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The Lean Assessment Process (LAP) Methodology: An iterative and multi-disciplinary method for identifying clinical needs, assessing technology acceptance and a precursor for early economic evaluation and adoption strategies

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Aim

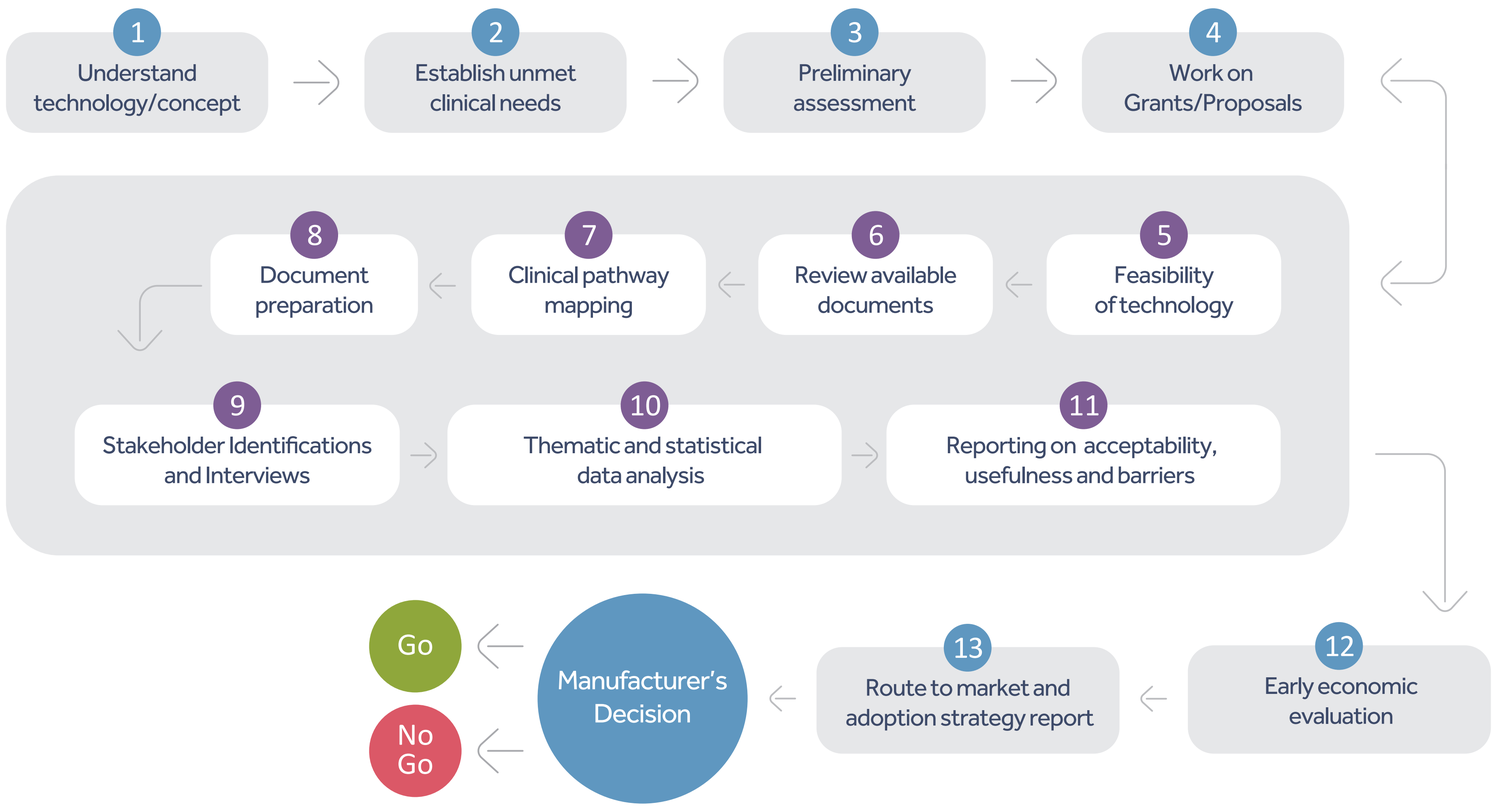
The aim of the study was to validate an iterative and multi-disciplinary Lean Assessment Process (LAP) methodology for identifying clinical needs, assessing technology acceptance and act as a precursor for early economic evaluation and adoption strategies.

Objectives

- To assess the potential impact of implementing this LAP methodology for identifying the clinical needs and usability of the proposed health care innovations
- To inform on the technology acceptance and barrier to adoption of the health care innovation by using LAP methodology
- To report on key insights from stakeholders and the summary to be used to form the basis for a subsequent early economic evaluation from LAP report
- To help accelerating the overall development of healthcare innovation to be adopted by NHS by using LAP methodology.

Lean Assessment Process Methodology

- The Lean Assessment Process (LAP) methodology engages experts in human factors and health economics, working closely with innovators, to engage with key stakeholders in care pathways.
- The study establishes the feasibility of the technology by a preliminary assessment of the design, value and evidence reliability in the early stage.
- LAP provides a structured method for achieving prioritisation of the unmet clinical needs and stakeholder preferences in the care pathway.
- The LAP methodology (Figure 1) is a process for providing structured input for healthcare innovators from stakeholders across the care pathway. By establishing the clinical need and usability (or not) of a product (or product concept) in care pathways, LAP informs a preliminary assessment of the product design, value, and evidence requirements.
- The LAP methodology focuses on generating an understanding of the potential benefits and acceptance of an innovative medical technology to facilitate adoption by the National Health Service (NHS) in England
- Stakeholder identification and engagement plays a central role, which underpins the identification of unmet clinical need. Where possible, early economic modelling quantifies the potential value to the healthcare systems.
- Key insights from payers and healthcare professionals are obtained and thematically analysed to form the basis for early economic analysis and route to market study, which includes key elements that need to be considered when designing a clinical trial or real-world evaluation and cost-effectiveness analysis.
- The value proposition of a healthcare innovation is informed by all the stakeholder opinions. Go/no-go decisions are underpinned by the different dimensions of evidence, namely clinical need and potential.
- Overall LAP study helps in supporting the manufacturers in deciding and refining the directions of development of their health technologies.



Methods

The LAP methodology was used to investigate and to explore the potential utility that the introduction of non-invasive imaging using multiparametric magnetic resonance (mpMR) can offer in the immediate and on-going management of patients with autoimmune hepatitis (AIH).

LAP methodology was used as an early Health Technology Assessment tool to explore the stakeholder's acceptance and barrier to adoption of introducing mpMR in the AIH care pathway to replace liver biopsy. The study also informed on the clinical need and usability for the use of mpMR in the AIH pathway to provide input for early economic evaluation.

Key insights from the health care professionals and payers were obtained by conducting the semi structured interviews. The interviews were thematically analysed to obtain stakeholders views on the unmet need, clinical usefulness and acceptance of mpMR in the immediate and on-going management of patients with autoimmune hepatitis. An understanding of stakeholder views on the potential impact of the proposed technology was developed into a subsequent early economic evaluation . Decision-analytic models were developed and tested to compare the indicative cost of monitoring AIH patients using the standard care versus mpMR scans highlighting the clinical need for the proposed technology.

The early economic model compared the indicative cost consequences of using a different method versus standard testing for a particular patient group within a healthcare setting. The early analysis reported on the cost benefit and validated the clinical pathway informing the optimum route to market and adoption strategies.

Results

The LAP report formed the basis for decision-analytic model to compare the cost and to assess the affordability of using mpMR as an alternative to liver biopsy for management of patients with AIH.

The LAP study was able to provide the required information to form the basis of the early economic analysis, thereby LAP can be used as a precursor for early economic evaluation. Additionally, the report also provides information on the adoption strategy including key elements needed to be considered when designing a clinical trial or a real-world cost-effectiveness analysis in future.

Conclusions

The LAP methodology, using a structured process for achieving prioritisation of clinical needs and usefulness and provided useful information for a subsequent early economic analysis. LAP can be used as a rapid tool to evaluate the initial value proposition and as a precursor for early economic evaluation and adoption strategies.

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