

# Statements of Principles: evidence-based compensation for Australian Veterans and serving defence personnel

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THE AUSTRALIAN REPATRIATION SYSTEM has its origins in 1918 with the establishment of the Department of Repatriation, now the Department of Veterans' Affairs, and is based on a notion of societal debt to returned service personnel. The Department of Veterans' Affairs now provides or coordinates many services, including health services, scholarships, commemorations, housing and pensions for Veterans, their dependants, and their survivors.

This article focuses on the system for establishing liability for compensation, based on Statements of Principles (SoPs). It describes the structure of the SoP system and the process for making SoPs, outlines some of the legislative and scientific constraints in which the process operates, and provides a brief evaluation. The SoPs now have direct relevance to serving personnel as well as veterans, as the SoPs are also the instruments used to determine claims under the new *Military Rehabilitation and Compensation Act 2004* (Cwlth).

## The Statement of Principles system

Statements of Principles are legal instruments which set out the factors that must exist to cause a particular kind of disease, injury or death that could be related to service, based on sound medical–scientific evidence (SMSE). The definitions of disease and SMSE are specified in the legislation (Box 1 and Box 2). SoPs are tabled in the Australian Parliament and are subject to parliamentary scrutiny. They are binding on decision makers.

The SoPs are determined and reviewed by the Repatriation Medical Authority (RMA). Up to the end of 2003, the RMA had produced nearly 1200 instruments covering 276 conditions. Conditions covered are wide ranging in nature and include chronic diseases, certain infections, psychiatric conditions, injuries, overuse syndromes and cancers.

The RMA is an independent statutory authority directly responsible to the Minister for Veterans' Affairs. It consists of five practitioners eminent in the field of medical science, supported by a secretariat of medical, research and administrative officers. Members of the RMA have broad experience in public health, public administration, research and clinical practice. One member is an experienced

## Abstract

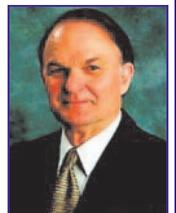
- ◆ Statements of Principles (SoPs) are legal instruments which set out the factors that must exist to cause a particular kind of disease, injury or death that could be related to service, based on sound medical–scientific evidence (SMSE). They are tabled in the Australian Parliament and are binding on decision makers. SoPs are the instruments used to determine liability under the *Veterans' Entitlements Act 1986* and the *Military Rehabilitation and Compensation Act 2004*. SoPs are regularly updated as new SMSE emerges.
- ◆ The Repatriation Medical Authority (RMA) is an independent statutory authority responsible to the Minister for Veterans' Affairs. It consists of five practitioners eminent in the field of medicine or medical science, and includes an experienced epidemiologist. The main role of the RMA is to determine SoPs.
- ◆ SoPs are determined at two standards of proof. For the *reasonable hypothesis* standard, the RMA must be of the view that the SMSE indicates that there is a reasonable hypothesis of a causal association between a factor and a condition. For the *balance of probabilities* standard, the RMA must be of the view that the SMSE shows that it is more probable than not that a factor is causally related to a disease. For both standards, the factors must be able to be potentially related to service.
- ◆ Veterans, organisations representing veterans or members of the ADF, as well as defence personnel, can request an investigation in respect of a disease and a factor or factors. Submission guidelines are available from the RMA or from the website. All current SoPs and investigations are accessible via the RMA website ([www.rma.gov.au](http://www.rma.gov.au)).

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## **I: Definition of disease in the Veterans' Entitlements Act 1986 (Cwlth), s 5D(1)**

Disease means:

- (a) any physical or mental ailment, disorder, defect or morbid condition (whether of sudden onset or gradual development); or
- (b) the recurrence of such an ailment, disorder, defect or morbid condition

*but does not include:*

- (c) the aggravation of such an ailment, disorder, defect or morbid condition; or
- (d) a temporary departure from:
  - (i) the normal physiological state; or
  - (ii) the accepted ranges of physiological or biochemical measures;that results from normal physiological stress (for example, the effect of exercise on blood pressure) or the temporary effect of extraneous agents (for example alcohol on blood cholesterol levels).

## **2: Definition of sound medical–scientific evidence in the Veterans' Entitlements Act 1986 (Cwlth), s 5AB(2)**

Information about a particular kind of injury, disease or death is taken to be *sound medical–scientific evidence* if:

- (a) the information:
  - (i) is consistent with material relating to medical science that has been published in a medical or scientific publication and has been, in the opinion of the Repatriation Medical Authority, subjected to a peer review process; or
  - (ii) in accordance with generally accepted medical practice, would serve as the basis for the diagnosis and management of a medical condition; and
- (b) in the case of information about how that kind of injury, disease or death may be caused — meets the applicable criteria for assessing causation currently applied in the field of epidemiology.

epidemiologist and all members have experience in the principles and practice of epidemiology.

The role of the RMA is to determine SoPs by assessing the SMSE for evidence of a causal association between potential risk factors and a given condition. From time to time, serving members or veterans have concerns about particular exposures (for example, depleted uranium, other heavy metals or various chemicals). However, it is *not* the role of the RMA to assess all the potential adverse health effects of specific exposures, and any request for an investigation must be made in respect of a particular kind of injury or disease.

Each SoP provides a definition of the condition and lists the factors causally related to the condition, according to the standards of proof specified by the *Veterans' Entitlements Act 1986* (Cwlth). At least one of the factors must be related to relevant service.

## **Establishment of the RMA**

Before the introduction of the SoP system, veterans' claims were investigated on a case-by-case basis within an adversarial legal system. Thus, the success of a claim could depend on the expert opinion about disease aetiology of a single medical practitioner and the ability of a veteran to appeal a decision. In 1992, the Auditor-General completed an efficiency audit of the compensation system,<sup>1</sup> and found that fundamental review was required because of inefficiencies, the need to better handle

veterans suffering from psychiatric conditions, and inequities arising from inconsistent decision-making.

A subsequent report commissioned by the then Minister for Veterans' Affairs recommended that legally binding SoPs be developed to provide objective, evidence-based guidance to decision makers who assess the contribution of service to a disease or injury.<sup>2</sup> The SoPs were to be developed with the assistance of an independent, expert medical committee to ensure that "maverick" medical opinions could no longer prevail over the body of SMSE.<sup>2</sup>

In 1994, the Veterans' Entitlements Act was amended to establish the RMA and define its functions and powers. The Specialist Medical Review Council was established at the same time, and is empowered to review the contents of an SoP or a decision by the RMA not to determine an SoP. The council can direct the RMA to include a factor or to carry out an investigation in respect of a factor.

Only certain types and/or periods of service are "eligible service" for the purposes of the Veterans' Entitlements Act. For service not covered by the Act, workers' compensation legislation applies, and in many cases there is dual eligibility. From 1 July 2004, the Military Rehabilitation and Compensation Act is effective for service-related injuries or diseases incurred by current serving members of the Australian Defence Force and replaces other workers' compensation legislation.

It should be noted that matters of fact relating to an individual's case, including the nature of service and any link between service and SoP factors, are not determined by the RMA. These matters are determined by delegates of

the Repatriation Commission, and there is a right of appeal to the Veterans' Review Board and the Administrative Appeals Tribunal. Matters of law can be appealed to the Federal Court and High Court.

### RMA processes

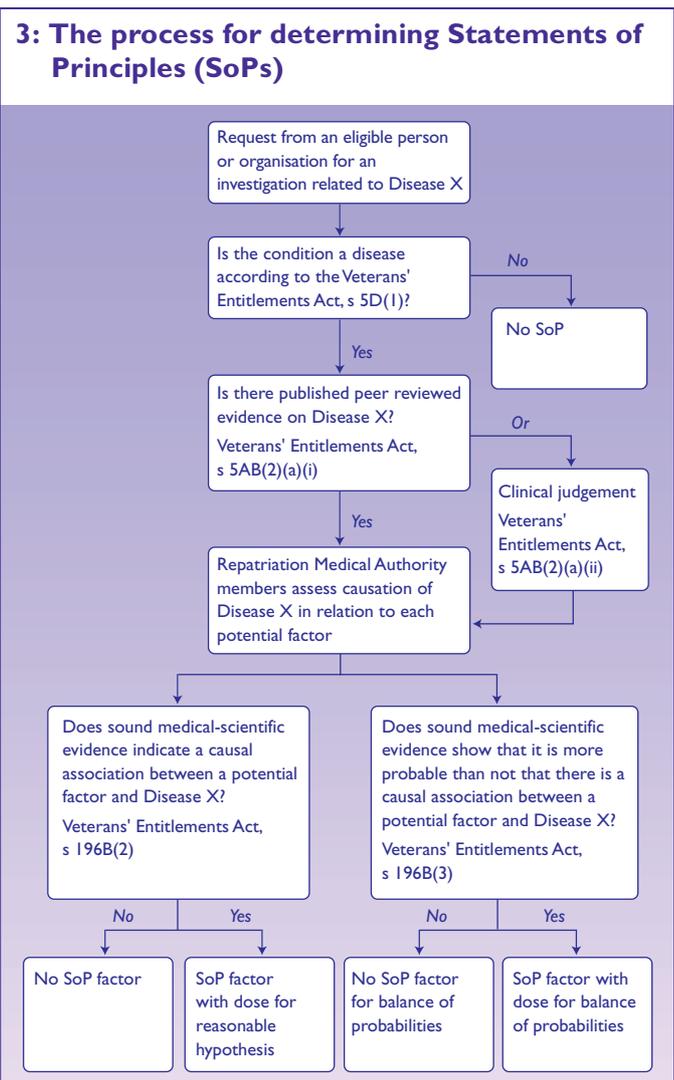
The RMA determines SoPs at two standards of proof. For veterans with an injury, disease or death that relates to operational service, hazardous service or peacekeeping service (warlike or non-warlike service for serving members), the *reasonable hypothesis* instrument applies. For a factor to be included in this instrument, the SMSE has to indicate or point to a reasonable hypothesis of a causal association between the factor and disease. For veterans with an injury, disease or death related to eligible war service and defence service (peacetime service for serving members), the *balance of probabilities* instrument applies. For a factor to be included in this instrument, the SMSE has to show that it is more probable than not that the factor is causally related to the disease.

Thus, depending on the strength of the evidence, a factor may be in both instruments, the reasonable hypothesis instrument only, or neither. Alternatively, a factor may be in both instruments but the dose may be lower in the reasonable hypothesis instrument. The SoP for ischaemic heart disease illustrates all of these potential outcomes, using as examples some of the factors that were considered in the submission.

Box 3 shows the process for making SoPs at the two standards of proof under the Veterans' Entitlements Act. Only certain parties are entitled to request an investigation. Under the Veterans' Entitlements Act, these parties include veterans, ex-service organisations and the Repatriation Commission. Under the Military Rehabilitation and Compensation Act, these parties include defence personnel, an organisation representing members of the ADF, and the Military Rehabilitation and Compensation Commission.

The legislation requires that the condition meet the Veterans' Entitlements Act definition of "disease" and that the RMA assess causation using published peer-reviewed evidence and standard epidemiological criteria. These last are based on a modification of the Bradford-Hill criteria,<sup>3,4</sup> and include temporality, strength of association, observation of a dose-response effect, biological plausibility, consistency with other evidence, and absence of alternative explanations for an association (chance, bias or confounding).

Consideration of the quality of the published evidence is an important part of the critical appraisal process. Articles are routinely selected on the basis of relevance, study quality, reliability and journal authority. The conclusions of studies of a more sophisticated design and which are



methodologically sound usually carry greater weight than less well conducted studies, because alternative explanations for associations are less likely.

Some decisions about causation are fairly clear. There is very strong evidence that diabetes mellitus is a risk factor for ischaemic heart disease, and this factor has been included in both instruments. Conversely, the evidence supporting periodontal disease as causally related to ischaemic heart disease is weak, limited and possibly confounded by diabetes and smoking, so this factor has not been included in either instrument.

Decision-making becomes more complicated when there is mixed evidence. There is an emerging consensus that passive smoking contributes to causing ischaemic heart disease, but there is still some debate as to whether this relationship is causal, confounding, or subject to publication and misclassification biases. There are also issues of how long after exposure the effect remains and how to express dose. In the literature, exposure is often expressed as spousal smoking, but people may be exposed to environmental

tobacco smoke outside the home, and spousal smoking is not very relevant to exposures in the military. A factor for passive smoking was included in both instruments, but with a lower dose in the reasonable hypothesis instrument (1000 hours of exposure to visible tobacco smoke haze in the reasonable hypothesis instrument and 10 000 hours in the balance-of-probabilities instrument).

The evidence as to whether depression is an independent risk factor for ischaemic heart disease, though tending to be positive, is still inconsistent and leaves open the possibility of alternative explanations. The strength of results sometimes depends on whether the outcome is morbidity from ischaemic heart disease or death from ischaemic heart disease. Depression may be acting as an independent causal factor in its own right, or the apparent effect of depression may be mediated by known risk factors. Thus, there is at present a factor for depression in the reasonable hypothesis instrument only, although the decision is open to reconsideration if stronger evidence emerges or the risk factors can be disentangled.

The legislation allows the RMA to make judgements of causality, particularly at the reasonable hypothesis level, on the basis of somewhat weaker evidence than might be accepted in other contexts. Nevertheless, the aim is to do so in a consistent manner, using comprehensive and systematic reviews of all the relevant information available.<sup>5</sup>

Throughout the process, the RMA communicates with SoP users in several ways. When it has decided to investigate a condition, the investigation is advertised in the Commonwealth Government *Gazette* and on the RMA website, and submissions can be made. The final instruments are also published in the *Gazette* and on the website. In addition, the RMA has regular mail-outs, publishes annual reports, holds conferences, and consults with organisations representing veterans and members of the forces.

## Legislative and scientific constraints

The ability to make SoPs or include factors is limited by certain clauses in the Veterans' Entitlements Act. Section 5D specifies the definition of disease (Box 1). Sometimes, it is not clear whether a condition can be considered a "disease" under the Act. Despite the findings in various studies of an excess of symptoms in the exposed group, the RMA was not able to make an SoP for "Gulf War syndrome", because the symptoms did not constitute a specific syndrome.<sup>6</sup> There is an overlap between the concepts of disease and illness, but "illness" refers to the subjective experience of poor health and may or may not reflect the process of a specific underlying disease.<sup>7</sup>

Another issue is that of risk factors: can a risk factor such as obesity or hypercholesterolaemia become a disease and, if so, at what point? The RMA has tended to take the

view that if a risk factor causes complications or requires treatment, it may become a disease. Thus, there are SoPs for morbid obesity, but not obesity, although obesity is still a risk factor in several SoPs.

Asymptomatic incidental findings can also be problematic in terms of whether they constitute a disease. For example, hiatus hernia is often an asymptomatic normal variant of ageing and does not become a problem until there is symptomatic reflux.

The Veterans' Entitlements Act definition of disease does not specify that any particular disease classification systems must be used, although the definitions may refer to the codes set out in the International Classification of Diseases, where they are helpful in clarifying disease definitions.

Subsection 5AB(2) specifies what information can be taken to be SMSE (Box 2). Material downloaded from the Internet is often submitted to the RMA, but this may not form part of the body of evidence for the purposes of establishing causation unless it has been peer reviewed. Similarly, although claimants may submit an unreferenced doctor's letter in support of their request for investigation of a particular factor, an expert opinion alone is not SMSE.

There are also scientific constraints on decisions about causation. Although an applicant may be concerned about unspecified "chemicals" or synergistic effects of chemicals or groups of exposures, the scientific process generally does not examine risk factors in this way. Risk factors or exposures are first clearly defined and studied in isolation, so as to be certain that any effects are due to that factor alone. Sometimes, additional studies or measures of interaction are performed, but only if there is a particular reason to suspect synergistic effects.

For any given disease, known causal factors contribute to only a fraction of cases. Conversely, for many diseases, very little is known about causal factors, and there may be little or no scientific literature available upon which to make a judgement. This is particularly true of some cancers. A decision must be made on the balance of evidence available, although the decision will be subject to review when there is further published evidence.

Retrospective studies of military populations are important to understand the experiences, exposures and health status of veterans, but such studies are frequently subject to particular flaws that make assessment of causation problematic. Sometimes, they do not address causation or, if they do, the long time elapsed since the potential exposures means that accurate measurement is no longer possible. Assessment of exposure is often based on the recall of subjects, which is known to be affected by disease status. Furthermore, deployed populations in the Australian military are usually small, which limits statistical power, especially in relation to rare exposures or rare conditions.

## Evaluation of the SoP system

The RMA has now been established for 10 years, and there is evidence that the SoP system has achieved what was intended (ie, to provide a system which is more equitable, more efficient and less adversarial than before). This was the conclusion of an independent review of the RMA and the SoP system carried out in 1997 by an eminent lawyer (Professor Dennis Pearce) and an eminent epidemiologist (Professor D'Arcy Holman).<sup>8</sup> The reviewers found that claims were processed faster and at less cost, and a greater proportion succeeded at the primary level. They concluded that the ability to make a successful claim was not dependent on an ability to find a supportive medical practitioner. The consistency of decision-making was harder to determine, but there was evidence of less variability between the states. A survey of decision makers at the Veterans' Review Board confirmed that the availability of the SoPs promoted consistency of decision-making at that level.<sup>9</sup>

In 2003, there were 70 490 claims for disability and death, of which 93.2% were covered by the SoPs. The overall acceptance rate for decisions covered by SoPs was 65.2%. Service-related smoking accounts for a large part of claims accepted, but there is no liability for smoking that occurred after 1 January 1988.

## Future challenges

An essential element of the success of the SoP model has been the establishment of an impartial body of scientists to make evidence-based decisions about causation, which may not be challenged in the courts.<sup>10</sup> The RMA has a continuing need to communicate and consult with SoP users, who now include defence personnel as well as ex-service organisations. The timely production and review of SoPs is a challenge for the RMA, partly because the scientific literature is continually evolving and expanding and partly because the evidence in relation to every potential risk factor must be examined every time a disease is investigated. With the new Military Rehabilitation and

Compensation Act now in force, the RMA will need to monitor claims and assess the need for making new SoPs or for considering new factors.

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