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Communicating with patients and the public about COVID-19 vaccine safety: recommendations from the Collaboration on Social Science in Immunisation.

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Background

On 8 April 2021, the Australian Technical Advisory Group on Immunisation (ATAGI) made the Pfizer BioNTech Coronavirus Disease 2019 (COVID-19) vaccine (Comirnaty) the preferred vaccine for adults aged under 50 years who have not received a first dose of COVID-19 Vaccine AstraZeneca.[1] This followed an established causal relationship between the AstraZeneca vaccine and a rare clotting condition named 'thrombosis with thrombocytopenia syndrome' (TTS).[2] This decision has affected the rollout nationally given Australia's limited vaccine portfolio: AstraZeneca is the mainstay for Australia's supply with 53.8 million doses, mostly through domestic production. ATAGI's recommendation occurred seven weeks into a rollout affected by limited global vaccine supply, difficulties in coordination between the commonwealth and state/territory governments, and intense media attention. With limited Pfizer vaccine available, the recommendation imposes a significant delay in the timeframe in which Australians could be protected from COVID-19 and an ongoing vulnerability for the coming winter.

The risk-benefit analysis for the AstraZeneca vaccine is balanced between a risk of TTS and benefit of preventing severe COVID-19. The equation is mainly affected by the amount of disease in the community and age. Older people are at greater risk from COVID-19, including Intensive Care Unit admission and death. Rates of TTS are currently estimated to occur at 6 per million people vaccinated but the estimates increase to 20-40 cases per million in those aged under 50 years.[3] TTS is a serious adverse event, requiring hospitalisation and with a death rate initially estimated at 25%.[1] Earlier case ascertainment may see this death rate reduce. It is not possible to determine who is at greater risk of thrombosis and cases must be identified early to receive timely non-heparin anti-coagulant therapy. Knowledge about TTS continues to evolve.

This article outlines the potential impacts of the AstraZeneca COVID-19 vaccine safety concerns. It consider the relevant heuristics and values affecting patient decision making and proposes some practical strategies for effective communication by clinicians and governments. The recommendations have been collaboratively developed by members of the Collaboration on Social Science in Immunisation (COSSI) steering group. COSSI is Australia's leading network to inform immunisation policy and practice with high quality evidence from the social sciences. The authors reflect social scientist, clinical, Aboriginal, consumer and program perspectives. The steering group met on 14 April, 2021 to formulate a set of observations and recommendations. These were grounded in knowledge from the field of risk communication; a specific guidance on communicating about COVID-19 vaccine

safety from the World Health Organization;[4] and our research-in-progress in Victoria, New South Wales and Western Australia examining public and professional attitudes to the COVID-19 vaccines.

Impacts of the COVID-19 Vaccine AstraZeneca recommendation

The new ATAGI recommendation poses significant risk communication challenges for clinicians and governments. Even small risks associated with the COVID-19 Vaccine AstraZeneca may be hard to tolerate in a country with limited local transmission, yet an outbreak remains almost inevitable. So far in Australia, tracking surveys have detected little to no reduction in willingness to have a COVID-19 vaccine. [5] [6] A decline in turounout observed among health care workers in NSW may reflect reduced confidence but also confusion and delay due to perceptions of vaccine availability.[7]

The impact of the perceived risk of TTS on younger females could be greater given this group is already hesitant about COVID-19 vaccination.[8] Young women have been viewing media reports since the beginning of 2021 about their cohort likely creating a vaccine hesitancy norm which may affect behaviour. Further, recent evidence suggests that those who are hesitant about vaccination may also lack trust in providers and governments - the very same institutions providing vaccine advice.[8]

While Australia remains in limited supply of vaccines, the impact on the estimated 24% of Australians unsure about having a COVID-19 vaccine may not be fully seen until supply outstrips demand later in the year.[9] Such longer term impacts on confidence were seen after the four month suspension of influenza vaccination for children aged less than 5 years in 2010, where it took nearly a decade for safety concerns to abate.[10]

Each age group may struggle to understand the risks and recommendations for COVID-19 vaccines. Current information could turn into misinformation as it travels through different messengers.[11] Given people aged under 50 years can still agree to receive the AstraZeneca vaccine, they may seek a risk-benefit discussion with their doctor or other vaccination provider. Some people aged 50 years and over may wish to wait for the Pfizer vaccine later in the year, preferring to do nothing at present, despite the uncertainty around hotel quarartine and a possible increase in disease rates at any time.

Understanding and assessing risk

Understanding the mental shortcuts people make and the values they bring to weighing risks is critical to informing effective risk communication. People rely on heuristics to process risk information. These are mental shortcuts that allow them to make rapid judgements when dealing with large volumes of information.[12] For example, people's overestimation of low-probability outcomes ("compression")

may make it difficult to give them a sense of scale when referring to a rare event such as TTS. Similarly, a serious but rare outcome, such as TTS, will be given more weighting if it is highly publicised ("availability"). Some people anticipate negative emotions because of a decision and thus avoid taking that course ("anticipated regret"), which may limit vaccine acceptance and affect a health care worker's willingness to recommend the AstraZeneca COVID-19 vaccine. Relatedly, people prefer to accept an outcome from doing nothing (not getting vaccinated) than an outcome from doing something (vaccinating) ("omission bias"), and avoid taking risks when the outcome is uncertain ("ambiguity aversion").

Heuristics are underscored by the values that affect how people think, feel, and act on risk. Values relevant to vaccine decision-making may include self-determination, fairness, minimising harm, and justice. For Aboriginal and Torres Strait Islander peoples, there are community and family obligations that will affect decisions and actions.

Clinical communication

Health care workers, especially those in primary care, will have a major role in helping people to assess their personal eligibility for a vaccine and to weigh the risks and benefits.

Support valid consent. The presence of a rare but serious adverse event highlights the imperative to ensure valid consent for vaccination defined in the Australian Immunisation Handbook as, "the voluntary agreement by an individual to a proposed procedure, which is given after sufficient, appropriate and reliable information about the procedure, including the potential risks and benefits." ATAGI has developed guidelines and discussion resources for immunisation providers on agreeing consent for COVID-19 vaccination.

Help people to weigh risk and benefit. To provide information on probabilities, risk comparisons have become common, such as comparing TTS risk to clots from the oral contraceptive pill, smoking, or a deep venous thrombosis from long haul flights. It is recommended that comparisons use risks and outcomes to help people understand magnitude, not to communicate the acceptability of a risk. The risks and their outcomes should also be similar.

Numerical risk formats enable a precise understanding of risk.[13] Add verbal formats for those with limited numeracy. Visuals also help people to understand risk and benefit, particularly those with low health-literacy or low English-proficiency, such as with icon arrays (see for example, https://askshareknow.com.au/resources/immunisation/covid19vaccination/). The same

denominator and time period should be used when comparing across risks. A smaller denominator makes the probability easier to understand.[13]

Since values and preferences are relevant to vaccine decisions, a health professional can elicit these as part of the weighing of vaccine risk and benefit using tools such as decision aids. When considering the benefits of vaccination, it may help to highlight the protection from vaccination for individuals and those around them, and to ask them what else they may value about being vaccinated.[14] Knowing if others are vaccinating also influences decisions.[15] Finally, a recommendation from a health care worker is a highly effective form of vaccination encouragement but should come with respect for autonomy.[15] Box 1 (available in PDF) sets out suggestions for structing a vaccination conversation with a 55-year-old female who has concerns about receiving the COVID-19 Vaccine AstraZeneca.

Public risk communication

Communicate frequently about process and outcomes. Governments should continue to communicate frequently and transparently. Ongoing policy decisions should involve a range of experts and stakeholders. Rationales should be clear. The ATAGI recommendation was timely and detailed. It included their various considerations, using clear and empathic language.[1] Moreover, it acknowledged inevitable trade-offs, such as an impact on confidence. The group includes consumer perspectives which were actively sought throughout the process.

Make values explicit. We recommend that public communication is explicit about values, particularly when decisions are made about the acceptability of a risk – to one's health, family, social and economic life.[16] It is vital that consumers are involved in decision processes and communication planning as this helps to ensure that decisions and messages are relevant and conversant with community values.

Use clear, accurate, actionable messages. Confusion among patients and providers is likely, owing to the complexity, nuance and dynamism of the changes, for example, misconstruing what "preferred" and "not recommended" means (neither mean AstraZeneca is *banned* in those aged under 50 years), or uncertainty about appropriate consenting processes for individuals aged less than 50 years who choose AstraZeneca vaccination. This will be intensified for key groups where information may not be tailored. Communicators announcing new risk information should inform audiences what it means for them and how they should respond. Messages should be developed with health literacy in mind and pre-tested to ensure they are understood and salient. Governments should continue to inform people

about the vaccine recommendations over time: previous safety-related program changes showed that an ongoing deficit of information contributed to persistent vaccine ambivalence.[17]

Promote vaccination but don't over-reassure. Highlight the benefits of vaccination that are relevant to people and resonate with their values, even in the context of low disease transmission. However, avoid over-reassuring people about vaccine safety with statements such as "the vaccine is safe for people over 50 years". Early overconfidence in rates of an outcome may also affect trust if data change. Signal the potential for estimates to be updated over time so the public are more ready for change.

Diversify communication channels and platforms. Research interviewees have told us they don't know where to look for reliable information that answers their specific questions. Multiple channels should be used and government information should be easy to access without having to search around. Many people rely on social media and messaging apps like WhatsApp, but different platforms are preferred depending on age and cultural background. TV and radio, including community programming in different languages, are also important avenues for communication. The federal, state and territory governments should enable local public health entities to communicate with their own communities about vaccination so it is appropriately tailored.

Identify and address misinformation. Information about the program may become rumour and misinformation as it spreads through the community. Some of our research participants have shared vaccination myths which contribute to their hesitancy. Proactively debunk myths that are spreading widely or affecting behaviour.[18]

Priortise key groups for communication. Aboriginal and Torres Strait Islander people may value the opportunity to ask questions and have discussions rather than fit the characterisation of being 'hesitant'. Consider the information needs of different health worker groups as well. Vaccine providers need support and information to respond to queries, but other health workers will also face questions and may not know how to respond. Health workers considering vaccination for themselves are a key group since they may be more vulnerable to COVID-19, at risk of transmission, and are also recommending the vaccine to their patients and communities.

Utilise credible spokespeople. We recommend that public health, vaccinology or medical professionals are the preferred voices to communicate about vaccine safety issues rather than politicians. Preliminary data from our research in Victoria and WA showed that health professionals and advisory bodies are trusted more than politicians when discussing adverse events following immunisation that affect peoples' health. Both health care workers and members of the public

prioritised in phases 1a and 1b preferred to hear information about vaccines from medical and scientific professionals.[19] Trusted spokespersons should spend time engaging with the community – attending community forums and answering questions to break down the gap between technical experts and the community. For people from culturally and linguistically diverse (CALD) communities, our national research suggests that CALD health professionals be the spokespeople, or that non-CALD health professionals partner with community and faith-based leaders.

Sustain trust. Trust in the Australian government can directly affect trust in the vaccine program.[8] Transparency and demonstrated efforts to work across the aisle will help to maintain and rebuild trust. The government's decision to assemble the national cabinet for more regular meetings was a positive move towards a more unified response.

Use data to inform action. Public responses to vaccine safety issues can sometimes relay on anecdotes about impact, and lack data to inform communication and planning. Data showing a decline in vaccination coverage does not disentangle the reasons for it to occur. While confidence in vaccine safety will inevitably be reduced in some, others may face difficulty with booking an appointment or perceived availability of the vaccine. A sole focus on hesitancy alone may come at the expense of understanding and addressing other barriers to vacciantion.

Monitor and evaluate. It is impossible to know if communication is effective unless it is evaluated. Mechanisms for monitoring public responses to information and barriers to vaccination can include reviews of hotline questions, social media listening, search analytics, pulse surveys, and qualitative research.

Conclusion

Achieving high COVID-19 vaccine coverage will be a significant challenge given Australia's supply, access and hesitancy challenges. Good risk communication and support for providers and citizens to make decisions about vaccination is essential as we can work towards protecting all Australians, opening our borders, and continuing to live optimally with SARS-CoV-2.

Box 1 Suggested structure when a patient is hesitant about vaccination, applied to a 55 year old female concerned about whether to have the COVID-19 Vaccine AstraZeneca.*

Communication practice	**Example**
Elicit questions and concerns	*You mentioned earlier some concerns about getting the COVID-19 vaccine. Can you tell me more?*
Acknowledge concerns	*It's understandable that you have some concerns.*
Set brief agenda	*Let's go through that concern about the clotting risk for you and also the possible benefits of having the vaccine soon. How does that sound?*
Share knowledge	*Can I share what I know so far? The risk from the vaccine is small – it may affect six people in every million in your age group. It can be quite serious if not treated early. Here is some information showing the risks of the rare blood clotting syndrome alongside the risks of going to ICU with COVID-19. I also have some information about what to look out for. This may help your decision.*
Elicit potential motivation to vaccinate	*What might be important to you about having the vaccine now?*
Set out options, share tailored recommendation.	*So if I could summarise, your options are to not vaccinate, to wait for Pfizer doses to be available later on, or to have the AstraZeneca vaccine right now. There are pros and cons of each option. Having looked at all the considerations, where are you leaning?* *I will respect whatever decision you make. I would like to see you get vaccinated sooner rather than later.*
Continue the conversation	*If there is an outbreak, the risk from COVID is increased, could we revisit your decision?*

Based on Sharing Knowledge About Immunisation approach.[20]
http://providers.talkingaboutimmunisation.org.au/

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