

Challenges in developing a patient-reported symptom-based risk stratification system for suspected head and neck cancer: Protocol for a qualitative case study

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Abstract

Background: The Symptom iNput Clinical (SYNC) system was developed to enhance the timely reporting of Head and Neck Cancer (HNC) symptoms and to ensure that high-risk patients receive faster diagnoses. A key feature of the system is a digital questionnaire co-designed with patient representatives to accommodate varying levels of digital literacy. The system integrates a validated algorithm that assigns risk scores to categorise cases as low or high risk, and a dashboard that supports clinicians by providing them with patient reports. However, the development process encountered challenges that necessitates a systematic evaluation of the process, roles, and experiences of team members.

Objective: This study aims to identify challenges faced during development, how these challenges were addressed, and the implications for future digital health innovations.

Methods: A qualitative single-case study approach will be employed, focusing on individuals involved in the SYNC system's development. Participants will be selected using a combination of purposive and snowball sampling to ensure diverse perspectives, using meeting minutes and recommendations from key stakeholders. A total of 8 to 12 participants will be interviewed, representing clinical, research, and IT roles. Data collection will involve semi-structured interviews which will be conducted through Microsoft Teams. The interviews are expected to last between 40–60 minutes each. These interviews will be audio-recorded, transcribed, and analysed using framework analysis in Dedoose. Actor-Network Theory (ANT) will guide the analysis by mapping interactions between human and non-human actors, such as developers, clinicians, and technological tools, to understand how they influenced the project's outcomes. Participant confidentiality will be maintained through data encryption, de-identification, and secure storage.

Results: The study anticipates identifying key barriers and facilitators in the SYNC system's development, including technical, organisational, and collaboration-related challenges. The findings are expected to provide a detailed account of the challenges encountered, such as delays, security concerns, and coordination issues, an insight into how these challenges were mitigated and lessons learned and recommendations for improving digital health technology development, including best practices for co-design, technical integration, and stakeholder engagement.

Conclusions: Conclusion: This case study will provide valuable insights into the complexities of developing digital health technologies, particularly in collaborative, multi-stakeholder environments. Documenting the challenges encountered in the SYNC system's development will contribute to best practices in digital health innovation.

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Challenges in developing a patient-reported symptom-based risk stratification system for suspected head and neck cancer: Protocol for a qualitative case study

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Abstract

Background: The Symptom iNput Clinical (SYNC) system was developed to enhance the timely reporting of Head and Neck Cancer (HNC) symptoms and to ensure that high-risk patients receive faster diagnoses. A key feature of the system is a digital questionnaire co-designed with patient representatives to accommodate varying levels of digital literacy. The system integrates a validated algorithm that assigns risk scores to categorise cases as low or high risk, and a dashboard that supports clinicians by providing them with patient reports. However, the development process encountered challenges that necessitates a systematic evaluation of the process, roles, and experiences of team members.

Objective: This study aims to identify challenges faced during development, how these challenges were addressed, and the implications for future digital health innovations.

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Expected Results: The study anticipates identifying key barriers and facilitators in the SYNC system's development, including technical, organisational, and collaboration-related challenges. The findings are expected to provide a detailed account of the challenges encountered, such as delays, security concerns, and coordination issues, an insight into how these challenges were mitigated and lessons learned and recommendations for improving digital health technology development, including best practices for co-design, technical integration, and stakeholder engagement.

Conclusion: This case study will provide valuable insights into the complexities of developing digital health technologies, particularly in collaborative, multi-stakeholder environments. Documenting the challenges encountered in the SYNC system's development will contribute to best practices in digital health innovation.

Keywords: challenges; head and neck cancer; patient-reported symptoms; risk stratification

Introduction

The development and evaluation of the Symptom iNput Clinical (SYNC) system aim to address key needs of Head and Neck Cancer (HNC) symptoms by enabling timely symptom reporting and faster diagnosis of high-risk patients thereby minimising anxiety and optimising healthcare resource use. A digital questionnaire was co-designed with relevant stakeholders, specifically patient representatives, to capture symptoms reported by patients in an accessible format to accommodate a range of health and digital literacy abilities (Odo et al, 2024). Using a validated algorithm, the system calculates a risk score and categorises cases as either low or high risk. The SYNC dashboard is designed to support clinicians and cancer care service management teams by enabling them to monitor where the patient is in the pathway, including patients who has received, completed, and returned the questionnaire. Additionally, the system will provide clinicians with patient-reported symptoms and risk levels, enhancing triage and faster diagnosis.

The process of developing the SYNC system encountered numerous delays and challenges. These challenges emphasised the need to systematically study and document the processes, roles, and perspectives of team members to inform future developments in digital health technology. The first step in tackling the challenges is to identify them. This study will capture the key experiences of those involved in the process and planning during the development of the SYNC system. This information gathered in this study will help those planning similar projects in the future.

Methods

This research will adopt a qualitative single-case study design. A case study is an empirical inquiry that involves the study of an individual unit, such as a person, community, or project, with a focus on developmental factors in relation to their environment (Flyvbjerg, 2011; Heale & Twycross, 2018) and involving the collection of multiple forms of data (Yin, 2003). This study will focus on individuals involved in the development of the SYNC system. The study will examine cross-team experiences and challenges, exploring how these factors influence the development processes. This method is chosen to enable an in-depth analysis of real-world challenges and the complex interactions between individuals, teams, and the technology.

Recruitment and Sampling Strategy

Participants will be selected using a combination of purposive and snowball sampling, which is particularly effective for engaging individuals with specific insights into the project's processes and challenges (Parker, C., Scott, S., & Geddes, A., 2019). We will review minutes of the past meetings and if someone is repeatedly mentioned or appears to have had a key influence on an element of study progress, we will highlight the individual as key in participant selection. Initial recruitment will be purposive selection of key individuals involved in the SYNC system's development, ensuring representation across the various teams involved in the development process (and including individuals with clinical, research and IT roles). They will be asked to recommend colleagues they believe could provide valuable input. In this way, stakeholders with smaller roles in the project will also be considered to ensure a broader range of perspectives and to enhance the credibility of the findings. We plan to recruit between 8 to 12 participants from different roles, especially those whose roles in the project were delayed due to challenges encountered. There is no consensus on the number of interviews required to provide an adequate understanding of experiences within a particular setting. However, this range allows for sufficient depth in identifying themes, while keeping data collection manageable.

In case of challenges in recruitment due to potential participants' work commitments or other concerns, we will extend the recruitment period and be flexible in scheduling interviews, e.g., offering them outside of normal working hours.

Data Collection

The study will employ multiple data collection methods which would consider both qualitative interview and document analysis. Data will be collected through semi-structured interviews conducted via Microsoft Teams. This will allow participants the flexibility to participate from their preferred location and avoids the logistical challenges of travel. Interviews will last between 40–60 minutes and will be audio-recorded with participants' consent. This approach will ensure a consistent format while enabling researchers to capture rich, detailed narratives. The interviews will focus on participants' roles, challenges experienced during the SYNC system development, and recommendations for improving similar projects (see Appendix A). In addition to conducting interviews, the researcher will undertake document review, considering relevant documents such as meeting minutes and other pertinent records, to gather insights into any documented challenges. Participants will also be asked to provide any available documents that could help uncover developmental challenges. This will offer a more comprehensive understanding of the issues.

Data Analysis

Framework analysis, a qualitative method that uses a structured matrix to organise and analyse data by case and code (Ritchie et al., 2003), will be utilised in this study. This method will ensure a clear audit trail for credibility and support input from the wider project teams, including those with limited qualitative analysis experience. Framework analysis will be conducted using Dedoose, with codes inductively and deductively derived from the Actor-Network Theory (ANT) (Latour, 1997). The aim is to understand how people, ideas, technologies, and nature form networks. To ensure dependability, a second researcher will review a sample of the interview transcripts and documents to identify any additional codes. The first researcher will then use the agreed codes to index the data. Coded data will be summarised in a matrix, enabling collaborative discussion regarding patterns in the data to further strengthen the reliability of the findings. Following these consensus meetings, the first researcher will use the matrix to produce narrative summaries of each theme, returning to the original data where necessary.

Guidance for qualitative studies in health informatics will be followed, ensuring the findings are robust and credible (Ancker et al., 2021). This guidance adheres to established criteria for transparency and rigor in qualitative research.

Ethics

The study protocol for the co-design of the SYNC system was reviewed and approved by the Committee for Clinical Research at the Royal Marsden (CCR5686) and the UK Health Research Authority (IRAS 315419). An amendment will be submitted to undertake this additional research. All participants will receive an information sheet and consent form via email, outlining the study's objectives, procedures, and ethical considerations. Participants will be given 48 hours where possible to review the documents and confirm their willingness to participate by responding to the researcher.

To safeguard participant confidentiality, the study will implement encryption for interview recordings during transmission and storage. During publications, the researcher will avoid reporting specific details that could single out a participant. Interview recordings will initially be stored on the University of Bradford secure servers and transcribed using Microsoft Teams. Following an interview, the transcript will be checked against the recording for accuracy and, once complete, the recording will be deleted. Interview transcripts will be uploaded to Dedoose, a secure and collaborative research and evaluation data analysis application, and access will be restricted to researchers involved through role-based access control and multi-factor authentication. All data will be de-identified before analysis to protect participant identities. Data will be stored securely and retained only until the completion of the EVEREST-HN study with a clear policy for deletion based on the University of Bradford storage and retention policy. Informed consent will outline how data will be handled, and participants will be informed of their rights regarding data withdrawal.

Theoretical Framework: Actor-Network Theory

The design and conduct of this study will be guided by Actor-Network Theory (ANT) (Latour, 1997). ANT provides a framework for understanding how both human (e.g., developers, clinicians, patients) and non-human actors (e.g., the SYNC system, organizational tools, and processes) interact within a network to influence the outcome of the project development. In the context of the SYNC system, ANT will help to uncover how these interactions shaped the project, such as how collaboration between diverse teams impacted decision-making and how technical challenges influenced workflow. By mapping these relationships, ANT will highlight critical factors contributing to the system's successes and challenges, offering insights for improving future digital health projects. These ANT concepts have informed the interview questions and will inform the codes used to index the transcripts and project documents.

ANT will be particularly useful in identifying how roles and responsibilities were distributed among team members and how these roles evolved over time. It will also help to uncover the influence of technical and organisational factors on the project's trajectory, offering valuable insights for refining processes in future digital health technology development.

Expected Results

This study is expected to provide a comprehensive analysis of the challenges encountered during the development of the SYNC system, as well as the lessons derived from addressing these challenges. Data collection is scheduled to commence in August 2025. At the time of this manuscript submission, participant recruitment has not yet started. The data analysis and the anticipated findings will be formally reported in the first quarter of 2026.

Potential limitations of the proposed methods

Snowball sampling may present several challenges. Since we are examining the experiences of individuals involved in the system's development, reliance on participants to recommend others could introduce selection bias, potentially limiting the diversity of perspectives captured. For instance, participants may predominantly refer colleagues within their immediate teams or with similar views, which could overlook critical voices or unique experiences. This lack of diversity may affect the generalisability of the findings, as insights might reflect only a subset of those involved in the project. Additionally, snowball sampling might not adequately capture perspectives from less-

connected stakeholders or peripheral team members, thus limiting understanding of complex interactions between technical and organisational factors. However, the use of minutes as secondary route to sampling might help mitigate this risk.

Another limitation is the challenge with a single case study design where it is may be hard to disguise identities, at least from other people within the case if not externally. To minimise this, findings will be reported in a more generalised form by combining responses where possible.

Discussion

This protocol describes the methods that will be used for capturing the experiences and challenges of developing the SYNC system and will offer actionable insights for designing and implementing similar technologies in health informatics. Using a qualitative case study approach, purposive and snowball sampling, and Actor-Network Theory, the findings will address collaboration challenges, promote inclusive co-design, and optimize technical integration. Findings will be disseminated through seminars, workshops, conferences, and journal publications to inform stakeholders and advance user-centred, scalable digital health innovations.

Conflicts of Interest: Non declared

Abbreviations: SYNC - The Symptom iNput Clinical, HNC – Head and Neck Cancer, ANT – Actor-Network Theory

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Appendix A: **Topic guide: Case study interviews**

The interview schedule is developmental. The questions will be tailored to each interviewee and additional questions may be added as the research progresses.

1. Introduction

- Can you tell me about yourself and describe your role in the SYNC system development project?
- At what stage(s) of the development process did you get involved?

2. Initial development and transition from Microsoft to RM-Digital

- Why was the development of the SYNC system initially assigned to Microsoft?
- Can you share insights into the reasons behind transitioning the development to RM-Digital?
- What challenges arose during this transition (e.g., communication, continuity, technical constraints)?
- How were these challenges addressed, if at all?

3. Design and development decisions

- What factors influenced the decision to focus on voice chat and web-based questionnaire, rather than incorporating SMS and WhatsApp?
- Were there any technical or user feedback-related constraints that led to this change?
- Do you think that these changes would impact the user acceptance?

4. Security and compliance concerns

- Were there specific challenges regarding data security, information governance (IG) compliance, or user trust?
- How were these concerns addressed during development?

5. Team dynamics and organisational factors

- Were there any difficulties in coordinating the teams e.g., developers, user researchers and other stakeholders?
- Was there any conflicting priorities or resource limitations that influenced the development process?

6. Reflections and lessons learned

- Looking back, what do you think were the most significant challenges in the development of the SYNC system?
- What would you do differently if you were to embark on a similar project again?
- Are there any key lessons learned from this experience that you believe should be shared with others developing digital healthcare technologies?