

# Implementation epidemiology: The study of the frequency, distribution and determinants of effective prevention practice

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#### **Abstract**

There is a growing literature demonstrating the limited extent to which quality evidence has led to injury prevention policy action. The innovation challenge now recognised throughout the world is not 'what works', but how to 'make it work' at the population level. The purpose of this paper is to introduce the concept of 'implementation epidemiology' as a methodology that enables the roles of injury prevention research and practice to be quantified within a single analytic process; and thus a methodology for facilitating the translation of injury research evidence to evidenced-based prevention practice. The contribution of 'implementation epidemiology' beyond the more traditionally defined scope of the discipline is to extend the definition of epidemiology from 'the study of the distribution and determinants of health conditions' to include the empirical measurement and quantification of determinants of implementation effectiveness. In order to consider injury research and practice within one methodological dimension, implementation epidemiology requires first a shift in the public health approach to injury prevention from the traditional proximal risk factor paradigm to a more ecological understanding of injury causation, and then a further shift in the notion of causation to incorporate within the eco-epidemiological models, not just the multilevel risk factors for injury, but also the determinants of widespread uptake of known countermeasures.

Keywords: models; policy; public health; implementation research

#### INTRODUCTION

The rapid development of new injury prevention knowledge is quickly outstripping society's capacity to implement it (Peek-Asa & Casteel, 2010). The World Report on Child Injury notes that many of the 830 000 child deaths per year and much of the injury related disability could be prevented if the extensive list of strategies and programmes, that have been shown to be efficacious in research circumstances, were implemented at the population level (World Health Organization, 2008). Road traffic injury is one of the best researched and best understood causes of serious injury, death and disability. "Evidence based interventions are available, yet governments throughout the world are not adopting and implementing them" (Hyder et al., 2012). Over the next 20 years the global burden of road traffic injury is expected to climb in absolute numbers by 65%, moving from the ninth leading cause of world morbidity and death to the 5th leading cause (World Health Organization, 2009, 2012). The single biggest question facing contemporary injury prevention is, "If we know 'what works' in research environments, why can we not 'make it work' in practice?" (Moller, 2004).

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The purpose of this paper is to introduce the concept of 'implementation epidemiology' as a methodology that enables the roles of injury prevention research and practice to be quantified within a single analytic process; and thus a methodology for facilitating the translation of injury research evidence to evidenced-based prevention practice. The benefits of our suggested approach are exemplified in the context of the challenges of injury prevention in Africa.

## THE RESEARCH TO PRACTICE BLOCK

The literature discussing the nature and aetiology of, and solutions to, the research to practice block is confusing. This confusion stems largely from the fact that most discussants implicitly assume a particular world view then argue a position not on the facts of the case, but on the tautological strength of the unstated assumptions on which their arguments were premised. The confusion is evident even in the differing definitions of key terms used. "Ask ten people what translational research means and you're likely to get ten different answers" (Butler, 2008). In particular, the nature of 'an injury prevention programme', the meaning of 'research', 'practice', 'knowledge', and of the various terms used to describe the process by which 'knowledge' is created and applied to support improvements in injury related harm, are all contested terms.

The National Institutes of Health (NIH) is a leader in the current debate, having established a specific programme and substantial funded activity in implementation science (National Institute of Health Research, 2013). The NIH approach is to classify translation and implementation into three main types. The first of these, "bench to bedside", refers to the process of developing laboratory based knowledge into a clinical intervention. The second is the process of scaling up known efficacious interventions to provide effective programmes for defined populations. The final grouping is where diffusion of innovation is completed and new knowledge is normalised as usual practice. This approach has grown from its roots in the medical model, and contains the underlying assumptions of medical practice. It is an approach most understandable in terms of the development of new drugs and new treatments, and the optimal inclusion of these treatments through existing health service delivery systems.

Similar initiatives have been developing throughout Europe (Travis, 2007). In Britain, for example, the National Institutes of Health Research have established a number of Biomedical Research Centres to push innovative biomedical research into clinical practice that benefits patients within their National Health System (National Institute of Health Research, 2013). Industry and non-government organisations throughout Europe have developed a clear commitment to translation as part of the biomedical research agenda (Alliance for Biomedical Research in Europe, 2012).

Improvements in health arise not only from biomedical research, but also come from changes in social and physical environmental exposures. The success of epidemiology in establishing the relationship between tobacco smoking and disease and in supporting changes in smoking-related social policy is well acknowledged. In an effort to improve translation of new epidemiological findings into policy action the American College of Epidemiology has outlined its understanding of the research to practice process in terms of a model that broadens the clinical perspective (Davis, Peterson, Bandiera, Carter-Pokras & Brownson, 2012). The model is a five-step, linear, unidirectional process that begins with the identification of a high priority, single issue. A story is developed around this issue "using epidemiological or other data" to underpin a "strong, evolving and probably long-term multidisciplinary team approach" (Davis et al., 2012). Scientists then reach consensus with stakeholders about the importance of change and finally consider the political and social environments in the context of which changes need to be made. This model recognises that the strategies for implementation are "situational and iterative" (Davis et al., 2012).

For the last ten years leading injury prevention researchers have been acutely aware of the problems translating their research findings into policy action, perhaps more acutely than their counterparts in other areas of public health (Hyder, Bloom, Leach, Syed, Peters & Future Health Systems, 2007; Pless, 2004, 2007). This heightened awareness is because the factors involved in preventing injury are largely beyond the jurisdiction of the health sector. The public health approach to

injury prevention requires those interested in health outcomes to engage local governments, schools, transport industries, and workplaces with the principles of injury prevention research, and persuade these stakeholders of the value of complying with suggested improvements in practice. The accumulation of published injury prevention knowledge is becoming a frustration to those not able to see this knowledge being applied in practice. The metaphor of a research to practice block has obvious appeal, and is a term being increasingly used in the injury prevention literature (Bugeja, McClure, Ozanne-Smith & Ibrahim, 2011; Mallonee, Fowler & Istre, 2006; Pless, 2004).

The orthodox explanation of the lack of translation of injury research to practice is based on the description of injury prevention as a four-staged, linear, and rational progress from research-based problem recognition (stage one), through risk factor identification (stage two), then countermeasure development (stage three), and finally (after a shift into the public domain), scaling up and implementing at the population level (stage four) (Sleet, Hopkins & Olson, 2003).

The four-stage, public health model of programme implementation is demonstrated by the most recent state-of-the-art initiative, Road Safety in ten countries (RS-10) (Hyder et al., 2012). This programme is currently being undertaken by a collaboration including the World Health Organization, Johns Hopkins University, the World Bank, the Global Road Safety Partnership, the Association for International Travel, and the World Resources Institute. The RS-10 programme has identified four risk factors (speed, seat belts, helmets, and alcohol) responsible for a large part of the growing number of serious road traffic injuries in lower- and middle-income countries. It aims to address these using a standardised approach involving the implementation in two or more specified sites per country, of "effective, evidence-based, and nationally relevant interventions" (Hyder et al., 2012). The mechanism for ensuring these evidence-based interventions are implemented involves the following components at the national level: a high-level working group of stakeholders; a joint national work plan; a review of road safety legislation; engagement and training of police; and national awareness and safety campaigns by non-government organisations (NGOs) (Hyder et al., 2012).

While the above road safety example has been provided as an illustration of the orthodox view of injury prevention in terms of a staged public health approach, it also exemplifies the difficulties that arise in trying to implement in practice what research has previously shown to be efficacious. The RS-10 programme is about international agencies knowing what works in road safety, and transferring this knowledge to in-country collaborations using a sophisticated communication process. The mechanism for ensuring subsequent national change rests with the high level committee of stakeholders whom it is hoped, are persuaded by the results of the externally funded, small scale, RS-10 demonstration activity.

It can be seen from the RS-10 example, that between stage three and stage four in the public health model the process moves from the restricted research world into the public world in which the research outputs are implemented. The transfer of knowledge is assumed to be a unidirectional process from researchers to implementers, facilitated by good communication (Brussoni, Towner & Hayes, 2006; Poulos, Donaldson & Finch, 2010). Problems with lack of implementation are most commonly perceived simply as breakdowns in this communication, with lack of transfer being fixable simply by improving communications (Davis et al., 2012; Woolf, 2008). Suggested ways of achieving quality communication include the creation of communication opportunities (collaborative forums and interactive exchanges), use of diversified communication media (written, oral, public meetings, electronic and visual), and use of quality communication material and staff trained to communicate effectively (Davis et al., 2012; Mallonee, Fowler & Istre, 2006; Poulos et al., 2010; Woolf, 2008). Improved communication would be based on a more overt acknowledgement of the systems and processes involved in translating efficacious interventions into widespread use (Green, 2006; Pless, 2004, 2007; Poulos et al., 2010; Tran, Hyder, Kulanthayan, Singh & Umar, 2009), and a recognition of the importance of selecting the most appropriate countermeasures for the implementation context (Ogilvie, Craig, Griffin, Macintyre & Wareham, 2009).

While the translation of research to practice was originally described as a linear process, it has more recently been recognised as an iterative process where the monitoring of changed practice feeds back into further research activity (Greenspan & Noonan, 2012). The Canadian Institute for Health coined the term Knowledge Transfer and Exchange (KTE) to describe the interactive process where research to policy action is best achieved by means of an interchange of knowledge between those who create and disseminate the knowledge and those who use the knowledge to improve health (Lomas, 2000a, 2000b, 2007). The main argument in this body of literature is that the breakdown in the transfer of knowledge from research to practice is a result of a simple disjunct between the type of evidence generally developed in research settings and the evidence required to make things work in real world contexts (Glasgow, Lichtenstein & Marcus, 2003; Hanson, Finch, Allegrante & Sleet, 2012). Bidirectional communication allows for practice-based evidence to support evidence-based practice to enable a better fit between the knowledge and the practice needs (Green, 2006; Hyder, 2007; Lavis, Oxman, Lewin & Fretheim, 2009). The translation process is as much one in which practitioners and policy makers 'pull' required information from a variety of sources, including scientific research, as it is one where researchers 'push' the results of their research onto a receptive audience (Bugeja, McClure, Ozanne-Smith & Ibrahim, 2011).

A more extreme version of the above explanation for research to practice block is that the problem arises not because of a simple disjunct between the type of evidence created and the type required, but that there is a complete disjunct between the world views of researchers and those of the communities who implement the knowledge. "It is not just that we do not understand each other, we are at cross purposes" (Hanson et al., 2012). Even at this extreme however, communication is provided as a solution. What we need is not a monologue from researchers to practitioners, but a dialogue; "researchers, practitioners, policy makers and community engaging in conversation in humility and an open mind" (Hanson et al., 2012). If the orthodox position can be likened to 'shouting louder across the divide', this approach could be described as 'listening harder across the divide'.

Hanson and colleagues (2012) argue that the solution to the implementation block is to integrate the experience from the full range of people responsible for effective prevention activity (Hanson, Allegrante, Sleet & Finch, 2012). This involves a collaboration between the citizens for whom the prevention systems are designed and the policy makers, researchers and practitioners who are involved in the design and implementation phases (Greenspan et al., 2012; Hanson, Hanson, Vardon, McFarlane, Lloyd, Muller & Durrheim, 2005; Lawrence, 2010; Sleet, Mercer, Hopkins Cole, Shults, Elder & Nichols, 2011).

#### INJURY PREVENTION RESEARCH AND PRACTICE

Injury research is the activity undertaken for the purpose of generating new knowledge about the nature and extent of the injury problem, its causes and its solutions (McClure, Stevenson & McEvoy, 2004). Descriptive research answers the 'what', 'where', 'when', 'who', 'how much', and 'how many'-type questions. This covers the nature, extent, and frequency of a defined entity.

Depending on the nature of the question to be answered, qualitative or quantitative research methods are used. Qualitative methods can be used to answer the 'what/who'-type questions (Ameratunga, 2004; Turner & McClure, 2004). Qualitative methods can ascertain, for example, the acceptability of particular interventions to related groups, and the extent to which the interventions are affordable, accessible, and sustainable (Ameratunga, 2004). Quantitative methods are generally used to answer the 'how much', 'how many' and 'why'-type questions.

Aetiological or causal research for the most part assumes a deterministic/probabilistic belief that things happen because of preceding events or circumstances, without which the consequent would not have occurred. These preceding events are called component causes and relate to the injured person, the nature of the energy exchange, or the environment in which this energy exchange occurred. Thus, aetiological research aims to identify the causes of an event or condition, and

estimate the types and magnitudes of the relationship between the cause and the outcome (McClure, Davis et al., 2010). Component causes may relate to individual or group level data, and may be products of other causes that preceded them. In a retrospective investigation, the actual causes of an event can be described. However, what injury research is really about is not the history of a specific event, but learning from observation to make generalisable statements that can be applied to other circumstances where the outcome has not yet occurred. Research is thus not so much about historical causes, but about relationships that may suggest causes, or potential causes for future events (McClure, Hughes et al., 2010).

Elements of a causal set that occur as conditions or attributes in non injury situations are termed 'risk factors' as these factors increase the probability of injury. Risk factors closely associated with the energy exchange process are called proximal risk factors and the contextual factors that support the existence of the proximal factors are referred to as distal determinants. 'Protective factors', those factors which decrease the risk (or probability) of a consequent injury outcome, such as seat belts to mitigate the risk of road traffic injury, are also considered as part of the causal set. Injury prevention practice is the process of reducing the prevalence of risk factors, and maximising protective factors to reduce the population level occurrence of consequent injuries (McClure, Hughes et al., 2010).

The traditional approach to the prevention of injury emphasises the importance of applying countermeasures which are proximally related to energy exchange (Haddon, 1970). This can be exemplified in the context of pedestrian injuries in sub-Saharan Africa (MacKenzie, Seedat, Swart & Mabunda, 2008). Following Haddon's principle of spatially separating the energy source from the target host, an appropriate countermeasure to address the risk of pedestrian injury is to construct pedestrian pathways alongside major roads. Haddon's strategies also suggest a range of other appropriate passive countermeasures such as pedestrian crossings, foot bridges, lighting and curbing at intersections and reducing total energy by decreasing speed limits through pedestrian zones (Ribbens, Everitt & Noah, 2008). When setting out to minimise pedestrian injury-related harm, it is important to consider multiple countermeasures that can be implemented using a range of strategies. This integrated package is what is traditionally considered to be 'an injury prevention programme' (Brussoni et al., 2006; Hyder et al., 2012).

An injury prevention programme in this classic sense is a circumscribed set of countermeasures delivered using a specific set of strategies to a target population. To be effective, the programme needs to engage policy makers, legislators and enforcement agencies, advocates, social marketers, behavioural change agents, and community members themselves (Howat, Cross & Sleet, 2004). The required intensity of a public health programme makes it hard to capture sufficient attention and resources to achieve success (McClure, Hughes et al., 2010).

The more important problem however, is that injury prevention programmes are not simply scaled up manifestations of the research projects which demonstrated the efficacy of the relevant countermeasures (Bugeja et al., 2011; Hanson et al., 2012; Hawe, Shiell & Riley, 2009). Efficacy studies are contrived activities, in which consenting participants undertake managed processes organised at the individual level. Implementation of an intervention in an efficacy study is tightly controlled within the protocols and resources available to the research team. Population-level injury prevention programmes, on the other hand, are complex social policy interventions, delivered to non-consenting members of the public using existing social infrastructures. Thus interventions are not isolated activities, but situationally-dependent events within larger system dynamics (Bugeja et al., 2011; Hanson et al., 2012; Hawe et al., 2009).

Injury prevention at the societal level needs to consider all causes in context and target the whole of society, not particular aspects of it, in the intervention process (McClure, 2012). If injury prevention is to change societal processes that increase the injury-related health and well-being of its citizens, then it cannot be "projectised" into simple interventions "delivered" to circumscribed community groups, it must instead be an activity undertaken by those responsible for the entire social system (McClure, Davis et al., 2010). Such a social policy approach will ensure that in all areas in which injury occurs,

human wellbeing is recognised as an essential performance requirement – and all those responsible for a given attribute of an individual or environment will hold themselves accountable for the extent to which this attribute puts human wellbeing at risk (McClure, 2012).

## IMPLEMENTATION EPIDEMIOLOGY

Implementation epidemiology can be defined as the study of the frequency, distribution and determinants of effective prevention practice. It follows from the above account of injury prevention practice that injury prevention research needs to be able to describe and quantify not just the biomedical pathways that are included within injury causal models, but also the political, social, and environmental risk factors relevant to the injury prevention process, together with the barriers and facilitators to intervention success. Implementation epidemiology allows for the contemporary notions of complex interactions between stakeholders with different premises and motivations, while at the same time combining this variety of drivers into a single scientific model of cause and effect. The innovative strength of implementation epidemiology is that it highlights opportunities to intervene upon the risk and prevention factors for intervention success, rather than simply (as epidemiology usually does) describing the risk factors for injury and leaving all considerations regarding the implementation process outside of the researchers' scope.

In the 1970s Haddon and his colleagues identified energy as the agent that caused injury in road crashes and advocated for use of seat belts as a countermeasure to prevent the transfer of energy from the car to the driver at the time of crash (Haddon, 1970). The remarkable ineffectiveness of seat belt programmes in the United States (approximately 64% population use by 1995) (Houston et al., 2005), compared with countries like Australia (greater than 95% population use by 1995) (ARUP Transportation Planning, 1995), is a clear demonstration of the fact that availability of efficacious interventions is not sufficient, in itself, to ensure programme success.

Using implementation epidemiology the differences between the United States and Australia that explained the differences in community seat belt wearing rates over the last half century, could have been identified and addressed. Between-country differences in seat belt wearing rates relate to the underlying contexts, policy development processes, policy implementation processes, resulting policy action and community response. Until we describe and understand the roles of these social structures with respect to each of the interventions bundled into programmes like RS-10, we will not be able to ensure effective implementation of what we know works in road safety.

The underlying contexts of seat belt wearing rates in a community relate to the economic, social, political and cultural norms of the country. Seat belt policy development is influenced by the specific features of the community groups, expertise, champions, and the way the media operates. Policy implementation depends on political will, competing priorities, available resources, and nature of the public support. Any policy action following the passing of seat belt legislature requires police capacity to enforce, available procedures for enforcing officers to follow, adequate availability of seat belts, opportunity for fitment, and supporting media engagement. Community response requires awareness, acceptance, and individual-level capacity on the part of road users to comply.

# ILLUSTRATION CASE STUDY: IMPLICATIONS AND OPPORTUNITIES FOR AFRICA

Throughout Africa, traffic related injury is recognised as a public health problem of major importance. The road traffic death rate in South Africa is estimated at 43 per 100 000, which is twice the world average (Suffla, Van Niekerk, Bowman, Matzopoulos & Seedat, 2008). The death rate across Africa is 32.2 per 100 000, (World Health Organization, 2009) and in contrast to the trend observed in high-income countries/regions, there is a substantial rise in road traffic death numbers and rates since the 1970s (World Health Organization, 2004).

Across the continent, there is an emerging political will to support implementation of definitive solutions to address the problem of traffic related injury. The need for a multisectoral response involving partnerships with all levels of government, NGOs, community groupings, and citizenry, is well recognised. The need to develop coordinated policies that integrate effective strategies with activities to strengthen underlying macroeconomic and social structures is an accepted practice (Suffla et al., 2008). Evidence-based polices exist, and can be implemented. Policies of different types are currently being implemented in different places across the continent. To a greater or lesser extent these will be successful. Future activity will be contingent on knowledge obtained from the present.

Now is the time to measure, and compare between jurisdictions, the extent to which this range of policies and processes have been implemented, and the extent to which they have been effective. Assessment of the effectiveness of community driven components, local contexts and the relationship between area-level and individual-level exposures cannot be accommodated using classic epidemiological designs such as randomised controlled trials (Davey, 2012; McClure, Davis et al., 2010; Rychetnik, Frommer, Hawe & Shiell, 2002; Sanson-Fisher, Bonevski, W & D'Este, 2007). Implementation epidemiology, in describing the frequency, distribution and determinants of effective injury prevention practice, is the way evaluation can be achieved. Responsibility for undertaking this evaluation lies collectively with the citizens, policy makers, researchers and practitioners engaged in the design and implementation of the prevention activity (Greenspan et al., 2012; Hanson, Hanson, Vardon, McFarlane, Lloyd, Muller & Durrheim, 2005; Lawrence, 2010; Sleet, Mercer, Hopkins Cole, Shults, Elder & Nichols, 2011).

Implementation epidemiology can enable the description throughout the continent of all factors related to causation of road traffic injury, at all levels of the web of causation. Particular attention can be focused on the underlying determinants, and structural factors that maintain the situations and precipitant events that increase or decrease the risk of road traffic injury. Outcome factors, when measured, will provide the evidence for the effectiveness of implementation of policies and changed practices. The resulting information will elucidate the causal pathways of change. In order to achieve this a whole of Africa collaborative effort is needed that documents the transition processes currently underway, to provide the evidence, to feed back into those same transition processes, suggestions for improving their effectiveness. Implementation epidemiology can be used now to measure and compare between jurisdictions the extent to which these range of current policies and processes have been implemented, and the extent to which they have been effective.

#### CONCLUSIONS

There are several establishment steps in the implementation epidemiological approach. First, we need to change our understanding of what an injury prevention programme is to include a more ecological understanding of injury prevention practice. This requires the inclusion of underlying risk factors as well as proximal risk factors in the epidemiological model of injury causation. Second, we need to extend the research process throughout the entire research to practice continuum so research is made integral to all efforts of implementation. This is achieved by including within the eco-epidemiological model of causation, the interventions themselves, and the factors that are barriers and facilitators to intervention success. Finally, we need to ensure the questions that are being asked by researchers are the questions for which the implementers need answers if they are to achieve their goals. The structure in which the implementation is to be conducted needs to be as important a consideration in determining research design as the abstract knowledge provided by discipline-based researchers.

Implementation epidemiology is a methodology that enables the roles of injury prevention research and practice to be quantified within a single analytic process and thus, a means of facilitating the translation of injury research evidence to evidenced-based prevention practice.

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