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Better explanations for diagnoses in your medical record: use and ratings of an information button to clarify diagnoses in a hospital patient portal

Submission date
05/04/2022

Recruitment status
No longer recruiting

Registration date
12/04/2022

Overall study status
Completed

Last Edited
17/04/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Doctors sometimes use difficult words. Many people don't understand these words. Therefore, we want to clarify medical diagnoses in a better way. For some diagnoses, a patient-friendly term or definition is available. Otherwise we use more general terms and definitions to clarify the diagnosis. The terms and definitions come from the medical terminology SNOMED CT. SNOMED CT browser is available at https://browser.ihtsdotools.org/ and the National Release Center of SNOMED CT Netherlands is based at Nictiz www.nictiz.nl.
We show these clarifications if you click on a diagnosis in the problem list in the patient portal. We aim to assess the use of this functionality. We also want to obtain feedback from patient portal users about the clarifications and to explore differences between the users.

Who can participate?
Any patient portal user using the patient portal Mijn Franciscus of Franciscus Gasthuis & Vlietland (in short "Franciscus") in The Netherlands.

What does the study involve?
When you access the patient portal and visit the problem list of your medical record, you can click on a diagnosis and read the clarification. Optionally, you can rate the clarification and provide feedback to improve the clarification.

What are the possible benefits and risks of participating?
Medical diagnoses sometimes have difficult names. The clarification is supposed to help you clarify these medical terms. Some clarifications may contain mistakes and may be incomplete. If you have any questions you can contact your medical doctor. The clarifications will be improved with your input.

Where is the study run from?
Amsterdam UMC (the Netherlands)

When is the study starting and how long is it expected to run for?
August 2020 to June 2022

Who is funding the study?
Franciscus, Amsterdam UMC, and ChipSoft (the Netherlands)

Who is the main contact?
Hugo van Mens, h.j.vanmens@amsterdamumc.nl

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
W21_259 # 21.285

Study information

Scientific Title
Diagnoses clarification by patient-friendly terms and definitions and generalization to concepts with patient-friendly terms and definitions: usage and quality improvement feedback in a real-time hospital patient portal

Study objectives
In this study, we aim to evaluate the implementation of diagnoses clarifications into the diagnosis list of a patient portal with actual users to assess to what extent it meets their information needs and to obtain feedback for further improvement of the clarification functionality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 10/03/2022, Data Protection Officer and Scientific Bureau of the participating hospital Franciscus Gasthuis & Vlietland (Kleiweg 500, 3045 PM, Rotterdam, Netherlands; +31(0) 104616161; wetenschapsbureau@franciscus.nl), ref: 2021-109
2. Waiver obtained 03/06/2021, Medical Ethics Review Committee of the Academic Medical Center (Meiberdreef 9, 1105 AZ, Amsterdam, Netherlands; +31(0)205669111; mecamc@amsterdamumc.nl), ref: W21_259 # 21.285. The waiver confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to the study and that official approval of the committee is not required.

Study design
Post-implementation study with re-use of routinely collected data about diagnoses routinely logged data about system usage and quality improvement feedback

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Explanation of diagnoses via a patient portal

Interventions
We have developed a method to generalize diagnoses to more general concepts that do have patient-friendly terms and definitions in the SNOMED CT Netherlands Patient-Friendly Extension (PFE), by employing the SNOMED CT hierarchy. We used SNOMED CT Netherlands March 2020 version for this purpose. We improve the clarifications based on the input from a validation study. Where available, we use synonyms and definitions from the September 2021 version of the PFE synonyms and definitions.

Patients, or their significant others that have been authorized by patients, use the patient portal, for instance, to view their medical data, schedule appointments, message their health care provider securely, and complete questionnaires. The clarifications will be implemented in the diagnosis list of the patient portal. The description of the diagnosis will be highlighted, underlined and provided with an info icon. When clicked, the diagnosis description and a clarification of the diagnosis will be displayed. For the quality improvement of the clarifications, users can provide feedback about the clarification. A warning will be displayed for the clarifications with supertypes, stating that the clarification was generated automatically and might contain mistakes. For questions about their diagnosis, patients will be referred to their doctors.

We will analyze usage data about the logins on the patient portal, diagnosis list views, which diagnoses are displayed when users view their diagnosis list, the number of diagnoses with clarifications and which info buttons were clicked by users. Secondly, a feedback question will be asked about the quality of the clarifications if users view a clarification. They are free to choose to provide feedback or not. Therefore, we expect fewer users to go further in the process of completing these steps, and some users to provide more input about different clarifications. Users may log in, view their diagnosis list, display clarifications and provide feedback multiple times. If users have any questions about the diagnoses or about the clarifications, they can address them through the contact form of the patient service desk.

Steps:
1. Login into the patient portal
2. Display diagnosis list

3. Click on the info button to display clarification
4. Provide feedback on the clarification displayed

Intervention Type
Other

Primary outcome measure
1. The coverage of the clarifications, measured as the median percentage of diagnoses with a clarification that was displayed per patient (number of diagnoses with a clarification divided by the number of diagnoses), measured during the 9-week study period
2. The use of the clarification functionality, measured as the median percentage of unique info-buttons clicked compared to the total number of info-buttons per patient (number of diagnoses with clarifications) displayed on the diagnosis list, as measured during the 9-week study period

Secondary outcome measures
1. User characteristics of users for each step: unique user logins, users that view their diagnosis list, users that clicked on any info button, user ratings, from the number of logins, views, clicks and ratings per user. User characteristics are user type (authorized or patient user), age group and gender, as measured during the 9-week study period
2. Diagnosis clarification level: for each diagnosis the number of times users log in for a patient with that diagnosis, number of times the diagnoses were viewed, the info button was clicked, and the feedback received. Users can rate the quality of the clarifications on a seven-point scale from very bad to very good and optionally describe in a free-text input field why they provided that rating. Measurements are about the 9-week study period

Overall study start date
20/08/2020

Completion date
06/06/2022

Eligibility

Key inclusion criteria
Any patient portal user. Patient portal users can be the patients themselves or others that are authorized to use the portal to access the patient’s EHR functionality through the portal. They can be authorized by the patient themselves or be the parents of a child that is a patient at the hospital for instance. The target number of participants concerns the expected number of users that will visit the patient portal's problem list during the study period.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants

3500

Total final enrolment
6530

Key exclusion criteria
Any user that uses the portal for testing purposes with a test account, e.g. an application manager.

Date of first enrolment
04/04/2022

Date of final enrolment
06/06/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
Franciscus Vlietland
Vlietlandplein 2
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Study participating centre
Franciscus Gasthuis
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Sponsor type
University/education

Website
https://www.amsterdamumc.org/

ROR
https://ror.org/05grdyy37

Funder(s)

Funder type
University/education

Funder Name
Amsterdam University Medical Centers

Alternative Name(s)
Amsterdam UMC, Amsterdam University Medical Centres, AUMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Funder Name
ChipSoft B.V.

Funder Name
Sint Franciscus Vlietland Groep

Results and Publications

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

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
Raw participant-level data are part of the medical record at Franciscus. Only aggregate data will be shared. Data specified in the protocol will be published along with the subsequent results publication. Raw, participant-level data from the medical record will remain in the medical record to ensure privacy and security and thus will not be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		11/04/2022	11/04/2022	No	Yes
Protocol file		11/04/2022	11/04/2022	No	No
Results article		01/04/2023	17/04/2023	Yes	No