Methodological challenges in rural road safety case-control studies.

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Abstract

A case-control study of serious crashes in an extensive rural area of North Queensland, Australia, is currently underway. Planning for the study took several years to bring to completion. Its original design involved interviews with persons admitted to major hospitals in the region as a consequence of a traffic crash and with drivers recruited at the roadside optimally at or near the same site one week later. To date this is the plan that has been followed, although problems with roadside recruitment have been encountered.

We propose to examine several issues which arose, and continue to arise, in the process of designing, piloting and execution of the study. Operational definitions of concepts such as "rural", "remote" and "serious", and unanticipated methodological and practical challenges involved in recruiting a comparison series will be explored. We will also present some of the many ethical, legal, organisational and logistic complications which we faced and still face in mounting such a study and the solutions proposed and subsequently employed to overcome them.

INTRODUCTION

In an exhaustive literature review Edmonston and co-workers concluded that "most road safety interventions are designed for urban environments and subsequently extrapolated to rural and remote areas. Due to major cultural differences, these … have not achieved the same level of success…" (Edmonston et al, 2005; see also FORS, 1995.) What is not so clear is whether in addition to cultural factors, there are differences between urban and rural regions in the constellation of risk factors contributing to traffic crashes. Clearly the three well-recognised factors, alcohol, speeding and fatigue, must play a role, but their relative importance may not be the same in the two environments, and there may be additional unrecognised factors present in the rural and remote setting as well.

It seems generally accepted that in the developed world rates of serious crashes, however defined, are higher on rural than on urban roads, whether per head of population or per total distance travelled (OECD, 1999), and this paper assumes this to be so. However, this perception, coupled with the recognition of possible cultural and etiological differences, was what motivated CARRS-Q and its principal funding source, the Motor Accident Insurance Commission of Queensland, to initiate planning early in 2000 for a case-control study of serious traffic crashes in a rural area of the State. Subsequently several State departments joined the Commission in a funding consortium. The design in outline was simplicity itself: recruit and interview cases in hospital following a traffic crash, and matched controls at the roadside on the same day of the week and at the same time as the crash one week later. Pilot recruitment of hospitalised participants commenced towards the end of 2003 and the study proper in March 2004.

This paper will present and discuss a few of the many methodological problems which arose at various stages during planning and execution, hoping thereby to illuminate and clarify some of the issues inherent in rural road safety research. Firstly, we discuss the concepts of rurality and remoteness; in our study, outside circumstances dictated the pragmatic approach

of excluding crashes which occurred within the urban areas of major towns. Secondly, having defined the cases as persons hospitalised for at least one day in consequence of a traffic crash, we present some of the ethical , privacy and confidentiality issues arising, notably the need to protect any sensitive behavioural information from outside scrutiny, and indicate how they were dealt with. Finally the problems of defining and recruiting a suitable control series of road users are raised, and the various approaches to their solution in the case of motor vehicles, none entirely satisfactory, described. (For pedestrians and pedal cyclists, the issues have not yet been confronted.)

Since this is to some extent a work in progress, we welcome suggestions and contributions from the floor.

STUDY AREA

We selected the northern part of Queensland as target region because of the Centre's previous research activities there and because of the existence of a well-established university (James Cook) in the largest city therein (Townsville), with associated academic units and staff in the second regional city (Cairns). Townsville and its suburbs had a population at the 2001 Census of almost 130,000; Cairns a population of 108,000, while just over 20,000 persons were then resident in Mount Isa, a mining town in the west of the region. Each of these three cities has a well-staffed and adequately equipped hospital, Townsville being the major tertiary centre for referrals. The entire region is 661,335 square kilometres in area and had in 2001 a population of some 454,000 persons, 11.3% of whom were classified as indigenous Australians.

DEFINING "RURAL " AND "REMOTE"

It would appear that much effort has gone into attempting to find widely acceptable definitions of "rural"(see e.g. a discussion paper from Statistics Canada issued in December 2002) There appear to be two main measures used in devising definitions, namely population density and proximity to and/or interaction with a conurbation, sometimes employed separately, sometimes jointly. Both rely on the existence of well-defined basic localities, variously described as, for instance, enumeration areas, counties, "communities" and the like, with known areas, populations and sometimes other characteristics such as patterns of travel and commuting. For various reasons but principally because of the way local authority areas are delineated and their populations enumerated, these are less appropriate to Queensland outside the South-East conurbation.

To a large extent, the underlying purposes of the classification will determine how rurality is defined; for instance, a definition appropriate to the provision of health or other services may be less useful for the purposes of traffic crash research. In the latter case road characteristics should perhaps also be considered – is, for instance, a major trunk road with attendant services (food, fuel, accommodation) running through a sparsely populated rural area to be placed in the same class as a local road in a similar region? Availability and speed of retrieval services in the event of a crash could be another relevant consideration.

Australian attempts at an acceptable classification of regions as "rural" or "remote", primarily for the purposes of health service delivery, have resulted in firstly the Rural and

Remote Area classification, subsequently modified to the Rural, Remote & Metropolitan Area classification (DPIE, 1994). The latter considers "metropolitan areas" to be cities with > 100,000 inhabitants, "rural zones" to contain large, small and other centres (25,000-<100,000, 10,00 - < 25,000, < 10,00 inhabitants, respectively), and "remote zones" to be composed of small (> 5000 population) and other areas. For smaller areas, an "index of remoteness" in terms of population density and distance from larger towns determines whether they are rural or remote. This is particularly useful as a method of giving classificatory authority to research or service delivery based on a more pragmatic approach to "rurality". A subsequent Australian index (ARIA, Department of health and Aged Care, 2001) uses "road distance from the closest service centre" to classify regions, with a later refinement based on census collection districts. One transport-related measure defines rurality on the basis of speed limits, but the prevalence of expressways within urban areas clearly undermines this approach.

Finally from the perspective of health promotion, including targeted road safety interventions, a definition based on the existence of a rural sub-culture with distinct attitudes to health care and traffic safety would be desirable (see e.g. Veitch 1995), if difficult to implement.

In practice, rurality was defined for the purposes of this study by the insistence of several members of the funding consortium that the two largest towns in the region be excised from the study area. The boundaries of the urban areas were as defined by the Australian Bureau of Statistics "Statistical Districts" even if these were not entirely coterminous with the local government boundaries. Crashes occurring in the third, smaller city or in the minor country towns in the region were hence implicitly defined by the study protocol as rural crashes, as would those outside but close to one of the large cities. This would accord with some definitions of rurality but not others.

While the entire region outside the two urban areas formed the nominal catchment area of a wider study, for the purposes of the case-control element, only crashes occurring within 100 kilometres of six designated hospitals were deemed to be eligible. Three of the latter were the major public hospitals in the three cities mentioned above and the remaining three were subsidiary hospitals included mainly in order to widen the area in which control drivers were to be recruited. These limits were a compromise between inclusiveness and accessibility.

CASES

Case definition

As mentioned above, the study was concerned only with serious crashes. Queensland Transport recognises five levels of crash severity: property damage only; minor injury; medical attention; injury requiring hospitalisation; and fatal, the level being defined by the most severely affected occupant in any involved vehicle. Other jurisdictions in Australia employ this classification or modifications thereof. Clearly the lowest two levels could not be considered serious, while injured vehicle occupants not treated in hospital would be virtually impossible to ascertain and access with any degree of completeness. We therefore adopted the working definition of a serious crash as one in which at least one involved person was admitted to hospital for at least 24 hours for injuries sustained in the crash. (Patients

retained in hospital beyond 24 hours for pre-existing medical or psychiatric conditions would not meet the criterion.)

It is clear that a wide range of injury severity could be covered. Lightly injured persons admitted principally for 24 hour observation would be included, whereas individuals with, for instance, long-bone fractures which could be treated to discharge in less than a day would not. However twenty-four hours is barely enough time for study staff to identify, locate, approach and interview potential subjects in a large and busy hospital, even if the interview itself could occasionally be arranged to take place post-discharge.

In a study aiming to be comprehensive, a number of crash types and victims must be included. We identified five classes of subject: motor-cyclists, drivers of other motor vehicles, passengers (including pillion passengers), pedal cyclists and pedestrians, each of which required a specifically designed questionnaire, with the possibility of a sixth class, long-distance truck drivers, being added if experience suggested the need.

Ethical and confidentiality issues

Questionnaire design and piloting for specific road user subgroups, while laborious, is conceptually straight-forward. Issues of privacy and ethics were more troublesome to resolve. Government privacy legislation seemed to indicate that even the presence of a trauma in-patient in the hospital, much less his or her identity or reason for admission, could not be revealed to researchers without the approval of the individual concerned. This necessitated a cumbersome procedure whereby a hospital employee, usually an attending nurse, would approach a suitable patient, judged well enough for interview, to request formal permission for a further approach by a study interviewer, who could only then seek informed and signed consent to participate. This inevitably tended to be seen by hospital staff as merely another chore, and, not surprisingly, the response rate in the pilot phase was unacceptably low. Discussions with hospital management led to modifications which largely avoided this, but the potential for missing eligible subjects is always present. There would no doubt be an element of randomness in such events, so the implications for bias may not be severe.

Some topics covered in the interview inevitably touch on sensitive issues of potentially illegal driving behaviour, including speeding and substance abuse, in the lead-up to the crash. During the interview this section is to be completed, where applicable, by the interviewee out of sight of the interviewer, placed in a sealed envelope and appended to the remainder of the instrument (ref to drug research). All questions in this section have pre-coded answers to minimise effort. Problems could arise with illiterate subjects or those unable to record their responses by reason of injury. In practice, many respondents in hospital preferred that the interviewer complete this section openly. On the other hand, indigenous persons are sometimes understandably mistrustful of authority and disposed to baulk at revealing sensitive information even with the proposed mechanism – or indeed unwilling to participate at all.

A more troublesome consideration is the possibility of legal action to access this information on the part of outside parties such as insurance companies or the police. While admissions made during such an interview are unlikely to be regarded as evidentiary on their own, it is conceivable that they could be compromising if taken together with other sources of evidence. Apart from ethical considerations it is important that those being interviewed can be assured of total confidentiality to maximise the chances of accurate reporting.

Consultations with a variety of legal sources could not establish whether information conducted in the course of research was protected against court subpoena. The solution we arrived at was to sever all connection between subjects' names and study numbers as soon as possible, and at most a week after interview, despite any inconvenience to the process of linking interview data to external sources of information, in particular police and ambulance service records. Names of participants would still of necessity be retained on signed consent forms, but it seemed unlikely that courts would allow litigants to trawl through these in an attempt to identify (perhaps by date and site of crash) any specific individual.

Linkage to the outside sources mentioned above raises other confidentiality issues; it is unlikely that police or ambulance records identified by name could be released to the study. However certain details – site, time and date of crash, make and colour of vehicle – would usually be common to outside records and interview data and could if necessary act as a linking mechanism.

CONTROLS

Case-control design requires that the reference group, to whom the set of cases – those experiencing the event under study – are to be compared, be representative of the population from which the cases are drawn. Unless a study is nested within an already available population sample, this is usually a counsel of perfection, seldom completely achievable in practice. When the method of recruitment of the reference group falls short of the ideal, the researcher must either demonstrate effective representativeness or attempt to correct for the biases introduced by whatever elements of non-representativeness can be identified.

In the present case, the population from which individuals involved in traffic crashes (other than passengers) are drawn would presumably be individuals of similar road user type (vehicle controllers, pedestrians, cyclists) passing the crash site at or near the same time and in the same direction. As a surrogate, drivers passing the crash site at or near the same time of day one week later, i.e. on the same day of the week, and in the same direction, could serve. As mentioned above this, in principle, is the design we initially adopted. Immediately a multitude of practical considerations presented themselves. We discuss here some of the more difficult issues. Note that controls for crashes occurring off public roads, which form a non-negligible proportion of vehicle crashes in rural Queensland, are clearly impracticable if not impossible to obtain, with the possible exception of private roads connecting mine sites to the public road system.

Sample size

To maximise statistical power to detect difference between the case and the control series it is important to have as large a sample as feasible. Typically, and as here, cases are in limited supply, whereas at most crash sites there should be dearth of control drivers or other required road users. Statistical theory shows that beyond three or four controls per case, the utility of collecting more control subjects falls off rapidly, and three to four control subjects per crash was our stated target in each relevant direction. We return to this issue below.

Issues specific to drivers and motorcyclists.

1) The matched crash site: According to the original design, research assistants were required to determine early in the interview whether the crash in question fell within the requisite catchment area firstly for the wider study and secondly for the case control study – not always straightforward even with detailed area maps being provided. Local residents should be able to describe the crash location with accuracy, but travellers from a distance may not. This information can often be confirmed with police and ambulance staff if confidentiality and time considerations can be overcome. If names cannot be used, vehicle characteristics could serve to identify the site of vehicle crashes.

Once it has been established where the site is and whether it falls within the area for control recruitment, an appropriate roadside area safe for stopping and interviewing must be identified. Many roads in the region will be winding and/or without wide, firm verges. Research into road safety cannot reasonably endanger road safety – and would not be permitted to do so by police and local authorities. Thus suitable data collection sites could well be some distance away from the location of the index crash.

Distance of recruitment site from crash site is of little consequence if the majority of vehicles passing the latter would of necessity also pass the former. This implies that there should not be a well-used public road intersecting the road on which the crash occurred between crash and recruitment site, nor a large number of entrances to private property. Recruited vehicles which turn out not to have passed the crash site can be screened out; however, vehicles passing the crash site which do not reach the recruitment area would be lost. A further complication would arise in the case of multiple-vehicle crashes, when controls would often have to be sought in opposite directions. Ideal sites would be in most areas be the exception rather than the rule. Clearly, more than the target number of drivers would need to be recruited at each site.

2) Ethics and confidentiality issues are similar in most ways to those discussed above in reference to crashed drivers, with one important difference. If an interviewer becomes aware that a driver has, say, been drinking heavily or is otherwise driving unsafely, “duty of care” would suggest that an effort, however futile, be made to prevent them proceeding, even perhaps to the extent of notifying the police. This would seriously undermine the study in many ways. Thus the sealed-envelope device, preventing the interviewer from learning of such behaviour until much later, becomes vital. Names of drivers need not be recorded, and telephonic follow-up would require only a telephone number and, say, a first name or nickname linked to an assigned identification code, to be destroyed immediately after contact.

3) Recruitment: It was originally planned to use the police to stop drivers at the selected site and invite them to participate, emphasising the voluntary nature of the exercise. While some local police commanders were prepared to take part, a headquarters’ scrutiny of the act determining police powers revealed that police were not permitted to stop vehicles for purely research purposes. Furthermore, one ethics committees had been apprehensive that having the police stop drivers was tantamount to “coercion”, but had tentatively sanctioned the practice conditional on the results of preliminary on-site research demonstrating that recruited drivers had not felt under undue pressure to participate.

Being able to bring vehicles to a complete halt before inviting their drivers to take part in the research would almost certainly been conducive to obtaining the maximum response rate.

Even drivers anxious to continue their journeys might have agreed to a telephone contact at some convenient later time. If drivers could not be stopped could they at least be slowed down? Various alternative strategies were considered. It had been thought at one time that the presence of an ambulance (preferably one no longer in routine service) and (off-duty) ambulance personnel would encourage drivers to stop, possibly together with "slow" signs wielded by traffic controllers. These are persons with some training who are empowered to direct and slow traffic at, for instance, road works or near major sporting events. Political and practical considerations soon led to the abandonment of the ambulance and traffic controller plans.

An examination of the location of crashes during the pilot phase revealed the prevalence in the area of service stations, suggesting that their operators be requested to allow their forecourts to be used as recruitment areas. This has proved acceptable to most. To encourage participation a $10 voucher redeemable at site is offered. Recruitment also took place at designated rest or vehicle inspection areas and similar public access sites. Drivers were invited to stop and participate by means of fixed signboards and, for a time, an electronic variable message sign hired for the occasion. These indicate that a university research site was ahead, and invite voluntary participation.

All these procedures yielded an unacceptably low response rate. Research staff reported that the length of the questionnaire was one factor. It could not be assumed that responses from compliant drivers, many of whom had stopped to rest or obtain fuel, were free of volunteer bias and representative of the source driving population. It was decided to abandon the matching study design after approximately 100 such participants had been recruited in this way and interviewed. However, a valid comparison series of drivers and motorcyclists is still needed.

It was suggested by members of the study advisory group that drivers of vehicles brought to halt at scheduled road works could be approached to agree to short interview with possible telephone follow up. Fresh ethics approval and the consent of the authorities responsible for the road works would need to be sought for this tactic. Initial discussions revealed a lack of official and research team enthusiasm for this procedure.

There have been other studies which have recruited vehicle controllers at the roadside. Two from Australasia (Haworth, Wells et al, 2004) have stopped motorcyclists for the purpose of interview, but their published reports do not describe in sufficient detail the procedures for persuading motor-cyclists to come to a halt. Both studies photographed all passing motorcyclists including those who failed to stop. This was in order to "record basic data for all" in one instance, and to note the conspicuity (sic) of their clothing in the second. Several North American studies involving roadside interviews and one from Australia have made use of police staff to bring passing motorists to a stop (Dussault et al 2000, Haworth et al 1997, Blomberg et al 2005), with satisfactory response rates. As mentioned above, we were debarred from so doing. Queensland and more recent Australia-wide privacy legislation would also preclude the use of license plates as a means of identification and subsequent contacting of passing drivers.

It is clear that case-control studies for which a police presence at the roadside was not possible have had to resort to less satisfactory means to recruit controls. This raises the question as to whether the resulting samples could be in any sense "representative of the population from which the cases are drawn". On the other hand it can be argued that,

whatever disclaimers attendant police officers may give, their (distant) presence may colour drivers' responses to sensitive questions about driving practices. Different law-enforcement cultures, including rules about admissibility of evidence, may elicit different reactions to police presence. Nonetheless, even with this caveat, we believe that a high response rate is preferable to the volunteer bias inherent in recruiting drivers either stopped for the purpose of rest or those prepared to stop at the roadside for research purposes.

One study of the prevalence of illicit drug use in drivers in North Queensland conducted by the CARRS- Q collected salivary swabs from drivers downstream from a police RBT site. The approval and cooperation of local police authorities was crucial to this methodology, which yielded a satisfactory response rate. At the time of writing the feasibility of this approach to obtaining a control series, coupled with a drastically shortening of the questionnaire, is being examined.

Another possible approach?

If it could be shown that a shortened form of the study instrument would result in a much higher response rate from drivers or riders stopped to refuel at petrol stations, would such a recruitment procedure also yield a usable control series? Periodic refuelling is an obligatory activity for motorists, and in the designated recruitment areas the great majority of fuel purchases would be at such outlets. (In more remote areas, many drivers might maintain bulk fuel stores on their property.) On the basis that the necessity to refuel is a random event in time, although not necessarily in location, could a procedure, possibly incorporating a random element, be designed to exploit this fact? Would it be necessary to exclude certain respondents who, for instance, set out from base only to refuel? A crucial item of information collected from drivers is the average amount of time they spent on the roads, local and remote, in a unit period, to enable re-weighting during subsequent analysis. In this case as well many more drivers or motor –cyclists would need to be recruited than the planned control-case ratio would suggest, with fixed and appropriate a priori rules for subsequent winnowing.

Pedestrian and pedal cyclist controls.

As far as the pedestrian component is concerned, it is questionable whether the "source population" alluded to above actually exists in any usable fashion. Virtually everyone able to do so walks at one time or another on public roads or footpaths. This is one unresolved issue. As to cyclists, a "source population" might well exist, but it is far from clear how to set about accessing it. Even though stopping cyclists safely is less of a problem than is the case with motor vehicles, recruitment at the crash site a week later is an option which is unlikely to prove feasible in practice.

CONCLUSION

What will be clear from the above rather discursive overview is firstly that the most careful planning is needed for this type of research in rural areas, and secondly that in most instances, even careful planning will not be enough. One general problem not dwelt on is the fact that universities and government departments are usually located in cities whereas the study area can be at some distance away, with all the opportunities for poor communication and misunderstandings that this entails. We have highlighted some of the difficulties we

encountered, and continue to encounter, which may at least alert future researchers to the need to prepare for something similar. It hardly needs remarking that each study area will have its own cultural, administrative, political and geographic circumstances, which will give rise to its own unique challenges.

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