Epidemiology and product safety — opportunities and limitations

In the late 1960s a new bicycle style — the high rise with a 'banana' seat — appeared on the American market. Soon after, a paper in *Pediatrics* stated that this new model was unstable, invited riders to attempt risky tricks, and consequently was associated with an increased frequency of injuries when compared with earlier bicycle models.[1] At the request of the National Commission on Product Safety, the predecessor to the Consumer Product Safety Commission (CPSC), I undertook the study reprinted as an 'Injury Classic' in this issue of *Injury Prevention* to examine whether the charges were true.[2]

Yes, high rise bikes were associated with higher injury rates per unit vehicles, but only, it turned out, because they more often were used by boys, who had higher injury rates no matter what types of bikes they rode. Exposure studies carried out in North Carolina at about the same time showed that boys have higher injury rates per unit riders because they use their bikes more often.[3] Injury rates per mile are similar for both sexes.

Republication of my 1971 study provides a chance to consider some of the opportunities and limitations associated with the use of epidemiology for product safety. Must one always await the results of such a study to insure that the most appropriate actions will be chosen, or can anecdotal evidence also serve a useful role in documenting hazards? Looking back at my experience over 35 years, I believe a case can be made for both types of reports.

As recent generations have learned from the Haddon models, products may be hazardous because they increase the frequency of injury, worsen its severity, or both.[4] The argument with the high rise bike was that either because of designed instability or design features that entice riders to take greater risks, the new bike resulted in an increased incidence of injury when compared with older versions. Questions about relative incidence can only be answered through use of some form of denominator, preferably exposure data. Questions about stability and other design factors may be raised through casual observation but can only be answered through engineering or ergonomic study.

Similar design related questions have arisen concerning the hazards of snowmobiles and all-terrain vehicles (ATVs). In the former case, studies using a variety of epidemiologic techniques, including comparative mishap rates of different vehicle makes, have pointed to the contribution of design, environmental, and user related factors in the occurrence and types of injuries.[5,6] With ATVs the higher frequency of injuries on three wheeled vehicles than on four wheelers was attributed to designed instability, and manufacture of three wheeled vehicles ceased.

Certainly, the presence of three wheels instead of four suggests lesser stability. But did the greater frequency of injury at a time when three wheelers were quite popular truly reflect instability, especially when operated by children, were more ATVs of this style in use, or was there a combination of these factors? We will never know the answer as, to my knowledge, exposure data were never collected. A subsequent decrease in frequency of injury could mean that the right action had been taken, or — equally plausible — that the fad had passed its peak and fewer people were using either three or four wheeled ATVs.

When is action warranted in the absence of exposure or other denominator data? There should be cause for alarm if a new product design is associated with an excess of severe injuries or ones that are difficult to treat. In such cases data about injury types without denominator information should be enough. Examples are injuries to legs from broken bicycle spokes (the small, apparently benign puncture wound often hides an extensive injury track), and genital injuries attributable to placement of the gear shift on the frame of the bike in front of the crotch.

As suggested above, a sudden rise in injuries with the introduction of a new product may reflect either increased use (for example, a fad), a learning process involving intricacies of operation, or design or construction problems. With in-line skates the rise in skate related injuries appears predominantly to reflect an increased interest in skating, especially by older children and young adults, rather than a new design hazard. Greater speed achievable with these skates is probably also a factor. The correct actions appears to have been taken to provide protective equipment and more benign skating environments.

On the other hand alteration of materials can have adverse effects independent of frequency of use. When toy trucks began to be made of soft plastic, but the axles continued to use metal, young children who fell onto these toys sometimes had the axle penetrate skull and brain tissue as the plastic collapsed but the metal rod did not.

Around 1970 a manufacturer flooded the market with 'clackers', two hard, heavy plastic balls attached to opposite ends of a string. This toy was a reconstituted version of the soft raffia balls which the Maori of New Zealand gracefully twirl and 'clack' together. It takes time to learn the skill, and emergency departments were besieged with children with broken arms and facial bones as the balls banged, not against each other, but into arms and cheeks. Furthermore, when the balls did contact each other they often spalled pieces of plastic which flew into eyes.

A similar epidemic of broken canines and incisors followed introduction of the 'time bomb', a hard plastic version of the old 'hot potato' game. The toy came with specific instructions about assigning points if the 'bomb's' internal buzzer went off while the toy was in mid-air, suggesting the manufacturer had anticipated that it might be tossed. It didn't take epidemiologic skill to realize in each case that a hazard existed. Nor should it have taken much foresight by the manufacturers to realize that a densely hard plastic missle can be far more hazardous than a soft pliable one.

Manufacturers and the injury control community often learn about emerging product hazards from reports of hospitalizations, such as through trauma registries. Many injuries associated with considerable disability are missed, however, by both interest groups because the injuries are treated in emergency departments or in physicians' or dentists' offices and only rarely require hospitalization.[7]

The National Electronic Injury Surveillance System of the CPSC to some extent avoids this limitation by monitoring a sampling of emergency departments throughout the

United States. Even this system, however, is likely to miss the relative importance per unit of exposure of regional seasonal problems (for example, snowmobiling only in northern states and only in winter), and the system includes only two pediatric hospitals. As Weiss *et al* have pointed out, this may severely bias reporting (HB Weiss *et al*, presentation to American Public Health Association, San Francisco, October 1993).

This editorial would be incomplete without a comment about the politics of product safety research. In 1969 I testified before the National Commission on Product Safety (NCPS) about the hazards of floor furnaces and the reluctance of manufacturers to acknowledge a problem or to institute corrective actions.[8] When, shortly after, the NCPS asked me to examine bicycle injuries they tried to get funds for the study from the bicycle manufacturers who, I was told, declined the 'offer'. Given my previous testimony, the manufacturers feared I might be biased in searching for problems.

When my study showed no unique problems with high rise bikes the NCPS appeared no happier about the actual results than the manufacturers had been with what they thought the results might be. Clearly, negative results were not to the commission's interest in showing how they were protecting the public. Thus, an idealistic young researcher learned about the hazards of a different product — the epidemiologic report — in the marketplace.

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1 Howell TR. Accidents and those bizarre bicycles. *Pediatrics* 1968; **42:** 214.
2 Waller JA. Bicycle ownership, use and injury patterns among elementary school children. *Pediatrics* 1971; **47:** 1042–50.
3 Pascarella EA. *A study of youthful bicycle riders in an urban community*. Chapel Hill, NC: Highway Safety Research Center, University of North Carolina, 1971.
4 Haddon W Jr. On the escape of tigers: an ecologic note. *Am J Public Health* 1970; **60:** 2229–34.
5 Waller JA. A survey of snowmobiling in Vermont. *Accid Anal Prev* 1975; **7:** 207–12.
6 Waller JA, Lamborn KR. Snowmobiling: characteristics of owners, patterns of use and injuries. *Accid Anal Prev* 1975; **7:** 213–23.
7 Waller JA, Skelly JM, Davis JH. Emergency department care and hospitalization as predictors of disability. *J Trauma* (in press).
8 Waller JA. Testimony about floor furnace burns before National Commission on Product Safety. *Hearings of the National Commission on Product Safety*. Washington, DC: NCPS, 1969; **3B:** 655–8.

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Where have all the programmes gone?

The phone in my office rings, it gets passed to me and the conversation goes something like this:

Caller: 'I work for the local health authority and I've just been appointed as accident prevention officer. I've got to do something about the number of children's accidents we have locally. They are a target area in *The Health of the Nation* strategy,[1] you know. What can I do to prevent accidents? What are other people like me doing that is effective? Are their programmes published anywhere?'

I stall for time as I know what's coming next. MH: 'What sort of accidents do you have? What are the local data telling you?'

Caller: 'Well, I've tried to find this out but no-one seems to have any data that are much use. The police tell me there are a lot of pedestrian accidents, especially in the summer. We seem to have a couple of deaths in house fires each year and one or two drownings. The hospital data are not much good; it just says that children are admitted with suspected head injuries or poisonings, but it doesn't say why'.

At this stage the conversation goes a bit quiet — except for the sound of my groan. I can refer the caller to the reviews of effective interventions by Pless,[2] Towner *et al*,[3] and Munro *et al*,[4] but that's about all (and I remember that these reviews highlight the point that many programme papers do not contain enough methodological information to allow others to replicate the work). These enable me to chat about swimming pool fencing, bike helmets, child restraints, child resistant closures, and a couple of other interventions, but to be effective these need legislative support, so the potential role of the health worker is very limited. They also tell me that multiagency working as a technique is effective. To finish the conversation, I tell the caller that he or she is not alone in their lack of useful data (in the UK). He or she rings off, disgruntled.

What I would really like to be able to say is 'There's an excellent new journal called *Injury Prevention* that is full of information from people in your situation. It will tell you about effective programmes that are being put in place and evaluated around the world. It will give you a host of good ideas, tell you exactly how to carry out the programmes, describe the evaluation techniques used, outline the cost of the programmes, and so on'. But at the moment, I cannot say this.

For those of us for whom the journal has been a longstanding dream, we are delighted by the quality and quantity of the research and epidemiological papers it has been carrying. The leading articles are constantly thought provoking and perceptive. The historical papers bring back memories of the greats. And the citations remind us that we have to cast our reading net much wider — and remind us that there are many journals that we are not reviewing.

But what has been missing from the journal to date is the answer to my caller's questions 'What can I do to prevent accidents? What are other people like me doing that is effective? Are their programmes published anywhere?' We are not receiving papers about intervention programmes, neither successful nor unsuccessful.

This is not a criticism of our present contributors but is a criticism of the people who implement programmes, who actually work to prevent accidents and injuries in their everyday jobs. Is it that no-one is putting programmes that can be shown to be effective in place, or is it that they just do