From the Department of Public Health Sciences
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# Towards Improved Trauma Care Outcomes in India

Studies of rates, trends and causes of mortality
in urban Indian university hospitals

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# Towards Improved Trauma Care Outcomes in India
## Studies of rates, trends and causes of mortality in urban Indian university hospitals

## THESIS FOR DOCTORAL DEGREE (Ph.D.)

By


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To,
My father-in-law,
Dr Chintamani Sunta, PhD
a scientist and thinker

# ABSTRACT

**Introduction** Injury is a serious threat to global public health. Every six seconds someone in the world dies as a result of injury, adding up to five million people a year. This is more than the number of deaths due to HIV/AIDS, tuberculosis, malaria and maternal deaths combined. Injury is the top killer among the youth (aged 15-29 years), usually male who are physically fit individuals in their economically productive years. About 90% of all injury deaths occur in Low-and-Middle Income Countries (LMICs). Two million lives could be saved annually if the injury mortality rates in LMICs were reduced to the same level as in High-Income Countries (HICs). This would require implementation of robust injury prevention policies and improved post-injury care within hospitals. In India, injury kills one million people every year. More than half of these patients reach hospitals alive. There is a paucity of data on trauma care outcomes of the injured within Indian hospitals. The aim of this thesis was to explore the rates, trends and causes of in-hospital trauma mortality in urban university hospitals in India.

**Methods** Four studies were conducted in urban university hospitals in India. Study I was a retrospective analysis of 24-hour in-hospital trauma mortality using three cohorts of admitted patients (1998, 2002, 2011) at a single hospital. Studies II-IV were prospective analyses of 30-day in-hospital trauma mortality in four hospitals. The variables collected by trained data collectors were mechanism of injury, transfer status, vital signs, injury to arrival time, arrival to investigation time, injury description by clinical, investigation and operative findings. Study IV used Delphi methods to define optimal trauma care within the urban university hospital context and peer review to evaluate each death for preventability. All patients were stratified by injury severity using the Injury Severity Score (ISS) into mild (1-8), moderate (9-15), severe (16-25), profound (26-75) ISS categories and by time to death into early (within 24 hours), delayed (between 24 hours and 7 days) or late mortality (between 8 and 30 days of in-hospital stay).

**Results** A declining trend of 24-hour in-hospital mortality was observed in an urban Indian university hospital between the years 1998 and 2015 (I,II). The 30-day mortality rate was 21.4% among all trauma patients admitted to the studied hospitals (II). Simple physiological scoring systems using on-admission vital-signs were comparable in performance to more complex anatomical scoring systems in predicting mortality (II,III). All assessed trauma scoring systems predicted 24-hour early mortality better than 30-day late mortality (III). It is likely that 58% of all trauma deaths in studied hospitals were preventable and two-thirds of all deaths in mild or moderately injured patients with an ISS<16. Issues with airway management (14.3%) and resuscitation with haemorrhage control (16.3%) were identified as contributors to early mortality. Traumatic brain injury and burns accounted for the majority of non-preventable deaths (IV). System-related issues were a lack of protocols, lack of adherence to protocols, pre-hospital delays and delays in imaging (II,IV).

**Conclusions** One in five trauma patients admitted to the urban university hospitals in India dies within 30-days and this rate is at least twice the mortality rate in HIC hospitals (II). The longitudinal trend in early in-hospital mortality shows a decline over 18 years (I,II). More than half of all in-hospital trauma deaths were preventable (IV). The steps towards improved trauma care outcomes are triage using vital signs (II,III), improved airway management, early haemorrhage control and resuscitation, establishing treatment protocols (IV), maintaining a trauma registry (II) and timely delivery of trauma care (II,IV). More research is needed to understand the causes of late mortality in trauma patients (IV).

# PREFACE


A face to the data: Introducing one person among the 16,000 data points

The late evening call for policeman-*hawaldar* Pandurang was routine. But he knew that it would change the future of the young family forever. Just another one of the 16,000 trauma patients recruited for this thesis, Vikas Patil was a father of two and commuted to work every day by Mumbai's lifeline, the suburban commuter train. He had train friends, who travelled every morning with him, quashed together on their daily ride to their offices. Vikas was a clerk with the Government's public works department. On just another day, he was rushing onto the train, when he missed a step and fell off the rail carriage. In a moment, he found himself in the crevice between the moving train and the platform. The admitting doctor asked him what happened? Between breaths, Vikas said that the Police brought him along in a police pick up van, after he was found in between the platform 6 and the railway track. A bystander saw him lying below the train and pulled him out. He suffered a left above-knee traumatic amputation. The bleeding stump was tied with some cloth and bandage. On his arrival at the trauma unit about 2 hours after the injury, there were further delays as there was no relative to sign for his admission nor pay for his CT scans. The free health care system is not really free. The brain CT scan was done after his relatives arrived and was normal. But his spine CT showed an undisplaced compressed fracture of the $12^{th}$ thoracic vertebra and a missed haemo-pneumothorax. Blood was requested for him. He complained about the pain and was breathless in the afternoon. He vomited and fell unconscious that night. He had to be intubated and put on the ventilator. It was in vain.

After decades of the daily adrenaline rush while treating victims of major trauma, suddenly the meaninglessness of it all struck me. There needs to be more to fixing broken heads and bones. The person to whom these dismembered body parts belong to, is classically a young man in his mid-thirtees with a toddler at home; when in a moment everything gets turned around. From an able bodied productive breadwinner, to a disabled dependent individual; that is if he survives.

The majority of patients who die as a result of trauma, reach an Indian hospital alive. In 2012, my main supervisor Johan asked me *why do so many of these patients die thereafter*? Surprisingly, after working for two decades as a hospital surgeon, I did not know. *Nor did I know how many died nor when they died.* A trauma registry may have yielded some answers, but there was none in India. There could not have been better partners to get this enterprise started than Sweden, a land of registries.

TITCO India

Credits: This logo and acronym was developed by Martin Gerdin for the project, which formed the basis of the four substudies across the research consortium of Indian universities. The pictures of trauma care delivery at the participating hospitals are by the research officers in the TITCO project.

# LIST OF SCIENTIFIC PAPERS

I. Gerdin M, Roy N, Dharap S, Kumar V, Khajanchi M, Tomson G, Tsai LF, Petzold M, von Schreeb J. Early Hospital Mortality among Adult Trauma Patients Significantly Declined between 1998-2011: Three Single-Centre Cohorts from Mumbai, India. PloS one. 2014 Mar 3;9(3):e90064. (Published)

II. Roy N, Gerdin M, Ghosh S, Gupta A, Kumar V, Khajanchi M, Schneider EB, Gruen R, Tomson G, von Schreeb J. 30-day in-hospital trauma mortality in four urban university hospitals using an Indian trauma registry. World journal of surgery. 2016 Jun 1;40(6):1299-307. (Published)

III. Roy N, Gerdin M, Schneider E, Veetil DK, Khajanchi M, Kumar V, Saha ML, Dharap S, Gupta A, Tomson G, von Schreeb J. Validation of international trauma scoring systems in urban trauma centres in India. Injury. 2016 Sep 20. (Published)

IV. Roy N, Kizhakke Veetil D, Khajanchi MU, Kumar V, Solomon H, Kamble J, J, Basak D, Tomson G, von Schreeb J. Learning from 2523 trauma deaths in India- opportunities to prevent in-hospital deaths. BMC Health Serv Res. 2017 16;17(1):142 (Published)

These papers will be referred to by their Roman numerals I-IV

# TABLE OF CONTENTS

# LIST OF ABBREVIATIONS

| | |
|---|---|
| AIS | Abbreviated Injury Scale |
| AUROCC | Area Under the Receiver Operating Characteristics Curve |
| CI | Confidence Interval |
| CT | Computed Tomography |
| DALY | Disability Adjusted Life Years |
| DGHS | Directorate General of Health Services |
| GBD | Global Burden of Disease |
| GCS | Glasgow Coma Scale |
| GDP | Gross Domestic Product |
| ICD | International Classifciation of Disease |
| ICISS | International Classification of Disease Injury Severity Score |
| IQR | Inter-Quartile Range |
| ISS | Injury Severity Scale |
| JPNATC | Jai Prakash Narayan Apex Trauma Centre |
| KEM | King Edward Memorial hospital, Mumbai |
| LMIC | Low-and-middle-income countries |
| LTM | Lokmanya Tilak Municipal General Hospital, Mumbai |
| MeSH | Medical Subject Headings |
| MoHFW | Ministry of Health and Family Welfare |
| MoRTH | Ministry of Road Traffic and Highways |
| NCD | Non-Communicable disease |
| NISS | New Injury Severity Score |
| NTDB | National Trauma Data Bank |
| OR | Odds Ratio |
| RTI | Road Traffic Injury |
| RTS | Revised Trauma Score |
| SBP | Systolic Blood Pressure |
| SDGs | Sustainable Development Goals |
| SDI | Socio-Demographic Index |
| SRR | Survival Risk Ratio |
| SSKM | Institute of Post-Graduate Medical Education and Research and Seth Sukhlal Karnani Memorial Hospital |
| TITCO | Towards Improved Trauma Care Outcomes |
| TRISS | TRauma and Injury Severity Score |
| UHC | Universal Health Coverage |
| USD | United States Dollar |
| WHO | World Health Organization |

# DEFINITIONS

| | |
|---|---|
| Early mortality | Death in hospital within 24 hours of admission, arrival or first set of vitals |
| Delayed mortality | Death in hospital between 24 hours and 7 days of admission |
| Global health | An area of study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide[1] |
| Health system | All organizations, people and actions who primary intent is to promote restore or maintain health (WHO) |
| Injury | Damage inflicted on the body as the direct or indirect result of an external force, with or without disruption of structural continuity[2] |
| Late mortality | Death in hospital between 7 days and 30 days of admission |
| Low-income country | Country with USD 1,0125 or less per capita income[3] |
| Middle-income country | Country with USD 1,026-USD 4,035 per capita income[3] |
| Predictor | A prognostic factor that can be used to estimate a probability of outcome of interest in future individuals |
| Risk factor | A prognostic factor that is assocaited with an increased probability of the outcome of interest |
| Trauma | Trauma is the clinical entity composed of the physical injury and the body's associated response, resultant disability and disorder[4] |
| Traumatology | The medical specialty which deals with wounds and injuries as well as resulting disability and disorders from physical traumas[4] |
| Variable | A clinical factor of interest, for example Glasgow Coma Scale |
| 30-day mortality | Death in hospital within 30 days of admission |

# 1 INTRODUCTION AND BACKGROUND

Injury and trauma are commonly used interchangeably. However, they have different meanings. Injury is the damage inflicted on the body as the direct or indirect result of an external force, with or without disruption of structural continuity.[2] Trauma is the clinical entity composed of the physical injury and the body's associated response, resultant disability and disorder.[4] Traumatology is a hospital-based medical speciality which deals with physical trauma and does not include psychological trauma.[4]

## 1.1 GLOBAL BURDEN OF DISEASE AND INJURY

Globally, injury is a serious threat to public health. Every six seconds someone in the world dies as a result of injury, totalling to about 14,000 people every day and 5 million people a year.[5] This is more than the number of deaths due to HIV/AIDS, tuberculosis, malaria and maternal deaths combined.[6,7]

As communicable diseases are being better controlled, we find that non-communicable diseases (NCDs) and injury have a rising share in the global burden of disease.[8] Communicable, maternal, neonatal, and nutritional diseases, accounted for 20.2 % of global deaths in 2015. Non-communicable diseases caused 71.3% of deaths and of those injuries resulted in 8.5% of deaths.[6] Injury was the 10$^{th}$ leading cause of death in 1990 and has climbed to being the 5$^{th}$ cause of death by 2015.[9]

About 90% of the injury deaths occur in low-and-middle income countries (LMICs).[10,11] In countries like Brazil and South Africa, more than half of the burden of NCDs are due to injuries. LMICs are dealing with a disproportionate burden of injury deaths, especially among the youth (the 15-29 year age group), where it is the top killer.[5] These are physically fit individuals, usually male, and in their economically productive years. Injury inordinately affects the lower socioeconomic groups.[12]

Road traffic injury (RTI) is the main cause of injury mortality. In 2015, 1.25 million people died of RTI.[13] It was among the top five causes of death in other middle-income countries like Indonesia, Malaysia, Thailand, and Vietnam. In four high-income countries[3]—Oman, Qatar, Saudi Arabia, and United Arab Emirates—road injury was the leading cause of death and disability.[14] Violence was the fifth most common cause of death in South Africa.[14]

In India, the bulk of the disease burden is now constituted by NCDs (39.1%) and Injuries (11.8%).[15] India has 21% of the world's injury deaths and 24% of Road traffic deaths[9] as seen in Table 1. India claims about a fourth of the transportation injuries and self-harm of the world and a fifth of unintentional injuries. India's rate of injury appears lower as compared to other middle-income countries[3] like Brazil and South Africa, as the selective burden of interpersonal violence is much lower in India as compared to these two countries.[9]

Between 2004 and 2030, injury-related deaths are estimated to increase by 30%; most of which will be attributable to road traffic injuries and suicides.[16] By 2030, unipolar depressive disorders, ischaemic heart disease, chronic obstructive pulmonary disease and road traffic injuries are projected to be the four leading causes of loss of disability-adjusted life years (DALYs) in India.

Controlling the injury related death and disability is therefore urgent. This can be done by implementing evidence-based measures before, during and after the injury event.[15] These are primary, secondary and tertiary strategies in injury prevention that mitigate the consequent damage.

In September 2015, road traffic deaths were highlighted in the Sustainable Development Goals (SDGs) by the United Nations General Assembly, which replaced the Millennium Developmental Goals (MDGs). Target number 3.6 declared that by 2020, the goal is to halve the number of global deaths from road traffic accidents while target 16.1 aims to significantly reduce all forms of violence and related deaths.[17]

Injury prevention is a primary strategy that plays an important role in pre-event interventions, addressing the circumstances causing injury, such as, traffic speed reduction, barriers to prevent drowning and drink-driving regulations. Secondary strategies aims at reducing the severity of injury should an event occur. They include use of child safety car seats, bicycle helmets and smoke alarms. However, injuries can never be completely prevented.

Therefore, in addition to the above, tertiary strategies are needed to ensure optimal treatment and rehabilitation following injuries. This includes effective first aid, and prehospital care and referral for the appropriate medical care. Mitigating the post-injury phase through improved care demands effective and timely responses from the global community.

Tertiary prevention was emphasized as policy in the World Health Assembly Resolution 60.22 (dated 23 May 2007)[18], which reiterated that the world's ministries of health need to:

- "Strengthen pre-hospital and emergency trauma care systems
- Identify a core set of trauma and emergency-care services, and to develop methods for assuring and documenting that such services are provided appropriately to all who need them
- To ensure that appropriate core competencies are part of relevant health curricula and to promote continuing education for providers of trauma and emergency care
- To provide support to Member states for design of quality-improvement programmes"

If implemented, the overall, 21% of the injury burden in LMICs (or 52.3 million DALYs) could have potentially been averted by basic emergency care. South Asia had the highest total avertable DALYs (17.4 million) by these measures. Road injury alone, comprises the largest total avertable burden in LMICs (16.1 million DALYs).[19] Those who did not reach the hospital alive were considered non-avertable. The avertable proportion is greater for fatal injuries than for nonfatal events (23 vs. 20%), suggesting that hospital-based emergency services for injuries are more effective at saving lives than ameliorating disability.[19]

## 1.2 INJURY MORTALITY IN INDIA: TRENDS, RATES AND MECHANISMS

The number of deaths from unintentional injuries as a whole has remained unchanged globally since 1990. As the world population has increased, the trend of age-standardized injury death rates shows decline by more than a quarter. Age-standardized death rates for transport injury decreased since 1990, with most deaths from road injuries.[14]

However, India goes against the global trend of deaths from all injuries. India has one-sixth (16%) of the world's population, but over one-fifth (21%) of world's injury mortality. This means that about 1 million people die of injuries every year in India.[6]

As shown in Figure 1, India's rate of injury deaths is on the rise over the years 1990 to 2015, represented in actual numbers (Figure 1a) and as a percentage of all causes of deaths (Figure 1b). WHO states that the number of road traffic deaths in the world has plateaued at 1.25 million deaths a year (Figure 2)[13] but in India, it continues to rise (Figure 1).

Table 1: Mortality rate: India's share of global injury deaths by mechanism

| Heads | Injury Groups | Injury Sub-groups | Deaths in numbers (in 1000s) | | India % | Death rate (per 100,000) | |
|---|---|---|---|---|---|---|---|
| | | | Global | India | Share | Global | India |
| Total population | | (in 1000s) | 7,349,472 | 1,211,051 | **16** | | |
| All Injuries | | | 4466 | 958 | **21** | 62.6 | 73 |
| **Transport Injuries** | | | 1400 | 336 | 24 | 19.3 | 25.6 |
| | *Road Injuries* | | 1312 | 298 | 23 | 18.1 | 22.7 |
| | | Pedestrian | 539 | 120 | 22 | 7.5 | 9.2 |
| | | Cyclist | 57 | 4 | 7 | 0.8 | 0.3 |
| | | Motorcyclist | 247 | 84 | **34** | 3.3 | 6.4 |
| | | Motor vehicle | 453 | 85 | 19 | 6.2 | 6.5 |
| | | Other | 18 | 3 | 17 | 0.2 | 0.3 |
| | *Other transport injuries* (Railway) | | 88 | 38 | **43** | 1.2 | 2.9 |
| **Unintentional injuries** | | | 1804 | 369 | 20 | 26 | 28.1 |
| | *Falls* | | 535 | 80 | 15 | 8.2 | 6.1 |
| | Drowning | | 277 | 53 | 19 | 3.8 | 4.1 |
| | *Fire* | | 180 | 61 | **34** | 2.5 | 4.7 |
| | Poisonings | | 129 | 11 | 9 | 1.8 | 0.8 |
| **Self-harm and interpersonal violence** | | | 1249 | 252 | 20 | 17.1 | 19.2 |
| | Self-harm | | 856 | 207 | 24 | 11.9 | 15.8 |
| | *Interpersonal* | *violence* | 393 | 44 | 11 | 5.3 | 3.4 |
| | | by firearm | 162 | 9 | 6 | 2.2 | 0.7 |
| | | by sharp object | 91 | 3 | 3 | 1.2 | 0.2 |
| | | by other means | 139 | 33 | 24 | 1.9 | 2.5 |

Mechanisms of injury not studied in this thesis are drowning, poisonings and self-harm (shaded). Data in bold represents more than double the expected injury rate. Data extracted from Global Burden of Disease 2015[6]

In India, 25 out of every 100,000 people die due to RTI, though the global figure is 19 persons per 100,000.[9,20] In other words, India witnessed nearly 500,000 RTIs in year 2015, which killed 146,000 people and injured more than three times that number. The minister of road transport and highways, Nitin Gadkari[21] admitted that 400 Indians die every day in road accidents. There are 17 deaths in 57 crashes each hour, with people aged between 15 and 34 years making up over 54% of those killed. He admitted that not much had changed after two years of dedicated work and sincere efforts by his government since 2015, but vowed to contain what he described as "human sacrifices" on the roads.

Table 1 tabulates India's share of each mechanism of injury as a share of the global burden of injuries. Burn injuries in India are double the global rate, and India accounts for a third of the global burden of burns. Interpersonal violence in India is much lower than the global averages. India also has a disproportionately large share (43%) of motorcyle, pedestrian, railway and other transport injury deaths.

One strategy to reduce the burden of injury in India may be to integrate trauma care into the national health system and national health policy.[22]

Figure 1a: India Injury deaths represented in actual numbers, as a trend from year 1990 to 2015 – Increasing trend of injury deaths in India

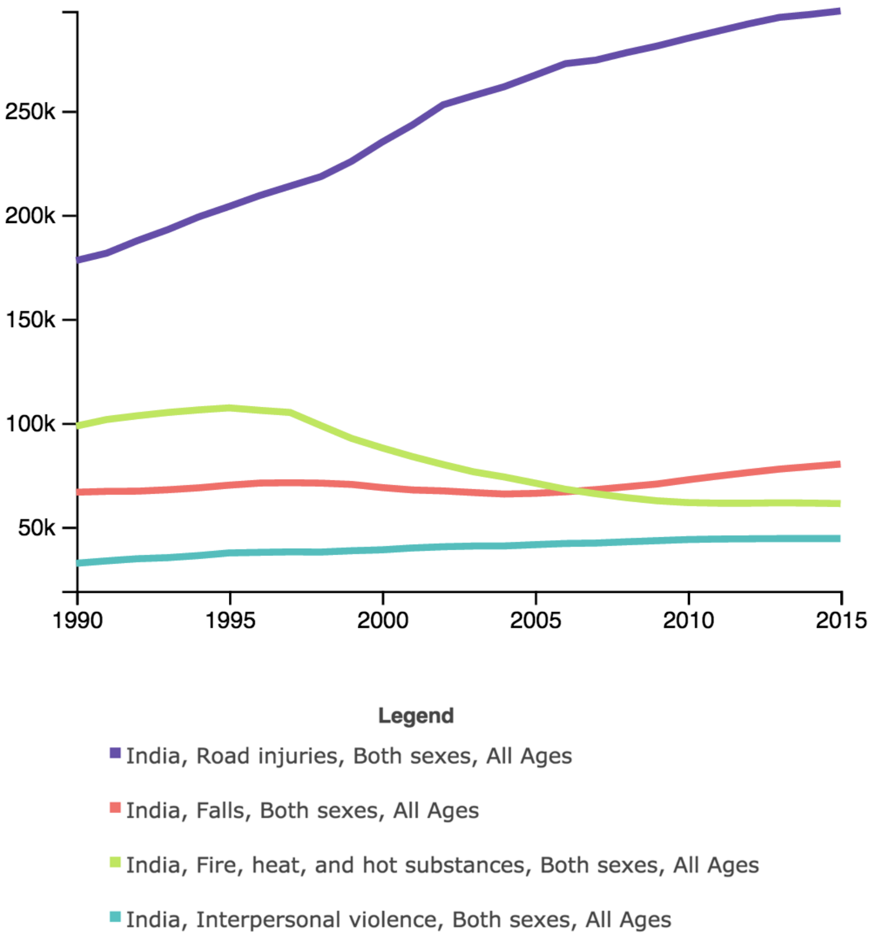



Figure 1b: India - Injury mortality trends from 1990-2015 represented as the proportion of injury deaths within all-cause deaths, in percentages

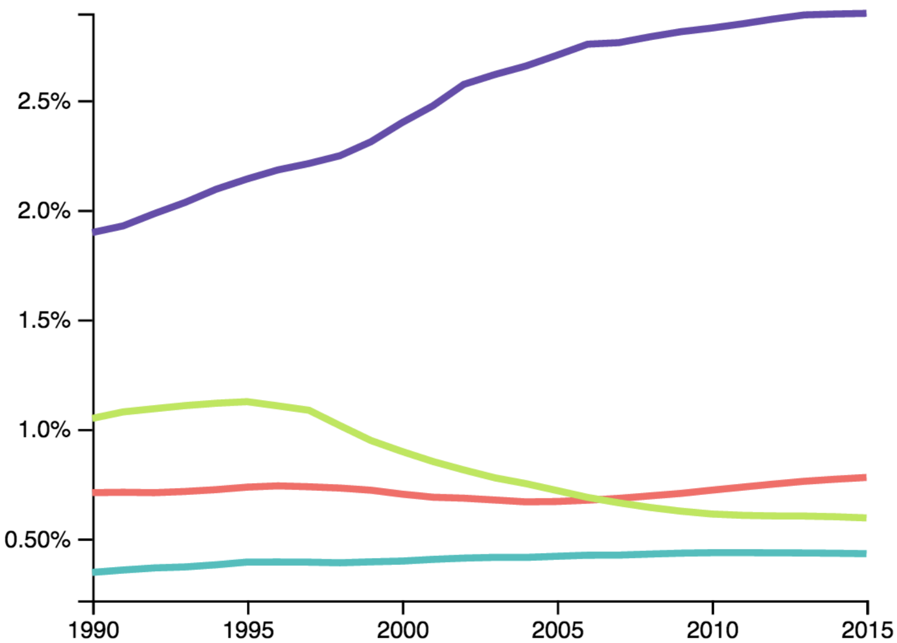


Figure 2a: Global Injury deaths represented in actual numbers, as a trend from year 1990 to 2015 - Global injury deaths have plateaued

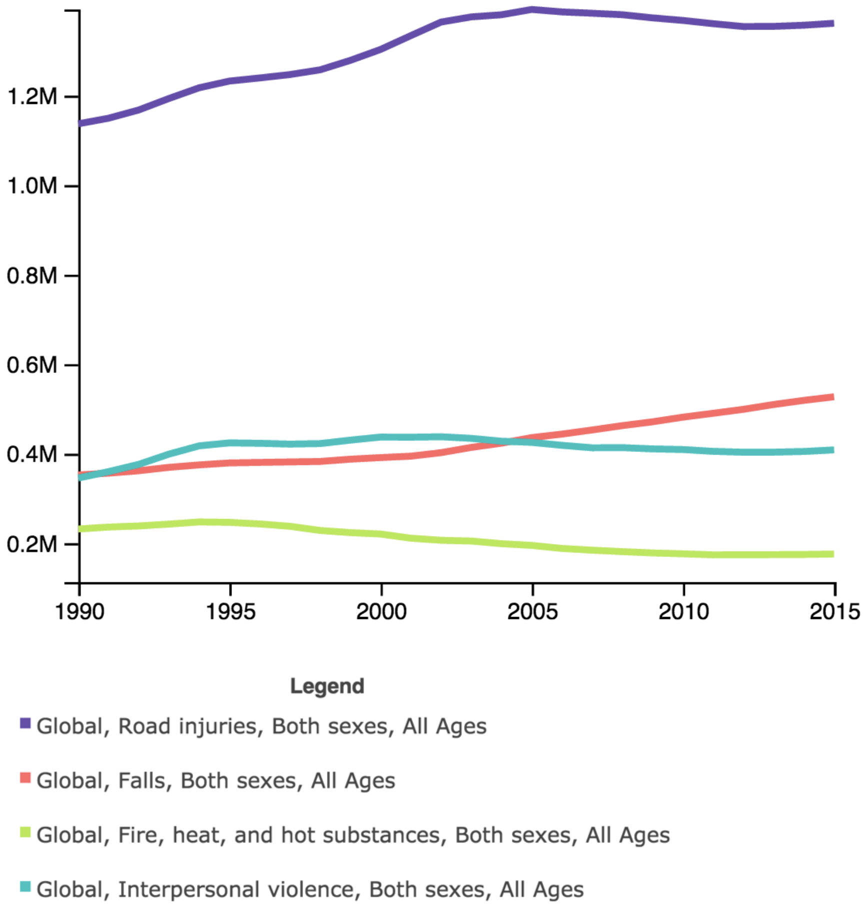
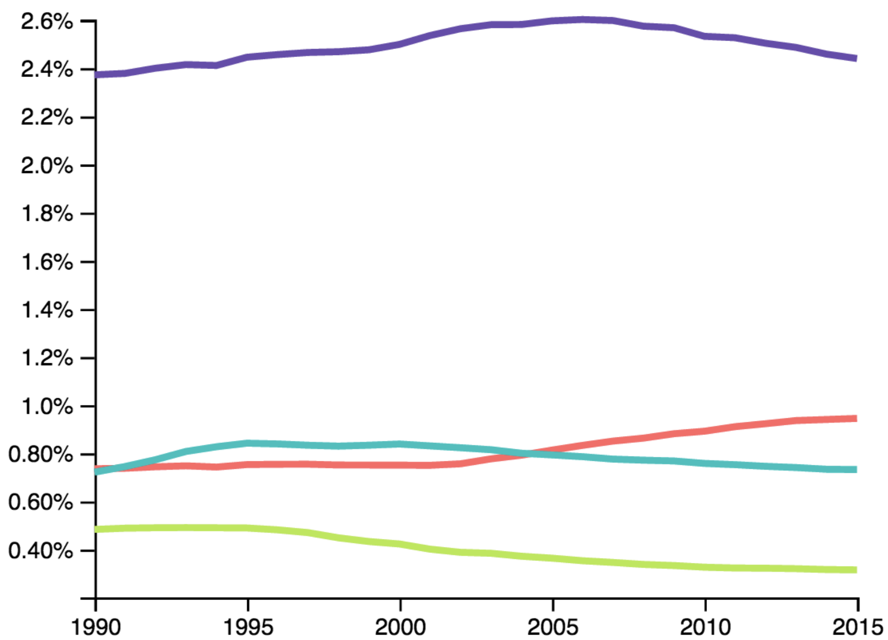



Figure 2b: Global - Injury Mortality trends 1990-2015 represented as the proportion of injury deaths within all-cause deaths, in percentages




Source: generated using the Global Burden of Disease 2015 data visualization tool[6]

## 1.3 NATIONAL HEALTH SYSTEMS AND POLICY IN INDIA

India is home to more than 1.2 billion people. Inequity is the norm in terms of gender, caste, poverty distribution and healthcare access. One-fourth of the world's poor - 370 million people - live in India, with 180 million under the poverty line (earning less than USD 1.90 a day).[3] Though it is the world's third-largest economy in terms of gross national income, it remains the poorest nation among the world's middle-income countries, with an annual per capita income of USD 1,410.[23] Table 2 compares India's health and economic indicators with a low (Uganda) and high income country (Sweden). Despite rapid economic growth, India was ranked 143rd of 188 countries[17], using the median health-related Socio-demographic index (SDI). SDI is based on a nation's average per person income, education levels and fertility rate.

Table 2: Comparative ranks and indices of a high, middle and low income country

| | **Sweden** | **India** | **Uganda** |
|---|---|---|---|
| Human Development Index Rank (UNDP) [24] | 14 | 130 | 163 |
| Population (2015)[3] | 10 million | 1200 million | 39 million |
| Gross Domestic Product (GDP) per capita in USD (2015)[3] | 50,580 | 1,598 | 705 |
| Life expectancy at birth (years)[24] | 82.2 | 68.0 | 58.5 |
| Health expenditure per capita (current USD, 2014) [3] | 6,808 | 75 | 52 |

India's healthcare system is characterized by multiple systems of medicine, mixed ownership and different kinds of delivery structures.[16] The private sector provides nearly 80% of outpatient care and about 60% of inpatient care.[25] The key challenges of the healthcare system in India are that it has a weak primary healthcare sector, unevenly distributed skilled human resources, a large and unregulated private sector, low public spending on health, poor health information systems, irrational use and spiralling costs of technology, weak governance and accountability.[26]

Health is a state subject in India. Within the Indian healthcare system, the central government is responsible for health policies, regulations and national disease control programs, whereas the individual states are responsible for healthcare delivery, financing and training of personnel.[27] In other words, the central government can only make model health laws to which states can voluntarily subscribe. This results in a weak health governance and regulation structure. A lack of infrastructure and workforce makes healthcare provision within Indian systems suboptimal.[28–30]

The government spending on health is 1.04% of the gross domestic product (GDP) in India[27], as compared to 3% in China and 8.3% in the USA. A comparable middle-income country like Thailand spends 4.1% of their GDP on healthcare of which 77.7% is paid by the government. Thailand is close to achieving universal healthcare (UHC).[27] India's overall healthcare spending is also 4.1% of the GDP, but the government only provides 1.04% of the GDP for healthcare. This means 70% of the health expenses are personal out-of-pocket expenditures. These personal health expenses constitute 6.9% of the monthly per capita expenditure of Indians in rural areas and 5.5% in urban areas.[22] Currently, for the health of every Indian, the central

Government spends Rs 325 (USD 4.95) and state governments spend an additional about Rs 632 (USD 9.60) in a whole year.

A median single health expenditure of 25% (interquartile range: 10%-40%) of monthly per capita expenditure is considered a "catastrophic health expenditure" and can push families into poverty.[30,31] This is particularly important in LMICs like India, where the inequity in health outcomes and access is demonstrated by indicators disaggregated for vulnerable groups. Care funded by social insurance schemes for the poorest third of the population is a suggested strategy for coping with this poverty creation.[16]

Priority setting in health care is a political decision. In India, maternal mortality is less than 0.55% of all mortalities and leprosy less than 0.01%.[23] But both have been high health priorities. National health programs in India provide universal coverage for less than 10% of mortalities and 15% of all morbidities. Alternative national models for fair priority setting are available from other LMICs.[32,33] However, injury has not been a priority, though India has 21% of the global injury burden and injury is 16% of the total disease burden among Indian adults.[16]

A *Yatri Suraksha* scheme was proposed in the draft National health Policy 2015[25], released by the Government of India. It stated "Deaths due to rail and road traffic accidents should decline through a combination of response and prevention measures that ensure road and rail safety" and that the concept could be expanded to include injuries from other causes. Under the 11th 5-year plan, the National Health Assurance Mission (NHAM) was launched in 2015 with a planned network of emergency life support ambulances linked to trauma management centres providing prehospital and post-hospital care. Rehabilitation care in the community and through the nearest health institutions would be made available, as 30% of the injured suffer serious disabilities.[25] These plans were only partially implemented and unevenly, until they were replaced by The National Health Policy (NHP 2017).

The NHP 2017 announced in March 2017 promises to increase the government health spending to 2.5% of the GDP by 2025 and raise life-expectancy from the current 67.5 years to 70 years by 2025. For trauma care, NHP 2017 recommends that for every 100,000 people, 200 beds are kept exclusively for receiving trauma patients within one hour of the trauma ('golden' hour). In the United States, they have 20 intensive care beds for every 100,000 people.[34] The NHP 2017 also supports the development of mass casualty management protocols for community health centres (CHCs) and higher facilities and emergency response protocols at all levels. The policy proposes creating an unified emergency response system, linked to a dedicated universal access number, with an emergency care network of life support ambulances and trauma management centres (one per 3 million people in urban areas and per 1 million in rural areas). This is key to the formulation of a trauma care policy. The NHP also recommends setting up a National Institute of Chronic disease which includes trauma care, to generate evidence for adopting cost effective approaches and showcase the best practices. To contain the burden of injuries, national health systems will eventually have to incorporate trauma systems into themselves.[35]

## 1.4 TRAUMA SYSTEMS: PAST, PRESENT AND FUTURE

A trauma system is an organized, co-ordinated multidisciplinary effort that delivers injury prevention, acute care and rehabilitation to the injured patient, and is intregated with the local public health system.[36–38] Through the the past and present, war and warfare has taught us much about trauma and trauma systems.[39] The intriguing historical perspective of the progress of trauma care organizing, preventing deaths[36] and the scientific understanding of improving outcomes over the past centuries is summarized in Panel 1.

**Panel 1: Trauma systems - The past**

*He who desires to practice surgery must go to war*
*– Hippocrates, Greek physician (c. 460-377 B.C.)*

In India, back in the 5th century, Fa Xian, a traveling Chinese Buddhist monk, described the earliest institution based healthcare system, a civic hospital system in India. The first extant of a medical encyclopedia, called *Charaka-samhita* (100 BCE), Charaka described how a hospital should be built. Sri Lanka has similar hospitals *Sivikasotthi-Sala* (437 BCE to 367 BCE) and Mihintale Hospital is perhaps, the oldest hospital in the world.[201] A hospital and medical school (*bimaristan)* also existed at Gundeshapur (271 CE) in the Persian empire (modern day Iran)where surgery was documented by researcher Mankah and surgeon, Susruta from India. The *Arthasastra*[202] (269–232 BCE) mentions that the Indian army had an ambulance service, with well-equipped surgeons (*Shalyarara* meaning 'arrow-remover) and women to prepare food and beverages.
The Smith Papyrus, an ancient Egyptian text (c.1600 BCE) with 48 document cases of penetrating wounds. Homer's Iliad, the 15,693 line epic poem set during the Trojan War (1260-1180 BC) in ancient Greece, documents the ten-year siege of the city of Troy (modern day Hisarlik, Turkey). It records 147 wounds in 48 patients with an overall mortality of 77.6%.[203] Hospital-temples (*asclepieia)* probably used opium-induced *enkoimesis* (a state of dream-like induced sleep) akin to anesthesia. In Rome (100 BCE), hospitals (*valetudinarian)* had a surge capacity of 10% and were the earliest trauma centres. There were dedicated army physicians, which has been recorded with epitaphs on tombstones. Constantinople (Istanbul) within the Roman empire (4 BCE) had hospitals (*basilias*), with staff, the Chief Physician (*archiatroi*), professional nurses (*hypourgoi*) and the orderlies (*hyperetai*).
With better, more recent accounts of European wars, accurate diagrams of the anatomy by Andreas Vesalius (1514-1564) were available. French military surgeon, Ambrose Par (1510-1590) described tourniquet use for major wounds, surgical nutrition and prosthetic devices for rehabilitation. Napolean's surgeon, Dominque Jean Larrey (1766-1842) set up the first organized trauma systems, with a dedicated frontline trauma surgeon, rapid prehospital transport (flying ambulances) and early surgery to take advantage of the "wound shock" analgesia phase besides preventing postoperative surgical infection.[39] *Karolinska Institutet* was founded in 1810 as an *"academy for the training of skilled army surgeons"* after one in three soldiers wounded in the Finnish War against Russia died in the field hospitals. The barber-surgeons had poor medical skills and Kung Karl XIII decided that Sweden needed to train surgeons to perform better in future wars. In the Crimean war (1853-1856) the French reduced post-surgery sepsis-related mortality from 43.3% to 2.6% by using ferrous chloride and to 6.6% with bromine respectively. Florence Nightingale introduced sanitation and critical care nursing in the Crimean War (1853-1856), when mortality from amputation was 26.3% (n=29,980). She rearranged the hospital beds so the most seriously ill were near to the nursing station. The Franco-Prussian war (1870-1902) had over two-thirds case-fatality in the combat injured, as the surgeons were reluctant to use Lister's antisepsis recommendations. In the Boer War (1899-1902), abdominal laparotomy yielded catastrophic results in penetrating abdominal wounds, after which the British ordered conservative (expectant) treatment, with better outcomes. At the start of first World War (1914-1918), abdominal injuries had an 85% mortality. With frontline surgical hospitals, the mortality was reduced to 56% for the British and 45% for the Americans. Blood transfusion was the major contribution of this war to trauma surgery. In the Second World War, shock units provided resuscitation for severely injured soldiers. In Borås in Sweden in 1952, a post-operative unit opened that could provide advanced monitoring and care.[204] Whilst the United States' and Israeli Trauma Systems have evolved significantly over the past 40 years, London established a trauma system in 2010 with four Major Trauma Centers and various regional systems were launched in England in 2012 and Scotland in 2016.[76] India still does not have an organized trauma system.
Note: BCE "Before the Common Era," and CE stands for "Common Era" which replaces BC and AD

**Panel 2:** The designated levels of trauma care as proposed in India as defined by the Ministry of Health and Family Welfare (MoHFW)[25]

**Level IV:** Equipped and manned mobile hospitals/ambulances.

**Level III:** Level III Trauma Care Facilities would provide initial evaluation and stabilization (surgically if appropriate) to the trauma patient. Comprehensive medical and surgical inpatient services would be made available to those patients who can be maintained in a stable or improving condition without specialized care. Emergency doctors and nurses, physicians, general surgeons, orthopaedic surgeons and anaesthetist would be available round the clock to assess, resuscitate, stabilize and initiate transfer as necessary to a higher-level trauma care facility. Such hospitals will have limited intensive care facilities, diagnostic capabilities, blood bank and other supportive services. The district hospitals with a bed capacity of 100 to 200 beds would be selected for level III care.

**Level II:** Level II Trauma Care Facilities would provide definitive care for severe trauma patients. Emergency physicians, general surgeons, orthopaedic surgeons and anaesthetists are in-house and available to the trauma patients immediately upon arrival. These facilities would also have on-call neurosurgeons and paediatricians. If neurosurgeons are not available, general surgeons trained in neuro surgery for a period of 6 months at teaching institutions would be made available round-the-clock. The facility should be equipped with an emergency department, intensive care unit, blood bank, rehabilitation services, comprehensive diagnostic capabilities and supportive services. The existing medical college hospitals or hospitals with bed strength of 300 to 500 beds should be identified as Level II Trauma Care Facilities.

**Level I:** Level I Trauma Care Facilities will provide the highest level of definitive and comprehensive care for patient with complex injuries. Emergency physicians, nurses and surgeons would be in-house and available to the trauma patient immediately on their arrival. The services of all specialties associated with trauma care, such as vascular surgery, interventional radiology, would be available round-the-clock. Facilities would be situated at essentially at a distance less than 750 to 800 km apart; although not necessarily along with the highway corridor. They would be tertiary care facilities to which patients requiring highly specialized medical care are referred. Due to the high levels of skill, specialists and infrastructure required, Level I Trauma Care Facilities should be only in medical university hospitals.

In HICs, improvements in planning and organization[40] for trauma care have been shown to decrease overall mortality by 15–20% and preventable deaths by 50%.[41] The cost of treating RTIs alone is more than the government's entire health budget of many LMICs including India.[36,42,43] The Global status on road safety published by the WHO[13], states that despite this massive economic and human toll by RTIs, LMICs have not invested in trauma systems.

In a significant legal judgment about trauma care in India, the Supreme court case of W/P no 295 Rajashekharan vs Union of India[44] catalyzed the strengthening of trauma systems. The judgement ordered the formation of a committee on road safety and adjudicated that trauma care should be available at every 100 km along the national highways.[44] The Government of India (GoI) responded by setting up a multi-ministry working group on Emergency care in India, involving the Ministry of Health & Family Welfare (MoHFW) and the Ministry of Road Transport & Highways (MoRTH). The deliverable in the proposed plan is to build 140 trauma hospitals along the golden quadrilateral of Mumbai, Delhi, Kolkata and Chennai (Figure 5). These four cities, each with a population of over 10 million, are the urban areas included in this thesis. Panel 2 lists the levels of trauma care facilities that are to be designated within India's existing health system by the MoHFW.

The government will use the existing WHO trauma care guidelines[45] for planning these comprehensive trauma care systems. Similarly, the Essential Trauma Care project (EsTC), jointly supported by the World Health Organization (WHO) and the International Association for Trauma and Surgical Intensive Care/International Society of Surgery (IATSIC/ISS), gives guidance on the systematic changes required in LMIC health systems.[46] The guidelines for EsTC[47] list 260 items of human (training, staffing) and physical (equipment, supplies) resources that are considered as either "essential" or "desirable" at different levels of the health care system. Essential items are those that are considered the most cost-effective and are universally applicable in countries at all economic levels; for example, basic airway equipment and pulse oximetry. Desirable items are those that add value but are not as cost-effective and are more applicable to middle-income environments or large urban centers; for example computed tomography (CT) scans.[48]

Trauma systems need to be benchmarked across states and countries, so that the best practices and evidence generated can help build robust and responsive health systems.[39] One way to compare across trauma centres uses the Trauma severity scoring systems.[49]

## 1.5 TRAUMA SCORING SYSTEMS

Trauma is not a single disease condition. It is combination of anatomical injuries, intensified by the physiological and metabolic response and influenced by age and co-morbidities. With multiple variables influencing trauma outcomes, research has attempted to convert the severity into a single number, with the use of trauma scoring systems.[49] There are many such scoring systems in use internationally which either use anatomical or physiological patient values, or a combination of both. While there is no perfect scoring system, as yet, they remain important for evaluating trauma care delivery and research. They provide a quantifiable number for grouping trauma patients by severity and allow comparisons across centres and treatment modalities. Most importantly, they have allowed traumatologists to have a set of common definitions and speak in a common language.[50] A brief outline follows of the common international scoring systems referred to, in this thesis.

The **Glasgow Coma Scale (GCS)**: Teasdale and Jennet of the University of Glasgow, Scotland developed this scale in 1974, in an early attempt to quantify the severity of head injury[51] and GCS has stood the test of time.[52] The scale is a sum of scores of three variables, namely, the best motor response, the best verbal response and eye opening to various stimuli.

A GCS of less than 8 denotes a severe injury. A GCS between 9 to 12 correlates with moderate injury and a GCS 13 to 15 with mild brain injury.[53]

**Revised Trauma Score (RTS)**: This physiological score is defined by three variables, the GCS, respiratory rate (RR) and the systolic blood pressure (SBP).[54] A coded value from 0 to 4 is assigned for each variable. The range of RTS is from 0 (worst) to 7.84 (best), with lower scores representing increasing severity. The RTS is a common and frequently used prehospital triage tool.

**Injury Severity Scale (ISS)**: ISS was the first anatomy based scoring system developed in 1974 by Susan Baker and colleagues.[55,56] ISS was based on the Abbreviated Injury Scale (AIS).[57,58] AIS was also developed in 1974 by the American medical association committee on medical aspects of automotive safety, which defined categories for severity of injuries in several anatomic areas. However, AIS failed to account for the cumulative effect of injury in different body areas. ISS addressed this limitation by calculating the sum of the squares ($ISS=a^2+b^2+c^2$) of the three highest AIS scores, each taken from an single anatomic area. ISS is used for retrospective analysis and this scale cannot be used during initial evaluation, as the patient's exact anatomic injuries are not known on arrival. The highest ISS score is 75. ISS was criticized, as a very severe single body area injury would be underscored. To overcome this shortcoming, the New Injury Severity Score (NISS)[59,60] was developed, which uses the three highest scores regardless of anatomic area.

The **International classification of disease injury severity score (ICISS)**: It is based on the international classification of disease (ICD) codes. The survival risk ratio (SRR) is the proportion of patients with a specific ICD-code who survived among all with the same condition. This score can range from 0 (none survived) to 1 (all survived) for a specific code. An ICISS of 0.4 represents a 40% probability of survival. There are multiple ways to use the SRRs to calculate patient outcomes. The conventional method is to consider the product of all of a patient's SRRs.[61–63]

**The Kampala Trauma Score (KTS)**[64,65]: Another primarily physiological score, in which Macleod, Kobusingye and co-workers added the most severe anatomic injury. KTS is designed specifically for use in LMIC settings. KTS performs at par with many of the more complex scoring systems like TRISS, even in HIC settings.[66]

Table 3: Components of the Kampala Trauma Score (KTS)

| **Age** *(years)* | |
|---|---|
| 5-55 | 2 |
| <5 or > 55 | 1 |
| **Systolic blood pressure** | |
| >89 *(mmHg)* | 4 |
| 50-89 | 3 |
| 1-49 | 2 |
| Undetectable | 1 |
| **Respiratory Rate** *(/min)* | |
| 10-29 | 3 |
| >30 | 2 |
| <9 | 1 |

| **Neurologic Status**(AVPU) | |
|---|---|
| Alert | 4 |
| Responds to verbal stimuli | 3 |
| Responds to painful stimuli | 2 |
| Unresponsive | 1 |
| **Serious injuries** | |
| None | 3 |
| 1 | 2 |
| >=2 | 1 |
| *Total score* | 5-16 |

The **TRauma score - Injury Severity Score (TRISS)**[67,68] combines the anatomic criteria of ISS with the physiological variables of RTS and was developed in 1981. The RTS score is calculated using weighted coefficients (derived from Champion's major trauma outcome MTOS study).[69,70]

Using logistic regression, the probability of survival (Ps) is calculated as:
The Ps equation is: $Ps = \frac{1}{1+e^{-b}}$

b is calculated by: $b = b0 + b1(RTS) + \ b2(ISS) + \ b3(AgeIndex)$

Inserting the 2009 TRISS $b$ coefficients[71] for blunt injury into the Ps equation gives:

$$Ps_{blunt} = \frac{1}{1+e^{-(-0.4499+0.8085(RTS)-0.0835(ISS)-1.7430(AgeIndex))}}$$

Inserting the coefficients for penetrating injury into the Ps equation gives:

$$Ps_{penetrating} = \frac{1}{1+e^{-(-2.5355+0.9934(RTS)-0.0651(ISS)-1.1360(AgeIndex))}}$$

*AgeIndex* is equal to 0 if patient age<55 years, and 1 if patient age≥55 years. For patients who are younger than 15 years, the blunt injury coefficients are used regardless of injury type.

TRISS and ISS are calculated retrospectively and though not useful in the clinical setting, they are very useful for trauma research.[72] Researchers use these scores to compare outcomes using trauma registries within countries and in between countries.

## 1.6 TRAUMA RESEARCH AND REGISTRY IN INDIA

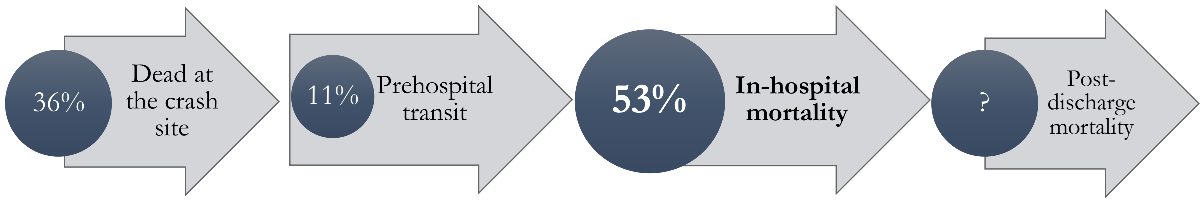
Trauma research is in its infancy in India.[73] Therefore, it lacks the opportunity for a research-driven policy agenda on injury prevention and trauma care.[74]

A search of PubMed indexed trauma articles from India over the last 10 years, yielded a majority of papers published from a single hospital or community based settings. The study designs were mainly cross-sectional or retrospective. Only a fourth of the studies had a prospective, case-case control, cohort or a longitudinal design, listed in the decreasing order of frequency. Less than 2% articles were multicentric, demonstrating a need for multi-institutional trauma registries for furthering trauma research. Trauma registries have been linked to improvements in trauma care outcomes.[75] Globally trauma registries like the National Trauma Data Bank (NTDB) of the USA serve as a benchmark for registries worldwide. Other high quality registries and trauma research initiatives are the Trauma Audit and Research Network (TARN)[76] in the United Kingdom and the Victorian State Trauma Registry (VSTR) in Australia.[77]

Like in other LMICs, there have been multiple attempts by the government departments and universities to initiate injury surveillance and trauma registry projects[78–80], with variable success. The most recently designated centre in India is at Dr. Ram Manohar Lohia Hospital, New Delhi called 'The National Injury Surveillance, Trauma Registry & Capacity Building Centre (NISC)' has been started by the Directorate General of Health Services (DGHS) at the Ministry of Health & Family Welfare (MoHFW), Government of India. It will be linked to all the designated Trauma Care Facilities in the country for the purpose of data collection and training.[81]

Currently in India, we find that the police keep the data on those who died at the site of the injury, the transport ministry has the data of the offending vehicle, the hospitals have data on those who arrive there dead or alive and currently, there is no data recorded on post-discharge mortality. The complete picture of trauma mortality at each phase of trauma care in India would be available by interconnecting these disparate databases, as done by Injury epidemiologist, G. Gururaj from Bangalore city in India, as dispalyed in Figure 3.

Figure 3: Percentage of RTI deaths by site of death, in the Indian trauma chain




Sources: Bangalore city traffic police data[82]

The phases of trauma care in India are prehospital care (by-standers), in-hospital care (initial and definitive) and rehabilitation. Figure 3 shows that in-hospital mortality in India contributes to the majority share (53%) of the trauma deaths.[82] If an efficient prehospital transport ambulance system existed in India, more seriously injured patients would be able to reach the hospital. The 11% patients dying in transit would now die in the hospital, raising the in-hospital mortality even further. In-hospital care, first needs to be improved in India and despite the existing delays in prehospital transit and a lack of prehospital trauma care; hospital improvement programs would greatly decrease mortality and complications rates.[28] This is supported by a study from Pakistan[83], where after organization of hospital trauma care services trauma patients were 4.9 times less likely to die, compared with those who were treated before reorganization.

## 1.7 SUMMARY OF KEY KNOWLEDGE GAPS

A significant knowledge gap in India's trauma mortality is that we do not know the proportion of patients who die, after reaching referral hospitals alive.[78] A baseline in-hospital mortality rate will provide the denominator, based on which researchers in the coming years, can measure improvement of trauma outcomes with the introduction an organized trauma system.[84] A yearly trend of improving trauma outcomes will encourage the health system to perform better.[85]

Clearly, there is an exigent demand to reduce in-hospital deaths in order to improve overall trauma outcomes in India. This thesis deals with the critical hospital phase of trauma care where the majority of lives are lost. It also explores the proportion and causes of deaths which could have been prevented.

The trauma burden is very high in urban densely populated cities and the trauma patients are mainly referred to public university hospitals in urban India. Therefore the most populous cities in India and the busiest trauma centres at each city were the natural sites for exploring these questions and addressing the knowledge gaps. Also, validation of internationally accepted tools for systematic data collection and trauma scoring, would allow for comparison of Indian trauma care delivery and outcomes to international benchmarks.

## 2 PROBLEM STATEMENT AND STUDY RATIONALE

Trauma is not a single disease condition. Trauma outcomes depend on the effects of the severe injury in relation to the patient's physiological reserve and the response of the healthcare system. Therefore, unlike a single diagnosis illnesses, the systems approach for trauma care is to focus on common pathways of healthcare delivery and patient outcomes.

In India, the current unknowns are:

- The baseline in-hospital mortality **rate** across urban hospitals in India
- Time **trends** in trauma mortality in hospitals
- **Process of care** time measurements in the absence of an organized India trauma prehospital and hospital system
- The **validity** of internationally used scoring systems, in the absence of a trauma registry or systematic collected data; as currently trauma care in India cannot be benchmarked with international comparisons of outcomes
- The proportion of trauma deaths that are **preventable** in the Indian in-hospital setting
- The possible **causes** of death and opportunities for improvement in trauma care in urban Indian hospitals

## 3 AIM OF THE THESIS AND SPECIFIC OBJECTIVES

### OVERALL AIM

To determine the rates, trends and causes of in-hospital mortality among trauma patients.

### SPECIFIC OBJECTIVES

Within the context of urban university hospitals in India

- To estimate the longitudinal trend and rate of 24-hour in-hospital trauma mortality *(Study I)*
- To determine the association between 30-day in-hospital mortality and on-admission physiological parameters and assess in-hospital care processes *(Study II)*
- To assess the validity of internationally used Trauma scoring systems in predicting in-hospital trauma mortality in India*(Study III)*
- To establish through peer-review of trauma deaths, the proportion and causes of preventable deaths in all in-hospital trauma deaths *(Study IV)*

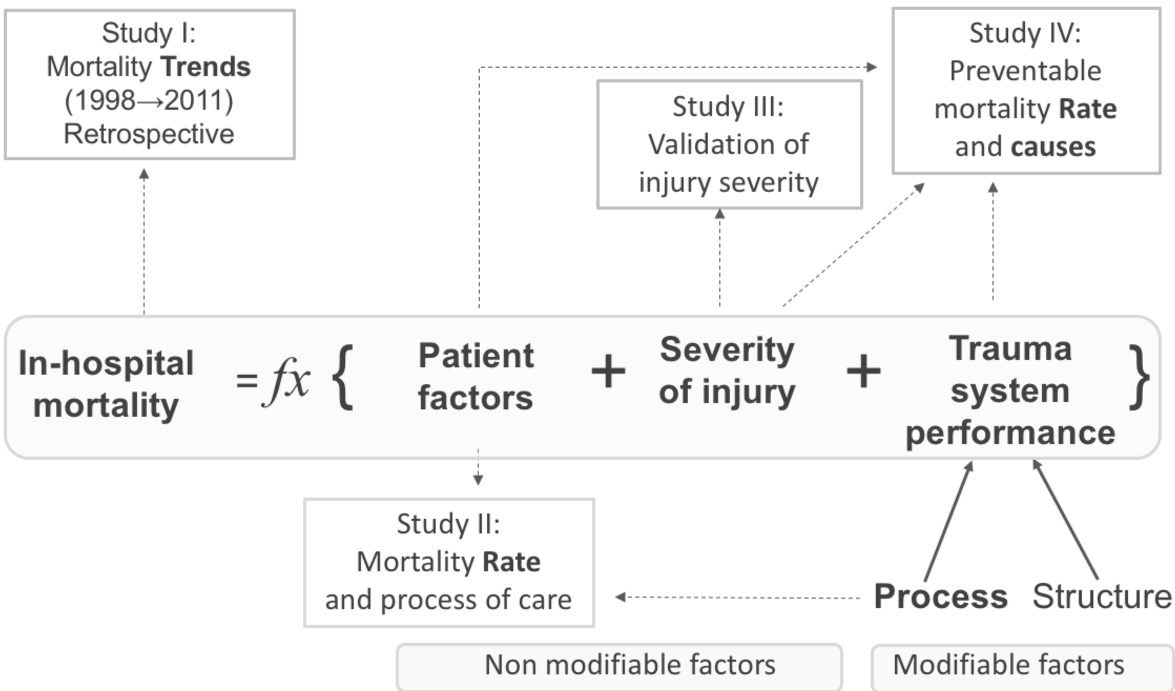
# 4 METHODS

## 4.1 RESEARCH FRAMEWORK

Figure 4 displays the interconnected link between the four substudies, as each one explores patient factors, severity of injury and trauma system performance and their association with outcome (in-hospital trauma mortality). Patient factors like age, co-morbidities, initial physiological deterioration are considered non-modifiable factors. Similarly, the degree and pattern of tissue injury are non-modifiable. However strategies that minimize physiological insult (e.g. resuscitation)[86], surgical interventions and response times are considered as modifiable factors influencing outcomes.[87]

Study I investigated the time-*trend* in 24-hour mortality over 14 years in urban hospitals, using retrospective cohorts collected over different time periods. This baseline 24-hour mortality *rate* was recalculated with a larger and systematically collected prospective dataset in study II, to include a longer 30-day outcome, as recommended by the American college of surgeons, which defined as death within 30 days of in-hospital stay.[88] The association of patient factors (variables such as age, sex, mechanism of injury, physiological vitals on admission to the trauma unit) and 30-day in-hospital outcomes was a part of the studies. Further, the performance or responsiveness of the trauma system was measured for baseline time indicators of processes and activities. Since there is no trauma system in existence in India, it may have been premature to test its performance. It was useful to note the variations in the current trauma care processes, both within the hospital and among studied hospitals.

Figure 4: Research framework of outcome as a function of patient factors, injury severity and trauma system performance




Modification of Prof. Russel Gruen's structure, process, outcome equation[89]

The physical infrastructure and resources of the hospital providing the care determines outcomes. The WHO guidelines[47] suggest the optimum and the minimum infrastructure for designated trauma care facilities. However, an infrastructure audit was not a part of my research, as there are no designated trauma centres (except for JPNATC at New Delhi). Severity of injuries has a strong association with mortality. Study III assessed the validity of the commonly used international trauma scoring systems for severity calculation, using Indian data. Study IV built upon Study III's severely injured categories, to explore which patient and system factors could be the *cause* of death of the admitted patient.

## 4.2 SUMMARY OF METHODS AT A GLANCE

Table 4: Summary of methods at a glance

| | Objective | Method Design | Study period | Population | Analysis |
|---|---|---|---|---|---|
| I | Longitudinal trend of early (24-hour) mortality | Retro-spective cohorts | Jan-Dec 1998, Aug 2001 - May 2002, Oct 2010 - Feb 2012 | 4,189 1 hosp | Multi-variate logistic regression |
| II | The 30-day in-hospital mortality rate | Pro-spective cohort | Oct 2013 – Feb 2015 | 11,209 4 hosp | Descriptive statistics, Wilcoxon rank-sum, Kaplan-Meier survival curves |
| III | Validation of international trauma scoring systems | Pro-spective cohort | Oct 2013 – Feb 2015 | 8,791 4 hosp | Calculation of scores, Chi-square test, ROC curves, Akaike Information Criterion, Pearson goodness of fit |
| IV | Proportion of preventable deaths | Pro-spective cohort | Oct 2013 – Feb 2015 | 11,671 5 hosp | Peer review and Delphi method |

## 4.3 STUDY CONTEXT AND PARTICIPATING SITES

The participating sites in our studies were urban university hospitals receiving high-volume trauma patients. They are located in India's most populated cities of New Delhi, Mumbai (previously called 'Bombay'), Chennai (previously called 'Madras') and Kolkata (previously called 'Calcutta'); each with a population of over 10 million people. These cities are geographically spread in the north, south, east and west of India, as seen in Figure 5. These are all public university hospitals and tertiary referral centres, where serious trauma patients are referred. With the limited prehospital system in India, the trauma referrals are directed by the police or lay-bystanders. These hospitals are classified as free-to-public with nominal user fees, facilitating access to care for the lower socioeconomic strata of the population, though the levels of trauma care provided at each centre vary.

The five university hospitals have trauma units providing trauma care, as a part of the general hospital, except the Jai Prakash Narayan Apex Trauma Centre in Delhi (JPNATC). There are no specialized Emergency physicians or Emergency department in any of the participating hospitals, nor an established system of triage (except at JPNATC). Individual speciality practitioners (e.g. general surgery, orthopaedics, plastic surgery, neurosurgery) accept the patients based on the predominant injury, which is not always obvious, on arrival of the patient. Private hospitals have not been providers of trauma care, as the medicolegal nature, cost of initial care, difficulty in recovering hospital fees, have all been deterrants for receiving trauma patients.[90,91] Private hospitals therefore transfer serious trauma patients to public hospitals in small private ambulances.[91] Also, trauma care expenditure is 2-4 times higher in the private hospitals as compared with that in public hospitals.[31] Therefore, the lay responders, bystanders and traffic police refer trauma patients to the public university-based hospitals, using informal transportation, such as private vehicles, taxis or the police van.

*All India Institute of Medical Sciences, New Delhi (AIIMS Delhi)*
The Jai Prakash Narayan Apex Trauma Centre (JPNATC)[92], is a standalone trauma centre and a part of the All-India Institute of Medical Sciences (AIIMS) Delhi, and are in nearby campuses. AIIMS is ranked as the no. 1 medical school in the country. It has been open to general public from November 2007, and has 180 trauma beds. To enable multi-disciplinary care, the centre's manpower and human resources are shared with the main AIIMS hospital. Trauma care is provided by rotating shifts from a pooled trauma workforce, while being a part of larger general speciality departments. The JPNATC sets the benchmark for trauma care in India. Trauma care nurses are unique to this centre and are empowered to perform triage and resuscitation. The JPNATC offers courses on Advanced Trauma Life Support (ATLS), Trauma nursing and use of ultrasonography in trauma. It also receives grants to promote research in trauma in the Indian context.

*Lokmanya Tilak Municipal General Hospital (LTM), Mumbai*
Established in 1964, LTM is a 1416-bed general hospital with over 60,000 yearly admissions, and is located at the termination of two major arterial roadways (the eastern and the western express highways).[93] This makes it the recipient hospital of vehicular crash victims in Mumbai. Further, its location close to the two of the three railway mass transit networks (the harbour line and the central line), directly brings in a large number of railway casualties, via the railway police. Another pool of assault and riot victims are received from the communally sensitive areas of Dharavi and Koliwada, close to the hospital. This referral pattern prompted LTM hospital to open the first dedicated trauma unit in the country in 1974. This unit has 14 intensive care trauma beds, with a stepdown unit which makes a total of 25 beds. There is a trauma operating theatre, adjoining the trauma unit. The CT scan machine is located in another building, about 250 metres away from the resuscitation area, with no dedicated access for the trauma victim.

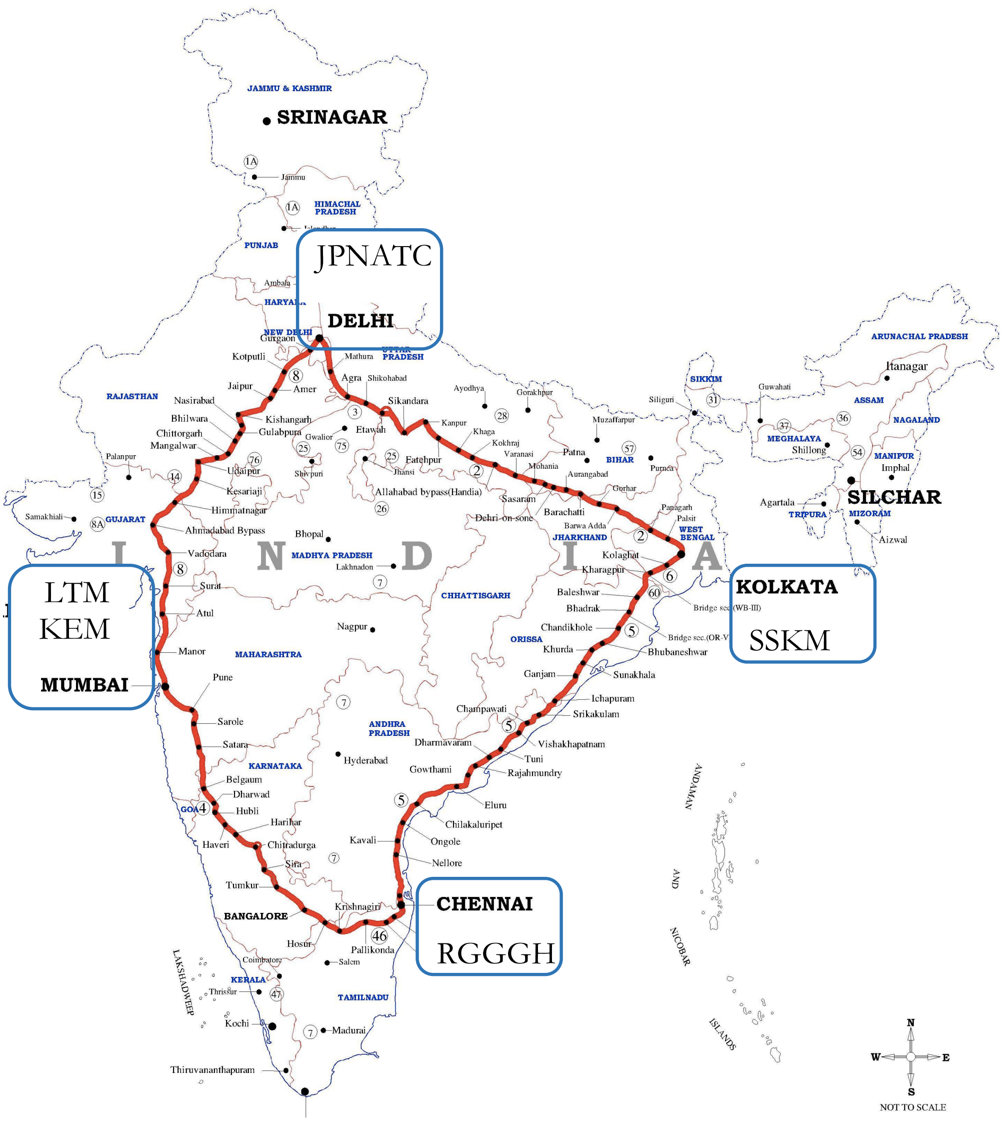
*King Edward Memorial (KEM) hospital, Mumbai*
KEM Hospital was founded in 1926, and the affiliated Seth Gordhandas Sunderdas Medical College (GSMC) is one of the premier medical universities in the country.[94] It has 1,615-beds and over 85,000 yearly admissions. It is also located in Mumbai, and receives trauma patient referrals that are lesser in severity and profile than LTM General hospital with a majority of falls, as the primary mechanism of injury. The Emergency services department has dedicated space and manpower, but there is no systematic triage of victims nor emergency physicians. It is manned by casualty officers (usually MBBS doctors) and interns. Speciality services of neurosurgery, plastic surgery, vascular surgery and critical care are available round-the-clock on a on-call basis. Emergency x-rays are always available and emergency ultrasonography and Computed Tomography (CT) scan services are available most of the time.

*Seth Sukhlal Karnani Memorial Hospital (SSKM), Kolkata*
Commonly known as PG hospital (The Presidency General Hospital) was opened to the non-European city-dwellers in 1770 and in year 1954 it was renamed as the Seth Sukhlal Karnani Memorial Hospital. Since 1957 SSKM has an attached teaching institute is the post-graduate institute of medical education and research (PGIMER).[95] SSKM has 1775 beds. It has a dedicated adjoining centre called the Bangur Institute of Neurosciences, and has a separate entrance to receive head injury patients. The main casualty department has one casualty officer,

with no dedicated space for resuscitation. The admitting wards and imaging facilities for CT scans and Magnetic Resonance Imaging (MRI) scans are spread across the campus.

*Rajiv Gandhi Government General Hospital (RGGGH), Chennai*
The hospital that would be the current Rajiv Gandhi Government General Hospital was established in 1664 under the British rule and in year 1842 allowed Indian patients. The affiliated Madras Medical College started in 1850.[96] The hospital has 1280 beds and the casualty department receives serious trauma patients via ambulances. The 108 prehospital network of government ambulances is operational in this city and picks up the patient at the injury site and directly transports them to RGGGH. The RGGGH emergency area has two adjoining wards, for general surgery admissions and for orthopaedic admissions. This hospital follows a 24-hour admission-for-observation policy for all patients admitted with injuries. The RGGGH has imaging facilities, operation theatre facilities and admitting wards in well-organized adjoining spaces. Data from RGGGH is included in study IV.

Figure 5: The research sites for the substudies in the largest cities of India




Source: National Highways Authority of India, Ministry of Road Transport and Highways (MoRTH), Government of India with the golden quadrilateral highways highlighted in red.

## 4.4 STUDY DESIGN AND SAMPLE SELECTION

To describe the trends in mortality Study I, we used a retrospective observational cohort design over three time periods (1998, 2002, 2011) at a single centre, the LTM Hospital in Mumbai. A prospective, observational multicentre cohort was the study design for studies II, III and IV. A systematic tool (Annex 1), based on the WHO trauma intake form (Figure 7) was developed and piloted for data collection for a multi-centre trauma registry. The data used in this thesis was collected from October 2013 to February 2015.

Study II and III had four participating Indian university hospitals: SSKM, Kolkata; LTM Mumbai; KEM, Mumbai and AIIMS, Delhi. Study IV included an additional site, RGH hospital, Chennai. Study IV was a sequential mixed-method design for these five Indian university hospitals. The formative phase of consensus about possible causes of death in in-hospital trauma patients, was by local and International expert groups. The evidence base for trauma deaths was weak in the Indian context and new knowledge had to be generated by Delpi methods. Delphi is the suitable approach in complex, multidisciplinary problems with considerable uncertainities and where causal models cannot be built or validated.[97] Also, Delphi face-to-face sessions[97] were used to standardize definitions of preventable deaths, as per the WHO criteria[98], as there was no existing standardized knowledge in this domain.[99,100] Panelists were trained in the peer-review and the verbal autopsy process by me.[101] This session included 3 trauma surgeons, 2 trauma researchers and a medical anthropologist. I followed this up with a practice session of mock cases from the WHO guidelines for trauma quality improvement.[45] Following this, a peer-review of each trauma death, yielded the proportion of preventable deaths. Problem identification included the description and definition of actions or events, which could have contributed or prevented the death. These were related to resuscitation, trauma-care protocols, airway, surgery and long stay complications. We identified opportunities for improvement for trauma care in this urban university hospital context.

## 4.5 MEASUREMENTS AND VARIABLES

The common variables across the three temporal datasets (1998, 2002 and 2011) used in Study I, were sex, age, mechanism of injury, year of cohort and anatomical injury severity. Early mortality (within 24-hours of admission) was the primary outcome. The datasets were collected prior to the start of my thesis work, and was for the purpose of studying trauma care outcomes at a single centre (LTM hospital). The data over 14 years was heterogenous, but had the common variables of interest for a time-trend analysis, namely age (defined as a categorical variable using internationally accepted cutoffs), systolic blood pressure (SBP), level of consciousness using the Glasgow Coma Scale (GCS) and injury description with a specific ICD-10 code. The anatomical injury severity score used in Study I was the ICISS (International classification of disease injury severity score).[61]

In studies II-IV, all adult patients (>15 years) presenting to the casualty department with a history of injury and who were admitted to inpatient care were included. The primary outcome was in-hospital trauma mortality within 30-days of admission. For each patient, the main variables of interest were SBP, GCS and age. The demographic variables included sex, transfer status, mode of transport and mechanism of injury. Clinical variables were oxgen saturation, respiratory rate, intubation status, haematological and biochemical parameters. Process of health care delivery measurements were injury to arrival time, arrival to investigation time and arrival to surgery time. The on-admission physiological variables were categorized using categories from the US National Trauma Data Bank (NTDB).[69]

## 4.6 DATA COLLECTION TEAMS

The 1998 and 2002 datasets were retrospective, which I had collected through review of paper-based case records. These case records were noted on the arrival of the trauma patient by the surgical resident on duty. I extracted the data about patient demographics, mechanism of injury, level of consciousness, injuries and mortality within 24 hours of admission (early mortality). The 1998 dataset was from 1st January to 31st December 1998 and had 2009 admitted patients. From 1st August, 2001 and 31st May 2001, I collected data on 1075 patients in the 2002 dataset for the purpose of studying prehospital care received before arrival at the trauma hospital.[91]

The length of follow up was 24 hours for all patients. Data for the 2011 dataset was prospectively collected by observation of trauma care and through case records, by a dedicated project data collector. This data on 1130 patients were collected from 15th October 2010 to 31st December 2011 and was supervised by a trauma surgeon. The data collection tool was the WHO intake form (Figure 7) and the data was analysed as a part of a multi-country WHO patient safety publication on piloting the Trauma care checklist.[102] Data collection was done in 8 hour shifts of direct observation of the staff delivering trauma care. These shifts covered all days of the week and all time periods of the day for a representative sample of all admitted trauma patients. For the 16 hours beyond the shifts of the data collector, patient data was collected from patient records. The WHO project defined the inclusion criteria as 'all limb and life threatening injuries', which is an admission criteria at the LTM hospital's trauma unit. The additional variables collected in this data set were detailed mechanism of injuries[103], such as pedestrian, 2-wheeler rider, 4-wheeler occupant, length of hospital stay, transfer status, operative and imaging investigation details.

To ensure data quality at each participating hospital in studies II-IV, data were collected in a similar fashion as the 2011 WHO study method, from 1st October 2013 to 31st February 2015. One data collector at each site, prospectively gathered on-admission data on a standardized intake form (Annex 1) for eight hours per day, by directly observing the staff delivering trauma care. This data collector was not employed by the hospital. All data collectors had a Master's degree in health sciences, and were continuously trained and supervised throughout the study period. They rotated daily through each 8-hour shifts (morning, evening and night followed by an off-day), including public holidays. After a month of pilot data collection, the formal recruitment was started. Data from the pilot phase was not used for the studies. The recruitment at each site is tabulated in Table 5.

If a parameter (e.g. oxygen saturation) was not documented or recorded, the data collector was allowed to ask the nurse or resident about it. For patients admitted outside of the 8-hour 'directly observed' shift, the data were retrieved from patient case records within the next few days. The data collected in unobserved periods were as consistent as the data collected in the directly observed period. Therefore, data collection from routine hospital case records was considered adequate. The data collector directly observed 25.3% of survivors and 24.4% of non-survivors, being provided trauma care.

Data collectors at each site, first entered all the data on a paper-based intake form. This form had the hospital inpatient number and also the study ID. There after the data were uploaded within 24 hours to a central server, after electronically entering the paper-based data onto a Microsoft Excel spreadsheet. The electronic data when uploaded, had only the study ID number and did not include any patient identifiers. I received only blinded data. The follow up data from 24 hours to the end point of the study (death, discharge or completion of a 30 day in-hospital stay) was updated after the patient reached one of these outcomes. On a weekly basis, my co-researchers and I conducted data review meetings over teleconference. These trauma team calls had participation of the investigators, data collectors, project managers and the trauma researchers. To ensure data consistency, a quality control check with a dataset collected independently and in duplicate was performed twice. Cross-checking of the paper records and the electronic database was done at the same time.

Table 5: Recruitment schedule of total cohort of 16,504 patients 2013-2015 at each site

| Hosp | Year | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Total | monthly |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **KEM** | 2013 | - | - | - | - | - | - | - | - | - | - | - | - | - | |
| | 2014 | - | 18 | 152 | 170 | 170 | 128 | 124 | 142 | 124 | 147 | 169 | 170 | 1514 | 137 |
| | 2015 | 180 | 167 | 181 | 5 | | | | | | | | | 533 | 133 |
| **LTM** | 2013 | - | - | - | - | - | - | - | 73 | 121 | 137 | 148 | 154 | 633 | 126 |
| | 2014 | 154 | 116 | 108 | 130 | 131 | 77 | 123 | 129 | 116 | 137 | 109 | 92 | 1422 | 118 |
| | 2015 | 119 | 96 | 125 | 90 | 86 | 30 | | | | | | | 546 | 91 |
| **JPNATC** | 2013 | - | - | - | - | - | - | - | - | - | 243 | 188 | 188 | 620 | 155 |
| | 2014 | 147 | 206 | 222 | 230 | 201 | 207 | 218 | 177 | 143 | 210 | 181 | 158 | 2300 | 191 |
| | 2015 | 149 | 193 | 80 | 145 | 200 | 206 | 217 | | | | | | 1190 | 170 |
| **SSKM** | 2013 | - | - | - | - | - | - | 10 | 321 | 410 | 361 | 298 | 297 | 1697 | 282 |
| | 2014 | 315 | 317 | 345 | 208 | 318 | 262 | 236 | 245 | 306 | 193 | 232 | 234 | 3211 | 267 |
| | 2015 | 241 | 142 | 176 | 223 | 218 | 260 | 155 | | | | | | 1415 | 202 |
| **RGGGH** | 2013 | - | - | - | - | - | - | - | - | - | - | - | - | - | |
| | 2014 | - | - | - | - | - | - | 8 | 23 | 33 | 26 | 88 | 102 | 280 | 47 |
| | 2015 | 175 | 155 | 150 | 167 | 200 | 194 | 102 | | | | | | 1143 | 163 |
| | | | | | | | | | | | | | | 16504 | |

## 4.7 DATA MANAGEMENT AND ANALYSIS

The three datasets in Study I, were merged using the common variables that were available. Duplicate entries of the same patient were removed. The outcome of interest was early hospital mortality, defined as death between admission and 24 hours. Odds ratios were calculated for the 2002 and 2011 cohorts (with the 1998 cohort as a reference), using a multivariate logistic regression analysis with early hospital mortality as the dependent variable. Age was defined as a categorical variable, with the conventionally used cut-offs of 15, 15–55 and 55 years.[69] The longitudinal trend of early mortality in major trauma was calculated, after imputing for missing data and adjusting for risk using the International classification of disease (ICD) based Injury severity score (ICISS). The international classification of disease injury severity score (ICISS) is based on the international classification of disease (ICD) codes. All injuries were given a ICD code, based on the ICD-10 structure. The single worst injury, which is the injury with the lowest Survival Risk Ratio (SRR) can be used effectively[104] and this was the method that we applied in Study I. Major trauma in Study I was defined as an ICISS score of <0.9.[105]

In Study II, the ISS was calculated using the abbreviated injury scale (AIS), for standardizing severity. The process-of-care measurements captured the performance of the local health service delivery system, as per the WHO recommendations for trauma improvement programmes. The rate of 30-day in-hospital trauma mortality was calculated and the association of demographic, physiological and process of care factors were assessed for early

(0–24 hours), delayed (1 day–7 days) and late (8–30 days) mortality. 11,209 trauma patients met inclusion criteria across all of the four hospitals during the study period. At the end of the study period, 1965 patients remained admitted in hospital who did not reach the endpoints of completion of 30-days in-hospital stay, death or discharge. These patients could not be counted as survivors and were censored from the analysis, leaving 9244 patients in the study.

In Study III, the anatomy-based Injury Severity Score (ISS) and New Injury Severity Scale (NISS) score, the physiology-focused Kampala Trauma Score (KTS) and the Revised Trauma Score (RTS) score were used, as well as the combined score TRauma Injury Severity Score (TRISS). These five international trauma scoring systems were validated with the study dataset, using the areas under the receiver operating characteristic curve (AUCROCC) for sensitivity and specificity of each scores' ability to predict inpatient mortality within 30 days. AUROCC was used to assess the performance of the various commonly used scoring systems, to predict a binary outcome, using the Delong et al method.[106] AUROCC is a measure of discrimination, which denotes how well the scoring systems can predict which patients have the outcome (dead) and without outcome (alive), based on the score. In other words, AUROCC is a means to measure the power of a test to separate two mutually exclusive subpopulations (survivors and dead) by plotting the true-positive fraction (sensitivity) against the false-positive fraction (1-specificity). The measurement range is from 0 to 1, where 1 represents perfect discrimination. A worthless model would be close to 0.5, which is no better than flipping a coin. The AUROCC can be interpreted as the proportion of times that a particular scoring system will correctly identify the patient with the highest risk of mortality, if repeatedly given a set of two cases from the dataset.

Model fit for the performance of individual scoring systems was accomplished by using the Akaike Information criterion (AIC). The log-likelihood of the model given the data reflects the overall fit of the model. The AIC penalizes for the addition of parameters, and thus selects a model that fits well but has a minimum number of parameters (i.e., simplicity and parsimony).[107] In itself, the value of the AIC for a given data set has no meaning. It becomes interesting when it is compared to the AIC of a series of models specified a priori, the model with the lowest AIC being the best model among all models specified for the data at hand.

In Study IV, all deaths within 30-days among hospitalized trauma patients were retrospectively abstracted (by me) using demography, mechanism of injury, transfer status, injury description by clinical, investigation and operative findings, injury severity score and time to death. No prehospital information was available as there is no formal prehospital care or transport. Patients who died after 30-days and patient records with insufficient information to allow death review, were excluded. The mechanism of injury was mechanical or thermal injury, and excluded poisoning and drownings.

For in-hospital mortality to be used for benchmarking, the death dataset was stratified[108] by the standardized Injury Severity Score (ISS) (by co-researchers DKV, JK, DB) into mild (1-8), moderate (9-15), severe (16-25), profound (26-75) ISS categories and by time to death within 24 hours, 7 days, 30 days (by me). Each death was evaluated for preventability [Preventable (P), Potentially preventable (PP), Non-preventable (NP) and Non-preventable but with care that could have been improved (NPI)].[45] Using an iterative anonymised Delphi process, the six panelists reached consensus about the contributors to deaths in trauma patients and also standardized definitions of optimal care and preventable deaths in the context of India. These were based on experience and prior biological knowledge about resuscitation, trauma-care protocols, airway, surgery or long stay complications. The insider panel included 4 trauma surgeons, a trauma researcher and a medical anthropologist (M:F=2:1). In another 'outsider' panel, out of nine invited, six international trauma experts (M:F=2:1) with experience of working in LMICs, completed an anonymous web-based Delphi session; to independently prioritize the contributors to death. In subsequent rounds, clarifications were sought and the each consensus group ranked the contributors on a scale of 10, independently and anonymously. Co-researchers DKV, VK, MUK and I reviewed each patient abstract for a probable cause of death and identified a broad area for improvement.

STATA (Release 12, StataCorp, Texas) was used for statistical analyses. A significance level of 5% and a confidence level of 95% were used. Data were summarized using median, inter-quartile range and range for numerical variables, as the continuous variables were non-normally distributed. Frequency tables were used for categorical variables. Chi-square test was used for bivariate analyses for categorical variables, and t-test or Wilcoxon rank sum test for numerical variables. Odds ratios were used in Study I after handling missing data using multiple imputation using chained equations by co-researcher MG.

Multiple imputation using chained equations was used to handle missing data to assuming that data was missing at random.[109] For each variable with missing data, we assessed the association between the probability of missing data and early hospital mortality using logistic regression. We found no significant associations, i.e. $p>.05$ in all analyses, and hence deemed multiple imputation as appropriate. We handled the missing data of our dataset in Study II and III by doing a complete case analysis (patients with complete data for calculating scores) and an all-case analysis. Similarly in Study III, we generated four AUROCC graphs of the all-case dataset and the complete case dataset and produced a very similar set of graphs, AUC values and log rank p values. Therefore only one set of four representative graphs were included in the published Study III, for clarity.

Kaplan-Meier survival curves were used in Study II to demonstrate the association of in-hospital mortality with physiological co-variates and interquartile ranges for the process of care indicators. Chi-square tests were used to determine the significance of the causes of preventable deaths in Study IV.

## 4.8 ETHICAL CONSIDERATIONS

The institutional ethics committees (IECs) of all participating hospitals granted waiver of individual informed consent. They agreed that consenting patients who may be semi-conscious and severely injured, was inappropriate in the acute trauma setting. We retained only patient study ID to maintain patient confidentiality. All identifiers that could be traced back to patients were removed by each participating site, before upload to the combined database. The variables collected were the routine trauma care parameters and no intervention was implemented. This did not in any way affect the care delivered to individual patients.

Hospital deindentification and confidentiality was of concern to the participating sites. Since process of care and alleged delays in delivering service were sensitive matters for the hospital authorities, disaggregated outcomes (mortality) at each hospital were not calculated as a part of this research. Also, the most contentious issues about delays in delivery of care were often, calculated retrospectively through times recorded on patient charts. The resources available to each of the participating hospitals was different and it was ethically incorrect to directly compare individual hospital outcomes. The focus of our research in the area of  process of trauma care delivery, was to identify the best practices at each hospital, rather than compare between them.

The datasets used in this thesis, spanned over 18 years. The early datasets (year 1998, 2002) were retrospectively collected from case records, before the advent of IECs. These datasets would have qualified for an ethics waiver, by today's standards. The LTM Hospital ethics committees was functioning at the time the 2011 dataset was being collected and was cleared by the IEC (reference IEC/22/10). For Study I, the 1998 and 2002 cohort datasets were cleared for the new analyses by the same IEC, as an amendment to IEC/22/10, letter number 342.

The dates and reference numbers of the ethics clearances demonstrate the practical delays in procuring ethics clearances, which varied by more than a year. This delayed the start of the project and data collection at the sites. Ethics clearances for Study II, III and IV were granted by IECs at each of the sites and the certificate numbers are LTM IEC/11/13 (dated 26th July 2013), Mumbai; KEM hospital IEC(I)/OUT/222/14, Mumbai (dated 4th March 2013); IPGME&R Research oversight committee Inst/IEC/279, Kolkata (dated 21st March 2013); Madras Medical College, EC Reg no ECR/270/Inst./TN/2013 (dated 5th August 2014), Chennai and AIIMS IEC/NP-279/2013 RP-01/2013 (dated 22nd August 2013), New Delhi.

The ethical challenges of international collaborative research were manifest. There was blatant opposition to the international authorship standards of academic research. Gift authorship had been the norm in India, with seniority being the criteria, rather than based on actual work and contribution. Repeated appeals for adherence to the international committee of medical journal editors (ICMJE) guidelines for authorship and Memorandums of understanding between the participating universities were contested, and eventually leading to withdrawal/dismissal of some of the participating sites, before the end of the study. Being high volume centres the sample size requirement was achieved before these events. Despite these unfortunate consequences, adherence to the culture of academic integrity has led to a change in the subsequent collaborative studies.

The ethics of directly observing healthcare providers at work and the consequent 'Hawthorne effect' remained a concern, especially in terms of delays in the processes of care. With our previous experience of piloting the WHO Trauma Care checklist project[102], we noted that the Hawthorne effect gets mitigated both among the observers and the observed over the first few weeks of the pilot phase.

## 4.9 PERSONAL FIELDWORK REFLECTIONS

The process of setting up the study in India had many challenges for original research, which included negotiating bureaucratic permissions, ethics clearances and presenting negative and inconvenient results to the collaborative partners. The research in the university hospitals were mainly, pharmaceutical trials. Being unexposed to academic and collaborative research arrangements, the expectation from partnership with a foreign university, like Karolinska Institutet, was that there would be some free equipment or donations received. The KI-India trauma project was initially categorized as a 'pharmaceutical study', and we paid the ethics committee fees commensurate with a pharmaceutical study.

Also, each site had many reasons/explanations, why processes could not be improved. They were convinced that if prehospital care improved, and patients came in early; outcomes would be better. In stark constrast, most providers were sure they knew the problems and they were already doing their best despite heavy workloads, poor funding and infrastructure. There was little more that they could do to improve the situation. Further, the potential principal investigators who were all heads of departments or senior Professors, believed that data collection would be easy and be done by the residents. It was pointed out that this model had failed over the last four decades in university hospitals receiving trauma patients. Also, the clinical residents were busy providing critical clinical service for long hours and were unlike to be systematic in their data collection, compromising on the quality of the data. We suggested that dedicated data collectors would be employed by KI's India partner (the Tata Institute of Social Sciences) so that there was no additional workload for trauma care providers. The data collectors would work independently alongside the trauma care team, while they were providing care.

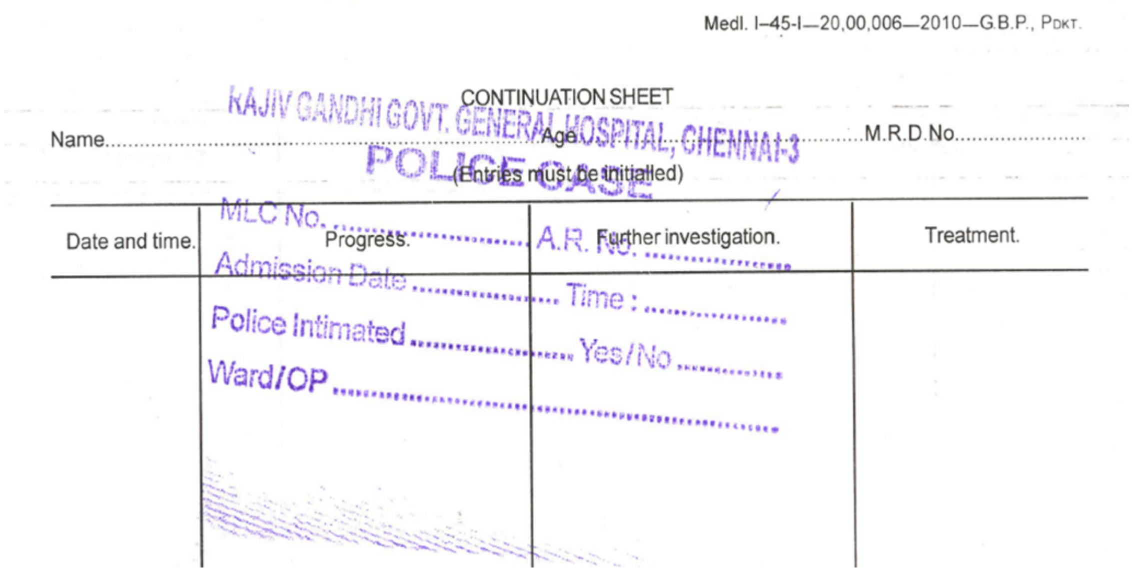
Multiple contact sessions with the hospital management on possible improvements in trauma care were critical to opening up the discussion for partnerships. We presented how hospitals are major contributors to mortality in India. Eventually, the 'Towards improved trauma care outcomes' (TITCO) collaborative research consortium was formed. Matching expectations was key to the collaboration, with an understanding that there would no free equipment, overseas trips nor monetary transactions, but only academic and technical exchange.

The first task was to achieve a systematic data collection tool. This meant changing the age-old rubber stamped blank paper form (Figure 6) being used for documentation in the casualty. We promoted the WHO trauma care intake form (Figure 7), as it was easy to convince our collaborating hospitals about this tool. The WHO brand still carries considerable weight in India. The TITCO study was close on the heels of a successful WHO multi-country study which piloted the use of a trauma care checklist.[102] The data collection point was chosen to be the area of receiving the patient within the casualty, to avoid intradepartmental surgical ward rivalry issues.

Candidates with a Master's degree in health sciences were selected, as data collectors at each site. This was the key step to the success of the research project and their meticulous supervision is described in the methodology section. An achievement of the project has been creating this cadre of independent trauma researchers and separating out the clinical and research teams, bringing in a culture of mutual respect. Hierarchical structures have melted slowly since, and clinicians now respect and understand the role of the 'non-physician researcher' in healthcare improvement. The round-the-clock shifts by the project data collectors and close weekly supervision by a core team from KI and India, ensured the start of the first systematically collected multi-institution trauma registry in India.

At the Swedish end of things, there was a reverse conundrum. Was this really research? Or was it just an audit? For a country which was so high up on the research ladder, my research questions were basic and primal in nature. The research gap is very wide between the two countries, and this could have been a disadvantage. But with a careful consideration of the contexts and individual strengths, we could turn these into advantages. My work fits in with the definition of research which is the systematic investigation and study of materials and sources, in order to establish facts and reach new conclusions. Before this thesis, we did not have the numbers nor know the rates of how many trauma patients died in urban hospitals, how long were the delays for patients receiving care, what were the causes of death and which of them were preventable. Nor did we know, if and how we could compare with the rest of the trauma world. If research means generating new knowledge, we have achieved it.

Figure 6: Hospital Rubber- stamped blank Casualty form used in RGGG Hospital, Chennai


Medl. I–45-I—20,00,006—2010—G.B.P., Pdkt.

CONTINUATION SHEET

RAJIV GANDHI GOVT. GENERAL HOSPITAL, CHENNAI-3

Name............ Age.......... M.R.D.No.....................

POLICE CASE

(Entries must be initialled)

| Date and time. | Progress. | Further investigation. | Treatment. |
|---|---|---|---|
| | MLC No. .............. A.R. No. .............. | | |
| | Admission Date .............. Time : .............. | | |
| | Police Intimated .............. Yes / No .............. | | |
| | Ward / OP .............................. | | |

Figure 7: WHO trauma care intake form

**Name:**__________________________Age:______Sex:
Time of Injury:__________ Time Arrived in ED_________
Date of injury:__________ Date Arrived in ED_________

**Mechansim of Injury:**

☐ Traffic injury (driver, passenger, cyclist, pedestrian, other)
☐ Gunshot Wound ☐ Stab wound
☐ Sexual assault ☐ Burn
☐ Struck/hit by person or object ☐ Unknown
☐ Fall (height_____) ☐Other________________

**Trauma related history:**
**Past Medical History:**
**Medications:**
**Initial vital signs:**

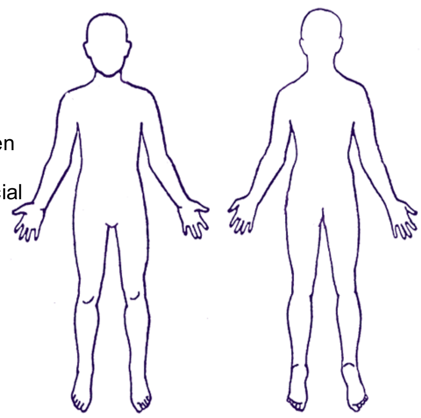
**Allergies:**
**Last Meal:**

| Time | | | |
|---|---|---|---|
| BP | | | |
| HR | | | |
| RR | | | |
| $O_2$Sat | | | |

**Initial GCS:**

| MOTOR | EYE | VERBAL |
|---|---|---|
| 6- Obeys Commands | 4- Spontaneous | 5- Oriented |
| 5- Localizes to Pain | 3- To Voice | 4- Confused |
| 4- Withdraws to Pain | 2- To Pain | 3- Inappropriate |
| 3- Abnormal Flexion | 1- None | 2- Incomprehensible |
| 2- Abnormal Extension | | 1- None |
| 1- None | | |

**Physical exam:**
**1** Fracture (open or closed)
**2** Sprain, strain or dislocation
**3** Cuts, bites or open wound
**4** Bruise or superficial injury
**5** Burns
**6** Concussion/ head injury
**7** Organ system injury
**8** Other
**9** Unknown



Pulse +/- Motor +/- Sensation +/-

Alcohol on breath**Y / N**

**Additional findings:**

**Chemistry:**
UA:
RBC:
Others:
**X-Rays:**
C-Spine-
Chest-
Pelvis-
Others-
**FAST/ DPL:**
**CT scans:**

**Provisional diagnoses:**
**Treatment started & plan for care:**
**Trauma Care Checklist completed by team**

**Name:** **Signature:**

# 5 RESULTS

## 5.1 ONE IN FIVE ADMITTED TRAUMA PATIENTS DIE IN URBAN INDIAN UNIVERSITY HOSPITALS (II)

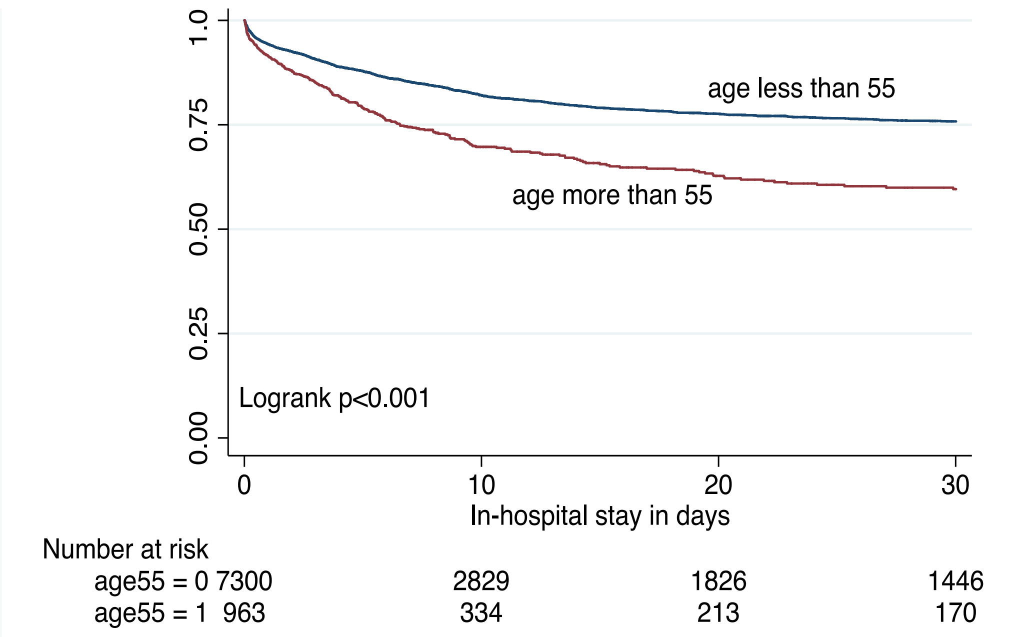
A fifth (21.4%) of all trauma patients died within 30 days of being admitted across all hospitals studied. The proportion of death within 24 hours (early mortality) in urban university hospitals was 7.3%, 9.2% died between 1 and 7 days (delayed mortality) and 4.9% from day 8 through day 30 (late mortality).

The variables associated with increasing in-hospital mortality when examined independently were age >55 years, presenting SBP< 90 and GCS< 12.

*Age*

The median age of the adult trauma patient admitted to the urban trauma units was 31.8 years, with an age range of >1 to 95 years. 78.9% of the trauma patients were male (Study I, II). The mean age was 30(± 18) years for survivors and 37 (± 18) years, for non-survivors (p<.001). Univariate logistic regression analyses showed that patients over 55 years of age had a significantly higher odds of early hospital mortality compared to patients younger than 15 years of age (OR= 1.81, CI = 1.07–3.05). Figure 8 graphically displays this improved survival for younger age groups, with in-hospital stay in days on the x-axis and the probability of survival on the y-axis. The decreasing numbers at risk through in-hospital stay is tabulated below the Kaplan-Meier survival graph.

Figure 8: Kaplan–Meier survival graph for age groups

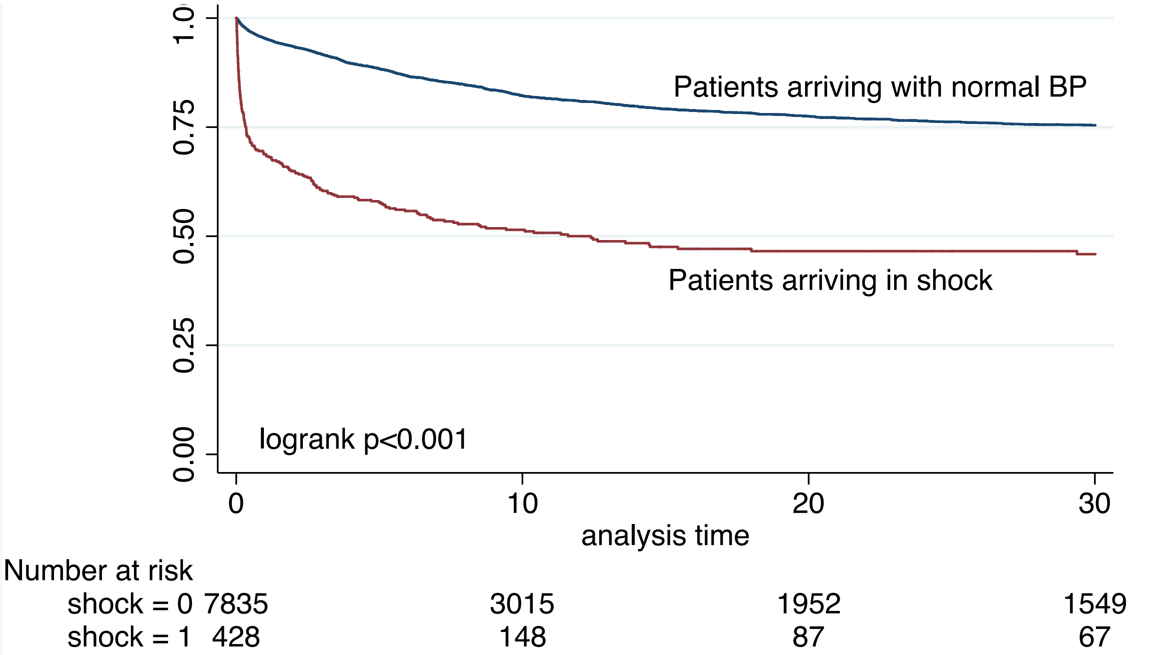



*Physiological vitals on admission*

Patients who died within 30 days, presented with poorer physiological status compared to those who were discharged alive. The physiological measures on arrival were differentially associated with early, delayed, and late mortality.
The on-admission systolic blood pressure and Glasgow Coma Score were near-normal in survivors, but was significantly lower in non-survivors and associated with both early and late mortality (p<.001). Higher SBP (Figure 9) and GCS scores (Figure 10) were associated with

longer survival among those who died prior to discharge, as was having a higher level of oxygen saturation.
For example, average (mean ± SD) systolic blood pressure (SBP) was lower (104 ± 36 mm of Hg) among those who died than among the survivors (116 ± 19 mm of Hg) (p<.001). A minor proportion (5.2%) of patients arrived in the trauma unit in shock (SBP<90 mm Hg) and had poor survival, as seen in Figure 9.

Figure 9: Kaplan–Meier survival graph of patients admitted in shock




Additionally, the median (IQR) GCS score was lower in those who died, with a GCS of 6 (4–11) than in those who survived with a GCS of 15 (12–15). This finding is easily visualized in Figure 10.

Figure 10: Kaplan–Meier survival graph as per on-admission Glasgow Coma Scale scores

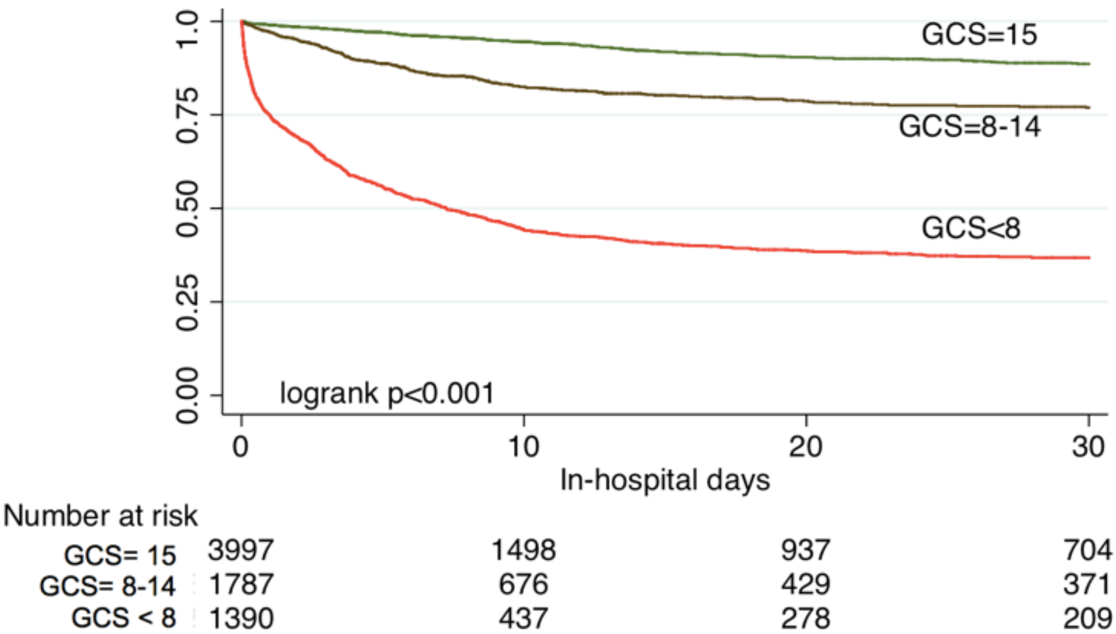
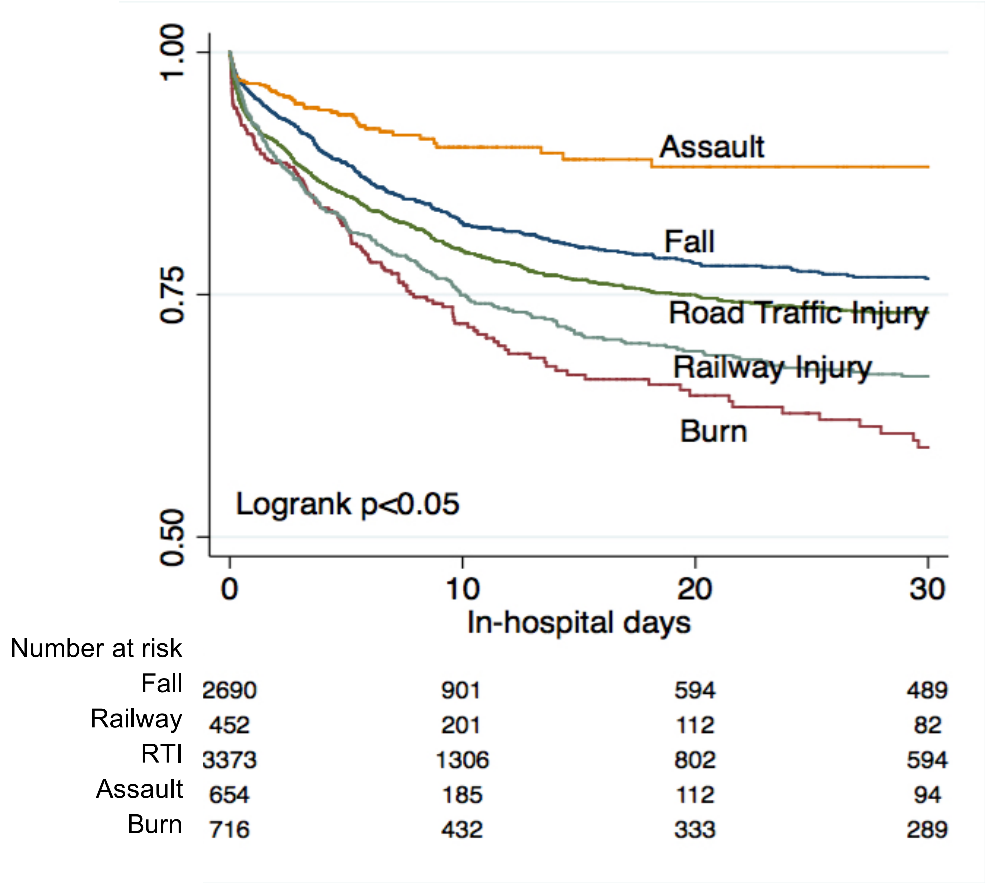


Figure 11: Kaplan–Meier survival graph as per mechanism of injury



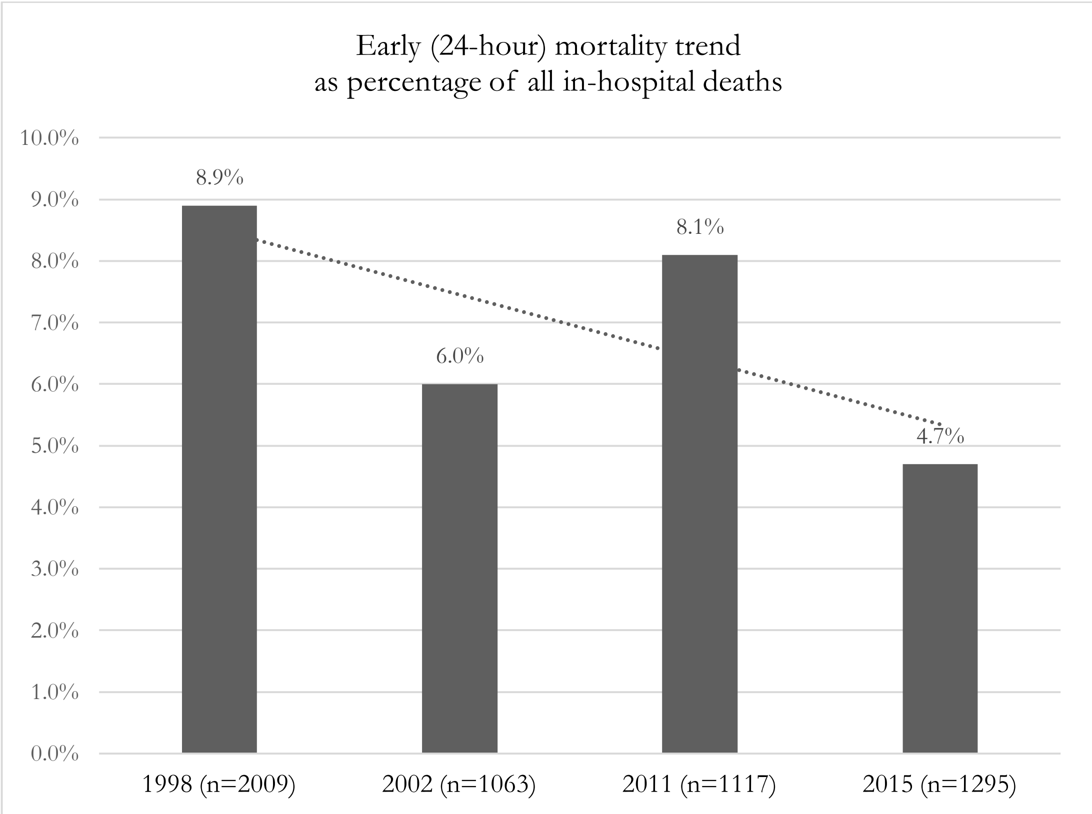

*Mechanism of injury*
The participating hospitals displayed a case-mix in keeping with the city's policies for referral from other smaller hospitals or the police department. The assault victims had the lowest case fatality rate (Figure 11). Burns patients or those who had been involved in railway related incidents demonstrated worse survival rates through their hospital stay, as compared with those injured by other mechanisms. Patients with railway injury (OR =3.21, CI = 2.26– 4.57) or a road traffic injury (OR = 1.78, CI = 1.24–2.55) had significantly higher odds of early hospital mortality compared to patients with falls. Burns and railway injuries also had a higher mean ISS score than assaults and falls.

The mechanism of injury and most common modes of transport, in both the survivor and non-survivor groups were comparable. Only a third of the patients (34.4%) came to the trauma unit directly from the injury site; and they came in regular taxis/auto-rickshaws (13.5%), private cars (12.4%) or police vans (9.3%). Among patients who had initially presented to other facilities (64.6%), ambulances were predominantly used for inter-facility transfer to the urban university hospitals.

## 5.2 DECLINING TREND IN EARLY IN-HOSPITAL TRAUMA MORTALITY (I,II)

Over a 18-year period from 1998-2015, there was a decline in the crude early hospital mortality rate across the longitudinal cohorts of adult trauma patients at a single institution, the LTM hospital in Mumbai. Figure 12 shows the year and size of each cohort on the x-axis and on the y-axis is the unadjusted proportion of patients who died within 24-hours, as a percentage of all in-hospital deaths. The overall early hospital mortality was 8.9% in 1998, 6% in 2002, 8.1% in 2011 (Study I) and 4.7% in 2015 (data from Study II).

Figure 12: Comparison of early hospital mortality across cohorts at a single institution




The median ICISS was 0.93, and 36.5% had major trauma (ICISS<0.9). The model was adjusted for sex, age, mechanism of injury and ICISS. After risk-adjustment for patient case-mix, improved survival was significant in the 2011 and 2001 cohorts, with the 1998 dataset as a reference. The early hospital mortality rate among major trauma patients was 13.4%, 11.3%, and 10.9% in 1998, 2002, and 2011 respectively, after risk adjustment.

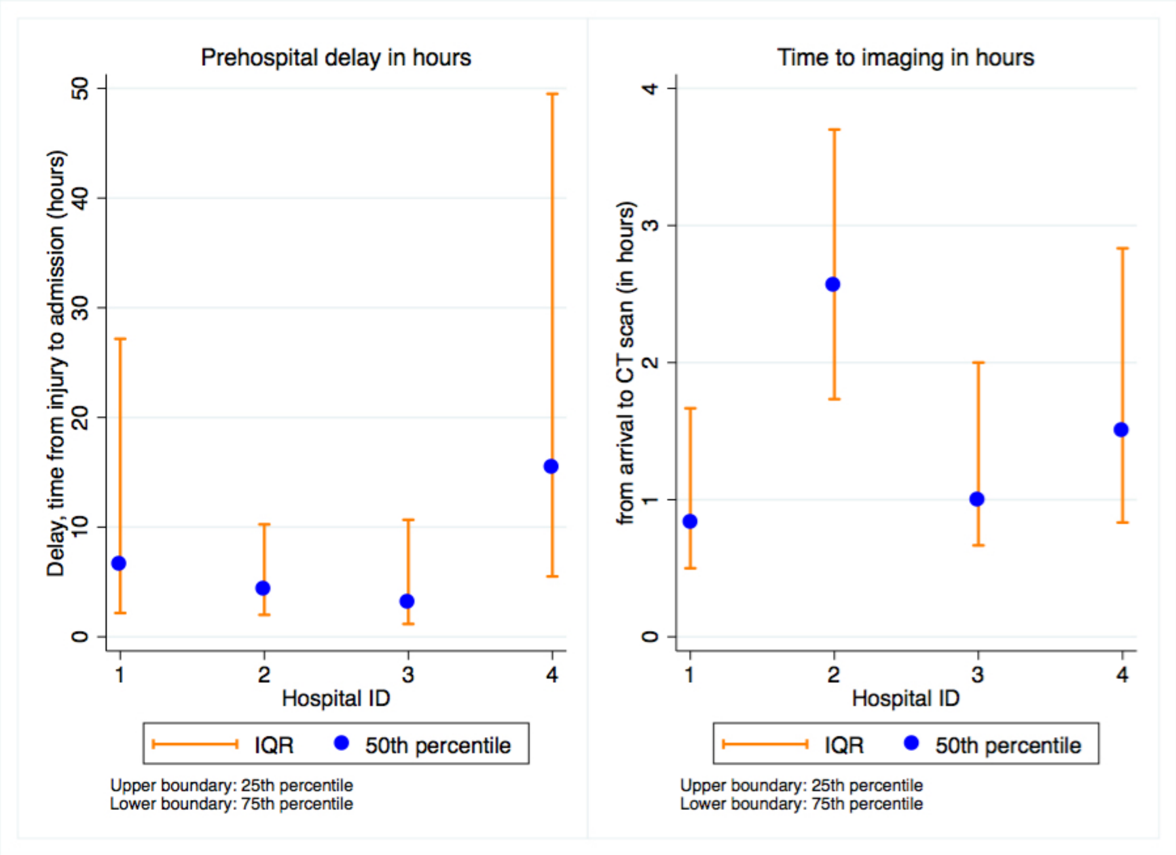
This decline was seen within age groups, sex, severity of injury and mechanisms of injury. The odds of early hospital mortality were significantly lower in 2011 (compared to 1998) in patients between 15 and 55 years of age (OR = 0.52, CI = 0.37–0.74), among males (OR = 0.57, CI = 0.41–0.78) and among patients with major trauma (OR =0.44, CI = 0.30–0.66). In patients with railway injury (OR = 0.39, CI =0.24–0.64) or road traffic injury (OR =0.60, CI = 0.36–1.00), the odds were significantly lower in 2011 as compared to 1998.

## 5.3 DELAYS IN CARE AND TRAUMA MORTALITY (II)

The process-of-care measurements captured the performance of the local health service delivery system in India, in the absence of a formal prehospital transport or trauma system. There were process-of-care delays from injury to reaching a hospital, being examined by a physician for vitals, investigated, or being operated and these were measured in Study II. Figure 13 shows the inter-hospital variation in prehospital delays and in-hospital delays for CT scan imaging.

The median prehospital delay was 6.4 hours (IQR 2-24). Prehospital delay (injury to arrival) and in-hospital delay (arrival to admission) did not significantly correlate with trauma mortality outcomes. Non-survivors had a shorter time from arrival to hospital admission than those who survived (1.3 vs. 2 hours; p=.8).

Figure 13: Process of care delays and Injury severity scores in trauma patients of 4 hospitals




Two-thirds of the admitted patients were transferred from other hospitals (range 48–82%), adding to delays in arrival. Patients who died were also more likely to have been endotracheally intubated at other facilities prior to transfer (8.5%) compared to the non-intubated transfers (1.5%, p<.001). There were no significant differences in patient profiles, delays and outcomes among the patients directly observed by the data collector and the non-observed group.

## 5.4 PHYSIOLOGICAL SCORES PREDICT MORTALITY AS WELL AS THE COMPLEX ANATOMICAL SCORES (III)

In the dataset of 7197 adult trauma patients, 4084 (56.7%) patients had all five scores available for a complete case analysis for validating the commonly used injury severity scores. Both physiologic scores (RTS, KTS) had better discrimination and goodness-of-fit than ISS or NISS as seen in Figure 14.

The ability of all injury scores to predict early 24-hour mortality, as demonstrated in Figure 15 was better than late 8-30 day mortality (Figure 17). The lower AIC score supports RTS (AIC=3221) over ISS (AIC=3929) as the most parsimonious model and as a better predictive regression model with the least number of variables.

There was no significant difference in performance of the severity scores between those trauma patients directly admitted to the trauma unit and the larger group of patients transferred from other facilities. The performance of the trauma scores did not improve in the subset of severely injured patients (ISS > 16).

Figure 14: AUROCC of trauma scores in predicting 30-day overall mortality

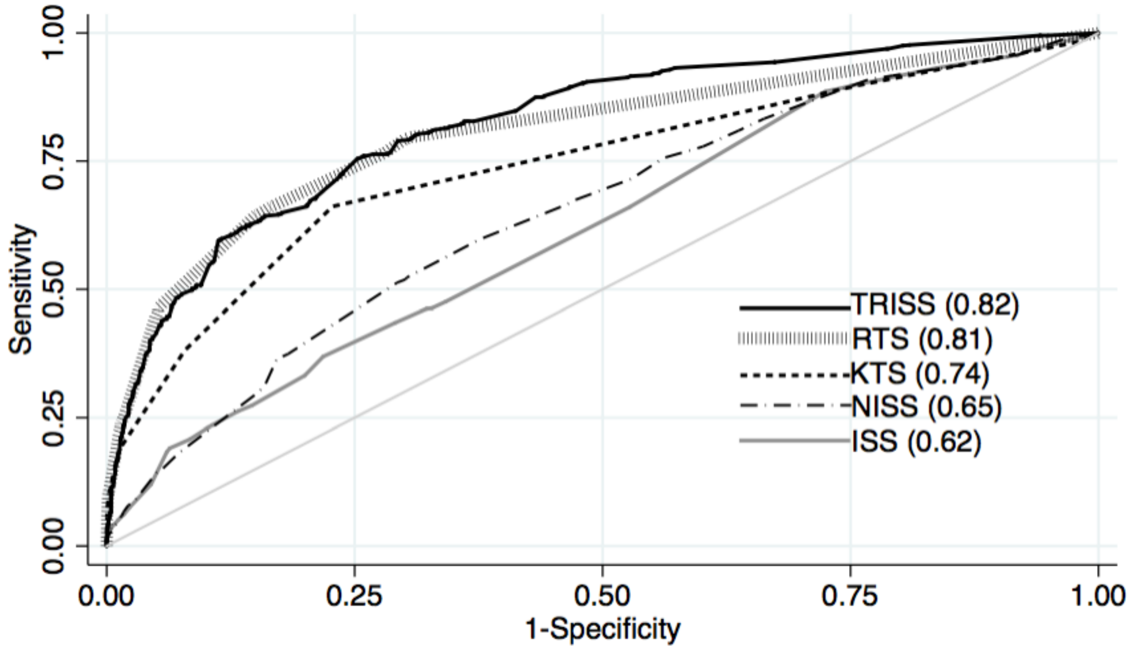



Figure 15: AUROCC of trauma scores in predicting 24-hour early mortality

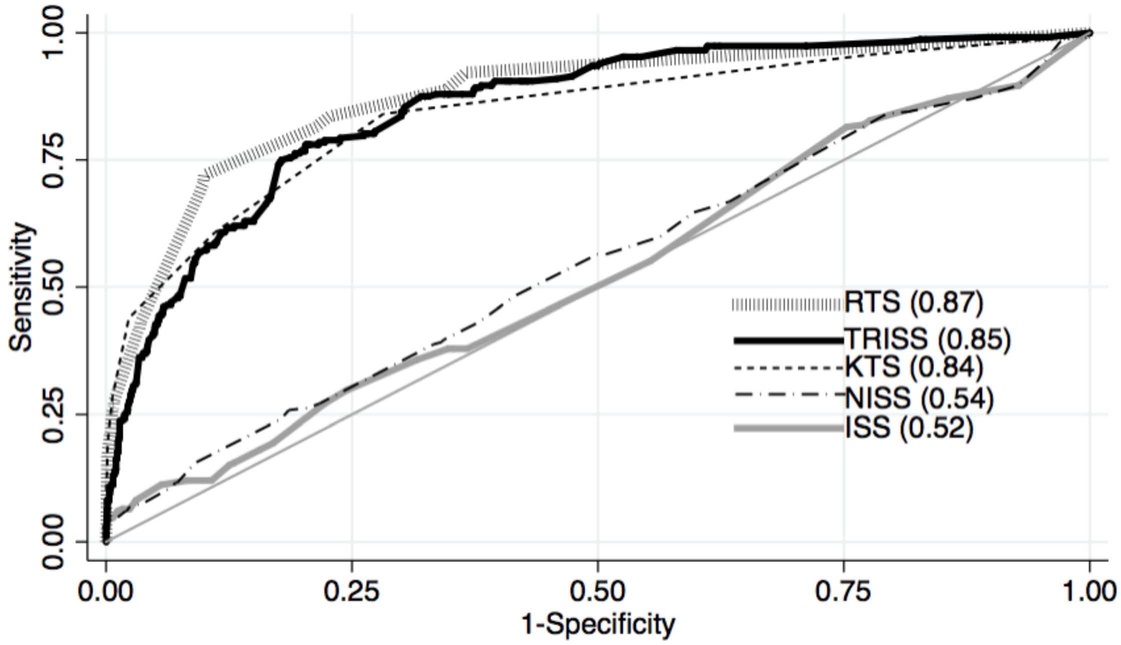


Figure 16: AUROCC of trauma scores in predicting 1-7 day delayed mortality

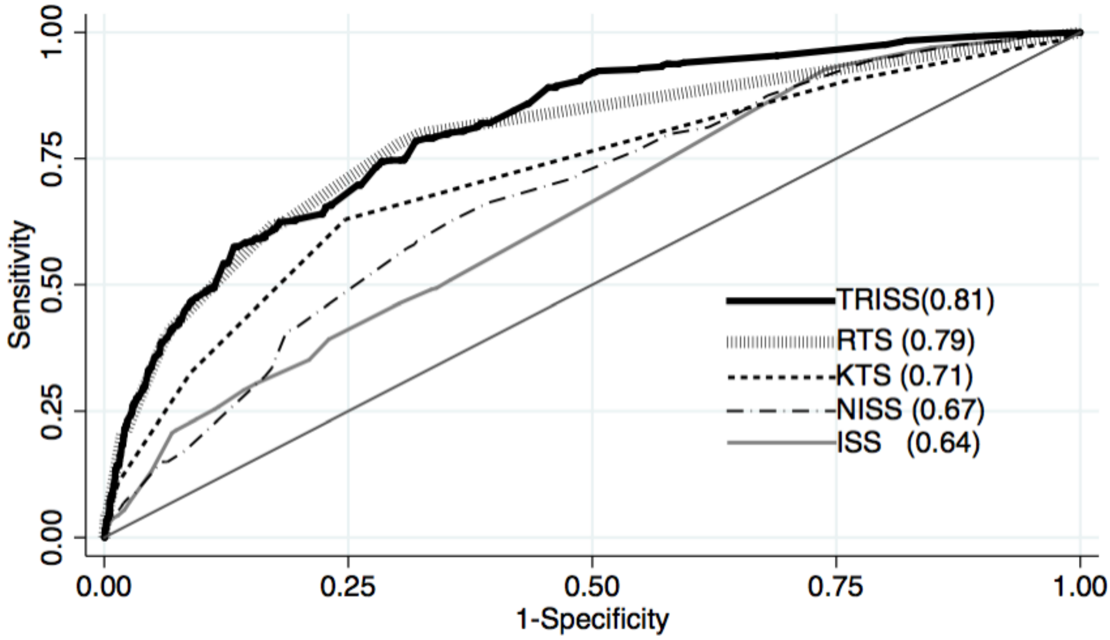
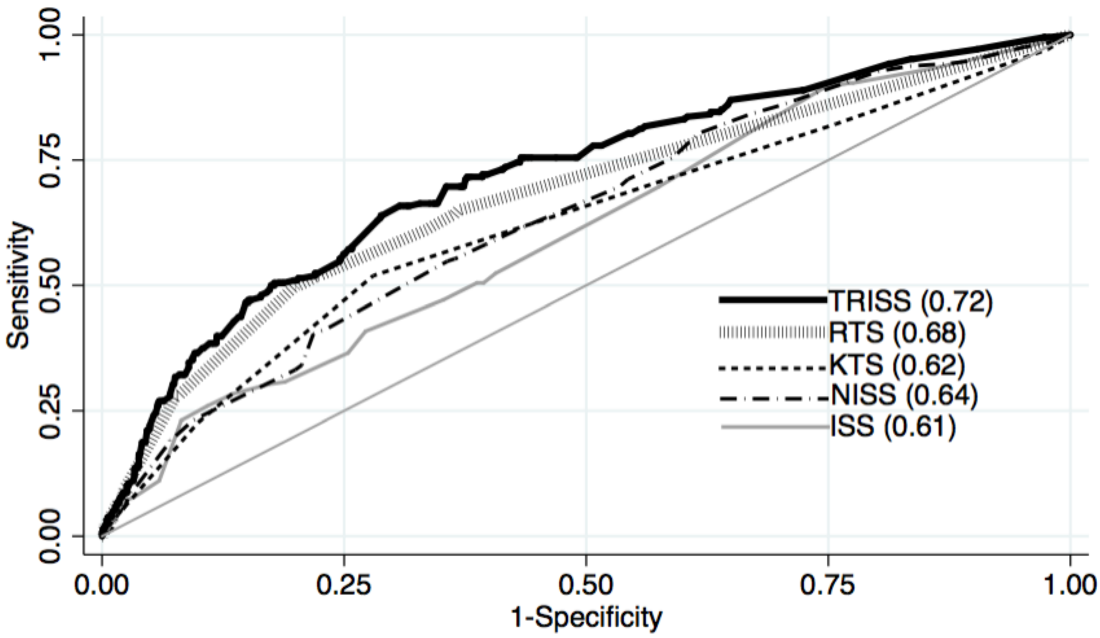



Figure 17: AUROCC of trauma scores in predicting 8-day to 30-day late mortality



## 5.5 MAJORITY OF IN-HOSPITAL TRAUMA DEATHS ARE PREVENTABLE (IV)

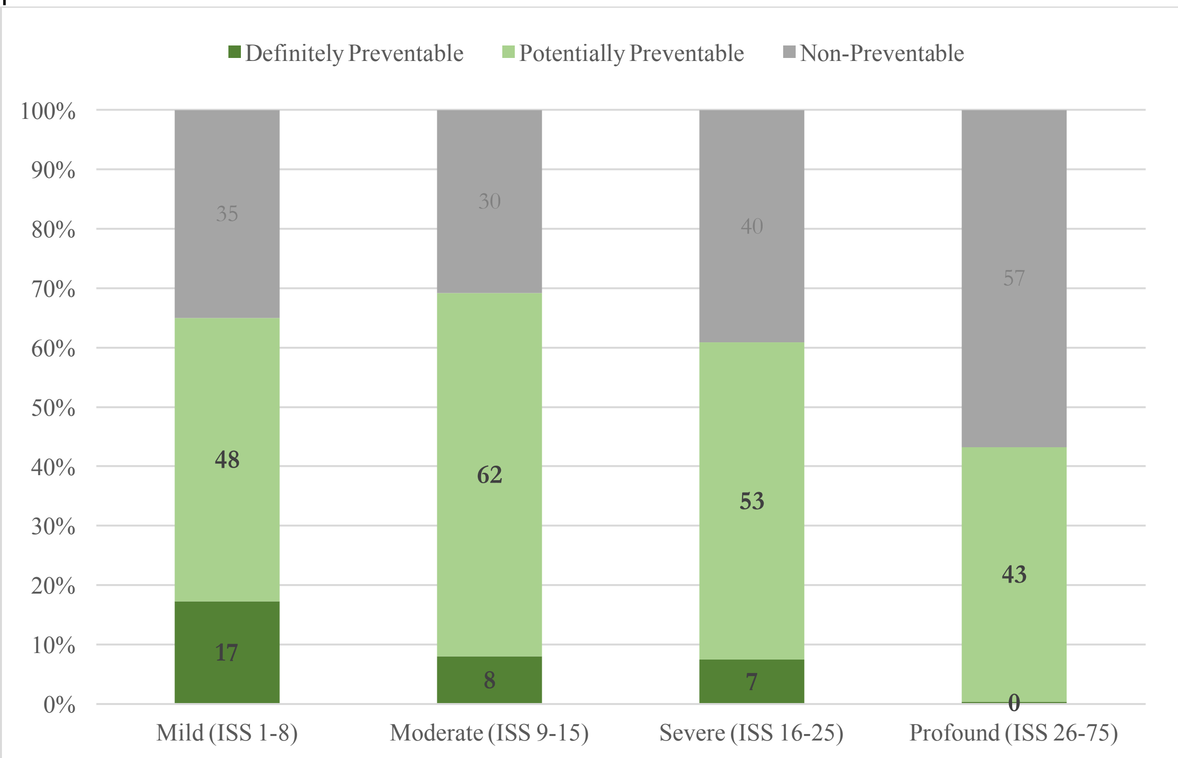
The overall proportion of preventable deaths among all deaths was 58%. In Study IV, of 11,671 trauma admissions, 2523 deaths (21.6%) occurred over 18 months in the 5 urban university hospitals in India. 466 (18.4%) patients were either misclassified, or had inadequate documentation or excluded, simply because the cause could not be determined. Quantitative categorization of 2057 deaths, yielded 233 in the mild ISS (<9) group, 922 in the moderate group (9-15), 571 in the severe group (16-25), and 331 in the profound ISS (>25) category group.

As shown Figure 18, there were more preventable deaths among the mild and moderately injured patients (ISS<16) when compared with more severely injured patients (ISS≥16). On peer-review of deaths, we found that severe traumatic brain injury and burns (>80% total body surface area) accounted for the majority of non-preventable deaths. Issues with airway management (14.3%) and resuscitation after hemorrhage (16.3%) were the most common contributors to preventable deaths.

The common contributing factors to trauma deaths as decided by the national and international panels by consensus were inadequate resuscitation after haemorrhage (16%), issues with airway management(14.3%) and long-stay complications. The early causes of death were haemorrhage, inadequate fluid resuscitation, and inadequate airway management. The late contributors to death were systemic factors, ventilator management, disseminated intravascular coagulation (DIC) and sepsis.

System-related issues included lack of protocols, lack of adherence to protocols and prehospital delays in arrival for care. Inappropriate surgical decisions, inappropriate surgeries, and prolonged surgeries were contributory to 3.5% of deaths.

Figure 18: Two-thirds of deaths are preventable among mild and moderately injured patients



# 6 DISCUSSION

As a result of this multi-hospital collaborative work, I have been able to establish some new knowledge in the field of urban trauma care in this thesis.

## 6.1 ESTABLISHING A 30-DAY MORTALITY RATE IN URBAN INDIAN UNIVERSITY HOSPITALS

One out of five trauma patients admitted to the participating hospitals died within 30 days (Study II), which is twice that found in similar HIC registry patients.[110,111] This is the identified gap between India trauma outcomes and HIC trauma outcomes. Previous studies have demonstrated six times higher mortality rates at other LMICs.[11,112–116] WHO states that there are two million lives to be saved, if we are able to close this gap in LMIC outcomes, and raise the survival rate to that of the HICs.[117]

The physiological variables analysed were selected from other international standard trauma registries, such as the Major Trauma Outcome study (MTOS) of the USA by Champion and co-workers.[111] We have validated this correlation using a large systematic dataset in Study II. My AUROCC graphs and findings suggest that physiologic scoring is more clinically useful for predicting mortality in low-resource settings in Study III.

SBP on admission (Figure 9) was significantly lower among non-survivors compared to survivors and this is similar in many HIC and LMIC studies.[110,111,118] Also, the small percentage (5.2 %) of patients arriving in shock suggests that many shocked patients in urban India may have died before reaching the hospital, as there was no prehospital fluid resuscitation available or from other causes. Our findings were supported by multiple studies, that lower on-admission GCS was found to be a predictor of in-hospital trauma mortality (Figure 10) and that the concentration of oxygen in patients' blood correlated well with survival.[119–123] These findings were not new, nor unusual.

## 6.2 TRENDS IN EARLY TRAUMA MORTALITY AND THE IMPORTANCE OF RISK-ADJUSTMENT

Study I and II showed that in terms of crude 24-hour mortality, there was a decline in mortality over 18 years at the busiest trauma centre, in the most densely populated Indian city of Mumbai. After risk-adjustment for patient case-mix in Study I, an improvement in survival was more distinct. This revealed the importance of risk-adjustment in trauma outcome studies. The observed reduction in early hospital mortality was most pronounced in patients with major trauma, while no significant changes could be detected in patients with minor trauma. This is similar to the temporal improvement seen in maternal and child health outcomes in Mumbai city, without specific interventions.[124]

One explanation for improved survival could be the gradual improvement in the weight and nutritional status of the average Indian over these years. The percentage of underweight men in the age group of 15-49 years with a Body Mass Index (BMI) of less than 18.5 kg/$m^2$ decreased from 34.2% in 2005-2006 to 15.3% in urban cities.[124] Further, the differences in outcomes and prevalence vary for each mechanism of injury. Case mix in cohorts and datasets is therefore an important consideration. Burns and railway injuries have higher mortality, as seen in Study I and II, but also have a higher ISS. In addition, better imaging modalities, monitoring and medicines may have translated into better outcomes in terms of early in-hospital mortality rates, over the years, but the association is not apparent.

It was important to establish this baseline mortality trend during at a time when there is no organized prehospital system to transfer the patient from the injury site and transport to the referral trauma centre. The exisiting ambulances are transport vehicles without any resuscitation equipment, and almost exclusively for inter-hospital transfers.[110] Therefore, the reduced odds of early hospital mortality cannot be attributed to improvements in prehospital care, but rather, if at all, to improved hospital trauma care.

However, the prehospital space in India is rapidly changing. A centralized ambulance service is being introduced in many states and future research will establish if this initiative improves survival from this baseline. A functioning prehospital system is generally considered a vital component of a modern trauma system and improvements in prehospital triage and care may influence overall mortality rates. A recent systematic review found that the implementation of prehospital systems in LMIC has led to reduced overall mortality rates.[125]

The implementation of trauma systems has been widely claimed as a major reason for reduced trauma mortality over time in HICs.[126–128] Studies from LMICs[112,129] suggest that mortality trends are unlikely to change without intervention.[38,47,48,130] In the state of Victoria, Australia, after documenting no improvement in the mortality rate between 1992-1998, a ministerial task force on trauma and emergency services was set up to introduce a new trauma system. Over a period of 10 years, mortality was halved after reorganizing the Victorian trauma system.[131] The trauma system concept originates from the designation of dedicated trauma centres in the US some 40 years ago.[39] Today such systems ideally include streamlined preventive, prehospital, hospital, and rehabilitative measures.[84]

## 6.3 PROCESS OF CARE INDICATORS AND DELAYS IN TRAUMA CARE

Study II documents the time delays in the process of caregiving to the trauma patient in Indian hospitals and the variations within them. There were delays in examining and recording the first set of vitals on arrival, which forms the basis of trauma triage. The delays from arrival of the patients to investigation and intervention varied between the participating trauma units Figure 13. Some of the delays could be attributed, in part, to the lack of formal prehospital care, prehospital notification, or prehospital transport.[91]

The median time of prehospital delay was 6.4 hours. Suprisingly, these existing delays in prehospital transit and a lack of prehospital trauma care did not correlate with 30-day outcomes. This warrants further research, as the premise of prehospital care and ambulances rests on shortening prehospital delay to the 'golden hour'.

Recording on-admission vitals are well within the purview of the nursing staff, and empowering the nurses in these trauma units[132] is likely to improve the triage process. In HIC trauma units, like in Victoria, Australia, similar problems with initial reception and management at the Emergency Room were the problem areas, before the implementation of a trauma system.[133] The current patient flow at one of the urban university hospitals is represented graphically in Annex 2.

Further research into these process-of-care indicators is required to determine whether these delays could be attributed to resource allocation or if the challenges are more administrative and managerial[84]. Also, if their association with trauma mortality is not clearly known. These time indicators will remain proxy indicators of health system performance, as described in the conceptual model (Figure 4). Since some trauma units did better than the others, the best practices from the well-performing hospitals in this study will be reviewed and, where appropriate, suggested as interventions in other Indian trauma units. The suggested interventions are triage using vital signs, surgical protocols for airway management, haemorrhage control and resuscitation and empowering the nurses to focus on the mild and moderately injured group (ISS<16).[132]

Overall improvements in the trauma system in India will need first require the adoption of appropriate actions as process guidelines, as demonstrated effectively by a modest Thai hospital in Khon Kaen[112] with trauma audit filters and in Karachi's Aga Khan University hospital.[83] The steps for systematic improvement in the Indian trauma care can begin by shifting the focus away from the individual providers and their errors. to a system-wide perspective.[98]

## 6.4 VALIDATION OF INTERNATIONAL SCORING SYSTEMS USING THE INDIAN URBAN DATASET

Study III demonstrated that the performance of the Kampala Trauma Score (KTS) from Uganda is comparable and may even outperform large database generated-scores, like TRISS, in LMIC study settings, like Cameroon[134] or even in the HICs, such as the USA.[65] While KTS is easy and inexpensive to calculate on arrival of the trauma patient, TRISS is a retrospective score, and requires much expertise and expense. TRISS has been the benchmark for trauma scoring and research for more than 20 years.[135,84,136] Therefore KTS can be considered more appropriate for LMICs as it a parsimonious scoring system, can be calculated at the bedside and does not require much more expertise or resources.[137–139] It may be suitable for use in the Indian urban clinical setting. TRISS will remain important for the trauma outcomes researcher for comparing between trauma centres within countries and between countries.[68,140]

The on-admission vital sign physiological scoring systems predicted early (0-24 hours) and delayed mortality (1-7 days), more accurately than late mortality (8-30 days). Though the mechanism of thermal injury is different, the outcome of severely burned patients were better predicted than for road traffic injuries, by the various scoring systems in the Indian dataset. Cassidy et al[141] found that RTI had a better mortality concordance in patients with ISS>15, as compared to burns. They suggested that adding age and burns body surface area would improve the ISS model for burn patients. The insignificant difference in the injury severity scores of the patients directly admitted to the university hospitals, when compared to the larger group of patients referred from other facilities, may be attributed to the lack of formal prehospital care, suggesting that the anatomic and physiologic status of both groups were similar and therefore the scores.[141,142]

ISS has a disadvantage, in that it is a retrospective calculation, since the exact anatomic injuries are not known at admission and therefore cannot be used to predict probable outcome or the risk of adverse outcome on arrival to the hospital.[143] Also, ISS also requires more resources for data collection in a standardized manner, training of expert and accredited coders in scoring and lastly, detailed investigations (preferably CT scans), intra-operative case notes and autopsy reports. It is important to note that these are not commonly available in the LMIC setting, because patients often do not get CT scans due to lack of affordability and resource limitations. This in turn, limits the use of ISS, which can predict mortality only with complete information. We found that NISS did not achieve any better discrimination and performed only marginally better than ISS. Though the newer score, the ICISS (ICD based injury severity score), claims to have better discrimination and statistical properties[72], but this did not prove to be a better performer than the first generation ones in my study. Additionally, it had no real use in the clinical setting.

The validation study (Study III) indicates that outcome prediction can never be very certain and all scores fail to predict complications which cause late 30-day mortality. Since TRISS was developed primarily on US data, it may lack validity outside the North American context.[144] Rutledge and colleagues[145] compared the ability of ISS and TRISS to predict survival and found an AUROCC of 0.67 for ISS and and AUROCC of 0.88 for TRISS. Our findings were similar with an AUROCC of 0.62 for ISS and and an AUROCC of 0.82 for TRISS. The improved predictive ability in the US dataset may be explained by the detailed injury reports that are recorded with extensive imaging, investigation and autopsy reports, which were unavailable in the India dataset. Japanese and Thai researchers showed that a modified TRISS, with context-adapted coefficients, resulted in more accurate predictions when used on their data.[146,147]

Similarly, calculating updated coefficients for the Indian trauma patient would be an area for further research. If researchers continue to retrospectively calculate KTS based on trauma registry data, it will be important to formalize a methodology for calculating each patient's number of serious injuries and to establish a conversion from GCS to AVPU score for neurological status.[65] An easier scoring system like the KTS will remain the practitioner's tool, to triage salvageable trauma patients, and to notify healthcare workers to trigger action-interventions.

## 6.5 PREVENTABLE CAUSES OF EARLY, LATE AND DELAYED DEATHS IN THE INDIAN TRAUMA PATIENT

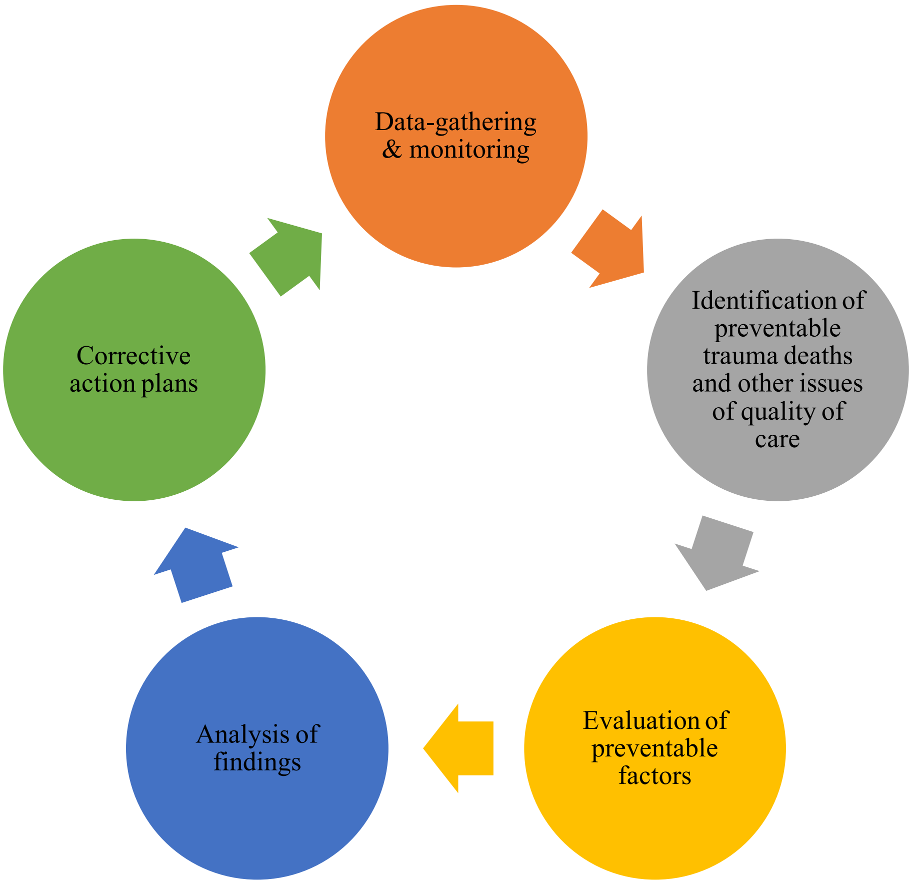
The preventable death rate was found to be 58% (Study IV). Estimating this rate fills a gap in knowledge because previously this measure was not known. The preventable trauma death rate is similar to other LMICs [148,99] but much higher than HICs.[149,150] The peer-review of the deaths determined that there was a large proportion of dead patients who had been mildly or moderately injured (ISS <16). The explanation could be that patients with mild injuries, may have had undiscovered fatal injuries which were missed as they were not investigated completely, before they died.

Inadequate fluid resuscitation and haemorrhage control were the leading causes of death (Study IV) in patients whose death was definitely preventable and this is similar in other studies.[151,152] Our finding of inadequate fluid resuscitation was a common problem found in other similar LMIC studies.[148] There are reports of lack of adherence to protocols leading to poor outcomes even in HICs[153], but the frequency is higher in LMICs.[148] Developing context-specific standard treatment protocols based on the best practices for hemostatic resuscitation[154] and damage control resuscitation models[155,152] seems like the way forward. The ATLS course or similar training initiatives are likely to improve the understanding of surgical physiology of the injured and the body's response to trauma. These initiatives will cover low-cost protocol-based interventions that include the placement of multiple large-bore intravenous (IV) access, nasogastric tubes, bladder catheterization for urine output monitoring, use of hypertonic solution (7.5 % saline) in the resuscitation of hypotensive patients[152] and early use of analgesics.[156]

In patients who underwent surgical interventions, we found that the intraoperative issues were less about skill and more about judgement. The outcomes may be independent of surgical volume at each hospital.[157] Though trauma patient volume is not described to influence mortality, this has not been tested in the LMIC setting.[158] These surgical judgement concerns resulted in delayed, prolonged and inappropriate surgeries, just as in HICs.[159] Interventions such as the presence of an attending surgeon[160,161], a trauma team leader during resuscitation[162], initiating academic trauma management programs[163] and grand rounds[83] via teleconference[164] have been shown to effective in reducing the rate of preventable deaths.

The problem areas identified in Study IV were resuscitation, lack of trauma-care protocols, airway, surgery and long stay complications. While the early causes of death were apparent such as haemorrhage and inadequate airway; the late contributors of death were probably systemic factors, ventilator management, disseminated intravascular coagulation and sepsis which were less distinguishable and largely unknown. Other factors mentioned in cause of trauma death studies include missed injuries, nosocomial pneumonia, surgical site infection, renal failure[165], pulmonary embolism, deep vein thrombosis, alcohol-use, acute respiratory distress syndrome, gastrointestinal Ulcers, pericardial tamponade, hyperkalemia, unintended extubation, intravascular catheter related complications, overdose, air embolism, coagulopathy[154] and mismatched transfusion. However, we could not capture these complications in our study patients. These factors would require more systematic research, before their contribution to trauma deaths can be determined in the Indian context.

Figure 19: The WHO pathway for Trauma Quality Improvement for closing the loop with corrective action plans[47]




## 6.6 OPPORTUNITIES FOR IMPROVEMENT IN TRAUMA HEALTH SYSTEMS

A national trauma registry (Study II) and the best practices of triage using vital signs, airway management, haemorrhage control and resuscitation in the mild and moderately injured group (Study IV) are useful to set goals for improved trauma survival. Improved survival is one of the SDG targets for 2030. Standardized data collection and treatment care using international protocols are proven measures in HICs, which will move India towards improved trauma care outcomes. Quantifying the preventable deaths presents an opportunity for improvement based on problem identification within the context of Indian urban university hospitals. Though the lack of resources dominates the narrative in LMICs about the challenges in trauma care delivery, several studies suggest that low-cost interventions, protocols and systems for supplies may be more beneficial than the mere addition of high-cost and mismatched resources.[148,166] As displayed in Figure 19, the first steps of the WHO pathway[47] have been taken with this research in terms of identification, evaluation and analysis have been completed by Studies II-IV.

The next step would be to close the WHO loop, with corrective actions. Systems-related issues such as suboptimal multidisciplinary collaboration and lack of a trauma leader; require incident investigations[167] and a moderated multidisciplinary mortality and morbidity meetings (M & M) for resolution. The WHO-recommended 'preventable death panel meetings' can also can improve system related issues. These meetings must be viewed as opportunities and should adopt the Avedis Donabedian approach of de-stigmatizing the individual as a target to "blame" for unfavourable outcomes.[168] This requires a wider mix of participants on these committees, like patient representatives and administration, who will address aspects of care beyond standard surgical and clinical care. Further research in identification, evaluation and analysis of root causes would be based on the taxonomy of five interacting root nodes: impact, type, domain, cause and prevention.[169] Other corrective action plans for improving trauma care outcomes by the American College of Surgeons/Committee on Trauma (ACS/COT) includes leadership, system development, legislation, finances, injury prevention, human resources[170], pre-hospital care, definitive care facilities, information systems, evaluation, disaster preparedness research[171] and maintenance of a trauma registry.[172]

Non-clinical processes of health-care delivery were identified in this study as an important contributor to trauma mortality. Frequent breakdowns of high-end technologies, like CT scanners and ventilators, or unavailable personnel were system related reasons that trauma patients did not receive adequate care.[41] These issues were not in direct control of the clinical team, but were major contributors to failures of treatment and care, though they did not correlate with mortality outcomes. The Essential trauma project[47] lists 260 items of human (training, staffing) and physical (equipment, supplies) which serves as a guide to priority resource allocation. Better engineering to improve durability are pulse oximetry, ventilators, and x-ray machines are a priority.[41] There is a potential role of local manufacturing in decreasing cost and increasing availability of key items.[22] Locally manufactured equipment such as pulse oximetry, X-ray equipment, and image intensifiers were available in India more than in other LMICs like Ghana and Mexico.[41] The National Health Policy 2017 promotes 'make in India' initiatives for technology and drugs, and is a step in the right direction.[22] With these progressive steps, India can close the loop on preventable urban trauma deaths through a systematic and standardized reporting system of all preventable errors.

# 7 METHODOLOGICAL CONSIDERATIONS

Pioneering work done has been done in this thesis for establishing a systematic trauma registry in India, that meets international standards. A previous WHO multi-country study piloting the Trauma care checklist and willing collaborators encouraged us to establish the multi-institutional academic Towards improved trauma care outcomes (TITCO) consortium in the busiest high-volume trauma centres in the largest cities of this very large country. However, since the research sites have been tertiary referral urban hospitals, my findings will not be externally valid for smaller rural hospitals or urban non-academic centres.

Population based studies are very few in India[173,174] and even fewer from rural India.[175,176] But the scant rural articles do caution interpretation about the external validity of my thesis.

The million deaths study uses an advanced form of verbal autopsy by non-medical evaluators in nationally-representative household clusters to determine the cause of injury death.[173] They found the national mortality rate for unintentional injury to be 58 per 100,000 (males 71, females 43) with higher rates in rural (60) than in urban areas (50). The highest rates were at ages 70 years or higher (410/100,000) with falls accounting for 63% of these deaths. Both of these, older age groups and falls, are under represented in my thesis, as it is acknowledged that these deaths are less likely to be medically certified and therefore attenuated in hospital-based registers and national estimates.[173] Also, while urban estimates are that 47% trauma victims die before reaching the hospital[82], the national household estimates are that 63% never reach the hospital.[173] Therefore, while in-hospital mortality was a feasible and reliable outcome measure, in this early and explorative work, there are significant problems with interpreting this outcome for hospital and system benchmarking purposes within the trauma care system.[89]

For Studies (I, II and III), I could use internationally validated tools and for Study IV, a new methodology was developed. In Study I, we used ICISS to quantify anatomical injury severity. Our rationale was that ICISS has been shown to perform well compared to the more conventional Injury Severity Score (ISS) and other established injury severity measures such as Trauma and Injury Severity Score (TRISS)[63,177], while also being easily computed using ICD-codes. We used the ICISS1 version of ICISS, which means that for overall scoring of patients' injury severity we counted only the worst injury, the lowest SRR. We chose ICISS1 because this version has been shown to have a higher predictive value compared to versions that take into account all of a patient's injuries.[104]

In the temporal mortality trends Study I , the difference in inclusion criteria between the three cohorts was expectedly a major limitation. To adjust for this limitation and to minimize bias, we adjusted our analyses for case-mix and also conducted several subgroup analyses. A second limitation was the use of ICISS to adjust for anatomical injury severity and used our own data to calculate SRRs and generate finals scores. We found no studies that referenced trauma populations for SRRs from LMICs. Therefore, being mindful of the same-sample bias we calculated SRRs from the combined 1998, 2002 and 2011 dataset and also calculated the ICISS from the same dataset.[178–180] This in part, can explain the good fit of ICISS and therefore we declared that our approach should only be considered explorative in nature. However, we argued that this was a more sensible approach compared to using SRRs derived from a completely different trauma HIC population, like New Zealand. Third, the analysis of available datasets meant that we were not able to choose our time-points. Unfortunately, retrospective inquiries into patient files spanning more than ten years back constituted a more or less impossible undertaking, as files are paper based and stored under variable conditions over time. Finally, the data did not allow us to explore outcome measures beyond mortality between admission and 24 hours. We do acknowledge that later mortality and functional outcomes are important and should be the focus of future prospective studies in the same setting.

*Trauma Registry considerations*

To overcome the problems of retrospective data and missing data, a systematic data collection trauma registry system was set up, for Study II-IV. We inherited the methodological limitations of the largest trauma registry, the National Trauma DataBank (NTDB) of the USA, as we used NTDB as a benchmark for comparison to our Indian dataset. The Major Trauma Outcome study[69,110] provided the coefficients for our scoring calculations (Study III) and is based on the NTDB.

NTDB is robustly examined by each institution contributing data and by NTDB staff to ensure accuracy, but is not a population based dataset and disproportionately includes large trauma centres with younger and more severely injured patients. This concern is noted in the Karolinska trauma registry[181], as in my research dataset of urban large university hospitals. The conclusion and understanding therefore have biases like in in any large, retrospective study of a 'convenience sample'. Inter-centre variability and reliability in data collection is known to be inconsistent in the NTDB, especially for dead-on-arrival patients. The database does not contain all the details on motor vehicle crash characteristics, pre-hospital care, or intra-hospital care, even though there is a prehospital and trauma system in existence in the USA. It is further acknowledged that injury aetiologies have differing outcomes, and need to be bundled together with caution, when calculating overall trauma mortality.[182]

The difference in performance of the severity scores between the directly admitted and the larger group of patients transferred from other facilities, was not significant (p=0.29). The time of admission is not a fixed time interval after injury, as there are prehospital delays in the LMIC setting. Therefore, vitals collected on-admissions are not at fixed intervals after the injury. In the absence of a prehospital system of care, there is little or no intervention at the field level, unlike in mature trauma systems where intubation and sedation are more common. These are areas of potential confounding, also also by our exclusion of dead-on-arrival patients, as there was no prehospital information available. But this may have affected our 30-day mortality calculation.[181] Using an imperfectly measured and surrogate variable for marking time, such as 'admission time to CT scan'; may be an oversimplification of a variable in an analysis model. This can be a cause of residual confounding. Also, the influence of injury prevention measures, such as seat belts and driving under the influence of alcohol on outcomes were not captured, since prehospital information was not available.

Implementing complex scoring protocols across the participating sites, in the absence of a trauma system, would be expensive and would yield incorrect data with incorrect abbreviated injury scale (AIS) estimates. We handled this limitation of interrater reliability and accuracy by having a single surgeon (DKV), do the AIS coding for all injuries of all 11,671 patients in the cohort to calculate the final Injury Severity score (ISS). Co-researcher DKV is certified in AIS coding by the association for the advancement of automotive medicine (AAAM).

Though ISS appears to be a continuous variable (0–75), it is not[183]. ISS is calculated as a sum of squares, and therefore some integers are mathematically impossible.[50] The impossible integers are 7, 15, 23, 28, 31, 37, 39, 40, 44, 46, 47, 49, 52, 53, 55, 56, 58, 60–65, 67–74. Also, ISS in not normally distributed and therefore caution has been advised when calculating means for co-relation with an outcome measure, as in Study II. ISS/NISS has a positively skewed distribution in various datasets[183] and transformation did not improve on the skewness.

Trauma patients who were transferred from other hospitals were two-thirds of the cohort being studied. These patients were at different phases of management before their interhospital transfer and the mortality rate has to be interpreted with caution.[184] To test this issue, we repeatedly compared the transferred versus the directly admitted groups, and found no significant difference on comparison of outcomes. However it is acknowledged that, preceding treatment could have an effect on the subsequent treatment received at the participating hospital, which can be classified as time-dependent confounding.

Though the 30-day mortality was our primary outcome, it is acknowledged that mortality after 30-days and upto a year[185] is of concern[186], especially in operated patients.[187,188] Further, it must be clarified that though the Road safety advocates[13] measure outcomes as 30 days from the time of injury and not admission to a hospital. In this thesis, the conventional 30-day in-hospital stay (admission to hospital to death or discharge) was considered as a primary outcome. In the group of patients who were admitted in smaller hospitals before being transferred, the road safety definition would introduce errors. The time that the patient arrived at the participating hospital was considered as a more accurate measurement.

We tend to introduce an 'indication bias', everytime we classify patients for outcomes based on a non-randomized intervention in our dataset. For example, let us take the procedure of endotracheal 'intubation', which was a strong predictor of death in Study II. Here we assume that each intubated patient, was intubated with a standard indication and infact that intubation was indeed, indicated in each case. Neither of these may be true. Therefore we refrained from stating that endotracheal intubation was a strong predictor of death. This also suggests a 'reverse causation', that the intervention actually caused death, when airway compromise requiring intubation is required only in the seriously injured group with a GCS<8.

Further, survival bias probably exists as some patients do die before treatment can be initiated. This is compounded by the fact that any trauma treatment is not constant and can change over time (time-dependent confounding again), whereas our capture data point was one time and cross-sectional. Also, we tend to assume the uniform effects of the condition and treatment over time. For example, exanguination was a contributor to early death, but may have had an effect on the 30-day mortality for those who survived the first 24 hours. This effect could not be captured in my thesis. These biases makes the study population different from the general population, limiting generalizability.

*Missing data*

The amount of missing data was noticeably reduced for vital sign recording of SBP, GCS, and RR in the 1998 and 2001 datasets, by the presence of a data collector in the 2011 WHO dataset and the current TITCO dataset. This emphasizes the importance of dedicated independent data collectors for maintaining trauma registries. Missing data is common in all registries and the effort is to minimize it.[78] Table 6 displays the disaggregated missing data from each site on each variable.

Table 6: Missing data -Completeness of data items by site in percentages in the dataset

| Site | Mortality | Age | Gender | Injury Type | Mechanism | ISS | SBP | GCS | Transpor | Referral | Injury time | Arrival Time | Intubation | ICU stay |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 96.2 | 100 | 100 | 99.9 | 99.7 | 97.5 | 99.7 | 99.9 | 99.7 | 100 | 99.1 | 99.9 | 24.9 | 98.5 |
| 2 | 94.7 | 100 | 100 | 99.5 | 99.6 | 89.6 | 38.5 | 42.6 | 98.7 | 98.5 | 96 | 98 | 1.6 | 99.9 |
| 3 | 72.3 | 99.9 | 99.9 | 99.4 | 98.2 | 96.3 | 97 | 96 | 99.8 | 99.8 | 99.2 | 99.8 | 23.5 | 72.3 |
| 4 | 14.7 | 99.6 | 100 | 99.8 | 99.6 | 98.7 | 45 | 5.6 | 99.8 | 100 | 94.6 | 72.5 | 29.2 | 85.5 |
| 5 | 72.6 | 100 | 99.9 | 100 | 100 | 90.3 | 72.6 | 82.2 | 96.8 | 99.9 | 99.4 | 99 | 0.2 | 72.2 |
| All | 70.10 | 99.9 | 99.9 | 99.8 | 99.4 | 94.5 | 70.5 | 65.3 | 98.9 | 99.7 | 97.7 | 93.9 | 15.8 5 | 85.7 |

Legend: Complete data in percentage

| | | | | |
|---|---|---|---|---|
| 100 % | 90-99% | 50-89% | 1-49% | <1 % |

It has also been an unexpected but consistent finding among LMIC registries that while an observational rate, such as the respiratory rate, is usually missing[64], a more complex scoring system like GCS is usually calculated and available. Respiratory rate is easy to collect but was missing in a third (36%) of patients in our dataset, as is common worldwide.[121] GCS is a 3-part score, more difficult to collect and calculate, but surprisingly, was available in 86% patients more often than systolic blood pressure (80%). This is in contrast to trauma databases worldwide[121] and is hard to explain, except by attribution to the surgery residency training culture.[122] Inter-rater reliability of GCS scoring has been shown to be low for inexperienced users. This is particularly true for the motor component.[189] Consciousness may be altered by metabolic derangements, hypoxia or hypotension rather than by a direct traumatic insult.[190,191]

Lower oxygen saturation was associated with mortality, but more than half of the oxygen saturation recordings were missing in this dataset. The most common reason for not recording the oxygen saturation was non-availability or non-functioning pulse oximeters. Using independent data collectors may reduce the missing data of vitals in registries in the future, and also by machine-read vital parameters, rather than the current practice of manual readings.

*Development of a peer-reviewed preventable deaths model*

For Study IV, we developed a Bayesian methodology. In Bayesian analysis, we do not analyze the data sample in isolation, but considered our data in the light of our previous clinical patient experience, opinions and prior biological knowledge of experts. There is a paucity of trauma researchers and experts in India.[78,192,193] The concept of an expert is central to Delphi studies and needs further examination. There were one group of experts who were international opinion leaders with many years of experience, but did not know the Indian context well. A national expert could also be someone who knew the local context, but did not have many years of trauma experience. Both types of experts were invaluable for the Delphi study. There was a deliberate attempt made to maintain a male:female ratio, trauma researcher:trauma surgeon ratio and a range of ages of the experts to reduce bias.

A 'prior distribution' was built up based on information and knowledge available with these national and international trauma experts, bringing in their understanding to the table. Numerical value were given and then weighted based on the researchers opinion, experience and prior research findings. Since there was no existing standardized knowledge in the causes of trauma deaths[99,100], as the first step, formative work was started by selecting a Delphi panel of 'insiders', who had worked in trauma care in the Indian context for at least two years. The expert group members gave consent before their participation in the Delphi consensus process.

A researcher bias is likely, when I was performing multiple roles, as a trainer for peer-review, explaining and conducting the Delphi process, and also participating as a peer-reviewer.[97] A researcher bias of steering the peer-review group towards a consensus and concluding on each death, was subtle but present.

The Delphi consensus group observed that there were factors like disseminated intravascular coagulation contributing to death, but the peer-review panel could not attribute these possible causes as they were not documented in the case records nor were autopsy findings available. Comorbidites are contributory to mortality.[12] These complications and adverse events could not be captured, and will require more sophisticated systems[194]of recording and diagnosis. With the given information, neither the exact cause of death nor a root cause analysis for trauma quality improvement was feasible in this study. It was easy for peer-reviewers to reject nearly all trauma death abstracts, as not containing requisite information for a conclusive cause of death.

If all information was available, the peer-review process would be redundant in determining a cause of death in these trauma patients.

The multidisciplinary preventable death panels as advocated by the WHO[45] was the piloted by me at three sites (JPNATC, LTM and KEM) alongwith WHO experts. The pilot revealed that the blame for death was repeatedly attributed to junior staff or some stakeholder not participating in the discussion. This was not useful in building consensus on preventability nor for formulating corrective plans. Therefore at half-time, the methodology for Study IV was changed to the Delphi method by expert multidisciplinary consensus, though it is known that the consensus process does not to lead to the best option but rather to a diluted non-controversial decision.[97]

There is no formal prehospital care for the injured in India, the opportunities for improvement and errors in that phase of care was unavailable. This phase contributed to half of the improvement opportunities in HIC centres.[149] Deaths occur before reaching the hospital, and this study of in-hospital deaths represents only a part of the whole trauma picture. The determination of preventable deaths (definitely preventable or potentially preventable) are subjective in all similar studies, especially across institutions and countries.[148] We did not calculate the interrater variability or reliability among the reviewers in this Indian registry, as it is variation is known, even in the comprehensive HIC trauma registries.

# 8 CONCLUSIONS AND POLICY IMPLICATIONS

- The 30-day mortality **rate** was 21.4% among trauma patients admitted to the studied urban referral hospitals in India. This is double the mortality rate observed in trauma centres in the HICs (II,III)
- The overall 24-hour trauma mortality rate in an Indian urban university hospital over the last two decades showed a declining **trend**, especially after risk-adjustment (I, II)
- Simple vital-sign scoring models were **comparable** in performance to more complex trauma scoring systems in predicting mortality (III)
- It is possible that 58% of the all trauma deaths in the studied hospitals were **preventable**. Two-thirds of all mild and moderately injured (ISS<16) patients trauma deaths were preventable (IV)
- The most common contributors to death were issues regarding airway management, fluid resuscitation and haemorrhage control. The identified opportunities for improvement were triage using vital signs, careful airway management, prompt haemorrhage control and early resuscitation within the mild and moderately injured group (IV)

In this thesis, I have ensured that research questions are generated from within the existing LMIC trauma systems, with the objective that good quality, appropriate, and relevant research gets translated into policy and practice.[195] Some of the policy implications of my work are listed below.

*Vital signs and empowerment of nurses for trauma triage: (Study II, IV)*
Since vital signs are the main triggers for action, for resuscitation (SBP) and airway management (Oxygen saturation); the nurses are the likely custodians for future trauma quality improvement.[196] We found that nurses, currently do not participate in the clinical care of the trauma patient. One of the sites (JPNATC) has already established the Trauma nurse co-ordinator positions and much of the triaging is done by nurses, as per predefined trauma protocols. The trauma nurse coordinator and the senior triage nurse have been identified as the key catalysts for change.[132] Training and investing in nurses pays richer dividends than expecting rotating residents and interns to record and document vital signs in a trauma victim. This is the model followed in most mature trauma systems. Problems with interrater reliability for GCS is known, but is unlikely to influence the trigger point for intervention.[190] The WHO trauma care checklist[102], intake form and minimum data set can be set as the standard case notes for all arriving trauma patients in any trauma unit and implemented through the trauma nurse coordinator.[132]

*Setting up a National trauma-registry*
In Study I and II, we have successfully piloted a multi-hospital trauma registry in India for the first time, using independent data collectors[195](employed centrally, but posted in the high-volume centres receiving trauma, burns and other emergencies). In the past, surgical, anaesthesia and orthopaedic residents have been unsuccessful in collecting systematic data within university hospitals, due to clinical committments. Data collection, systematic analysis and building a strong case/argument, based on volumes and outcomes is vital for a research-driven advocacy for trauma care policy. The learning from sophisticated trauma registries is available and universities worldwide are keen to share their registry expertise.[78]

*Transforming the current major teaching hospitals into major trauma centres*
Study II & IV demonstrates that instead of the current non-viable plan of standalone trauma centres along the highways, upgrading the teaching hospitals to major trauma centres is the way forward for trauma care in India.[197] The organization characteristics of trauma centres are

strong clinical leadership, a multidisciplinary approach to services and organizational commitment to reduce delays in the process of care (e.g. time to CT scan, time to surgical intervention, time from admission to first recording of blood pressure).

*Preventable death panels and working groups*

The mildly and moderately injured (ISS<16) are the subsets of trauma patients, who can be saved, as shown in Study IV. This group will need intensive monitoring. Generating ownership for improving outcomes and corrective actions via moderated discussion sessions, will allow for local solutions to emerge from within the group of care-givers.[169] Further, organizational and administrative restructuring of trauma care in university hospitals will improve the process of care parameters.

# 9 FURTHER RESEARCH

Mortality remains a gross measure for outcomes.[198] This thesis is obsessed with binary outcomes of lived/died, but life is what happens in between. For every death, injury produces disability many fold with lifelong consequences. Morbidity and disability were dealt very superficially in this thesis (Study IV). The 30-day data capture (Study II & III) was not sensitive to record complications, morbidity and disability.

Injury severity scoring and mortality have been central to this thesis, but were designed to only calculate the probability of death. For example, a bilateral amputee in our dataset would merit an injury severity score of 9 (not severely injured). However, the consequences for his or her life are immense. Injuries that a trauma patient does not die from, such as the loss of a thumb, would not find a place in my research. A better measure for further research would be the disability-adjusted life years (DALY) for overall disease burden in the population, and is expressed as the number of years lost due to living with the health condition or its consequences or premature mortality. DALY allows for comparisons of the overall health and life expectancy between different countries.[199]

The Global Burden of Diseases study in 2015 estimated that injuries cost the global population about 275 million years of healthy life every year, causing 11% of disability-adjusted life years worldwide.[15,199] The burden of disease attributed to injuries is expected to rise in the years ahead. By the year 2020, injuries are predicted to be the third leading cause of death and disability worldwide.[14] More relevant to the Indian context, is that injuries are perhaps the biggest creator of poverty in LMICs due to catastrophic medical expenditure.[200] A very conservative expenditure estimate of an average Rs.7,282 (USD 112) is spent on each RTI victim treated in a urban university hospital in this research. When combined with the mortality figures from Study I, II and IV, the cost to public hospitals for treating RTI cases in 2015 was Rs. 304,902,670 (USD 4.7 million).

This makes a strong case for investing this money in road safety and the post-crash response as advocated by the World health assembly resolutions. Also, it is important to note that the health ministry spends on the treatment of road traffic injuries, when the transport ministry should be held responsible. Further research and advocacy emerging from my work, will place the onus of responsibility with the automobile manufacturing companies who are partners in road safety, a model that is practiced in many countries. In the Australian (Victoria State Transport Accident Commission)[128] model, the accident commission picks up the expense for post-crash trauma care and rehabilitation. National Health Policy 2017[22], is optimistic and promises similar universal access to quality healthcare and technology despite financial barriers

# 10 REFLECTIONS FOR THE FUTURE

The next phase of my post-doc trauma research will be to test the interventions and best practices within trauma hospital systems, as suggested in my thesis. This will include larger participation in the trauma registry and incorporating systematic data collection as a routine part of the trauma systems of India. For the Ministry of Health and Family Welfare, my concurrent step will be to formulate context-specific standard treatment guidelines, based on the best practices, for receiving major trauma trauma patients. In my capacity as a Lancet commissioner for Global Surgery, Lancet commissioner for NCDs and Injuries in the poorest billion, an expert collaborator with the Global burden of disease project and as a member of the Indian Ministry of Health's Working group on Emergency care in India; I am uniquely positioned to use this learning, to advocate for policy changes and health systems reform at the country level.

# 11 ANNEX

## 11.1 ANNEX 1: TITCO INTAKE FORM FOR SYSTEMATIC DATA COLLECTION

| | | | | | |
|---|---|---|---|---|---|
| 1. Hospital: Masked | | Patient file | Masked | Ward: | |
| 2. Patient study ID: | | | | | |
| 3. Directly observed? | | SUBMIT | | RETRIEVE | |
| 4. Inclusion criteria | | | | | |
| DEMOGRAPHIC DATA | | | | | |
| 5. Age | | 6. Sex | | 7. Patient transferred from other | |
| 8. Date of injury | | | | 9. Time of injury | |
| 10. Date of arrival | | | | 11. Time of arrival | |
| 12. Date of | | | | 13. Time of | |
| 14. Mechanism of | | 15. Mode of transportation to hospital | | | |
| 16. Type of injury | | 17. Arrived walking without support from | | | |
| FIRST SET OF VITALS, WITHIN 24 HOURS FROM ARRIVAL | | | | | |
| 18. SBP | | 19. SpO2 | | 20. Patient given O2 when | |
| 21. RR | | 22. HR | | 23. GCS Total | |
| 24. GCS Eye | | 25. GCS | | 26. GCS Motor | |
| 27. Date of | | | | 28. Time of measurement | |
| SECOND SET OF VITALS, WITHIN 24 HOURS FROM ARRIVAL | | | | | |
| 29. SBP | | 30. SpO2 | | 31. Patient given O2 when | |
| 32. RR | | 33. HR | | 34. GCS Total | |
| 35. GCS Eye | | 36. GCS | | 37. GCS Motor | |
| 38. Date of | | | | 39. Time of measurement | |
| PROCEDURES, WITHIN 1 HOUR FROM ARRIVAL | | | | | |
| 40. Intubated | | 41. | | 42. Intercostal drain | |
| 43. Patient to OT | | 44. Units of whole blood or PCV received | | | |
| PROCEDURES, BETWEEN 1 AND 24 HOURS FROM ARRIVAL | | | | | |
| 45. Intubated | | 46. | | 47. Intercostal drain | |
| 48. Patient to OT | | 49. Units of whole blood or PCV received | | | |
| SURGERY, WITHIN 24 HOURS FROM ARRIVAL | | | | | |
| 50. Type of surgery | | | | | |
| 51. Length of surgery (hours) | | | | 52. SBP at start: | |
| RADIOLOGY, WITHIN 24 HOURS FROM ARRIVAL | | | | | |
| 53. CT | | 54. FAST | | 55. X-ray | |
| 56. Date of CT | | | | 57. Time of CT | |
| FIRST SET OF BLOOD PARAMETERS, WITHIN 24 HOURS FROM ARRIVAL | | | | | |
| 58. Haemoglobin | | 59. | | 60. Blood glucose level | |
| 61. Serum creatinine | | | | 62. Blood urea nitrogen | |
| FOLLOW UP | | | | | |
| 63. Length of | | 64. ICU | In hours | 65. Patient died? | |
| 66.death/discharge/d | | 67. Time of | or discharge | | |
| 68. DAMA or abscond? | | | | | |

INJURY DATA (use another page if not enough space below)

External injuries and injuries not covered in reports specified below

From X-ray report:
From FAST-report:

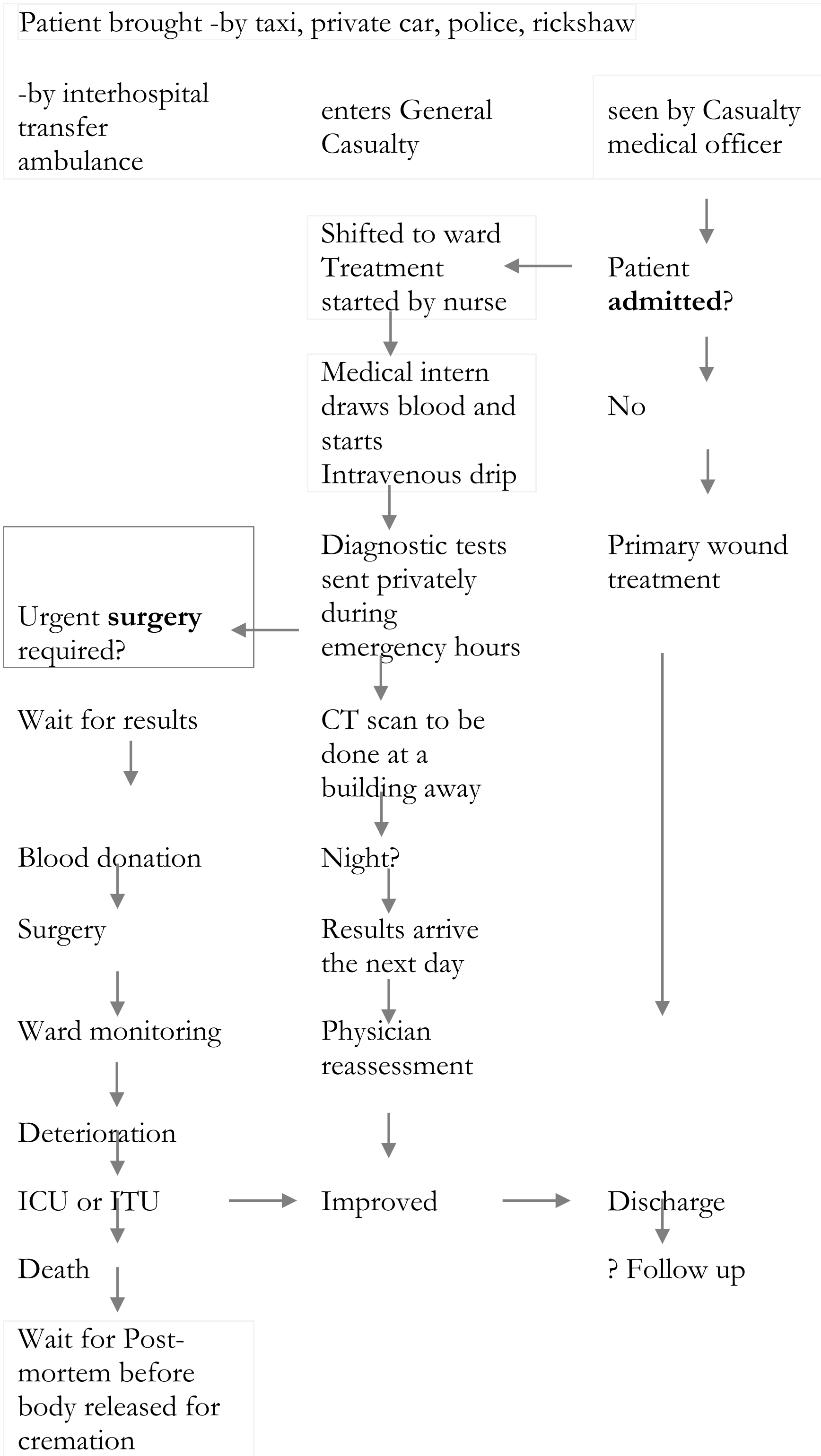
From CT – report:

Operative findings:

**Inclusion criteria:** Potentially life-threatening injury, defined as all patients
1) admitted with history of any of the below specified injury mechanisms, or
2) with history of any of the below specified injury mechanisms who die between arrival and admission, or
3) admitted with potentially life-threatening injury as assessed by treating physician, or
4) kept for observation in yellow area with history of any of the below specified injury mechanisms

Exclusion criteria:
1) Isolated limb injury
2) Dead on arrival

## 11.2 ANNEX 2: TRAUMA PATIENT FLOW AT A PARTICIPATING SITE (SSKM, KOLKATA)




- as narrated by the SSKM project research officer

## 12 ACKNOWLEDGEMENTS

It's all about the journey!

Indeed, and it has been a remarkable one at that and I enjoyed it very much. I have met some of the most wonderful and amazing people on the way who made this ride as much fun, as fascinating. This journey has taken me from the certainty of a surgeon (when in doubt, cut it out) to the uncertainty of a epidemiologist (well….it depends).

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