

BIVDA



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Report on systemic challenges with BIVDA sustainability group

How do we innovate together to improve sustainability
of the British IVD industry?

14th June 2022



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Report compiled by Alex Cole
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1	Alex Cole / Dan Noakes	Steven Bagshaw	NA	Steven Bagshaw	Original report compiled

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1 Executive summary

Held at BIVDA's second annual sustainability seminar, the CPI team introduced to the audience sustainability, systems thinking and the effectiveness of systemic challenges. As part of an interactive session facilitated by CPI, the BIVDA members and other stakeholders present, i.e., NHS England (procurement team), described their difficulty in addressing sustainability within their organisation and the wider system, and the group discussed how systems think could result in better outcomes.

The themes discussed included:

- Regulation – current regulations do not support sustainability improvements.
- Eco-system – the NHS has great sustainability initiatives but for British IVD, the NHS is not their only customer, and so we need to think globally.
- Reformulation – the IVD industry is keen to move to “greener” alternatives for chemicals and materials, however, more sustainable alternatives do not always perform as well as traditional materials.
- Waste – the IVD industry produces significant quantities of biological waste, including hazardous liquid waste. These are generally in very small quantities but when aggregated, can result in a significant cost for disposal because of their category of waste (hazardous).
- Packaging – IVD often uses difficult to recycle packaging materials, e.g., multi-material laminates. Opportunity to improve.
- Fulfilment – NHS LEAN practices are leading to multiple frequent deliveries to locations. Systemic change needed to reduce deliveries and promote predictive/bulk ordering.
- Patient testing – many tests could be avoided to reduce the environmental impact of IVD.
- Lab practices – lab practices, e.g., pathology, do not always promote sustainability and can be wasteful. Programmes are in place, but many labs are do not follow them.

BIVDA members and CPI were tasked to prioritise specific challenges above and expand these further, in order to define key systemic challenges to focus on and identify “challenge owners” who can work with CPI to develop a deeper understanding of these challenges with the intent to co-create system solutions.

2 Introduction

2.1 Location and date

- Royal College of Anaesthetists, Red Lion Square, London
- 9th June 2022

2.2 Facilitators

- Alex Cole – Head of Strategic Marketing – CPI
- Dan Noakes – Systemic Challenge Lead – CPI

2.3 Audience

Group of 33 comprising:

- **Challenge owners (NHS England procurement and sustainability teams)** – addressing sustainability challenges including Scope 1, 2 and 3 emissions by stipulating that all suppliers must now meet new tender requirements (Evergreen), which will enable the NHS to meet their targets for sustainability and circular economy
- **Challenge solvers (Suppliers to NHS and other health care providers)** – required to adjust business practices to conform to NHS reporting and tendering process, by demonstrating measuring, monitoring and improvement of sustainability perform, against NHS targets.

2.4 NHS sustainability programmes

Presented before the interactive session, presentations were delivered by the NHS on their sustainability programmes. This is summarised here but for a full overview, please contact BIVDA (Helen Dent) for more details or to be put in touch with the NHS team who delivered these presentations

The NHS is a major UK employer and comprises of 1.3 million staff members. It is working on significant initiatives to reduce its carbon emissions and, in 2020, it introduced the “Greener NHS Programme”, which targets net zero carbon for all direct NHS emissions (Scope 1 and 2) by 2040. NHS initiatives to date include funding competitions (SBRI, NIHR and MRC); research and innovation programmes;

workforce changes and digital innovation. They have embedded a Net Zero framework in all funding competitions and procurement contracts.

Analysis of NHS carbon emissions suggests 25% of carbon emissions are attributable to 'other supply chain' emissions, whilst Medicines & Chemical, Buildings or greenhouse gases used in medical devices or procedures, e.g., nitrous oxide, account for 20%, 10% and 5% respectively.

3 Systemic challenges

3.1 Background

The facilitators introduced the concepts of systemic challenges and how multiple stakeholders can come together to solve the challenges identified.

For the discussions with the BIVDA stakeholders, the following scope was identified: “Transitioning to sustainable and circular business models for better patient outcomes” and systematic challenges were described by the following:

- Addresses major societal issues
- To transition to better long-term outcomes
- Convening industry and other stakeholders
- Solve the challenge together
- Provide benefits across the system

The status of stakeholder discussions falls within the Definition phase of a systemic challenge i.e., identifying the symptoms, the desired outcomes, specific challenges, and challenge statements across the complete system.

3.2 Interactive session

The BIVDA sustainability group were provided with the following prompt questions:

- What are the sustainability challenges for stakeholders across the supply chain?
- Is this something that the IVD industry can solve on our own?
- Is the challenge large enough that we would get support from large companies or governments?

3.3 Summary of discussion

This section captures the messages discussed by the audience in long format, it is summarised in Table 1 later in the document.

(1) the NHS should form a significant part of our system thinking, however, we need to consider a global system rather than just the UK system

- The UK has many distributors of global IVD devices that they sell to the NHS. If we want to change the system to be more sustainable then we would need to involve the global large corporates and other manufacturers of IVD (distributors cannot do it themselves).
- MedTech Europe's recent research showed that the biggest markets for IVD were the US and Germany followed by the ROW. Out of 27 'European' countries, the UK ranked 26 for spending. This demonstrates the need to consider a broader market, beyond the NHS and towards global markets.

(2) Deposit return schemes can provide benefits, but may not be relevant to the IVD industry

- Deposit return schemes were discussed and the exemplar systems in Germany for FMCG packaging was focused on. Questions were raised about whether something like this could be applicable to IVD in the UK.

(3) "Green" chemistry and materials are important to the IVD industry, but innovators need to be aware that their properties need to be commensurate with the materials they are replacing. This is due to the inherent risk in failure of IVD devices should materials not function as specified.

- The IVD industry is a heavy user of Commercial-off-the-shelf (COTS) chemicals and plastics. The industry uses a wide range of raw materials but often in small quantities. There is an opportunity to change to "green" solvents, chemicals, and plastics but they would need to meet the same performance criteria as the currently used materials. The team cited examples of where green materials were used that were not fit for purpose. There is an additional challenge within the MedTech/IVD industry such that if materials do not have the required properties, they can put patient safety at risk.
- There is a need for green surfactants and titrants. Not only for IVD but also for pharma, e.g., producing vaccines.
 - Challenge is to make "green" plastics, chemicals and other materials used in IVD that has the required properties to function as existing materials
 - the level of risk to patient means mature solutions are needed and validated with plenty of evidence before deploying anything new onto the market.
- Recycling or reusing devices, packaging etc from IVD is often difficult as they are likely to be contaminated with hazardous chemicals or (human) biological material.

(4) The current IVD regulations do not promote sustainability

- IVDR promotes patient safety and device/IVD functionality as a priority. Single use technologies are often the chosen solution for meeting regulations.
- There was once a culture of re-using medical technologies sterilisation, however, these practices have been replaced with single use. There is scope to re-engage with the regulator, to understand if there is an opportunity to re-use materials, because extending the life of medical technologies (use-phase) reducing the carbon footprint of the item over its lifetime and of the entire system when compared to single-use materials and devices.

(5) Many materials used in the IVD industry are ‘multi-material’ and would be difficult to recycle. Functional properties/specifications would need to be preserved but there may be some recycling opportunities should single material components be developed

- Many IVD components including packaging and sterile barriers are multilaminated. This would be difficult to recycle. Barrier materials that use only one material (also known as mono-material), therefore, are needed that improve recyclability.
- Hospitals do not always have space to segregate materials. Although there is some segregation, this is not by material, it is by waste category, e.g., general waste, yellow bag.

(6) The IVD industry throughout the COVID pandemic was a large producer of plastic waste, e.g., lateral flow tests.

- There is an opportunity to use “green” polymers within POC tests and LFTs.
- As in point (4) current regulations do not encourage the use of new (and potentially more sustainable) materials

(7) The current NHS procurement systems potentially promote higher CO2 emissions through frequent “just in time” deliveries of medical devices and IVD tests

- Frameworks include delivery but often tests are purchased and delivered on demand as stores have been removed from a number of NHS sites.
- The NHS does have some warehousing but often IVD is not stored, and none of them have cold storage facilities.
- Forward planning or changes to procurement rules would result in CO2e savings for the NHS, and for NHS suppliers.

3.4 Systemic thinking output document.

Table 1 shows the data extracted from the Ideation Session arising from CPI's process for initiating Systems Thinking.

Table 1 – Sustainability and systems thinking ideation

Audience		
Group of 33 comprising		
<ul style="list-style-type: none"> Challenge owners - NHS procurement and sustainability teams Challenge solvers - NHS supply companies 		
(1) Symptoms		
<ul style="list-style-type: none"> Ageing population with deteriorating health Climate change Ocean plastic pollution 		
(2) Desired Outcomes		
<ul style="list-style-type: none"> Prioritise patient safety Zero carbon emissions Zero harmful chemicals Zero problem packaging, e.g., plastics and multilaminates Zero waste elimination, i.e., circular economy (avoid landfill and incineration) 		
(3) Specific problems		
Identifier	Description	General problem
Regulation	<ul style="list-style-type: none"> Current EU and UK regulations promote safety and do not consider sustainability 	Regulations for a sustainable and safe IVD market
Eco-system	<ul style="list-style-type: none"> NHS is not the only customer to IVD suppliers (often global companies), yet IVD suppliers are required to redirect business practices to align with NHS tender requirements. There is a need for harmonised and consistent global standards and systems of practice across global supply chains. Difficulty identifying greenwashing versus commitment to sustainability and circular economy in businesses outside of your own creates uncertainty, which is essentially when deciding to partner or tender. Consider cost allocated to waste disposal by each business and their understanding of both manufacturing waste and post-consumer wastes, which can be attributed to their business activities (products, services) 	Global standards & practices, and tendering format for sustainability and circular economy in IVD global markets.
Re-formulate	<ul style="list-style-type: none"> Identifying the correct eco-replacement chemicals, e.g., bio-surfactants, for reformulations that are safe, stable (achieves required shelf life) and or recyclable. Greener alternative may impact shelf-life stability and incur significant cost for regulatory approval (minimum 3 years) IVD has been wasteful throughout the pandemic, opportunity to develop new materials for products such as lateral flow tests that come from a more sustainable source. However, as above, significant cost may be incurred for regulatory approval. Other greenhouse gases may be released to atmosphere from medical devices and procedure, e.g., asthma inhalers and pain alleviating gases (nitrous oxide). Reformulate to powders instead of pressurised gas increases options for more sustainable materials for device and packaging 	Toolbox for substituting for greener alternatives when reformulating
Wastes	<ul style="list-style-type: none"> IVD community produces significant quantities of biological waste, including hazardous liquid waste. These are generally in very small quantities but when aggregated, can present a significant cost for disposal because of its category of waste (hazardous). 	Sustainable innovations in IVD waste management

	<ul style="list-style-type: none"> Some medicines have options for refill, e.g., co-codamol, however, there are only a few refilling centres from 1 or 2 manufacturers in EU. 	
Packaging	<ul style="list-style-type: none"> Barrier materials for primary packaging often comprise of multi-materials, e.g., laminates, which are difficult to recycle. For labelling, an adhesive that works across temperature range (e.g., suitable for cold chain and stability testing) but dissolves above an elevated temperature, e.g., hot caustic wash, is required 	Sustainable innovations in IVD packaging
Fulfilment	<ul style="list-style-type: none"> LEAN NHS processes are resulting in multiple deliveries of low numbers of items per delivery to NHS facilities. Supply agreements require just in time (same day) delivery which is resulting in multiple frequent automotive deliveries and hence carbon emissions. NHS does not always have adequate warehousing facilities (i.e., lack of cold storage). 	System optimisation for logistics and fulfilment based on sustainability and multi partner win-win
Patient Testing	<ul style="list-style-type: none"> Concerns over overuse of testing. Potential to reduce. 	Protocols for testing and when not to test
Standard practices (labs)	<ul style="list-style-type: none"> Standard lab practices do not always promote sustainability, e.g., 30 well plates used on a 96 well plate. Resulting in significant waste 	Globally adopted standard operating procedures (SOPs) for IVD labs

(4) Systemic Challenge

<i>Challenge</i>		<i>Challenge owners</i>
1	To be defined	To be defined
2
3

4 Next steps

BIVDA members and CPI to prioritise specific challenges above and expand these further, in order to define key systemic challenges to focus on and identify “challenge owners” who can work with CPI to develop a deeper understanding of these challenges with the intent to co-create system solutions.



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