

The Changing Face of Qualitative Interviewing in Clinical Outcomes Assessments Research: Conducting Qualitative Interviews Post COVID-19

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Background

- Qualitative interviews are an important method for collecting in-depth patient experience data.
- In-person interviews have typically been considered the gold standard by both researchers and regulators even though literature has indicated virtual interviews are equal.¹⁻¹⁰
- The Covid-19 pandemic curtailed the ability to conduct in-person interviews and necessitated a move to virtual interviews.
- It is important to consider, therefore, how this may have affected clinical outcomes assessments (COA) qualitative research and whether virtual interviewing is an equivalent and viable option to face-to-face interviewing moving forward.
- The latest FDA Patient-Focused Drug Development (PFDD) guidance has also acknowledged this change form of qualitative interviewing.¹¹

Results

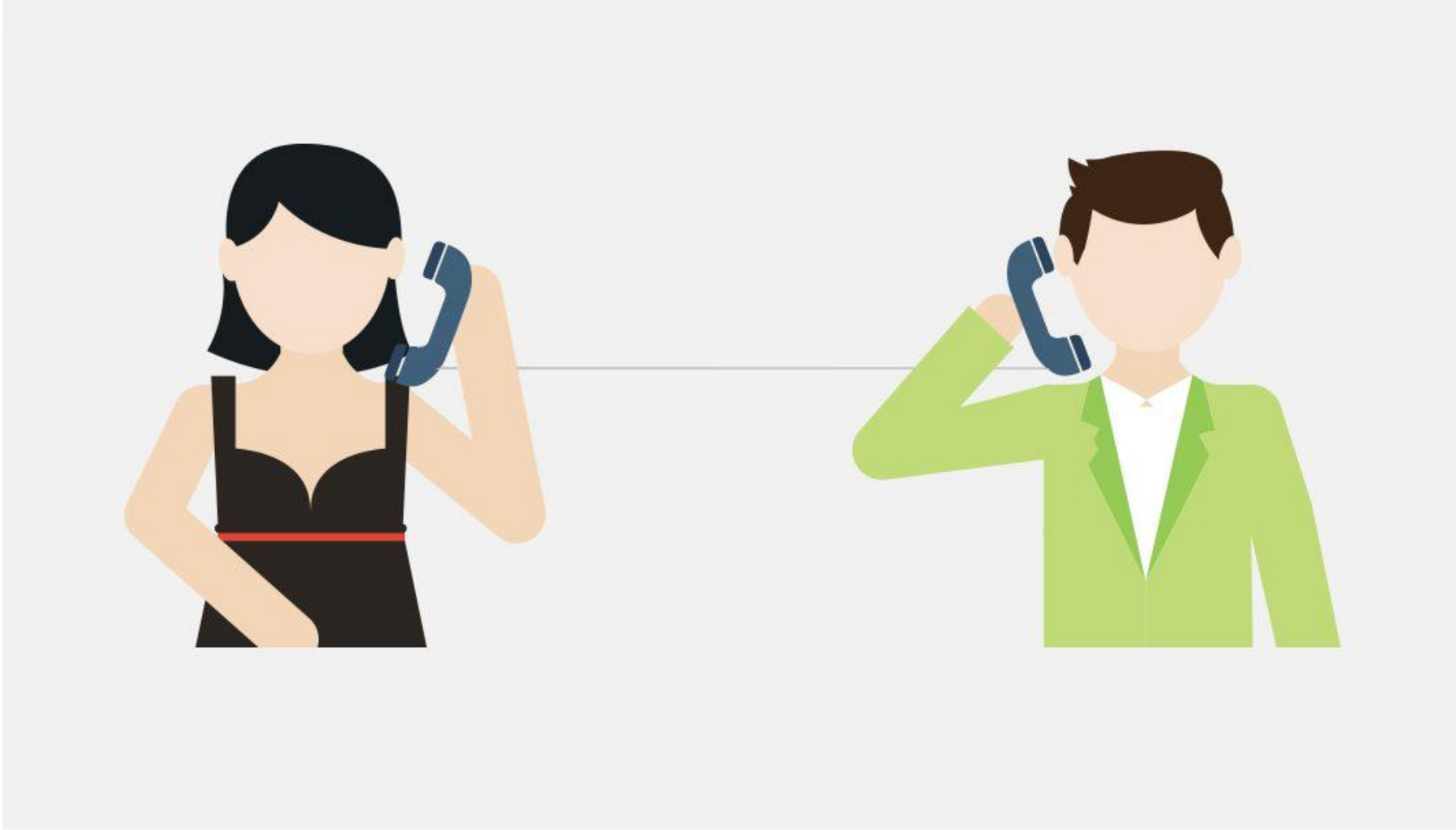
Key findings

When comparing Face-to-Face vs. Virtual interviewing, 4 main observations were made:

- Quality of interviews and **data collected appears to be equal**
- Virtual interviews **eliminate the burden** of travel and unnecessary health risks for patients
- Technological issues** of joining virtual interviews **were minimal**, if any
- Virtual interviews appear to **be well-received by participants**.

1. Quality of interviews and data collected appears to be equal

- Following a review of all virtual interviews conducted by the researchers no changes to data analysis or reporting were needed to compensate based on format.
- Data collected during virtual interviews was consistent with data collected during face-to-face interview.
- Developing rapport virtually did not affect patients' willingness to share intimate details about their experience; in fact, patients appeared to feel *more* comfortable sharing information on sensitive topics and/or embarrassing symptoms when not in a face-to-face environment.
- No participants in any study raised any concerns with interviewers in a virtual interview.
- Ensuring that you have a high-quality stable microphone with clear audio can improve your connection to the participants, thus assist in rapport development.



2. Virtual interviews eliminate the burden of travel and unnecessary health risks for patients

- Patients who agree to participate in COA qualitative research often have significant health challenges in which travel to/from an interview site and interviewing time may be burdensome to both the patient and family members.
- These health conditions also put patients at increased risk of exposure to COVID-19 or other infections.
- Virtual interviews can be scheduled at a time convenient for the patient and conducted within the comfort of their own homes.
- Virtual interviewing is a more empathetic, patient-first method for conducting qualitative interviews, over traditional face-to-face interviews.

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Objectives

- The objective was to explore the impact of conducting phone interviews on the quality of qualitative data collected when compared to face-to-face interviews.

Methodology

- The researchers are experienced qualitative researchers who have been involved with qualitative studies and COA research for 10 – 15 years.
- Over the past 2 years, the authors have conducted or been involved in over 300 virtual interviews due to the impact of COVID-19. The interviews have been conducted across a range of indications and across multiple countries, age groups, and ethnic groups.
- The authors then compared observations of the virtual interviews to previously conducted face-to-face interviews, with specific attention to the quality of the interview and the resulting data.

3. Technological issues of joining virtual interviews were minimal, if any

- Minimal technological-based issues were experienced during the interviews
- Increased familiarity with video calling platforms and teleconferencing technology during the pandemic resulted in minimal issues/difficulties joining the interview.
- Clear instructions, with the option of a practice call, helped to mitigate any concerns or difficulties participants experienced.

4. Virtual interviews appear to be well received by participants.

- Participants did not raise any concerns with the virtual interview they engaged with.
- Some participants, who had previously been involved with face-to-face studies indicated that they preferred this approach.



FDA PFDD Guidance 2

- In PFDD Guidance 2, the FDA also highlights the strengths and limitations of phone and virtual interviews
 - Benefits:** Participants not being limited by geographic location, can join from a familiar environment thus feeling more relaxed, minimizes travel and disruptions to the participant's life, and supports those who may have disabilities which makes travel difficult.
 - Potential limitations:** May be difficult to develop rapport, the participant may not have a private space, there may be disruptions from family etc., may not have access to a certain technology or may have difficulties or problems using that technology.
- This reflects the experience of the research team. However, despite the potential limitations proposed by the guidance, the researchers had not encountered an occasion where rapport was not successfully established. In addition, the research team has found that technical difficulties can be easily mitigated by providing support and guidance to the participant by scheduling a pre-interview 'run-through'.

Conclusions

- Based on the authors' experiences of conducting and being involved in interviewing during the COVID-19 pandemic, there was no impact on the quality of the data collected from virtual interviews when compared to face-to-face interviews. Therefore, virtual interviews appear to offer the **same quality of data as in-person interviews**.
 - This is supportive of previous published research¹⁻¹⁰
- Virtual interviews **reduce the burden** on the participant since the participant does not need to travel for the interview.
- Reduces the risk of acquiring or spreading communicable diseases** such as COVID-19 for participants, particularly those with high-risk conditions.
- Regulators appear to be initially responding positively to this approach. It may be that it will become the preferred method for qualitative interviews in this field.