Accelerated Access Review: UK Mapping

For web publication

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This is independent research commissioned by the Accelerated Access Review. The views expressed are those of the authors and not necessarily those of the Accelerated Access Review.
Dear Reader,

This report presents the work undertaken in Workstream 1 of the Accelerated Access – Innovative Medicines and Medical Technologies Review during March 2015. For this workstream the consortium of Monitor Deloitte, CASMI and King’s Fund focused on describing the end-to-end ‘pathways’ for pharma, medtech and in vitro diagnostics by which innovative medical technologies pass from conception to widespread patient access, identifying key barriers to rapid NHS adoption of such innovations, challenges to Industry and opportunities to improve patient access. The overarching aim of this work was to improve patients’ health outcomes and experience through faster access to efficacious medical innovations (including digital), not to expand the market for manufacturers of innovations per se or to promote innovation for its own sake.

We used extensive interviews, desk research and stakeholder workshops to build up our analysis of the pathways as they stand today and identify the perceived barriers to rapid adoption of innovation in the UK. As such this document is a single ‘snap-shot’ of how health economy participants view the current environment and may not reflect all the initiatives currently in place to address these barriers and challenges, either because the stakeholders we spoke with are not yet seeing results or because they are not aware of these programmes.

We interviewed a wide range of stakeholders from across the health economy, including Industry, the Public Sector, Academia and Charities. In the available time frame we were not able to focus on interviewing a significant number of frontline clinicians and this will be an important activity for the next phase of this work.

We note that many of the highlighted barriers are being addressed in whole or in part by a series of existing initiatives. The key initiatives that are not yet built into our analysis are:

- The NHS Five Year Forward View that committed to exploring new mechanisms for achieving quicker adoption of cost-effective innovation through partnerships, including with patients and voluntary sector organisations;
- The EU’s Innovative Medicines Initiative to increase the speed of development of better and safer medicine through Europe’s largest public-private partnership;
- The NHS Commissioning through Evaluation programme to examine real world clinical evidence in the absence of full trial data (e.g., expansion of the indication for use of stereotactic ablative radiotherapy beyond non-small cell lung cancer);

This document raises a series of interim questions regarding how best to improve NHS patient access to innovation, which will be addressed in much greater detail in the next phase of the Accelerated Access – Innovative Medicines and Medical Technologies Review. The next stage of the review will consult, review and recommend policies aimed at improving access.

Monitor Deloitte, CASMI and King’s Fund
Contents

- Executive Summary
- Introduction
- Detailed Findings - Medicines
- Detailed Findings – Medical Devices
- Detailed Findings – In vitro Diagnostics
- Future-Proofing the system
- Methodology

### Executive Summary

This report represents the work undertaken in workstream 1 of the Accelerated Access – Innovative Medicines and Medical Technologies Review. This workstream focused on the end-to-end pathways for pharma, medtech and *in vitro* diagnostics, identifying the barriers to rapid adoption of innovation, challenges to Industry and the opportunities to improve the pathways. For each type of technology reviewed the pathways were broken down into development, regulation, national reimbursement and local commissioning and adoption, so challenges and HMG influence levels on improvement opportunities could be assessed.

### Methodology

To develop the final report the outputs of four phases of work were combined:

<table>
<thead>
<tr>
<th>Desk research</th>
<th>Interviews</th>
<th>Workshops</th>
<th>Synthesis</th>
</tr>
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<tbody>
<tr>
<td>Insights gathered from: desk research, OLS, Deloitte, CASMI, King’s Fund, case studies shared</td>
<td>Over 50 people interviews on from Industry, Public Sector, Academia and Charities</td>
<td>20 participants on 20th March</td>
<td>Led by the Deloitte team supported by CASMI and King’s Fund</td>
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<td>100 participants on 24th March</td>
<td>15 participants on 17th April</td>
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### Cross-cutting challenges

Our research has highlighted four cross-cutting challenges for early patient access to innovative pharmaceuticals, medical devices and *in vitro* diagnostics:

- **Alignment across key stakeholders**
- **Counterproductive incentives**
- **Data, evidence & measurement**
- **Culture**

Additional challenges have been identified for all pathway phases by development, regulation, reimbursement and local adoption.

### Future proofing

In assessing how future proof are the pathways for digital health and precision medicine the following questions were asked:
1. What is the current pathway?
2. Is it fit for purpose?
3. What needs to change?

Both pathways are currently relatively unclear: digital is not currently a pathway at all and the addition of a companion diagnostic complicates the existing pharma pathway. Neither are considered to be fit for the future. To future proof both pathways better data, evidence and measurement are required. In addition digital health needs to incorporate new funding models and precision medicine pathway needs to integrate the companion diagnostic into both the assessment and funding mechanisms. Future-proofing the pathways for other advanced therapies, such as cellular / genetic therapies, will require similar though substantial higher effort.

### Opportunities to review in Phase 2

Twelve opportunities have been prioritised to take forward into Phase 2 of the review. These twelve areas include a forward-looking update of the end-to-end pathways for pharma, precision medicine, medtech and digital health. They also reflect the identified cross-cutting challenges: alignment across key stakeholders; counterproductive incentives; data, evidence and measurement; and culture. The remaining four opportunities relate to specific areas of importance at key parts of the pathway or the role of key stakeholders: patient engagement, the clinical development environment in the NHS, local adoption incentives, and the role of regional centres such as AHSNs.

Challenges to early access

Throughout this report we consider two sets of access challenges for innovative pharmaceuticals, medical devices and in vitro diagnostics.

1. Cross-cutting challenges

   - Alignment across key stakeholders
   - Counterproductive incentives
   - Data, evidence & measurement
   - Culture

   Apply across whole end-to-end pathway

   Apply across all 3 sectors

2. Sector & pathway-specific challenges

   Vary by pathway stage

   Vary by sector

Source: Stakeholder interviews, workshops and Deloitte analysis
Four key challenges

Our research highlighted four cross-cutting challenges for early access to innovative pharmaceuticals, medical devices and *in vitro* diagnostics:

**Alignment across key stakeholders**
- Stakeholders and organisations along the pathway are not aligned with the explicit goal of working together to bring innovations more reliably and rapidly to patients. This reduces the adoption of innovative pharmaceuticals, medical devices and *in vitro* diagnostics. The problem is most acute across and between national reimbursement and local adoption and industry understanding of NHS clinical priorities. It’s also felt that patients have limited opportunity to have their voice their views along the pathway.

**Counterproductive incentives**
- Counterproductive incentives, such as internal budget siloes within and between NHS organisations dis-incentivises the adoption of innovation where the costs and value realised are not aligned. Short financial time horizons (and a lack of easy vehicles to invest in multi-year returns) and an individual organisation’s financial position, rather than a whole system view further dis-incentivises investments that may save costs and improve outcomes at an aggregate level.

**Data, evidence & measurement**
- Evidence is not being used as an effective enabler to facilitate the development, reimbursement and adoption of innovative medicines and medical technology. There is a lack of clarity (and often availability) around the evidence that is required at each stage of the pathway, particularly in medical technology and for SMEs.

**Culture**
- Lack of trust between NHS and Industry is a key barrier to more collaborative working across the end-to-end pathway. Other cultural barriers to the adoption of innovative medicines and medtech include local risk aversion, distrust of external data and evidence, non-constructive competition between NHS organisations and resistance / lack of capacity to implement significant change.
Challenges: Pharmaceuticals

Our research also highlighted a number of specific challenges to pharma by pathway stage

**Cross-cutting**

- Alignment across key stakeholders
- Counterproductive incentives
- Data, evidence & measurement
- Culture

**Development**

- Barriers to conduct clinical research in NHS
- NHS staff capacity for research
- Duplication of effort in early development
- Limited access to early approval

**Regulation**

- Lack of early dialogue
- Misaligned perception of risk / benefit

**National Reimbursement**

- Evidence Requirement
- Different definitions of value
- Misalignment of stakeholder objectives

**Local Commissioning and Adoption**

- Process duplications
- Budget siloes
- Lack of accountability
- Lack of outcome transparency

Source: Stakeholder interviews, workshops and Deloitte analysis
Challenges: Medical devices

Our research also highlighted a number of specific and different challenges to medical devices by pathway stage

Cross-cutting

- Alignment across key stakeholders
- Counterproductive incentives
- Data, evidence & measurement
- Culture

Development

- Lack of clinical & commercial capability
- NHS trial approvals process

Regulation

- Lack of early dialogue
- Low barriers to entry creating later adoption problems

National Reimbursement

- Lack of funding mandate
- Lack of commercialisation capability
- NICE turnaround times
- System requires Industry push

Local Commissioning and Adoption

- Unclear route to market
- Process duplication
- Budget siloes
- Speed of pricing / contracting update
- SME expertise / scale

Source: Stakeholder interviews, workshops and Deloitte analysis

Challenges: *In vitro* diagnostics

Our research also highlighted a number of challenges that are specific to *in vitro* diagnostics by pathway stage.
Opportunities for improved access

We have identified 12 priority opportunities for improved patient access to innovations, grouped into 3 areas:

1. **End-to-end access pathway opportunities**
   - Four opportunities that each address the patient access pathway for a specific set of innovative products

2. **Cross-cutting opportunities**
   - Four opportunities that address each of the four identified cross-cutting challenges

3. **Pathway stage-targeted opportunities**
   - Four opportunities that address specific parts of the pathway for specific products, where research indicated a particular challenge

Source: Stakeholder interviews, workshops and Deloitte analysis
Top areas for review in phase 2

Based on our research, interviews and workshops, we recommend the following opportunities to take forward into Phase 2

1. Further review of pharma pathway opportunities and future proof for agile pathways
2. Further review of medtech pathway to standardise and improve parity with pharma
3. Future proof for precision medicine pathway
4. Lightly regulate and develop systems to support adoption of digital health technologies
5. Review organisational mandates and alignment to support adoption
6. Funding of innovation, system incentives and contracting mechanisms in the NHS
7. Role of data to support the end-to-end pathway and adoption of innovation
8. Assess cultural barriers to collaborative working, e.g. facilitate earlier dialogue
9. Clinical development environment and incentives for NHS involvement
10. Reimbursement methodologies to incorporate early access and RWE
11. Promote patient engagement throughout the end-to-end pathway
12. Role of regional centres e.g. AHSNs as test beds and drivers of innovation

Source: Stakeholder interviews, workshops and Deloitte analysis

Accelerated Access Review

The review will make recommendations to government on opportunities to accelerate access for NHS patients to innovate medicines and medtech.

The Accelerated Access – Innovative Medicines and Medical Technologies Review (IMMTR) announced by George Freeman on 20th November 2014 will consider how the healthcare and regulatory systems can best respond and adapt to the new landscape of digital diagnostics, genomics and precision medicine. The review will consider how to speed up access for NHS patients to cost-effective new diagnostics, medicines and devices.

With initial findings being reported in late Summer, the work will identify key challenges across the end-to-end pathway and provide opportunities for change to accelerate patient access of upcoming innovative medicine and medtech in the current pathways. Specifically the review will achieve the following outcomes:

- Identify key priorities for action
- Provide implementable suggestions for change to accelerate innovation access
- Develop a sustainable framework to support and drive medical innovation
- Consider the long term landscape for innovation adoption

There are a number of workstreams contributing to the review and this report focuses on Workstream 1. The objective of workstream 1 is to assess the As-Is environment in the UK and the barriers to getting patients earlier access to medical innovation.
Workstream 1 objectives

There were 5 key aims of workstream 1; these aims are covered in this report with the associated detailed end-to-end pathways created to support workstream 1

1. To map the current processes and pathways through which innovative medicines, devices and diagnostics are assessed from proof of concept through regulation, cost-effectiveness assessment and adoption in the UK

2. To understand how these processes and pathways work in practice

3. To identify issues, barriers and opportunities within the UK’s current approach, and highlight how and when innovation creates the opportunity to evolve the processes and pathways now and in the future

4. To identify particular areas within current pathways and processes that will be challenged by the new types of product and environment, assess the degree to which the system is future-proofed and identify priority areas for change

5. To identify the key features which allow rapid development in ‘analogous sectors (innovative, high market failure, high upfront costs, large-scale public use), and to explore whether any of these features – or lessons learnt from them – could be effectively mirrored in the development pathways for medicines, devices and diagnostics

Whilst regulatory issues will be considered UK-wide, cost effectiveness and adoption will be examined on an England-only basis
Pharmaceutical pathway summary

This is a linear representation of a process that is not perfectly linear. The pharmaceutical pathway has not significantly changed for many years.
Medical devices pathway summary

At a high level, the medical devices pathway has fewer component processes than the equivalent pathway for innovative pharmaceuticals.
In vitro diagnostics pathway summary

Currently, the route to patients for in vitro diagnostics does not differ significantly from that of other medical devices.
This review considers the current patient access pathways for three key product types:

- Pharmaceuticals
- Medical Devices
- In vitro diagnostics

Each pathway has been broken down into four stages:

- Development
- Regulation
- National Reimbursement
- Local Commissioning and Adoption

Notes: (1) In vitro diagnostics have been considered as a distinct group as they fall under a distinct Directive to medical devices. Other kinds of diagnostics (e.g., CT scanners) are classed as medtech by the regulatory framework.
How to read this document (2/2)

Each detailed section below contains the following slides:

1. Recap of the detailed pathway for that stage

2. Stage-specific challenges

3. Illustrative quotes

4. Stakeholder views of the key challenges
Contents

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Future-Proofing the system

Methodology
Challenges: Pharmaceuticals

Our research also highlighted a number of specific challenges to pharma by pathway stage

Cross-cutting

Alignment across key stakeholders

Counterproductive incentives

Data, evidence & measurement

Culture

Development

Regulation

National Reimbursement

Local Commissioning and Adoption

Barriers to conduct clinical research in NHS

Lack of early dialogue

Evidence Requirements

Process duplications

NHS staff capacity for research

Misaligned perception of risk / benefit

Different definitions of value

Budget siloes

Duplication of effort in early development

Limited access to early approval

Misalignment of stakeholder objectives

Lack of accountability

Lack of early dialogue

Limited access to early approval

Cross-cutting

Source: Stakeholder interviews, workshops and Deloitte analysis

Pharma: Development
Development: Detailed Pathway

Key
- Small molecules
- Biologics
- Vaccines

Source: Stakeholder interviews, workshops and Deloitte analysis

Development: Key Challenges

Our research highlighted three key challenges in the development stage for innovative medicines:

**Barriers to conduct clinical research in NHS**
- **Multiple barriers** exist for performing clinical trials in the UK compared to other countries:
  - **Low relative adoption** of innovative medicines (limiting comparator use);
  - **Administrative burden** of trial set up with the NHS; and
  - **Poor data infrastructure**

**NHS staff capacity for research**
- **NHS staffing constraints** and **few incentives** to engage in clinical research has resulted in a low **availability of research focussed healthcare professionals** to conduct research in the NHS

**Duplication of effort in early development**
- Considerable **duplication of research effort** exists during early stage development due a **lack of collaboration during the pre-competitive stage**.
  - In particular, interviewees highlighted a lack of Industry-Academia and Industry-Industry collaboration, where **knowledge of success or failure is not shared**, potentially resulting in wasted effort

Source: Stakeholder interviews, workshops and Deloitte analysis

Development: *Illustrative Quotes*

Quotes summarise some of the key challenges in the development stage for innovative medicines

**COMMENTS ON DEVELOPMENT**

"The UK has lost up to two-thirds of their market in clinical trials. In the UK it takes 2 years to start a trial from when you pick up the phone; in the US it takes a year. When you go to China they have 40,000 pre-screened patients and they can start in a month"

"The NHS needs to invest more around trials"

"There is an increasing cost and development time due to NHS overheads, different contracts and approvals"

"There are opportunities to use data assets more wisely in the NHS"

"Technology is locked up inside a company"

"Chief executives are not interested in research"

"The ability of conducting clinical trials in the UK is limited by not adopting the latest medicine"

"Are we more focused on targets that are marketable and flavour-of-the-year with government?"

"Trial patient recruitment is limited by clinician capacity in the trusts"

"Incentives offered are not proportional to amount of work we put in (clinical research)"

Key:
- Industry
- NHS
- Charities
- HMG / ALBs

<table>
<thead>
<tr>
<th>INDUSTRY VIEWS</th>
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<tbody>
<tr>
<td>• Consensus among interviewed stakeholders that <strong>UK has a strong capability</strong> to conduct medical research and development</td>
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<tr>
<td>• There is a <strong>lack of incentives</strong> and recognition for clinicians and nurses to <strong>work on clinical trials</strong></td>
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<tr>
<td>• Interviewees mentioned <strong>increasing cost and efforts</strong> associated with setting up clinical trials in the NHS with <strong>duplicated contract negotiation and stakeholder engagement</strong> in each trust</td>
</tr>
<tr>
<td>• <strong>Misalignment of commercial interests and risks</strong> between stakeholders resulting in loss of research value; value is further lost via duplicating development efforts with different stakeholders</td>
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<thead>
<tr>
<th>HMG / ALBs VIEWS</th>
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<tr>
<td>• Industry is reluctant to engage NICE and others on product development and evidence collection at an early stage</td>
</tr>
<tr>
<td>• <strong>Fees are a potential barrier</strong> to early stage companies in seeking advice, particularly for SMEs</td>
</tr>
<tr>
<td>• Knowledge and technologies are <strong>not shared between Industry and other organisations</strong> during the pre-competitive stage to enable the risk of early development to be better shared</td>
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<th>NHS VIEWS</th>
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<tr>
<td>• The NHS interviewees mentioned a <strong>lack of specialised R&amp;D nurses, clinician capacity and time</strong> for conducting trials</td>
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<tr>
<td>• The <strong>level of revenue</strong> generated by taking part in trials <strong>doesn’t reflect the workload</strong> required</td>
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<tr>
<td>• Payment is based on recruitment number, <strong>not the complexity</strong> of the study</td>
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<tr>
<td>• There is <strong>misalignment between local and global office of study sponsor</strong> leading to multiple negotiation processes</td>
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<td>• NHS data are robust and can support licensing, but there is a <strong>poor data management</strong></td>
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<th>CHARITY VIEWS</th>
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<tbody>
<tr>
<td>• Patient groups feel like that the <strong>current development process is too long</strong> and the development paradigm <strong>does not work for rare and highly stratified</strong> molecularly targeted therapies</td>
</tr>
<tr>
<td>• Concerns that the <strong>industry cannot invest without reasonable prospect of returns</strong>, especially for small patient populations</td>
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</table>
Pharma: Regulation
Regulation: Detailed Pathway

**Key**
- **Small molecules**
- **Biologics**
- **Vaccines**

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**Is EMA approval mandatory?**

- **Yes**
  - Primary route for market access approval
    - Application submission to CHMP
    - Assessment report from (co-)rapporteur; CHMP provides comments
    - Applicant responds
    - Joint assessment report from (co-)rapporteur; CHMP provides comments
    - Applicant responds to comments and submits label documents
    - Approved by CHMP for market access?
      - Yes
        - Approved for market access
      - No

- **No**
  - Identification of subgroup with higher efficacy
  - Secondary route for market access approval
    - Application submission to MHRA and/or Concerned Member States
    - Assessment report from MHRA and/or Concerned Member States
    - Applicant responds
    - Further assessment by MHRA and/or Concerned Member States
    - Approved by MHRA for market access?
      - Yes
        - Approved for market access
      - No

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**Centralised Procedure by Committee for Medicinal Products for Human Use (CHMP), EMA**

EMA mandatory for small molecules treating any of the following diseases:
- AIDS
- cancer
- neurodegenerative disorder
- diabetes
- auto-immune dysfunctions
- viral diseases
- orphan diseases
- vaccines

*Note: The process is faster for vaccines; accelerated procedure available for products bring major benefits (process approximately 2 months shorter)*

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**Decentralised Procedure, Mutual Recognition Procedure and National Procedure, MHRA**

*Note: National reimbursement processes can begin before regulatory approval has been granted*

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Source: Stakeholder interviews, workshops and Deloitte analysis

Regulation: **Key Challenges**

Our research highlighted three key challenges in the regulatory stage for innovative medicines:

- **Lack of early dialogue**
  - Selective uptake by industry of available advice on protocol and trial design and low update of HTA early dialogue:
    - for SMEs price is a concern;
    - big pharma feel they already have sufficient in-house capability

- **Misaligned perception of risk / benefit**
  - Different perception of risk and benefit balance across different stakeholder groups; for example very high unmet need patient groups are willing to adopt earlier, but current systems are unable to take these scenarios into account

- **Limited access to early approval**
  - Although becoming more common, conditional regulatory approval on limited (Phase I / Phase II) clinical data sets based on continued demonstration of safety and efficacy is restricted to certain product types.
  - This reduces the speed of access to regulatory approval

Source: Stakeholder interviews, workshops and Deloitte analysis

Quotes summarise some of the key challenges in the regulatory stage for innovative medicines.

**COMMENTS ON REGULATION**

- "EAMS is a compassionate use scheme, without reimbursement."
- "Evidence required to approve drugs is too long, patients don’t have the time."
- "Regulation is not a problem as soon as Industry have a capable team working on the application."
- "Companies consider MHRA as an authority, rather than advice provider."
- "MHRA fee is a barrier for Academia and early phase entrepreneurs to develop products."
- "A randomised control trial is taking other variables out, not reflecting patients’ real conditions."
- "Are adequate safeguards in place for early access schemes?"

**Key:**
- Industry
- NHS
- Charities
- HMG / ALBs

Source: Stakeholder interviews, workshops and Deloitte analysis

Regulation: Stakeholder Views

INDUSTRY VIEWS

• There is a high barrier for receiving conditional approval from the regulatory authorities
• Industry stakeholders are hesitant to engage with adaptive pathway schemes, since there is a lack of reimbursement and a clear adoption plan at the end of scheme
• On early dialogue interviewees have expressed that:
  – SMEs consider the service costly and unnecessary as they do not intend to seek licensing directly
  – Large pharma consider that they are able to assess regulatory requirements with internal capabilities

HMG / ALB VIEWS

• Industry is not engaging with regulatory bodies for scientific advice around data requirements, especially during earlier stages of development
• Agile pathways and fast track processes are available, but only for medicines addressing unmet clinical needs or offering major benefits

NHS VIEWS

• There is a strong opinion from NHS stakeholders that the licensing process needs to speed up
• A few participants raised concerns around whether adequate safeguards are in place for early access schemes
• Clinicians have commented that the selection criteria for randomised controlled trials do not represent the common patient populations

CHARITY VIEWS

• Representatives from patient groups have expressed that patients with unmet clinical needs are willing to accept innovative treatment at a higher risk, but the current regulation is too rigid for this to happen
• The current review process is too long
• A “one size fit all approach” assessment might not work for different disease areas

Source: Stakeholder interviews, workshops and Deloitte analysis
Pharma: National Reimbursement
Vaccines

ROUTE FOR NON-TAP RECOMMENDED DRUGS

**NHS Specialised Commissioning Evaluation** – 3-12 months

- Possible specialised commissioning?
  - Yes
    - National Cancer Drug Evaluation – 3-12 months
      - Selected by the National Cancer Drug Panel for assessment?
        - Yes
          - Evidence gathering
          - National Cancer Drug Fund Panel assessment
        - No
          - Not available under national reimbursement or commissioning scheme
      - No
        - Evidence gathering
        - National Cancer Drug Fund Panel assessment
      - Listed on national Cancer Drug Fund cohort policy list?
        - Yes
          - National Cancer Drug Fund Evaluation – 3-12 months
        - No
          - Not available under national reimbursement or commissioning scheme
  - No
    - Evidence gathering
    - National Cancer Drug Fund Panel assessment

**Specialised Commissioning Oversight Group (SCOG) approval**?
  - Yes
    - Central procurement negotiation with the Commercial Medicines Unit
    - National reimbursement and commissioning procedures completed
  - No
    - NICE guidance published

Note: National reimbursement processes can begin before regulatory approval has been granted

**Vaccines**

**Single Technology Appraisal Process** – c. 9 months

- Scoping and evidence gathering
- Assessment
- Develop recommendations
- Guidance published

- Consultation

For single medicine, with a single indication where value proposition is increased benefit for more cost, especially where expected uptake or unit costs are high

For multiple medicines, with one or more indications, where value proposition is increased benefit for more cost, where expected uptake or unit costs are high

**Multiple Technology Appraisal Process** – c. 12 months

- Consultation

**Highly Specialised Technology Evaluation** – c. 9 months

- Consultation

For single medicine, with a single indication, only considers drugs for very rare conditions

Submit for NICE evaluation (including with a patient access scheme proposal)?

- Yes
  - Topic selected by NICE?
    - Yes
      - Recommendation from NICE?
        - Yes
          - Yes
        - No
          - No
  - No
    - Cancer drug?
      - Yes
        - Yes
        - No
      - No
        - No

Resubmit to NICE with a patient access scheme proposal?

- Yes
  - Recommendation from NICE?
    - Yes
      - Yes
    - No
      - No
  - No
    - Cancer drug?
      - Yes
        - Yes
        - No
      - No
        - No

No

*Some medicines may have initially been funded via Commissioning through Evaluation, where the evidence base at the time did not yet demonstrate sufficient clinical and cost effectiveness for its routine use*
National Reimbursement: Key Challenges

Our research highlighted three key challenges in national reimbursement for early adoption of innovative therapeutic medicines:

- **Evidence requirement**
  - Evidence requirements for pricing and reimbursement are not typically considered by Industry during earlier stages of development activity (in part due to the global nature of data collection), resulting in iteration of the assessment process or failure to demonstrate sufficient value.

- **Different definitions of value**
  - Industry and public sector are misaligned on the question of a drug’s value, e.g.,
    - Industry disagrees on the methodologies applied by NICE and other HTA bodies to assess the cost-effectiveness and optimal use of medicines;
    - Some parts of public sector consider the NICE cost per QALY threshold to be too high.

- **Misalignment of stakeholder objectives**
  - Misalignment of objectives between NICE and other stakeholders (e.g. NHS England, patient groups and Industry) over strategic priorities and technology implementation, leading to low or slow adoption of NICE-recommended medicines
    - E.g. different priorities for innovation within the organisation mandates of NICE (assesses cost-effectiveness), NHS England (budget balancing focus) and Monitor (provider-level governance compliance).

National Reimbursement: Illustrative Quotes

Quotes summarise some of the key challenges in national reimbursement of innovative therapeutic medicines

COMMENTS ON NATIONAL REIMBURSEMENT

“NICE recommendations can put a real financial burden on commissioners and can take away their autonomy”

“Pharma often not ready and lacks preparedness to have data / reimbursement conversations with NICE”

“The issue with CDF is that it incentives activity, rather than prevention”

“NICE and NHS England should have more realistic expectations around data requirements”

“NHS England has too many decision making layers”

“National funding bodies are not hearing patients’ voice”

“The issue with CDF is that it incentives activity, rather than prevention”

“NICE should take wider consideration of the cost of a disease, such as social cost and cost to GDP”

“CDF was a ‘sticking plaster’ and if NICE value assessment changed for specialised medicine, it would not be needed”

“NICE should be more explicit on the patients that have been used in studies and use more real world evidence in assessments”

“Lack of multi indication reimbursement models to assess innovation of more personalised health care”

Key:
- Industry
- NHS
- Charities
- HMG / ALBs

Source: Stakeholder interviews, workshops and Deloitte analysis

Industrial stakeholders agreed that there is a misalignment of data requirement between NICE and regulatory bodies.

- The current assessment by NICE and NHS England does not support flexible pricing or personalised medicine.
- NICE’s methodologies are considered too academic, not taking full account of the value of medicines and the assessment logic is not used for other areas of NHS (e.g. A&E, single-sex wards).
- Decision-making process for specialised medicine in NHS England is not transparent.

There is no alignment between NICE and NHS England on prioritising or highlighting unmet clinical needs, making NICE’s selection process difficult.

Companies are not engaging early for advice on evidence requirement from NICE.

Interviewees from the NHS indicated that although NICE assessment is comprehensive, it is standardised and may not reflect local needs.

- There was a feeling from some participants that NICE should ensure assessments make it easier for commissioners to adopt (i.e. more information on patients that have been used in studies, more real world evidence use).
- Some interviewees felt that NICE recommendations can put financial burdens on commissioners and reduce their autonomy.

NICE assessment is not considering the overall cost effectiveness to patient and society.

- NICE and NHS England selection as seen not drawing attention to small patient group treatment.

Source: Stakeholder interviews, workshops and Deloitte analysis
Pharma: Local Commissioning & Adoption
Local commissioning & adoption: Detailed Pathway

**Key**
- Small molecules
- Biologics
- Vaccines

**Source:** Stakeholder interviews, workshops and Deloitte analysis


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**Process must be iterated for each local health economy in turn to achieve maximum adoption**

- Regional/Area Prescribing Committee may impose patient access restrictions
- Trust Prescribing Committee may impose patient access restrictions
- CCG Prescribing Committee may impose patient access restrictions
- CCG Prescribing Committee topic selection
- Trust Prescribing Committee topic selection

- Evidence and advice gathering
- Regional/area prescribing Committee topic selection

- Financial assessment
- Stakeholder engagement
- Local patient access listing
- Clinical guidance development

**Adoption of medicine after first access**

- Industry - primary care clinician engagement
- Clinician - patient engagement and decision making
- Policy drivers (e.g. NHS Constitution, NICE Clinical Guidelines, Prescribing Guidelines, CCG Outcome Indicator Set)
- Policy penalties (e.g. General Medical Services Contract)
- Incentives (e.g. Quality, Innovation, Productivity and Prevention Program, Commissioning for Quality and Innovation Scheme, Prescribing Incentive Scheme)
- Peer-to-peer benchmarking (e.g. Innovation Scorecard, NICE implementation Collaborative, Medicines Optimisation Collaborative)

**Local patient access in primary care**

---

**Iterate across local health economies**

- Listed on provider formulary
- Local patient access
- Wide-spread patient access in primary care

- 3 months – 2 years
- 2 years – 15 years

**Diffusion through health economy**

- Patient access

---

*Including advise from regional and area organisations, such as Medicines Management Groups*
Key Challenges
Our research highlighted four key challenges in local commissioning for early adoption of innovative therapeutic medicines

**Process duplication**
- There is significant duplication of effort, with multiple bodies conducting similar reviews of the same data. The lack of central coordination results in no clear route to market requiring costly sales process duplication to address all CCGs / providers for Industry

**Budget Siloes**
- Internal budget siloes between NHS organisations and within departments of an organisation disincentivizes adoption where cost and value realised are not aligned
  - In addition costs and benefits accruing in different budgeting time periods further limits adoption as effective mechanisms of funding over a longer timeframe are not available

**Lack of accountability**
- Local adoption of innovative medicines can be slow / hesitant with limited decision-making accountability to national policy, even for NICE-recommended or specialised commissioning medicines

**Lack of outcome transparency**
- Real world effectiveness is not standardly captured or reported, this hinders the creation of an evidence base that could be used to drive adoption of medicines that are seen to be cost-effective in practice.
  - Few or no incentives for decommissioning of products
  - Complicated and poorly understood local decision-making processes

Source: Stakeholder interviews, workshops and Deloitte analysis

Local commissioning & adoption: *Illustrative Quotes*

Quotes summarise some of the key challenges in national reimbursement of innovative therapeutic medicines

**COMMENTS ON LOCAL COMMISSIONING AND ADOPTION**

- "NHS is paid via input / output, not by outcome"
- "Diffusion is not as expected after NICE approval"
- "It doesn't matter if drugs are NICE recommended... there is a finite budget to fund new drugs"
- "No one consistent approach to adopt and diffuse medicine adoption; sales team find it difficult to justify the COGS vs Revenue in the UK"
- "Access is difficult when patients live in an area not covered by a specialised centre"
- "Some clinicians are very conservative with new prescriptions"
- "There is no incentive to develop and adopt innovation in the NHS: only 2% budget is set for adopting innovation"
- "NHS is focusing on extending life expectation, not life quality"
- "The way the [Health and Social Care] act has split up organisational responsibilities has made it really difficult to get things done"

Source: Stakeholder interviews, workshops and Deloitte analysis

Local commissioning & adoption: Stakeholder Views

**INDUSTRY VIEWS**

- Industrial stakeholders emphasised that there are duplicated assessments of the same medicine across CCGs and providers, causing delays and variation of adoption.
- There is a lack of budget to adopt innovative medicines and lack of flexibility to system change despite clear evidence of good benefit / cost balance.
- Industrial stakeholders also agreed there is misalignment of incentives to promote adoption and few penalties if they don’t.

**HMG / ALB VIEWS**

- NICE and NHS England’s decisions are not been carried out by local providers and 90 days formulary listing rule is used as an excuse to delay adoption.
- Interviews with ALB representatives indicated that providers are not assessed based on their adoption of innovation.

**NHS VIEWS**

- It is difficult to adopt new products especially those requiring system redesign e.g. through double-running cost of old and new adding a burden to the medicine budget.
- It is challenging to bring providers together and to balance different incentives and benefits for pathway redesign.
- NHS stakeholders interviewed indicated that new medicines are often too expensive and there is a lack of funding for adoption.
- Individual clinicians have different view on drugs and it is difficult to change their prescription behaviours.

**CHARITY VIEWS**

- NHS commissioners are not focusing on quality of life, but on meeting performance standards and financial savings.
- Many patient groups mentioned that some specialised drugs are only available in selected providers, resulting in a longer delay for patients to access these treatments in some areas.
- There are also concerns that Industry is only focusing on getting reimbursement, not on what clinicians or patients need.

Source: Stakeholder interviews, workshops and Deloitte analysis

Pharma: Case Studies
## Background

- Non-Vitamin K antagonist oral anticoagulants (NOACs) include dabigatran, rivaroxaban and apixaban were approved by NICE in 2014 as options for stroke prevention
- They were recommended as first-line therapy over traditional treatments (e.g., warfarin & aspirin) and demonstrated improvements in both clinical efficacy and cardiac risk management
- NOACs costs are significantly higher than traditional treatments
- However NICE has concluded that the drugs are cost-effective and must be available to patients for on-label use
- The EHRA, NICE and European Society of Cardiology have all issued separated guidelines recommending NOACs

## Issues

- Despite the NICE recommendation, adoption has been limited
- Clinicians believe in the superior safety of aspirin which was communicated in NICE 2006 guideline while some remain unaware of the development of novel medicines in the recent years
- Moreover, primary care practitioners often do not want to take responsibility for the first prescription of a NOAC, preferring instead to refer patients to secondary care anticoagulant clinics, which increases system costs
- Data from Quality and Outcomes Framework, which details GP practice performance, indicates that only 65% of eligible patients in England received NOACs between 2012 – 2013

## Challenges

- Alignment across key stakeholders
- Culture
- Budget Siloes
- Lack of accountability
- Lack of outcome transparency

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Note: EHRA = European Heart Rhythm Association
Source: NICE, EHRA, European Society of Cardiology, Deloitte interviews

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Challenges: Medical devices

Our research also highlighted a number of specific and different challenges to medical devices by pathway stage

**Cross-cutting**

- **Alignment across key stakeholders**
- **Counterproductive incentives**
- **Data, evidence & measurement**
- **Culture**

**Development**

- Lack of clinical & commercial capability
- NHS trial approvals process

**Regulation**

- Lack of early dialogue
- Low barriers to entry creating later adoption problems

**National Reimbursement**

- Lack of funding mandate
- Lack of commercialisation capability
- NICE turnaround times
- System requires Industry push

**Local Commissioning and Adoption**

- Unclear route to market
- Process duplication
- Budget siloes
- Speed of pricing / contracting update
- SME expertise / scale

Source: Stakeholder interviews, workshops and Deloitte analysis

Medical devices: Development
Development: Detailed Pathway

- **Basic research**: Identification of need
- **Scientific development**: Product prototyping
- **Class II & Class III devices (including radiation-based diagnostics)**:
  - Basic research
  - Identification of need
  - Go / No Go decision
  - Product prototyping
  - Product testing
  - Product scale-up feasibility studies
  - Go / No Go decision
  - Developed product
- **General non-companion in vitro diagnostics**:
  - Basic research
  - Identification of need
  - Go / No Go decision
  - Product prototyping
  - Product testing
  - Product scale-up feasibility studies
  - Go / No Go decision
  - Developed product
- **General companion in vitro diagnostics**:
  - Basic research
  - Identification of need
  - Go / No Go decision
  - Product prototyping
  - Product testing
  - Product scale-up feasibility studies
  - Go / No Go decision
  - Developed product
- **High risk in vitro diagnostics**:
  - Basic research
  - Identification of need
  - Go / No Go decision
  - Product prototyping
  - Product testing
  - Product scale-up feasibility studies
  - Go / No Go decision
  - Developed product

**Clinical testing**
Comprises of clinical validation (IVD only), clinical utility testing and health economic assessments (not all products). Clinical testing can occur in the NHS or another healthcare system.

- **Analytic validation**
  - Some medical devices and in vitro diagnostics undergo clinical testing prior to regulatory engagement.

- **Clinical evidence gathered**
  - Loop iterated as necessary but not shown to aide clarity.

- **Further clinical evidence required**
  - (for regulatory purposes or NICE evaluation).

Source: Stakeholder interviews, workshops and Deloitte analysis
Key Challenges

Our research highlighted two key challenges in the development stage for innovative medical devices:

- **Lack of clinical & commercial capability**
  - Some concerns that there can be a **focus within development**, particularly for SMEs, on **solving engineering challenges** rather than **identifying a clinical need** and generating evidence of clinical benefit and **commercialisation**, leading to adoption problems downstream.

- **NHS trial approvals process**
  - **Slow trial approval processes** (e.g., ethics and data / sample consenting) raise **costs of clinical evidence collection** (especially for SMEs), delaying adoption.

Source: Stakeholder interviews, workshops and Deloitte analysis
Quotes summarise some of the key challenges in the development stage for innovative medical devices.

**COMMENTS ON DEVELOPMENT**

- "There is an increasing cost and time of development due to NHS overheads, different contracts and approvals."
- "There is a high cost burden of developing products in the UK."
- "The real problem lies in adoption rather than in the development or regulatory stages."
- "Industry doesn’t focus enough on thinking about adoption in the development stage, which causes them problems later on."
- "It doesn’t matter how much evidence a manufacturer gathers in development as everyone will want to re-validate it anyway."
- "UK SME management often lack the commercial awareness that is seen in the US SMEs."
- "Most companies want to work with the NHS but find it very difficult."
- "Getting trials approved in the NHS takes too long."
- "There is an urgent need to increase research and engage Industry."

Key:
- Industry
- NHS
- Charities
- HMG / ALBs

Source: Stakeholder interviews, workshops and Deloitte analysis

**Stakeholder Views**

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<td><strong>Industry views</strong></td>
<td>• Most Industry stakeholders believe the NHS trials approvals process is too time consuming</td>
<td>• HMG / ALBs are of the view that Industry do not focus enough time and resources thinking about their route to market in the development stage, which leads to adoption problems later</td>
<td>• There is a feeling that it does not matter how much evidence manufacturers gather in the development stage as local commissioners and providers will want to re-validate it locally</td>
<td>• Charities feel that there is an urgent need to increase research and engage Industry, especially for disease areas where there has been no or limited treatment or care advances in the last decade</td>
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<td>• The cost of clinical trials is a burden for SMEs, particularly in developing clinical evidence</td>
<td>• HMG / ALBs think that companies do not always see the value of early dialogue conversations, especially around study design and evidence requirements</td>
<td>• Generally Industry focus on solving the engineering problems rather than generating evidence of clinical benefit</td>
<td>• The NHS should encourage more patients and clinicians to get involved with clinical research</td>
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<td>• Industry feel that there are limited incentives for Trusts and healthcare professionals to get involved with clinical trials</td>
<td>• Fees are a barrier, particularly for SMEs to engage earlier with HMG / ALBs</td>
<td>• Successful companies focus on generating evidence of clinical benefit and are clear about their route to adoption</td>
<td>• Specific diseases could be used as a ‘test-bed’ for reform from development through to adoption</td>
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<td>• A few stakeholders think grant funding should be directed to medical devices that have a high chance of being adopted</td>
<td>• Sense that commercialisation capability is a problem, especially for SMEs</td>
<td>• A few stakeholders think grant funding should be directed to medical devices that have a high chance of being adopted</td>
<td>• The review should build on what is already working</td>
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Source: Stakeholder interviews, workshops and Deloitte analysis
Medical devices: Regulation
Regulation: Detailed Pathway

Key
- Non-sterile non-measuring Class I devices
- Sterile or measuring Class I devices
- Class II & Class III devices (including radiation-based diagnostics)
- General non-companion in vitro diagnostics
- General companion in vitro diagnostics
- High risk in vitro diagnostics (including self-testing)

- Determine product class, regulatory framework and need for Authorised Representative
- Has sufficient clinical evidence been collected?
- No
- Prepare Technical File / Design Dossier
- CE Marking Certificate issued
- MHRA registration
- Declaration of Conformity
- Affix CE mark, Market authorised product
- Market authorised product
- <1 month – 2 years

Developed product
- Further clinical testing
- Has sufficient clinical evidence been collected?
- Yes
- Implement a Quality Management System
  Most companies apply ISO 13485 to achieve QMS compliance
- Notified Body audit
- Prepare Technical File / Design Dossier
- CE Marking Certificate issued
- MHRA registration
- Declaration of Conformity
- Affix CE mark, Market authorised product
- Market authorised product
- <1 month – 2 years

Source: Stakeholder interviews, workshops and Deloitte analysis

Key Challenges

Our research highlighted two key challenges in the regulatory stage for innovative medical devices:

- **Lack of early dialogue**
  - Low uptake of available advice on protocol and trial design
    - Not seen as value-add for companies with deep experience
    - Seen as too large a time and cost investment for SMEs
    - Lack of engagement and uncertainty about effectiveness of this dialogue reduces partnering

- **Low barriers to entry creating later adoption problems**
  - The relative ease in which companies are able to CE mark medical devices, compared to successfully navigating reimbursement and commissioning procedures, results in later adoption problems. Too often studies in the development stage, particularly those carried out by SMEs, are not adequate for national or local reimbursement and/or commissioning purposes

Source: Stakeholder interviews, workshops and Deloitte analysis

Regulation: *Illustrative Quotes*

Quotes summarise some of the key challenges in the regulatory stage for innovative medical devices

**COMMENTS ON REGULATION**

- "We like the CE marking but we are worried the process will get tougher"
- "Companies don’t consider us as an advice provider"
- "There should be a directory and ratings system for all CE marked medtech"
- "Fees would be a barrier for SMEs to engage with us"
- "Regulation is not the bottleneck in the system"
- "We think there needs to be more joined up thinking at a global level around regulation"

**Key:**
- Industry
- NHS
- Charities
- HMG / ALBs

Source: Stakeholder interviews, workshops and Deloitte analysis
### Stakeholder Views

#### INDUSTRY VIEWS
- Most Industry stakeholders do not believe regulation is too onerous.
- However, there is a feeling that the lower evidence requirements for CE marking compared to reimbursement and commissioning procedures result in later adoption problems where studies have focused on meeting regulatory requirements rather than reimbursement and commissioning evidence requirements.
- Limited early dialogue between Industry and HMG / ALBs.
- Some Industry stakeholders feel Notified Body audits are too slow and that they do not feel engaged with Notified Bodies.

#### HMG / ALBs VIEWS
- HMG / ALBs are of the view that Industry do not focus enough time and resources thinking about their route to market in the regulatory stage, which leads to later adoption problems.
- HMG / ALBs think that companies do not always see the value of early dialogue conversations with HMG / ALBs.
- Fees are a potential barrier for SME early engagement.
- Feel that Industry generally just considers the MHRA as a regulatory authority, rather than an agency that is able to provide advice.

#### NHS VIEWS
- There is the feeling in the NHS that the regulatory stage is the stage that is least challenging.
- There is currently not a list of all CE marked devices, which means adoption often relies on Industry push rather than NHS pull.

#### CHARITY VIEWS
- Demand for more joined up thinking around regulation globally.
- Specific diseases could be used as a ‘test-bed’ for reform from development through to adoption.
- The review should build on what is already working.

---

Source: Stakeholder interviews, workshops and Deloitte analysis.
Medical devices: National Reimbursement
Key Challenges

Our research highlighted four key challenges in the national reimbursement stage for innovative medical devices:

- **Lack of funding mandate**
  
  Only medical devices assessed by the NICE Technology Appraisal Programme and found to be cost effective carry a funding mandate. Cost-effective Medical Technology Evaluation Programme (MTEP) recommendations are purely advisory and do not carry a funding mandate, with limited effect on local adoption.
  
  - The majority of medical devices are assessed via MTEP.

- **Lack of commercialisation capability**
  
  Manufacturers (especially SMEs) and healthcare professionals sometimes struggle to articulate the value proposition of medical devices, especially using processes originally designed for pharmaceuticals.

- **NICE turnaround times**
  
  NICE evaluation timelines can be too long, especially when compared to the innovation cycle of medical devices (often iterative), sometimes leading to the launch of product v2 before NICE has completed an assessment of v1.

- **System requires Industry push**
  
  Suggestion that Industry (especially SMEs) are unwilling to engage with NICE at early dialogue opportunities or submit products for assessment due to concerns about success rates, the additional cost and time of gathering sufficient evidence for the NICE assessment process versus the outcome achieved.

Note: MTEP = Medical Technologies Evaluation Programme

Source: Stakeholder interviews, workshops and Deloitte analysis

National Reimbursement: *Illustrative Quotes*

Quotes summarise some of the key challenges in the national reimbursement stage for innovative medical devices.

**National Reimbursement: Illustrative Quotes**

“Medtech companies rarely collect adequate evidence for evaluation by NICE”

“We want parity with pharma from a reimbursement perspective”

“NICE and NHS England should have more realistic expectations around data requirements”

“I don’t feel there is alignment between NHS England’s and NICE’s strategic priorities”

“Few but increasing numbers of companies are gathering further evidence after consulting NICE so their device can then be evaluated by NICE”

“The whole NICE approach to medical technology needs reviewing”

“NICE should take wider consideration of the cost of a disease, such as social cost and cost to GDP”

“RCTs are not appropriate for most of medtech... There should be a focus on real world evidence for reimbursement and commissioning”

“There’s not necessarily an advantage to getting a NICE recommendation as no one has to adopt [the medical technology]”

**COMMENTS ON NATIONAL REIMBURSEMENT**

Key:
- Industry
- NHS
- Charities
- HMG / ALBs

Source: Stakeholder interviews, workshops and Deloitte analysis


**INDUSTRY VIEWS**

- Industry would like NICE recommended medical devices to have a **funding mandate** attached to them
- Feeling that medtech **value propositions can be hard to articulate** in processes that were originally designed for pharma
- Feeling that **NICE turnaround times can be too long**, especially when compared to the innovation cycle
- Suggestion that Industry (especially SMEs) are **unwilling to engage with NICE** at early dialogue opportunities or submit products for assessment due to **concerns about success rates** and the **additional time and cost** of gathering further evidence

**HMG / ALBs VIEWS**

- There is the general belief that there could be **better alignment** between HMG /ALBs (e.g., between NHS England, NICE and the Department of Health)
- Suggestion that NICE should be having **early dialogue** with Industry in the regulatory and development stages so that the correct advice and **guidance on evidence collection** for national reimbursement and local adoption purposes can be provided
- Companies should be **encouraged to submit to NICE** at the same time that companies begin the CE marking process

**NHS VIEWS**

- There is the feeling that in the NHS that there is a **disjoint between national and local organisations**; for instance, a recommendation from NICE does not mean that there will be widespread adoption of an **in vitro** diagnostic across CCGs / providers
- There should be **greater use of real world evidence**, rather than RCTs

**CHARITY VIEWS**

- NICE assessment is **not considering** the overall **cost effectiveness** to patient and society
- Feeling that NICE **topic selection** does not focus enough attention on medtech that would only affect a **small group** of patients
- **Specific diseases** could be used as a ‘test-bed’ for reform from development through to adoption
- The review should **build on** what is **already working**
Medical devices: Local Commissioning & Adoption
Local commissioning & adoption: Detailed Pathway

Process must be iterated for each local health economy in turn to achieve maximum adoption

Adoption of technology after first access

*Time to wide-spread / maximum patient access, (i.e. via clinician to clinician and industry to clinician diffusion) is dependent on:
• NICE TAP or other NICE recommendations
• Specialised commissioning
• Clinical guidelines
• Training
• Innovativeness of the product
• Complexity of the value proposition

Patient access*

Diffusion through health economy

2 years – 15 years +

Funding package negotiation*

Funding agreement reached

Provider procurement (de-commissioning if applicable)

Local patient access

Patient access*

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Key Challenges

Our research highlighted five key challenges in the local commissioning and adoption stage for innovative medical devices:

**Unclear route to market**
- No consistent route to local markets exists for many medical devices, with value evidence requirements heavily dependent on local stakeholder preferences. There is also a heavy reliance of personal relationships to drive adoption.

**Process duplication**
- Lack of central coordination and clear route to market results in significant sales process duplication across CCGs and/or providers.

**Budget siloes**
- Internal budget siloes within and between NHS organisations dis-incentivises the adoption of medical devices where the costs and value realised are not aligned.
  - Short budget horizons and lost income from lower utilisation further dis-incentivises investments in medical devices that would result in savings at an aggregate level.

**Speed of pricing / contracting update**
- Medical devices often experience long delays before price and contract update (e.g., inclusion on Tariff), creating strong dis-incentives for adoption by acute Trusts. Additionally, large multi-year service contracts can stifle competition and the uptake of innovative medical devices.

**SME expertise / scale**
- SME manufacturers report significant cost-of-sales issues resulting from the need to repetitively engage multiple stakeholders in LHEs across multiple LHEs, as well as uncertainty as to how best to engage.
Quotes summarise some of the key challenges in the local commissioning and adoption stage for innovative medical devices.

**Illustrative Quotes**

**COMMENTS LOCAL COMMISSIONING AND ADOPTION**

- "Need to support commissioners to make smarter decisions – use a framework for knowledge transfer and use AHSNs to promote the transfer of knowledge"  
- "Lack of funding direction for medical technology means that NICE appraisals are not seen to be as important as pharma"  
- "There are significant perverse incentives in the NHS"  
- "There is no incentive to develop and adopt innovation in the NHS"  
- "The tariff can incentivise you to do the wrong thing"  
- "Everyone says, 'I want to trial it locally too…my patients are different'"  
- "The problem is that no medtech has been successfully rolled out nationally"  
- "At a local level, there is often different buy-in from different providers to change the system"  
- "Stretch to call it a pathway – it’s not fit for purpose"  
- "Only get speedy adoption of products that replace existing technologies [at less cost], as tariff update is not required"  
- "At a local level, there is often different buy-in from different providers to change the system"  
- "Often it’s engineering science, not medical science, that should be driving adoption decisions, but people don’t think that way"  
- "Even procurement managers say, ‘I don’t understand procurement’"  

**Key:**  
- Industry  
- NHS  
- Charities  
- HMG / ALBs  

Stakeholder Views

**INDUSTRY VIEWS**

- Industry stakeholders interviewed are strongly of the opinion that local commissioning and adoption of medtech is the greatest barrier to patient access.
- No clear route to market, with high variability between LHEs and access highly dependent on clinician relationships.
- Lack of funding mandate for non-TAP NICE-assessed products limits adoption.
- Affordability considered a key barrier to adoption for cost-effective (i.e. not cost-saving) innovations.
- Situation especially acute for SMEs due to lack of scale.

**HMG / ALBs VIEWS**

- Agreement among interviewed stakeholders that adoption, especially at local level, is complex and slow.
- Lack of a clear route to market identified as a problem.
- Acceptance that lack of funding mandate for most NICE-recommended medtech limits local commissioner willingness to pay for innovative medtech.
- Feeling that lack of central coordination results in significant duplication across CCGs and / or providers.
- Sense that commercialisation capability is a problem, especially for SMEs.

**NHS VIEWS**

- Majority of interviewed NHS stakeholders believed that local commissioning and adoption is the greatest barrier to access.
- Major barriers to clinician use of medtech are financial:
  - Speed of pricing and contracting update (e.g., inclusion on Tariff) even for NICE-recommended products.
  - Departmental and LHE budget silos and horizons limit the uptake of products, especially where benefits will accrue across multiple care pathways and settings of care.
  - Double running costs when changes occur.
- Desire to test medtech on own patients before adopting.

**CHARITY VIEWS**

- Feeling that NHS commissioners do not focus enough on patients and their quality of life, and spend too much time meeting minimum performance standards and financing constraints.
- Feel that some inequalities between LHEs are due to variation in the adoption of innovative medtech.
- Specific diseases could be used as a ‘test-bed’ for reform from development through to adoption.

Notes: LHE = Local Health Economy; TAP = Technology Appraisal Programme.
Source: Stakeholder interviews, workshops and Deloitte analysis.

Medical devices: Case Studies
Case study - Medical devices (1/2)

Adoption of soft tissue support and repair in breast reconstruction surgery is limited by exclusion from National Tariff

**Background**

- Breast reconstruction is offered to all patients considering a mastectomy
- Based on the results and outcomes of data from the US experience of Soft Tissue Support and Repair (STSR) in breast reconstruction surgery, it is believed that STSR offers a better patient experience with significant immediate and long-term patient benefits
- In the short term, the appropriate patient would benefit from either a direct reduction in the number of operations required or much reduced theatre time with subsequently reduced morbidity versus other procedures
- In the longer term, US data confirms that downstream complications with STSR are significantly reduced versus a 2-stage approach
- STSR requires the use of implantable medical devices such as acellular dermal matrices or other novel implantable devices

**Issues**

- Currently there is no specific OPCS code for Soft Tissue Support and Repair (STSR) in breast reconstruction surgery
- Recent attempts at introducing OPCS codes have not been successful
- As a result, funding needs be found from outside the National Tariff on a Trust-by-Trust basis
- Local clinicians have to get funding at a local level by:
  - Securing approval on a trial basis
  - Negotiating for local CCG top-up funding
  - Using existing theatre budget to fund STSRs
- The lengthy and variable process of getting funding for the procedure limits and slows local adoption, while process duplication from Trust-to-Trust limits the widespread adoption of the procedure (and the related medical devices used in the procedure)

**Challenges**

- Alignment across key stakeholders
- Counterproductive incentives
- Unclear route to market
- Process duplication
- Budget siloes
- Speed of pricing / contracting update
Case study - Medical devices (2/2)

Adoption of cardiac devices with longer battery life is poor because procurement decisions are often made to meet short-term budget constraints.

**Background**

- Cardiac devices such as implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy devices with integrated defibrillators (CRT-D) are first line treatments for correcting life-threatening cardiac arrhythmias. These are effective tools to slow the progression of heart failure for at risk patients.
- These devices are implanted inside the body and replaced every 4 to 5 years as their battery life deteriorates.
- Patients require several device replacements over their lifetimes, which creates additional costs to the healthcare system and increases the risk of complications for patients with each procedure.
- Many device manufacturers have improved their battery technology, creating new products with battery lives > 10 years.

**Issues**

- New devices with longer battery lives are more expensive to acquire, but are proven to be cost-effective in the medium term. It is estimated that a 30% cost saving to the system is achieved with the new long-life devices.
- Despite the cost-saving and clinical recommendations, many Trusts do not procure the long-life devices as they are not fully reimbursed for them through the national tariff and local top-ups.
- Commissioners make decision based on short-term budget constraints.
- There are often no / limited incentives to locally adopt products / services that prevent the need for further healthcare interventions, and bring benefits or system savings over the long-term.
- Moreover, overall savings for the local health economy from adopting the long-life devices results in a loss of revenue to Trust budgets from a reduction in follow-up procedures.

**Challenges**

- Alignment across key stakeholders
- Counterproductive incentives
- Unclear route to market
- Process duplication
- Budget siloes
- Speed of pricing / contracting update
Challenges: *In vitro* diagnostics

Our research also highlighted a number of challenges that are specific to *in vitro* diagnostics by pathway stage

Cross-cutting

- Alignment across key stakeholders
- Counterproductive incentives
- Data, evidence & measurement
- Culture

Development

- Lack of clinical & commercial capability
- NHS trial approvals process
- Lack of patent protection (e.g., in-house tests)

Regulation

- Lack of early dialogue
- Uneven requirements vs. in-house tests
- Potential for greater regulatory burden under new system

National Reimbursement

- Lack of funding mandate
- Lack of commercialisation capability
- System requires Industry push

Local Commissioning and Adoption

- Unclear route to market
- Process duplication
- Budget siloes
- Contracting

Notes: (1) CDx = co-diagnostics; Source: Stakeholder interviews, workshops and Deloitte analysis

In vitro Diagnostics: Development
Development: **Detailed Pathway**

- **Basic research**
- Identification of need
- Go / No Go decision
- Scientific development
- Product prototyping

- **Class II & Class III devices (including radiation-based diagnostics)**
- **General non-companion in vitro diagnostics**
- **General companion in vitro diagnostics**
- **High risk in vitro diagnostics**

**Clinical testing**
Comprises of clinical validation (IVD only), clinical utility testing and health economic assessments (not all products). Clinical testing can occur in the NHS or another healthcare system.

- Engage external research stakeholders
- Study design and appraisal
- MHRA (pre-clinical), NRES (research ethics), and NIHR CRN (protocol feasibility) approval?
- Patient recruitment and trials
- Analysis of results

**Analytic validation**

- Some medical devices and in vitro diagnostics undergo clinical testing prior to regulatory engagement

- Clinical evidence gathered
- Loop iterated as necessary but not shown to aide clarity
- Further clinical evidence required (for regulatory purposes or NICE evaluation)

**Initiation of clinical testing**

- Go / No Go decision
- Developed product

**Go / No Go decision**

- Product scale-up feasibility studies
- Developed product

**6 months – 20 years**

Key Challenges

Our research highlighted three key challenges in development for the early access to innovative *in vitro* diagnostics:

- **Lack of clinical & commercial capability**
  - Some concerns that there can be a focus within development, particularly for SMEs, on solving the scientific diagnostic marker challenge rather than identifying a clinical need and focusing on generating evidence of clinical benefit and commercialisation, leading to adoption problems downstream.

- **NHS trial approvals process**
  - Slow approval processes (e.g., ethics and data / sample consenting) raise costs of clinical evidence collection (especially for SMEs), delaying adoption.
    - Particularly, increased restrictions in access to tissue / blood for diagnostics development.

- **Lack of patent protection (e.g., in-house tests)**
  - *In vitro* diagnostic tests can suffer from lack of strong IP protection with loss of exclusivity to in-house testing’ by hospital labs, dis-incentivizing investment in development.
    - This problem is exacerbated by long NICE assessment times, which can result in rivals coming to market before the original test has completed NICE assessment.

Note: In-house tests are tests developed by the NHS in-house (i.e. within pathology laboratories of individual NHS trusts)
Source: Stakeholder interviews, workshops and Deloitte analysis
Development: *Illustrative Quotes*

Quotes summarise some of the key challenges in the development stage for innovative *in vitro* diagnostics

**COMMENTS ON DEVELOPMENT**

- "There is an increasing cost and time of development due to NHS overheads, different contracts and approvals" (Industry)
- "There is a high cost burden of developing products in the UK" (NHS)
- "The real problem lies in adoption rather than in the development or regulatory stages" (Charities)
- "Most companies want to work with the NHS but find it very difficult" (HMG / ALBs)
- "The NHS are infringing on patents [and IP by developing their own tests]" (Industry)
- "Getting trials approved in the NHS takes too long" (NHS)
- "Industry doesn’t focus enough on thinking about adoption in the development stage, which causes them problems later on" (Industry)
- "The ethics approval process needs to be simplified" (Charities)
- "It is incredibly hard for Industry to access patient tissue samples" (Industry)
- "UK SME management often lack the commercial awareness that is seen in the US SMEs" (HMG / ALBs)
- "There is an urgent need to increase research and engage Industry" (Charities)

**Key:**
- Industry
- NHS
- Charities
- HMG / ALBs

Source: Stakeholder interviews, workshops and Deloitte analysis
**Stakeholder Views**

**INDUSTRY VIEWS**
- Most Industry stakeholders believe the **NHS trials approvals process is too time consuming**
- The **cost of clinical trials** is a burden for SMEs
- Industry feel that there are **limited incentives** for Trusts and healthcare professionals to get involved with clinical trials
- **Successful companies focus** on generating evidence of clinical benefit and are clear about their **route to adoption**
- Industry feel that the **NHS infringes on its IP** by developing some in-house tests, but **Industry rarely takes action** against the NHS out of fear of damaging relationships

**HMG / ALBs VIEWS**
- HMG / ALBs are of the view that **Industry do not focus** enough time and resources to think about their **route to market** in the development stage, which leads to **later adoption problems**
- HMG / ALBs think that **companies do not always see the value** of early dialogue conversations with HMG / ALBs, especially around study design and evidence requirements
- **Fees** are a potential **barrier for SMEs** to engage earlier with HMG / ALBs
- Sense that **commercialisation capability** is a problem, especially for SMEs

**NHS VIEWS**
- There is a feeling that it **does not matter how much evidence manufacturers** gather in the development stage as **local commissioners and providers** will want to re-validate locally
- It is incredibly **hard for Industry to access patient tissue samples** for research purposes
- Most companies want to work with the NHS but find it **hard to partner with the NHS**
- **Staff capacity limits** the NHS’s ability to work in the development of innovative **in vitro** diagnostics
- The NHS **infringe** on Industry **patents** with some in-house tests

**CHARITY VIEWS**
- Charities feel that there is an urgent need to **increase research and engage Industry**, especially for disease areas where there has been no or limited treatment or care advances in the last decade
- The NHS should **encourage more patients and clinicians to get involved with clinical research**
- **Specific diseases** could be used as a ‘test-bed’ for reform from development through to adoption
- The review should **build on** what is **already working**

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Source: Stakeholder interviews, workshops and Deloitte analysis

*In vitro* Diagnostics: Regulation
Regulation: Detailed Pathway

1. **Determine product class, regulatory framework and need for Authorised Representative**
   - Non-sterile non-measuring Class I devices
   - Sterile or measuring Class I devices
   - Class II & Class III devices (including radiation-based diagnostics)
   - General non-companion in vitro diagnostics
   - General companion in vitro diagnostics
   - High risk in vitro diagnostics (including self-testing)

2. **Has sufficient clinical evidence been collected?**
   - No: Further clinical testing
   - Yes: Prepare Technical File / Design Dossier

3. **Implement a Quality Management System**
   - Most companies apply ISO 13485 to achieve QMS compliance

4. **Notified Body audit**
   - CE Marking Certificate issued
   - MHRA registration

5. **Declaration of Conformity**
   - Affix CE mark, Market authorised product

6. **Developed product**

7. **Prepare Technical File / Design Dossier**
   - CE Marking Certificate issued / MHRA registration

8. **Market authorised product**

9. **<1 month – 2 years**

Source: Stakeholder interviews, workshops and Deloitte analysis

Key Challenges
Our research highlighted two key challenges in the regulatory stage for the early access to innovative *in vitro* diagnostics

**Lack of early dialogue**
- **Low uptake of available advice** on protocol and trial design
  - Not seen as *value-add* for companies with deep experience
  - Seen as **too large a time and cost investment** for SMEs
  - Lack of engagement and **uncertainty about effectiveness** of this dialogue reduces partnering

**Uneven requirements vs. in-house tests**
- **Commercially developed** *in vitro* diagnostics are required to **generate evidence for CE marking**. This is **not** a requirement for equivalent tests **developed in-house** by healthcare providers, leading to **disincentives for Industry investment**, and potential quality issues

**Potential for greater regulatory burden**
- The **European Union** is currently finalising a **new regulatory Directive** for *in vitro* diagnostics, which is planned for completion in 2016 and **implementation by 2021**
  - Some Industry bodies have raised concerns that this **new system has the potential to significantly increase the evidence requirements** of CE marking without requiring the same of ‘in-house’ diagnostics

**Source:** Stakeholder interviews, workshops and Deloitte analysis
Regulation: *Illustrative Quotes*

Quotes summarise some of the key challenges in the regulatory stage for innovative *in vitro* diagnostics

**COMMENTS ON REGULATION**

“We like the CE marking but we are worried the process will get tougher”

“Companies don’t consider us as an advice provider”

“It’s not safe or a fair playing field with in-house tests being regulated so lightly”

“We think there needs to be more joined up thinking at a global level around regulation”

“There should be a directory and ratings system for all CE marked medtech”

“Fees would be a barrier for SMEs to engage with us”

“Regulation is not the bottleneck in the system”


Source: Stakeholder interviews, workshops and Deloitte analysis

Key:
- **Industry**
- **NHS**
- **Charities**
- **HMG / ALBs**
Stakeholder Views

**INDUSTRY VIEWS**
- Most Industry stakeholders do not believe regulation is too onerous
- However, there is a feeling that the lower evidence requirements for CE marking compared to reimbursement and commissioning procedures result in later adoption problems where studies have focused on meeting regulatory requirements rather than reimbursement and commissioning evidence requirements
- Limited early dialogue between Industry and HMG / ALBs
- Feel that NHS in-house testing is not adequately regulated
- Concerned that new EU regulation will increase costs

**HMG / ALBs VIEWS**
- HMG / ALBs are of the view that Industry do not focus enough time and resources thinking about their route to market in the regulatory stage, which leads to later adoption problems
- HMG / ALBs think that companies do not always see the value of early dialogue conversations with HMG / ALBs
- Fees are a potential barrier for SME early engagement
- Feel that Industry generally just considers the MHRA as a regulatory authority, rather than an agency that is able to provide advice

**NHS VIEWS**
- There is the feeling in the NHS that the regulatory stage is the stage that is least challenging
- There is currently not a list of all CE marked in vitro diagnostics, which means adoption often relies on Industry push rather than NHS pull

**CHARITY VIEWS**
- Demand for more joined up thinking around regulation globally
- Specific diseases could be used as a ‘test-bed’ for reform from development through to adoption
- The review should build on what is already working

Source: Stakeholder interviews, workshops and Deloitte analysis
In vitro Diagnostics: National Reimbursement
National reimbursement: Detailed Pathway

Medical Technologies Evaluation Programme (MTEP) – c. 9 months
- Scoping and evidence gathering
- Assessment and consultation
- Draft recommendations
- Consultation
- Final recommendations
- Pre-publishing final checks
- Guidance published

Where cost saving or cost neutral with incremental health gain
- Possible specialised commissioning?
- Yes
- No (most)

Diagnostics Assessment Programme (DAP) – c. 9-15 months
- Scoping and evidence gathering
- Assessment and consultation
- Draft recommendations
- Consultation
- Final recommendations
- Pre-publishing final checks
- Guidance published

Where value proposition is a greater benefit at a greater cost
- Interventional Procedure Process (IPP) – c. 9 months
- Scoping and evidence gathering
- Assessment and consultation
- Draft recommendations
- Consultation
- Final recommendations
- Pre-publishing final checks
- Guidance published

For surgical procedures, where irradiative energy is used, and where body cavities are accessed
- MTEP, IPP or DAP NICE recommendation?
- No
- Yes

Possible specialised commissioning?
- Yes
- No (most)

Single Technology Appraisal Process – c. 9 months
- Scoping and evidence gathering
- Consultation
- Assessment
- Consultation
- Final recommendations
- Final recommendations
- Pre-publishing final checks
- Guidance published

Where value proposition is increased benefit for more cost, especially where high uptake is expected or unit costs are high
- NICE guidance published
- 9 months – 3 years

Multiple Technology Appraisal Process – c. 12 months
- Scoping and evidence gathering
- Consultation
- Assessment
- Consultation
- Final recommendations
- Final recommendations
- Pre-publishing final checks
- Guidance published

Where value proposition is increased benefit for more cost, especially where high uptake is expected or unit costs are high

"Product eligible when CE mark is expected within 12 months
- Notification of medical technology to NICE by sponsor*
- Very few
- Increasing

Notification of medical technology to NICE by sponsor*
- Very few
- Increasing

"*Product eligible when CE mark is expected within 12 months
- NICE guidance published
- 9 months – 3 years

Key
- Non-sterile non-measuring Class I devices
- Sterile or measuring Class I devices
- Class II & Class III devices (including radiation-based diagnostics)
- General non-companion in vitro diagnostics
- General companion in vitro diagnostics
- High risk in vitro diagnostics (including self-testing)

Source: Stakeholder interviews, workshops and Deloitte analysis
Key Challenges

Our research highlighted four key challenges in the national reimbursement and commissioning stage for the early access to innovative \textit{in vitro} diagnostics

- \textbf{Lack of funding mandate}: \textit{In vitro} diagnostics recommended by the DAP do not receive a funding mandate, with limited effect on local adoption. Where a drug and its CDx is recommended through the NICE TAP, there is no funding mandate for the CDx (while the drug component has a funding mandate). In practice, we’ve heard that TAP recommended CDx are not being funded locally or being funded by pharma.

- \textbf{Lack of commercialisation capability}: Manufacturers, especially SMEs, and healthcare professionals sometimes struggle to articulate and measure the value proposition of \textit{in vitro} diagnostics, especially during processes originally designed for pharmaceuticals and when the value realised by a diagnostic may take several years to realise.

- \textbf{System requires Industry push}: Suggestion that Industry (especially SMEs) are unwilling to engage with NICE at early dialogue opportunities or submit products for assessment due to concerns about success rates and the additional cost and time of gathering sufficient evidence for the NICE assessment process.

- \textbf{Usual funding streams don’t cover CDx}: Currently, pharmaceutical companies pay for a considerable proportion of companion diagnostic tests due to uncertainties around the funding of companion diagnostics by the NHS (e.g., the Cancer Drugs Fund does not fund CDx even when the partner drug is funded).

\textbf{Notes:} CDx = co-diagnostics; TAP = Technology Appraisal Programme; DAP = Diagnostics Assessment Programme

\textbf{Source:} Stakeholder interviews, workshops and Deloitte analysis

Quotes summarise some of the key challenges in the national reimbursement stage for innovative in vitro diagnostics

**COMMENTS ON NATIONAL REIMBURSEMENT**

- "Medtech companies rarely collect adequate evidence for evaluation by NICE"
- "I don’t feel there is alignment between NHS England’s and NICE’s strategic priorities"
- "We want parity with pharma from a reimbursement perspective"
- "NICE and NHS England should have more realistic expectations around data requirements"
- "Few but increasing numbers of companies are gathering further evidence after consulting NICE [so their device can be evaluated by NICE]"
- "The whole NICE approach to medical technology needs reviewing"
- "NICE should take wider consideration of the cost of a disease, such as social cost and cost to GDP"
- "There’s not necessarily an advantage to getting a NICE recommendation as no one has to adopt [the medical technology]"
- "It’s ridiculous that the Cancer Drugs Fund does not fund CDx when a CDx partner drug is on the CDF list"

**Key:**
- Industry
- NHS
- Charities
- HMG / ALBs
**INDUSTRY VIEWS**

- Industry would like NICE-recommended *in vitro* diagnostics to have a funding mandate
- Feeling that *in vitro* diagnostics value propositions can be hard to articulate in processes that were originally designed for pharma
- Feeling that NICE turnaround times can be too long, especially when compared to the innovation cycle
- Suggestion that Industry (especially SMEs) are unwilling to engage with NICE at early dialogue opportunities or submit products for assessment due to concerns about success rates and the additional time and cost of gathering further evidence

**HMG / ALBs VIEWS**

- There is the general belief that there could be better alignment between HMG /ALBs (e.g., between NHS England, NICE and the Department of Health)
- Suggestion that NICE should be having early dialogue with Industry in the regulatory and development stages so that the correct advice and guidance on evidence collection for national reimbursement and local adoption purposes can be provided
- Companies should be encouraged to submit to NICE at the same time that companies begin the CE marking process

**NHS VIEWS**

- There is the feeling that in the NHS that there is a disjoint between national and local organisations; for instance, a recommendation from NICE does not mean that there will be widespread adoption of an *in vitro* diagnostic across CCGs / providers

**CHARITY VIEWS**

- NICE assessment is not considering the overall cost effectiveness to patient and society
- Feeling that NICE topic selection does not focus enough attention on *in vitro* diagnostics that would only affect a small group of patients
- Specific diseases could be used as a ‘test-bed’ for reform from development through to adoption
- The review should build on what is already working

Source: Stakeholder interviews, workshops and Deloitte analysis

In vitro Diagnostics: Local Commissioning & Adoption
Key Challenges

Our research highlighted four key challenges in the local commissioning and adoption stage for the early access to innovative *in vitro* diagnostics:

- **Unclear route to market**
  - No consistent route to local markets exists for many *in vitro* diagnostics, with a wide range of contracting arrangements from simple one-off local orders through to standing orders of tens of millions of pounds. There is also a heavy reliance of personal relationships to drive adoption.

- **Process duplication**
  - Lack of central coordination and clear route to market results in significant sales process duplication across CCGs and / or providers. Additionally, the process of getting an *in vitro* diagnostic compatible with many multiplex assay platforms is costly, especially for SMEs.

- **Budget siloes**
  - Internal budget siloes within and between NHS organisations dis-incentivises the adoption of *in vitro* diagnostics where the costs and value realised are not aligned (e.g. pathology vs therapeutic / pathway budgets)
    - Budget short-sightedness further dis-incentivise investments that would save costs at an aggregate level
  - There is currently little standardisation of process and documentation for contracts, which results in the use of procurement intermediaries and reduces prices. Additionally, the use of managed service contracts with long renewal terms limits innovation, competition and creates barriers to change in the NHS (see case study)

Source: Stakeholder interviews, workshops and Deloitte analysis

**Illustrative Quotes**

Quotes summarise some of the key challenges in the local commissioning and adoption stage for innovative *in vitro* diagnostics

**COMMENTS ON LOCAL COMMISSIONING AND ADOPTION**

- "Only get speedy adoption of products that replace existing technologies [at less cost], as tariff update is not required"
- "Lack of funding direction for medical technology means that NICE appraisals are not seen to be as important as pharma"
- "There are significant perverse incentives in the NHS… such as using more invasive diagnostics when a less invasive diagnostic would be equally effective and cost the system less"
- "Everyone says, 'I want to trial it locally too…my patients are different'"
- "There is no incentive to develop and adopt innovation in the NHS"
- "Need to support commissioners to make smarter decisions – use a framework for knowledge transfer and use AHSNs to promote the transfer of knowledge"
- "Stretch to call it a pathway – it’s not fit for purpose"
- "At a local level, there is often different buy-in from different providers to change the system"
- "Even procurement managers say, ‘I don’t understand procurement’"

**Key:**
- Industry
- NHS
- Charities
- HMG / ALBs

Source: Stakeholder interviews, workshops and Deloitte analysis
Industry stakeholders interviewed are strongly of the opinion that local commissioning and adoption of medtech is the greatest barrier to patient access.

- No clear route to market, with high variability between LHEs and access highly dependent on clinician relationships
- Lack of funding mandate for non-TAP NICE-assessed products limits adoption
- Feeling that in vitro diagnostics are just considered a system overhead cost by commissioners
- Little contract standardisation, which particularly affects SMEs

Majority of interviewed NHS stakeholders believed that local commissioning and adoption is the greatest barrier to access.

- Major barriers to clinician use of in vitro diagnostics are financial:
  - Speed of pricing and contracting update (e.g., inclusion on Tariff) even for NICE-recommended products
  - Departmental and LHE budget silos and horizons limit the uptake of products, especially where benefits will accrue across multiple care pathways and settings of care
  - Double running costs when changes occur

Feeling that NHS commissioners do not focus enough on patients and their quality of life, and spend too much time meeting minimum performance standards and financing constraints.

- Feel that some inequalities between LHEs are due to variation in the adoption of innovative medtech
- Specific diseases could be used as a ‘test-bed’ for reform from development through to adoption
In vitro Diagnostics: Case studies
Case study – *In vitro* diagnostics (1/2)

A non-invasive pre-natal test has had limited adoption due to discussions around the inclusion in the national Tariff for the maternity pathway

**Background**

- Non-Invasive Pre-Natal Testing (NIPT) uses cell-free foetal DNA from a mother’s blood sample to analyse chromosomal abnormalities such as Down’s Syndrome, Edwards Syndrome and Patau Syndrome. The test is less invasive than the alternative amniocentesis/CVS, currently offered for mothers with above 1:150 probability.
- An NHS hospital has developed the capabilities to deliver the test in their lab.
- The test is not offered as part of the current NHS maternity pathway and the RAPID trial has been designed to gather evidence.
- The inclusion in the NHS maternity pathway and overall widespread adoption is the main challenge.

**Issues**

- The new service at the offered price is less than the invasive test for the NHS, but adoption at Trust level has not been widespread.
- As a new service development, Trusts need to discuss the introduction of NIPT with CCGs to be included as part of the maternity pathway and to be paid under the national tariff.
- Trusts and CCGs are not considering whole system costs as they only look at the maternity pathway and not all the additional costs to the system.
- The inclusion in the National Screening Programme is a lengthy process which leads to adoption in some areas of England, increasing the inequality access to services.

**Challenges**

- Counterproductive incentives
- Lack of funding mandate
- Usual funding streams don’t cover CDx
- Unclear route to market
- Process duplication
- Budget siloes
- Contracting

**Source:** Stakeholder interviews, workshops and Deloitte analysis
Case study – *In vitro* diagnostics (2/2)

The use of a calprotectin test on individuals with chronic intestinal symptoms saves money and is recommended by NICE, but tests are not widely used.

### Background

- In primary care a common diagnostic challenge is the management of patients with chronic intestinal symptoms, in particular the differentiation of IBD, which includes both Crohn’s Disease (CD) and Ulcerative Colitis (UC), from IBS.
- There are simple, accurate and differentiating tests, to aid in management and referral decisions for such patients (calprotectin tests) that are not widely used.
- Referral to secondary care is straightforward in patients with acute symptoms or “red flag” features, such as blood in stool, nocturnal symptoms, weight loss, family history of colon cancer or presence of clinical signs.
- However, the majority of patients comprise a mixed group with both identifiable pathologies and “functional” condition.

### Issues

- The use of a calprotectin test on individuals with chronic intestinal symptoms saves money downstream in terms of an outpatient appointment, endoscopy and follow up appointments.
- Cost benefit analysis suggests that widespread adoption of point-of-care calprotectin tests would save the NHS c.£200m but adoption is not widespread due to perverse incentives.
- Overall savings for the local health economy are seen as a loss of revenue to Trust budgets, who are paid per episode using the Payments by Results Tariff.
- NICE produced guidance in October 2013 recommending the use of faecal calprotectin testing to help doctors distinguish between inflammatory bowel diseases.
- Despite the aggregate cost savings and NICE guidance, there has been limited adoption of calprotectin tests.

### Challenges

- Counterproductive incentives
- Lack of funding mandate
- Usual funding streams don’t cover CDx
- Unclear route to market
- Process duplication
- Budget siloes
- Contracting

Source: Stakeholder interviews, workshops and Deloitte analysis

Future proofing

We’ve considered whether the current pathways for digital health and precision medicine are fit for purpose.

We’ve considered:

1. The current pathway

2. Key stakeholder views and the current barriers to adoption

3. What is needed to make the pathways future proof

Source: Stakeholder interviews, workshops and Deloitte analysis

Future proofing: *Digital health*

The current pathway from development to adoption for digital health is varied.

**Illustrative pathway: apps**

- Often no / very limited clinical or cost-effectiveness evidence is collected.
- No / very limited regulation for most TEC solutions / products.
- The MHRA are increasingly being challenged by TEC solution / product classification as software that has a medical purpose are sometimes classified as a medical device under the Medical Device Directive.
- No / limited national reimbursement mechanisms for most TEC solutions / products.

**Regulation**

**National Reimbursement**

**Local Commissioning and Adoption**

Industry / Tech funded

HCP / Commissioner / Provider funded

Patient / Consumer funded

NHS choices health apps library and the European Directory of Health Apps helps to drive adoption.

Notes: TEC = Technology-Enabled Care; Currently some consumer wearables and apps will fall within the regulatory definition of a medical device; Stakeholder interviews, workshops and Deloitte analysis.
Future proofing: *Digital health*

The digital health pathway is not fit for purpose with a number of significant barriers to widespread adoption.

**Barriers to adoption / Key Challenges**

- **Standards**
  - A lack of common standards on data protection, privacy and security
  - Poor interoperability and a need for interoperability standards

- **Regulation**
  - The need for a clear legal and regulatory framework
  - Concerns over patient safety, quality of product and security

- **Reimbursement**
  - Inadequate funding and reimbursement models restrict adoption

- **Culture and infrastructure**
  - Cultural resistance, impacting accessibility and equality of access, user attitudes and limited appreciation of how technology can improve patient outcomes
  - Limited evidence on cost-effectiveness and concerns about the need to develop this evidence (although capability is increasing and costs are falling)
Future proofing: Digital health

There are a number of barriers that need to be addressed for the digital health pathway to be future proofed.

**What is needed?**

- **Standards**
  - Common standards on data protection, privacy and security (for data and devices)
  - A common and trusted framework for the development and collection of evidence on clinical and cost-effectiveness for TEC solutions/products
  - Interoperability capability and standards
  - TEC solution/product safety and quality standardisation

- **Regulation**
  - A clear legal and risk-stratified regulatory framework

- **Reimbursement**
  - New funding and reimbursement models: e.g., streamline market access by providing clarity on who bears the cost of TEC solutions/products and allocate a separate funding pot/budget for TEC solutions/products

- **Culture and infrastructure**
  - A better understanding of how TEC solutions/products can improve patient outcomes and/or reduce system costs
  - Widespread respect and use of approved TEC solution/product directories
  - More patient and clinical engagement in the design and development of TEC solutions/products
  - Better provision of specialised training, support and incentives to use TEC solutions/products where they will improve patient outcomes and/or reduce system costs
  - National and local mechanisms for TEC solutions/products to feed into pathway re-design
  - New models of care based on alliances and partnerships between TEC companies and traditional providers

Note: TEC = Technology-Enabled Care
Source: Stakeholder interviews, workshops and Deloitte analysis

Future proofing: *Precision Medicine/Companion Diagnostics*

Precision medicine requires the system to reward innovations that by definition reduce the number of recipients of a given treatment option.

**Illustrative pathway: Separate, multi-tier, multi-speed, proliferation of stakeholders**

Slow
- Biological challenge
- Marker challenge

Fast
- Safety & Efficacy
- Validation
- Cost effectiveness assessment

Development → Regulation → National Reimbursement → Local Commissioning and Adoption

Companies are challenged by the uptake routes and downstream uncertainty to invest in co-development programs. Diagnostic development can compete for budget and confuse the commercial considerations around NPV.

Different bodies tasked with assessment of the products will force developers to manage a number of multi-speed processes to bring products whose value relies on combination use to market together.

Consensus needed on appropriate methodology to account for system benefits, assessment on limited data and iteration based on later outcomes.

For precision medicine benefits will be more easily realised at scale making adoption of national guidance a priority.

Significant risk that at a local level the addition of further complexity to an already complex decision making landscape will limit widespread adoption.

Source: Stakeholder interviews, workshops and Deloitte analysis

Future proofing: Precision medicine and companion diagnostics

A rapidly developing technical ability to stratify patients suitability of treatment options will require paradigm shift in development and adoption

Most of our pipeline is already stratified medicines of some form

It is difficult to develop these products in combination because the development pathways are so different

The current structures and methodologies are not adequate to assess the true value of a diagnostic tool at the point of care

Real world evidence will be needed to demonstrate improved outcomes from selective use of products based on individual response rates… it is coming… we are not ready

Barriers to adoption / Key Challenges

- No clearly defined pathway for the simultaneous development, review and adoption of therapeutic agents in combination with tests to identify those patients who will benefit

- An increasing proportion of Industry pipeline are stratified medicines

- The struggle for cost effectiveness models to show value for the system of highly specialised medicine is likely to be exacerbated by increasingly stratified, and therefore smaller, disease subpopulations
- The purchase of a diagnostic test is separated from the procurement of a therapeutic option
- Delivery models place diagnostic responsibility with pathology function
- Current structures demonstrate weak links between prescriber and pathology

Source: Stakeholder interviews, workshops and Deloitte analysis

Future proofing: *Precision medicine and companion diagnostics*

The promise of precision medicine includes savings through a improved medicines use and a longer timeframe to recoup savings

**What is needed?**

- Horizon scanning to identify precision medicines and the implications on the appraisal pathway
- A specific (possibly fast track) approvals process for medicines to be approved with a diagnostic test underpinned by a commitment to adoption to reduce risk for stakeholders including the approvers
- HTA models that can take restricted use/specificity into account and use with a companion diagnostic
- Preferential funding for medicines and/or their companion tests where use of the test will limit prescribing
- Development of outcomes based, patient or specific pricing models
- Incorporate screening cost into cost effectiveness calculations (cost sharing models between payer and provider)
- Health system capability to track of value delivered through improved outcomes and iterative pricing and reimbursement models reflecting this, with a an ability to be updated based on demonstrated benefit
- Adoption of treatment pathway modification to allow diagnostic testing and immediate real-time availability of data to prescribers
- Flexibility to allow both bench and bedside diagnostic models and adapt delivery of care to either as needed

Source: Stakeholder interviews, workshops and Deloitte analysis

### Methodology

To develop the final report the outputs of 4 phases of work were combined for the key challenge themes, case studies and opportunities.

<table>
<thead>
<tr>
<th>Why?</th>
<th>Desk research</th>
<th>Interviews</th>
<th>Workshops</th>
<th>Synthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>• To gather publicly available data</td>
<td>• To gather views and opinions of each stakeholder</td>
<td>• To test hypothesis, discuss ideas and define priorities</td>
<td>• To identify, refine and prioritise barriers within the UK’s current approach</td>
<td></td>
</tr>
<tr>
<td>• Understand how the current situation should work in paper</td>
<td>• To compare to the “in paper” current situation</td>
<td>• To prioritise opportunities for the next phase</td>
<td>• To prioritise opportunities</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What?</th>
<th>Desk research</th>
<th>Interviews</th>
<th>Workshops</th>
<th>Synthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Case study research</td>
<td>• Interviews with main stakeholders involved in the development pathways of medicines, devices and diagnostics</td>
<td>• Interactive sessions, with plenary, break-out sessions and presentations</td>
<td>• Quantitative and qualitative analysis of the key themes from the interviews and workshops</td>
<td></td>
</tr>
<tr>
<td>• On-line/web-site navigation</td>
<td>• Papers/literature review</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Who?</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Led by the Deloitte team insights were gathered from:</td>
<td>• Over 50 people were interviewed from Industry, Public Sector, Academia and Charities by telephone or face-to-face for 30-90 minutes</td>
<td>• 20 participants from Industry, Public Sector, Academia and Charities for a morning session on 20th March</td>
<td>• Led by the Deloitte team supported by CASMI and King’s Fund</td>
<td></td>
</tr>
<tr>
<td>• Desk research</td>
<td>• Materials shared by OLS</td>
<td>• 100 participants from Industry, Public Sector, Academia and Charities for a lunchtime session on 24th March</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Deloitte</td>
<td>• CASMI</td>
<td>• 15 representatives from AHSNs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The King’s Fund</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Case studies shared by NICE and Industry</td>
<td></td>
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</tbody>
</table>
Product timing estimation

Product pathway timing estimation was generated from desk research combined with stakeholder interviews and workshops.
## Medtech product classification

Medtech products have been classified into 6 groups based on the current EU regulatory classification system with the additional of CDx.

<table>
<thead>
<tr>
<th>Medtech product classification</th>
<th>Description</th>
<th>Examples</th>
<th>Key</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-sterile non-measuring Class I devices</td>
<td>- Non-invasive devices that either do not touch patients or are only in contact with unbroken skin</td>
<td>• Hospital beds</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Wheelchairs</td>
<td></td>
</tr>
<tr>
<td>Sterile or measuring Class I devices</td>
<td>- Non-invasive measuring devices that touch patients directly or are in contact with broken skin</td>
<td>• Scalpels</td>
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<tr>
<td></td>
<td>- Invasive devices that are only used transiently in human body cavities</td>
<td>• Forceps</td>
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<tr>
<td></td>
<td></td>
<td>• Thermometer</td>
<td></td>
</tr>
<tr>
<td>Class II &amp; Class III devices (includes radiation-based diagnostics)</td>
<td>- Surgically invasive devices</td>
<td>• Muscle stimulators</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Implantable or other invasive devices</td>
<td>• Hearing aids</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Active devices that are intended to administer substances, image the human body, or are for direct diagnosis or monitoring purposes</td>
<td>• Drug eluting stents</td>
<td></td>
</tr>
<tr>
<td>General non-companion diagnostics <em>in vitro</em> diagnostics</td>
<td>- Non-CDx test that samples tissue or body fluid outside of the body</td>
<td>• Blood type tests</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Immunity tests</td>
<td></td>
</tr>
<tr>
<td>General companion diagnostics <em>in vitro</em> diagnostics</td>
<td>- <em>in vitro</em> diagnostic that provides info. that is essential for the safe &amp; effective use of a corresponding therapeutic product</td>
<td>• HER2 mutation tests</td>
<td></td>
</tr>
<tr>
<td>High risk <em>in vitro</em> diagnostics (including self-testing)</td>
<td>- Self-testing or in Annex II on List A or B of In-Vitro Diagnostic Devices Directive (98/79/EC)</td>
<td>• HIV tests</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Blood glucose tests</td>
<td></td>
</tr>
</tbody>
</table>

*Note: Currently some consumer wearables and apps will fall within the regulatory definition of a medical device.

Source: Emergo Group, European Commission, stakeholder interviews, workshops and Deloitte analysis

Innovation stakeholder map

We have interviewed across the UK health economy to assess views on innovation.

**European stakeholders**
- EMA
- EPFIA
- National bodies

**Life sciences stakeholders**
- Pharma Companies
- Diagnostics Companies
- Medical Devices Companies

**Digital stakeholders**
- Digital apps
- mHealth

**Associations**
- ABPI
- ABHI

**Charities and Academia**
- Academia
- NIHR
- Voluntary Sector

**Interviewed**

**Organisation not interviewed**

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<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptive licensing or Agile pathways</td>
<td>Adaptive licensing is a prospectively planned, flexible approach to regulation of drugs and biologics. Through iterative phases of evidence gathering to reduce uncertainties followed by regulatory evaluation and license adaptation, AL seeks to maximize the positive impact of new drugs on public health by balancing timely access for patients with the need to assess and to provide adequate evolving information on benefits and harms so that better-informed patient-care decisions can be made</td>
</tr>
<tr>
<td>Biologics</td>
<td>Biologics are a class of large molecule drugs based on proteins that have a therapeutic effect. They are typically copies or optimised versions of endogenous human proteins (e.g., insulin, trastuzumab)</td>
</tr>
<tr>
<td>Digital Health</td>
<td>Digital healthcare involves the use of information and communication technologies to help address the health problems and challenges faced by patients. These technologies include both hardware and software solutions and services (e.g., wearables, apps)</td>
</tr>
<tr>
<td>Early dialogue</td>
<td>An early dialogue allows input from HTA bodies on the development of the health technology. Early dialogue is prospective in nature as it focuses on development strategies and not on pre-evaluation of data</td>
</tr>
<tr>
<td>Genomics</td>
<td>Genomics is defined as the study of genes and their functions, and related techniques. The main difference between genomics and genetics is that genetics scrutinizes the functioning and composition of the single gene where as genomics addresses all genes and their inter relationships in order to identify their combined influence on the growth and development of the organism</td>
</tr>
<tr>
<td>In vitro diagnostics</td>
<td>In vitro diagnostics refers to a wide range of medical laboratory tests that are used to diagnose diseases and monitor the clinical status of patients using samples of blood, cells or other tissues obtained from a patient</td>
</tr>
<tr>
<td>In-house tests</td>
<td>In-house tests are tests developed by the NHS in-house (i.e. within pathology laboratories of individual NHS trusts)</td>
</tr>
<tr>
<td>Precision (previously stratified) medicine</td>
<td>Precision medicine is the use of genomic, epigenomic, exposure, and other molecular information to select the best therapeutic strategy in order to improve health outcomes, such as effectiveness and safety, for a targeted group of patients sharing similar biological characteristics</td>
</tr>
<tr>
<td>Medical devices</td>
<td>A medical device is an instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body (which would make it a drug). For the purposes of this report, medical devices do not include in vitro diagnostics</td>
</tr>
<tr>
<td>Real world evidence (or data)</td>
<td>Real world evidence or data is evidence or data that are collected outside the controlled constraints of conventional randomised controlled trials to evaluate what is happening in normal clinical practice</td>
</tr>
<tr>
<td>Small molecules</td>
<td>A small molecule is a low molecular weight compound that regulates a biological process through binding to the target protein in the human body. They are typically chemically manufactured active substance (e.g., aspirin, paracetamol)</td>
</tr>
<tr>
<td>Vaccines</td>
<td>Vaccines are biological preparations that provide active acquired immunity to a particular disease. They typically contain an agent that resembles a disease-causing microorganism (e.g., flu vaccine, Hepatitis B vaccine)</td>
</tr>
</tbody>
</table>
Limitations to the pathway analysis

Limitations of the pathways shown in this document.

1. The pathways included in this document are generalised and are created using desk research, stakeholder involvement and Deloitte analysis.

2. They are illustrative and can not be considered exhaustive.

3. To simplify the pathway some non-linear elements of the pathway are shown in a linear manners