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Hospital alerting via electronic noticeboard (HAVEN)

Submission date
20/05/2016

Recruitment status
No longer recruiting

Registration date
27/07/2016

Overall study status
Completed

Last Edited
25/03/2021

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Late recognition of deteriorating patients (i.e their condition getting worse) in hospitals causes delays in treatment for these patients, which then results in an increase in mortality (ill health) and morbidity (death) despite the widespread introduction of vital sign-based "early warning scores".
Therefore, developing systems that recognise earlier when a patient is at risk of a severe but reversible deterioration in health is a key goal for the NHS. The HAVEN Project aims to produce a hospital-wide IT system that enables a continuous risk assessment in all hospital patients, and predicts those at risk of deterioration.

Who can participate?
Data are collated from the records of all adult patients over the age of 18 who are admitted to all participating hospitals. Data without identifying information are sent to the central office in Oxford. Staff members from Oxford and Portsmouth trusts are also recruited to help design the user interface.

What does the study involve?
An IT system is developed that routinely stores electronic data (including demographics, laboratory results and vital signs recordings) to create a continuous risk assessment. Data is gathered from different local databases; at present they are not integrated or displayed in a way that supports decision making or calculation of patient risk. Risk prediction algorithms are then developed (programs that look at the information and decide whether a patient is likely to be at risk of deteriorating) and tested. These use the records of patients who are admitted to hospital and then admitted to an intensive care unit (ICU) after two or more days in hospital. The information about these patients illustrates the pathway from the first signs of deterioration on the ward to ICU admission. There is no direct involvement for patients who are included in the project. Information from their hospital stay is collected by the NHS IT groups in a way that will allow the university-based research team to review the information without knowing who the people are. During the project, the automatic system is checked to see whether it has correctly recognised if patients needed intensive care treatment during their hospital stay. Doctors and nurses who are part of the research team need access to individual patient information to check this. The algorithms are used to create an interface allowing clinical staff to identify, rank,

review and treat patients who, without acute medical intervention (treatment), will deteriorate and require ICU admission. Members of staff are asked questions about the information they would look for to recognise that a patient was becoming unwell. They are then observed as they carry out their usual daily tasks.

What are the possible benefits and risks of participating?
There are no risks to patients whose data is used in the project and the potential benefit is the development of a hospital-wide IT system that is capable of recognising patients at risk of deterioration. Clinical participants (healthcare staff) will need to find time to meet with the research team to discuss the project plans in some detail as well as participate in the cognitive task analysis and user interface testing.

Where is the study run from?
The project is run from the University of Oxford. It takes place at the University of Portsmouth, Portsmouth Hospitals NHS Trust, and Oxford University Hospitals NHS Foundation Trust. Other hospitals taking part provide data only.

When is the study starting and how long is it expected to run for?
August 2015 to March 2023

Who is funding the study?
Department of Health and the Wellcome Trust through the Health Innovation Challenge Fund provided the initial project funding. The ongoing work is funded by the NIHR Oxford Biomedical Research Centre.

Who is the main contact?
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Contact information

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Public

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Protocol serial number
160405-HAVEN-v1

Study information

Scientific Title
Hospital Alerting Via Electronic Noticeboard (HAVEN)

Acronym
HAVEN

Study objectives
Production of a hospital-wide IT system that enables a continuous risk assessment in all hospital patients, optimised for end-user functionality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. South Central Oxford C Research Ethics Committee, 20/06/2016, ref: 16/SC/0264
2. Confidentiality Advisory Group, 04/07/2016, ref: 16/CAG/0066

Primary study design
Observational

Study design
Observational mixed quantitative/qualitative study

Study type(s)
Other

Health condition(s) or problem(s) studied
Patients at risk of deterioration (and requiring intensive care unit admission) in hospital

Interventions

Patients will be identified by the system as likely (or not) to require intensive care unit admission. The system generated results will be compared against reality and discrepancies reviewed.

Creation of the risk prediction score will be a multi-stage process involving:
1. Candidate Variable Selection
Candidate variables will be selected by a systematic review of variables associated with in-hospital deterioration; analysis of data of 5000 admissions to ICUs at the Royal Berkshire Hospital, the Churchill Hospital, Oxford and the John Radcliffe Hospital, Oxford to identify common factors to patients admitted from general wards; analysis of 127,000 patient episodes in Portsmouth Hospital to obtain information on patents who did not require ICU admission, and compare the frequency of candidate variables between those who deteriorated and those who remained stable; and a modified two-round
Delphi Process to review possible candidate variables identified in the above processes and to obtain further suggestions for variables of interest.
2. Score Creation
To create the risk prediction score, the project will utilise standard statistical approaches (including linear and non-linear regression), machine learning techniques and techniques such as Gaussian processes for trend analysis using trajectories in multi-dimensional input space. Algorithms will be developed in which correlations between the various time-series are learned automatically, allowing early detection of physiological deterioration by identifying unexpected changes in correlation or other changes in dynamics. The algorithms will include probabilistic, Bayesian methods that can cope with missing or artefactual data from one or more input time-series in a principled, robust
manner, as is required for a realistic real-time risk estimation system.
3. Score Validation
The risk prediction score will be validated by comparing observed ICU admissions with predicted ICU admissions. The goodness-of-fit of observed to expected ICU admissions will be described using the Hosmer-Lemeshow (HL) test.
4. Clinical Expert Review
The first risk prediction model will be run on new inpatient episodes. A list of false negatives (patients in whom the algorithm reported a low risk, but the patient was admitted to ICU) and false positives (patients in whom the algorithm reported a high risk, but the patient was not admitted to ICU) will be generated. Clinicials from the project team to examine these patients' standard clinical records (EPR, paper notes, etc) to determine new factors (or combinations of factors) used by the clinical team to
determine the patients' need for ICU.
5. Score Re-validation
The score will be re-validated following the modifications made to the risk algorithm after step iv.

Intervention Type
Other

Primary outcome(s)
1. Validated risk prediction score identifying at least 50% of deteriorating patients admitted to the ICU at least 12 hrs ahead of their admission, with a false positive rate of under 60%. This will be validated by comparing observed ICU admissions with predicted ICU admissions. The goodness-of-fit of observed to expected ICU admissions will be described using the Hosmer-Lemeshow (HL) test. This outcome will be measured during the second half of 2017
2. Data aggregation software in place capable of supplying all data fields to the algorithm

3. Working interface complete with functional underlying software and prototype graphics. A minimum success criterion would be usability scale results above average (>68%). This will be designed using Human Factors methods. This will involve process mapping and task analysis of existing workflows used to recognise deterioration of patients on the ward. Knowledge gained will be used to produce a design specification for the interface. This will then be tested formally assessing efficiency, effectiveness and user satisfaction as outlined in ISO 9421

The end of the study will be a key timepoint for overall evaluation of the outcomes from the project.

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Aged 16 years and over
1. Admitted to any hospital from Portsmouth Hospitals NHS Trust since 1st January 2010 or Oxford University Hospitals NHS Foundation Trust since 1st January 2014

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
All

Total final enrolment
496710

Key exclusion criteria
1. Patients <16 years of age
2. Patients whose data are not entered into local electronic patient records

Date of first enrolment
01/08/2015

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Oxford
United Kingdom
OX3 9DU

Study participating centre
Portsmouth Hospitals NHS Trust
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Royal Berkshire NHS Foundation Trust
London Road
Reading
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RG1 5AN

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Department of Health/Wellcome Trust Health Innovation Challenge Fund

Funder Name
NIHR Oxford Biomedical Research Centre

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. Currently researchers need to apply to Peter Watkinson (HAVEN Chief Investigator) to access the de-identified data. Applicants will need to outline their hypothesis and analysis plan. Valid submissions will be reviewed by a 'Data Access Committee' who will grant access (or not). At the end of the HAVEN project the trialists will provide a full access statement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2021	25/03/2021	Yes	No
Protocol article	protocol	11/09/2019	31/07/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	development of mathemetical model	16/07/2020	31/07/2020	Yes	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes