

REPORT

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Road Traffic Injuries in Malawi with special focus on the role of alcohol

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Summary

Driving under the influence of alcohol is one of the principal causes of road traffic crashes (RTCs) [1]. The use of alcohol is also a risk factor for other road users, such as pedestrians and bicyclists. The association of alcohol in injurious and fatal RTCs has been well documented in most high-income countries, but data for low- and middle-income countries is scarce, particularly for African countries [2].

The study was a collaborative effort between Kamuzu Central Hospital (KCH), the Norwegian Institute of Public Health (NIPH) and Oslo University Hospital (OUH), with the financial support of UK Aid through the Global Road Safety Facility (GRSF) hosted by the World Bank, the International Council on Alcohol Drugs and Traffic Safety (ICADTS) and the Norwegian Council for Road Safety (Trygg Trafikk). The objective of the study was to generate new knowledge about road traffic injuries in Malawi and the extent of traffic accidents related to alcohol use, to increase capacity to conduct alcohol testing, and develop a database for the findings, which in turn will form the basis for future policymaking to reduce traffic accidents.

The objectives were achieved through collecting data on patients who sought treatment after road traffic crashes and admitted to the Emergency Department at KCH in Lilongwe, Malawi. A questionnaire was developed for data collection in cooperation between the project groups in Norway and Malawi. The data included basic information about the patients, alcohol use before the injury, and information about accident circumstances, including types of road users and vehicles involved. Participation was voluntary and anonymous. All weekdays, weekends and nights were covered. Alcohol was measured using a breathalyzer or saliva test for those who were not able to blow. Knowledge and training of local KCH employees to perform alcohol testing and record data were an important aspect of this study.

The project was approved by the National Health Science Research Committee (NHSRC) in Malawi. The Regional Committee for Medical and Health Research Ethics in Norway was consulted, and their conclusion was that no formal application was needed, with reference to the Norwegian Health Research Act Section, §2 and 4a. A Data Protection Impact Assessment was performed as required by NIPH.

There were 1251 patients in the study, representing nearly 95 per cent of those who were asked to participate. The results show a rather high prevalence of alcohol use among several injured road user groups (totally about 25 percent), particularly among those injured during weekend nights and evenings, but also during weekday evenings and nights. It was estimated that about 15 per cent of injured motor vehicle drivers and riders had BACs above the legal limit of 0.8 grams/L at the time of the crash. The findings also show that it is important to focus on bus/minibus/lorry drivers who often carry passengers, where about one out of five tested positive for alcohol. It is worth noting that pedestrians had the highest prevalence of alcohol use before being injured. They constitute a vulnerable group; they often walk in the dark with no road lighting, no pavements, walkways or safe places to cross the road. Combined with alcohol use their injury risk is even higher.

The collected data can contribute to future road traffic safety procedures and measures. The long-term goal is to contribute to sustainable development goal 3, target 3.6, to reduce by half the number of global RTC deaths and injuries.

This study shows the importance of collecting adequate and relevant data for health authorities particularly in low- and middle-income countries in battling the challenge of alcohol-related road traffic crashes, deaths and injuries. Due to the COVID-19 pandemic, a number of recommendations were presented to Malawian authorities at a virtual seminar held in autumn 2020.

Sammendrag

Hvert år dør ca. 1,3 millioner personer i trafikkulykker, 30-50 millioner blir skadet. Malawi er et av verdens fattigste land som ligger i sørøst-Afrika og har over 18 millioner innbyggere. Malawi er nå blant verdens 10 land med flest dødsulykker (over 30 døde/100 000 innbyggere, Norge har mindre enn 2/100 000). Det er lite kunnskap om årsakene til ulykkene, bl.a. omfanget av alkoholrelaterte ulykker. Landets alkoholgrense er 0,8 promille for førere av alle grupper motorkjøretøy.

Å kjøre under påvirkning av alkohol er en av hovedårsakene til trafikkulykker [1]. Bruken av alkohol er også en risikofaktor for andre trafikanter, som fotgjengere og syklist. Det er godt dokumentert at alkohol er en faktor i skadelige og dødelige trafikkulykker i de fleste høyinntektsland, men data for lav- og mellom-inntektsland mangler, spesielt for afrikanske land [2].

Denne studien var et samarbeidsprosjekt mellom Kamuzu Central Hospital (KCH), Folkehelseinstituttet og Oslo Universitetssykehus, med økonomisk støtte fra UK Aid gjennom Verdensbankens Global Road Safety Facility (GRSF), the International Council on Alcohol, Drugs and Traffic Safety (ICADTS) og Trygg Trafikk. Målet var å generere ny kunnskap om veitrafikk skader i Malawi og omfanget av trafikkulykker knyttet til alkoholbruk, å øke kompetansen i å utføre alkohol-testing, og utvikle en database for å registrere resultatene. Hensikten var å gi et evidensbasert grunnlag for framtidig politikk utforming for å redusere trafikkulykker.

Målene ble nådd gjennom å samle inn data om pasienter som søkte behandling etter trafikkulykker og som ble innlagt ved Akuttavdelingen ved KCH i Lilongwe, Malawi. Et spørreskjema ble utviklet i samarbeid med prosjektgruppene i Norge og Malawi. Dataomfanget inkluderte bl.a. grunnleggende informasjon om pasientene, alkohol bruk før skaden, i tillegg til opplysninger om omstendighetene rundt ulykken inkludert type trafikant og kjøretøy. Deltakelse var frivillig og all data ble anonymisert. Alle ukedager ble dekket i undersøkelsen, likeså helger og netter. Alkohol ble målt ved bruk av alkometer eller spyttprøver for pasienter som ikke var i stand til å blåse. Kunnskapsoverføring og opplæring av lokale KCH ansatte i å gjennomføre alkohol testing og dataregistrering var en viktig del av denne studien.

Prosjektet var godkjent av den etiske komiteen i Malawi (NHSRC), og regional etisk komité for medisinsk og helsefaglig forskningsetikk (REK) ble konsultert. Deres konklusjon var at ingen formell søknad til REK var nødvendig med henvisning til Helseforskningsloven §2 and 4a. I tillegg ble det gjennomført en personvernkonsekvensutredning, i tråd med General Data Protection Regulation (GDPR) og krav fra Folkehelseinstituttet.

Det var 1251 pasienter i studien, nærmere 95 % av de som ble spurt om å delta. Resultatene viser høy prevalens av alkohol bruk blant mange ulike grupper skadde trafikanter (totalt ca. 25%), spesielt blant de skadde under helgene (kveld og natt), men også mye på ukekvelde- og netter. Omtrent 15% av de skadde førerne av motorkjøretøy hadde alkohol-konsentrasjon i blodet høyere enn lovlig grense på 0,8 promille på tidspunktet for ulykken. Funnene viser også at det er viktig å fokusere på førerne av buss/minibuss/lastebiler, som ofte har passasjerer om bord, hvorav en av fem testet positivt for alkohol. Det er verdt å merke at fotgjengere hadde høyest prevalens av alkoholbruk før de ble skadd. De er en

sårbar gruppe; de går ofte i mørket uten veitrafikk lys og uten fotgjengerfelt eller trygge steder å krysse veien. Kombinert med alkoholbruk er risikoen for skade enda høyere.

De innsamlede data kan bidra til framtidige veisikkerhetsprosedyrer og tiltak. Det langsiktige målet er å bidra til bærekraftsmål 3, delmål 3.6, å halvere antall dødsfall og skader i verden forårsaket av trafikkulykker.

Denne studien viser hvor viktig det er å samle inn tilstrekkelig og relevant data for helsemyndigheter spesielt i lav- og mellom-inntektsland i kampen mot alkohol-relaterte trafikkulykker, dødsfall og skader. En rekke anbefalinger ble presentert malawiske myndigheter under et virtuelt seminar, på grunn av COVID-19 pandemien, som fant sted høsten 2020.

Glossary

BAC	Blood alcohol concentration
DALY	Disability-Adjusted Life Years
GDPR	General Data Protection Regulation
GRSF	Global Road Safety Facility
HIC	High Income Countries
ICADTS	International Council on Alcohol, Drugs & Traffic Safety
KCH	Kamuzu Central Hospital
LMIC	Low- and Middle-Income Country
NHSRC	National Health Sciences Research Committee
NIPH	Norwegian Institute of Public Health
OUH	Oslo University Hospital
REK	Norwegian National Committee for Medical and Health Research Ethics
RTC	Road Traffic Crashes
UN	United Nations

Introduction

Background

Involvement in road traffic crashes (RTC) is one of the most important causes for physical and psychosocial disease burden and early death worldwide. For the age group 5-29 years, it is the leading cause of death [1]. According to the analysis of DALY (Disability Adjusted Life Years) rates [3], RTC involvement is ranked among the 10 most common causes of premature death [3]. In high-income countries (HIC), the number of fatal RTCs has decreased during the last years, while the number has increased in low- and middle-income countries (LMIC) [1]. Worldwide, about 90 per cent of the crashes are recorded in LMIC (2016), while these countries had only about 60 per cent of the motor vehicles [1].

In 2006, the World Bank together with donor partners established The Global Road Safety Facility (GRSF), which is a global multi-donor fund. Its mission is to help governments develop capacity for road safety management and scale up road safety delivery in LMIC, including scientific and technological capacities [4]. In 2010, the United Nations announced the Decade of Action for Road Safety with the goal of halving the global number of road traffic deaths by 2020, in line with Sustainable Development Goal 3, target 3.6. During these ten years, the number of fatal RTCs has been reduced in most HIC, while an increase has been observed in LMIC, where few effective measures have been implemented. The focus period has since been extended to 2030 for actions to reduce fatal RTCs. More systematic work on preventive actions for road traffic safety in LMIC is needed. A recent report published by the World Bank in collaboration with Bloomberg Philanthropies concluded that reducing road traffic injuries in LMIC would have a positive effect on national income growth. A long-term income growth of 7 to 22 per cent increase in GDP per capita over 24 years can be achieved through substantial reduction in road traffic injuries in line with the current UN targets [5].

In Sub-Saharan Africa, road traffic injuries are a major concern. The annual incidence of road traffic deaths in the WHO African region is 26.6 pr. 100 000 inhabitants, while the corresponding number for Europe is 9.3/100 000 [1]. The share of crashes involving alcohol in Africa is reported to vary from 8 to 39 per cent depending on subregion and selected patient groups [6].

Whereas 60 per cent of countries in the world with laws meeting best practice in terms of drink driving are from the European region, only two per cent are from the African region [1]. In Africa, every country has a national drink driving law, though only 75 per cent are based on blood alcohol content (BAC). Of these, only 25 per cent of countries have a BAC limit equal or lower than 0.5g/L as recommended. Data on drink driving remains limited in many countries and is necessary to understanding the magnitude of the problem as well as to evaluate the impact of efforts to prevent it.

The UN encourages targeting actions during the Decade of Action, by establishing five pillars and later 12 Global Road Safety Targets. Under the fourth pillar “Safer Road Users”, is target 9: by 2030, halve the number of road traffic injuries and fatalities related to drivers using alcohol, and/or achieve a reduction in those related to other psychoactive substances [7]. Specific actions to take in Africa are designed in the African Action Plan for the Decade for Action. In this plan, activities aiming to reduce drink driving are the following: (i) set rules to reduce alcohol and drug related crashes and injuries and seek compliance with drink

driving laws and evidence-based standards; (ii) harmonize the rules at sub-regional level [8].

Alcohol and Road Traffic Injuries in Malawi

Malawi is located in southeastern Africa (Figure 1) and has approximately 18 million inhabitants (in 2018). The country represents one of the world's poorest countries, and among one of the 10 worst countries in terms of road traffic fatalities [1].



Figure 1. Map of Malawi (Wikimedia.org. Credit: OCHA)

In Malawi, the estimated annual number of road traffic fatalities is 31 per 100,000 inhabitants in 2016 [1]. Among the fatal RTC victims in Malawi, 50 per cent are pedestrians, 19 per cent are cyclists or riders of motorized 2 and 3-wheelers, 25 per cent are passengers of all vehicles and 6 per cent are drivers of all vehicles [1]. Among the victims of crash fatalities in Malawi, there are three times as many men as women (while the average ratio in Africa is two men for one woman).

Malawi has a national drink driving law limiting the BAC to 0.8g/L for all motor vehicle drivers and enabling police to implement random drink driving tests. Yet, best practices would be a BAC limit not exceeding 0.5g/L for general population and not exceeding 0.2g/L for young and novice drivers. Additionally, it is difficult to evaluate the efficiency of these national measures, as the number of road crash fatalities involving alcohol in Malawi is unknown. Malawi lacks accurate data on alcohol and drug use as contributing factors in RTCs because government entities and Malawian hospitals lack equipment to analyse alcohol and drugs in blood samples. It has also been reported that Malawian police have few breathalyzers.

The only data available is unrelated to road traffic injuries. Indeed, the estimated average alcohol consumption per capita (age 15+) in Malawi, as reported by the WHO, is 3.7 litres pure alcohol in 2016 (6.4 litres among males, 1.0 litres among females) and the estimated

average consumption among drinkers is 15.5 litres (18.9 litres among males and 7.2 litres among females) [10]. A household survey conducted in 2012 found that 27 per cent of males and 1.6 per cent of females had consumed alcohol the last 12 months [11]. Binge drinking was found to be common; on average, male alcohol users drank five or more standard alcohol units (defined as 12.5 grams alcohol) on each of 96 drinking sessions during the last 12 months [11].



Photo 1: Welcome sign on road between airport and centre of Lilongwe (Photo Credit: Elin H. Wyller)

Research collaboration with Kamuzu Central Hospital, Malawi

Beginning in 2019, a GRSF grant enabled data collection and analysis on road traffic injuries in Malawi with a special focus on the role of alcohol as part of the research conducted by the NIPH and OUH. The short-term goal of the project was to generate new knowledge about road traffic injuries in Malawi and the extent of traffic crashes related to alcohol use, to increase capacity to conduct alcohol testing and develop a database for the findings. The long-term goal was that the Malawian authorities, especially representatives from the Ministries of Health, Transport and Justice, including the police, can use the project data for planning purposes to prioritize preventive measures to decrease the number of debilitating and fatal RTCs.

The NIPH has been a long-term partner in Malawi's health sector, which includes among several efforts to establish a National Public Health Institute in Malawi. The planning of the project started in 2014 in collaboration between the former International Department at NIPH, the Section of Drug Abuse Research of Oslo University Hospital, (OUH), which formerly was organized as part of NIPH, and ICADTS. The involved researchers have long experience in studying the effect of alcohol and drug use on road traffic safety in Norway, the European Union, United States, Russia, and Brazil.

The study was implemented at KCH, the largest hospital in Malawi, located in the capital Lilongwe, in collaboration with Dr. Sven Young (Norwegian orthopaedic surgeon who

worked several years at KCH), Dr. Jonathan Ngoma (Hospital Director), Dr. Carlos Varela (Head of the Emergency Department) and other surgeons at KCH.



Photo 2: Kamuzu Central Hospital entrance (Photo Credit: Hallvard Gjerde)

KCH treats several thousand injured patients involved in RTCs every year and has performed several research projects on RTC injuries. Indeed, previous research showed that the number of patients injured in RTCs and treated at KCH increased more than 60 per cent from 2009 to 2015. Furthermore, research has also shown that the trend has continued [12], and that children and pedestrians have represented a significant proportion of the injured patients [13], but little has been known about the role of alcohol before this study.

A questionnaire was designed in collaboration with the staff at the Emergency Department at KCH. This provided a framework to collect data related to the level of alcohol in breath and oral fluid from the patients injured in RTCs and admitted to the Emergency Department for treatment. The questionnaire included data points regarding patient age, gender, education, type of road user, profession, crash circumstances, including the place and time of the crash, types of vehicles and road users involved, method of transport to the hospital, type of treatment, availability of medical equipment, and rehabilitation possibilities (Annex 1).

Ethical approvals, contracts and preparations

Prior to commencement of the study, the project secured the necessary ethical approvals from the National Health Sciences Research Committee (NHSRC) in Malawi (approval no. 1962/2018). The Regional Committee for Medical and Health Research Ethics in Norway concluded that no formal application was needed, with reference to the Norwegian Health Research Act Section, §2 and 4a. A Data Protection Impact Assessment was performed as required by the NIPH.

Contracts were agreed upon between all parties to regulate the collaboration, ethical considerations, data handling and roles of each institution. KCH owns all raw data gathered upon completion of the project.

A vendor approval from the World Bank (WB) had to be secured for NIPH, since the Institute had not previously received project support from the WB. The Norwegian Church Aid in Lilongwe contributed with administrative support for payments to remunerate the doctors who coordinated the project work locally and the doctors who recruited the patients in addition to administrative equipment. The Norwegian project group held an information seminar in 2019 for staff at KCH about alcohol and accident risks in general, in addition to the goals and implementation plan for the project. The Norwegian team also held a seminar for the doctors at KCH to train them for alcohol testing and data recording in the database template.

Method

Patient Recruitment

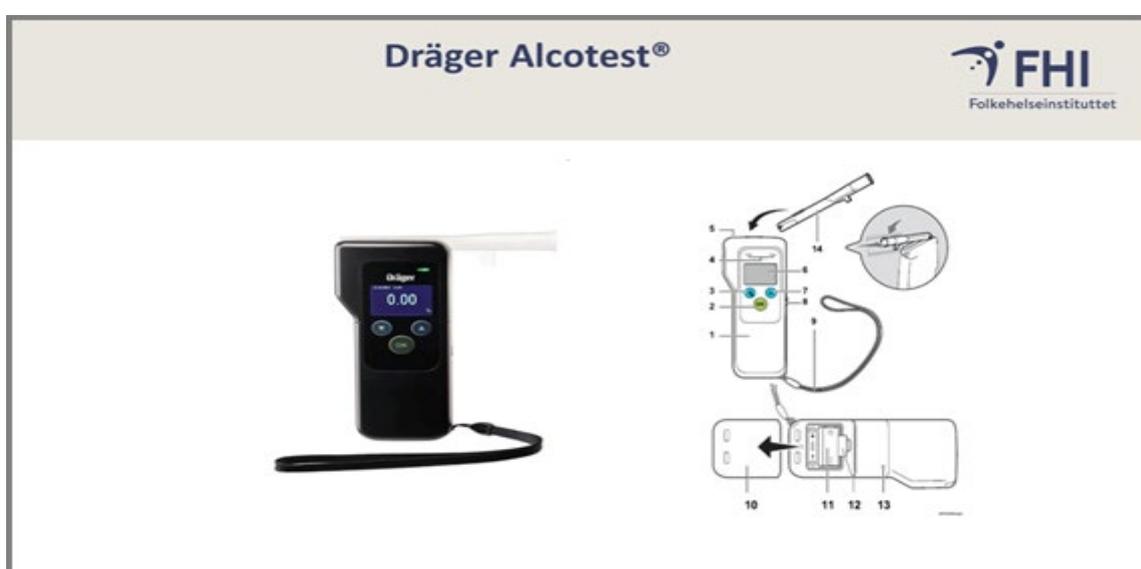
Doctors at KCH recruited the patients during a three-month period in 2019. All persons at least 18 years of age that were admitted to the Emergency Department at KCH for road user injuries involving any form of road traffic crashes (motor vehicle drivers, motor cyclists, moped riders, ox cart drivers, cyclists, passengers, and pedestrians) were asked to participate in the project. The doctors recruited and informed patients about the project both orally and by using a written leaflet (English and Chichewa).



Photo 3: Kamuzu Central Hospital emergency room (Photo credit: Hallvard Gjerde)

Project participation was voluntary, and the patients signed an informed consent form. The doctors recorded patients who refused participation. All patient information and the crash circumstances were anonymized. The recruitment covered all weekdays, weekends and nights. The questionnaire was filled out electronically using iPads (see printed version in Annex 1).

As soon as possible after arrival and acceptance of participation, alcohol was measured using a breathalyzer (Dräger Alcotest 5820, Drägerwerk AG & Co., Lübeck, Germany) or a saliva test (Q.E.D.® A150, OraShure Technologies, Inc., Bethlehem, PA, USA) for those not able to blow (see Graphic 1 and 2). Alcohol concentrations corresponding to BAC of 0.10g/L or higher were regarded as positive. If the time between crash involvement and arrival at hospital was more than a few hours, alcohol testing of breath or saliva might not reflect the presence of alcohol in the body at the time of injury due to metabolism and elimination of alcohol. Therefore, the patients were also asked whether they had used alcohol before the injury. Data on alcohol use before the injury was therefore either based on a positive test for alcohol in breath or saliva or self-reported alcohol use. Patients were also asked about factors indicating hazardous drinking habits by using the AUDIT-C questionnaire [14, 15], which was adapted to the local context in Malawi (Annex 1, Item 8).



Graphic 1. Instrument used for determination of alcohol in breath



Graphic 2. Determination of alcohol in saliva

If alcohol was measured in saliva from an unconscious patient, the result was not used before the patient was conscious and able to give consent. For patients who died at the hospital, all recorded information was deleted.

Blood alcohol concentrations above the legal limit of 0.8g/L

Alcohol is eliminated from the body at an almost constant rate after the first few drinks [16, 17]. It can therefore be possible to estimate the BAC at a previous time point by back calculation. After drinking on an empty stomach, the elimination rate of alcohol from blood falls within the range 0.10–0.15g/L per hour, and in non-fasted subjects, the rate of elimination tends to be in the range 0.15–0.20g/per hour. In alcoholics during detoxification, the ethanol elimination rate might be higher. The slope of the BAC declining phase is slightly steeper in women compared with men, which seems to be related to gender differences in liver weight in relation to lean body mass. In moderate drinkers, 0.15g/L per hour remains a good average value for the population [17]. This alcohol elimination value is therefore used in forensic medicine to back calculate the most likely BAC at an earlier time point and was also used in this project to estimate the BAC at the time of injury. The estimates are inaccurate if the patient consumed alcohol after the injury.

If a person had a BAC of 0.8g/L at the time of the crash, the BAC would be on average about zero five hours later. In order to estimate the proportion of road users with a BAC above the legal limit of 0.8g/L, only those who were tested for alcohol within five hours after the RTC should be assessed. This is because a person with a BAC of 0.9g/L would have no alcohol in their blood if tested six hours later or more, and the proportion of illegal BAC cannot be estimated.

The patients were also asked to identify the exact location where they sustained their injury. This was done by using a Google map application on a tablet. With help from the interviewer, the patient examined maps and aerial photos and were thus able to pinpoint the location. The coordinates of the location were saved into the data file of the patient, and by using the free software QGIS, we were able to demonstrate different aspects of these locations on maps.

Results

Of 1347 eligible patients who were asked to participate during the period of about three months, 1259 (93.5 per cent) gave informed consent. Eight patients were not tested for alcohol and thus excluded, resulting in 1251 adult patients in the final study cohort that was tested for alcohol and/or asked about alcohol intake before the injury. Passengers constituted the largest group of injured road users (35.9 percent), followed by pedestrians (17.6 percent), bicyclists (14.6 percent), drivers of cars and pickups (14.5 percent), motorcyclists (12.0 percent), drivers of buses, minibuses and lorries (4.2 percent), and unknown (1.2 percent).

Table 1 gives an overview of the hours between the crashes and time of examination at KCH, showing that more than 40 per cent of the patients were examined at the hospital at least three hours after the crashes, and about 15 per cent after more than six hours. Some of these patients may have had an intake of alcohol before the crash, but had become sober before arrival at KCH. One reason for the long time between injury and arrival at the hospital may be due to a lack of ambulances or other available transport.

Table 1. Positive alcohol test and self-reported alcohol use in relation to time between crash and examination

	Time between crash and alcohol test (hours)						
	<2:00	2:00- 2:59	3:00- 5:59	6:00- 11:59	12:00- 23:59	24+	Unkn.
No. of patients	632	190	240	53	61	49	26
Positive alcohol test (%)	19.1	22.6	30.8	13.2	3.3	4.1	11.5
Self-reported use (%)	15.7	18.9	22.1	7.5	23.0	20.4	19.2
Either positive alcohol test or self-reported use (%)	21.7	26.8	35.0	13.2	23.0	20.4	30.8

In order to obtain more complete data on alcohol use, self-reported data were combined with alcohol test results in the data presented in Figures 1 and Table 2. The prevalence of alcohol thus reflects that the patients either tested positive for alcohol or reported alcohol intake before the injury, or both.

Figure 1 shows the total prevalence of alcohol use recorded among the included patients, divided into males, females, and different age groups. The highest prevalence of alcohol was found among males (30.7 per cent) and very few among females (2.5 per cent), who represented 19.2 per cent of the patients. Patients aged 45 years and older had the lowest prevalence of alcohol. Minor variations were found among the other age groups.

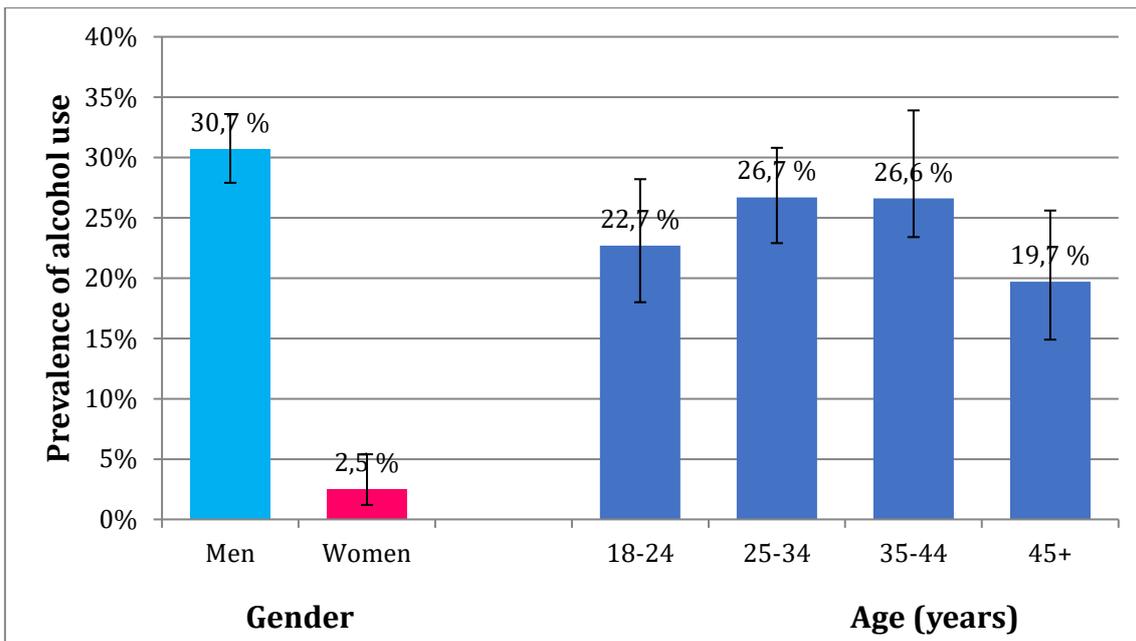


Figure 1. Prevalence (%) of alcohol use across gender and age groups. Vertical bars indicate 95% confidence intervals.

Those with no formal education showed highest values (Figure 2). However, the number of patients in this group was very low (n=36) and the proportion of alcohol use may therefore be inaccurate.

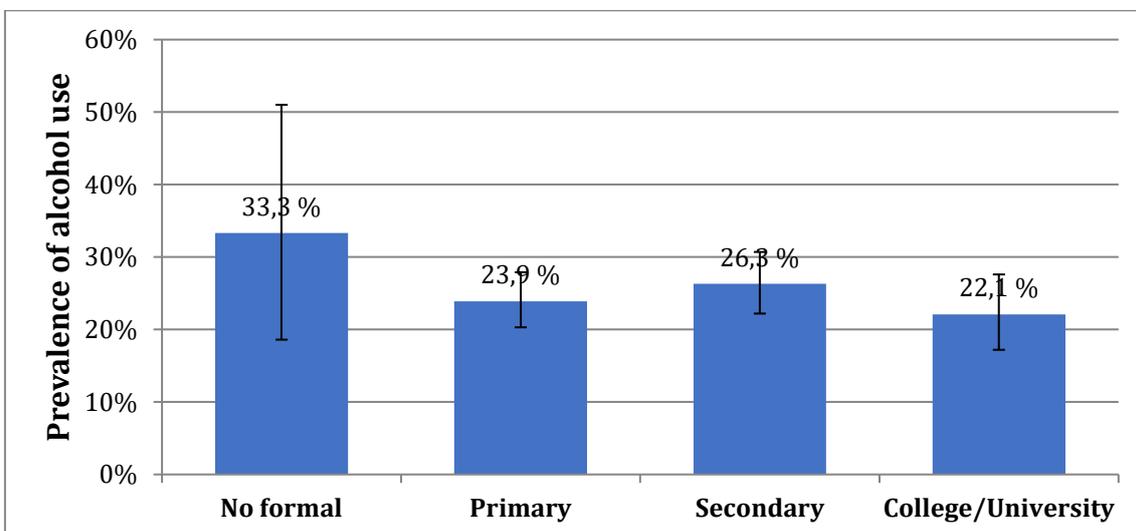


Figure 2. Prevalence (%) of alcohol use by level of education. Vertical bars indicate 95% confidence intervals.

Figure 3 shows the prevalence of alcohol use across different road user groups. The highest prevalence of alcohol use was recorded among pedestrians (41.8 per cent). For the other road users, the prevalence of alcohol use varied from 19.1 to 24.0 per cent, with car/pickup drivers and motorcycle riders as those with highest prevalence and bicycle riders with the lowest. It is also worth noting that 20.8 per cent of the injured bus/minibus/lorry drivers had used alcohol.

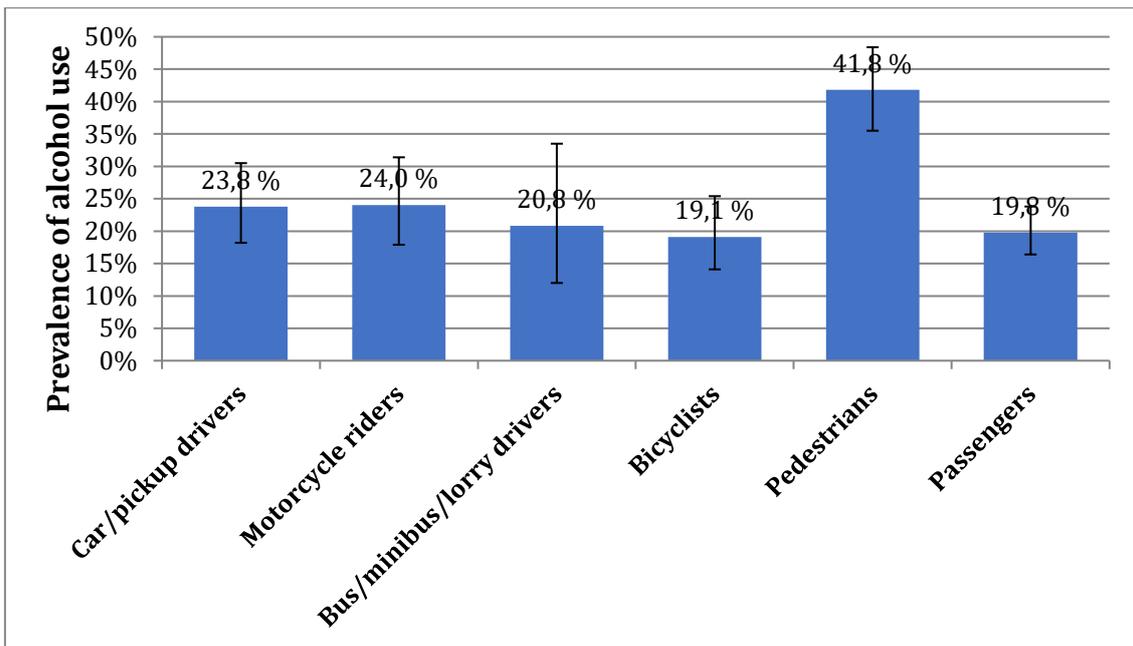


Figure 3. Alcohol use before injury among road user groups. Vertical bars indicate 95% confidence intervals.



Photo 4. Pedestrians and bicyclists along highway M1 (Photo Credit: Hallvard Gjerde)



Photo 5. Pedestrians and bicyclists along highway M14 (Photo Credit: Hallvard Gjerde)

Rather few road traffic injuries (6.5 per cent) were recorded during late night and early morning (between midnight and 6 am) for all days during the week, but the prevalence of alcohol was high (Figure 4). For the time periods between 6 pm and midnight, the prevalence of alcohol was also high, particularly in weekends with a prevalence of almost 60 per cent. It highlights the risk to which the road users are exposed during this time of day. High proportion of alcohol-impaired road users during night-time may be an interesting finding for the police when they plan roadside controls.

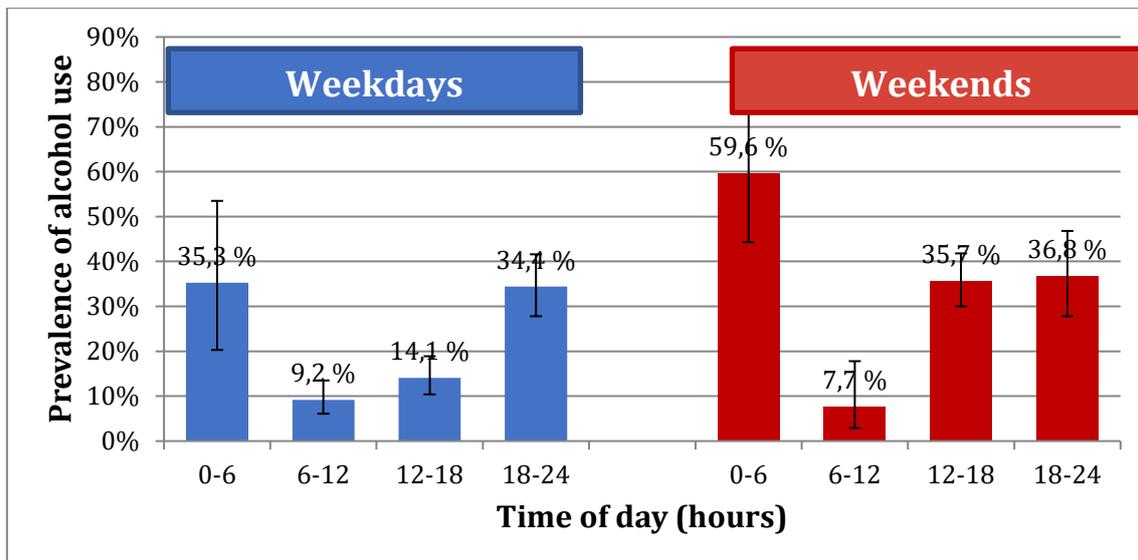


Figure 4. Alcohol use in relation to time of road traffic injury. *Weekend was defined as starting Friday 18:00 and ending Monday 06:59.* Vertical bars indicate 95% confidence intervals.

A positive AUDIT-C score indicates a hazardous or harmful drinking pattern. The AUDIT-C findings are presented in Table 2 and show higher prevalence of positive scores among males than females and highest prevalence for the age group 25-44 years. A particularly

large proportion of those who had been drinking before the injury had positive AUDIT-C scores, indicating that a very large proportion of those were heavy or hazardous drinkers.

Table 2. Prevalence (%) of hazardous drinking as measured by the AUDIT-C questionnaire

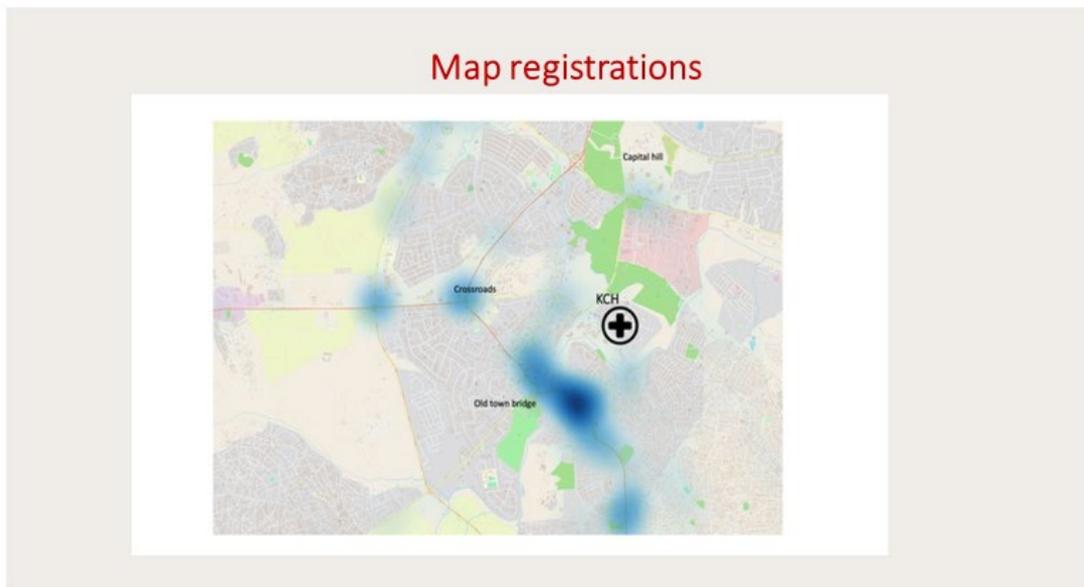
	Positive AUDIT-C test* (%)	Confidence interval (95% CI)
Gender^a		
Males (n=972)	26.0	23.3-28.9
Females (n=240)	4.2	2.1-7.8
Age (years)^b		
18-24 (n=256)	14.5	10.5-19.5
25-34 (n=470)	26.0	22.1-30.2
35-44 (n=293)	22.9	18.3-28.2
45+ (n=204)	18.1	13.2-24.3
Alcohol status		
No alcohol use before injury (n=931)	9.6	7.8-11.7
Alcohol use before injury (n=296)	58.8	52.9-64.4

*AUDIT-C results ≥ 3 for women, ≥ 4 for men. A total of 1227 participants with valid AUDIT-C results were included. ^aGender had not been recorded for 15 participants. ^bAge had not been recorded for 4 participants.

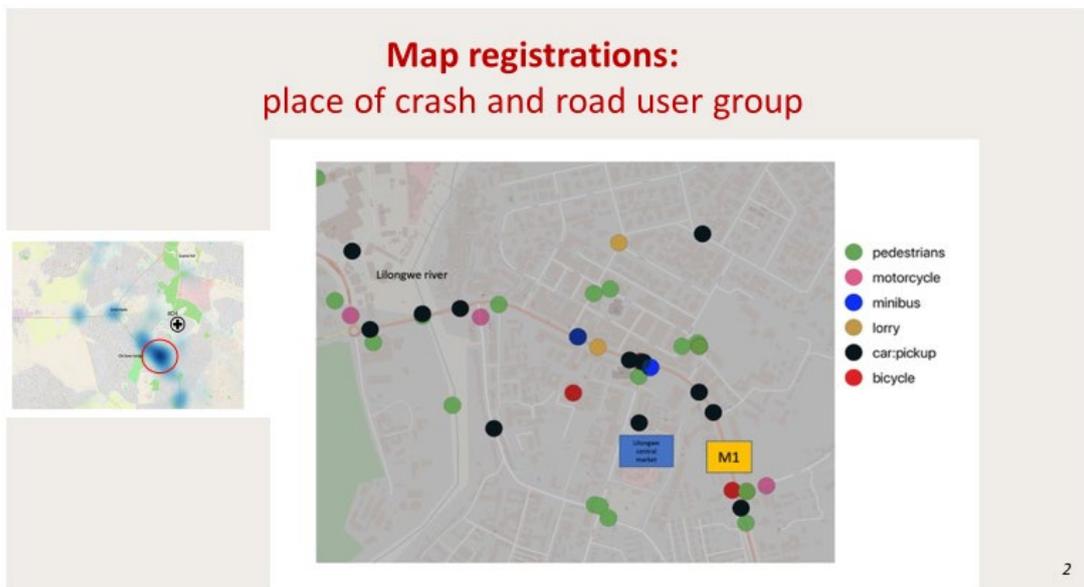
In total, 1026 of the 1251 included road users were tested for alcohol within five hours after the crash. Of those, 329 were motor vehicle drivers. The BACs at the time of crash were back calculated for those patients. An estimated total of 15.2 per cent of the injured motor vehicle drivers had BAC above 0.8g/L at the time of the RTC, if they had not consumed alcohol between the crash and arrival to the hospital. The estimated proportion with BAC above 0.8g/L was 13.9 per cent for MC riders, 15.8 per cent for car and pickup drivers, and 16.3 per cent for drivers of buses, minibuses and lorries. More information about the alcohol results are also available in a paper published in Traffic Injury Prevention [18].

The data collected include information related to the locations of road traffic injuries, and injuries among pedestrians and bicyclists, type of necessary equipment for injury treatment available at the hospital, mode of transport, and prognosis for the patients. Findings of geographical cluster data can be valuable information for transport authorities when planning improvement of accident-prone roads.

The results of the geographical mapping are published in a separate paper [19], and a sample of these geographical results are presented below. These examples show a heatmap for a selection of the crash hotspots in the vicinity of Lilongwe (Graphic 3) and the various road user groups involved in accidents within a distance of approximately one kilometre (Graphic 4). This illustrates how the data can be used to target public awareness and driver breath testing campaigns.



Graphic 3: Road traffic crashes, hotspot locations in the vicinity of Lilongwe



Graphic 4: A map section of one of the hotspots according to road user groups

Discussion

As only a small proportion of the patients refused participation in the study (5 per cent of the 1347 eligible patients), the result is representative for injured road users in Malawi. Yet, the data must be compared to previous studies and findings, in Malawi and other countries, to interpret the results comprehensively in their context.

Based on an earlier survey and comments from people living in Malawi [10, 11], the prevalence of alcohol was higher than expected. The prevalence of alcohol use in different road user groups varied from 19.1 to 41.8 percent, with the highest prevalence among pedestrians, followed by car/pickup drivers and motorcycle riders, and bicycle riders with the lowest. The findings confirm that the proportion of patients who used alcohol was much higher among men than females. The prevalence of alcohol use was highest among those without formal education, although not significantly different statistically from other patients due to the small number of patients in this group.

The results of the study indicate that a large proportion of the injured pedestrians had used alcohol (about 42 per cent), which is significantly higher than for other groups of injured road users (19-24 per cent). This finding is similar to the results of a study in Uganda [20], where the pedestrians had a much higher prevalence of alcohol use than drivers. A study from Ghana on non-fatally injured road crash casualties found that 34 per cent had detectable BAC concentrations [21]. The prevalence of alcohol was highest among cyclists (53 per cent) and motorcyclists (34 per cent) in that study. Another Ghanaian study found a different pattern, with approximately the same alcohol prevalence in pedestrians and drivers of 32-35 per cent [22]. A study from the Ivory Coast found that the prevalence of alcohol-impairment (BAC > 0.5g/L) was higher among injured light 4-wheel drivers (41 per cent) than among pedestrians (17 per cent) [23]. However, these studies are difficult to compare, as the selected groups of patients were different from our study.

For the other road users, the prevalence of alcohol use varied from 19.1 to 24 per cent, with car/pickup drivers and motorcycle riders as those with highest prevalence and bicycle riders with the lowest. Based on an earlier survey and comments from people living in Malawi [10, 11], the prevalence of alcohol was higher than expected. The findings confirm that the proportion of patients who used alcohol was much higher among men than females. The prevalence of alcohol use was highest among those without formal education, although not significantly different statistically from other patients due to the small number of patients in this group. For comparison, studies in Ghana found that the prevalence of alcohol use among drivers without formal education was higher than among those with primary, secondary or higher education [24, 25], and an American study found highest prevalence of alcohol among killed drivers with the lowest education [26].

The proportion of pedestrians recruited in the study was surprisingly low (about 18 per cent), compared to earlier published data on injured RTC patients treated at KCH (32.3 per cent) during the period from 2009 – 2015 [12]. The reason for this under-representation is unknown. The high prevalence of alcohol among pedestrians is an important finding of the study, even though there is no legal alcohol limit for this group of road users. With roads lacking pavements, walkways, marked pedestrian zebra crossings, and road lighting, the security for pedestrians is far from optimal. Combined with alcohol use the risk is heightened. A separate paper about injuries sustained by pedestrians and cyclists in this study is published in Malawi Medical Journal [27].

The number of injured drivers of buses, minibuses, and lorries in the study was low, but they often drive with passengers, and are therefore a cause for concern. Alcohol had been used by one out of five in this group of drivers. Many countries have stronger regulations for drivers of public transport, often with zero tolerance for alcohol [28]. In total, we estimated that about 15 per cent of the motor vehicle drivers had BAC above the legal limit of 0.8g/L at the time of the crash. This proportion is similar to findings among injured drivers in several European countries (BAC \geq 0.5g/L ranging from 16 to 38 per cent) [29], but lower than the estimated prevalence of 35 per cent above a BAC of 0.8g/L among light 4-wheel drivers in the Ivory Coast [23].

The study's findings showed rather high prevalence of alcohol use among some of the road user groups, especially during weekdays and weekend nights. These findings should be taken into account by the police when planning road traffic controls, including alcohol breath testing.

Conclusion and recommendations

If the UN's commitment to reduce by half the global number of deaths due to traffic accidents by 2030 is to be achieved, authorities, researchers, law enforcement officials and NGOs have to focus primarily on LMICs, where there has been a significant increase in RTCs for several years. These countries need help in implementing effective measures, in addition to financial and scientific support. An action plan for diverse security measures should be implemented in each country with priority given to measures with the largest and most reliable impact. For this, LMICs need good statistics about the causes of accidents, lacking in many countries as well as data on DALY. The costs involved in disability-adjusted life years include medical treatment, rehabilitation, lost income and lost ability to provide for the family, crash investigation etc. A report from the World Bank presents calculations from several LMICs. For example, cost savings estimated in GDP varied from 7-22 per cent for Tanzania, the Philippines, India, China and Thailand [5] and an increase in welfare advantages. Such calculations are a useful tool for national authorities with regard to their limited budgets.

The following actions are recommended for Malawi:

1. Malawi has a high BAC legal limit (0.8g/L). Authorities should consider lowering the BAC legal limit to 0.5g/L in accordance with recommendations from WHO [30], like most European countries, Canada and other countries have done, as well as the state of Utah in the USA. Any changes must be followed by sustained and widely disseminated information and educational campaigns.
2. The findings show that approximately one out of five commercial drivers, particularly drivers carrying passengers, were involved in alcohol related crashes. For this group, a lower legal BAC limit should be considered. A lower BAC limit for commercial drivers has been implemented in many countries, such as 0.4g/L in the USA [31] and 0.2g/L in many European countries [32].
3. The Malawi Road Traffic Offences and Penalties for driving a vehicle while under the influence of intoxicating liquor or drugs, as regulated in section 139 of the Road Traffic Act, needs to be enforced. To ensure such enforcement, adequate resources need to be allocated to traffic police.

4. Findings from map registrations showed that many RTCs were recorded in clusters, which varied for the different road user groups. Safety improvement of those areas should therefore be prioritized.
 5. The police should focus their controls on time periods with high frequency of alcohol related crashes, primarily weekend nights but also weekday nights. In order to do so, the police must be provided with the necessary testing equipment.
 6. Reflective gear for pedestrians should be recommended and provided, as well as instalment of road lighting, speed calming measures, and safer pedestrian crossings.
 7. The data from this study should be disseminated, shared and discussed by stakeholders in Malawi from the different sectors: health, transport, police and education.
 8. It is important that the authorities representing health, transport, police and education develop plans for a comprehensive information and educational campaign on alcohol use as an important risk factor for road traffic safety. Radio, newspapers, TV programs and other type of informational media need to be engaged in such campaigns.
 9. In addition, corruption must be avoided and replaced with a Culture of Road Safety that joins forces across sectors to combat drunk driving and injurious and fatal RTCs.
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Appendices

Annex 1: Questionnaire

*The aim is to develop an electronic version of the questionnaire for tablets.
As back-up, an equivalent printed version may be filled in, and data transferred to the electronic database.*

1. Information about officer recording data (drop down menu)

- Medical Intern
- Clinical officer Intern
- Junior Surgery registrar
- Senior Surgery registrar
- Clinical officer
- Data recording / study officer
- Hospital Clerk
- Consultant surgeon 0
- other

2. Information about the patient

Patient number (automatically generated)

Date & Time of recruitment to study / filling in survey (calendar function)

Age: ____

Gender: *Male / Female*

Home: *Rural / urban*

Occupation (drop down menu)

- *Subsistence farmer*
- *Construction / labourer*
- *Plumber/Electrician/carpenter*
- *Mechanic/Technician*
- *Baker/Cook/Restaurant*
- *Driver/Conductor*
- *Student/Pupil*
- *Teacher*
- *Housewife*
- *Tailor/Artist*
- *Clergy / Pastor*
- *Police/Soldier*
- *Health Care Worker (Working in public or private Health Institution)*
- *Other civil servant / government employee*
- *Non-governmental organization or business employee / Office / Bank worker*
- *Business owner/manager*
- *Vendor / salesman/-woman*

- *Housekeeper/Gardener*
- *Security Guard*
- *Unemployed*
- *Other* _____

Level of education (drop down menu)

- No formal education
- Primary
- Secondary
- College / University

3. Alcohol and drug use before the accident

Does the patient report to have taken alcohol before the accident?

(or does guardian report that patient has taken alcohol): Yes / No / not known

Alcohol test result

Alcohol test type	Alcohol test result	Date - time
Breath		
Saliva		

Does the patient report use of cannabis short time before the accident?

(or does guardian report that patient has used cannabis): (Yes / No / not known)

4. Information about the road traffic accident

Date & Time of accident (select from calendar function on tablet for uniform recording)

Date & Time of arrival at KCH (select from calendar function for uniform recording)

Did patient go/was brought to another facility before KCH? Yes / No

If yes: What kind of facility (drop down menu)

- Police station
- Health Centre
- Private health centre / facility
- Government District Hospital
- CHAM Hospital

Date & Time of arrival at mentioned first primary/secondary health facility (calendar function)

Time from accident to arrival at first (health) facility (automatically generated)

Time from accident to arrival at hospital (automatically generated)

Place of accident

- Road surface: *paved / unpaved*
- Type of site: *rural / urban*
- Hard shoulder at site: *Yes / No / Not applicable*
- Sidewalk/pavement at site: *Yes / No / Not applicable*
- Zebra crossing? *Yes, elevated / Yes, painted / No / Not applicable*

Speed limit

Town or trade centre (speed limit 50-60) / Highway (speed limit 100)

Name / description of road: _____

Area & exact location: _____

Name of Town / village: _____

(Electronic mapping function may be included)

Type of road user and type of accident

Patient's vehicle	Patient			Collision with										
	Pedestrian	Driver / rider	Passenger	None	Bicycle	Motorcycle	Motor tricycle	Car / pickup	Minibus	Bus	Lorry	Ox cart	Animal	Other
None (pedestrian)														
Bicycle														
Motorcycle														
Motor tricycle														
Car/pickup, cab														
Minibus														
Bus														
Lorry, cab														
Lorry/pickup, open bed														
Ox cart														
Other														

Safety equipment

For MC driver or passenger: Helmet (Yes / No)

For pedestrian, cyclists and MC: reflective clothing or reflective device? (Yes / No)

For car/van/bus/minibus/lorry, driver or passenger: wearing seatbelt (Yes / No)

If injured pedestrian or cyclist (drop down menu)

- Standing / Walking / cycling next to or close to the road (not on the road itself)
- Walking / cycling on the shoulder or edge of the road
- Trying to cross the road
- Other, please specify: _____

Why was the victim on the road? (drop down menu)

- On way to/from school

- On way to/from work
- On way to/from market / trading centre / town for personal errands
- Business trip
- On way to function; eg. Funeral, wedding etc
- On way to/from hospital / health clinic etc
- Other, please state_____

5. Transport and price to hospital

Price (mwk) of minibus from place of residence to nearest hospital: (drop down menu)

- Not applicable, just a short walk
- Less than 500 (0 – 499)
- 500 – 1000
- 1001 – 1500
- 1500 – 2000
- 2001 – 2500
- 2501 – 3000
- 3001 – 3500
- 3501 – 4000
- 4001 – 4500
- 4501 – 5000
- over 5000

Price (mwk) of minibus from place of residence to KCH (drop down menu):

- Not applicable, just a short walk
- Less than 500
- 500 – 1000
- 1001 – 1500
- 1500 – 2000
- 2001 – 2500
- 2501 – 3000
- 3001 – 3500
- 3501 – 4000
- 4001 – 4500
- 4501 – 5000
- over 5000

Mode of transport to KCH (drop down menu)

- Ambulance from accident site
- Ambulance from district health centre of hospital
- Police
- Paid public transport (minibus / bus)
- Paid taxi / tricycle taxi
- Paid kabaza / bicycle taxi
- Walked

- Own vehicle
- Brought by well-wishers / bystanders
- Brought by vehicle involved in the accident
- Other, please specify:_____

6. Injury and treatment plan

Poly trauma patient? Yes / No

Glasgow Coma Scale (GCS) (drop down menu)

From 3 to 15

Body Site (select all that apply)

Head/scalp

Face

Cervical spine

Thoracolumbar spine

Shoulder

Upper arm

Lower arm

Hand

Chest

Abdomen

Pelvis

Hip

Thigh

Knee

Lower leg/ankle

Foot

Type of injury (select all that apply)

Soft tissue injury

Fracture, closed

Fracture, open

Neurological injury (CNS/brain/spinal cord)

Neurological injury (peripheral nerve)

Internal chest organ injury (haemorrhage/lung injury)

Perforated hollow viscous

Internal abdominal/pelvic haemorrhage

Other

Treatment plan (select all that apply)

1 Conservative management, discharged

2 Minor surgery or casting

3 Observation in ward, consider surgery

4 In need of surgery to save function

5 In need of surgery to save life

6 in need of ICU / HDU

Is patient in need of blood transfusion? Yes / no

If yes: how many pints estimated (drop down menu)

- 1 pint
- 2 pints
- 3
- 4
- >4

If yes: Was blood available? Yes / No

Was Hb or Full blood count available for this patient within 1 hour? Yes / No

Were other blood tests available within 1 hour? Yes / No

Was a pulseoximeter available for this patient in casualty? Yes / No

Was blood pressure manometer available for this patient in Casualty? Yes / No

Was oxygen available for this patient in Casualty? Yes / No

Were ALL needed supplies for this patient (IV fluids, canullas, drugs, bandages, chest tubes etc) available? Yes / No

If No: what was missing? (drop down menu, select all that apply)

- IV cannula
- IV fluids
- Cleaning solution (Chlorhexidine, Iodine etc)
- IV giving sets
- Chest tube
- Stiff neck collar
- Essential drug (eg pain killer/morphine, antibiotics, adrenalin, etc)
- bandage
- Sterile dressings
- Plaster of Paris
- Strapping for skin traction
- Suture material / set
- Gloves
- Aprons
- Face masks
- Other: please specify: _____

Was radiology urgently needed? Yes / No

If yes:

Was radiology (FAST / USS / CT / x-ray) available within 30 minutes if needed?

Was radiology (FAST / USS / x-ray) available in casualty? Yes / No

If radiology was done, was it of acceptable quality? Yes / No /Not appcable

Prognosis with available treatment at KCH (drop down menu)

- 1 Likely to fully recover (minor, acceptable scars etc)
- 2 Minor deformity or disability likely (major scars, functionally unimportant deformity)
- 3 Moderate disability likely (deformity leading to reduced function or limp but little effect on work or activities of daily living)
- 4 Major disability likely (affects ability to work or activities of daily living)
- 5 Fatal injury (death confirmed or expected)

Did lack of available infrastructure, supplies or services affect, or is expected to affect, outcome:

Yes / No

If yes, which of the following directly affected the outcome for this patient: (select all that apply)

- Lack of pre hospital care and trauma ambulance services
- Lack of Staff in Casualty department
- Lack of equipment in Casualty department
- Too much time used in casualty before emergency treatment
- Too long time waiting in wards before definitive treatment
- Lack of trauma reception and team training for casualty / surgery staff
- Lack of timely Radiology service (trauma series, CT, USS/FAST etc)
- Lack of timely blood test results
- Lack of blood products
- Lack of ICU / HDU capacity
- Lack of operating theatre time / access
- Lack of theatre supplies (gowns, drapes, bandages, drugs, implants etc)
- Lack of water or electricity
- Other: please specify: _____

7. Previous road traffic accidents

How many times have you been involved in a road traffic accident during last 2 years?

Specify each accident:

Type of road user (driver/ MC rider/ passenger/ cyclist/ pedestrian)	Injured (Yes / No)	Number of visits to doctor or hospital	Economic impact (little/moderate/severe)
1			
2			
3			
4			

8. Use of alcohol ("AUDIT C")**8.1. Do you sometimes drink alcohol? (Yes / No)**

If no, skip following questions.

8.2. How often do you have a drink containing alcohol?

Never (0)

Monthly or less (1)

Two to four times a month (2)

Two to three times per week (3)

Four or more times a week (4)

8.3. How many drinks* containing alcohol do you have on a typical day when you are drinking?

1 or 2 (0)

3 or 4 (1)

5 or 6 (2)

7 to 9 (3)

10 or more (4)

8.4. How often do you have six or more drinks* on one occasion?

Never (0)

Less than Monthly (1)

Monthly (2)

Two to three times per week (3)

Four or more times a week (4)

*Explained with examples on next page

Alcohol drinks (number of standard units)

Information given to participants to help estimate the number of alcohol units consumed^a (10 g alcohol per unit in accordance with the World Health Organization's AUDIT Guideline). The information was accompanied by photos of bottles.

<i>Commercial drinks</i>			
Type	Volume	Alcohol content	Approximate number of alcohol units
Beer, 3.7-4.7% ABV ^b	330 mL	10-12 g	1 unit
Beer, 3.7-4.7% ABV	500-640 mL	15-24 g	2 units
Beer, 4% ABV	1000 mL	32 g	3 units
Gin/brandy/whisky/rhum/vodka, 43% ABV	200 mL	68 g	7 units
Gin/brandy/whisky/rhum/vodka, 43% ABV	750 mL	255 g	26 units
Wine, 12% ABV	120 mL	11 g	1 unit
Wine, 12% ABV	750 mL	71 g	7 units
<i>Traditional drinks^c</i>			
Distilled spirits (kachasu, gaso), average 34% ABV	200 mL	54 g	5 units
Distilled spirits (kachasu, gaso), average 34% ABV	750 mL	201 g	20 units
Traditional wine (tea, banana, masau; average 3.6% ABV)	750 mL	21 g	2 units
Traditional corn beer (chikokeyani, ntonjani, masese, kabanga); average 2.4% ABV	1000 mL	19 g	2 units

^aSundet M, Kajombo C, Mulima G, Bogstrand ST, Varela C, Young S, Christophersen AS, Gjerde H. Prevalence of alcohol use among road traffic crash victims presenting to a Malawian Central Hospital: a cross-sectional study. *Traffic Injury Prevention* 2020;21(8): 527-532. <https://doi.org/10.1080/15389588.2020.1819990>

^bABV = alcohol by volume.

^cMwagomba BL, Currie D, Nyirenda M, Baldacchino A. 2017. Adaptation and validation of alcohol use disorder identification test (AUDIT) in Malawi. Poster presented at the International Society of Addiction Medicine Annual Conference, October 26-29, 2017; Abu Dhabi, UAE.

Annex 2: Development and implementation of a system for recording road traffic injury information in a national data base

I. Background

Kamuzu Central Hospital (KCH), the Norwegian Institute of Public Health (NIPH) and Oslo University Hospital (OUH) are collaborating on the project *Traffic accident injuries in Malawi – with special focus on the role of alcohol*. The project will record data from patients injured in traffic accidents admitted to the emergency ward at KCH. The data collected from each patient is based on a questionnaire designed by KCH and NIPH/OUH. The data include information about the patient's age, gender, occupation, education, alcohol and drug use before the accident, actual testing for alcohol in patients admitted to the casualty department at KCH using breathalyzers or oral fluid tests (saliva), information about the road traffic accident itself and GPS data to determine the location of the accident. In addition, the questionnaire asks for information about the transport to the hospital, injury and treatment plan and general use of alcohol.

II. Database on road traffic accidents in Malawi

The questionnaire has now been transformed to an iPad app, and data will be transferred to a computer-based database (a paper-and-pencil questionnaire may alternatively be used to record data, for subsequent transfer to the database, although this may be relevant only if including other hospitals). Information for each patient injured in a road traffic crash admitted to KCH casualty/emergency ward is recorded; see below for more details in 3.0 Description and Operating instructions.

The uniqueness of this database is that it includes results from standard alcohol testing and GPS data. The potential use and impact of such a surveillance registry for traffic accidents is that it can be integrated into a future national monitoring system for traffic accidents, or general trauma monitoring, if national authorities view this useful.

After this pilot phase has been completed, discussions will be initiated with KCH and central authorities in Malawi across sectors on what is needed with regard to national statistics, and whether data can be imported from, or merged with, other relevant registries.

NIPH has already commenced discussions with the Ministry of Health (MoH), the Directorate of Road Traffic and Safety Services in the Ministry of Transport and Public Works, as well as the World Bank. We would also like to discuss the potential of this database with the Central Monitoring and Evaluation Division in the Planning and Policy Department at the MoH. There is a strong interest and desire to build up an evidence base and scale this project up at a national level. If district hospitals are included in the future, the knowledge gleaned from such an expanded evidence base will greatly contribute to finding solutions to reduce the number of injuries and casualties that pose a great health economic burden in Malawi.

III. Schematic description of data sampling:

1. The FileMaker Pro 14 Advanced (FileMaker Inc., Santa Clara, CA) software was used to make an app containing a digital version of the questionnaire.
2. The app was transferred to iPads and used for registration of questionnaire data at KCH.
3. Recorded data is saved to an excel file which is locally stored on the iPad.
4. For each iPad, the excel file is manually transferred to a computer using an usb cable. The excel file from each iPad is then merged into a final master database excel file, containing all the data.

The iPads are secured with passwords, while the questionnaire app is secured with personal passwords for each recording officer.

Annex 3: Standard data collection procedures for patients injured in road traffic crashes treated at hospitals in Malawi

I. Background

A routine for investigation of road traffic injuries with special focus on the role of alcohol at Kamuzu Central Hospital has been approved (See current version of SOP no. 1, Annex 1). The present Deliverable 3 can be applied to other hospitals in Malawi for studying patients injured in road traffic crashes. Although not a Standard Operating Procedure, this deliverable can serve as a guideline for other hospitals to follow and can be revised according to local context.

II. Procedure

Patient participation in the study shall be voluntary. All information about the patients shall be anonymized.

II.1 Data collection

- All project workers recruiting patients, recording information and performing alcohol tests should be trained by the project lead. Instructions should be available at the testing site
- Selected hospital staff / surgeons on call shall recruit patients of both genders at least 18 years or older admitted to an emergency department
- Selected hospital staff /surgeons on call shall recruit patients at night and daytime all days of the week
- Selected hospital staff /surgeons on call shall give each patient information about the project, obtain their written consent if they are willing and record the results and all information in a questionnaire
- Tests for alcohol can be performed if approved by the Ethical Committee of Malawi and the Hospital Director. The alcohol tests should be performed with either a breathalyzer or a saliva test for those not able to give an acceptable breath test
- The questionnaire may be paper-based or electronic. The data shall be transferred to a dedicated database specified by the Hospital Director
- The patient's name or date of birth shall not be recorded

II.2 Alcohol tests (if applicable)

II.2.a Breathalyzer (Dräger or similar equipment)

- For patients able to blow: The patient is shown by selected staff / surgeon on call how to blow into a single-use mouthpiece connected to the alcohol reader instrument
- The selected staff / surgeon on call records the result of the breathalyzer test into the current questionnaire form

II.2.b Saliva tests (QED or similar equipment)

- For patients unable to blow: The selected staff / surgeon on call places the saliva collector in the patient's mouth in accordance with recommendations from the manufacturer

- The selected staff / surgeon on call records the result of the saliva test into the current questionnaire form

III. Data analyses and management

To avoid backward identification of patients, the data must be protected from unauthorized access. No one except dedicated staff shall be able to access patient information.

- Selected hospital staff /surgeon on call must sign a confidentiality statement
- Selected hospital staff /surgeon on call shall destroy all information from unconscious patients who subsequently decline to participate
- Selected hospital staff shall ensure that the database is protected from unauthorized access with username and password and further locked securely in a filing cabinet or safe
- Selected hospital staff shall store the confidentiality statements and patient consent forms in a different locked filing cabinet or safe
- Data analyses, publications and dissemination activities shall be performed according to international ethical standards
- Only anonymous data shall be transferred to other parties after acceptance of necessary ethical rules, or disseminated
- All data extracted for any publications and reports should be destroyed upon completion of the study including all reports and publications

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