# A Framework for Analysing Learning Health Systems:

# Are we removing the most impactful barriers?

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# ABSTRACT

**Objective:** Learning Health Systems (LHS) are one of the major computing advances in healthcare. However, no prior research has systematically analysed barriers and facilitators for LHS. This paper presents an investigation into the barriers, benefits and facilitating factors for LHS in order to create a basis for their successful implementation and adoption.

**Method:** First, the ITPOSMO-BBF framework was developed based on the established ITPOSMO (Information, Technology, Processes, Objectives, Staffing, Management and Other factors) framework, extending it for analysing barriers, benefits and facilitators. Second, the new framework was applied to LHS.

**Results:** We found that LHS shares similar barriers and facilitators with Electronic Health Records (EHR); in particular, most facilitator effort in implementing EHR and LHS goes towards barriers categorised as *human factors*, even though they were seen to carry fewer benefits. Barriers whose resolution would bring significant benefits in safety, quality and health outcomes remain. **Discussion:** LHS envisage constant generation of new clinical knowledge and practice based on the central role of collections of EHR. Once LHS are constructed and operational, they trigger new data streams into the EHR. So LHS and EHR have a symbiotic relationship. The implementation and adoption of EHRs has proved and continues to prove challenging and there are many lessons for LHS arising from these challenges.

**Conclusion:** Successful adoption of LHS should take account of the framework proposed in this paper, especially with respect to its focus on removing barriers that have the most impact.

### **1. Introduction**

Learning Health Systems (LHS) were developed as a vehicle to advance clinical safety, health research and improve patientcentred care, with the added goal to more fully realise the benefits and potential of electronic health records (EHR) [1-3]. The learning component of LHS can occur at multiple levels, including the personal level for individual actors (when educating doctors, patients, caregivers etc.), the team and organisational level (when revising work practice and care pathways), and at the whole system level (when the LHS demonstrates holistic learning). This work primarily focuses on learning that uses knowledge derived from collections of EHR as a digital support system to introduce programmed improvements (when introducing new workflow or decision support) or as automated learning (as promised by the introduction of AI within clinical systems).

Our exploration of LHS began by discovering that much work describing LHS is not actually identified as such within the LHS domain: something we described as the *research community awareness challenge* [4]. To aid researchers in appropriately identifying their works within the domain, this research group provided a taxonomy describing the nine types of LHS commonly observed in the literature, and a unifying framework showing how each type positions within the larger learning health organisation [1]. In this work we focus on the notion of *barriers, benefits* and *facilitators*, their identification, impact and application. *Barriers* are those things that inhibit implementation and use of a particular technology or system, such as health information systems (HIS) and LHS. *Benefits* are the positive outcomes realised by resolving a barrier through engaging a facilitator. *Facilitators* are those interventions described as easing the burden of implementation and use of a technology such as EHR. A facilitator is targeted towards resolving one or more related barriers.

EHR are the enabling technology for LHS. Considerable research has consolidated knowledge on barriers, benefits and facilitators for EHR implementations [5-7]. However, in the LHS domain the picture is considerably different. We believe a gap exists in the research literature in that with the exception of passing reference to LHS barriers, no such consolidation of knowledge on barriers and benefits for LHS adoption could be found. There is reference to a link between EHR barriers and LHS barriers [8] albeit without any analytical framework. It is necessary to develop approaches for analysis and mitigation of

barriers in order to facilitate LHS, just as LHS should benefit patients through the conduct of more precise, individualised medical practice [1]. This paper presents a literature review used to close the research gap and develop such an analysis framework. The main focus of this work is therefore the development and application of that framework for use in analysing and consolidating barriers and facilitators that may be encountered in LHS implementations, and determining whether benefits already identified from implementations of EHR are similar to those that may result from implementing LHS.

In the information systems literature one observed and widely used framework for evaluating implementation challenges is ITPOSMO. ITPOSMO identifies seven dimensions for exploring the gap between a system's design and the reality of its implementation: Information, Technology, Processes, Objectives, Staffing, Management and Other factors [9]. The ITPOSMO framework was originally proposed for evaluating e-government projects, but it has since been used to evaluate EHR projects and help explain why health information systems succeed or fail [10]. Our work extends the ITPOSMO framework to support the comparative analysis of barriers, benefits and facilitators for both EHR and LHS. This led to a new framework, which we call ITPOSMO-BBF, that was then used to explore the literature on barriers, benefits and facilitators for LHS.

Hence, this paper presents results of an investigation into those things that hinder or enable technology use in healthcare environments. In particular, it presents a framework for classifying and analysing barriers and facilitators and contrasting facilitators with the degree of benefit authors have ascribed to them. One of our key objectives is to help those implementing LHS to identify their own major barriers and optimise their efforts with facilitators that will not only address those barriers, but whose impact will maximise implementation success.

The rest of this paper is organised as follows: Section 2 introduces the concept of LHS and presents the background and context of the research problem. Section 3 presents the methodology, particularly the framework developed for addressing the problem. The results of applying that method to the literature are presented in Section 4, along with discussion, before we conclude the paper.

## 2. Learning Health Systems

EHR are repositories of retrospective, current and prospective patient data stored in digital form, with the intention of supporting efficient, quality healthcare service delivery [11]. Those implementing EHR have long complained of slow adoption and limited implementation success rates [12-15]. LHS represents a vision to transform healthcare [16, 17]. This vision includes leveraging recent and ongoing developments in EHRs by developing new knowledge from the ever-increasing amounts of digital routine health data accumulating within them [17, 18], and innovating learning from the slower population-based processes of evidence based medicine (EBM), using rapid identification of new knowledge to deliver precision medicine [17, 19]. Large collections of EHR are the fuel for LHS, giving statistical power to population level insights and the EHR also provides the delivery mechanism for decision support tools that allow clinicians to diagnose and tailor treatment decisions using patient-level data in real time [18]. While EHR have existed in some form for more than forty years, LHS have existed for less than one quarter of that, and the bulk of LHS research and development has only occurred since 2011 [1].

EHR have become almost ubiquitous in healthcare, yet many hospitals and clinics in these countries still employ a mixture of paper and electronic records [20-23]. Among those EHR implementations in the hospital setting, many offer only limited functionality and occur as isolated islands of information, with separate EHRs tied to a particular ward, medical specialty, or care pathway [24]. There have been some spectacular failures to realise the initial promise of EHRs, as with the UK's National Program for IT wherein the NHS failed to deliver effective national hospital EHRs [25]. The design of many EHRs, particularly those from the USA, comes from health service billing software that can conflict with the needs of clinicians leading to both workflow and information presentation challenges in clinical use [26]. The data within medical records typically exists within a specific context and there are some limitations on transferring it to another context, or work needed to support that transfer [27].

Many commercial EHR solutions have proprietary and cost barriers to integration with other systems and sources of health data relevant to the individual patient [28, 29]. With the best intentions, many healthcare organisations have self-inflicted these issues by layering inflexible new technology over existing processes and procedures in the belief that EHR implementation meant simply replacing paper records with electronic systems [23, 30]. The result too often has been implementations of EHR that have failed to improve quality of care, increase efficiency, or reduce healthcare costs [31, 32]. Behind this is a lack of understanding about how clinicians interact with computers, and disagreement as to whether such interaction enables or inhibits patient-centred care [33]. Successful implementation of new EHRs requires clinician- and user-led processes that re-evaluate practices and procedures, with a requisite period of adaption and training for those who will use the resulting combination of new IT systems, documentation procedures and clinical workflows [34, 35].

There is growing recognition that LHS can exist at different scales from department to organisation and across multiple organisational boundaries [1, 2], but in all cases they are limited by the functionality, quality and interoperability of their underlying EHRs [1, 36-38]. Our research is motivated by the belief that an understanding of EHR barriers, benefits and facilitators is essential for those implementing LHS because a successful EHR is a pre-requisite and because the challenges faced in EHR implementation are symptomatic of a range of deeper issues that impact on any major innovation in digital health.

## 3. Method

Our literature review followed the systematic method for identifying benefits and barriers as described in [39]. The method is divided into three phases: *Search and selection*, *Categorisation* and *Analysis*.

#### 1. Search and Selection

There were two parts to the literature search. For EHRs, an initial search used the search terms ("Electronic Healthcare Record" + "Barriers" + "Benefits" + "Facilitating Factors"). A second search replaced "Healthcare" with "Health" while preserving the remaining search terms. We used a combined search engine drawing on the following repositories: Scopia, Science Direct, PubMed, EBSCOhost, DOAJ, and Elsevier.

Articles were included where they presented a scoping or systematic review of EHR implementations, providing analysis and discussion of all three elements: barriers, benefits, and facilitators. Those not meeting these requirements were rejected. For alignment with our LHS literature review [1], articles more than 10 years old were also rejected.

For the literature on LHS, we used the search and inclusion criteria described in our previous paper [1], which used the plain language search terms ("LHS" and "learning healthcare systems") to identify works that presented or proposed a solution self-identified within the LHS domain.

#### 2. Categorisation

Collected literature was divided into two sets: those providing statistical metrics for barriers and benefits, and those that did not. The analysis framework was adapted from the method used in [24] and is shown in Figure 1. Content Analysis and Thematic Analysis [40] and Formal Concept Analysis [41] were used to identify and classify the barriers and benefits described from implementing EHR and LHS.

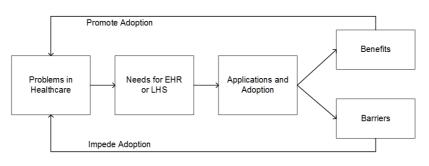


Figure 1: Research Framework

#### 3. Analysis

Finally, we contrasted, compared and analysed the barriers and benefits described in the EHR and LHS literature sets using an extension of the ITPOSMO methodology. This effort sought to identify similarities between facilitating factors from established EHR and LHS implementations. Precedents exist for expanding ITPOSMO to enable additional scope and functionality, including: service quality analysis [42], survey-based study of consumer and public perceptions [43], and Socratic analysis of local e-Government [44]. Our ITPOSMO-BBF model used in this work adopts the aspects and dimensions of the original ITPOSMO framework [9] and combines these with a framework for analysing barriers and facilitators from [45]. The ITPOSMO framework is conventionally used to structure analysis of the gap between expectations and reality in IT projects. For our analysis, we extended ITPOSMO by adding an additional component, benefits, which may be realised directly from either mitigation of barriers or application of facilitators. This additional component, along with representation of the percentage of literature from which each barrier or facilitator was drawn, form the three sections of our ITPOSMO-BBF diagrammatic approach shown in Figure 2.

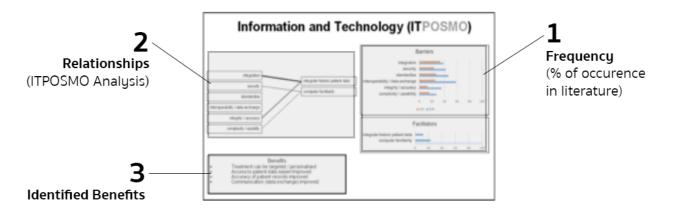


Figure 2: Representation of the ITPOSMO-BBF Diagram Structure

The ITPOSMO-BBF diagram structure: (1) identifies barriers and facilitators to implementation of LHS discussed in the literature; (2) quantifies the relationships between facilitators and specific barriers, and; (3) identifies benefits that authors believe will be realised when these barriers are resolved. While ITPOSMO was developed as a retrospective analysis of projects that have already completed, ITPOSMO-BBF can be used with barriers and facilitators data to understand, plan for and mitigate potential barriers prior to a new implementation of LHS.

Each of the four ITPOSMO-BBF diagrams in the Results section provide key data, including: the percentage of EHR and LHS literature identifying an individual barrier or facilitator; the contextual relationships observed in authors discussion of barriers and facilitators; and the corresponding benefits authors ascribe either to resolving the identified barriers; or engaging

with the described facilitators. The frequency of attention drawn by authors to each relationship between a barrier and facilitator is shown with a weighted line. Figure 3 identifies the relationship between the thickness or weight of each relationship line, and the number of authors who identified that particular relationship.

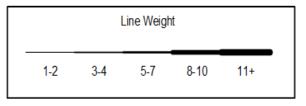


Figure 3: Line Weights and Number of Papers

# 4. Results

#### 4.1 Results of Literature Search

We identified 26 papers from the EHR review that, along with the 230 papers already identified in [1], met the selection criteria. The process for resolving the literature collections for this paper are shown in Figure 4 for EHR, and Figure 5 for LHS.

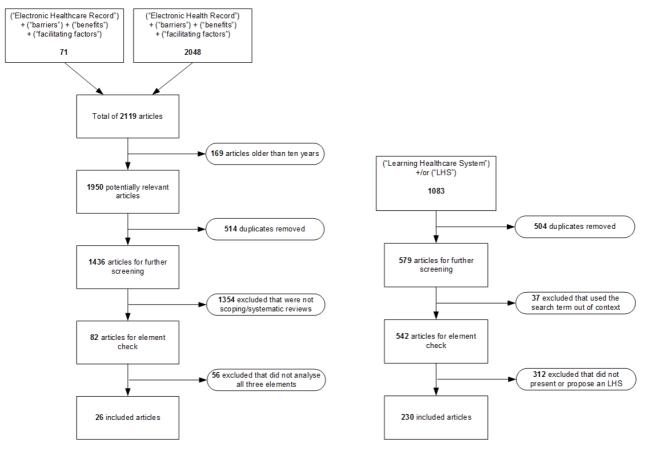


Figure 4: EHR Literature Selection

Figure 5: LHS Literature Selection

Out of 82 scoping or systematic reviews of EHR implementations, 26 provided analysis and discussion on all three of our research elements: barriers, benefits and facilitators. The literature for LHS is currently limited and no scoping or systematic reviews were identified within the selected literature so instead we conducted a thematic review of the content of the 230 selected LHS papers

linked to the three elements.

#### 4.2 Thematic Analysis of Barriers and Facilitators

Content and thematic analysis [40] was used to identify barrier, benefit and facilitator themes, while also examining the context in which authors described themes and the overall frequency of their use within the collected literature. It was possible to categorise many of the themes identified within an overall summary or key theme: a grouping of related *like* themes. These key themes are described in Table 1, which lists the LHS and EHR literature from which that theme was identified, and whether it was discussed by the authors in the context of a barrier inhibiting implementation or use, or if appropriately engaged, would serve as a facilitator for new implementations. For example: in Table 1, key theme 3 concerns concepts of *data standardisation, integration* and *interoperability* has been encountered as a barrier with respect to implementation of LHS and EHR in 14 and 11 papers respectively. Resolving the issues of key theme 3 is also described as a potential facilitator of LHS and EHR in 8 and 5 papers respectively.

#### Table 1: LHS and EHR Literature categorised according to results of Thematic Analysis

	Key Themes	Barrier		Facilitator	
	-	LHS	EHR	LHS	EHR
1	Willingness, interest or motivation to <b>adopt</b> new HIS and frameworks	[12, 13, 46-52]	[7, 53-56]	[12, 48, 57-60]	[61]
2	<b>Training</b> and skills with computer systems and HIS	[52, 62-65]	[66, 67]	[68, 69]	[5, 54, 70-73]
3	Data <b>standardisation</b> , <b>interoperability</b> and <b>integration</b>	[12, 13, 15, 46, 49, 65, 69, 74-81]	[14, 15, 48, 50, 61, 64, 75, 78, 82-84]	[57, 74, 76, 77, 85- 88]	[3, 70, 73, 82, 89]
4	Changes to <b>legislation</b> , <b>policy</b> and government-mandated financial factors ( <b>incentives</b> or <b>penalties</b> )	[12, 48, 49, 60-62, 67, 75, 87, 90-95]	[12, 50, 67, 82, 84, 96]	[48, 61, 82, 85, 91, 93, 94, 97-100]	[6, 14, 15, 61, 83, 86, 96, 101, 102]
5	Capital investment, implementation, maintenance and support costs	[12, 49, 58, 101, 103- 108]	[5, 6, 15, 50, 53-56, 67, 70, 71, 73, 89, 109- 111]	[3, 13, 18, 63, 64, 66, 85, 104, 107, 112]	[6, 7, 50, 56, 73, 89, 109, 111]
6	Impact of LHS on health outcomes and patient-clinician encounter within the patient care <b>workflow</b>	[46, 48, 61, 67, 75, 78, 84, 86, 101]	[6, 7, 53-55, 70-73, 89, 109, 111]	[46, 77]	
7	Privacy, security, data integrity and accuracy	[3, 12, 47-49, 52, 57, 61, 62, 75, 77, 78, 81, 83, 86, 92, 101, 102, 106, 113, 114]	[5, 7, 15, 46, 53-56, 67, 70, 73, 96, 111, 115]	[76, 85]	[6, 65, 73]
8	Approvals and <b>ethics</b> oversight for use of digital health data	[64, 65, 90, 96, 101, 113, 116-120]	[78, 121]	[96, 101]	
9	Organisational <b>culture</b> , management and clinician attitudes to change	[13, 17, 52, 57, 64, 65, 80, 85, 87, 94, 122]	[53, 54, 70, 109, 111, 115, 123]	[3, 69, 80, 87, 124]	[70, 111, 125]
10	Identifying and involving all relevant stakeholders			[3, 58, 87, 105, 106, 118, 124, 131]	[7, 54, 55, 78, 111]

Figure 6 shows that each of the key themes fall within one of the ITPOSMO dimensions, except for key themes four and seven which fall across the boundaries of two domains. It was important to map the key themes to the ITPOSMO elements to reveal where authors were focusing their efforts and identify whether barriers existed for which limited or no mitigation through application of facilitators had occurred.

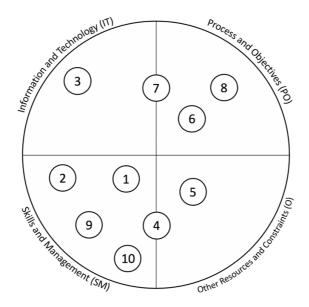


Figure 6: Linking Key Themes to ITPOSMO (Numbers shown identify themes listed in Table 1)

Table 1 maps the literature to the key themes that are significant with respect to barriers, benefits and facilitators. Figure 6 then maps these key themes to the ITPOSMO elements, or domains, which form the basis of ITPOSMO-BBF that this paper uses as its analytical framework.

#### 4.3 Application of ITPOSMO-BBF Methodology

#### 4.3.1 Information and Technology

A number of Information and Technology barriers were described by authors as shown in Table 1. These were most often issues that arose resulting from the stand-alone and bespoke nature of health systems, coupled with a lack of ability to combine systems or data in any simple, inexpensive or meaningful way. Little effort has been expended in devising facilitators to resolving these barriers, even though there are important benefits that could be realised. Figure 7 shows that the most frequently discussed facilitator that authors considered would realise a number of the listed benefits was the seemingly simple act of integrating historic patient data so that any new system presented a complete picture of the patient.

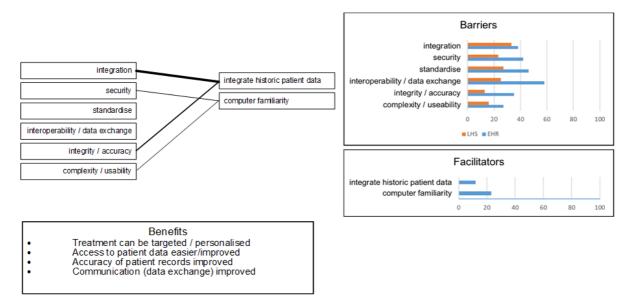
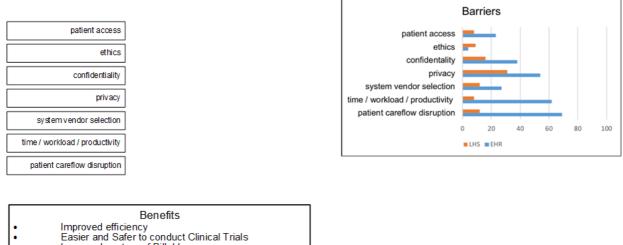


Figure 7: Information and Technology (ITPOSMO)

#### 4.3.2 Process and Objectives

Many of the Process and Objectives (PO) barriers might reasonably appear to fall within the remit of ethicists. The small number remaining were raised by clinicians who work closest with patients, namely nurses and general practitioners. Many of the potential benefits authors felt would result from resolving the PO barriers would appear to deal directly with issues of patient safety and confidence with health services, yet surprisingly no single facilitator was directly attributable to resolving one of the PO barriers and realising the benefits presented in Figure 8.



•	Easier and Safer to conduct Clinical Trials
•	Improved capture of Billables
•	Improved quality of care
•	Improved patient safety
•	Reduction in treatment errors
•	Improved patient privacy
•	Improved health outcomes

Figure 8: Process and Objectives (IT**PO**SMO)

#### 4.3.3 Skills and Management

Most effort aimed at facilitating EHR has gone towards resolving 'human factor' barriers, even though the literature only makes one reference to a benefit as shown in the Skills and Management (SM) element of ITPOSMO in Figure 9. Even in the case of

technical support and training, these were described by authors in the context of developing skills and managing staff resistance, yet no single author reported that any of these facilitators was actually reducing staff resistance to technology or improving adoption rates for EHR. While there is strong interest directed towards resolving adoption issues, the facilitators presently being employed do not appear to have substantially resolved these issues, as the EHR adoption problem persists.

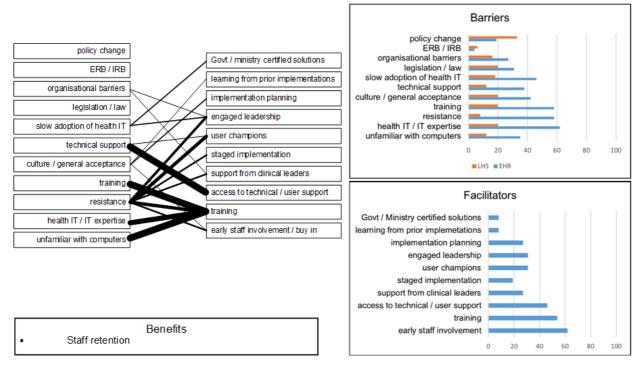


Figure 9: Skills and Management (ITPOSMO)

#### 4.3.4 Other Resources and Constraints

The other resources and constraints (O) element shown in Figure 10 reviews those attributes not falling within the first three ITPOSMO elements, including finance, maintenance, and user and systems support. While financial incentives that had been enshrined in the laws of countries like the U.S. was discussed by more than half of all EHR papers, only three mentioned the potential for penalties for non-adoption contained in the same legislation to be a facilitator. Note however, that none of the three led to the belief that the threat of penalties had helped an implementation of HIS.

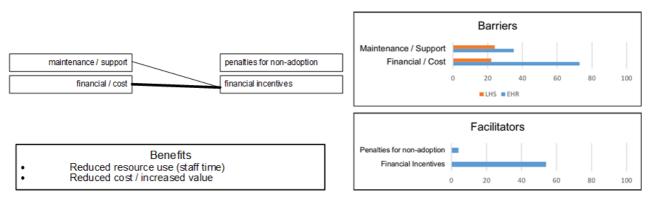


Figure 10: Other Resources and Constraints (ITPOSMO)

### 4.4 Barriers

Almost every author spoke of barriers or challenges in implementing EHR and LHS. Some present as *barriers to entry*, such as the high financial burden to implement and support HIS technology [6, 54, 70] and issues relating to complicated and inconsistent legislation [7, 55, 56]. Others present as *barriers to success*, including the need for data and systems standardisation [7, 54, 73, 109], and issues with interoperability [5, 7, 53] or integration [53, 71]. Many also describe *barriers to organisational culture* [132], such as clinical users and patients expressing negative attitudes towards, and reservations with, the use of computing systems, resistance to potential changes in workflow that it was believed could disrupt the flow of patient care [6, 53, 71] the impact on time management [5, 73, 89], and opposition to the need for training and staff development in HIS use [6, 70, 71]. The potential for issues of data accuracy and integrity were said to arise from the use of HIS, with lasting impacts for patient care and health outcomes [7, 54, 73, 89]. Concerns were expressed that systems producing, storing, exchanging or amalgamating health data would negatively affect patient privacy and confidentiality [5, 53, 70, 109], with adequate data security seen as an unresolved primary challenge [70, 73, 111]. We also identified barriers that arose from overpromised HIS technology and budget overruns that add to negative perceptions of EHR and LHS.

### 4.5 Facilitators

Overcoming barriers has represented a significant challenge for EHR implementations, which is why organisations invest in efforts to identify and engage facilitators that will lead to successful implementations [53, 70, 71]. Some problems are seen as endemic and specific to the IT industry [71], while others require change in health policy and legislation [6, 53, 71]. The literature demonstrates that patience [71], committed leadership [53, 109], systematic planning, and incremental implementation [70, 109] have considerably positive effects [71, 109]. Early collaboration with clinical users [53, 70], provision of general computer and EHR-specific training [54, 70, 71, 109], and engaging user champions to drive acceptance and reduce user frustration [70, 72, 111] were substantial human factors that counter resistance. Resistance is considered significant enough factor that some medical schools mandate or recommend students complete specific training in the implementation and use of HIS [133-135].

### 4.6 Benefits

Organisations contemplating HIS implementation do so with some intention of realising one or more benefits [136]. While it could be argued that any benefit improves the health of patients, even indirectly, this research found that benefits fall broadly into two categories. First, there are those that have a direct positive effect on health outcomes for patients. These include any that increase patient safety [7, 70], reduce harm from treatment or medication errors [70, 73], or improve the overall quality of healthcare [6, 54, 73]. Second, those seeking to improve some metric of healthcare delivery: increasing efficiencies and accountability [6, 54, 70], or reducing waste and over-consumption of resources, which accordingly increases the overall capacity of healthcare systems [6, 70, 109]. A key point was that while LHS are seen to significantly benefit the conduct of many types of clinical trials, EHR were not discussed by any author as doing so to any similar degree. This in spite of the fact that EHRs are the constituent components of all LHS.

## **5. Discussion**

While the benefits of LHS build and significantly expand on those put forward for EHR, the barriers described for both are similar. This confirms LHS are inheriting unresolved challenges from EHR. For this reason, we chose to also investigate the

factors identified as facilitating EHR implementation to assess whether it is possible that these may aid in resolving LHS implementation challenges.

#### 5.1 Acceptance of EHR

A novel causal factor receiving attention is *digital disruption*. Digital disruption is a catch-all term for a range of related issues, described as *the changes facilitated by the introduction of digital technologies that occur at a pace and magnitude that disrupt established ways of value creation, social interactions, doing business and, more generally, our way of thinking [137]. One group in Australia have attributed the failure of more than half of all EHR system implementations to poor understanding and management of digital disruption, failure to understand and manage disruption to clinical workflows, the anxiety this engenders in staff, staff dissatisfaction, and the concerns for the quality and safety of care being delivered during the digital transformation [138]. Elements of digital disruption are seen in almost all of the barriers identified in this work. Facilitators, such as those which stipulate early staff involvement, staff training, and user championing have been promoted for many years as mitigants for these barriers. If the issues raised by [138] as elements of digital disruption are still evident, it is possibly because the selected facilitators do not adequately deal with the barriers identified, or they were not successfully employed by the authors during their hospital's implementation project. Policymakers and clinicians still struggle with barriers that only serve to limit widespread acceptance and adoption of HIS [139-141].* 

#### 5.2 The Legal Position for eHealth Technologies

It is common for the hospitals implementing HIS to not even be party to the contract [142]. This is certainly the case when health departments and state organisations use *centrally negotiated contracts* (CNC) [142]. CNC use impacts communication, placing multiple layers of organisations between clinical user and developer [142]. CNCs prevent HIS users from having proactive roles in negotiating terms in HIS vendor contracts [26], exacerbating issues when they do occur as vendors cannot always be expected to make decisions in the best interests of the delivery of healthcare [26].

All healthcare procedures, tools, products and services come with inherent risks, along with patient-harboured expectations of the level of quality and the standards of care [143]. Legislation on general liability in most countries makes reference to standards a patient may reasonably expect [143]. The questions that are much harder to answer are: whether a duty of care is owed when issues arise out of the use of EHR and LHS; and who owes that duty of care to the patient? While legislation and the common law *Bolam Test* in countries following the English legal tradition deal with situations where treating physicians breach a duty of care, it seems that no current legislation adequately contemplates or addresses general liability or duty of care issues arising from use of the multitude of eHealth products, from the seemingly simple EHR through to the multitude of complicated diagnostic medical devices, implantable technologies, software products, and prescribable mHealth apps [143, 144].

#### 5.3 Enabling LHS

The barriers identified by this study represent the substantive issues impeding implementation and adoption of LHS. However, few authors are asking the right questions, such as: how can health departments achieve subject matter expertise in all technology, legal, compliance and privacy aspects? Nor are they recognising that these issues must be resolved in order to achieve a secure data repository to support LHS [3, 48]. The literature contains abundant discussion of requirements or elements of a solution to one or more of the barriers, mostly revolving around calls for a new and common set of standards [48, 93]. However, we conclude that the absence of universal and effective LHS shows these barriers remain unresolved. While LHS have been developed that are intended to learn from evidence-based literatures, patents, genomics and other non-patient data, LHS can only be successful in their ultimate goal of delivering ubiquitous *individualised* or *personalised* healthcare when data from EHR are made available. Data sharing to create large-scale data warehouses will only occur when clinicians and patients can trust that methods and systems

used are protecting their privacy. Even then, ethics review processes may still impede the realisation of knowledge that can come from LHS.

It became clear during this study that the majority of facilitation efforts are focused on human factors, and more specifically the mitigation of negative aspects arising from a general resistance to change. More facilitators fell within the Skills and Management aspect of ITPOSMO-BBF than any other: an aspect domain that primarily deals with staff, the skills they possess, whether these are sufficient to using the HIS being implemented, and the structure and style of management within the healthcare organisation [9, 42]. While many of these facilitators should lead towards a smoother and more successful implementation, only one benefit was directly ascribed by authors to this aspect domain: staff retention. As a result, the greatest mitigation effort has been focused in an area that on review has least amount of tangible benefit. Other areas described with benefits bringing more significant impact on patient safety, health outcomes and efficiency, such as those of the Process and Objectives aspects are left unresolved. Further research is needed to provide those implementing HIS with a more focused toolkit capable of mitigating a wider range of barriers and enabling delivery of the broadest possible benefits.

It is for those involved in developing HIS to actively participate in counteracting the barriers and changing negative perceptions. The barriers and issues for LHS identified in this research were largely similar to those previously ascribed to EHR, with the key additional issue that good quality EHRs are a necessity to enable LHS [1]. Variations on *Meaningful Use* legislation seen in the USA, UK and Australia are aimed at supporting use of EHR in LHS, motivating expensive government-operated national solutions like Care.data (UK), Shared Care Records (NZ) and MyHealth (AUS). While the cost to implement and maintain standardised EHR repositories in support of LHS may seem substantial, the cost savings promoted as justification for engaging LHS are potentially many times more significant [64].

Many government, academic and private organisations are funding research into novel health technologies aimed at realising the benefits identified by this study. A key theme within the facilitating factors for EHRs is clinician involvement, whether it be through early involvement, or ongoing as HIS are integrated into the patient care environment. Many health technology implementations have lacked the input and involvement of appropriate stakeholder group members. Seeking input from all stakeholders who will impact and be impacted by the HIS is a significant factor in reducing resistance and increasing adoption of technology that has the potential to help many [145]. While there has been a call for clinicians and their training organisations to engage with technologists, those working in the technology sector must be similarly called to seek clinician involvement [145, 146]. Clinicians and technologists must work as co-investigators and leaders in the research and implementation of health technologies. Engaging each other as leaders and stakeholders to influence HIS design and implementation [146, 147].

While this paper starts from the premise that comparative review of the EHR implementation literature can provide a framework for analysis of LHS implementation, with the potential to increase the number of successful implementations, future work to extend this might also include comparison through analysis using other established quality improvement and change management frameworks. Such analysis was outside the scope of this particular work.

## 6. Summary and Conclusion

Prior to this report there had been no study into the barriers, benefits and facilitators for LHS implementation. Each of the EHR reviews used in this study discussed facilitators for successful implementation. We found that EHR and LHS share many similar barriers and facilitators and argue that some or all EHR benefits are relevant to and could be drawn from LHS. This may not be unexpected, as EHR are a key enabling technology for LHS, both are HIS, and LHS are poised to be as disruptive a technology to healthcare as EHR have been. We believe the primary goal in researching and designing new HIS is that they be used to make more precise diagnosis, select personalised treatment options, and improve overall health outcomes for patients. We argue that of all the potential facilitators discussed, ensuring the widest and most appropriate group of stakeholders, including patients, may

be the most significant factor for ensuring success in the implementation of any new health technology.

Learning Health Systems have potential to be one of the major computing technological advances in healthcare. The objective of this paper was to present an analysis from an investigation of the barriers, benefits and facilitating factors identified from the literature of EHR and LHS. This was undertaken in order to create a basis for discussion on how best to expedite successful implementation and adoption of LHS for clinical application. In the methodology for this paper, we used an extension of the ITPOSMO methodology, we termed ITPOSMO-BBF. A key result is that although no prior research has analysed barriers and facilitators for LHS, EHR and LHS are seen to share similar barriers and facilitators. We also found that most facilitator effort in implementing both EHR and LHS involve addressing barriers that are best described as human factors, even though they carried the least number of author-identified benefits. The Process and Objectives barriers which would appear to bring the greatest number of patient outcome, safety and quality benefits remain unresolved, requiring significantly more attention in order to ensure the goals of LHS can be realised.

LHS envisage the constant generation of new clinical knowledge and operational insights based on the central role of clinical knowledge and collections of EHR. Once LHS are constructed and made operational, they can trigger new data streams of knowledge into the EHR, drawn from the analysis of thousands of prior patient interactions contrasted with evidence and experiential knowledge. In this vision LHS and EHR have a symbiotic relationship. The implementation and adoption of EHRs has proved challenging for many organisations around the world and there are many lessons arising from these challenges for LHS. This paper is unique in presenting a framework for, and a systematic analysis using, a new framework based on extending ITPOSMO with consideration of benefits, and consolidation of overall knowledge relating to barriers, benefits and facilitators. This framework simply and succinctly relates barriers to facilitators, and aids those implementing LHS to understand where the significant or important benefits can be realised. ITPOSMO-BBF will aid those implementing LHS to ensure their facilitation efforts can be focused in commensurate amounts to the degree of benefit that comes from resolving each set of barriers.

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#### **Competing Interests**

No author identified a competing interest relevant to this research.

#### Contributors

SM performed the primary research and prepared the first draft. OJ proposed the basis for the framework, refined by SM and KD. Clinical input and review were provided by DB. Model presentation was refined by HP and OJ with editorial review and rewrites by KD, OJ, TG and NF. KD and NF supervised the research. All authors contributed, commented and approved the final draft.

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