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Feasibility study of MiADE, a system for analysing text in electronic health records at the point of care

Submission date 10/10/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/10/2023	**Overall study status** Completed	
Last Edited 17/03/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This study aims to evaluate a computer program called MiADE which is designed to make it easier for clinicians to enter information in electronic health records in a structured, coded form. The study will assess the performance and utility of the system, and inform future improvements and developments.

Who can participate?
Clinicians at UCLH and inpatients managed under the care of a participating team during the study period

What does the study involve?
The study is a before-and-after comparison of the recording of structured information in electronic health records with and without the MiADE system. Clinicians participating in the study will be trained in the use of the new system and asked to fill in questionnaire surveys. The researchers will compare the average number of structured entries recorded per patient before and after switching on the MiADE system. They will observe a sample of outpatient consultations and interview a sample of patients to find out how the system affects their experience of the consultation. They will also interview a sample of clinicians working in the inpatient and outpatient settings.

What are the possible benefits and risks of participating?
Participants will be able to improve the usability of electronic health record systems, and thereby improve the quality of data within the systems. This will support safer patient care and better research. The risks for study participants are minimal.

Where is the study run from?
University College Hospital London (UCLH) (UK)

When is the study starting and how long is it expected to run for?
December 2020 to March 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Anoop Shah, a.shah@ucl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
322887

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57302, IRAS 322887

Study information

Scientific Title
Non-randomised feasibility study of point of care natural language processing using the MiADE system to assist structured clinical documentation

Study objectives

The study hypothesis is that the MiADE point of care natural language processing system increases the number of diagnoses, medication and allergies recorded by clinicians in a structured way in the electronic health record.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/08/2023, South Central - Hampshire A Research Ethics Committee (Health Research Authority, 2 Redman Place, London, E20 1JQ, UK; +44 (0)207 104 8120, +44 (0)207 104 8210, +44 (0)207 104 8290; hampshirea.rec.hra.nhs.uk), ref: 23/SC/0221

Study design
Non-randomized; Both; Design type: Process of Care, Other, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Health services research

Interventions
This study consists of two substudies (inpatient and outpatient studies), each of which are non-randomised intervention studies with before and after comparison. The outpatient study also includes an embedded qualitative substudy for a subset of consultations, with patient and clinician interviews.

Three time periods will be analysed. The primary comparison will be between pre-MiADE and post-MiADE once clinicians have been consented into the study, as they will have received training and the comparison will show the change in behaviour that results from the system being available. There is a possibility that structured recording may improve after clinicians enter the study because of the Hawthorne effect, so a prior 8-week period will also be studied in order to evaluate this effect.

The MiADE system will be made available according to clinician-level permissions, which can be switched on or off. This will allow clinicians' use of problem lists and other structured data to be compared before and after the system is switched on. There will be a period of at least 4 weeks between clinicians entering the study and having the MiADE system switched on.

Study 1 (Outpatient study):
Consultants and specialty doctors who see outpatients will be recruited via institutional communications and networks. Interested clinicians will be consented and receive training on the use of the system, as described below. They will be asked to fill in a survey on their level of experience and comfort with EHR systems. They will have the MiADE system switched on within their EHR user profile so that they have access to it from a particular date. Electronic health records of outpatients in the clinics linked to the clinician will be assessed between the training session and MiADE switch-on, and for 8 weeks after MiADE is switched on. The crude number of entries per patient in the problem list, medication record and allergy record will be calculated for outpatients seen by the clinician during this interval.

Embedded qualitative substudy:
For each clinician in the qualitative substudy, a sample of at least 2 outpatient consultations will be observed before the MiADE system is switched on for the clinician, and 2 outpatient consultations will be observed after the MiADE system is switched on. For each observed consultation, consent will be sought from the patient prior to the consultation. The researcher will sit in the consultation and observe the overall consultation, as well as timing the overall consultation and how long the clinician spends interacting with the EHR. A semi-structured interview will be held with the patient after the consultation either in person (if clinic space is available) or by telephone.

After MiADE has been switched on and clinicians have been using it for at least a month, they will undergo a semi-structured interview with the researcher.

Study 2 (Inpatient study):
Inpatient clinical teams will be recruited to the study. Within each team, the clinicians (consultants, specialty and foundation doctors who see inpatients) will be recruited, consented and trained. Doctors rotate through clinical teams every few months, so the MiADE system will be switched on for the relevant clinicians at a time point halfway through the four-month rotation, to allow comparison of the completeness of structured recording of diagnoses on the problem list before and after the switch on. The ‘gold standard’ of recording diagnoses will be the ICD-10 coded billing diagnoses which are assigned by the clinical coding team based on a review of the entire medical record after a patient is discharged. Diagnoses will be aggregated by groups of ICD-10 codes, and a diagnosis will be considered as included in the problem list if any SNOMED CT concept which maps to an ICD-10 code in the group was recorded on or prior to the patient’s discharge date. This flexibility of mapping will be permitted as different professionals may assign different clinical codes to the same condition based on their interpretation and judgement, especially for cases where an exact code does not exist. The proportion of ICD-10 code groups with a problem list entry will be calculated per patient and aggregated across the patients under the care of the clinical team during the study period. All inpatient clinicians will be asked to complete surveys before and after having the MiADE system switched on. For a sample of 5 clinicians, semi-structured interviews will be held with the clinicians after they have been using MiADE for at least two weeks, using the same questions as for outpatient doctors except for the question on medications, as MiADE for inpatients does not handle medications.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Study 1 (outpatient):
Number of structured entries for diagnoses, medication and allergies recorded by the clinician in outpatient consultations; Timepoint(s): Comparison before and after switching on the MiADE system

Study 2 (inpatient):
The proportion of ICD-10 coded billing diagnoses for which a similar SNOMED CT concept is present in the problem list for inpatients, evaluated at the point of discharge; Timepoint(s): Comparison before and after switching on the MiADE system

Secondary outcome measures
1. The proportion of structured data items suggested by MiADE that are accepted by the clinician for entry into the structured record during the period that the MiADE system is active
2. The distribution of computing time required per consultation note during the period that the MiADE system is active
3. Clinician and patient perceptions of structured data recording in electronic health records and the MiADE system: quantitative measures from categorical survey responses and qualitative measures from interviews and free-text survey responses, at least 2 weeks after the MiADE system has been switched on

Overall study start date
01/12/2020

Completion date
31/03/2025

Eligibility

Key inclusion criteria
Study 1 clinician inclusion criteria:
Any interested clinicians who have their own clinic list at UCLH and see outpatients, who consent to be part of the study. A subset of at least five clinicians will be purposively sampled to include a range of specialties for the observation substudy, and they will undergo observed consultations.

Study 1 patient inclusion criteria:
All outpatients seen by the clinician from 2 months before being consented until 2 months after the MiADE system is switched on for included clinicians. For clinicians selected for observation (at least 5), the researchers will observe at least two consultations from one or more clinics before and two consultations from one or more clinics after the MiADE system is switched on will be observed. Hence the minimum number of observed consultations will be 20.

Study 2 clinician inclusion criteria:
All clinicians within interested inpatient teams at UCLH.

Study 2 patient inclusion criteria:
All inpatients managed under the care of a participating team during the study period.

Participant type(s)

Patient, Health professional

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
121

Key exclusion criteria
There are no patient exclusions.

If patients are unable to give written consent, the study will be discussed with a consultee who will be asked to give advice as to whether the patient would wish to be included in the study. A decision on whether or not to include the patient in the study will be based on a best interests assessment.

Date of first enrolment
23/10/2023

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Uclh
250 Euston Road
London
United Kingdom
NW1 2PQ

Study participating centre
University College Hospital Elizabeth Garrett Anderson Wing
235 Euston Road

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United Kingdom
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Study participating centre
Hospital for Tropical Diseases
4 St Pancras Way
London
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Study participating centre
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Study participating centre
National Hospital for Neurology & Neurosurgery
Queen Square
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WC1N 3BG

Study participating centre
Royal London Hospital for Integrated Medicine
60 Great Ormond Street
London
United Kingdom
WC1N 3HR

Study participating centre
Uch at Westmorland Street
16-18 Westmoreland Street
London
United Kingdom
W1G 8PH

Study participating centre
University College Hospital Grafton Way Building
1 Grafton Way
London
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WC1E 6AS

Study participating centre
Uch Macmillan Cancer Care Centre
Huntley Street
London
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WC1E 6AG

Sponsor information

Organisation
University College London

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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: AI_AWARD01864

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because they consist of individual patient data, which cannot be shared because of patient confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Clinician information sheet version 2	24/07/2023	12/10/2023	No	No
Participant information sheet	version 2	24/07/2023	12/10/2023	No	Yes
Protocol file	version 1.1		12/10/2023	No	No
Protocol file	version 2.0		21/06/2024	No	No