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Safety and acceptability of a natural-language AI assistant to deliver clinical follow-up to cataract surgery patients: Proposal for a pragmatic evaluation

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Abstract

Background: Due to an ageing population, the demand for many services is exceeding the capacity of the clinical workforce. As a result, staff are facing a crisis of burnout from being pressured to deliver high-volume workloads, driving increasing costs for providers. Artificial intelligence, in the form of conversational agents, presents a possible opportunity to enable efficiencies in the delivery of care.

Aims and Objectives: This study aims to evaluate the effectiveness, usability, and acceptability of Dora - an AI-enabled autonomous telemedicine call - for detection of post-operative cataract surgery patients who require further assessment. The study's objectives are to: 1) establish Dora's efficacy in comparison to an expert clinician, 2) determine baseline sensitivity and specificity for detection of true complications, 3) evaluate patient acceptability, 4) collect evidence for cost-effectiveness, and 5) capture data to support further development and evaluation.

Methods: Based on implementation science, the interdisciplinary study will be a mixed-methods phase one pilot establishing inter-observer reliability of the system, usability, and acceptability. This will be done using using the following scales and frameworks: the system usability scale; assessment of Health Information Technology Interventions in Evidence-Based Medicine Evaluation Framework; the telehealth usability questionnaire (TUQ); the Non-Adoption, Abandonment and Challenges to the Scale-up, Spread and Suitability (NASSS) framework.

Results: The results will be included in the final evaluation paper, which we aim to publish in 2022. The study will last eighteen months: seven months of evaluation and intervention refinement, nine months of implementation and follow-up, and two months of post-evaluation analysis and write-up.

Conclusions: The project's key contributions will be evidence on artificial intelligence voice conversational agent effectiveness, and associated usability and acceptability.

Keywords

Artificial Intelligence (MeSH), Natural Language Processing (MeSH), Telemedicine (MeSH), Cataract (MeSH), Aftercare (MeSH), Speech Recognition Software (MeSH); Medical Informatics (MeSH); Health Services (MeSH); Health Communication (MeSH); Delivery of Healthcare (MeSH); Patient Acceptance of Health Care (MeSH); Mental Health (MeSH); Cell Phone (MeSH); Internet (MeSH); Conversational Agent; Chatbot; Expert Systems; Dialogue System; Relational Agent

Introduction

Background and Rationale

Clinical problem

The UK's ageing population is causing an increased demand for healthcare services that is exceeding clinical capacity [1]. With staff pressured to deliver high-volume workloads, the resulting burnout crisis is increasing costs for healthcare providers. Demand has been further exacerbated by the Covid-19 pandemic, as the widespread cancellation of elective care has created a large backlog of clinical work [2]. However, a large proportion of this clinical work is taken up by highly repetitive and low skill tasks, preventing staff from working 'at the top of their licence'. Therefore, there is a need to improve the efficiency in the delivery of care, and to collect data that can be analysed to support routine improvement and optimization, through the automation of routine clinical interactions.

One area of care where improved efficiency is urgently needed is cataract surgery. Cataract surgery is already the most common operation in the NHS, with approximately 450,000 procedures conducted per year [3]. COVID-19 has caused record delays in receiving planned surgeries [4], and average wait times for cataract surgery were already approximately 2.5 months [5]. The ageing population will also have a significant impact on the number of patients with cataracts, which is expected to double between now and 2050 [6]. The cataract pathway is also an ideal case for optimisation because there is little variability and high levels of patient safety; the most significant complication (endophthalmitis) occurs in fewer than 1 in 1,000 cases [7]. To address this clinical need, this study aims to collect data on the effectiveness, usability, and acceptability of an artificial intelligence (AI) natural language assistant for delivering cataract surgery follow-up checks.

Current system and its limitations

Like most operations, cataract surgery requires a post-operative check to monitor for complications and assess success. This has historically been performed with a face-to-face visit; it is currently standard procedure for 72% of NHS Trusts [8]. However, this post-operative system has a high operational demand and is not always necessary; a recent ophthalmology GIRFT report stated that a hospital review of cataract surgery patients is not required, as long as follow-up arrangements are in place [8]. In the current context of the Covid-19 pandemic, face-to-face visits also pose a high risk for virus transmission due to the proximity of patient and clinician.

Whilst this project focuses on cataract surgery follow-up, the underlying platform will be applicable to a wide range of routine clinical tasks. The need for an effective automated tool is especially great as a 'new normal' of widespread remote clinical care is established in the wake of COVID-19.

User needs

Using AI-enabled automation is a novel approach for patient care and patient perspectives are mixed [9,10]. Research with cataract surgery patients during the development of this solution found that while many patients stated that they would prefer a clinician to provide the follow-up, this opinion was contingent on the quality of the system and service [11]. Most patients rated the solution highly on simplicity and ease of use and expressed appreciation for the additional convenience of a telephone follow-up [11].

The patients also suggested that the AI system might be less rushed than a clinician and would have the benefit of freeing up nurses' time for other clinical work. This is supported by internal company research into the clinical outcomes of 300 cataract surgery follow-up calls identified that only 10% of patients telephoned by expert clinicians were determined to need a face-to-face review. Therefore, an automated telephone follow-up could significantly reduce the number of clinical appointments necessary to deliver post-operative care.

Solution Overview

The solution developed to improve clinical efficiency for cataract surgery follow-up is a natural language, voice telemedicine conversation delivered to patients via telephone call. For the patient, this is intended to be no different than a regular telemedicine consultation with a doctor or nurse; it does not require the download of an app, the provision of a device, or any training. This is important because the populations that consume the majority of healthcare services (elderly and socio-economically disadvantaged) tend to be relatively more digitally disenfranchised.

The solution - a natural-language AI assistant called Dora - has been developed by Ufonia Limited. By the start of the clinical testing described in this protocol, validation with Ufonia's development partners at Buckinghamshire Healthcare NHS Trust will be complete and Dora will be at TRL5. By the end of this study, the solution will be at TRL6, having been demonstrated in a relevant clinical setting.

Key features

Dora uses a variety of AI technologies to deliver the patient follow-up call, including: speech transcription, natural language understanding, a machine-learning conversation model to enable contextual conversations, and speech generation. Together, these technologies cover the input, processing and analysis, and output needed to maintain a natural conversation. Dora is currently delivered via a telephone connection as a real-time, stand-alone system: the operator inputs individual patient details to initiate the call and completes a summary in the electronic health record (EHR) afterwards.

Benefits of Proposed Solution

The solution is aligned with NHS aims to improve efficiency and increase digitally-enable care [8,12]. Cataract surgery follow-up provides a good launching point for further

development of digital solutions, as it typifies many routine telemedicine care processes that could be similarly automated. Once the platform is established technically and operationally in individual institutions, a local network effect will make subsequent use-cases easier and quicker to deploy. Beyond the replacement of existing pathways, the solution has the future opportunity to deliver proactive (rather than reactive) follow-up to patients with long-term conditions. This is possible because automation removes the capacity constraints of human-led follow-up, thus enabling regular contact that could intercept deteriorations early before they become costly to the patient and health system.

For healthcare staff

The solution is expected to have significant benefits for healthcare staff by reducing their clinical burden. Preliminary company research suggests that Dora will reduce the number of patients who require follow-up with a clinician by approximately 90%. This reduces the type of high-volume, repetitive task that contributes to burnout and allows clinicians to be redeployed to higher value activities, where their skills, insight, and empathy can be best utilised. In addition, telephone follow-up reduces the risk of COVID-19 transmission and frees up hospital space to help meet the increasing patient demand.

For patients

The system also has several benefits for patients. Dora will provide a reliable, consistent safety-net after surgery. Patients will be able to ask questions about their recovery (such as when to drive, swim, stop taking eye drops) just as they would with a human clinician. The system is convenient because it does not require them to travel to hospital and can take place at the time or duration that suits them. Reducing the number of in-person follow-ups will allow clinicians to perform other clinical activities, making patients more likely to receive timely care for their initial cataract surgery or for other conditions. This will be evaluated as part of the study by examining the number of surgeries conducted.

Aims and Objectives

The purpose of the study is to evaluate the usability, acceptability, and effectiveness of Ufonia's autonomous cataract follow-up call system (Dora) at detecting patients that require further assessment. The primary aims are to establish preliminary evidence that Dora is safe, to evaluate its sensitivity and specificity, and to determine what can be learned to improve its design for future studies.

In order to achieve these aims, there are five key objectives:

1. To establish baseline rates of efficacy, sensitivity, and specificity for Dora's detection of patients that require further assessment.
2. To evaluate patient acceptability of an autonomous call in comparison with existing standards of care.

3. To evaluate cost-effectiveness of autonomous calls in comparison with existing standards of care.
4. To capture conversational data to train future versions of the system.
5. To capture data and assess study feasibility to inform development of a Phase 2 efficacy-orientated trial.

Research Questions

From these aims and objectives, four main research questions were defined to guide the project:

1. What are the factors impacting the effectiveness of Dora's conversational call follow-up to determine patients that require further assessment?
2. Can Dora sufficiently support conversation and patient engagement to collect the data needed to allow Dora's computational capabilities to perform an accurate assessment?
3. What are the perceived benefits and barriers of using conversational agents for patient follow-up?
4. Is Dora more cost-effective than existing standards of care?

Methods

Study Design

Using an implementation science construct, the study will be a phase one pilot study to develop evidence regarding the feasibility, acceptability and potential effectiveness of Dora and to identify factors influencing effectiveness. The study will last eighteen months: six months of evaluation and intervention refinement, nine months of implementation and follow-up, and three months of post-evaluation analysis and write-up.

Research Participants

The study population will incorporate two clinical sites: the Imperial College Healthcare NHS Trust and the Oxford University Hospitals NHS Trust. The population at the Imperial College site is drawn from the North West London (NWL) Collaboration of Clinical Commissioning Groups (CCGs) and is densely populated, highly diverse, highly mobile, and relatively young [13]. Black, Asian, and other minority ethnic groups make up 37% of the resident population in the West London CCG [14] and 20% of London residents do not speak English as a first language [15].

In contrast to London, the Oxfordshire population is less diverse but more rural [16]. Although it is growing in ethnic diversity, residents are primarily of a white British background; in 2011, approximately 84% of Oxfordshire residents identified as white British (compared to the national average of ~80%) [17]. It also found that 16% of the Oxfordshire population do not

speak English as their main language (compared to the national average of 8%) [18]. In terms of age, the population of Oxfordshire is similar to national profile, particularly for older ages [19].

Recruitment

Recruitment will take place at sites in the Imperial College Healthcare and Oxford University Hospitals NHS Trusts that conduct cataract surgeries. Study information will be shared with cataract surgery patients at their initial visit (and via post or telephone call for patients who are delayed by COVID-19 or cannot visit in person). Informed consent will be obtained at the time of pre-assessment (in-person or virtually depending on the current COVID-19 guidelines). In the discharge lounge following surgery, patients who have consented to participate will be given further information to remind them about the call from Dora. This work will be performed by a dedicated research nurse at each site.

Study Duration and Follow-Up

The proposed study will conduct telemedicine calls with patients in addition to their standard of care. In common with 72% of NHS Trusts, Imperial sees all of their post-operative cataract patients at a face-to-face out-patient appointment with an ophthalmologist. This is conducted four weeks following the procedure. Therefore, patients will receive their call from Dora between 1 and 3 days before their scheduled appointment (day 25-27 post-surgery).

In contrast, the Oxford NHS Trust does not proactively review their patients. Instead, they rely on patients to seek help if they have concerns. Patients will receive their call from Dora between day 25 and 27 post-surgery, the same as patients at the Imperial sites. However, they will not have a subsequent appointment with an ophthalmologist unless it is deemed necessary during the call.

This variation in practice is important as it will help demonstrate that Dora can be integrated into different pathways. It will also provide a range of sensitivities to input into the health economic models to determine if Dora provides cost-effectiveness in different settings.

Procedure

While patients typically have cataracts in both eyes, procedures are typically done on one eye at a time in the UK. As this is a pragmatic study, patients undergoing either 1st or 2nd eye surgery will be recruited. This should be in balanced proportion due to the random nature of operating timing, but differences between groups will be examined in the post-hoc analysis. Given that the usual interval between cataract surgeries is more than six months, it is unlikely that the same patient will be recruited twice in the study. If there are any cases where the same patient is recruited, they will be excluded from participating a second time.

Dora call

The call that patients will receive from Dora will include several conversational elements:

- Greeting and introduction
- Identification of patient
- Cataract follow-up questions
- Patient's queries
- (Decision)
- Questions about acceptability
- Closure of call

The entire conversation will be supervised by an expert clinician (an ophthalmology research fellow). This clinician will be able to interrupt the call at any point if the system fails, the patient struggles to interact with it, or Dora does not collect sufficient information from the patient.

The cataract follow-up questions will classify five key symptoms: redness, pain, reduced vision, flashing lights, and floaters. Both Dora and the supervising clinician (masked to each other) will independently indicate for each symptom, whether the symptom is:

1. Absent (e.g. no pain)
2. Present but not clinically significant (e.g. mild gritty sensation)
3. Present and clinically significant (e.g. deep and persistent pain)
4. Insufficient information for classification

Issues identified in response to any of these questions will prompt the need for face-to-face review. The complexity of the model comes from evaluating the exact nature of these symptoms - e.g. distinguishing between improving redness in the corner of the eye (due to the local anaesthetic injection) from widespread redness that has progressed, which may represent infection. The conversational nature of the model enables it to ask patients further questions to clarify their responses and assess the significance of the reported symptoms.

If clarifying points are necessary for the clinician to make a decision, DORA will hand over to the clinician who will ask the necessary questions, and then document updated assessments for symptoms and overall management before handing back to DORA for FAQ's and patient evaluation. Either 12 or 18 data points will be collected from one call depending on if clarifying questions are asked.

If the call is uninterrupted, Dora will make a decision about the patient's management plan. Once the cataract follow-up questions have been completed, the clinician will also set their own decision, masked to the decision the system has made (see Table 1). For this project, the supervising clinician's decision - made based on the information from the call with DORA's decision masked - is considered the gold-standard for evaluation. For each patient, the final decision about the management plan can be:

1. Discharge (and/or add to waiting list for second eye cataract surgery, and/or continue follow up as previously planned in ophthalmology clinic)

2. Eye casualty review within 1 week
3. Same day eye casualty review

Table 1. Outcome communicated to patient at end of call depending on the blinded decision of Dora and the clinician

Clinician decision	Does not need review	Needs review	Insufficient information
Outcome	No review	Review	Interrupt call

If the patient needs review they will either be seen at the scheduled appointment the following day, or if one is not scheduled (at Oxford or if pathways change due to COVID-19), by the clinical fellow the following day. If they are found to have a complication, they will enter the existing NHS care pathways as they would with typical care. If the complication is deemed urgent by the clinician, the patient will be seen the same day.

Theoretical Framework

The evaluation of baseline efficacy, sensitivity and specificity, feasibility of study design, acceptability and usability shall be conducted using the following scales and theoretical models/frameworks:

1. the system usability scale [20];
2. assessment of Health Information Technology Interventions in Evidence-Based Medicine Evaluation Framework [21];
3. the telehealth usability questionnaire (TUQ) [22];
4. long-term adoption and suitability to further trials will be evaluated using the Non-Adoption, Abandonment and Challenges to the Scale-up, Spread and Suitability (NASSS) framework [23].

Data collection

The key element of the conversation that this study will assess is Dora's ability to make 'correct' decisions: about whether review is necessary and for the individual questions about the key symptoms. For this project, the correct decision is that which the supervising clinician makes based on the information they hear. Therefore, the key data to be collected are Dora and the clinician's decisions.

The call will also collect data about the individual patient's condition. The follow-up questions are aligned to existing cataract patient-reported outcome measures so that they meet the needs of responsible clinicians and can be used to populate the National Ophthalmology Database [3].

Usability and acceptability of the system will be assessed through automated questions at the end of each call. In addition, a sample of patients who have a good and poor experience will be approached to have a more in depth interview (as detailed in the Ethics section).

Data analysis

The primary analysis will be the calculation of a kappa statistic of inter-observer (Dora & clinician) reliability of the decision made. Additionally, the outcome of the assessment will be compared with the 'real' complication rate determined by any face-to-face assessments. This will be established by identification of any patient presentation within 60-days after the last call. Given the specialist nature of ophthalmology services it can be assured that patients will present through the eye casualty services offered by each site. This analysis will provide baseline sensitivity and specificity data for use in preparing subsequent evaluations of efficacy.

The usability and acceptability questions delivered at the end of the call will be analysed quantitatively based on the scales' scoring criteria - for instance, a score above 80 on the System Usability Scale is generally considered to indicate an above average user experience [24]. The interview recordings will be transcribed and assessed using thematic analysis.

Bias

To prevent participation bias, there will be no exclusion of participants who are willing to take part in the study, unless they have a relationship with any of the researchers associated with the study (to avoid conflicts of interest). To address unconscious bias or other forms of interview recruitment issues, interview participants will be selected randomly by a computer script of consented participants. Quantitative analysis of usage experience will include all participants to avoid recruitment bias. Participants' levels of education will be recorded to note possible ways education impacts intervention use.

It is vital to maintain the integrity of the study and avoid commercial influence on results. Therefore, a research contract will be established between Ufonia and the academic research partners enabling unrestricted right of publication of non-confidential information and independence of study implementation.

Risks

The Covid-19 pandemic has raised potential issues for recruitment for the study. To address this risk, an ethics submission will enable remote informed consent if restrictions prohibit face-to-face contact.

Risks regarding the system include it failing to detect patients who require urgent clinical review - this will be mitigated by having an expert clinician supervise the call in real-time, able to intervene if needed. The risk of lack of trust in the system has been mitigated by an extensive co-creation process for Dora that focused on user-centred design.

The interviews are scheduled to take place for between 40 to 60 minutes in order to mitigate time risk to participants. The nature of interview questions avoid areas of cultural or psychological sensitivity and are purely focused on impact of the intervention. To control any potential perceived issues in this area, participant confidentiality is protected using data protection procedures that are compliant with the General Data Protection Regulation [25].

Ethical Considerations

Study governance

Research ethics will be sought at host institutions for study implementation. This manuscript provides an overview of the study approach but will be subject to further revision prior to ethical submission. An independent study steering board composed of the Academic PI, Co-Academic PI, a study researcher, a member of the public and an external researcher will meet every two months to review progress against the study plan and to assure study ethics are being followed. Reports shall be distributed for review by the project team for action. To ensure the validity, reliability and transferability of the study findings, the Consolidated Standards of Reporting Trials (CONSORT), Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT), and Consolidated Criteria for Reporting Qualitative Studies (COREQ) guidelines, including additional AI-related extensions, will be followed and recorded.

Informed consent

BERA guidelines have been followed for voluntary informed consent, use of methods, and university policies in the event there are issues in delivery [26]. Prior to completing informed consent, participants will be given information that fully describes the process of the study, including why their participation is necessary, how their data will be used, and who the results will be reported to. As many patients are understandably concerned about how their data will be used, data management will be explained in detail as part of the consent process. It will also make clear their right to withdraw from the study at any time and have their data destroyed. Patients will also be asked to separately consent for their data to be used to further train the conversational systems. Declining to share this conversation data will not affect patients' participation in the study or their clinical care.

Data management

The Ufonia system stores patient identifiable data as part of the clinical record. Explicit consent is obtained from patients to use that data in ongoing development. The solution is in compliance with the General Data Protection Regulation (GDPR) [25] as well as being built to meet specific NHS regulations. For the proposed study, the organisations involved (including each Trusts' Data Protection Officer and Caldicott Guardian) will undertake a Data Protection Impact Assessment and, where needed, create Information Sharing Agreements to ensure compliance with relevant data protection regulation. Ufonia will act as the data processor and the individual hospitals will remain the data controllers.

During the study implementation, each participant will be given a unique identifier. The primary key between unique ID and participant will be securely held and given to the participant as a reference ID. Data will be analysed using the unique IDs; the primary key is only maintained to enable participants to withdraw their data from the study. If such a request is made before data aggregation or publication, all of their corresponding data and files shall be destroyed.

Audio recordings, transcriptions, and meta-data about the calls will be securely stored in UK data-centres with strict role-based access control. The transcription service will only have reference to the unique IDs and the audio recording will be reviewed by the PI to remove any identifying information before being shared. Patient identifiable data will not be sold to any other party and will not be shared with any organisation unless they are a partner in the study and have an appropriate information sharing agreement in place. In accordance with GDPR requirements, records of consent will be kept for three years after the publication of final study results [25].

Results

The evaluation is expected to show that the conversational technology can conduct an accurate assessment and that it is acceptable to different populations with different backgrounds. Additionally, the results will demonstrate how successfully the system can be delivered in organisations with different clinical pathways and can integrate with their existing platforms.

Discussion

Overview

This project will establish strong foundational evidence for the use and wider deployment of a novel application of artificial intelligence technologies. The platform has the potential to transform the delivery of care across multiple clinical pathways by reducing costs, increasing capacity, and improving the convenience and experience for patients and professionals. A trial protocol is being prepared for MHRA approval.

The key outputs from this project will provide:

1. Safety and preliminary efficacy data for regulatory approval through CE marking and possible CQC registration.
2. Proposed structure and implementation model for further clinical trials.
3. Health economic data to support wider roll-out and ongoing evaluation.
4. Results submitted for peer-reviewed publication.

Limitations

A limitation of Dora is that, at present, patients with cognitive difficulties, hearing impairment or non-English speakers will not be able to use the system, facing the same limitations they currently do with human telemedicine services.

A limitation of the study is that a direct comparison about the number of issues identified during routine follow-up cannot be made between the Oxford and Imperial sites. This is because the Oxford NHS Trust does not proactively review patients, instead relying on them to present themselves to their eye casualty service. This introduces a potential risk for missed complications if Dora does not decide that a review is needed. However, this risk is minimized by the expert clinician oversight and is a part of the current standard of care at the Oxford NHS Trust.

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Author Contributions

NdP conceived of the study topic and designed and drafted the proposal. GM, EL, MMI, EN, and KX contributed to the drafting and revision of the proposal. Final revision was conducted by EM.

Conflicts of Interest

EL, NdP, and GM are all employees of Ufonia Limited, a voice artificial intelligence company. NdP is employed part-time by Oxford University Hospitals NHS Trust and responsible for the development of innovation activities at the Trust. His work for Ufonia has been approved by his line manager (Chief Digital and Partnerships Officer) and declared in the Trust's register of interests. None of the resources he is responsible for within the Trust are used to support the project. He is also Clinical Lead for the Thames Valley & Surrey Local Health and Care Records Programme, his work for Ufonia has been declared in the Programme's register of interests.

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