Health Innovation East Midlands

Local change, national impact

Introducing Innovation to the NHS

Tim Robinson

13th May 2025

An innovation ‘docking station’

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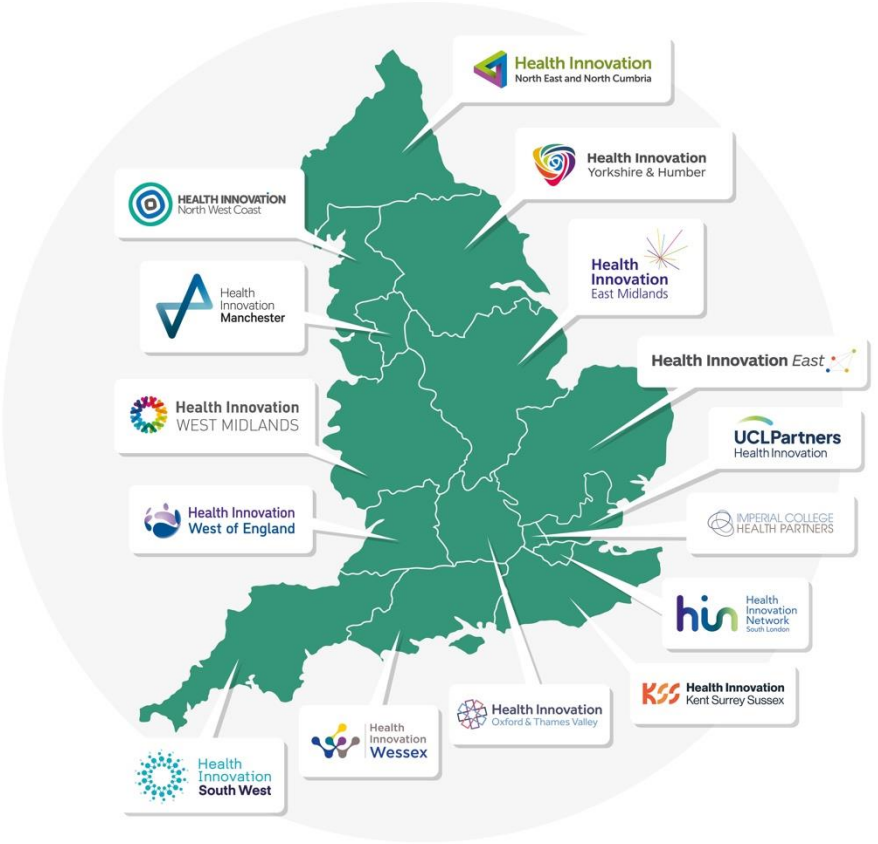
- HIEM is one of 15 Health Innovation Networks (HINs) – commissioned by the NHS to operate as the innovation arms for our ICSs and partners.
- We tackle national problems, with local understanding.
- And local problems, with national expertise.
- Each health innovation network is fully-embedded in their local health and research ecosystem.
- This drives economic prosperity and growth in all parts of the country and ensures that everyone benefits from innovation.



What is health innovation? Our definition …

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The development and implementation of new ideas, technologies, and processes to improve the quality and efficiency of healthcare services – finding better ways to deliver care, improve patient outcomes & enhance the overall patient experience.

There are several types of innovation used in the NHS – they fit into three broad categories:

1. **MedTech medical devices and equipment** – e.g., diagnostic tools, monitoring equipment & surgical instruments that help health professionals diagnose and treat patients more effectively.
2. **Digital health technologies** – e.g., mobile apps, telemedicine platforms & electronic health records that help patients and health professionals to access and share information more easily.
3. **Service innovation** – e.g., new approaches to delivering care which help to transform the overall patient experience.

Innovation can be incremental, transformative, or disruptive / radical:

- **Incremental Innovation** is an improvement to something that already exists within the health and care system that positively affects the delivery of care.
- **Transformative Innovation** applies to a new application of something that already exists.
- **Disruptive or radical innovation** applies to something that is completely new that responds to an unmet need in the health and care system.

NHS structure – a changing picture

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DHSC

NHS England

ICB

Acute Hospital Trust

Community Provider

Mental Heath Trust

GP Practice

PCN

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Health Innovation Academy

Register for our free on demand courses for all healthcare innovators

- Short courses covering the innovation pathway
- Innovator success stories
- Ask the Expert sessions

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Further information

- **Email:** healthinnovation-em@nottingham.ac.uk
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- **Bluesky:** @healthinn-em.bsky.social
- **X:** @Healthinn_em
- **Sign up to our newsletters:** healthinnovation-em.org.uk/updates
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NHS Innovation Service
Supporting healthcare innovators

Office for Life Sciences

NHS

Innovate Local

MedTech & HealthTech

The Criticality of a clear Regulatory Strategy

Al Mills
Business Development Director

SEQUEL CONSULTANTS LTD

Connecting you to the Regulatory expert you need

AL MILLS

Today we'll cover…..

- Regulatory Risk
- Intended use
- Regulatory Planning
- Regulatory Strategy
- Demonstrate inextricable link with Commercial Strategy

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Simple Example on Regulatory Risk – Scalpel

more risk = more evidence

Claimed Intended Use	EU Risk Classification	Regulatory Risk Profile
Cut paper as part of crafting	Not a medical device	Cannot be used for a medical purpose – no medical harm
Shave hair as part of surgical prep	EU Class I	Low risk of harm
Cut into skin as part of surgery	EU Class IIA	Medium risk of harm
Cut into brain tissue as part of surgery	EU Class III	High risk of harm

Intended use & Product Classification

Your Product classification is a combination of

- Patient risk
- What the product does
- Where and how it's used
- Who is operating it
- What clinical indication it's targeting
- What your marketing materials say

A clearly defined Intended use is critical

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Regulatory Planning – *prepare to pivot*

- Consider Patient Risk/ Intended Use/ Marketing Claims
- Consider multiple territories
- Time to Market
- Pivot? MVP? Alternative first market?
- Best Pathway?
- Regulatory Burden
- Qualifying evidence
- Time and cost

Core components of a Regulatory Strategy

- Robust Product Classification
- Deep dive on the intended market
- Gather clinical evidence from investigations/ post-market data
- Details of every regulation & standard required for approval
- Document Complete Regulatory Pathway

This is a key document when looking at grant or commercial funding submissions

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Right steps in the Right order

1. ***DEFINE YOUR PRODUCT*** carefully and ensure that your regulatory strategy and requirements have been considered at the beginning of your project
2. ***SEEK HELP*** from a regulatory professional to ensure rules interpreted correctly
3. ***ENGAGE WITH CUSTOMERS*** to ensure that the product materially satisfies a real need and will be used as you expect
4. ***PLAN, UNDERSTAND & COMPILE*** exactly what information & technical documentation you need to meet the requirements
5. ***PREFERABLY*** in a Medical Device ***QUALITY MANAGEMENT SYSTEM***

DON'T BE AFRAID TO ASK

CONNECT WITH THE EXPERT YOU NEED

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Q & A

www.sequelconsultants.org

Evidence for NHS Success

Max Bardwell

13th May 2025

Health Tech Enterprise

HTE supports innovators across the whole Innovation Development Pathway

Driving Innovation

- IP & Commercialisation Strategy
- User Insights & Market Research
- Training & Entrepreneurship

Generating Evidence

- Funding & Investment
- Health Economics
- Regulation & Human Factors

Delivering Growth

- Net Zero
- Real-world Evaluation
- Global Market Access

Health Tech Enterprise

Lower Costs are no Longer Enough for Procurement

Procurement Routes into the NHS vary according to the product, the value of the product, the care pathway and the target user. A summary of procurement routes for the for companies selling to the NHS are below.

- Government tenders and contracts
- National procurement frameworks and NHS tenders
- Selling via NHS Supply Chain
- Selling through collaborative purchasing arrangements
- Selling direct to NHS organisations *e.g.* Trusts / ICSs
- NHS initiatives for new innovations

An additional, indirect route to the NHS, is, of course, to sell/licence your products and services to an existing supplier to the NHS.

Value Proposition

Vs.

"How much does this cost?“

"Does this reduce the overall cost of care?"

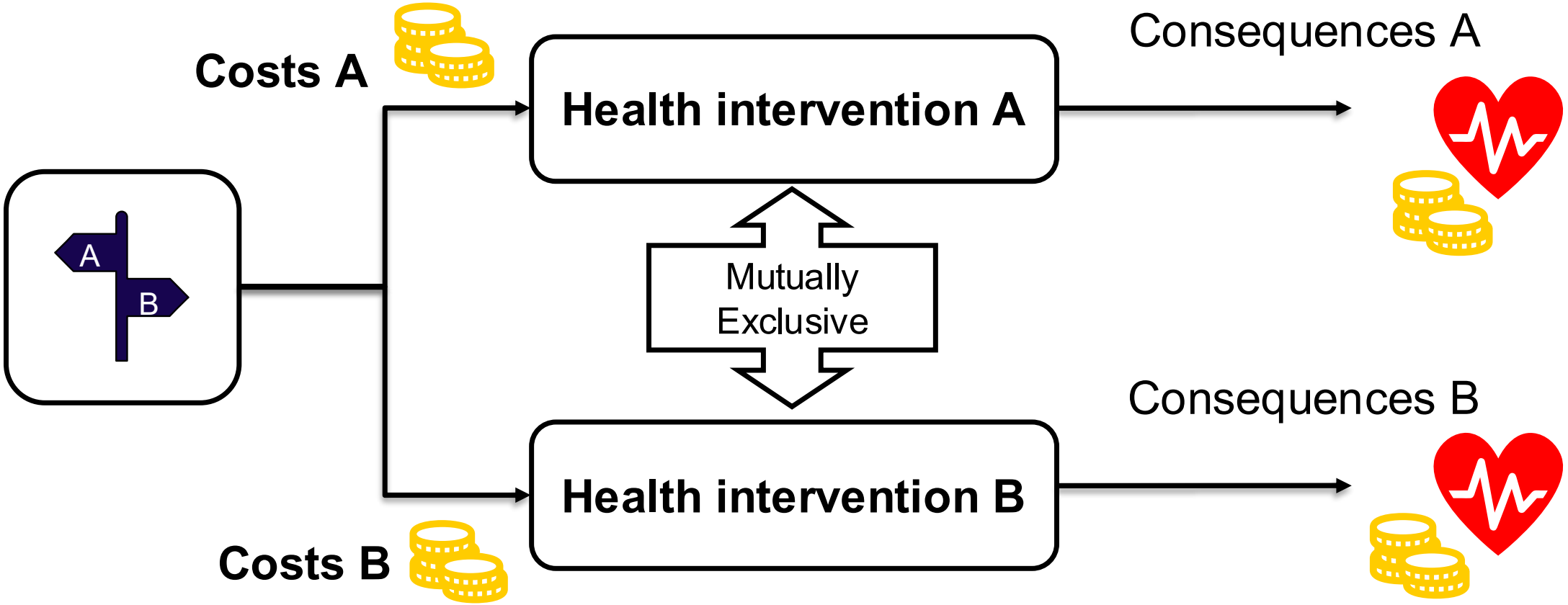
What additional benefits or value can you deliver to the NHS?

How can you show evidence of the value of your product?

The Use of Health Economics and why it Matters

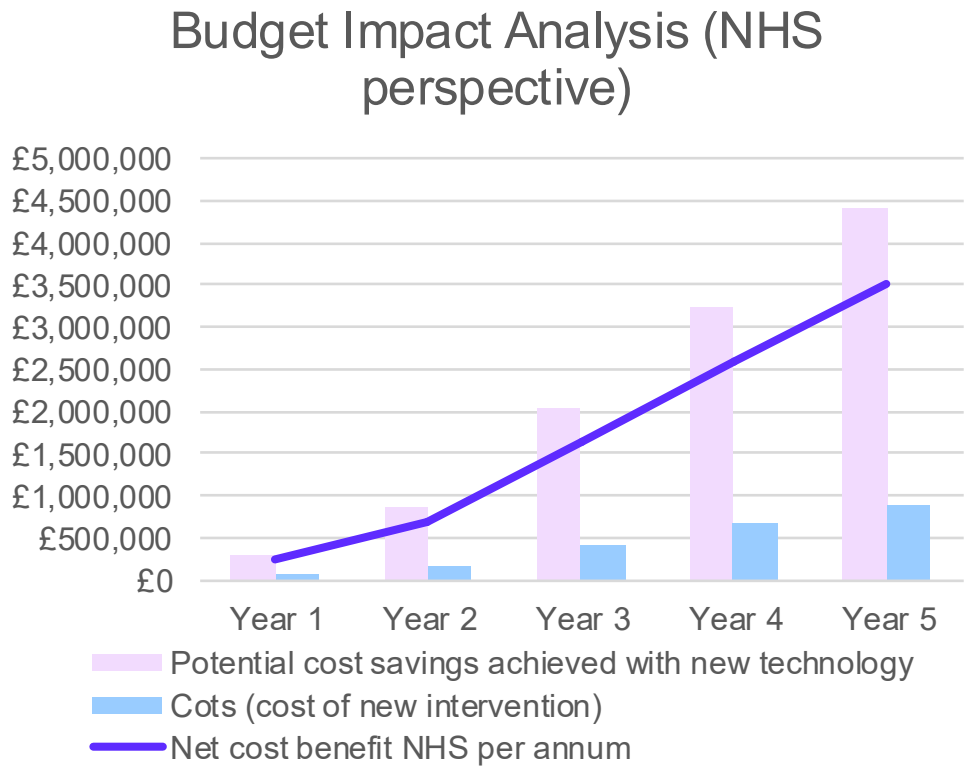
- Health Economic Models are used to demonstrate the value of health innovations and to help compare alternative treatments in an environment of constrained resources.
- Different types of models: Budget Impact Analysis (BIA), Cost Effectiveness Analysis and Cost Consequence Analysis.
- When can it be used - during product development, testing and clinical trials as well as market entry.
- A health economic model can help:
  - Clarify optimal positioning of new technology in the care pathway.
  - Identify key data collection parameters during trials.
  - Convince budget holders/NICE that your intervention is value for money & cost-effective.

Health Economic Evaluations Comparisons



Budget Impact Analysis (BIA) tend to be used an early stage to determine the impact of a technology on a specific budget

- Evaluates the financial consequences of adoption of a new intervention from the perspective of the budget holder
- Does not account for a change in health state unless it can be measured in monetary terms
- Presents financial streams over a period of time based on the rate of uptake of the new technology



Case Study:Odon Assist^{tm} MNHI

Health Tech Enterprise helped MNHI by simulating the real-life impact that its OdonAssist™ inflatable obstetric device for assisted vaginal birth could have in the maternity space.

The health economic model allowed the MNHI team to demonstrate that based on the literature and study outcomes use of the OdonAssist™ and the reduction in adverse events for the infant and mother would generate significant cost savings through reduced litigation and births via Caesarean section

The health economics model was invaluable in identifying where the greatest savings in the care pathway were to be made, securing further investment and in getting interest from NHS trusts in the product

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