THE LEARNING HEALTHCARE PROJECT
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The Potential of Learning Healthcare Systems

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Contents

Executive Overview

The complexity of many health conditions and the heterogeneity of patient characteristics and comorbidities mean that Randomised Controlled Trials, with strict exclusion criteria, often do not apply to the patients found in clinic. Simultaneously, a proliferation of treatment options and clinical research make it impossible for clinicians to keep up-to-date with all but the narrowest of fields [1-4]. Healthcare faces other challenges from growing and ageing populations [5], rising levels of chronic illness [6], constrained budgets and health inequalities [7, 8].

At the same time, the Internet and big data analytics have begun to transform other industries. It has been proposed that when this technology is combined with, improved outcomes measurement and systematic behaviour change techniques, Learning Healthcare Systems could emerge. A Learning Healthcare System is defined, by the Institute of Medicine (IoM) [9], as a system in which,

> *"science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."*

Learning Healthcare Systems can take many forms, but each follows a similar cycle of assembling, analysing and interpreting data, followed by feeding it back into practice and creating a change [10] (Figure 2).

Building Blocks of a Learning Healthcare System

Routinely collected **data within the healthcare system** will drive a Learning Healthcare System. There are major challenges to collecting this data in a way that can be processed electronically. Often data recorded by clinicians is incomplete or of poor quality [11, 12]. The way that data is encoded often varies between organisations, making interoperability between systems difficult [13, 14]. There are also technological and information governance issues relating to how and where such data is stored [13].

Data from outside the healthcare system is likely to become increasingly important with the emergence of new wearable technologies and web platforms that give patients more control over their own data [15, 16]. The importance of these technologies remains to be proven.

Improved **outcomes measurement** will demonstrate what works, not just in terms of mortality, but also against a hierarchy of other outcomes that are important to the patient [17]. New automated collection methods will reduce the cost of collating this information.

Ultimately, a Learning Healthcare System will only be successful if it can achieve **behaviour change**, both of clinicians and of patients [18]. On-going advances in behaviour change research offer the potential for a systematic approach to changing behaviour, that is comprehensive and evidence based [19]. This approach can be embedded in the implementation of Learning Healthcare Systems.

Public concern over healthcare data sharing offers an early glimpse of the controversy that could accompany the implementation of Learning Healthcare Systems. The current **ethics framework** that treats clinical practice and research differently will struggle to accommodate Learning Healthcare Systems [20]. A new framework has been proposed, that places moral obligations on patients, clinicians and researchers [21].

Use cases in the Learning Healthcare System

Intelligent automation will reduce the burden on clinicians and improve care by "making the right thing, the easy thing to do" [22]. This may include automating routine aspects of care, prepopulating orders and clinic notes, and summarising case notes [16].

Learning Healthcare Systems have the potential to revolutionise **Comparative Effectiveness Research (CER)**. There is scope for much greater use of observational studies and pragmatic RCTs that could help to fill gaps in the evidence base more quickly and at lower cost [10]. Ultimately, insights could be generated into the likely effectiveness of different treatments in a particular patient. Traditional RCTs will continue and Learning Healthcare Systems could be used to identify eligible patients and ease data collection [16].

Improved data on outcomes will allow benchmarking between different providers. This will lead to improvement through a process known as positive deviance [23]. **Positive deviants** (really good providers) will be identified, they will be studied to generate hypotheses about their performance that can be tested and evidence can be disseminated to other organisations.

Real-time **surveillance systems** are being developed to track epidemiological phenomena and adverse events related to new treatments [24]. These use routinely recorded data and allow much more timely learning to take place.

Predictive models can be developed to identify instances where there is a high risk that low quality or unnecessarily expensive care will occur [22]. Further impactibility modelling can help to identify which of those instances are most likely to respond to mitigation [25].

Clinical Decision Support Systems can be used to support clinicians in dealing with unfamiliar or high-risk situations. These systems can be powered by machine-readable guidelines and can be integrated into Electronic Health Records (EHRs) [26].

Implications

Learning Healthcare Systems will have significant **workforce implications** [10, 27]. They will certainly not remove the need for clinicians, but over time they will alter the skill set needed and may impact the type and number required. Likewise, there will be implications for researchers and a greater role for informaticians.

Learning Healthcare Systems will be based within or rely upon healthcare providers. They must be **acceptable to providers**. This means that they must align with the provider's goals and they must have the support of clinicians, managers and the board [20].

Learning Healthcare Systems will have an important role in supporting and evaluating **new delivery models**. They will offer a level of data on their performance that was previously unavailable.

Quality regulation can be approached differently within a Learning Healthcare System. Better data can mean more targeted inspections and more timely judgements. It also raises the possibility for regulators to identify risk factors before poor care actually occurs.

Learning Healthcare Systems are also compatible with the **value based healthcare delivery agenda**. As well as improving quality, they may help to address the cost crisis in healthcare through, earlier diagnosis, personalised treatments, fewer errors and more affordable research methodologies [10, 28]. However, building the sociotechnical infrastructure will also carry significant costs [29] and so far, there has been little robust **economic evaluation**.

Themes for the Future

Early Learning Healthcare Systems are already emerging, but the field is at a nascent stage of development, with many providers still recording patient encounters in paper files. The next five years are likely to see progress on this as well as the development of large intra and inter-organisational Learning Healthcare Systems. Outcome based reimbursement models may aid these developments. The development of platforms combining, standards and technical infrastructure may allow small organisations to build and distribute Learning Healthcare Systems at much lower cost. This could hugely increase participation and progress. The providers of these platforms could hold significant power and might require regulatory intervention.

With these foundations in place, progress might accelerate towards the ten-year timeframe, as broad-based developer ecosystems emerge and the concept of Learning Healthcare Systems creeps into public and professional awareness. Ultimately, Learning Healthcare Systems are likely to transform the way that healthcare is delivered.

An Agenda for Change

This report presents a positive view on the potential of Learning Healthcare Systems, however, it is not inevitable that this potential will be realised in a timely fashion. Recommendations, aimed at achieving this potential, have been grouped under three themes, below. Further details can be found throughout the report.

Theme One: Digitise Healthcare

The "Digitisation" of Healthcare is underway. In the US, adoption of electronic health records has been accelerated by The Affordable Care Act and Meaningful Use incentives [15]. In England, primary care has achieved near universal uptake of EHRs and NHS England have set a goal for secondary care to be "paper-free at the point of care" by 2020 [30]. Progress against this goal has been embedded in the commissioning framework and the quality inspection regime, which will make compliance a high priority.

These are necessary developments, but they are not sufficient to enable Learning Healthcare Systems. There is also a risk that simply creating electronic versions of paper notes will be a costly diversion from creating true sociotechnical Learning Healthcare Systems that can support the use cases outlined in this report. It will be necessary to collect, assemble and process more relevant data and medical knowledge in digital formats and to do it in a more efficient way. Great efforts will be required to ensure that patients and the public are informed about and engaged with the development of these systems. There could also be important workforce implications that could constrain development if not anticipated.

Recommendations

1	Promote rapid adoption of EHRs. **(Page 16)**	Government, Commissioners, Providers
2	Ensure interoperability between EHRs using contractual frameworks or regulation if necessary. **(Page 19)**	Government, Commissioners, Providers
3	Encourage development of systems that can display large patient generated datasets in ways that are both concise and informative. **(Page 20)**	Research funders, Academics, IT vendors
6	Give patients access to their healthcare data, including the ability to add their own data in a structured format and the ability to flag inaccuracies. **(Page 21)**	Government, Providers, IT vendors
7	Incentivise outcomes measurement through outcomes based commissioning. **(Page 23)**	Government, Commissioners
10	Further research on optimal ways to engage the public and reduce their concerns around secondary uses of patient data. **(Page 28)**	Research funders, Academics
11	A review of Information Governance, case law, common law, statute and NHS policy statements, backed by public consultation, to clarify how the principles and rules apply specifically to Learning Healthcare Systems. **(Page 29)**	Government
12	Organisations developing Learning Healthcare Systems should adopt the Engagement, Transparency and Accountability approach at every step. **(Page 31)**	Providers, Academics
21	NICE and other guideline writing organisations should publish machine-readable guidelines alongside their human readable equivalents. **(Page 40)**	Guideline producing organisations
22	Organisations responsible for clinical education and training should consider the skills and competencies that will be required during the careers of this and the next generation of clinicians and should reflect this in their curricula. **(Page 43)**	Medical schools, postgraduate institutions, education and training providers
23	Review the potential impact on the type and number of, researchers, clinicians and informaticians required within the health service. **(Page 43)**	Workforce planning organisations

Theme Two: Develop Learning Healthcare System Use Cases and Platforms for their Development and Deployment

This report outlines six use cases that have already been implemented by healthcare organisations. It also recognises the huge infrastructure investment that is often required to support these use cases and sees the development of reusable platform components as the route to exponential growth in the development and deployment of Learning Healthcare Systems. With the great potential of platforms also come considerable risks of limited functionality and market abuse by their providers.

The following recommendations promote the broader deployment of these use cases but also encourage a better understanding of the platforms that that are developing to support this.

Recommendations

4	Further independent research is required to appraise the potential uses of patient generated data. **(Page 20)**	Research funders, Academics
13	Identify further opportunities for more intelligent automation to improve care and reduce workload. **(Page 33)**	Research funders, Academics, Providers, IT Vendors
14	Consider the potential to achieve greater impact by increasing the proportion of research funding allocated to observational studies and pragmatic trials run thorough LHS. **(Page 35)**	Research funders
15	Traditional RCTs should consider whether they can reduce costs though automated data collection. **(Page 35)**	Academics/Researchers, Research funders
16	Traditional RCTs should consider whether they can improve recruitment by using EHR data to identify potential participants. **(Page 35)**	Academics/Researchers, Research funders
17	Encourage providers to engage in positive deviance exercises using available outcomes data. **(Page 37)**	Providers, Commissioners, Regulators, Research funders
18	Increase utilisation of existing surveillance networks. **(Page 37)**	Research funders
19	Assess where predictive modeling could be employed to improve services or increase efficiency. **(Page 39)**	Research funders, Academics, Providers, IT Vendors
25	Independent research, to identify the type of platforms that are currently developing, the breadth of their potential use and any potential market issues that might arise. **(Page 47)**	Research funders, Academics, Regulators

Theme Three: Ensure that Learning Healthcare Systems Create Positive Change

A Learning Healthcare System is about more than IT and informatics. Technical solutions alone or even journal articles and guidelines will not improve health outcomes at the pace required [31]. Improvement will only be possible if the system produces a change in the behaviour of patients, clinicians, providers, commissioners and other actors [15]. This aspect of any Learning Healthcare System should incorporate evidence-based behavior change theory.

Some of the use cases outlined in this report are intended to generate medical knowledge while others are analogous to new clinical investigations and treatments. As such, there is potential for harm and while they are already likely to be regulated as medical devices, it is important that they are evaluated to the same standard as other research methodologies, investigations and treatments. It is also important that these use cases are shown to be cost effective in the settings where they are implemented.

Recommendations

5	Further independent research is required to evaluate the effectiveness of different types of health apps. **(Page 20)**	Research funders, Academics
8	Evaluation studies to ensure the validity and reliability of innovative new outcomes collection methods. **(Page 23)**	Research funders, Academics
9	Encourage the use of evidence-based behaviour change theory within Learning Healthcare Systems, possibly by including it as a criterion in funding decisions. **(Page 26)**	Providers, Research funders, Academics
20	The screening criteria, proposed by Wilson and Jungner (or some modification thereof), should be applied when deciding whether to employ a predictive model. **(Page 39)**	Providers, Research funders, Academics, Regulators
24	Detailed economic evaluation of existing and planned elements of Learning Healthcare Systems should be carried out. **(Page 45)**	Research funders, Academics

Background

Modern medicine has brought remarkable advances. The application of scientific rigour to the art of healing has resulted in a better understanding of diseases, a proliferation of new treatments and has given hope to many. In large areas of medicine however, the complexity of the health condition and the heterogeneity of patient characteristics mean that experimental studies such as Randomised Controlled Trials (RCTs) are too costly to conduct [32]. When they are conducted, the exclusion criteria often make it difficult to generalise the results to real patients [33].

Furthermore, the proliferation of new studies means that it is impossible for practitioners to keep abreast of the latest developments in all but the very narrowest of fields [34]. Even evidence based medicine approaches, such as the development of systematic review methodologies [35] can only partially address this problem because of the volume and complexity of studies. The net result is that much medical practice still relies on gut feeling and all of the associated biases [36].

In addition to the rapid expansion in the evidence base, healthcare faces other challenges from growing and ageing populations [5], rising levels of chronic illness [6], constrained budgets [28], health inequalities, and the proliferation of high cost interventions that bring diminishing returns in terms of the health improvements that they provide [7]. Improvements in productivity, within clinical microsystems and across entire health systems, are urgently sought [37]. Variations in practice, that cannot be justified, are increasingly seen as unacceptable [38], but healthcare organisations and clinicians, often do not have the capability, opportunity or motivation to drive change, because of other pressures.

A recent Health Foundation report identified seven key success factors (Figure 1) for promoting change at any level in the healthcare system [39]. The report maps these factors onto eight other models of change dating back almost three decades. That so many models of change have been developed and that successful change remains an elusive goal, suggests that at least one fundamentally new development will be required to improve the situation.

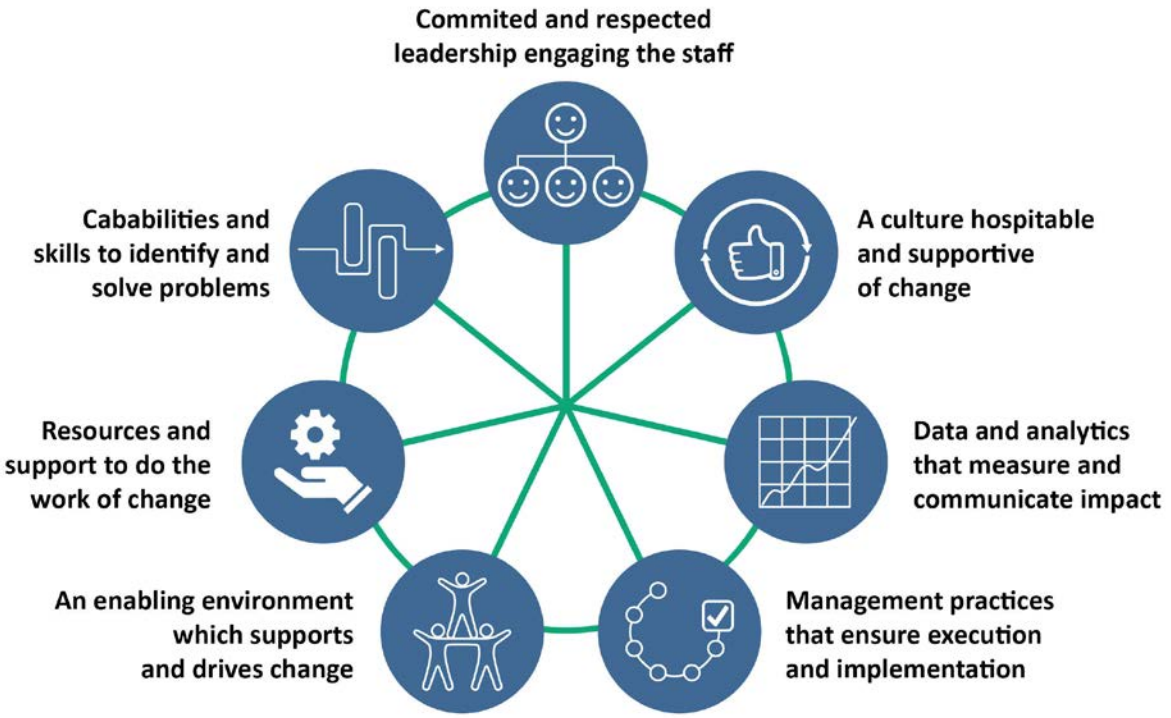

Figure 1. Seven success factors for change in the NHS. Reproduced from [39]

This report argues that there are at least three such fundamental developments within sight and that their realisation could facilitate more successful change within healthcare. These developments are:

1. Routine data collection and analytics
2. Outcomes measurement
3. Systematic behaviour change theory and techniques

Routinely collected data has long been used to improve healthcare. Indeed, Florence Nightingale in the nineteenth century [40] and Ernest Codman in the early twentieth century [41], famously used routine data to compile outcome measures. Modern behaviour change efforts also date back to the 1930s [42] and before. The factor that can now help to bring each of these developments to fruition within healthcare is the development of digital infrastructure [11]. This can automate processes that were previously infeasible, apply enormous computational power and instantly link data recorded in distant geographies. To date, healthcare has lagged other industries in its use of data [32] but the roll out of Electronic Health Records (EHRs) and recent development of standards suggest that this could change.

Realising the benefits of these developments will require a new ethics framework that enables rapid learning while also reassuring patients and the public. Outcomes measurement, routine data analytics and systematic behavior change techniques, along with a new supportive ethics framework, are discussed in the section entitled, Building Blocks of a Learning Health System.

Learning Healthcare Systems

A Learning Healthcare System is defined, by the Institute of Medicine (IoM) [9], as a system in which,

> *"science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."*

The term has been promoted by the IoM, whose many publications on the topic have provided a backbone to the literature [9]. Professor Friedman describes a cycle with processes that are common to all Learning Health Systems [43]:

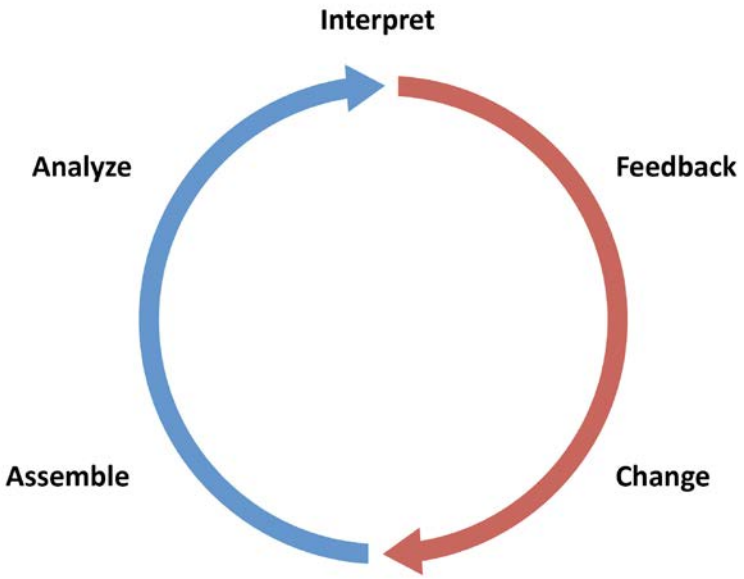

Figure 2. The Learning Health System Cycle. Reproduced from [43]

According to Professor Friedman, any Learning Healthcare System has three components [10]:

1. Afferent (Blue) side:
    - Assemble the data from various sources
    - Analyse the data by various means
    - Interpret the findings
2. Efferent (Red) side:
    - Feeding findings back into the system in various formats
    - Changing practice
3. Scale: Can be institutional, national, international

A Learning Healthcare System is a sociotechnical system [32]. The blue/afferent side is made possible by recent technical innovations, but the red/efferent side is an enormous interdisciplinary challenge incorporating, behavioural psychology, communication science, implementation science, behavioural economics, policy science and organisational theory [10].

Such systems can be based on any of the cyclical improvement approaches, such as Plan, Do, Study, Act, but they explicitly use technical and social approaches to learn and improve with every patient who is treated. In this report, we focus on behaviour change techniques as an effective mechanism to ensure that knowledge generated by Learning Healthcare Systems is fed back into the system to achieve change (the red side of the cycle).

There is no single Learning Healthcare System. Rather there are many manifestations, at different scales. It could be a department that tracks its patient's outcomes in order to learn and improve its practice. It could be a provider that builds predictive models, from elements of its EHR, which allow it to forecast demand and reallocate resources more effectively. It could be a national distributed network drawing tens of millions of patient records from multiple providers, to assess the effectiveness of particular treatment.

This study identifies six key use cases that have been selected because they meet the definition of a Learning Healthcare System and they represent areas in which significant progress has been made:

- Intelligent Automation
- Comparative Effectiveness Research
- Positive Deviance
- Surveillance
- Predictive Modelling
- Clinical Decision Support

Electronic Health Records provide a data source and a user interface to many Learning Healthcare Systems, but on their own, they do not represent the entire sociotechnical cycle outlined in Figure 2.

Many healthcare systems have been using electronic products to improve their services for a considerable time. These have included [44]:

- Information Websites
- Mobile Apps
- Service Directories
- Online Appointment Booking
- Telemedicine
- Social Media Presence

These and other systems may be valuable and are likely to be rolled out more widely in the years to come, but they are outwith the scope of this report, except where they form part of a Learning Healthcare System.

Learning Healthcare Systems have major, workforce, organisational, regulatory and economic implications for society. These are discussed in the section entitled Implications. The development of these systems is neither inevitable nor likely

to be universally welcomed. Further work is required to ensure that they realise their potential to improve healthcare and this is discussed in the section entitled Themes for the Future.

Aims and Methodology

This study aimed to explore the meaning, feasibility and implications of the Learning Healthcare System concept.

It was rooted in an English context, but it was recognised that much significant work on Learning Healthcare Systems was taking place in other countries, particularly in the US, so many of our interviews and site visits took place there. While our findings are particularly aimed at the English healthcare system, where the Learning Healthcare System concept has been largely unknown, they are also of much wider relevance.

Phase 0

A website was set up (www.learninghealthcareproject.org) at the beginning of the project and was updated with interview and seminar synopses and emerging findings, as the consultations took place. The site was promoted through a number of online channels. Members of the public, patients and experts were invited to comment on the items uploaded to the site, so that their feedback could be reflected in the final report.

Phase 1

A scan of the literature was conducted to identify relevant academic, grey and commercial literature on this topic.

Phase 2

Two expert seminars were planned to address gaps in the literature:

1. Working Model Seminar: A seminar was due to be held in Boston to explore the technical feasibility of Learning Healthcare Systems. Boston was chosen because it is a world centre in the development of this topic. Unfortunately, this seminar was cancelled because of poor weather. The individual participants (see acknowledgements) were interviewed separately.
2. System Implications and Acceptability Seminar: A seminar was held in London to explore the ethical, legal, regulatory, workforce planning, training, and economic implications of these potential developments. London was chosen for this seminar because it is a major healthcare administrative centre and home to a number of patient groups, think tanks, medical ethics centres, statistical, regulatory and healthcare planning organisations and health technology companies. This seminar had around 20 participants (see acknowledgements) with 6 focus group sessions. Two of these sessions were added to cover technical gaps left by the Boston seminar.

The seminars identified points around which there was a high degree of consensus, those where there was significant uncertainty, and those about which the participants did not have sufficient information to report.

In association with the seminars, in-depth interviews were held with experts (see acknowledgements) in key fields. These interviews were used to seek clarification or further information on issues that could not be resolved from the literature or during the seminars. Around 25 interviews were conducted.

Phase 3

A thematic analysis, of the literature, seminar and interviews was conducted to generate the final report, outlining our findings. The aims of this report are to:

- Raise awareness of the Learning Healthcare System concept
- Identify what action is required to realise the benefits and mitigate the negative implications of such systems
- To inform and focus The Health Foundation's future work in this area

The audience is intended to be wide, including, patients, clinicians, providers, commissioners, politicians and research funding bodies.

Building Blocks of a Learning Healthcare System

For Learning Healthcare Systems to enable rapid change, several building blocks will need to be in place. These include, accessible and comprehensive routine data, outcomes measurement, behaviour change techniques and an ethics framework that enables their use.

This study has found examples in which each of these building blocks has been implemented at some scale, but none have been mainstreamed in a way that would enable low cost development of Learning Healthcare Systems.

Data within the Healthcare System

Learning Healthcare Systems seek to capture and generate knowledge from the data flowing from routine care. They then feed this knowledge back into the healthcare system in a way that changes the behavior of actors to improve outcomes. They are fueled by routinely collected data. Much of that data currently comes from sources such as, Hospital Episode Statistics (HES) in England, claims data in the US and clinical records. These records are generally organised around the provider rather than the patient [45], so a complete picture requires input from primary care, secondary care, payors/ commissioners, patients and other systems.

As well as outcome measures, which will be discussed specifically in the Outcomes Measurement subsection, Learning Healthcare System use cases will require contextual data (patient and other factors) and data relating to the interventions provided. Much of this is recorded in the medical record, traditionally a paper file associated with each patient. Increasingly, these records are being moved onto electronic systems. However, digitisation does not necessarily make the information amenable to analysis [46].

Capturing data

There is almost always a reduction in the depth of meaning when data is recorded during a clinical encounter. In other words, what is recorded often does not reflect exactly what took place. For example, important negatives are often not recorded and context is lost [47]. There are doubts about whether the data recorded in the course of treatment is currently rich enough to support statistically firm conclusions [48].

Poor data input means that, at best, complex mapping and parsing is required to make sense of it and, at worst, the data is not suitable for secondary uses within a Learning Healthcare System [49]. There are differing approaches to obtaining data from an EHR [32]. Highly structured input fields can be used to ensure high data quality or Natural Language Processing (NLP) can be applied to make sense of free text [32]. Currently, much HES data is entered by non-clinical coders who must interpret handwritten paper notes.

Optum Labs, a US research partnership with access to health records for 40 million patients and claims data for a further 150 million, has used both approaches. They found that clinicians do not like to use structured fields and often leave them blank, so around 70% of their data is codified using NLP [32] .

Participants reported that NLP is either a very useful tool already [32] or has the potential to progress quickly [50] within a research context, but importantly, it was not currently considered to be ready for use in safety critical systems such as decision support [49, 51].

Intelligent dynamic templating systems, akin to predictive text, that facilitate structuring of what the clinician is recording, in real time, offer a hybrid approach that has proven effective in some EHR implementations [47].

Genomic data is expected to become increasingly important within Learning Healthcare Systems. Just as with data from any other source, genomic data that are standardised, comparable, and consistent would be more easily reused for discovery in multiple contexts beyond the original one [52]. The sources of genomic data currently include tests for inborn errors of metabolism (such as newborn screening tests), chromosome studies (such as cytogenetic tests), array comparative genomic hybridization, DNA-based Mendelian disorder testing, and tumor sequencing. Many of these results are currently stored as PDFs in the EHR, making it difficult to achieve any secondary use [52].

Completeness

Analytics generally requires structured data that is comparable between different patients and different providers.

In the US, claims data provides the most comprehensive picture of patient interactions with the health system across multiple providers [53]. This lacks clinical detail, which would ideally come from EHRs [32]. Unfortunately, a single patient may be seen by several different providers, each with their own incompatible EHR, which can make it difficult or impossible to complete the data.

For example, a single hospital may be unable to complete a re-hospitalisation study with just their own data because they are unable to track patients who were admitted to another hospital. It would not be possible to differentiate between, patients who die, move away or remain healthy and are not re-hospitalised. This creates the potential to introduce bias by only using available data [49].

In England, HES data, collected by the Health and Social Care Information Centre (HSCIC) provides, demographic, diagnostic and intervention data for all inpatient episodes, along with very limited details of outpatient episodes and data on A&E attendances. Data is recorded through Patient Administrative Systems (PAS) at an individual provider level. This includes administrative data such as patient demographic information, as well as diagnostic and procedure codes. This is then submitted to a data warehouse called Secondary Uses Service (SUS). Elements of this data then undergo cleaning and data quality checks before being published as HES data [54].

In 2013, the care.data project was due to add GP data to the collection. That phase has been delayed due to Information Governance concerns [55].

Quality of data

There are concerns about the quality of comprehensive claims and HES data. For example, the error rate in hospital data in some circumstances can be greater than 20% [12, 56]. Currently around 70% of hospital records in the UK are still handwritten and completion of HES data relies on human coders who effectively practice NLP at the provider level. It is often difficult to assess whether HES data accurately represents what actually happened in the clinical encounter [12].

Recommendation 1	
Promote rapid adoption of EHRs.	Government, Commissioners, Providers

Incomplete data such as under-coding of comorbidities is also a significant problem. For example, there may be a record of an intervention for diabetes, such as an amputation procedure in secondary care, but the data generated on discharge is often lacking the diabetes flag. This can be quite significantly under coded, with the National Diabetes Audit estimating that approximately 30-40% of cases are not flagged [18].

These errors can be compensated for by linking primary care datasets with the secondary care data sets [18] or by augmenting HES data with additional manual coding from paper records [57]. These approaches can be time consuming and can raise Information Governance concerns.

Geisinger Health System have found that the data items that are most frequently viewed, and that are viewed by several stakeholders, tend to be the most accurate. Sharing data with patients has proven to be an effective way of improving data quality [22].

Storage and access

In Learning Healthcare Systems that span more than one organisation, data can be stored and accessed through centralised or distributed networks. In a centralised network, the data is periodically uploaded to a central repository, from which it can then be accessed for secondary uses. HES data from the English NHS is an example of this approach. It simplifies access to data as only one location needs to be queried. The researcher may also be able to "eye ball" the underlying data. Although patient data can be deidentified, centralised systems can still create, security, proprietary, legal and privacy concerns, because patients can sometimes be reidentified and the provider, who may be legally responsible for the security of data that they have collected, loses operational control [13].

The alternative, distributed network configuration leaves the data holder in control of their protected data. The FDA Mini-Sentinel program (an active surveillance system for monitoring the safety of FDA regulated medical products) is a good example.

Queries are sent to each node (organisation) in the network. They each return results (often aggregated) in an agreed common data model, to a coordinating centre. A mapping must be agreed between each node and the common data model and the distributed implementation is more complex than the centralised approach. However, it overcomes many of the privacy issues and the participating organisations maintain operational control of their data [49]. They may even choose to review each query before releasing the data.

Interoperability

Interoperability is the ability of one system to work with another. Learning Healthcare Systems are often networks of networks, rather than a single unified system [58]. It is therefore necessary to share and use data that has been collected and stored in different systems. This requires standards for [14]:

- The terminology used to describe things that exist in the real world
- The content and format of data
- The transport of data
- The security of data

There is no perfect solution to the challenge of interoperability. There are many different approaches and the one that is appropriate depends on the particular use case [32]. Interoperability for research and interoperability for patient management are very different things. To simply move data from one provider to another, so that it can be viewed, is relatively straightforward. It does not matter how it is transmitted, providing that it is labelled properly. However, if it is to be analysed, then it needs to be standardised and this is much more difficult [49]. A feature of the Learning Healthcare System concept is that clinical care and research would become harder to distinguish [59].

Even within one organisation, there are often multiple separate systems that are divided by speciality and function, such as pharmacy, radiology, laboratory etc. This presents problems for linking an individual person's data together and can lead to duplication of data. This gives rise to the need for a lot of "plumbing" technologies [16]. Therefore, there is a lot of work involved in generating a longitudinal record, even for an individual. This can be automated, but each system requires a different approach [16]. Longitudinal data presents an additional problem, because systems and data representations often change over time [59]. The UK NHS number facilitates this process, while in the US, there is no universal identifier for healthcare.

Institutions with electronic records do not necessarily have good data. Typically, datasets have a lot of inconsistencies and must be checked and cleaned before secondary uses can be exploited [16].

The first point of failure usually occurs at the point of collection. True interoperability requires consistent data collection, however, there is often no agreement on what the acceptable values are. For example, biochemistry results are recorded differently in different places. These could be standardised on their way into the EHR, rather than requiring complex mapping and parsing steps at a later stage [49].

One of the biggest challenges to interoperability is in the semantics, the meaning, of the data. For research, semantics are often more important than in clinical practice, because it is crucial to know exactly what a piece of data refers to and how it was measured when comparing across different systems, For example, in the US, there is not an agreed way to define certain types of "visits" and it is often difficult to distinguish between a hospitalisation and an emergency department visit. From outside, it is difficult to make sense of that data. The metadata is often not clear enough to describe the dataset or data streams for appropriate use in research. This makes it difficult for the researcher who is trying to re-use this data [49].

In the UK, HES/SUS data and Read code data are standardised across providers. This overcomes many of the interoperability issues [57]. However, when extracting richer data from EHRs and other systems, the coding structures used by providers can create major challenges [12]. Different coding structures can also make it difficult to link primary and secondary care data. These definitional issues make data exchange very challenging [12].

There are also problems with how EHRs are deployed by different vendors that can make it difficult to share data across provider settings [60]. Often the functionality available in a particular implementation of an EHR locks its data into that particular use case and scale. It may be highly specialised and is not easily adapted to other purposes. The assumption is often made that large datasets in EHRs can be easily processed, but that is not always possible [47].

EHR vendors recognise the potential of secondary uses, but they argue that interoperability is not their primary task and that they do not exist to supply data for research purposes. They highlight the fact that there are significant costs incurred from providing data sharing from host systems and that it can compromise their primary objective of providing an uninterrupted clinical records service [51]. This perspective supports the view that currently, there are insufficient requirements or incentives in place to achieve interoperability [60].

This is recognised by the Institute of Medicine (IoM), who are exploring open source platforms and open APIs. The IoM does not have a mandate to impose a technical solution, so it is trying to achieve consensus. It would be for government to insist that any system, funded from the public purse, should satisfy agreed interoperability requirements [11]. The US Office of the National Coordinator for Health Information Technology has published a 10-year vision to achieve an interoperable health IT infrastructure, capable of supporting a Learning Healthcare System [14].

There was consensus that standards have a significant role to play in ensuring data quality and interoperability. It was agreed that the focus of standards should be on how data is collected and processed rather than what is collected, so that standards do not have to be continually rewritten [59].

A central body driving standards is important to progress this field. The lack of such a body in the past has meant that commercial entities were left to develop their own standards and as competitive organisations, they did not necessarily have the public good as their only concern [59].

In the UK, HSCIC is the industry standards body [61]. They do not seek to control how hospitals handle data within their own systems, but they do see it as their role to specify the format of external data exchange and reporting. This will be based on the Academy of Medical Royal Colleges documentation for interchanging data [12]. There was broad support, from our focus group, for the progress that HSCIC have already made [59]. There is a role for government in providing legislation and a contractual framework to promote the adoption of standards [59], however, the standard setting process should be as inclusive as possible [47].

Recommendation 2	
Ensure interoperability between EHRs using contractual frameworks or regulation if necessary	Government, Commissioners, Providers

Data from outside the Healthcare System

As the processing power and connectivity of mobile devices have increased and the number of on-board sensors has multiplied, there has been increasing interest in the role that these advancements can play in a Learning Healthcare System. At the same time, an increasing proportion of the population are engaging with social media and other online services within the public and private sector.

These developments are driving an exponential growth in the amount of routine data available about individuals. There is some hope that personalisation will offer a way to improve quality and outcomes within medicine and that data generated outside the healthcare system will enable that process [48].

New wearable technologies and the emergence of products such as the Apple HealthKit and Google Fit, could produce a change in how people interact with their own data. Mobile apps allow patients to be a lot more connected to their information [16]. This can then be integrated with the EHR [62].

There is evidence that some patients are beginning to coordinate their own data for self-care purposes and there is a huge range of health related apps already available [18]. Patients with chronic or serious conditions have displayed a much higher use rate of apps designed for them than has been enjoyed by the general health apps. Their primary motivation may not be to become research subjects, but that may be a secondary benefit [48].

Patientslikeme [63] is a web platform that allows patients to share their health related experiences in a highly structured format that can be used by other patients and by researchers. With over 300,000 members, it has shown that there is an appetite for this sort of service.

Many more people use general social media platforms and they post large amounts of information that could be highly predictive of how well they may fare with regard to their health. Some believe that this source of data could rival genomics in terms of the value that it could provide to healthcare. Big data methodologies would need to be developed further to process such vast quantities of data, but such techniques may become feasible in the next 5-10 years [15].

Monitoring technologies that record and analyse vital signs may see significant improvement and advances in analytics could help to reduce false positive alarms within such monitoring systems [15].

Bringing this data into the healthcare system will be a challenge and might have implications for the doctor/patient relationship. In some instances doctors may be keen to engage with this data. In general practice, for example, doctors may

only see a patient for 10 minutes once every 6 months. In this time, it is difficult to collect all of the relevant information and patients may have forgotten important issues. It may be helpful if the patient can bring a wealth of data to the consultation, but only if it can be visualised quickly and in a meaningful way by the GP [48].

Recommendation 3

Encourage development of systems that can display large patient generated datasets in ways that are both concise and informative	Research funders, Academics, IT vendors

Analysing and interpreting the data from these potential new sources may produce associations that were previously unknown, but it is not clear how researchers would get access to this data and whether it could be linked to data from within the healthcare system. In England, HSCIC could potentially provide the context, the mechanics and the safe haven where this work could be done [12].

Ultimately, the use of data generated outside of the healthcare system will depend on its usefulness and validity [48]. This has not yet been demonstrated on a large scale and there remains significant scepticism about how useful this area will ultimately become. There are many examples of health apps that are downloaded but rarely used [48]. There are also big questions around who owns this data and how it will be used by the organisations who facilitate its collection [12]. With regard to data from social media, there needs to be a societal discussion as to what data it is acceptable to mine [15].

Recommendation 4

Further independent research is required to appraise the potential uses of patient generated data	Research funders, Academics

Recommendation 5

Further independent research is required to evaluate the effectiveness of different types of health apps	Research funders, Academics

There is a concern that the patients with the highest needs and highest costs in the healthcare system are also less likely to own smart phones or engage with online services [15]. Patients with the most complex needs often, have a combination of physical and mental ill health, coupled with sensory impairment, drug and alcohol problems, may not speak the local language or may be homeless. Even if smartphones and Internet access became ubiquitous, such technologies may not necessarily benefit these patient groups.

Often the most disruptive technology will come from outside of the healthcare market, but will be adapted into it [15]. Developments in other industries offer interesting examples. In the US, Mint.com [64] aggregates financial data at the individual level. The user provides the service with log in details for their bank accounts and credit cards. The website then analyses all of the user's financial data and presents it back through a suite of visualisation tools, making recommendations on how they could save money by shopping elsewhere or switching to different providers.

As patients begin to access their health records online and generate additional health related data, such a system might help them to make sense of it and might even make suggestions about treatment options to be discussed with their GP.

Recommendation 6

Give patients access to their healthcare data, including the ability to add their own data in a structured format and the ability to flag inaccuracies	Government, Providers, IT vendors

Outcomes Measurement

Improving health outcomes, through the prevention, diagnosis and treatment of illness, is the stated reason why most healthcare systems exist. It is therefore unfortunate that robust outcome measures are usually not collected routinely as part of the provision of care. If patients are followed up, clinicians often record only subjective, unstandardised measures of response to treatment. When outcomes measurement does take place, it usually extends only to crude uni-dimensional measures, such as mortality. More often, process measures are used as proxies for outcomes, but these often do not capture what was intended and can be subject to gaming [18].

Outcomes measurement is a key building block of a Learning Healthcare System [11]. Unless it includes standardised details of how outcomes vary under different circumstances, routinely collected data will be of limited value in improving healthcare delivery [15].

There is recognition that measuring outcomes is central to improving the quality of healthcare [18, 28, 53]. Currently collected routine data can sometimes provide insights into outcomes [57] and many providers and national organisations have begun measurement programmes [17]. These efforts have often used process measures or a narrow range of outcomes, for example, just mortality, to make judgements about the quality of care. Even in 1863, Florence Nightingale had highlighted the reductionist nature of this approach:

> *"If the function of a hospital were to kill the sick, statistical comparisons of this nature would be admissible." [40]*

Professor Porter [65] has proposed a three-tiered hierarchy of outcomes measures that captures the multiple dimensions of a patient's health (Figure 3). This hierarchy highlights the importance of survival/mortality, but also takes account of other significant outcomes such as, degree of recovery, time to recovery, harm caused during treatment, recurrences and long-term consequences of care.

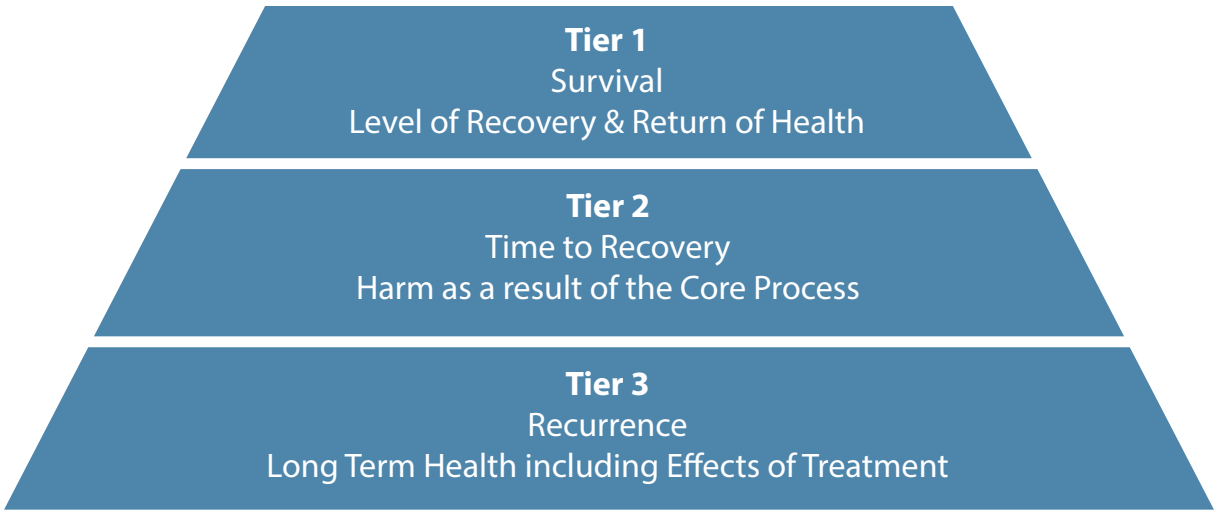

Figure 3. The Outcome Measures Hierarchy. Reproduced from [65]

This hierarchy does not indicate which outcome measures should be collected in a particular situation. That will depend on the condition in question and on what is important to that particular patient group.

The International Consortium for Health Outcomes Measurement (ICHOM) has been set up to define global Standard Sets of outcome measures for each medical condition and to drive adoption and reporting of these measures worldwide [17]. Essentially, these Standard Sets populate Porter's [65] hierarchy for each condition. They are created through international collaborations among patients, clinicians and outcomes researchers. ICHOM also support a scalable implementation network to assist partners to implement the Standard Sets [17].

Currently, it is unusual for outcome measures to be collected in such a structured and robust way [18, 65], but by 2017, ICHOM aim to have published 50 Standard Sets covering outcomes measurement for more than 50% of the global disease burden in developed countries [17]. This work is open source and ICHOM is aware of 60 partners who are already implementing standard sets in 18 countries [17]. ICHOM have the goal of covering half of all medical care with transparent medical data in 10 years [53]. This study has detected significant interest in adopting this approach within the English health system.

Participants believed that in the near future, there will be a completely different landscape for outcomes measurement. There will be increased focus on the patient, with reimbursement to providers based on outcomes [18]. An increasingly fragmented provider market may mean that the payer/commissioner or a national body, such as the HSCIC in England, must take a more proactive role in tracking outcomes [53]. This is already the case with billing data in the US and HES data in England.

As the volume of outcomes data increases, it will become easier to make risk adjustments for case mix and other factors [66].

Recommendation 7

Incentivise outcomes measurement through outcomes based commissioning	Government, Commissioners

Data Collection

Research trials collect detailed and standardised outcomes, but these are often too narrow or too burdensome for use in routine practice. There is a strong sense that clinicians are already overstretched and will not tolerate additional tasks that do not enhance the care of the patient who they are currently treating [16].

While detailed clinician completed outcome scales may be appropriate in certain circumstances, they will not be a sustainable universal solution. For many one off treatments, it does not make sense to bring patients back, just to record their outcomes [51]. Several other approaches have been proposed.

Some smaller EHR suppliers have already incorporated outcomes measurement and ICHOM have detected increasing interest in this approach from larger suppliers. For example, MD Anderson, in the US, has been exploring how the ICHOM Standard Sets could be integrated with the Epic EHR [17].

Natural Language Processing might be used to create structured outcome data from free text clinical notes [50], but this could be subject to error and in many cases, the clinical notes simply do not contain sufficient detail.

There is now a range of vendors who offer services to automate the collection of patient-reported outcomes [18]. These systems can automatically call patients to elicit outcome measures or can use web portals and mobile apps to engage patients. The cost of implementation is falling quickly [53].

Organisations are beginning to explore passive recordings from mobile apps as an alternative to actively collecting Patient Reported Outcome Measurements (PROMs) [28]. For example, mobility following treatment can be measured by asking the patient or it can be collected through the sensors on the patient's smart phone. This is an example of "out of app behaviour". Another gaming app estimates the severity of autism using "in app behaviour", behaviour patterns within a game, and "out of app behaviour", the way the iPad is held and the way that the screen is touched [18].

Ginger.io use passive mobile data to examine how people interact with social networks via their smart phone. They also incorporate PROMs via condition specific surveys and combine the results using behavioural analytics that can produce a depression score [18].

Using a range of different collection methods will allow triangulation of results across the outcomes measurement hierarchy, making the system more resistant to gaming and bias.

Recommendation 8

Evaluation studies to ensure the validity and reliability of innovative new outcomes collection methods	Research funders, Academics

Leadership buy-in

Buy-in from both senior management and clinical leadership is critical. Clinicians are often quickly convinced of the value of measuring outcomes, but they may not be in the management of their organisation, therefore it is essential to gain strategic buy-in from the senior management as well [53]. This can be achieved when they realise that there are feasible alternatives to measuring administrative data and process measures that do not represent value for the patient [17].

Conclusion

Outcomes measurement will form an important building block of the Learning Healthcare System. There appears to be a solid trend in that direction. This is enabled by new technological solutions and by a recognition that it is difficult to improve what is not measured. The most obvious use of outcomes data will be in driving improvement by benchmarking teams and organisations, but this data will also drive other aspects of Learning Healthcare Systems, such as predictive modelling and comparative effectiveness research. These use cases will be discussed in later sections.

Behaviour Change

There was consensus among our participants that a Learning Healthcare System is about more than IT and informatics. Technical solutions alone or even journal articles and guidelines will not improve health outcomes at the pace required [31]. This is demonstrated by the estimate that knowledge transfer, "from bench to bedside", currently takes up to 17 years [10].

"Translating the findings of data analysis and research into a change in practice can be a real challenge and the level of effort depends on what you are doing. If it is a simple process change it can be done quickly and efficiently, for example a formulary change has a level of effort of one. Introducing a new concept that begins to change behaviour, such as a guideline, increases that level of effort to about ten. Changes that go against people's beliefs move up to an effort level of one hundred. Asking a practitioner to change their own behaviour in a fundamentally different way, for example supporting shared decision making, may have a level of effort even higher than this." [32]

The technology underpinning Learning Healthcare Systems already exists but creating the culture of change has been cited as the harder problem to solve [32]. It is not simply about delivering knowledge to the point of care, it is about ensuring that the knowledge results in a change in behaviour, by patients, clinicians, providers, commissioners and other actors, to improve outcomes [15].

Implementation science is the study of methods to promote the integration of research findings and evidence into healthcare policy and practice [67]. This must be an integral element of any Learning Healthcare System. Implementation science is a broad and developing field, but the issue most commonly cited by participants was change and this generally meant behavior change. A recent report from the Health Foundation identifies four barriers to making change [39]:

- Shortage of capability to make change
- Insufficient 'headspace' to make change
- Lack of recognition that change is needed
- Limited motivation for change

This and other models of change suggest general interventions that may help to overcome these barriers, however, most do not offer a systematic method for tailoring interventions to a particular context.

The Behaviour Change Wheel (BCW) (Figure 4) [19] is a systematic method for designing, implementing and evaluating behaviour change interventions in any setting. It is based on 19 existing theoretical frameworks. It offers a process that could be integrated into a Learning Healthcare System, to ensure that the insights generated by the informatics are translated into behaviour change and ultimately, improvement in health outcomes (the red side of the cycle – Figure 2).

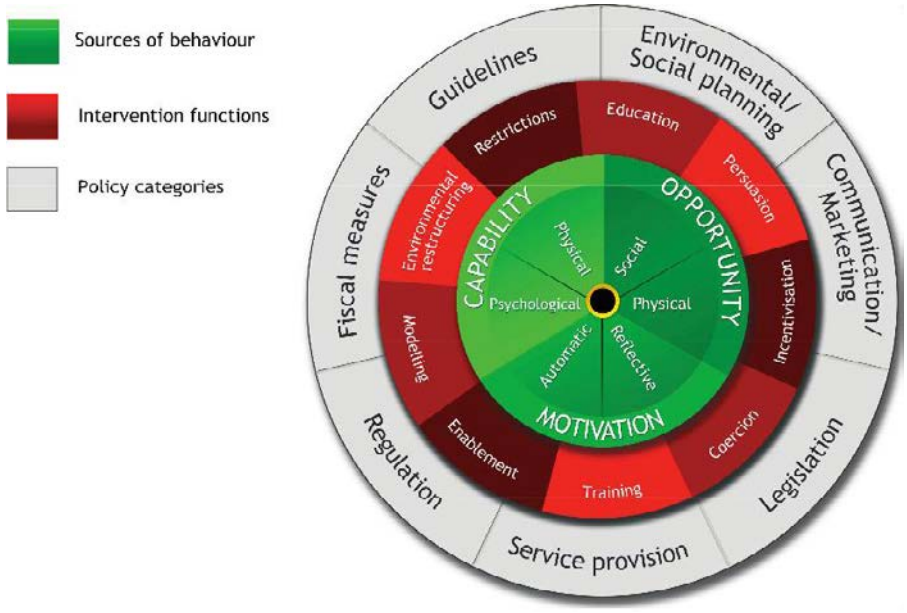

Figure 4. The Behaviour Change Wheel. Reproduced from [19]

The hub of the BCW is concerned with understanding the behaviour that has to be changed. This is achieved using the COM-B model (Figure 5).

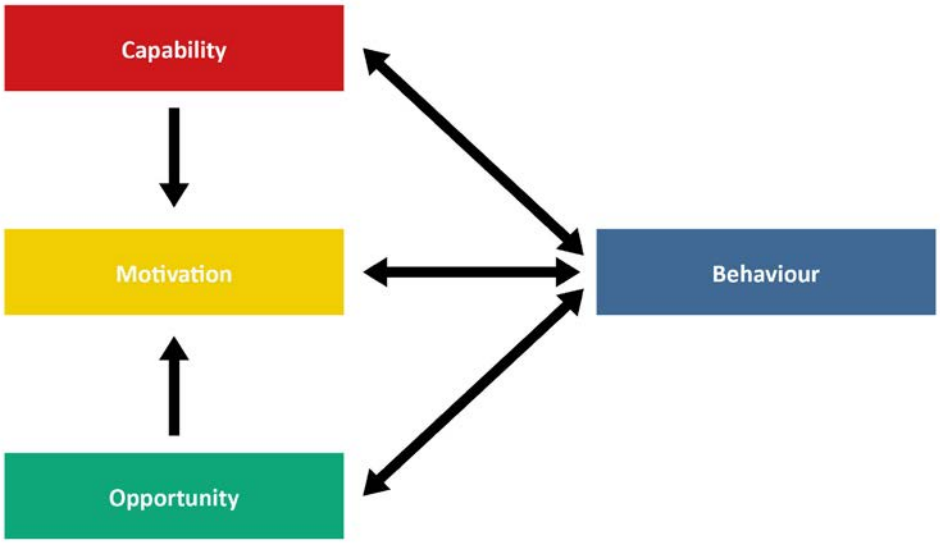

Figure 5. The COM-B Framework for understanding behaviour. Reproduced from [19]

Changing the behaviour of an individual, group or population, requires a change in, capability, opportunity, motivation or some combination of the three potential barriers. These map neatly onto those barriers identified above, in the Health Foundation Report [39]. Multiple methods can be employed to elicit this understanding from a range of stakeholders, depending on the nature of the behaviour and the resources available. For example, standardised questionnaires have already been developed [68]. Each element of the COM-B model has two sub-components as shown in the BCW (Figure 4).

The next element of the wheel outlines the set of possible intervention functions, which are broad categories of means by which an intervention can change behaviour). These include, Education, Persuasion, Incentivisation, Coercion, Training, Enablement, Modelling, Environmental Restructuring and Restrictions [68].

The BCW guide [68] provides a matrix that links the COM-B model to the intervention functions [19]. For example, if the barrier to behaviour change is identified as Physical Capability, then Training and Enablement are two potential functions that the intervention could serve. If the barrier to change has been identified as relating to Reflective Motivation, then the intervention could serve the functions of Education, Persuasion, Incentivisation and Coercion (or a combination of these).

The final element on the BCW is the set of possible policy categories; seven ways in which policy could deliver the intervention. These include, Communication/Marketing, Guidelines, Fiscal Measures, Regulation, Legislation, Environmental/Social Planning and Service Provision [68]. Again, a matrix has been created in the BCW guide that links intervention functions to policy categories.

In order to operationalise the BCW, the intervention functions are linked to Behaviour Change Techniques (BCTs), which are the smallest, active components of an intervention, designed to change behaviour (e.g. self-monitoring, goal setting, action planning, etc.). A taxonomy of 93 techniques has been developed [69], which can be used to describe BCTs used in interventions. The most frequently used BCTs have been mapped onto the intervention functions of the BCW.

The BCW enables a theoretical and systematic approach to be taken to intervention design. The COM-B model can be used to analyse user data and help 'diagnose' what needs to shift in order for change to occur. Guided by matrices in the BCW guide and a set of criteria (the 'APEASE' criteria), the most appropriate intervention functions, policy categories and BCTs for the context, behaviour and population of the intervention, can be selected [68] [70].

Elements of this process could be automated within a Learning Healthcare System and crucially, evidence could be collected on the effectiveness and cost effectiveness of each of the BCTs in various situations, resulting in further learning. There are already early examples of the BCW being integrated in the design of mHealth apps [71, 72].

Behaviour change will be required to enable patients, clinicians and organisations to adopt a Learning Healthcare System. It will also be required to ensure that they act on the evidence generated by a Learning Healthcare System, thus completing what Professor Freidman terms the red (or efferent) side of the cycle (Figure 1) [10].

The BCW has been constructed from an analysis of existing frameworks and has been assessed in terms of its reliability in practice [19]. If it is to improve healthcare outcomes, then any Learning Healthcare System must have a method of delivering behaviour change at its heart [10].

Recommendation 9

Encourage the use of evidence-based behaviour change theory within Learning Healthcare Systems, possibly by including it as a criterion in funding decisions.	Providers, Research funders, Academics

Patient Acceptability, Information Governance and an Ethics Framework

Patient Acceptability

More than any other group, Learning Healthcare Systems will have implications for patients. The participant recruitment process for this study suggested that they may also be one of the most difficult groups to engage. This may reflect many factors including accessibility and the general lack of awareness of the topic among the public [73].

A significant proportion of the population in most countries have experienced a large increase in their use of computers, mobile phones and the Internet over the last 10 years. Among communication, shopping, banking, information retrieval, etc. health stands out as an area whose electronic interface with the public has remained relatively undeveloped. Healthcare is yet to go through the change that these other industries have experienced, where people have fully engaged with technology and online services.

There is a growing expectation for online interaction with the health service, as evidenced by the growth of services such as, Patient Opinion [74] and Patientslikeme [63]. This follows a general trend whereby it is becoming more acceptable, at least for a proportion of the population, to share personal details online [31]. For others, they may feel comfortable booking appointments or ordering repeat medications, but it is unclear whether the majority are yet ready to use online services for sharing individual health information [51]. It is also unclear what secondary uses of healthcare data the public will find acceptable.

A study in the UK identified some fear among the public that routinely collected health data might be used by Government to cut spending on healthcare or that sensitive information might fall into "the wrong hands", with individuals being identified and stigmatised or disadvantaged in some way [75]. The same study found that health data is viewed differently from other types of data.

There is little objection to aggregated patient data being used for the general good, as long as commercial gain is not the priority. There is however, significant discomfort with the idea of health data being linked with non-health data, such as patient records with supermarket loyalty cards to inform health promotion messages. When part of a behaviour change intervention, this may even be viewed as a threat to free will. Other types of data linkage are less controversial [75].

It was felt that, at least in the UK, there has been a loss of confidence in established authorities, with the proportion of people trusting the NHS to steward their data appropriately reportedly falling below 50% [12].

Communication with patients and the public, about this process, is seen as critical. There have been examples when poor communication has actually increased worry about data sharing [22]. There is a sense that the media is more sensitive to risks to confidentiality than to the harm that could be prevented by sharing data. Apart from confirming the adage that "bad news sells", this phenomenon would appear to be an example of the behavioural economic effect that willingness-to-pay is usually lower than willingness to accept [76]. This is a major risk to the development of Learning healthcare Systems, but also has implications for how any argument for data sharing might be framed.

An informed public discussion is called for [15] and in the US, the IoM is currently building a network of patient advisory councils around this topic [11]. Attitudes in the UK are likely to be quite different as there have not been the historical commercial interests in healthcare and the requirements to share data in order to get insurance coverage [12].

Another UK study found significant resistance to the idea of linking routine data, among a sample of the public. However, when these people engaged in a two-day workshop on the topic, their views became significantly more positive (except in relation to commercial uses) [73]. This intensity of engagement is clearly not feasible on a population level, so thought

must be given to how best to engage. Perhaps a strategy that focuses engagement on the harshest critics can help to develop a system that addresses most objections.

Another strategy is to target all public interfaces with the healthcare system, with a multimedia campaign, so that the Learning Healthcare System concept becomes common knowledge [77]. Any campaign must also justify the need for a Learning Healthcare System. There may not be a realisation among a proportion of the public, that there are still huge gaps in our medical knowledge and in our ability to run safe, effective and efficient healthcare providers [77].

While recent controversies and their impact on programmes such as care.data might suggest a political push for ever-greater restrictions on the use of routine data, there is also a feeling that excessive controls will threaten the viability of Learning Healthcare Systems. For example, there is increasing use of secure data labs [78]. Traditionally, researchers might receive regular downloads of pseudonymised datasets, such as HES, that could potentially be maliciously re-identified. Increasingly, researchers will have to visit secure data facilities to do their analyses on computers with no access to the Internet. Results will have to be checked and approved prior to release from the facility. This approach has been shown to reduce public concern [73], however, it could curtail many use cases of the Learning Healthcare System and would make international comparative work very difficult.

Recommendation 10

Further research on optimal ways to engage the public and reduce their concerns around secondary uses of patient data	Research funders, Academics

In clinical practice, Learning Healthcare Systems offer the opportunity for clinicians to deliver truly patient centred care, by helping them to take account of patient preferences. For example, by allowing them to leverage many sources of information to help weigh investigation and treatment options according to what is important to the individual patient, rather than presenting a one-size-fits-all "best option". This would require patients to move up the activation/engagement scale, from those who do not want to understand or engage in their care, through those who want to understand what is happening, but be told what they should do, to those who want to understand and manage their own care [15]

Recent research has shown a positive link between activation level and other outcomes [79]. It is important to consider the implications of this for the patient and their role in the system. Patients will need to be supported and educated to enable active engagement and the system must support this. Further research is required to understand how this can be achieved [60].

Information Governance

Information Governance (IG) is therefore critical to the viability of a Learning Healthcare System. Data must be, obtained, held, used and shared, within a robust, ethically based IG framework. In the UK, this issue was addressed by the Information Governance Review (2013) [78].

The issue is complicated both by legality and by public perception. In the UK, an IG framework must take account of, case law, common law, several different statutes and decades of NHS policy statements. This appears to be a particularly complex situation compared to other countries. For example, in the US, the Health Information Portability and Accountability Act (HIPAA) is a single act of Congress that sets out what an organisation needs to do if they want to use patient data. Even the US system has been considered inhospitable to Learning Healthcare Systems [11]

Recommendation 11	
A review of Information Governance, case law, common law, statute and NHS policy statements, backed by public consultation, to clarify how the principles and rules apply specifically to Learning Healthcare Systems	Government

A New Ethical Framework

There is a feeling that, as Learning Healthcare Systems begin to blur the boundaries between clinical practice and research, it no longer makes sense to hold the traditional distinction between clinical (light touch) and research (onerous) ethical approval processes [20, 77, 80].

This view is supported by Faden et al. [21], who reject the idea that, from an ethics standpoint, clinical research and clinical practice are different. Their work represents the first attempt to create an ethics framework to support the transition to a Learning Healthcare System. They believe that there is a three-pronged moral justification for transitioning to a Learning Healthcare System:

- The establishment of a just healthcare system
- The achievement of high quality healthcare
- The achievement of economic well being

Their framework consists of seven obligations [20]:

1. Respect the rights and dignity of patients
2. Respect clinician judgments
3. Provide optimal clinical care to each patient
4. Avoid imposing nonclinical risks and burdens on patients
5. Address health inequalities
6. Conduct continuous learning activities that improve the quality of clinical care and health care systems
7. Contribute to the common purpose of improving the quality and value of clinical care and health care systems

These obligations fall, to a greater or lesser extent on, clinicians, researchers, healthcare managers, commissioners and providers. The seventh obligation falls on patients and the authors are clear that it cannot be discharged through financial payment alone, rather, everyone must participate in learning activities, so long as those activities do not breach the first four obligations. This obligation on patients is based on what John Rawls calls the principle of the common good and is relatively new to healthcare [21].

This framework has the effect of making learning easier by reducing the overprotection of patients from learning activities that do not undermine their interests or rights. They argue that this over protection currently deters learning (e.g. through research), resulting in significant harm to patients. In practice, this could mean the use of a streamlined consent process or, in some cases, no consent process at all within a Learning Healthcare System [81].

This framework challenges the relevance of traditional ethical frameworks, so it is interesting to note that one of its authors is Professor Beauchamp, familiar to all doctors as co-author of the four principles of biomedical ethics [82], the traditional framework most commonly taught in medical schools.

Faden et al.'s framework has had a mixed reception [20]:

- Significant enthusiasm from those supportive of Learning Healthcare Systems and from those in the bioethics community whose views are that multiple options for informed consent may be acceptable in different types of circumstances
- More reservation amongst those doubtful about Learning Healthcare Systems in general and from

those wedded to the view that the traditional informed consent model is the only morally acceptable approach for clinical research

The idea of studies without informed consent has been controversial. This ignores the double standard that patients often don't have informed choice in other situations, for example, in quality improvement studies [20]. It should be acknowledged that there are alternatives to informed consent that are worth exploring. Engagement with patients and the public regarding which procedures need consent and which don't, will be key to the development of this change [20].

Most participants agreed that an opt out system was appropriate for the use of routine patient data within a Learning Healthcare System [77], however, it is also important to consider where the opt in or opt out sits in the process. For example, an opt in system might be appropriate if the decision is about whether commercial organisations should be allowed access to data. These decisions would depend on the particular use cases.

Implementing a New Ethical Framework

This framework could not be implemented immediately within our current healthcare system and would require a phased approach [20]. Some healthcare systems are currently more suited for this development than others. To be successful, implementation of the framework will require a number of steps [20]:

- The healthcare system leadership must have the vision and commitment to have an ethically robust Learning Healthcare System
    - There should be a culture within the institution or system to endorse this approach
        - This may be easier in a system like NHS than in a more fragmented system such as the US
        - Documents such as the NHS constitution may be helpful in this regard
- Clinicians must be carefully involved
- Patients must be involved and play a central role in decisions about which types of studies or projects could go forward with which different types of consent or disclosure

The "ETA" approach is important in the development of the Learning Healthcare System and is relevant to the ethical foundation of such a system [20]:

- **E**ngagement
    - Massive engagement of stakeholders, especially patients and the public, is required. It is important for them to understand the reasons for the system and that it will help to deliver current best care
    - Patients should help decide what sort of studies should require full informed consent, streamlined consent or no consent at all
- **T**ransparency
    - Be open that the system is committed to learning from care
    - Ensure that when joining a health system, the public is aware that the aim is to learn from care and to constantly improve
- **A**ccountability
    - Let people know when care does change as a result of learning activities. Use multiple methods including newsletters, websites etc.
    - Accountability from the system side in making sure that care actually does change and improve as a result of learning. The justification for streamlined consent or disclosure approaches is that these will facilitate more learning, which is ultimately in patients' best interests. If the learning does not translate into changes in care, then the ethical "contract" is no longer valid

The ETA approach was echoed by our focus group on Ethics and Information Governance [77].

Recommendation 12	
Organisations developing Learning Healthcare Systems should adopt the Engagement, Transparency and Accountability approach at every step	Providers, Academics

Use Cases in the Learning Healthcare System

There are many potential sociotechnical configurations that would meet the definition of a Learning Healthcare System. The six use cases outlined below represent the systems that were most often cited by participants. They each rely on routinely collected data and medical knowledge that is assembled, analysed and interpreted, before being fed back into the healthcare system with the aim of promoting behaviour change.

Each use case has already been demonstrated at least at proof of concept stage. As these use cases are implemented throughout the healthcare system, it is expected that they will form an interrelated mesh of learning cycles that have the potential to promote rapid improvement in quality and cost effectiveness. It is however, important not to underestimate the challenges involved in implementing such systems at scale.

Intelligent Automation

Clinicians have traditionally spent significant time performing basic tasks that would not constitute working "at the top of their license" and this does not add value. There is also an acknowledgement that clinicians are already busy and that adding to their workload is unlikely to result in adherence to system improvements [22]. This has resulted in significant interest in the automation of tasks. Automation in healthcare has been underway for many decades, driven by improvements in machinery and communication systems. Much of this would not constitute a Learning Healthcare System, but routine data and analytics offer the potential for automation to move closer to core clinical processes.

At Geisinger Health System [22], certain aspects of routine management and preventative interventions for well patients have been automated [83]. This has increased the likelihood of these activities occurring and has freed clinicians to focus more time on managing the minority of patients with multiple active chronic conditions. Within consultations, a new initiative called SuperNote, has been launched to improve the quality of notes by prepopulating clinic notes with existing data. An "intelligent automation" function has also been integrated with the EHR, to pre-prepare tasks and orders that are likely to be required, based on the patient's problem list [22].

IBM are currently developing their "knowledge driven analytics" system, Watson, to leverage unstructured information using Natural Language Processing (NLP) techniques. They hope that this will allow at least partial automation of two tasks that have been central to the role of the clinician:

1. Leveraging the growing body of medical literature:
   - It is not possible for clinicians to keep up to date with all publications, so the goal is to move beyond simple article search capabilities and train Watson to perform deeper analytics on the text, to understand the entities and the relationships described there to leverage further insight for the individual patient
2. Using the unstructured information in the patient history:
   - A lot of what is captured in electronic notes is unstructured. This can contain a lot of significant information, such as the justification for a particular treatment choice or the connections between symptoms, diagnosis and lab tests. In large longitudinal clinical records, there can often be over 1,000 pages. The goal here is to use Watson to produce accurate and relevant summaries of patient records

Aspects of these systems are currently being trialed at Memorial Sloan Kettering Cancer Centre and at MD Anderson [16].

There is significant scope for further traditional automation and for knowledge driven automation in healthcare, to save resources and to ensure that important activities are undertaken.

Recommendation 13	
Identify further opportunities for more intelligent automation to improve care and reduce workload	Research funders, Academics, Providers, IT Vendors

Comparative Effectiveness Research

Large Randomised Controlled Trials (RCTs) and meta-analyses of RCTs are currently considered to be the Gold Standard form of evidence that underpins Evidence Based Practice. The reasons for this are well rehearsed, primarily that they can determine causal relationships while reducing confounders and bias [84].

The limitations of RCTs are also well understood. They are expensive and time consuming and it can be unethical to expose patients to treatments believed to be ineffective or even harmful [84]. In addition, RCTs are not well adapted to the complexity of health conditions and the heterogeneity of patient characteristics. They generally have strict inclusion and exclusion criteria, meaning that their results may not apply to the diverse patients, suffering from multiple co-morbidities, who are most often encountered in the real world [1-4, 32].

It would be infeasible to conduct RCTs to address all of the potential treatments for all variations of all conditions in all of the different patient groups, with their genetic and environmental predispositions and their multiple comorbidities. The result is that there remain huge gaps in the evidence base. Often, clinicians do not have the evidence to recommend one treatment or another. Ultimately, decisions are made on the basis of limited personal experience. Effectively, these decisions represent millions of "n of 1" experiments, taking place globally, every day [32].

Currently, learning from these experiments is limited to the clinicians involved. The advent of the EHR offers the potential for this practice-based evidence to be recorded and used in a more systematic way.

A Green Button

It has been proposed that a function could be developed, within the EHR, to allow clinicians to leverage aggregate patient data for decision making at the point of care [85].

In this system, if the clinician did not have evidence on the relative effectiveness of different treatments for a particular patient and had no guideline to follow, they would click a "Green 'patients like mine' Button". The EHR would identify all patients with similar characteristics (genetic, comorbidities, age, etc.), who have previously had that particular condition. It would identify the treatments that they have received and the outcomes achieved. It would then suggest the optimal treatment for that particular patient, taking account of their preferences. This approach has already been implemented on a small scale, by manually extracting and aggregating EHR data [86].

The IBM data driven analytics team have supported the EuResist project [87] that examines data relating to patients who are suffering from HIV and are treated with anti-retrovirals in Europe. Data is gathered into a database containing information on phenotype, genotype of the viral strain, treatment given and outcomes achieved. This information can be used, in a semi-automated way, to assess which treatment might work best for a new patient. In the case of EuResist, the clinicians were around 66% effective in choosing the best treatment on the first attempt. By comparison, the system was reported to be around 78% effective [16].

If these approaches could be automated and expanded to a broad range of conditions, they would be a key use case of the Learning Healthcare System [10]. This capability is cited at the outer range of the 10-Year Vision to Achieve an Interoperable Health IT Infrastructure, published by the US Office of the National Coordinator for Health Information Technology [14]. Many observers foresee major obstacles to such a system:

- No other patient is truly like me [10]
- More robust outcomes measurement would be required [15]
- The answers would not be clear-cut. Clinicians would have to interpret the results carefully to avoid getting the wrong answer [49]
- There are ethical issues related to this use of EHR data [85]

Observational Research

Observational research, including, cohort, cross sectional and case-control studies have long been used in situations where RCTs are too expensive, unethical or when sufficient participants cannot be recruited [88]. They are observational because the participants are not randomised or pre-assigned to an exposure. The choice of treatments is up to patients and their physicians [89]. Increasingly, these studies are being viewed as complimentary to, rather than inferior to, RCTs. Under the correct conditions, they can even provide evidence of causal relationships [90].

It is now possible to conduct observational research, using routinely collected patient data, that would not previously have been possible [50]. Currently in the US, it is possible to examine certain outcomes with high confidence, as they are captured uniformly across multiple systems. Acute myocardial infarction or hip fracture requiring surgical repair are examples. There is good evidence that these events are

captured and the data is sensitive and highly specific. It is then possible to associate these outcomes with various types of exposures or treatments [50].

In the UK, this type of research has been undertaken using secondary care HES and SUS data, which is sometimes augmented by additional coding at the provider level [57]. In primary care, large databases such a QResearch provide similar functionality [91].

According to Dr Wallace at Optum Labs, who are already conducting research on a database containing 150 million patient records, research has reached an inflection point. He notes that in 20th century medicine, a great deal of the cost of clinical trials was associated with data collection. Observational studies are so much cheaper that hundreds can be conducted for the price of one RCT [32]. Dr Wallace places this in historical terms:

"Research is changing from a hunter/gatherer mode, where huge amounts of effort is invested to associate data with rare events, to a harvest mode in which huge amounts of data are used more efficiently to give insight." [32]

The content and quality of the underlying data is currently a limiting factor in the usefulness of comparative effectiveness research using routine data. Rigorous recording of outcomes could allow a step change in this kind of research [18]. For example, the ICHOM Low Back Pain Standard Set (see Outcome Measurement) would provide an effective set of outcome and case-mix indicators to study the comparative effectiveness of instrumented versus non-instrumented fusion for spondylolisthesis [53]. This would also require the recording of important contextual information. In this example, it would be necessary to clarify what is meant by instrumented and non-instrumented [53].

There are also significant methodological concerns. With observational CER, it is possible to control for some confounding factors and not for others. Often a hybrid approach is required, where sophisticated automated analysis of thousands or millions of electronic records can be paired with a manual review of several hundred, to confirm accuracy. This technique was used successfully in a study looking at the link between rotavirus vaccine and intussusception [92]. This is a powerful technique that could also be extended to patient reported outcomes [50].

Pragmatic Randomised Controlled Trials

In Pragmatic Randomised Controlled Trials, the design mimics routine clinical practice [93]. This means relaxing exclusion criteria, not using placebos, accepting non-concordance with treatment and delivering care as it is delivered in the real world. It offers a measure of effectiveness that is generalisable [94]. Participants pointed out that such studies lend themselves to being conducted within a Learning Healthcare System. For example, the EHR could be configured to randomise patients.

"Suppose that you are in clinic, about to start an SSRI, but you don't know which one to go for. Why not allow the system to randomise the patient… the patient wouldn't need to be contacted again [by the researchers] – all of the outcomes would be collected in routine data so it massively decreases the cost of doing an RCT."

This sort of study, that brings together research and clinical practice, would raise the sort of ethical questions around consent, which have been discussed in previous sections.

Recommendation 14

Consider the potential to achieve greater impact by increasing the proportion of research funding allocated to observational studies and pragmatic trials run thorough LHS	Research funders

Recommendation 15

Traditional RCTs should consider whether they can reduce costs though automated data collection	Academics/ Researchers, Research funders

Clinical Trial Recruitment

There will still be a need for traditional RCTs in certain circumstances [32]. Recruitment of sufficient numbers of participants is a challenge for researchers and patients often miss out on clinical trials from which they could benefit. EHR data can be used to identify patients who are suitable for certain RCTs. The IBM Watson team have demonstrated this ability in collaboration with the Mayo Clinic [95]. In the UK, the Clinical Record Interactive Search (CRIS) system, developed by South London & Maudley NHS Trust has been used to deliver similar functionality [96].

Recommendation 16

Traditional RCTs should consider whether they can improve recruitment by using EHR data to identify potential participants	Academics/ Researchers, Research funders

Conclusion

No participants claimed that the RCT is dead, but rather that other methodologies will be required if we are to bridge the evidence gap experienced by modern medicine. Observational studies can deliver useful results quickly at relatively low cost and they do not put patients at risk, through experimental exposure. The development of EHRs and rigorous outcomes measurement, offer the potential to accelerate the use of observational research. This may require the development of a new ethics framework.

Even when RCTs are still required, Learning Health Systems can help with recruitment, randomisation and data collection. Many of these potential developments pose major training and workforce implications that will be discussed in the Implications section of this report.

Positive Deviance

Data for operational management, such as for simple rotas, logistics, production management, flow management, etc, in healthcare could be significantly improved [12]. Analytics based on routine data, including outcome measures, would also enable the use of more robust research methodologies for understanding comparative performance in different contexts.

"This could challenge the current view, held by many researchers and clinicians, that we can only trust answers if we have a Randomised Controlled Trial and three decimal points." "In real life, we say, shop A is doing well and shop B is not doing well, so what is shop A doing that shop B isn't. We can then try different approaches and try different hypothesis in real time. This would have enormous potential for improving quality and safety. Poor care causes significant harm and better routine data could allow a much quicker management response." [12]

This view was echoed by ICHOM, who felt that adoption of findings from traditional comparative effectiveness research is unacceptably slow. They believe that people need to experience an innovation in practice and then take it back to their own institution. They seek to compare the outcomes of institution A and institution B rather than treatment A versus treatment B [53]:

"If we give clinicians outcomes data compared to their peers, they will say, 'hey, why is this place doing so much better than us?' That motivates them to visit those institutions and pull into their practices the innovations developed there." [53]

It might also become apparent that organisations are delivering an equally high quality of care, but that some are doing it more cheaply than the others, thus improving value.

This approach to improvement is known as positive deviance and follows these steps [23]:

1. Identify positive deviants, high performing organisations
2. Study them in depth to identify hypotheses about practices driving their performance
3. Test hypotheses statistically in larger representative samples of organisations
4. Work with potential adopters to disseminate evidence about best practice

The positive deviance approach is particularly appropriate in situations where [23]:

- Organisations can be ranked reliably based on valid performance measures
- There is substantial natural variation in performance within an industry
- Openness about practices to achieve exceptional performance exists
- There is an engaged constituency to promote uptake of discovered practices

These criteria have traditionally been met within a small number of medical conditions and impressive results have been reported [23]. The availability of routine data, including outcomes measures, will enable a much larger proportion of healthcare to meet these criteria and to adopt the approach.

Recommendation 17

Encourage providers to engage in positive deviance exercises using available outcomes data	Providers, Commissioners, Regulators, Research funders

Surveillance

An advantage of recording outcomes and other routine data electronically, is that it can be collated and analysed in near real time. This feature holds out the potential for surveillance use cases such as, epidemiological studies and monitoring the safety of new treatments.

The US FDA has set up a nationwide electronic post-marketing product safety system called Mini-Sentinel [50]. The system has 18 data partners, encompassing data from almost 178 million patients. This allows the FDA to track potential safety issues associated with approved drugs and other medical products [97].

The Mini-Sentinel project uses a distributed network. The data partners, such as providers, maintain operational control over their data. They receive queries (data requests) from a coordinating centre and approve the release of the aggregated results. This protects patient privacy [49]. Because the data partners must approve each query and each data release, it takes a number of weeks to compile the results of a nationwide query. In the past, it has taken years for harmful adverse effects to be recognised and mitigated. This sort of system could reduce that time significantly [98].

Mini-Sentinel is a pilot project for a larger "Sentinel" project that is currently under development. These systems are particularly good at identifying adverse events that are relatively common in the general population, such as, heart attack, depression and suicide, which are otherwise difficult to associate with causal agents.

QSurveillance is a real time clinical surveillance system based on data from over 3,000 general practices throughout the UK. It was used to monitor the progress of the influenza pandemic in 2009 [24]. Indicators such as, flu-like symptoms, pneumonia, antiviral use, deaths, gastroenteritis, heat stroke, vaccinations, etc. are extracted from the EMIS EHR, using a distributed network configuration. During the pandemic, daily extracts were provided to local and national authorities who were managing the response.

Surveillance systems require a methodology that is simpler than that required for comparative effectiveness research, therefore, the use of these systems is relatively more advanced. Access to routine data enables a shift from passive towards active surveillance. Passive surveillance approaches, such as the Yellow Card Scheme [99], operated by the UK Medicine and Healthcare Products Regulatory Agency (MHRA), rely on reporting of events or emerging case-studies. Active surveillance allows regulators to monitor for issues and to quickly mine distributed networks for answers to particular questions [98].

Recommendation 18

Increase utilisation of existing surveillance networks	Research funders

Predictive Modeling

Within medicine, there are a large number of interactions that generate data. Pattern recognition in this data can be used to infer what might happen in the future, given a particular set of circumstances [16]. If it is possible to identify situations with a high risk of negative outcomes, then prevention is sometimes possible [16].

The IHI have outlined their Triple Aim [100], to:

- Improve the patient experience of care
- Improve the health of populations
- Reduce the per capita cost of healthcare

Models have been built, using routine data, that can identify "Triple Fail" events, those that simultaneously fail to meet each criterion of the Triple Aim [101]. Readmission models are commonly cited, but they could be extended to cover a wide range of other Triple Fail events such as:

- Over-medicalised death
- Starting haemodialysis prematurely
- Over-invasive treatment when a preference sensitive decision aid would have nudged a patient towards a less invasive option

Impactibility models identify which high-risk circumstances are most likely to be amenable to intervention or which interventions would be most effective in particular situations. As such, impactibility models represent a way of improving the cost effectiveness of the intervention since it is not "wasted" on high-risk individuals who are not going to benefit from the intervention [25].

These approaches fit well with the philosophy of proactively managing healthcare, which is particularly attractive to those health systems that combine both payer and provider [16]. This was the case at Geisinger who employ a team of clinicians and industrial systems engineers to develop predictive models that use routinely collected data to identify situations where intervention could avoid costly events that adversely impact patient care [22].

As well as models to predict clinical events, Geisinger have expanded their modelling to predict system level events, such as spikes in hospital activity and to tackle logistical inefficiencies, such as patients who are likely not to attend appointments. In the later example, some clinics were experiencing no show rates of up to 47%. Patients were not receiving the care that they needed and clinic time was being wasted. A model was developed that drew 100 predictive variables from the EHR. This was refined until the 40 best predictors were identified. The model now stratifies all patients according to their risk of not attending. High-risk patients receive a phone call from the clinic prior to the appointment. This has resulted in a 24% reduction in no shows [22].

There is a belief that, in the future, data from electronic records can be integrated with genetic and social care data and perhaps even data harvested from social media and wearable technology to enhance predictive models further [18].

If health and social care data could be integrated, then it would become possible to build predictive models that estimate the future social care needs of patients currently moving through the healthcare system. This could reduce delayed discharges, improve outcomes and improve patient experience [59].

There was also a feeling that healthcare is behind some other industries in the way that it uses routine data for predictive modeling. For example, Amazon.com use historical data to suggest other purchases. The gas industry has also used routine data to develop better predictive supply and demand models. This has allowed them to redesign their storage infrastructure, reducing the need for large community based storage facilities [18].

Some approaches to impactibility modeling can reduce healthcare inequalities, others can worsen them [25].

- Impactibility models that seek to prioritise those people who are receiving sub-quality care will tend to reduce health care inequalities because low quality care tends to be commoner in more deprived areas (the

inverse care law)

- Impactibility models that prioritise patients with particular diseases that tend to respond well to intervention, (the so-called ambulatory care sensitive diseases, like heart failure), are likely to reduce health inequalities because these diseases are often more prevalent in patients from lower socioeconomic groups.
- In contrast, impactibility models that attempt to de-prioritise those people who are least engaged (e.g., who have poor English language skills, have drug and alcohol problems, or cognitive impairment), might exclude some of the most vulnerable people in society.

Predictive modeling and impactibility modeling are effectively forms of screening because they generate true positives, true negatives, false positives and false negatives. Just as with other forms of screening, there are harms associated with false positives and false negatives. We should therefore use the Wilson and Jungner criteria (or some modification thereof) [102], developed for the WHO, when considering the appropriateness of a predictive modelling programme [103].

Recommendation 19	
Assess where predictive modeling could be employed to improve services or increase efficiency	Research funders, Academics, Providers, IT Vendors

Recommendation 20	
The screening criteria, proposed by Wilson and Jungner (or some modification thereof), should be applied when deciding whether to employ a predictive model	Providers, Research funders, Academics, Regulators

Clinical Decision Support

It is impossible for clinicians to stay up to date with the medical literature in all but the narrowest fields of medicine [80]. This contributes to wide variations in practice between clinicians and regions. Clinical decision support systems (CDSSs) have been proposed as one potential remedy to this problem.

A clinical decision support system has been defined as "an electronic system designed to aid directly in clinical decision making, in which characteristics of individual patients are used to generate patient-specific assessments or recommendations that are then presented to clinicians for consideration" [104]. Patient facing decision support systems are also available [105].

There are conflicting accounts regarding the success of existing systems, but a recent systematic review concluded that, across clinical settings, new generation CDSSs integrated with EHRs do not affect mortality, might moderately improve morbidity outcomes and had only a small impact on cost [106]. Other studies have had more positive findings [107].

Participants acknowledged that existing systems have had mixed results [80], but expressed optimism about the potential for future systems. As the amount of genetic, social and monitoring data relating to each patient increases, it will become more difficult for clinicians to weigh it systematically, without the help of electronic systems [80].

There is increasing interest in the field. For example, The American Society for Clinical Oncology (ASCO) aim to roll out decision support tools for breast cancer this year [80]. If successful examples can be demonstrated, then these tools could become widespread [80].

There is an appetite for machine readable guidelines that can be consumed by a Learning Healthcare System and can drive decision support systems [10]. They could also be compared against routinely collected data retrospectively, to assess whether patients have been treated in line with best practice.

OpenClinical.net, a collaboration between University College London, Oxford University and Deontics Ltd., aims to create and maintain an open access and open source repository of medical knowledge in a machine readable format. Currently OpenClinical content makes use of the PROforma process modelling language to facilitate the creation of machine readable clinical guidelines [108]. Novel decision support systems could be developed more rapidly if NICE and other guideline writing organisations produced machine readable guidelines alongside their human readable equivalents [29].

Recommendation 21

NICE and other guideline writing organisations should publish machine readable guidelines alongside their human readable equivalents	Guideline producing organisations

Such systems will be more successful if they preserve the physician's role in forming a relationship with the patient and sharing the decision-making [32]. "Decision directive" tools will not work, but "decision supportive" tools would be more likely to be successful and more acceptable to physicians [51].

"Doctors don't go to university to be told by a computer what to do … would you use your satnav to tell you how to drive to work every day?" that is the equivalent of "if you see someone with conjunctivitis, do you need guidance to give fucithalmic? … Experience has told us that physicians do not want the paperclip popping up giving this information." [51]

What is needed is something with more understanding, that can help guide more complicated cases, for example patients with complex comorbidities and social problems. These are the biggest burden on resources and the source of more frequent mistakes, as physicians may not have considered all of the complexities. These should not just be solely decision support but should help structure a care plan that involves the MDT, which would lead to better clinical outcomes [51].

Geisinger Health System have combined decision support with automation and integrated it into their EHR, so that the system uses the patient's problem list to pre-prepare tasks and orders, in line with best practice standards, ahead of the consultation. The aim is, "making the right thing, the easy thing to do." [22]

Ultimately, Clinical Decision Support Systems will be appropriate for changing clinician behaviour in a certain set of situations. The decision to employ such a solution should be arrived at following an analysis of the situation that is conducted within an evidence-based behaviour change framework, as discussed previously.

Making any decision relies on a combination of information and preferences. The information may be objective, but the preferences are subjective and involve values, so they should be exposed to the user [109]. To ensure meaningful shared decision-making, the patient should also be able to adjust the preferences within a clinical decision support system.

Implications

Widespread implementation of these use cases could enable rapid learning and lead to improvements in the quality and reductions in the cost of healthcare delivery, as discussed in the previous section. It could also have more widespread implications for healthcare systems. Some of these implications are outlined below.

Workforce Implications

Learning Healthcare Systems will have significant implications for many of the professionals currently associated with the health service [27].

Researchers

To realise the potential of Learning Healthcare Systems, the health services research community will have to upgrade their skills and change the way that they work [60]. Most members of the health services research community have relied on administrative data, to generate retrospective studies that have been clinically valuable. Doing research with complex, clinically rich data, from a broad representation of the population will require new training [60]. Researchers will also have to work more closely with clinicians and health care managers.

Clinicians

Bold claims have been made, in the media [110], that computers and big data analytics could eventually replace doctors and other clinicians. This view was not supported by any of the participants in this study. It was felt that such developments should complement and extend the capabilities of the healthcare professionals:

"People do not want to see "Dr Watson", they want to see a doctor who is backed up by the knowledge of Watson. It is important not to forget the unique qualities a doctor brings to the relationship with the patient that cannot be offloaded to the IT side, such as empathy, intuition, autonomy as a doctor, and accountability to the patient. " [32]

While Learning Healthcare Systems will not eliminate the need for clinicians, they may alter the number and type of clinicians that are required, in ways that are difficult to predict.

There was agreement that Learning Healthcare Systems will change the role of clinicians, but also that it will not succeed without the support of a majority of clinicians. For example, any system that increases their workload, without demonstrating significant benefit for them or their patients will not be accepted [16].

While the implementation of Electronic Health Records has been often been associated with increased clinical time spent on administrative tasks [46], the most innovative providers have been using automation to reduce the time that clinicians spend on administrative tasks. This could increase their productivity and reduce errors. It is hoped that a greater range of tasks can be automated [16].

In future, the ability to harness routine data to make judgments about comparative effectiveness, that are specific to individual patients, will be a powerful tool for clinicians, but will require a new set of competencies. Namely the [10]:

1. Ability to know when you are right or wrong
2. Ability to ask a good question
3. Ability to deal with fuzzy information

"The knowledge cloud will not provide clear answers. Doctors will become organisers and question askers. They will provide the scaffold for patients and carers." [10] IT systems are unlikely to replace this role in the foreseeable future.

In the development of modern medicine, the role of clinician has become disassociated from the role of researcher. Researchers are there to ask questions and supply knowledge that subsequently trickles down to the clinicians. The development of Learning Healthcare Systems means that the skills mix in the system will have to change [32].

There is a sense that as the clinician role changes, it will incorporate more research activity [11]. Clinicians will both be generating data and will have access to much more data than they have been used to. Extra training will be required for them to be productive in this environment [60]. What this training will involve has not yet been clearly defined and in the US, AcademyHealth has just established an education council to think about this issue [60].

Clinicians will no longer need to remember a vast number of facts [12], but they may need to be:

- More aware of how the data that they record might be used by the system [27]
- Able to interpret results of routine data analytics [10, 27, 32, 60]
- Able to leverage data from non-healthcare system sources [27]
- Able to interpret and act upon feedback on their practice [31]
- Able to live with continual change [27]

This may require a fundamentally different system of clinical education and training that would be more responsive to the needs of the service [12].

IT and Informatics Professionals

There is often a lack of appreciation of the difference between Health IT and Health Informatics. The priority for IT is the maintenance of clinical systems with a high level of reliability. Informatics is concerned with deriving insight from data [27]. While most healthcare organisations employ IT staff and infrastructure, there is more variation in their informatics investment.

Some organisations have begun to invest heavily in informatics. University Hospitals Birmingham has employed a data analytics team, including professionals from other data intensive industries. This has allowed them to gather greater insights from routinely collected data. For example, doctors with abnormal prescribing behaviour can be identified and offered targeted training [27]. In the US, health systems like Geisinger are also investing heavily in these skills, in the belief that they will improve outcomes and reduce costs [22]. There is a wide range of clinical informatics related roles that do not yet exist in sufficient numbers [27].

There is potentially a role for a new type of professional that works between the clinician, researcher and informatician, the "new medical librarians" [50]. These professionals would help clinicians to ask the right questions and to understand the implications and limitations of the answers produced by the system.

Conclusion

Learning Healthcare Systems seem unlikely to remove the need for clinicians, but the skills required by those clinicians and the researchers and informaticians who support them, will certainly continue to change. There is a need to train people to handle the change that seems certain to arise in the future [27].

Recommendation 22	
Organisations responsible for clinical education and training should consider the skills and competencies that will be required during the careers of this and the next generation of clinicians and should reflect this in their curricula	Medical schools, Postgraduate institutions, Education and training providers

Recommendation 23	
Review the potential impact on the type and number of, researchers, clinicians and informaticians required within the health service	Workforce planning organisations

Provider Acceptability

Like individual clinicians, many healthcare organisations are already working at capacity and are focused on relatively short-term financial, process and regulatory targets. Elements of a Learning Healthcare System that are not aligned with these targets or that require upfront investment for long-term payback, may achieve limited uptake. Elements of a Learning Healthcare System that are viewed as a public good, such as the contribution of data to publicly funded research with open access to results, may be seen as a luxury that is only affordable for organisations who trade on their national reputation or who are dominant in their market [22]. Other organisations may require additional incentives to participate.

Clinicians can be powerful advocates for Learning Healthcare Systems within an organisation. If they do not engage with a system, then it will struggle to succeed. Even when clinicians are supportive, they may not be able to achieve implementation without management buy in [17]. This depends on alignment with the organisation's aims.

Ultimately, support from the organisation's board is crucial in providing the philosophical commitment required to implement a Learning Healthcare System [60]. In recognition of this, in the US, the IoM are forming a national network of CEOs to help advocate for Learning Healthcare Systems [11].

Delivery Models

Learning Healthcare Systems are not simply digital networks, they are networks of real world healthcare commissioners and providers, supported by a digital infrastructure. They will reflect the organisational structures within which they exist. In many countries, that means that they are currently fragmented systems. In the UK for example, there is a traditional divide between primary care, community services and hospitals and between social care, physical and mental health [8]. There is also a divide between the organisations that pay for care and those who provide it.

These divisions increase the complexity of data sharing and create perverse incentives within the Learning Healthcare System. Development can be slowed because the benefits accrue to organisations other than those that have made the investment [16]. The lack of common standards has resulted in a proliferation of incompatible systems [59].

New models of care have been proposed and are beginning to be implemented in the UK and elsewhere [8]. There is recognition that services need to be integrated and coordinated around the patient [8]. Learning Healthcare Systems will

make it easier to evaluate different models of care in a timely way. It should be possible to identify components that are not working and to allow the rapid reconfiguration of services around the needs of patients, using virtual organisations, rather than regular costly top-down structural reorganisations. Both contractual frameworks and transparency around outcomes may be required to facilitate cooperation within potentially competitive health economies [111].

Value

Value in healthcare is the health outcome created per unit of money spent [45], therefore maximising value involves achieving the best outcomes at the lowest cost. The measurement of outcomes, along with improving data on costs could, for the first time, allow the routine measurement and comparison of value within healthcare.

The "Value Agenda", outlined by Porter and Lee [112] involves six interconnected components that increase value in healthcare delivery:

1. Organise into integrated practice units
2. Measure outcomes and costs for every patient
3. Move to bundled payments for care cycles
4. Integrate care delivery across separate facilities
5. Expand excellent services across geography

The first five are supported by the final component:

6. Build an enabling information technology platform

Learning Healthcare Systems can support each of these components. 1 and 5 represent the new delivery models discussed in the previous section. Outcomes measurement has been discussed in the building blocks section. Predictive models and decision support systems could enable clinicians and managers to make decisions that improve value, helping to standardising approaches within and across separate facilities. More generally, the Comparative Effectiveness Research and positive deviance use cases have the potential to enable rapid learning and dissemination regarding new interventions and delivery mechanisms that improve value.

Cost Effectiveness and Economic Evaluation

Costs are a major concern for patients, clinicians, providers, commissioners and governments [17]. Claims have been made that, by improving value, Learning Healthcare Systems can help to solve the cost crisis in healthcare [113]. At the same time, the considerable costs of implementing, maintaining and administering the required infrastructure have often been overlooked [51].

Many of the claimed savings have face validity. For example, the potential for earlier diagnosis, more personalised treatment regimes, fewer medical errors and cheaper research methodologies would seem to suggest significant potential for direct and indirect savings. However, there has been little robust economic evaluation of the elements of Learning Healthcare Systems that already exist and little economic appraisal of the elements that have been proposed [60].

There will be some scepticism about potential savings following the failure, so far, to realise the efficiency gains that had been hoped for from EHRs [46, 60]. Economic evaluation and appraisal work is urgently required to complete the case for or against the development of the various components of the Learning Healthcare System.

Recommendation 24	
Detailed economic evaluation of existing and planned elements of Learning Healthcare Systems should be carried out	Research funders, Academics

Regulation of Quality in a Learning Healthcare System

The quality of healthcare is regulated in a variety of ways internationally. Routinely collected data often provides a foundation to that regulation. In England, quality is regulated by the Care Quality Commission (CQC). Attention is focused on the inspections carried out by the CQC, however, routine data is used extensively before and during inspections [114].

Over 200 routinely collected provider level indicators are tracked by the CQC, in relation to acute and mental health hospital providers and GP services. These indicators are aggregated, for each sector, to give a risk banding for each provider. They cover areas as diverse as waiting times, mortality rates and staff survey results. This process is known as Intelligent Monitoring [115].

This information is published [114] and is used to prioritise providers for inspection. In the inspection planning phase, more bespoke indicators are requested from providers, sometimes down to the service level. All of these indicators are combined in a "data pack" relating to a provider. The inspection team use the data pack to guide their inspection and to triangulate findings.

The indicators used for Intelligent Monitoring are sourced from a variety health service databases and represent indicators that are available, rather than the indicators that might ideally be selected. Many providers, such as private mental health providers, do not report enough indicators to produce a sensible interpretation. Even with the maximum available set of indicators, Intelligent Monitoring can only provide 'smoke signals' and comprehensive inspection is required to make a judgement on the safety, effectiveness, responsiveness, compassion and leadership of each organisation.

In the UK, early Learning Healthcare Systems, including analysis of HES data [57] and patient feedback websites [31] are already finding their way into the quality regulation process. Broader implementation of comprehensive outcome measurement would give regulators and patients a much better impression of the quality of providers and even individual services than is currently available. This could allow much more cost effective, timely and targeted inspection. Predictive modelling might take this a step further by actually allowing regulators and providers to identify emerging risks before harm is caused to patients.

Themes for the Future

In 2013, an expert workshop was convened, by the US National Science Foundation, to establish the research agenda for Learning Healthcare Systems [116]. It identified 106 research questions around four system level requirements that a Learning Healthcare System must satisfy:

1. A LHS trusted and valued by all stakeholders
2. An economically sustainable and governable LHS
3. An adaptable, self-improving, stable, certifiable and responsive LHS
4. A LHS capable of engendering a virtuous cycle of health improvement

The coming years are likely to see progress across each of these requirements. This section highlights some of the areas considered to be particularly important.

Much of the discussion in this report may seem like science fiction to clinicians who still work in organisations that use paper clinical notes. In the US, there has been significant adoption of electronic health records over the last five years [46]. The Affordable Care Act and Meaningful Use incentives have meant that adoption has been more complete and that systems have enjoyed more functionality than in the UK [15].

The UK enjoys world-leading use of primary care EHRs, but is behind in the adoption of such systems in secondary care. NHS England have set a goal for the NHS to be "paper-free at the point of care" by 2020 [30]. Progress against this goal is being embedded in the commissioning framework and the quality inspection regime, which will make compliance a high priority. There is likely to be significant progress on this prerequisite of Learning Healthcare Systems. This is expected to bring multiple near term benefits [46] [15]:

- Improved medication safety
- Easier to identify patients who should be included on a more appropriate pathway
- More efficient tracking of care for patients with chronic conditions
- Easier collection of data on standards of care
- Potentially increased efficiency. For example, automation and prompts regarding tests due for preventative measures

These are necessary developments, but they are not sufficient to enable Learning Healthcare Systems. There is a risk that simply creating electronic versions of paper notes will be a costly diversion from creating true sociotechnical Learning Healthcare Systems that can support the use cases outlined in this report.

Participants noted significant uncertainty about what progress might be made in this field over time. They believe that the next five years will see, increasing efforts to learn from routine data, improvement of the related user interfaces, further development of outcome measures and outcomes based reimbursement, progress on interoperability and more acceptance of data sharing by patients [17, 28, 80].

Professor Friedman defines the next five years as the "Institutional Stage", when the following could be achieved [10]:

- The maturation of inter-organisational networks that are now forming (e.g. PCORI CDRNs, CancerLinQ, Cancer Research Network): These will address problems requiring multiple institutions e.g. public health and rare diseases
- Intra-organisational networks or learning organisations will evolve: Large healthcare delivery systems will become learning entities
- Development of the platform components for the LHS
    - Standards
    - Technical components
    - Implementations

- Best practice
- A knowledge base of how to learn

Platform components are important because they will enable the rapid development and distribution of Learning Healthcare Systems. Currently, projects to implement large scale Learning Healthcare Systems, such as TRANSfoRm [117] and FDA Mini-Sentinel must first develop an expensive distributed network infrastructure and rules for its operation, before the Learning Healthcare System functions can be deployed. This is analogous to recreating a new version of the Internet every time a new website is launched. Currently this is only possible for large EHR vendors and well-funded academic collaborations. These organisations cannot, by themselves, develop all of the potential applications that could benefit healthcare.

Once the infrastructure is in place, for example, in the form of truly interoperable EHRs, individual organisations (e.g. governments, providers, research organisations, patient groups, technology companies) will be able to deploy and share innovative Learning Healthcare Systems at low cost. They will also be able to reuse components of systems developed by other organisations, rather than having to reinvent the wheel each time. This would dramatically reduce the cost and time taken to build useful systems in a similar way to which the development of HTTP and HTML allowed anyone to develop and share their own website on the Internet. As more organisations begin developing systems, novel use cases may emerge that have not yet been considered and an ever-broader coverage of health care and other sectors may be achieved [16].

For example, an organisation might develop a new predictive model that enables providers to improve care or reduce costs. Currently, this model would need to be implemented separately in every provider, making uptake unacceptably slow. If the appropriate platform is in place, then the distributing organisation could trade or give away their solution, possibly through some brokering service, so that other organisations could deploy it on their system almost as consumer would download an app. The model could then run against every patient on that provider's system, flagging up results for clinical consideration.

It is not yet clear who will control these platforms. Publicly funded projects, such as TRANSFoRm [117] and FDA Mini-Sentinel [49] are currently developing open source systems. There are private companies, such as IBM [118], who are encouraging developer ecosystems around their core technologies. There are also

public-private, not for profit partnerships, such as QResearch [91]. Large EHR vendors are also developing Learning Healthcare System components that can be rapidly deployed, but only to providers who use their particular system [119]. It is not yet clear whether any of these platforms will become dominant or even widely accepted.

A variety of approaches will probably co-exist and the market structure in each country is likely to be influenced by the political and economic context. For example, innovation in the US has been more market driven than in the UK [15]. There may eventually be a role for market regulators, such as the Competition and Markets Authority in the UK, in ensuring that platform operators do not abuse their position.

Recommendation 25

Independent research, to identify the type of platforms that are currently developing, the breadth of their potential use and any potential market issues that might arise	Research funders, Academics, Regulators

Professor Friedman envisages the five to ten year period as being the "Consumer Stage", potentially characterised by [10]:

- The emergence of the consumer as the most important stakeholder
- The concept of the LHS creeping into consumer awareness. "The consumer will become the glue that will hold the system together", potentially bringing data from a wider range of sources and seeking analysis from multiple providers
- Interoperability will be tackled
- LHSs will scale, becoming true networks of networks
- Governance will emerge
- Privacy concerns will continue, but best practice may emerge for managing this issue
- There may be a move towards a safety culture where errors are seen as a learning opportunity

There is also likely to be significant progress on outcomes measurement, for example, ICHOM have set the goal of covering half of all medical care with transparent medical data within 10 years [53]. With this level of coverage, benchmarking would become wide spread and the public would likely demand transparency.

Given the nature of this field, no participants were prepared to speculate on precise developments beyond ten years, except to say that they are likely to be transformative.

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Figures

Glossary of Terms and Abbreviations

Analytics (Data)	The process of examining raw datasets to derive new meaning/information about the dataset
API	Application Program Interface, how different software components interact
ASCO	The American Society for Clinical Oncology (US)
BCTs	Behaviour Change Techniques
BCW	Behaviour Change Wheel
Behavioural Economics	The use of psychological insights to interpret economic decision making
Behavioural Psychology	The study and alteration of people's behaviour
Big Data	Large datasets that require complex processing, often analysed computationally to reveal patterns or trends
care.data	A programme in England to make anonymised data from General Practice records available via the Health and Social Care Information Centre
CDRN	Clinical Data Research Network (US)
CDSS	Clinical Decision Support System
CEO	Chief Executive Officer
CER	Comparative Effectiveness Research
Claims Data	Data recorded for health insurance payment systems
Commissioner (Health)	Individuals or bodies responsible for planning and funding healthcare delivery
Communication Science	The study of how information is shared
CQC	Care Quality Commission (England)
Data Mining	The process of examining datasets to derive new meaning/information
EHR	Electronic Health Record
Evidence Based Practice	The application of best available research findings to clinical practice
False Negative	A result that wrongly indicates a condition or attribute to be absent
False Positive	A result that wrongly indicates a condition or attribute to be present

FDA	Food and Drug Administration (US)
GP	General Practice/General Practitioner
HES	See Hospital Episode Statistics (England)
HIPAA	Health Information Portability and Accountability Act (US)
Hospital Episode Statistics	Published data from HSCIC containing details of all admissions to NHS hospitals in England, derived from Secondary Uses Services data
HSCIC	Health and Social Care Information Centre (England)
ICHOM	International Consortium for Health Outcome Measurement
IG	Information Governance
IHI	Institute for Healthcare Improvement
Impactibility Model	A model aiming to identify patients for whom preventative intervention is likely to be successful
Implementation Science	The examination of how research and evidence is integrated into healthcare
Informatics	Computer information science, processing data and engineering of information systems
Informed Consent	Permission given with a full understanding of issue
Interoperability	The ability of different systems to communicate
IoM	Institute of Medicine (US)
LHS	Learning Healthcare System
Longitudinal Data	Data collected over a period of time
MDT	Multi-Disciplinary Team
Meta-Analysis	Statistical methods for combining results of multiple studies
Metadata	Data describing other data or the container of other data
N of 1 Trial/Experiment	A trial in which only one individual is involved
Natural Language Processing	The ability of a computer program to interpret human language, e.g. within free text
NHS	National Health Service (UK)
NICE	National Institue for Health and Care Excellence (England)

NLP	See Natural Language Processing
Observational Research	A research technique in which participants are not randomised or pre-assigned to an exposure
Open Source	Software where the original source code is freely available for use and modification
Organisational Theory	The study of organisations and their structures, relationships and interactions
PAS	See Patient Administrative System
Patient Administrative System	Information systems used to record data about care provided to patients
Payors	A company or agency that pays for health services
PCORI	Patient Centered Outcomes Research Institute (US)
PDF	A file format for capturing and sending digital documents
Policy Science	The study of how policy is developed
Primary Care	Healthcare provided in the community as a first point of contact with the healthcare system, e.g. a GP
PROM	Patient Reported Outcome Measure
Provider (Health)	An organisation in the business of preventing or treating illness, e.g. a hospital group
RCT	Randomised Controlled Trial
Read Codes	The standard clinical terminology used in General Practice in the UK and elsewhere
Routine Data	Any data that is collected as part of the normal provision of care
Secondary Care	Healthcare provided by a specialist in a hospital or community setting, e.g. cardiology
Secondary Use	The use of data for purposes other than those for which it was originally collected, such as care delivery data being used for research
Secondary Uses Services	A repository of healthcare data in England
Secure Data Lab	A physical research facility with strict controls on the data that is allowed to leave the facility
Semantics (Data)	The meaning of data
SSRIs	Selective Serotonin Reuptake Inhibitors, a type of antidepressant

Standards (Data)	The rules used for describing, recording and transmitting data
SUS	See Secondary Uses Services
Telemedicine	Remote diagnosis and treatment enabled by telecommunication systems
XML	Extensible Markup Language