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Title

The role of early health economics within implementation science: the case of innovative hearing treatments

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Abstract

Background: Early health economic modelling (HEM) is increasingly used to inform the design, pricing and market access of health innovations before clinical efficacy is established. How this early economic evidence is generated, interpreted and acted upon by industry, regulators, clinicians and government bodies remains poorly understood. Implementation science offers structured pathways for planning adoption, but existing theories, models and frameworks treat cost and value as largely implicit or underspecified. Innovative hearing treatments (IHTs) for sensorineural hearing loss, including drug, cell and gene therapies currently entering the clinical domain, exemplify this gap. This paper aims to extend the Structured Pathway for Real-world ImplemeNTation (SPRINT) framework, a practice-oriented implementation science tool derived from Normalization Process Theory, by integrating early HEM as an explicit domain alongside its implementation science stages and strategies.

Methods: We adopted a framework-development design. Two previously published early HEM studies of IHTs, in age-related and idiopathic sudden-onset sensorineural hearing loss, served as worked examples through which to explore interactions between health economic methods and each SPRINT stage. Drawing on the authorship team's expertise in health economics, implementation science and clinical practice, we mapped the analyses conducted in these models onto the relevant SPRINT stages and strategies.

Results: The resulting extended framework, ECONO-SPRINT, adds a health economics domain to each of SPRINT's six stages, specifying where health economics and implementation science strategies can be generated and interpreted together and where each needs to stand alone. The worked examples show how headroom, scenario,

sensitivity, threshold, value of information and budget impact analyses align with successive stages of the implementation pathway and expose a persistent gap between cost-effectiveness and affordability that neither discipline addresses alone.

Conclusions: ECONO-SPRINT is a theoretical development amenable to prospective instrument development and evaluation. Although generated through an IHT case study, we argue that the framework is transferable to other high-cost, potentially curative innovations facing the same tension between cost-effectiveness and affordability. Future work should apply and test it prospectively, generating health economic and implementation science evidence together as an innovation progresses through its lifecycle.

Keywords: Hearing loss; innovative hearing treatment; gene therapy; early health economics; health technology assessment; implementation science; Normalization Process Theory

Contributions to the literature

- Researchers in implementation science and health economics increasingly call for the two fields to work together, but most guidance stays general and few papers show how it can be done in practice
- Existing implementation frameworks mention costs and resources inconsistently, and most economic methods for implementation focus on late-stage costing rather than the early years of an innovation's development

- This paper demonstrates integration by combining a specific economic method (early health economic modelling) with an established, evidence-based implementation pathway (SPRINT)
- The result, ECONO-SPRINT, offers a practical structure for planning and evaluating adoption prospectively, across an innovation's lifecycle

Background

Implementation science '*is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care*'.[1] A substantial body of work now specifies the implementation strategies through which this is achieved, including Proctor et al.'s recommendations for naming, defining and operationalising strategies,[2] and the Expert Recommendations for Implementing Change (ERIC) compilation of 73 strategies.[3] Building on this, the recently published Structured Pathway for Real-world ImplemeNTation (SPRINT) framework organises 22 implementation strategies derived from Normalization Process Theory (NPT) into six sequential stages, offering a practice-oriented and theoretically informed route from mobilisation through to normalisation.[4,5] However, economic constructs remain inadequately represented within implementation theories, models and frameworks (TMFs). A narrative review of 26 commonly used TMFs found wide variation in how costs, resources, funding and benefit were considered. It also showed that implementing an innovation displaces existing financial and non-financial resources.[6] Where cost does appear, it is typically positioned as one implementation outcome among several,[7] rather than as a vital domain for planning adoption.

Health economists have developed methods to determine whether the value of a novel strategy is worth its extra costs. Cost-effectiveness of a novel strategy is increasingly recognised as a determinant of whether organisational decision-makers adopt an intervention. Taking a different approach implementation costs also have a more prominent role with tools such as the Cost of Implementing New Strategies (COINS) map implementation resources onto defined implementation stages. [8] Standardised approaches to evaluating the cost-effectiveness of implementation programmes themselves have also been proposed, reconciling value of implementation and policy cost-effectiveness perspectives.[9] A recent scoping review identified 42 such methods, grouped into policy cost-effectiveness, value of information and value of implementation, mixed methods and costing approaches. It concluded that no single method captures all relevant implementation considerations. [10] Implementation research generally focuses on *how*, and at *what cost*, an intervention can be delivered and sustained in practice. Meredith et al.'s recent call to action extends this by identifying opportunities for integration across the whole innovation pathway but does not specify which economic methods should be integrated with which implementation activities.[11]

Health economic modelling (HEM) is one such method and is suited to the early stages of an innovation's lifecycle. HEM is a method of economic evaluation that uses decision-analytic models to synthesise available evidence on a healthcare pathway and estimate the expected costs and health outcomes of an innovation relative to the current standard of care.[12] Whereas health economics and reimbursement are traditionally considered only once clinical efficacy is established,[13] early HEM draws on assumptions, expert

opinion and analyses such as headroom, scenario, sensitivity and threshold analysis to explore whether, and under what conditions, an innovation could be cost-effective. This informs an innovation's design, further research, service delivery, feasibility, market access and pricing,[14] and establishes '*commercial viability*' by identifying key value drivers, characterising uncertainty and enabling early dialogue with commissioning bodies.[15] As early HEM simulates the healthcare pathway, it also captures how an innovation may disrupt existing practice, a question central to implementation science. Policy is moving in the same direction, as in 2022, the UK's National Institute for Health and Care Excellence (NICE) introduced the Early Value Assessment (EVA) framework to rapidly assess new technologies addressing unmet need.[16] Yet how this early evidence is generated, interpreted and acted upon by industry, regulators, clinicians and government bodies remains poorly understood, and no implementation science TMF currently makes early HEM an explicit component of adoption planning.

Innovative hearing treatments (IHTs) for sensorineural hearing loss (SNHL) provide a timely worked example. Hearing loss is projected to affect nearly 2.5 billion people by 2050.[17] Current treatment of SNHL, the most common form of HL, is limited to hearing aids and cochlear implantation, which amplify sound but do not make it clearer nor restore natural hearing.[18] With public and private investment, new approaches to hearing loss are being developed, such as drug, cell and gene therapies aiming to protect, restore or regenerate the hearing system. Recently, gene therapy has shown clinical efficacy in a rare genetic form caused by mutations in the otoferlin gene, sparking further investment in the field.[19,20] Two early HEM studies co-authored by this team modelled IHTs for age-related (AR) and idiopathic sudden-onset (IS) SNHL across the full clinical

pathway, estimating cost per Quality-Adjusted Life Year (QALY) against standard of care.[21,22]

This paper aims to extend the SPRINT framework by integrating early HEM as an explicit domain alongside its implementation science stages and strategies. Using the two IHT models as worked examples, we explore where health economic methods interact with each SPRINT stage and propose ECONO-SPRINT as a theoretical development amenable to prospective instrument development and evaluation.

Methods

Design

We adopted a framework-development design, in which an existing implementation framework was extended through the structured application of two published early HEM studies as worked examples.[21,22] The design is conceptual as the models were used retrospectively to examine where, and how, health economic activities interact with each stage of the SPRINT implementation pathway. SPRINT's six stages (start with mobilisation, fit-to-setting, ensure staff participation, enable action, work through the learning loop, and achieve normalisation) and their 22 strategies provide defined points at which health economic activities can be located within implementation processes.[4]

Health economic modelling in innovative hearing treatments

Two early HEM studies were selected as worked examples because they were conducted before clinical efficacy data were available and, between them, employed the principal early HEM analyses.[21,22] Both used decision-analytic models in which patients moved between SNHL severity health states, populated with assumptions and expert opinion in place of trial data, from a UK NHS perspective. The analyses undertaken comprised

model conceptualisation with stakeholder input, headroom analysis, scenario and sensitivity analysis, threshold analysis, value of information analysis and budget impact analysis. This range allowed interactions to be explored across the whole SPRINT pathway rather than a single stage, and the authorship team's involvement in both models gave access to the reasoning behind each analysis.

Theoretical development process

The framework was developed in four steps. First, two authors (AH, an implementation scientist, and MS, a health economist) worked jointly through each SPRINT stage and its strategies, tracing each strategy back to the NPT construct from which it derives to make explicit the relevant implementation work. For each strategy, MS then specified the health economic evidence that implementation work would require, and the analysis that would generate it. Second, these activities were written up as a draft health economics domain. Third, AH worked through the two early HEM studies to identify how and at what point in each model's development the identified activities had been undertaken, drawing on the published reports and the authorship team's knowledge of the modelling process. Where an activity mapped to more than one stage, this was retained and noted rather than forced into a single allocation. Fourth, for internal validation, the draft framework was reviewed by AS, an Ear, Nose and Throat (ENT) surgeon and lead co-author of the HEMs. The final draft was then shared with all authors, including CM, the SPRINT framework's lead developer, for fidelity to its underlying NPT constructs, and MR and NM for accuracy of the health economic and clinical content. Discrepancies at each stage were resolved through open dialogue across successive iterations of the framework until consensus was reached among all authors. Deriving the

health economic domain from SPRINT's strategies before examining the worked examples ensured that activities were specified by the implementation work they serve, rather than by the reporting within the two HEMs. The full mapping, linking each health economic activity to its SPRINT stage and strategy, is presented in Table 1 and Figure 1.

Results

See Table 1 for the 'Extended SPRINT Framework: Health Economics Methods Mapped onto Implementation Science Strategies'.

Stage 1 – Start with mobilisation

The first SPRINT stage converts intentions into action through developing a formal plan, explicitly defining ownership and authority, and securing resources prior to implementation. Introducing IHTs and their associated ear delivery systems in practice requires significant resource investment, and an early HEM addresses this by estimating health effects, costs, and health opportunity costs. At a national level, decision-makers face political pressure from clinicians, patient groups, incumbents, and other interest groups over which interventions get adopted. However, HEM has the advantage of surfacing these competing interests and making the underlying reasoning behind decisions more transparent. Therefore, IHT developers and commissioners must decide whether an early HEM is conducted internally to inform the business case, or independently for an objective, best-practice assessment. The Landry et al. (2022) model, validated by 24 professional stakeholders, illustrates one solution.[21] The model incorporated a measure of functional impairment into every SNHL health state, since stakeholders reasoned the traditional pure-tone average classification did not reflect patient experience. Building a credible early HEM is itself a mobilisation exercise,

mapping and consulting stakeholders to model clinical pathways, comparators, and target populations for cost-effectiveness analysis. As part of that process, engaging commissioners from the outset appears an effective means of identifying and overcoming barriers that typically slow implementation.

Stage 2 – Fit-to-setting

The second SPRINT stage distinguishes between fixed and adaptable components of the innovation, understands pathway disruptions; and allocates resources. In health economics, an innovation is 'fit-to-setting' when there is demonstrable unmet need in the current care pathway, and plausible scenarios exist for cost-effectiveness within that setting. Early health economics operationalises this through headroom and scenario analysis, evaluable before clinical or market data exist, requiring only the care pathway and cost structure, not an actual price, effectiveness estimate, or marketed product.

Headroom analysis estimates the maximum room for improvement in a care pathway modelling a hypothetical 'perfect' technology (100% effective, zero cost), against current standard of care. The resulting incremental net monetary benefit (iNMB) represents the ceiling value a future innovation could capture – a monetary expression of unmet need. A small ceiling leaves minimal room for added value; a large ceiling justifies further investment. In Mandavia et al. (2020), our headroom analysis produced an iNMB of £39,032 (95% CI: £21,103-£56,962), driven by a QALY gain of 1.61 and cost savings of £6,805 per patient, indicating that IHTs could meaningfully improve current NHS care pathways. In Landry et al. (2022), the headroom analysis yielded an iNMB of £20,017 (95% CI: £11,299–£28,737), driven by a QALY gain of 0.78 and cost savings of £4,451 per patient. Together, these analyses demonstrate the first component of fit-to-setting: both

identify, in NHS-specific monetary terms, that current UK hearing care pathways leave room for improvement in outcomes and costs, and both indicate the maximum cost at which an IHT would remain cost-effective.

Whilst headroom analysis only shows that an opportunity exists as opposed to whether it can be realised, scenario analysis maps the conditions under which a health innovation remains cost-effective. In Landry et al. (2022), we modelled six scenarios with two variable contextual dimensions: the population eligible for treatment based on HL severity; and the level of recovery achieved, from full recovery with normal hearing versus recovery by one or two health states (mild, moderate, severe, and profound). Restricting eligibility to patients with more severe HL, reduced the iNMB as fewer patients benefited from the IHT; yet, modelling only partial recovery reduced the iNMB even more sharply, since most of the financial value in the headroom analysis was derived from QALY gains and downstream cost savings associated with full restoration of hearing. Mandavia et al. (2020) similarly used scenario analysis and found that the cost-effectiveness for ISSNHL therapeutics depended strongly on the age of the patient at treatment, severity of HL, and identification of specific circumstances such as early diagnosis and treatment initiation. Both studies demonstrate that cost-effectiveness for IHTs, in an NHS setting, is highly sensitive to the severity distribution of initial HL health state across the patient population and the extent to which it restores hearing function.

Stage 3 – Ensure staff participation

The third SPRINT stage aims to strengthen shared buy-in from all stakeholders (commissioners, government organisation and funding bodies, leadership, clinicians, other hospital staff), supported by communicating value and hands-on leadership.

Firstly, a business case prepared early would support national and organisational decision-makers in planning for the adoption of IHTs in future budgets and in redirecting funds as necessary. Whilst a conventional business case is built on established efficacy, a confirmed price and a budget impact estimate, an early business case is necessarily indicative. It draws on headroom and scenario analysis to show whether an innovation could plausibly offer value, and under what assumptions, so that decision-makers can anticipate its arrival. Economic evidence of this kind addresses the reluctance of leaders to commit funds without financial justification,[7] and makes explicit what remains uncertain and when that uncertainty is expected to resolve. In health economics, this translates to early budget impact analysis for identifying 'cash-releasing' efficiencies that enable resource reallocation, so the innovation is affordable and embeds successfully. Cash-releasing benefits directly affect the operational decisions surrounding new interventions, and their realisation needs explicit acknowledgement through distinguishable resource allocations.

Secondly, early HEM identifies which components of the IHT, implementation process and healthcare pathway will improve, and therefore, how stakeholders will benefit from it, and what it will cost. In this context, benefits relate to patient outcomes, such as improved health state in HL; whilst costs provide insights into how existing healthcare pathways will be continued, adapted or disrupted. HEM's confidence intervals for expected outcomes present a degree of certainty that may be persuasive for a clinically trained and often sceptical audience. The Landry et al. (2022) headroom analysis reported above illustrates this, with confidence intervals around the iNMB, QALY gain and cost savings per patient.[21] Its scenario analyses showed IHT benefits concentrated

in severe and profound SNHL health states, allowing clinicians to consider benefit estimates specific to their own caseload. Together, these figures, including uncertainty, can support staff acceptance of an IHT. However, HEMs only typically reflect a health-system payer perspective. Additional factors, such as policy and governance, can be understood through a multi-disciplinary approach with implementation science.

Stage 4 – Enable action

The fourth SPRINT stage consists of integration work aligning skillsets, capacity, relationships, communication and organisational support.

The interaction, communication and knowledge exchange between the different stakeholders in the adoption and uptake of IHTs is critical. Implementation strategies highlight the importance of training and education across clinicians and other hospital staff, leadership and service users.[5] However, in health economics, training costs are typically not considered. Discussions are ongoing about including the 'learning curve', the time taken for staff (clinicians and team members) to learn an innovation and the respective changes associated with its implementation during which it is used below its full potential, in early HEM. This remains a live, underdeveloped area, discussed mainly for complex interventions such as new operations.[12] More broadly, as HEM operates at a national or system level, neither headroom nor scenario analysis captures organisational-level barriers to staff and patient engagement with IHTs. Therefore, training costs are typically excluded, as they are considered temporary and lack clear funding allocation. The same applies to the small changes in organisational processes that training usually brings with it, such as adjustments to shift patterns, referral routes or documentation; these are rarely costed separately, yet in combination they represent

the real resource demand of enabling action, in accordance with the NPT construct of Collective Action.[23]

Neither of our models included training or organisational change costs in the implementation of IHTs.[21,22] As both are integral to implementation and sustainability, future HEM may include the cost of implementation as a distinct category, treating training and process change as a continuous overhead so that the resources needed to embed an innovation are planned for rather than absorbed. Further methodological developments in this area are needed.

Stage 5 – Work through the learning loop

The fifth SPRINT stage aims to iteratively refine the innovation and delivery through monitoring and feedback. HEM conducted in the earlier stages of an innovation's development are built on assumptions and placeholder estimates for components and parameters that cannot yet be observed, such as efficacy, uptake, complication rates and actual costs. At this SPRINT stage, lifecycle health economics – re-running the HEM as real-world data emerge – replaces initial assumed values and establishes how the innovation's estimated value changes as a result. Sensitivity, threshold and value of information analyses are important tools to monitor these developments and adjust implementation strategies. Sensitivity and value of information analyses can determine if further investigation is required, whilst threshold analysis identifies the point at which the innovation becomes cost-effective. Our IS-SNHL sensitivity analysis showed that uncertainty in utilities for certain health conditions influenced cost-effectiveness and should therefore be further researched in greater detail.[22] Updating a HEM as evidence is

generated during the development process, should be considered within the wider learning loop and feedback stage.

Stage 6 – Achieve normalisation

The final SPRINT stage assesses the extent to which the innovation has become embedded, or normalised, in everyday practice. It was agreed that the hypothetical timeframe between Stage 5 and Stage 6 of the SPRINT framework marks a transition point as analysis shifts from early and exploratory health economics to a confirmatory procedure. Early HEM, as observed in Mandavia et al. (2020) and Landry et al. (2022), is exploratory, as it estimates what a hypothetical IHT could be worth, to guide research and development, pricing strategy, and implementation planning, but it remains non-committal and non-binding. Assessing normalisation, concerns a technology that has already been in use and has passed the institutional health technology appraisal process (in the UK, principally NICE technology appraisal), thus determining whether, and under what conditions, a health system is obliged to fund it.

However, funding can hinder normalisation and wider adoption of IHTs, such as when certain clinical or cost-effectiveness evidence remains uncertain at launch or the impact on the budget is large. To address this, payment strategies are operationalised to support healthcare systems in accessing high-cost IHTs. Payment strategies include negotiating price based on market size and buying power; advance purchasing guarantees securing lower unit costs via that large-volume purchases; government subsidies tied to purchasing promises stimulating supplier competition; graduated payments linked to demonstrated effectiveness; and patient co-payments. How far these strategies are used in practice is difficult to assess, as negotiated pricing arrangements between NHS

England, NICE and manufacturers remain confidential, even to the committees appraising the evidence. As in Stage 3, budget impact and value of information analysis could determine cash-benefit realisation over time, informing government and industry pricing discussions relevant to the specific innovation and implementation process. In turn, this could predict levels of normalisation and sustainment as well as spread and scale.

Combined, these results integrate health economics and implementation science within ECONO-SPRINT. Figure 1 translates the framework onto a timeline of the innovation lifecycle, showing where each discipline's methods apply and how they inform one another as an innovation progresses from early development through to real-world adoption and scale-up.

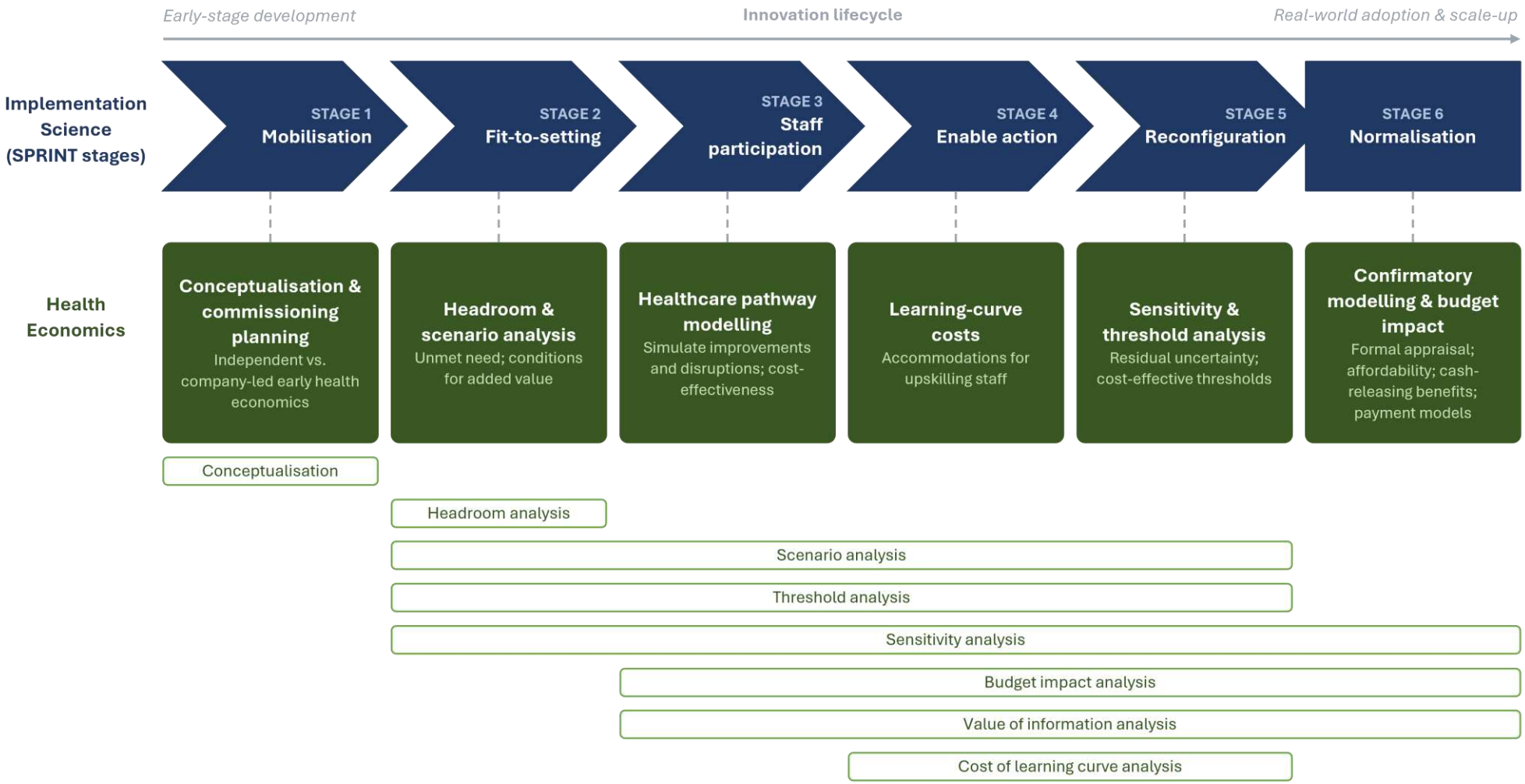
Table 1. Extended SPRINT Framework: Health Economics Methods Mapped onto Implementation Science Strategies

#	Implementation Science Domain	Health Economics Domain
Stage 1		
SPRINT · Start with mobilisation		
HEALTH ECONOMICS · Conceptualisation & commissioning planning		
1	Develop a formal implementation plan: who will do what, when, under what decision rules.	**Conduct interviews with multi-level stakeholders**, including commissioners, and **conduct health economic modelling conceptualisation**. *Links to strategy #7*.
2	Define who is responsible for each element of implementation and with what authority.	Assign responsibility and authority, with reference to commissioners, whether the early health economic model will be conducted independently or internally. *Links to strategy #6*.
3	Identify and secure the required resources and check that the time is right and the setting is ready.	Identify and plan resource allocation based on changes to healthcare pathway, as part of model conceptualisation. *Links to strategy #6*.
Stage 2		
SPRINT · Fit-to-setting		
HEALTH ECONOMICS · Headroom and scenario analysis		
4	Systematically identify which elements can be adapted to your setting, and how to preserve the core components that make the intervention work.	Conduct **headroom and scenario analysis** to determine under which circumstances and settings the innovation is cost-effective. *Links to strategy #5*.
5	Understand exactly how the intervention will disrupt existing pathways, routines, and workflows and plan for that disruption rather than discovering it.	**Conduct health economic modelling** to simulate the healthcare pathway, accounting for how the innovation may disrupt existing ways of working. *Links to strategy #3, #4*.
6	Appoint and properly resource champions to drive implementation and spread operational knowledge of the intervention.	Appoint and resource implementation 'champions', and train them to report on data required for health economic modelling. *Links to strategy #2, #3*.
7	Identify and address the practical and organisational barriers that stop staff and patients engaging.	Identify system level economic barriers along the healthcare pathway. *Links to strategy #1, #5*.
Stage 3		
SPRINT · Ensure staff participation		

HEALTH ECONOMICS · Healthcare pathway modelling		
8	Show team members, concretely, how the change improves practice.	**Conduct health economic modelling,** demonstrating improvements in practice through simulating the healthcare pathway. *Links to strategy #10*.
9	Agree what success looks like and how it will be judged.	Health economics basis success on cost-effectiveness at a national level. *Links to strategy #4*.
10	Make explicit who the intervention benefits - patients, staff, the service - and communicate the value honestly.	Modelling demonstrates improvements for patients and added value through simulating the healthcare pathway. *Links to strategy #8*.
11	Keep leadership hands-on and visible to sustain commitment.	Involve commissioners and national level stakeholders in early health economics and communicate findings downstream.
Stage 4		
SPRINT · Enable action		
HEALTH ECONOMICS · Learning-curve costs		
12	Make sure the intervention works without destabilising other core activities.	*Links to strategy #5*.
13	Establish trust, reliability, and protection through relationships and collaboration.	*Links to strategy #8, #9, #10, #11*.
14	Provide the skills, training, and tools people actually need to perform the new practice.	Undertake a **cost of learning curve analysis,** taking into account increased cost and reduced quality of life depending on recipient
Stage 5		
SPRINT · Work through the learning loop		
HEALTH ECONOMICS · Sensitivity and threshold analysis		
15	Track participation, fidelity, and outcomes.	Monitoring health economic data throughout the implementation process. *Links to strategy #4, 5, 8, 14*.
16	Use planned, organised, structured channels to interpret the data and reflect on staff and patient experience together.	*Links to strategy #13*.
17	Keep reactive and informal channels open.	*Links to strategy #13*.
18	Revise workflows and components based on what is learned.	Iteratively **update health economic model** at different timepoints**,** using relevant analyses such as **sensitivity, threshold and value of information analyses**, during the implementation process. *Links to strategy #15*.
Stage 6		
SPRINT · Achieve normalisation		

HEALTH ECONOMICS · Confirmatory modelling and budget impact		
19	Train staff to collect, interpret, and use implementation data themselves.	*Links to strategy #6, #14, #15*.
20	Update team structures and role descriptions to reflect the new way of working.	*Links to strategy #1, #2, #3, #4, #5, #7, #18*.
21	Revise policies, guidelines, and governance so the change is institutionally embedded.	**Conduct formal health economic evaluation** and submit to relevant body. Relevant body will determine appropriate payment schemes or managed entry agreements based on cash-releasing benefits, budget impact and value of information analyses. *Links to strategy #1, #2, #3, #4, #5, #7, #18*.
22	Define what counts as successful normalisation, and for whom.	Determine level of cost-effectiveness and affordability. *Links to strategy #9, #19*.

Figure 1. SPRINT framework stages and the health economics domain across an innovation's lifecycle



*Note: SPRINT stages are non-linear. Later stages may expose weaknesses in earlier ones, requiring iterative revision.

Discussion

ECONO-SPRINT

This is one of the first responses to Meredith et al.'s call for closer integration between health economics and implementation science.[11] Their call was framed in general terms, around the potential for integration to optimise implementation strategies, generate robust value-for-money evidence and improve care delivery. This paper responds by demonstrating integration rather than proposing it. ECONO-SPRINT combines a specific economic method, early HEM, with a workable, theoretically informed and evidence-based implementation pathway that tracks a defined developmental timeline from early, pre-market evidence generation through to formal adoption and normalisation.

ECONO-SPRINT encourages prospective, joined-up use of both disciplines from the outset of adoption planning, rather than treating health economic evidence as something layered on retrospectively.[11] While SPRINT's stages and strategies are conceptually distinct from one another, layering health economic activities across them reveals considerable overlap, with a given analysis often speaking to more than one stage and strategy at once. This convergence points to the value of a multidisciplinary structure that makes explicit where health economic and implementation science evidence can be generated and interpreted together, and where each instead needs to stand on its own.

Meredith et al. (2026) also note that stronger integration may help clarify the equity impacts of implementation strategies and guide their design toward more equitable care and outcomes.[11] Equity was not a primary focus of this paper, but ECONO-SPRINT offers

a structure through which such considerations, for example whether unmet medical need or affordability differ across patient subgroups, could be systematically incorporated in future work.

Viewing early health economics through the SPRINT pathway reorganises the findings in a manner that neither discipline could achieve alone. From a health economics perspective, the findings highlight a set of technical disputes such as determining the maximum costs of the innovation in which it could still deliver added value, how affordability differs from cost-effectiveness, and which payment model best manages risk. For implementation science, the same findings describe a set of implementation tasks such as agreeing what counts as legitimate evidence, assigning responsibility for producing and interpreting it, and building the organisational trust needed for stakeholders to execute implementation. The health economics domain makes visible work that existing implementation science TMFs largely leave implicit or underspecified.[6] For example, NPT and the Theoretical Domains Framework include no dedicated economic domain;[4, 5, xxiv] the Consolidated Framework for Implementation Research names cost only as a single construct within its Intervention Characteristics domain;[xxv] and the ERIC strategies includes a financial cluster that remains also underspecified.[3] Instead, ECONO-SPRINT treats cost and value as a structured set of analyses, following the same staged, leadership-dependent pattern SPRINT identifies elsewhere in implementation.

Contextual implications

The impact of HEM on adoption decisions is also dependent on national context. NICE's EVA assumes that producing an early economic model is itself sufficient to inform

adoption decisions, yet our findings show that a model's influence depends on how it is built, who is involved in building it, and whether stakeholders trust the assumptions behind it. The EVA will therefore require mechanisms for managing the political and organisational dimensions of economic evidence. This policy landscape continues to evolve. The £20,000 per QALY gained threshold under which the two worked examples operated,[21,22] has since risen to £25,000.[xxvi] Additionally, the recent NHS 10 Year Health Plan introduced the National HealthTech Access Programme (NHAP) alongside EVA to fast-track reimbursement for select high-impact technologies.[xxvii] However, NHAP's promise of accelerated, system-wide reimbursement does not close the cost-effectiveness–affordability gap identified in this paper, as a technology fast-tracked under NHAP could still arrive at a price individual commissioners cannot fund, reproducing the funding mandate problem in accelerated form. If anything, NHAP's pace makes the case for an explicit health economics domain within SPRINT more urgent, since faster decisions leave less time to build stakeholder trust in the evidence.

Implications for industry and decision-makers

For industry, the findings suggest that pricing strategies for IHTs cannot be set from a cost-effectiveness model alone, as a price point that clears the NICE threshold may still be unaffordable for the commissioner expected to fund it; and affordability concerns of this kind are a distinct, separable risk to manage alongside cost-effectiveness. Novel payment strategies, particularly graduated and outcomes-linked models, are one means of managing this risk, but they require investment in long-term outcome monitoring infrastructure that does not yet exist for IHTs, and that industry and the NHS would need to build jointly. For UK decision-makers, the gap between a NICE funding mandate and

deliverable funding at commissioner level points to a need for earlier, more explicit business case development, informed by the same early HEM this paper describes, so that affordability is assessed alongside cost-effectiveness rather than discovered afterward. The confidentiality of price negotiations reinforces this, as neither commissioners nor appraisal committees see the outcome of negotiations, each party arrives with its own private assessment of value. Therefore, early threshold analysis provides that assessment before negotiations begin and supplies the evidential basis for graduated or outcome-linked payments as EVA and NHAP accelerate access decisions. Furthermore, to be successful, legal and regulatory frameworks within healthcare systems will need to evolve to accommodate these types of novel payment strategies. This includes governance frameworks for data sharing and quality standards for data collection, analysis, and interpretation.

Strengths and limitations

This study uses a cross-disciplinary approach that does not sit within the established conventions of either health economics or implementation science. Credibility was supported through investigator triangulation across three disciplines; theoretical triangulation between NPT and decision-analytic modelling; and the iterative review process, which provided interpretive flexibility consistent with recent conceptualisations of researcher creativity as an analytic resource rather than a source of bias.[xxviii] However, as the worked examples and the framework's authorship overlap, the potential for confirmation bias cannot be excluded. This was mitigated through iterative reviews from authors not involved in the initial mapping, including the SPRINT framework's originator.

Additionally, the worked examples are drawn from a single therapy area and innovation type, with ECONO-SPRINT generated through retrospective application of the two published models. ECONO-SPRINT's transferability to other therapy areas and interventions, and its value in the prospective role for which it is designed, should be tested in future research.

Conclusion

This paper extends the SPRINT framework by integrating early HEM as an explicit domain alongside its implementation science stages and strategies. Using two early HEM studies of IHTs as worked examples, we have specified where health economic and implementation science evidence can be generated and interpreted together, and where each needs to stand alone, across the innovation lifecycle. The resulting framework, ECONO-SPRINT, gives stakeholders a shared, prospective language for adoption planning from the earliest stages of development, and is a theoretical development amenable to prospective instrument development and evaluation. Although generated through an IHT case study, we argue the framework is transferable to any high-impact innovation facing the same tension between cost-effectiveness and affordability. As EVA and NHAP accelerate reimbursement decisions, the case for this integration will only grow more pressing.

List of Abbreviations

Age-related (AR)

Confidence interval (CI)

Cost of Implementing New Strategies (COINS)

Early Value Assessment (EVA)

Ear, Nose and Throat (ENT)

Expert Recommendations for Implementing Change (ERIC)

Hearing loss (HL)

Health economic modelling (HEM)

Incremental net monetary benefit (iNMB)

Idiopathic sudden-onset (IS)

Innovative hearing treatments (IHTs)

Quality-Adjusted Life Year (QALY)

National HealthTech Access Programme (NHAP)

National Health Service (NHS)

National Institute for Health and Care Excellence (NICE)

Normalization Process Theory (NPT)

Sensorineural hearing loss (SNHL)

Structured Pathway for Real-world ImplemeNTation (SPRINT) framework

Theories, models and frameworks (TMFs)

Declarations

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Availability of data and materials

All data generated or analysed during this study are included in these published article that can be found in the reference list: May et al. (2026); Landry et al. (2022); and Mandavia et al. (2020).

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

AH: conceptualisation; draft; review. MS: conceptualisation; draft; review. AS: Expert consultant; review. CM: Expert consultant; review. MR: Review. NM: Review. All authors read and approved the final manuscript.

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