

Multi Centre Study on Non-Standard Motorcycle Helmet Use (MSC-NSMHU)

***An initiative of the Road Traffic Injuries Research Network
(RTIRN)***

Study Protocol

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With the financial support of the World Bank through their Global
Road Safety Facility

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1. Introduction

a. Overview

Motorcycles are a common and increasing form of transport in many low and middle-income countries (LMIC) and, unfortunately, an increasing cause of mortality, morbidity and disability. There are many studies that describe the efficacy of “standard” helmets – i.e. those that meet a recognised safety standard - in reducing serious head injuries to motorcyclist during a collision. However, there is limited evidence describing the efficacy of “non-standard” helmets in minimising head injuries, despite the observation that such helmets are increasingly commonly used in many LMIC. Arguably, such helmets are not likely to offer the same degree of protection as standard helmets and so are less likely to contribute to reductions in levels of motorcycle-related mortality, morbidity and disability.

The extent to which non-standard helmets are being used in many LMIC has not been widely documented. Consequently whether their use truly represents a public health problem and whether efforts to deter non-standard helmet use would be potentially useful cannot yet be determined. If indeed they are being widely used, then it would be important to determine why they are being used, as such knowledge might well identify factors that might be the subject of intervention initiatives.

The proposed multi centre study was designed to address the paucity of information about the prevalence and determinants of non-standard motorcycle helmet use (NSMHU) in LMIC. This document provides a detailed outline of the aims, methods and other matters related to the conduct of this study and serves as a guide to the conduct of all aspects of this study and the role and responsibilities of those involved.

b. Goal and objectives of the study

The primary goal of this study is to provide reliable and valid information for governments and other policymakers to facilitate decisions and the potential development of intervention strategies that might lead to reductions in motorcycle-related mortality, morbidity and disability in LMIC.

The specific objectives of the study are:

- To identify the prevalence of non-standard helmet use among helmet wearing motorcyclists in participating LMIC
- To assess the determinants of non-standard helmet use in participating LMIC
- To identify the cost differentials between standard and non-standard helmets in participating LMIC
- To describe current legislation regarding the manufacture, import, sale and use of non-standard helmets in participating LMIC
- To identify enforcement policies and practices with regard to the manufacture, import, sale and use of non-standard helmets in participating LMIC

c. Sub-studies

In order to address the study goal and objectives, three sub-studies will be undertaken.

- A cross-sectional survey of helmet-wearing motorcyclists will be undertaken to identify the prevalence and determinants of non-standard helmet use
- A market survey will be undertaken to identify the costs of both standard and non-standard helmets
- A review of available and readily accessible documentation will be undertaken in order to describe current legislation and current enforcement policies and practices.

d. Definitions

- i. **Motorcycle** - a two-wheeled vehicle powered by an engine. The wheels are in-line and at higher speed the motorcycle remains upright and stable by virtue of gyroscopic forces: at lower speeds continual adjustment of the steering by the rider gives stability; also known as motorbike. The operational definition does not include a non-motorised two-wheeler, moped, etc.
- ii. **Helmet** – a standard head protective device consisting of a rigid shell, energy absorption system and chin strap intended to be worn to provide protection for the head or portions thereof, against impact, flying of falling objects, electric shock, penetration, heat and flame. A device worn on the head, designed to mitigate the adverse effects of a blow to the head within a specified area.
- iii. **Non-standard helmet** – a consistent and agreed definition of a non-standard helmet is not available across all participating countries. However the following criteria would generally be agreed:
 - a helmet that does not meet the standards approved by the national/regional/international authorities; it will not have any certification marking
 - such helmets may include construction helmets, horse riding hats or other inappropriate forms of head protection
 - helmets that have been significantly damaged (eg that are cracked), even if they were originally certified as standard helmets, are considered to be non-standard helmets

2. Sub-study 1: Cross-sectional survey

a. Aims and objectives

The aim of this sub-study is to identify the prevalence and determinants of non-standard helmet use in the participating LMICs. Specifically, the objectives of the study are:

- To identify the prevalence of non-standard helmet use among helmet wearing motorcyclists in participating LMIC
- To assess the determinants of non-standard helmet use in participating LMIC

b. Study participants

i. Sampling and recruitment

Ideally the study population should be representative of the population of interest – namely all motorcyclists riding motorcycles and wearing helmets, within in a defined area (this excludes those riding scooters and mopeds). Ideally, this means that a random sample of all such motorcyclists should be included in the study. However, given limited resources, a non-random, purposive sample of motorcyclists stopping at petrol stations, provides the most feasible, and potentially most bias-free sample of study participants.

For each collaborating centre, a defined urban centre will identified – recognising that the size and nature of each selected urban centre will vary across the collaborating centres. Each collaborating centre will then identify the petrol station or stations that are closest to the town hall (or similar iconic building – city hall, town office, mayor's office) and permission will be sought from the petrol station owners/managers to undertake the cross-sectional survey. If permission is not received, then the next closest petrol station will be approached.

Study participants will be recruited between October and December 2008, on weekdays/business days during daylight hours.

All motorcyclists – drivers and passengers - stopping to purchase petrol and wearing a helmet will be eligible for participation in the survey. In practice, while in some instances it might be possible to invite all/consecutive motorcyclists stopping for petrol to participate in the study, in those instances where the volume of potential motorcyclists is greater than the numbers of available study staff, a sampling framework will be employed that selects the next available motorcyclist once an interview is completed.

Eligible motorcyclists will be approached at the time they stop to purchase petrol and invited to participate in the survey. Where required by local ethics committees, they will be asked to sign a “consent to participate” form. Observed information on each eligible motorcyclist invited to participate in the survey will be recorded by the interviewer, regardless of whether the motorcyclist also

agrees to participate in the survey. This information will be recorded at the completion of each interaction with eligible motorcyclists.

ii. Sample size

Information will be collected on all motorcyclists (wearing helmets) who are approached to participate in the survey, regardless of whether they complete an interview. However, a minimum of 500 completed interviews/questionnaires is sought from each collaborating centre. In total, therefore, the number of data forms will differ across the collaborating centres, dependant on the response rates achieved.

A sample of 500 completed interview/questionnaires for each collaborating centre has been selected to ensure that there are a sufficient number of respondents wearing non-standard helmets to enable analyses to be taken comparing those wearing and not wearing standard helmets. While the proportions wearing non-standard helmets may be as high as 66% (as was observed in a recent study undertaken in southern China), they may well be as low as 10%.

c. Data collection

Data collection comprises two components: one component (Part A) comprises information solicited from the motorcyclist and the other component (Part B) comprises information observed by the interviewer.

All data will be collected on paper forms, using the main language spoken in the country.

The information sought in Part A includes information about the helmet used by the motorcyclist, information about the motorcycle and its use, and some personal demographic details.

The information collected in Part B includes observed information on the helmet and the motorcycle and some demographic details.

All information sought in part A is designed to be collected within a period of five minutes, thus minimising disruption to the motorcyclists. Information collected in Part B is designed to be observed and documented within a similar period, but should not impede the activity of the motorcyclist and documentation can occur even after the motorcyclist has moved on.

i. Data collection instruments

Appendix 1 comprises a copy of the study data collection instruments (including Part A and Part B).

ii. Consent

Consent will need to be sought from all individuals invited to participate in the study, in order to complete Part A of the study data collection instrument. However, the nature of this consent – whether verbal or written – may vary at each collaborating site, dependant on the requirements of the local ethics. Consent is not required to complete Part B.

iii. Identification of non-standard helmets

Reliable and valid identification of non-standard helmets is a key issue for this study. Helmets that can clearly be identified as cracked and damaged, or that can clearly be identified as construction helmets or horse-riding helmets provide obvious examples of non-standard helmets.

The presence and siting of certification marking or a sticker confirming that a helmet meets national and/or international standards provides, arguably, the most reliable and valid method of determining that a helmet is standard (and therefore excludes its identification as non-standard). However, not all countries have legislation pertaining to the use of non-standard helmets and so may not require certification marking. Additionally, such certification is not always visible on the outside of the helmet and/or it is possible that such certification marking may not be genuine. Without proper examination of helmets, which is not feasible in this study, the presence and siting of certification marking as the “gold standard” may lead to an overestimation of the prevalence of non-standard helmets, for those countries where such certification is not required or where the certification is only visible inside the helmet. Conversely, in those countries where fake certification marking is likely, this approach may lead to an underestimation of the prevalence of non-standard helmets.

All interviewers will be provided with training to enhance the rigor with which helmets can be correctly identified as standard or non-standard, given the circumstances that exist at each collaborating site. Each site will need to document the training procedures that are implemented.

d. Data entry and management

Data entry will occur at each collaborating centre, using a web-based electronic data system (EDS) developed by The George Institute for International Health in Australia. The EDS will require translation of information in each data collection form into English. Information will be automatically transferred to The George Institute at the completion of data entry for each questionnaire. In-built checks will ensure that only relevant information is captured in the system and data queries will be generated automatically for any additional anomalies that are identified.

The EDS will facilitate the generation of report updates for each site and for the entire data collection at timely intervals. An initial summary report will be generated for each site (and the Co-ordinating Centre) after the first 50 data entries.

e. Data analysis

A pre-determined data analysis plan will be agreed by all collaborators. Information outlining the prevalence of non-standard helmet use and factors associated with non-standard helmet use will be generated initially and further analyses will be determined and agreed based on the initial findings.

f. Pilot phase

Prior to undertaking the study, each collaborating site will undertake a pilot phase to determine the feasibility of recruitment, based on the methodology described above, and the feasibility of data collection. This phase will not include data entry.

Access to petrol stations for recruitment and data collection will be assessed and up to 25 potential participants will be approached and invited to participate. Response rates will be assessed. Data collection will be undertaken for both those who agree to participate and those who do not. The feasibility of obtaining responses to the data collection forms will be assessed.

Suggested amendments to the recruitment and data collection methods will be forwarded to the Co-ordinating Centre as soon as is feasible, but no later than the middle of September. While it is anticipated that any amendments will be minor variants to the protocol and will not substantially affect the overall study design, all centres will be advised of these amendments and any overall amendments to the overall study design will be confirmed by the beginning of October.

3. Sub-study 2: Market survey

a. Aims and objectives

The aim of this sub-study is to determine whether there are differences in the retail costs of standard and non-standard motorcycle helmets being sold in LMICs.

The specific objective is to identify the cost ratio of standard to non-standard helmets being sold in convenience samples of retail outlets in urban sites associated with each of the collaborating centres.

b. Market selection

A representative survey of outlets selling helmets would require a census of all outlets in a specific geographical area (the site or the city for example) and then a random (or stratified random sample) of such outlets. In the absence of the requisite sampling frame (lack of registered helmet outlets), restricted time (since surveying tens of outlets might take weeks), scarce resources, and need (where the main focus of the larger study is actual wearing rates for non-standard helmets) the ideal process cannot be undertaken. [Please note we are also not conducting a retail audit and are

not measuring the volume of amount of sales.] As a result, we will perform a market survey of helmets using a systematic and standardized approach but based on convenience sampling.

i. Sample selection

The same urban site that is being utilised to conduct sub-study 1 should be used for this sub-study. The main types of different retail outlets (up to 5 types) will need to be identified. These retail types might include:

- Formal retail shops selling only automobile or motorcycle and related products
- Formal retail general shops and super markets also selling helmets
- Informal road vendors (individuals) or little roadside shops selling helmets

Three or more outlets will be selected from each category, such that a maximum of 15 outlets will be selected to be included in this sub-study from each site. In the selection of these different outlets it is recommended that sites are geographically dispersed to maximise the potential heterogeneity of the outlets.

Study staff/interviewers will approach the retail owner/manager/seller and seek permission to ask a few questions. While in most instances this should not require a formal written consent process, some ethics committees may require this – each team will seek clarification from their ethics committees.

c. Data collection

All data will be collected on paper forms, ideally in English, but if necessary, using the main language spoken in the country. Data collection will be undertaken between August and December 2008.

The seller will be requested to identify the maximum and minimum cost prices of standard and non-standard helmets and relevant information pertaining to each of these helmets will be recorded.

i. Data collection instrument

Appendix 2 comprises a copy of the study data collection instrument.

d. Data management

Completed data collection instruments (in English) should be faxed to the co-ordinating centre in Malaysia with copies of the original retained by the collaborating sites, at least until the study is completed, but longer, if and as required by local ethics committees.

Co-ordinating centre staff will review submitted data collection instruments to ensure all relevant data has been captured – follow-up queries will be generated as soon as possible so that errors and omissions can be rectified in a timely fashion.

e. Data presentation

A pre-determined data presentation plan will be agreed by all collaborators. Information identifying the cost ratio between standard and non-standard helmets will be outlined, taking into consideration outlet type and other any other relevant information.

4. Sub-study 3: Review of legislation and practice

a. Aims and objectives

The aim of this sub-study is to identify and document current legislation and practice relating to the manufacture, import, sale and use of non-standard helmets in LMICs. The specific objectives are:

- To describe current legislation regarding the manufacture, import, sale and use of non-standard helmets in participating LMIC
- To identify enforcement policies and practices with regard to the manufacture, import, sale and use of non-standard helmets in participating LMIC

b. Data collection

Data collection will comprise two components relating to each of the study objectives. For those collaborating sites, where legislation is non-existent, the second component will obviously not be required. Data collection will be undertaken between August and December 2008.

All data will be collected on paper forms, ideally in English, but if necessary using the main language spoken in the country.

i. Data sources

The identification of current legislation regarding the manufacture, import, sale and use of non-standard motorcycle helmets pertains to legislation for the urban site in which sub-studies 1 and 2 are undertaken. Such *legislation* may be national and/or local and the data sources for this legislation may be multiple and differ across the collaborating sites. Summary information on the relevant legislation will be captured using a standardised data collection instrument. Each collaborating site will need to access and retain copies of the relevant legislation.

Where relevant, the identification of information on *enforcement* policies and practices will need to be accessed through local enforcement agencies relevant to the urban

site in which sub-studies 1 and 2 are undertaken. Summary information on the relevant enforcement policies will be captured using a standardised data collection instrument. However, again, each collaborating site will need to access and retain copies of the documented enforcement policies.

Where such enforcement policies exist, data will be sought on the numbers of documented citations/offences for the relevant urban site, for the most recent 12 months period for which data are available. A standardised data collection instrument will be used to document this information.

ii. Data collection instrument

Appendix 3 comprises a copy of the study data collection instruments relating to both components of this sub-study

c. Data management

Completed data collection instruments (in English) should be faxed to the co-ordinating centre in Malaysia with copies of the original retained by the collaborating sites, at least until the study is completed, but longer, if and as required by local ethics committees.

Co-ordinating centre staff will review submitted data collection instruments to ensure all relevant data has been captured – follow-up queries will be generated as soon as possible so that errors and omissions can be rectified in a timely fashion.

d. Data presentation

A pre-determined data presentation plan will be agreed by all collaborators. Information outlining the extent and nature of legislation, policies and practices relating to the manufacture, import, sales and use of non-standard helmets in the selected LMICs will be outlined.

5. Ethical issues

Each collaborating centre will seek ethical approval for the conduct of the study, including each of the sub-studies, from their local/institutional ethics committees. Appropriate consent procedures (verbal and/or written) will be sought for those sub-studies for such information as is required by relevant local ethics committees. A copy of the ethics approval (including all documents) will be sent to the Co-ordinating Centre.

6. Publications and presentations

All opportunities to publish and present the findings of the study will be encouraged and supported. Such opportunities may include but will not be limited to the following: peer-reviewed scientific publications, scientific and popular press publications, reports for stakeholders, and conference presentations. To facilitate the dissemination of the study findings as broadly and transparently as possible a dissemination policy has been agreed and adopted by all collaborators.

At least one main peer-reviewed publication, presenting the collective findings from the study, will be produced under the authorship of the collaborative group. We will aim for significant media coverage associated with the release of this paper and/or the presentation of the main findings.

Key presentations of the main study findings will be sought/made at the 2009 Global Forum for Health Research annual meeting and the 2010 World Injury Conference – ideally in association with a broader session at which several presentations on the study can be made.

Stakeholder reports and presentations will be prepared for the World Bank, the Global Forum for Health Research, the World Health Organisation and the United Nations Road Safety Collaboration.

i. Dissemination policy

- All publications/presentations of the main findings will be submitted/presented in the name of the collaborative group.
- All publication/presentation materials relating to the main findings will be agreed by all collaborators.
- The Co-ordinating centre will maintain a central database of all publications and presentations from the study and all collaborators presenting on behalf of the collaborative group will be required to provide details of all publications and presentations to

9. Timelines

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|-----------------|--|
| ■ May 2008 | Methods workshop |
| ■ Jun-Aug 2008 | Preparation, contracts, and approvals for study |
| ■ Aug-Sept 2008 | Pilot phase of sub-study 1; data collection for other studies |
| ■ Oct-Dec 2008 | Data collection for sub-study 1; data collection for other studies |

- Aug-Dec 2008 Data entry and data transmission to Malaysia/Sydney
- Nov 2008 – Jan 2009 Data analysis/presentation and paper drafting
- Feb 2009 Workshop to finalize analyses and paper(s)
- Mar-Apr 2009 Finalise and submit paper, draft presentation/s
- May-July Preparation of further papers for publication and second workshop to support country publications (to be confirmed)

10. Roles and responsibilities

i. Collaborating centres

- Input into study design and analysis
- Responsible for site data collection
- Input into publications and dissemination of findings

ii. Co-ordinating centre

- Key liaison between all study participants – primary link between the study collaborators and other participants
- Management of contracts; dissemination of study materials
- Organisation and facilitation of study workshops
- Oversight of quality control
- Data management and presentation for Sub-studies 2 and 3
- Responsibility for preparing first draft of main publication

iii. The George Institute for International Health

- Data management and analysis for Sub-study 1
- Communication with and update of the Co-ordinating Centre on data input and analysis progress.

iv. RTIRN Board/Study Executive Committee

- Overall guidance and management of the study
- Input into study design and analysis
- Input into publications and dissemination
- Support to individual investigators in preparation of site-specific dissemination
- Responsible for funds acquisition and guarantor to funders

v. RTIRN Secretariat

- Provision of support to Executive Committee and coordinating centre
- Indirect support to investigators



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