the broader healthcare system; or it the interaction

between ACDSS and human clinician results in unanticipated biases (DeCamp & Lindvall, 2020). Whatever the exact cause of the bias – selection, feature, label, social, epistemological, latent, or other – the result is likely to be the same: increasing inequality and inequity.

5.3.3.2 Amplifying the effects of the Inverse Care Law

First described by Julian Tudor Hart in 1971, the Inverse Care Law states that 'availability of good medical care tends to vary inversely with the need for it in the population served' (The Lancet, 2021; Watt, 2018). Although initially intended to describe geographical variations in care (i.e., the biosphere), suggesting that those in rural areas might have more health needs but poorer access to healthcare, the law is now more applicable to the infosphere with access to appropriate health information being particularly difficult for those who need it most (Eysenbach, 2000). In short the inverse care law has now become the "inverse information law" (Eysenbach, 2000) or "inverse data law" (Ameen et al., 2023) and the infosphere has become a social determinant of health (Morley, Cowls, Taddeo, et al., 2020). This is a complex issue with multiple root causes, including inequitable access to digital technologies and information infrastructure; variable levels of ehealth literacy; and different levels of trust in the healthcare system resulting in different levels of engagement with digital health platforms (Davies et al., 2021; Geneviève et al., 2020), all of which have implications for the potential impact of ACDSS implementation on the equality and equity of healthcare provided by the NHS.

The implications of the inverse information law for equality and equity in the NHS post ACDSS-implementation stem from the fourth 'p' in P4 medicine: participatory (Geneviève et al., 2020). The assumption that ACDSS can be used to provide far more targeted (or personalised) predictions of ill-health, preventive advice to prevent ill-health, and interventions to treat ill-health, relies on the assumption that all people will be equally willing and equally able to engage in self-surveillance (Lupton, 2013), to provide the ACDSS with augmented insights from self-tracking devices, home monitoring devices, or self-reported measures on the effects of specific treatments. As described above, these are the tasks assigned to and the behaviours expected of the modern-day 'good patient'; patients are no longer supposed to be passive recipients of healthcare technologies, including ACDSS, but 'co-innovators' (Kerr et al., 2018) paying for their care through the provision of ever-more detailed data about themselves and their lives. The inverse information law, however, suggests that those who may benefit most from this very precise monitoring of their health and wellbeing, and from very specific predictions from ACDSS, are the least likely to be able to provide the data necessary to grease the wheels of the process and vice versa. Individuals with higher income will, for example,

be more likely to afford the latest self-tracking devices and to pay for genomic sequencing, and those with higher e-health literacy are more likely to be able to monitor and record factors such as food intake and air pollution quality (I51, Interview, 8 November 2022). This can lead to the mis-targeting of screening to the already over-served creating self-reinforcing feedback loops where, for example, those with more money or greater e-health literacy, access [preventive] care services more easily, there is more data on them, therefore, risk is easier to predict and they end up further accessing the care system more frequently (Holzmeyer, 2021; I58, Interview, 10 November 2022; Myskja & Steinsbekk, 2020; Paulus & Kent, 2020). Over time, this may result in scarce resources being diverted away from services targeted at populations less able to act as good patients (Gray et al., 2017) or less willing to participate in this 'dataveillance' for historical reasons related to lack of trust in the healthcare system – an issue that is particularly common among Black and South Asian communities (Wilson et al., 2022). This is why, when the NHS first introduced preventative check-ups in 2008 the Faculty of Public Health stated "we should be focusing on disadvantaged communities – not finding more worried well" (Braillon et al., 2015), and why there are growing concerns about the fairness of ACDSS-enabled care.

Ultimately, such changed patterns of care – combined with the issues of bias described above – create the potential for ACDSS implementation to result in increased discriminatory profiling (Abettan, 2016; Savard, 2013) and, as a consequence, undermine the NHS's ability and claim to provide equal care for all of equal need.

5.4 Conclusion

The preceding scenario-based analysis makes it clear that unless carefully designed the implementation of ACDSS, might not lead to better outcomes. The implementation of ACDSS might instead decrease patient satisfaction with their care (Gray et al., 2017), and could have a very negative impact on individual patients, on particular population groups, on trust in the institution of the NHS itself, and ultimately on the effectiveness and safety of healthcare (Morley, Machado, Burr, et al., 2020).

The scenarios might seem extreme and could be critiqued for being too catastrophic when – as outlined in Chapter One – the intention behind the desire to implement ACDSS into the NHS is positive and the underpinning logic is sound. However, denying the possibility of these future scenarios creates a situation where it is possible for healthcare policymakers to turn a blind eye to the potential for ACDSS tools to be ineffective or drivers of increases in inequality of health outcomes (Wardrope, 2015) or, indeed as stressed, to do long-lasting damage to the NHS's ability to operate in accordance with its key values: everyone counts; compassion; respect and dignity; improving lives; for

patients; and a commitment to quality care (Department of Health and Social Care, 2021d). It is important that sufficient attention is paid to these values, and to the threats they face, as the NHS is constantly making decisions and dealing with issues that are value laden. Shifts in the underpinning values could, therefore, have significant (and unpredictable) ramifications for the whole system, resulting in significant and undesirable normative re-alignment (Molnár-Gábor, 2020b; Savard, 2013). Or, to put it another way, ethical foresight analysis is essential if policymakers are to avoid a situation in which the NHS becomes a healthcare system that suits the algorithms but is not socially desirable or even acceptable (Robbins, 2020). In short, forewarned is forearmed. By identifying the scenarios that should ideally be avoided, the requirements for the underpinning information infrastructure within which ACDSS will be implemented, to enable the resulting ACDSS-enabled NLHS to benefit from positive intended emergence whilst avoiding the risks of negative unintended emergence can be identified. It is the task of the next chapter to identify these specific requirements.

6. Mind the Gap

6.1 Introduction

The preceding two chapters have concluded the needing moment, or the Originate phase, of the design process. Their combined results have revealed that the NHS's information infrastructure needs a re-design if attempts to implement ACDSS are to succeed. This is because the current information infrastructure design is run-through with disorganised complexity, which is causing two significant problems. First, it is increasing the likelihood of implementation failure and consequently increasing the likelihood that the NHS will miss out on the opportunity to capitalise on the benefits of successful ACDSS implementation. Second, it is exacerbating the harmful re-ontologising potential of negative unintended emergence. It is now clear, therefore, that if this thesis is to achieve its aim of designing the information infrastructure to enable the NHS to capitalise on the dual advantage of ACDSS, then its redesign efforts, or its visioning attempts, must focus on establishing how these complexity-derived risks can be designed out of the NHS's information infrastructure so that the benefits of ACDSS implementation can be realised.

This does not mean that an effort should be made to come up with an information infrastructure design that is 'simple' or devoid of complexity. For the reasons outlined in Chapter One this would likely be a mistake, and result in a repeat of the errors made by system designers in the past that resulted in costly failures like the National Programme for IT. Instead, it is far better to accept the lessons of systems theory and acknowledge that whilst complexity cannot be entirely avoided, it can – as alluded to in Chapter Four – be made more *organised* and so more manageable (McDermid, 2000) .

As explained by Weaver (1948) there is a clear distinction between disorganised and organised complexity. A system plagued by disorganised complexity, such as the NHS's current information infrastructure, is one comprised of interactions between innumerable variables each of which is exhibiting individually erratic, and perhaps even entirely unknown, behaviour. Individuals seeking to understand this kind of complexity often suffer from information overload, and cannot identify adequate solutions to the resultant problems (Glanville, 2008; Salingaros, 2014). In contrast, a system characterised by organised complexity is one comprised of regular, specific, and ordered interactions between a large number of variables, none of which behave in individually erratic or unknowable ways (Paniagua, 2023). Individuals seeking to understand this kind of complexity are far less likely to suffer from information overload, and far more likely to uncover large amounts of 'interesting information.'

Consequently, they are readily able to identify the specific governing rules that will proactively mitigate any risks of failure or harmful re-ontologising emergence (Bawden, 2007; Paniagua, 2023; Salingaros, 2014). It is clear, therefore, that as this thesis enters the second (or Focus) phase of the design process, its ambition must be to develop a vision for a necessarily complex, but organised, NHS information infrastructure design that can ensure the successful implementation of ACDSS. This is the purpose of this chapter: to develop the information infrastructure vision, expressed as vision and delivery information infrastructure requirements, and assess how likely it is that these requirements will be met by current policy. Exactly how this will be done is explained in the next section (section 6.2).

6.2 Method

The process of organising complexity primarily involves reducing the amount of raw information needed to describe the system, by identifying common abstractions and mechanisms that define the rules and positions, rights, and obligations of individual system components so that they can be *re-designed* into an organised structure with clear principles guiding their interactions (Booch & Booch, 2007; Paniagua, 2023; Salingaros, 2014). As highlighted in the literature review in Chapter Two, most previous organisational attempts of this nature have focused on identifying the quantifiable barriers and enablers to AI adoption (e.g., (Barnett et al., 2011; Fujimori et al., 2022; McLachlan et al., 2019; J. Watson et al., 2020). This is a reductionist approach to organising, closely linked to the practices of linear causation, reverse engineering, and waterfall models of system definition and design (Bouch et al., 2015; Paniagua, 2023). In short, it is an approach that assumes simplification is possible and that this can be achieved by extracting quantifiable information about the individual variables (or components) in the system and how they interact (Paniagua, 2023). This might seem reasonable at first glance. However, assuming that complexity can be organised by adopting a reductionist approach to simplification ignores the reality that: (a) some fundamental system components are non-quantitative and so elude easy identification and measurement (Kritz, 2017); and (b) successful system design often involves engaging with and resolving difficult trade-offs that are not surfaced in linear models (McDermid, 2000). This is why, as highlighted in Chapter One, reductionism is inapposite to design.

Unlike the reductionist barriers-and-enablers approach to the organisation of complexity, design-based approaches actively acknowledge the need to see beyond quantifiable variables. This is why (as has been stressed throughout) the main focus of design processes is on the elicitation of requirements: a far broader abstraction that can handle trade-offs; differing stakeholder demands;

various interactions between system components, designers, and users; multiple functions; and the inherent mutability of some variables (Bouch et al., 2015; Maier & Fadel, 2006; Paniagua, 2023). As such, the primary purpose of this chapter is the description and deep analysis of the information infrastructure requirements for successful ACDSS implementation. Specifically, this chapter seeks to answer RQB (i):

> RQB: What are the ideal NHS information infrastructure requirements to enable the successful implementation of ACDSS? How likely is it that these requirements will be met by current policy?

It does this following a multi-stage analysis based on the "Information, Technology, Processes, Objectives, Staffing and skills, Management systems and structures, and Other resources" (ITPOSMO) model developed by Heeks and colleagues (1999). This model was selected because: (i) it is specifically designed to evaluate the planned implementations of healthcare information systems; (ii) it covers each of the success requirements (technically feasible, socially acceptable, ethically justifiable, and legally compliant); and (c) the domains of the model (information, technology etc.) align closely with the domains within the information infrastructure definition given in Chapter One and are henceforth referred to as 'information infrastructure domains'

First, to answer "what are the ideal information infrastructure requirements to enable the successful implementation of ACDSS?" within each of the information infrastructure domains specific limitations of the current information infrastructure design (identified in Chapter Four), were linked to (i) specific risks associated with re-ontologising emergence (identified in Chapter Five); (ii) a high-level vision requirement summarising what the system (ACDSS-enabled NLHS) needs to be provided with to mitigate these risks and capitalise on the benefits of ACDSS; and (iii) a series of specific requirements that the information infrastructure design must deliver if this vision requirement is to be realised. This layered approach was adopted to ensure the requirements elicited are specifically tied to the aim, to design an information infrastructure that enables the NHS to benefit from the dual advantage of ACDSS: capitalising on positive intended emergence and proactively mitigating the risks of negative unintended emergence. All the requirements were derived from an inductive thematic analysis of the semi-structured interviews and the literature included in the realist review.

Second, to answer "how likely is it that these requirements will be met by current policy?", each of the policy documents identified in the search described in Chapter Three were reviewed in

detail, to see if any of the rhetorical statements (i.e., the NHS will deliver _); policy commitments (i.e., by 2025 all NHS hospitals will have _); policy goals and aims (i.e., the ambition is for the NHS to become _); or guidelines (i.e., developers of NHS technology must _), aligned with the delivery requirements necessary to meet the vision requirement. In other words, each of the policy documents was searched to see if its contents indicated that the relevant ideal requirements might be met by current policy. A gap score, ranging from 0-10 (with 0 representing no difference between ideal requirements and policy reality, 5 representing some difference, and 10 representing complete and radical difference) (Gomez & Heeks, 2016) was then assigned to each Information Infrastructure domain, representing what Ackerman (2000) describes as the sociotechnical gap or "the divide between what we know we must support socially [the ideal requirements] and what we can support technically [the requirements covered by policy]" (Ehsan et al., 2023).

This analysis results in (i) a vision for what the system (ACDSS-enabled NLHS) requires from its information infrastructure if it is to capitalise on the dual advantage of ACDSS; and (ii) a realisation that these requirements are unlikely to be met by current policy unless action is taken to close the sociotechnical gap. The following pages will now describe these results in detail.

6.3. Results and discussion: from epistemic certainty to meaningful accountability

The results of the analysis above will now be discussed. For clarity, each of the first six domains of the ITPOSMO model ('other' is excluded) is discussed in sequence, and in isolation. The discussion within each domain also follows a consistent structure, mirroring the steps of the analysis described above. First, a summary of the relevant areas of disorganised complexity (from chapter four), and resultant risks of unintended re-ontologising emergence (chapter five) is presented. This is used to lead into the ideal vision requirement for each domain which is introduced second. In each instance, the ideal vision requirement is intended to summarise what a re-designed NHS information infrastructure must provide the desired ACDSS-enabled NLHS if it is to capitalise on the benefits of intended emergence and mitigate the risks of unintended emergence (i.e., if the NHS is to capitalise on the dual advantage of ACDSS). Third, each of the delivery requirements (i.e., what the information infrastructure is required to deliver if the vision requirement is to be realised) is described in turn, and the likelihood of these requirements being met by current policy developments is discussed. Finally, a sociotechnical gap score for each domain is provided. This may make the narrative feel formulaic in places – this is by design, to make the volume of included information easier to navigate. The

concluding discussion summarises the findings, introduces the average 'gap' score, and discusses what must be done next.

6.3.1 Information

6.3.1.1 Ideal requirements: guaranteeing epistemic certainty

In the context of ACDSS, there are two relevant components to the 'Information' (or clinical content to return to the definition in Chapter One) information infrastructure domain:

1. Training data: patient data such as X-Ray images or Electronic Health Record (EHR) data used to train the ACDSS knowledge engine algorithms).
2. Output data: medical advice produced by ACDSS such as a diagnosis or a risk score.

Chapter Four revealed that both components are negatively impacted by the disorganised complexity plaguing the current information infrastructure design. Specifically, section 4.2.2, highlighted the fact that because all NHS data is technically administrative data, is predominantly 'quantitative' and can be fraught with problems of error, missingness, and messiness which can negatively affect both the quality and quantity of training data available. Section 4.2.2 also highlighted the fact that the current user experience of ACDSS is poor, and section 4.2.4 stressed that clinicians do not receive sufficient training on using ACDSS, design issues that can negatively affect the interpretability of output data.

Chapter Five then revealed that these design flaws related to the quality, quantity, and interpretability of ACDSS input and output data, may increase the risk of negative re-ontologising emergence related to the NHS's commitment to providing excellent care for all. On one hand, problems related to the quality and quantity of training data may increase the risk of ACDSS being informed by biased algorithms that police patients to meet baseline norms that will never be achievable given their circumstances resulting in the patients being categorised as 'bad patients' less deserving of care (sections 5.3.1.1, 5.3.1.2, 5.3.3.1). On the other hand, problems with the interpretability of output data may result in a loss of quality interaction between patients and clinicians, lessening their ability to equally engage in the sharing of information for the purpose of reaching a mutually agreeable treatment plan, and so undermining the trust that needs to exist between the two for the patient to benefit from a positive experience of care (section 5.3.2.2)

To avoid these risks of negative re-ontologising emergence, whilst enabling the NHS to capitalise on the benefits of positive intended emergence, the NHS information infrastructure needs

to be redesigned so that it provides the system (the desired ACDSS-enabled NLHS) with epistemic certainty (I27, Interview, 26 October 2022; I66, Interview, 21 November 2022). More specifically:

> *Vision Requirement 1*
> To avoid the risks of negative re-ontologising emergence associated with the impacts of disorganised complexity in the NHS's information infrastructure on ACDSS (i)training data and (ii)output data, the NHS's information infrastructure needs to be re-designed to provide the system with epistemic certainty. This is so that clinicians are confident ACDSS outputs are valid, valuable, and constructed to improve their capacity to make shared decisions that will ultimately lead to better outcomes for their patients.

Realising this vision requirement, requires all those responsible for creating, curating, and collating NHS datasets that become ACDSS inputs to accept 'epistemological responsibility' (Baalen et al., 2021). All relevant stakeholders must acknowledge the fact that to "create, or fail to correct datasets, that are of poor quality, incomplete, or unrepresentative is not merely a technical issue but an ethical concern" (S. S.-J. Lee, 2021, p. 59). Additionally, it requires that all those responsible for designing the frontend aspects of ACDSS, including the user interface, the information presentation, and the workflow timing, acknowledge that if ACDSS is to gain the acceptance and trust of clinicians (and patients) it must be designed to deliver information in a way that supports, rather than undermines, their cognitive workflows and mental models (Rezaei-Yazdi & Buckingham, 2018) (I7, Interview, 17 October 2022). More precisely:

> *Epistemic certainty delivery requirements*
> To provide the system with epistemic certainty, the NHS's information infrastructure must deliver consistently good data quality, sufficient data quantity, and reliable data interpretability.

Table 19 summarises these ideal information vision and delivery requirements before the next section analyses how likely it is that they will be met by current policy.

Current information infrastructure design flaw(s)	Associated risk(s) of re-ontologising emergence	Vision Requirement	Delivery Requirements
• Administrative data that may be biased, messy, error-prone, or plagued by missingness being used to train ACDSS models. • Clinicians using ACDSS that provides a poor user experience with limited training.	• ACDSS trained on biased, overly quantitative, or potentially inaccurate data, may result in some patients or groups of patients being unethically. classified as bad patients. • Uninterpretable ACDSS outputs might hinder open information exchange between patients and clinicians, preventing the formation of trusted relationships, and reducing the quality of care.	• Epistemic certainty: clinicians are confident ACDSS outputs are valid, valuable, and constructed to improve their capacity to make shared decisions that will ultimately lead to better outcomes for their patients.	• Consistently good data quality, • Sufficient data quantity. • Reliable data interpretability.

Table 19. Summary of the "Information" information infrastructure domain current design flaws, associated risks, and ideal vision and delivery requirements.

6.3.1.2 Requirements covered by policy: only data quantity is on the radar

It has now been established that to provide the system with epistemic certainty, an information infrastructure that delivers consistent data quality, sufficient data quantity, and reliable data interpretability, is required. Rhetorical and thematic policy analysis reveals that whilst there is some alignment in current policy with the data quantity requirement, there is little to no alignment with – or even recognition of – the data quality and data interpretability requirements. It seems, therefore, unlikely that the epistemic certainty requirement will be met.

To start with the requirement for sufficient data quantity. Ideally, for data quantity to be sufficient to train ACDSS, it needs to be representative of the population that the ACDSS will be used to 'treat' once deployed. This is to mitigate the risks of epistemological bias as far as possible, by ensuring all potential types of patient (gender, ethnicity, disease profile, age, multi-morbidities, and more) are included 'in-sample' at the point of training, so that there are no 'out-of-sample' drops in performance at the point of care (Challen et al., 2019; I2, Interview, 17 October 2022; I7, Interview, 17 October 2022). *The Life Sciences Industrial Strategy* (Bell & Office for Life Sciences, 2017), NHS data strategy (*Data Saves Lives*) (Department of Health and Social Care, 2022e) and report from the CQC's Regulatory Sandbox regarding the use of Machine Learning in diagnostic services (MHRA & CQC, 2022), all refer to the need to create population datasets or at-scale datasets implying a recognition of the requirement to provide ACDSS developers with access to sufficient, and sufficiently representative,

data. In addition, the 2021-2022 implementation plan for Genome UK (Department of Health and Social Care et al., 2021) includes a commitment to rolling out genome sequencing to a wider proportion of the population for the purpose of improving the representativeness of genomic data in terms of ethnicity and rare disease diagnoses. This is, however, the closest any of the policies get to recognising the need to consider more nuanced aspects of representativeness, such as case representativeness (i.e., the number of patients with a specific condition in a training dataset). Furthermore, there appears to be an assumption that the need to improve representativeness applies only to clinical (e.g., Electronic Health Record) and genomic datasets. There is no acknowledgement of the fact that the digital divide might mean that other datasets which are alluded to, for example data from wearables (referenced by *A Plan for Digital Health and Social Care* (Department of Health and Social Care, 2022a)), may also need augmenting before they can be considered representative. Thus, whilst there is some recognition of the requirement to provide ACDSS developers with access to sufficient data quantity, the meaning of this requirement is far narrower in a policy context than it is in the ideal context.

Moving to data quality. Data quality is an aggregate measure of the extent to which a dataset is 'fit for purpose,' or the extent to which the data is 'doing what you think it's doing' (I21, Interview, 21 October 2022). Ideally, good quality datasets are those that are complete with all necessary features; free from duplicates ('unique'); up-to-date and readily accessible at the point of need ('timely'); accurate according to an agreed source of truth; concordant (e.g., blood cell count is recorded in a standard format across all data-sources); plausible (i.e. capable of accurately representing the real-world object or construct it is linked to); and, relevant to or suitable for the task at hand (Bian et al., 2020). To provide consistently good data quality would require system-wide commitment to data standardisation, curation, and documentation (Goldacre & Morley, 2022). This is not acknowledged in the current policy documents. The importance of data quality is recognised in the cross-government *Data Quality Framework* (Government Data Quality Hub, 2020) which requires all government data projects to 'commit to data quality.' However, what exactly this means is not made explicit and is not further contextualised in any of the other more health-specific policies. Furthermore, there is very limited recognition of the need to standardise and improve the curation, standardisation, and documentation of existing datasets. There is a brief reference to the importance of curation in the *National AI Strategy* (Office for Artificial Intelligence et al., 2021) which states that the Office for AI "will consider what valuable datasets the government should purposefully incentivise or curate that will accelerate the development of valuable AI applications." Additionally, the *Women's Health Strategy* (Department of

Health and Social Care, 2022d), *Social Care Reform White Paper*(Department of Health and Social Care, 2021b) and *Data Saves Lives* (Department of Health and Social Care, 2022e) all reference the need to improve the recording of demographic and social care data. However, there is no mention of how this might be done, how it might be funded, or how current missingness incidences caused by poor data collection might be overcome in the interim.

Finally, to data interpretability. In an ideal sense, providing reliable data interpretability from ACDSS requires NHS information infrastructure that ensures: (a) ACDSS delivers the right information, at the right time, in the right intervention format, at the right time in the workflow, using the right channel (Cánovas-Segura et al., 2023; Olakotan & Yusof, 2020); and (b) the advice provided by ACDSS is explainable (Char et al., 2020b; Eardley et al., 2023; the Precise4Q consortium et al., 2020). None of the five rights are mentioned in current policy either explicitly or implicitly. Explainability does feature in both *the Data Ethics Framework* (Central Digital and Data Office, 2020) and in the policy document produced for the G7 "*Principles for the evaluation of AI or ML-enabled Medical Devices to assure safety, effectiveness, and ethicality*" (Department of Health and Social Care & G7, 2021). However, in both instances this is a very high-level acknowledgement of the concept of explainability, not what it means in practice either in terms of acceptable explainability techniques or what level of explanation a clinician might need at the point of care. This leaves data interpretability in the overall weakest position from a policy perspective.

Overall, the current policy requirements for both data quality and data quantity are overly narrow, missing many key aspects and providing little to no guidance to ACDSS developers on *how* exactly they might translate these principal requirements into practical design decisions. Moreover, the policy requirements for data interpretability are almost entirely missing. The connection between epistemic certainty and data interpretability, data quantity, and data quality is never made. It can, therefore, be concluded that the sociotechnical gap between the ideal Information information infrastructure requirements and the Information requirements covered by policy is moderate and can be quantified with a gap score of 6**.** This suggests that it is relatively unlikely that the ideal Information requirements for NHS information infrastructure will be met.

6.3.2 Technology

6.3.2.1 Ideal requirements: guaranteeing robust information exchange

As with the Information domain, there are two distinct components to the 'Technology' (or hardware and software, and human computer interface, to return to the definition in Chapter One) information infrastructure domain:

1. Backend: the underpinning hardware and software supporting the development of ACDSS, such as data access mechanisms.
2. Frontend: the hardware and software supporting the deployment of ACDSS at the point of care, such as EHR integration mechanisms.

Again, chapter four revealed that both components are negatively impacted by the disorganised complexity plaguing the current information infrastructure design. Sections, 4.2.2 and 4.3.5 outlined the implementation problems raised by the unnecessarily complex and non-transparent ACDSS development pipeline, lack of interoperability between NHS systems, and legacy technology architecture. Of particular concern, is the fact that ACDSS implementation first needs access to very large volumes of potentially highly sensitive information for algorithm training purposes, and second needs to be integrated into live clinical systems to gain access to patient-level data in real-time. Without this access to patient data at either end of the implementation pipeline, ACDSS would not be able to provide clinicians with advice tailored to the specific patient. However, current disorganised complexity, and consequential lack of data access mechanisms and interoperability, means that this 'access' typically relies on a significant number of insecure information flows that are poorly controlled and rarely audited (section 4.2.6) (Goldacre & Morley, 2022; Zhang, Morley, et al., 2023).

Chapter Five revealed that these design flaws related to data access and exchange as well as interoperability and integration (backend and frontend hardware and software) may increase the risk of negative re-ontologising emergence related to the NHS's commitment to patient centricity and the value of the fundamentals of caring. Problems related to the lack of control patients have over how their data or their 'data self' is being manipulated or used to inform their care, can undermine patients' right 'not to know' and threaten privacy. This, in turn, can damage the psychological integrity of patients and undermine their autonomy (section 5.3.1.3). In addition, the greater involvement of private third parties in the collection, curation, and use of NHS patient data may change power dynamics in ways that impact trust in the system, and trust between patients and clinicians – particularly if this involvement invokes concerns regarding surveillance of both patients and clinicians

(section 5.3.2.1). Finally, all these problems may be exacerbated by the fact that the system may struggle to identify and correct any breaches of privacy or trust, as the complexity of the development pipeline and corresponding data flows may challenge current models of accountability (section 5.3.2.3).

To avoid these risks of negative re-ontologising emergence, whilst enabling the NHS to capitalise on the benefits of positive intended emergence, the NHS information infrastructure needs to be redesigned so that it provides the system with robust information exchange between all stakeholders involved in the ACDSS implementation pipeline (Detmer, 2003; Dixon & Grannis, 2020; Mashima & Ahamad, 2012; Praveen et al., 2022). More specifically:

> *Vision requirement 2*
> To avoid the risks of negative re-ontologising emergence associated with the impacts of disorganised complexity in the NHS's information infrastructure on ACDSS (i) backend and (ii) frontend, the NHS's information infrastructure needs to be re-designed to provide the system with robust information exchange. This is so that ACDSS facilitates the trustworthy and caring exchange of information (e.g., symptoms diagnoses, treatments, phenotype profiles, genotype profiles) between patients (at both an aggregate and individual level) to (a) ACDSS developers; (b) policymakers and regulators responsible for determining the standards of care; and (c) clinicians on the frontline (Detmer, 2003; Dixon & Grannis, 2020; Mashima & Ahamad, 2012; Praveen et al., 2022)..

Realising this vision requirement first requires the development of mechanisms that ensure as much health data is recorded as accurately and comprehensively as possible at source, in a way that also does not interfere with or undermine the compassionate and caring exchange of information between clinician and patient in a clinical consultation, to minimise the need for multiple separate sources of data (i.e., well-designed EHRs). Second, to enable the exchange of information with ACDSS developers for training purposes, it requires (a) investment in privacy preserving data access mechanisms that minimise the need for the NHS to rely on privacy-infringing deidentification and dissemination methods of exchange; and (b) system-wide protection from vendor lock-in to prevent NHS data assets becoming ever-more siloed. Third, to ensure clinicians can exchange information with ACDSS at the point of care, again without interrupting the caring exchange of information between patient and clinician, it requires ACDSS to be seamlessly integrated into existing clinical systems. More precisely:

Information exchange delivery requirements

To provide the system with robust information exchange, the NHS's information infrastructure must deliver comprehensive user-friendly electronic health records, privacy preserving data access mechanisms, seamless ACDSS system integration, and system-wide protection from vendor lock-in.

Table 20 summarises these ideal technology vision and delivery requirements before the next section analyses how likely it is that they will be met by current policy.

Current information infrastructure design flaw(s)	Associated risk(s) of re-ontologising emergence	Vision Requirement	Delivery Requirements
• The implementation of ACDSS involves the exchange of large volumes of sensitive patient data between a significant number of stakeholders – including Government stakeholders and private third-party stakeholders. This exchange currently relies on insecure, non-transparent, and rarely audited data flows. • To be useful at the point of care, ACDSS must also be integrated directly into clinical systems and provided with access to live patient data for the purpose of providing personalised advice. This is currently hindered by issues of interoperability and legacy technology.	• Relying on poorly controlled, privacy-threatening, data flows for the exchange of information between key stakeholders in the ACDSS implementation pipeline, can leave patients unsure about what is happening to their data self – a fact that can damage their psychological integrity, undermine autonomy, and threaten trust. • Large numbers of uncontrolled and non-audited data flows between the NHS and private third parties, can also change power dynamics in ways that leave both patients and clinicians feeling surveilled. • Lack of clear accountability mechanisms makes it difficult to locate and correct breaches of privacy or trust.	• Robust information exchange: ACDSS facilitates the trustworthy and caring exchange of information (e.g., symptoms diagnoses, treatments, phenotype profiles, genotype profiles) between patients (at both an aggregate and individual level) to (a) ACDSS developers; (b) policymakers and regulators responsible for determining the standards of care; and (c) clinicians on the frontline.	• User friendly EHR design. • Privacy-preserving data access mechanisms. • Seamless ACDSS system integration. • System-wide protection from vendor lock-in.

Table 20. Summary of the "Technology" information infrastructure domain current design flaws, associated risks, and ideal vision and delivery requirements.

6.3.2.2 Requirements covered by policy: prioritising data access

It has now been established that to provide the system with robust information exchange, an information infrastructure that delivers user-friendly EHRs, privacy-preserving data access

mechanisms, seamless ACDSS integration, and system-wide protection from vendor lock-in is required. Rhetorical and thematic policy analysis reveals a growing focus on the hardware and software needed to support the development of ACDSS in the backend, with privacy-preservation being a noteworthy policy priority of the last couple of years. However, the hardware and software needed to support the implementation and seamless integration of ACDSS in the frontend is not benefiting from the same level of policy consideration. As such, it cannot yet be concluded that there is sufficient attention being paid to the need for robust information exchange between all stakeholders in the ACDSS implementation pipeline.

To start with the comprehensive user-friendly EHR requirement. Ideally, this requires co-designing, with clinicians, a standardised EHR template (or templates for different clinical settings) that (a) finds an appropriate balance between providing a good user experience and enabling the capture of the full complexity of clinical encounters (I4, Interview, 17 October 2022); and (b) makes good (high-quality and comprehensive) data capture a simple by-product of the 'day job' for clinicians rather than an additional unnecessarily burdensome task (I33, Interview, 28 October 2022). This should lessen the chances of crucial information going unrecorded or being recorded inaccurately (I4, Interview, 17 October 2022; I65, Interview, 18 November 2022).

Important as ensuring EHR design enables the accurate and comprehensive recording of clinical information is, current policy is still primarily focused on ensuring all NHS organisations have access to an EHR rather than prioritising the design quality (or even standardisation) of said EHRs. For example, *A Plan for Digital Health and Social Care* (Department of Health and Social Care, 2022a) includes the aim to ensure 90% of NHS Hospital Trusts have an EHR by the end of 2023 and 80% of registered adult social care providers have digital records by 2025. The only policy statements, commitments or guidelines that come close to the user-friendly EHR design are those that relate to user-centric design in general. For instance, the *NHS Long-Term Plan* (NHS England, 2019) includes the ambition that 'patients, clinicians, and the carers working with them will have technology designed to help them,' and *A Guide to Good Practice for Digital and Data-Driven Health Technologies* (Department of Health and Social Care, 2021a)includes the top-level guideline 'ensure that the product is easy to use and accessible to all users'. The difficulty experienced by software developers translating between such high-level principles and practical design means that the impact of such abstract policy statements is likely to be limited.

Moving to the privacy-preserving data access mechanisms requirement. Ideally, privacy-preserving data access requires the development of secure platforms (or Trusted Research

Environments (TREs)) that are capable of technically implementing the principle of confidentiality to balance the need to protect individual patient privacy with the potential societal benefit derived from ACDSS development, whilst also being technically capable of supporting the use of AI. Ideally, the exact way in which TREs achieve this goal should be agreed by a representative group of stakeholders, to ensure the final standardised TRE design satisfies patients, clinicians, regulators, and ACDSS developers (Goldacre & Morley, 2022; I20, Interview, 21 October 2022; Riso et al., 2017; Stockdale et al., 2019; Williams & Pigeot, 2017).

Unlike EHR design, the importance of privacy-preserving platforms has received significant policy attention in recent years. The *Life Sciences Vision* (Department for Business, Energy, and Industrial Strategy & Office for Life Sciences, 2021)*, Genome-UK implementation plan* (Department of Health and Social Care et al., 2021)*, A Plan for Digital Health and Social Care* (Department of Health and Social Care, 2022a)*,* and the *Secure Data Environments for NHS Health and Social Care Data Policy Guidelines* (Department of Health and Social Care, 2022c) all reference the need for – and signal an intention to build – privacy-preserving secure data platforms. Indeed, the *Secure Data Environments for NHS Health and Social Care Data Policy Guidelines* (Department of Health and Social Care, 2022c) state that Secure Data Environments (the NHS's term for TREs) will become the default way to access NHS Health and Social Care Data for research and analysis. This suggests that, at a high level at least, the requirement might be met. However, what is currently lacking is clarity and specificity regarding the exact technical specifications that will be required or mandated of NHS SDEs. Without this level of detail, it is not clear whether the NHS SDEs that are currently in development will be technically capable of supporting the development and training of the more complex models (i.e., unsupervised machine learning models) that typically 'drive' the knowledge engines of ACDSS. Indeed, some suggest that they might not be (C. (Xaroula) Kerasidou et al., 2023). Furthermore, the need for these platforms to be designed, built, and deployed in a way that is considered socially acceptable appears to have gone largely unrecognised, or at least underestimated, by current policy developments (I7, Interview, 17 October 2022; I38, Interview, 31 October 2022; I54, Interview, 9 November 2022). It is, for example, widely believed that a £480 million contract for a national 'NHS Federated Data Platform' will be awarded to the American company Palantir, despite significant public reservations about NHS data being 'owned' or accessed by private foreign companies that are perceived to prioritise profit over public good (Foxglove Legal & Doctors' Association UK, 2023) (more on this in Chapter Eight).

Finally, to the seamless system integration and protection from vendor lock-in requirements. Ideally this requires: (a) semantic interoperability so that different components of the NHS's technical information infrastructure – including different ACDSS – can exchange information in way that ensures the receiving component interprets the information as the transmitting component intended (Ahmadian et al., 2011; Stevens et al., 2022; Verheij et al., 2018): and (b) a commitment to modularity, open-source software development, and non-exclusive contracts (Amarasingham et al., 2014; Bettencourt-Silva et al., 2012; Blaser et al., 2007; Bucur et al., 2016). Meeting these requirements should help make the ACDSS development pipeline more efficient and encourage competition between ACDSS developers, (hopefully) leading to better performing ACDSS overall.

This connection between interoperability, modularity, open contracting, and successful ACDSS implementation is not well recognised by current policy. Although *Data Saves Lives* (Department of Health and Social Care, 2022e) commits to ensuring that 'the data architecture underpinning the health and social care system can easily work together to make more effective and efficient use of data', and *Health and Social Care Integration: joining up care for people, places, and populations* (Department of Health and Social Care, 2022b)explicitly acknowledges the fact that (algorithmic) clinical decisions support tools must be embedded within electronic health records to improve clinical outcomes and reduce unwarranted variations in care, the two 'requirements' are not connected. This could lead to issues of contradiction or poor implementation. Similarly, whilst there are several high-level commitments to open-source and modularity—for example *The Technology Code of Practice* (Central Digital and Data Office, 2021) includes the guidelines 'be open and use open source' and 'make use of open standards'—these requirements are rarely explicitly attached to health technology, and come with no guidance on how alignment with these commitments might actually be achieved. Finally, beyond the requirement to 'not prevent the use of data for other beneficial purposes' included in *Data Sharing Governance Framework* (Central Digital and Data Office, 2022), none of the included documents directly acknowledge the importance of preventing vendor lock-in and exclusive contracts. Current policy would, for example, allow one EHR provider to prevent the integration of an ACDSS developed by a different EHR provider or different technology company even *if* it had been proven safe, effective, and beneficial. This is problematic because, for equality and equity purposes, all patients should be able to benefit from all potentially beneficial ACDSS, regardless of whether they are registered at a practice with EHR software provided by company A or company B. Allowing EHR providers to block the integration of ACDSS developed by external parties would prevent this from

being possible. In such an instance, rather than reducing unwarranted variations in care, the implementation of ACDSS would exacerbate it.

Overall, the current policy requirements for EHR design, privacy-preserving data access, and system integration are mixed and lacking in specificity. General digitisation ambitions (i.e., ensuring all NHS organisations have an EHR) are prioritised above all other priorities including interoperability and ACDSSS implementation, and whilst the 'what' of privacy preserving platforms has now been acknowledged this has not yet been translated into a 'how' that would meet the overarching success criteria. Perhaps most crucially, none of the connections between these different 'technology requirements' are acknowledged, creating ample opportunity for contradictions to arise. It can, therefore, be concluded that the sociotechnical gap between the ideal Technology information infrastructure requirements and the Technology requirements covered by policy is also moderate and can be quantified with a gap score of 6. Again, this suggests that it is relatively unlikely that the ideal Technology requirements for NHS information infrastructure will be met.

6.3.3 Process

6.3.3.1 Ideal requirements: guaranteeing validated outcomes

There are multiple components to the 'Process' (or system measurements and monitoring to return to the information infrastructure definition in Chapter One) information infrastructure domain. This is because it encompasses all the stages involved in the ACDSS lifecycle, from defining the purpose of the ACDSS to ongoing impact evaluation after it has been deployed (Amarasingham et al., 2014; De Silva & Alahakoon, 2022).

Chapter Four revealed that this entire lifecycle is negatively impacted by the disorganised complexity currently plaguing the information infrastructure design. Specifically, section 4.3.3. revealed that the entire process from ideation through to post-deployment monitoring lacks standardisation, systemisation, and rigour. (I50, Interview, 7 November 2022). There is no standardised method for verifying, validating or evaluating the performance of ACDSS either 'in-silico' in the lab or 'in-socio' in clinical settings; the evidence base supporting claims that ACDSS can genuinely improve patient and system outcomes is extremely poor; the black box nature of many ACDSS algorithms makes their interrogation difficult; and the overall value proposition of ACDSS to the NHS – particularly to clinicians who have a duty of care to their patients – is limited.

Chapter Five revealed that these design flaws related to the lack of rigour surrounding the ACDSS lifecycle, and the consequential poor quality evidence base, may increase the risk of negative

re-ontologising emergence related to the NHS's commitment to patient centricity, the fundamentals of caring, and available to all. First, sections 5.3.1 and 5.3.1.2, highlighted the fact that at the core of patient centricity, is a commitment to the tenets of evidence-based medicine and informed consent. A lack of evidence surrounding the genuine benefits of ACDSS means its use may undermine – rather than enhance – the commitment of clinicians to practicing according to the tenets of evidence-based medicine, and clinicians cannot explain clearly and transparently to their patients the risks and benefits of a treatment plan that involves the advice of ACDSS if these risks and benefits are unknown. In addition, if there is a lack of evidence supporting the ability of ACDSS to genuinely deliver improvements in patient outcomes via its advice, it may be that it is providing advice that is inappropriate for specific patients – offering advice that they cannot act on, for example. As discussed above, this may limit patients' ability to satisfactorily fulfil the sick role and so may lead to them becoming classified as bad patients. Next, section 5.3.2.1 stressed that as part of the commitment to the fundamentals of caring, clinicians are required to uphold the Hippocratic oath 'do no harm' by fulfilling their role as learned intermediaries. If clinicians are unaware how ACDSS works, and do not know, for instance, how well calibrated it is and therefore how likely it is that it might lead harms related to false positives (overdiagnosis), then this may undermine their ability to fulfil their learned intermediary role. Finally, section 5.3.3.2, highlighted the potential for ACDSS use to exacerbate the impacts of the inverse data law on unwarranted variations in care. If ACDSS is not subject to rigorous and robust post-deployment monitoring, the impact of such effects may never become known or corrected.

To avoid these risks of negative re-ontologising emergence, whilst enabling the NHS to capitalise on the benefits of positive intended emergence, the NHS information infrastructure needs to be redesigned so that it provides the system with validated outcomes. More specifically:

> *Vision requirement 3*
>
> To avoid the risks of negative re-ontologising emergence associated with the impacts of disorganised complexity in the NHS's information infrastructure on the quality of evidence supporting claims of ACDSS efficacy and safety, the NHS's information infrastructure needs to be re-designed to provide the system with validated outcomes. This is so that ACDSS enables clinicians to uphold and enhance the tenets of evidence-based medicine, to ensure all care in the NHS is delivered to an appropriate standard following the best evidence to deliver the best possible health outcome for the specific patient in question.

Realising this vision requirement, requires the coming-together of key stakeholders to develop procedures, protocols and standards that: (a) span the entire ACDSS implementation pipeline from ideation and identification of outcomes, to model selection, development, and testing, to implementation, and ongoing use; and (b) cover everything from 'best modelling practices' to 'guidelines for independent ACDSS evaluation' (Amarasingham et al., 2016). More precisely:

> *Validated outcomes delivery requirements*
> To provide the system with validated outcomes, the NHS's information infrastructure must deliver clearly stated clinical outcomes, mindful model development, rigorous technical validation, rigorous clinical evaluation, careful local calibration, and ongoing impact evaluation.

Table 21 summarises these ideal process vision and delivery requirements before the next section analyses how likely it is that they will be met by current policy.

Current information infrastructure design flaw(s)	**Associated risk(s) of re-ontologising emergence**	**Vision Requirement**	**Delivery Requirements**
• The lack of standardisation, systematisation, and rigour surrounding the entire ACDSS implementation process (or ACDSS lifecycle) from ideation through to post-deployment monitoring, is resulting in a poor-quality evidence base supporting claims that ACDSS can genuinely deliver improvements in patient and system outcomes safely.	• Poor quality evidence regarding the benefits and risks of ACDSS use, as well as the efficacy of its advice, can undermine the extent to which patients are able to give informed consent and may result in patients being given inappropriate advice. This may negatively affect the NHS's commitment to patient centricity. • Poor quality evidence undermines clinicians' ability to abide by the principles of evidence-based medicine and to fulfil their role as learned intermediaries. This may negatively affect the NHS's commitment to the fundamentals of caring. • Lack of structured monitoring post-deployment may mean negative impacts of	• Validated outcomes: ACDSS enables clinicians to uphold and enhance the tenets of evidence-based medicine, to ensure all care in the NHS is delivered to an appropriate standard following the best evidence to deliver the best possible health outcome for the specific patient in question.	• Clearly stated clinical outcomes • Mindful model development • Rigorous technical validation • Rigorous clinical evaluation • Careful local calibration • Ongoing impact evaluation.

	ACDSS use on unwarranted variations in care go unnoticed and un-rectified.		

Table 21. Summary of the "Process" information infrastructure domain current design flaws, associated risks, and ideal vision and delivery requirements.

6.3.3.2 Requirements covered by policy: clinical outcomes are not user needs

It has now been established that to provide the system with validated outcomes, an information infrastructure that delivers clearly stated clinical outcomes, mindful model development, rigorous technical validation, rigorous clinical evaluation, careful local calibration, and ongoing impact evaluation, is required. Rhetorical and thematic policy analysis reveals that whilst there is a high-level acknowledgement of the importance of each individual stage in the ACDSS lifecycle, there is less awareness of the need to define a standardised end-to-end process that will result in validated outcomes for NHS patients.

To begin with the requirement to start the ACDSS lifecycle with a clearly stated clinical outcome. More than simply stating that the ACDSS is, for example, designed to screen patients for risk of developing Type II Diabetes, ideally this requires ACDSS developers to collaborate closely with clinicians and commissioners ("co-design" (Donia & Shaw, 2021)) to identify: (a) a clinical problem, the diagnosis, treatment, or prediction of which could be improved with the introduction of ACDSS (J. A. Balch & Loftus, 2023; Cresswell & Sheikh, 2016; Crigger et al., 2022; P. S. Hall & Morris, 2017); (b) the appropriate care pathway, and point in that care pathway, into which ACDSS would be implemented (Booth, 2003; Dent & Tutt, 2014; Eason et al., 2013; González-Ferrer et al., 2013); (c) the specific measurable clinical outcome that is expected to be achieved for patients (e.g., X% reduction of risk) and for the learning healthcare system (e.g., X% reduction in incidence, X% reduction in costs of care for X) (McCartney & Berman Brown, 1999; Pai et al., 2014; Paulus & Kent, 2020); and (d) the cost benefit ratio of achieving these outcomes via ACDSS (Ji et al., 2021; T. H. Wagner et al., 2020). This should ensure that from the outset there is a clear link between system need (i.e., cost reduction, efficiency improvement, better patient satisfaction), clinical outcome, care pathway, and clinical intervention (ACDSS). It should also help prevent any situations in which ACDSS is developed either based on a misunderstanding of the causality of a particular clinical problem, or with the intention of targeting an unachievable or undesirable outcome (I7, Interview, 17 October 2022; I29, Interview, 27 October 2022).

To an extent, the importance of drawing a clear line from system need, to ACDSS intervention, to defined clinical outcome is recognised in current policy. For instance, the *Evidence Standards for Digital*

Health Technologies (NICE, 2022) state that digital health technologies (including AI) must have a clearly intended purpose target population, care pathway, and a clear plan for achieving cost-effectiveness. The *NHS Long-Term Plan* (NHS England, 2019) and the *Life Sciences Vision* (Department for Business, Energy, and Industrial Strategy & Office for Life Sciences, 2021) also stress the importance of aligning AI with clearly defined clinical pathways. However, it is more common for current policy to stress the importance of designing for user needs, and the importance of involving clinicians and commissioners from the start of the lifecycle goes largely unacknowledged.

Moving to the requirement to ensure the model(s) embedded within the ACDSS knowledge engine are developed mindfully. Ideally, this requires a high-level acknowledgement of the fact that each decision about which model to use, which training data set to select, which features to include, whether to optimise for accuracy, explainability, or efficiency, and so on, has an impact on the ability of ACDSS to deliver the desired outcome. More specifically, it requires purposeful model selection (in terms of what type of model to be used) and intentional feature selection and enrichment (I47, Interview, 4 November 2022), with consideration being given at each stage to key trade-offs (Zikos, 2017), as well as the clear and open documentation of all these decisions (McCradden, Joshi, et al., 2020).

Unlike the clearly stated outcome requirement, this mindful model development requirement is almost entirely absent from current policy. Guideline documents *Assessing if AI is the Right Solution* (Central Digital and Data Office & Office for Artificial Intelligence, 2019a) and *Good Machine Learning Practice for Medical Device Development: Guiding Principles* (MHRA, 2021b) note the importance of "choosing the right model for the challenge" and "ensuring model design is tailored to the available data and reflects the intended use of the device." However, there is no guidance on what this means, no acknowledgement of the fact that decisions regarding model selection and model design might impact negatively on other requirements, no requirement to document decisions for reproducibility and inspection purposes, and no acknowledgement of the fact that some types of models come with additional considerations (for example, unsupervised models are harder to validate).

Next, to the rigorous technical validation and rigorous clinical evaluation requirements. Ideally this requires the development of a standardised (and enforced) validation and evaluation protocol which ensures all ACDSS are: (i) subject to multiple rounds of internal, temporal, and external validation (Lisboa, 2002) to determine the strengths and weakness of the knowledge engine algorithms in terms of accuracy, robustness, and comparative performance against a 'gold-standard' benchmark (Bulgarelli et al., 2020; I39, Interview, 31 October 2022); and (ii) subject to a multi-phase clinical

evaluation to generate evidence of efficacy in a trial setting and in a 'real-world' setting (Bindels et al., 2001; Kyrimi et al., 2021; P. L. Miller, 1986; Ngiam & Khor, 2019a). Ideally, the results of all these 'tests' should be published openly.

At a high level, the importance of these validation and evaluation requirements is well recognised in current policy. *A Plan for Digital Health and Social Care* (Department of Health and Social Care, 2022a), for example, includes a commitment to "develop unified standards for the efficacy and safety testing of AI solutions working the MHRA and NICE" and the *Evidence Standards for Digital Health Technologies* (NICE, 2022) includes the requirement that "digital health technologies must provide evidence of the digital health technology's effectiveness to support its claimed benefits." However, there are several crucial deficiencies in the current policy requirements. First, validation is simplified to mean validating the performance of an algorithm against a sub-set of the training dataset to see if the 'accuracy' declines on the unseen data: no definition of accuracy is provided and there are no mentions of the need to also test for factors such as robustness, or to separately validate the performance for different subgroups of the population. Second, there is an underlying assumption that the type of knowledge-engine algorithm in question is irrelevant to the design of the validation and evaluation processes, i.e., it is assumed that a supervised machine learning algorithm can be validated and evaluated in the same way that a zero-shot learning algorithm or large language model can be validated and evaluated. Finally, there is no acknowledgement of the need to ensure the results of all validation and evaluation processes are reported openly. There is, therefore, currently no requirement to ensure validation and evaluation processes are either scrutable or reproducible.

Finally, to the requirements for local calibration and ongoing impact evaluation. First, this ideally requires testing any ACDSS bought 'off the shelf' in its new environment to see if any aspects of its design from the weightings of individual parameters within the knowledge engine algorithms to the interface design, need to be re-calibrated before it can 'go live.' This should help ensure there are no unexpected drops in performance due to differences in, for example, the demographic make-up of the population in the new setting, or alternative working practices or care pathways. Second, this requires subjecting ACDSS to regular re-evaluation once it is deployed (I27, Interview, 26 October 2022; Park & Han, 2018). As with the first phases of evaluation, this regular re-evaluation should encompass more than just the technical performance of ACDSS. Regular re-evaluations should also assess ACDSS's utility to clinicians – including the impact on workflow, job satisfaction, and burnout; impact on the clinical outcome determined at the beginning; impact on secondary patient outcomes including experience of care; impact on system efficiency; impact on patient safety; ongoing cost

effectiveness; and ability to keep up with evolving patterns of disease (Cohen et al., 2014; Jankovic & Chen, 2020; Reisman, 1996a; Roller et al., 2023; Shortliffe & Sepúlveda, 2018b; J. Watson et al., 2020; Yu & Kohane, 2019).

Current policy documents appear to considerably underestimate the importance of these two final process requirements. *Guidelines for AI procurement* (Office for Artificial Intelligence et al., 2020) includes the requirement to "test the model on an ongoing basis: and *Planning and Preparing for AI Implementation* (Central Digital and Data Office & Office for Artificial Intelligence, 2019b) includes the requirements to "assess how to integrate the AI into existing technology and services" and "evaluate the live service and iterate appropriately", but otherwise, the requirements to consider local calibration and ongoing impact evaluation are almost entirely absent from current policy. This absence is particularly noticeable in the NICE guidance document *Evidence Standards for Digital Health Technologies* (NICE, 2022)which does not acknowledge the need to generate local evidence of efficacy as well as global evidence and implicitly assumes that algorithmic performance remains static over time, regardless of model, dataset, or population drift.

Overall, the current policy requirements for the standardisation of the ACDSS implementation process (ACDSS lifecycle) are fragmented and fail to lay out a coherent vision for an end-to-end process that would ensure a consistent focus throughout, from the agreement of a clear clinical outcome to the ongoing impact evaluation. Without this clear and coherent end-to-end vision, there are too many opportunities for the focus on outcomes to be lost, or the outcomes to be manipulated to better suit ACDSS developers (or specific clinical institutions) and not to best suit patients. It can, therefore, be concluded that the 'sociotechnical gap' between the ideal Process information infrastructure requirements and the Process requirements covered by policy, is considerable and can be quantified with a gap score of 8. This suggests that it is highly unlikely that the ideal process requirements for NHS information infrastructure will be met.

6.3.4 Objectives and Values

6.3.4.1 Ideal requirements: ensuring values are protected

The components of the 'objectives and values' (internal organisational policies to return to the definition in Chapter One) information infrastructure domain are the principles, values, and rights (henceforth values) set out in the NHS Constitution, that need to be embedded into the technical design of ACDSS and its supporting information infrastructure.

As has been made clear throughout this chapter, and the preceding chapter, it is the overall level of disorganised complexity in the NHS's current information infrastructure design that is posing a threat to the NHS's values by increasing the risk of negative re-ontologising emergence, rather than any one specific design flaw. This means that, to a certain extent, all the re-design requirements discussed in this chapter are objectives and values requirements. However, the importance of the NHS's core values to, for example, the public's willingness to keep funding it through taxes and the Government's willingness to keep supporting it politically, is such that this indirect support for the NHS's values is necessary, but insufficient. The only way to truly avoid all the risks of negative re-ontologising emergence on the NHS's core values, is to ensure consideration of the impact on the NHS's values is built into *every* information infrastructure decision made by policymakers and to ensure all ACDSS stakeholders – including private third-party NHS 'newcomers' – are aware of the importance of the values. In other words, to avoid the risks of negative re-ontologising emergence, whilst enabling the NHS to capitalise on the benefits of positive intended emergence, the NHS information infrastructure needs to be redesigned so that it provides the system with protected values (McHale, 2013; Zikmundová, 2022). More specifically:

> *Vision requirement 4*
> To avoid the risks of negative re-ontologising emergence associated with the overarching level of disorganised complexity in the NHS's information infrastructure on the NHS's core values following ACDSS implementation, the NHS's information infrastructure needs to be re-designed to provide the system with actively protected values (I7, personal communication, 17 October 2022; I38, personal communication, 31 October 2022). This is so that ACDSS not only upholds, but actively protects the core values of the NHS from all trade-offs or dilutions (Baron & Spranca, 1997).

Realising this vision requirement requires explicit commitment from all stakeholders involved in the implementation of ACDSS to the values set out in the NHS Constitution: the NHS provides a comprehensive service available to all, the NHS aspires to the highest standards of excellence and professionalism (it provides high quality care that is safe, effective, and focused on patient experience), and the patient will be at the heart of everything the NHS does (Department of Health and Social Care, 2021d). More precisely:

Actively protected values delivery requirements

To provide the system with actively protected values, the NHS's information infrastructure must deliver a commitment to the principle of collective provision, commitment to the principle of patient centricity, and commitment to high quality care.

Table 22 summarises these ideal objectives and values vision and delivery requirements before the next section analyses how likely it is that they will be met by current policy.

Current information infrastructure design flaw(s)	Associated risk(s) of re-ontologising emergence	Vision Requirement	Delivery Requirements
• Overarching lack of disorganised complexity throughout the current information infrastructure design increasing the risk of negative re-ontologising emergence.	• The patient may be displaced from the centre of care. • The fundamentals of caring may be forgotten. • The NHS may cease to be for all.	• Actively protected values: ACDSS not only upholds, but actively protects the core values of the NHS from all trade-offs or dilutions	• Commitment to collective provision. • Commitment to patient centricity. • Commitment to quality care.

Table 22. Summary of the "Objectives and Values" information infrastructure domain current design flaws, associated risks, and ideal vision and delivery requirements.

6.3.4.2 Requirements covered by policy: transparency is not all that is required

It has now been established that to provide the system with actively protected values, an information infrastructure that delivers commitment to collective provision, commitment to patient centricity, and commitment to quality care is required. Rhetorical and thematic policy analysis reveals an overarching assumption spread throughout current policy that the core values of the NHS can be protected simply by committing to the principles of transparency and fairness which are equated with the concept of 'trustworthiness.' Whilst fairness and transparency are important principles in the field of AI ethics (Hagendorff, 2020b), and can be seen as supporting the principles of collective provision and quality care, they are neither sufficient to protect the core NHS values nor necessarily synonymous with trustworthiness which is often far more conditional (Calnan & Rowe, 2008).

To start with the required commitment to the principle of collective provision. Ideally, this requires ensuring algorithmically enhanced healthcare can still be classified as a public good: one to which everyone has an equal right to access and benefit from, and an equal responsibility to contribute to and protect. Of course, this requires representative datasets, local calibration, and a balancing of the rights to individual privacy and societal benefit. However, it also requires ensuring no decisions regarding what an acceptable use of ACDSS is, how ACDSS should be evaluated, how ACDSS should

be governed, and more, should be made in isolation of community interests. This, in turn, imposes two requirements on those responsible for making these decisions. First, it requires those considering designing, purchasing, or implementing ACDSS to assess its potential use as *if it were* a new 'screening programme' and thus subject to assessment against the UK National Screening Committee (UK NSC) criteria. Specifically, there should be procedures in place to ensure: (a) the opportunity cost of the ACDSS has been economically balanced in relation to expenditure on medical care as a whole i.e., any cost benefit analyses conduced should have regard to the effective use of available resource; (b) all other options for managing the targeted condition/outcome should have been considered to ensure that there are no more cost effective options available – in particular no options that have a lower associated risk of overdiagnosis and over-treatment; (c) evidence relating to wider benefits and harms, for example those relating to family members or other group members, should be taken into account; and (d) there should be evidence that the complete screening programme is clinically, socially, and ethically acceptable to health professionals and the public (National Screening Committee, 2022). Second, and related to the last screening committee criteria, it requires the development of coherent strategy for building the 'social legitimacy' (Sexton et al., 2017) of ACDSS initiatives, based on collectively agreed boundaries on data and ACDSS use, and analysis of the distribution of benefits and risks to different groups of patients of implemented ACDSS, and its results, in different situations (Amarasingham et al., 2014).

Policy recognition of these requirements designed to protect the principle of collective provision is limited. As mentioned above, there are high-level commitments to the concept of fairness. For instance, *Data Saves Lives* (Department of Health and Social Care, 2022e) includes the commitment to "report on the Health Foundation AI ethics initiative exploring how to use AI-driven tech to improve health outcomes for ethnic minority populations in the UK." Similarly, there are some light-touch commitments to building social legitimacy through participatory governance. For instance, *Data Saves Lives* (Department of Health and Social Care, 2022e) also includes the commitment to co-design a transparency statement as part of a regularly updated online hub, setting out how publicly held health and care data is used across the sector" and to "develop a simple opt-out system that provides clarity and choice" so that individuals have greater control over what their data is used for (including in the context of ACDSS). These illustrative examples highlight how shallowly each of these requirements are interpreted in current policy.

Moving to the required commitment to the principle of patient centricity. Ideally, keeping this commitment requires that ACDSS and clinicians view patients holistically and protect their autonomy,

in particular, their right to be involved in the decision-making process regarding their care. Pragmatically, this requires ensuring the use of ACDSS does not ignore the phenomenological perspective, i.e., the first-person (or patient) perspective, in clinical reasoning (Chin-Yee & Upshur, 2019), and that the outputs from ACDSS are seen as nothing more than a recommendation given to both the clinician *and* the patient for them to discuss (I8, Interview, 17 October 2022). At the start of the implementation pipeline this requires providing ACDSS developers with access to patient-centred data: data that captures their lived experiences, their preferences, their values, and their own knowledge about their own body (Chin-Yee & Upshur, 2019). At the end of the implementation pipeline (or at the point in the pipeline where ACDSS has been deployed at the point of care), this requires ensuring that patients consent to the use of ACDSS in their care and that ACDSS outputs or recommendations, can always be overruled (I11, Interview, 18 October 2022).

As with the requirements to protect the principle of collective provision, these patient-centric requirements also receive limited attention in current policy. There is a requirement in the *Interim Guidance on Incorporating AI into the NHS Breast Screening Programme* (UK National Screening Committee, 2021) to "ensure the patient information and consent processes are satisfactory." However, beyond this, at best the patient centric requirements can be considered components of the principles "respect for persons"; "participation" and "accounting for decisions" included in *A Guide to Good Practice for Digital and Data-Driven Health Technologies* (Department of Health and Social Care, 2021a).

Finally, to the required commitment to the principle of quality care. Ideally, this requires putting in place strategies that demonstrate to patients and clinicians the accuracy, reliability, and competence of ACDSS, and ACDSS developers (Calnan & Rowe, 2008; C. Jones et al., 2021), so that it is easier for clinicians, patients, researchers, and indeed other ACDSS developers to assess the performance claims made by developers of specific ACDSS (C. Jones et al., 2021). Specifically, ACDSS developers should be required to meet the high standards of transparency of their methods, and reproducibility of their findings, expected of any clinical research programmes. In short, just as all clinical trials are expected to pre-register and publicly report their results, so should all ACDSS evaluations (I61, Interview, 11 November 2022). This would help build the trust necessary to ensure excellent experiences, and thus excellent standards, of care.

Despite the importance of protecting the trust necessary to ensure clinical excellence, the requirements related to quality care do not appear consistently in current policy documents. As mentioned above, there are several references to the importance of transparency in general. For example, the *UK National Data Strategy* states "we will explore appropriate and effective mechanisms

to deliver more transparency on the use of algorithmic assisted decision-making within the public sector" (Department for Digital, Culture, Media & Sport, 2020). However, these types of high-level commitments to transparency are limited in their effectiveness to genuinely meet the ideal requirements.

Overall, the current policy requirements for the protection of the NHS's core values are weak. There is an over-reliance on high-level principle-based guidelines that do not align directly with the NHS's core values, cannot easily be translated into practical requirements for ACDSS developers or NHS organisations to follow, and cannot protect the NHS against accusations of 'ethics-washing' (Floridi, 2019). It can, therefore, be concluded that the 'sociotechnical gap' between the ideal Objectives and Values information infrastructure requirements and the Objectives and Values requirements covered by policy is significant and can be quantified with a gap score of 9. This suggests that it is extremely unlikely that the ideal Objectives and Values requirements for NHS information infrastructure will be met.

6.3.5 Staff and Knowledge

6.3.5.1 Ideal requirements: supporting autonomous staff

The Staff and Knowledge (or people, workflow and communication to return to the definition in Chapter One) information infrastructure domain is comprised of the skills required by key staff groups in the ACDSS implementation pipeline (frontline clinicians, NHS analysts, and NHS senior leaders) to use, govern, and analyse the outputs from ACDSS, in a way that is safe, effective, and in-keeping with the core values of the NHS.

Chapter Four revealed that these skill components are also negatively impacted by the disorganised complexity plaguing the current information infrastructure design. Specifically, section 4.2.4 highlighted the fact that currently willingness to adopt ACDSS amongst clinicians is partly suppressed by the belief that ACDSS use might increase rather than decrease cognitive burden. Some clinicians believe this to be the case because (a) they receive very little training in the use, interpretation, and validation of algorithmic models which, when combined with their black box nature, leaves clinicians feeling as though ACDSS may challenge their epistemic authority. In addition, section 4.2.2 highlighted the fact that because ACDSS does not always give clinicians control over when to access its advice, it can be seen as overly interruptive to their cognitive workflow – further exacerbating its potential to increase cognitive burden rather than decrease it. Finally, section 4.2.4, also highlighted the perception that exists among some clinicians, that ACDSS might be used by senior leaders or NHS

analysts to unfairly scrutinise, or performance manage the behaviour of clinicians. This is a concern that is especially prevalent when clinicians do not feel as though the senior leaders or analysts in question have the skills to ask sensible questions of the data returned by ACDSS (Goldacre & Morley, 2022).

Chapter Five revealed that these design flaws related to the potential for ACDSS to undermine rather than support clinicians' cognitive workflow, may once again increase the risk of negative re-ontologising emergence related to the NHS's commitment to the fundamentals of caring. Section 5.3.2.1 stressed that unless (a) clinicians are provided with the skills and confidence to question any outputs from ACDSS; and (b) policymakers, senior leaders and NHS analysts understand that ACDSS is simply an assistive tool rather than an omniscient algorithm, clinicians and the system may succumb to automation bias. Clinicians may become de-skilled and lose the ability to critically question the outputs of ACDSS, or even contextualise it for the specific patient. The system may see ACDSS as the gold standard against which all clinicians should be measured and suggest that clinicians may be liable if they do not follow the advice of ACDSS to the letter. This may result in a loss of the 'human touch' in clinical consultations, i.e., loss of the importance of factors such as empathy, and an increase in the rate of e-iatrogenesis (information related harm) occurring to patients due to a mismatch between the insight or advice provided by the ACDSS and the real-life of the patient. Overall, such shifts may worsen the experience of care for patients, resulting in a loss of trust and an undermining of the fundamentals of caring.

To avoid these risks of negative re-ontologising emergence, whilst enabling the NHS to capitalise on the benefits of positive intended emergence, the NHS information infrastructure needs to be redesigned so that it provides the system with autonomous staff. More specifically:

> *Vision requirement 5*
>
> To avoid the risks of negative re-ontologising emergence associated with the impacts of disorganised complexity in the NHS's information infrastructure on the ability of clinicians to resist the effects of automation bias, the NHS's information infrastructure needs to be re-designed to provide the system with autonomous staff. This is so the autonomy of clinical staff over their decisions regarding their patients is maintained as is their confidence to not question their 'right' to this autonomy even when using ACDSS.

Realising this vision requirement requires a commitment to maintaining the epistemic authority of clinicians, making it clear to all stakeholders – including patients – that ACDSS is simply a tool

available to aid clinicians, to help them keep up with the latest developments in the field, and to enable more targeted (or personalised) and preventative care. ACDSS should not, in any way, be viewed as a 'replacement' for clinicians. Upholding this commitment requires ensuring all those responsible for deciding (a) how ACDSS should be used and governed in the healthcare system (NHS senior leaders); (b) how the 'feedback' from ACDSS should be interpreted and acted upon (NHS analytical community); and (c) how the recommendations produced by ACDSS should be viewed and used at the point of care (NHS clinicians), have the necessary skills to understand how ACDSS works (Tsopra et al., 2023), what its limitations are, how its outputs should be interpreted and contextualised, and how to identify errors (be they information, logical, or statistical errors (A. Gilson et al., 2023)) in ACDSS outputs (I26, Interview, 26 October 2022; I34, Interview, 28 October 2022; I40, Interview, 31 October 2022). More precisely:

> *Autonomous staff delivery requirements*
> To provide the system with autonomous staff, the NHS's information infrastructure must deliver data-literate senior commissioners, regulators, and policymakers; a highly skilled and appropriately valued analytics workforce; and clinicians with the confidence to protect their epistemic authority (Abouzahra & Guenter, 2022; Goldacre & Morley, 2022; I34, Interview, 28 October 2022; I50, Interview, 7 November 2022)

Table 23 summarises these ideal staff and knowledge vision and delivery requirements before the next section analyses how likely it is that they will be met by current policy.

Current information infrastructure design flaw(s)	Associated risk(s) of re-ontologising emergence	Vision Requirement	Delivery Requirements
• Clinicians do not receive sufficient training regarding the use of ACDSS, which may also have black box elements, this can leave them vulnerable to automation bias – believing that the ACDSS is always right even if its advice does not appear to accurately reflect the patient's context. • NHS analysts and NHS senior leaders may use the outputs of ACDSS to inappropriately surveil or performance monitor clinicians, positioning ACDSS as the gold standard that clinicians must always meet.	• Clinicians and the system may succumb to automation bias. ACDSS cannot replicate the human aspects of care so without clinicians acting as intermediaries these aspects may be lost and the rates of e-iatrogenesis may increase if there is a mismatch between the ACDSS advice and the patient's context. • The ultimate effect may be a worsening of the experience of care and a consequential loss of trust between patients and clinicians.	• Autonomous staff: the autonomy of clinical staff over their decisions regarding their patients is maintained, as is their confidence to not question their 'right' to this autonomy even when using ACDSS.	• Data-literate senior commissioners, regulators, and policymakers. • Highly skilled and appropriately valued analytics workforce. • Clinicians with the confidence to protect their epistemic authority.

Table 23. Summary of the "Staff and Knowledge" information infrastructure domain current design flaws, associated risks, and ideal vision and delivery requirements.

6.3.5.2 Requirements covered by policy: recognising the importance of technical training

It has now been established that to provide the system with autonomous staff, an information infrastructure that delivers data literate senior leaders, a highly skilled and appropriately valued analytics workforce, and clinicians with the confidence to maintain their epistemic authority, is required. Rhetorical and thematic policy analysis reveals that there is relatively close alignment between these ideal requirements regarding Staff and Knowledge and the requirements covered by policy. All three delivery requirements are covered extensively, and evenly, by the included policy documents and in many instances the lower-level requirements are also covered.

To start with the requirement to provide the system with data-literate senior leaders. From an ideal design perspective, this requires ensuring senior leaders in the NHS, i.e., those of director-level and above in NHS policy, commissioning, or regulation positions, have at least a basic understanding of how NHS data is collected, stored, analysed, and used to train ACDSS; how ACDSS works, what its uses and limitations are, how it should be evaluated to ensure safety; how to translate NHS system needs into language that can be interpreted by ACDSS developers; how to build staff consensus about

ACDSS implementation so that it is seen as a positive development and not a cost-cutting 'replacement' plan; and how to independently assess the claims made by ACDSS developers and other technology companies before making any procurement decisions (I4, Interview, 17 October 2022; I26, Interview 26 October 2022; I43, Interview, 31 October 2023; I49, Interview, 7 November 2022). Requiring NHS senior leaders to develop these skills should help them to make sensible commissioning and procurement decisions, to have the confidence to stand-up to sometimes overbearing technology companies, and ultimately to have the ability to ask 'good questions' of their staff and of ACDSS (Goldacre & Morley, 2022).

Although this Staff and Knowledge requirement receives less attention in current policy documents than the other two autonomous staff delivery requirements, this is not to say that its importance goes entirely unacknowledged: just that it is acknowledged less frequently. *The future of healthcare: our vision for digital, data and technology* (Department of Health and Social Care, 2018), for example, includes the comprehensive requirement that "all health and care organisations should ensure board-level understanding of how data and technology drives their services and strategies." The more recent *A plan for digital health and social care* (Department of Health and Social Care, 2022a) reiterates this requirement in the context of Integrated Care Boards (the latest 'type' of management organisation in the NHS). Ensuring board-level policymakers, commissioners, regulators, and other senior system leaders have a comprehensive understanding of the data and technology (including ACDSS) which they govern will significantly increase the likelihood that the use of ACDSS is not inappropriately forced on clinicians in a way that may undermine their autonomy over their decision-making capacity.

Moving to the requirement to provide the system with a highly skilled and appropriately valued NHS analytics workforce. Ideally, this first requires recognising the fact that analysing data and insights generated by ACDSS for the purpose of generating insights into population health and service performance is a "non-trivial task requiring skills and expertise that span multiple disciplines" from sophisticated statistical methods (Cosgriff et al., 2019, p. 2), to data ethics, data management, and software engineering (Dhindsa et al., 2018; I9, Interview, 17 October 2023; I21, Interview, 21 October 2022; Lee, 2017). Next, it requires acknowledging that individuals with these skills are already part of the NHS system, but retaining these individuals, and hiring more to cope with the significant increase in data volume is becoming increasingly difficult as the value of data science and analytical skills increases in the 'private market' but remains static within the NHS (I5, Interview, 17 October 2022). Thus, what is ultimately required is a shift in how NHS analysts are perceived and compensated by

the system. Specifically, an NHS analytics workforce development plan is required, that, at a minimum, must cover 'rebranding' NHS analysts as clinical staff rather than admin or clerical staff, improving salaries, and providing access to continuing professional development, so that the overall position and 'value' of the analytics workforce is elevated (Goldacre et al., 2020; Goldacre & Morley, 2022; I20, Interview, 21 October 2022; Scobie & Castle-Clarke, 2020).

Fortunately, the importance of appropriately rewarding the NHS analytics workforce is now well-recognised in current policy documents. *The future of healthcare: our vision for digital, data, and technology* (Department of Health and Social Care, 2018), for example, highlights 'the need to recruit and retain specialist non-clinical professions such as a highly skilled and well-resourced data science and analytics workforce to make the best use of all the data that is unlocked.' Similarly, the *Life Sciences vision* (Department for Business, Energy, and Industrial Strategy & Office for Life Sciences, 2021) commits to taking concerted action to 'develop and recruit the data and analytical skills in the US and wider ecosystem that will be critical for utilising and delivering the full potential of the UK's health data.' There is even a commitment in *Data Saves Lives* (Department of Health and Social Care, 2022e) to regularly review and revise the training needs of the analytical workforce to ensure the workforce can stay up to date with the latest advances in the field. Indeed, of all requirements discussed in this chapter, this requirement to value the analytical workforce and ensure those within it are given appropriate status, compensation, and access to necessary training, is the most comprehensively 'met' by the current policy developments.

Finally, to the requirement to give clinicians the confidence to protect their epistemic authority. Ideally, clinicians should be required to develop skills related to AI development (specifically its benefits and limitations) (J. He et al., 2019b), health informatics (Fridsma, 2018), health information exchange, and risk prediction (Amarasingham et al., 2016). Requiring clinicians to develop skills in these areas will help ensure they feel comfortable explaining any outputs to patients and questioning any unexpected outputs (i.e., recommendations or advice) (Goddard et al., 2014; McCradden, Joshi, et al., 2020) i.e., they will hopefully have the confidence necessary to maintain their epistemic authority over ACDSS. Of course, clinicians should not be required to develop these skills independently. Ideally, training should be provided at multiple levels: (a) at university (Amarasingham et al., 2016; Fridsma, 2018; He et al., 2019; I24, Interview, 24 October 2022); (b) during clinical rotations; (c) as part of continuing professional development (which should be championed locally) (Abbott et al., 2014; I13, Interview, 19 October 2022); and (d) as part of any planned ACDSS implementation (Kealey et al., 2013).

This requirement to appropriately train clinicians is, again, well recognised in current policy. The *UK national data strategy* (Department for Digital, Culture, Media & Sport, 2020)*, A plan for digital health and social care* (Department of Health and Social Care, 2022a)*,* and *Guidelines for AI procurement* (Office for Artificial Intelligence et al., 2020) all refer to the need to include a variety of technical subjects in foundational training courses, such as undergraduate courses, to ensure the future and incoming workforce have the skills they will require to interact with emerging technologies (including ACDSS). For example, *A plan for digital health and social care* (Department of Health and Social Care, 2022a) includes the commitment to "embed digital skills development into academic curricula". These kinds of commitments suggest that, even if policy does not explicitly acknowledge the need to protect the epistemic authority of clinicians, the requirement to support protection of this authority through comprehensive technical training will at least be partially met.

Overall, the current policy requirements for the protection of clinician's autonomy over their decision making following the implementation of CDSS is relatively strong. Even if the need to protect the autonomy of clinicians is not explicitly acknowledged, the enabling requirements are well-recognised and – for the most part at least – sufficiently covered by current policy developments. Therefore, it can be concluded that the 'sociotechnical gap' between the ideal Skills and Knowledge information infrastructure requirements and the Skills and Knowledge requirements covered by policy is narrow and can be quantified with a gap score of 3. This suggests that it is likely that the ideal 'staff and knowledge' requirements for NHS information infrastructure will be met.

6.3.6 Management Systems and Structures

6.3.6.1 Ideal requirements: ensuring meaningful accountability

As with 'process,' there are multiple components to the 'management systems and structures' (or external rules, regulations, and pressures to return to the definition in Chapter One) information infrastructure domain as it encompasses all the 'harder' governance requirements for successful ACDSS implementation (Floridi, 2018b). Specifically, the components are:

1. Information governance regulations
2. Procurement and commercial partnership regulations
3. Medical device regulations and clinical or safety governance regulations
4. Liability and consumer protection regulations

Chapter Four revealed that, yet again, all components are negatively impacted by the disorganised complexity plaguing the current information infrastructure design. Specifically, section 4.2.6 highlighted the fact that the pace of ACDSS development has far outstripped that of the necessary regulatory, legal, and ethical frameworks. Confusing and confused information governance regulations are currently doing little to protect against public-trust-damaging uses of NHS data but frequently blocking 'public good' uses (including for ACDSS implementation)(Goldacre & Morley, 2022); medical device regulations do not clearly cover ACDSS allowing unsafe and unevidenced ACDSS to be deployed in the NHS with little to no oversight (I27, Interview, 26 October 2022; I61, Interview, 11 November 2022); lack of clarity regarding clinical liability is leaving clinicians exposed and acting as a considerable barrier to ACDSS adoption (e.g., Allaërt & Dusserre, 1992; Prictor et al., 2020; Tobia et al., 2021); insufficient consumer (or patient) protection is leaving patients harmed by e-iatrogenesis with no route to recompense (e.g., Brown & Desai, 2023; Čartolovni et al., 2022; Gerke et al., 2020); unfit-for-purpose discrimination law allows ACDSS developers to consider 'fairness' a 'nice-to-have' rather than an essential feature (Favaretto et al., 2019b); and limited guidance, regarding the clinical oversight requirements, for organisations deploying ACDSS leaves patients vulnerable to ACDSS-related safety hazards (Bowman, 2013).

Chapter Five revealed that these design flaws related to the inability of regulatory mechanisms associated with 'process accountability' (monitoring systems that ensure all agents in the system are operating effectively and safety) to keep pace with the development of ACDSS may further increase the risks of negative re-ontologising emergence related to the NHS's commitment to the provision of excellent, safe, and effective care. To be precise, section 5.3.2.3 stressed that robust process accountability mechanisms provide the foundation upon which trusted relationships between clinicians and patients form. Therefore, by disrupting the loci, domains, and procedures of process accountability as described above, the implementation of ACDSS may destabilise the foundations of trust and, over time, de-legitimise the healthcare system from the public's perspective.

To avoid these risks of negative re-ontologising emergence, whilst enabling the NHS to capitalise on the benefits of positive intended emergence, the NHS information infrastructure needs to be redesigned so that it provides meaningful accountability (Albahri et al., 2023). More specifically:

> *Vision requirement 6*
> To avoid the risks of negative re-ontologising emergence associated with the impacts of disorganised complexity in the NHS's information infrastructure on the governance mechanisms ensuring ACDSS is safe and effective, the NHS's information infrastructure

needs to be re-designed to provide the system with meaningful accountability. This is so that ACDSS implementation is supported by a proportionate governance framework that guarantees ACDSS developers, deployers, and users are meaningfully accountable (Bovens, Goodin, Schillemans, Bovens, et al., 2014) to patients and the public for the software they implement.

Realising this vision requirement requires the development of a principled proportionate governance framework (Sethi & Laurie, 2013)that is appropriately adaptive, flexible, inclusive, reflexive, and responsive, and ensures responsibility for patient safety is imposed on all "entities involved in the research, invention, innovation, dissemination, and application" (R. Clarke, 2019, p. 406) of ACDSS . More precisely:

Meaningful accountability delivery requirements

To provide the system with meaningful accountability, the NHS's information infrastructure must deliver systemic oversight via fit for purpose information governance, clearly regulated medical devices, clinician and patient protection, and auditability.

Table 24 summarises these ideal management systems and structures vision and delivery requirements before the next section analyses how likely it is that they will be met by current policy.

Current information infrastructure design flaw(s)	Associated risk(s) of re-ontologising emergence	Vision Requirement	Delivery Requirements
• All mechanisms associated with process accountability (e.g., information governance regulation, medical device regulation) are struggling to keep pace with the development of ACDSS.	• Process accountability is a pre-requisite for building trusting relationships between clinicians and patients and for patients and the public viewing the healthcare system as legitimate. Disruption to process accountability may, therefore, result in the de-legitimisation of the healthcare system from the perspective of the public.	• Meaningful accountability: ACDSS implementation is supported by a proportionate governance framework that guarantees ACDSS developers, deployers, and users are meaningfully accountable to patients and the public for the software they implement.	• Fit for purpose information governance • Clearly regulated medical devices • Clinician and patient protection • Auditability

Table 24. Summary of the "Management systems and structures" information infrastructure domain current design flaws, associated risks, and ideal vision and delivery requirements.

6.3.6.2 Requirements covered by policy: the clarity is in the details

It has now been established that to provide the system with meaningful accountability, and information infrastructure that delivers fit for purpose information governance, clearly regulated medical devices, clinician and patient protection, and auditability, is required. Rhetorical and thematic policy analysis reveals that at a high-level of abstraction, the overarching policy ambition is relatively aligned with the ideal ambition to create a principled proportionate governance framework that delivers meaningful systemic oversight or accountability. For example, *A pro-innovation approach to AI regulation* (Department for Science, Innovation and Technology & Office for Artificial Intelligence, 2023)states that the Government's ambition is to "put in place a new framework to bring clarity and coherence to the AI regulatory landscape," going on to explain that the regime is "designed to be pro-innovation, proportionate, trustworthy, adaptable, clear, and collaborative" and that it is "underpinned by five principles: safety, security, and robustness; appropriate transparency and explainability; accountability and governance; and contestability and redress." However, a secondary ambition running through all included policy documents to remove friction and regulatory burden to make it easier (a) for innovators to develop new products (including ACDSS); and (b) NHS organisations to procure new technology (including ACDSS), is currently preventing this alignment from being realised.

To start with the requirement for the overarching governance framework to deliver a fit for purpose information governance regime. Ideally, this would require developing an information governance regime that: clarifies, simplifies, and (where appropriate) centralises NHS data ownership and controllership; enforces transparency; embeds ethical review as standard practice for all data access requests; and harmonises data use cases. An information governance regime that meets all these requirements would help ensure that: (a) patients are given more nuanced consent or opt-out options based on data use rather than extraction source (Zhang, Ashrafian, et al., 2023); (b) ACDSS innovators do not have to interact with more than 9000 individual data controllers to create a representative training dataset (I3, personal communication, 17 October 2022; I5, personal communication, 17 October 2022; Mirchev et al., 2020); (c) patients and publics can easily identify where their data has 'gone', what it has been used for (including what ACDSS models it has been used to train), and what system benefits have been derived from its use (Bartoletti, 2019b; Goldacre & Morley, 2022; Kraft et al., 2018); (d) ethical concerns such as discrimination, stigmatisation, privacy infringement, fairness, and outcomes, are *always* considered even in instances where only retrospective or de-identified data is used (Ferretti et al., 2021; I5, Interview, 17 October 2022; Ienca et al., 2018; Mann et al., 2016; Vayena & Tasioulas, 2016); and (e) the risk of NHS organisations accidentally breaking data protection

law when implementing ACDSS (which is designed to complete research, direct care, and service evaluation tasks simultaneously) is minimised (L.-Y. A. Chen & Fawcett, 2019; Townend, 2018).

Information governance is a rapidly developing area of policy for the NHS, and the UK Government more broadly. However, there is currently a disconnect between high-level commitments such as "we will overhaul the governance on data access to ensure that patients, NHS organisations, and registries have the confidence and clarity they need to engage with innovators, bringing more consistency and efficiency in decision-making whilst adhering to the highest data protection standards" (Department for Business, Energy, and Industrial Strategy & Office for Life Sciences, 2021), and the underlying ambition to make access to data easier by "lifting compliance burdens were possible" (Department for Digital, Culture, Media & Sport, 2020). It is not clear how these two seemingly opposing ambitions are being rationalised nor how context-specific decisions about which 'ambition' to prioritise when are being made. Consequently, there is currently no guarantee that the ambition to 'remove friction' from the information governance regime will not come at the cost of the other ideal requirements.

Moving to the requirement for the overarching governance framework to deliver medical device regulation that clearly, and comprehensively, covers ACDSS. From an ideal perspective, the requirements here are threefold. First, the scope of medical device regulation and its applicability to ACDSS requires expansion and clarification so that all ACDSS is covered – including ACDSS developed and deployed 'in-house' by individual NHS clinicians (I19, Interview, 20 October 2022; I27, Interview, 26 October 2022; I50, Interview, 7 November 2022; McKee & Wouters, 2022). Second, a lifecycle approach to the regulation of ACDSS as software as a medical device (SaMD) is required (Char et al., 2020b; Hwang et al., 2019b; Magrabi et al., 2013): one that recognises that, because of factors such as dataset drift and model evolution, there is no 'finish line' to ACDSS development (I17, Interview, 20 October 2022; I18, Interview, 20 October 2022; Kelly et al., 2019; Mahadevaiah et al., 2020; Sendak et al., 2020) and none of the process requirements set out in section 6.3.1 are 'nice-to-haves' but vitally important safety criteria that should be mandated by law. Third, and finally, a cross-agency and collaborative approach to SaMD regulation will be required (Blaser et al., 2007; I7, personal communication, 17 October 2022).

Like information governance policy, medical device regulation is currently undergoing rapid and extensive re-development. The MHRA has stated that it is "focused on ensuring that the requirements [for SaMD] are clear, supported by clarificatory guidance and streamlined processes that work for software, as well as bolstered with the tools to demonstrate compliance, for instance, via the

designation of standards" (MHRA, 2021c). In addition, the MHRA has committed to broadening the scope of UK SaMD regulations to include all devices that involve "a set of instructions that process input data and creates output data" (MHRA, 2022b). This would, in theory, bring ACDSS clearly within the scope of SaMD regulations. However, there are significant discrepancies between the ideal requirements and the policy requirements at the more detailed level of abstraction. There are, for example, no plans to set out specific requirements for SaMD involving AI, and there is no intention to regulate the generation of evidence of efficacy for ACDSS. Instead, considerations such as evidence of efficacy and monitoring for factors such as dataset drift either do not appear, or only appear in light-touch guidance. Even the requirement to commit to more cross-agency collaboration is lacking – appearing only in the context of cybersecurity, and not in the context of, for example, safe usage of ACDSS.

Next to the requirement for the overarching governance framework to ensure the protection of clinicians and patients. Ideally, this requires both an efficient medical liability system which aims to incentivise ACDSS adoption and compensate any injured parties, and an efficient anti-discrimination system which aims to prevent ACDSS-related discrimination and compensate any injured parties (i.e., patients). More practically, this requires a combination of negligence, strict liability, safety, and anti-discrimination laws that ensure clinicians retain the right to autonomously make decisions (see section 6.3.5.1) and develop a 'buyer-beware' attitude to the use of ACDSS (I27, Interview, 26 October 2022), and patients know how to advocate for themselves if they experience harm (including harm related to discrimination.)

Discussions regarding liability, clinical governance, consumer protection, and even anti-discrimination law are currently almost entirely absent from the included policy documents. There are several high-level, indirectly related requirements. For example, *Interim Guidance on Incorporating Artificial Intelligence into the NHS Breast Screening Programme* (UK National Screening Committee, 2021) includes the requirement to "ensure there are systems in place to report incidents;" the *Digital Technology Assessment Criteria* (NHS England, 2021) include the requirements to "ensure compliance with clinical safety standards," "detail the clinical risk management system," and "comply with the law;" and *Guidelines for AI procurement* (Office for Artificial Intelligence et al., 2020) includes the requirement to "complete an AI impact assessment". However, there are no more detailed guidelines, commitments or recommendations that would bring the overall policy requirements for clinician and patient protection in closer alignment with the ideal requirements.

Lastly, to the requirement for the overarching governance framework to deliver auditability. Ideally, this requires ensuring the entire ACDSS implementation pipeline from development, to procurement, to deployment, and finally to ongoing evaluation, adheres to the principle of 'procedural regularity' (Morley et al., 2021) so that it can be subject to a structured process of ethics-based auditing (Doyal, 1992; Mökander et al., 2021). First, this requires establishing procedures, at every stage of the implementation pipeline, that enable functionality auditing (i.e., the rationale behind decisions); code auditing (i.e., reviewing the source code of the ACDSS knowledge engine algorithmics); and impact auditing (i.e., reviewing the severity and prevalence of the effect of ACDSS on patient outcomes and the system as a whole). Second, this ideally requires establishing a central clinical governance committee (Amarasingham et al., 2014; Reddy et al., 2019), augmented with individuals with technical skills, to take on the responsibility for commissioning and overseeing regular audits, for sanctioning 'bad actors' (Kraft et al., 2018, 2018), and for making difficult decisions to 'turn off' any ACDSS that is found to be poorly performing. Third, and finally, this ideally requires the development of guidelines that stress the necessity of openly reporting the results, and decisions, of all ACDSS development phases (Bates et al., 2020).

In stark contrast to the policy requirements for the other three headline ideal requirements within this domain, the requirement to ensure auditability of the ACDSS implementation pipeline appears to be well recognised and covered in detail in current policy documents. *The Roadmap to an Effective AI Assurance Ecosystem* (Centre for Data Ethics and Innovation, 2021), makes the overarching commitment to auditability clear, stating that "our vision is that the UK will have a thriving and effective AI assurance ecosystem within the next five years." Similarly, the *AI Roadmap* (Centre for Data Ethics and Innovation, 2021) states that "the UK must lead in finding ways to enable public scrutiny and input to automated decision-making and help ensure that the public can trust AI." This ambition is then translated into several more detailed requirements, such as the requirement in *Assessing if AI is the Right Solution* (Central Digital and Data Office & Office for Artificial Intelligence, 2019a) to "record where AI is in use, what it is being used for, who was involved in its development, how it has been assessed, what other terms rely on the technology" or the requirements in *Understanding AI Ethics and Safety* (Central Digital and Data Office & Office for Artificial Intelligence, 2019c) to "implement activity monitoring to allow for oversight and review throughout the entire project" and "ensure it is possible to explain to affected stakeholders how and why a model performed in the way it did in a specific context." Even procurement is covered in detail by several documents

including *Guidelines for AI procurement* (Office for Artificial Intelligence et al., 2020) and *A buyer's guide to AI for health and care* (NHS England, 2020).

Overall, the current policy requirements for the development of a principled proportionate ACDSS governance framework are mixed. There is clear recognition of the overarching need to ensure regulation mandates the safe, effective, and ethical deployment of ACDSS, but the competing priority to ensure a friction-free route-to-market for technology companies wishing to sell into the NHS prevents this ambition from being translated into more detailed specific requirements. It can, therefore, be concluded that the sociotechnical gap between the ideal information infrastructure requirements for management structures and systems and the requirements covered by policy is moderate and can be quantified with a score of 7. This suggests that it is relatively unlikely that the ideal 'management systems and structures' requirements for NHS information infrastructure will be met.

6.4 Conclusion

The first purpose of this chapter was to develop the ideal vision for a necessarily complex, but organised NHS information infrastructure design that can ensure the successful implementation of ACDSS. Having identified: (a) what each domain of the information infrastructure must provide the desired ACDSS-enabled NLHS to ensure it is able to capitalise on the benefits of ACDSS; and (b) what is required to mitigate any of the re-ontologising emergence risks described in Chapter Five, and associated with the disorganised complexity described in Chapter Four, it is now possible to combine these two levels of requirements into the ideal vision as follows:

Vision for the ideal NHS information Infrastructure

To ensure the NHS can capitalise on the benefits of ACDSS whilst pro-actively mitigating the risks, it requires an information infrastructure that provides the desired ACDSS-enabled NLHS with:

1. **Epistemic certainty:** clinicians are confident ACDSS outputs are valid, valuable, and constructed to improve their capacity to make shared decisions that will ultimately lead to better outcomes for their patients.
2. **Robust information exchange:** ACDSS facilitates the trustworthy and caring exchange of information (e.g., symptoms diagnoses, treatments, phenotype profiles, genotype profiles) between patients (at both an aggregate and individual level) to (a)

ACDSS developers; (b) policymakers and regulators responsible for determining the standards of care; and (c) clinicians on the frontline.

3. **Validated outcomes:** ACDSS enables clinicians to uphold and enhance the tenets of evidence-based medicine, to ensure all care in the NHS is delivered to an appropriate standard following the best evidence to deliver the best possible health outcome for the specific patient in question.
4. **Actively protected values:** ACDSS not only upholds, but actively protects the core values of the NHS from all trade-offs or dilutions.
5. **Autonomous staff:** the autonomy of clinical staff over their decisions regarding their patients is maintained, as is their confidence to not question their 'right' to this autonomy even when using ACDSS.
6. **Meaningful accountability:** ACDSS implementation is supported by a proportionate governance framework that guarantees ACDSS developers, deployers, and users are meaningfully accountable to patients and the public for the software they implement.

To ensure the information infrastructure can provide the desired ACDSS-enabled NLHS with epistemic certainty, robust information exchange, validated outcomes, actively protected values, autonomous staff, and meaningful accountability, it must be re-designed to deliver:

1. Consistently good data quality, sufficient data quantity, reliable data interpretability.
2. User friendly EHR design, privacy-preserving data access mechanisms, seamless ACDSS integration, system-wide protection from vendor lock-in.
3. Clearly stated clinical outcomes, mindful model development, rigorous technical validation, rigorous clinical evaluation, careful local calibration, ongoing impact evaluation.
4. Commitment to collective provision, commitment to patient centricity, commitment to quality care.
5. Data-literate senior leaders commissioners, regulators, and policymakers, highly skilled and appropriately valued analytics workforce, clinicians with the confidence to protect their epistemic authority.
6. Fit for purpose information governance, clearly regulated medical devices, clinician and patient protection, auditability.

Figure 2 shows how these vision and delivery requirements can be combined to begin to form the conceptual model for the successful implementation of ACDSS into the NHS, highlighting what policymakers should be trying to provide and deliver when developing policy which influences (either directly or indirectly) NHS information infrastructure. However, what it does not show is the results of the secondary analysis conducted in this chapter: the gap analysis assessing how likely it is that these vision and delivery requirements will be met by current policy.

The results of the secondary gap analysis are, instead, summarised in Table 25 which shows that the gap between the ideal requirements and the requirements covered by policy varies in size depending on the information infrastructure domain, from a quantified gap score of 3 (staff and knowledge) to a quantified gap score of 9 (objectives and values). The average (mean) quantified gap is, therefore, 6.5.

This is a moderately sized gap, suggesting that currently it is reasonably unlikely that *all* the ideal vision and delivery information infrastructure requirements will be met by current policy developments. Yet, it is not an insurmountable gap: it can almost certainly be closed. However, before the requirements needed to close the gap can be identified, it is first necessary to understand why the gap exists. In other words, it is first necessary to answer the second part of question RQB: "what underpinning assumptions and contextual factors might limit the likelihood of the ideal requirements being met by current policy" It is only by answering this question first that it can be ensured that the final identified requirements are possible, pragmatic, and desirable – in keeping with the aims of design set out in Chapter One. Answering this question is the task of the next chapter.

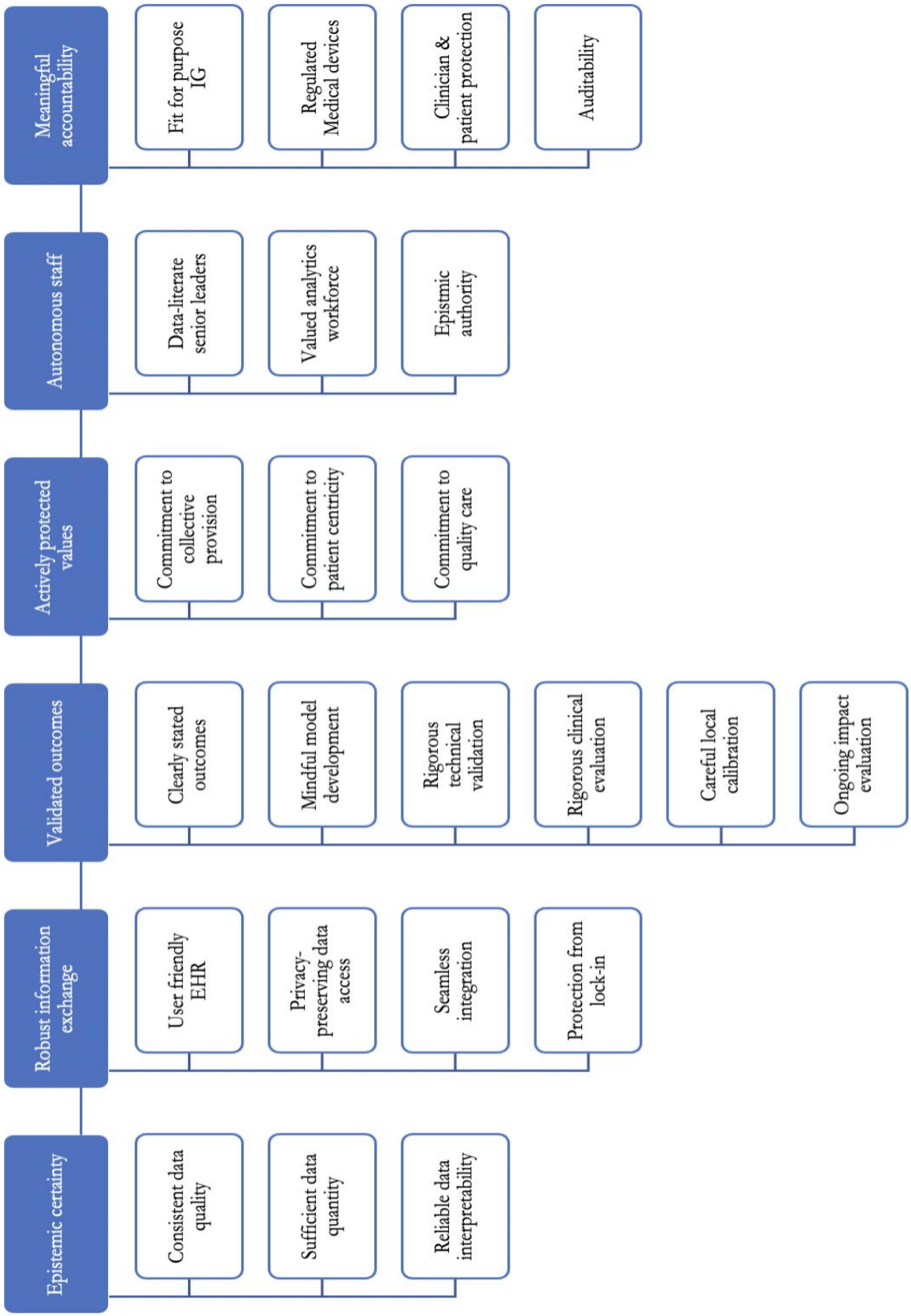

Figure 2. Conceptual model of vision and delivery information infrastructure requirements for successful ACDSS implementation into the NHS

Domain	Vision & Delivery Requirements	Covered by policy?	Gap Score

Information	• Epistemic Certainty:
	  • Consistent data quality
	  • Sufficient data quantity
	  • Reliable data interpretability
		No mention of epistemic certainty
		
		Data Quality is mentioned at a high-level, is relatively narrowly defined, and consistency *receives limited attention*
		
		Data Quantity is presumed to be primarily about creating larger datasets that are population representative in terms of ethnicity, age, and gender.
		
		Data Interpretability is barely recognised, except explainability which is acknowledged at a high level.
			6 (moderate difference between ideal design and policy reality, unlikely that ideal requirements will be met)

Technology	• Robust Information Exchange:
	  • User friendly EHR design
	  • Privacy preserving data access
	  • Seamless system integration
	  • Protection from vendor lock-in
		Recognition of the importance of robust information exchange is implied.
		
		No meaningful acknowledgement of the need to create user-friendly EHR designs to prevent data quality issues arising at source.
		
		Considerable focus on enabling privacy-enhancing data access, albeit concern over its implementation.
		
		Issues related to interoperability and vendor lock-in are acknowledged but at an exceptionally high-level that may be difficult to act on.
			6 (moderate difference between ideal design and policy reality, unlikely that ideal requirements will be met)

Process	• Validated ACDSS Outcomes:
	  • Clearly stated clinical outcomes
	  • Mindful model development
	  • Rigorous technical validation
	
	  • Rigorous clinical evaluation
	  • Careful local calibration
		User needs and defined clinical outcomes are assumed to be the same
		
		The importance of mindful model development is not recognised, and is almost entirely absent from current policy development.
		
		Technical validation and clinical evaluation are both covered in current policy documents, but only at a high-level with no recognition of (for example) the variations that
			8 (considerable difference between ideal and policy requirements, ideal requirements highly unlikely to be met)

	• Ongoing impact monitoring	might be necessary given different types of algorithms. Very limited recognition of the requirements for local calibration and ongoing impact monitoring.	
Objectives and Values	• Actively protected values: • Commitment to collective provision • Commitment to patient centricity • Commitment to quality care.	Limited recognition of the commitments to collective provision and patient centricity. Some recognition of the importance of committing to quality care, but high-level and difficult to implement. Overall, over-reliance on policies extolling the importance of transparency and fairness, which are assumed to be associated with the broader concept of' trustworthiness'	**9** (significant difference between ideal and policy requirements, extremely unlikely that ideal requirements will be met)
Staff and Knowledge	• Autonomous staff: • Data-literate senior leaders. • Highly skilled and valued NHS analytics workforce. • Clinicians with the confidence to protect their epistemic authority.	Infrequent but comprehensive recognition of the need to upskill senior leaders. Detailed plan for upskilling and 'rebranding' the NHS analytics workforce. Limited direct recognition of the need to protect clinician's epistemic authority, but comprehensive recognition of the need to provide data science training.	**3** (limited difference between ideal and policy requirements, likely that ideal requirements will be met).
Management Systems and Structures	• Meaningful Accountability • Fit-for-Purpose Information Governance • Clearly regulated medical devices • Clinician and patient protection • - Auditability	Considerable policy attention is focused on regulation, especially information governance and medical device regulation, but the pace of change is slow and undermined by the desire to keep the regulatory environment 'light touch'.	**7** (moderate difference between ideal design and policy reality, unlikely that ideal requirements will be met)
Average (mean)			**6.5**

Table 25. Summarising the analysis of the sociotechnical gap between the ideal requirements and the requirements covered by policy in each of the information infrastructure domains.

7. Putting ACDSS in the right frame

7.1 Introduction

Following the analysis of the preceding three chapters, it is now known a) why the current NHS's information infrastructure is failing to support the implementation of ACDSS (mismanaged and disorganised complexity); b) what changes to this infrastructure are required to increase the chances of success (making complexity more organised and better managed); c) what the consequences will be if these changes are not made (increased likelihood of negative re-ontologising emergence); d) what the ideal benefit-enhancing and risk-mitigating (henceforth 'vision') information infrastructure requirements are (epistemic certainty, robust information exchange, validated outcomes, protected values, autonomous staff, and meaningful accountability); and e) that the likelihood of these ideal requirements being met given current policy developments is low (see Table 26).

Information infrastructure domain	Current information infrastructure design flaw(s) (Areas of complexity)	Associated re-ontologising emergence risks	Ideal vision requirement	Sociotechnical gap Score
Information	Administrative data that may be biased, messy, error-prone, or plagued by missingness being used to train ACDSS models. Clinicians using ACDSS that provides a poor user experience with limited training.	ACDSS trained on biased, overly quantitative, or potentially inaccurate data, may result in some patients or groups of patients being unethically. classified as bad patients. Uninterpretable ACDSS outputs might hinder open information exchange between patients and clinicians, preventing the formation of trusted relationships, and reducing the quality of care.	Epistemic certainty	6
Technology	The implementation of ACDSS involves the exchange of large volumes of sensitive patient data between a significant number of stakeholders – including Government stakeholders and private third-party stakeholders. This exchange currently relies on insecure, non-transparent, and rarely audited data flows.	Relying on poorly controlled, privacy-threatening, data flows for the exchange of information between key stakeholders in the ACDSS implementation pipeline, can leave patients unsure about what is happening to their data self – a fact that can damage their psychological integrity, undermine autonomy, and threaten trust. Large numbers of uncontrolled and non-audited data flows	Robust information exchange	6

	To be useful at the point of care, ACDSS must also be integrated directly into clinical systems and provided with access to live patient data for the purpose of providing personalised advice. This is currently hindered by issues of interoperability and legacy technology.	between the NHS and private third parties, can also change power dynamics in ways that leave both patients and clinicians feeling surveilled. Lack of clear accountability mechanisms makes it difficult to locate and correct breaches of privacy or trust.		
Process	The lack of standardisation, systematisation, and rigour surrounding the entire ACDSS implementation process (or ACDSS lifecycle) from ideation through to post-deployment monitoring, is resulting in a poor-quality evidence base supporting claims that ACDSS can genuinely deliver improvements in patient and system outcomes safely.	Poor quality evidence regarding the benefits and risks of ACDSS use, as well as the efficacy of its advice, can undermine the extent to which patients are able to give informed consent and may result in patients being given inappropriate advice. This may negatively affect the NHS's commitment to patient centricity. Poor quality evidence undermines clinicians' ability to abide by the principles of evidence-based medicine and to fulfil their role as learned intermediaries. This may negatively affect the NHS's commitment to the fundamentals of caring. Lack of structured monitoring post-deployment may mean negative impacts of ACDSS use on unwarranted variations in care go unnoticed and un-rectified.	Validated outcomes	8
Objectives and values	Overarching lack of disorganised complexity throughout the current information infrastructure design increasing the risk of negative re-ontologising emergence.	The patient may be displaced from the centre of care. The fundamentals of caring may be forgotten. The NHS may cease to be for all.	Actively protected outcomes	9
Staff and knowledge	Clinicians do not receive sufficient training regarding the use of ACDSS, which may also have black box elements, this can leave them vulnerable to automation bias – believing that the ACDSS is always right even if its advice does	Clinicians and the system may succumb to automation bias. ACDSS cannot replicate the human aspects of care so without clinicians acting as intermediaries these aspects may be lost and the rates of e-iatrogenesis may increase if there is a mismatch between	Autonomous staff	3

	not appear to accurately reflect the patient's context. NHS analysts and NHS senior leaders may use the outputs of ACDSS to inappropriately surveil or performance monitor clinicians, positioning ACDSS as the gold standard that clinicians must always meet.	the ACDSS advice and the patient's context. The ultimate effect may be a worsening of the experience of care and a consequential loss of trust between patients and clinicians.		
Management systems and structures	All mechanisms associated with process accountability (e.g., information governance regulation, medical device regulation) are struggling to keep pace with the development of ACDSS.	Process accountability is a pre-requisite for building trusting relationships between clinicians and patients and for patients and the public viewing the healthcare system as legitimate. Disruption to process accountability may, therefore, result in the de-legitimisation of the healthcare system from the perspective of the public.	Meaningful accountability	7

Table 26. Summary of current information infrastructure design flaws (areas of complexity), associated risks of re-ontologising emergence, ideal vision requirement, and sociotechnical gap score from Chapters 4, 5, and 6

The likelihood of the ideal vision requirements being met by current policy developments is low because, although the average sociotechnical gap is not so wide as to be insurmountable, it is considerable – particularly in the objectives and values, process, and management systems and structures information infrastructure domains. Current policy documents feel ad-hoc, lacking an overarching 'vision' for the NHS's information infrastructure, and are often too surface-level, lacking in specificity and leaving too much open to chance with very little guidance on what should be built or designed to bring the ideal vision into reality. Thus, as it stands, the likelihood that the NHS will be able to capitalise on the benefits of ACDSS implementation whilst mitigating the risks is currently limited. Therefore, if this thesis is to achieve its aim of designing the information infrastructure that will help the NHS to capitalise on the benefits (positive intended emergence) of ACDSS whilst mitigating the risks (negative re-ontologising emergence), it is essential that the requirements for closing this gap – in the form of recommended policy actions – be identified. However, if these last set of requirements are to be realistic and pragmatic (as is the aim of design), then it is first necessary to understand *why* the gap, between the ideal vision requirements and the requirements covered by policy, exists.

In some instances, there are relatively obvious explanations for why the gap exists, and why it varies in width depending on the information infrastructure domain in question. For instance, the very

wide gap between the ideal and policy management systems and structures requirements can be attributed to the fact that the policy requirements are conflicted: caught between the aim of firming up regulation and positioning the UK as a global centre for AI safety, and the ambition to encourage rapid innovation by de-regulating and removing friction from the path-to-market for AI companies. Alternatively, the far narrower gap between the ideal and the on-the-ground staff and knowledge requirements can be attributed to the fact that upskilling the workforce, is a task that the NHS, and the wider UK Government is readily familiar with. There are already processes and protocols in place for reviewing curricula, for identifying skills gaps, and for investing in the development of the future workforce through the provision of scholarships and clear career pathways. Indeed, the successful creation of the Government-wide Digital, Data and Technology (DDAT) workforce in 2017 is evidence that UK policymakers are familiar with tasks of this nature. However, such readily apparent explanations are not available to explain the gap between the ideal and on-the-ground reality requirements in all the domains, and – even when they are available – do not provide sufficient detail to enable the elicitation of gap closure policy action requirements. For this, a much deeper understanding of the reasons for the gap's existence is necessary (The Design Council & The Point People, 2020).

To develop this deeper understanding, a Foucauldian, or poststructuralist, critique is needed. This does not simply mean stating that 'things are not good the way they are.' Instead, it means seeking answers regarding on "what type of assumptions, of familiar notions, of established, unexamined ways of thinking the expected practices are based" (Bacchi, 2009; Foucault, 2001, p. 456), with the expected practices in this context being the current policy developments. Again, this does not mean simply identifying the assumptions underpinning current relevant policy statements and listing them but assessing the assumptions from a normative perspective. This is a problematising approach to understanding why the gap exists, and thus far more in keeping with the philosophical approach taken by this thesis (as explained in Chapters Two and Three). Completing this problematisation of the current requirements covered by policy (and the ideal requirements) is the task of this chapter. Specifically, it seeks to answer RQB(ii) which, to restate, is:

> RQB(ii) What underpinning assumptions and contextual factors might limit the likelihood of the ideal requirements being met by current policy?

Exactly how the chapter will do this is explained in the next section.

7.2. Methodology

To answer the question "what underpinning assumptions and contextual factors might limit the likelihood of the ideal requirements being met by current policy?", and so develop a deep understanding of why the sociotechnical gap exists between the ideal vision requirements and the requirements covered by policy, a "what's the problem represented to be" (WPR) approach to policy analysis is needed.

Developed by Bacchi (2009), the WPR approach to policy analysis applies the critical theory of evidence-based policy to analyse *how* the current policy developments have come into being through the combination of evidence, politics, judgement and debate (Head, 2008). In so doing, the WPR approach aims to provide a systematic method for identifying, and assessing, the taken-for-granted assumptions that exist within current government policies and policy proposals (i.e., the policy documents included in the analysis described in Chapter Three), by interrogating the way in which the problem that the policy is trying to fix is framed. This is a form of reverse engineering: using the solutions suggested in current policy documents (what they cover, what they leave out, who they impact, and more – the frame) to gain insight into the underpinning thinking that has informed their development, or to gain a deep conceptual understanding of the policy problematisation process (Bacchi, 2009).

In this way, WPR analysis can help answer the question "why does the gap between the ideal and policy vision requirements exist" by identifying the meaning (the cultural values, ontological and epistemological assumptions, theories and philosophies) that needed to be in place for the ideal requirements *and* the requirements covered by policy to come into being (Bacchi, 2009). In so doing, WPR approaches highlight the fact that differences in problem framings (i.e., the framing of the problem how to implement ACDSS successfully) are neither inevitable nor the product of a natural evolution (Bacchi, 2009). In short, WPR foregrounds the epistemological frame problem (i.e., how do you identify *a priori* what is and is not relevant to a particular problem and solution(S. Murray, 2016)) and so helps to highlight the fact that policy problems, and their proposed solutions are socially constructed (Coburn, 2006). Indeed, this is why problematisation is the first stage of technology shaping according to strong structuration theory (Greenhalgh et al., 2019). Conducting analysis in this way emphasises the complex relationship between science and policy (Marmot, 2004), and can be used to (a) understand where policy has failed in the past; and (b) to plan for future policies and their implementation (Walt et al., 2008). Thus, the aims of WPR analysis align perfectly with the task of this chapter.

Specifically, a three-stage analysis process was conducted to answer RQB (ii). First, a WPR analysis was conducted of the included policy documents, relying on rhetorical analysis techniques (as discussed in Chapter Three), and drawing on insights from the semi-structured interviews, to draw out the assumptions, theories, and philosophies (henceforth assumptions) underpinning the current relevant policy developments. Second, a parallel analysis of the documents included in the realist review (described in Chapter Three) was conducted, so that the assumptions underpinning the ideal requirements could be compared to those underpinning the requirements included in current policy documents. Third, a theoretical analysis was conducted, to explain where the assumptions underpinning the requirements covered by policy have come from, and why they differ to those underpinning the ideal requirements. Specifically, this analysis drew on the most relevant social science theories identified by the literature review described in Chapter Two: neo-institutional theory, dramaturgical theory, actor-network theory, and strong structuration theory (e.g., Cresswell et al., 2010; Currie, 2012; Greenhalgh & Papoutsi, 2019; Hajer, 2003; Jensen et al., 2009; Macfarlane et al., 2013; Pawson et al., 2005). The results of these three analyses were then combined into a narrative synthesis (see Chapter Three) presented below.

7.3. Results and discussion: more than a difference of opinion

The following narrative synthesis proceeds in three sections, mirroring the three-stage analysis described above. First, the identified assumptions underpinning the on-the-ground policy requirements (the what) are described, and how these compare to the assumptions underpinning the ideal requirements is considered. Second, an explanation for how the assumptions underpinning the requirements covered by policy came to be (the why) is provided. Third, and finally, the implications of these findings for the overall likely success of the information infrastructure re-design process (the so what) are discussed. In this way the following narrative provides answers to the what, the why, and the so what of the question "what assumptions and contextual factors might limit the likelihood of the ideal requirements being met by policy?". The discussion concludes that the sociotechnical gap between the ideal requirements, and the requirements covered by policy documents, can be attributed to the fact that there is currently a lack of agreement between key stakeholder groups with regards to the *function* of the desired ACDSS-enabled NLHS and thus there is a lack of agreement regarding the *form* of the information infrastructure needed to successfully implement ACDSS for this purpose.

7.3.1. Different frames: different solutions

To start with the what, WPR and rhetorical analysis of the policy documents (a) supported by insights from the semi-structured interviews and key theories; and (b) compared with WPR analysis of the articles included in the realist review, revealed stark differences in the assumptions underpinning the requirements covered by policy and the assumptions underpinning the ideal 'vision' information infrastructure requirements. These differences in assumptions relate to:

1. The size and shape of the re-design challenge
2. The so-called art of the possible
3. The relationship between information and action
4. The role of regulation in supporting innovation

Each of these four assumption categories will now be discussed in turn.

7.3.1.1 The size and shape of the re-design challenge

In Chapter One, it was explained that the central motivation behind the current policy drive to implement ACDSS into the NHS is a desire to change the *modus operandi* of the NHS by turning it into a national learning healthcare system (NLHS). It was also explained that many of the NHS's prior large-scale technology transformation programmes have failed, in part due to a tendency of policymakers to assume that technology implementation is a straightforward linear process. Such assumptions, it was argued, ignore the impact of sociotechnical complexity on technology implementation success. It was stressed, therefore, that to avoid the reductionist-related failure of the past, a more complexity informed design-based approach to ACDSS implementation would be necessary.

Much of the literature included in the realist review, and many of the interviewees, agreed with this perspective, approaching the proposed implementation of ACDSS and the necessary re-design of the NHS's information infrastructure as a second order change. A second order change is a change involving "alteration of the system's basic governing rules" that "shifts the system as a whole irreversibly to a new paradigm" (Ashburner et al., 1996a, p. 2). Viewing the implementation of ACDSS as a second order change creates a wide frame for the 'problem' of re-designing the NHS's supporting information infrastructure, and highlights the fact that the relationships between ACDSS, ACDSS developers, clinicians, patients, and the healthcare system are more likely to be "contested, variable, and disorderly" than immediately harmonious (Holton & Boyd, 2021, p. 188). Consequently, the ideal

requirements approach the challenge of re-designing the NHS's information infrastructure from a systems-level of abstraction, "wrapping together" various considerations from regulatory standards to the end-user experience, and taking an end-to-end strategic approach to implementation (I2, Interview, 17 October 2022; I33, Interview, 28 October 2022; I43, Interview, 31 October 2023).

In contrast, much current policy appears to rest on the assumption that the implementation of ACDSS is only a first-order change: requiring some incremental changes to specific aspects of the information infrastructure, but no re-design of its core operation (Ashburner et al., 1996a, p. 2). This results in a much narrower problem frame. Single (often well publicised) issues such as the 'rubbish in, rubbish out' problem are recognised, for example, there are very targeted policy statements requiring datasets and products to be tested for issues of bias (e.g., Department of Health and Social Care, 2021). However, policy commonly deals with these issues in isolation, disconnected from wider system needs and related requirements (I17, Interview, 20 October 2022). For instance, policies related to data collection, and the need to reduce the number of duplicative data flows in the NHS, might reference the importance of interoperability, but not EHR design, data timeliness, or the need to upskill staff to deal with data recorded in different formats (I23, Interview, 24 October 2022). The result is an overall picture of ACDSS implementation policy that feels thin and fragmented.

This policy 'thinness' is exacerbated by the fact that much current policy is also underpinned by a related assumption of technological determinism (M. Shaw et al., 2011). This assumption, which is imbued by (a) a powerful belief in what boyd and Crawford (2012) refer to as the mythology of big data; and (b) magical thinking (Dixon-Woods et al., 2011), is evident in statements such as "Clinical decision support tools, within an electronic health record *will* improve clinical outcomes and reduce unwarranted variation" (Department of Health and Social Care, 2022 (emphasis added)). Such deterministic statements give the impression that policymakers currently believe that ACDSS need only be made available for purchase by the NHS to deliver its benefits (Department of Health and Social Care, 2023; I56, Interview, 10 November 2022). This then explains why, for example, policy focused on incentivising uptake of ACDSS is emerging (e.g., Department of Health and Social Care, 2023), in the absence of policy focused on meeting pre-requisite requirements such as upgrading legacy hardware or revising data protection regulation to enable seamless ACDSS integration (I15, Interview, 19 October 2022; I17, Interview, 20 October 2022; I38, Interview, 31 October 2022; I54, Interview, 9 November 2022;Kerr et al., 2018).

7.3.1.2 The art of the possible

In Chapter One, it was also highlighted that whilst innumerable benefits of ACDSS have been hypothesised, very few have been realised. This point was re-emphasised in Chapter Four, which stressed that currently the exact value proposition of ACDSS is unclear. Chapter Five explained that this is problematic because the lack of evidence of benefits may expose both clinicians and patients to harm by undermining the system's ability to abide by the tenets of evidence-based medicine. This is why, in Chapter Six, it was made clear that 'validated outcomes' is an ideal vision requirement.

These arguments highlight the fact that articles included in the realist review, and thus the ideal requirements, are underpinned by an awareness that just because a particular benefit of ACDSS use is possible, does not mean that it is either plausible or desirable. Of course, this does not mean that the literature included in the realist review, is entirely immune to exaggerated assumptions regarding the art of the possible. Section 4.3.3 did, for instance, note that there is evidence of spin and hyperbole in the academic literature (Andaur Navarro et al., 2023). However, most of the articles included in the realist review caveat that whilst it is possible that ACDSS will deliver significant benefits for the healthcare system, realising these benefits, and testing their desirability, will take some time. Reddy and colleagues (2019) for example, observe that real-time ACDSS may not be available for another five years at least, and 'AI clinicians' may be at least another 25 years away[15]. Similarly, Blease and colleagues (2019) note that just because ACDSS might be useful for diagnostic support in primary care settings, does not mean that this is desirable to GPs themselves who are concerned that this might result in a loss of nuance in clinical consultations and a consequential decline in the standard of care. Again, these differences between the possible and the plausible and desirable were echoed by clinical and technical interviewees, with several noting that "we are nowhere near close" to realising the promised potential of ACDSS for the NHS (I7, Interview, 17 October 2022; I21, Interview, 21 October 2022; I30, Interview, 28 October 2022).

In contrast, many of the included policy documents appear to be underpinned by an assumption that ACDSS is already provenly capable of delivering all the many hypothesised NLHS benefits and, therefore, realising these benefits in the near-term future will be relatively easy. This assumption is evident in the confidence of statements such as "we will use [A]CDSS in diagnostics to improve the provision of the most appropriate test at the right time, improve the safety and quality of care, and reduce the overall cost through the roll-out of iRefer" (Department of Health and Social Care, 2022a) and "we will roll-out digital infrastructure that will enable diagnostic networks to make

[15] Note that these time frames have been adjusted for the time difference between 2019 and 2023.

use of AI to reduce repetitive tasks, increase the throughput speed of diagnostic results reporting, and provide enhanced post-processing of imaging datasets" (Department of Health and Social Care, 2022a). In both instances the use of the phrase 'roll-out' implies that the AI technology itself, and the supporting infrastructure, is already available and all that is needed is to ensure its spread across the NHS.

Interviewees were also keen to comment on this tendency for policy to assume that the possible and the plausible are one and the same, noting that there is often a disconnect between the people on the frontline (either in terms of clinical care or in terms of information infrastructure) and policymakers who are sometimes distracted by "clever boxes of tricks" and forget to pay attention to the necessary or required "stuff in the middle" (I5, Interview, 17 October 2022; I17, Interview, 20 October 2022; I50, Interview, 7 November 2022). This assumed overlap between the possible and the plausible implies a lack of awareness of the fact that, in institutions as complex as the NHS, there is not always an overlap between what *must* happen, what *should* happen, and what *does* happen (T. Scott, 2003a; W. R. Scott, 2000), and that it is indeed sometimes more common for these three 'pillars' to diverge rather than merge. This explains (a) why the information infrastructure goal posts are constantly moving in policy documents (e.g., the date of full digitisation has moved from 2005 to 2011, to 2020, and now to 2025 (Cross, 2019; Health and Social Care Select Committee, 2023)); and (b) why there is more focus in current policy documents on surface level or adoption requirements (e.g., staff and knowledge requirements) than there is on deeper level or technical underpinning requirements (e.g., information or technology requirements).

7.3.1.3 The relationship between information and action

Chapter Five highlighted the potential risks of re-ontologising emergence related to changing what counts as evidence of illness (see section 5.3.1.1); redefining the notion of a good patient (see section 5.3.1.2); and shifting power dynamics resulting in a loss of trust between patients and clinicians (see section 5.3.2.1). Picking up on these risks, Chapter Six, highlighted the need to design the NHS's information infrastructure around the vision requirements of (a) autonomous staff, so that clinicians retain their epistemic authority whilst using ACDSS; and (b) protected values, so that patients are still treated holistically and placed at the centre of care by ACDSS (see sections 6.3.4.2, 6.3.5.1).

These discussions highlight the fact that articles included in the realist review, and thus the ideal requirements, are underpinned by an awareness that the relationship between information, and the behaviour of patients and clinicians (i.e., 'action') is not straightforward. Indeed, unless carefully

considered, the use, interpretation, and representation of information can cause harm, be unethically manipulative (i.e., 'nudging' (A. Aggarwal et al., 2014; Hofmann & Stanak, 2018)) and risk returning medicine to an outdated paternalistic model (Morley & Floridi, 2020b). This is why the ideal delivery requirements related to the relevant vision requitements cover everything from user experience, interaction design, explainability, data quality, and the need to ensure information exchange between clinicians and patients is still 'caring' and not overly mediated by ACDSS (Cornetta & Brown, 2013). There is a recognition built into all these requirements that the relationship between information and action is not always rational and may be impacted by a range of factors, including personal values, digital health literacy, personal circumstances (i.e., factors related to the social determinants of health), and difference tolerance levels for uncertainty.

Such a nuanced understanding of the complex relationship between information and action, and the potential for this to be manipulated for reasons related to power and hidden agendas appears to be largely missing from current policy developments. Instead, most current policy seems to rest on info-liberal assumptions of rationality (Lock & Nguyen, 2018). More specifically, there appears to be an assumption in current policy that ACDSS implementation will result in an immediate 'improvement' in decision making via a simple linear process (Sandiford et al., 1992; M. Shaw et al., 2011):

1. ACDSS provides clinicians with more information about the patient at the point of care;
2. Clinicians understand this information to be more accurate than the information they, themselves, recall about the patient and the patient's circumstances;
3. Patients unquestioningly accept that ACDSS 'knows' the best treatment for them;
4. Clinicians and patients absorb all the information provided by ACDSS; and
5. Clinicians and patients make rational decisions based on clinical or scientific (not emotional) evidence of utility, efficacy, and efficiency.

In short, current policy appears to rest on the assumption that ACDSS will be automatically 'empowering' for clinicians, patients, and the wider system. For example, the *Ten Tech Priorities* from the (then) Department for Digital, Cultural, Media and Sport (2021) included the statement "by removing barriers to responsible data sharing and use we aim to become the world's number one data destination [….] where data improves life for people across the UK". It does not say *where* data is used to enable the improvement of life, or even how, but simply that data will improve the lives of people across the UK. This assumes a rational and linear relationship between provision of data (information), and better outcomes.

This info-liberal 'empowering' assumption leaves psychological, emotional, value-based, or any softer elements of clinical judgment (Chin-Yee & Upshur, 2018; Dixon-Woods et al., 2011) out of the ACDSS problem frame. This explains why many of the ideal requirements regarding the presentation, and interpretation of information are missing from current policy. For example, there are no policy requirements related to A/B testing of different 'pop-up' formats, auditing the impact of different 'alerts' on decision-making processes. Nor are there any policy requirements related to the need to include social determinants of health data, patient-reported outcomes data, or even value-based data into ACDSS to ensure these less 'rational' sources of knowledge about a patient's health are included in the ACDSS 'decision-making' process.

7.3.1.4 The role of regulation in supporting innovation

Chapter Four made clear that the pace of ACDSS development is currently outpacing that of related 'hard' (i.e., regulatory) governance mechanisms. Chapter Five stressed that this is problematic because process accountability, or the existence of well-established mechanisms to guarantee safety and efficacy, is a pre-requisite for trusting relationships forming between patients and clinicians. Chapter Six explained that this is why 'meaningful accountability', is a key ideal vision requirement, and the development of a proportionate governance framework including fit for purpose information governance and clearly regulated medical devices is a vital ideal delivery requirement.

Articles in the realist review put forward this view that "smart regulation" is a pre-requisite for ACDSS implementation success (P. Li et al., 2023). Clarke (2019) for instance noted that without appropriate regulation, AI design (in this instance ACDSS) might breach social acceptability norms. The counterfactual to this argument of course implies that regulation is essential for ensuring ACDSS design is socially acceptable (i.e., successful). Clinical interviewees and NHS commissioners also echoed this argument, stressing that users and beneficiaries of ACDSS need to feel protected from its potential harmful effects to deem its use ethically justifiable and arguing that 'soft' governance measures (ethics frameworks, standards or internal policies) have insufficient 'teeth' for this purpose (I17, personal communication, 20 October 2022; I44, personal communication, 19 October 2022; Rességuier & Rodrigues, 2020).

Much current policy, however, appears not to subscribe to this belief that hard regulatory mechanisms are required for implementation success. Instead, many current policy developments appear to be underpinned by the assumption that 'soft' governance measures will (a) offer sufficient protection to patients and clinicians from the potential harms presented by ACDSS; and (b) sufficiently incentivise the highly fragmented NHS to conform to necessary data quality,

interoperability, and privacy standards. Indeed, there appears to be an assumption in current policy that regulation (or 'hard' governance) would stifle innovation and prevent the NHS from capitalising on the benefits of ACDSS (P. Li et al., 2023). This is clear, for example, in commitments from the MHRA to "focus on ensuring that friction is taken out of the market" (MHRA, 2021c) or the statement in the *UK National Data Strategy* that "[the Government] will work in partnership with the ICO to lift compliance burdens wherever possible on businesses, especially SMEs" (Department for Digital, Culture, Media & Sport, 2020). Policy commitments such as these, explain why so few of the management systems and structures ideal delivery requirements are covered by current policy.

7.3.1.5 No evidence? No problem?

With the preceding analysis having been completed, it is now clear that the assumptions underpinning current policy related to the (a) size and shape of the re-design challenge; (b) art of the possible; (c) relationship between information and action; and (d) role of regulation in supporting innovation, are not supported by either the academic literature nor the opinions of key system stakeholders – particularly clinicians, clinical academics, and social scientists. The question is then why, if there is so little evidence to support the justifiability of these assumptions, do they continue to pervade developing policy? Answering this question is the task of the next section.

7.3.2. Policy Influencers

To understand why these seemingly unfounded assumptions continue to pervade relevant developing policy (i.e., 'the why'), it is first necessary to highlight the fact that "although the use of research-derived evidence may be a key feature of most policy models, it is not a certainty that scientific evidence will carry as much weight in 'real-world' policymaking as other types of evidence" (Brownson et al., 2009, p. 1576). Indeed, as Löblová (2018) explains, the relationship between evidence and policy is very rarely linear, and it is very rare that there is only one relevant evidence-base (Head, 2008). It is far more likely that there are multiple evidence bases upon which policymakers draw. Which 'base' becomes the dominant source of evidence depends more on the influence of the different stakeholder groups responsible for developing different evidence bases than on the quantifiable strength of the evidence itself. This is because of the role epistemic communities play in the development of policy.

According to Haas (1992, p. 3) "an epistemic community is a network of professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area." These communities, which group around

particular problem framings, exist and exert influence in all areas of policy. However, epistemic communities are most heavily relied upon to provide expert input into the policy development process under conditions of uncertainty. For example, when policy problems – like the implementation of ACDSS – involve a particularly 'technical' or 'new' issue that policymakers do not feel fully equipped to deal with. In such instances, policymakers may turn to epistemic communities to articulate the cause and effect relationships (i.e. the evidence) they need to understand to determine how best to intervene through policy (Dunlop, 2012). This greater reliance on epistemic communities then gives the communities greater control over the production of knowledge used by policymakers to make decisions in these circumstances (Dunlop, 2012) .

In the context of ACDSS, clinicians, social scientists, ethicists, and academic researchers including research software engineers together represent an epistemic community responsible for producing scientific evidence that is typically disseminated through research papers, academic conferences, and other 'formal' channels. Evidence produced by this scientific epistemic community is often balanced, highly detailed, complex, and technical. In short, it is evidence that is likely to be considered 'high quality' according to the GRADE evidence criteria (Guyatt et al., 2008), and is the evidence that underpins the ideal requirements. However, in the context of policymaking, particularly in the context of a technically challenging policy domain such as ACDSS, it is not necessarily the quality of the evidence that dictates its influence, but rather its accessibility and interpretability. Whilst evidence produced by this scientific epistemic community may be high quality, it is vast, difficult for policymakers to access, and often requires considerable skill to interpret (Brownson et al., 2009). As a consequence of these accessibility and interpretability limitations, evidence produced by the scientific epistemic community leaves itself vulnerable to being eclipsed by evidence produced by other competing communities that is more practical, accessible, interpretable, and readily actionable (Head, 2008; Löblová, 2018). This is why in technical policy domains, including ACDSS, policymakers are more likely to defer to 'technical' (or 'technological') epistemic communities (Haas, 1992; Macfarlane et al., 2013a): in this instance the community comprised of third-party (often private) ACDSS developers. Evidence produced by this community is not only more accessible and digestible (disseminated through large public events and the public press), but also more aligned with the current Government's ambition to use AI to transform the economy and become a "global hub for innovation by 2035" (HM Government, 2022). It is perhaps not surprising, therefore, that it is this technical epistemic community that clearly has the dominant influence over current ACDSS-relevant policy developments.

This dominant influence of the technical epistemic community over current relevant policy, is evident from the Government's approach to organising the "Global AI Safety Summit". The Safety Summit was announced by UK Prime Minister Rishi Sunak, on the 7th of June 2023 following a roundtable he hosted in May, attended by the CEOs of three private AI companies: OpenAI, DeepMind (owned by Google), and Anthropic. The announcement of the summit claimed that "breakthroughs in AI continue to improve lives – from enabling paralysed people to walk to discovering superbug-killing antibiotics" and was accompanied by quotes from Demis Habbis, CEO and Co-Founder of DeepMind; Dario Amoidei, CEO and Co-Founder of Anthropic; Alexander Karp, CEO and Co-Founder of Palantir Technologies; Hugh Milward, Vice President of Microsoft UK; and Dr Marc Warner, CEO of Faculty (Prime Minister's Office, 10 Downing Street & The Rt Hon Rishi Sunak MP, 2023) – all representatives of private AI companies. In response to this announcement, Dame Wendy Hall, regius professor of computer science at the University of Southampton and co-chair of the UK Government's 2017 AI review, was quoted in the Financial Times saying that "my worry about the summit is that the advice is coming mainly from the big tech companies themselves, is it right for the people making money out of this to be the people designing the regulation vehicle?" (Criddle et al., 2023). Yet, despite such criticism, no public efforts have been made to redress the clear influence of private big tech companies over the event and, undoubtedly, its outputs. Instead, Prime Minister Rishi Sunak made clear the Government's intention to continue to prioritise the views of 'big tech' during his opening speech for London Tech Week, explaining "we must act – and act quickly – if we want not only to retain our position as one of the world's tech capitals but to go even further and make this the best country in the world to start, grow, and invest in tech businesses" (Prime Minister's Office, 10 Downing Street & Rt Hon Rishi Sunak PM, 2023).

Interviewees made clear that this domineering influence of the technical epistemic community is also a feature of specific AI for health policy. One research software engineer wishing to present the views of the scientific community to the Government, for example, stated that it has "been incredibly difficult to be able to get an audience in front of somebody like NHS England and have that 'vision' conversation" (I10, Interview, 18 October 2022). Given this influence of the technical epistemic community, it is perhaps to be expected that assumptions of determinism, rationality, and a negative effect of hard governance on innovation, continue to underpin developing policy. It is in the interests of tech companies to push a deterministic narrative, and to lobby for lighter touch governance. Furthermore, individuals in the technical epistemic community tend to have less frontline experience of the NHS (I2, Interview, 17 October 2022; I3, Interview, 17 October 2022; I62, Interview,

14 November 2022), either from a clinical or a backend infrastructural perspective, and are, therefore, less likely to see either the full scale of the infrastructural challenge or the full complexity (non-rationality) of clinical decision-making processes.

On the surface, this dominant influence of the technical epistemic community on developing policy might not appear to be problematic. There is nothing to say definitively that the ideal requirements derived from the realist review, and influenced by the scientific epistemic community, are the only *right* requirements. The technical epistemic community, including ACDSS developers, undoubtedly have more experience designing and developing deployable "off-the-shelf" software than the scientific epistemic community, and technical projects should be led by individuals and organisations with technical expertise (Goldacre & Morley, 2022; I46, Interview, 4 November 2022). However, the issue is not only that the technical epistemic community generates evidence of a different kind to the scientific epistemic community, and that this evidence is clearly predicated on different assumptions. The issue is also that, as highlighted in 4.2.6, these two different communities are comprised of individuals and organisations with very different value systems, experiences, and knowledge of the sociocultural, infrastructural, and ethical intricacies of healthcare in general – and the NHS specifically. These differences, as discussed in the final section below, have far bigger implications for the likelihood that policymakers can design and deliver an NHS information infrastructure capable of enabling the successful implementation of ACDSS (remembering that success is defined as technically feasible, and socially acceptable, ethically justifiable, legally compliant), and, consequently, enabling the NHS to capitalise on the dual advantage of ACDSS.

7.3.3 Form follows function

The differences in the composition, values, experiences, and assumptions of the scientific and technical epistemic communities not only impact the way that specific risk-mitigating or vision requirements are interpreted or operationalised in policy. These differences also have an impact on the design of the overall system's function, i.e., what an ACDSS-enabled NLHS should be expected to achieve.

This is evident from the fact that, when asked "what would a successful future ACDSS-enabled NLHS look like" members of these different communities give very different answers.

Members of the NHS-experienced scientific epistemic community give grounded, relatively simple, and constrained answers focused on:

1. Filling communication gaps between different NHS organisations (for example primary care and secondary care organisations);
2. Ensuring clinicians and patients have access to rich information about the patient, their history, and their preferences at the point of care to make shared decision-making more streamlined; and
3. Providing clinicians with access to real-time advice for very specific 'decisions' such as flagging patients that might need to be recalled for further testing or identifying potential errors in prescribing.

For example[16]:

> "The whole system should have access to all data about a patient, so that all decisions could be made more efficiently, and access to treatment or even diagnosis could be more streamlined."
>
> "Using AI to tackle well-targeted, narrow, problems at both the patient and population level. Not aiming to improve everything all at once but making small incremental improvements to fill communication gaps."
>
> "The aim should be just to get the basics right. Workload should be manageable, the system should know what is happening at the primary care level, e.g., all returns should be correct, and hospitals have access to all the information about patients seamlessly."
>
> "Clinicians and prescribers should have access to a system that pulls together all the available information about that patient at the point of care so that they can make more informed decisions and they should be alerted if they are going to make an error."

Patients give relatively similar answers, focused almost exclusively on using ACDSS to improve the experience of care through more joined-up communication. For example:

> "Everyone in the system should be able to access all patient's data, and there should be an element of tracking and advanced warning built into the system."
>
> "Information flowing through the system easily, so that there are no gaps in communication, and patients are helped to make decisions about their own care so that they feel as though they are in charge."

[16] These examples are all paraphrased answers given by interviewees to the question "Imagine we have created a data-driven future healthcare system, what does success look like?" The examples are not ascribed to individual interviewees i.e., citations are not given, to protect the anonymity of the interviewees.

In contrast, members of the NHS-newcomer technical epistemic community give far more ambitious, less grounded, and less culturally informed answers focused on:

1. Algorithmic screening and predictive 'wellness' (i.e., not just the prediction of disease, but the continual improvement of health);
2. Personalised risk stratification and continuous monitoring encouraging people to take more responsibility for their own health; and
3. Closely monitored frontline services, surveilled for compliance and efficiency purposes.

For example:

> "It will be a more efficient system with better outcomes, less in person visits and more algorithmic screening, so hospitals become less busy."
>
> "With more data, the NHS should become the "National Wellness Service"
>
> "Patients should know if they are going to get ill and what they can do about it so they can take responsibility for their own health. This should be supported by continuous monitoring and risk screening. This should support the ideal paradigm: preventable, predictable, monitored in real-time, connected, and flexible."
>
> "Everyone should have oversight of how all their lifestyle decisions affect their health and what they can do to improve their health outcomes. Ultimately, this should help us see healthcare entirely differently, moving away from treating sickness to maximising wellness and lifestyle."

Unsurprisingly, given the influence of this technical epistemic community on the development of policy described above, policymakers give very similar answers focused on:

1. Efficient diagnosis, ensuring patients get access to care faster in primary care settings, reducing costs for the system;
2. Predictive interventions, moving the system away from a focus on illness to a focus on overall wellness, empowering individuals to take better care of their own health; and
3. Closely monitored frontline services.

For example:

> "Helping patients faster so that we have a healthier population. This would mean knowing what is going to happen in the future so that we can intervene earlier."

> "Ultimately it comes back to the three Es economy, efficiency, and effectiveness – measured improvements across those three things in terms of numbers of people seen, treated, discharged early."
>
> "Better informed policy decisions regarding what services are needed, where, when, and how much they should cost."

It is clear from these different answers that the different assumptions (derived from different values, cultures, and experiences) of the two epistemic communities, are not only resulting in different interpretations of requirements at a low level of abstraction, but also in different interpretations of the overall success requirements at a strategic or high level of abstraction (I2, Interview, 17 October 2022; I3, Interview, 17 October 2022; I62, Interview, 14 November 2022). The two levels are, of course, highly connected as, as explained in Chapter One, form follows function. It is to be expected, therefore, that the information infrastructure form (i.e., operationalisation of the ideal vision and delivery requirements) designed by the scientific epistemic community to meet their desired ACDSS-enabled NLHS function, would differ from the information infrastructure form designed by the technical epistemic community (and latterly policymakers) to meet their desired ACDSS-enabled NLHS function. In other words, differences in the assumptions, values, cultures, and experiences of the (a) scientific epistemic community and of the (b) technical epistemic community, result in differences in the desired function of the ACDSS-enabled NLHS which, in turn, results in different interpretations of the information infrastructure form necessary to support the relevant function. This explains why the sociotechnical gap between the ideal requirements (influenced by the scientific epistemic community) and the requirements covered by policy (influenced by the technical epistemic community) exists.

The implications of attributing the existence of the sociotechnical gap between the ideal requirements and the requirements covered by policy to differences in the assumptions held by the scientific epistemic community and the technical epistemic community, resulting in different interpretations of the intended function of the desired ACDSS-enabled NLHS, and so different interpretations of the information infrastructure form necessary to support said function, are two-fold. First, this attribution means that the sociotechnical gap cannot be closed by simply 'adding in' the missing requirements to existing policy or lobbying for different interpretations of requirements already covered by policy but operationalised in a way that does not match the ideal. This would, at best, be a temporary fix. The gap would likely re-open when, for example, developments in technology necessitated a re-evaluating of the requirements by both communities. Instead, the gap must be closed

by negating the influence of the differences in assumptions at source, by identifying a unifying function that all stakeholders -regardless of their epistemic community membership – can support.

Second, this attribution means that, because the main users and beneficiaries of the ACDSS-enabled NLHS primarily belong to the scientific epistemic community, and the designers of the system primarily belong to the technical epistemic community, unless the gap is closed in the manner described above, the designers may produce an information infrastructure form that enables an ACDSS-related function that the end users and beneficiaries of the system do not want. In other words, unless the sociotechnical gap is closed through the identification of a unifying function, it is possible that the system designers will produce an information infrastructure form that supports a function that may be technically feasible and even legally compliant but is unlikely to be either socially acceptable or ethically justifiable. In short, unless the negative influence of the two different sets of assumptions on the different interpretations of system requirements is negated at source by the identification of a unifying function, it is very unlikely that ACDSS implementation will be successful. Instead, the system would be 'overfitted' to suit a socially unacceptable and ethically unjustifiable function, resulting in abandonment of the technology, a likely increase in negative unintended consequences, and a persistent pattern of failure (Winhall & Leadbeater, 2020). Avoiding this outcome must, therefore, be the primary goal of the next and final empirical chapter.

7.4. Conclusion

The primary aim of this chapter was to answer RQB(ii) and so develop an understanding as to why the sociotechnical gap between the ideal vision requirements and the requirements covered by current policy exists.

Over the course of the analysis included in this chapter, it has become clear that the sociotechnical gap exists because the ideal requirements are influenced by the scientific epistemic community, whilst the requirements covered by policy are influenced by the technical epistemic community. These two communities are both equally important in the development of ACDSS, but their views on what the function of the intended ACDSS-enabled NLHS should be, and therefore what the necessary form of the supporting information infrastructure is, differ considerable due to differences in underpinning assumptions, values, and experiences. On the surface this may not appear to be problematic. There may be circumstances where the influence of a technical epistemic community on the development of policy raises no concerns. The problem in this context, is that the main beneficiaries and users of the intended ACDSS-enabled NLHS belong to the scientific

community whilst the designers of the system belong to the technical epistemic community. This is creating a scenario where it is possible that the designers (primarily policymakers) may produce an NHS information infrastructure that supports an ACDSS-enabled NLHS function that is neither socially acceptable nor ethically justifiable to the primary beneficiaries and users. Were this to be the outcome of the information infrastructure design process, it is highly unlikely that the implementation of ACDSS would be successfully, meaning that it would be highly unlikely that this thesis could achieve its aim of enabling the NHS to capitalise on the dual advantage of ACDSS.

Worryingly, there is some evidence that the process of designing the NHS's information infrastructure to better suit the system designers than the system beneficiaries has already begun (I7, Interview, 17 October 2022) (I11, Interview, 18 October 2022). Several members of the scientific epistemic community, for example, suggested during interviews that they believe the current policy direction will result in an information infrastructure form that supports the use of ACDSS by private companies, but not by the NHS (I22, Interview, 21 October 2022; I30, Interview, 28 October 2022; I49, Interview, 7 November 2022). Being aware of this process starting is important because there is a recursive relationship between strategy → policy → experts delivering strategy goals → epistemic community membership → policy influence. It is essential, therefore, that this feedback loop be interrupted before it becomes self-reinforcing and the chances of designing an NHS information infrastructure for the successful implementation of ACDSS become infinitesimally small.

Interrupting this feedback loop and closing the sociotechnical gap before it is too late, is, therefore, the aim of the next and final empirical chapter: the design chapter. Specifically, it will aim to do this by (a) identifying a unifying (or broadly acceptable) conceptual function for the desired ACDSS-enabled NLHS; (2) identifying the requirements that will operationalise the ideal vision and delivery requirements in a way that is in-keeping with this function (so that form follows function); and (c) identifying a series of recommended policy design-actions that can bring this conceptual model into being in a way that is not only technically feasible, socially acceptable, ethically justifiable, and legally compliant, but also pragmatic and achievable.

8. A recipe for success

8.1 Introduction

The preceding four chapters (chapters Four – Seven) have concluded the Originate (or 'needing') and Focus (or 'vision') phases of design and provided answers to RQA and RQB.

First, in answering RQA(i) and RQA(ii), chapters Four and Five concluded that current efforts to implement ACDSS into the NHS are failing because of mismanaged disorganised complexity in the NHS's current information infrastructure, and that this is concerning because it increases the risk of negative re-ontologising emergence resulting from the implementation of ACDSS. Specifically, Chapter Four found that the NHS's current information infrastructure is wrought through with mismanaged disorganised complexity in all seven of the domains of the NASSS framework: (a) the range of conditions that the NHS is trying to 'treat' (predict, prevent, and personalise treatment for) with the implementation of ACDSS is extremely broad and difficult to define; (b) the underlying software and hardware needed to support ACDSS is out-of-date, rarely interoperable, and difficult to update due to issues with vendor lock-in; (c) NHS data is primarily administrative data that presents researchers (including ACDSS developers) with a range of data quality concerns; (d) NHS data is also highly sensitive, and balancing protection of privacy with the need to provide broad access for ACDSS development purposes is difficult due to a lack of privacy-preserving data access mechanisms; (e) the development of ACDSS relies heavily on the involvement of private third-parties which is resulting in considerable changes to power dynamics that are difficult to control, and presenting concerns regarding intellectual property, knowledge transfer, and shared 'value'; (f) willingness to adopt ACDSS among clinicians and patients is conditional and dependent on considerations of utility and usability that are rarely enforced or standardised; (g) the value of ACDSS to patients, clinicians, and 'the system' remains unevidenced both in terms of evidence of efficacy and evidence of cost effectiveness; (h) and finally the governance framework is struggling to keep pace with the development of ACDSS which is damaging public trust.

Following this, Chapter Five found that unless this complexity is made more organised and more manageable through the identification of common abstractions (requirements), then the risks of negative re-ontologising emergence will outweigh the benefits of ACDSS implementation. In particular, sections 5.3.1, 5.3.2 and 5.3.3 found that the current level of disorganised complexity in the NHS's information infrastructure is increasing the risk of negative re-ontologising emergence related to: (a) what counts as knowledge about illness; (b) what counts as good patient behaviour; (c) the

patient's right not to know; (d) changing power dynamics; (e)the ethics of care; (f) process accountability; (g) epistemic and social bias; and (h) the inverse data law. Ultimately, the chapter concluded, that unless the complexity plaguing the current design of the NHS's information infrastructure is made more organised, these re-ontologising emergence risks may result in the patient being displaced from the centre of care, the fundamentals of caring being disrupted, and the NHS ceasing to be for all.

Second, in answering RQB(i), Chapter Six concluded that to mitigate the risks of negative re-ontologising emergence resulting from the implementation of ACDSS, the complexity in the NHS's information infrastructure needs to be organised (or re-designed) around a vision of six benefit-enabling and risk-mitigating requirements. Specifically, Chapter Six found that to ensure the NHS can capitalise on the desired NLHS benefits of ACDSS implementation and avoid the risks of negative re-ontologising emergence, the supporting information infrastructure needs to be designed to provide the system with epistemic certainty, robust information exchange, validated outcomes, actively protected values, autonomous staff, and meaningful accountability. More precisely, the analysis found that the re-designed NHS information infrastructure needs to provide the system with the six vision requirements by delivering: (a) consistently good data quality, sufficient data quantity, and reliable data interpretability; (b) user friendly EHR design, privacy-preserving data access mechanisms, seamless ACDSS integration, and system-wide protection from vendor lock-in; (c) clearly stated clinical outcomes, mindful model development, rigorous technical validation, rigorous clinical evaluation, careful local calibration, and ongoing impact evaluation; (d) commitment to collective provision, commitment to patient centricity, and commitment to quality care; and (e) fit for purpose information governance, clearly regulated medical devices, clinician and patient protection, and auditability.

Whilst the identification of these vision and delivery requirements was, of course, a positive step forward towards this thesis's aim of designing the information infrastructure to help the NHS capitalise on the dual advantage of ACDSS, Chapter Six also found that these vision requirements are unlikely to be met by current policy. The sociotechnical gap analysis found that there is a significant gap between the ideal vision and delivery requirements, and the requirements covered by current policy. Current policy is adhoc, and highly abstract, narrowing in only occasionally on very specific 'niche' requirements (such as explainability) without connecting these to a wider system vision. Consequently, the chapter concluded that further requirements for closing this sociotechnical gap would need to be identified, but first it would be necessary to understand why the gap exists.

Following this, Chapter Seven found that the sociotechnical gap between the ideal vision and enabling requirements, and the requirements covered by current policy exists because whilst the ideal requirements are primarily influenced by the 'scientific' epistemic community, the policy requirements are primarily influenced by the 'technical' epistemic community. The scientific epistemic community is comprised of clinicians, clinical researchers, social scientists, research software engineers, and research data scientists, with deep knowledge of the NHS's values, culture, and information infrastructure. In contrast, the technical epistemic community is comprised of third-party private software providers who have deep practical experience of developing 'off-the-shelf' software but less experience of the NHS and its values, culture, or information infrastructure. Consequently, the ideal requirements and the requirements covered by policy, influenced as they are by the two different communities, are underpinned by different assumptions about what the desired function of the ACDS-enabled NLHS should be. In turn, as – as explained in Chapter One - form follows function (Cameron et al., 2016), these different assumptions are driving different interpretations of the ideal vision and delivery requirements. This is concerning because it suggests there is a risk that the system designers (influenced by the technical epistemic community) will design an information infrastructure that supports an ACDSS-enabled function that the users and beneficiaries of the system (members of the scientific epistemic community) do not want. Were this scenario to come to pass, the implementation of ACDSS into the NHS may well be both technically feasible, and legally compliant, but it is unlikely to be socially acceptable or ethically justifiable. Since, as established in Chapter Two, for implementation to be successful, all four success criteria need to be met, this would suggest that designing an information infrastructure to meet the desired function of the technical epistemic community, but not the scientific community, would result in implementation failure. The chapter concluded, therefore, that to close the sociotechnical gap it would be necessary to first identify a unifying function that all stakeholders (i.e., members of both epistemic communities) can support to negate the negative influence of assumptions of determinism, rationality and more at source. This would then enable the identification of a final set of design-action (or policy action) requirements that would operationalise the vision and delivery requirements in keeping with the agreed function requirements.

With these *a priori* conclusions in mind, it is the purpose of this final empirical chapter – the long-awaited *design* chapter – to identify these final requirements for closing the sociotechnical gap in keeping with the unifying function. In so doing, as form follows function via concept, it will complete

the final conceptual model for the successful implementation of ACDSS into the NHS. Exactly how it will do this is the topic of the next section.

8.2 Method

The above summary of the findings of the preceding four chapters acts as a reminder of two key facts. First, that form follows function (Cameron et al., 2016). Second, that the sociotechnical gap between the ideal information infrastructure requirements and the requirements covered by policy exists because of differences in the assumptions underpinning the ideal and the policy requirements, resulting in different interpretations of (a) the function of the desired ACDSS-enabled NLHS; and consequently (b) the ideal vision and delivery information infrastructure requirements (i.e., the form) needed to support the successful implementation of ACDSS in order to deliver the function of the ACDSS-enabled NLHS. Therefore, if the final requirements for closing the sociotechnical gap are to be identified, a two-step analysis process must be completed:

1. A unifying function that is acceptable to the users and beneficiaries of the system, and that negates the influence of the technical epistemic community's assumptions at source, must be identified.
2. The recommended policy design actions for operationalising the ideal requirements in accordance with the function – i.e., the requirements for closing the sociotechnical gap - must be identified.

Hence, the research question for this chapter, and the final research question for this thesis, RQC, is:

> RQC: "What is the unifying function of the desired ACDSS-enabled NLHS? How might policy successfully operationalise the ideal requirements to meet this function?)"

To answer this question, the 'dialectical approach to policy' is needed. Developed by Mitroff and Emshoff (1979), the dialectical approach to policy analysis is specifically designed to help identify new policy 'answers' or 'solutions' to previously identified problems (i.e., develop new design actions for policymakers to ensure the previously identified ideal requirements are met). It sets out the following four analytical tasks (1) identify the assumptions that are preventing new solutions from being realised (see Chapter Seven); (2) identify how these assumptions can be negated; (3) collect data on what the

new solutions should achieve (i.e., what is an acceptable *function* to the users and beneficiaries of the system); and (4) develop counter strategies (i.e., developing new recommended design-actions for policymakers that will ensure the ideal requirements are met in accordance with the relevant function concept, and so ensure the sociotechnical gap is closed).

The following pages present a narrative synthesis (see Chapter Three) of the results of these analytical tasks. To start, each of the assumptions outlined in Chapter Seven are re-visited and analysed from the perspective 'how could the unifying function of the desired ACDSS-enabled NLHS be shaped so that these assumptions are negated at source?' In each instance, theoretical insights from the realist review and applied insights from the semi-structured interviews are relied upon to support the analysis and extract a series of 'function shaping rules' specifically designed to negate the influence of the assumptions at source. The consequences (in terms of not meeting the ideal requirements and so not enabling the successful implementation of ACDSS) of failing to negate the assumptions at source are also highlighted. Next, by analysing the answers given by interviewees to the question "what does a successful ACDSS-enabled future look like" (highlighted in Chapter Seven) and "what should ACDSS aim to achieve", the acceptable function of the future system, according to users and beneficiaries, is described. Third, these two sources of data (the shaping rules for the function that will negate the assumptions at source, and the acceptable function according to the users and beneficiaries of the future system) are combined and subject to conceptual analysis to extract a unifying conceptual function for the desired ACDSS-enabled NLHS that is informed by theory, understandable to policymakers, deliverable by ACDSS developers, and acceptable to clinicians and patients. Finally, as form is mapped to function*,* via concept*,* each of the concepts within the function is mapped to (a) the success criteria requirements (technically feasible, socially acceptable, ethically justifiable, and legally compliant); (b) the ideal vision and delivery requirements; and (c) a final set of policy action requirements for operationalising the ideal requirements in accordance with the function. This is in keeping with the middle-out approach to systems engineering (Bouch et al., 2015; Eason et al., 2013) and is similar to the mapping approach used by Bian and colleagues (2020) to synthesise data quality (DQ) dimensions (i.e. requirements) and assessment methods of real-world data, especially EHRs (i.e., operationalising mechanisms).

8.3 Results and Discussion

8.3.1 Negating the Assumptions

As outlined in the method above, the starting point for the development of the unified acceptable function, is the identification of a set of rules for shaping the function so that it (a) negates the influence of the technical epistemic community's assumptions on policy, at source; and (b) is acceptable to the users and beneficiaries of the system. For this purpose, each of the assumptions will now be briefly revisited, and the specific success, ideal, and delivery requirements impacted by the influence of each assumption on policy will be highlighted. This brief analysis then enables the elicitation of the function-shaping rules. As in Chapter Six, parts of the narrative may feel formulaic. This is, again, by design, to lessen the burden of absorbing such a large quantity of information.

8.3.1.1 Sometimes less is more

To start with the assumptions that: (a) the implementation of ACDSS into the NHS represents first-order change, not second-order change, that simply by being available on the market ACDSS will automatically improve clinical outcomes and reduce unwarranted variation; and (b) that a theoretically possible use or benefit of ACDSS is the same as a plausible or desirable use or benefit. The combined consequence of these assumptions is policy that underestimates the size and scale of the challenge of ACDSS implementation; pays little heed to the number of confounding factors that can interrupt the causal chain between technical solution and clinical outcome; and does not sufficiently challenge the level of disorganised complexity associated with the premise of P4 medicine and the NHS's legacy technology stack (see sections 4.3.1 and 4.3.2). For example, as discussed in Chapter Six (6.3.1.2 and 6.3.2.2), there is very little recognition in current policy of the connection between the technical design of the informational pipeline (from the point of data collection (EHR input) to data output (ACDSS integrated into an EHR with user friendly interface)), and the extent to which clinicians feel confident in the advice given to them by ACDSS. This gives the impression that policymakers believe that simply presenting information to clinicians via ACDSS will improve outcomes, regardless of the quality of the information or its interpretability, and so all that is needed from a policy perspective is a focus on the 'adoption and spread' of ACDSS. In turn, this explains why current policy feels ad hoc, disjointed, and surface level, and why the sociotechnical gap between the ideal information and technology requirements (epistemic certainty and robust information exchange), and the information and technology requirements covered by policy, is so substantial. Unless these assumptions are negated by design, via the unified function of the desired ACDSS-enabled NLHS, their negative influence on policy will continue to undermine the likelihood that future policy will ensure the technical feasibility

or social acceptability of ACDSS implementation and increase the likelihood that ACDSS implementation will result in undesirable re-ontologising emergence.

To ensure the negative influence of these 'magical thinking' assumptions is negated by the design of the ACDSS-enabled NLHS function, said function must:

1. Have a narrow, theory-informed scope that is focused on 'getting the basics' right (I7, Interview, 17 October 2022; I9, Interview, 17 October 2023; Sarkar, 2022);
2. Avoid giving the impression that more information is always better (or that quantity matters more than quality);
3. Avoid implying that ACDSS use will always result in better outcomes for all patients;
4. Be sufficiently flexible to allow for contextual variation in interpretation (Catchpole & Alfred, 2018); and
5. Be grounded in the theory of evidence-based medicine and agile software design i.e., focused on *incremental* improvements (I7, personal communication, 17 October 2022; I29, Interview, 27 October 2022) (Greenhalgh et al., 2014).

8.3.1.2 Review, and reassure, don't dictate

Next is the info-liberal assumption that the relationship between information and action (or decision) is always, linear, direct, and rational, and that all relevant information is quantifiable. The result of the influence of this assumption on policy, is policy that discounts the intermediating role of the clinician in the clinical encounter, underestimating the importance of semantic understanding, contextualisation, and empathetic communication, and implying that clinical decision-making is a simple straightforward process of rule following. For example, as highlighted in section 6.3.4.2, there are currently no requirements within policy to ensure the advice provided by ACDSS accounts for the patient as a whole (i.e., treats them holistically) rather than as a series of disambiguated symptoms, leaving out factors such as the patient's personal values and their social determinants from the clinical decision-making process. Similarly, there are no requirements in current policy to consider how ACDSS might interrupt the decision-making process followed by clinicians, or how the presentation of the information might be used to inappropriately influence or nudge clinical decision making in one direction over another – regardless of a patient's preferences (Hofmann & Stanak, 2018). Even at the 'extreme' ends of the ACDSS implementation pipeline, the limitations of this assumption are felt. First, as discussed in section 6.3.1.2, a relatively narrow definition of 'bias' is used throughout policy requirements relating to data representativeness, potentially excluding other aspects of 'missingness'

from policy that might influence the extent to which the information provided by ACDSS is 'accurate' for all patients. Second, there is limited focus in current policy on the need to ensure regular (or continuous) monitoring of ACDSS-related outcomes, and the need to ensure clinicians can both customise the interface and provide feedback to the ACDSS developer if they feel the information offered to them is not serving them or their patients (see 6.3.3.2). These examples all give the impression that policymakers believe that provided the technical or 'quantifiable' performance of ACDSS has been validated prior to implementation, the impact on the quality of decision-making (i.e., the impact on the 'rationality' or rule-following of the decision-making process) and thus the experience of the clinical encounter for patients will be positive. This explains why current policy feels disconnected from the foundations of caring and the values of the NHS (because these 'softer' aspects of healthcare are viewed as unimportant). In turn this explains why the sociotechnical gap between the ideal objectives and values requirements (actively protected values) and the objectives and values requirements covered by policy is so significant, and why the importance of maintaining clinicians' autonomy (epistemic authority) is not made explicit in the staff and knowledge requirements covered by policy. Unless these assumptions are negated by design, via the unified function of the desired ACDSS-enabled NLHS, their negative influence on policy will continue to undermine the likelihood that future policy will ensure the ethical justifiability of ACDSS implementation and increase the likelihood that ACDSS implementation will result in undesirable re-ontologising emergence.

To ensure the negative influence of this 'presumed rationality' assumption is negated by the design of the ACDSS-enabled NLHS function, said function must:

6. Avoid making the role of the clinician as a learned intermediary null and void (Drazen, 2002; Goetz & Growdon, 2008; Morley & Floridi, 2023);
7. Position ACDSS as one element of a much larger whole (I7, Interview, 17 October 2022; I13, Interview, 19 October 2022);
8. Be something that can be built up slowly over time (I29, Interview, 27 October 2022; I30, Interview, 28 October 2022; I56, Interview, 10 November 2022);
9. Keep the 'patient in the loop' (I33, Interview, 28 October 2022; I68, Interview, 21 November 2022);
10. Focus on recommendations and second opinions rather than decisions (Baalen et al., 2021; I9, Interview, 17 October 2023; I13, Interview, 19 October 2022; I27, Interview, 26 October 2022); and

11. Be intended to support the competence of clinicians rather than undermine it (I8, Interview, 17 October 2022; I21, Interview, 21 October 2022; Jones et al., 2021).

8.3.1.3 Regulation friendly innovation, not innovation friendly regulation

Finally, there is the assumption that regulation is antithetical to innovation. As discussed in section 6.3.6.2, this is the most visible of the assumptions underpinning current policy developments, with its influence even evident in the titles of policy documents such as *Innovation Friendly Regulation* (Regulatory Horizons Council, 2022). The combined result of this assumption invading all areas of policy relevant to process accountability from medical device regulation through to the NHS long-term workforce plan, is policy that falls foul of "AI exceptionalism." In other words, policy that disregards evidence which shows patients, the public, and clinicians view regulation and control as a pre-requisite for trusting new healthcare technologies (Bouwman et al., 2015; Gille et al., 2021; Hester et al., 2015; I61, Interview, 11 November 2022). The overriding impression given is that policymakers believe that the risk of harm arising from the implementation of ACDSS is limited, after all it is 'just' software, it is not directly interventional, and whilst sticks and stones (interventional medical devices) may break bones, words (informational software) will never hurt. This explains why much of current policy feels 'toothless' and why the sociotechnical gap between the ideal process, and management systems and structures requirements (validated outcomes and meaningful accountability), and the process, and management systems and structures requirements covered by policy, is so significant. Unless these assumptions are negated by design, via the unified function of the desired ACDSS-enabled NLHS, their negative influence on policy will continue to undermine the likelihood that future policy will ensure the legal compliance of ACDSS implementation and increase the likelihood that ACDSS implementation will result in undesirable re-ontologising emergence.

To ensure the negative influence of this 'regulation is antithetical to innovation' assumption is negated by the design of the ACDSS-enabled NLHS function, said function must:

12. Rest on the principle *primum non nocere* (first, do no harm);
13. Be tied closely to use cases for which there is a clear, robust, evidence base; and
14. Avoid implying that ACDSS is non-interventional.

This brings the total number of 'shaping rules' for the unifying function to fourteen. These rules having been established, it is now time to condense them, and identify what function, shaped by these rules, would be acceptable to the users and beneficiaries of the designed system.

8.3.2 Designing for the users and beneficiaries

Following the analysis in the previous section, it has now been established that if the influence of the technical epistemic community's assumptions on policy is to be negated at source, said function must be:

1. Relatively narrow in scope - positioning ACDSS as one part of a much larger 'whole' and avoiding the impression that quantity of information matters more than quality;
2. Focused on getting the basics right; grounded in the theory of evidence-based medicine (tied closely to use cases for which there is a clear, robust, evidence base) and based on the principle of *primum non nocere* (recognising that ACDSS is interventional);
3. Sufficiently flexible and adaptable to allow for contextualisation and incremental expansion;
4. Centred on 'recommendations' and 'second opinions' rather than 'decisions'; and
5. Intended to support (a) the competence of clinicians – particularly their role as learned intermediaries, and (b) shared decision-making.

Now, as outlined in the method above, it is time to complete the second step in the development of a unified function, and identify a function shaped by these rules that is acceptable to the main users and beneficiaries of the ACDSS-enabled NLHS: clinicians, patients, and system managers.

8.3.2.1 For clinicians maximise relevance to minimise uncertainty

For clinicians, an acceptable function of the desired ACDSS-enabled NLHS shaped by these rules is:

> *Clinician acceptable function*
> Improving the utility and usability of relevant NHS information at the point of care.

Specifically, for clinicians, acceptability is predicated on the system being designed to fill contextually specific knowledge gaps at the point of need to: (a) minimise the duration of uncertainty about the (e.g.,) benefits and hazards of a particular treatment to as close to zero as possible (I27, Interview, 26 October 2022); and (b) improve continuity of care by smoothing information exchange (I61, Inteview, 11 November 2022; I62, Interview, 14 November 2022). The range of acceptable knowledge gaps is wide, covering anything from the clinician's own experience (e.g., less experienced clinicians may wish to access support from ACDSS more frequently), the patient's condition (e.g., if it is a rare condition that GPs are unlikely to ever 'see' more than once), population health requirements (e.g., which patients should be booked for a screening appointment), or pathway compliance (e.g., what is the

current gold-standard treatment for a patient with Y profile and X condition) (I8, Interview, 17 October 2022; I51, Interview, 8 November 2022) . However, what is clear, is that if the function is to be acceptable, the knowledge gaps must be selected by clinicians and be tailored to individual clinician performance and preference (I11, Interview, 18 October 2022; I33, Interview, 28 October 2022; I49, Interview, 7 November 2022; I70, Interview, 21 November 2022). In other words, the function must be designed to support the bottom-up identification of knowledge gaps (I18, Interview, 20 October 2022), the filling of which clinicians would find genuinely useful, rather than the forced imposition of overwhelming volumes of new information intended to fill perceived knowledge gaps by system managers or ACDSS developers (I22, Interview, 21 October 2022). Even these narrow uses are still only acceptable if (a) clinicians can see how the ACDSS has reached its conclusion (i.e., provided there is evidence of the information's validity); and (b) it is clearly tied to genuinely understandable, useful, and relevant information about the patient (i.e., information from an EHR, the relevancy of which is evidenced. Information from an (e.g.,) unvalidated sensing device in the patient's home that might possibly be indicative of a specific condition is unlikely to meet this second criteria (I19, Interview, 20 October 2022; I53, Interview, 9 November 2023; I59, Interview, 11 November 2022; I66, Interview, 21 November 2022).

Other functions, for example functions designed to subject the population to near continuous risk screening, or to frequently prompt clinicians "have you thought of X", are perceived to be overly invasive, potentially wasteful, contributors to ontic occlusion, and ultimately unacceptable (I33, Interview, 28 October 2022) (Mittelstadt & Floridi, 2016). Such broader use functions would also fail to fall within the shaping rules, particularly the rules designed to negate the negative influence of the deterministic and magical thinking assumptions on the likelihood of the information and technological requirements being met by policy, and thus may undermine the technical feasibility and social acceptability of ACDSS implementation.

8.3.2.2 For patients a decision shared is a decision halved

For patients**,** an acceptable function of the desired ACDSS-enabled NLHS shaped by these rules is:

> *Patient acceptable function*
> Improving the trustworthiness of information used to inform shared decisions about care.

Specifically, for patients, acceptability is predicated on the system being designed to (a) enable clinicians and patients to effectively exchange information (qualitative, value-based, and 'experiential':

patient → clinician, quantitative, efficiency-based, and scientific: clinician → patient); and (b) help clinicians and patients navigate the ever shifting balance of agency and patiency (N.-F. Wagner, 2019) in the relationship depending on the specific nature of the 'decision' and the current circumstances of the patient. Designing the system to support this function, enables clinicians and patients to treat ACDSS as a digital companion (Morley & Floridi, 2020b): neither attempting to empower patients to take action to prevent any possible ill health (and consequently redefining good patients) nor attempting to algorithmically enhance the extent to which clinicians feel justified in acting paternalistically towards their patients. By ensuring the patient's experiences, values, preferences, and external circumstances are recorded and given equal weight to any clinical factor in a decision-making process, a system designed to support this function can ensure treatment is both personalised and evidenced in a true sense (I3, Interview, 17 October 2022; I33, Interview, 28 October 2022). In addition, by fulfilling a more supportive role, ACDSS can support rather than undermine clinician's epistemic authority, and limit the chances of clinician's falling foul of automation bias. In other words, an ACDSS-enabled NLHS with this function can help ensure that (a) treatment decisions are not simply stratified at a group level in a way that might result in uniqueness neglect (Heyen & Salloch, 2021); and (b) the evidence used in making clinical decisions is interpreted and combined with experience in keeping with the full-definition of evidence-based medicine (Sackett et al., 1996). At the same time, by using ACDSS as an external repository for the wills, desires, or preferences of individual patients, and how these preferences are affected by factors such as such as trust in clinician, newness or severity of symptoms, or confidence (Morley & Floridi, 2020b), an ACDSS-enabled NLHS with this function can help ensure clinicians are better able to navigate the complex relationship between social factors, rationality, and the desire of individual patient's to be involved in making decisions about their care (Morley & Floridi, 2020b, p. 1172; Walach & Loughlin, 2018). In turn, this can help ensure patients feel as though they have been genuinely listened to and that the shared decision reached is truly in their best interest (i.e., that the information used to make the decision was trustworthy and not unethically manipulative) (Chin-Yee & Upshur, 2018; Lorenzini et al., 2023; Mikkelsen et al., 2023; Nurek & Kostopoulou, 2023).

Other functions, for example functions designed to police clinicians and unduly penalise them for not always following rules exactly -even when deviation may be justified - or designed to measure the health of patients against a decontextualised norm and nudge them into changing their behaviour, are perceived to be vulnerable to manipulation for nefarious purposes, devoid of care, and ultimately unacceptable. Such purely (quantitative) data-driven functions would also fail to fall within the shaping

rules, particularly the rules designed to negate the negative influence of the rationality assumption on the likelihood of the objectives and values requirements being met by policy, and thus may undermine the ethical justifiability of ACDSS implementation.

8.3.2.3 For system managers it's all about the evidence

For system managers (i.e., commissioners, NHS analysts) an acceptable *function* of the desired ACDSS-enabled NLHS shaped by these rules, is:

> *System manager acceptable function*
> Improving the evidence base (effectiveness of information) used to inform public health and service planning decisions.

Specifically, for system managers, acceptability is predicated on the system being designed to 'tackle the edges of the bell curve' (I24, Interview, 24 October 2022): to

1. Focus on areas of care, or services, where there is excellent evidence supporting best practice, but this best practice is not being followed for the whole population, specific parts of the population in specific locations, or for specific groups *within* the population (e.g., patients of a particular gender identity or ethnicity), and this is having a (specific) negative impact on outcomes;
2. Understand *why* the best practice is not being followed (is it for example that the best practice is out-of-date, clinicians are unaware of the practice, patients do not consent to the best practice treatment or do not find the treatment plan tolerable, or another reason);
3. Identify specific targeted policy interventions for improving compliance with best practice (for example, deploying a national-level pop-up via ACDSS);
4. Monitor and measure the impact of the interventions; and
5. Provide evidence of the impact back to clinicians, patients, and the wider public (I8, Interview, 17 October 2022; I44, Interview, 19 October 2022; I61, Interview, 11 November 2022).

To ensure acceptability, all parts of this process must be carefully validated, from the algorithms used to identify non-compliance with best practice, to those used to enhance compliance and monitor impact, to the mechanisms used for feeding information back to clinicians and more.

Other functions, for example functions designed exclusively to identify opportunities within the system for cost cutting, or designed to identify potential changes to care pathways or services in

the absence of theory (Anderson, 2008), or designed to 'improve performance' through the deployment of generic ACDSS in the absence of clearly defined outcomes, causal pathways, or interventions, are perceived to be attempts to 'boil the ocean' (I44, Interview, 19 October 2022) that might expose patients to harm or clinicians to issues of liability. Such 'everything, everywhere, all at once' *functions* would also fail to fall within the shaping rules, particularly the rules designed to negate the negative influence of the 'regulation is antithetical to innovation' assumption on the likelihood of the process and management systems and structures requirements being met by policy, and thus may undermine the legal compliance of ACDSS implementation.

Now that these 'shaped' and acceptable functions have been described, a final unified conceptual function can be identified. This is the task of the next section.

8.3.3. A unified conceptual function

The results of the analysis in the preceding two sections have revealed that that an acceptable function of the desired ACDSS-enabled NLHS that negates the influence of the technical epistemic community's assumptions on policy at source, is a function designed to improve the: (i) utility and usability of relevant NHS information at the point care; (ii) trustworthiness of information used to inform shared decisions about care; and (iii) effectiveness of information used to inform public health and service planning decisions.

From this it can be extrapolated that the ideal function of the desired ACDSS-enabled NLHS is a function of information need, rather than information want. This is to say that the system should not be designed to meet every possible informational want that could be met through the implementation of ACDSS, but to only meet informational needs (P. H. Schwartz & Meslin, 2008) that satisfy the following two conditions: (a) a clear information purpose; and (b) information available that is known to contribute to the achievement of that information purpose (i.e., where there is robust scientific evidence demonstrating its efficacy in meeting the information purpose) (Derr, 1983). Therefore, the *function* of the ACDSS-enabled NLHS, used to guide the form of the supporting information infrastructure, should be as follows:

> *ACDSS-enabled NLHS Function:*
> Maximise the **utility, usability, efficacy, and trustworthiness** of existing NHS information for the purpose of meeting clearly identifiable information needs.

As the preceding analysis also indicated, each of these concepts (information utility, usability, efficacy, and trustworthiness) can be mapped to the success criteria and the ideal requirements: (1) utility and usability, are aligned most closely with the information, and technology requirements, and so with the success criteria technical feasibility, and social acceptability; (2) trustworthiness is aligned most closely with the objectives and values, and skills and knowledge requirements, and so with the success criteria ethical justifiability; and (3) efficacy is aligned most closely with the process, and management systems and structures requirements, and so with the success criteria legal compliance.

With these linkages having been established, it is now possible to bring together the beginnings of the conceptual model for the successful implementation of ACDSS into the NHS for the purpose of creating an ACDSS-enabled NLHS designed to deliver the above outlined *function.* Model A is presented in Figure 3 and shows the partially completed conceptual model for the successful implementation of ACDSS into the NHS. To be precise, it shows the success criteria requirements, conceptual function requirements (abbreviated to utility, usability, efficacy, trustworthiness), ideal vision requirements, and ideal delivery requirements (see Chapter Six). The Model highlights the inter-linkages between these different conceptual requirements (Kritz, 2017), and shows how the conceptual system function guides the design of the supporting information infrastructure's form .

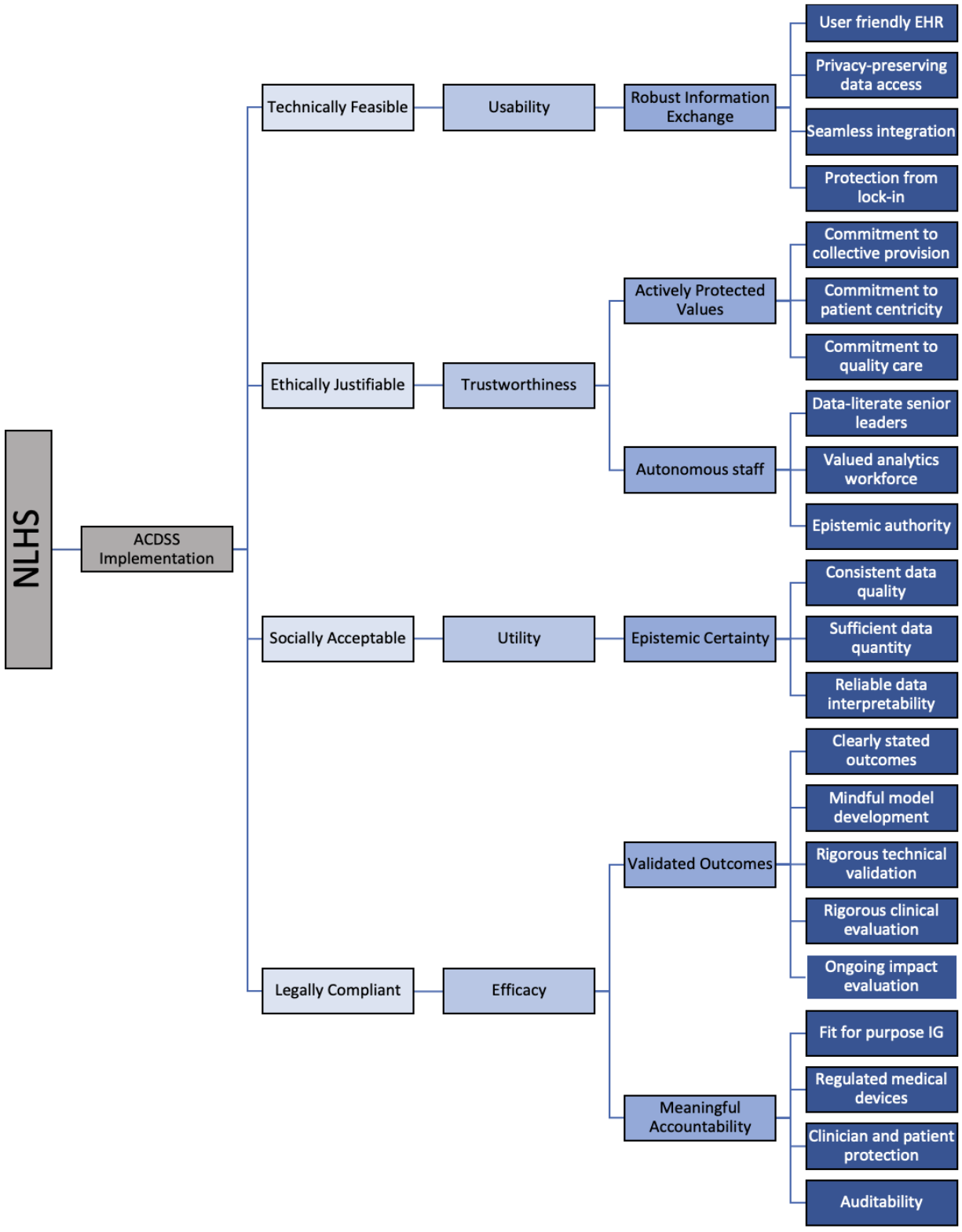

Figure 3. Conceptual Model A for the successful implementation of ACDSS into the NHS showing the connections between the NLHS, ACDSS implementation, success requirements, unifying function requirements, ideal vision requirements, and ideal delivery requirements.

In keeping with the middle-out approach to systems engineering (Bouch et al., 2015) mentioned in the introduction of this chapter, this model can be read in two ways. First from top to bottom (i.e., top-down) it reads as:

1. To become a learning healthcare system, the NHS requires the successful implementation of ACDSS.
2. Successful implementation requires a supporting information infrastructure that ensures the implementation is **technically feasible, ethically justifiable, socially acceptable, and legally compliant.**
3. As form follows function, if the supporting information infrastructure is to ensure ACDSS implementation is technically feasible, ethically justifiable, socially acceptable, and legally compliant, it requires a design that is intended to support the function "maximise the **utility, usability, efficacy, and trustworthiness** of existing NHS information for the purpose of meeting clearly identifiable information needs".
4. If the information infrastructure is to support the function of maximising information utility, usability, efficacy, and trustworthiness, it requires a design intended to provide the system with **epistemic certainty, robust information exchange, validated outcomes, protected values, autonomous staff, and meaningful accountability**.
5. To provide the system with epistemic certainty, robust information exchange, validated outcomes, protected values, autonomous staff, and meaningful accountability, the information infrastructure requires a form that delivers **consistent data quality; sufficient data quantity; reliable data interpretability; UX focused EHR design; privacy enhancing data access; seamless system integration; protection from vendor lock-in; clearly stated clinical objectives; mindful model development; rigorous technical validation; rigorous clinical evaluation; careful local calibration; ongoing impact evaluation; commitment to collective provision; commitment to patient centricity; commitment to quality care; protection of clinician epistemic authority; valued informatics workforce; skilled leadership; fit for purpose IG; regulated medical devices; clinician and patient protection; and distributed responsibility.**

This top-down reading is useful for guiding the overall strategy of relevant policy development.

In other words, it tells policymakers *what* a coherent ACDSS implementation strategy should cover. However, this top-down reading does not tell policymakers *how* to operationalise this strategy in a way that closes the sociotechnical gap. In short, it does not tell policymakers how to design an information infrastructure form that meets these requirements. For this purpose, the model needs an additional (currently absent) layer. It can then to be read bottom-up as a tool for assessing whether specific policy decisions (i.e., design actions) regarding the operationalisation of the ideal requirements also meet the function requirements and the success requirements, and thus whether the design action will support the ambition to enable the NHS to capitalise on the dual advantage of ACDSS. It is best to illustrate this bottom-up reading with an example before it can be used to identify the final requirements for closing the sociotechnical gap and completing the model. It is the purpose of the next section to provide this example.

8.3.3.1 NHS Federated Data Platform: maximising information utility, usability, efficacy, and trustworthiness?

In late 2022, NHS England proposed procuring a 'Federated Data Platform' (FDP), or a centralised data analytics platform, described as the "future operating system for the health service", and intended to bring together multiple streams of siloed data from a very wide range of NHS organisations (NHS England, 2022a). The tender for the platform went live in January (NHS England, 2023b), but has yet to be awarded. The platform is intended to focus on "care pathway management", "remote monitoring", "forecasting, monitoring, and evaluation", and "automation". It is clear, therefore, that NHS England hopes it will become a core part of the NHS's future information infrastructure, support the implementation of ACDSS, and so ensure "health and care providers have the information they need at their fingertips" (NHS England, 2023a, p. 1).

On the surface, the platform can be interpreted as being intended to operationalise the ideal information, and ideal technology requirements. Specifically, it appears to be intended to provide the NHS with epistemic certainty, and robust information exchange requirements, by delivering consistent data quality, sufficient data representativeness, privacy enhancing data access, and seamless system integration. Therefore, it appears to be intended to maximise the utility and usability of existing NHS information for specific information needs, and so ensure that the future implementation of ACDSS is technical feasible and socially acceptable. The FDP intends to operationalise these delivery, vision, and function requirements by providing "a single access point to patient data for hospitals, GPs, and social care" (Foxglove Legal & Doctors' Association UK, 2023, p. 9). This single access point (single platform), is supposed to be private and secure by design, intuitive and accessible, and focused on

'comprehensive integration' (NHS England, 2023a). The platform is then supposed to be used by NHS Trusts and Integrated Care Systems to "address their most pressing challenges" and enhance their ability to make "informed and effective decisions" (NHS England, 2023a). However, on closer inspection it becomes clear that the plans for the platform are filled with flawed thinking and linked to the technical epistemic community's assumptions – particularly the deterministic and 'magical thinking' assumptions. There is for example, no recognition in the tender documents for the FDP of the challenges associated with making NHS systems interoperable, nor of the need to ensure different data sources are well curated and harmonised, there is instead an assumption that all the NHS need do is procure the platform and the desired results will happen. This is not surprising as the assumptions are not negated at source because the function the platform is designed to meet is clearly predicated on information want rather than information need.

That the function is linked to information want rather than information need, is evident for two reasons. First, the prospectus for the platform lists five use cases for the information it provides access to: population health management; care coordination (discharges, anticipatory care, virtual wards, elective hubs); elective recovery; vaccination and immunisation; and supply chain (NHS England, 2023a). These use cases meet neither of the necessary conditions for an information need. It is not clear where the use cases have arisen from, the NHS already has a system for monitoring vaccination and information status for example, and "population health management" could mean almost anything. As such there is no real clear purpose for any of the use cases. Furthermore, it is not clear what information the FDP will collect and surface to contribute to the achievement of these use cases, and so there is no evidence that the information the platform may have access to can contribute to the achievement of the use cases. Indeed, there is only negative evidence, as several pilots of the platform (currently supplied by Palantir's Foundry software), have failed and had to be paused indefinitely (Foxglove Legal & Doctors' Association UK, 2023). Second, the scope of the FDP (at least in terms of its value) keeps expanding with no clear explanation (Foxglove Legal & Doctors' Association UK, 2023). When it was first announced, the contract for the tender was worth £240 million, then £360 million, and now £480 million (Hoek, 2022; NHS England, 2023b; Ungoed-Thomas, 2022). In the absence of specific information needs, it is not clear how the utility and usability of existing NHS information can be maximised to meet said needs. Consequently, the scope of the platform keeps expanding, and it is unclear how the design (i.e., the *form*) of the FDP will ensure either epistemic certainty or robust information exchange. It is, therefore, unclear how it will support the

technical feasibility or social acceptability of future ACDSS implementation, and so it is also unclear how it will help ensure the NHS is able to capitalise on the benefits of ACDSS and mitigate the risks.

This is just one narrow example. The same process could have been completed for the proposed policy to "co-design a data pact setting out how the NHS will use health and care data" (Department of Health and Social Care, 2022e) (including for ACDSS development). This can be interpreted as being intended to a (a) deliver commitment to patient centricity; (b) provide the system with actively protected values; (c) maximise trustworthiness of existing NHS information; and (d) ensure the ethical justifiability of ACDSS implementation. The exact example chosen is unimportant, as the point is merely to show how, by reading the conceptual model bottom-up (FDP → enabling requirements → vision requirements → *function* → success criteria) the model can be used to assess whether a particular policy decision (or design action) will meet its targeted requirements in a way that will ensure the successful implementation of ACDSS and so enable the NHS to capitalise on the benefits (positive intended emergence) of ACDSS and mitigate the risks (negative unintended or re-ontologising emergence).

With this process having been explicated, it is now possible to move on to the final task of this chapter, and thus the final task of this thesis: identifying a final set of requirements (in the form of recommended design actions for policymakers) for operationalising the ideal requirements in accordance with the relevant function concept. This is the purpose of the next and final section.

8.3.4 A final set of requirements

Following the analysis in the previous sections, it is now known that to ensure the NHS can capitalise on the dual advantage of ACDSS it needs an information infrastructure designed to maximise the utility, usability, efficacy, and trustworthiness of existing NHS information to meet specific information needs. It is also known that to deliver this function, the NHS information infrastructure needs to provide the system (ACDSS-enabled NLHS) with epistemic certainty, robust information exchange, validated outcomes, actively protected values, autonomous staff, and meaningful accountability. Finally, it is known that to provide the NHS with the six preceding vision requirements, the information infrastructure needs to deliver consistently good data quality; sufficient data quantity; reliable data interpretability; UX focused EHR design; privacy enhancing data access; seamless system integration; protection from vendor lock-in; clearly stated clinical objectives; mindful model development; rigorous technical validation; rigorous clinical evaluation; careful local calibration; ongoing impact evaluation; commitment to collective provision; commitment to patient centricity;

commitment to quality care; data-literate senior leaders; protection of clinician epistemic authority; valued informatics workforce; fit for purpose IG; regulated medical devices; clinician and patient protection; and auditability. What is not yet known, is how to operationalise these delivery and vision requirements to meet the function, and therefore success requirements. In other words, it is not known how to design an information infrastructure that meets all these requirements, because the exact policy design requirements have not yet been identified. The purpose of this last section is, therefore, to answer the final part of RQC and identify these requirements. It does this by taking each of the conceptual function requirements (utility, usability, efficacy, trustworthiness) in turn, and presenting a policy user story in the form of: "To meet X requirement, policy that focuses on X is required, so that X results". In each user story the "policy that focuses on X" represents the final conceptual requirement to be included in the final conceptual model, and the "so that" ties directly back to the unified function via the shaping rules described earlier. It is important to note that whilst each conceptual function requirement is described in sequence, and in isolation, and each set of delivery, vision, and success requirements are tied exclusively in this presentation to one function requirement, this is only for the purpose of clarity. All requirements are necessary (albeit not sufficient) requirements for success.

8.3.4.1 Usability

To ensure ACDSS implementation is **technically feasible**, the supporting information infrastructure must be designed to **maximise the usability** of existing NHS information for specific information needs. This requires designing information infrastructure that provides the system **robust information exchange**. In turn, this requires designing information infrastructure that delivers **UX focused EHR design; privacy enhancing data access; seamless system integration; and protection from vendor lock-in.** To operationalise these concepts in accordance with the relevant *function* concept, the NHS should focus on developing policy that:

1. Standardises **EHR design templates** developed with and for clinicians, with usability and interoperability in mind. The aim should be to ensure all EHRs in use in the NHS follow a standardised, interoperable, and user-friendly design (with variation in design being associated with specific specialities, not supplier (I13, Interview, 19 October 2022), so that:
    a. All the information needed to support the development of ACDSS for specific purposes is collected at source, minimising the likelihood that issues such as

accuracy of clinical coding, missingness, 'messiness', and bias undermine the usability of existing NHS information for meeting specific information needs (I4, Interview, 17 October 2022);

b. The design of EHRs does not restrict the range of clinical information that can be recorded, or 'nudge' clinician behaviour in particular directions that might lead to ACDSS making inaccurate inferences related to causality of disease, efficacy of treatment options, or the suitability of the care pathway, for specific information needs (Bezemer et al., 2019; Osop & Sahama, 2019; I65, Interview, 18 November 2022);

c. Good data capture, that can help ensure ACDSS is able to meet specific information needs accurately, becomes a simple by-product of the 'day-job' for clinicians, rather than an additional burdensome task for which they are not appropriately compensated (I33, Interview, 28 October 2022); and

d. ACDSS integration with EHRs is made as smooth as possible, and performance risks associated with the difference in quality of ACDSS training data and real-world data, for specific information purposes, are minimised.

2. Enables **Model-to-Data (MTD) approaches to ACDSS knowledge algorithm development** (facilitates the development of ACDSS without granting researchers (or ACDSS developers) direct, physical access to the data (Bergquist et al., 2020)). The aim should be to minimise the need to move data away from its source location and extract data from well-curated, harmonised, ACDSS-ready data assets, so that:

   a. The NHS can host larger, multimodal, well curated databases in fewer locations (as above) (Z. Ahmed, 2020; Bousquet et al., 2011; Saqi et al., 2016), each of which can afford to invest more heavily in security (Ienca et al., 2018) and standardised Governance rules (Amarasingham et al., 2016) that can be enforced through technical design (e.g., through log-in and logging protocols) (Goldacre & Morley, 2022);

   b. ACDSS developers can gain access to the large volumes of data needed to train accurate and generalisable ACDSS models for specific information needs (J. Balch et al., 2021; Miotto et al., 2018), without the data having to flow around the system in a way that increases privacy risk, undermines public trust, and creates multiple

opportunities for data errors to be introduced during the 'sharing' process (I47, Interview, 4 November 2022);

c. The need to pseudonymise or apply principles of 'data minimisation' is reduced, since there is no risk of data being seen or used for purposes other than the development of ACDSS for a specific information need, and thus the development of ACDSS can benefit from access to full, far more detailed, clinical records;
d. The data access pipeline becomes more auditable, so that patients, publics, and clinicians can 'check' what data has been accessed, where, by whom, and for what purpose (Goldacre & Morley, 2022); and
e. ACDSS developers do not have to 'negotiate' separately with each individual NHS Trust, GP practice, or Integrated Care System to gain access to the data necessary which can cause delays in the development process, but also reduce the clarity of the connection between information need, information access request, ACDSS algorithm development, ACDSS implementation (I44, Interview, 19 October 2022).

3. Mandates compliance with **interoperability standards** for all ACDSS developers, EHR providers, and other IT system suppliers. The aim should be to ensure only EHRs and ACDSS provably compliant with relevant interoperability standards are procured and implemented in NHS organisations, so that:
    a. Clinicians wishing to use ACDSS do not need to log into multiple different systems with multiple different passwords each requiring additional manual data entry for different information needs (I61, Interview, 11 November 2022);
    b. Clinicians can, instead, interact with one well-designed user-friendly interface embedded within an EHR, capable of liaising with multiple different knowledge 'back-ends', with each model responsible for specific information needs. The integration is so seamless that the clinician is given the impression that they are only ever interacting with one piece of software that is accounting for multiple clinical parameters and is not adding to their sense of burden (I59, Interview, 11 November 2022); and

c. System-level analysis of the impact of ACDSS on clinical outcomes and performance is not confounded by issues related to integration, interoperability, and thus interpretability.

4. Combines **ACDSS** with **audit and feedback** to make ACDSS more contextually specific (i.e., more closely linked to specific information needs). The aim should be to ensure that ACDSS not only provides advice personalised to the patient, but also to the clinician, so that:
    a. ACDSS provides advice in the context of previous decisions made by the specific clinician it is advising, i.e., the advice is tailored to the individual clinician's specific information need and not a generic need. For instance, if ACDSS knows the rule that treating patients with X profile and X condition with Y drug is most effective and safe, but there are exceptions to the rule, and a specific clinician deviates from this rule the ACDSS should know whether this is the first time the clinician has deviated from the rule, and thus it is likely a well-reasoned deviation and should not necessarily be corrected lest this 'nudge' the clinician in an unhelpful direction, or whether the clinician always deviates from this rule, and thus it is more likely that they do not know the 'rule' (i.e., they have a more 'severe' specific information need) (I27, Interview, 26 October 2022);
    b. Clinicians can update the knowledge of specific ACDSS if they feel it is out-of-date, does not account for specific patient considerations, or provides advice that is unusable or unactionable (i.e., it is not sufficiently meeting the specific information need) (I11, Interview, 18 October 2022; I70, Interview, 21 November 2022; Rubins et al., 2019);
    c. The exact way in which ACDSS presents information to clinicians can be A/B tested for usability to maximise the extent to which the specific ACDSS is able to meet the specific information need (I61, Interview, 11 November 2022);
    d. The relationship between ACDSS is a two-way partnership, where the clinician remains firmly in the loop and the interactions between the two are more conversational than 'algorithmically paternalistic' (I16, Interview, 20 October 2022); and

e. System managers can use ACDSS as a mechanism to enforce changes to care pathways, improve compliance with the principles of Evidence Based Medicine, and make effective population health interventions.

5. Mandates **modular design** and **local customisability** of ACDSS. The aim should be to ensure each NHS organisation, and even each individual NHS clinician, can select in a 'plug and play' fashion the exact ACDSS modules they wish to use, so that:
    a. Clinicians do not become overwhelmed by, or overly dependent on, ACDSS, but are able to exert some degree of independent control over when (i.e., for what specific information needs) they wish to access support and when they do not, making ACDSS use more proportionate to specific information need (I33, Interview, 28 October 2022; Jankovic & Chen, 2020; Olakotan & Mohd Yusof, 2021);
    b. Clinicians and organisational managers are able to determine when ACDSS intervenes in a specific workflow or care pathway i.e., they can determine at what point the specific information need arises (Hall & Morris, 2017; I61, Interview, 11 November 2022);
    c. Organisational managers, in particular clinical risk managers, can exert some control over when ACDSS is most needed (i.e., when the specific information need is greatest). For instance, a hospital might decide that when a recently qualified doctor oversees triaging patients, the ACDSS should always intervene in the clinical encounter, even if the patient being reviewed is routine, as part of an ongoing training programme. However, the same hospital might decide that for experienced consultants the ACDSS need only intervene when the consultant is dealing with a rare disease, a severe drug interaction, or something similar (I33, Interview, 28 October 2022); and
    d. Different components of the overarching ACDSS, e.g., knowledge algorithms, user interface, back-end knowledge base, can be updated and 'swapped in and out' without enforced obsolescence to enable ACDSS to 'keep up' with the latest evidence (for example) regarding a specific information need without having to take the entire system offline (Blaser et al., 2007; Castaneda et al., 2015).

8.3.4.2 Utility

To ensure ACDSS implementation is **socially acceptable**, the supporting information infrastructure must be designed to **maximise the utility** of existing NHS information for specific information needs. This requires designing information infrastructure that provides the system **epistemic certainty**. This, in turn, requires designing information infrastructure to **deliver consistent data quality, sufficient data quantity, and reliable data interpretability**. To operationalise these concepts in accordance with the relevant *function* concept, the NHS requires policy that:

1. **Values 'data work'** and prioritises the **curation** and **harmonisation** of **multi-modal population representative datasets** (Auffray et al., 2016; I65, Interview, 18 November 2022). The aim should be to ensure only ACDSS trained and validated on **NHS ACDSS-ready datasets** is implemented, so that:
    a. The NHS is able to signpost ACDSS developers to known data assets that have been carefully curated to meet specific needs and contain all the information relevant to meet said need including, not only EHR data, but also genomic, imaging, pathology, environmental, and socioeconomic data (S. S.-J. Lee, 2021; Zikos, 2017);
    b. The NHS is able to tell ACDSS developers upfront what the limitations of specific data assets are for specific uses for example, if the dataset is missing key information that would result in out-of-sample errors for specific uses (Challen et al., 2019);
    c. The NHS knows the underpinning assumptions of any ACDSS-ready data assets, and knows of any processing that was conducted (e.g., labelling, data imputation, sparse encoding, the reclassifying of data into clinically or logically relevant subgroups, or matrix factorisation (Bezemer et al., 2019; Wiens et al., 2019a)) to overcome issues such as missingness that might impact the accuracy of the dataset for the purpose and can report these assumptions and processing efforts transparently;
    d. The NHS can ensure key data assets are not used for purposes that would be inappropriate i.e., for uses that the data have not been validated for (L. M. Lee, 2017); and ACDSS developers can spend less time linking 'disparate and dirty data'

and more time developing and validating the ACDSS models themselves (I44, Interview, 19 October 2022).

2. Makes **explainability** a standardised (ideally mandatory) requirement of ACDSS. The aim should be to ensure only ACDSS that is able to 'explain' its recommendation is implemented, so that:
    a. NHS clinicians are able to verify during the consultation whether the recommendation provided by the ACDSS is based on information relevant to the specific information need (i.e., it is not basing it on unevidenced information) (Baalen et al., 2021; Char et al., 2020b; Panch, Mattie, & Atun, 2019);
    b. ACDSS does not create an informational asymmetry between patients, clinicians, and itself (Braun et al., 2021) in a way that might inhibit the ability of clinicians and patients to reach a shared decision for a specific purpose;
    c. ACDSS can provide 'warnings' if it is being used for a patient that would count as an 'out-of-sample patient' for that specific use case (I30, Interview, 28 October 2022).

3. Positions **clinicians as the originators** of ACDSS demand from the beginning of the ACDSS development pipeline. The aim should be to ensure only ACDSS that has been identified as being in demand (i.e., needed) by frontline clinicians is implemented, so that:
    a. All ACDSS development is tied to a very clear, specific, clinical informational need that NHS clinicians believe will be met (beneficially) through the implementation of ACDSS;
    b. All ACDSS is seen as relevant and essential by NHS clinicians – maximising perceived utility (Shortliffe & Sepúlveda, 2018b); ACDSS is not perceived by NHS clinicians to be 'time wasting' (Shortliffe & Sepúlveda, 2018b); and
    c. All ACDSS is designed to provide information that has been deemed by NHS clinicians to be vivid and salient for a specific purpose, reducing the risk of alert fatigue and information chaos (Beasley et al., 2011; Bigman et al., 2021; Hall & Morris, 2017; I13, Interview, 19 October 2022).

8.3.4.3 Trustworthiness

To ensure ACDSS implementation is ethically justifiable, the supporting information infrastructure must be designed to maximise the trustworthiness of existing NHS information for specific information needs. This **requires** designing information infrastructure that provides the system protected values and autonomous staff. In turn, this **requires** commitment to collective provision; commitment to patient centricity; commitment to quality care; protection of clinician epistemic authority; valued informatics workforce; and skilled leadership. To operationalise these concepts in accordance with the relevant *function* concept, the NHS should focus on developing policy that:

1. Ensures ACDSS is built by teams with **diverse skill and lived experiences** who recognise cultural and personal differences in values and healthcare priorities**.** The aim should be to ensure all ACDSS meets specific information needs from a range of perspectives, so that:
    a. The extent to which the normative construction of the 'knowledge' used by ACDSS to meet specific information needs precludes the perspective of alternative means of meeting said need (e.g., more culturally or ethically sensitive responses) is minimised as far as is possible and desirable (Goldenberg, 2006; I3, Interview, 17 October 2022);
    b. The risk that in meeting specific information needs, ACDSS implementation results in 'transformative effects' on society related to bias is mitigated through social action as well as technical action (i.e. bias is not only seen as a technical problem) (Tsamados et al., 2022); and
    c. ACDSS respects value pluralism, acknowledging that patients (and clinicians) have different values, and different priorities, and that meeting information needs in a way that ignores this fact would be overly paternalistic (Catchpole & Alfred, 2018; A. Kerasidou, 2021; McDougall, 2019).

2. Mandates the **involvement of patients, and publics in the development of ACDSS** from the start of the development pipeline. The aim should be to ensure only ACDSS that are designed to meet a 'patient-approved' information need are implemented into the NHS, so that:

a. Patients and publics are treated as 'true interlocuters' in the identification of suitable information needs and suitable 'solutions' to these needs, rather than a 'problem to be overcome' (Aitken et al., 2019);
b. The implementation of ACDSS into the NHS does not undermine the extent to which the NHS is perceived and treated as a 'public' institution and a public good (I38, Interview, 31 October 2022; I54, Interview, 9 November 2022);
c. The social license to develop and implement ACDSS into the NHS for the purpose of meeting specific information needs is maintained (R. Aggarwal et al., 2021; P. Carter et al., 2015; Horn & Kerasidou, 2020; Muller et al., 2021);
d. Patient's autonomy is protected from the beginning of the ACDSS development, and – by being treated as partners (Blasimme & Vayena, 2016) - they are seen as having an equal right to dictate the information needs of the NHS as both clinicians and system managers; and
e. ACDSS developers are made aware of their moral duty to patients, and not so distanced that the impact of their 'product' is invisible (Townend, 2018).

3. Ensures equal attention is paid to the **collection, curation, standardisation, and integration of 'qualitative' health information** as is paid to the collection, curation, standardisation, and integration of 'quantitative' health information (Almeida et al., 2020; S. S.-J. Lee, 2021). The aim should be to ensure ACDSS in use acts as a 'digital companion' (Morley & Floridi, 2020b) and views all information needs as *shared* information needs (Heyen & Salloch, 2021), so that:
    a. All patient rights, including meta-rights, such as the 'right not to know' (Andorno, 2004c) are protected via the collection of appropriate information, and technical design, recognising that just because a clinician has a specific information need, does not mean that the patient also has the same information need;
    b. Patient-reported outcomes (Calvert et al., 2015) are considered as important as 'quantitative' or measurable outcomes in the monitoring of ACDSS effectiveness at meeting specific information needs;
    c. 'Soft' qualities of information needs, such as the need to meet these in an empathetic and contextualised fashion are given due attention in the development of ACDSS (Heyen & Salloch, 2021; Savulescu, 1996); and

d. Advice produced by ACDSS in response to a specific information need is predicated on 'capability' not *just* efficacy i.e., what are the 'real' options available to the specific patient, for treating their condition, or improving their health, based on their circumstance, values, and preferences (Brall & Schröder-Bäck, 2016).

4. Protects and encourages the development of **provably trustworthy relationships between patients and clinicians**. The aim should be to ensure ACDSS use does not overly-mediate the therapeutic relationship in a way that may damage trustworthiness from a patient perspective (for example, by removing empathy from the interaction), but rather enhances the connection between the two parties, so that:
    a. The experience of ACDSS-enabled care remains positive for all parties;
    b. Patients still feel as though they are in the 'driving seat' of all decisions, and that these have been made based on a true understanding of their best interests; and
    c. The importance of the human aspects of care are never forgotten or forced out through the introduction of ACDSS.

5. Establishes a technical "**Buddy System"** for senior leaders and provides them with access to appropriate data science training. The aim should be to ensure no decisions regarding the development, deployment, use, or analysis of ACDSS is made without input from individuals with both management experience and data science experience, so that:
    a. Any ACDSS use mandated by system managers is grounded in technical reality and tied closely to an information need – that has been assessed from a technical feasibility perspective.
    b. Any ACDSS use mandated by system managers is informed by the practices of agile software design and intended to be incrementally improved over time.
    c. Any ACDSS desired by the system, for example by clinicians (see clinicians as originators of demand) is also assessed from the perspective of connecting the intended outcome to wider system need and technical capability of the system.

6. Solidifies the **status of the NHS analytics workforce as clinical, not clerical,** and provides individual analysts with meaningful career paths and access to **continuing professional development** (Fridsma, 2018; Goldacre et al., 2020; Goldacre & Morley,

2022). The aim should be to ensure the NHS is a desirable employment opportunity for highly skilled data scientists, so that:

a. Analysts reviewing the outputs of ACDSS for the purpose of making informed decisions about NHS services, are aware of the limitations of the data they are working with, and aware of the most appropriate techniques for analysing the outputs and do not try to retrospectively apply the outputs of ACDSS to an information want rather than the appropriate information need.
b. The system-level interpretation of ACDSS outputs is led by individuals with clear contextual knowledge, and the NHS does not have to rely solely on the input of private third-party analytics provides with limited knowledge of the values and realities of the NHS.
c. Skilled analysts are available to inform the development of technical policy, for example, guidelines for model and feature-selection, ensuring these policies are fit-for-purpose.

7. Protects the **clinician's right to override** ACDSS advice (I33, Interview, 28 October 2022). The aim should be to ensure clinicians only act on the advice of ACDSS if it meets their information need in a way that they feel is reasonable, accurate, and in keeping with the 'best interests' of their patient, so that:
    a. The role of clinicians as 'learned intermediaries' in the consultation, their autonomy over decision making, and the trust this builds in clinician-patient interaction is protected and maintained;
    b. ACDSS meets information needs in keeping with the 'true' meaning of evidence-based medicine i.e., contextualised, interpreted, and combined with lived experience; and
    c. The complexity and variability of healthcare is never underestimated nor presumed to be reducible to a series of 'if this, then that' rules (Bezemer et al., 2019)

8.3.4.4 Efficacy

To ensure ACDSS implementation is **legally compliant**, the supporting information infrastructure must be designed to **maximise the efficacy** of existing NHS information for specific information needs. This requires designing information infrastructure that provides the system **validated**

outcomes and meaningful accountability. In turn this requires designing information infrastructure that delivers **clearly stated clinical objectives; mindful model development; rigorous technical validation; rigorous clinical evaluation; careful local calibration; ongoing impact evaluation; fit for purpose Information Governance; regulated medical devices; clinician and patient protection; and auditability.** To operationalise these concepts in accordance with the relevant function concept, the NHS should focus on developing policy that:

1. Requires all ACDSS to be subject to a **Health Technology Assessment** (HTA) (W. Chen et al., 2023; Love-Koh et al., 2018) process run by the National Institute for Clinical Excellence (NIC) and (if predictive) reviewed by the **National Screening Committee** (NSC). The aim should be to ensure only NICE and NSC approved ACDSS is implemented into the NHS, *and,* that once ACDSS has been approved by NICE, NHS organisations are required to implement the ACDSS *if* they have that specific information need, so that:
    a. All ACDSS are, from the outset, linked to a clearly stated outcome, its contribution to which can be quantified via a transparent, independent, review of its evidence of efficacy (see in-silico and in-socio testing)
    b. All NHS patients benefit from the implementation of ACDSS that meets specific information needs as soon as possible, thus meeting the requirement in the NHS constitution referenced in Chapter One;
    c. All ACDSS is evaluated from a standardised, and contextualised, cost-effectiveness perspective and it is established that the ACDSS is meeting an information need that is of system-wide (or public health) importance, will not result in costly 'overdiagnosis', and will not take away essential resources from other 'information needs' for little gain (i.e., the trade-off between resource use and benefit is assessed) (Braveman & Tarimo, 1996; Edwards & Hall, 1992; Juengst & McGowan, 2018; V. X. Liu et al., 2019);
    d. Funding is made available for developing appropriate methods for ACDSS HTA via the National Institute for Health Research (NIHR) (I32, Interview, 28 October 2022); and

e. All ACDSS is subject to open public debate before being implemented, thus ensuring patients and publics are involved in assessing whether the ACDSS meets a socially acceptable information need.

2. Provides **guidance** on best practice for **model development and feature selection.** The aim should be to (a) ensure that decisions regarding what model to use in a specific ACDSS knowledge engine is tied directly to the specific ACDSS use case (targeted information need) and not because of a particular trend in machine learning or similar; and (b) ensure that features selected for use in knowledge engine models are appropriate to the information need, and available from frontline systems, so that:
    a. All aspects of ACDSS design are tied directly to a use case for which there is a clear, robust evidence base from model to feature selection and beyond; and
    b. ACDSS is not developed on the false belief that more information (i.e., more features or more complex models) is always better in all circumstances.

3. Centralises and streamlines '**in silico' and 'in socio' model testing for robustness, reliability, accuracy, efficacy, and safety** (including local), and **mandates transparent reporting of evaluation results**. The aim should be to ensure only ACDSS that has been tested according to the 'NHS ACDSS verification, validation, evaluation method' and published results in an auditable format are implemented in the NHS, so that:
    a. All ACDSS is subject to the same process (subject to standardised variation for model type) of internal validation, temporal validation, external validation, and local calibration, against ACDSS-ready NHS datasets, and thus all ACDSS are held to the same high-performance standard (i.e., all ACDSS is required to (and provably can) meet its specific information need accurately, safely, robustly, and reliably) (Lisboa, 2002; Parikh, Obermeyer, et al., 2019);
    b. ACDSS developers, regulators, and users are provided with access to a secure testing environment that acts as a 'halfway house' between open code and proprietary development (I40, Interview, 31 October 2022);
    c. ACDSS developers cannot unfairly benefit from a process of 'validation shopping' where they choose the process for validation and evaluation that is likely to result in the most positive results, but might not meet the standards required by the NHS;

d. ACDSS developers cannot make false claims regarding the performance of their ACDSS, they cannot for example claim that it can meet more information needs, for a wider or more diverse range of patients than it can (Andaur Navarro et al., 2023);
e. All patients and clinicians can access a verifiable record of the performance of any ACDSS that is used to meet a specific information in the care of a specific patient (Hernandez-Boussard et al., 2020);
f. ACDSS developers cannot rely solely on reporting basic statistical performance measures, such as AUROC, as indicators of clinical efficacy (or the ability of an ACDSS to meet a specific information need) (Bulgarelli et al., 2020; I39, Interview, 31 October 2022);
g. Individuals responsible for commissioning and procuring ACDSS for within their organisation do not feel solely responsible (and thus apprehensive) about assessing whether ACDSS being 'sold' to them can genuinely meet their organisation's information needs; and
h. System managers relying on aggregate data from ACDSS outputs to inform decisions about population health and care pathways are confident that the information they are relying upon is accurate and reliable.

4. Establishes a centrally accessible but **roving data science team.** The aim should be to ensure any NHS organisation wishing to deploy ACDSS within their organisation has access to the staff, skills, and knowledge needed for local calibration, so that:
    a. The possibilities of harms resulting from a drop in performance due to unknown 'out of sample' errors (or bias) are reduced as far as possible;
    b. ACDSS interface and set-up (including how often to intervene) can be appropriately customised to suit the specific organisation's specific information needs (see audit and feedback); and
    c. Unwarranted variation in outcomes resulting from variations in the quality of ACDSS local deployment is avoided.

5. Ensures sufficient **oversight of ACDSS integration and use** (Choudhury, 2022; Fujimori et al., 2022; Rundo et al., 2020). The aim should be to ensure all clinicians know how to use ACDSS safely and effectively, and that liability is clarified, so that:
    a. Clinicians feel confident using ACDSS to meet their specific information needs within specific parameters, and patients know when and how to advocate for themselves if they feel as though there has been a misuse of ACDSS during their care (Allaërt & Dusserre, 1992; Bertoli & Grembi, 2017; Prictor et al., 2020);
    b. Regulators (for example CQC) are aware of any safety issues arising from inappropriate use of or inappropriate methods of interaction with, ACDSS, and can intervene if necessary either by removing specific ACDSS from use or by feeding back to the developers safety issues; and
    c. Clinicians also have a central authority to report any safety concerns to and know that the ACDSS developers will be required to act upon the concern and make any requisite changes to the design.

6. Simplifies **data ownership, controllership, use case, and consent.** The aim should be to ensure that decisions regarding what NHS data can be used for, who by, and how it can be accessed is tied to information need, not arbitrary categorisation of 'task' or point of extraction, so that:
    a. The likelihood of NHS data being accessed for unethical, non-justifiable, or non-consented purposes is reduced, whilst the potential for NHS data to be used to meet genuine beneficial information needs is maximised;
    b. ACDSS developers, researchers, or others, cannot 'game' the system for example claiming to be developing an algorithm for 'service evaluation' purposes (when it is for risk prediction purposes) and thus evading the need for ethical review; and
    c. The information governance regime is more interpretable, understandable, and transparent to all, improving patient and public trust, and mitigating the likelihood that ACDSS developers or NHS organisations may make well-meaning but ill-informed decisions regarding data access and use.

7. Requires all ACDSS to be **classified as Software as Medical Device (SaMD), registered, and regularly reported** on publicly. The aim should be to ensure no

unregulated ACDSS is deployed into the NHS, and to create a register of all ACDSS in use, so that:

a. All ACDSS is legally bound to an intended use (i.e., it is legally bound to meeting a specific information need);
b. All ACDSS developers are legally required to generate high-quality, independently validated and verified, evidence of efficacy for all ACDSS (i.e., it is a legal requirement to ensure the second condition of information need is met);
c. All ACDSS is regularly monitored once it is deployed to ensure that it is continuing to meet its information need safely, effectively, and for all patients, and ensuring all issues that might undermine the extent to which ACDSS is able to meet its information need (such as algorithm drift, population drift, context drift) are identified and rectified in real-time;
d. Responsibility, and therefore accountability, for errors in ACDSS outputs that result in patient harm is clarified, and the pathway to rectification is clear;

8. Restores and enhances **the liability, discrimination, and consumer protection** components of process accountability. The aim should be to ensure all clinicians are aware of the edges of their responsibility as are ACDSS developers, and patients are aware of what they should expect from care providers using ACDSS and how to seek compensation if harm occurs, so that:
    a. ACDSS users are encouraged to remain aware of the possibility of automation bias, and the importance of continuing to act as learned intermediaries even when using ACDSS;
    b. ACDSS users are discouraged from using ACDSS to meet information wants that may be unvalidated, or unregulated, rather than using ACDSS to meet specific information needs that have been validated and regulated; and
    c. No ACDSS developers, users, or even beneficiaries are under the impression that ACDSS is 'just' software incapable of causing harm.

9. Mandates that all decisions along the ACDSS implementation pipeline from ideation through to deployment and use be **clearly and publicly documented.** The aim should be to ensure any patient, member of the public, clinician, or other stakeholder can (should

they wish to) verify any claims made by ACDSS developers, system managers, or others regarding the efficacy, safety, or effectiveness of any specific ACDSS, so that:

a. The rationale for developing and deploying any ACDSS is publicly accessible to encourage transparency regarding decisions linking specific ACDSS to specific information needs;
b. All ACDSS is clearly and transparently tied to a use case for which there is a clear, robust, and publicly accessible evidence base;
c. All patients can be reassured of its safety, efficacy, and cost-effectiveness, and, therefore, of the system's commitment to *primum non nocere;* and
d. The entire **pipeline of ACDSS development is auditable**, and **'bad actors'** can be identified and **sanctioned.**

8.3.5 A conceptual model for the successful implementation of ACDSS into the NHS

Following the identification of the assumption-negating shaping rules and the acceptable function, the preceding section identified a final set of 24 policy design action requirements. These can now be added to Conceptual Model A (Figure 3), to produce the final conceptual model for the successful implementation of ACDSS into the NHS linking the success requirement, conceptual function requirements, vision requirements, delivery requirements, and policy action requirements. By linking together all these requirements, the model shows how the implementation of ACDSS into the NHS can be technically feasible, socially acceptable, ethically justifiable, and legally compliant and, ultimately, how the NHS can be enabled to capitalise on the dual advantage of ACDSS: maximising the benefits (positive intended emergence) and mitigating the risks (negative unintended re-ontologising emergence). Figure 4 presents the final model.

Figure 4. Conceptual Model B. Final conceptual model for the successful implementation of ACDSS into the NHS showing the connections between the NLHS, ACDSS implementation, success requirements, unifying function requirements, vision requirements, delivery requirements, and policy design-action requirements.

Reading this final conceptual model top-down provides an answer to the ORQ, which to re-state is:

> ORQ: What are the information infrastructure requirements for the successful implementation of ACDSS into the NHS?

It provides this answer by establishing that if the NHS is to become an ACDSS-enabled NLHS it **requires:**

1. Supporting information infrastructure that ensures the implementation of ACDSS is technically feasible, ethically justifiable, socially acceptable, and legally compliant. This in turn requires:
2. An information infrastructure design that is intended to support the function "maximise the utility, usability, efficacy, and trustworthiness of existing NHS information for the purpose of meeting clearly identifiable information needs". This in turn requires:
3. An information infrastructure design intended to provide the system with epistemic certainty, robust information exchange, validated outcomes, protected values, autonomous staff, and meaningful accountability. This in turn requires:
4. An information infrastructure design intended to deliver consistently good data quality; sufficient data quantity; reliable data interpretability; UX focused EHR design; privacy enhancing data access; seamless system integration; protection from vendor lock-in; clearly stated clinical objectives; mindful model development; rigorous technical validation; rigorous clinical evaluation; careful local calibration; ongoing impact evaluation; commitment to collective provision; commitment to patient centricity; commitment to quality care; protection of clinician epistemic authority; valued informatics workforce; da-literate leaders; fit for purpose Information Governance; regulated medical devices; clinician and patient protection; and auditability. This in turn requires:
5. Policy that is focused on EHR design templates; model-to-data ACDSS development approaches; interoperability standards; audit and feedback; modularity and local customisability; data-work; NHS ACDSS-ready data assets; clinicians as originators of demand; value pluralism; patient and public involvement and engagement; qualitative health information; provably trustworthy relationships; a technical buddy system; the status of NHS analysts as clinical not clerical; the clinician's right to override; HTA and NSC review of ACDSS; model development and feature selection guidance; 'in silico' and

'in socio' model testing; roving data science teams; oversight of ACDSS integration and use' data governance simplification and clarification; regulation of ACDSS as SaMD; process accountability regarding liability, discrimination, and consumer protection; and public documentation.

Alternatively, reading the final model bottom to top, establishes what policymakers should focus on if they wish to develop an information infrastructure that will enable the NHS to capitalise on the dual advantage of ACDSS. In this way, the bottom-up reading of the model meets the aim of this thesis which, to re-state, was:

> Aim: Design an information infrastructure that will enable the NHS to capitalise on the dual advantage of ACDSS.

Thus, with the ORQ answered and the aim, at least theoretically met, it is now time to bring this thesis to an end. This will be the purpose of the final concluding chapter.

8.4 Conclusion

By (a) identifying the unifying acceptable function for the desired ACDSS-enabled NLHS; (b) outlining the final policy actions required to operationalise the ideal vision and delivery requirements in keeping with this function; and (c) connecting these final requirements to the success requirements, conceptual function requirements, ideal vision requirements, and ideal delivery requirements, this chapter has finally delivered the long-promised conceptual model for the successful implementation of ACDSS into the NHS. In delivering this model, this chapter has also provided an answer to the overarching research question of this thesis and helped demonstrate that this thesis has now met its aim and reached its conclusion. The model is not, however, without its limitations. It is only a model of necessary requirements, in keeping with the logic of design, and it has not been subject to external validation in its final form. Further future work will be required to iterate the model and identify the 'sufficient' requirements. It is the task of the final concluding chapter to discuss these limitations and next steps in more detail.

9. An algorithmically enhanced NHS: conclusions, contributions, limitations, and next steps

9.1 Summary

This thesis started with the premise that whilst after 75 years of existence the NHS is still one of England's most beloved institutions, it is struggling to cope with the pressures of providing comprehensive free-at-the-point of need healthcare to complex, often elderly and multi-morbid, 21st century patients. Satisfaction with the healthcare service is declining, outcomes are worsening, and there is a burgeoning workforce crisis that looks set to escalate. The limited effectiveness of previous small-scale policy interventions, such as introducing payment for performance schemes into primary care, or requiring patients to pay for prescriptions, has given policymakers the impression that – if the NHS is to survive for another 75 years – a more radical change will be required. Specifically, policymakers have become enamoured with the idea of turning the NHS into a learning healthcare system (NLHS) via the implementation of Algorithmic Clinical Decision Support Software (ACDSS). Policymakers hope that by transforming the NHS into an ACDSS-enabled NLHS, and introducing new information feedback loops, the NHS can 'learn' how to most efficiently produce the best outcomes and so become more efficient, more effective, and more sustainable (Blasimme & Vayena, 2016), as well as more evidence-based, less wasteful, and less harmful (Braithwaite et al., 2020). However, as promising as these potential benefits of ACDSS implementation sound, capitalising on them, without introducing benefit-outweighing risks, is proving challenging for the NHS. Current attempts at implementation are failing – heightening the likelihood that excitement in ACDSS might dwindle and the technology may be abandoned before any of the potential benefits can be realised. Although policymakers are aware of the importance of closing this implementation gap doing so is difficult because it is not a problem that can be solved through traditional top-down planned approaches to policy and technology implementation. Instead, Chapter One argued, that a more flexible systems-design-based approach is needed, one that focuses on identifying the information infrastructure (underlying architecture) requirements that will support the successful implementation of ACDSS into the NHS and enable it to capitalise on the benefits of ACDSS whilst mitigating the potential risks (the 'dual advantage'). Hence, the overarching research question for this thesis became:

> *ORQ*: What are the information infrastructure requirements for the successful implementation of ACDSS in the NHS?

With the aim being:

> Aim: To design the information infrastructure that will enable the NHS to capitalise on the dual advantage of ACDSS.

Following the steps of the logic of design as a conceptual logic of requirements (Floridi, 2017b), and the process of hierarchic decomposition popularised by systems engineering approaches to architecture design (Cameron et al., 2016), this overarching question was broken down into a series of three sub-research questions:

> RQA: (i) Why is the current NHS information infrastructure design resulting in ACDSS implementation failure? What changes are required to increase the likelihood of implementation success? (ii) What would be the consequences if these changes were not made, or if the wrong changes were made?
>
> RQB: (i) What are the ideal NHS information infrastructure requirements to enable the successful implementation of ACDSS? How likely is it that these requirements will be met by current policy? (ii) What underpinning assumptions and contextual factors might limit the likelihood of the ideal requirements being met by current policy?
>
> RQC "What is the unifying function of the desired ACDSS-enabled NLHS? How might policy successfully operationalise the ideal requirements to meet this function?"

Over the course of five empirical chapters each drawing on a conceptual, thematic, and rhetorical analysis of 213 articles included in a realist review, 73 semi-structured interviews, and 62 policy documents, the answers to these questions were drawn out, and it became clear that:

A. The current design of the NHS's information infrastructure is resulting in ACDS implementation failure because it is wrought through with mismanaged disorganised complexity which is making the system harder to manage and increasing the risk of negative re-ontologising emergence occurring. To increase the chances of success, this mismanaged disorganised complexity, must become more organised through the

identification of common abstractions (requirements) otherwise the risks or re-ontologising emergence will remain great. If the risks of negative re-ontologising emergence, related to the implementation of ACDS, are not reduced through the identification of requirements intended to organise the complexity present in the NHS's information infrastructure, then the implementation of ACDSS into the NHS may result in the patient being displaced from the centre of care, the fundamentals of caring being disrupted, and the NHS ceasing to be for all.

B. To organise the complexity currently plaguing the NHS's information infrastructure, it needs to be redesigned to ideally provide the NHS with epistemic certainty, robust information exchange, validated outcomes, actively protected values, autonomous staff, and meaningful accountability (vision requirements). To provide the NHS with these requirements, the NHS's information infrastructure must deliver consistently good data, quality sufficient data quantity, and reliable data interpretability; UX focused EHR design, privacy-preserving data access mechanisms, seamless system integration, and system-wide protection from vendor lock-in; clearly stated clinical outcomes, mindful model development, robust technical validation, robust clinical evaluation, careful local calibration, and ongoing impact monitoring; commitment to collective provision, commitment to patient centricity, and commitment to quality care; data-literate senior leaders, valued informatics workforce, and protection of the clinician's epistemic authority; fit for purpose information governance, regulated medical devices, clinician and patient protection, and auditability. The concern is that, given current relevant policy developments, the likelihood of these ideal requirements being met is relatively low because there is a considerable sociotechnical gap between the ideal requirements and the requirements covered by policy. This sociotechnical gap exists because the ideal requirements are primarily influenced by the scientific epistemic community, whilst the requirements covered by policy are primarily influenced by the technical epistemic community. These two communities hold different assumptions regarding the size and scale of the implementation challenge, the art of the possible, the relationship between information and action, and the role of regulation in supporting innovation. These differences in assumptions are driving different interpretations of the function of the intended ACDSS-enabled NLHS which, in turn, is driving different interpretations of the ideal requirements (i.e., the form of the information infrastructure). To close the

sociotechnical gap and increase the likelihood of the ideal requirements being met, a unified acceptable function, from which the appropriate operationalisation of the form can follow, is needed. Otherwise, there is a possibility that the system designers (policymakers influenced by the technical epistemic community) may design an information infrastructure that supports an ACDSS-enabled NLHS function that is not acceptable to the main system users and beneficiaries (clinicians and patients, represented by the scientific epistemic community).

C. To close the sociotechnical gap, the NHS's information infrastructure must be designed to support an ACDSS-enabled NLHS function of "maximising the utility, usability, efficacy, and trustworthiness of existing NHS information for specific information needs." To operationalise the ideal vision and delivery requirements in keeping with this function, policy that focuses on the following is required: EHR design templates; model-to-data ACDSS development approaches; interoperability standards; audit and feedback; modularity and local customisability; data-work; NHS ACDSS-ready data assets; clinicians as originators of demand; value pluralism; patient and public involvement and engagement; qualitative health information; provably trustworthy relationships; a technical buddy system; the status of NHS analysts as clinical not clerical; the clinician's right to override; HTA and NSC review of ACDSS; model development and feature selection guidance; 'in silico' and 'in socio' model testing; roving data science teams; oversight of ACDSS integration and use' data governance simplification and clarification; regulation of ACDSS as SaMD; process accountability regarding liability, discrimination, and consumer protection; and public documentation

By combining these answers, a conceptual model for the successful implementation of ACSS into the NHS was derived.

The model (figure 4), which shows the connection between the success requirements, conceptual function requirements, ideal vision requirements, ideal delivery requirements, and policy design requirements, can be read from the top down (success requirements → function requirements → ideal vision requirements → ideal delivery requirements → policy action requirements) to answer the overarching research question (see Table 27) or bottom-up (policy action requirements → ideal delivery requirements → ideal vision requirements → function requirements → success requirements)

to show policymakers what they need to do to meet this thesis's aim of designing an information infrastructure design to enable the NHS to capitalise on the dual advantage of ACDSS into the NHS.

Information Infrastructure requirements for the successful implementation of ACDSS into the NHS
1. Supporting information infrastructure that ensures the implementation of ACDSS is technically feasible, ethically justifiable, socially acceptable, and legally compliant. This in turn requires: 2. An information infrastructure design that is intended to support the function "maximise the utility, usability, efficacy, and trustworthiness of existing NHS information for the purpose of meeting clearly identifiable information needs". This in turn requires: 3. An information infrastructure design intended to provide the system with epistemic certainty, robust information exchange, validated outcomes, protected values, autonomous staff, and meaningful accountability. This in turn requires: 4. An information infrastructure design intended to deliver consistently good data quality; sufficient data quantity; reliable data interpretability; UX focused EHR design; privacy enhancing data access; seamless system integration; protection from vendor lock-in; clearly stated clinical objectives; mindful model development; rigorous technical validation; rigorous clinical evaluation; careful local calibration; ongoing impact evaluation; commitment to collective provision; commitment to patient centricity; commitment to quality care; protection of clinician epistemic authority; valued informatics workforce; da-literate leaders; fit for purpose Information Governance; regulated medical devices; clinician and patient protection; and auditability. This in turn requires: 5. Policy that is focused on EHR design templates; model-to-data ACDSS development approaches; interoperability standards; audit and feedback; modularity and local customisability; data-work; NHS ACDSS-ready data assets; clinicians as originators of demand; value pluralism; patient and public involvement and engagement; qualitative health information; provably trustworthy relationships; a technical buddy system; the status of NHS analysts as clinical not clerical; the clinician's right to override; HTA and NSC review of ACDSS; model development and feature selection guidance; 'in silico' and 'in socio' model testing; roving data science teams; oversight of ACDSS integration and use' data governance simplification and clarification; regulation of ACDSS as SaMD; process accountability regarding liability, discrimination, and consumer protection; and public documentation.

Table 27. Final information infrastructure requirements for the successful implementation of ACDSS into the NHS

Thus, in providing an answer to the overarching research question and demonstrating how this answer can also meet this thesis's aim, the final conceptual model represents this thesis's conclusion. The contributions of this conclusion to the literature on the topic of using AI in healthcare can now be discussed.

9.2 Contributions

The contributions of this thesis's conclusion, represented in the final conceptual model (figure 4), to the existing literature on the topic of using AI in healthcare are threefold. First, from a methodological perspective it has demonstrated how the logic of design as a conceptual logic of requirements can be used to successfully identify the requirements needed to close the AI implementation gap. This is a generalisable finding that may be of use to other healthcare systems struggling to identify how exactly to capitalise on the many potential benefits of AI (via ACDSS) whilst mitigating the risks.

Second, from a theoretical perspective, it has demonstrated how to move the concept of the learning healthcare system from the purely theoretical realm of 'what' to the more practical realm of 'how' via the implementation of ACDSS, by defining the function of the learning healthcare system first and allowing the form of the enabling system (in this instance information infrastructure) follow. This lowers the level of abstraction of the existing learning healthcare system literature, and provides a more concrete goal for healthcare systems, data scientists, social scientists healthcare policymakers, and AI developers to aim for. This may aid collaboration between the different groups.

Third, and finally, from a practical perspective, it has produced a new comprehensive systems-level conceptual model for the successful implementation of ACDSS into a healthcare system. The model joins together numerous previously independent concepts from different bodies of literature from the very highly abstract, to the more grounded and more specific. In so doing, it demonstrates how technical, ethical, legal, and social considerations are mutually dependent and need to be evaluated interdependently rather than independently. This, in turn, demonstrates the value of complex theorising about information infrastructure and how this can be used to assess whether a complex construct such as an "algorithmically enhanced NHS" is both possible and desirable – which, in this case, it is. Although the model is applied specifically to the case of the NHS in England, as the NHS is widely considered to be the healthcare system with the greatest chance of becoming a learning healthcare system given its unique advantages of being a single payer system with a large volume of centrally 'owned' longitudinal data, it is possible that the model can be seen as an example of best practice from which other healthcare systems may be able to learn.

As valuable as these contributions may be, it is important that they are not overstated and that the limitations of the final model, as well as other aspects of this thesis are recognised and discussed.

9.3 Limitations and next steps

To start with the most prosaic limitation: the logic of design is focused on the elicitation of necessary requirements not sufficient requirements (Floridi, 2017b). This is in keeping with the aim of design being adequacy, not perfection (Glanville, 2008). Consequently, the final conceptual model is only comprised of necessary requirements, not sufficient requirements. In other words, the model does not tell policymakers exactly what to do, what to build, or what to commission in response to the policy design requirements to enable the successful implementation of ACDSS into the NHS. Options for these 'sufficient' requirements include: (a) creating a user forum for clinicians to submit information need requests, in the form of user stories, to be matched to ACDSS already available to meet this need or to ACDSS developers willing to 'solve' the need; (b) creating an ACDSS-specific procurement framework – like an ACDSS 'app store' - to ensure NHS organisations wishing to implement ACDSS have access to a dedicated list of ACDSS and ACDSS providers that has been through an approved process of verification, validation, and evaluation; and (c) establishing an NHS ACDSS development and testing centre so all development takes place 'in house' and follows a pre-approved, transparent, and well documented process. However, these, and other options would need to be robustly tested with all stakeholders, ideally subject to public consultation, before they can be considered recommendations. Truly successful ACDSS implementation will only be possible if both the necessary requirements identified in this thesis, and the sufficient requirements that must be identified through stakeholder engagement, are met. It is, therefore, essential that this next phase of stakeholder engagement happens, and happens soon.

Linked to this limitation of necessary, but not sufficient requirements, is a second limitation regarding the model's middle level of abstraction (Bouch et al., 2015). Whilst it has lowered the level of abstraction from, for example, the purely theoretical level of ethical principles, the model is still operating at a middle-level or relatively abstract level of abstraction. Concepts such as "simplified data ownership, controllership, and use case" are still high-level enough as to be open to interpretation. Furthermore, requirements such as "guidelines regarding model selection and feature selection" may not result in sufficiently precise instructions for ACDSS developers, leaving a remaining degree of uncertainty. Wherever there is uncertainty or room for interpretation, there is potential for 'misinterpretation' or interpretation that may be technically unfeasible, socially unacceptable, ethically unjustifiable, or illegal. It is essential, therefore, that the results of this thesis be combined with the results of other studies focusing on a lower level of abstraction, for example studies focusing on the exact best practice for algorithm design in healthcare settings.

Next, design is intended to be an iterative process. This is why, there are an additional two steps to the logic of design as a conceptual logic of requirements that have not been completed in this thesis: "build" and "use" (Floridi, 2017b). These phases focus on testing the results of the design process, receiving feedback, and iterating in response. Whilst the final conceptual model has been iterated multiple times in the development of this thesis, particularly during the interview phase of the research, it has not been piloted nor reviewed as a completed whole. It is likely, indeed desirable, therefore that it will need to go through further rounds of iteration following a pilot study with, for example, one NHS integrated care board, and further stakeholder engagement. It is particularly important that this happen, and further independent voices are brought in to review the outputs, given the subjective nature of the interpretivist methodology used to produce the model. Whilst every step possible has been taken to remove author-bias from the process, all research is influenced by the researcher's positionality and this thesis will be no different. Given personal experience it is, for example, likely that thesis focuses more heavily on privacy requirements (e.g., requirements for "privacy-preserving data access mechanisms" and "model-to-data approaches to model development") than other researchers might and focuses less on other requirements that other researchers might deem more important. Similarly, the methods used for interviewees likely meant that, not only is there an uneven split of all stakeholders in terms of role representation, but also in terms of attitude representation. In short, it is likely that the interviewees included are more supportive of the ACDSS-enabled NLHS concept than the "average" as few interviewees disagreed entirely with the premise or with any of the suggested recommendations. It is vital, therefore, that the model be subject to external independent critique, piloting, and further rounds of iteration.

Finally, there are limitations in terms of the likelihood of achieving change on this scale within the NHS regardless of the quality of the model. First, most practically, many of the NHS's current struggles are the direct results of a lack of resources, both in terms of funding and staffing. The concept of an ACDSS-enabled NLHS is too new for the resource implications to be known. It is not known, for example, whether implementing ACDSS would genuinely result in much hoped-for efficiency (and therefore reduced cost) benefits or whether the resource costs associated with implementation may outweigh the benefits and have done little other than divert vital resources from other more effective policy interventions. This is another reason why piloting the concept before any attempts to scale are made is vital – to avoid the risk of policymakers catching "single-solution-it is" (McDermid, 2000) and neglecting to consider other alternative solutions to either implementing ACDSS, or, to the current crises facing the NHS other than the NLHS concept. Second, more theoretically, there is abundant

evidence to suggest "institutional isomorphism" (Currie, 2012) and the "Einstellung effect" (Bilalić et al 2008) may make it near impossible to achieve the necessary degree of change to bring this model into being either from the perspective of encouraging policymakers to move away from plan-and-control approaches to implementation, or from the perspective of encouraging all parts of the system to willingly adopt ACDSS. In other words, the prior knowledge of "how things work" (Einstellung), and institutionalised behaviours, norms, and attitudes (isomorphism) may prevent policymakers and other system stakeholders from seeing the potential of adopting new ways of working. This again, highlights the importance of further iterating both the concept of the NLHS itself, and the model for realising the NLHS via the successful implementation of ACDSS with a broader range of stakeholders than those included in this study.

9.4 Conclusion

This thesis started with the knowledge that the NHS is struggling to cope following the UK's exit from the European Union and the impact of the COVID-19 crisis and that, in enabling the NHS to become a NLHS, the implementation of ACDSS might help the NHS overcome these challenges if only it was known how to close the ACDSS implementation gap. It has ended with the knowledge that to close the implementation gap a supporting information infrastructure characterised by a high-degree of organised complexity and designed to meet the ACDSS-enabled NLHS function of "maximising the utility, usability, efficacy, and trustworthiness of existing NHS information for specific information needs" is required. This new knowledge represents a not-insignificant step forwards towards the goal of enabling the NHS to capitalise on the dual advantage of ACDSS, and perhaps a small step towards enabling healthcare in general to benefit from the many potential advantages of AI. However, balancing the contributions of this thesis with appropriate recognition of the limitations, and ensuring the outlined next steps (future research involving the identification of sufficient requirements, further stakeholder engagement, piloting, and iterating) happen, is vital. This is vital, not only because honesty about limitations and needed further work will help improve the quality of the research, but also because the future of the NHS is too important not to insist every single proposed solution, recommendation, or decision is viewed from all possible angles and subject to intense scrutiny. As one interviewee put it "we cannot move fast and break things, when the things we might break are people's lives." The NHS might never have been in a deeper crisis, but its central premise of "comprehensive care, free at the point of need, for all" is undeniably worth fighting for (Abbasi, 2023). Hopefully, this thesis has made a small contribution to this fight. Hopefully others will

feel equally motivated to contribute more. Hopefully the NHS will continue to exist for the next 75 years.

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I4. (2022, October 17). *Interview with Technologist* (J. Morley, Interviewer) [Online Interview].

I5. (2022, October 17). *Interview with Technologist* (J. Morley, Interviewer) [Personal communication].

I6. (2022, October 17). *Interview with Clinician* (J. Morley, Interviewer) [Online Interview].

I7. (2022, October 17). *Interview with Clinician* (J. Morley, Interviewer) [Online Interview].

I8. (2022, October 17). *Interview with Patient* (J. Morley, Interviewer) [Online Interview].

I9. (2023, October 17). *Interview with UX Designer* (J. Morley, Interviewer) [Online Interview].

I10. (2022, October 18). *Inerview with Software Engineer* (J. Morley, Interviewer) [Online Interview].

I11. (2022, October 18). *Interview with Patient* (J. Morley, Interviewer) [Online Interview].

I13. (2022, October 19). *Interview with Clinician* (J. Morley, Interviewer) [Online Interview].

I15. (2022, October 19). *Interview with NHS Analyst* (J. Morley, Interviewer) [Personal communication].

I16. (2022, October 20). *Interview with NHS Analyst* (J. Morley, Interviewer) [Online Interview].

I17. (2022, October 20). *Interview with Policy Official* (J. Morley, Interviewer) [Online Interview].

I18. (2022, October 20). *Interview with Clinical Academic* (J. Morley, Interviewer) [Online Interview].

I19. (2022, October 20). *Interview with Clinical Academic* (J. Morley, Interviewer) [Online Interview].

I20. (2022, October 21). *Interview with Software Engineer* (J. Morley, Interviewer) [Online Interview].

I21. (2022, October 21). *Interview with NHS Analyst* (J. Morley, Interviewer) [Online Interview].

I22. (2022, October 21). *Interview with Clinical Academic* (J. Morley, Interviewer) [Personal communication].

I23. (2022, October 24). *Interview with Technologist* (J. Morley, Interviewer) [Online Interview].

I24. (2022, October 24). *Interview with Clinician (CMO)* (J. Morley, Interviewer) [Personal communication].

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I26. (2022, October 26). *Interview with Data Scientist* (J. Morley, Interviewer) [Online Interview].

I27. (2022, October 26). *Interview with Clinical Academic* (J. Morley, Interviewer) [Online Interview].

I29. (2022, October 27). *Interview with Policy Official* (J. Morley, Interviewer) [Online Interview].

I30. (2022, October 28). *Interview with Clinician (Radiologist)* (J. Morley, Interviewer) [Online Interview].

I32. (2022, October 28). *Interview with Policy Official* (J. Morley, Interviewer) [Online Interview].

I33. (2022, October 28). *Interview with Clinician (Pharmacist)* (J. Morley, Interviewer) [Online Interview].

I34. (2022, October 28). *Interview with NHS Analyst* (J. Morley, Interviewer) [Online Interview].

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I39. (2022, October 31). *Interview with Software Engineer* (J. Morley, Interviewer) [Online Interview].

I40. (2022, October 31). *Interview with Compliance Officer* (J. Morley, Interviewer) [Online Interview].

I41. (2022, October 31). *Interview with Privacy Campaigner* (J. Morley, Interviewer) [Online Interview].

I43. (2023, October 31). *Interview with Technologist* (J. Morley, Interviewer) [Online Interview].

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I50. (2022, July 11). *Interview with Clinical Informatician* [Online Interview].

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I57. (2022, October 11). *Interview with Clinical Entrepreneur* (J. Morley, Interviewer) [Online Interview].

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I59. (2022, November 11). *Interview with Clinician (Pharmacist)* (J. Morley, Interviewer) [Online Interview].

I60. (2022, November 11). *Interview with Service Designer* (J. Morley, Interviewer) [Online Interview].

I61. (2022, November 11). *Interview with Clinical Academic* (J. Morley, Interviewer) [Online Interview].

I62. (2022, November 14). *Interview with Policy Official* (J. Morley, Interviewer) [Online Interview].

I65. (2022, November 18). *Interview with Data Scientist* (J. Morley, Interviewer) [Online Interview].

I66. (2022, November 21). *Interview with Clinical Academic* (J. Morley, Interviewer) [Online Interview].

I67. (2022, November 21). *Interview with Technologist* (J. Morley, Interviewer) [Online Interview].

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Appendix A: realist review articles

Included articles

Realist Review: Included from first round of review

1. Abbott, Patricia A., Joanne Foster, Heimar de Fatima Marin, and Patricia C. Dykes. 2014. 'Complexity and the Science of Implementation in Health IT—Knowledge Gaps and Future Visions'. *International Journal of Medical Informatics* 83(7): e12–22.
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Example Theming of realist review articles: Information Requirements

Note: note in Chapter 6 not all of these articles may have been included in the final realist review, others may have been added for triangulation purposes

	Reference	Year	Author Location	Subject Area	Recommendations
1	Shortliffe, E., Sepulveda, M (2018) Clinical Decision Support in the Era of Artificial Intelligence. JAMA 320(21) pp.2199-2200 doi:10.1001/jama.2018.17163	2018	USA	Medical	**Reliable data interpretability** Time efficient Respectful in knowledge delivery
2	Ngiam, Kee Yuan, and Ing Wei Khor. 'Big Data and Machine Learning Algorithms for Health-Care Delivery'. The Lancet Oncology 20, no. 5 (May 2019): e262–73. https://doi.org/10.1016/S1470-2045(19)30149-4.	2019	Singapore	Medical	**Consistent data quality** Data must be labelled Data must be curated Missingness must be handled
3	Challen, R., J. Denny, M. Pitt, L. Gompels, T. Edwards, and K. Tsaneva-Atanasova. 'Artificial Intelligence, Bias and Clinical Safety'. BMJ Quality and Safety 28, no. 3 (2019): 231–37. https://doi.org/10.1136/bmjqs-2018-008370.	2019	UK	Medical	**Reliable data interpretability** No Black Box **Sufficient data quantity** Train on large, diverse, and balanced datasets to account for distributional drift **Sufficient data quantity** Training and Location data must match in context
4	Ellahham, Samer, Nour Ellahham, and Mecit Can Emre Simsekler. 2020. 'Application of Artificial Intelligence in the Health Care Safety Context: Opportunities and Challenges'. *American Journal of Medical Quality* 35(4): 341–48.	2020	USA	Medical	**Sufficient data quantity** Train on large, diverse, and balanced datasets to account for distributional drift Include outliers in training datasets
5	Lee, Lisa M. 2017. 'Ethics and Subsequent Use of Electronic Health Record Data'. *Journal of Biomedical Informatics* 71: 143–46.	2017	USA	Informatics	**Consistent data quality** Evaluate EHR validity
6	Braun, Matthias, Patrik Hummel, Susanne Beck, and Peter Dabrock. 2021. 'Primer on an Ethics of AI-Based Decision Support Systems in the Clinic'. *Journal of Medical Ethics* 47(12): e3–e3.	2021	EU	Ethics	**Reliable data interpretability** No Black Box Explainability
7	Amann, Julia et al. 2020. 'Explainability for Artificial Intelligence in Healthcare: A Multidisciplinary Perspective'. *BMC Medical Informatics and Decision Making* 20(1): 310.	2020	EU	Informatics	**Reliable data interpretability** Explainability
8	Awaysheh, Abdullah et al. 2019. 'Review of Medical Decision Support and Machine-Learning Methods'.	2019	USA	Medical	**Consistent data quality** Data must be curated

	Veterinary Pathology 56(4): 512–25.				
9	Char, Danton S., Michael D. Abràmoff, and Chris Feudtner. 2020. 'Identifying Ethical Considerations for Machine Learning Healthcare Applications'. *The American Journal of Bioethics* 20(11): 7–17.	2020	USA	Ethics	**Reliable data interpretability** Explainability
10	Avellan, Tero, Sumita Sharma, and Markku Turunen. 2020. 'AI for All: Defining the What, Why, and How of Inclusive AI'. In Proceedings of the 23rd International Conference on Academic Mindtrek, AcademicMindtrek '20, New York, NY, USA: Association for Computing Machinery, 142–44. https://doi.org/10.1145/3377290.3377317 (August 24, 2022).	2020	EU	Computer Science	**Sufficient data quantity** Train on large, diverse, and balanced datasets to account for distributional drift
11	Gianfrancesco, Milena A., Suzanne Tamang, Jinoos Yazdany, and Gabriela Schmajuk. 2018. 'Potential Biases in Machine Learning Algorithms Using Electronic Health Record Data'. *JAMA Internal Medicine* 178(11): 1544.	2018	USA	Medical	**Sufficient data quantity** Train on large, diverse, and balanced datasets to account for distributional drift Training and Location data must match in context
12	Panch, T., H. Mattie, and R. Atun. 'Artificial Intelligence and Algorithmic Bias: Implications for Health Systems'. Journal of Global Health 9, no. 2 (2019). https://doi.org/10.7189/jogh.09.020318.	2019	USA	Medical	**Sufficient data quantity** Train on large, diverse, and balanced datasets to account for distributional drift **Reliable data interpretability** Explainability
13	Chen, Po-Hsuan Cameron, Yun Liu, and Lily Peng. 2019. 'How to Develop Machine Learning Models for Healthcare'. *Nature Materials* 18(5): 410–14.	2019	USA	Engineering	**Consistent data quality** Data must be curated **Sufficient data quantity** Train on large, diverse, and balanced datasets to account for distributional drift Ground truth reference datasets Include outliers in training datasets
14	He, Jianxing, Sally L. Baxter, Jie Xu, Jiming Xu, Xingtao Zhou, and Kang Zhang. 'The Practical Implementation of Artificial Intelligence Technologies in Medicine'. Nature Medicine 25, no. 1 (January 2019): 30–36. https://doi.org/10.1038/s41591-018-0307-0.	2019	China	Medical	**Sufficient data quantity** Ground truth reference datasets

15	Wiens, Jenna et al. 2019. 'Do No Harm: A Roadmap for Responsible Machine Learning for Health Care'. *Nature Medicine* 25(9): 1337–40.	2019	USA	Medical	**Sufficient data quality** Data must be curated
16	Park, Seong Ho, and Kyunghwa Han. 'Methodologic Guide for Evaluating Clinical Performance and Effect of Artificial Intelligence Technology for Medical Diagnosis and Prediction'. Radiology 286, no. 3 (March 2018): 800–809. https://doi.org/10.1148/radiol.2017171920	2018	[South Korea – but generalisable]	Medical	**Consistent data quality** Respectful in knowledge delivery Time efficient
17	Rigby, Michael J., Carol Hulm, Don Detmer, and Luca Buccoliero. 2007. 'Enabling the Safe and Effective Implementation of Health Informatics Systems–Validating Rolling Out the ECDL/ICDL Health Supplement'. *MEDINFO 2007*: 1347–51.	2007	UK	Informatics	**Reliable data interpretability** Explainability
18	Almeida, João Rafael et al. 2020. 'Enhancing Decision-Making Systems with Relevant Patient Information by Leveraging Clinical Notes'. In Proceedings of the 13th International Joint Conference on Biomedical Engineering Systems and Technologies - Volume 5 HEALTHINF: HEALTHINF, Science and Technology Publications, 254–62. https://ruc.udc.es/dspace/handle/2183/26881 (August 24, 2022).	2020	EU	Engineering	**Consistent data quality** Data must be curated Data must be labelled
19	Amarasingham, Ruben et al. 2016. 'Consensus Statement on Electronic Health Predictive Analytics: A Guiding Framework to Address Challenges'. *eGEMs (Generating Evidence & Methods to improve patient outcomes)* 4(1): 3.	2016	USA	Medical	**Sufficient data quantity** Train on large, diverse, and balanced datasets to account for distributional drift Ground truth reference datasets Data must be multi-modal **Consistent data quality** Data must be curated
20	Auffray, Charles et al. 2016. 'Making Sense of Big Data in Health Research: Towards an EU Action Plan'. *Genome Medicine* 8(1): 71.	2016	EU	Medical	**Consistent data quality** Data must be curated **Sufficient data quantity** Data must be multi-modal

21	Beasley, J. W. et al. 2011. 'Information Chaos in Primary Care: Implications for Physician Performance and Patient Safety'. *The Journal of the American Board of Family Medicine* 24(6): 745–51.	2011	USA	Medical	**Reliable data interpretability** Time efficient Readily actionable
22	Bezemer, Tim et al. 2019. 'A Human(e) Factor in Clinical Decision Support Systems'. *Journal of Medical Internet Research* 21(3): e11732.	2019	EU	Informatics	**Consistent data quality** Data must be curated Data must be labelled **Sufficient data quantity** Data must be multi-modal
23	Bietz, Matthew J et al. 2016. 'Opportunities and Challenges in the Use of Personal Health Data for Health Research'. *Journal of the American Medical Informatics Association* 23(e1): e42–48.	2016	USA	Informatics	**Reliable data interpretability** No Black Box
24	Bigman, Yochanan E. et al. 2021. 'Threat of Racial and Economic Inequality Increases Preference for Algorithm Decision-Making'. *Computers in Human Behavior* 122: 106859.	2021	USA	Behavioural Science	**Reliable data interpretability** Time efficient Readily actionable
25	Brown, Cary A. 2006. 'The Application of Complex Adaptive Systems Theory to Clinical Practice in Rehabilitation'. *Disability and Rehabilitation* 28(9): 587–93.	2006	UK	Medical	**Sufficient data quantity** Data must be multi-modal
26	Calvert, Melanie, Rob Thwaites, Derek Kyte, and Nancy Devlin. 2015. 'Putting Patient-Reported Outcomes on the "Big Data Road Map"'. *Journal of the Royal Society of Medicine* 108(8): 299–303.	2015	UK	Medical	**Sufficient data quantity** Data must be multi-modal
27	Catchpole, Ken, and Myrtede Alfred. 2018. 'Industrial Conceptualization of Health Care Versus the Naturalistic Decision-Making Paradigm: Work as Imagined Versus Work as Done'. *Journal of Cognitive Engineering and Decision Making* 12(3): 222–26.	2018	USA	Engineering	**Reliable data interpretability** Readily actionable **Sufficient data quantity** Data must be multi-modal
28	Chin-Yee, Benjamin, and Ross Upshur. 2018. 'Clinical Judgement in the Era of Big Data and Predictive Analytics'. *Journal of Evaluation in Clinical Practice* 24(3): 638–45.	2018	Canada	Medical	**Sufficient data quantity** Data must be multi-modal
29	Gurupur, Varadraj, and Thomas T. H. Wan. 2020. 'Inherent Bias in Artificial Intelligence-Based Decision Support Systems for Healthcare'. *Medicina* 56(3): 141.	2020	USA	Medical	**Sufficient data quantity** Data must be multi-modal

30	Hall, Peter S., and Andrew Morris. 2017. 'Predictive Analytics and Population Health'. In Key Advances in Clinical Informatics, Elsevier, 217–25. https://doi.org/10.1016/B978-0-12-809523-2.00015-7	2017	UK	Informatics	**Reliable data interpretability** Time efficient Readily actionable
31	Hill, Elizabeth M, Emma L Turner, Richard M Martin, and Jenny L Donovan. 2013. "'Let's Get the Best Quality Research We Can": Public Awareness and Acceptance of Consent to Use Existing Data in Health Research: A Systematic Review and Qualitative Study'. BMC Medical Research Methodology 13(1): 72.	2013	UK	Medical	**Sufficient data quantity** Ground truth reference datasets
32	Jones, C., Thornton, J., & Wyatt, J. (2021). Enhancing trust in clinical decision support systems: A framework for developers. BMJ HEALTH & CARE INFORMATICS, 28(1). https://doi.org/10.1136/bmjhci-2020-100247	2021	UK	Informatics	**Reliable data interpretability** No Black Box
33	Kilsdonk, E., L.W. Peute, and M.W.M. Jaspers. 2017. 'Factors Influencing Implementation Success of Guideline-Based Clinical Decision Support Systems: A Systematic Review and Gaps Analysis'. *International Journal of Medical Informatics* 98: 56–64.	2017	EU	Informatics	**Reliable data interpretability** Readily actionable Time efficient Explainability **Sufficient data quantity** Data must be multi-modal
34	Kwon, I.-W. G., Kim, S.-H., & Martin, D. (2021). Integrating social determinants of health to precision medicine through digital transformation: An exploratory roadmap. International Journal of Environmental Research and Public Health, 18(9). Scopus. https://doi.org/10.3390/ijerph18095018	2021	USA	Medical	**Sufficient data quantity** Data must be multi-modal
35	Lee, S. S.-J. (2021a). Obligations of the "Gift": Reciprocity and Responsibility in Precision Medicine. American Journal of Bioethics, 21(4), 57–66. Scopus. https://doi.org/10.1080/15265161.2020.1851813	2021	USA	Ethics	**Consistent data quality** Data must be curated **Sufficient data quantity** Data must be multi-modal Ground truth reference datasets

36	Mirchev, Martin, Iskra Mircheva, and Albena Kerekovska. 2020. 'The Academic Viewpoint on Patient Data Ownership in the Context of Big Data: Scoping Review'. *Journal of Medical Internet Research* 22(8): e22214.	2020	EU	Informatics	**Sufficient data quantity** Ground truth reference datasets
37	Olakotan, Olufisayo Olusegun, and Maryati Mohd. Yusof. 2020. 'Evaluating the Alert Appropriateness of Clinical Decision Support Systems in Supporting Clinical Workflow'. *Journal of Biomedical Informatics* 106: 103453.	2020	Malaysia	Informatics	**Reliable data interpretability** Time efficient Readily actionable
38	Watson, J., Hutyra, C. A., Clancy, S. M., Chandiramani, A., Bedoya, A., Ilangovan, K., Nderitu, N., & Poon, E. G. (2020a). Overcoming barriers to the adoption and implementation of predictive modeling and machine learning in clinical care: What can we learn from US academic medical centers? JAMIA Open, 3(2), 167–172. Scopus. https://doi.org/10.1093/jamiaopen/ooz046	2020	USA	Informatics	**Reliable data interpretability** Time efficient Readily actionable
39	Osop, Hamzah, and Tony Sahama. 2019. 'Systems Design Framework for a Practice-Based Evidence Approached Clinical Decision Support Systems'. In Proceedings of the Australasian Computer Science Week Multiconference, Sydney NSW Australia: ACM, 1–6. https://dl.acm.org/doi/10.1145/3290688.3290742 (August 24, 2022).	2019	Australia	Engineering	**Sufficient data quantity** Data must be multi-modal
40	Rezaei-Yazdi, Ali, and Christopher D. Buckingham. 2018. 'Capturing Human Intelligence for Modelling Cognitive-Based Clinical Decision Support Agents'. In Artificial Life and Intelligent Agents, Communications in Computer and Information Science, eds. Peter R. Lewis, Christopher J. Headleand, Steve Battle, and Panagiotis D. Ritsos. Cham: Springer International Publishing, 105–16.	2018	UK	Computer Science	**Reliable data interpretability** Time efficient Readily actionable

41	Baalen, Sophie, Mieke Boon, and Petra Verhoef. 2021. 'From Clinical Decision Support to Clinical Reasoning Support Systems'. *Journal of Evaluation in Clinical Practice* 27(3): 520–28.	2021	EU	Medical	**Reliable data interpretability** No Black Box Explainability
42	Verheij, Robert A, Vasa Curcin, Brendan C Delaney, and Mark M McGilchrist. 2018. 'Possible Sources of Bias in Primary Care Electronic Health Record Data Use and Reuse'. *Journal of Medical Internet Research* 20(5): e185.	2018	EU	Informatics	**Consistent data quality** Data must be curated
43	Zikos, Dimitrios. 2017. 'A Framework to Design Successful Clinical Decision Support Systems'. In Proceedings of the 10th International Conference on PErvasive Technologies Related to Assistive Environments, Island of Rhodes Greece: ACM, 185–88. https://dl.acm.org/doi/10.1145/3056540.3064960 (August 24, 2022).	2017	USA	Engineering	**Reliable data interpretability** Respectful in knowledge delivery Relevant Time efficient Readily actionable
44	Vayena, Effy, and John Tasioulas. 2016. 'The Dynamics of Big Data and Human Rights: The Case of Scientific Research'. *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences* 374(2083): 20160129.	2016	EU	Ethics	Ground truth reference datasets

Appendix B: Interview topic guide

Semi-Structured Interviews Topic Guide

Interview topics will be largely led by the interests of each individual participant. However, as a guide, topics likely to be covered include:

The history of the NHS

- Founding values
- Ongoing struggles related to funding and efficiency
- Experience of large-scale technical projects e.g., care.data, National Programme for IT, DeepMind and the Royal Free
- Attitudes towards innovation
- Policy regarding innovation, data-driven technology and AI specifically
- Investment in the development of AI, e.g., £250 million NHS AI Lab
- NHS use of data for variation in care analysis, performance management, predictive purposes
- Restructures, reforms, and models used to manage change in the NHS

Clinical Decision Support Software/ Algorithmic Clinical Decision Support Software/Predictive analytics

- What it is
- What it can be used for
- History of its development
- Opportunities it presents the NHS
- Challenges of implementing it in the NHS at scale o Risks presented by its use in the NHS
- Barriers/Enablers to adoption and spread
- Trust in it
- Potential impact of its use in the NHS

P4 Medicine

- What it is.
- Why it is appealing to policymakers/ NHS managers?
- How is it governed?
- What are the risks of moving to a predictive, preventative model of care?
- Who might benefit from this model of care, who might be harmed?
- What are the barriers/enablers to the use of approaches informed by P4 medicine in the NHS?

Screening

- What are the benefits of preventative screening?
- What are the potential disbenefits?
- How could the NHS screening programme be improved?
- What role might AI/ACDSS play in the NHS screening programme?
- What are the barriers/enablers to widening the scope of the NHS screening programme?

Medical Device Regulation

- How does medical device regulation apply to software?
- What are the challenges of regulating AI/ACDSS for use in the NHS? What are the limitations of the current medical device regulation?
- How might medical device regulation be improved?
- Does current medical device regulation offer sufficient protection to patients form potential harms of ACDSS?

Data Policy

- Influential health data policies
- Intersection between data protection law and common law
- How is the law changing following England's exist from the EU?
- How does data policy help/hinder the development and use of ACDSS in the NHS?
- How could data policy be altered so that it is more supportive of the use of ACDSS in the NHS?

Appendix C: Example interview theming

Interviewee #	Themes
1	• Industry will play an important role in the development of ACDSS but it isn't trusted and this is a major issue. It prevents different parts of the system from playing to their strengths **REQs: OBJECTIVES AND VALUES** • Integrating into pathways is really challenging. It is very easy to get something working in a research environment, translating it into practice is a completely different task. **COMPLEXITY** • The NHS has a significant advantage because of the social contract – people know that their data is used but they believe that everyone will benefit from it. **REQs: OBJECTIVES AND VALUES** • Evaluation will be crucial and there is a need to accept that this will take time and will require proper legislative framework. **REQs: PROCESS** • Currently the legislative framework regarding audit vs. research vs. direct care vs. population management is a massive barrier. **COMPLEXITY**
2	• There is a considerable gap between the policy rhetoric and the on-the-ground reality and there is currently little to no strategy designed to tackle that. On the one hand there are announcements about fun AI stuff and on the other, nobody can find a working computer to use on their ward round. **ASSUMPTIONS** • A lot is made about the amazing NHS data, but policy rarely recognises that not all of it is very good quality. It might be written on paper at 2am by a very tired junior doctor who isn't really focusing on the data quality and then we're expecting to build huge complex diagnostic models off this? It doesn't seem very realistic. **REQS: INFORMATION** • It's no use designing from the top down and not thinking about the end user. There is a real need to think about the implications from the beginning and this is why building platforms that enable users who are closer to local data and clinical care to build CDSS that work for them and can then be validated is a better option because they will know what functionality is needed and what will be most useful. There are also elements here about the importance of open-source and enabling local tailoring of nationally developed solutions. **DESIGN: UTILITY** • There are lots of unrecognised barriers in the wider system that add to additional complexity – most notably legacy contracts that nobody is monitoring, and nobody knows how will impact on the ability to deliver on policy promises. **COMPLEXITY** • We need to think through the trade-offs when it comes to re-ontologising. For example, if we focus too much on patient privacy and small number suppression, or accuracy, there is a real risk that this translates into just deleting people from records unnecessarily i.e., trans individuals. How do we balance accuracy with what feels authentic body knowledge to the individuals we are aiming to treat? **RE-ONTOLOGISING EMERGENCE**
4	• There is a concern that there has been an oversell on the value of NHS data – a lot of it is inaccurate because there have been so few studies done of the UX of EHRs, then lots of it is in text rather than in structured data which is really very difficult to extract **REQs: INFORMATION** • There is a big issue with legacy systems. They have been set up in propriety, inflexible ways and yet there is little recognition of this. Instead, there seems to be a naïve assumption that you can just add another system in, and it will just automatically work. You wouldn't get this type of naïve assumption anywhere else. **COMPLEXITY/ ASSUMPTIONS** • Lack of skills at the senior leadership level means that there is a real risk of buying the Kool Aid and wasting a tonne of money that could then result in a chilling effect **REQS: STAFF** • Every (e.g.,) hospital has a completely different technical set-up. Even if they're all using windows, the way that the windows environment is set up varies hugely between the different hospitals. **COMPLEXITY** • To make things work, we need to build from the bottom up and prove out small solutions as we go, rather than assuming that it will be possible to buy a silver bullet. **DESIGN: UTILITY**

	• Cultural change is hard in the NHS and there is a risk that people will be resistant to the use of (e.g.,) CDSS because it might find skeletons in the closet that people don't want to have to deal with. **COMPLEXITY** • There is a significant conflict of interest between those who use the data and those who capture it. Often the use of data for systems like CDSS could be perceived as snooping and this will really put people off. **RE-ONTOLOGISING/DESIGN: TRUST**
5	• I think that a major barrier is a lack of understanding of the art of the possible **ASSUMPTIONS** • There are numerous challenges around who controls the data and who can access the data **COMPLEXITY** • It's not clear whether those making decisions about what data to use and how it can be used, really understand the potential for good and the potential for harm in the data they are discussing **REQs: STAFF** • The UK has better data than almost anywhere in the world so it should have a natural advantage in this space but the data protection regulation acts as a major barrier, particularly the issue of multiple data controllers. **REQS: MANAGEMENT SYSTEMS AND STRUCTURES.** • Policy rhetoric tends to focus on either the individual level i.e., who can see my record, or the giant population level type of interventions, there's little attention paid to the middle layer of e.g., targeted interventions to groups. **ASSUMPTIONS** • The skills problem doesn't only exist in the NHS/in senior management, there's also a disconnect between the people who have the skills to develop e.g., risk prediction algorithms in the middle layer, and the mentality/interest that this group of people have. **REQs: STAFF**
7	• Basic if/then CDSS that interrupt the workflow are often more damaging than they are helpful. They can interrupt the workflow and increase cognitive burden in a way that will receive a lot of push-back and they can push clinicians into worse behaviours. It's better to deploy the CDSS in a way that enables the clinician to decide whether or not to interact with it and at what time. **REQs: INFORMATION** • There is a difference, however, between CDSS tools that are 'have you thought of this' and CDSS tools that act as guardrails and protect against error e.g., tools that flag drug interactions. Those are far less risky and are more likely to be accepted. **DESIGN: UTILITY/TRUST** • It's not really clear to me if there is actually a well-defined use case or problem that we are attempting to solve. Often it feels as though technologists from silicon valley are just trying to impose solutions on the healthcare system without rally understanding the clinical context, simply because they can get hold of the data that will enable them to do that. **ASSUMPTIONS** • It's essential in the development of CDSS that they are clinically led and that all stakeholders are involved in developing them and understanding the context in which they will be used. **DESIGN: UTILITY/TRUST** • There's a concern that rather than being used to increase access, the use of CDSS or digital tools is just used to provide subpar services to those who are already marginalised and most vulnerable for example those with mental health issues being 'treated' with chatbots. There is definitely a trend towards using the tech sector to build bandages but what they're actually doing is creating further layers of monetization and pulling value away from the healthcare sector rather than providing it back. **RE-ONTOLOGISING EMERGENCE** • It's important to remember that testing and training still continue once the system is 'live.' For example, potentially the only way to identify false positives/negatives and train the model out of making the same mistakes is once the system has been deployed and humans can correct the problems. **REQS: PROCESS** • This retraining of systems though does introduce new labour for clinicians and this again changes the nature of what it means to be a clinician and disrupts the relationship in ways that we might not necessarily understand. **RE-ONTOLOGISING EMERGENCE** • Liability is redistributed through the training of models. It's not necessarily consented or regulated. There's also a real risk that nefarious actors could manipulate that system e.g., by embedding in their own biases. All of this needs to be monitored and regulated. Basic if/then CDSS that interrupt the workflow are often more damaging than they are helpful. They can interrupt the workflow and increase cognitive burden in a way that will receive a lot of push-back and they can push clinicians into worse behaviours. It's better to deploy the CDSS in a way that

	enables the clinician to decide whether or not to interact with it and at what time. **REQS: INFORMATION**
8	• Medical baselines that are used to teach systems to recognise normal or abnormal are often biased (for example based on cis white men) and this could become very problematic if there is no way of overriding the baseline description. **RE-ONTOLOGISING EMERGENCE** • One way to build trust is through results and at the moment the healthcare system struggles with this. It's really difficult to see where the money goes and what the results of that spend were. **ADDITIONAL COMPLEXITY/DESIGN TRUST** • Patients are aware of the potential implications of things being recorded on their record even now. There is potential that the greater use of CDSS could be seen as increased surveillance and thus exposing themselves to more risk/ exposing others to risk and discrimination. (it's also an opportunity if you see CDSS as being more objective). **RE-ONTOLOGISING EMERGENCE** • Frame the use of CDSS as providing a solution for the majority and then identifying options for those that fall outside of the majority. **DESIGN: TRUST**
14	• Information governance is used as an excuse not to do difficult things, whereas when the time is taken to understand the risks and the benefits it's often a very simple task. **REQS: MANAGEMENT SYSTEMS AND STRUCTURES** • Data quality gets bandied about as an issue a lot but there is not standard vocabulary for talking about it and therefore, no standard way of overcoming the potential issues. **REQS: INFORMATION** • There is a conflict between reproducibility and flexibility. We want to be able to reproduce analytical results quickly but at the same time the requirements of the system are constantly changing. **ADDITIONAL COMPLEXITY** • One of the main barriers to better use of data for decision making in the healthcare system as a whole is a lack of stewardship from senior leaders. **REQS: SKILLS** • Any legislation or regulative or governance framework needs to be clear and interpretable otherwise fear and misunderstanding becomes a barrier to it working in the way that it was intended. **REQS**: **MANAGEMENT SYSTEMS AND STRUCTURES**
17	• It's also that AI is very technical and to really understand how it works and its implications you kind of have to work with it. Policymakers often don't get that chance & so they might think the issue is the design of the algorithm, whereas actually it's an issue with the whole system **ASSUMPTIONS** • Ensuring the successful development, deployment, and use of AI is about more than just code. It's a system, it's about having the right people, and it's about communication. **REQs: PROCESS** • Risks include bias and data privacy. But the regulations exist in multiple different places and you have to stitch them together which just isn't helpful. **REQs: MANAGEMENT SYSTEMS AND STRUCTURES**
21	• Policymakers have got caught up with the idea that the NHS has amazing huge perfect data. But the truth is we have narrow data on a lot of people. **ASSUMPTIONS** • There needs to be much clearer rules about what data is used for what, and making sure it's not used to beat people over the head with. **DESIGN: TRUST** • CDSS tools are almost never going to be seen as cost effective because they take so much time and resource to develop and the chances are that any one tool will only ever really improve the lives of five or six people **ADDITIONAL COMPLEXITY** • Policymakers have developed a tendency to think that we need more information to understand everything and that more information will always be the answer. But often, it's not. It's not the answer if you can't do anything about it. **ASSUMPTIONS** • Multidisciplinary teams are good but only if those teams provide opportunities for their members to learn the edges of other disciplines. **REQS: STAFF** • We have to be really careful that we don't fall into a trap of thinking that because algorithms have more data or aren't human they make better, more objective decisions than human clinicians because that really isn't true. **RE-ONTOLOGISING EMERGENCE**

27	• CDSS should be giving advice to clinicians in context of their other decisions. If they always override the guidance on blood thinning, for example, then the chances are the doctor doesn't know the guidance. If they override the guidance on blood thinning only occasionally, it's likely they are doing it for good reason. **DESIGN: UTILITY** • CDSS must be seen as buyer beware – it's advice to the clinician, but it shouldn't be the final word. **REQS**: **MANAGEMENT SYSTEMS AND STRUCTURES/ DESIGN: TRUST** (note this comes up twice) • Currently pop-ups are a wild west. We have this incredibly well-used technology that's at the cutting edge of everything that everybody says they want and we have no framework for it at all, no technical framework but also no evidence base. It's all chaos and confusion. **ADDITIONAL COMPLEXITY/REQs: PROCESS/** • With pop-ups there is either very expensive randomised controlled trials of one pop-up or High-Church social science research about how doctors feel about computers. There's nothing really in between. **REQS: PROCESS** • The NHS is already defacto spending an enormous amount of money on pop-ups because of how much clinician time they waste, and yet we've never evaluated them. **ADDITIONAL COMPLEXITY/ ASSUMPTIONS** • We need an open competitive market place of pop-ups where people are pooling knowledge and skills. This doesn't have to be in conflict with commercial ambitions. **DESIGN: EFFICACY/TRUST** • We need a sensible framework that makes evaluation rational and doesn't cause the costs to skyrocket. For example, a platform that lets you do A/B testing. **REQS: PROCESS/**
33	• The systems need to be configurable by the clinicians themselves, otherwise they are really no use to anyone. **DESIGN: UTILITY** • You need the data to train the systems and deploy them well but most of it is recorded badly as a by-product and it's not easy to work with etc. **REQs: INFORMATION** • There are already loads of regulations and standards but AI falls through the gaps in a lot of places and also just having the standard in place doesn't really do anything. People need to be handheld through the standard or the regulation otherwise nothing changes. **REQs: MANAGEMENT SYSTEMS AND STRUCTURES** • The pop-ups need to be as unobtrusive and as useful as possible if we expect clinicians to react to them positively. **DESIGN: USABILITY/ UTILITY** • There may be some instances where the CDSS has to be associated with a hard stop i.e., do not prescribe this under any circumstances. But there will always be exceptions to the rule. So it must be possible to override, this just must be hard to do and there must be a SOP in place to cover that scenario. Then you need to monitor that people aren't using the escape hatch too frequently. **DESIGN**: **USABILITY/UTILITY** • We also need to remember patient consent and do they actually want decisions about their care being delegated to an algorithm. **DESIGN: TRUST** • The systems also need to be able to take into account patient preferences and to be able to explain their decisions. **DESIGN: TRUST**
41	• Many of the claims by AI for health companies – particularly diagnostic chatbots – are completely bogus. And there is a real risk that over-hyped and unvalidated claims have muddied the waters and caused a slowdown of adoption by clinicians. To get more scale-up of successful solutions we might actually have to have a step back. **ASSUMPTIONS** • CDSS is a really high bar. Most of the time what we're talking about is automatic triage or referrals – referring back into a human led system. **ASSUMPTIONS** • At most CDSS should be seen as providing an opinion and a second opinion, a second tiered opinion at most. **DESIGN: TRUST** • The fact that transitioning healthcare from a paper world into the digital world is a profound and sometimes fundamental change that is not always paid sufficient attention. **RE-ONTOLOGISING EMERGENCE** • Digital transformation keeps being messed up repeatedly because the system has fundamentally misunderstood a bunch of human stuff. **ASSUMPTIONS**

	• We should be cautious that as soon as you give AI to doctors you are ramping up the paternalism factor and there should be things in place to counterbalance that. **RE-ONTOLOGISING EMERGENCE** • The bizarre thing about 'patient centricity' is that digitalisation seems to suggest the exact opposite. It's more like targeted adverting. **RE-ONTOLOGISING EMERGENCE**
50	• The thing to remember is that informatics departments aren't really statistical or analytical departments. So when they get told to use e.g., powerBI to make xyz report or now they're supposed to use ML, it wouldn't occur to them to, for example, put in place a confidence interval. People are missing really basic stats skills. **REQS: STAFF** • The thing is that policymakers etc. all think that a diagnosis is a diagnosis. It's not. It's not always trustworthy. It requires a lot of very manual cleaning and validating. **REQS: INFORMATION/DESIGN: TRUST** • There is a lack of rigour surrounding the whole enterprise. Not just from a validation perspective, but even from a should we do this, is it helpful perspective. **REQS**: **PROCESS** • It's currently all really grey. It's not clear at all when something is a medical device or not. This all adds to the lack of rigour. **MANAGEMENT SYSTEMS AND STRUCTURES** • Policymakers are so focused on the box of tricks in the middle that are very clever but they aren't solving the basic things. **ASSUMPTIONS** • There are multiple stages to rigorous implementation, there is data curation upfront, there's validating the model in a test setting, there's testing it in a live setting, then there's monitoring it for drift and degradation over time. **REQS: PROCESS**
56	• SNOMED codes are missing half the time and many rural hospitals are still running entirely paper-based systems. **REQS: INFORMATION** • We need to enforce slower timelines and more openness, as well as shared knowledge about what works and how different things were evaluated, by who **DESIGN: TRUST** • So I think at the minute bring it back to the present of course, I think at the end of what we do is we look for very simple solutions into what we already know are complex systems and then we get frustrated when they don't work. **COMPLEXITY**
61	• There are two main types of CDSS there is CDSS that is triggered by the clinician and there is CDSS that is automatically triggered and used to almost 'train clinicians' both are useful, both need to be embedded in the EHR. **REQs**: **TECHNOLOGY** • We should be applying the same rules that we apply to human CDSS to software CDSS. They should be registered, they should be monitored, they should be regulated. **REQs: MANAGEMENT SYSTEMS AND STRUCTURES/ TRUST** • We should be doing more RCTs and A/B testing of pop-ups so that we know what works etc. **REQs: PROCESS** • The system will benefit hugely just from focusing on what we know already works but that people aren't doing it. We have a unique opportunity in English primary care to do this. **DESIGN: UTILITY** • We have to start building the pipelines, so evaluate the most effective way of delivering safety measures, then when new content is ready we know exactly how to deliver it. And this shortens the pipeline from evidence generation to implementation from years to minutes. **DESIGN: UTILTIY** • The number of organisations potentially producing content for CDSS is currently huge but it's not well managed or connected. It's often people just producing PDFs that are never read. We need it to be a systematic process. **COMPLEXITY** • The temptation will be to say every clinical study or drug company can just smash out a pop-up, but we should hugely caution against this it would pose a significant safety risk and it would undermine years of policy work to ensure there is a clear barrier between clinical implementation and drug companies. **DESIGN: UTILITY** • We have to remember where we are currently. Most of the time new knowledge is disseminated by somebody sending a pdf to their friend up the road. It's not fast and it's not necessarily safe. **ASSUMPTION**

	• There is a big focus on continuity of care and often this is interpreted as it needing to be one person managing all your care but that's correlation not causation. The bigger issue is information transfer. If we can use pop-ups to help solve that problem we would make a big difference. **DESIGN: UTILTY**
67	• Technology means nothing if you don't have an end user that wants to use. Clinical engagement has to be the starting point and the heart of any CDSS project. **DESIGN: UTILITY/TRUST** • One of the main barriers to development is that software requires revenue funding whereas the NHS is still very much stuck in capital funding mode and it's just not sustainable. **COMPLEXITY** • There needs to be a platform and open-sourced approach, with more people sharing what they've developed rather than the NHS reinventing the wheel in every single locality. **DESIGN: TRUST/UTILITY**
72	• The NHS makes the same mistakes over and over again when it comes to IT projects, and this is at least partly because it is so fragmented. **COMPLEXITY.** • It's impossible to optimise for just one thing because it will always have a knock-on effect somewhere else e.g., if you're hitting your financial targets, then you're probably going to find that infection rates have gone up. So the triangle always ends up wonky. **COMPLEXITY** • The thing that would put people off would be if they thought this was all linked to big brother and somebody spying on them. **RE-ONTOLOGISING EMERGENCE/DESIGN TRUST**

Appendix D: Included policy documents

Included documents

Policy Papers

1. Life Sciences Industrial Strategy (August 2017)
2. The Future of Healthcare: Our vision for digital, data, and technology (October 2018)
3. Prevention is better than cure: our vision to help you live well for longer (November 2018)
4. Life Sciences Sector Deal 2, 2018 (December 2018)
5. NHS Long-Term Plan (January 2019)
6. Regulation for the Fourth Industrial Revolution (June 2019)
7. UK National Data Strategy (September 2020)
8. Genome UK: The Future of Healthcare (September 2020)
9. AI Roadmap (January 2021)
10. Integration and Innovation: working together to improve health and social care for all (February 2021)
11. Saving and Improving Lives: The Future of UK Clinical Research Delivery (March 2021)
12. DCMS: Our ten tech priorities (March 2021)
13. Genome UK: 2021-2022 implementation plan (May 2021)
14. Life Sciences Vision (July 2021)
15. National AI strategy (September 2021)
16. The Roadmap to an Effective AI Assurance Ecosystem (December 2021)
17. People at the heart of care: adult social care reform white paper (December 2021)
18. Deliverable1: Principles for the evolution of AI or ML-enabled Medical Devices to assure safety, effectiveness, and ethicality (December 2021)
19. Deliverable 2: Principles to support the development and deployment of AI or ML-enabled medical devices across jurisdictions (December 2021)
20. Health and Social Care Integration: Joining up care for people, places, and populations (Feb 2022)
21. Digital Regulation: Driving growth and unlocking innovation (June 2022)
22. The Future of AI for health and social care: enabling a learning health and social care system (Draft NHS AI strategy) (June 2022)
23. Data Saves Lives (June 2022)
24. A plan for digital health and social care (June 2022)
25. Establishing a pro-innovation approach to regulating AI (July 2022)
26. Intellectual Property and investment in AI (July 2022)
27. Women's Health Strategy for England (August 2022)
28. Genome UK: 2022 to 2025 (December 2022)
29. England Rare Diseases Action Plan 2023: main report (Feb 2023)
30. Medical Technology Strategy (Feb 2023)
31. A pro-innovation approach to AI regulation (March 2023)
32. The UK Science and Technology Framework (March 2023)
33. Announcement of new regulatory pathway set to support safe patient access to innovative medical technologies (May 2023)
34. NHS Mandate 20203 (June 2023)
35. NHS Long Term Workforce Plan. (June 2023).

Guidance Documents

36. Assessing if AI is the Right Solution (June 2019)
37. Planning and preparing for AI Implementation (June 2019)
38. Understanding AI Ethics and Safety (June 2019)
39. Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation (July 2019)
40. NCSC Dealing with Data (August 2019)
41. Guidelines for AI Procurement (June 2020)
42. Data Ethics Framework (September 2020)
43. A Buyer's guide to AI in Health and Care (September 2020)

44. The Caldicott Principles (December 2020)
45. A Guide to good practice for digital and data-driven health technologies (January 2021)
46. Digital Technology Assessment Criteria (February 2021)
47. Ethics, Transparency and Accountability for Automated Decision-Making (May 2021)
48. Interim Guidance on Incorporating Artificial Intelligence into the NHS Breast Screening Programme. (May 2021)
49. The Technology Code of Practice (July 2021)
50. Software and AI as a Medical Device Change Programme (September 2021)
51. Good Machine Learning Practice for Medical Device Development: Guiding Principles (October 2021)
52. Algorithmic Transparency Template (December 2021, updated 2023)
53. Evidence Standards for Digital Health Technologies (August 2022)
54. Criteria for a population screening programme (September 2022)
55. Secure Data Environment for NHS Health and Social Care Data - Policy Guidelines (December 2022)
56. Crafting an intended purpose in the context of SaMD (March 2023)
57. Design and build digital services for the NHS (April 2023)
58. Care Data Matters: A Roadmap for Better Data for Adult Social Care (May 2023)
59. Medical Device Stand-Alone Software Including Apps (May 2023, originally published August 2014)

Consultations

60. Advancing our health: prevention in the 2020s consultation (July 2019)
61. Government response to the consultation on the future regulation of medical devices in the UK (June 2022)
62. Data: A new Direction - Government Response to Consultation (June 2022)

Example theming: information requirements

Policy Document	Statement, Commitment, or Policy Requirement	**Information Infrastructure Requirement**
1. Life Sciences Industrial Strategy (August 2017)	A data ecosystem that enables the NHS to understand the value of products and improve care pathways should build towards the full population of 65m, with longitudinal data across health and care in order to be globally competitive and to provide the highest quality research and care.	Sufficient Data Quantity
2. A plan for digital health and social care (June 2022)	Make it possible for users to share their genomic profile via the NHS App so that it can be used by care teams	Consistent Data Quality
	Make it possible for users to link wearable devices and other health-related data to an online NHS profile	Consistent Data Quality
3. Genome UK: 2021-2022 implementation plan (May 2021)	A major drive, led by Genomics England, to improve the diversity of genomic data, addressing the historic under-representation of data from ethnic minority groups in genomic datasets, which results in health inequalities.	Sufficient Data Quantity
	Roll-out whole genome sequencing to patients with a suspected rare disease and certain cancers in the NHS GMS, in partnership with Genomics England.	Sufficient Data Quantity
	Our Future Health (formerly known as the Accelerating Detection of Disease challenge) will help drive developments in the next generation of diagnostics and clinical tools – including the evaluation of polygenic risk scores (PRS), drug discovery, and smart clinical trials.	Sufficient Data Quantity
4.National AI strategy (September 2021)	We will consider what valuable datasets the government should purposefully incentivise or curate that will accelerate the development of valuable AI applications	Consistent Data Quality
5. People at the heart of care: adult social care reform white paper (December 2021)	Move away from aggregate data collections towards anonymised client-level data collections to bring adult social care data more in line with NHS patient data	Consistent Data Quality

6. Data Saves Lives (June 2022)	Create at-scale datasets that bring together the different types of health data to develop new tools for prevention, diagnostics, and clinical decision support through the data for R&D programme	Sufficient Data Quantity
	Bring together genomics data, and work with NHSEI to ensure genomic data generated through clinical care is fed back into patients' records.	Consistent Data Quality
	Establish a data framework for adult social care, setting out what data the sector needs to collect, the purpose of those collections, and the standards governing them, with a move towards client-level data collections and away from aggregate data collections.	Consistent Data Quality
	Improve demographic data quality and reduce burden to staff and people by providing online registration and proactively contacting people when we believe their details are out of date.	Consistent Data Quality
7. Women's Health Strategy for England (August 2022)	When data is collected, it should be categorised and analysed by demographic characteristics such as ethnicity, age, sex, and geography. This is to understand: where disparities in health outcomes and experiences exist; how they vary between different groups; their causes; how to tackle them (both through policy and clinical evaluation).	Consistent Data Quality
8. Genome UK: 2022 to 2025 (December 2022)	All patients will have a pharmacogenomic profile attached to their medical records	Consistent Data Quality
9. Using Machine Learning in Diagnostic Services: A Report with Recommendations from CQC's Regulatory Sandbox. (March 2020)	NHSE should work with regulators and other national bodies to improve the data and related infrastructure required for clinical validation. It will require larger datasets that have the right metadata and represent the population that the tool will be used for. It is important for effective validation and public trust that the validation data is not available to developers for training algorithms.	Sufficient Data Quantity
10. Data Ethics Framework (September 2020)	Ensure Explainability	Easy Data Interpretability
11. Government Data Quality Hub. 'The Government Data Quality Framework'. *GOV.UK*. (December 2020).	Commit to data quality	Consistent Data Quality
	Assess quality throughout the data lifecycle	Consistent Data Quality
	Communicate data quality clearly and effectively	Consistent Data Quality
	Anticipate changes affecting data quality	Consistent Data Quality
12. Deliverable1: Principles for the evolution of AI or ML-enabled Medical Devices to assure safety, effectiveness, and ethicality (December 2021)	Manufacturers should consider ethical implications from design to deployment, including representativeness, Explainability, discrimination, and wider impact.	Sufficient Data Quantity Easy Data Interpretability