The socio-technical nature of LHSs makes their evaluation a complex undertaking. We convened an expert workshop to identify the issues and formulate some practical guidance for those developing LHSs.

Core questions addressed in the workshop:
- What is the question?
- What would the decision maker, looking at a LHS, want to know before implementing it?
- How could we gather that evidence in a reliable way?
- How do we know that we have done the right thing?

Quantitative economic methods generally compare two or more intervention options in relation to their cost and consequences. Commonly used methods include cost effectiveness, cost-utility and cost-benefit analysis.

With respect to LHS, what should we compare the LHS to?
- Do nothing
- Alternative LHS
- Tweaks to the LHS

RCTs could also be a useful method to evaluate the effectiveness and efficiency of LHSs. Other forms of experimental design may also be useful. For example the use of stepped
wedge design approaches to evaluate the sequential roll-out of LHSs to participants (individuals or clusters) over time. Other approaches might be adaptive clinical trial design. These designs could also be employed to evaluate the effectiveness and efficiency of LHSs by observing participant outcomes on a prescribed schedule, and modifying parameters of the trial protocol in accordance with those observations.

Qualitative evaluation methods generally explore how people make sense of the world and experience events. Qualitative data could be collected through direct or participant observation, interviews, focus groups and from documentary analysis. For example, a qualitative study might explore how it feels to be a patient with a long-term condition and aim to gain insight into how people make sense of and manage these situations. In the context of LHSs a qualitative evaluation could try to explore user acceptability issues and the barriers and facilitators to implementation. A qualitative evaluation of usability and engagement could also inform the potential design and development of LHSs (i.e. what can be built in the software) as well as help to understand if people/patients are managing their condition better and what impact does this have to their quality of life.

One way of thinking about the evaluation of a Learning Health System is to think about the following aspects of the system:

- Structure
- Process
- Outcomes

Defining the outcomes and measures (i.e. feasibility, user experience and acceptability) of the evaluation strategy are the key issues to consider in terms of appropriate methodology.

What would the decision maker, looking at a LHS, want to know before implementing it?

- Risk of introducing inequality / Digital inclusion
- Are there individual and system-wide indicators of performance/harm?
- Metrics beyond health – social care, education, justice system, employment, etc.
- Adoption indicators – will people use it?
- Patient outcomes – will it work?
- How much will it cost?
- Population-level metrics/interventions vs individual level (PLM)
- Population-level national data + local case studies with interviews. Mixed methods
- Routine data might be more timely and less resource intensive than other mixed methods but there are limitations in what data is available?
- May need to use proxy measures for long term outcomes and patient centred outcomes.
- Understand the mechanisms by which the intervention works – can we make it work better?

Considerations when modelling with proxy measures:

- Need to understand the timeframe in which you would expect to see a difference
- Need evidence of downstream impact of the proxy on the real outcome of interest
• This could lead to only looking at very specific measures and missing the broader interactions
• The costs of the LHS may arise in different sectors/part of the health service from the benefits
• How do we compare different outcomes – e.g. what are better exam results worth?
• Modelling may require you to narrow your question down to a very specific active ingredient, which is reductionist. You should therefore be aware of the limitations of the analysis you are undertaking.
• A complex intervention will require a complex evaluation
• We may not be sure whether the data is trustworthy, which could reduce the value for decision making
• Need to be clear about the limitations of the model/evaluation and these must be clearly communicated. It can be very helpful to co-design both the evaluation and how the results are visualised in dashboards, etc.
• Need to think about other external developments that may be having an impact.
• All data used will be subject to some uncertainty. The impact of this uncertainty should be explored as part of the study.

Factors considered by a healthcare organisation appraising an investment opportunity:
- There is an initial decision about whether this is something that our organisation should look at. This may involve a few management meetings. How does something get through the door?
  o May come from within the Trust, clinical leaders may see things developed locally or collaborations elsewhere.
  o National dictates – the response to these varies depending on evidence.
  o Partnerships – with other organisations – ICS/Commissioners/etc.
  o Is there local autonomy with delegated authority to try something?
    o Does it need Trust-wide board approval (most decisions are made below this level). Different level of business case at each scale.
- Who is recommending something is really important, as well as the idea.
- Are we starting from scratch or is this an incremental improvement?
- Not always an all or nothing decision. We might decide to pilot it. This would have a lower threshold.
- We may decide to go all in because there is overwhelming evidence.

Considerations in running a pilot study:
• The service would be rolled out with more limited scope
• Shows the feasibility of measuring the chosen outcomes
• Shows resources used for what is delivered
• Can start to assess the knock-on impact on other services
• Hypothesised impacts can be tested
• Can help to work out which outcomes can be measured
• Input/resources/costs/feasibility of the process of scaling up/acceptability to intended users/what work will it create for users
• What works, for whom, under which circumstances
• Can lay out and test the hypothesis?
A logic model is one option

- Think about how and what data to collect
  - What is already out there?
  - Can you use routine data?
  - It is often worth including some qualitative work (interviews/focus groups) to gain a deeper understanding

A logic model can be a useful tool for planning the evaluation strategy. It represents a hypothesis or ‘theory of change’ about how an intervention works. They can help prioritise and structure data collection and analysis to explore the main aspects of an intervention and relationships between them. This data can be used to help to explain how the intervention works to achieve its outcomes, or sometimes why it does not work.

There are pre-screening questions:
- Does this seem to impact the things which we are interested in?
- Does the team seem credible?
- Is the evidence from a credible source?
- Nuts and bolts of the evaluation are less important for some decision-makers

The social context of innovation is important. Sometimes the political context influences development, sometimes it is something else.

Organisations are good at asking for evidence, but often take the result on face value, without considering the methodology used to generate it.

Considerations when evaluating Learning Health Systems as they change over time:
- What it achieves and the appropriate outcome measures may change
- Available data may change
- It may be appropriate to change the methodology
- It may be necessary to use intermediate outcomes, if you are clear on the mechanisms through which they impact end goals. This can involve significant uncertainty
- We should not be prescriptive about which methodology/framework to use, but rather offer a range of options
- Focus on the skills and knowledge that people need to have to do this
- The QI community may argue that traditional evaluation methodologies are not suitable and using a counterfactual would be impractical. A PDSA cycle (or Lean) approach might be more appropriate – can be used at different scales. Traditionally at local level with rapid cycles, but can work at larger scales. Based on manufacturing industries, so has measurement built into it. The question is whether you can generalise from that and whether it is reliable, as it is uncontrolled
- Ethnographies of practice – the study of how people make sense of what they are doing and how this influences how they work (Nick Collenni – Warwick University). Dave Snowden, use of narrative in sensemaking

When considering rolling out an intervention in a different environment, for example, from Health, into Social Care, consider whether the different settings have homogenous
The NASSS framework might be a helpful framework for comprehensively identifying similarities and differences between settings.

It may be important to get different sectors (e.g. health, social care, housing, voluntary sector, etc.) involved in the evaluation:
- They should be able to focus the evaluation on their work
- IG and data sharing could be a challenge

You need to identify the active ingredients (and actors) in a complex intervention and include them in the evaluation:
- Then we need to think about whether these active ingredients have interactions that we might fail to capture. Talk to the people delivering the interventions, they probably know where the interactions lay.
- A more comprehensive evaluation will require more time and resource. It may well need to be outsourced. Need to decide how important it is to pick all these interactions up. May require an NIHR programme grant and this could take 7-9 years. Generally wouldn’t work for a LHS. Might be useful to draw out important principles.
- Participatory design method¹ Who is in the constellation of care. Helps you to identify all of the actors. This must explore a specific context in detail.

An organisation may well need external support, from a University, Consultancy, Government or other organisation, to do an evaluation. Common reasons to bring in an external organisation include:
- To provide extra capacity
- To provide expertise that the organisation does not already have inhouse
- To provide an independent perspective and reduce conflicts of interest