Official title of the study:

Implementation of the Individual Danish Emergency Process Triage (I-DEPT)

Statistical analysis plan

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Principal Investigator (PI) Professor Kasper Iversen[1,2], M.D., D.M.Sc.,

Co-PI Pernille B. Nielsen, M.D.

Chief Statisticians

Kasper Madsen, Theis Lange, Ph.D.

Contributors to analysis and interpretation of data

Statisticians, Primary Investigators and Steering Committee

This document contains the statistical analysis plan for the I-DEPT study. The statistical analysis plan has been completed prior to the availability of the outcome data and aims to clarify the analyses.

Short summary

Triage systems have been implemented in most emergency departments (ED) to minimize crowding and treatment delays that can result in adverse patient outcomes. Triage systems with limited room for clinical judgment are used by emergency departments (EDs) worldwide. The Individual Danish Emergency Process Triage (I-DEPT) is a new simplified triage system with a clinical assessment. I-DEPT is designed to simplify risk prediction and to reintroduce clinical judgment as the central part of triage. In this trial we compare I-DEPT with a traditional triage model in terms of risk prediction and patient outcomes, with a focus on 30-day mortality.
Intervention: I-DEPT is a new triage system constructed from data collected from 12 000 ED patient visits at a large Danish hospital. I-DEPT solely consists of a quick score of vital signs followed by a basic clinical assessment by an ED nurse. The final triage level results from a score calculated after measurement of vital signs corresponding to a triage level of 1–4, that is then adjusted by the ED nurse, who can either up-triage (up to 2 steps) or down-triage (1 step) according to clinical assessment with no specific explanation needed. The development of the I-DEPT (former called Copenhagen Triage Algorithm, CTA) has previously been described in detail (1). I-DEPT has previously been compared to the Danish Emergency Process Triage (DEPT) which is a local adaption of Adaptive Process Triage. The two triage systems were compared in a non-inferiority, two-center cluster-randomized crossover study, where I-DEPT was non-inferior to a traditional triage algorithm by short term mortality, and superior in predicting 30-day mortality (2).
Control: DEPT; is a local adaption of the Adaptive Process Triage (ADAPT), triage model developed in Sweden in 2006 like most other well-known triage models, was the standard triage model used in the study. It includes the presenting (or chief) complaint in addition to a list of vital signs with cut-off values corresponding to each triage level. These are both registered, and the final triage level is determined by the most urgent triage level assigned
Both triage systems identify five levels of urgency with colors (red, orange, yellow, green,

and blue). The least urgent of these (the fifth level) was excluded from this study as it is defined as non-emergent patients (e.g. minor injuries) and includes no indication for measuring vital signs.

Aim of the study

The aim of the study is to investigate the impact of I-DEPT that has a systematic involvement of clinical assessment and the possibility to adjust the triage. I-DEPT will be compared to the existing DEPT with a focus on mortality, critical illness/distribution within risk groups and time to assessment

Hypothesis

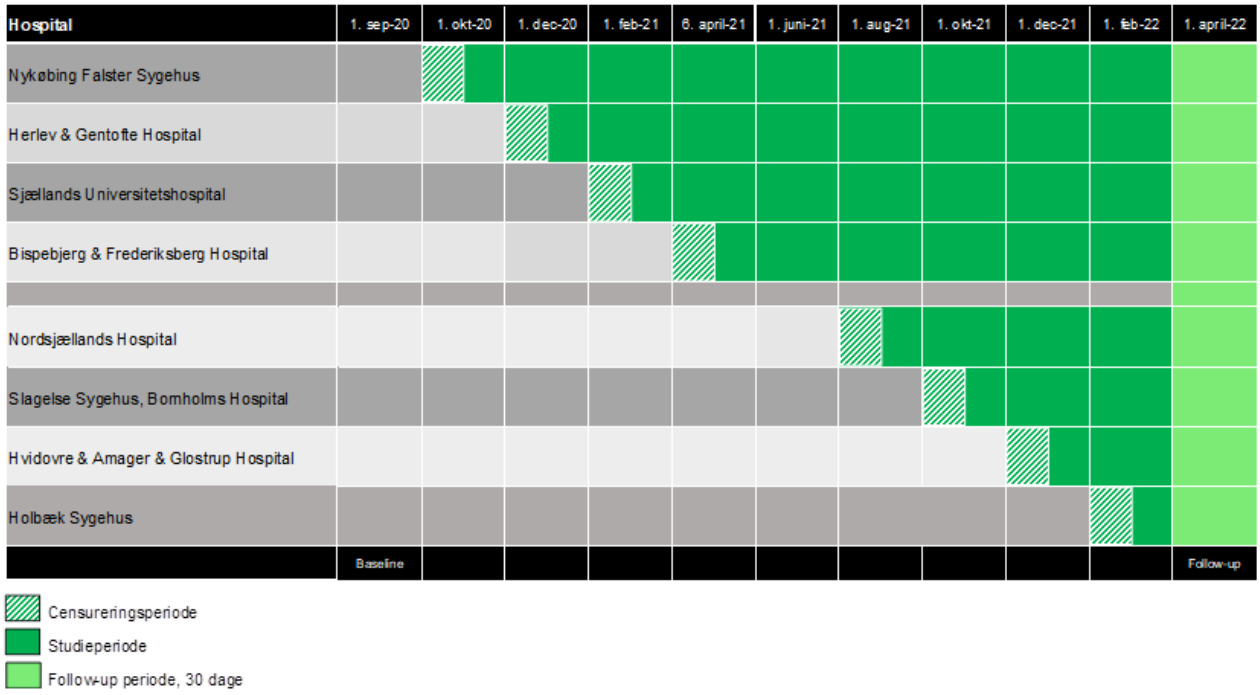
The main hypothesis is that I-DEPT will be non-inferior to the existing DEPT regarding 30-day mortality.

Timeline

The study will start at October 1, 2020. Due to implementation patients will be enrolled from November 1, 2020 with planned end of inclusion, April 1, 2022. Follow-up will be concluded on May 1, 2022. The primary analysis will be conducted when the last patient has been followed for 30 days and data is available, which is expected to be November 2022.

Study design;

Figure 1: Cluster-randomised step-wedged" design



Note: There was a break between implementation at Bispebjerg og Nordsjaelland

The reason for the break was organisational challenges due to summer holidays with lower staffing in that period.

Inclusion/Exclusion criteria

Eligible Emergency departments

1. Located in the Capital Region or Region Zealand in Denmark
2. Arrival of acutely admitted patients at the on-site Emergency department
3. Systemised use of Triage

Patient inclusion criteria

1. ≥18 years at contact to participating emergency department

Patients will be included at the first admission in the study period (index admission) and will remain in this group (intervention/control) for a follow-up period of 30 days.

All subsequent admissions (readmissions) will be ignored with regards to treatment group (i.e., you stay in the group you were first admitted into).

Exclusion

1. Patients presenting in the ED with minor injuries (e.g. sprained ankle or minor cuts/abrasions) as they are triaged as blue (level 5) in both systems which typically precludes measurement of vital signs
2. Patient admitted directly to specialty ward (without contact to the emergency department)

Definition of clusters

Eligible hospitals can consist of one or two units. A hospital is defined based on its administrative organisation and catchment area. Each hospital will generate one cluster and two (time) periods (control and intervention). See schematic figure 1

Randomisation

Prior to the study start participating clusters will be randomised to start as either intervention or control. Eight clusters are available. The randomisation were performed using computer-generated numbers.

Ethics

The study was presented to the Regional Ethics Committee, who decided that no formal approval was needed in accordance with Danish law. Data management has been approved by the Danish Data Protection Agency (ID: P-2022-405).

Data:

The first 30 days after implementation of I-DEPT will be censored to minimize carry over effect. At follow-up (30 days after inclusion of last patient) the following data is collected from the National Patient Registry (NPR) and the electronic patient journal system Sundhedsplatformen:

- Contacts with the hospital system in the trial period.
- Information regarding admissions (date, time and place of admission and discharge, admission disrupted by patient).

- Information on vital signs and triage level
- Diagnoses (follow-up during study period, historical and in relation to index admission).
- Date of death or emigration (only very few cases of emigration are expected).

Outcomes:

Following outcomes are registered at clinicaltrials.gov (NCT04571021) on September 30, 2020

I-DEPT= Intervention

DEPT = Control

Primary outcome:

- All-cause mortality within 30 days following triage in the index admission by non-inferiority (I-DEPT vs. DEPT)

Secondary outcomes

- All-cause mortality within 2 days following triage in the index admission (I-DEPT vs. DEPT)
- Distribution of patients within triage categories (I-DEPT vs. DEPT) including all-cause mortality within 30-days
    - There are four categories in both triage algorithms used in this study: (green (least urgent), yellow, orange, and red (most urgent))
- Patients in the orange triage category (I-DEPT vs. DEPT) – including all-cause mortality within 30-days
    - Number of patients assigned to the orange category – previous study showed a significant decrease in this patient group
- Doctor assessment (I-DEPT vs. DEPT)
    - Time from triage to arrival of a doctor – Note* Timestamp for arrival of doctor need to be discussed
- Length of stay (I-DEPT vs. DEPT)
    - The total number of days admitted to a hospital within 30 days
- Time in the Emergency Department (I-DEPT vs. DEPT)

    - Time spent in the Emergency department from triage to either admission, transfer or discharge

- Patients left without being seen (I-DEPT vs. DEPT)
    - Number of patients leaving the Emergency Department without being assessed by a doctor

- Number of admissions to ICU (I-DEPT vs. DEPT) within 24 hours

Additional secondary outcomes – added July 2022

- Days alive out of hospital within 30 days after admission (I-DEPT vs. DEPT)
- Analyses of primary and secondary outcomes will be repeated with 60 days of censoring after implementation.

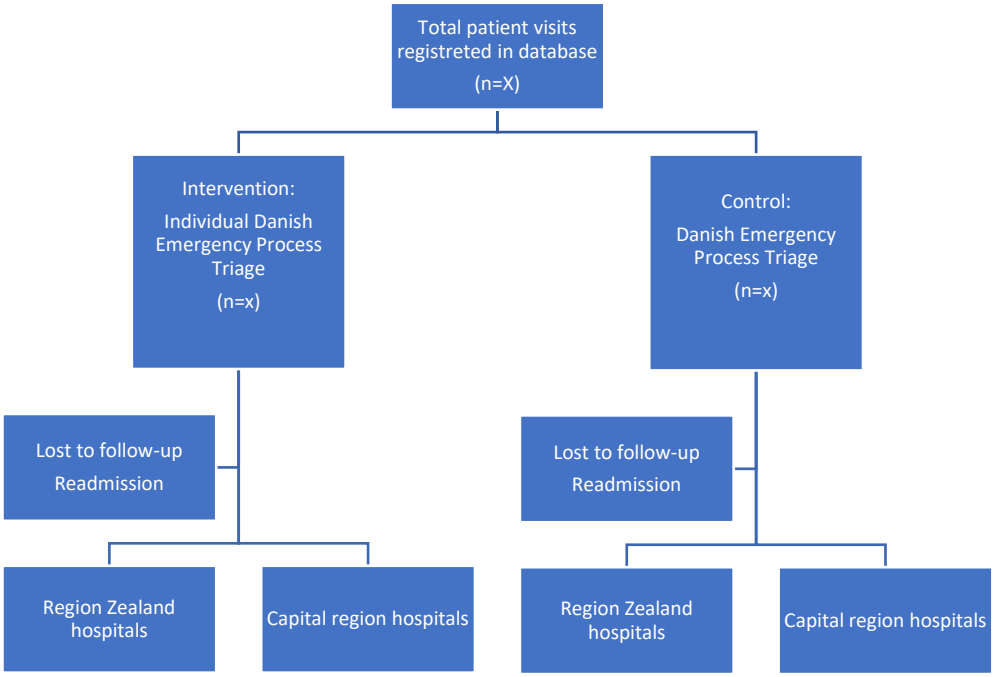
Additional Post-hoc analyses – added January 2023

- Doctor assessment (I-DEPT vs. DEPT)
  Time from triage to arrival of a doctor – Note* Timestamp for arrival of doctor need to be discussed – divided into triage groups.
- Analyses of primary and secondary outcomes will be repeated with 90 days of censoring after implementation.

Statistical plan for main outcome paper

Consort diagram:

Schematic consort diagram – following will be reported



Baseline description of groups:

Table 1

	I-DEPT	DEPT	P value
Triage: Red (most urgent), n (%)			*p=X*
Female, n (%)			
Age, years,			
Systolic Blood Pressure, mmHg			
Heart rate, pr. min			
Respiratory rate, pr. min			
Arterial oxygen saturation, %			
Temperature, degrees Celsius			
Triage: Orange, n (%)			*p=X*
Female, n (%)			
Age, years,			
Systolic Blood Pressure, mmHg			
Heart rate, pr. min			
Respiratory rate, pr. min			
Arterial oxygen saturation, %			
Temperature, degrees Celsius			
Triage: Yellow, n (%)			*p=X*
Female, n (%)			
Age, years,			
Systolic Blood Pressure, mmHg			
Heart rate, pr. min			
Respiratory rate, pr. min			
Arterial oxygen saturation, %			
Temperature, degrees Celsius			
Triage: Green (least urgent), n (%)			*p=X*
Female, n (%)			
Age, years,			
Systolic Blood Pressure, mmHg			
Heart rate, pr. min			
Respiratory rate, pr. min			
Arterial oxygen saturation, %			
Temperature, degrees Celsius			
Missing triage			*p=X*

Table of summary statistics for patients for each group (intervention or control) will be presented for each triage of the four triage groups with baseline variables shown in Table 1.

Continuous variables will be summarized with mean and standard deviation or interquartile range (based on non-missing sample size).

Categorical variables will be reported as frequency and percentages (based on non-missing sample size) and number of missing values.

Categorical variables will be tested with chi-square.

Primary outcome analysis:

The primary outcomes will be an analysis of all-cause mortality within 30 days.

Patients will be followed as one cohort and data will be analysed as randomised and in accordance with the intention-to-treat principle.

- Patients (18+) will be included at the first admission at the participating hospitals in the study period (index admission) and will remain in this group (intervention/control) for follow-up of 30 days.
- Admission is defined as any contact to an emergency department where a Triage is performed
- Any patient lost to follow-up will be censored at the last time known to be alive.

Censored periods: Each period will start with 30 days of implementation, and the end of the study is followed by an observation period of 30 days. Periods of implementation and observation will be censored in the analyses (patients admitted in these periods will not be included in the analyses).

Main analysis

Logistic regression that accounts for clustering with adjustment for hospital ID, age, and sex, period (e.g., calendar month).

Results will be presented with distribution n (%) and Odds Ratio with a 95% Confidens interval and Risk difference with 95% Confidens interval. The assumption is that the actual intervention effect is 0. Non-inferiority will be assessed based on the risk difference with a non-inferiority margin (Δ) of 0.5%.

Cumulative incidence plots (1-survival) will be calculated using the Kaplan-Meier method and presented with Hazard Ratio and 95% Confidens interval and adjusted for the same variables as the main analysis.

Additional cox regression censoring for "Do not resuscitate order" will also be performed.

Sensitivity analyses of the primary endpoint:

In addition to the ITT analysis, a per-protocol analysis will be performed. In this analysis, interventional patients with missing or incomplete triage will be excluded.

Subgroup analyses of primary endpoint:

The primary outcomes will be calculated for the following subgroups, including a test for interactions.

Results will be presented with distribution n (%) and Odds Ratio with a 95% Confidens interval and illustrated in a Forrest plot and/or Cumulative incidence plots (1-survival) will be calculated using the Kaplan-Meier method.

Following subgroups are planned:

- Triage groups (green to red)
- Age (≤39 years, 40 to 69 years, ≥ 70 years)
- Medical specialties
- Surgical specialties

Secondary endpoints:

<u>Patients in the orange triage category (I-DEPT vs. DEPT) – including all-cause mortality within 30-days</u>:

Main analysis

Same as primary outcome:
Logistic regression that accounts for clustering with adjustment for hospital ID, age, and sex, period

Results will be presented with distribution n(%) and Odds Ratio with a 95% Confidens interval

Doctor assessment (I-DEPT vs. DEPT)

- Time from triage to arrival of a doctor

Main analysis

Distribution will be investigated with Boxplot

Cox regression following the same adjustment principles as for the primary outcome (age, sex, hospital id, period)

Results will be presented with Hazard ratio with a 95% Confidens interval

Length of stay (I-DEPT vs. DEPT)

- The total number of days admitted to a hospital within 30 days

Main analysis

Distribution will be investigated with Boxplot

Linear regression following the same adjustment principles as for the primary outcome (age, sex, hospital id, period?)

Results will be presented with mean days (SD or Interquarentile range) for both groups and difference in hours with a 95% Confidens interval

Time in the Emergency Department (I-DEPT vs. DEPT)

- Time spent in the Emergency department from triage to either admission, transfer or discharge

Main analysis

Linear regression following the same adjustment principles as for the primary outcome (age, sex, hospital id, period?)

Results will be presented with mean hours (SD eller Interquarentile range) for both groups and difference in hours with a 95% Confidens interval

Patients left Emergency department without being seen (I-DEPT vs. DEPT)

- Number of patients leaving the Emergency Department without being assessed by a doctor

Main analysis
Analysis – Logistic regression that accounts for clustering with adjustment for hospital ID, age, and sex, period??

Results will be presented with distribution n (%) and Odds Ratio with a 95% Confidens interval

Number of admissions to ICU (I-DEPT vs. DEPT) within 24 hours

Main analysis
Analysis - Logistic regression that accounts for clustering with adjustment for hospital ID, age, and sex, period

Results will be presented with distribution n (%) and Odds Ratio with a 95% Confidens interval

Days out of hospital within 30 days after admission (I-DEPT vs. DEPT)

Main analysis

Distribution will be investigated with Boxplot

Linear regression following the same adjustment principles as for the primary outcome (age, sex, hospital id, period?)

Results will be presented with mean days (SD or Interquarentile range) for both groups and difference in hours with a 95% Confidens interval

Handling of missing data:

The primary outcome analysis should be subject to no or little missing data as it is based on Danish register data. Patients lost to follow-up (tourists) will be censored at the last registration.

If more than 5% of data is missing on a variable included in planned analyses, multiple imputation will be introduced.

Additional Post-hoc analyses (planned ultimo July 2022)

Analyses of primary and secondary outcomes will be repeated with 60 days of censoring after implementation.

Analyses of primary and secondary outcomes will be repeated with 90 days of censoring after implementation.