# Applying the NASSS Framework to Learning Health Systems

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## Background

The promise of Learning Health Systems is that they will revolutionize healthcare practice. That they will enable personalized proactive services by capturing and analysing clinical data to continuously inform and improve health decision making and practice (Friedman et al., 2010; 2015; Bernstein et al., 2015)

Five years since our original report <<Ref>> and thirteen years since the IoM popularised the concept of a Learning Health System <<REF>>, no nation, region or single healthcare provider has fully realised the promise. Some projects have been discontinued due to limited funding while others lacked an appreciation of the ethical, policy, economic, and technical dimensions that need to be addressed when implementing such systems <<Maniatopoulos et al.>> For these and other reasons, over the same period, healthcare has increasingly been recognised as a complex adaptive system <<Ref Braithwaite>>.

The traditional ‘pipeline’ model of healthcare innovation envisaged progress through taking basic research into prototype, then Randomised Controlled Trial, publication and guideline production, resulting in a change in practice <<Ref Braithwaite>>.

Early Learning Health System thinking recognised the limitations of the traditional pipeline model. Randomised Controlled Trials could not answer all the clinical questions about the variety of real-world patients. Even when evidence existed, it was often not widely employed. Learning Health Systems offered an improvement, showing how routinely collected data could provide answers to more questions and how digital systems could deliver that knowledge to the point of care. The pipeline became a cycle, but it maintained a stepwise nature.

The original definition of a Learning Health System <<Ref IoM>> hints at the complexity of the undertaking – 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.”

Our original report recognised a range of challenges in developing a Learning Health System, based on our study of international exemplars. These challenges included, co-morbidities, technology, interoperability, Data Quality, Information Governance, regulation, ethics, leadership, behaviour change, patient, clinician and organisational acceptability, and value <<Ref 2015 Report>>.

So far, there has been no accepted framework for considering these challenges when planning, implementing and evaluating Learning Health Systems. Most effort has been spent on developing technical aspects of the Learning Health System <<Ref>>. Consequently, we have not seen widespread adoption, scale-up and spread of Learning Health Systems.

## A Framework

In 2017, Prof Greenhalgh et al. <<Ref>> reviewed 28 technology implementation frameworks and integrated the findings with 400 hours of ethnograpghic observation and 165 semistructured interviews, to develop the Nonadoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) Framework for Health and Care Technologies.

The NASSS Framework identifies a range of challenges across seven domains (see Figure A), each of which can be classified as simple (straightforward, predictable, few components), complicated (multiple interacting components) or complex (dynamic, unpredictable, not easily disaggregated into components).

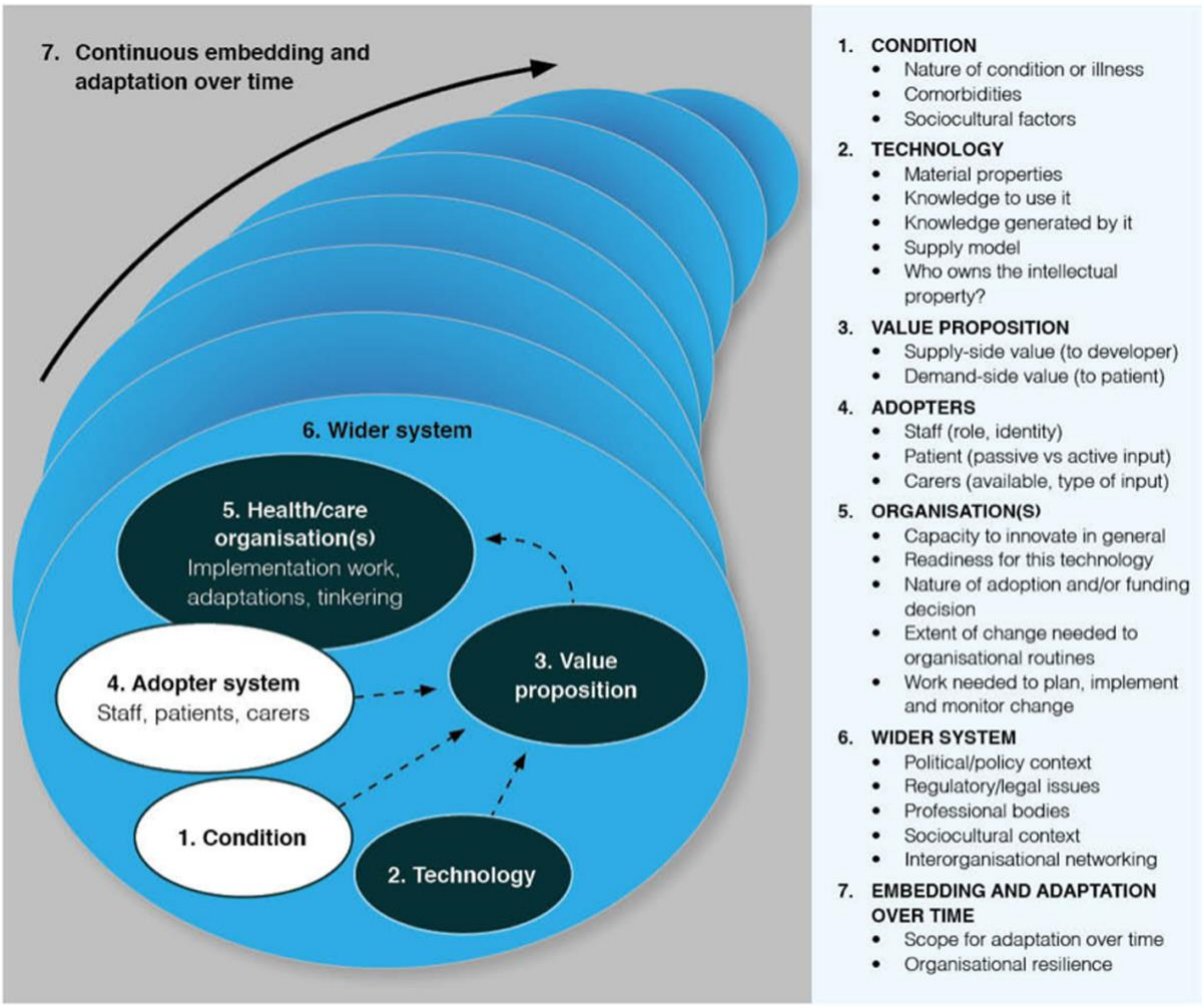

Figure A: The NASSS Framework[1]

This Framework has been operationalised within a series of tools called NASSS-CAT (Complexity Assessment Tool) <<Ref>>. Box 1 describes each tool and when it should be used.

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| Box 1a: NASSS-CAT Tools | Prof Greenhalgh has developed three freely available versions of the NASSS-CAT Tools[2]:<br><br>• NASSS-CAT Long: A sixteen page qualitative and quantitative assessment tool that could be used for project design, due diligence, planning and monitoring. It also includes components designed to shape the project. <Ref><br>• NASSS-CAT Project: A four page quantitative project monitoring tool for tracking, reducing and responding to subjective complexity as it changes over time. <Ref><br>• NASSS-CAT Short: A three page semi-quantitative short version.<Link> |

[1] https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-019-1463-x/figures/1

[2] Link to Trish's presentation.

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| | Each tool guides the user through the process, enabling them to operationalise the NASSS Framework, even without extensive experience. The tools encourage discussion and co-design with the project stakeholders. |

The aims of these tools are summarised in Figure B.

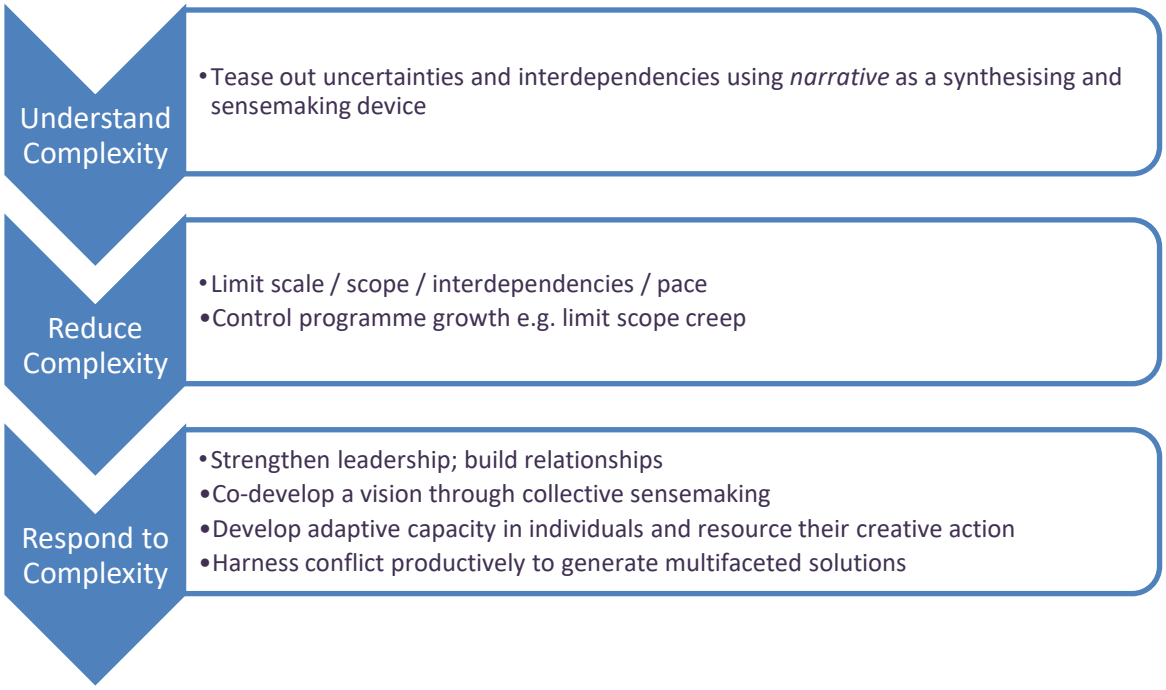


Figure B: The NASSS-CAT (Complexity Assessment Tool)[3]

We conducted a one-day expert workshop, chaired by Prof Greenhalgh and attended by a group of experts in Learning Health Systems and implementation science <<Link to list of attendees>>. This workshop considered how the NASSS Framework could be applied to Learning Health Systems, using four Learning Health System exemplars (Box 2 – 5 below). The workshop outputs, supplemented by relevant literature are outlined in the following sections.

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| Box 2: HealthTracker | A Clinical Decision Support Tool which incorporates ten different clinical practice guidelines into a single on-screen algorithm on the clinician's desktop. It provides estimates of cardiovascular risk, suggests further investigations and lifestyle changes. The tool was deployed in 60 general practices in Australia. A series of evaluations showed some positive impacts from deployment but also wide variations in the tool's use between clinicians and practices. |

[3] <<Link to Trish's presentation>>

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| | https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-019-1463-x |
| Box 3: PatientsLikeME | PatientsLikeMe is a US based web platform that allows patients around the world to share their health related experiences (and outcomes) in a highly structured format. It was established by brothers, Jamie and Ben Heywood, after their brother Stephen was diagnosed with Amyotrophic Lateral Sclerosis (ALS). Since 2011, patients have been able to record experiences living with a large range of other conditions. The platform now has 750,000 members. The data can be used by individual patients or researchers, to learn from the experience of each patient. This data has also been linked to biological data and used to train AI algorithms. Recent studies have shown the platform's peer-peer connections improve self-management and self-efficacy for users. (ADD REF)<br><br>https://www.patientslikeme.com/about |
| Box 4: Evelina London - Children and Young People's Health Partnership (CYPHP) | The Evelina London CYPHP model provides coordinated and tailored care for children and young people that is responsive to their needs. It integrates primary and secondary physical health, mental health, social care and education, through MDT meetings. Anticipatory care is enabled by using a population health model that enables early identification and intervention through primary and secondary care data systems. Combining routine health administration data with patient generated data, via a portal, provides children's health teams with the information to plan care appropriate to children's physical, mental, and social needs. Templates embedded in electronic health records, guidelines, and decision support tools promote evidence-based care and systematic collection of data on quality of care and outcomes. The data generated is combined with other evidence to enable continuous improvement in a Learning Health System.<br><br>The Evelina London CYPHP model covers two inner-city boroughs of South London (Lambeth and Southwark) with poor child health outcomes and high accident and emergency rates for CYP, emergency hospital admission and hospital appointments use <Ref>. Currently, the Evelina London CYPHP model has been implemented across general practices, schools and hospitals within Lambeth and Southwark. |
| Box 5: TRANSFoRm | The TRANSFoRm project developed the technology to enable a rapid learning healthcare system that could improve patient care by speeding up translational research, enabling more cost-effective Randomised Control Trials and by deploying diagnostic decision support. The project brought together a multidisciplinary consortium of 21 partner organisations from 10 EU member |

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| | states and deployed on multiple EHR systems across several countries. |

## Understand Complexity

The following sections outline how each domain can be applied, to understand the level of complexity, with examples from Boxes 2-5.

### The Condition

The clinical scenario at which the technology is aimed, is critical to its likelihood of success. Previous studies have found that only a fraction of potential cases were deemed suitable for the technology because of the complexity of their condition, comorbidities or sociocultural situation. In reality, most patients are an exception to the general model.

The **HealthTracker** tool produced lifestyle recommendations that worked for patients with a structured lifestyle. However, patients at risk of cardiovascular disease often had mental and physical co-morbidities, as well as socio-demographic factors that made it difficult to comply with preventative lifestyle changes.

**PatientsLikeMe** started by covering one serious, fatal, and untreatable condition – ALS. Over time, it expanded to cover a wide range of other conditions, starting with other neurological conditions such as MS and Parkinson's, but later broadening out into other chronic conditions such as mood disorders, autoimmune and rheumatological diseases, as well as oncology and rare diseases. Patients with more serious conditions with fewer treatment options were more likely to engage in the platform continuously. For example, non-terminal chronic conditions such as psoriasis had less uptake. (Ref https://www.mmm-online.com/home/channel/suppliers/how-to-make-healthcare-innovation-work-in-the-real-world-mercks-partnership-with-patientslikeme/). Patients waiting for an organ transplant were highly engaged while on the waiting list, much less so once they had successfully undergone surgery.

**CYPHP** is a model of healthcare for children and young people, as well as a health system strengthening initiative. Therefore it benefits patients and populations. Guiding principles include anticipatory care, bio-psycho-social care, and equity. Services are tailored to need using child-specific data gathered via a patient and parent portal, together with system-level administrative data and registries. CYPHP integrates care for children and young people across primary and secondary care, joining up mental and physical health, and putting prevention and health promotion at the heart of care.

**TRANSFoRm** initially focused on diagnosis in abdominal pain. This is a well-defined field, but one that involves biopsychosocial complexities. The project later focused on colorectal cancer which is more tightly defined.

## The Technology

Usability and dependability have often been cited as reasons for the failure of technology interventions. There has often been a failure to adequately prototype and test systems. There is also a risk that data produced by technologies could be misinterpreted by patients or clinicians, particularly if it does not directly measure the underlying illness. Skills and training requirements can also be a barrier to scale up and spread. Systems that are plug and play / off the shelf and can be replaced by other equivalent systems avoid the risk of lock in or provider failure.

**HealthTracker** had been co-designed with clinicians and was visually appealing, but technical glitches disrupted workflows and slowed down the EHR, so many clinicians stopped using it.

**PatientsLikeMe** established a reliable cloud-based database with an appealing user interface. Complexity was limited by the decision not to interface with Electronic Record Systems. As time went on, more advanced analytical capabilities were developed, but the system remained easy to use, in some ways resembling a dating website.

**CYPHP** The core technologies are population health registers from primary and secondary care, used to identify risk or diagnoses; shared inter-operable clinical notes between primary and secondary care; and a patient or parent portal supporting self-referral, collecting biopsychosocial data for tailoring care to meet need, and providing health promotion and supported self-management information. The patient portal connects to a research database, and with patient or parent consent, participation in formal research evaluation.

**TRANSFoRm** built a decision support system and a user interface from reusable components and used an ontology to overcome the challenge of interoperability between EHRs. Building and then sustaining interfaces with each of the EHRs was the most burdensome task.

## The Value Proposition

Is the particular technology worth developing and for whom does it generate value? If there is no clear business case the private company will be unable to scale and spread. If there is no value to the organisation (e.g. hospital, GP practice) then it will be equally likely to fail. This value can include, benefit to patients or improved efficiency and can rely on reimbursement and payment mechanisms.

**HealthTracker** had a complex and varied value proposition for Government, GPs and patients, making it difficult to assess value as a whole.

**PatientsLikeMe** had great value to the patients who used it. It gave them a sense of community and sometimes of being believed. It also helped them to make decisions about their own care, with many changing clinicians as a result. Despite this, it was felt that charging patients would deter use and hosting advertisements would damage its independence. The data was valuable to researchers, pharmaceutical companies and to the medicines regulator, but only a biased subset of users submitted enough data to be analysed. This was the primary source of funding

(alongside grants) and enabled a peak turnover of multiple millions in revenue per year. For example, it was used to look at the impact from the launch of a new drug. It had limited value to the health system, in which many clinicians ignored the data, although some found it useful to compare their practice with the community.

**CYPHP** demonstrated value to patients and families through more joined up care, reduced delays, better quality and safer care. For example, specialist nurses and doctors work and share data between hospital, primary care, and community organisations to support children. The system also provided access to additional expertise for clinicians, linking clinicians in teams across organisational and professional boundaries. There was concern that additional need might be uncovered that could not be met by existing commissioner budgets. CYPHP's population health approach to early identification and universal coverage has indeed uncovered unmet need; for example 45% of children in the community with asthma have poorly controlled symptoms requiring clinical support. However early intervention and joined up care has delivered cost savings, and the service is cost-effective and commissioned. Moreover the population health management approach has reduced inequalities in access to care; delivering more early intervention to the children who need it most.

**TRANSFoRm** the project could be shown to improve diagnostic accuracy in some situations and was acceptable to patients and GPs, however, there were concerns that it might result in increase demand on other parts of the system if deployed more widely.

### The Adopter System

The staff, patients and carers who have to adopt and continue to use the system are critical to its success. Previous studies have shown that staff sometimes abandon technology because of usability issues, but more often do so because of threats to their scope of practice, fear of job loss or safety/welfare of patients. Patients often abandon technology because usability and the amount of work required of them. Weak social networks or a lack of skills among carers can result in non-use of technology, so these assumptions must be made explicit.

Fewer than one third of GPs used **HealthTracker** for more than half of eligible patients. This was thought to be for a combination of technical and sociocultural reasons, as well as unwritten clinical assumptions. For example, alerts that appear after the clinician has decided to do something can cause cognitive dissonance.

**PatientsLikeMe** was eagerly adopted by patients, reaching 750,000 members. As discussed, adoption varied by condition and also by age and gender. Stage of illness was also important with people more likely to sign up at diagnosis or when their condition changes. Patient activation[4] <<Ref>> was another important factor. Little effort was made to drive adoption by clinicians. PatientsLikeMe did not employ any senior clinicians.

[4] https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/supporting-people-manage-health-patient-activation-may14.pdf

**CYPHP's** Learning Health System adopters include patients, parents, and professionals. The portal was developed from an existing effective portal, and linked to existing EHRs. From a professional perspective there have been a number of issues. Interoperability between primary and secondary care clinical notes and prescribing were challenging to achieve, but practical work-around solutions were found and care effectively crosses boundaries. Concerns about where professional liability and accountability would sit in a multiagency multidisciplinary system were overcome through a partnership with shared governance for the programme, and clinical governance agreed by clinical teams. CYPHP achieved adoption by moving from disruption to embedding new ways of working within business-as-usual systems by a combination of hearts and minds, parent power, clinical common sense, and effective management.

**TRANSFoRm** was only adopted by a trial group. It was clinician-facing and was shown to be acceptable to GPs <<Ref>>.

### The Organisation

The organisation's capacity and readiness for change will influence the uptake and scale-up of technology internally. The decision on whether to fund and support a particular technology will be influenced by the business modelling, yet it is often impossible to predict costs and benefits in advance. Organisational slack can make this process possible. New technology that requires significant disruption to existing routines can create resistance. The work involved in implementation is often extensive and underestimated at the planning stage and there must be a shared vision about what the technology can and cannot achieve. In some cases, innovation can be achieved by joining with another, more innovative organisation.

Poor technical and support infrastructure meant that some organisations could not support **HealthTracker**. There was also a varying capacity for innovation and quality improvement. The size and governance structure also had an impact. Some small practices struggled to support the change while others benefited from streamlined decision making. In other practices, inflexible job roles did not support use.

**PatientsLikeMe** sought, but did not achieve adoption by existing healthcare organisations.

**CYPHP** is a clinical-academic programme functioning as an Active Learning Partnership. Bringing together 3 Foundation Trust hospitals including a mental health provider, primary care providers across two London boroughs, local authorities and public health with commissioners, and a University Institute, as a formal partnership with shared decision-making and governance. Building trust took time but has resulted in profound change being embedded across the system. CYPHP is supported by a mixed funding model, including hospital charitable foundation and local CCGs. A twin track evaluation programme includes both pragmatic NHS service evaluation to respond to provider and commissioner needs for rapid information to support decision-making, and a rigorous research-standard evaluation providing new knowledge about effective models of care for children and young people.

**TRANSFoRm** required cooperation from several EHR vendors and participation was not always a priority for them, resulting in delays.

### Wider Context

The wider institutional, policy and sociotechnical context has often been identified as a key factor in the failure of an organisation moving from demonstration project to a mainstreamed service that was transferable and sustainable. This context can include, policy, political, IG, interoperability, legal, market, IP and regulatory considerations.

**HealthTracker** implemented existing guidelines, but had limited success in securing endorsement from well-established professional societies. Attempts to embed it within the reimbursement model failed because of the novelty of the idea.

**PatientsLikeMe** expanded beyond patient reported experiences and outcomes, to become a biobank. It raised a $100 million investment and a critical technology partnership with a Chinese genetic research firm and grew to 250 staff. Shortly afterwards, a review by the Committee on Foreign Investment in the US (CIFUS) ordered a divestment by the Chinese firm, as part of the wider deterioration in US-China relations. This prompted the rapid sale of PatientsLikeMe in 2019 and the loss of a significant part of the workforce.

For **CYPHP**, Information Governance and public trust have been central. Challenges have included the legislative constructs around competition between providers and pressures to maintain organisational financial balance, though promoting cooperation has been supported by policy, and crucially through building relationships at all levels of organisations: executive, managerial, clinical, administrative. A strong patient focus has been core to success. Ensuring the flow of data between organisations requires a complicated set of data sharing agreements, to enable data flowing from multiple providers, for direct clinical care, service evaluation and research. Intra-organisational liability has also presented challenges, but a Partnership approach, as described above, has enabled effective shared governance at organisational and clinical levels.

**TRANSFoRm** started as an EU funded project. The UK's participation in such schemes following Brexit is uncertain.

### Embedding and Adaption over Time

Things will change during the implementation and beyond. To be successful, the technology must be able to adapt to such change. Likewise, the organisation must have the resilience to respond to critical events and must have a reflexive approach.

**HealthTracker** required knowledgeable staff and was hard to sustain when staff turnover was high. The developer was slow to update the software in response to bugs and over time, competing systems emerged. Eventually though, the regulatory system caught up and created opportunities to align with reimbursements and broader digital strategy.

**PatientsLikeMe** grew and adapted over time, making the transition from start-up to mature business, expanding its user base, generating revenue and investment. Ultimately, it was subject to an unforeseen international event that came close to destroying the business. It continues to operate in a much-reduced form and it remains to be seen how it will develop in future.

**CYPHP** technology and organisational structures have evolved over time, as the network of organisations has grown and funding has become available. The involvement of university partners has ensured flexible learning capability. Being part of the organisational landscape has helped CYPHP to adapt to changes such as new EHRs and new patient administration systems.

**TRANSFoRm** maintaining interfaces with a range of EHRs as they change has been a huge challenge and threatens sustainability.

## Reducing and Responding to Complexity

Prof Greenhalgh et al.[5] have adapted principles first outlined by Lanham et al.[6] so that they are relevant to managing complexity within the development of a Learning Health System:

- Acknowledge unpredictability—designers of interventions should contemplate multiple plausible futures; implementation teams should tailor designs to local context and view surprises as opportunities
- Recognise self organisation—designers should expect their designs to be modified, perhaps extensively, as they are taken up in different settings; implementation teams should actively capture data and feed it into the adaptation process
- Facilitate interdependencies—designers should develop methods to assess the nature and strength of interdependencies; implementation teams should attend to these relationships, reinforcing existing ones where appropriate and facilitating new ones
- Encourage sensemaking—designers should build focused experimentation into their designs; implementation teams should encourage participants to ask questions, admit ignorance, explore paradoxes, exchange different viewpoints, and reflect collectively
- Develop adaptive capability in staff—individuals should be trained not merely to complete tasks as directed but to tinker with technologies and processes and make judgments when faced with incomplete or ambiguous data
- Attend to human relationships—embedding innovation requires people to work together to solve emergent problems using give-and-take and “muddling through”

[5] https://www.bmj.com/content/bmj/365/bmj.l2068.full.pdf
[6] https://www.ncbi.nlm.nih.gov/pubmed/22819737

- Harness conflict productively—there is rarely a single, right way of tackling a complex problem, so view conflicting perspectives as the raw ingredients for multifaceted solutions

## Considerations in applying the NASSS Framework to Learning Health System Projects?

The conclusion of our workshop was that the NASSS Framework and NASSS-CAT could be applied to a broad range of Learning Health Systems and that this would be useful in selecting which projects to fund, designing them, implementing them and evaluating the results. A number of questions were raised and resolved by participants:

- A true LHS is comprised of all 7 domains, not just technology.
- Not all domains are relevant in each case.
- The NASSS Framework could usefully be applied to the whole LHS or separately to the component interventions?
- The NASSS Framework does not have to be used mechanistically, but can act as a reference to guide a comprehensive discussion.
- In discussion, it sometimes felt like important considerations were not covered in the framework, but ultimately, all were resolved to one or more domain during group discussion.