June Raine: How we backed a COVID-19 vaccine before rest of the West

The year 2020 has been a difficult one for us all. As COVID-19 has affected almost every aspect of our lives, it has at times been hard to foresee an end. But last week, we reached an important milestone in our fight against the disease. On Wednesday, my Agency the MHRA announced the authorisation of the Pfizer/BioNTech COVID-19 vaccine for supply here, making the UK the first country in the Western hemisphere to issue an approval.

Before some 30 years at the MHRA and its predecessor, working on keeping medicines safe for the public, I was a general practitioner for 5 years. Patient safety has always been at the heart of my work. It has been no different for this vaccine, nor will it be for the others to come.

People rightly ask me how we achieved this outcome before others.

While the first batch of data from Pfizer was not submitted to the MHRA until early October, we began preparing our safety surveillance systems months before.

In early June, we set up an independent Expert Working Group to take some of the important safety work forward. In August, a second Working Group was formed with different expertise – this time to advise the MHRA on the benefits and risks of the COVID-19 vaccines in development. Formed from 48 experts from outside of the MHRA, these groups include virologists, epidemiologists, immunologists and toxicologists. It also includes lay membership.

In September, we started preparing our laboratories for 'independent batch testing' of this vaccine. Although the vaccine manufacturers carry out their own comprehensive testing regimes on the batches of vaccine they produce, it's of vital importance that tests focusing on safety and quality are conducted independently, too.

In the UK, this independent testing is performed by the National Institute for Biological Standards and Control (NIBSC), which is part of the MHRA. Before any batch can reach the public, the NIBSC will conduct a rigorous assessment to check that it is consistent with characteristics derived from results for batches previously shown to be safe and effective in clinical trials, or routine clinical use. This work began in November.

COVID-19 vaccines, including this one, are being developed in a coordinated way that allows some stages of the assessment process to happen in parallel, allowing us to condense the time needed. The expected high standards of safety, quality and effectiveness are not compromised in any way. This 'rolling review' – a regulatory tool that allows us to review the data as they become available from ongoing studies, rather than waiting for it to be submitted as a full package– has been key.

There have been several submissions of data sent us to us by Pfizer/BioNTech since October. This means that we had already made good progress on our review by the time the final clinical submission was sent to us on the 23 November. This is why I like to think of it as climbing a mountain – months of careful planning and preparation; ready at the base camp when the interim data arrive; and when the final package arrives, we are ready to scale the peak.

As the data came in, our scientific and clinical experts robustly and thoroughly reviewed it with great scientific rigour. We pored over pages of information and data, looking at all aspects – from the laboratory studies to the clinical trials, and more. We looked at how the vaccine protects people from COVID-19, the level of protection it provides and how long for. We analysed the data on safety, its stability and how it needs to be stored. The list goes on. Our assessors have worked around the clock, reviewing hundreds of pages of data.

On top of this, we also have a range of experts inspecting the sites used across the whole lifecycle of the vaccine, from its initial development in a lab to its manufacture and distribution, once approved. Our inspectors work to legislation that incorporates internationally recognised quality standards.

Of course, no stone should be left unturned. And that's why it's important that we don't just rely on our own analysis. So, once we have reviewed the data, we seek advice from the Government's independent advisory body, the Commission on Human Medicines. They critically assess the data too before advising the UK government on the safety, quality and effectiveness of any vaccine.

On 1 December we received a letter from the Department of Health and Social Care asking us to authorise the Pfizer/BioNTech vaccine under Regulation 174, an EU provision introduced in national law that allows for the authorisation of a medicine in response to a public health need.

This means that, instead of having to go through the centralised licensing route of the European Medicines Agency (as most vaccines do until the end of the transition period), we were able to authorise the supply of the vaccine based on public health need, provided the batches meet specific conditions laid out by us. For those concerned about this, I can assure you without reservation that the standards we have worked to are equivalent to those around the world – no corners have been cut.

But our work doesn't end there. As with any medicine, COVID-19 vaccines require continuous safety monitoring to ensure the benefits in protecting people outweigh any side effects or potential risks. The MHRA has responsibility in law to continuously evaluate all medicinal products on the UK market and this vaccine is no exception.

While this battle is in no way over, I hope that this decision, underpinned by months of scientific rigour and analysis, will bring hope to those who have seen some of their darker days during this pandemic. I also owe a huge

debt of thanks to all those whose expertise, dedication and inspiring work have brought us this far on our journey.

The original article can be found on The Times' website.

New playbook launched to step up construction sector productivity and innovation

- New Construction Playbook details how government and industry can better work together to deliver public sector works in a more modern and efficient way
- It also outlines green initiatives for the construction industry to minimise greenhouse gas emissions of projects
- The new guidance has been developed in consultation with construction industry

New plans on how government will work with the construction sector to make sure public sector works are delivered faster, better and greener have been launched today.

In 2018, public sector works contributed some £117 billion to the UK economy, as well as supporting over two million jobs.

The Construction Playbook, launched today, outlines what government expects from these works, from new roads and railway lines to schools, hospitals and prisons.

The Playbook also outlines the key role the construction sector will play in both the UK's recovery from the coronavirus pandemic and work to bring greenhouse gas emissions down to net zero by 2050. Green initiatives in the Playbook include promoting the use of carbon assessments to understand and minimise the greenhouse emissions of projects.

Other specific measures include:

- Providing greater certainty to industry through long term plans for key programmes. This will include longer term contracting across a range of areas which will give industry the certainty required to invest in new technologies, delivering improved productivity and efficiency savings
- Incentivising industry to innovate by focusing on the output of what we want a project to achieve, rather than micromanaging how it is done
- Modernising construction by standardising designs and parts, as well as embedding digital technologies including the UK Building Information Management Framework

- Greater focus on building positive relationships with robust contract management between project leads and industry
- Investing more in training and apprenticeships, driving forward innovation in construction, boost productivity and focus on value for money in public sector developments

Learning lessons from the Grenfell Tower tragedy, the Construction Playbook also makes it clear that the construction sector must put safety at the heart of everything it does.

Cabinet Office Minister Lord Agnew, said:

> As the largest construction sector customer, government is in an ideal position to ensure that the industry is productive, professional and delivers value for money for taxpayers.
>
> By adopting the new Construction Playbook, developed with industry partners, we will help ensure that the sector becomes greener and more innovative.

Andy Mitchell, the CEO of Tideway and Co-Chair of Construction Leadership Council:

> The Government can influence the whole direction that our sector takes with the way it buys new public buildings and infrastructure.
>
> The Construction Leadership Council is delighted that Government is showing real leadership in this regard. The Construction Playbook commits us all to drive positive change with better, long-term relationships and more efficient ways of working. The CLC will give its support to engage the industry to play its part in embedding the Playbook recommendations across our sector.

Michael Graham, the Chairman of the Graham Group said:

> This is a fantastic opportunity for industry and the Government to come together and change the face of UK construction to deliver sustained value for money and a more stable, productive industry.
>
> The launch of the Construction Playbook is only the start of the journey and we look forward to playing our role to help deliver these better outcomes.

The Construction Playbook has been created following months of detailed talks between the government and the construction sector. The measures launched today have been backed by construction firms and business associations from across the industry.

The document also outlines how the Government will strengthen the financial assessment of all the suppliers it works with to make sure projects are delivered on time and to budget.

For more details of the Construction Playbook visit here

Independent Monitoring Authority chair and members appointments

The Lord Chancellor, the Rt Hon Robert Buckland QC, has appointed Sir Ashley Fox to be the first chair of the Independent Monitoring Authority for the Citizens' Rights Agreements (IMA) for a tenure of 4 years. His appointment commenced on 8 December 2020 and run until 7 December 2024.

Sir Ashley's appointment follows a Justice Select Committee pre-appointment hearing on 24 November and the publication of the Committee's report into the same on 3 December. The Lord Chancellor and Sir Ashley have noted the report's contents and recommendations.

The Lord Chancellor has also made the following Non-Executive Member Appointments.

- Punam Birly has been appointed as non-executive member of the IMA for a 2 year tenure;
- Marcus Killick has been appointed as non-executive member with knowledge about conditions in Gibraltar relating to citizens' rights for a 3 year tenure; and
- Leo O'Reilly has been appointed as non-executive member with knowledge about conditions in Northern Ireland relating to citizens' rights for a 3 year tenure.

The appointees all commenced their tenure on 8 December 2020.

Non-executive appointments to the IMA are not currently regulated by the Commissioner for Public Appointments.

However, the Chair and Members have been appointed following fair and open competitions run in line with the process set out in the Governance Code on Public Appointments.

Further campaigns are currently underway to appoint a member with knowledge of the conditions in Scotland relating to the rights of citizens under the EU Withdrawal Agreement and EEA EFTA Separation Agreement, and a member with knowledge of the conditions in Wales relating to those rights, with the appointments expected to be announced by the end of January and the end of February 2021, respectively.

Independent Monitoring Authority for the Citizens' Rights Agreements

The IMA is a brand-new public body, which has been established under the EU (Withdrawal Agreement) Act 2020 (EUWAA). The IMA needs to be operational by the end of 2020. The chair of the IMA will play a crucial role in establishing the IMA's early direction and effectiveness, and in winning the confidence of its stakeholders.

Under the provisions set out in EUWAA, the IMA will have the power to receive complaints, launch inquiries and initiate legal proceedings. The IMA will also have a role in reviewing the effectiveness of the citizens' rights legislative framework, for instance by reviewing draft legislation. The legislation also provides that it is important for the IMA to focus on general or systemic failures in the implementation of the citizens' rights agreements, as well as receiving and investigating individual complaints. The IMA will have to publish guidance on how it will exercise its functions.

Biographies

Sir Ashley Fox – Chair of the IMA:

Sir Ashley is a business consultant providing strategic advice on the European Union. Since 2015 he has been the lay member on the Leadership Nomination Committee of the Royal Institution of Chartered Surveyors. Sir Ashley served as MEP for the South West of England and Gibraltar from 2009 to 2019. He was Leader of the Conservative MEPs from 2014 to 2019. Prior to being elected Sir Ashley practised as a solicitor in Bristol.

Punam Birly – Member:

Punam was a Partner at KPMG LLP (UK) from 2008 – 2020. She was Head of Employment and Immigration within the Tax and Legal Services Practice and the lead on People related Brexit issues. She is an EU/international social security specialist. She is a Solicitor of the Senior Courts of England and Wales and previously worked at Andersen, Deloitte and PwC.

Marcus Killick – Member with knowledge about conditions in Gibraltar relating to citizens' rights:

Marcus qualified as a Barrister at Law (England and Wales), an Attorney at Law (New York), and a Chartered Fellow of the Chartered Institute of Securities and Investment. His current role is Chief Executive Officer of ISOLAS LLP, one of Gibraltar's leading law firms.

Leo O'Reilly – Member with knowledge about conditions in Northern Ireland relating to citizens' rights:

Leo is a Non-Executive Audit and Risk Committee Member of the Office of the Police Ombudsman for Northern Ireland. He was a former civil servant in the Northern Ireland Civil Service with over 27 years' experience as a senior civil servant covering a diverse range of functions and activities across

government in both NI and GB. These include over 11 years as the Permanent Secretary of three Northern Ireland departments.

NDG announces new Caldicott Principle and guidance on Caldicott Guardians

The National Data Guardian for Health and Social Care (NDG) Dame Fiona Caldicott has today published the outcomes from a public consultation that she ran to seek views on her intention to:

- revise the existing 7 Caldicott Principles
- introduce a new principle about ensuring there are no surprises for patients and service users about the use of their confidential information
- issue guidance about the role of Caldicott Guardians using her statutory powers

The consultation response contains a revised – and expanded – set of 8 Caldicott Principles and includes a commitment to issue guidance about Caldicott Guardians in 2021.

The Caldicott Principles, first introduced in 1997 and previously amended in 2013, are guidelines applied widely across the field of health and social care information governance to ensure that people's data is kept safe and used appropriately. Caldicott Guardians support the upholding of these principles at an organisational level.

The new principle's purpose is to make clear that patient and service user expectations must be considered and informed when confidential information is used, to ensure 'no surprises' about the handling or sharing of their data. Following feedback from the consultation, the wording of this new, eighth principle is:

Principle 8: Inform patients and service users about how their confidential information is used

A range of steps should be taken to ensure no surprises for patients and service users, so they can have clear expectations about how and why their confidential information is used, and what choices they have about this. These steps will vary depending on the use: as a minimum, this should include providing accessible, relevant and appropriate information – in some cases, greater engagement will be required.

Its introduction was prompted by a careful consideration of the role that the legal concept of 'reasonable expectations' should play in shaping the circumstances under which health and care data may be legitimately shared.

The NDG does not envisage that this principle will establish reasonable expectations as a legal basis in its own right to meet the duty of confidence. However, given the influence of the Caldicott Principles, she does believe it will helpfully emphasise the perspective of patients and service users in decisions to use and share confidential information.

The consultation response also confirms the NDG's intention to issue guidance using her statutory powers in 2021 about the appointment of Caldicott Guardians for all public bodies within the health and adult social care sector in England, and all organisations which contract with such public bodies to deliver health or adult social care services. The guidance will define the roles and responsibilities of Caldicott Guardians and how they should be supported by their organisations. The guidance will provide flexibility for organisations for which it is not proportionate to appoint a dedicated Caldicott Guardian and will suggest options/models to ensure those organisations can still have a Caldicott function.

Supporting resources will be made available for those who need to appoint a Caldicott Guardian or establish a Caldicott function within their organisations.

This will be the first time that the National Data Guardian has issued statutory guidance using her powers under the Health and Social Care (National Data Guardian) Act 2018.

Notes to editors

The consultation was conducted via a written survey, which received 194 responses, and eight online focus groups involving 88 patients, social care service users and members of the public. These activities were supplemented by engagement with key individuals and organisations from across the health and care system, before and during the consultation period.

A set of six principles was first published as part of The Caldicott Committee's Report on the Review of Patient-Identifiable Information published in 1997 to serve as good practice guidelines to be applied to the use of confidential information within the NHS. A further principle was added in 2013 as part of The Information Governance Review.

The 1997 review also recommended that a senior person, preferably a health professional, should be nominated in each health organisation to act as a guardian, responsible for safeguarding the confidentiality of patient information. These became known as Caldicott Guardians. Local authorities with adult social care responsibilities have been required to have one since 2002. There are over 18,000 Caldicott Guardians in post today.

The National Data Guardian has published a blog post on this topic.

For further information contact Jenny Westaway, Head of the Office of the National Data Guardian on j.westaway@nhs.net or 07827 955 604

Why Caldicott Principles and Caldicott Guardians are still relevant in 2020

Today we have published the outcomes of a consultation that we held earlier this year about the Caldicott Principles and the role of Caldicott Guardians. The consultation response contains a revised – and expanded – set of 8 Caldicott Principles. It also confirms our intention to issue guidance in 2021 that will increase the number (and type) of organisations which should appoint a Caldicott Guardian.

I am coming to the end of my term in March as National Data Guardian for Health and Care in England, and also my career in the NHS. In this period of reflection, I look back with some satisfaction that 23 years after their inception, Caldicott Principles and Caldicott Guardians are still considered valuable and useful. It still seems strange to me that they bear my name, as that was definitely not my recommendation or intention.

The principles were introduced in 1997 as part of a review I led into patient-identifiable information, which was motivated by concerns about patient confidentiality at a time of rapidly expanding use of information technology in the service. We proposed six principles based on common sense to safeguard confidentiality.

The same review also introduced Caldicott Guardians in the NHS, and subsequently in local authorities. We thought that all organisations handling patient and service users' health data should have a senior person with a specific responsibility for protecting the confidentiality of that information. Today this role is very well-established; there are now more than 18,000 Caldicott Guardians – and not just in health and care: some organisations in other sectors, such as prisons, police and the armed forces appoint them too.

There has been much change since the role was first established, and we wanted to obtain a clear understanding of people's current views on its value. In particular, the introduction of additional information governance (IG) roles into health and care settings, such as data protection officers (DPOs) and senior information risk owners (SIROs) has changed the landscape. Considering this, we wanted to 'test the temperature': did people on the ground still feel the role was as helpful? And did people feel that patients and service users across a broader range of settings would benefit from the services of Caldicott Guardians?

What we heard was a resounding 'yes'. This reinforced my firm belief that where health and care data is being used, Caldicott Guardians can bring something nuanced and very specific to discussions and decision-making. Their deep understanding of how health and care data is different to other data (in many cases because they are clinicians and care providers themselves)

positions them as knowledgeable advocates for patients. Whilst the other IG roles are equally valuable in terms of ensuring that the legality and technical protections are as they should be, Caldicott Guardians have a different ‘flavour’ and, rightly, are often referred to as the conscience of their organisations.

I believe that even well-established principles and conventions should be reviewed from time to time. It has been seven years since we last revised the Caldicott Principles by adding a seventh principle to encourage better information sharing, and so this seemed a good time to reconsider them. Many discussions in recent years had led my Panel and me to conclude that the principles would benefit from an addition – a new tenet that would serve as a simple guide for frontline workers making data sharing decisions.

This new principle focuses on ensuring that expectations of patients and care users are considered and met when decisions about data sharing are made. Working with them and the public to ensure that data use aligns with expectations has been a mainstay of my work.

It was this belief, for instance, that led us to develop the proposal for the National Data Opt-out. We listened carefully to what people said they wanted and recommended an opt-out scheme because we heard that an important element of building trust was to give people a real choice about the use of their data.

And only by demonstrating that health and social care can be trusted to be respectful and do the right thing with people’s data will we earn the goodwill to use their data.

The roll-out of the National Data Opt-out across health and care organisations is on pause until March. This is so that health and care organisations which had not yet implemented it could concentrate on tackling the pandemic, rather than introducing this change. But the reasons for the opt-out remain as important as ever. I am a keen advocate of data use and have not opted out myself. However, by providing people with a mechanism to do, we show that we uphold the commitment that we made and respect people’s decisions.

The remaining months of my term as NDG fall in a period when it will be important for the system to consider how to deal with the emergency measures that were introduced in response to the pandemic. No assumption should be made that what is put in place during a public health crisis will be appropriate when the level of threat to public health recedes. There are many innovations and changes that should be kept. Equally, others do not remain appropriate outside of the context of a pandemic.

For example, to slow the spread of coronavirus, the Government has passed a law that makes failing to isolate when required, or giving false information to contact tracers, a criminal offence. Regulations have been introduced so that NHS Test and Trace may set aside the duty of confidence to share information with police to enforce this law in individual cases. It is vital that we all obey the rules to control the spread of the virus, and I

understand that this is the purpose of these newly identified offences. We were glad to see that a memorandum of understanding sets out that minimum information should be passed to law enforcement, and that no data is passed to the police from the COVID-19 app. Nonetheless, I am concerned that the current arrangement may also have the unintended consequence of reducing people's readiness to seek care, and would not want this to be seen as a precedent for sharing health and care information with the police beyond this pandemic.

Meanwhile, we have also seen a constructive coming together both within and outside the sector as people have joined forces to both manage the pandemic and keep our health and care system operating effectively. In a blog post that I wrote in April, I said how reassuring I had found it to see so many examples of rapid and focussed action and problem solving. This momentum has never slowed, despite the many challenges; this makes me feel extremely proud of – and thankful for – the dedication of those who work in our health and care services.

Over the last few weeks, we have had some wonderful news about vaccine development: a light at the end of the tunnel. This breakthrough gives us some hope that we can now start to think about – and plan for – a time beyond the current crisis. And as we do consider that, and think about what data use should look like in a post coronavirus landscape, we must continue to listen to the public. We have already begun to see emerging evidence which suggests that people are becoming more knowledgeable about the importance of health and care data, and more accepting of its use. We now have an opportunity to build on this growing awareness. And at this time, transparency will be key to providing the reassurance that earns confidence. We must make a concerted effort to engage with the people whose data we hold before making important decisions about it.

You can read more about our consultation response in our press release