2 Design and implementation

This chapter sets out the key elements in the design and implementation of the Validation Study. It describes the study population, the conditions being validated and the validation criteria. A description of the survey and how it was conducted is provided, as is a discussion of the problems experienced in its implementation, the effects these had, and how they were resolved.

For the purpose of the Validation Study, the definition of veteran is a serviceman who was posted to Vietnam who responded to the Morbidity Study.

2.1 Study design

In summary, the study design sought to:

- survey all veterans reporting selected medical conditions in the Morbidity Study;
- obtain the veterans' and, where appropriate, their children's consent to validate their medical condition;
- undertake the validation by surveying medical practitioners or matching reported conditions to disease or death registers; and then
- compare the number of validated conditions with the number expected based on Australian community standards as determined in the Morbidity Study.

The methods used to achieve this study design aimed to:

- ensure the comparability of the results with population-based estimates of disease in the community;
- ensure high participation rates from veterans, their children and their doctors while minimising the impact of the study upon them; and
- ensure the confidentiality of personal information used in this study.

In establishing this study design it was critical to define the criteria by which conditions would be accepted as valid. Although the specific criteria varied slightly among the conditions, the general underlying principles were the same. These principles are set out in section 2.1.4 below.

2.1.1 Data considerations

The data that were collected in the Morbidity Study by the survey firm AC Neilsen were used as the basis for the Validation Study. The Morbidity Study was a voluntary survey of the health of all living Vietnam veterans, their spouses and their children. The purpose of this study was to obtain health-related baseline data about Vietnam veterans that could be used for short, medium and longer term policy development.

Data from the Morbidity Study were transferred to AIHW by the DVA and AC Neilsen with Ethics Committee approval and are protected under the *Australian Institute of Health and Welfare Act 1987*. The original survey forms are held in a secure environment with the original data collector, AC Neilsen, and at the completion of the Validation Study will be

deposited with the Australian Archives under the custodianship of the AIHW. The electronic version of the data was transferred to the AIHW, where its has been physically and electronically secured with access restricted to those undertaking the study.

This transfer of data was declared to those completing the Morbidity Study survey by the covering letter to the veteran. This letter stated: 'At the end of the study all source data will be transferred to the Australian Institute of Health and Welfare for safe custody and, in turn, for more detailed analysis of veterans' health status.'

Data generated from this study are protected under the *Commonwealth Privacy Act 1988* and the AIHW Act. Subject to the approval of the AIHW Ethics Committee, and after liaison with the DVA to ensure that the concerns of veterans are respected, this data may be used for further analysis of veterans' health status'.

2.1.2 Selecting the Validation Study population

The population for the Validation Study is a subset of all Vietnam veterans who participated in the Morbidity Study.

The study population used for the Morbidity Study was derived from all male Vietnam veterans on the Nominal Roll of Vietnam Veterans (DVA 1997b), but excluded:

- those who died in service;
- those who died between the end of the Vietnam war and 1997; and
- those whose address could not be obtained from the electoral roll.

The Validation Study population was extracted from the population used in the Morbidity Study, but excluded:

- those who could not be contacted at their last known address or where information about them was incomplete;
- those who did not respond to the Morbidity Study survey; and
- those veterans or their children who did not have a condition selected in the Validation Study.

The Validation Study population therefore comprised 6,842 veterans and their children.

Veterans who had died between the Morbidity Study and the implementation of the Validation Study in September 1998 were identified by matching the Morbidity Study population with the National Death Index (NDI). Matching to the NDI was undertaken using automated matching algorithms or manual search. These algorithms looked for the level of match between the complete name, transpositions of name components, phonetic and common variants of name components, dates of birth and minor variations of these dates. Where a veteran was found to have a corresponding death registration in the NDI, the cause of death, date of death and place of death were recorded where available.

These deceased veterans were considered as non-respondents to the Validation Study survey, except where a death certificate or a record in the NDI provided validation for the reported condition. The children of these veterans were excluded as no address information was available to contact them and it was believed that contacting the widow of the recently deceased veteran could cause emotional distress.

There were 36 veterans whose names were not available from the Morbidity Study data, but whose condition information was consistent with the scope of the study. Though the address information for these veterans was available, it was considered inappropriate to send confidential information to the generic 'householder' in an attempt to contact them.

These veterans' conditions are treated in the analysis as 'not able to be validated' (see definition in section 2.1.4).

Veterans who did not participate in the Morbidity Study, but who subsequently identified themselves and were included in the Validation Study population, are referred to as 'new veterans'. Many of these veterans resided overseas or had incorrect address information at the time of the Morbidity Study. Conditions relating to these veterans are treated separately in the analysis of the validation results (see section 2.3.3).

2.1.3 Conditions selected for the Validation Study

The conditions selected for validation in veterans include a number of specific cancers, multiple sclerosis and motor neurone disease. For veterans' children, cancer, various congenital abnormalities and deaths were selected for validation (Table 2.1).

These conditions were selected for validation because it was considered vital that unequivocal evidence be established of the prevalence of each condition. Such evidence is considered essential as a basis for further policy action and a foundation for studies into causality (DVA 1998a).

It is recognised that one veteran or their child may have more than one condition, e.g. melanoma and colon cancer. For the purposes of the Validation Study, analyses will focus on the number and types of conditions rather than the number of veterans affected.

Table 2.1: Conditions nominated for validation

Veterans' conditions	Veterans' children's conditions
Head and neck cancer	Leukaemia
Lung cancer	Wilm's tumour
Cancer of the colon	Cancer of the nervous system
Soft tissue sarcoma	Other cancers
Melanoma	Spina bifida
Cancer of the prostate	Down syndrome
Male breast cancer	Tracheo-oesophageal fistula
Cancer of the testis	Anencephaly
Cancer of the eye	Cleft lip/palate
Non-Hodgkin's lymphoma	Absent body part
Leukaemia	Extra body part
Other cancers	Death by accident/other
Multiple sclerosis (MS)	Death by illness
Motor neurone disease (MND)	Death by suicide

A requirement of the study protocol was to separate leukaemia into its four major sub-classifications (acute and chronic lymphatic leukaemia, and acute and chronic myeloid leukaemia) and spina bifida into its two main types (maxima and occulta). These disease sub-types have distinct risk factors that may be related to particular exposures during war service. The clinically significant form of spina bifida is maxima, whereas occulta is often only diagnosed during the investigation of other health complaints, e.g. back injury. For most of these conditions, the separations were achieved. However, some validation reports were not able to be definitive on this classification.

During the validation process, it was found that a high number of the reported cancers of the colon were actually cancer of the rectum. The Study Advisory Committee decided that the cancers of the rectum should be combined with the cancers of the colon to make a colorectal cancer category. As these two cancers were not considered together in the Morbidity Study, an Australian community standard was not available. This meant that a new community standard for colorectal cancer needed to be derived. The AIHW achieved this using the computer software program called DISMOD© and the method is outlined in Appendix 16.

During the conduct of this study, it was found that the validation of MS and MND and their classification into possible, probable and definite categories was too difficult to achieve in the available time frame. This was due to the need to obtain detailed medical data rather than a simple diagnosis, with the possibility of further clinical assessment for some veterans. In order to remedy this situation a separate study is being conducted which will review clinical notes and in some circumstances examine veterans, with their consent, to validate and classify their conditions. The information on multiple sclerosis (MS) and motor neurone disease (MND) in this report is limited to those cases where a definite confirmation is evident from the information available (mostly death certificates).

2.1.4 Validation procedures

Validation of the conditions and causes of death reported in this study require them to be allocated to a validation category based on the evidence provided by a validation source.

A validation source is defined as the provider of medical information that can confirm the existence of a condition. The validation sources used in this study are:

- medical documents (e.g. pathology results)
- doctor's certification (e.g. a response to a validation study questionnaire or a standard doctor's certificate)
- records on a disease or death register.

The validation sources used in this study, the issues surrounding their use, and their application to specific conditions are described in more detail in section 2.3.

In this discussion, the term 'veteran', 'veteran's child' or 'veteran's spouse', or any other reporting source will be replaced by the term 'respondent'. This avoids lengthy repetition of the terminology and avoids the difficulty of defining who completed the Validation Study survey form and who gave the permission for validation to occur.

There are three validation categories used for this study:

Validated

A condition is considered 'validated' if sufficient information has been provided by the validation source to confirm that the condition currently exists or has existed at some time.

Not validated

A condition is considered 'not validated' where information received from the validation source indicates clearly that the specified condition does not or has not existed in the respondent to the best of their knowledge. This category also applies where the respondent and their condition does not exist on a disease or death register or where a respondent clearly indicates that they do not have the specified condition.

Not able to be validated

A condition is considered 'not able to be validated' where the validation source nominated by the respondent cannot be contacted or accessed, or where the validation source indicates that it is not able to confirm or deny the existence of the condition. A condition is also considered 'not able to be validated' where the respondent (while acknowledging one condition) fails to either confirm or deny another of their conditions reported in the Morbidity Study.

Where veterans or their children have been sent a survey form and no response has been received, the conditions associated with these veterans or their children are categorised as 'not able to be validated'.

2.2 Survey methods

Veterans, veterans' children and medical validation sources were surveyed using tailored questionnaires. The questionnaires and accompanying information (Appendixes 4–15) were drafted by the project team with the guidance of the Study Advisory Committee. The questionnaires were designed to collect or confirm key elements of information pertinent to the validation and classification of the conditions—name, address, date of birth, condition, validation source, permission to validate and consent signature.

Questionnaires sent to veterans, their children, and validation sources were personally addressed where possible. However, the initial questionnaires directed to veterans regarding their children were not personalised, as little personal information was known about these children from the Morbidity Study.

2.2.1 The survey components

The Validation Study was conducted in several stages summarised in Table 2.2 and described in detail below. This staged approach was necessitated by:

- the requirement to obtain permission from the veterans and veterans' children (where the child was 17 or over, and not under guardianship arrangements) to validate their conditions;
- the need to seek validation information from the nominated validation source or alternatives; and
- the need to raise response rates for various conditions to an acceptable level.

Table 2.2: Validation Study—survey stages

Stage	Implementation date	People involved	Information sought	Appendix no.[a]
Pilot study	15 September 1998	50 veterans	Veteran confirmation of self-reported condition, validation source, permission.	
Initial mail-out to veterans	14 October 1998	6,842 veterans	Veteran confirmation of self-reported condition, validation source, permission. Child name and details, condition/death confirmation, child address or veteran permission.	4
First reminder mail-out to veterans	23 November 1998	3,345 veterans	Reminder to veterans to complete the previously supplied survey package.	5
Second reminder mail-out to veterans	9 February 1999	3,306 veterans	Veteran confirmation of self-reported condition, validation source, permission. Child name and details, condition/death confirmation, child address or veteran permission.	6
Telephone prompting of veterans	16–26 February 1999	1,625 veterans with children, 82 veterans with MS and MND	All veterans who had not responded with living children who have conditions other than absent or extra body parts. All veterans with MS and MND.	10
Mail-out to children				
Part 1	22 January 1999	498 children	Child confirmation of veteran-reported condition, validation source, permission.	8
Part 2	19 April 1999	303 children		
Reminder mail-out to children	19 April 1999	159 children	Child confirmation of veteran-reported condition, validation source, permission.	9
Telephone prompting of children				
Part 1	1 June 1999	305 children	All veterans' children who had not returned their survey form.	10
Part 2	19 July 1999	193 children		
Mail-out to doctors for veterans' conditions:				
Part 1	29 March 1999	251 veterans	Validation of veterans' conditions via nominated doctor.	11
Part 2	25 June 1999	359 veterans		
Part 3	5 August 1999	289 veterans		
Mail-out to doctors for children's conditions:				
Part 1	26 May 1999	255 children	Validation of children's conditions via nominated doctor.	11
Part 2	5 July 1999	262 children		
Reminder mail-out to doctors	28 June 1999	364	Reminder to validate veterans' conditions.	12
Telephone prompting of doctors	5 July 1999	Related to 303 veterans 92 children	Validation of all outstanding conditions.	13
Telephone calls to veterans who had not reported all children conditions identified in the Morbidity Study	7–8 September 1999	251 veterans	Confirmation of unreported condition.	15

(a) Appendixes are located at the end of this report and contain documentation for each survey stage described in this table.

The pilot study

The purpose of the pilot study was to test the following elements:

- suitability of the survey form and supporting documentation for veterans
- data preparation and extraction
- mailing house mail merge and delivery functions
- the helpline facility
- response rates
- validation procedures.

The pilot study surveyed 50 veterans whose conditions were reported as cancer. An additional 10 'dummy' names and conditions with AIHW staff addresses were added to the list without the knowledge of the mailing house to test the quality and speed of the delivery system. The pilot survey consisted of a personalised introductory letter from the AIHW, a generic support letter from the Repatriation Commissioner, an information sheet, a number of survey forms corresponding to the number of cancers reported by the veteran in the Morbidity Study, and a reply-paid envelope. The survey forms had printed on them the veteran's name and address, his condition and an identification number.

The response to this survey was positive and therefore survey materials changed little for the main survey. No pilot of the child survey form was undertaken due to time constraints.

The Validation Study survey

The Validation Study survey comprised three separate components:

- An initial survey of veterans, asking for confirmation of any condition they reported for themselves, a signed consent to validate their condition, a validation source, and a confirmation of their contact details. A child survey form was included for each child condition reported in the Morbidity Study. While the number of conditions in the veterans' children was known, attribution of these conditions to a particular child was not possible from the Morbidity Study data. The child survey form requested information on the name, date of birth and sex of each child, and the year and place of diagnosis for each child's conditions to enable validation of these conditions. In cases where the children were aged 17 or over, the child's contact details were requested to enable contact with the child to obtain their permission to proceed with the validation.
- A survey of veterans' children aged 17 and over, seeking their signed consent to validate each condition reported by their father, the year and place of diagnosis and a validation source.
- A survey of doctors and hospitals nominated by veterans and their children as their validation source.

Lower than expected response rates to each of these surveys resulted in a number of follow-up reminders. These reminders were initially mailed out, followed by telephone contact shortly after. Details of the various mail-outs and reminders to veterans, veterans' children and doctors are described below.

Survey of veterans

(i) Initial mail-out

The initial package sent to veterans consisted of introductory letters from the AIHW and the Repatriation Commissioner, one or more survey forms directed at the veteran and/or his children, an information sheet about the study, and a reply-paid envelope. This package was distributed in October 1998, with almost 7,000 packages sent to the last known address of the veteran. A media release was timed to coincide with this mail-out. The Validation Study survey consisted of the same components as the pilot survey (Appendix 4) with some slight modifications based on feedback from the veterans. Unlike the pilot survey, this mail-out also included the veterans whose children reportedly had conditions requiring validation.

A response time of 3 weeks was allowed for the respondents. Some distribution delays (up to 2 weeks) were experienced in northern Queensland and the north-western areas of

Western Australia. All veterans in these areas, and those veterans contacting the study requiring additional response time, were given an extension.

It was discovered in this mail-out that, due to problems in the original data file, approximately 30 veterans received an incorrect form (i.e. conditions were not specified correctly) or did not receive a children's form when they should have. This problem was fixed by distributing a corrected set of forms with an apology letter.

Responses received from the veterans were entered into a database, date stamped and filed. Although the majority of veterans returned their survey forms completed, some survey packages were returned to the AIHW unopened as the veteran no longer lived at that address. Attempts were made to find alternative addresses from the DVA computer systems or from the *Telstra White Pages* (1999). This work was done by AIHW project staff only and did not involve DVA staff, thereby maintaining confidentiality of the veterans' information. Where this alternative address was also incorrect, the veteran was treated as a non-respondent. Veterans indicating they did not wish to participate in this study or any further study were recorded on the database and their condition allocated a 'not able to be validated' response.

Additional forms were also sent to veterans who had not participated in the Morbidity Study but who had contacted the Validation Study wishing to participate. These veterans were surveyed in the same manner as other veterans, and are referred to as 'new veterans' (see section 2.3.3).

(ii) First reminder mail-out

A personalised reminder letter was posted to all veterans (3,345) who had not provided responses by late November (Appendix 5). The letter referred the veteran to the previously supplied survey package and reminded him of the helpline facility. A letter of encouragement from the Minister and veterans' representatives was also inlcuded.

This mail-out also took the opportunity to supply corrected or additional forms to veterans who required them.

(iii) Second reminder mail-out

The second reminder package was sent to 3,306 veterans who had not responded by the end of January, or whose package was returned to sender. This package contained a letter from the Minister for Veterans' Affairs, with short messages of encouragement from veterans' representatives accompanied by their photographs (Appendix 6). It also contained a reissue of the survey forms, and a media release from the Minister for Veterans' Affairs.

Additional veterans who identified themselves as having one or more of the selected conditions in the Validation Study but who were missed in the original Morbidity Study, or did not respond to that survey, were also sent a package in this mail-out.

(iv) Telephone prompting of veterans

As a result of the reminder mail-outs, the response rate for all veterans' conditions apart from multiple sclerosis and motor neurone disease reached acceptable levels. However, the initial response rate from veterans about their children was below the necessary level to provide confidence in the final validation results. Consequently, the Study Advisory Committee advocated the use of telephone prompting for the purposes of improving the response rates. After Ethics Committee approval, telephone numbers were obtained from the *Telstra White Pages* (1999) for selected veterans who had not responded. In following up children's conditions, only veterans whose children were believed to be alive were

contacted, as contacting veterans whose children had died was believed to impose too great a respondent burden. All non-responding veterans who reported multiple sclerosis or motor neurone disease were also contacted.

A team of AIHW staff undertook the telephone prompting. In advance of the prompting, the staff were trained in several areas:

- the study protocols
- the database technology
- techniques in dealing with telephone prompting
- current issues of concern to veterans (study and non-study related).

This training was delivered by the study director and project officer with assistance from a senior counsellor from the Vietnam Veterans' Counselling Service. A protocol for this telephone prompting work was established to assist the staff (Appendix 10).

The telephone prompting team called approximately 700 households between 5.30 p.m. and 9 p.m. (local time) in the period 16–26 February. The telephone prompting sought to establish whether the household was that of a Vietnam veteran, whether the veteran had received the survey package and whether he had difficulties completing the survey, and to offer assistance in completing the package. The staff also offered information about the results of the Morbidity Study and reasons for the Validation Study.

The veterans generally responded positively to the telephone calls. Most indicated that they would complete and return their form soon. Some were concerned that the due date had passed, but they were reassured that their response was still required for the study. Response rates increased substantially after this prompting.

Survey of veterans' children

(i) Initial mail-out

Where responding veterans indicated that they had a child aged 17 or over, and not under guardianship arrangements, a tailored survey package was sent to the child (Appendix 8). This package sought a confirmation of the child's condition, a signed consent to validate their condition, a validation source, and a confirmation of their contact details. The survey package was sent to 792 children in January and April 1999, and to children's guardians in less than 10 cases. The AIHW also complied with veterans' special requests relating to the distribution of survey packages.

(ii) Reminder mail-out to children

A reminder package was sent to 159 veterans' children in April who had not returned their forms from the initial mail-out in January. This package contained a reminder letter addressed to the child of the veteran, an information sheet and a child survey form (Appendix 9).

(iii) Telephone prompting

Approximately 300 veterans' children who had not responded to the survey were contacted by telephone at the beginning of June with a further 200 in July. Their telephone numbers were obtained from notations on their father's survey form or from the *Telstra White Pages* (1999). This telephone prompting focused on children with all conditions excluding those with absent or extra body parts (whose response rate was acceptable) and was conducted using the protocol at Appendix 10. The response of the veterans' children was positive and had the effect of moving the response rate from 44% to 75% within a month.

Survey of doctors

(i) Initial mail-outs

In March, June and August, doctors were either faxed or posted a copy of the veterans' and children's survey responses (including their consent), together with a study explanatory letter and a short survey for them to complete (Appendix 11). The doctors' contact details, which were extracted from the veterans' survey forms and the *Medical Directory of Australia* (AMPCO 1998), were personalised on the letter and survey form, and the reported condition was printed on the form. In some instances the doctor was no longer in this listing and further enquiries via *Telstra White Pages* (1999) proved unsuccessful. These cases were allocated to the 'not able to be validated' category.

Doctors were encouraged to return the survey form, and the importance of the study was stressed. They were also offered a standard consultation fee as reimbursement of costs incurred in completing the survey, including the cost of any consultation with the patient in relation to this study. Approximately 100 doctors took advantage of this compensation.

(ii) Reminder mail-out/telephone prompting

The contribution of doctors in the validation of the veterans' and children's conditions was vital to the success of the Validation Study. Consequently, after an initial poor response rate from doctors, a reminder mail-out of the validation package was undertaken (Appendix 12). This was followed by telephone prompting of approximately 400 doctors (Appendix 13). The doctors or their office staff were alerted to the due date of the survey, to the compensation available and to the importance of the study. Doctors almost always indicated a willingness to assist with the study. The telephone prompting had a significant effect, moving the response rate from 45% to approximately 85%.

(iii) Self-validation packages

In a small number of cases veterans or their children indicated a willingness to participate in the Validation Study, but did not provide AIHW with the consent to link their records to validation sources or to contact their doctor. In these circumstances, veterans or their children were sent a self-validation package (Appendix 14). This package contained essentially the same materials as those in the doctors' package described above, but it allowed the veteran or their children to visit their doctor and complete the form with the doctor. In these cases an offer was made to the veteran or their child to meet transport and consultation costs.

2.2.2 Advertising the Validation Study

The Validation Study was advertised throughout the veteran and general community. A series of press statements from the Minister for Veterans' Affairs was released. These statements covered the study aims and its progress, called for community support, and announced the study's anticipated completion date. Each of these statements had the effect of increasing response rates. Responses were generated not only from veterans eligible for the study but also from those who were not eligible but had an interest in the study and/or the preceding Morbidity Study.

The study was also widely publicised through newsletters (*VetAffairs*, *Veterans' Health*), ex-service organisations (e.g. Vietnam Veterans' Association of Australia (VVAA), National Council and Australian Veterans and Defence Service Council (AVADSC), Returned and Services League of Australia, Vietnam Veterans' Federation of Australia (VVFA)) and on

the DVA web site. DVA representatives provided information and fielded questions relating to the study in its meetings with veterans. Veteran representatives on the Study Advisory Committee also acted as advocates for the study, as did the heads of the veterans' organisations and the Vietnam Veterans Counselling Service. Based on responses received through the study helpline (see below), there was good evidence that information about the study was disseminated effectively through the veteran community networks.

These strategies were used as a broad measure to support the survey, but response rates in particular groups needed to be raised significantly to give the study statistical validity. To provide this boost, telephone prompting of the veterans and their children was undertaken as discussed previously.

Helpline

A freecall helpline was established to provide information to veterans, their families and those interested in the survey. AIHW staff operated the helpline from 9 a.m. until 9 p.m. in the initial stages of the survey and in business hours thereafter. Over 1,000 calls were received, with 80% of calls logged before the end of March 1999. Most calls were less than 10 minutes in length, but some lasted up to an hour.

Most callers to the helpline were positive in their attitude towards the survey. Callers generally fitted into one of several categories:

- reporting other conditions outside the study scope
- reporting new conditions in the study scope
- reporting recent deaths in veterans or their children
- needing clarification on medical terminology
- providing change of address or other details
- checking on the survey return date
- seeking copies of the results from the original study
- wishing to know if a friend had received a form.

In most cases, the outcome of these calls was to send the veteran additional survey forms. In the initial stages of the study, calls were from veterans or their partners, but in the latter stages the majority of calls were from doctors wishing to confirm details about validation procedures.

The helpline had several callers who, unfortunately, were emotionally distressed and in need of further counselling. This counselling was arranged through the Vietnam Veterans Counselling Service in their local area. Occasionally, callers were angry and abusive. However, the staff had been trained to deal with these situations and in many cases the caller was placated. For the most part, callers were friendly, helpful and willing to contribute and gave the study team additional insights into their ill-health, social problems and their Vietnam service.

2.3 Validation methodology

2.3.1 Methodology for validation of conditions and causes of death

The study protocol developed to validate each study condition adopted the following criteria:

- where an appropriate disease or death register is available for the validation of conditions, then it should be used as the 'gold standard' and no further follow-up should occur with alternative sources unless ambiguities were found in the record or the registers;
- for all other conditions, validation should be with doctors nominated by the veterans or their children.

Under these criteria, the primary validation source for deaths is the State, Territory and national death registries; for cancers it is the State, Territory and national cancer registries; and for congenital malformations it is the Congenital Malformations Register (CMR). In the following sections the process of validation using each of these registers and the nominated doctor source is discussed.

Validation of death with the National Death Index (NDI) and Registries of Births, Deaths and Marriages

The NDI, maintained by AIHW, contains identifiable information for all deaths occurring in Australia from 1980. Records prior to 1980 are held by the State and Territory Registries of Birth Deaths and Marriages. Where the respondent acknowledged that the death of a veteran or a veteran's child had occurred, information on the date and place of death was provided by the respondent. Depending on the reported date of death, a comparison of the respondent's personal identifiers was made with either the NDI or a State/Territory Registry of Birth Deaths and Marriages. This comparison was undertaken using automated matching algorithms or by manual search. These algorithms looked for the level of match between the complete name, transpositions of name components, phonetic and common variants of name components, dates of birth and minor variations, sex, and place of diagnosis.

Where a death registration was identified, the cause of death, date of death and place of death were examined. If the cause of death nominated by the respondent was consistent at the International Classification of Diseases, 9th Revision (ICD-9) (WHO 1977), three-digit level with that recorded on the death registries, a 'validated' entry was made on the respondent's record. Where the cause of death nominated by the respondent was not the same as the cause recorded on the death registries, a 'validated—different cause of death' entry was made on the respondent's record. Where a respondent's report of a death was unable to be confirmed on the death registries, a 'not validated' entry was recorded.

The cause of death used by the Validation Study was the underlying cause as coded by the Australian Bureau of Statistics (ABS). This underlying cause may not necessarily reflect the nominated condition for validation, as this condition may have been listed on the death certificate as leading to death but not as the underlying cause. Multiple-cause-of-death data for Australia are available only from 1997, and therefore have not been used in this study. In some instances, this may lead to an underestimation of the number of deaths validated.

Many of the children's deaths reported in the Morbidity Study were not subsequently reported to the Validation Study by veterans, so they could not be validated unless further action was taken. The alternative for validation of these deaths was to extract data from the original Morbidity Study file which listed the veteran's surname, the birth year of his children, their sex and their State of residence. This file was then matched against the NDI using automated matching. The result of this matching was that for surnames which were common (e.g. Smith) there were many potential matches, and identifying the correct death was impossible, so these reported deaths were 'not able to be validated'. For less common names, identifying the correct match was easier and many of these could be validated.

Where the respondent's nominated details of the death were missing or ambiguous, the case was followed up where possible through the respondent's nominated doctor. Where no such doctor was provided by the respondent, an entry of 'not able to be validated' was recorded.

Validation of congenital conditions with the Congenital Malformations Register (CMR)

The CMR is maintained by the AIHW National Perinatal Statistics Unit (NPSU) in Sydney. This register contains de-identified information on major congenital malformations diagnosed in liveborn infants in the first 28 days, or in stillbirths of at least 20 weeks gestation or 400 g birthweight (AIHW NPSU 1998). However, this register contains only data relating to births since 1980, with data for 1980–1981 incomplete in coverage. All of the congenital malformations proposed for validation in this study, with the exception of extra body parts, are included on the CMR, i.e. spina bifida, anencephaly, Down syndrome, tracheo-oesophageal fistula, and cleft lip or palate.

Where the respondent reported a congenital malformation, an assessment of the date and place of diagnosis was made using information provided by the respondent. If this diagnosis date fell within the period of data available through the CMR (1982–1996) a comparison of the respondent's sex, date of birth, and condition was made with the registrations on the CMR.

If the abnormality nominated by the respondent was consistent, at the ICD-9 (WHO 1977) three-digit level, with that recorded on the CMR, a 'validated' entry was made on the respondent's record. Where the abnormality nominated by the respondent was not the same as the type recorded on the CMR, or a respondent's nominated abnormality was unable to be confirmed on the CMR, a 'not validated' entry was recorded.

Where the respondent's nominated abnormality was diagnosed outside the period covered by the CMR, or the date of diagnosis was not provided, the case was followed up where possible through the respondent's nominated doctor. Where no such doctor was provided by the respondent, or the doctor could not be contacted, an entry of 'not able to be validated' was recorded.

Validation of cancers with the National Cancer Statistics Clearing House (NCSCH) and State and Territory cancer registries

The NCSCH is maintained by AIHW, and contains data provided by State and Territory cancer registries on all cases of cancer diagnosed in Australia since 1982. However, for some States and Territories, information is available prior to 1982. Table 2.3 shows the time period covered by each of the State and Territory registers.

Where the respondent recorded that the condition they had was a form of cancer, the date and place of diagnosis was also provided by the respondent. If this diagnosis date fell within the period of data available through the NCSCH or the extended collections of the State and Territory cancer registries, a comparison of the respondent's personal identifiers was made with the cancer registrations. This comparison was undertaken using automated matching algorithms. These algorithms looked for the level of match between the complete name, transpositions of name components, phonetic and common variants of name components, dates of birth and minor variations, sex, and place of diagnosis.

Table 2.3: Cancer registry coverage

Cancer registry	Time period covered
New South Wales	1972–1996
Victoria	1982–1996, parts of 1970–1981
Queensland	1982–1996
Western Australia	1982–1997
South Australia	1977–1997
Tasmania	1978–1997
Australian Capital Territory	1972–1996
Northern Territory	1981–1996
National Cancer Statistics Clearing House	1982–1996

Where a respondent was found to have a corresponding registration in the cancer registry, the cancer type and diagnosis date were examined. If the cancer nominated by the respondent was consistent, at the ICD-9 (WHO 1977) three-digit level, with that recorded on the cancer registry, a 'validated' entry was made on the respondent's record. Where the cancer nominated by the respondent was not the same as the cancer type recorded on the cancer registry, a 'cancer—different primary site' entry was made on the respondent's record. In these cases the correct condition was then added to the respondent's record and validated. Where a respondent's nominated cancer was unable to be confirmed on the cancer registry, a 'not validated' entry was recorded.

Where the respondent's nominated cancer was diagnosed outside of the period covered by the cancer registries or the date was not provided, the case was followed up where possible through the respondent's nominated doctor. Where no such doctor was provided by the respondent, or the doctor could not be contacted, an entry of 'not able to be validated' was recorded.

Validation of conditions with doctors/hospitals/medical records offices

Where conditions were unable to be validated through any of the disease-based data collections, validation was attempted through the respondents' nominated doctors, hospitals or other medical records authorities (e.g. Central Army Records Office), hereafter referred to collectively as clinicians. This was undertaken by recording the clinician's details supplied by respondents and matching these with the *Medical Directory of Australia* (AMPCO 1998) or the *Telstra White Pages* (Telstra 1999) to confirm the practitioner's current address, telephone and facsimile numbers. Where a suitable level of information was obtained to contact the clinician, a medical validation form was sent to the clinician (Appendix 11). This medical validation form sought from the clinician a clear statement to indicate whether the respondent had ever had the condition nominated, and/or had died from a particular cause. The clinician was also given the opportunity to provide additional comment, or alternative conditions or causes of death to that originally nominated by the respondent. Where the clinician confirmed the condition, a 'validated' entry was made on the respondent's record. Where the condition/cause of death nominated by the respondent was not the same as that recorded on the medical validation form, a 'not validated' entry was recorded. If the clinician was unable to indicate whether the condition/cause of death occurred, a 'not able to be validated' entry was recorded on the respondent's record.

As a final validation strategy, DVA claims records were examined for all veterans whose conditions were unable to be validated through the various medical registers or nominated

doctors/hospitals/medical records offices. This examination was undertaken by AIHW staff, and did not involve DVA staff examining individual veteran records.

2.3.2 Issues relating to the validation of specific conditions

Veterans often reported multiple conditions. Each condition in this study was treated separately for validation purposes. Table 2.4 provides a description of the number of conditions veterans reported. It is possible that veterans may have given more than one report about the one condition in the Morbidity Study, e.g. melanoma and cancer of the head and neck, which would tend to increase the number of conditions not validated.

Table 2.4: Number of conditions reported by veterans

Number of conditions	Number of veterans
1 condition	3,884
2 conditions	1,320
3 conditions	123
4 conditions	23
5 or more conditions	3

The major reason for conditions reported in the Morbidity Study being 'not validated', was the misinterpretation/misallocation of conditions by veterans, often due to the misinterpretation of the medical terminology.

Table 2.5 provides a range of examples of this misallocation.

Some notable examples of misinterpretation/misallocation were:

- non-melanocytic skin cancer instead of melanoma
- rectal cancer instead of colon cancer
- any intellectual disability instead of Down syndrome
- scoliosis or curvature of the spine instead of spina bifida
- benign tumours instead of malignant tumours.

The misallocations were discovered from respondent notations on survey forms, on investigation of the condition with validation sources, and through discussions with respondents on the helpline.

The net result of these misallocations was to reduce the number of reports on certain conditions. However, this was balanced in part by some of these reports being reallocated to their correct condition if they remained of interest to this study. Those conditions that were discovered to be outside the scope of this study were not considered.

One of the more common misallocations was that of cancer. Whereas the validation source and the community standards refer to the primary site (or first site of occurrence) of the cancer, some veterans indicated where the metastases (or spread of the cancer) had occurred. These cases were reallocated to their primary site classification and validated. For example, a veteran may have reported bone cancer, but the primary cancer was in the lung. Some cancers were also misallocated in the Morbidity Study, e.g. mesothelioma of the pleura to lung cancer, and Hodgkin's disease to non-Hodgkin's lymphoma. In the Validation Study, these cancers were reallocated to the 'other cancers' group so as to be comparable with the community standards.

Among children's conditions, the misinterpretation of certain conditions resulted in a substantial number of conditions that were reported in the Morbidity Study not being reported in the Validation Study. This issue was investigated and resolved by telephoning veterans (where permission was given to contact veterans for further information), and asking whether any of their children had suffered the condition reported in the Morbidity Study.

Table 2.5: Self-reported conditions misallocated to study conditions

Study condition	Alternative conditions misallocated
Veterans' conditions	
Head and neck cancer	Cancer of another primary site or benign tumour, non-melanocytic skin cancer (e.g. basal cell carcinoma, squamous cell carcinoma), sun cancer, solar keratosis, sun spots
Melanoma	Cancer of another primary site or benign tumour, non-melanocytic skin cancer, sun cancer, solar keratosis, sun spots
Soft tissue sarcoma	Cancer of another primary site or benign tumour, non-melanocytic skin cancer, sun cancer, solar keratosis
Lung cancer	Cancer of another primary site or benign tumour, mesothelioma
Cancer of the colon (bowel)	Cancer of another primary site or benign tumour, cancer of the rectum, Crohn's disease
Male breast cancer	Cancer of another primary site or benign tumour, non-melanocytic skin cancer, sun cancer, solar keratosis
Cancer of the testis	Cancer of another primary site or benign tumour
Cancer of the prostate	Cancer of another primary site or benign tumour, benign prostatic hyperplasia
Non-Hodgkin's lymphoma	Cancer of another primary site or benign tumour
Leukaemia	Cancer of another primary site or benign tumour, anaemia, high white cell count, any blood disorder
Other cancers	Benign tumour
Multiple sclerosis	Devic's disease, scoliosis, atherosclerosis, cirrhosis of the liver
Motor neurone disease	Post-traumatic stress disorder, any nervous disorder
Veterans' children's conditions	
Wilm's tumour	Cancer of another primary site or benign tumour
Leukaemia	Cancer of another primary site or benign tumour, anaemia, high white cell count, any blood disorder
Spina bifida	Scoliosis, curvature of the spine, hydrocephalus, any other congenital malformation, any other spinal condition
Down syndrome	Any other intellectual disability
Anencephaly	Hydrocephalus, encephalitis, any other congenital malformation
Tracheo-oesophageal fistula	Tonsillitis, throat problems
Absent body part	Hole in the heart, missing teeth, missing vetebra or disc, missing tonsils, reduced size organs, any congenital malformation, amputation, excision
Extra body part	Enlarged organs, any congenital malformation
Cleft lip/palate	Any other congenital malformation
Death by suicide	Accident, drug overdose
Death by accident/other	Abortion, stillbirth, sudden infant death syndrome
Death by illness	Suicide

A difficult area for condition allocation was in relation to absent and extra body parts. There are no international criteria to describe the types of organs or body parts involved, or the severity of the condition. For absent body parts, the community standard used in the Morbidity study was based on 'limb reduction defects' reported in *Congenital Malformations, Australia 1995* (AIHW NPSU 1998). 'Limb reduction defects' are

characterised by total or partial absence or severe hypoplasia of skeletal structures of the limbs (AIHW NPSU 1998). To enable valid comparison with the community standard, the definition of absent body parts in the validation process was restricted to conditions of the arms and legs.

In the case of extra body parts, no community standards are available to enable an assessment of any difference in the prevalence between the general population and the veterans' children. This study took a conservative approach whereby, in order to validate the condition, it had to be a significant extra body part. These parts were divided into digit, limb, organ or system where the deformity:

- causes significant impairment or a reduction in function, or
- requires significant treatment or management to be corrected, or
- poses a significant risk to life.

These criteria therefore exclude conditions such as missing teeth or an enlarged organ.

2.3.3 'New veterans' and 'new conditions'

During the course of the study, a number of male veterans who had not participated in the Morbidity Study survey came forward to offer their information. Additional survey forms were forwarded to these veterans and subsequently to their children. These veterans, for the purposes of this study, were termed 'new veterans'. In some instances, veterans who participated in the Morbidity Study reported conditions that they and/or their children had developed since that study. These conditions were termed 'new conditions'.

Although information on 'new veterans' and 'new conditions' has been recorded in the study data systems, it has been treated separately in the analysis (see section 3.2.5) to prevent biasing the results of this study. Bias would be introduced into the results because conditions reported by 'new veterans' are not considered representative of the total veteran population. The reason 'new veterans' have contacted the Validation Study is because they have had one or more conditions diagnosed. 'New veterans' could be included in the validation results only if all living veterans not in the Morbidity Study were included in the calculation of the prevalence rate. Similarly, 'new conditions' could be included in the analysis only if 'new conditions' were obtained from all living veterans, rather than only the Validation Study population.

2.3.4 'Extra conditions'

Some veterans who participated in the Validation Study identified additional conditions that were diagnosed prior to, but not reported in, the Morbidity Study. For example, they may have reported melanoma in the Morbidity Study, but reported melanoma and colon cancer in the Validation Study. In these cases, the additional condition is referred to in the Validation Study as an 'extra condition'. If this 'extra condition' was found to have been diagnosed prior to the 1997 survey, it was assumed that the veteran 'should have' reported it to the Morbidity Study. The condition was therefore added to the reported conditions and validated for the purposes of this study.

2.3.5 Non-respondents and 'not able to be validated' responses

As with most surveys, there were a number of non-respondents to the Validation Study survey. A similar situation arose with those veterans and their children who did respond,

but whose response relating to their condition was not able to be validated. There are several ways in which conditions related to non-respondents, and those not able to be validated, can be dealt with.

Five models dealing with this issue were considered in the analysis of the results. The impact of these models is discussed in Chapter 4. Initially the Study Advisory Committee recommended a fairly general approach by reallocating both the non-respondent conditions and conditions not able to be validated proportionally between the validated and non-validated responses (Model 5). However, in reviewing the results of the survey, it was found that the non-response component was larger than expected and would have a significant impact on estimating the number of validated conditions. This model was difficult to sustain given the lack of knowledge about the likelihood of validation in this group. This lack of knowledge reduced confidence in this model, so alternatives were considered which adopted a more conservative approach. These alternatives are discussed in section 4.4. Model 3 was adopted for reporting purposes and is described below.

In Model 3 the conditions that were not able to be validated are proportionally allocated between the validated and not validated conditions as it is assumed that they would have the same distribution as the validated and not validated conditions. The non-respondents are not counted towards the number of validated conditions because not enough is known about them to make any assumption as to the distribution of their conditions as validated and not validated.

There are many explanations why veterans or their children did not respond to the survey which include:

- veterans or their children were not able to be contacted (e.g. moved residence, overseas)
- veterans were too ill or had died recently
- veterans believe they had stated their condition or that of their children satisfactorily to the Morbidity Study and should not have to do so again
- veterans or their children do not have the condition.

The first three of these explanations imply that the non-respondents were unable to return their forms and so probably had a similar distribution to the responders. Only the final explanation suggests that the non-respondents differed from the respondents in that it suggests all of the respondents did not have the condition they reported in the Morbidity Study. Because we do not know which of these explanations or combinations of these explanations are the truth, we cannot adequately redistribute this group.

The impact of this model is to reduce the number of validated conditions to a level where there is confidence in the result. It is a minimalist position, where any subsequently validated conditions from the non-respondent group can only add to the overall number of validated conditions. This ensures that conditions found to be elevated above the Australian community standard, as derived in the Morbidity Study, are in a position which would demand recognition as significant health problems in veterans or their children.

Deaths in veterans' children were treated differently to the other conditions. Since a method could be adopted that allowed the linking of the non-respondents with the NDI (section 2.3.1), then any death that could not be matched is placed in the 'not able to be

validated' category. These have been allocated proportionally between the validated and not validated responses.

Non-response to specific children's conditions

In a substantial number of cases, children's conditions reported by veterans in the Morbidity Study were not reported to the Validation Study. To resolve these anomalies, veterans were telephoned, where they had given permission to contact them again, and asked whether any of their children had ever suffered from these conditions (Appendix 15). In 90% of cases, veterans reported that none of their children had ever suffered from the previously reported condition(s) and the condition was consequently marked 'not validated'. This situation was consistent across all children's conditions. The most common reasons provided by veterans for the difference in responses between the two studies were that they had been incorrectly reported in the Morbidity Study, or that they had misunderstood the meaning of the condition in the Morbidity Study. Conditions that were acknowledged by the veterans as existing progressed through the normal validation procedures.

For those veterans not able to be contacted by telephone, an adjustment was made on a similar basis to the results of the telephone follow-up, with 90% of conditions marked 'not validated'.