**Study plan**

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**Salar Mohammed**

**073-920 67 71**

**salar.mohammed@stud.ki.se**

**How do transfers and updating of clinical prediction models for trauma triage affect mistriage rates?**

**Introduction**

Physical trauma, injuries stands for 9% of global mortality. More than 5 million people die anually due to trauma and it is one of the leading mortality causes in individuals under 44 years old (1) Prediction models used in trauma care seek to facilitate categorizing of medical care regarding time frame and place. Models have and are still being developed to predict death or survival rates in patients. Many models are built on vital-parameters such as systolic blood pressure(SBP) and respiratory rate(RR) and other variables such as Glascow Coma Scale, GCS. (2). The variables are later put in a system to determine the level of trauma. Advancement of these models are in many cases being made limited to a specified location or setting and are later being used in other circumstances. Also, they are developed on a national level using databases for that specific country and is being used in other parts of the world. This study seeks to answer if transferring prediction models from a country and applying it in another country affects mistriage rates. Mistriage rates is measured as either over- or undertriage. Updating the prediction models may have an impact on mistriage rates also.

**Aim**

Asses how transfers of prediction models for trauma triage affect mistriage rates. If the mistriage rates are adversely affected by model transfers, asses how model updating affect the mistriage rates.

**Material and methods**

Study design

This is a registry-based cohort study with data being collected from the Swedish trauma registry, SweTrau, from the US national trauma data bank, NTDB and the Indian Improved Trauma Cara Outcomes TITCO.

Setting

Each dataset will be divided into samples of three; development, updating and validation samples. Logistic regression will be used to develop the models in the development samples. An estimation of the mistriage rates in the validation samples models and will be compared to it self and to the other validation sample from the other databases. The updating samples will be tested in different settings and compared to see how model updating affect the mistriage rates.

Participants

The **inclusion** criteria in patients registered in SweTrau are:

* All patient that have experienced a traumatic event in which a trauma protocol has been activated in a hospital
* Admitted patients with or without trauma protocol activation
* Patients transferred to the hospital <7 days after the traumatic event and with a NISS score of >15.

**Exclusion** criteria for SweTrau:

* Patients whose only traumatic injury is chronic subdural hematoma
* Trauma protocol activation without an underlying traumatic event(6)

För amerikanska registret: Hittar inte ink eller exl kriterier

**Inclusion** criteria for TITCO:

* Patients presenting to the casualty department with injury sustained from road traffic, railway, assault or burns admitted to hospital for treatment
* Patients who died after arrival(before admission)

**Exclusion** criteria for TITCO:

* Patients who were dead on arrival(7)

Individuals 15 years or older registered in all three registers, SweTrau, NTDB and TITCO cohort. >15 years was the cut off because everything below that activates trauma team for pediatrics in many cases and is also used in various studies as the age limit(3)(4)(5).

Data sources/measurement

Every parameter will be obtained from NTDB, SweTrau and TITCO. SBP, RR, GCS, ASA, NISS and ISS sex and age have been registered or calculated by workers in hospitals(physicians, nurses, assistant nurse).

Bias

Possible when coding. The programming will be double checked by an experienced colleague. Confirmation bias is also a risk when conducting data.

Study size

All patients in SweTrau, NTDB and TITCO over 15 years of age and that fits the inclusion criteria to be in the register.

Patient cohort

Age, sex, ASA(American Society of Anaesthesiologist physical status classification system), ISS(Injury Severity Score) and NISS(New ISS).

Variables

SBP, RR and GCS will be used as quantitive variables to develop the models.

Model outcome: Mortality within 30 days of the traumatic event

Study outcome: ISS. ISS ≥15 major trauma. ISS<15 minor trauma. (hur lägger man till “större än eller lika med”?)

Statistical methods

The data will be derived from three sources. SweTrau, NTDB and TITCO. Each dataset will be splitted in three samples. One development, updating and validation sample. In the development sample, the model is going to be developed and put in the validation samples of itself and to the others aswell. For example: A model is going to be developed in Swetrau development sample. This model will be put in its own validation sample to see how well it performed. Also it will be put into the validation sample of both NTDB and TITCO separately to estimate how well the model performs when used in a different register. This will be repeated for each dataset. Then to answer the second question a updating sample will be developed and put in the same way like previous example. The models will be made from using SBP, RR and GCS(independent variable) and all cause mortality within 30 days(dependent).

The development and validation sample will consist of a number of events and non events. Events being mortality within 30 days and non events patients that survived 30 days after the trauma. The models will therefor be developed, validated, updated and then compared. Everything will be made in the R program. The models will be made from logistic regression. As mentioned above, SBP, RR and GCS will be used in the model development. All cause mortality within 30 days will be used as a dependable variable.

After the model have been developed, it needs to be validated. Using the model to estimate probability of all cause 30 day mortality in each validation sample will give us model performance which will be measured with values of over- or undertriage(together mistriage). The model will be updated and then compared (with 95% confidence intervals). This procedure(development, validation, update and comparison) will be repeated for every country.

**Ethical considerations**

Autonomy-respect

The patients can withdraw from the register if they choose to do so. They are not in all cases informed that the information can be used in a study. In that case, we have a responsibility to treat the data with respect like we will do with all data used in this study.

The principle of beneficence

The study will hopefully improve the management of trauma care and contribute to better healthcare for patients.

The principle of nonmaleficence

No intervention is being made so there is no risk for physical harm. Data leakage will be the biggest risk for harm and integrity.

The principle of justice

All patients are depersonalized and anonymous when the data is being obtained. The information gained from the registry will either way be treated equal.

*Ethical Permit*

2015/426-31 and 2016/461-32

**Referenser**

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**Time plan**

3-15 September: Write study plan. 16-28 September: Write analysis plan. 29 September - 28 October: Initial analysis and prepare half time report. 29 October - 30 November: Complete analysis and write results. 1 December - 2 January: Write discussion and finalise thesis.

**Backup plan**

All the data exist and there is minimal risk that the data can not be used. One potential problem is that the programming takes longer than usual. In this case there will be experienced (supervisor or other) people that will guide me along the way.