Multi-centre validation and clinical experience of EzaPredictive for the Emergency Room and clinical departments

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Objective 1: Compare the predictions of the EzaPredictive 1.0 ML models for hospital admission, ER LOS, and hospital LOS with healthcare professional predictions. Objective 2: Assess healthcare professional experience and acceptance of EzaPredictive...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53270

Source
ToetsingOnline

Brief title
Validation Study EzaPredictive 1.0

Condition

- Other condition

Synonym
nvt

Health condition

verblijfsduur en/of opname van SEH patiënten en ligduur klinische patiënten

Research involving

Human

Sponsors and support

Primary sponsor: Expertisecentrum Zorgalgoritmen
Source(s) of monetary or material Support: vanuit Expertisecentrum Zorgalgoritmen;opgericht door 29 SAZ ziekenhuizen

Intervention

Keyword: Algorithms, Clinical Departments, Emergency Room, Medical Device

Outcome measures

Primary outcome

The main study endpoints for the first objective (comparing predictions of ML and healthcare professionals) are the predictive performance of healthcare professionals and ML models.

The main study endpoints for the second objective (assessing healthcare professional experience of ML software) are the questionnaire outputs regarding healthcare professional experience with the EzaPredictive 1.0 software.

Secondary outcome

The secondary study endpoints for the first objective (comparing predictions of ML and healthcare professionals) is the inter-rater reliability between healthcare professionals and ML models.

Study description

Background summary

Patient flow management has become increasingly important for hospital systems. Novel machine learning (ML) methods may aid by giving information that supports

health care professionals in their patient flow management at the emergency room (ER) and clinical departments. However, few of these prediction models have been implemented in clinical practice and we know little about the added value of these tools for supporting health care professionals in their patient flow management. Moreover, few studies have investigated the clinical experience and acceptance of these ML support tools.
We therefore propose to study these aspects for the EzaPredictive 1.0 tool. EzaPredictive 1.0 provides explainable ML predictions for hospital admission, ER length of stay (LOS), and hospital LOS.

Study objective

Objective 1: Compare the predictions of the EzaPredictive 1.0 ML models for hospital admission, ER LOS, and hospital LOS with healthcare professional predictions.
Objective 2: Assess healthcare professional experience and acceptance of EzaPredictive 1.0 for supporting their patient flow management.

Study design

For objective 1, we plan to perform a multi-centre observational study in at least two Dutch general hospitals that are different from the hospitals where the EzaPredictive 1.0 software was developed and two Dutch general hospitals that participated in the development of EzaPredictive 1.0. In this study, we will compare the predictive performance and inter-rater reliability of the (individual) healthcare professionals, and the ML algorithms contained in the EzaPredictive 1.0 software. Predictions will be collected across two phases. During the first phase, healthcare professionals are blinded to the ML outcomes. During the second phase, ML outcomes for the patient are shown to healthcare professionals after they*ve reported their predictions for that patient.
For objective 2, we give the healthcare professionals the full experience of EzaPredictive 1.0 in a third phase of the study. In this phase the overview page with ML predictions of all patients of a department are shown to healthcare professionals, in addition to the ML predictions per patient. A the end of this third phase, we distribute questionnaires to gather healthcare professional feedback on the acceptability and usability of EzaPredictive 1.0 in supporting them in their patient flow management.

Study burden and risks

Risks: The current investigation will not directly affect patient care. During the second phase of the observational study, real-time ML predictions of a patient will be shown after healthcare professionals have provided their own estimates for that patient to encourage interaction with and learning from the tool*s insights. During the third phase of the study, real-time ML predictions

of a patient as well as the overview of real-time ML predictions for all patients of a department are shown to assess healthcare professional experience of the EzaPredictive 1.0 software in a qualitative questionnaire study.
The intended use of the EzaPredictive 1.0 software is limited to support on patient flow management, explicitly excluding diagnostic or therapeutic use (MDR class I). Healthcare professionals will be clearly instructed on the intended and correct use of the EzaPredictive 1.0 software. Any effect during this study will therefore be logistic in nature and at most affect the timing of certain decisions if permissible (e.g., arranging a hospital admission). The risks for patients associated with this study are therefore negligible. The risks for healthcare professionals are minimal with proper training.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthcare professionals in the participating hospitals, who
(1) are involved in patient flow management,
(2) work in an emergency department, acute admission department or inpatient department during the study period and
(3) have received the necessary instruction beforehand

Exclusion criteria

Healthcare professionals are excluded when it is not realistic to expect that he/she will be able to make estimates for a minimum of 10 patients, given the number of shifts he/she has scheduled during the study period.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-10-2023
Enrollment:	250
Type:	Actual

Medical products/devices used

Generic name:	EzaPredictive 1.0
Registration:	No

Ethics review

Approved WMO Date:	20-09-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84800.000.23