METHODOLOGICAL ISSUES

Introduction: The Scientific Basis for Injury Control

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Archie Cochrane was a British epidemiologist whose guiding motto was, All effective health care should be free (1). While there is a spectrum of availability of health care across nations of the world, there is increasing unanimity on the need to base what is done on scientific evidence of effectiveness. This movement to evidence-based medicine has expanded beyond the boundaries of traditional personal health care and now includes efforts in nursing, public health, the social sciences, health policy, and health management. In these fields, application of scarce resources to accomplish the greatest good demands that only effective interventions be implemented.

This is certainly true of the field of injury control. The magnitude of the problem is very large, and resources devoted to prevention, treatment, and rehabilitation of trauma are scarce. The argument that an intervention is worthwhile if it “can save just one life” is specious. The same resources applied to an effective intervention might save one hundred or one thousand lives. Moreover, the potential to do harm by implementing ineffective interventions is great. For example, the Cambridge-Somerville Project was an ambitious randomized controlled trial to prevent juvenile delinquency, violence, and injury (2). Social workers were assigned to visit families of intervention group participants monthly for a mean of 4.5 years to provide concrete services to high-risk boys and to act as their advocates with schools, courts, and other official agencies. When these boys were followed into adulthood, the rate of crime, violence, and untimely death in the intervention group was found to be higher than that in the control group. In another example, treatment of severe traumatic brain injury has traditionally included control of increased intracranial pressure through hyperventilation. However, when subjected to a randomized controlled trial, hyperventilated patients were found to have worse outcomes than patients not undergoing hyperventilation (3). The hazards of doing the wrong thing are great.

In this article, I discuss application of evidence-based medicine to the field of injury control and use of the methodologies described in this volume to further advance research.

FRAMEWORK FOR CONSIDERING SCIENTIFIC EVIDENCE

The conceptual model in figure 1 can provide a framework for examining application of scientific evidence to the field of injury control. Reducing deaths, productive years of life lost, and morbidity from trauma requires much more than primary prevention. It also requires attention to the medical care of the injured patient and long-term rehabilitation to return that person as much as possible to his or her preinjury potential.

Etiologic research entails understanding the causes of injury and the resulting morbidity and mortality, with the goal that removal of this cause can either prevent the injury or prevent its consequences. Etiologic research is the guiding scientific basis for everything downstream in this model, forming the basis for intervention programs and ultimately their effect on outcomes. Etiologic research, when viewed in the context of the broad paradigm of injury control, is necessary in a number of areas. Included are risk and protective factors in the classic epidemiologic dimensions of the host, agent, and environment. Biomechanics research investigates the human tolerances to energy transfer and injury that result when energy exceeds these thresholds. If this energy transfer does occur, understanding how the human organism responds can lead to interventions to modulate that response to improve outcomes.

Understanding the etiology of injury and the damage to the organism should guide development and evaluation of inter-
vention efforts. These interventions can be in the form of primary prevention programs such as safe storage of guns or use of bicycle helmets. Changes in the construction of motor vehicles have been guided, at least in part, by biomechanics studies of injured people, supplemented by dummy tests and computer modeling (4). Interventions to modulate the inflammatory response to trauma have been guided by results of basic science studies in molecular biology (5).

The ultimate goal of injury control efforts is to improve outcomes—both fewer injuries and improved outcomes for those injured. Therefore, the effectiveness of prevention programs must be gauged by the proportion of people practicing the intervention behavior and by how many injuries were prevented. The outcome of intervention trials in clinical care must be judged on improvements in functional outcomes, such as return to work or school, and the cost-effectiveness of these interventions.

This article attempts to relate how the methods described in the subsequent articles in this section can be used to address the current needs of the injury control field for etiologic research, intervention research, and outcomes research.

**ETIOLOGIC RESEARCH**

Identification of injuries is the first step in determining their causes. The goal of injury surveillance is to provide accurate, unbiased information on who is injured, the circumstances of the injuries, the use of protective devices (or the lack thereof), and the outcome. Horan and Mallonee (6) give us a wealth of information on various surveillance systems capturing injury data. However, it is important to recognize that the representativeness of the sample and the quality of the data vary tremendously from one system to another. For example, the accuracy of information on seat belt use in emergency department data is likely much lower than that in the Crashworthiness Data System, in which seat belt use is determined by investigators examining the vehicle after a crash (7).

It is important to recognize that surveillance systems are very expensive to maintain on an ongoing basis and that much information can be gained at far less cost from linkage of available databases. This linkage has been the basis for the CODES projects funded by the US National Highway Traffic Safety Administration (8). Linkage has also been used very successfully by many injury control investigators. For example, Cummings et al. (9) used the Fatality Analysis Reporting System, the General Estimates System, and a database of air bags in vehicles linked to their vehicle identification number to determine the effectiveness of passenger air bags in preventing deaths in crashes.

After having determined the number of injuries, we need an accurate denominator to calculate injury rates. Many studies simply use person-years from census data. However, exposure to risk of injury is far from equal across the population. Individual measures of exposure are necessary to calculate accurate rates and provide a theoretical model for considering the individual risks of injury.
The next step in etiologic studies is to determine the role of risk factors in injury occurrence (or prevention). Randomized controlled trials would provide the best information but often are impossible to conduct, especially when examining risk factors for injuries. Few persons are likely to agree to participate in a randomized trial of, for example, gun ownership and its effects on suicide in the home. Therefore, observational studies may be the only option. In conducting traditional cohort studies, the investigator would collect outcome data on all those persons exposed and all those unexposed to the risk factors. If the outcome is rare (e.g., death in a motor vehicle crash), such studies would entail collecting data on a very large group of persons. Cummings et al. (10) elegantly describe in this volume an uncommonly used study design—a matched-pairs cohort study. This design dramatically increases study efficiency because it eliminates the need to collect data on pairs in which neither member has the outcome of interest (e.g., death). Cummings et al. (9, 11, 12) have used this design to great advantage in injury research.

The network of risk factors that produce injuries is complex and, in most cases, involves the community in which the person lives. The “eco-epidemiologic” approach can take into account the interaction of population and environmental factors on the persons to enable better understanding of injury risk and etiology.

INTERVENTION RESEARCH

The goal of etiologic research is to guide development of intervention programs to prevent injuries and their consequences. Interventions can be successful in accomplishing this goal only if they have been shown to be successful at least under ideal, experimental circumstances. While this step does not guarantee successful implementation, without it the hopes of reducing injuries are fruitless.

Over the last decade, a number of attempts have been made to critically examine the evidence for effective interventions in all phases of injury control: prevention, acute care, and rehabilitation. These interventions have been summarized in a variety of places, including the Cochrane Library, supplements in the American Journal of Preventive Medicine (13–17), and the peer-reviewed literature. Trauma surgeons and neurosurgeons have made great efforts to develop evidence-based practice (18, 19). The evidence base in the rehabilitation field is scanty, especially regarding rehabilitation of patients with traumatic brain injury (20). Interventions for further systematic review have recently been suggested (21).

Once implemented, programs must be evaluated, as described by Doll et al. (22) in this volume. Program evaluation is necessary to satisfy funders and to keep members of community coalitions interested. More importantly, it provides the opportunity to continually improve the effectiveness of the intervention to accomplish its goals. Rapid cycle improvement and evaluation, especially as espoused by the Institute for Healthcare Improvement, has begun to make substantial changes in the way that quality assurance programs are run in hospitals (23). These same techniques can be used to evaluate and improve injury control programs on a much faster cycle than has been the case in the past.

OUTCOMES RESEARCH

Outcomes from intervention efforts can be measured in many different ways (figure 2).Traditionally, many interventions were measured by reported changes in knowledge, attitudes, and beliefs. However, a great deal of research over the last few decades indicates that these are poor proxies for the outcome of intervention efforts because of substantial reporting biases. On the other hand, deaths are clearly an important outcome to examine. Death has been the major outcome for many injury control studies and continues to remain important. However, the field must move beyond survival as its most important measure of success. As in other fields of medicine, functional impairment and outcome have become the sine qua non by which outcome is measured. Unfortunately, this is an all-too-uncommon occurrence in the injury field. For example, a recent systematic review of the outcome of burn injuries revealed that since 1966, only 10 studies have included return to work as a major determinant of outcome (24). When the outcome of either intervention programs or trauma care has been measured, the results are often surprising (2, 25).

Many of the articles in this volume offer important methodological strategies for examining the impact of interventions. Some of the most effective injury control strategies are legislative, such as mandatory motorcycle helmet use laws, seat belt laws, and drunk driving legislation. The injury surveillance systems described by Horan and Mallonee (6) can provide the data needed to determine the population-based impact of these laws. Observational studies such as case-control and matched-pairs cohort designs can also be used to examine the effectiveness of protective strategies on the risk of injuries. For example, case-control studies have clearly demonstrated the protective effect of bicycle helmets.
on the risk of head and brain injury (26, 27). Case-control designs can be applied to a wide variety of other injury problems (28). The matched-pairs cohort design (10) has been used to examine the effectiveness of driver-side (12) and passenger-side air bags (9) in reducing the risk of death and how this risk is modified by whether the occupant is restrained.

CONCLUSIONS

At the beginning of the 21st century, injury continues to take a large toll on the lives of people both here and abroad. However, the last few decades have resulted in substantial progress not only in reducing the impact of injuries but also in developing tools and a scientific base on which to build new interventions. Etiologic research must become more sophisticated to better unravel the complex interplay of factors contributing to injury risk and occurrence as well as affecting the likelihood of recovery from injury. Interventions must be evidence based if scarce resources are to be used wisely.

REFERENCES