Appendix 3

ANTHRAX VACCINATIONS

While standard vaccinations[1] are not identified as having caused any problems, anthrax vaccinations are seen by some as evidence of a lack of community standards in the provision of health care services, and a lack of 'duty of care'. The major issue concerning anthrax vaccinations[2] is whether some ADF personnel had an opportunity to exercise informed consent. Other concerns have also been expressed, including the quality of some batches of vaccine, the safety and efficacy of the product, and possible long term effects.[3]

The issue of informed consent for 2nd Gulf War vaccinations

The Defence perception of consent is that any individual undertaking a standard vaccination program has in effect consented to its use.

> In the administration of routine vaccination to our people, in accordance with current civilian practice, there is implied consent. So where a vaccine is made routinely available and is on a routine vaccination schedule, the fact that a person presents themselves for vaccination is usually sufficient to imply that they understand the risks and the nature of what they are receiving.[4]

However, acceptance of standard vaccinations may be based on the premise that, in spite of some limited adverse effects, these are generally safe and that consent was

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1 These standard vaccinations are listed at Budget Estimates, FADT, 4 June 2003, p. 365.

2 It was suggested that mencevax ACWY vaccinations—against meningococcal disease A, C, W135 and Y—were given at the same time as the anti-anthrax vaccine (Budget Estimates, FADT, 4 June 2003, p. 365), but in fact were given before the *Kanimbla* left Australia. There was no consent form used: ('We did not require a signed consent form for the mencevax. Mencevax has been a routine immunisation for operationally deployed personnel for quite some time', Additional Estimates, FADT, 4 June 2003, p. 372) but General Cosgrove stated that anyone who had not agreed to this vaccination would not have been able to deploy (Budget Estimates, FADT, 4 June 2003, p. 364).

3 It is stated that there were also Air Force and Army personnel on board the *Kanimbla* who would have received information about the vaccination at the same time as naval personnel (Additional Estimates, FADT, 12 February 2003, p. 71). For simplicity's sake, the discussion refers to naval personnel insofar as the relevant actions were taken by the navy and it appears that only naval personnel made a decision not to accept the vaccination.

4 *Committee Hansard*, p. 51. See also Additional Estimates, FADT, 12 February 2003, p. 40:'Within Defence Health, we obviously treat our men and women we serve in exactly the same way as other citizens of Australia. Implicit in that is that, when they receive any health care, there is informed consent on their behalf so they understand what is being put forward to them, what the ramifications of that may be and they always retain the right to decide whether they will or will not proceed'.

'informed' in the sense of the individual having enough readily available information to make a choice and being familiar with the issue of side effects, often over a period of years:

> A wide range of immunisations are offered to Australia citizens both in childhood and in adult life that are common, community accepted standards and it is therefore expected that most people would be familiar with those immunisations and would understand their benefits and possible consequences. In that sense, we do not require a signed consent form when people receive routine immunisations.[5]

Unlicensed or unregistered vaccines

Anti-anthrax and some other vaccines are classed as unlicensed or unregistered, terms which are used for vaccines which are not registered with the Therapeutic Goods Administration (TGA) as items of common use. The TGA has no direct administrative responsibility for use of such items, and delegates this authority: in this case to the CDF, or to a medically qualified person. The delegation requires that 'ADF members are fully informed of benefits and risks'.[6]

The Defence submission states that consent with respect to the use of unregistered vaccines is covered by 'ADF policy [which] provides comprehensive guidance on matters of informed consent…'[7]

> In the case of an unregistered vaccine there is a much greater responsibility on us to provide people with information, answer any reasonable questions that they ask of us and ensure that when they receive the vaccine that it is truly done under the provisions of informed consent—that is, they know the risks, they know the reasons why it has been given and they have made the decision freely.[8]

Where a consent form does not provide full information about other implications, an individual may or may not be able to make an informed decision about the full impact of the procedure, regardless of whether consent is given.[9] With respect to the Navy, this wider issue does not appear to have been considered. It would appear that the 'consent' form included two options—one being that consent was given, the other that

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5 Senate Estimates, FADT, 12 February 2003, p. 41.

6 *Submission* 9, Defence Organisation, p. 6, paragraph 25. One of the reasons perhaps for concerns is that different standards may apply in deployments where Australia is not in command of its own forces, *Submission* 5, Regular Defence Force Welfare Association Inc., p. 3, paragraphs 12, 17. Consent was not an option for US forces in respect of anthrax vaccinations, Senate Estimates, FADT, 12 February 2003, pp. 37–38.

7 *Submission* 9, Defence Organisation, p.6, paragraph 26.

8 *Committee Hansard*, pp 51–52.

9 For example, the refusal to have a child vaccinated has led to non-payment of various benefits. This consequence was openly stated and known to those who choose not to proceed, see www.health.gov.au/pubhlth/strateg/immunis/7point.htm, *The Seven Point Plan.*

it was not - and that certain consequences might follow. Everyone signed the consent form, and in some cases it is likely that it was the information on the form or the absence of other information on consequences, which at least contributed to the decision made not to agree to the vaccination.

This is apparent from a response to a complaint made by one of the sailors from the *Kanimbla*, which notes:

> You say that …your informed consent [ie non–consent] was based on the briefing, which advised that there would be no administrative action taken against [n]on–consenting personnel.[10]

It has also been stated that the consent form available at the time included the words 'may not participate in deployment' (if vaccination was refused), rather than the words 'will not participate'.[11] The consent form which was given to *Kanimbla*[12] personnel, dated 29 January 2003, reads: 'I understand that I may refuse to accept Anthrax vaccine without prejudicing my medical care but that I may not be eligible for specific operational deployments'.[13] This is true also of the form dated 6th February 2003. Insofar as this information led individuals to believe that they would remain on the ship, it was misleading. Later comment that the form was going to be changed and would make it clear that continuation with a specific deployment was not possible,[14] does not address this concern.

Similarly the statement that there was in place a policy that those who were not vaccinated were not deployable[15] does not effectively counter the statement that the specific briefing on the ship about this particular vaccination stated that no adverse administrative action would be taken. It is unlikely that the difference between no administrative action and the consequences of failing to meet a 'policy' was appreciated in the circumstances, accounting for some of the confusion experienced when personnel were removed, having become non-deployable to the MEAO exercise.

It is also to be noted that long after personnel were removed from ships, the information available on the defence website[16] and still there in mid July 2004, did not clarify many issues:

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10 *Submission* 10, Mrs Screaton, p. 6. This is taken from the document Redress of Grievance, part of Submission 10.

11 *Submission* 10, Mrs Screaton, p. 3.

12 *Submission* 10, Mrs Screaton, p. 4.

13 See below, Attachment A, document 1.

14 Redress of Grievance, p. 4, paragraphs 15–16.

15 *Submission* 10, Mrs Screaton, p. 6; 'I am satisfied that there was no need to provide an advance explanation of the possibility of medical re–categorisation to the ship's company'.

16 The information on the website—see www.defence.gov.au/dps/dhs/infocentre —as at mid July 2004 was dated August 2003, well after the date by which documents concerning the effect of not agreeing to the anti-anthrax vaccine were supposed to have been changed.

> **11. What happens if I don't get vaccinated?**
>
> Getting the vaccine is not compulsory and you may refuse to receive the vaccine at any stage (even if you have already had one or two injections). You will not be punished or discriminated against because you have not elected to be vaccinated, however, because of ADF risk management procedures you ***may*** not be allowed to deploy to, or remain in, certain areas overseas if you have not been vaccinated.
>
> The Defence Health Service recommends all personnel at risk be vaccinated.
>
> **12. Will declining [the] Anthrax] vaccination affect my individual readiness status?**
>
> Although vaccination against Anthrax is voluntary, and can be declined, members will not be deemed fit to deploy to certain overseas areas. They can deploy, however, to other areas where Anthrax vaccination is not required and therefore your individual readiness status will not change.[17]

Any individual reading this would understand that they would not be able to go to areas where anthrax was a risk, but it is not clear that if one were already on the way there, one would be removed. But it is clear, especially in the answer to Q12, that their 'readiness to deploy' status would not be changed in respect of *all* deployments. However, in response to some queries raised, the Chief of Navy wrote that the revised policy manual dated June 2003 clarified the issue:

> Any uncertainty for similar situations in the future has been removed with June 2003 issue of ADFP 1.2.2.1—Immunisation Procedures which replaced ADFP 702 as outlined [above].[18]

This policy manual[19] is somewhat different in tone and ruling to the advice that still remains on the website, and some differences within the manual itself can only continue the same confusion that previously existed. It states, for example:

- Failure to undertake a vaccination program *can* lead to members being deemed non–deployable, and *may* lead to a review of their fitness to continue serving in the ADF.[20]
- There will be no vaccination waivers[21]

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17 www.defence.gov.au/dpe/dhs/infoline/anthrax, FAQ, Q 11, Q 12, emphasis added.

18 *Submission* 10, Mrs Screaton, p. 5.

19 See *Submission* 9, Defence Organisation, Attachment D.

20 *Submission* 9, Defence Organisation, Attachment D, Chapter 1, paragraph 1.4.

21 *Submission* 9, Defence Organisation, Attachment D, Chapter 2, paragraph 2.9.

- Any member [of the ADF] who is not current with routine and any designated additional vaccinations *is not* compliant with Individual Readiness and therefore *is* unfit to deploy.[22]

It would be preferable to clarify the situation, which seems to have moved from not being able to deploy to areas where a specific threat exists or was believed to exist (website information) to not being able to deploy at all (policy manual). On the other hand, the section on anthrax vaccinations within the policy manual states:

> If vaccination is declined, however, that member *may* not be considered eligible to deploy to regions or environments where there is a threat of Anthrax exposure.[23]

This contrasts somewhat with the policy manual that was in place during the deployment period, which states:

> Any member who refuses vaccination with Anthrax *is not to be* deployed to regions or environments where there is a threat of Anthrax exposure.[24]

From the above, it is still unclear what the formal position is with regard to deployments. Nonetheless, it was stated by General Cosgrove in February 2003 that non deployment in MEAO was always going to be the response to those who did not take the vaccination:

> **Senator CHRIS EVANS—**In terms of the decision about procedure, when was it determined that those who were unwilling to take the vaccine *would not* be allowed to stay in the theatre of operations?
>
> **Gen. Cosgrove**—That was an in–principle decision when we decided that was the regime necessary.[25]

If this was so, it is unfortunate that this was not made obvious to personnel at the beginning, through being on the consent form.

With respect to at least one of those members of the ADF who refused the vaccination, there was a re–classification of status to MEC 207 for a 12 month period.[26] This did not prevent deployment *per se*. For other persons who were returned

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22 *Submission* 9, Defence Organisation, Attachment D, Chapter 2, paragraph 2.10.

23 *Submission* 9, Defence Organisation, Attachment D, Chapter 5, paragraph 5.10 (c). See also Redress of Grievance Determination, p. 9, paragraph 47 which quotes the relevant paragraph, 5.11.c.

24 Redress of Grievance Determination, p. 9, paragraph 47.

25 Additional Estimates, FADT, 12 February 2003, p. 36, emphasis added; see also p. 37.

26 *Submission* 10, Mrs Screaton, pp. 5-6 MEC 207 is defined as 'fit for deployment or sea going service except in geographic areas as defined', Redress of Grievance Determination, p. 8, paragraph 42.

to Australia, it was stated that they would not be subjected to 'institutionalised retribution', although it is not clear if their medical status was also changed:

> **Senator BARTLETT**—But what are the implications of not taking it?
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> **Gen. Cosgrove**—They will not be kept in the environment where those hazards are felt to be possible.
>
> **Senator BARTLETT**—That is all—they are just redeployed elsewhere?
>
> **Gen. Cosgrove**—Yes.
>
> **Senator BARTLETT**—So you are able to guarantee that there are no other adverse career or other consequences for people?
>
> **Gen. Cosgrove**—I mentioned the personal perceptions amongst some people who say yes and a very small number who may say no. All I will say is there will be no institutionalised retribution or anything of that nature…[27]

The timing of vaccinations for Navy personnel

According to Defence, sufficient time was available at least for non-Navy personnel to receive information on the anthrax vaccine and even to consult other persons about it,[28] allowing 'informed consent' to be given. Anyone who did not agree to the vaccination did not go on the deployment.[29] According to Air Commodore Austin, the ADF generally hopes to have sufficient notice of deployment to give vaccinations 'in accordance with the manufacturer's recommendation':

> What we do not want to do is to shorten the administration regimen or increase the number of shots.[30]

With respect to some Navy personnel (on the *Kanimbla*), the main issue is whether personnel should have been told before embarkation from Australia that they would require an anthrax vaccination.[31] This is distinct from the issue of whether there was sufficient time for vaccinations to be completed prior to embarkation.[32]

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27 Additional Estimates, FADT, 12 February 2003, p. 24.

28 *Committee Hansard*, p. 52.

29 Approximately 10 non–Navy personnel did not agree to the vaccination.

30 Additional Estimates, FADT, 4 June 2003, p. 365.

31 There was some discussion in Senate Estimates about whether personnel on ships would have had access to public information available in January that anti-anthrax shots would be provided—see Additional Estimates FADT, 12 February 2003, pp. 34–35. Even if they had, they may not have considered it further since nothing was formalised until later.

32 *Committee Hansard,* p. 65: 'Clearly we are also talking about the issue of when the members were advised of the program, and that does not have to be linked directly to when the vaccine is administered. They are actually two parts of the process'.

The *in principle* decision that anti–anthrax vaccine would be required was taken by 10 January 2003.[33] From evidence provided, it appears that a decision was made not to advise of the need for this prior to embarkation, whenever embarkation was to occur and whichever ships would be commissioned.[34]

The main reasons for this are given as:

- It was not known which ships and therefore personnel would be affected;
- Once this decision was made there was no time to give the vaccine before embarkation on the basis that staff would be required to undertake various physical tasks, and the known side effects might interfere with these.[35]

The first factor is in accordance with the principle that vaccinations are not given unless required, although this also needs to take into account the amount of time for vaccinations to become effective. However, there seems to be no good reason why personnel could not have been informed as soon as the decision was made about which ships were to be deployed,[36] regardless of when the vaccine was to be given. On 4 February personnel were advised of the need for anthrax vaccinations, and these were given on 5 February.[37] Thus there was only one day in which to obtain other information, and it appears that this was insufficient for the MO on board the *Kanimbla*.[38]

If non–navy personnel had been given sufficient time to discuss the issues, and were able to consult with relatives, the issue cannot be one of confidentiality. Had personnel been advised when ships were still in port, those who chose not to have the vaccine would have been in no worse position in terms of a removal than those in other forces who made a similar decision. As far as adequacy of available information is concerned, when personnel *were* informed it appears that navy personnel did not have access to as wide a range of information as those in the army and air force did.

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33 Additional Estimates, FADT, 18 February 2004, p. 65; however, see also *Committee Hansard*, p. 57, Senator Bishop—the information that militarised anthrax could be used in the 2nd Gulf War was known by approximately 11 January 2003.

34 Submission 9A, Defence Organisation, Q2, part (j). The order to vaccinate was given on 3 February 2003, and implemented on the *Kanimbla* on 5 February 2003 (*Submission* 10, Mrs Screaton, pp. 3–4)

35 *Submission* 9A, Defence Organisation, Q2(j). However, according to one submission, the greater part of these tasks had been completed prior to leaving Darwin for the second time—see *Submission* 10, Mrs Screaton**,** pp. 2–3.

36 20 January 2003—see Additional Estimates, FADT, 18 February 2004, p. 65.

37 *Submission* 10, Mrs Screaton, pp. 1–3.

38 See also www.defence.gov.audpe/dhs/infoline/Anthrax FAQ: ‘Almost all medical personnel who deploy with you will have undergone specialist NBC training. The ADF runs an intensive two week course that teaches medical personnel about recognising and treating NBC injuries, including Anthrax’.

According to Air Commodore Austin, a wide range of information was available and there was time to consult with others.[39] The same manufacturer's material or product information may have been available to both Navy and non–Navy personnel, but the fact that the ships had embarked reduced the access of navy personnel to other sources of information and opportunities for consideration with people outside the system. Although one example was given of a radio consultation with another doctor, [40] this is not the same as being free to raise the matter over a longer period of time and seek information from other sources. Having information on the vaccine on the consent form does not in itself demonstrate that the information was taken from a range of sources.[41]

According to one source, the information available to naval personnel was not detailed, and it was stated in a report on the individual's complaints that even the manufacturer's information (for the UK vaccine) was not as useful as that provided generally with medicines in Australia.[42]

> The leaflet is dated December 2002 and does not identify the medium or media used to carry the active components of the vaccine or attempt to identify the chemical composition of any of the non–active ingredients of the vaccine.
>
> The leaflet does not indicate whether any of the possible "undesirable effects" of the vaccine is related to the active ingredients or could be related to other chemicals in the vaccine.
>
> The other electronic information made available to him [the Medical Officer on board the Kanimbla] by [the] Deputy Fleet Medical Officer (DFMO) would have taken some time to search to see whether it addressed issues as specific as this one.[43]

Regardless of what is generally provided with Australian medicines, however, the apparent shortage of information can hardly be excused. It may be that the Medical Officer was unaware of the fact that anti–anthrax vaccinations were to be given, unless the ship's commanding officer had advised other officers:[44]

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39 *Committee Hansard*, p. 52.

40 See *Committee Hansard*, p. 52 where it is stated that one naval officer at least had the opportunity to discuss possible long term effects with an external source.

41 It was stated that although policy did not require that information on the vaccine and its date of expiry be on the consent form, this was in fact done at least for the Navy (*Kanimbla* and *Darwin*), *Committee Hansard*, p. 60. However, other information in the Redress of Grievance (p. 4, paragraphs 10(d), (e), and (f)) states that required information was not listed at all, but this was apparently an error.

42 *Submission* 10, Mrs Screaton, p. 7.

43 *Submission* 10, Mrs Screaton, p. 7. However, the information provided on the UK Ministry of Defence website about the UK vaccine is detailed, and does provide the information referred to above.

44 Additional Estimates, FADT, 12 February 2003, p.32.

> **Vice Adm. Ritchie**—The commanding officer of the *Kanimbla* would definitely have been aware that there was going to be a requirement. As to whether or not the commanding officer of *Kanimbla* told his ship's company in a formal manner, we can only ascertain that by asking him.[45]

The vaccine itself had been provided before *Kanimbla* left Sydney:[46]

> **Vice Adm. Ritchie**—In a nutshell, the vaccine was provided to *Kanimbla* the day before *Kanimbla* left Sydney, on 22 January, and in the period between 22 January and 4 February further information, the consent form, clearance to use the particular vaccine and education material was provided to the ship.[47]

However, if the medical officer was unaware, he/she would not have had much opportunity to go through the relevant material and see if there were issues which might be raised by personnel but which were not addressed in any of the documents.[48]

One issue that was raised was the components of the vaccine and of the media in which these were held, and it is stated that the MO on board the *Kanimbla* did not have the answers to these questions.[49] Given that some people may have needed to know to clarify the issue of possible allergies to the agent in which the vaccine is carried or possible severe reactions to the vaccine itself,[50] this was information that should have been provided, especially as it may have affected the level of informed consent. In fact, the consent form dated 29 January 2003, which was the one used on the *Kanimbla*, has a section listing those people who should not receive the vaccine, or should temporarily defer receipt.[51] These include those who are immuno–compromised, have HIV, or an active infection/illness with fever. The form dated 6 February also has this information.

While it is not obvious what other information had been forwarded electronically to the *Kanimbla*, the data provided by the UK Ministry of Defence (MoD) on the UK vaccine was extremely detailed,[52] and did include information on the components of

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45 Additional Estimates, FADT, 12 February 2003, p. 35.

46 Additional Estimates, FADT, 12 February 2003, p. 31.

47 Additional Estimates, FADT, 12 February 2003, p.31.

48 Additional Estimates, FADT, 12 February 2003, p. 31: 'the ship's captain was aware that he would have to have an education program once he announced that he was going to do this and he sought extra material to enable him, the medical officer and the psychologist who was on board that ship to explain that to individuals collectively and then individually as each one talked through the business'.

49 *Submission* 10, Mrs Screaton, pp. 6–7.

50 Although the likelihood of this was limited, as there is no live anthrax in the US or UK vaccines.

51 See Attachment A, document 1, paragraph 21.

52 See United Kingdom, Ministry of Defence, *Anthrax, Voluntary Immunisation Programme, A Guide for Medical Staff*, 2000.

the vaccine and the agent, although this was dated 2000. The UK MoD link is on the Department of Defence website on this issue.[53]

The process of vaccination does not seem to have been fully thought through and as a result the medical/nursing staff were perhaps ill–equipped to handle some queries. The responsibility for this is difficult to determine, because confidentiality appears to have played some part in access to information such as the health plan:

> **Vice Adm. Ritchie**—…there was some degree of classification around the health plan for Operation Bastille. Therefore, I do not think that it was appropriate for those sorts of things to be talked about until such time as it was decided to put that health plan into action… The health plan, which comes down through the theatre, had a classification on it that would not allow it to be discussed openly on the ship.[54]

Nonetheless, it seems unlikely that the MO at least would have been unaware of some basic components of the health plan such as the intention to give anthrax vaccinations. It is obviously important to ensure that MOs have access to basic technical information which they can translate into everyday language for the benefit of personnel in general.

This point has been conceded to some extent:

> Nevertheless the experience of these briefings does suggest that precise questions of this kind can be asked and is better that the information be available. As ADF personnel become better trained and with more specialized engineering and scientific skills, the possibility of such questioning obviously increases. It is desirable, with new vaccinations, that education programs be planned thoroughly after a focus group of personnel have been used to draw out the range of possible questions that are likely to arise for the MO. Accordingly I have made a recommendation to Chief of Staff, Maritime Headquarters that this should occur in future.[55]

That it was a mistake not to provide information to naval personnel prior to departure from Australia is now conceded by the ADF.[56] The problems that have occurred for

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53 As noted above at footnote 41, the Australian Defence website also notes that a special course was available on the anthrax vaccine for medical officers, although this may not have been known to the deployed MOs.

54 Additional Estimates, FADT, 12 February 2003, p. 32.

55 *Submission* 10, Mrs Screaton, p. 7. Material available by 18 March 2003 in fact provides some detail on the components of the vaccine and its media, although how easily this information was understood is unknown, as the language used is quite technical, www.defence.gov.au/dpe/dhs/infocentre/anthrax/FAQ, Q5 and Q6.

56 *Committee Hansard,* p .53: 'The lessons learnt report highlights that as being a failure on our part because it could certainly be construed that it was taking away people's freedom of choice and that there was an unintended but potential degree of coercion being exercised on these people by the very fact that they had already embarked onboard ship heading towards an area of operations'.

some personnel in the Navy (having to be taken off ships)[57] did not occur for those in the RAAF and other naval personnel who did not consent, although this seems to have been the case only because they were already in the Middle East and 'were moved back routinely on aircraft that were operating in and out of the gulf'.[58] The issue has therefore become one of whether some navy personnel were discriminated against through the more public circumstances of their return, and, to some extent, whether there was undue pressure on them, while aboard, to be vaccinated.[59]

The quality of vaccines used

A further issue with respect to anthrax has been the quality of the vaccine used. This issue seems to have arisen in part at least because of the some of the reported reactions which were considered excessive, and some queries about the 'use by' date of the imported vaccine,[60] in respect both of Afghanistan and 2nd Gulf War deployments.

The ADF has noted that when reporting of reactions is required, one may have 'over reporting' and a 'higher than expected side effect profile'.[61] Those reactions to the anti-anthrax vaccine which have been noted, primarily a sore arm or an inability to use the arm where the injection was given, or short term fever, are not in themselves seen as out of the ordinary. They would not be considered adverse reactions in the sense of being registered,[62] and they would have been expected by management given that one of the reasons for not advising navy personnel of anthrax vaccinations in January 2003 was said to be the need to deploy, which required a certain amount of physical labour:

> In preparing a ship for deployment there is a lot of hard physical labour on the part of the men and women embarked on the ship and I believe that was a factor that was considered by the commander of the ship in terms of delaying the administration of the vaccine, because once a ship is actually embarked and crew go into a normal work–rest cycle there are fewer physical demands upon them and therefore there will be less operational impact of the vaccine.[63]

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57 Other Navy personnel on the Darwin and the Anzac who refused the anti-anthrax vaccine were already in the Gulf; those on the *Kanimbla* landed on Christmas Island and were flown home from there, Senate Estimates, FADT, 3 June 2003, pp. 374–375.

58 Senate Estimates, FADT, 3 June 2003, p. 373, General Cosgrove.

59 See above, Chapter 2.

60 The ADF has stated that some personnel believe they received anti–anthrax vaccinations during Gulf War 1, and that this has led to a belief that various illnesses are linked to such vaccinations (*Committee Hansard*, p. 61). Because the anthrax vaccine is used only when circumstances require, some of the terminology used ('unlicensed', 'unregistered') may have suggested to personnel that it was unsafe.

61 *Committee Hansard,* p. 53.

62 Major reactions are registered with the Adverse Drug Reaction Unit, Therapeutic Goods Administration, see www.tga.health.gov.au/adr

63 *Committee Hansard,* p. 65.

Defence witnesses noted that the problems of assessing the effects of the anthrax vaccine were both 'over reporting' of what be seen as normal side effects, and the lack of knowledge of the effects of other factors:

> …the rates that we saw when we looked at it in the light of other confounders that may have been present, such as co–administration of other vaccines or the physical activities that people were engaged with, made it very difficult for us to determine whether it was as a direct consequence of a problem with the vaccine or just part of the normal distribution of what we would have expected to see. [64]

The issue of other vaccine administration, however, appears to lead to further confusion. It appears from Defence evidence that mencevax had already been given to the crew of the *Kanimbla* prior to its departure from Australia, and therefore the confounding of other vaccinations would have been limited for those personnel.[65] For personnel on other ships, the mencevax vaccine was not given until later.[66]

Although Defence believes that there are no difficulties in administering both mencevax and anti–anthrax on the same day, at different vaccination sites,[67] other information suggests that this would not be best practice. Anthrax shots themselves should not be given as part of a combined vaccination.[68] The Australian Defence Force Vaccination Handbook itself states that:

> **Anthrax vaccination is not to be given concurrently with other vaccines**. This will reduce the incidence of more severe advents from occurring.[69]

Product information on mencevax states that:

> No information is available concerning the effects of drugs, intercurrent illnesses or other vaccines on the response to the administration of Mencevax.[70]

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64 *Committee Hansard,* p. 54.

65 Additional Estimates, FADT, 4 June 2003, p. 378.

66 Additionl Estimates, FADT, 4 June 2003, pp. 365,372, 378–379.

67 'in general, anthrax and mencevax may well be administered on the same day at two different locations [ie, vaccination sites on the body]', Additional Estimates, FADT, 4 June 2003, p. 365.

68 'Interactions with other Medicaments and other forms of Interaction. The vaccine should be used alone. There is no evidence for the safe use in combination with other vaccines or medicinal products'. See United Kingdom Ministry of Defence, *Anthrax, Voluntary Immunisation Programme*, *A Guide for Medical Staff*, p. 26, at www.mod.uk/ linked_files/mod_vip_mo_guide

69 *Submission* 9, Defence Organisation, Attachment D, *Immunisation Procedures*, Chapter 5, Section 5.12.

70 See www.avn.org.au/Vaccinations%20/Information/Meningococcal_mencevax

The NHMRC, in the *Australian Immunisation Handbook*, is referred to as stating that it is appropriate to give one of the anti-meningococcal vaccines in conjunction with other items in the Australian Standard Vaccination Schedule (ASVS): 'the vaccine may be administered simultaneously with other vaccines in the ASVS'.[71] However, anthrax is not a part of the ASVS, and the above statement applies only to the Meningococcal C conjugate vaccines (MenCCV), while Mencevax is a Meningococcal polysaccharide (4vMenPV).

It is ironic that the one fact that would have been a sound medical reason for not giving anthrax shots prior to departure—that there was to be an interval after the mencevax shot—was not referred to, although this does not overcome the issue of not providing information on the need for an anthrax vaccination.

Efficacy and safety of the vaccine

Since anthrax and some other vaccines have been used rarely, it is inevitable that there will be concerns about them, well founded or otherwise. Anthrax vaccinations were formerly used mostly by persons working in industries where there was constant contact with animal skins.[72] Because of the limited use, there have been few studies undertaken, and by the time of the 2nd Gulf War, the two studies that had recently been undertaken could not provide definitive information on long term effects. Any difference between exposure from animal skins and militarised anthrax is not mentioned.

The United Kingdom Ministry of Defence website, however, states that:

> Independent medical advice from the MoD's Advisory Group on Medical Countermeasures has confirmed that anthrax immunisation is safe and effective. Anthrax vaccine has been used routinely to protect those at risk from anthrax since 1963 and licensed in the UK since 1979. Many thousands of people, including laboratory workers, veterinary surgeons, abattoir workers and military personnel, have safely benefited from the high levels of protection that anthrax immunisation confers.[73]

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71 See National Health and Medical Research Council, *Australian Immunisation Handbook*, p.167. In this context, 'simultaneously' presumably means 'on the same day as' or 'at the same time as' (although not at the same site, or mixed in with other vaccines).

72 AVA was initially administered on a limited basis, primarily to protect veterinarians and workers processing animal products such as hair or hides that could be contaminated with anthrax spores. The Institute of Medicine, National Academy of Science ran two projects on anthrax, with the following reports: Committee to Review the CDC Anthrax Vaccine Safety and Efficacy Research Program, *CDC Anthrax Vaccine Safety & Efficacy Research Program: Interim Report*, 2001, and Committee to Assess the Safety and Efficacy of the Anthrax Vaccine, *The Anthrax Vaccine: Is It Safe? Does It Work?,* Washington,2002, see *The Anthrax Vaccine: Is It Safe? Does It Work?,* Executive Summary, p.1.

73 United Kingdom, Ministry of Defence, *Anthrax Vaccine*, see www.mod.uk/issues/anthrax/vaccine.htm

Nonetheless, any study of longer term effect and of the interplay of factors such as repeated vaccination, use of other vaccinations and to exposures to other substances in a war zone will take some time to complete and any conclusions can only be described as provisional at this point.

Anthrax vaccinations in the first Gulf War

Some of the concerns raised about anthrax vaccinations related to the first Gulf War although such concerns may have gained strength because of the later controversy about their use in the 2nd Gulf War. According to Defence, no personnel received anti-anthrax shots in the 1st Gulf War, apart from those who were working with US or UK forces who would have followed the vaccination program of those countries.[74]

> We were very aware that a large number of the people who had deployed as a part of the first Gulf War firmly believed that they had received anthrax vaccine as part of that deployment. When that was reviewed, we found that almost none of them had in fact received the anthrax vaccination. There had clearly been a misunderstanding on their part about the vaccines that they had received as part of that deployment.[75]

> In Gulf War I, I think we administered quantities of anthrax vaccine to very small groups of people, mainly those that were involved in the sensitive site examinations. These were specialist teams of personnel whose job it was to go into Iraq after the first Gulf War and seek out weapons of mass destruction sites—also, those who were part of the UN teams that were doing site surveys.[76]

Afghanistan deployment

According to Defence, the anthrax vaccine used for troops deployed to Afghanistan[77] had been obtained from the UK and at one time a batch of this was thought to have been affected by a breach of storage temperature. Some of this vaccine had resulted in high levels of adverse reaction amongst personnel deployed to Afghanistan,[78] and led to the anti-anthrax program for Australian troops in Afghanistan being suspended for two months from November 2001.[79] However, after testing, the vaccine was deemed to be safe. [80] The vaccine had been manufactured in January 2001 and the expiry date was January 2003.[81]

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74 Additional Estimates, FADT, 12 February 2003, p. 37.

75 *Committee Hansard,* p. 61.

76 *Committee Hansard,* p. 62.

77 See Additional Estimates 2002-2003, FADT, *Answers to Questions on Notice*, Question 3, p. 50.

78 Budget Estimates 2003–2004, FADT, 3 June 2003, pp. 376 and 377.

79 *Submission* 9A, Defence Organisation, Q2(b).

80 *Committee Hansard*, p. 56 (Air Commodore Austin).

81 *Submission* 9A, Defence, Q2.

Second Gulf War

The vaccine used for the 2nd Gulf War deployment came from both the US[82] and the UK. The date of manufacture of the UK vaccine used for this deployment was February 2002, with an expiry date of February 2004.Although there were some problems with the UK vaccine, these seem to relate only to a batch used in the 1st Gulf War, and, later, the difficulty in obtaining the required product on schedule. The US vaccine had expiry dates of August 2003, February 2004 and June 2004,[83] which indicates that they were manufactured in 1999 and 2000 respectively, as the US vaccine has a four–year life. The US report on the Safety and Efficacy of the Anthrax vaccine [84] notes that the production of the vaccine was halted in February 1998 as a result of adverse reactions,[85] and the facility was the subject of review. [86] This report is somewhat obscure about the results of the assessment of the production prior to its review:

> The newly produced vaccine is expected to have greater assurance of consistency than the vaccine produced at the time of its original licensure.[87]

The report concluded that the method of vaccination—subcutaneous—and also the number of shots required might account for the adverse reactions, recommending that research continue to develop options for administering the vaccine and to determine if fewer doses could be given.[88] The expiry dates of the U.S. vaccine used in Australia

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82 *Committee Hansard,* p. 59.

83 *Submission* 9A, Defence Organisation, Q2—which means the date of manufacture would have been 4 years previously if the same process was used in post 1998 manufacture—see *Committee Hansard*, p. 60. However, if it had been decanted, the shelf life would have been one year, *Committee Hansard*, p. 58

84 *The Anthrax Vaccine: Is It Safe? Does It Work?,* Executive Summary, p. 1.

85 None of the adverse effects noted from the US vaccine was considered serious, although it is not entirely clear if testing included batches made prior to the review of the manufacturing facility:

After examining data from numerous case reports and especially epidemiologic studies (see *The Anthrax Vaccine: Is It Safe? Does It Work?* Chapters 5 and 6), the committee also concluded that AVA is reasonably safe. 'Within hours or days following vaccination, it is fairly common for recipients to experience some local events (e.g., redness, itching, swelling, or tenderness at the injection site), while a smaller number of vaccine recipients experience some systemic events (e.g., fever and malaise). But these immediate reactions, and the rates at which they occur, are comparable to those observed with other vaccines regularly administered to adults,' *The Anthrax Vaccine: Is It Safe? Does It Work?,* Executive Summary, p. 2.

86 The study was also to address the issue of validation of the manufacturing process, with a consideration of discrepancies identified by the US Food and Drug Administration (FDA) in February 1998, the definition of vaccine components, and identification of gaps in existing research (*The Anthrax Vaccine: Is It Safe? Does It Work?,* Executive Summary, p. 2).

87 *The Anthrax Vaccine: Is It Safe? Does It Work?*, Executive Summary, p. 2.

88 'Finding: The currently licensed subcutaneous route of administration of AVA and the six-dose vaccination schedule appear to be associated with a higher incidence of immediate–onset, local effects than is intramuscular administration or a vaccination schedule with fewer doses of AVA. The frequencies of immediate-onset, systemic events were low and were not affected by

for the 2nd Gulf War indicate that it was manufactured after the review of the faulty manufacturing process, and was therefore less likely to be of a variable standard.

Storage issues

There appears to be some confusion about the effect of vaccines which may not have been maintained at the correct temperature. In evidence it was stated that if this occurs:

> It does not make the vaccine unsafe; it cannot result in any significant adverse impact on the individual. It simply reduces the efficacy of the vaccine. [89]

Nonetheless, once the cold chain has been broken, the loss of efficacy should not be discounted:

> The 'cold–chain' is the system of transporting and storing vaccines within the temperature range of 2°C to 8°C from the place of manufacture to the point of administration. This temperature range is recommended because outside this range vaccines may (very quickly) lose their potency. ***Immunisation service providers should maintain their vaccine refrigerators as close as possible to 5°C, as this gives a safety margin of + or – 3°C.*** Maintenance of the cold–chain system requires that processes are in place to ensure that a potent vaccine reaches recipients.[90]

Although the above statement on there being no adverse effects may be intended to mean only that the individual won't have an *adverse* reaction, a loss of efficacy could be crucial at any stage and would have an 'adverse impact' on the individual in that they may not receive a full primary dose. [91]

There has been little reference to issues of vaccine storage in the inquiry. However, one submission did state that vaccination against anthrax was required for some personnel who had volunteered to work at the Sydney Olympic Games, and that the vaccine provided for them was out of date[92] and may have deviated from cold storage

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the route of administration. Recommendation: DoD [Department of Defense] should continue to support the efforts of CDC [Centers for Disease Control] to study the reactogenicity and immunogenicity of an alternative route of AVA administration and of a reduced number of vaccine doses', *The Anthrax Vaccine: Is It Safe? Does It Work?*, Executive Summary p. 13.

89 Budget Estimates, FADT, 4 June 2003, p. 377.

90 National Health and Medical Research Council, *The Australian Immunisation Handbook*, 8th edition, Canberra 2003, p. 41, emphasis in text.

91 There is also a reference to another storage incident when material was returned to the manufacturer for checking because of a 'minor deviation in temperature' (Senate Estimates, FADT, 3 June 2003, p. 377). Reference to a 'lower' side effect 'profile' (Senate Estimates, FADT, 3 June 2003, p. 378) in this particular case might in fact indicate a reduced efficacy, although the vaccine was found to be both effective and safe. Possibly the deviation in temperature was not beyond the limits recommended.

92 *Submission* 7, Mr Laboo, p. 1.

standards.[93] The same submission also stated that second vaccinations had been prepared two weeks earlier in syringes and stored in a 'travel' fridge,[94] and that no consent form was provided.[95] The *Australian Immunisation Handbook* states that small fridges are those least likely to be able to maintain the stable temperature of between 2–8C required for storage of anti-anthrax and many other vaccines.[96] While larger fridges are acceptable, special vaccine holding fridges are the best option. Of even more importance, no vaccination should be given from a syringe that has been pre-prepared two weeks in advance, when there can be little control over access to the storage unit, and contamination is possible. Although Defence has noted that it now has approval 'to store Anthrax multi–dose vaccine vials for periods of up to 28 days once the first dose has been removed, [97] this is distinct from storing syringes. Out of date vaccines should have been disposed of.

The information in this submission indicates a very low and in fact unacceptable level of medical service provision, well below acceptable community standards. If the information is accurate, any of the ADF personnel who received these vaccinations and went on to serve in the 2nd Gulf War, could have been at risk through not receiving an appropriate level of vaccination. It is also possible that the vaccine, which was from the US, and had an expiry date of March 2000,[98] was from stock manufactured under less than acceptable conditions, since it would have been produced in March 1996.[99]

Did Australian personnel receive an effective measure of vaccination?

Given that anti–anthrax was little used it is not surprising that there was limited awareness of manufacturing and dose details, and the extent of coverage provided by part of the primary dose. Some of this confusion was obvious in the early months of 2003, when questions were asked about the amount of time from the first vaccination before 'effective cover or protection is provided'.[100] There was also uncertainty about the difference between 'effective' and 'maximum' protection,[101] and the number of

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93 *Submission* 7, Mr Laboo, p. 2—reference is made to the vaccine being carried from Sydney to Brisbane in a 'small styrofoam esky'. For information on the use of such items—although within a larger fridge—see *Australian Immunisation Handbook*, pp.42, 46.

94 *Submission* 7, Mr Laboo, p. 2-3

95 The ADF should therefore check the medical file of the relevant personnel to see if the batch is recorded and determine if this batch would be deemed ineffective.

96 National Health and Medical Research Council, *The Australian Immunisation Handbook*, 8th edition, Canberra 2003, p. 41. See also *Submission* 9, Defence Organisation, Attachment ADFP, 1.2.2.1, *Immunisation Procedures*, Chapter 7, p. 7–1, paragraphs 7.1–7.5.

97 See www.defence.gov.au/dpe/dhs/infocentre/anthrax vaccine.

98 *Submission* 7, Mr Laboo, p. 1.

99 The US vaccine manufacturer was the subject of an adverse FDA notice, also followed up by the US General Accounting Office (GAO) on vaccine manufactured up to and including 1998.

100 Additional Estimates, FADT, 12 February 2003, pp. 29–30, 47–48.

101 Additional Estimates, FADT, 12 February 2003, p. 30.

shots in a 'primary' program.[102] Although these issues were raised after the major publicity on anthrax vaccinations in early February 2003, senior ADF officials themselves were unclear on some aspects of the program.[103]

The US vaccine comprises six shots for what is called a primary program, and annual boosters thereafter.[104] The six shots are completed 18 months after the one given at 12 months, so in effect the time for full coverage is two and a half years. The United Kingdom vaccine comprises 4 shots for a complete primary course, three given over 6 weeks, and the fourth at six months after the third shot. Annual boosters are then required. While the first three UK vaccinations are given at 0, 3, and 6 weeks, the US ones are given at 0, 2, and 4 weeks. This may have been the source of some of the early confusion about the date by which some level of protection is available.

Both the US and the UK have argued that their inoculation programs were commenced prior to any specific conflict in order to provide maximum protection. Their emphasis therefore is on the time at which there is 100% protection rather than a level of up to 90%. UK information does not deny that some protection is available earlier, but emphasises that 'fully effective' protection is better and the main reason why troops in the UK are vaccinated as much in advance as possible:

> Immunisation against anthrax takes six months to become fully effective. This is much longer than the warning we might have of a change in the threat, and longer than the time–scales over which our Forces could be asked to deploy to a high–threat area. Therefore, it makes sense to offer it to personnel in advance. Previously, we have offered immunisation against anthrax to personnel deploying on operations to the Gulf and to those in specialist NBC units. We have always kept the scope of the programme under review, contingent on new stocks of the vaccine. Now that new supplies are available, and because we cannot expect to predict exactly where or when a threat might arise, or which units of our Armed Forces might be called upon to respond, we have decided to expand the immunisation programme so that all Service personnel, including reservists and those essential civilians who are likely to deploy on operations overseas, are routinely offered immunisation against anthrax[105]

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102 Additional Estimates, FADT, 12 February 2003, pp. 47–48.

103 See also Commonwealth Department of Health and Ageing, Population Health Division, Q and A on Anthrax , www.health.gov.au, where information relates only to the US vaccine: 'The vaccination itself involves six doses, three given two weeks apart followed by three additional injections given at 6, 12, and 18 months, after the first dose. An annual booster is required to maintain ongoing immunity'.

104 The first three doses are given 2 weeks apart, and the following doses are given 6, 12, and 18 months after administration of the first dose. Annual booster doses are required, Committee to Assess the Safety and Efficacy of the Anthrax Vaccine, *The Anthrax Vaccine: Is It Safe? Does It Work?,* Washington,2002, Executive Summary, p. 5.

105 United Kingdom Ministry of Defence, at www.mod.uk/issues/anthrax/faqs

The phrase 'takes six months to become fully effective' may mean six months from the first vaccination, or six months after the third vaccination. If the latter is meant, it would be more accurate to say 'takes 7.5 months'.

The US claims that full protection is only available after the complete first course of the US vaccine:

> Immunization for our troops is a prudent action. The immunization program will consist of a series of six inoculations per Service member over an 18–month period, followed by an annual booster. Although protection levels increase as shots in the primary series are given; the entire six–shot series is required for full protection, as determined by the FDA.[106]

How many shots are required for elementary protection?

The emphasis by the Australian Defence department, however, is more on acquiring a high, rather than 100%, level of protection. It notes, therefore, the distinction to be made between the completion of the primary schedule and the earlier time by which adequate protection is available:

> Both vaccines provide some protection after the second injection and good protection after the third injection (ie after four or six weeks). If you are exposed to anthrax before you have had your third dose, you may be given antibiotic treatment.[107]

The Australian Immunisation Handbook states that:

> A number of studies suggest greater than 90% production of protective antibodies after the third dose of anthrax vaccine.[108]

Material provided by Defence on the level of protection available after three shots does not make apparent the fact that very few personnel would have received the full primary dose of even the UK vaccine by the time their deployment to the 2nd Gulf War was completed. Since a decision was made to cease the anthrax vaccinations in April 2003,[109] only approximately two months after commencing them, and there was no exposure to anthrax, testing by Australia of vaccine efficacy at particular points in time did not occur. With respect to the number of personnel deployed to the 2nd Gulf War who were vaccinated on more than one occasion, Defence advised that

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106 US Defense Department Report, 22 May 1998, Anthrax vaccination, Partnership for Peace exercises, (1040), *[Secretary of Defense] Cohen Orders Total Military Force Anthrax Vaccination to Proceed'*, www. defenselink.mil/otherinfo/protection.html

107 www.defence.gov.au/dpe/dhs/infocentre/anthrax . The consent form dated 29 January 2003, which refers to both the UK and the US vaccines, is misleading when it states 'primary schedules' are complete at 18 months, which is true only of the US vaccine (Attachment A, document 1, p. 3, paragraph 14).

108 National Health and Medical Research Council, *The Australian Immunisation Handbook* ,8th edition, Canberra 2003, Part 2, p. 82. The reference immediately before was to the US vaccine.

109 Senate Estimates, FADT, 4 June 2003, p. 382.

353 personnel received two doses of anthrax vaccine, 2,263 received three doses, and 17 previously vaccinated (and presumably having received a full primary course) received a booster.[110] It is assumed that the 2,263 persons who received three doses would have had 90% protection. The alternative is that they had received one shot for the Afghanistan conflict and then two shots, although this would have meant some considerable delay between the first and second shots. The 353 who received two shots may have been deployed later, with the program ceasing before the third shot was due.

There is no specific reference in the Defence submission to the post deployment follow up of vaccine programs, and it is not clear if anyone who received the first three shots completed the program upon return.[111] Those who had received the US vaccine were likely to need another three shots, and those who received the UK vaccine may have needed at least the final one. Annual boosters would continue the immunity conferred by a full course. According to Defence, incomplete vaccination courses are generally continued where they had been left off,[112] so that a person who had missed the six-month shot of the UK vaccine would be given this, and then proceed with the booster one year later.

On its website, Defence states that:

> You must complete the primary schedule for your vaccine type. If a longer interval than that recommended in the schedule has elapsed since your last dose, you should resume the schedule, extending the times according to the schedule.[113]

Although this issue may be one of particular concern for current personnel, it is one which would also affect reservists since they would need to keep track of their immunisation status, and are not necessarily aware of whether they received the US or the UK vaccine.

Accuracy of vaccination records

In its submission, Defence stated that JHSA was responsible for 'conducting the majority of inoculations'[114] and that 'a database of non–standard vaccinations administered (for example anthrax and smallpox) is held at HQAST.[115] It also states that 'all vaccines administered to ADF personnel are recorded in medical documentation and that 'DHSB has a responsibility to retain details of ADF personnel

110 *Submission* 9A, Defence Organisation, Q5.

111 See above, Chapter 2, paragraph 2.58.

112 *Submission* 9, Defence Organisation, Attachment D,

113 www.defence.gov.au/dpe/dhs/infocentre/anthrax vaccine.

114 *Submission* 9, Defence Organisation, p.3, paragraph 11.

115 *Submission* 9, Defence Organisation, p. 5, paragraph 22.

who are administered any vaccine not registered with the Therapeutic Goods Administration, including batch details'.[116]

> The requirement is that, if an ADF member receives a vaccination, that information is to be recorded in the member's international certificate of vaccination—ICV. That is an international document. Whilst it comes out rebadged under an ADF number, it follows international policy requirements.[117]
>
> There is a second part to the recording of the information and that is that an entry should be made into the member's medical record onto one of the running sheets in that record. So there are actually two points of entry of information—which should in fact say exactly the same thing. It should show the nature of the vaccine, the brand name, the dosage, the date of administration and the batch number. That is the obligatory information that is recorded.[118]

Other information suggests that this has not always been the case. The submission referred to above on out of date vaccines also noted that there was no consent form available,[119] and that this form was said to have been 'no longer in use' (in 2000). However, this may have been an anomaly, with the Olympic Games not being seen as a deployment. The situation with respect to this case, including any lack of accurate recording of information, such as batch details, is best dealt with through an assessment of the safety and efficacy of the material used.

Another submission stated that some vaccinations in the First Gulf War had only been recorded on the WHO form (the ICV) and not on the personal medical file.[120] However, there seems to be no reason why such information could not be transferred to the personal file, including in cases where non-standard vaccines may have been given because the individual was working under other forces.[121]

A third instance was stated in the Redress of Grievance document, where it is claimed in respect of *Kanimbla* personnel, that:

- 10(d) Only the date of vaccination not the shelf life or batch number were recorded.
- (e) The shelf life of the vaccination and the batch number are unable to be provided because these were not recorded. The vaccines were checked at the time of inoculation to ensure they were in date and the

116 *Submission* 9, Defence Organisation, p. 6, paragraph 26.

117 *Committee Hansard,* p. 60.

118 *Committee Hansard,* p. 61. See also *Submission* 9, Defence Organisation, Attachment D, Chapter 2, Sections 2.24–2.26.

119 *Submission* 7, Mr. Laboo, p. 2.

120 *Submission* 5, Regular Defence Force Welfare Association, p. 3, paragraph 17.

121 *Committee Hansard*, p. 62.

batch number was recorded on the packaging or the ampoules which were destroyed after vaccination.

- (f) The batch number of vaccinations is sometimes recorded but there is no strict requirement to do so… Rarely will [the batch number] be used in post retail recall of medications and there has been no recall by the manufacturers of any batch numbers of Anthrax vaccine used by the ADF.[122]

Strictly speaking, there may have been no manufacturer's recall of the UK vaccine, but there have been instances in which a check has been initiated by others, including in the United Kingdom with batch No. 348E, during the first Gulf War.[123] However, the statement that there is no requirement to record the batch number is inaccurate. This statement was written in January 2004, but it was stated in February 2004 that this information was incorrect and that the batch numbers had been recorded.[124]

Another concern with medical records is whether data are available on the need for additional shots or boosters, and whether there is currently in place a system which produces such information. It is apparent from the information on HealthKEYS that this will operate in the future, but in the meantime there is a need for accurate records for individuals.

Assessment of information overall

The anthrax vaccine issue highlights some problems, including the ease with which misinformation can circulate. One of these is that it is important for long term credibility to make accurate statements about what is and is not known about unusual vaccinations, as the available information provided by various sources can be misleading if not seen within context.

Issue of long term safety of the vaccine

Although some work was undertaken in the 1960s and later on the effect of vaccine on textile mill workers in limiting anthrax,[125] the anthrax they may have been exposed to was not a militarised form.[126] In these circumstances, to say that there are no data

122 Redress of Grievance, p. 3, paragraphs 10 (d), (e) and (f).

123 United Kingdom, Ministry of Defence, *Background to the use of Medical Countermeasures to protect British forces during the Gulf War (Operation Granby)*, at www.mod.uk/issues/gulfwar/info/medical/mcm. It had been decided that ' use of pertussis as an adjuvant could significantly reduce the numbers and severity of casualties in the event of an anthrax-based BW attack,' paragraph 51.

124 Additional Estimates, FADT, 18 February 2004, p. 62.

125 *The Anthrax Vaccine: Is It Safe? Does It Work?,* Washington,2002, Executive Summary, pp.9–10.

126 See www.defence.gov.au/dpe/dhs/infocentre/anthrax: 'As a biological weapon, anthrax bacteria would be released into the air in invisible clouds that when inhaled by personnel would infect them with anthrax. The first symptoms of this type of 'inhalational' anthrax would

demonstrating long–term effects may easily be read as meaning 'there **are** no long term effects'. Even the comment that 'the literature on safety suggests it is a safe vaccine'[127] would have to be read with caution, bearing in mind the very recent date of the studies on long term outcomes.

Both Defence and the Repatriation Commission state they are not aware of 'any research that suggests there are long–term harmful effects from anthrax vaccinations',[128] but this view must also be seen within the context of research based on the 1st and 2nd Gulf Wars. Both are too recent to provide information on effects that may not occur for some time, and may also be affected by interaction with other vaccinations and exposure to other substances. The response by the AMA to the Department of Health's statement was more cautious:

> I don't think we have enough data in the medical press, certainly in the peer reviewed medical journals, that would convince medical practitioners in Australia of the safety and efficacy of this vaccine'. And 'If they [the ADF] have that data, [that the vaccine was safe] the medical profession in Australia would very much like to see it.[129]

The US report on the safety of anthrax vaccinations, though generally positive, also noted that there was insufficient epidemiological evidence:

> The committee found no evidence that vaccine recipients face an increased risk of experiencing life–threatening or permanently disabling adverse events immediately after receiving AVA, when compared with the general population. Nor did it find any convincing evidence that vaccine recipients face elevated risk of developing adverse health effects over the longer term**,** although data are limited in this regard (as they are for all vaccines).[130]

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generally appear within a week (typically 2–3 days) and include flu–like symptoms, general lethargy and mild fever. Without treatment, these would quickly progress to serious breathing difficulties, collapse, shock, and, in almost all cases, death'.

127 *Committee Hansard*, p.75. See also interview with then AMA President Kerryn Phelps, 14 February 2003, at www. abc.net.au/am/s784207.htm, see Attachment A, document 2.

128 *Committee Hansard,* p. 75.

129 www.abc.net.au/am/s784207.htm—

130 Committee to Assess the Safety and Efficacy of the Anthrax Vaccine, *The Anthrax Vaccine: Is It Safe? Does It Work?,* Washington,2002, Executive Summary, p. 2.

ATTACHMENT A

Document 1: Copy of consent form dated 29 January 2003

Version: 29-Jan-03
Page 1 of 4
Unit
Number
Rank
Surname
Given Name
Date of Birth Sex

CONSENT FORM FOR ADMINISTRATION OF ANTHRAX VACCINE

I, ...
(full name)

hereby consent / do not consent * to the administration of Anthrax vaccine for myself.
(* Strike out whichever is not applicable)

In addition I confirm that:

- I understand that this product is not registered by the Therapeutic Goods Administration for sale in Australia but it has been approved for importation;
- I have read the information provided on pages 2–4, relating to the use of Anthrax vaccine and have understood the information presented;
- I have discussed the use of the above with the medical officer and been given the opportunity to ask questions;
- I understand that I may refuse to accept Anthrax vaccine without prejudicing my medical care but that I may not be eligible for operational deployment; and I have signed this form in the presence of an ADF Health Care professional.

Signed:..... Date:.....

I confirm that I have discussed the relevant products with the above named.

Signed:..... Date:.....

Printed Name:.....

Position/Designation:.....

ANTHRAX IMMUNISATION INFORMATION SHEET

WHAT IS ANTHRAX?

1. Anthrax is a serious illness caused by the bacterium, *Bacillus anthracis.* It is primarily a disease of plant-eating animals - cattle and sheep being common hosts. Human infection with anthrax can result in death, even with the best available treatment.

2. It is not a new disease, having been recorded from around 1500 BC. During the 1930s, extensive research was conducted in Germany, Russia, and Japan toward the use of anthrax as a biological weapon. During World War II, several countries produced anthrax, yet Japan was the only country to use it as a biological warfare agent. Since 1945 several countries have developed anthrax as a biological weapon, including the former Soviet Union and Iraq.

HOW IS IT SPREAD?

3. Human infection with anthrax can be caused by direct contact with products from infected animals (hides, hair or wool), eating infected meat or inhaling anthrax spores. Natural infection through direct contact or ingestion is very uncommon due to widespread measures to control the disease. The greatest threat from anthrax for ADF personnel is inhalation of aerosol spores produced as a biological warfare agent.

WHAT HAPPENS TO PEOPLE WHO ARE INFECTED WITH ANTHRAX?

4. There are two main forms of anthrax, cutaneous (skin) and inhalation, based on route of entry to the body. The incubation period for anthrax is usually 1 to 7 days, with most cases occurring within 2 days of exposure. The incubation period for inhalational anthrax has been recorded up to 60 days. Inhalational anthrax results in death in 90—100% of cases.

5. The first symptoms of inhalation anthrax are flu-like symptoms such as sore throat, mild fever, chest pain, cough and muscular pain. Within 2 to 3 days, serious breathing difficulties, collapse and shock develop. Death occurs within 24 to 36 hours of development of these serious symptoms.

CAN PEOPLE WITH INHALATION ANTHRAX BE TREATED?

6. After exposure to anthrax, treatment with antibiotics may be effective in preventing disease if it is begun before the onset of any symptoms. To be optimally effective, preventive treatment should be started within hours of exposure. As aerosol spores are invisible, tasteless and odourless, personnel may be exposed without their knowledge. Once symptoms have started, the efficacy of antibiotic treatment is very poor. If not treated immediately and aggressively in a state–of–art hospital centre, once severe symptoms develop, 45% to 80% of patients will die.

DO INFECTED PERSONS SPREAD THE DISEASE TO OTHERS?

7. Anthrax is not spread from person to person.

WHY IS ANTHRAX AN EFFECTIVE BIOLOGICAL WARFARE AGENT?

8. Anthrax bacteria are capable of forming spores, which are thick walled inactive forms. Bacterial spores may survive quite extraordinary extremes of temperature, dehydration or chemical insult. Spores are easily stored and remain dangerous for a long period.

9. Anthrax spores are well suited for delivery by missiles or bombs. They can also be dispersed by small devices using explosives, generators that use either explosives or compressed air, or spray devices. Anthrax would most likely be dispersed in aerosol form.

HOW CAN ANTHRAX INFECTION BE PREVENTED?

10. The single best way to protect against many life–threatening diseases is via vaccination. Vaccines work by stimulating the human body's natural defences to prevent the development of a disease if later exposed to it.

IS THERE MORE THAN ONE TYPE ANTHRAX VACCINE?

11. Two types of anthrax vaccine are available for ADF personnel, one made in the United States and the other made in the United Kingdom. These vaccines are equally effective in preventing anthrax infection. Although each vaccine is approved for use in its country of manufacture, the Therapeutic Goods Administration (TGA) has not registered them for general use in Australia. TGA has, however, approved the importation and subsequent administration of these vaccines to ADF personnel and for other persons, such as veterinary surgeons, considered being at–risk. Vaccination should be completed with the one type of vaccine, as the vaccines are not interchangeable.

HOW EFFECTIVE ARE THE VACCINES?

12. No vaccine provides 100% protection. However, the available evidence indicates that both types of vaccine provide equally effective protection against anthrax.

HOW QUICKLY DO THE VACCINES PROVIDE PROTECTION?

13. Both vaccines provide some protection after the second injection and good protection after the third injection (ie after four or six weeks). If you are exposed to anthrax before you have had your third dose, you may be given antibiotic treatment.

HOW LONG DOES PROTECTION PROVIDED BY ANTHRAX VACCINES LAST?

14. In order to maintain immunity, personnel require a booster vaccine dose each year after completion of the primary schedule. The primary schedules are complete at the 18 month injection.

WHAT HAPPENS IF I HAVE ALREADY HAD SOME VACCINE DOSES?

15. You must complete the primary schedule for your vaccine type. If a longer interval than that recommended in the schedule has elapsed since your last dose, you should resume the schedule, extending the times according to the schedule. Additional doses to compensate for any delay are not required.

CAN I GET ANTHRAX INFECTION FROM VACCINATION?

16. Neither type of anthrax vaccine contains live bacteria. Therefore, they do not introduce any form of anthrax infection.

WHAT ARE THE POSSIBLE ADVERSE EFFECTS OF THE VACCINES?

17. **Local reactions.** Reactions at the injection site usually last from one to three days and go away without treatment. Redness, itching, and/or swelling, occurs in up to one third of men and up to two thirds of women following anthrax vaccination. Such reactions are usually only small but in rare cases may be up to 13 centimetres in diameter. Soreness or local pain occurs in up to one fifth of persons vaccinated. A lump at the injection site is common, occurring in up to 90% of people vaccinated. The lump may persist for a few weeks.

18. **Systemic reactions**. Reactions away from the injection site occur in up to one third of people vaccinated. These reactions may include muscle aches, joint aches, chills, low–grade fever, decreased appetite, headaches, nausea, and swollen glands. They usually go away in a few days.

19. **Acute allergic reactions.** These reactions, which may be severe, are very rare (about 1 in 100,000) but may occur with anthrax vaccines, as with any vaccine. There is no evidence that other types of serious reactions occur with either type of anthrax vaccine.

WHAT DO I DO IF I EXPERIENCE ADVERSE EFFECTS?

20. You should avoid strenuous exercise for at least 48 hours following local or systemic reactions. You should report to your ADF Health Care professional for further advice. Treatment will not usually be required. It is very unlikely that you will not be able to complete the schedule.

WHO SHOULD NOT HAVE ANTHRAX VACCINATION?

21. The following should not have anthrax vaccine at all:

a. Persons who have had an acute allergic reaction to a previous dose of anthrax vaccine or to any of the vaccine's components,

b. Persons younger than 18 or older than 65,

c. Persons who are HIV positive.

22. Vaccination should be temporarily deferred in the following circumstances:

a. Pregnancy, suspected pregnancy,

b. Women who are breast feeding,

c. Active infection/illness with fever,

d. Depressed immune response, including corticosteroid or other immuno–suppressive treatment.

IS THE VACCINE COMPULSORY? WHAT HAPPENS IF I DON'T HAVE IT?

23. Anthrax vaccination is not compulsory. However, if the Joint Health Support Agency Health Support Plan for a particular operation indicates that Anthrax vaccination is a requirement, personnel who decline vaccination may not be considered eligible for deployment to that operation.

ARE ANTIBIOTICS AN ALTERNATIVE TO VACCINATION FOR PREVENTION OF ANTHRAX?

24. No. Long-term antibiotic treatment is not an acceptable alternative to vaccination because it is less effective in preventing infection and has unacceptable side effects.

ONCE I HAVE BEEN VACCINATED, DO I NEED TO DO ANYTHING ELSE TO PROTECT MYSELF AFTER EXPOSURE TO ANTHRAX?

25. Even when fully immunised, antibiotics may be still indicated after aerosol exposure, to achieve survival as close to 100% survival as possible.

WHERE CAN I GET FURTHER INFORMATION?

26. Ask your ADF Health Care professional, as there is a great deal of information available.

Document 2: ABC Radio interview of Dr Kerryn Phelps

Navy message to soldiers

AM—Friday, 14 February, 2003, 00:00:00

Reporter: Jo Mazzocchi

LINDA MOTTRAM: Meanwhile, faced with the dissent within the ranks, the Chief of the Navy, Vice Admiral Chris Ritchie, has been forced to take the highly unusual step of delivering a message to all serving Australian Navy personnel that the anthrax vaccine is safe.

But now, Australia's peak medical lobby group, the Australian Medical Association, has joined those taking the opposite view, in a contribution that will only complicate life for Australian defence personnel caught in the middle of the debate with life and death issues looming.

Jo Mazzocchi reports that Vice Admiral Ritchie has also publicly rebuked the young sailor who told the media of his concerns about taking the anthrax vaccine.

JO MAZZOCCHI: The Chief of the Navy rebuked the young sailor, Able Seaman Simon Bond, who sparked this controversy, by saying that the types of breaches that have occurred in the last twenty four hours "create far greater upset for families for our people than they are of any help to either individuals or your mates".

But judging by the depth of public confusion over this issue, some might disagree, claiming Able Seaman Simon Bond has in fact done them a favour.

The Australian Medical Association says the sailor has acted as a catalyst on the issue.

AMA President Dr. Kerryn Phelps.

KERRYN PHELPS: Look I think that raising issues and speaking about the concerns that his colleagues have is not really causing any harm.

I mean if what this does is act as a catalyst for the Defence Forces to release the information that they have about safety and efficacy then I think it would have done a power of good.

JO MAZZOCCHI: Today in Sydney, there are more farewells for the final deployment of defence personnel to the Gulf.

It is now believed vaccinations are being carried out before they leave, but defence sources are refusing to confirm that.

In his message, the Vice Admiral also stressed that the anthrax vaccine is safe, saying it has been very widely used with no greater incidence or side effects or risks of complications than those associated with any other vaccine.

And that's a view shared by Australia's Chief Medical Health Officer, Professor Richard Smallwood, who says the vaccine is regarded as safe and effective.

But Kerryn Phelps is not convinced.

KERRYN PHELPS: I don't think we have enough data in the medical press, certainly in the peer reviewed medical journals, that would convince medical practitioners in Australia of the safety and efficacy of this vaccine.

The truth is sometimes difficult and I'm not in the business of propaganda, what I'm about is to express what I believe is the medical profession's view on this particular incident.

JO MAZZOCCHI: So there's no clear cut, definitive study either way?

KERRYN PHELPS: Not that the peer reviewed medical literature has available to it.

JO MAZZOCCHI: When the Chief of Navy Vice Admiral Chris Ritchie sends out a message and says the vaccine is safe and effective, what is your response to that?

KERRYN PHELPS: If they have that data, the medical profession in Australia would very much like to see it.

LINDA MOTTRAM: AMA President Kerryn Phelps speaking to our reporter Jo Mazzocchi.