2020 - The year of unexpected challenges



Robert Best CEO & Executive Director MIMS Australia Pty Ltd MIMS New Zealand Ltd eHealthWise Services Ptv Ltd President - MSIA (Medical Software Industry Association) of Australia

I would like to welcome all our readers, partners and customers to this Spring MIMS Matters edition for 2020. I sincerely hope you have managed to cope, as best possible, during what has been an incredibly difficult March-September 2020 period. During the course of 2019/20 Summer. I referenced how difficult it was to celebrate the festive season that had passed, whilst seeing the devastation caused by bushfires and drought to many parts of our beautiful country, especially the regional townships. As we entered into 2020, we were full of hope that the worst was behind us, and that we could move forward.

Our core focus for 2020 was to continue driving MIMS as the leading company, brand and product of choice for Australian Healthcare professionals. We endeavoured to improve our products and provide innovative solutions to our partners across the Healthcare ecosystem. However, towards the end of Q1 of this calendar year, it became apparent that the critical importance of MIMS was to closely engage with our Customers during COVID-19, and ensuring easy access to Medicines Information became our primary focus.

The MIMS team worked extremely hard with: Aged Care facilities, Hospitals, GP clinics, Specialists and many more health modalities, to ensure unrestricted access to our MIMS Medicines Information by either extending or doubling current User access free of charge during this difficult period.

I'm grateful to the MIMS team for delivering this initiative.

The impact of COVID-19 across the entire economy has been dramatic and far reaching. When we closed our MIMS and eHealthWise doors in March. we had no idea for how long and what was ahead of us. Since then, together with Customers, Medical Software partners, and key industry bodies, such as MSIA, we have collaborated to ensure the challenges of those we service were prioritised.

We believe that the hard work and dedication of many Healthcare professionals, and the general population, has ensured the reopening of many businesses across Australia safely.

We also furthered our presence by launching Phase 1 of our much anticipated Regional Web Services (WS) MIMS platform. This new WS API platform will allow all our Medical, Clinical and Dispensing Software Vendor Partners to seamlessly integrate with a range of MIMS content, and enhance their ability to move quickly and easily between geographic markets, territories and countries from a development and commercial enablement standpoint. We also worked on local product enhancement initiatives, including the redesign and development of MIMS Online, and the redesign of IVS Online, improving functionality and user experience.

During this time, we were delighted to have Cairns & Hinterland Hospital and Health Service sign a new 3 year Information and Communication Technology (ICT) agreement with eHealthWise to use our award winning THELMA solution for patient eligibility, patient verification and hospital electronic claims. As part of our eClaiming roadmap development this year, Services Australia published a deadline of March 2022 for all cloud-based vendors transacting with Medicare to be on the new Web Services paradigm.

I am proud to advise that eHealthWise is at the forefront of development for all Medicare Web Services transactions with Medicare. We will be one of the first vendors to complete development and go into testing to achieve our Notice of Integration (NOI) certification under the new Web Service paradigm.

So, as we work through Spring and into the warmer Summer months, I would like to take this opportunity to thank you for your contribution to the Australian healthcare industry, during an incredibly difficult year, and to reassure you that MIMS and eHealthWise will continue on our commitment to provide you with the best products, services and support in order to allow you to remain focused on what you do best!

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NAPSA Congress 2020



The National Australian Pharmacy Students' Association (NAPSA) held its annual premier event, NAPSA Congress, from the 23rd to the 29th of January 2020 at the University of Newcastle. With 350 students attending, NAPSA, along with the University of Newcastle's Association of Pharmacy Students (UoNAPS), put on a fun-filled event over the few days, inspiring the future pharmacists to lead the way.

NAPSA Congress is an incredible event that offers education, networking, a trade-show hall and social events to Australia's most motivated and enthusiastic pharmacy students. It offers amazing opportunities to hear from inspiring speakers, learn about pharmacy industries and interact with likeminded individuals from all over the country.

MIMS, as always, enjoyed being part of this wonderful experience. This year MIMS provided an educational session on the journey of medicines information and knowledge and the pivotal role it plays in the patient cycle of care, and the safe and effective use of medicines. Later, we had the opportunity to interact with the wonderful students more closely, being able to chat, advise and answer interesting questions. Students enjoyed learning about the diverse usage of MIMS, both as a reference source and as data integrated into health software systems.

MIMS wishes these bright NAPSA members all the best for their remaining pharmacy journey and looks forward to working with a new cohort of professionals in the future. We look forward to continuing to support NAPSA and the great opportunities they provide for pharmacy students.

MIMS/Guild Intern of the Year 2019



Member for the seat of Bean Lucinda Kenny

Simon Blacker, Pharmacy Guild of Australia (ACT) President

I was just 14 when my pharmacy journey began, where I worked in a small community pharmacy on the northside of Canberra. This was where I worked as a pharmacist assistant for 11 years before moving southside, to Calwell Capital Chemist. I made this somewhat difficult move a quarter of the way through my internship. I made the decision to uproot to allow the opportunity for growth and I certainly received that within the Capital Chemist group.

Working as a pharmacist within such a supportive group allowed me to utilise my skills to provide the utmost care and support for the community. This network gave me the time and tools I needed, enabling me to operate by the two mantras I live by every single work day: "Never see a need without doing something about it" and "People may forget what you've said but they will never forget how you made them feel". Thank you kindly to MIMS Australia for granting me this award and for supporting young pharmacists and their accomplishments. I have always had a passion and special interest in dermatology. As pharmacists, we are often the first point of call for skin related conditions. Upon receiving the educational grant, I would love to utilise it to significantly upskill in the area of dermatology. Like the other specialties, my idea is to implement a dermatology related clinic within pharmacy. Overall, the grant will facilitate and grow my career in ways that will evolve and positively reflect the pharmacy profession as a whole.

Since I was 14, I have always dreamt of ownership with the liberty of implementing new ideas. I would love to immerse myself within the community and be able to provide specialised services, such as (but not limited to) dermatology consultations, within my pharmacy. Wherever I take my career, it's to positively impact the lives of others.

Lucinda Kenny

Virtual Conferences... Interim solution, or here to stay?



The year 2020 has certainly brought many challenges to health and society, both on a personal and professional level. These changing times have required us all to adapt, with COVID-19 being the driving force for innovation in the virtual world. Virtual meet-ups have become the new norm, with platforms, such as Zoom, becoming the common ground, keeping us all connected, wherever we may be. Staff working from home, travel restrictions and enforced lockdowns have all affected the dynamics of how we connect, making 2020 a very different year for MIMS, as well as the wider health community. We have not been able to interact and network with our peers and industry professionals in

person at conferences and events, however, we have gotten on board with exploring the virtual offerings.

MIMS attended the Australian Pharmacy Professional (APP) Conference for pharmacists and exhibited at the Australian Veterinary Association (AVA) VetFest Conference for veterinary professionals. We have enjoyed the experience so far and see the potential for the practice to continue. Virtual conferences may have gained traction as a substitute to live events due to the challenges of COVID-19, but may well end up becoming the new world of connecting and interacting with the health community.

Australian Digital Health Agency 2020 Innovation Challenge





The 2020 Innovation Challenge was launched in May by the Australian Digital Health Agency (ADHA) in the midst of a global pandemic, not only to support the Australian digital healthcare system but to advance our digital health services post-COVID-19.

Robert Best, the CEO of MIMS Australia & MIMS New Zealand and the President of Medical Software Industry Association (MSIA), was one of the panellists for the Challenge. He said, "For over 55 years, MIMS has been, and continues to be, supporting the Australian healthcare system. It has been my pleasure to be invited as a panellist for the ADHA 2020 Innovation Challenge that showcased an exceptional range of homegrown, Australian digital health innovations. Congratulations to the winners, and I look forward to the implementation of their solutions and continuous development of digital health to improve medication safety and patient health outcomes across Australia.

ADHA media release article - "Winners of Innovation Challenge to help future proof Australia's healthcare system announced"

23 June 2020

The Australian Digital Health Agency has announced the winners of the Innovation Challenge championing digital health innovation to provide a healthier future for Australians through connected healthcare.

Through the National Digital Health Strategy, the government is partnering with our internationally competitive and vibrant health technology sector at a time when the use of technology in health and social care has never been more important.

Australian Digital Health Agency Chief Digital Officer, Steven Issa congratulated the winners who were determined through a competitive process and thanked all applicants for participating in the Innovation Challenge.

"We were delighted to see such interest in this challenge when we received 395 applications from the Australian industry and academia on how to solve key healthcare challenges. It was difficult to determine the finalists with so many highly innovative ideas. Thank you to all who submitted applications and congratulations to the winners," he said.

"It's great to see so many working hard to develop innovative solutions to help ensure a sustainable and fair healthcare system."

The winners of the challenge are:

Murdoch Children's Research
 Institute for their solution, Allergy Pal, a
 digital management platform for children
 with a moderate to severe food allergy
 seeking to build a national database of
 patients with food allergies and facilitate
 greater continuity of care and improved
 patient health outcomes.

- **CareMonitor** for their digital Shared Care and Remote Monitoring Platform designed to provide Australians with a seamless transition of services across the health system and management of patients diagnosed with COVID-19 or other chronic health issues in record time.
- Oculo for their solution to link mobile technologies for the remote capture of objective measures of visual function to inform telehealth decisions and care pathways for eye care.
- Fred IT Group for their solution enabling Australians to easily access their prescriptions electronically through WhatsApp.
- **Pen CS** for their solution, Disease Tracker, a primary care clinical data and analytics platform that improves epidemic surveillance, emergency response and clinical outcomes through point-of-care decision support.

The Agency will now collaborate closely with the successful applicants to assist them to co-design their solution and assist with plans for national scaling.

"As restrictions are eased and Australians come out of hibernation, we want them to access health and care services – especially if they have been putting their health on hold over the past few months. I want to reassure the community that they can access healthcare services safely – whether that be through social distancing in healthcare settings or through the new technology that has taken off this year," Mr Issa said.

"The winners of our challenge are providing amazing digital tools to improve the quality of healthcare services – by improving the quality of telehealth consultations, providing an app for consumers to store their digital prescriptions and making it easier for people to manage their allergies. We are also increasing the capacity of the health system by better using the data we have to assist health services plan for and respond to the needs of the community."

"We will continue to work with innovators, academia, peak bodies, employers and health industry stakeholders to make sure healthcare workers have the necessary skills to embrace digital technology. This can be done in healthcare through the National Digital Health Workforce and Education Roadmap."

The Agency would also like to thank the Innovation Challenge partners for their support of this initiative.

This media release has been edited with permission to re-publish. Please visit the ADHA website for the full media release.

Cairns & Hinterland Hospital and Health Service Signs New 3 Year User Agreement with eHealthWise

Cairns & Hinterland Hospital and Health Service (Cairns HHHS) has signed a new 3 year Information and Communication Technology (ICT) agreement with eHealthWise to use its award winning THELMA solution for patient eligibility, patient verification and hospital electronic claims.

Cairns HHHS provides excellence in healthcare, wellbeing, research and education in Far North Queensland. It provides an extensive range of health services at more than 30 regional, rural and remote facilities across a geographical area of 142,900 square kilometres, ranging from Cairns to Tully in the south, Cow Bay in the north and Croydon in the west. Services delivered include surgery, trauma care, paediatrics, general and specialist medicine, intensive care, cardiology, mental health, outpatient, maternity and neonatal care, aged and dementia care, emergency medicine, environmental health, and general public health.

Business Development Director of eHealthWise, Stuart Davies said, as part of a drive to streamline private patient billing,

"Cairns HHHS needed a comprehensive and easy to use electronic billing solution for privately insured patients. eHealthWise's award winning THELMA platform is the perfect fit for their organisation, as the solution drives billing efficiencies and revenue for the health service. Thelma can integrate with Queensland Health's Patient Administration System (PAS) to seamlessly deliver electronic claiming, enabling end-toend electronic billing of in-patient hospital claims to the private health funds via Medicare ECLIPSE. This new billing functionality will allow Cairns HHHS billing staff to reduce the duplication and errors inherent in manual billing processes, and it also speeds up private patient claim payment times facilitating a large improvement in cash flow.

We are delighted to be working with Queensland Health and look forward to implementing efficiencies that they will gain from our solution.

Medicare Web Services Project Update

Last year, Services Australia published a deadline of March 2022 for all cloud-based vendors transacting with Medicare to be on the new Web Services paradigm. The current client adapter model will be sunset as of March 2022. eHealthWise is at the forefront of development for all Medicare Web Services transactions with Medicare, including all Online Eligibility Checks (OEC) and claim types, such as bulk bill, In-patient Medical Claims (IMC), In-patient Hospital Claims (IHC) and Department of Veterans' Affairs (DVA) claims. We will be one of the first vendors to complete development and

IPSF APRO/MIMS Interprofessional Collaboration Webinar – Healthcare Professionals Collaboration in Response to COVID-19



Professor Richard Harvey, a clinical psychiatrist and MIMS Australia Advisory Board member, was invited to speak as a mental health practitioner during the Healthcare Professionals Collaboration in Response to COVID-19 webinar, which was organised by the International Pharmaceutical Students' Federation Asia Pacific Regional Office (IPSF APRO) and our MIMS regional colleagues in Singapore.

The webinar was broadcasted to IPSF APRO members with the aim of improving understanding of specific roles of each healthcare professional in overcoming COVID-19 in their respective healthcare settings, as well as, the challenges and opportunities to deliver optimal patient-centred care. The panel of the event were healthcare professionals with different areas of expertise across the Asia Pacific region. The speakers were:

Dr. Noel Yeo, Senior Vice President from Parkway Hospitals, Singapore

Ms. Elaine Ng, Group Head of Nursing from IHH Healthcare Berhad

go into testing to achieve our Notice of Integration (NOI) certification under the new Web Service paradigm.

As part of the transition process, Stuart Davies now serves as the Chair for the Medical Software Industry Association (MSIA) Modernisation Services Australia Taskforce. This taskforce seeks to provide industry liaison with Medicare around the issue facing healthcare providers and vendors moving their cloud-based platforms to the Web Services model.

About eHealthWise

eHealthWise Services is a wholly owned subsidiary of MIMS Australia. Since 2001, eHealthWise has been the provider of THELMA Services – a highly secure, cloud-based, low cost electronic health administration transaction solution designed to simplify the healthcare revenue cycle and payment processing. eHealthWise's solutions enable clients to improve efficiency, cash flow and liberate staff time to improve the quality of patient care, and can be interfaced to any Patient Management System. In the last financial year, eHealthWise processed in excess of AUD\$900 million of claims value for our customers. Since 2006, we have been an accredited Medicare Integration Partner, offering our innovative intelligence built into THELMA and have been facilitating the exchange of real-time information and business transactions between health industry partners including: hospitals, health funds, Medicare Australia, medical practitioners and diagnostic providers.

For more information, visit www.ehealthwise.com.au

Ms. Hazel Faye R. Docuyanan, President of Philippine Society of Hospital Pharmacists, Philippines

Prof. Richard Harvey, Clinical Psychiatrist & Founder of Telepsych Online, Australia

Dr. Dennis Jacobus, Medical Director & Head of Diagnos Genomics from Diagnos Laboratorium Utama, Indonesia

The key advice from Professor Harvey on managing mental health and general wellbeing was "being kind, connecting with and being supportive of others during COVID-19."

MIMS has a strong presence in 17 countries across the Asia Pacific region, and is the leading multichannel provider of trusted medicines information. IPSF APRO represents more than 70,000 members from 18 countries across Asia Pacific. The event took place with great success reaching out to IPSF APRO members. It was broadcasted live on Zoom with over 4,000 attendees and, due to its popularity, was made available on Facebook Live reaching another 16,000+ participants.



MIMS IVS is the only fully indexed, searchable product in the market that lists available brands of Australian-registered veterinary medicines and products. Launched in July 2019, IVS Cloud is searchable by product name and generic, and contains comprehensive medicines information including composition, actions, indications, contraindications, dosage and administration, and presentation.

IVS Cloud is updated quarterly, in March, June, September and December, keeping vets up-to-date with new products and registrations. In order to provide the best, most complete resource for the Australian veterinary community, MIMS IVS will be integrating a whole new database of product labels and safety data sheets, enhancing the resource with all the information you need. MIMS will be holding a webinar series later in the year to showcase IVS Cloud and its developments.

> MIMS IVS Cloud is available online at **www.ivs.com.au**. MIMS IVS is also available in the annual book and CD format.





IVS Online has a new look

IVS Online, New Zealand's comprehensive veterinary medicines resource, has undergone a revamp project to update its interface with a new look, providing a modern feel and better user experience. The new look of IVS Online comes with:

- **O** New headers
- O Modern colour scheme
- O Bigger, more prominent search bar
- O Improvement to layout and space
- O Mobile screen optimisation

IVS Online is available online at **<u>www.ivsonline.co.nz</u>**. IVS Annual is also available in the annual book format.

Electronic Prescriptions



Electronic Prescription Token supplied by eRx Script Exchange

The implementation of electronic prescriptions is part of the Australian Government budget initiative to improve efficiency of the current Pharmaceutical Benefits Scheme (PBS) claiming system and medicines safety. It gives patients the option to obtain either a physical or paperless prescription.¹

Electronic prescriptions can be delivered by either the token model or Active Script List. Through the token model, which is currently available, patients can receive their prescription token by email or SMS. Active Script List is expected to be implemented by the end of 2020, giving patients more flexibility to access their medicines digitally and to authorise pharmacists and doctors to access their profile.²

The COVID-19 pandemic has fast-tracked the roll out period of electronic prescriptions in Australia. The first paperless prescription was successfully prescribed and dispensed in Victoria May 2020. By September, eRx Script Exchange has successfully enabled electronic prescriptions in all Australian jurisdictions. Pharmacist and CEO of Fred IT Group, Paul Naismith, emphasised the foundational role of electronic prescriptions in a modern healthcare network, saying, "This is a significant leap forward for healthcare in Australia. The achievement of national electronic prescriptions is vital to modern healthcare delivery based on flexibility for patients and state-of-the-art systems for healthcare professionals." – Fred IT³

For more information about electronic prescriptions for prescribing and dispensing¹, contact:

- Australian Digital Health Agency electronic prescribing technical framework, help@digitalhealth.gov.au
- Department of Health legislative framework, **ePrescribing@health.gov.au**
- Services Australia PBS or RPBA claim systems and Healthcare identifiers service, devsupport@servicesaustralia.gov.au

¹ Department of Health, "Electronic Prescribing", viewed 15 September 2020, https://www.health.gov.au/initiatives-andprograms/electronic-prescribing

² eRX Script Exchange, "ePrescribing", viewed 15 September 2020, https://www.erx.com.au/eprescribing/

³ Fred IT, "The Latest Fred News", viewed 15 September 2020, https://www.fred.com. au/category/news/

Active Ingredient Prescribing

Active Ingredient Prescribing (AIP) was announced as part of the 2018-19 Budget, supporting the Government's commitment to the development and implementation of electronic prescribing. This initiative aims to ensure consistent and standardised medicines information to support safe and appropriate use of medicines. It is expected to provide a number of benefits, including:

- Empowering and equipping prescriber communities and patients to better understand the active ingredients in their medicines;
- Reducing patient safety concerns relating to patients taking multiple doses of medicines due to confusion;
- Assisting conversations between pharmacists and patients concerning generic alternatives;
- Decreasing out-of-pocket expenses for patients by promoting the uptake of generic and biosimilar medicines;
- Improving the financial sustainability of the Pharmaceutical Benefits Scheme (PBS), with savings to be reinvested to list new medicines and health technologies on the PBS;

- Enhancing prescribers' stewardship role of the PBS, and encouraging more sustainable prescribing practices; and
- Aligning Australian prescribing practices with International standards.

Preserving prescribers' clinical decisionmaking autonomy and choice of medicine has been a major consideration throughout the development of the initiative. Prescribers will continue to be able to choose a specific brand of medicine for their patient, and can include a brand name on the prescription wherever they believe it is necessary for the treatment of their patient.

The Department of Health has amended the *National Health (Pharmaceutical Benefits)* Regulations 2017 to require the inclusion of active ingredients on all Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS (RPBS) prescriptions, except for:

- Handwritten prescriptions;
- Paper based medication charts in the residential aged care sector;
- Medicinal items with four or more active ingredients; and
- Other items determined by the Secretary for safety or practicality reasons.

Prescribers may continue to include a brand name on prescriptions wherever clinically necessary for their patient. Where a brand name is included on prescriptions, the active ingredient must appear first. Prescribers also retain the ability to disallow brand substitution. Prescribing software is not able to automatically include brand names on prescriptions by default.

The Department of Health is working with the clinical software industry to make appropriate changes to their software to align with the amended legislative requirements from 31 October 2019. The legislative changes include a transition period to enable the changes to be made and to ensure prescribers are using software which generates prescriptions in accordance with these requirements by 1 February 2021.

MIMS Australia has been working to incorporate the required updates and changes into the MIMS medicines knowledge database, ensuring a smooth transition for our vendor partners as they align with AIP standards.

For more information on AIP announcements and resources, please visit https://www. pbs.gov.au/info/general/active-ingredientprescribing

Sourced from: Australian Government Department of Health 2020, Active Ingredient Prescribing Fact Sheet, The Department of Health, available at https://www.pbs.gov.au/ general/active-ingredient-prescribing/ Active-Ingredient-Prescribing-Fact-Sheet.pdf

Telehealth Services Supporting the National COVID-19 Health Plan





Telehealth services have been around for a number of years, but have only recently become more available for the wider population of patients and healthcare providers.

Telehealth services use information and communications technologies (ICTs) to deliver healthcare services, typically when the patient and the provider are separated by distance. They encompass diagnosis, treatment, preventive or curative aspects, and other related processes, such as education, delivered via phone, video-calls or specific mobile apps.^{1,2}

Telehealth can be a cost effective, convenient alternative to the more traditional face-to-face consultations, particularly when time, distance and cultural barriers prevent or delay the delivery of timely and appropriate healthcare services and educational support. They can improve patient outcomes and provide greater efficiency in the way healthcare is delivered.^{1,2}

Although previously predominantly used to improve access to healthcare for those living in rural and remote areas, COVID-19 has disrupted this focus and highlighted telehealth services as an essential avenue towards greater healthcare access for all Australians.

In response to the challenges of COVID-19 lockdown restrictions, commencing 13 March 2020, the Australian Government approved new temporary Medicare Benefits Schedule (MBS) telehealth items to allow patients who cannot attend, or do not require, face-to-face consultations to use telehealth services and to reduce the risk of community transmission. These items are available to general/medical practitioners, nurse practitioners, midwives, allied health providers and dental practitioners, for a service which may be provided by telehealth, only if it is safe and clinically appropriate to do so. From 20 July 2020, additional legislative requirements for general practitioners (GPs) and other medical practitioners (OMPs) working in general practice required that a telehealth service could only be provided for patients with whom they have an existing relationship, and there are limited exemptions to this requirement.³

These new MBS items allow all Australians to access essential Medicare funded health services in their home while they undergo self-isolation or quarantine, reducing the risk of unnecessary exposure to COVID-19 and the risk of infection to the wider community. This allows better continuity of care by allowing patients to regularly communicate with their provider, which, in turn, promotes positive health outcomes.⁴ Video-conferencing is the preferred method for telehealth services, however, phone calls may also be used as an alternative. Greater access to these telehealth services aims to help protect health providers and patients, as well as patients with conditions requiring face-to-face service.4

Telehealth services are available to all eligible Australians under Medicare and these services will be available until 31 March 2021.³

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³ Australian Government Department of Health 2020, MBS Changes Factsheet: COVID-19 Temporary MBS Telehealth Services, Medicare Benefits Schedule (MBS) Online, viewed 25 September 2020, http://www.mbsonline.gov.au/ internet/mbsonline/publishing.nsf/Content/ 0C514FB809FBBEC7CA28852E00223AFE/\$File/ Factsheet-COVID-19-Bulk-billed-MBS%20telehealth-Services-Overarching-17.09.2020.pdf

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Global race for COVID-19 vaccine gains momentum

Elvira Manzano

The global race for a COVID-19 vaccine moves at an unprecedented speed, buoyed by public pressure and geopolitical crosscurrents that were punctuated by deaths and infections around the world. Seven vaccine candidates already entered human clinical testing. Nearly 70 more are in the pipeline.

One of the frontrunners, ChAdOx1 nCoV-19, a vaccine the University of Oxford, UK, is developing with AstraZeneca, showed promising preliminary results in the phase 1/2 clinical trial. ChAdOx1 nCoV-19, also known as AZD1222 vaccine, was demonstrated to be safe, with only a few side effects, and induced strong immune responses. It provoked a T-cell response peaking at 14 days post-vaccination, and an antibody response within 28 days.¹ The vaccine was tested vs a meningococcal conjugate vaccine in 1,077 healthy adults (age 18-55 years) who had no history of COVID-19 from 5 UK hospitals. ChAdOx1 nCoV-19 showed an acceptable safety and tolerability profile, with headache and fatigue as the most commonly reported reactions. There were no serious adverse events related to ChAdOx1 nCoV-19. The results were "encouraging and an important milestone" in the search for a COVID-19 vaccine, said Dr Andrew Pollard, lead investigator and professor of paediatric infection and immunity, University of Oxford.

ChAdOx1 nCoV-19 is made from a weakened version of adenovirus, a common cold virus that causes infections in chimpanzees. The virus was genetically modified to code for the SARS-CoV-2 virus spike protein. Dr Sarah Gilbert, professor of vaccinology, University of Oxford, and one of the investigators of the



ChAdOx1 nCoV19 study, said the results, while encouraging, should not be trumpeted too soon. "It is too early to tell ... the difficulty is that we don't know how strong the immune response needs to be," she said. "We can't tell, just by looking at immune responses, whether this vaccine is going to protect people or not." The only way to find out is to do phase III trials and "wait for people to be infected to know if the vaccine can work," she added.

The team has now advanced to phase III trials, enrolling 30,000 patients.² The speed at which the vaccine has made through the testing process is quite impressive. What usually takes years, has only taken months. If successful, Oxford's programme would leapfrog all other COVID-19 vaccines in development. "Yet, for any vaccine to be useful, we not only need larger studies in [places where] COVID-19 is still at a high rate. We need to be reasonably sure that the protection lasts for a considerable time," commented Professor Stephen Evans from the London School of Hygiene and Tropical Medicine, London, UK, who is unaffiliated with the study. "The trial should also include people older than 55 years."

Meanwhile, preliminary results from an ongoing German phase I/II trial of an mRNA vaccine, BNT162b1, by Pfizer and BioNTech, support the positive findings from the US trial. BNT162b1, targeting the RBD*SARS-CoV-2, produced neutralising antibody responses in humans beyond the levels observed in convalescent sera at low doses.³

Other big players, US-based biotech company Moderna and the US National Institute of Allergy and Infectious Diseases (NIAID), are also capitalising on the newer messenger RNA technology to develop a COVID-19 vaccine. Early data on the first 45 healthy adults (age 18-55 years) enrolled in Seattle and Emory University sites in Atlanta, US, who were vaccinated twice, at 28 days apart, with the mRNA-1273 COVID-19 vaccine (25 µg, 100 µg, or 250 µg dose), showed that the vaccine induced anti-SARS-CoV-2 immune responses. There were no trial-limiting safety concerns identified.⁴

Contact:

In a related commentary, Dr Penny Heaton of the Bill & Melinda Gates Medical Research Institute in Cambridge, Massachusetts, US, said the world has born witness to the compression of the typical 3-9 years of vaccine work into 6 months.⁵ While the data look promising, she cautioned that much work remains to be done, partly because the 250 µg dose was linked to severe systemic side effects without increasing efficacy beyond the 100 µg dose. "It is prudent to evaluate doses of 100 µg and lower to define the regimen that provides the most appropriate benefit-risk profile for this vaccine," she said.⁵

Experts do not anticipate full approval of a vaccine before early 2021. With reports from Elaine Soliven.

*RBD: receptor-binding domain

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³ Mulligan, M.J. et al. (2020). Phase 1/2 Study to Describe the Safety and Immunogenicity of a COVID-19 RNA Vaccine Candidate (BNT162b1) in Adults 18 to 55 Years of Age: Interim Report. medRxiv. https://doi.org/10.1101/2020.06.30.20142570.

⁴ Jackson, L.A. et al. (2020). An mRNA Vaccine against SARS-CoV-2 – Preliminary Report. The New England Journal of Medicine. https://doi.org/10.1056/ NEJMoa2022483.

⁵ Heaton, P.M. (2020). The Covid-19 Vaccine-Development Multiverse. The New England Journal of Medicine. https://doi.org/10.1056/NEJMe2025111.

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