# Trauma treatment delay

A retrospective cohort study on the factors affecting the delays in trauma care

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## Abstract

Introduction: Trauma remains a global health challenge, leading to millions of deaths each year. The biggest impact can be seen in low to middle income countries, but in high income countries, trauma systems have been developed to lower the mortality and morbidity associated with trauma. To further improve on these systems, conferences are held to better the care patients receive and to identify errors made, called opportunities for improvement, one of the more common being delayed treatment. Aim: This retrospective cohort study aimed to determine the associations between different patient level factors and receiving delayed treatment. Material and Methods: This study used the database of Karolinska university hospital to run a logistical regression linking the outcome, delayed treatment, to variables, observed patient level factors. Patients treated for trauma at the hospital between 2012 and 2022 were included, with ISS>9 and/or trauma code activation. Exclusion criterias were not being screened for OFI and missing values in any of the observed variables. Results: Higher ISS and RR was linked to higher rates of delay in treatment (ISS, OR 1.03, 95% CI 1.01-1.06)(RR, OR 1.04, 95% CI 1.01-1.08), while a lower GCS also was linked to delayed treatment (OR 0.93, 95% CI 0.87-1.00). Number of injuries showed a correlation to higher rates of delay, but not when adjusted for. The remaining variables showed no correlation. Conclusion: Our study suggests that it is mostly more severely injured and less awake patients that receive delayed treatment.

Inledning: Trauma är fortfarande en global hälsoutmaning som skördar miljontals liv varje år. Den största effekten kan ses i låg till medelinkomstländer, men i höginkomstländer har traumasystem utvecklats för att sänka morbiditeten och mortaliteten relaterat till trauma. För att ytterliggare förbättra dessa system hålls konferenser för att förbättra vården patienter får och identifiera misstag som gjorts, så kallade förbättringsmöjligheter, där försenad vård är en av de vanligaste. Syfte: Denna retrospektiva kohortstudie syftade till att identifiera associationen mellan patientfaktorer och försenad vård. Material och Metod: Denna studie använde Karolinska universitetssjukhusets databas för att köra en logistisk regression som kopplar utfallet, försenad vård, till variabler, observerade patientnivåfaktorer. Patienter som behandlades för trauma på sjukhuset mellan 2012 och 2022 inkluderades, med ISS>9 och/eller traumakodaktivering. Exklusionskriterier var om patient inte screenades för ofi samt om de saknade värden i de undersökta variablerna. Resultat: Högre ISS och AF var kopplade till högre grad av försenad vård (ISS, OR 1.03, 95% CI 1.01-1.06)(RR, OR 1.04, 95% CI 1.01-1.08), medan ett lägre GCS också var kopplad till försenad vård (OR 0.93, 95% CI 0.87-1.00). Antalet skador visade först ett samband med högre förseningsfrekvens, men inte i den justerade analysen. De återstående variablerna visade ingen korrelation. Slutsats: Vår studie tyder på att det mestadels är svårare skadade och mindre vakna patienter som får försenad behandling.

Keywords: Trauma, Delay to treatment, Patient factors.

### Introduction

#### **Definition**

Trauma, defined as the clinical entity composed of physical injury and the body's associated response (1), is and has long been a major cause of death around the world (2). The trauma system plays an important

part in modern healthcare and has shown to lower mortality and morbidity in injured patients through many means, such as hospital care, patient follow up and prevention programs (3).

# Trauma globally

Trauma is often divided into two subgroups, blunt force trauma and penetrating trauma. Blunt force trauma is when an object or force strikes the body, often causing bruising, broken bones or deep cuts. Examples of blunt trauma could be car crashes, falls or direct blows to the body. Penetrating trauma is when an object pierces the skin or body and creates an open wound. Examples of penetrating trauma are gunshot wounds and stab wounds (4). Differences exist between the two groups, as blunt trauma patients tend to be more injured on arrival to the hospital and as such, require more resources and are hospitalized for a longer periods (5).

Today, trauma takes the lives of around 4,4 million people each year, almost 8% of all deaths (2). In the United States, trauma is the 4th leading cause of death among the general population and the leading cause for people between the ages of 1 and 44 (6). It is also an important cause of hospitalization and morbidity among all age groups, including seniors, and is responsible for an estimated 10% of all years lived with a disability globally. This has a significant burden on social and economic level, costing countries billions of US dollars each year in healthcare and lost productivity (7). Studies estimate the cost of trauma care being between 18,500\$ and 41,500\$ per patient in high income countries (HIC), depending on the country (8). However, it has been shown that this burden is not evenly distributed between or within countries.

Many social factors such as age, sex and social status play a major role in the risk of dying from trauma, with young men with low socio-economic status being at most risk (2). But it is not only patient level factors that affect what effect trauma has on people. About 90% of all trauma related deaths occur in low-and middle-income countries (LMIC), with death rates by trauma also being higher than in HIC. Even within these LMIC, people of poorer socio-economic status have higher death rates from trauma. Problems identified within these countries that contribute to these statisitics were infrastructure, education and training, attributed to lack of funding, brain drain to HIC and lack of availability of basic amenities (9). In HIC where funding and governance over the healthcare system is better designed, functioning trauma systems and dedicated trauma centers exist that have been shown to lower mortality but also improve functional outcome in trauma patients (10).

### Trauma systems

Trauma systems are infrastructures that exist to provide and optimize care for injured patients starting with injury recognition and triage, transport to appropriate trauma center, inpatient care and outpatient follow-up. Beyond the clinical side, trauma systems work with outreach, education and advocacy, data collection through registries, research, funding, and disaster preparedness and response. A comprehensive and functioning trauma system requires strong leadership and engagement at the trauma center, regional and national level (7). This system is crucial to provide care for trauma patients, both in reducing morbidity and mortality in this patient group. Earlier studies from Sweden have shown that treating severely injured patients at a trauma center is associated with a 41% lower adjusted 30-day mortality rate compared to being treated at a non trauma care center due to them being more capable of treating these patients, with potential survival benefit increasing with higher injury severity (11). Other studies have shown similar results, showing that treating injured patients at trauma centers is associated with a 15-30% decrease in mortality (12–15).

During the last three decades, the introduction of trauma systems has contributed to lowering the incidence of preventable death. This is attributed to the improvements in care for acute brain injuries and bleeding control. The incidence of late death because of sepsis and multiple organ failure has also been lowered, possibly a result of better and earlier resuscitation (16). Functioning trauma systems saves lives in the hospital, but their work outside of the hospital is just as important. Data collection from injured patients, such as mechanism of injury or mortality, are essential for creating databases that can be used for research. In turn, that research can be used for planning injury prevention programs that target the most common injuries in the most efficient ways, e.g. teen drivers, children, specific occupations etc. These injury prevention programs can be planned on trauma center, organizational or government level(17).

Trauma teams are multidisciplinary and operate in these centers. They play a pivotal role in the treatment of the trauma patient, as they provide the initial care in the critical stage of trauma. In Sweden, trauma teams are lead by a team leader who is a surgeon, and include practitioners from the specialities of intensive care, orthopedics, nursing and support staff(18). For the trauma team to be mobilized, a trauma code has to be activated, often by an emergency nurse. The nurse uses information gathered by the first responders to assess if the patient fits any of the criteria for trauma code. Most healthcare facilities have established criteria or guidelines that trigger trauma code activation. These criteria typically include mechanisms of injury, physiological criteria, anatomical criteria and other specific indicators of severe trauma. There are different levels of trauma code with different criteria correlating with severity of injury, with level 1 mobilizing the most personnel to the trauma room. Once in the trauma room, the team works systematically to manage the patients injuries. They handle the most urgent problems first, such as airways and breathing, with the aim to rapidly assess and stabilise the patient, prioritise their injuries and arrange for site of definitive care. (19)

## Opportunities for improvement

Many hospitals have a trauma registry where they log the patients information and timeline of what happened. The extent of the registry varies, with HIC having more complete registries. In Sweden, 48 out of the 49 hospitals receiving trauma patients are connected to the national registry SweTrau, which functions as a national database designed to enable scientific processing with epidemiological technology (20) This logging of information is important work, as a cornerstone of trauma quality improvement programs is multidisciplinary MoM conferences. The MoM conference is a meeting where different specialities who work with trauma care sit down and discuss deaths and complications in order to look for preventable factors. These conferences are performed in many hospitals globally, almost everywhere where there are formal medical specialty departments and sometimes in smaller hospitals as well (21). In Sweden, many hospitals have mortality conferences on deceased patient cases, but only one has MoM conferences to better their trauma care on patients who lived (22). The reason being that this expansion of MoM conferences takes time and resources, which is why all hospitals don't implement this.

The endpoint of these MoM conferences are opportunities for improvement (OFI). At the end of the conference, consensus is reached regarding the existence of an OFI and implementation of corrective action. This process is effective, as it has been shown that this review is associated with high-quality trauma care (23). Examples of OFI may include lack of resources and management errors. One common OFI is delayed treatment. According to previous studies, among the preventable or possibly preventable deaths in trauma patients, delay in treatment has been identified as a major error contributing to death, found in up to 52.9% of patients in said group (24). Delayed treatment has been shown to have adverse effects on patients, showing why it is such an important issue and the need to develop strategies to combat (25,26). Although it is such a common OFI, the patient level factors associated with delayed treatment are poorly understood. There may be several factors that correlate with receiving delayed treatment, but they have yet to be identified. Mapping these factors may help in identifying patients that might be at risk for receiving delayed treatment before it happens.

#### Aim

This retrospective cohort study aimed to determine the associations between different patient level factors and receiving delayed treatment.

# Methods

### Setting

The Karolinska University hospital, which is the equivalent of a trauma level 1 hospital, admits 1500 trauma patients each year. To be included in the trauma registry, a patient must be over 15 years of age, had ISS>9 and/or had trauma code activation. They get added to both the Karolinska Trauma registry as well as the national trauma registry (SweTrau). The registry includes data on vital signs, injuries, interventions and

patient information. Another database, the trauma care quality database includes information relevant for MoM conferences. At Karolinska University Hospital, patients who die during hospital stay gets their case sent to a MoM everytime. However, for the rest of the patients, two specialized nurses determine whether they are. Several audit filters are set up to flag for patients with possible OFIs. Audit filters may include low SBP, high RR, EMS scene time greater than 20 mins etc. Flagged patients are then reviewed by these two nurses who decide if there is a possible OFI, in which case their case is sent to a MoM conference for further review.

### Study design

We conducted a registry based cohort study using data from the trauma registry and trauma care quality database at the Karolinska University Hospital in Solna. The trauma registry includes 14,022 patients treated between 2012 and 2022. The trauma care quality database is a subset of the trauma registry and includes about 8000 patients selected for review between 2013 and 2022. This project linked the two databases and assessed how different patient level factors, such as age, sex, blood pressure, and injury severity, are associated with delayed treatment using logistic regression.

#### Outcome

The outcome is the OFI delayed treatment. An OFI is any failure in care, e.g. clinical judgement error, any preventable or potentially preventable death, missed diagnosis, technical error and delayed treatment as identified and decided my the MoM conference. The outcomes we used were "long time until CT" and "long time until operation", which will be referred to as delayed treatment from now on.

### **Participants**

The database only includes patients 15 years old and above, ISS >9 and/or trauma team activation. Inclusion in the study further required that the patients has been assessed for OFIs. Patients were excluded if they were missing information in one of the examined patient factors.

### Variables

The independent variables are gender, GCS on arrival, respiratory rate on arrival, systolic blood pressure on arrival, number of injuries, ISS and age. Of these variables, GCS, respiratory rate, systolic blood pressure, number of injuries, ISS and age are used as continuous variables in the analysis. Gender is used as a categorical variable.

For missing hospital values in GCS, RR and SBP, values collected from EMT personnel before arrival to hospital were used. This was accomplished by identifying missing data in the column for the hospital value of the variable and, if available, replacing the row in the dataset with the prehospital value. If a prehospital value is missing, the patient is excluded from the study.

### Data sources/measurement

The data comes from the trauma registry and trauma care quality database.

### **Bias**

Selection bias as this is a retrospective post hoc cohort study where the outcome has occurred before the study began.

Misclassification bias as the conference may reach a consensus that is wrong, alternatively that the two specialized nurses going through the patients flagged for audit filters might misclassify patients or that the audit filter misses a patient with ofi.

# Study size

The study size is all of the eligible patients that was treated at the hospital between 2012 and 2022. Starting 2013 only a subgroup of patients were screened for OFIs, but starting 2017 all patients that are included in the database are screened for OFIs. Out of the 14,022 patients in the database, 7,378 were included in the study, with the rest being excluded due to either not being screened for ofi or missing values in the examined variables. 72 patients were deemed to have received delayed treatment. However, only 70 patients with the registered outcome were included in the study due to missing values among two of the patients.

### Statistical methods

Multivariable and univariable logistical regression. A 5% significance level and 95% confidence levels will be used.

Rstudio was used to clean and prepare the data from the database. The data was processed to have the variables customized to fit into the logistical regression model, such as making them into factors, renaming outcomes in the database and replacing or removing unknown values. The variables were either binary or continuous. While writing the code, it was tested on scrambled data so to avoid selection bias as much as possible. When the code was finished, it was run on the unscrambled data for a result.

Using the one in ten rule, 7 independent variables were used for the logistical regression given that we have 70 patients with delayed treatment. The one in ten rule states that for every variable examined, 10 events are needed in the group. In this case, this means that because we have 70 patients with the examined outcome, we can have 7 variables.

The logistical regression is run through Rstudio using the glm command. It was ran several times to make an adjusted table and 7 unadjusted, one for each variable. To make the tables, the package gtsummary was used to visualize the adjusted and unadjusted regression individually, then merging them together into one table.

This process was the only time generative AI was used in the writing process. It was used to make snippets of code for a specific purpose, revise and optimize code and find solutions when written code was not functioning properly.

#### Ethical considerations

An ethical problem that might be brought up is the anonymity of the patients. In the registry, patients social security number is present and could theoretically be used to identify the patient in question. This will not be a problem though, as in the analysis, the social security number is removed from the data before the logistical regression is ran. Furthermore, the results will be presented with patients grouped together, not individually. This will make it impossible for anyone to identify patients. During the analysis, a VPN was used to access the database to ensure that no data was leaked or used for other purposes. Ethical permit is required and exists. The ethical review number is 2021-02541 and 2021-03531.

# Results

Out of the 14,022 patients receiving trauma care at Karolinska University Hospital, 5,710 patients were not screened for ofi, which excludes them from the study and leaves 8,312 patients that have been screened for ofi.

As we were running the logistic regression, additional patients were excluded from the study due to missing data. Among the 8,312 patients screened for ofi, 7,378 were included in the study. 934 patients were excluded from the study due to missing values in one or more variables. This left us with 70 patients in the delayed treatment group and 7,308 patients in the no delay to treatment group. Figure 1 below illustrates the exclusion and inclusion of patients.

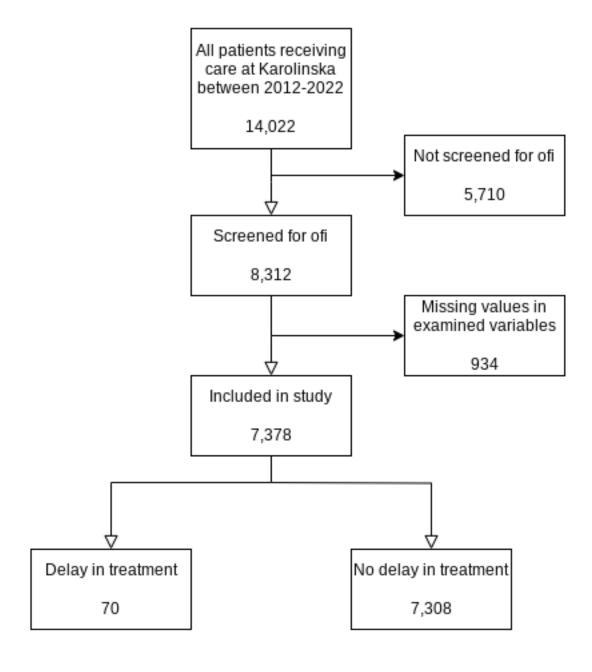


Table 1 shows the characteristics of the group used in the logistic regression. Most of the patients were men, 68%, with that being a bit higher in the delayed treatment group, 74%. The mean value for the ISS score was 10.18, with that value being higher in the outcome group, at 16.81. The mean age of the patients was 45.18 years old, with it being around the same in the delayed treatment group at 45.50. The mean number of injuries among the delayed treatment patients was at 6.33, which is higher than in the overall group at 4.76. The mean SBP was 137.33, with a standard deviation of 25.69. Mean respiratory rate was 18.59 with it being slightly higher in the outcome population at 20.39. Lastly, mean GCS was 13.93, being lower among patients with delayed treatment at 12.56.

table1

	No delay to treatment,	Delay to treatment,		Overall, $N =$
Characteristic	N = 7,308	N = 70	p-value	7,378
Gender			0.3	
K	2,314 (32%)	18 (26%)		2,332 (32%)
M	4,994 (68%)	52 (74%)		5,046 (68%)
ISS	$10.12\pm10.44$	$16.81 \pm 10.24$	< 0.001	$10.18 \pm 10.46$
Age (years)	$45.18 \pm 21.40$	$45.50 \pm 22.08$	> 0.9	$45.18 \pm 21.41$
Number of	$4.75 \pm 4.39$	$6.33 \pm 4.84$	0.008	$4.76 \pm 4.40$
injuries				
Systolic blood	$137.34 \pm 25.64$	$136.79 \pm 30.81$	0.9	$137.33 \pm 25.69$
pressure				
Respiratory rate	$18.57 \pm 5.13$	$20.39 \pm 6.06$	0.015	$18.59 \pm 5.14$
GCS	$13.94 \pm 2.60$	$12.56 \pm 3.53$	0.002	$13.93 \pm 2.62$

In the following table, result1, the results from the logistical regression analysis is displayed.

The odds ratio is calculated both unadjusted and adjusted. A 95% confidence interval was used with the p value shown in the table.

The analysis shows that some variables seem to have a association with patients receiving delayed treatment. ISS and respiratory rate (RR) both have a trend that patient with lower values seem to have a lower incidence of delayed treatment, in both unadjusted

(ISS, OR 1.04, 95% CI 1.02-1.05)(RR, OR 1.06, 95% CI 1.02-1.09) and adjusted analyses (ISS, OR 1.03, 95% CI 1.01-1.06)(RR, OR 1.04, 95% CI 1.01-1.08). GCS had the opposite correlation, with higher GCS often having lower incidence of delayed treatment, both unadjusted (OR 0.88, 95% CI 0.83-0.94) and adjusted (OR 0.93, 95% CI 0.87-1.00). Number of injuries had the association of higher number of injuries having higher incidence of delayed treatment unadjusted (OR 1.06, 95% CI 1.02-1.10), but that association was not seen when adjusted for. The three remaining variables, age, gender and SBP, were not shown to be linked to the outcome.

result1

Characteristic	OR	95% CI	p-value	OR	95% CI	p-value
Gender						
K		_		_	_	
M	1.34	0.80,  2.35	0.29	1.22	0.72, 2.15	0.48
ISS	1.04	1.02, 1.05	< 0.001	1.03	1.01, 1.06	0.003
Age	1.00	0.99, 1.01	0.90	1.00	0.98, 1.01	0.54
Number_of_injuries	1.06	1.02, 1.10	0.003	0.98	0.93, 1.04	0.59
$Systolic\_blood\_pressure$	1.00	0.99, 1.01	0.86	1.00	1.0, 1.01	0.50
Respiratory_rate	1.06	1.02, 1.09	0.003	1.04	1.01, 1.08	0.018
Total_GCS	0.88	0.83,  0.94	< 0.001	0.93	0.87, 1.00	0.038

# Discussion

These results show a possible correlation between some variables and the presence of delayed treatment. A lower GCS had a correlation with delayed treatment while a higher ISS had the same correlation. This suggests that a more heavily injured and less conscious patient is more prone to receiving delayed treatment. Compared to a previous study analysing the same data but with OFI as the outcome, this result is similar to what they found using the same database (27). As the mentioned study suggests, this could be explained

by that lower GCS as well as higher ISS indicates severe trauma. More injured patients often requires a more complex management and more interventions. More interventions leave more room for delay to these interventions, why they are more prone to delay in treatment. Respiratory rate also had the correlation that lower respiratory rate correlated with lower rates of delayed treatment among the patients. As the interval is >10 to <29 in the triage guideline, both too low and too high respiratory rate is not desirable(28). This might have a similar explanation to ISS and GCS, that patients with tachypnea might receive higher rates of delayed treatment because they are more severely injured, therefore a higher risk of missing a possible injury. The previous study also found this, but the correlation dissapeared when adjusted for, which was hypothesised being due to its shared variability with the ISS variable(27). In this study, this was the case for number of injuries, as it and ISS is often correlated as a more severely injured patient will both score higher on ISS and number of injuries. Therefore, we hypothesize that the effect of number of injuries become insignificant when adjusting for ISS.

Not many studies regarding trauma and patient level factors have had delayed treatment as their outcome, while many analysing mortality. Some similarities exist with which patient level factors predict the outcome, with higher mortality being seen in patients with lower GCS and higher ISS [(29)](30). Increased age was also a factor linked to mortality, which was not seen to be linked to delayed treatment in this study. An older patient is more likely to have co-morbidities that might affect their mortality but not increase their likelihood of receiving delayed treatment the same way ISS and GCS does(31).

It is important to keep in mind that delay in treatment does not have a set limit of time as a where under it is within the accepted timeframe and if you go over it, it is considered delayed treatment. The audit filters flag for a wait for CT over 30 minutes and a wait for operation over 60 minutes, which then gets reviewed by previously mentioned two specialized nurses. However, if a patient has a longer wait, it does not necessarily mean that there was a delay. If it takes a longer time for a trauma patient to receive a CT or operation, it might be because there was more urgent matters who had to be taken care of, alternatively, the MoM conference might deem it as the delay was justified for other reasons. The point is that the mean waiting time for CT and operation is higher than 30 and 60 minutes respectively when looking at the database. Using this audit filter as the definition for delay would not mean anything, as the majority of patients would be classified as having waited for too long. Instead, it is the MoM conferences that decide if the delay had any adverse effects for the patient, such as an injury worsening during the time spent waiting without a clear motivation to why it had to wait. It is these cases that they label it as the ofi "too long until CT" or "Too long until operation".

Limitations In this study, one of the limitations was the number of people having the recorded outcome being quite small, leading us into having to limit the number of variables we wanted to examine. Furthermore, the original plan was to divide RR, SBP and GCS into revised trauma score (RTS) categories, from 1-4. However, many of the RTS variables had few to no patients with the observed outcome. This led to separation in the logistic regression in these variables, referring to when an outcome variable separates a predictor variable completely, which occurs when the predictor is only associated with one outcome value (32). In the case of these variables, it was only RTS 3 and 4 who had patients with the observed outcome, which left RTS 1 and 2 with confidence intervals of 0.00 to infinity. This way would have been the best way to examine these variables, but as that was not possible with this group of patients, we resorted to making these variables continuous. We considered expanding the outcome group to include more OFI, but opted for the solution used in the study instead as we were solely interested in this OFI for this study.

The problem mentioned above with too few patients in the outcome group made this into a post hoc analysis. As we did not know the number of people who received delayed treatment when we handled the scrambled data, we ran the code on the real data when we had too many variables for the dataset. Therefore, we had to change the variables after having seen the real data, making it a post hoc analysis. This could in theory open up for possible selection bias, as we might choose variables which give us results we are looking for. However, all the variables included in the final analysis were already included in the first one. Variables were only removed, not added after having seen the real data. The best way to have gone about this would have been to just look at the amount of people who received delayed treatment before choosing the variables. Then, choosing an amount of variables that would work with the amount of patients. This would have avoided

making it post hoc and changing the variables after seeing the data.

On discussing possible biases, misclassification bias might also be present in this study, though it is something that we cannot control in this study. As previously mentioned, the possible existence of an OFI is decided during the MoM conferences, where they then add it to the database. However, they might not always be right in their judgement and misclassify from time to time, leading to patients landing in the wrong group in the analysis. Also, some patients might have been missed even before reaching the MoM conference. The patients included in the conference are selected through audit filters and two specialized nurses, and patients might be missed in this stage. This bias should not be big enough to have a significant impact on the results, but can be kept in mind.

Clinical applications Further analysing the results and it's clinical applications, the results can be interpreted as that it is mostly injured patients with affected consciousness that receive delayed treatment. The clinical applications of this can be seen as we need to do more to avoid this delay for this patient group. If clinicians are aware of that these patients receive delayed treatment more frequently, active steps can be taken towards reducing this risk and bettering the trauma care.

Regarding health equity when looking at the patient demographics, it is clear that the majority admitted to trauma care are men, with it being slightly higher in the delay to treatment group. However, not high enough to be statistically significant. The fact that gender did not show an increased odds ratio should be seen as a positive sign. It suggests that among trauma patients, there is no systematic delay based on this patient level factor.

Generalisability Discussing the generalisability of this study, we included the all the trauma patients treated and Karolinska University Hospital and excluded 40.7% of that population based on that they had not been screened for ofi. Additional patients were excluded because of missing data, but no distinct groups except the not screened patients were removed. On that basis, this population should be a general representation of trauma patients at the equivalent of a level 1 trauma center, making this study generalisable. While the population only represents Karolinska university hospital, the conclusion is should be applicable to the whole trauma population.

Future studies In future studies building upon this one, various methods to further examine the correlation between delayed treatment and various variables, alternatively using another OFI as the outcome variable. Examining different variables such as highest hospital care lever, intubation status or first emergency procedure performed might be interesting variables, among others. To be able to do this, more patients in the outcome group would be needed, either by expanding the register to several hospitals, or expanding the outcome group by adding different ofi. This however would make the study less specific for delayed treatment. Further studies might also look into different ofi other than delayed treatment, such as missed injury, faulty communication or triage.

#### Conclusion

In conclusion, based on this small population, the results suggests that it is mostly more injured and patients with affected consciousness that receive delayed treatment. However, due to the limitations of this study, the result should only be seen as something to keep in mind when treating patients as further studies need to be conducted on this subject.

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