Guest editorial

Postmarketing surveillance of injury countermeasures

Postmarketing surveillance is a procedure to monitor use of a drug or other therapeutic agent after it has been licensed for general use, and particularly the occurrence of associated adverse effects. With the burgeoning pharmacopoeia available to physicians, and with increasing concern about therapeutic adverse effects, postmarketing surveillance has become a vital component of the evaluation of antisepsis interventions. Even large scale clinical trials cannot emulate the use of therapeutic agents after general marketing. Sample sizes of such trials are never adequate to reliably determine the risk of rare adverse events. Trial conditions are also often different to those seen with use in the general community, where compliance, drug interactions, prescriber variation in dose and indication, and other factors operate together to potentially modify the expected benefits and disadvantages of a particular drug or vaccine.

The same applies to injury countermeasures, which represent a broad range of techniques including engineering solutions (vehicle passenger restraints, domestic swimming pool enclosures and self-closing/locking gates, bicycle helmets, etc), consumer product design solutions (non-flammable textiles for children’s sleepwear, poison cabinet locks, curly cords, etc), restricted access to hazardous products (hand guns and automatic/semiautomatic weapons, child resistant closures, etc), and education programs, to name a few. In addition, we have developed ways to package or implement these solutions. The principle tools are social marketing, legislation, enforcement, and community development. Few would disagree that all such interventions should be subject to rigorous effectiveness evaluation. And postmarketing surveillance is equally important.

In general, injury countermeasure postmarketing surveillance should aim to monitor both the intended and the unintended effects of the countermeasure. Various injury surveillance systems can be used to achieve this end, and they are. For example, the progressive strategy during the 1980s in Victoria to introduce bicycle helmet use culminating in legislated compulsory helmet use for all from July 1991 was shown to be associated with a similarly progressive reduction in the incidence of head injuries to bicyclists. Statewide hospital inpatient data, data from sentinel injury surveillance systems for emergency department treated injuries, and police, road authority, and traffic insurance claim sources were all employed to monitor the impact of promotion strategies and then the law.

Early postmarketing surveillance after the introduction of Victoria’s helmet law showed that bicycle usage fell, accounting for a proportion of the post-law drop in head injury incidence. Opponents of such legislation elsewhere are now arguing that this reduction in cycling is an undesirable and unintended effect that will have a broader and more significant adverse health impact on cardiovascular disease through exercise reduction. Such opponents of a helmet law have so far failed to quantitatively demonstrate whether this might be the case given levels of bicycle use and forms of alternate transportation used by those who might not wish to use a helmet (for example, walking). But, injury researchers have also failed to demonstrate whether the observed reduction has persisted after the early period studied.

It is also important to monitor the extent to which the intervention has been applied (including the application of enforcement). This permits the linking of the intervention to relevant injury outcomes. In Queensland in the early 1990s, after many years of promotion, education, and agitation, the state government mandated domestic swimming pool enclosures for both new and existing pools. Subsequently, there was a steep drop in toddler drownings. However, there has been no survey of the extent to which compliance with the law has occurred, and it is not known how many pools have been protected. To be sure, those post-law drownings which have occurred have been carefully studied, and the absence of a functioning, standards compliant fence and gate has been noted for virtually every immersion death (Robert Pitt, personal communication). Elsewhere in Australia, attempts to introduce similar legislation have been hampered by our failure to demonstrate widespread implementation of protective enclosures. Opponents have consistently argued that observed reductions in drowning are merely the result of media attention to drowning risk for toddlers, and consequent improve-
ment in parent supervision. Other postmarketing surveillance requirements include the monitoring of the durability of the product and determining whether the countermeasure has been applied as intended (for example bicycle helmet fit).³

What's needed is a systematic approach to injury countermeasure postmarketing surveillance. Only then will the full value of the countermeasure for the world community at large be realized. In Australia, we are on the threshold of introducing groundbreaking gun control laws (afflicting both gun access and registration). Public support arising from the recent shocking Port Arthur massacre in Tasmania has lead to previously almost unimaginable cooperation to introduce strict, uniform state and national gun control laws. Injury control supporters will need to continue swimming strongly against the tide of the gun lobby backlash which will inevitably persist after implementation of the legislation. Postmarketing surveillance of this measure will be vital to ensure its continuing survival.

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Closing remarks from the Haddon Memorial Plenary Session

You have experienced an unusual week, which reinforces the work that occupies your lives by offering new ideas and a broad exposure to diverse subjects. You have had daily choices between sessions dealing with the place of injuries (schools, work, home, highways), risk factors (alcohol, firearms, fireworks, vehicles), technical considerations (measurement, exposure, evaluation), and content (product safety, land mines, war, interpersonal violence).

The question now is how to put this all together. How do we understand where it fits? How can we feel some coherence, some understanding of how we all relate? How does it help that you have attended this conference? It has given us some identity. The feeling we are part of a growing movement.

When Thucydides was asked when justice would come to Athens, the philosopher replied, "Justice will come to Athens when those who are not injured are as indignant as those who are injured." What a great motto that would make for this movement. This conference has helped us become indignant on behalf of those who have been injured and those who never should be injured in the future.

Attending has helped me to get a different perspective and I have several conclusions.

1. You are pioneers in an exceedingly diverse undertaking. If we would show you pictures of a bench scientist working on DNA, an emergency room physician saving a life threatened by toxic shock, and a public health worker giving an immunization in Africa, you might have trouble seeing the relationship. If we said all were working on the control of infectious diseases, the relationship would be immediately clear. Similarly, the goal of eliminating unnecessary injury is what joins all of us despite diverse daily activities.

2. I also conclude that you are activists, positive people, who would not be doing this unless you honestly believed that you can change the world.

3. Despite being pioneers, you have a great tradition to fall back on with experiences, guidelines, and information on what works and how to make it work.

4. You have a busy, exciting, and productive decade ahead.

The tradition

While you see yourselves as pioneers, let me for a moment tie you to the great public health culture. We build on a proud tradition which is this year celebrating its 200th anniversary. It was in 1796 that Edward Jenner, after 11 years of observing the protection that milkmaids appeared to have during smallpox outbreaks, worked up the courage to take material from the cowpox lesion on the hand of Sarah Nelmes, and transfer it to the arm of James Phipps. Three weeks later, with a mental burden which I can't imagine, he tried to give James smallpox. The boy was immune. This began a chain of events that led to smallpox eradication, polio vaccine, measles vaccine, and some day will lead to vaccines for AIDS and malaria.

Public health includes countless such chains, such as the work of Oliver Wendell Holmes and Semmelweis on handwashing which led to our current knowledge of sanitation. Work on tuberculosis, iodine, vitamin A, etc., bit by bit leading to the science of public health. It all adds up and in the past third of a century, infant mortality rates have dropped by half, while life expectancy for the world has increased by 15 years, an average of 10 and a half hours a day for every person in the world.

But don't miss the point that two centuries of advances finally paid off in the recent decades. Public health accumulates. It took 180 years to eradicate smallpox after vaccine became available. It will take 45 years to eradicate polio. But we are getting better and faster at using our tools and injury control has already paid off in its first years and will continue to get better.

As the boundaries of public health expanded from infectious diseases, to chronic diseases, to life style factors, environmental health, occupational health, injury control and now even to mental health, the tools have been refined. While these tools are many, they emanate from only two concepts.

CONCEPT 1

This is a cause and effect world. Stephen Hawking has written that the whole history of science has been the