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UK armed forces responses to an informed consent policy for anthrax vaccination: A paradoxical effect?

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Abstract

Background: In recognition of concerns that anthrax vaccination might be a trigger for "Gulf war syndrome", anthrax vaccinations were offered to UK armed forces in the 2003 Iraq conflict using explicit as opposed to implicit consent, as is the policy for all other vaccinations. This paper examines responses of personnel to this policy.
Methods: Qualitative analysis of free text responses to a question inviting comments on any concerns about the anthrax vaccination, asked in the context of a questionnaire assessing military health amongst 1000 members of the UK armed forces following the invasion of Iraq in 2003.
Results: Two hundred and two (20.2%) respondents made comments reflecting concerns about the vaccine's effectiveness and its safety. These appeared to be magnified by suspicions about the motives behind the informed consent policy for anthrax but not other vaccinations.
Conclusion: While the informed consent policy for anthrax vaccinations was intended to decrease concern, it may inadvertently have had the opposite effect.

Keywords: Anthrax; Vaccination; Military; Informed consent; Trust

1. Introduction

In the build-up to the 1991 Gulf war the decision was taken to vaccinate UK armed forces against the risk of biological attack, anthrax vaccine being one of the medical countermeasures used. Anthrax vaccination, along with other vaccines available for UK armed forces personnel, was not compulsory. It was however given under implied rather than explicit consent. Uptake of the vaccine was generally high, between 55 and 69% [1,2]

Subsequent to the 1991 Gulf war increasing numbers of veterans started to report ill health that they believe to be related to their participation in the war. When formal epidemiological studies were commissioned, the results confirmed that those who served in the Gulf reported increased ill health when compared to appropriately matched controls [2–5].

Many Gulf war veterans attributed their health problems to their exposure to the anthrax vaccine. However, the true contribution made by anthrax vaccination to the observed health problems has been difficult to establish. Our research group reported epidemiological evidence linking the use of anthrax vaccine to some long-term symptomatic ill health. Our results showed a modest (OR = 1.4) association between self-reported anthrax vaccination and multiple physical symptoms [2]. Veterans who reported receiving multiple vaccinations, especially during deployment have a higher risk

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of such symptoms [2,6]. These findings have not been replicated in subsequent studies, not limited to Gulf veterans alone of UK, Canadian and US armed forces that have failed to show any particular adverse effects of anthrax vaccine [7–10].

In the build-up to the 2003 Iraq conflict the decision was taken to continue to provide protection against the threat of biological warfare. By this time the Ministry of Defence (MoD) had changed its general policy on the administration of the vaccine to explicitly offer it voluntarily based on informed consent. Whilst not accepting the epidemiological evidence reviewed above, it also as a precautionary measure decided to end the use of the pertussis/anthrax combination and give anthrax vaccine without any adjuvant [11].

There were several reasons for these changes. Even if the science remained uncertain, in the public mind anthrax vaccination was linked with the so-called "Gulf war syndrome". Vaccine safety in general was now an even greater cause of public anxiety and concern following the MMR crisis, which contributed to, and was symptomatic of, a general scepticism toward vaccines, and a reduction in public confidence [12].

Finally, there has been a general rise in medical consumerism, a decline in medical authority, an increased scepticism of medical paternalism, and a greater emphasis placed across society on the concept of informed consent [13].

So before the conflict in Iraq anthrax vaccine was offered to the armed force personnel on a voluntary basis supported by a vaccine information programme (VIP), which consisted of video and written information, intended to strengthen informed consent. Personnel were then given a cooling off period before being asked to sign a consent form and being vaccinated. The aim of the policy is to dispel rumours linking the vaccine to Gulf war syndrome and to increase confidence and uptake. It is important to note that these procedures only applied to the anthrax vaccine, and not to any other of the many routine vaccinations provided to the armed forces.

In this study we examine the consequences of that change in policy.

2. Method

The study sample was drawn from the written responses to questions in a large epidemiological survey of military health and well being of the UK armed forces after the 2003 Iraq conflict. The study used a subset of the total population: 1000 UK armed forces personnel who were randomly selected from across the three services of Royal Navy, Army and Royal Air Force. All the personnel surveyed were regulars who served in the 2003 Iraq conflict, and all had been offered anthrax vaccination as part of the new policy.

Questionnaires were delivered through either a postal survey or by visiting military bases and asking personnel to fill out their questionnaires. Individuals were advised that participation was voluntary and that answers were confidential. The Ministry of Defence Naval Research Ethics Committee MOD(N)PREC gave approval for the study.

The questionnaire included numerous measures concerning physical and psychological health, career and service background and demographics. It also included a section on medical countermeasures including the anthrax vaccine. Within that section was a free text question asking: "If you currently have any concerns about the anthrax vaccine please explain". The aim of this question was to identify which concerns the VIP material did not address, and to discover the concerns personnel may have held about the change in policy.

The constant comparative method of analysis was employed to analyse the qualitative data obtained [14–17]. Raw data was broken down into segments of texts that shared similar themes and were then grouped into initial subcategories, each containing data with common themes. These sub-categories were constructed as various themes emerged and allocated a descriptive title by the author. Further analysis was undertaken to group together sub-categories by comparing similarities, or differences, to identify main categories that whilst overlapping had unique themes. Constant comparative analysis permitted a conceptual theory of potential barriers to informed consent to be formulated, with main categories and key themes identified. In the results, quotations showing a non-identifying respondent ID have been used to illustrate these themes.

3. Results

Two hundred and two (20.2%) of the 1000 questionnaires contained responses to the free text question about anthrax, and which gave 231 separate concerns about the anthrax vaccination. That left 798 completed questionnaires in which there was no response to the section on anthrax concerns. The rates of vaccine uptake between the groups were similar (55.2% reported concerns group versus 62.6% no reported concerns). Mean age of personnel was also similar (33.1 versus 31.3) (Table 1). Overall, we cannot be certain that those completing the relevant section are all those who had con-

Table 1
Demographics between those participants that completed the question asking about concerns held towards the anthrax vaccine versus those who did not complete the question

	Accepted vaccine	Mean age (years)	Gender		Rank	
			Male	Female	Officer	Non-officer
Reported concerns	55.2%	33.1	87.9%	12.1%	29.3%	70.7%
Did not report concerns	62.6%	31.3	94.5%	5.5%	12.7%	87.3%

cerns, and nor can we be sure that those who ignored that section did not have concerns. But it seems reasonable to assume that those with more concerns were more likely to report them to us, and that the study can still shed light on the issue. Those who responded to that question the majority (97%) stated they had concerns about the anthrax vaccination. Analysis of these concerns generated nine sub-categories (Box 1) from which three main categories were defined (Box 2).

Box 1: Sub-categories from initial analysis stage.

Concern over long term side effects:

"Still unproven what long term effects are?" [S84]
"What sort of side effects may harm me in the future." [S18]

Negative Press:

"Have heard horror stories." [S52]
"It has received bad publicity." [S10]

Concerned the vaccine was not properly administered:

"I had to take the third vaccine twice because the med centre missed my file." [S56]
"Follow-up vaccinations were not chased up." [S137]

Anthrax not seen as a threat:

"Was it given due to a threat (specific or non-specific?), and how real was the threat?" [S108]
"Doubt the adversary would use anthrax." [S100]

Insufficient information to make an informed choice:

"I don't know enough about the drug to make an informed choice." [S16]
"At the time of Op Telic 1[1] little information about the injections was given to us." [S57]

Efficacy of vaccine:

"Although the vaccine has been proved and tested, you don't know whether it would work for definite when it came to the crunch." [S31]
"I understand there are a number of different types of anthrax. How would we know we would have the correct vaccine?" [S188]

Concern of vaccine effect on fertility:

"Effects on my future fertility and children." [S73]
"Concerned about having a family in the future because both my husband and I have had the anthrax vaccinations." [S51]

Policy difference between anthrax and other vaccines:

"If the vaccine was voluntary, why did people have to sign to say they had it?" [S36]
"I want to know why this vaccine was optional and every other vaccine was compulsory?" [S61]

Issues of trust:

"We hear reports from Doctors that it is not as safe as they say." [S21]
"Total distrust of situation/establishment." [S81]

Box 2: The five main categories and the key theme.

1. Concern about safety.
2. Concern about effectiveness.
3. Concern about informed consent.

Categories 1–3 form the *KEY THEME*, which is TRUST.

3.1. Category 1: concern about safety (40.6%)

This was the most common category of concerns, incorporating the worries of service personnel that the anthrax vaccination caused 'Gulf war syndrome'. These worries were compounded by the media's negative reporting of the safety of the vaccine.

"It has received bad publicity." [S10]

Most people felt that there was a real chance that the anthrax vaccination could be detrimental to their future health.

"What sort of side effects may harm me in the future?" [S18]

Whilst the majority of responders voiced concerns that the vaccine could cause idiopathic illnesses a proportion (11.9%) felt the vaccine could cause specific problems with their fertility.

"Does it ruin your chances of getting pregnant?" [S150]

[1] Op Telic is the code name used by the British Armed Forces to refer to the 2003 Iraq conflict.

"I was forced to have it once, I will not be forced again." [S159]

"Total distrust of situation/establishment." [S81]

The policy towards anthrax immunisation during the 2003 Iraq conflict only seemed to further damage trust and increase confusion. People felt that they were not being fully informed about the vaccination.

"I wonder why most of our medical staff did not take it even though they told us it was perfectly safe." [S87]

3.2. Category 2: concern about effectiveness (27.6%)

Perceived poor efficacy of the vaccine was common. It was felt by many that the vaccine was not an effective medical countermeasure against biological attack.

"Not convinced by its effectiveness." [S37]

Concerns were also centred on rumours that the vaccine offered would not protect against weapons grade anthrax.

"I do not believe it protects against the anthrax strain that could be used in biological warfare." [S98]

Or that the vaccine was not delivered properly which could result in it not protecting against a biological attack.

"Follow-up vaccinations were not chased up." [S137]

3.3. Category 3: concern about informed consent (31.8%)

Making an informed consent is reliant on having adequate information on which to base a decision. Specific concerns were voiced that material provided did not provide enough information to make an informed consent.

"I don't know enough about the drug to make an informed choice." [S16]

Or that the materials provided did not address the concerns held by service personnel.

"Dissatisfied with the lack of information about the effects, symptoms (long-term)." [S14]

"Figures of adverse reactions not at hand when briefed." [S58]

This category also incorporates suspicion of motives behind the change in policy from compulsory to voluntary with signed consent, and why the policy towards the anthrax vaccine is different than other vaccines.

"I want to know why this vaccine was optional and every other vaccine was compulsory." [S61]

"It is not a regularly given vaccine, and the 'Gulf war syndrome' stories gave me cause for concern." [S142]

Whilst the purpose of the voluntary policy with written consent was designed to decrease worries, armed forces personnel reported the opposite, suggesting that it increased anxiety over the vaccine.

"Heard horror stories, concerned because we were made to sign consent forms beforehand." [S52]

"Why was it voluntary? Gulf war syndrome from the last conflict was caused by a cocktail of vaccinations." [S169]

"Why is it now voluntary and not during Op Granby?[2]" [193]

4. Discussion

This study is part of a wider quantitative long-term study into the uptake of, side effects and possible long-term health effects, if any, of the medical countermeasures including anthrax vaccination used as part of the preparations for the conflict in Iraq. The current qualitative study was deliberately "embedded" within the larger quantitative study to take advantage of the sample size and representativeness of the cohort. We believe that the results of this study do shed light on the some of the issues, concerns and problems that remain with the anthrax vaccine programme, but more broadly, the problems that can result when informed consent is sought in circumstances where it has not been directly required before.

During the preparation to the 2003 Iraq conflict the UK armed forces introduced a voluntary anthrax vaccination policy with written informed consent. One purpose of this change in policy was to restore confidence in their vaccination programme while providing protection for service personnel against the threat of biological attack. This consisted of new information package specifically related to the anthrax vaccine (the VIP), personnel required to sign a form saying that they had received this information. Acceptance or refusal of the vaccine was also required to be entered in their medical records. Some individual units went further and introduced specific consent forms related to the anthrax vaccine. Despite this shift in policy this paper has highlighted that 'trust' is the key barrier to providing informed consent and confidence in the anthrax vaccination programme. Mistrust was associated with all three main categories found. This ranged from suspicion that the information provided to help provide an informed consent did not adequately address the concerns of personnel, to confusion over the disparity in policies between anthrax and other vaccines.

There are a number of factors that may have contributed to the ongoing problems with the vaccination programme. The legacy of the 1991 Gulf war and subsequent ill health of veterans [2–4] has created an atmosphere of suspicion concerning health in general, and medical counter measures such as the anthrax vaccine in particular. Outside the military, infectious diseases are no longer the scourges they once

[2] Op Granby is the code name used by the UK armed forces to refer to the 1991 Gulf war.

were—ironically because of the success of immunisation programmes. At the same time we have witnessed general social changes towards increased concerns about risk rather than benefit [18].

The public are becoming more informed on health matters, and there is no reason to believe the armed forces are any different [15]. There is a general lack of confidence in public institutions as a whole, including both medicine and the armed forces [19–21].

The study provided a good opportunity to investigate the shift of policy for the administration of a medical countermeasure away from the traditional paternalistic approach of stating what is good for you to one focused on providing informed consent. Military culture, based on the giving and receiving of orders, has traditionally provided an exaggerated form of such paternalism. Military culture thus provides a natural experiment to study the consequences of a shift from paternalism to informed consent.

So why did the change in policy not provide an end to the suspicion of the vaccine, and why did it in some seemingly achieve the opposite? For some of our sample, suspicion increased, and the switch towards informed consent, greater information and the need to sign a consent form seemed to suggest that there was something particular dangerous about this vaccine which did not apply to other vaccines such as tetanus, cholera and so on, which were given at the same time but without the same education package, paperwork or consent form. At present the future of the VIP programme is under review.

What was missing was trust. Many of the respondents made it clear that they did not trust MoD on this issue. Hence they interpreted the change in policy as proof that MoD was "covering up" evidence that the vaccine was in fact harmful. They did not believe the material they were shown, and also believed that they were still being coerced into accepting the vaccine.

Thus in a situation where trust is in short supply, what seems like a trust building, confidence inspiring shift in policy may not achieve the desired goals. Informed consent may be desirable on ethical, or legal grounds, but it may not inevitably lead to the expected positive consequences.

Whilst it is a truism to say that the military are different from civilians, and that most of us do not need protecting against biological warfare, the issues raised by the case of anthrax vaccination and the armed forces do have resonance in the civil sector.

Whilst the military provide an exaggeration of the situation for the general public, parallels can be drawn. Medical intervention programmes for the general public are also moving away from paternalism to that of aiding patients make an informed consent. The introduction of prostrate screening in America is an example for the general public where a policy was changed to give informed consent but instead has caused increased levels of stress and anxiety with increased numbers getting screened [20] without evidence that screening decreases prostate cancer mortality rates [21]. Within the area of screening some evidence has suggested that offering informed consent actually lowers uptake [22].

Consumer advocates may argue that there is no limit to what potential participants in a study or recipients of a health intervention should be told, but, like all interventions, the giving of information is an intervention that has side effects, some of them unexpected. Here we argue that the giving of more information about the vaccine, and the request for informed consent, did indeed cause unanticipated side effects, which caused some people to react in a manner making them less likely to accept the intervention, not more.

The change of policy may also have had beneficial effects. It is possible that those who decided to take the vaccine did so with more confidence that previously. In turn, this may lead to a decrease in side effects. In subsequent studies of this cohort we will be investigating that possibility directly. The military are aware of the issues and have decided to abandon the VIP programme, and give all vaccines under the same procedures.

The purpose behind the introduction of the informed consent policy for the anthrax vaccine may have been to reduce concerns and increase confidence in the vaccine but this also reflects an important shift in public health away from medical paternalism to one that places greater emphasis on informed consent. As we have shown in this paper providing informed consent can actually increase concerns, this raises the interesting question of even though there appeared to be an increase of concerns does the military have an ethical obligation to provide informed consent to its personnel. Does an informed consent policy that actually increases anxiety fail to achieve its goal and are the informed consent procedures as currently used in medical research applicable to routine medical care and preventive medicine practices?

This paper has reported the concerns held by UK armed forces personnel towards the anthrax vaccination programme conducted by the UK armed forces prior to the 2003 Iraq conflict. The findings of this paper are limited due to the representativeness of those who participated. Eighty percent of participants did not complete the question asking about concerns held towards the anthrax vaccine. Whilst uptake levels between the two groups were similar it is not known why they did not respond. Was it they held no concerns or that they simply missed out the question? It is plausible that the study simply provided a forum for concerns that service personnel already had about the anthrax vaccine prior to the introduction of the informed consent policy. This may explain the reporting of concerns related to the effectiveness and to a less extent the safety of the vaccine but not those directly associated with informed consent. Further, it is also possible that the epidemiological study itself, as well as the introduction of the informed consent policy increased concerns by framing the anthrax vaccine as having a negative effect on health. We will be representing the detailed quantitative epidemiological evidence on vaccine uptake, perceived coercion, decision making and side effects elsewhere. In this paper

we have elected to analyse the qualitative dataset only, using the quantitative data to set these responses in context.

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