THE GEORGE INSTITUTE
for Global Health

Conducting research on road traffic injuries – where do I start? Research design, ethics and consent.

Rebecca Ivers, Director, Injury Division, The George Institute
Associate Professor,
Sydney School of Public Health, University of Sydney, Australia

Outline of presentation

- Defining the question you want to ask
- The research design
- Ethics approvals
- The consent process
- Useful references
- Case studies

Defining the question you want to ask

- **What do you want to know?**
  - How many people are killed each year in road crashes?
  - What proportion of people wear helmets/seatbelts/drink drive?
  - Is a program you have implemented effective?
- **Who is the answer for?**
  - Researchers, policy makers?
- **Define the aims of the study**
  - The aims should be driven by the hypothesis you propose to test
  - Aims should be focused and relevant to the audience
- **Define the population**
  - People (age, gender, road user)
  - Place (urban/rural)
  - Time (when, for how long)

Has the question already been answered?

- **Review the literature:**
  - Search pubmed
  - Search the Cochrane Library for systematic reviews

    http://www.cochrane.org/ (main site)

    http://injuries.cochrane.org/ (injuries group)

Research design – quantitative studies

- **Study type will depend on the question you are asking**
- Descriptive: describing the size of a problem
  - Surveillance from routinely collected data
  - Community survey
- Examination of risk factors: examining associations between exposure and outcome
  - Case control study
  - Cohort study
- Examination of effectiveness of intervention or program: experimental designs
  - Randomised or quasi randomised control trials
  - Interrupted time series studies
  - Pre-post designs

Examples

- **Descriptive:**
  - Surveillance e.g. using police or coroner's record, verbal autopsy
  - Simple surveys e.g. observations of helmet wearing rates
- **Examination of risk factors:**
  - Case-control study of relationship between sleep and risk of crash
  - Cohort study examining disability after road traffic injury
- **Effectiveness of program:**
  - Controlled pre-post study examining campaign to increase restraint use
  - Randomised trial of motorcycle rider training

Research design – qualitative studies

- Qualitative research also uses a rigorous scientific approach (including focus groups, interviews)
- Seeks to provide answers to questions via in depth exploration from the perspective of the population of interest
- May provide culturally specific information about the values, opinions, behaviours, and social contexts of particular populations
- Seeks to provide a rich and complex understanding of a an issue
- Not generalisable to broad population
- Supplements quantitative research

Example of mixed methods research in RTI

- **Pedestrian injuries in Mexico: a multi-method approach. Hijar et al. Social Science & Medicine Volume 57, Issue 11, December 2003, Pages 2149-2159.**

"Conclusions: The combination of quantitative and qualitative methods allows us to see the specific importance of some determinants of pedestrian injuries. Spatial, epidemiological, and social perspectives help point out the local accident characteristics which must be considered before defining preventive interventions"

Feasibility

- Work within your budget and capabilities
- Seek appropriate partners
- Better to do a small well conducted study than a badly conducted large one
- Consider sample size – will you have enough study participants to find a statistical effect?
- Refer to statisticians and/or sample size calculators

Ethics approvals

- **Commonly accepted that research requires review by an ethics committee**
  - May be called institutional review boards, human research ethics committee
- **Why do we need to consider ethics in research?**
  - To monitor and manage risk to participants
  - Manage conflict of interest
  - Avoid exploitation

Where to find ethics committees?

- **Can be difficult to find in LMIC**
  - Universities
  - Hospitals
  - Government department
- **Form your own?**

  Requires: a chairperson; lay people, research experts, a member with expertise in care, counselling of treatment of people (eg doctor, psychologist, nurse), a minister of religion or similar, a lawyer. Should have equal numbers of men and women.
- **Challenges:** funding, training, independence, and political commitment (Kass)
- **Facilitators in LMIC:** funders, aid agencies, journals

The consent process

- **Consent is required when:**
  - You are collecting personal information e.g. asking participants questions about themselves including information that may identify them
  - You are collecting identified participant information from other sources eg medical records

- **When is it not required?**
  - Anonymous observations eg seatbelt wearing rates
  - Anonymous questionnaires from participants – implied consent may be sufficient ie if the person answers the questions it implies they are happy to give consent

Information on consent form

- **Identification of institution, researchers and title of study**
- **A statement (and signature) from the participant that they have had the study explained to them, they understand what they are agreeing to, and acknowledgement that:**
  - they have read the information about the study, they understand risks and inconveniences
  - They understand participation is voluntary and they may withdraw at any time
  - They understand they may be recorded or videotaped
  - They understand the confidentiality requirements and that their identify will be protected

Special cases

- Parental consent required for children
- Definition changes by country, may be <18 or <16 years
- If a potential participant lacks the capacity to consent, a person or appropriate statutory body with legal authority should be consulted for consent
- Special cases may also include delayed consent for situations where time factors may prohibit consent eg in emergency medical situations

Data collection

- **Requires standardised measures – previously validated where possible**
  - Consider what others have done previously
  - Use standard definitions eg ICD10 coding for external cause of injury, standard definition of RTI deaths (eg within 30 days of crash)
- **Training of observers**
- **Comparison of measurements by different observers to ensure consistency**
- **Consider safety of data collectors**

Useful references

- Kass NE, Hyder AA, Ajuwon A, Appiah-Poku J, Barsdorf N (2007) The structure and function of research ethics committees in Africa: A case study. PLoS Med 4(1): e3. doi:10.1371/journal.pmed.0040003

- Research Ethics Training: Family Health International: http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/index.htm

- **A guide for using statistics for evidence based policy, 2010** http://www.abs.gov.au/ausstats/abs@.nsf/mf/1500.0

CASE STUDIES

- **Jagnoor – use of verbal autopsy to examine road traffic injuries in India**
- **Ha Nguyen – measuring disability in Vietnam**