Australian Doctor.

Multidose vials: worth the risk?

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MEDICOLEGAL: When the swine flu pandemic threatened our shores, the Federal Government was quick to introduce multidose vials for vaccination. But are the benefits really worth the risk of cross-contamination? By Heather Hillam and Cheree Corbin

It's the nature of pandemics to cause alarm. In August this year, the UN Food and Agriculture Organisation urged heightened surveillance in the wake of the spread of a mutant strain of H5N1 avian flu with "unpredictable risks to human health".[1] Although the threat was quickly put in context by the WHO and Australia's new Chief Medical Officer Dr Chris Baggoley, the UN announcement raises questions of pandemic readiness and calls to mind the way the Federal Government responded to the H1N1 swine flu pandemic in late 2009.

Health Minister Nicola Roxon's response then was to announce a deal with CSL Limited to produce Panvax, which would be delivered in multidose vials – and this is still the plan for the future (see box below).

Multidose vials, according to the Australian Technical Advisory Group on Immunisation, are no longer "routinely used" in general healthcare, so the government's decision to authorise their use for a mass vaccination program provoked a furore among some doctors and experts.[2]

Two years later, the dust may have settled on the swine flu vaccination debate, but what has been resolved about multidose vials and pandemic vaccinations, and what should GPs expect next time?

Chief among the experts' concern in 2009 was the question of increased infection risk from the use of the vials.

"Everyone knows there is an increased risk of cross-infection when you use a multidose vial," says Sydney GP and medicolegal expert Dr Craig Lilienthal, who didn't support the government's vaccination delivery decision. "No medical organisation supports the use of multidose vials because of the increased risk of cross-infection."

However, at the time, the AMA did in fact support the government's decision to purchase the vials. As the AMA representative on the national immunisation committee, Dr Steve Hambleton was involved in pandemic planning and the vaccination rollout and says GPs have long been managing cross-infection. "It is what we do every day."

As a result, he says the AMA was confident it could reassure the government that GPs were well placed to deliver the vaccines "safely, with no risk of cross-contamination".

"There is no risk if you follow proper infection guidelines," Dr Hambleton says.

Delusional strategy?

The use of multidose vials is a strategy Professor Peter Collignon describes as "almost delusional". Speaking on behalf of the Australian Infection Control Association, Professor Collignon says multidose vials are a "stupid measure from an infection-control point of view".

"It's arguable that the risk is small," he says. "But when you create a vaccine in multidose vials, and you deliver that to millions of people, that risk is exponentially increased. And it's not warranted. Single-use vials engineer out the risk."

He points out that over the years, here and abroad, there have been a number of instances of infection linked to the vials, citing cases in Spain, Germany and the US. He says countries are turning away from this delivery method.

"For the past 10–20 years, microbiologists in Australia have been trying to get rid of multidose vials," says Professor Collignon, a professor of microbiology and infectious diseases at the Australian National University medical school.

"Everywhere is getting rid of them, so why did the government take this retrograde step?"

President of the Australian Society of Infectious Diseases Dr Thomas Gottlieb told Australian Doctor he believed the government and vaccine producer CSL rushed to the decision to use the vials.

"We thought there was a lack of good discourse in making the decision," he says. "It's not that GPs can't use multidose vials, but the option to provide single-dose vials should have been there. We knew the likelihood of infection control disaster was unlikely, but it is always a risk, because of the human factor."

In an article in the journal Vaccine last year, a team of infectious diseases experts, including Dr Gottlieb, wrote: "Clear vaccination protocols have been widely promulgated as part of the pandemic H1N1 '09 vaccine rollout. The assumption is that well-trained health professionals do not make errors, but this is not so."[3]

Even though Dr Lilienthal wasn't in favour of the decision, he says his practice "effectively excludes the risk of cross-infection".

"The way we used them in our practice was that if there were 10 shots in a [vial], the nurse drew up all 10 at once, so there was no risk of cross-infection," he says.

"So there was no patient present. They draw them up in syringes and put them in the fridge. When the patient arrives, they put a needle on a single-use syringe and administer it."

Weighing up risk

RACGP spokesperson, Dr Ronald McCoy, was involved in writing and reviewing the administration guidelines for the Panvax vaccine. He says the issue of infection risk is a discussion that needs to be had, "but at the crux of it is this issue of risk, which is a probability. There is scope for people to not get vaccinated, and so put themselves at more risk".

Dr McCoy says multidose vials enable the vaccine to be supplied more quickly, which is clearly important when facing a pandemic, and any associated risk must be considered in light of the method protecting patients from a potentially dangerous disease.

It was this need for speed that partly prompted the government to sign off on multidose vials. According to the Australian Technical Advisory Group on Immunisation, they allow for "the earliest possible availability of H1N1 vaccine by improving the efficiency of vaccine manufacture and administration. By these means, the maximum number of people, especially those more vulnerable to severe complications of influenza, can receive H1NI vaccination as early as possible."

In June 2009, the WHO raised the global influenza alert for swine flu to level 6 – "the first influenza pandemic since 1968", according to the Department of Health and Ageing's report Pandemic (H1N1) Influenza 2009.[4] In Australia, a report on the first-dose clinical trial of CSL's Panvax was delivered to the government on 3 September 2009 and the national vaccination program was underway by 30 September.

A question of consent

The speed at which the national vaccination program was released was too fast, according to Dr Mark Diamond (PhD) and Dr Angela O'Brien-Malone (PhD).

In an article published in the Medical Journal of Australia earlier this year, the psychologists wrote of their concern that in the rush to release Panvax in multidose vials, many aspects of good risk management were overlooked.[5]

Dr Diamond argued that introducing a new vaccination delivery method for use in the face of a pandemic was a risky move. "At times of high stress we're going to present GPs with a novel form of delivery and expect no errors? That is just unrealistic."

He told Australian Doctor while he believes the risks posed were "very low", it should be up to the patient to determine whether they would accept those risks.

Dr Diamond and Dr O'Brien-Malone were critical that information on the risks was not included in the sheets and consent forms distributed by the health department with the pandemic (H1N1) 2009 influenza virus.

Dr Diamond suggested this may have left GPs more vulnerable. "There was no suggestion that the vaccinating health professional should discuss the risks associated with the use of multidose vials with the patient."

He and Dr O'Brien-Malone are calling on the government to engage with the medical profession to consider how the risks should be discussed with patients in the future. They suggest the consent form that was designed for the pandemic 2009 influenza should be reworked into a guide GPs could use when discussing these risks with patients.

Given the Australian Health Management Plan for Pandemic Influenza relies on multidose vials, that conversation needs to happen sooner, rather than later, they say.

Where does it end?

The RACGP's Dr McCoy, who was a GP for 15 years, says while he understands the legal issues raised in the MJA article by Dr Diamond and Dr O'Brien-Malone, it leaves him wondering, "Where do we stop?"

"Do we explain for every procedure that we're following infection-control guidelines and that we wipe the seats down every day?" he says. "The reality is, we've got this stuff facing us, but we've still got the next patient to treat."

Other GPs are also critical. Adelaide GP Dr Jill Maxwell was chairman of the Medical Insurance Group Australia when the government announced H1N1 vaccines would be supplied in multidose vials. She sees flaws in the argument GPs should be advising patients of risks that can only occur if the vials are not used safely.

"It is not normal practice to warn patients that, 'If I do something grossly wrong or improper, that would pose a risk to you'," Dr Maxwell says. "It is in that vein that I see the use of multidose vials."

A recent flick through the world news revealed headlines such as "Mutant bird flu in poultry delivered on wild wings" and "CDC uncovers a new swine flu". Later this year, Warner Bros will release its action thriller Contagion, with the tagline "Nothing spreads like fear".

Never far from our minds, how best to tackle a global outbreak of disease is a question all governments are required to address.

"But not during a pandemic," Dr Diamond says. "That's not the time."

IN DEFENCE

"The policy has not changed." That's the word from the Department of Health and Ageing.

According to a department spokeswoman, multidose vials are the preferred method for pandemic influenza vaccine because of their shorter manufacturing time, which means the maximum number of people – especially those identified as more vulnerable to severe complications of influenza – can receive the vaccine as early as possible.

In response to the concerns raised by experts about infection risk, the deparment says, "The RACGP developed guidelines on safe medical practice for multidose vials in consultation with the Australian Technical Advisory Group on Immunisation.

"This information was disseminated to GPs and other vaccinators prior to the commencement of the pandemic vaccination program in Australia, and the guidelines on proper use to avoid cross-contamination were included with each delivery of vaccine to immunisation providers. GP peak bodies were comfortable with the use of [the vials] in 2009, and believe the GP workforce in Australia is competent in the use of multidose vials.

"Multidose vials are also used for distribution and administration of seasonal influenza vaccine in many comparable countries, including the USA and Canada."

AMA president Dr Steve Hambleton says the volume capacity of multidose vials makes them the best choice.

"For 1000 doses you need 50 [multidose vials] – a small tray which can fit on a shelf in a fridge." He says the equivalent issued in individual doses would take up one cubic metre of space. "It wasn't practical because of volume to keep that many individual doses in the fridge."

He says GPs' proven track record in cold chain security was part of the reason the AMA recommended to the minister that GPs be used to give the vaccines. If single dose vials had been issued, he says GPs wouldn't have been able to store them safely.

References

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