Accelerating access to the four D's: diagnostics, drugs, devices and digital health

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Mark Campbell, Associate Director, NICE
Sir Bruce Keogh, National Medical Director, NHS England
Richard Stubbs, Commercial Director, Yorkshire & Humber Academic Health Science Network
The review aims to accelerate access to innovative drugs, devices and diagnostics for NHS patients

Currently:
• Can take 10-15 years to get a new product from discovery into the system and can cost over £1 billion;
• No standard pathway for new medtech or digital products;
• Increasing public debate around access to these products (e.g. Cancer Drugs Fund, Hep C).

Trials (from proof of concept) → Regulation → National reimbursement → Adoption/diffusion

The review’s Terms of Reference highlight how it will:
• Address innovative medicines, devices and diagnostics equally (digital products also a focus);
• Explore how to accelerate use of data and evidence to drive development, commissioning and decommissioning; and,
• Recognise the importance of patient voice and patient trust.

Given the funding landscape, cost-effectiveness and affordability will be front and centre of recommendations.

The review will not:
• Alter the 2014 Pharmaceutical Price Regulation Scheme (ends 2019);
• Overlook existing statutory responsibilities of NHS bodies;
• Overlook relevant European legislation.

The review will conclude by the end of 2015, with an interim report in the late summer. Our approach will allow a wide range of stakeholders an opportunity to contribute views on the future scheme.
We see some good opportunities to deliver benefits

• Good for **patients**
  o Opportunity to access novel drugs and treatments more quickly

• Good for the **NHS**
  o Simplifying and joining up processes
  o Making good, cost-effective, products available to patients more quickly – driving potential for better outcomes at the same/lower cost. **Affordability** will be front and centre of the review.

• Good for **research organisations and charities**
  o Embedding them and their patient populations in the process from the start

• Good for **business**
  o Simplifying pathways and joining up assets in existing landscape
  o Giving good products earlier access to patients (generating data, demonstrating value)

• Good for **this country**
  o Making us the best place in the world to design, develop and deploy innovative products
The review will build on existing initiatives in the early access landscape, forging a coherent runway through these to benefit patients, innovators and the healthcare system.

**TheGlobal Fund**
- Ebola response
- Dementia

**MHRA**
- Early Access to Medicines Scheme
- STAMP expert group
- Triennial review (via DH)

**NICE** National Institute for Health and Care Excellence
- Office for market access
- Innovative funding models
- Triennial review (via DH)

**Royal Academy of Engineering**
- Dowling Review

**NHS England**
- Cancer Taskforce
- Test beds
- Road map to innovation support
- New models of care

**Monitor**
- Review of specialised tariff

**NURSE REVIEW OF RESEARCH COUNCILS**

**IPPR**
- Adopt and Diffuse – barriers to innovation in the NHS

**Academy of Medical Sciences**
- Social contract
- Real world evidence

**Roche**
- Medicines Access in Europe

**Reengineering medicines development**

**NEWDGs** New Drug Development Paradigm's

**Medicines Access in Europe**
There is a clearly defined decision-making process within the review’s governance structure:

- The review is a ‘review with independent Chair’.
- As the review’s independent Chair, **Sir Hugh Taylor will make recommendations to relevant ministers (Minister for Life Sciences/SoS Health)**.
- Sir Hugh’s recommendations will have input from:
  - Professor Sir John Bell and the review’s External Advisory Group;
  - The review’s strategic steering group, chaired by Una O’Brien;
  - The workstream champions;
  - The review team, staffed by OLS and DH officials and secondees from key stakeholder organisations; and,
  - Wider stakeholders.
- None of these groups have a veto on recommendations made by the review’s final report, which will be made by Sir Hugh Taylor.
The review is engaging with a number of stakeholder groups. The NHS is a key part of this engagement, as are patients and their representatives, industry, other public bodies and the Government.

So far, we have engaged with over 200 stakeholders, with more events and digital engagement planned throughout the year.
We also need to engage at every level of the NHS. NHS England are bought into the review at the highest levels and we are also engaging with frontline decision makers.

• Sir Hugh has met Sir Bruce Keogh about the review, and is meeting Simon Stevens in the coming days.

• The team have had productive discussions about the review with NHS England Directors and Simon Stevens’s clinical fellows.

• NHS England are working with the review team to ensure that the review engages widely across the NHS.

• The review’s stakeholder engagement plan has been drawn up with the support of NHS England.

• As Chair of Guy’s and St. Thomas’s, Sir Hugh brings NHS management experience to the very top of the review.

• Rob Webster, Chief Exec of NHS Confederation, is championing workstream 4 (NHS adoption and diffusion).

• Our session at the NHS Confed Conference, with attendees from frontline organisations.

• Sir Hugh has met with the Chief Executive of the Academy of Medical Royal Colleges, and we are running an event with the Royal Colleges.

• Frontline decision makers will input into each workstream and will be key to building the review’s recommendations.
The review will look at the end-to-end pathways for innovative medicines, medtech and digital health products.

**Three end to end pathways:**

- **Medicines:** to include developing/refining future-proofed pathways for genomics and precision medicines (with companion diagnostics).
- **Medical technologies:** to include developing/refining future-proofed pathways for standalone diagnostics.
- **Digital health:** to include designing pathways tailored specifically towards next generation digital products and addressing particular issues e.g. designing technology risk stratification principles and acknowledging data interoperability requirements.

**Addressed via four workstreams, each with an external champion:**

1. **Articulating need, priorities and principles for innovation**
   - Stuart Dollow, Verrmilion
2. **Accelerated development pathways**
   - Richard Barker, CASMI
3. **Affordable national funding models to drive innovation**
   - Richard Murray, King’s Fund
4. **Supporting affordable uptake and adoption**
   - Rob Webster, NHS Confed

**Underpinned by patient and user engagement:**

Patient and user engagement

Hilary Newiss, National Voices

*for further details, see Annex A*
Each workstream has a clear purpose and scope; we will now start to work with you on developing potential solutions

**Workstream 1** will develop a transparent framework for early dialogue and collaboration which drives transformative innovation and supports partnerships from end to end.

**Scope:**
- Horizon scanning;
- Identifying patient and NHS needs and sharing with innovators;
- Early dialogue on value of innovation;
- Early advice services;
- Strengthening partnership and collaboration.

**Workstream 2** aims to streamline regulatory processes and articulate a clear accelerated process for innovative products; or to build a best practice pathway where this does not exist.

**Scope:**
- Regulatory processes (fast-tracking opportunities);
- Evidence requirements agreed across stakeholders, inc. for products with small patient populations;
- Review of Early Access to Medicines Scheme;
- EU legislation – flexibilities, medium term reform.

**Workstream 3** will propose solutions to integrate or accelerate national reimbursement processes and fund clinically and cost-effective innovation across the pathway.

**Scope:**
- NICE framework and scope
- Flexible reimbursement models
- CDF and associated funding
- Tariff
- Concepts of affordability and value

**Out of scope:**
- 2014 PPRS, QALY design and threshold

**Workstream 4** aims to accelerate the speed at which clinically and cost effective innovative products are commissioned and get to NHS patients.

**Scope:**
- Commissioning, adoption and diffusion i.e. from agreement on reimbursement levels to the point at which a product is being used across England;
- Incentivising decision makers to drive uptake of appropriate innovation, inc. financial incentives;
- Streamlining routes to market/contracting;
- Leverage of wider govt/ALB initiative.

Hilary Newiss: Patient Input
We are delighted to have on the panel...

**Sir Bruce Keogh**, National Medical Director, NHS England

**Mark Campbell**, Associate Director, Medical Technologies Evaluation Programme, NICE

**Richard Stubbs**, Yorkshire and Humber Academic Health Science Network
Table discussions: We would also like to hear your views on the key workstream areas on the following questions…

**1. Need, priorities and principles for innovation**
- How can we better align industry, the NHS, research charities and academia to better understand and respond to patient needs?
- How to incorporate patient views in the development process for medicines, devices and diagnostics?
- What improvements can we make to the existing system?

**2. Accelerated development pathways**
- How do we incentivise and increase NHS engagement in clinical trials?
- How can the clinical trials process be refined to encourage use of new methodologies and include greater use of real world data?
- How do we ensure a joined-up landscape for regulation of precision medicines and companion diagnostics?

**3. Affordable national funding models**
- How can we evolve the way we assess pharmaceutical products, medical technology and diagnostics?
- How can we streamline the way we fund innovation?
- How could affordability be assessed? And who should be responsible for this?

**4. Supporting adoption and diffusion**
- How can we improve the diffusion of innovative products across the NHS?
- How can decision-makers be incentivised to create and drive a culture of innovation?
- What are the barriers for uptake and adoption of new innovative products for:
  - Clinical decision-makers
  - NHS providers
  - Commissioning bodies?
We want as many people as possible to feed in to the review

• We want to involve as many people and groups as possible so we can explore the answers together.

• We need to bring in your experience and expertise in a more detailed way. Can you help us explore these issues?

• We will shortly be launching a website for the review which will set out how to get involved in more detail. This will include:
  – Joining ‘virtual’ working groups for each of the big questions we are looking at;
  – Attending stakeholder events;
  – Contributing via crowd sourcing tools which we plan to use

• You will also be able to keep in touch with the review by signing up for email updates or following the review on twitter at @AccelAccess.
Annex: External Advisory Group and Strategic Steering Group

The External Advisory Group's role is to:

- Generate recommendations to accelerate access (recognising both cost-effectiveness and affordability);
- Champion the review among stakeholders;
- Bring in wider expertise and generate buy-in for recommendations;
- Bring expertise around innovation in the pipeline, including digital; and,
- Champion individual workstreams (where required).

The Strategic Steering Group’s role is to:

Refine review content:

- Provide policy input and wider contacts; and,
- Act as a critical friend to appraise options and help refine recommendations.

Pave the way for implementation of recommendations:

- Raise support for and knowledge about the review;
- Facilitate cross-departmental discussion on emerging recommendations; and,
- Generate buy-in for recommendations.

Chair: Sir John Bell
- Prof Richard Barker
- Kate Bingham
- Chris Brinsmead
- Prof Sir John Burn
- Dr Mike Capaldi
- Dr Stuart Dollow
- Prof Jeremy Farrar
- Prof Sir David Fish
- Noel Gordon
- John Jeans
- Alastair Kent
- Dr Jonathan Knowles
- Dr Harpal Kumar
- Dr Jeremy Levin
- Prof David Lomas
- Raj Long
- Prof Graham Lord
- Eric Low
- Prof Sir Alex Markham
- Dr Keith McNeil
- Kevin Moore

Chair: Una O’Brien, DH
- Dame Sally Davies, CMO
- Will Cavendish, DH
- David Williams, DH Finance
- Nicole Mather, OLS
- Martin Donnelly, BIS
- Bernadette Kelly, BIS
- UKTI [TBC]
- Simon Stevens, NHSE
- Sir Bruce Keogh, NHSE
- Keith Ridge, NHSE
- Sir Andrew Dillon, NICE
- Sir Mike Rawlins, MHRA
- John Kingman, HMT
- Nick Seddon, No.10