

Defining functional requirements for a self-management solution for Hypertrophic Cardiomyopathy patients – a multi-stakeholder multi-framework approach

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Abstract

The SMASH-HCM project seeks to advance the management of hypertrophic cardiomyopathy (HCM) through the creation of a human digital-twin-based platform. The aim of the work described in this paper is to carry out the first step of developing the platform: the collection of design and functional requirements together with the end-users. This study focuses on defining the functional requirements for a digital health solution aimed at enhancing HCM patient self-management within this project. Drawing on Requirements Engineering principles, the work integrates key concepts such as health literacy, personalisation, behaviour change frameworks, and gamification to ensure the platform aligns with patient and clinical needs.

The methodology included a literature review, development of user personas through AI-assisted techniques, and structured user story mapping. Engagement with clinicians and patient advocates provided critical insights, and frameworks such as the Behaviour Change Wheel and Octalysis were applied to inform the design process and improve user engagement.

The analysis resulted in 19 design requirements for overall usability and usefulness of an HCM platform designed from a patient perspective and 19 functional requirements that address core aspects of HCM management and the patient's preferences and needs. These include the development of interactive educational tools, features for monitoring health and lifestyle data, risk assessment visualisation, and improved communication channels between patients and clinicians. The findings emphasise the importance of intuitive, accessible, and effective tools to encourage sustained engagement and empower patients to manage their condition. By incorporating user-centred design principles and aligning with clinical objectives, the proposed solution aims to facilitate better health outcomes and long-term patient engagement.

Keywords: precision medicine, cardiomyopathy, hypertrophic, decision support systems, clinical, software design, user-centered design, digital health

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Introduction

Hypertrophic cardiomyopathy (HCM) is the most common inherited heart disease (prevalence 1:200 - 1:500) [1], it is manifested by thickening of cardiac walls, increasing risks of arrhythmia, and sudden cardiac death. HCM is a multifactorial and multiorgan disease with multiple manifestations, giving rise to a range of symptoms and complications. It affects all age groups from children to the elderly, and can cause not only cardiac, but also mental effects and comorbidities that lower the quality of life. It is a leading cause of death among young athletes. Currently, despite the diverse geno- and phenotypes of the disease, all HCM patients are treated similarly, leading to suboptimal interventions and outcomes. A major challenge in managing HCM is the lack of knowledge or tools for individual risk prediction [2].

The EU funded project SMASH-HCM [3] develops a digital-twin based decision support solution to improve disease management, for clinicians and for patients. Digital twins in the context of humans, in a wider context also referred to as Virtual Human Twins (VHT), are defined by the European Virtual Human Twins Initiative [4] as a digital representation of a human health or disease state, taking into account different levels of human anatomy, using software models and data that are designed to mimic and predict behaviour of their physical counterparts. The project develops a human digital-twin-based platform by combining clinical research, cardiology, radiology, cell biology, -omics tools, biophysical computational modelling, artificial intelligence (AI) and machine learning (ML), biomedical signal and image processing, clinical decision support system development, innovation management, and social sciences to address the unmet clinical and substantial societal and psychological needs.

For patients, there exist information resources about the disease, such as hcmcare.com and PCNA's tools [5]. Although they provide easily accessible information about the disease, these tools do not use individualized measurements and do not provide personalized guidance over time. The American College of Cardiologists also provides additional materials, such as symptom trackers and exercise planners as pdf forms, to facilitate discussions with the care team [6] but are not meant for dynamic personalized management in between those discussions.

One aim of the project is to develop, for patients, a digital tool that provides them with personalised guidance on topics such as understanding the disease and potential impacts of lifestyle choices, and to collect personally relevant health, information. To empower them to live life with HCM in the best way possible.

To be successful, it is essential that the tool is co-developed with end-users (healthcare professionals, such as cardiologists, and patients) engaged throughout the entire development and validation cycle. For example, via interviews, focus groups, use case elicitations, and iterative prototype and visualization development [7, 8].

This paper reports on the research undertaken as the first step of developing the platform: to identify the end user functional requirements. As first step, and the main aim of this paper, is the collection of design and functional requirements together with the end-users. The two research questions are, firstly; how should such a platform deliver the desirable HCM patient support functions to optimise its overall usability and usefulness, and how can they be covered in design requirements? Secondly, what should the platform deliver in terms of the HCM-specific desirable content that patients would like in a platform, and how can this be captured in

functional requirements? This paper thus summarises formal research on the design requirements for a patient platform. By integrating findings from a systematic literature review, and based on those, using a requirements engineering theoretical framework that is described in chapter 2, it captures the views of patient advocates, from organisations connected to cardiovascular or specifically cardiomyopathy patients. These then lead to initial requirements for the application that function as start for the software developers towards the implementation.

Material and methods

The theoretical framework for this study integrates key concepts outlined in an earlier performed systematic literature review carried out by the authors [9], highlighting the need for an integrative approach to improving patient engagement and outcomes in health technology.

The literature review identified themes that could be addressed to make health apps engaging and thus positively impact usage and treatment outcomes. Key concepts include personalization, health literacy, behavior change approaches, and gamification, all of which address specific challenges in maintaining patient engagement with ongoing use of health apps. Personalization ensures that health solutions are tailored to individual needs, enhancing their relevance and effectiveness [10, 11]. Incorporating health literacy is crucial for the accessibility and understandability of solutions, which in turn improves patients' ability to manage their own health [12]. Behavior Change approaches provide a structured way to promote behavior change by focusing on users' capabilities, opportunities, and motivations, as emphasized by the Behavior Change Wheel (BCW) model [13, 14]. Finally, gamification techniques are being integrated into

health apps to make them more engaging and motivating for users, using, for example, rewards and leaderboards to maintain user engagement [15, 16]. These elements reflect a wide understanding of patient behavior and motivations, which is essential for effectively engaging patients in their own care. This, combined with continuous improvement and user-centered design [17, 18] aims to enhance the usability and adoption of the application. Collaboration with experts from different fields enriches the development process and ensures that the tool is comprehensive, clinically relevant, and technologically advanced [19, 20]. Together, these approaches provide a solid theoretical foundation for developing health apps that meet functional requirements while improving user engagement and satisfaction.

The overall work was driven by Requirements Engineering (RE) [21], a process that seeks to ensure that the product being developed effectively meets the needs of users. By systematically capturing and analysing user functional requirements, RE helps build a solid foundation for the tool, ensuring that each feature significantly contributes to patient self-management. Following User-Centred Design (UCD) [22] principles has sought to ensure that the requirements definition being developed focuses on the user experience.

In the process of defining patient functional requirements, we started by creating personas based on the "The Voice of the Patient" report [23]. The report provided in-depth insights into HCM diagnosis, treatment, and follow-up of patients. Key aspects of the impact of hypertrophic cardiomyopathy on patients' lives based on this report include daily life challenges, such as limitations in physical activity and social isolation caused by symptoms, variable treatment responses and their side effects, concerns about heredity, and significant emotional

and psychological burdens, which highlight the need for individually tailored care and support. The user personas were created using the ChatGPT-4 artificial intelligence model from OpenAI [24], which was selected for its advanced natural language processing capabilities. ChatGPT-4 was prompted with a summary of the report's key aspects, highlighting the importance of health literacy levels [25]. This information enabled the AI-based application to create detailed and nuanced user personas that reflected the demographics, skills, and needs of HCM patients. These AI-generated personas were subsequently reviewed and validated by a human-expert-in-the-loop to ensure that they accurately represented the intended user base and included variations in health awareness. Using generative AI in this context is particularly effective because it efficiently aggregates the data provided into coherent user profiles, facilitating the process of defining initial user requirements. Six user personas were created. The process aimed to cover different user groups, special needs, motivations and health literacy/awareness.

Examples of personas are given below:

Retired senior (68 years)

Retired, former accountant, with moderate health awareness. Has increasing fatigue and shortness of breath with minimal exertion. Fears worsening symptoms and loss of function. Wants to understand his illness, maintain independence, and actively participate in the lives of his grandchildren. Highly motivated to maintain independence and health care, but needs simple tools to effectively manage symptoms. Wants to maintain a social life and interaction with his peers. Fear of sudden worsening of symptoms - need to get prompt medical attention.

Curious family member (35 years)

Journalist with high health awareness. Has mild symptoms but is concerned about HCM running in the family. Wants to gather and share information about HCM with relatives and help them understand the importance of heredity. Finds it challenging to find reliable information and support about heredity and to motivate relatives to participate in screening.

Young athlete (22 years old)

University student and competitive athlete with low health literacy. Recently diagnosed with HCM, which affects endurance and performance. Wants to continue competitive sports as safely as possible and manage symptoms effectively. The challenge is balancing the demands of competitive sports and health, the need to find apps and tools suitable for sports.

After this, on-line meetings were arranged to discuss with 6 patient organization representatives and 7 clinicians from the UK, Finland, France, and Italy to collect expert views on patient requirements and feedback on our approach. Patient representatives reinforced the importance of communication channels between patients and clinicians as well as the collection of patient reported outcome measures and mental health outcomes. Clinicians' views on patient care and software use highlighted the need to develop patient-centered digital tools that support monitoring of quality of life and physical management of the disease and integrate with patient associations to provide comprehensive support to patients at different stages. These views [26] provided important insights into patient care and were used as a basis for creating user stories that were structured to describe users' needs and goals, such as heart rate monitoring, medication reminders, and social support. The analysis of user

stories began with a user story mapping [27], which provided a clear structure for organizing and reviewing the stories. This allowed for rapid identification of key themes and user needs. Theming user stories helped to differentiate between the specific requirements of different user groups. For example, some stories might focus more on social support needs, while others emphasized the importance of real-time monitoring or alerts in managing care. These themes guided the formulation of functional and design requirements, ensuring that the health application being developed meets the diverse expectations and needs of different users.

The themes were then further refined by incorporating elements of the BCW model [28], which provided a structured approach to assessing users' capabilities and motivation, and enabled the design of more targeted interventions. The model was used

to identify the interventions that would best support user behaviour change and effective use of the app. This helped define functional and design requirements that support long-term engagement and active participation in the app. These measures ensured that functional and design requirements were realistic, practical, and above all, relevant to user needs.

The Octalysis framework [29] was integrated in the last stage of process to enhance user engagement through gamification. Its use provided a systematic approach to analysing how different gamification elements could be aligned with the motivational drivers identified in functional and design requirements. Key elements from the Octalysis framework, such as points, badges, and leaderboards, were considered for integration into the digital health tool to make the user experience more engaging. The general methodology is outlined in Figure 1.

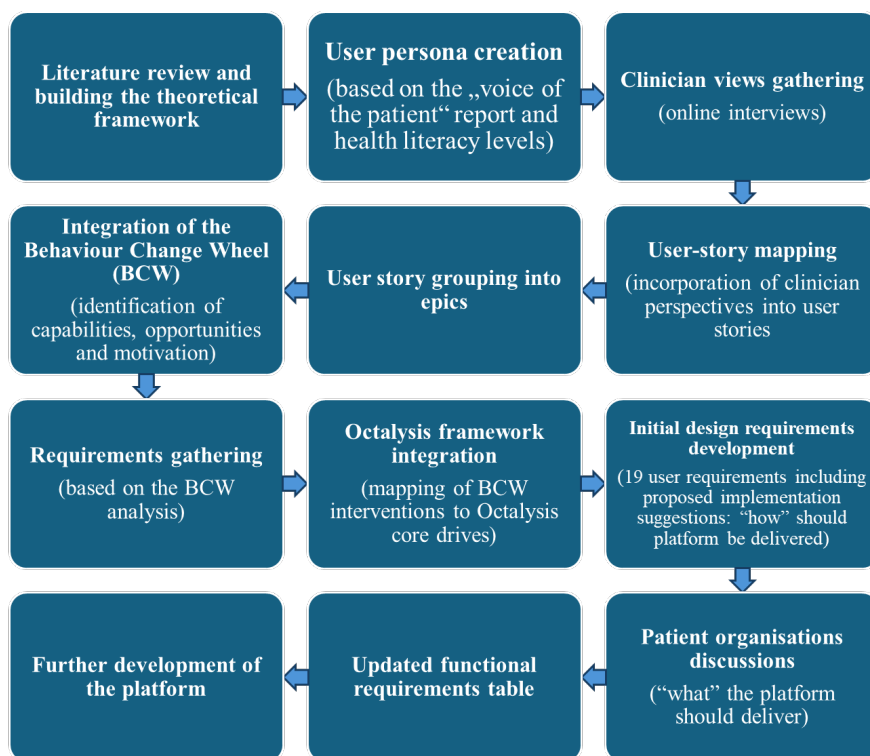


Figure 1. Diagrammatic representation of the methodology pursued in developing the patient requirements.

Results

The study's results provide design requirements and functional requirements by integrating patient feedback, clinical insights, and behavioural science principles to support effective self-management of hypertrophic cardiomyopathy (HCM).

Design requirements

The process resulted in 19 key design requirements that aim to ensure that the application being developed supports the needs of users in the most diverse way possible. For example, personalized reports provide concrete information about the user's health status, while intuitive tools, such as symptom diaries, facilitate users' daily self-care.

Table 1. Design requirements.

Req. No	Design Requirement	Implementation Suggestion
1 *	Personalized Reports	Develop a dashboard that automatically customizes, and updates based on user data.
2	Reward System for Sharing Information	Implement a system that randomly surprises users with unexpected rewards to enhance engagement.
3	Real-Time Feedback	Develop features that provide immediate feedback on users' health activities, such as instant alerts or immediate updates.
4	Interactive Educational Modules	Utilize interactive modules with real-time feedback to improve learning and retention.
5	Intuitive Tools	Develop user-friendly tools that are easy to navigate and provide immediate, actionable insights into users' health status.
6	Training for Proactive Health Care	Offer certificates and bonuses for completing training modules to motivate further learning.
7	Community and Peer Support in Healthcare	Use social features like group quests to foster community bonding and support.
8	User-Friendly Community Platform	Develop a platform that allows easy access to discussions and support groups.
9	Accessibility and Usability	Create tutorial levels that guide users through app features, catering to all skill levels.
10	Clear Instructions and Tutorial Videos	Use a skill tree approach for tutorial videos to let users choose their learning path.
11	Recognitions and Community Events	Implement leaderboards and achievement galleries to showcase and motivate users.
12	Integration with Other Services	Use power-ups as rewards for linking the app with other services, enhancing features or content.
13	Social Networking Guides	Incorporate role-playing elements to guide new users, enhancing social interactions.
14	Visually Attractive Reports	Design interactive visuals that users can explore to uncover health insights in an engaging manner.
15	Educational Materials and Resources	Include mini games related to health topics that provide educational content in an interactive format.
16	Easy Access to Information Repository	Implement a quest finder to recommend articles and resources based on user behaviour and goals.
17 *	Adjustable Personal Health Reports	Enable configuration to allow users to personalize their health reports with themes that reflect their progress.
18	Educational Materials for Gathering Health Information	Offer challenge levels that users unlock by completing tasks, increasing structured learning.
19	Immediate Connection Feature	Integrate an SOS button that is easily accessible.

*Req 1 and Req 17: Personalised Reports persuade users to stay engaged by showing immediate progress, while Personal Health Reports enable users to take control of their health with actionable insights and personalized visual enhancements.

The prioritization of user requirements was a reflective process based on a comprehensive literature review, patient-centered insights, and clinician consultations. The primary goal of increasing engagement in self-care drives this prioritization, focusing on requirements that improve users' ability to manage their health, encourage continued engagement, and enhance the user experience in daily self-care. This informed prioritization, based on the synthesis of data accumulated during the study, ensures that all 19 requirements are tailored to effectively motivate and engage patients to use the app. The most important features were personalized reports that visualize the user's health status and increase the user's motivation to use the application. In addition, real-time alerts and intuitive tools make the user's everyday life easier and improve their ability to manage their own health.

Functional requirements

This section summarises the main functions requested by patients to enable them to collect data primarily for their own benefit, and to have access to HCM educational resources and personalised care pathway and lifestyle guidance.

- The current status of risk factors for HCM such as smoking status, alcohol consumption, the new occurrence within the family of an HCM diagnosis, or an event such as arrhythmia.
- A summary of the broader list of health conditions they have, regular medication across all of their health issues and a place to record short-term treatments.
- A tracking screen through which to monitor their exercise activities: the nature, duration, and intensity at the level of detail they choose.

- Routine collection of known HCM-influencing lifestyle factors such as diet. A patient and clinician could discuss on which lifestyle elements are most relevant to their individual care.

- Influences on and decisions the patient wishes to action regarding change in career that may be necessary as a result of an HCM diagnosis, or any change in the health status such as the development of new symptoms.

- A diary of symptoms or other HCM related events and their ongoing status, also checklists to prompt the recording of negative findings (things not experienced), and offering graphical displays of trends.

- Tracking the status of health outcome measures agreed with their clinician to be personally relevant, captured using visualizations, with thresholds to trigger contacting their clinician.

- Setting and tracking wellness and lifestyle against personalised goals agreed with their clinician.

- Additional aspects of life that are not directly related to assessing health, in particular to capture the ability to fulfil a person's life expectations, possibly covering relationships, social life, work, etc.

- Any special needs (e.g., if a patient is neurodiverse or is not proficient in the national language), mostly as a reminder for care team members.

- Support network listing the non-professional carers who support the patient.

Monitoring data - SMASH-HCM is not issuing patients with wearable technologies during the project. However, it is possible that some will use wearable monitoring technologies (e.g., heart rate or ECG via a smart watch, blood pressure). A monitoring data section is therefore requested to be considered. SMASH-HCM will explore if it is appropriate to provide this access in the patient platform.

The provision of tailored lifestyle advice and education - Patient specific education and guidance is desired by patients to support improved quality of life; activities to reduce the risk of co-morbidities and complications; and avoidance of factors worsening symptoms. This refers to advice that has been personalised by the clinician, not automatically generated.

A summary of the patient's personalised care plan - SMASH-HCM aims for its clinician-facing tools to support the customisation of care plans to maximise relevance to individual patients (personalised care plans). The patients felt it would be valuable for them to have access to a copy of this plan – as a personal aide memoire - so that they know the current plan and what might be the future options should they experience a change in their health situation. This could be a simple visualisation, and does not need to be interactive.

Support with taking medicines - Possible functions to support HCM patients with any medicines they are taking could include reminders, and a diary for side effects or for tracking improvements.

A display of risk scores - Patients would like to be able to see the risk scores that clinicians use, and trends in their values. Some patients felt that they would like to see this to feel an informed partner in care planning decisions. However, this information should only be given electronically to the patient if they wish to see it: some will be interested and some will find it too scary. It was noted that the concept of risk can be hard to communicate, even graphically.

A link to information pages - Patient organisations have several resources developed that patients might find useful as pointers to their national patient organisation website and direct links to specific resources in their language.

A method of communicating to the patient's clinician - The patient organisations indicated that individual patients would like the ability to use the platform to communicate with their clinical team members to raise questions, highlight events, and seek advice. However, a two-way channel of communication through an app developed by a research project is unlikely to be endorsed by clinicians and their organisations. An alternative, simple, option is to provide a memo function for patients to keep note of topics and queries they wish to raise at their next consultation.

General requirements - It should be possible for a patient to provide access to their clinical team to information they have collected, in case the patient has made observations they would like to discuss during a clinic visit. If a patient is undergoing regular monitoring, it may also be appropriate that clinicians have access to this ongoing monitoring information so that they can detect any issues with a given patient that warrant discussing how best to handle a new issue. For this to be practical, an AI-assisted system may be needed that is able to direct physicians only to the urgent or important situations.

There are inevitably non-functional requirements to take on board as well, to do with the accurate identification of patients, their authentication within the app and information security measures.

Discussion

The integration of digital health solutions in managing HCM has gained momentum, aiming to enhance early detection, patient engagement, and self-management. Recent advancements have introduced digital tools targeting HCM management from a clinical perspective and target technically robust tools and models informed and trained on large datasets (e.g., a Convolutional neural network to

develop an AI-ECG for the detection of HCM from standard 12-lead ECGs [30]). Notably, a recent publication [31] involved the Hypertrophic Cardiomyopathy Association (HCMA) to develop a digital care navigator for HCM patients. This platform aims to educate and empower HCM patients and their families. Such tools can be pivotal in providing personalized education, support and resources, enhancing patient engagement and adherence to management plans. While specific metrics on digital care navigator effectiveness and impact are yet to be published, such platforms are designed to enhance patient engagement, which is a critical component of effective disease management. The publication found that engaged patients are more likely to adhere to treatment plans, attend regular follow-ups, and make informed lifestyle choices, all of which can positively influence disease progression and quality of life. However, the methodology to determine functional patient requirements to such tools often remain cryptic.

In our study, clinicians and patients were central to defining the platform's functional and design requirements. Additionally, the expertise of technical stakeholders, including developers and system engineers, was considered essential to assess resource needs, technical feasibility, and needed interdisciplinary collaboration for each of the requirements. Based on these requirements and to support implementation, our identified requirements were prioritised into three phases:

- **Prototype Phase:** High-priority features achievable within 2–5 years, such as a reward system for sharing information, community platforms, accessibility improvements, instructional materials, and adjustable personalised health reports.
- **Midterm Phase:** Features requiring more resources, including personalised reports, intuitive

tools, peer support systems, integration with external services, and engaging educational materials.

- **Later Phase:** Features applicable for long-term development, such as real-time feedback, interactive educational modules, proactive healthcare training, recognition events, and social networking guides.

This phased approach allows for iterative refinement and adaptation to evolving stakeholder feedback or unforeseen challenges during development.

As a limitation, the study's reliance on qualitative data restricts the generalisability of the findings across the broader HCM population. Proposed features have yet to be piloted in real-world settings, leaving their usability, effectiveness, and ecological validity untested. Future research is to include large-scale validation through iterative testing and longitudinal studies to refine the platform and evaluate its impact on health outcomes.

Conclusion

This work described the functional requirements development process and it contributes to evidence supporting user-centred design in digital health, reinforcing the importance of participatory approaches in addressing complex health management needs. It provides a foundation for developing an HCM self-management platform that prioritises usability, engagement, and personalisation, offering a framework for similar health technology initiatives.

Although the original aim of this work was to identify areas of patient self-care that could benefit from decision support solutions, feedback from patients revealed a preference for a platform that prioritises accessibility and utility. Responses emphasised the need for an informative system they could

consult regularly and use to log health data, with additional care support and information features beyond self-care decision support. This feedback suggests that the perceived role of decision support per se is still rather limited. Feedback provided by developers of the technology helped to place the requirements on an implementation timeline.

Future research focuses on implementing these requirements into prototypes with mechanisms for iterative testing and refinement. Addressing challenges such as clinical integration, data security, and scalability are essential for ensuring widespread adoption, adherence, and effectiveness of digital twin technologies. A participatory design approach and emphasis on user engagement aligns

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with current best practices in digital health research. The insights gained from this work contribute to the ongoing discourse on effective strategies for developing digital health platforms that are both user-friendly and clinically effective.

Conflict of interest statement

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