

# Minimizing Bias in a Case-Control Study of Farm Injury

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**ABSTRACT.** *We report on our strategies to minimize bias in the FIRM study, a prospective case-control study of risk factors for serious farmwork-related injury. The study base is adult males working on farms in the catchment regions of 14 larger regional hospitals in one Australian state. Cases are identified on presentation to the emergency departments, while age-matched controls are recruited via random telephone survey. Eligibility criteria for cases include a maximum abbreviated injury severity score of at least 2, to minimize the potential for selection bias against those with less severe injuries treated outside the hospital system. An audit at one hospital showed that 93% of eligible patients identified in the electronic surveillance system had been approached regarding participation. Results to date show that 38% of those approached decline to have their contact details made available to researchers. Those who decline are asked to complete two key questions to enable comparison with those who participate. Control recruitment relies on telephoning regional households until an individual from the study base, satisfying the matching criteria, is identified. This process minimizes the potential for selecting against farm workers who may live off-farm. Ninety-four percent of age-matched eligible controls have participated to date. We are testing a dynamic pool of individuals identified as study base members but not matched on the first call to determine its effect on the probabilities of selection. Our strategies appear to be minimizing detection, selection, and response bias, thereby enhancing the validity of the study results.*

**Keywords.** *Agricultural injuries, Bias, Case control, Recruitment, Risk factors.*

Strategies to minimize various sources of bias are a key component of observational epidemiological studies. Detection, selection, response, and information biases, and confounding, may lead to biased point estimates of associations and hence incorrect conclusions (Rothman and Greenland, 1998). Appropriate recruitment mechanisms for cases and controls can limit the extent of many of these biases. Selection bias is a particular threat to injury case-control studies that rely on hospitals as the case source (Roberts, 1995), and recruitment of controls from the relevant study base is a challenge shared by all case-control studies (Wacholder et al., 1992).

We are conducting a case-control study ( $F_{\text{arm}} I_{\text{injury}} R_{\text{risk among}} M_{\text{en}}$  or FIRM) to identify farm injury risk factors among male farmers and farm workers. Cases are being recruited

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through hospitals, and the study base is a dynamic one. This article addresses two questions: (1) what are the potential sources of detection, selection, and response bias in the FIRM study? and (2) what mechanisms can be introduced to minimize and/or measure these biases? We describe the potential sources of these biases and the measures we have introduced to limit, or estimate, their effect. Preliminary data are presented to indicate the likely success of these measures.

## Methods

### Overview of Study Design

#### HYPOTHESIS

The FIRM study has a case-control design, which tests the hypothesis that the following farm and individual factors are significantly associated with serious farmwork-related injury among men:

- Presence of injury hazards on the farm.
- Absence of farm safety features or systems.
- History of injury on the farm.
- Major changes to size of operations, staffing, commodity prices, production methods, or equipment in previous 12 months.
- Previous personal farm injury.
- Low level of education.
- Less than 10 years farming experience.
- No previous safety training.

The study is restricted to men, who comprise 95% of fatal (Franklin et al., 2000), and 71% of farmwork-related injuries admitted to hospital (unpublished data from Victorian Injury Surveillance System).

#### *Definitions*

The study region comprises the catchment areas (defined by zipcode) of the major regional hospitals in the state of Victoria, Australia. The study base is adult males (16 years and older) working on study region farms. Agriculture is defined as crop and livestock activities classified according to the Australian and New Zealand Standard Industrial Classification (ABS, 1992) and excludes forestry and fishing. The commodity range produced by Victorian farms reflects most commodity types produced in Australia (ABS, 2003).

Cases are members of the study base who sustain a serious farmwork-related injury after January 2003. Farmwork includes paid or unpaid work related to the agricultural livelihood of the person, their employer, or relative. Serious injuries are those with an abbreviated injury severity (AIS) score of 2 or higher (AAAM, 2001). The AIS is a numerical measure of damage due to injury and ranges from 1, for minor injury, to 6 for an unsurvivable injury. It is based on anatomical location and the actual type of injury, rather than physiological measures. For example, a closed fracture of the humerus would score AIS 2, whereas a traumatic partial or complete amputation above the knee would score AIS 4. The AIS is an ordinal scale, meaning that, for example, an AIS 4 injury is not twice as severe as an AIS 2 injury. Minor injuries (AIS 1) are excluded from this study, as most of these have a very short-term impact on function and are not costly to the individual, the farm, or society. Furthermore, substantial detection bias would be introduced, as the majority of AIS 1 injuries are not treated within the hospital system, requiring either self-treatment or treatment by a family physician. Controls are randomly

selected members of the study base who are age-matched to a case within a  $\pm 5$  year age range and who worked on a farm at the time of the case injury.

### *Case Recruitment*

Fatally injured cases are recruited prospectively through the principal registrar at the Victorian Coroner's Court, where all fatal work-related incidents are reported and investigated. A letter of invitation to participate is dispatched 6 to 8 weeks after the date of death to the case next of kin, as recorded by the Coroner's Court. Advice from the Coroner's Court indicated that many families are showing interest in explanations for fatal incidents at this time, and are open to the prospect of discussing the details. Next of kin wishing to participate return the consent form to Monash University and are interviewed as proxy respondents.

Non-fatally injured cases are recruited prospectively through the emergency departments of the 14 participating regional hospitals and five metropolitan hospitals, including those with major trauma centers and those with specialist services such as microsurgery and ophthalmology, to which the 14 regional hospitals refer the most serious cases. The 19 study hospitals treat 74% of farmwork-related injuries occurring in the study region and admitted to hospitals in Victoria (unpublished data from the Victorian Admitted Episodes Database). All except four of these hospitals have an electronic injury surveillance system and contribute to the Victorian Emergency Minimum Dataset (VEMD) under an agreement with the Victorian Department of Human Services. The VEMD records details of injuries treated at hospital emergency departments according to the National Data Standards for Injury Surveillance. Each hospital is responsible for the staff training required to collect VEMD data, and the hospitals receive regular feedback on data completeness and quality. Consequently, details on the location where each presenting injury has occurred are sought as a matter of routine in each of the hospitals contributing to the VEMD.

Male patients over 16 years of age who sustain an injury on a farm are approached by hospital staff seeking approval to give patient contact details to Monash University for the purposes of contacting them regarding the study. Once consent to contact is given, the remainder of the screening and recruitment process is conducted by FIRM study staff (fig. 1). Hospital staff are unable to complete the full recruitment process of explanation and informed consent due to time constraints. FIRM study staff deliver ongoing education and training sessions regarding eligibility criteria to emergency department staff at all study hospitals, and strategically located posters remind staff of the eligibility criteria for the study and the consent to contact process.

### *Control Recruitment*

When a case is enrolled, two matching controls are recruited by telephone using contact numbers from the study areas selected randomly from the electronic white pages (fig. 2). Proxy interviews with the next of kin are conducted for controls matched to a fatally injured case. An unusual feature of control recruitment is a "dynamic pool," which was introduced as an efficiency measure. The most resource-intensive component of control recruitment is the large number of telephone calls required to identify farmers and farm workers who are members of the study base and hence eligible as controls. Eligible controls who do not age-match a case are placed in the pool for possible matching with cases occurring in the future. These controls remain in the pool for a maximum of one month after their initial contact, to ensure that controls are exposed during approximately the same season as the cases. If possible, selection of controls is made from the pool in order of decreasing time in the pool. Following this, if controls are still required for a case, then recruitment reverts to the random telephone number approach (fig. 2).

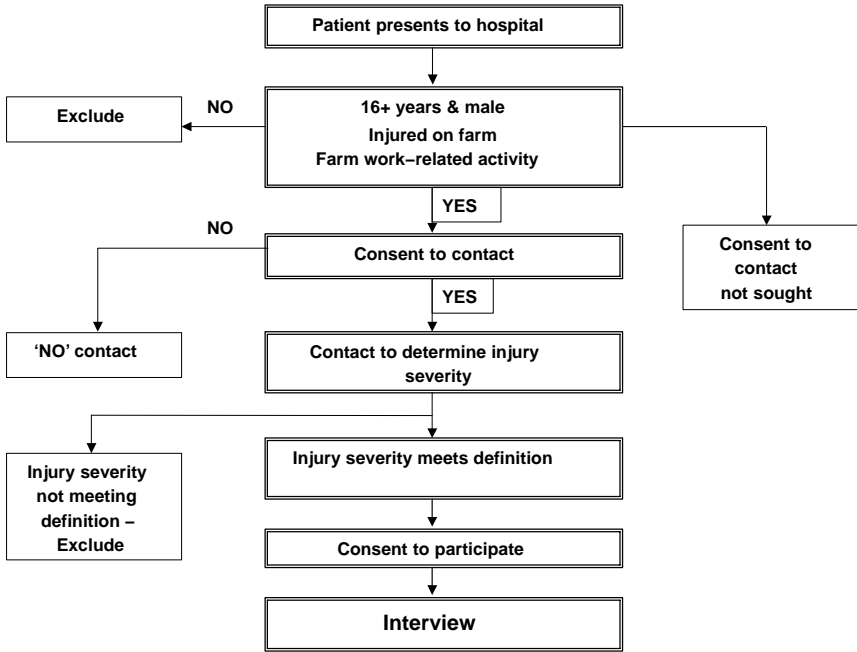


Figure 1. Recruitment of non-fatally injured cases (Farm Injury Risk among Men study, Victoria Australia).

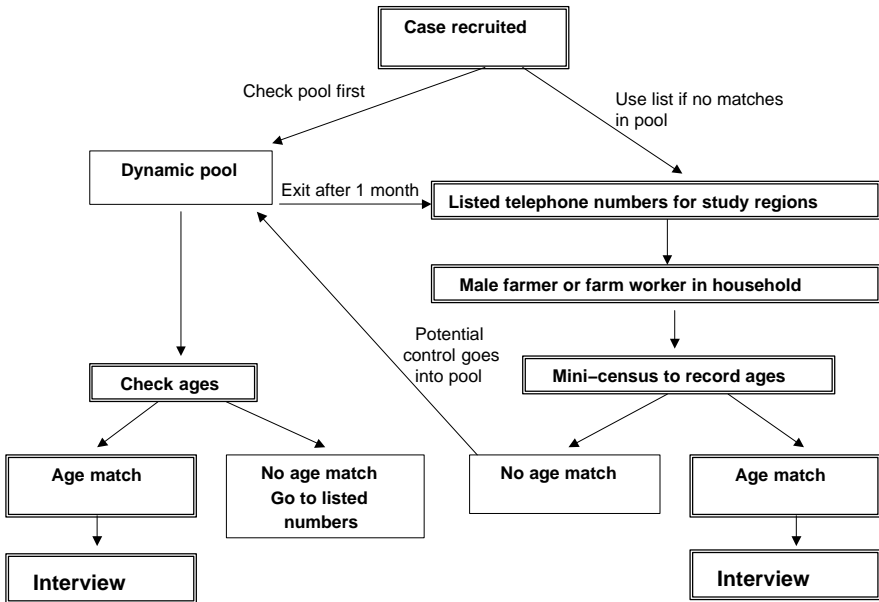


Figure 2. Control recruitment (Farm Injury Risk among Men study, Victoria Australia).

## Potential Bias in Case Recruitment

### DETECTION AND SELECTION BIAS

Detection bias may occur in non-fatal case recruitment if those with less serious injuries are treated by their family physician rather than at a hospital emergency department. This is most likely to occur for AIS 2 cases (e.g., deep laceration longer than 10 cm to the hand), as those with an AIS of 3 (e.g., fractured femur) or higher would almost certainly present to hospital for treatment. Bias could then arise if the reasons for presentation to the family physician are associated with any of the risk factors of interest. For example, remoteness from rural centers may result in family physician presentation for an AIS 2 injury rather than presentation to a more distant hospital. Remoteness may also be associated with a lower level of safety training, due to reduced accessibility to training opportunities.

The potential for such bias is being assessed by a measure of injury treatment preference administered to both cases and controls. Five common farm injuries of AIS 3 or lower, and their injury mechanisms, were identified from the VEMD. Scenario descriptions were developed from this surveillance data for each injury, including the likely level of functional impairment determined by a physician member of the study team (table 1). The scenarios are included in the questionnaire, and cases and controls are asked to select the type of medical treatment (none, local doctor or community nurse, nearest hospital) they would likely seek for each injury scenario. Comparison of case and control responses will indicate the presence and extent of this type of detection bias, the impact of which will be controlled in the analysis.

An alternative strategy for minimizing case detection bias would have been to define serious injury as having a minimum AIS score of 3. However, this would have significantly increased the time required to recruit the required sample size.

Similarly, detection bias could arise if eligible cases with more serious injuries are taken directly to a metropolitan hospital for treatment. The recruitment processes at five key metropolitan hospitals will minimize the extent of this detection bias.

Following presentation to a study hospital, recruitment is contingent upon potential cases being detected. Posters have been placed in the waiting and treatment areas of all participating hospitals in an attempt to facilitate detection. In addition, rural ambulance officers have been asked to prompt staff when delivering an eligible patient. Progress updates are provided for staff notice boards, and FIRM study staff are in regular contact with hospital emergency department staff.

Participation in VEMD may enhance detection at those study hospitals with electronic surveillance systems, since staff at these hospitals routinely ask injured patients for details of the location of their injury and the activity being undertaken at the time of

**Table 1. Injury treatment preference scenarios (Farm Injury Risk among Men study, Victoria Australia, 2003).**

1	You injured your hand so that the skin on the palm of your hand was pulled off as if it was a glove.
2	You got a knock on your head, severe enough to make you unconscious for up to an hour.
3	Your motorbike fell on your ankle and you got a bad bruising, which meant you couldn't walk, and it was still too painful to walk the next day.
4	Something very heavy fell on your forearm, resulting in an open wound through which you could see fragments of bone, and you were not able to move your arm properly.
5	You cut your shin on a sharp edge of a piece of machinery. The cut did not appear to be deep, and you were able to stop the bleeding fairly easily.

injury. Differential detection due to the electronic surveillance system will only result in detection bias if the reasons for presenting to these hospitals are associated with the study risk factors of interest. This is possibly the case for at least one hospital without the surveillance system, which is in a relatively isolated area of the state. However, the four study hospitals without the surveillance system are expected to contribute 10% of cases to the study, minimizing the impact of detection bias.

A regular system of checking the electronic injury surveillance system and following up any eligible patients who have been missed by the recruitment process has been implemented at most study hospitals. However, this relies on the location code (for farm) and activity code (for work related) being correctly completed and entered into the surveillance system. Therefore, we are conducting retrospective medical record audits of a random sample of all unintentional injury presentations among men 16 years and older to ascertain the extent to which eligible patients are not detected by either the recruitment processes or the injury surveillance system. In the one audit completed to date, records of males 16 years and older presenting for treatment of an unintentional injury over a three-month period were initially selected, and the sample was then restricted to those coded to locations which are, or could be, farms (farm, home, industrial/construction areas, other specified, and unspecified), and coded to activities which are, or could be, work related (work for income, other work, leisure, other specified, and unspecified) ( $n = 596$ ). A 20% sample ( $n = 120$ ) was then selected for manual data extraction from the written patient medical record. Each record was reviewed to determine if the injury was definitely farmwork related, possibly farmwork related (information suggestive of a farmwork-related injury but insufficient for definitive classification), or definitely not farmwork related.

### *Response Bias*

Potential response bias associated with the fatal cases will be assessed using data from the National Coronial Information System, when the coronial investigations are complete, to compare the case details for those proxy respondents who do and do not participate in the study.

There are several points in the non-fatal case recruitment process at which response bias may occur. Firstly, potential participants must consent to their details being made available to study staff. Those who decline to be contacted are asked to complete two key questions to enable comparison with those who participate. These questions capture previous personal farm injury and years of experience in agriculture, which are variables identified in an earlier pilot study as indicating increased risk of farmwork-related injury among men 16 years and older (unpublished data).

The second response bias point occurs when those who have agreed to be contacted are not actually contactable. Five attempts to make contact on different days and at different times of the day are required by the protocol. The final response bias point occurs when eligible cases are contacted and decline to participate.

## **Potential Bias in Control Recruitment**

### **DETECTION AND SELECTION BIAS**

We have used listed telephone numbers for control recruitment, rather than, for example, farming organization or farm census lists, as we wanted to recruit farm workers and contractors independently of the farm owners or managers so that employees would have an equal opportunity for participation. The study area covers a large proportion of rural Victoria, and the selection process has included farm workers and contractors living off-farm and those working on a casual basis in the agricultural sector. Detection bias may occur in our control selection process if members of the study base do not live in a

household with a listed telephone number. Australian Bureau of Statistics data indicate that 97.5% of rural households in Victoria have a telephone connection. The control recruitment process would therefore miss farm workers living in the very small proportion of households without a telephone, in addition to itinerant workers and workers living on the capital city metropolitan fringe who may travel to nearby farms for work. In order to avoid bias from this source, we can exclude cases who do not have a telephone or whose telephone number does not appear on the list used for control recruitment.

Detection bias could also arise if farm operators or workers on our list are not contactable. As for the case recruitment, up to five telephone calls are made on different days and at different times before a number is declared not contactable.

Once a household is contacted, inaccurate reporting of the status of the household as a farm, or one in which farm workers reside, is a possibility. In addition, households may terminate the telephone call before their status can be determined. The proportion of contacted households that are farms could be validated against census data, which would indicate any substantial under-reporting of farm households in our study.

Controls in the dynamic pool have an altered probability of selection compared with the controls on the main list. While likely to be relatively small, we can quantify the altered probability by monitoring the entry and exit of controls to and from the dynamic pool, the time spent in the pool, and opportunities for selection while in the pool.

#### *Response Bias*

Response bias could be problematic if substantial numbers of detected controls decline to participate in the study.

## Results

### **Case Recruitment**

#### **DETECTION AND SELECTION BIAS**

It is reasonable to assume that no detection or selection bias exists for fatally injured cases, as all are required to be reported to the Coroner's office, and all next of kin are invited to participate.

Good measures are in place to ascertain the extent of, and control for, detection and selection bias related to possible differential preferences among the cases and controls for sources of medical treatment.

Interrogation of the electronic injury surveillance system conducted at one study hospital to date has shown that 93% (37/40) of male patients 16 years and older identified in the injury surveillance system as eligible had been approached regarding participation. However, this relies on the location code (for farm) and activity code (for work related) being correctly completed and entered into the surveillance system. In this same hospital, the retrospective medical record audit results showed that 15% of 120 audited records ( $n = 18$ ) were identified as definite farmwork-related injuries, six of which had an AIS of 2 or greater and would therefore have been eligible for the study. Five of these six patients had been approached regarding participation, indicating good detection of eligible cases in this particular hospital.

#### *Response Bias*

A total of seven fatalities occurred to September 2003, and one proxy respondent has participated in the study. The National Coronial Information System has not yet been accessed for details of the non-participating fatalities; however, the ratio of fatal to non-fatal cases is expected to be low, and therefore any response bias is likely to have minimal impact on the overall study. Currently, this ratio is 1:30.

**Table 2. Number of potential cases who agreed to be contacted and who were not contactable (Farm Injury Risk among Men study, Victoria Australia, 2003).**

	April	May	June	July	Aug.	Sept.
Agreed to contact ( <i>n</i> )	32	47	61	68	83	102
Not contactable ( <i>n</i> )	6	7	10	10	10	10

We found that to September 2003, 38% (70/186) of potential non-fatal cases approached by the hospitals declined to have their contact details made available. This proportion has been relatively stable since recruitment began (ranging from 38% to 43%), despite considerable publicity of the study during May and June 2003 in the rural media and in relevant specialist publications. In an attempt to increase participation, the consent to contact form has recently been modified slightly to include an endorsement by the Victorian Farmers Federation.

Fifty-nine percent (41/70) of potential cases declining to be contacted to date have completed the key two questions, which will allow comparison with those who do participate. Conversely, this information is missing for 22% of potential cases.

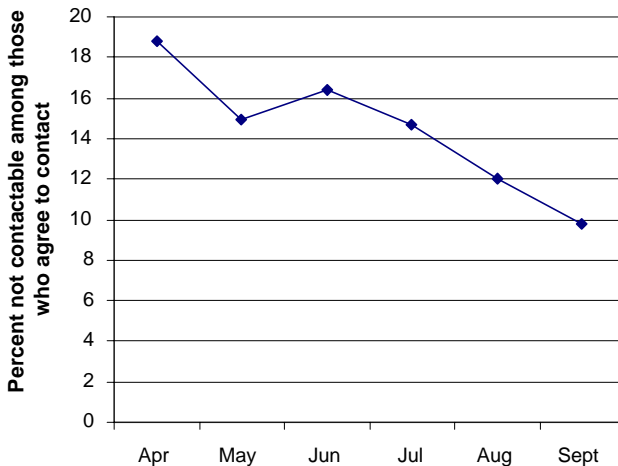
Early in the study, 19% of those who had agreed to be contacted could not be contacted. The protocol was subsequently changed to collect two contact telephone numbers, one of which is a permanent number and neither of which are for mobile telephones, which were often switched off or not responding due to the incomplete coverage of rural areas by the mobile telephone network. The contact rate has improved since study commencement (table 2 and fig. 3).

The final response bias point for non-fatally injured cases occurs when eligible cases are contacted and decline to participate. To date, 17% (20/116) of people in this category have declined.

### Control Recruitment

#### DETECTION AND SELECTION BIAS

The potential for detection and selection bias in control recruitment appears relatively low. Currently, 14% (440/3239) of valid numbers have not been contactable, and a small proportion of households terminate the telephone call before their status can be



**Figure 3. Trends in non-contactable potential cases (Farm Injury Risk among Men study, Victoria Australia, 2003).**

determined (3%, 87/2548 answered numbers). If the proportion of farms among these households is the same as those for which farm status can be determined, then 3.3% of these non-contactable households are farms or include farm workers.

The dynamic pool has considerably enhanced study efficiency. In the initial nine months of the study, 19 eligible controls had passed through the pool, ten of whom exited the pool before an age-matched case occurred. Among the nine who were selected as an age match, seven were interviewed as control participants, and two declined to participate when re-contacted. These seven controls comprised 22% of all controls recruited at this time. Each control recruited via the dynamic pool saves 83 phone calls, and 4 hours of staff time. At this point, the dynamic pool has therefore saved 581 phone calls and reduced the time required for control recruitment by 28 hours.

### *Response Bias*

There has been a relatively low level of non-response among the potential controls to September 2003. We have contacted 2635 households for which farm or farm worker status has been determined, and detected 87 farms or farm worker households. Eighteen percent (16/87) of confirmed farms or farm worker households have declined to participate before proceeding to the age-matching step, and 6% (3/46) of age-matched eligible controls have declined to participate.

## Conclusion

Mounting a case-control study represents some significant practical challenges. Principal among these is minimizing bias. We have put in place a number of safeguards to prevent bias in recruitment for the FIRM study. Where bias is potentially present, we are collecting data with the aim of quantifying the likely magnitude of the bias and making appropriate adjustments at analysis. Thus far, detection and selection bias in the FIRM study appear to be minimal.

Most cases seem to be detected by our systems and are approached for participation. The most significant issue for case recruitment is the potential for response bias, primarily arising as a result of potential cases not giving the hospitals permission to provide their contact details to Monash University. Anecdotal evidence from FIRM study staff undertaking recruitment suggests that general concern regarding security of contact details, and a specific concern regarding potential investigation by regulatory authorities, are key barriers, combined with hospital staff having inadequate time to describe data security measures that may reassure potential participants. This need for the hospitals to seek permission is a consequence of the Victorian Health Records Act 2001, which was fully promulgated just prior to study commencement. We are holding discussions with the Health Services Commissioner to identify more efficient screening mechanisms that are compatible with the Act. Other researchers in Australia, and in the U.K., have also noted that provisions of health records and privacy legislation, while intended to protect the privacy of health information, have the potential to significantly impinge on research quality (O'Grady and Nolan, 2004; Peto et al., 2004).

Similarly, procedures for control recruitment in the FIRM study are ensuring minimal detection, selection, and response bias. Systems are in place to quantify the impact of the dynamic pool on probability of selection for controls.

There are many points at which bias can arise in case-control studies. Systems to minimize, monitor, and measure these biases have the potential to enhance the validity of the study results.

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