WHO COLLABORATIVE STUDY ON ALCOHOL AND INJURIES

PROTOCOL

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This is by no means a comprehensive document, but should serve as a guide to various aspects of the study.
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1. Background

In 1998, about 5.8 million people died of injuries world-wide, and injuries caused 16% of the global burden of disease (WHO, 1999). More than 95% of injury deaths occurred in the developing world. Despite the magnitude of the problem, injuries are not recognised as a public health priority. Young people in their most productive periods of life are particularly prone to injuries and violence.

Alcohol involvement in injuries has been demonstrated in numerous studies. In the USA alone, about 50,000 deaths occur each year due to alcohol-related intentional and unintentional injuries (Stinson and DeBakey, 1992), and alcohol is involved in up to 30% of adult hospital admissions, particularly those to emergency rooms (Cherpitel, 1989; Umbricht-Schneiter et al., 1991). The problem of alcohol-related injuries is particularly alarming in many developing countries, where alcohol consumption is increasing, injury rates are extremely high, and appropriate public health policies have not been implemented.

Effective prevention of injuries is dependent on the understanding of the epidemiology. Forming an effective system of relevant data collection is vital to define the nature and extent of the problem, to identify and evaluate risk factors, and to set priorities for policy development. Establishing and monitoring alcohol's involvement in fatal and non-fatal injuries should be an important component of the surveillance system. Currently there is no system of relevant data collection in the majority of developing countries, but the Violence and Injury Department of the WHO, in collaboration with its partners, is in the process of developing Injury Surveillance Guidelines for Less Resourced Countries.
2. The purpose of this document

The purpose of this document is to provide guidelines for the standardisation of data gathering for the Collaborative Study on Alcohol and Injuries. It is by no means definitive and should be used in conjunction with:

- the terms of reference document
- recommendations for preparing site proposals
- Registration, Screening, Assessment and Questionnaire Forms
- the master code book

3. Introduction to Study

The WHO Collaborative Study on Alcohol and Injuries comprises four main components:

- feasibility study of Y91 coding for assessment and recording of alcohol intoxication in emergency rooms
- documentation of alcohol involvement in non-fatal injuries among emergency room attendees
- quantitative survey among emergency room attendees using a specifically designed questionnaire
- qualitative study of current local system of assessment and recording alcohol involvement in injuries.

The project is being implemented by the WHO Department of Mental Health and Substance Dependence / Management of Substance Dependence team (MSD/MSB) in co-operation with the WHO Department of Violence and Injury Prevention (VIP).
4. Study Objectives

At a consultative meeting of potential Principal Investigators held in Prague in March 2000, it was agreed that the main focus of the study on alcohol involvement in non-fatal injuries will be on emergency room (ER) patients of metropolitan hospitals, and the objectives of the study will be:

- To test in different societies the ability of emergency room staff to assess and record the degree of alcohol intoxication in injured patients using ICD-10 Y91 coding
- To develop and pilot the materials to assist ER staff in assessing and coding the degree of alcohol intoxication
- To document the proportion of victims of non-fatal injuries with alcohol intoxication in a probability sample of emergency room patients at each site
- To explore the ways in which alcohol assessments/measurements could be worked into routine ER practice
- To examine the context in which drinking had occurred prior to the injury and other drinking variables (amount, type of beverage, etc.) in different cultural settings
- To collect information on the association of patterns of drinking with injuries
- To identify prerequisites for establishing surveillance systems for alcohol involvement in non-fatal injuries in each site.

The reasons why emergency rooms were chosen as the setting for the study were the following:

- emergency rooms are the best health care facilities in terms of representativeness of the population of non-fatally injured persons
- for the objectives of the study a short time span between the time of injury and assessment is needed, and emergency rooms in almost all countries deal with acute cases of injuries
- injury surveillance systems for non-fatal injuries are being developed in many emergency rooms.
5. Recruitment

5.1 Sample size

The assessment of alcohol intoxication and associated injury should be conducted on a probability sample of 500 emergency room patients with injuries from each site. Each consenting patient should be:

- clinically assessed for alcohol intoxication by a trained nurse or doctor using ICDY91 codes
- have a breath specimen taken by a field worker for alcohol using an ALCO-SENSOR III breathalyser
- interviewed about alcohol usage using a specifically designed questionnaire by the field worker.

The sample size of 500 (with completed assessment and interview) is a minimum for each site, but sites may include more cases in the study if they wish.

5.2 Setting

A large metropolitan general hospital should be selected. It is important to avoid selection bias by recruiting cases from specialist trauma centres like, for example, head trauma or spinal cord centres.

5.3 Sampling procedure and analysis plan

The sample will be collected on a ‘shift’ basis with the same fixed proportion of patients from each shift eligible for inclusion being invited to participate in the study. The fixed proportion might be set at every or every second (third etc.) eligible attendee. The proportion depends on the average number of admissions in each particular emergency room and ensures the researchers are not overloaded as well as the potential of lost or missed eligible attendees is minimised. If a proportion of injuries with alcohol involvement is very low in a particular site, it is possible to consider a possibility of disproportionate sampling with recruitment of 300 cases.
using the above-mentioned procedure, and 200 patients - over the weekends when the proportion of alcohol-involved injuries is expected to be the highest (with subsequent weighting of the samples). It is recommended to consult with the study co-ordinators before switching to disproportionate sampling.

Patients who are unable to be interviewed in the ER should be followed up once they have been admitted to a ward. Patients not requiring admission should have all data collected before they leave the hospital.

It is recommended that the research team include at least two field workers working simultaneously so that one person can maintain the integrity of the sample.

5.4 Inclusion and exclusion criteria

- The age limit for recruitment into the study is set at 18 years in view of ethical considerations. This limit may be lowered to 15 years at individual sites which are interested in sampling youth in the study provided that all ethical requirements are met.

- All patients need to give informed consent prior to inclusion in the study. Individual sites may decide, in consultation with their local ethics committees to include unconscious and / or ventilated patients by obtaining permission from relatives or the doctor / medical superintendent of the hospital.

- Only patients presenting to the facility within 6 hours of their injury should be included in the study.

5.5 Participating Countries

<table>
<thead>
<tr>
<th>Argentina</th>
<th>Belarus</th>
<th>Brasil</th>
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<tbody>
<tr>
<td>Canada</td>
<td>Czech Republic</td>
<td>India</td>
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<tr>
<td>Mexico</td>
<td>Mozambique</td>
<td>South Africa</td>
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<tr>
<td>USA</td>
<td>New Zealand</td>
<td>Sweden</td>
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6. Data collection and assessment procedures

The data to be collected on each patient will include the following:

- Clinical assessment of the degree of alcohol intoxication by a trained ER nurse or doctor using the principles of ICD-10 Y91 coding
- Breath analysis for alcohol involvement
- Basic social and demographic variables
- Self-reported drinking-related variables
- Data on the cause of the injury and injuries sustained

Furthermore, researchers will be required to obtain the following information:

- Qualitative data on current recording and reporting systems for non-fatal casualties with alcohol involvement.
- Qualitative descriptive data on the possibilities for or barriers to establishing injury/alcohol surveillance systems in the ER

6.1 Questionnaire Preparation

Individual Project Sites are encouraged to use all of the Core questions in the Registration, Screening, Assessment and Questionnaire Forms, unless resources are so limited that the only way to conduct the study is to cut out parts of the questionnaire.

The questionnaire has been designed to permit insertion by individual Project Sites of additional questions and items of local interest. Additional questions should be issued a unique question number – these additions should be brought to the attention of the WHO co-ordinators.

Each project site is responsible for finalising its own questionnaire (and for creating additional interviewer instructions where needed for the local items). If a site decides not to add any new items then any optional questions which the site chooses not to use should be eliminated from the questionnaire to avoid interviewer confusion.
As far as possible please prepare the questionnaire in a similar format to the one provided by the WHO. Do not change the meaning of any questions. Under no circumstances should the question order be rearranged, or question numbers changed. In particular do no change the numbers preceding the items or categories in multi-part questions. These serve to identify separate variables for computer data-entry. Please send a copy of your Site Specific questionnaire to the WHO. If possible, where a questionnaire has been translated, this should be sent to the WHO for checking of translation adequacy. In translation, substitute appropriate colloquial terms where appropriate. Please follow the WHO guidelines on translation.

### 6.2 Process of interview/assessment

Two field workers should be assigned to each shift during the study period. For the purpose of this protocol these field workers will be referred to as ‘Field worker A’ and ‘Field worker B’.

Field worker A should be in the triage area so that he/she can register each patient who presents to the trauma unit during the allocated time period and approach each patient, explain the study and get informed consent from them for inclusion in the study.

Patients who refuse consent should only have Section A (Registration Form) and Section B (Screening) completed wherefore the interview should be terminated. These forms (for patients who refuse consent) should be kept in a separate file.

Consenting patients should then be assessed by a medical doctor or trained triage nurse with respect to clinical intoxication (see section on Assessing a patient for alcohol intoxication). The clinician should document evaluation of the patient’s clinical level of intoxication in Section C. **This assessment MUST be done prior to Field worker B taking over and conducting the interview and obtaining a breath specimen.**
Once the clinical assessment has been conducted, Field worker B should then conduct:

- **Section D**: The breath alcohol analysis
- **Section E**: Injury Questionnaire
- **Section F**: Drinking prior to Injury
- **Section G**: Typical drinking habits
- **Section H**: Drinking pattern exactly one week before injury (this is an optional section, but the sites are encouraged to conduct at least feasibility testing of this section)
- **Section I**: Background information
- **Section K**: Termination of Interview

Should it not be possible to interview the patient, then **Section J** (Non-interview Report) should be completed by Field worker B.

If Field worker A has the time, he/she can assist Field worker B with the interview.

Please take note of the organogram on the next page for a more detailed explanation of the process of the interview.
Interview all injured patients presenting during sampling timeframe

SECTION A + B

Was consent given for the study?

YES

Conduct Clinical Assessment

SECTION C

NO

Thank and break off interview

Conduct Breath Analysis & Injury Data

SECTION D + E

Can the patient talk well enough to be interviewed now?

NO

YES

Can the patient be interviewed later

YES

Conduct Interview Items

SECTION F+G+H

NO

Document patient demographics (SECTION I) & time interview ended (SECTION K)
6.3 Completing the Recruitment, Assessment and Interview Booklet

6.3.1 Section A : Recruitment Form

QA01 Each patient must be given a sequential number starting at 001 and going up to 999. These numbers should be prefixed with the unique Project Site code (see QA03), e.g. patient 1 at the South African site would be given the code SA001.

QA02 In lieu of the patients name, a hospital admission or registration number should be inserted so that the patient can be followed up should he/she be admitted to a ward. Patients names can be used only on removable stickers, which should be removed after completion of an interview.

QA03 Each site will be provided with a two character unique Collaborating Project Site Identification Code (see below). It is suggested that this be incorporated into the questionnaire at preparation time, rather than completing it later.

<table>
<thead>
<tr>
<th>COUNTRY</th>
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<tbody>
<tr>
<td>USA</td>
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<td>Czech Republic</td>
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<td>South Africa</td>
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<td>Argentina</td>
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<td>Belarus</td>
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QA04 Each field worker should be given a unique Field worker Identification Code, again prefixed by the site code, e.g. South African field worker number 1 should be given a
code SA01. Keep a list of field workers names and codes. Each field worker should know their own code.

QA05 The date of recruitment should be inserted in the format dd/mm/yyyy.

QA06 The time of recruitment should be inserted using the 24 hour clock, i.e. 16h00 not 4pm.

QA07 Insert the patients age at last birthday. If the patient’s exact age is not known then put in an approximate age in years.

QA08 Indicate the patients gender.

QA09 Briefly describe the patients main complaint or problem, e.g. fell and broke arm, stabbed in chest with knife, etc.

6.3.2 Section B : Screening

The field worker should introduce themselves to the patient and give a brief explanation of what the study is about.

QB01 Ask the patient how long ago the injury occurred. Since this study has a 6 hour cut-off point, if the injury occurred more than 6 hours previously, the patient should be thanked and the interview broken off.

QB02 Ask the patient if this is the first treatment they are receiving for this specific injury. If he/she is reattending the facility for an old injury then thank them and break off the interview.

If the injury occurred 6 or less hours before and the patient is not reattending, read the consent form to him/her and explain that they are not obliged to consent and that they may withdraw from the study at any point and that this will not jeopardise the management of their injury.
Please make sure to explain that the alcohol results will be used for research purposes only and cannot be held against them in a court of law. Alcohol results will not be documented on the patients hospital notes.

Get the patient to sign the consent form or give verbal consent (depending on the requirements of your local ethical committee). If the patient is not able to sign for themselves then get a relative or the attending doctor to give consent (depending on approval by your local ethics committee).

QB03 Indicate whether the consent form was signed.

QB04 If the consent form was not signed, please indicate the reason by ticking the appropriate box. If the reason for not signing the form is not one of the options please specify the reason under ‘other’. This will be coded at a later stage.

6.3.3 Observational Assessment of Alcohol Intoxication

A training session should be held to introduce clinical signs of different levels of alcohol intoxication based on the ICD Y91 codes.

**Y91.0 Mild alcohol intoxication**

  Slight smell of alcohol on breath, facial flushing, slightly slurred speech, slight impairment of fine motor co-ordination, talkativeness, slightly altered attention and/or judgement, some relaxation/lowering of inhibitions, mild euphoria, unimpaired ability to co-operate.

  For other people it is not always obvious that the person is intoxicated even if interacting with them.

**Y91.1 Moderate alcohol intoxication**

  Smell of alcohol on breath, facial flushing, red or watery eyes, slurred speech, decreased motor co-ordination, garrulousness, clearly impaired attention and or judgement, impaired communication, moderate disturbances in emotional and behavioural functions and
responses, euphoria, elation or irritated mood, reduced level of frustration tolerance, impaired ability to co-operate, lateral gaze nystagmus.

For other people it is obvious that a person is intoxicated if interacting with them or performing coordination-demanding tasks. However, moderate alcohol intoxication is not always obvious for other people without interaction with them or performance of coordination-demanding tasks.

**Y91.2 Severe alcohol intoxication**

Prominent smell of alcohol on breath, severely slurred speech, gross unsteadiness, severe difficulty in co-ordination, irrational behaviour, severely impaired attention and/judgement, severely impaired communication, severe disturbances in emotional and behavioural functions and responses, euphoria, elation or irritated mood, significantly reduced level of frustration tolerance, aggressiveness, clearly impaired ability to co-operate.

For other people it is obvious that a person is severely intoxicated even without any interaction with them. It is possible to establish communication with a person, though communication and interaction are severely impaired due to intoxication.

**Y91.3 Very severe alcohol intoxication**

Prominent smell of alcohol on breath, disoriented, asleep or difficult to arouse or comatose, unable to communicate, unable to co-operate, respiratory and circulatory depression

It is often unclear whether a person is soporose / comatose due to alcohol intoxication or other medical condition, or both.

Section C should be completed by the doctor on duty or triage nurse in the trauma unit at the time of the patients presentation.

**QC01** The time of this assessment should be noted, please use the 24 hours clock, i.e. 16h00 not 4pm.

**QC02** Place an x in the appropriate space in the table based on your evaluation of the patients signs and symptoms of alcohol intoxication. Note, if the patient does not manifest any of these signs and symptoms please leave the table blank.
QC03 Based on your evaluation of the patient and prior training with regard to Y91 codes, indicate the patients level of intoxication in the table. If it is not possible to assess the patient adequately but you suspect that there is alcohol involvement please tick Y91.9.

QC04 Using your clinical judgement and experience, please indicate whether you think that the patient is intoxicated with alcohol only or if there are other drugs involved. You can ask the patient (self report) or obtain other collateral information (from relatives, patient in possession of drugs, drug levels). Please indicate in the table how you came to your decision. Please do not guess, if you have no collateral or the patient is not able to communicate, please tick the box ‘not sure’.

QC05a Please state your name for the record, just a surname.

QC05b Please state your designation, e.g. registered nurse, medical officer, etc.

### 6.3.4 Section D: Breath Analysis for Alcohol Intoxication

Field worker B should do the breath alcohol analysis.

In the black ALCO-SENSOR box you will find:
- An ALCO-SENSOR III intoximeter
- A passive adapter
- A couple of small cups for the passive adapter
- A screwdriver (for calibration purposes)
- ALCO-SENSOR III Manual
- A couple of blow tubes (additional tubes have also been supplied)

Furthermore, you should have a MINI-ALCO calibration can.

All field workers should be trained on how to take an adequate sample of breath for analysis. Basic operating instructions are as follows (but more detail can be obtained by reading the ALCO-SENSOR Manual supplied with the intoximeter):
1. Remove unit from box. Note temperature window on back of unit.
2. Mount mouthpiece (SET button must be depressed).
3. Press READ button and hold down for 5 to 10 seconds to verify unit is ready to use.
4. Depress SET button.
5. Instruct subject to blow steadily for as long as possible.
6. Push READ button before exhalation ceases (but not less than 3 seconds after blowing starts)
7. Keep READ button depressed until maximum reading is obtained (about 3 seconds)
8. Record the result
9. Discard the mouthpiece

If the ALCO-SENSOR III displays 888 this indicates that the battery is not strong enough to support an accurate reading and needs to be replaced. Replace the battery by following the procedure on Page 20 of the ALCO-SENSOR III Manual.

Practice sessions should be held during the pilot phase of the study so that there is standardisation of the procedure. Field workers should know how to use the passive adapter on the ALCO-SENSOR III. This is not adequately explained in the ALCO-SENSOR III Manual so the instructions below should be followed:

| 1. Attach the passive adapter to the top of the ALCO-SENSOR III intoximeter |
| 2. Attach one of the small plastic cup devices to the passive adapter   |
| 3. Depress the SET button                                               |
| 4. Place the cup device close to the patients mouth or over the endotrachial tube if the patient is ventilated (it cup does not have to be pressed against the patient’s mouth, it just needs to be in close proximity to capture exhaled air since the adapter sucks the exhaled air into the unit) |
| 5. Depress the QUICK DRAW button on the back of the passive adapter (you will hear a ‘whizzing’ sound) |
| 6. Depress the READ button after the ‘whizzing’ sound stops until you obtain a digital display of the result |
| 7. Record the result                                                   |
| 8. Disinfect the small plastic cup device since you might be required to use them repeatedly. |

Make sure that the intoximeter has been flushed between patients by depressing the SET BUTTON a number of times. This purges the machine of any residual alcohol. Sufficient time should also be allowed for all traces of alcohol to be eliminated. Keeping the SET BUTTON depressed when the machine is not in use, accelerates this process. If the above precautions are not observed, cumulative alcohol results with occur.
Please follow the instructions in the ALCO-SENSOR III Manual precisely, particularly with regard to calibrating the equipment (see page 12: Accuracy check procedure using mini-alco can). Although the manual recommends that you only do calibrations every month, we ask that you calibrate the ALCO-SENSOR III intoximeter at the following times:

- Before commencing the study
- After 200 patients
- After 400 patients

QD01 Please note the time that the breath specimen is taken, using the 24 hour clock, i.e. 16h00 not 4pm.

QD02 Please indicate which field worker has taken the specimen by including his/her Code Number.

QD03 Each ALCO-SENSOR supplied by the WHO will have a code number on the back of the machine. Please check this number and write it down in the box provided.

QD04 Please write down the breathalyser level to two digits after the decimal point.

QD05 If you could not obtain a specimen of breath from the patient please indicate why this was not possible. If the reason is not included in the list provided please write the reason down under ‘other’.

QD06 If you needed to use the passive adapter in order to obtain the specimen please check the YES box.

6.3.5 Section E: Injury Questionnaire

Field worker B should indicate to the patient that he/she is going to ask them a few questions about how they were injured, where, etc.
If the patient is not able to talk, please complete as many of these variables as possible by consulting the patient’s notes or observing the patient yourself.

QE01 Ask the patient to tell you what happened to him/her. Please record verbatim what he/she says and write it in the appropriate space on the questionnaire. Based on what the patient tells you, please indicate the nature of their injury by ticking the appropriate box or boxes (if more than one applies). If you cannot categorise their injury into one of the suggestions, please tick ‘other’ and specify the nature of the injury.

QE02 Please ask the patient how he/she was injured and categorise only one response, i.e. the main cause of the injury. Again, if you cannot categorise the injury, please tick ‘other’ and state how the patient was injured.

QE03 Categorise the patients injuries according to intent, based on what he/she has already told you. If you are unsure of the intent, you might need to ask the patient again, particularly if you suspect that an injury was self-inflicted. If the injury was unintentional, self-inflicted or due to legal action please skip out question QE04 and QE05 and go straight to QE06.

QE04 *For violence-related injuries only.*
Ask the patient if he/she knew his/her perpetrator and then categorise this according to the list. If the list does not include the option suggested by the patient, please tick ‘other’ and specify who the perpetrator was in the space provided.

QE05 *For violence-related injuries only*
Ask the patient, whether he/she thinks or knows whether their perpetrator had been drinking alcohol before their fight. If the patient actually saw their perpetrator drinking then tick, YES, definitely. If the patient only suspects that he/she had been drinking but did not actually see them doing so, then tick SUSPECTED.
QE06  Ask the patient where he/she was when they were injured. You might need to prompt the patient or check the patient’s notes. Categorise the response, tick ‘other’ if the option is not available, and please specify where the injury took place.

QE07  Ask the patient what he/she was doing when they were injured. You might need to prompt the patient. Categorise the response, tick ‘other’ if the option is not available, and please specify what the patient was doing.

6.3.6  Section F : Drinking prior to Injury

If the patient is able to communicate well enough while in the trauma unit the following sections should be completed. If the patient requires an urgent intervention these sections can be delayed until he/she is more stable in a ward, but please ensure that you record all contacts with the patient (see last page - Record of Contacts). If the patient does not require ward admission and is thus going to be discharged after treatment, these questions MUST be completed before he/she leaves the hospital.

QF01  Please insert the date of the interview in the format dd/mm/yyyy.

QF02  Please insert the time of the interview using the 24 hour clock, i.e. 16h00 not 4pm.

QF03  Indicate which field worker is doing the interviewing by including his/her unique identifier.

Give the patient a brief explanation of what the interview is about. Assure him/her that confidentiality will be maintained and that the information will be used for research purposes only.

QF04  Ask the patient if he/she had any alcohol to drink in the six hours leading up to their injury/accident. If they did not, please skip to Section G.
QF05 Ask the patient when he/she started drinking. Insert the date and time into QF05a (using dd/mm/yyyy format) and QF05b (using the 24 hour clock).

QF06 Ask the patient when they had their last drink. Insert the date and time into QF06a (using dd/mm/yyyy format) and QF06b (using the 24 hour clock).

QF07 Explain to the patient that you are now going to ask him/her exactly what they had to drink and how much they had to drink in the 6 hours before their injury. If you are unable to categorise the type of drink according to alcohol content please just write down the commercial name of the drink. You will need to make a list of all the regular types of drinks consumed in your area and check the bottle/can label for the alcohol content. Keep this list with your Master Coding Booklet.

You need to insert the absolute alcohol totals when you code the questionnaire. These may be calculated by multiplying the volume of the consumed drink by the alcohol content.

Example: 500ml of low alcohol beer would be, 500 x 2.5% or 500 x 2.5 ÷100 = 12.5 ml of absolute alcohol.

Do this for each type of alcohol consumed and insert the results into the column marked ‘absolute alcohol total’. The total amount of absolute alcohol consumed must be calculated by adding together all the absolute alcohol totals.

QF08 Ask the patient where he/she had been drinking in the 6 hours prior to their injury. If there was more than one place please tick all the applicable codes. If the place does not appear in the list, please write it in under ‘other’.

QF09 Ask the patient where he/she had their last drink. Please code only one option.

QF10 Ask the patient how drunk he/she was feeling just before they were injured. Read the list to the patient and prompt if necessary. Please code only one option.
QF11  Ask the patient whether his/her drinking session was cut short by their injury. In other words, had they not been injured, would they have continued drinking.

QF12  If the patient indicates that they would have continued drinking, then ask them what and how much they would have continued to drink. Since this is a very subjective question, it can be omitted if you feel that the answers you will get from the patients will not be valid.

If the patient can answer these questions, please calculate the absolute alcohol for each drink and the total absolute alcohol consumed as explained in QF07.

QF13  Ask the patient if he/she had any alcohol to drink between the time that they were injured and the time that they presented to hospital. Since there is a 6 hour cut off period between injury and presentation, you can prompt the patient by saying something like, you were injured at X time but only came to hospital at Y time. Did you have any alcohol to drink during this time.

QF14  Ask the patient if he/she thinks that the accident or injury would still have occurred had they not been drinking. In other words, do they think that their alcohol consumption contributed to the injury causation.

6.3.7 Section G : Typical Drinking Patterns

Explain to the patient that you are now going to ask him/her about their typical drinking habits. You need to tell them again, that all their answers will be kept in the strictest confidence and that their answers will be used for research purposes only.

ALL THE QUESTIONS IN THIS SECTION PERTAIN TO ALCOHOL DRINKING IN THE LAST YEAR (past 12 months). You might need to constantly remind the patient of this fact as you ask the following questions.
If the patient has not consumed any alcohol in the last year, please skip this section and go on to the next section.

QG01  Ask the patient how often they drink alcohol (any type of alcohol including home brews). You may need to prompt by offering them the options included in the questionnaire.

QG02  Ask the patient to think about a typical drinking session and tell you how much they usually drink, what they drink. You need to calculate the absolute alcohol total for each drink and the total absolute alcohol consumed as explained in QF07.

QG03  Ask the patient how often (in the last year) they have consumed 12 or more drinks. You may need to prompt by offering them the options included in the questionnaire.

QG04  Now ask the patient how often (in the last year) they have consumed between 5 and 11 drinks. Again, you may need to prompt by offering them the options included in the questionnaire.

QG05a-QG05d  The next four questions assess the patients dependence on alcohol. All the questions pertain to alcohol drinking in the last year. If the patient refuses to answer these questions, please tick the appropriate box. Do not pressurise the patient to answer – remember they have a right to refuse to answer any questions.

QG06  Ask the patient if he/she has found that over the last year they need to drink much more alcohol than before in order to obtain the same sort of effects, or whether their regular amount of alcohol has less effect on them.

QG07  Ask the patient whether he/she has sustained an injury (not counting the present one) in the last year. Only count those injuries which required treatment – a simple cut finger requiring a plaster does not count.
If the patient has been injured in the last year, ask him/her how many times they required treatment.

### 6.3.8 Section H : Drinking Pattern Exactly one week before Injury

**QH01** You need to ask the patient to think about where they were at exactly the same time a week before. You will need to prompt the patient by saying something like, you said that you were injured at 10.00 this morning. Today is Saturday. Now at 10.00 last Saturday morning where were you. You might need to read the list of options to the patient. You may code more than one option.

**QH02** Remind the patient that you are still talking about exactly one week ago. Give him/her the time and day again. Ask him/her if they had any alcohol to drink in the six hours leading up to this time. If they say NO, or DON’T KNOW, then you need to skip to the next section.

**QH03** If the patient indicates that he/she had been drinking the week before, then you need to ask them if they can remember what they had had to drink and how much. You will need to calculate the absolute total alcohol for each drink and the total absolute alcohol consumed as you did for QF07.

### 6.3.9 Section I : Background Information

Please try to obtain this information even if you have not been able to interview the patient because of the severity of their injuries. Often this type of information is included in the patients hospital notes, or can be obtained from relatives.

**QI01** Ask the patient, or find out, how many years of formal education they have completed. Note that a year must have been completed to count. If for example, they dropped out in Grade 11, then only 10 years of formal education were completed. If the patient has
tertiary education such as a diploma or degree, then add the number of years each course took to complete to their school education, e.g. a 2 year diploma would be $12 + 2 = 14$.

QI02 Ask the patient, or find out, whether they work 30 hours or more a week in a paid job. If yes, then skip the next question and go on to QI04.

QI03 If the patient is not in a paid job for more than 30 hours a week, ask him/her what they do when they are not working. Tick the appropriate option. If it is not included, please write it in under the ‘other’ option.

QI04 Ask the patient if they are willing to divulge their monthly personal income. NOTE that this question is optional. If the patient does not want to divulge this information, please do not pressurise him/her. Write down in your own currency the monthly amount, remembering to insert the currency symbol, e.g. US$, £, R, etc. During coding, these amounts should be converted into the equivalent US dollars and then further categorised into very low, low, middle, high, very high based on the average income for each country.

QI05 Ask the patient, or check the hospital records, for his/her place of residence. Include both the suburb (QI05a) and city (QI05b).

Thank the patient for helping with the study and ask them if they have any comments or suggestions to make about the questions or interview.

6.3.10 Section J : Non-interview Report

If you were unable to interview the patient, or needed to terminate the interview process at any stage and could not continue, please complete this section. Please include the date and time and why the patient could not be interviewed. If the appropriate option does not appear in the list, please mark ‘other’ and specify the reason.
6.3.11 Section K : Termination of Interview

Please document the time the interview ended and the total length of the interview in minutes. This might be difficult if the interview was conducted in sections, but please attempt to complete this question.

6.3.12 Record of Contacts

Please record every contact you have with the patient and explain why the interview process was halted, e.g. patient sent to theatre, too ill to be interviewed, etc.

6.3.13 Information to Patient and Consent Form

On the last page of the Booklet you may add the information which you require the field worker to read to the patient. This information must include an outline of the study, why you are conducting it, how it will be of benefit, as well as the patient’s

- right to refuse participation; and
- right to withdraw from participation at any time without adverse consequences.

The field worker who obtains consent from the patient needs to explain who he/she is and tell the patient that all information obtained will be used for research purposes only and confidentiality will be maintained.

Patients must give informed consent. This may be in the form of a signed consent form (see example) or verbal depending on your ethical committee requirements. If the patient gives verbal consent then his/her name never appears on any of the forms.
Example of an informed consent form requiring a signature

I, ___________________________ (study participant) hereby give consent to taking part in this alcohol and injury study.
I have had the study explained to be by _______________________________ (field worker) and understand the study and that I have the right to withdraw from participation at any time without adverse consequences. I have not been coerced into this study and do so of my own free will.
I accept that my name will not appear on the research form and that the alcohol results will be used for research purposes only and cannot be used against me in a Court of Law.
I understand that any information I give will be held in the strictest confidence by the researchers.
Signed: ___________________________ Date ______________

6.4 The Master Code book

The Master Code book contains core codes. Use of a uniform coding system permits cross-country comparisons for analysis. The Code book will be updated every time project sites request codes for new categories or items. Updated versions of the Master Code book will be sent to each site as soon as a modification occurs.

Codes from the Master Code book are used for three purposes:

- As the item number for a local item added by an individual Project Site. These are pre-coded into the questionnaire during questionnaire preparation. Using a core code from the Master Code book as the item number will permit us to match items across sites for analysis.
• For responses to certain types of open-ended questionnaire. If the appropriate code does not appear in the response set on the questionnaire, it should be looked up and coded after the interview.
• To identify ‘Other’ items in multi-part questions. These should be looked up and coded after the interview.

7. Data Maintenance and Analysis

The WHO will supply you with an EPI INFO qes file for data capture. Sites are encouraged to download the latest EPI INFO software from the CDC site at http://www.cdc.gov/epiinfo/

Data collected on consumption of alcohol at the time of and after the injury, at the same time period one week earlier and on the usual frequency/quantity will be analysed as a case-crossover design. Conditional logistic regression for matched case control data will be used to estimate the effect of changes in alcohol consumption on the risk of an injury. The collection of both usual frequency and consumption at the same time period one week earlier will enable us to estimate relative risks using both the pair-matched approach and the usual frequency approach to a case-crossover analysis. This will enable us to investigate any recall bias (Maclure, 1991; Mittleman, Maclure & Robins, 1995; Petridou et al, 1998).

Descriptive statistics will include estimates of the proportions of injuries in which alcohol is involved by demographics, day of week, time of day, severity of injury, violence, alcohol type and amount.

Each site will enter and verify their own data.

Local investigators will have ownership of the data but each site will be required to send cleaned datasets in electronic format to the WHO. The WHO will provide access to the central datasets for comparative analysis. Two-site, three-site, etc. comparisons will be made by arrangement between site investigators and the WHO. Multi-country cross-site comparative analysis will be undertaken by the WHO.
8. Project Management

The study will take approximately 1.5 - 2 years. The following time line is suggested:

<table>
<thead>
<tr>
<th>Activities</th>
<th>Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stages</td>
<td>1-3</td>
</tr>
<tr>
<td>Assessment /Site visits</td>
<td></td>
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<tr>
<td>Development of Guidelines and protocol</td>
<td></td>
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<tr>
<td>Pilot test</td>
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<tr>
<td>Training</td>
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<tr>
<td>Data collection</td>
<td></td>
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<tr>
<td>Evaluation</td>
<td></td>
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<tr>
<td>Analysis/dissemination</td>
<td></td>
</tr>
<tr>
<td>Seminar/conference</td>
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</tbody>
</table>

The WHO will co-ordinate the study and provide financial assistance for sites in developing countries.

A meeting of Principal Investigators will be held at the end of the project to assist with the drafting of the final report and the main publication for the study.

9. Reporting

Each site must inform WHO about the study implementation, including the progress of the study and problems which have arisen, and supply reports to the WHO in accordance with the terms of reference.
10. Publications

Sites are encouraged to publish their own data. The WHO must be acknowledged in publications and kept informed about publication plans. At least one joint publication by the WHO will be produced to report on the overall results of the project with site investigators as co-authors (provided that they invested into the draft of the publications).

A final WHO report will be produced for publication in January 2002. This report will include:

- the project as a whole
- country chapters
- cross-site analysis
- recommendations for the future.

At some later stage the multi-country database may be merged with other similar data set in order to obtain more representative data.