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"...a little more knowledge lights our way"

Priorities for medicines research were discussed recently at a joint ABPI/Welsh NHS Confederation meeting at the Senedd. The clear message, Wales needs to be ready for the treatments coming over the hill.

This piece was originally published by the Bevan Foundation – please use this link to access the article.

What comes to mind when you think of the biggest unmet needs in modern medicine? Is it cancers and Alzheimer's disease? Or, after the last year, is it infectious diseases and respiratory disorders? Or perhaps it's the rare diseases that collectively affect thousands of people across Wales every day?

New data, discussed by an international panel of experts with stakeholders across Wales recently, reveals that these disease areas are amongst the top priorities for researchers running global clinical trials for the medicines and vaccines of the future.

Even last year, and despite the challenge and disruption caused by the COVID-19 pandemic, around 5,000 commercially funded clinical trials were launched globally. With a quarter of these trials focused on cancer, diseases with high societal impact dominate the pipeline, including those for Alzheimer's disease, respiratory conditions, rare diseases, and ground-breaking cell and gene therapies.

Thomas Allvin of the European Federation of Pharmaceutical Industries and Associations (EFPIA) discussed their Pipeline Review, which paints this picture of a healthy innovation pipeline, focused on major unmet needs. Whilst he covered a wide cohort of disease areas in other sessions, when speaking to Members of the Senedd, in an event sponsored by Jack Sargeant MS, he chose to concentrate on one - Alzheimer's.

According to Alzheimer's Research UK, in the ten-years from 2010 to 2020, the number of people on the dementia register in Wales rose from 15,389 to 22,686[1], an increase of over 32%. However, not everyone with dementia has a diagnosis. This can be for many reasons, including the difficulty of diagnosis in the early stages of the disease, its slow progression, and limited public awareness of the causes of dementia.

At present, medicines for Alzheimer's can only treat the symptoms of the disease. The hope is that future treatments will be able to delay onset or progression which would be a significant step forward and would help patients live an independent life for longer. Whilst the NHS would undoubtedly benefit from delays to the high levels of healthcare need associated with severe Alzheimer's, there could also be a reduction in reliance on social care and, most importantly, the army of family members who care for their loved ones.

As with most other innovations in patient care, when future Alzheimer's therapies demonstrate clinical and cost effectiveness, they will be financed in Wales through the medicines budget held for hospital medicines. However, the greatest value would be realised elsewhere, in social care for example. This causes a budgeting conflict and policymakers

[1] https://www.dementiastatistics.org/statistics/diagnoses-in-the-uk/

Continued overleaf

will need to ensure that access to these innovative therapies is not compromised due to one budget needing to increase, whilst other budgets across Government benefit.

Thomas' message was clear; Wales needs to be ready for the treatments coming over the hill. Current delays in Alzheimer's diagnosis will need to be addressed, not least the paucity of available testing, such as neuroimaging and lumbar puncture. New developments in diagnostics, like biomarker testing, will be just one important part of this. With recent clinical developments giving hope that these therapies might soon become available, it will be crucial to establish programmes that can screen and diagnose large numbers of patients with mild dementia quickly and accurately. This is where our recent experience with population wide testing and treating COVID-19 may provide useful, real-life experience.

In concluding the session at the Senedd, Rhys ab Owen MS – Chair of the Cross-Party Group on Dementia – very appropriately quoted Yoda.

"In a dark place we find ourselves and a little more knowledge lights our way".

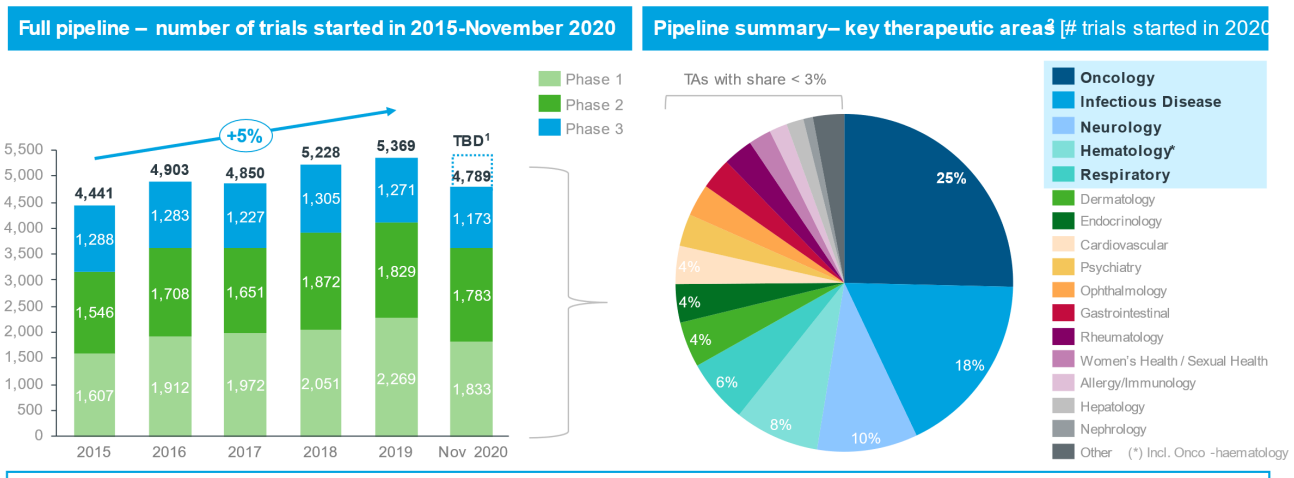
Whilst the Pipeline Review inspires optimism about the overall trajectory of medical innovation, it comes with a caveat. Wales capacity to continue to develop and adopt the results of these research efforts requires fresh thinking about our research ecosystem and health and care infrastructure.

This thinking has started, with the governments of the four nations of the UK recently publishing a joint implementation plan for clinical research. It includes important goals for the future of clinical trials here in Wales, including:

- Embedding clinical research in the NHS to create a pro-research culture with resource and capacity allocated to deliver streamlined and high-quality clinical research.
- Improving equitable access to clinical research to make the involvement and participation in clinical research as easy as possible for patients and the public regardless of where they live, their gender or their ethnicity.
- Developing a sustainable and supported research workforce by offering rewarding opportunities to all healthcare and research staff of all professional backgrounds.

This UK-wide implementation plan is strongly aligned to the 10-year strategy for NHS Wales, A Healthier Wales, which identifies the intent for individuals to be at the heart of transformation and modernisation of health and care services, and where research is fundamental and fully embedded in high quality care. While past innovations have improved patient outcomes, the coming wave of advances can go much further, and now is the moment for preparation, as well as celebration.

The volume of initiated clinical trials has increased year on year since 2015 with oncology having the most extensive pipeline



The volume of pipeline activity has continued to increase over the last years. Assuming that in 2020 the average number of clinical trials launched per month will remain as in the period of Jan 2020 – Nov 2020, total number of clinical trials started in 2020 will be similar to 2019 (-3%).

Source: Clarivate AnalyticsCortellis,**Aug 2020** (TA's share) and **Nov 2020** (total number of trials); Phase II includes Phases I/II, II, IIa, IIb. Phase III includes Phase II/III and III. Terminated trials were excluded from the analysis. Trials not industry sponsoredand device trials were excluded; (1) Total number of trials started in 2020 to be defined – final number will be available in the beginning of 2021; (2) Data from August 2020

IQVIA_EFPIA Pipeline Review 2021 Full Report

IQVIA 3

Let's put research at the heart of the NHS

Clinical research is the backbone of high-quality patient care.

According to studies by the National Institute for Health Research (NIHR), which works alongside Health and Care Research Wales (HCRW), patients treated in 'research-active' NHS hospitals have improved outcomes, lower mortality rates, and increased confidence in the quality of care received.

In 2020/21, and despite the COVID-19 pandemic, 1,147 participants across Wales took part in HCRW-supported commercial contract research - up from 838 from 2019/20. This is important because research benefits the NHS - for every patient recruited onto a commercial clinical trial between 2016 and 2018, the NHS in England received more than £9,000 from life sciences companies, and, where a trial medicine replaced the standard of care treatment, saved £5,813[2].

Similarly, research makes economic sense - most recently demonstrated by Kings College London's 2019 study, which found that for every £1 of public money invested in UK medical research, the UK receives around 25p back in health gains and GDP benefits every year.

The COVID-19 pandemic has also underlined how a globally interconnected research effort is essential for health systems to plan for and combat population health threats. As we have seen over the last eighteen months, research collaboration has driven extraordinarily rapid novel vaccine and treatment development, repurposing of existing medicines and global sharing of best clinical practice. The response to COVID-19 has seen more patients, staff and NHS sites engage in clinical research than ever before, reflecting the fact that the criticality of research activity is now much more widely understood and appreciated.

And yet...

Despite all these many benefits to patients, the NHS, the economy and global health, NHS organisations currently have a legal duty only to 'promote' research, rather than to engage in it. This leads to widespread variability in terms of patients' ability to benefit from cutting-edge innovation, slows the development of health data assets, inhibits the fostering of an innovation culture across the NHS and ultimately exacerbates health inequalities.

To support NHS recovery and continue to reap the benefits of clinical research, we need to build the current enthusiasm for research into routine healthcare in the UK. By seizing and building on the fantastic response during the pandemic, we can begin to make real progress towards fostering an innovation culture within the NHS, increasing the diversity and inclusivity of people participating in trials and raising the quality of care for all conditions.

We can also significantly boost delivery of the aspirations contained in the four UK government's Vision for Clinical Research Delivery, which outlines how the UK will transform the way clinical research is designed, approved, and conducted, through more patient-centred, innovative, and pragmatic approaches. Of course, a mandatory requirement to conduct research will only be effective if it is accompanied by appropriate resources and skills development to enable NHS staff to engage with research and contribute to building health data assets.

This is an opportunity to take a transformational step towards delivering world-leading patient outcomes in a world-class NHS.

Let's make it happen.

[2] https://www.nihr.ac.uk/documents/%20impact-and-value-of-the-nihr-clinical-research-network-2019-%20infographic-summarising-key-findings/22486

Five steps to urgently advance COVID-19 vaccine equity

Innovative vaccine manufacturers and biotech companies are at the forefront of the global effort to develop and manufacture COVID-19 vaccines[3]. This massive effort is succeeding. After more than 200 clinical trials and nearly 300 partnerships and collaborations among manufacturers worldwide, production has increased, in just a few months from zero to 2.2 billion COVID-19 vaccine doses by the end of May with an astounding estimate of 11 billion doses by the end of 2021. This will be enough doses to vaccinate the world's adult population.

Critically, however, COVID-19 vaccines currently are not equally reaching all priority populations worldwide.

Manufacturers, governments, and non-governmental organisations must work together to take urgent steps to further address this inequity. Immediate action must focus on stepping up responsible dose sharing and maximising production without compromising quality or safety. To do so, innovative vaccine manufacturers and biotech companies commit to:

1 Step up dose sharing

- Immediately work with governments that have significant domestic supplies of COVID-19 vaccine doses to share a meaningful proportion of their doses with low- and lower-middle-income countries in a responsible and timely way through COVAX or other efficient established mechanisms
- Expend every effort to make additional uncommitted COVID-19 vaccine doses available to low- and lower-middle-income countries, through COVAX or other efficient established mechanisms

2 Continue to optimise production

- Undertake all practicable efforts to maximise COVID-19 vaccine output without compromising safety and quality, including through additional collaborations with partners that can produce significant quantities
- Work with governments and individual suppliers of raw materials and components to determine how to quickly and safely facilitate scale-up needed for COVID-19 vaccine manufacturing

3 Call out trade barriers to be eliminated

- Identify trade barriers for critical input materials and support Coalition for Epidemic Preparedness Innovations' (CEPI's) effort to create an independent platform that would identify and address gaps in these inputs and facilitate voluntary matchmaking for fill and finish capacity through the newly established COVAX Supply Chain and Manufacturing Task Force
- Urge governments, in coordination with the World Trade Organization (WTO), to eliminate all trade and regulatory barriers to export and to adopt policies that facilitate and expedite the cross-border supply of key raw materials, essential manufacturing materials, vaccines along with the prioritised movement of skilled workforce needed for COVID-19 vaccine manufacturing

4 Support country readiness

- Partner with governments on COVID-19 vaccine deployment, particularly in low- and lower-middle-income countries, to ensure that they are ready and able to deploy available doses within their shelf-life
- Mitigate the risks to the production and deployment of other vaccines that remain vital to public health worldwide

5 Drive further innovation

- Prioritise the development of new COVID-19 vaccines, including vaccines effective against variants of concern
- Urge governments to guarantee unhindered access to pathogens (e.g. samples and sequences) of any COVID-19 variants to support the development of new vaccine and treatments

[3] This joint statement is signed by the ABPI, the Biotechnology Innovation Organization (BIO), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Council of Biotechnology Associations (ICBA), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Pharmaceutical Research and Manufacturers of America (PhRMA) and Vaccines Europe.

2021 pharmaceutical industry Code of Practice launched

The Association of the British Pharmaceutical Industry (ABPI) 2021 Code of Practice came into force from 1st July 2021[4], alongside a set of new ABPI Principles to help companies operate to high ethical standards.

The ABPI Code of Practice is the industry's commitment to operate in a professional, ethical, and transparent manner, for the benefit of patients and the public. It is independently administered by the Prescription Medicines Code of Practice Authority (PMCPA).

The 2021 Code has been updated to make the Code easier for companies to use in their day-to-day activities, to reflect changes in the environment companies operate in and to reflect updates to the European Code. Some new elements increase transparency and others will help companies work together with the NHS within an ethical framework to improve patient care. All the changes are intended to help the industry continue to uphold high standards. The requirements in the existing Code already go above and beyond the law.

The new Code is arranged in six themed sections:

- overarching requirements
- promotion to health professionals and other relevant decision makers
- interactions with health professionals, other relevant decision makers and healthcare organisations
- interactions with health professionals, other relevant decision makers, healthcare organisations, patient organisations and the public including patients and journalists
- specific requirements for interactions with the public, including patients and journalists and patient organisations
- annual disclosure requirements

ABPI Principles

The ABPI is also putting increased emphasis on the **ABPI Principles**, which sit alongside the Code. They are key to how the pharmaceutical industry operates and essential in building trust. All companies are expected to embed them in their organisations.

The principles are:

- Benefitting patients
- Acting with integrity
- Promoting transparency
- Treating everyone with respect

[4] Most requirements of the new Code came into force on 1st July, with the exception of an additional grace period until December 31st for companies transitioning ongoing MEGS to donations or collaborative working.

ABPI response to government's 'vision' for life sciences

The four nations of the UK have come together to launch its 10-year strategy for the UK's life sciences sector with a plan to build on successes of COVID-19 response and accelerate delivery of innovations to patients. The Vision outlines seven critical healthcare missions that governments, industry, the NHS, academia and medical research charities will work together on at speed to solve – from cancer treatment to tackling dementia.

In response, Richard Torbett, Chief Executive of the ABPI, said: "This is an ambitious statement about how the UK can become a life sciences superpower. We've seen just how important the partnership between industry, the government and the NHS has been to the response to the pandemic, and we need to take the same approach if we are going to make the UK a global hub for life sciences.

"By putting the NHS at the centre of the vision, we can also deliver for patients and make the UK the best place in the world to research, develop, manufacture, and use the latest medicines and vaccines."

Who we are

The Association of the British Pharmaceutical Industry (ABPI) exists to make the UK the best place in the world to research, develop and use new medicines and vaccines. We represent companies of all sizes who invest in discovering the medicines of the future.

Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Governments and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines.

Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

For further information about any of the issues in this Bulletin or about ABPI Cymru Wales, please contact:

Dr Richard Greville,
Director ABPI Cymru Wales

Email: rgreville@abpi.org.uk
Tel: 029 2045 4297

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