How To Conduct Qualitative Studies For Digital Health Technologies.

An expert guide by:

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This carousel is compiled using the following resources:

Guidance

Choose evaluation methods: evaluating digital health products

Compare different evaluation approaches and choose an appropriate method.

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Qualitative Methods in Health Care Research

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Available here:

https://www.gov.uk/guidance/choose-evaluation-methods-evaluating-digital-health-products#qualitative-studies

https://pubmed.ncbi.nlm.nih.gov/34084317/

Section 1:

What is qualitative research and why is it important?

INTRODUCTION

Qualitative research can be good for understanding the **thoughts and experiences** of users of digital health products.

It can give a richer explanation of what is happening.

For Example,

A quantitative approach could describe **patterns of disengagement** with an app and what **demographic factors** predict disengagement,

but a qualitative approach can **describe why users stopped using the app**.

What is Qualitative Research?

Qualitative research involves:

- Broadly stated questions about **human experiences and realities**,
- Studied through sustained contact with the **individual in their natural environments**,
- Producing **rich, descriptive data** that will help us to understand those individual's experiences."

Purpose of Qualitative Research

The qualitative method of inquiry examines the **'how' and 'why'** of decision making, rather than the **'when,' 'what,' and 'where.'**

Unlike quantitative methods, the objective of qualitative inquiry is to **explore, narrate, and explain the phenomena** and make sense of the complex reality.

Understanding the richness and complexity of human behaviour **is the crux of qualitative research.**

For Regulatory Purpose.

“Qualitative studies can be used for **formative usability evaluation**, that is informing the design of a device's user interface to assure safety & security.

Also similarly for the **risks & misuse of reporting** from some analysis SaMD, to ensure that the users (lay user i.e. patient or carer, or HCP user, or whoever) gets and acts on the message that is intended to be conveyed. “

Mike Pogose

Director of Quality Assurance and Regulatory Affairs at Hardian Health.

For Digital Compliance

“Qualitative user research can be used in DTAC section D which covers the **usability and accessibility criteria** of digital health technologies. This will assist with sections D1.1 to D1.31.”

Michael Bell

Partner at Acorn Compliance

When to use qualitative methods?

Use them when:

- You want a more in-depth understanding of **users' thoughts and experiences** of your product.

- You're developing your product, to **work out how to improve it** (formative or iterative evaluation).

- You have **open-ended questions**.

Types of questions they answer.

- What was users' **overall experience** of the product?
- How did users feel **during their journey** through the product?
- What do users want to see in a **new version** of the product?

Weakness of Qualitative Studies

While qualitative studies can describe the range of views among participants, **they are weak at saying how many participants hold different views**.

Results from qualitative studies are **hard to generalise** to other participants.

But,

The number of participants needed **can be much lower** than for other evaluation methods.

However, the amount of information you get from each participant **can be much higher**, so usually more time is spent with each participant.

Section 2:

Steps to conduct good qualitative research.

Start with the Question.

Qualitative questions are **exploratory** and are **open-ended**.

A well-formulated study question forms the basis for:

- Developing a **protocol**,
- Guides the **selection of design**,
- **Data collection** methods.

PCO framework

A commonly used framework for designing a qualitative research question is the 'PCO framework'.

P stands for the **population** under study,

C stands for the **context** of exploration,

O stands for the **outcome**/s of interest.

The PCO framework guides researchers in crafting a focused study question.

For example.

In the question,

“What are the experiences of mothers on parenting children with Thalassemia?"

The **population** is “mothers of children with Thalassemia,"

The **context** is “parenting children with Thalassemia,"

The **outcome** of interest is “experiences."

Qualitative research methods

Once you have your research question, you will then need to **choose the best methodology** to answer it.

There are **5 key methods** commonly used in digital health:

- Contextual inquiry
- Ethnographic study
- Focus group study
- Interview study
- Usability testing

Contextual Inquiry

When conducting research, we often ask people questions (for example, in a survey) about what they usually do and have done in the past.

However, human memory can be unreliable.

A study designed using contextual inquiry tries to overcome this issue by **observing people in their context** while **inquiring** (observing and questioning).

Contextual Inquiry

Contextual inquiry uses a combination of **observation** and **interviews**.

The length of a contextual inquiry can vary from an hour to several days, depending on participants' availability and the complexity of the processes you are trying to understand.

What to use it for

Use contextual inquiry to:

- inform **product or service development** (formative or iterative evaluation)

- **develop a new feature** for your digital product.

Pros

Benefits of contextual inquiry include:

- it can provide a nuanced and rich understanding of **how and why people engage with their environment**, factors that are often not reported

- it **reduces recall problems** – when results are distorted by the fact that people use their memory when removed from their environment

- it is usually conducted with a **small number of participants**.

Cons

Drawbacks of contextual inquiry include:

- contextual inquiry is not intended to tell you **if your digital product is effective.**

- **it can be subjective**, as it is very dependent on the researcher's interpretation and skills.

Examples of Contextual Inquiry in Digital Health:

Herrmann and others (2017), Watts your usage? A field study of householders' literacy for residential electricity data. Authors used contextual inquiry with think aloud to find out how users interpret the graphs of their electricity usage on a website.

Vanhoof and others (2018), Shedding light on an unknown reality in solid organ transplant patients' self-management: A contextual inquiry study. In this contextual inquiry, the team explored how patients who received a transplant self-manage their health behaviours and medications. As part of their recommendations, they argue that digital self-management intervention can play an important role as an addition to face-to-face interactions.

Ho and others (2013), Needs and workflow assessment prior to implementation of a digital pathology infrastructure for the US Air Force Medical Service. An example of the use of contextual enquiry to identify the needs and requirements of pathologists with an aim to explore the potential to develop a digital pathology system.

Ethnographic studies

Ethnography involves **observing people in their own environment** to understand their experiences, perspectives and everyday practices.

This can give in-depth insight into a particular context, group or culture.

Ethnography uses **different research techniques**, which may include:

- **Observations**
- **Taking field notes**
- **Informal conversations**
- **Interviews**
- **Document analysis**
- **Surveys**
- **Filming and photography.**

Ethnographic studies

Ethnography **investigates the whole setting** rather than a digital product in isolation. It focuses on exploring experiences (how someone might use the product in practice), not testing hypotheses.

What to use it for

Use ethnography to describe how a particular group or community works. For example, you could focus on the **experiences** of:

- **professionals** delivering a digital health service
- **changes in routine practices** in health services because of digital tools
- **patients living with a health condition** and using digital tools.

Pros

- it can offer a **deeper understanding of experiences and local practices** than quantitative studies or qualitative studies that only rely on interviewing (what people do versus what they say)

- it can uncover experiences, knowledge and perspectives **that other methods miss out** because of its real world focus and flexible approach

- it can give a voice to **seldom-heard groups** and perspectives that have been marginalised or overlooked

- it can uncover **unintended consequences of changes** made

Cons

- it **usually involves extensive field work** – this is time-consuming and needs experience, although rapid ethnographic approaches are increasingly being used

- it **can be subjective** because it's very dependent on the evaluator's interpretation and skills

- **negotiating permissions and access** to carry out observational work can be difficult

Examples of ethnographic studies in digital health

Ventres and others (2006), Physicians, Patients, and the Electronic Health Record: An Ethnographic Analysis. An example of an ethnographic study of how electronic health records change the interaction between patients and physicians.

Sturesson and others (2018), Clinicians' Selection Criteria for Video Visits in Outpatient Care: Qualitative Study. Following the introduction of video visits with patients in outpatient care in Sweden, researchers conducted an ethnographic study to investigate how clinicians used this new healthcare delivery.

Solvoll and others (2013), Physicians Interrupted by Mobile Devices in Hospitals: Understanding the Interaction Between Devices, Roles, and Duties. This study investigated the impact of interruptions caused by mobile phones to the working practices of physicians in Norway.

Focus Group Study

Focus groups are facilitated group discussions. The facilitator is the person guiding the discussion. Carry out a focus group study if you want to **understand people's views and experiences.**

What to use it for

Focus groups use group dynamics to get shared experiences **of people with similar characteristics**. This is different from an interview study, where the focus is on individuals.

Focus groups can be used to get feedback **before, during, or after** your product is developed.

How to carry out a focus group study

. Think about what you want to find out in advance to the session.

. Decide how many focus groups to conduct.

. One approach is to keep recruiting participants until you are not getting any new insights from focus groups (saturation of answers).

Focus groups need facilitators. They should:

. encourage participants to discuss their views openly.

. use prompts and questions to make sure the discussion points you are interested in are covered.

Pros

- group dynamics can **promote discussion**, idea sharing and debate

- they provide **a breadth of shared experiences** from people with similar characteristics, for example people experiencing similar health conditions or health professionals using your digital product

- they **can be used at every stage** of creating a digital product, from finding out more about the needs of your users to refining and testing new content and features of your product

Cons

- staff needed – **you will need a facilitator** who encourages discussion and possibly also a separate note-taker

. it **might be difficult to get the users you need** together in one room at the same time.

Examples of focus group studies in digital health.

Garrido and others (2019), Young People's Response to Six Smartphone Apps for Anxiety and Depression: Focus Group Study. The team ran focus groups with young people to find out about users' needs to inform and recommend the development of the apps.

Alkhaldi and others (2017), Promoting Engagement With a Digital Health Intervention (HeLP-Diabetes) Using Email and Text Message Prompts: Mixed-Methods Study. Researchers wanted to find out how best to use prompts to promote engagement with an online intervention for Type 2 Diabetes.

Lally and others (2018), Feasibility of Synchronous Online Focus Groups of Rural Breast Cancer Survivors on Web-Based Distress Self-Management. The team ran online focus groups exploring the views of an online intervention for breast cancer survivors.

Interview Study

Interviews with users of a digital health product can be carried out to understand their **views and experiences**.

How to carry out an interview study

You can use interviews to collect **quantitative or qualitative data or both**.

Semi-structured interviews are a common approach for collecting qualitative data. These involve **open-ended discussion** with the participant, guided by a pre-existing plan.

Write a discussion guide with a few important questions in advance and use this to guide your conversation.

Pros

- provide **in-depth insight** into experiences
- can be carried out with **low numbers of participants**.

Cons

- can be **time-consuming** to carry out
- require participants to **give some of their time**
- can describe the range of user views, but **not how common each view** is

Examples of interview studies in digital health

Gowin and others (2015), Health and Fitness App Use in College Students: A Qualitative Study. This study interviewed participants about a range of different apps.

Thies and others (2017), Lack of Adoption of a Mobile App to Support Patient Self-Management of Diabetes and Hypertension in a Federally Qualified Health Center: Interview Analysis of Staff and Patients in a Failed Randomized Trial. Researchersinterviewed patients and staff about their experience of the app and how it was introduced to patients to understand what had happened.

Crane and others (2017), Factors Influencing Usability of a Smartphone App to Reduce Excessive Alcohol Consumption: Think Aloud and Interview Studies. Researchers conducted 2 sorts of interview studies about an app to reduce alcohol consumption. The first was a ‘think aloud’ study, the second was an interview after users had been given the app to use for 2 weeks.

Usability testing

Usability testing looks at whether a digital product or service is **usable, effective and acceptable** to users.

The insights you get are usually qualitative, but you can do quantitative usability testing by **introducing metrics such as task completion time** or clicks to completion.

What to use it for

Usability testing can be used at all stages of product development, from early prototypes to iterative improvement of existing products. Use it to:

- learn more about **your users and their needs**
- test whether you are **meeting user needs**
- work out how to **make your product better**

How to carry out usability testing

1. Participants are asked to complete specific tasks using the product you have designed.

They may be asked to think aloud as they complete tasks or reflect on their experience of using the product or prototype afterwards.

2. Have clear tasks and success criteria.

For example, you might want to ask a user to find a specific piece of information. The success criteria would be them completing the task.

3. Have one person administering questions (facilitator) and one person taking notes (support).

You may want to record the session so that it is easy to refer back to. You could record the audio, the screen and the users' hands using the screen.

Pros

- usability testing is a well-established way to identify common usability issues.

- it is relatively easy to do as you do not need any special equipment or many participants

- it is a low-cost, low-risk way to gather feedback

Cons

- because you are asking users to complete a task in a controlled environment, it may not reflect how they naturally use the product or the challenges they would face in real life

- it can be time consuming to conduct usability testing with participants, especially if you need to travel to where they are located

- it can be challenging to find the right participants.
If participants are not right, the insights you gather can have lower value or be misleading.

Examples of usability testing in digital health

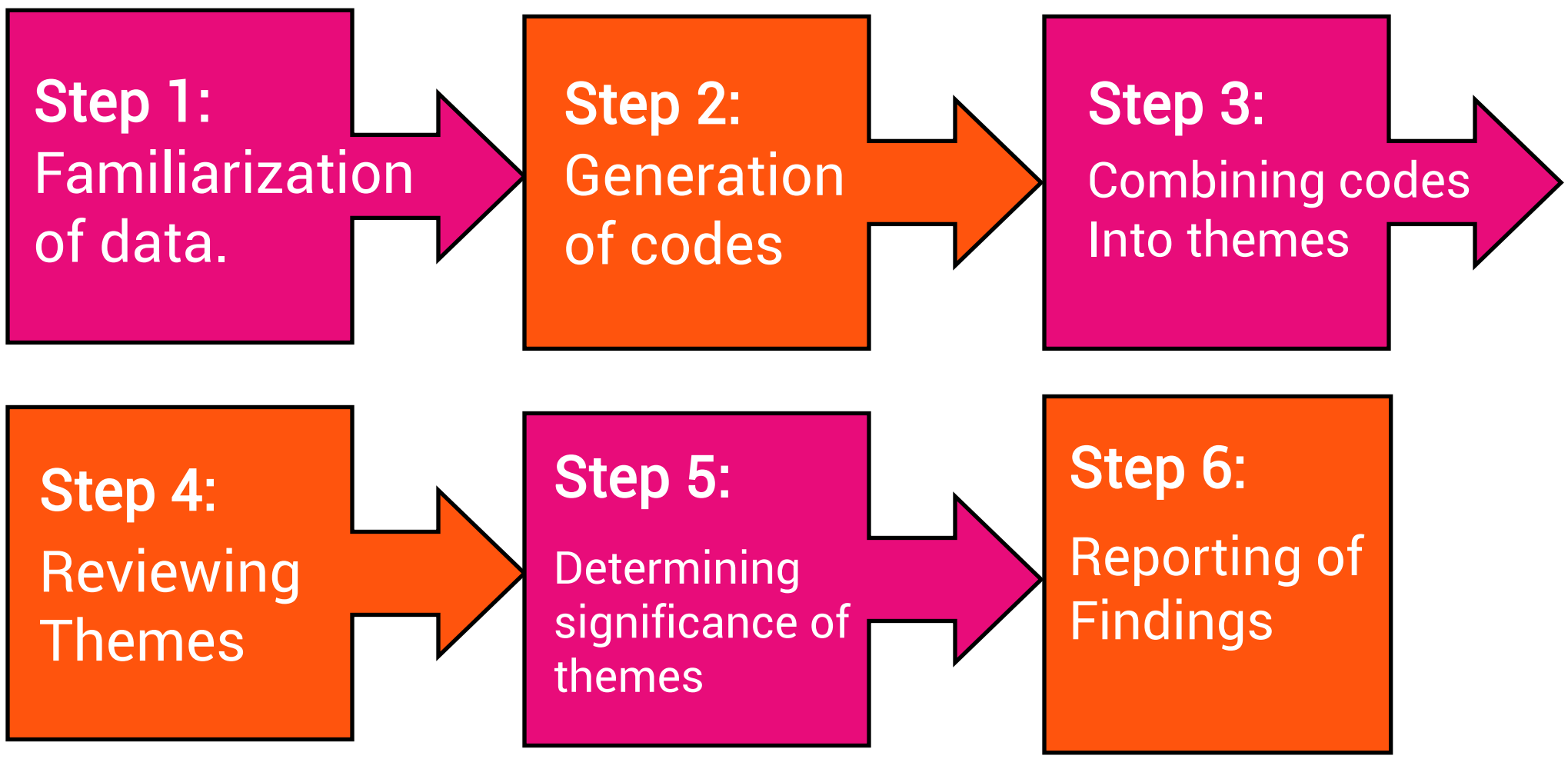
Diamantidis and others (2015), Remote Usability Testing and Satisfaction with a Mobile Health Medication Inquiry System in CKD.

Colligan and others (2015), Cognitive workload changes for nurses transitioning from a legacy system with paper documentation to a commercial electronic health record – this was a quantitative study of usability using standard measures of cognitive work-load.

How to analyse qualitative data

Unlike statistics used to analyse quantitative data, qualitative data are often analysed using **thematic analysis.**

The **6-phase coding framework** for thematic analysis is used to identify themes and patterns in the data. The phases are:



How to report qualitative data

Consolidated Criteria for Reporting Qualitative Research (COREQ) is the widely used reporting guideline for qualitative research.

This **32-item checklist** assists researchers in reporting all the major aspects related to the study.

The three major domains of COREQ are the **'research team and reflexivity'**, **'study design'**, and **'analysis and findings'**.

Hope you found this helpful!

This is a series we are making to help HealthTech Innovators access better resources.

Just our small way of helping!