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1 Introduction:

Qualitative research is a diverse group of interpretative methods which aim to explore, understand and explain people's experiences using non-numerical data [1]. Although still dominated by quantitative research methodology, the use of qualitative research methodology in clinical and healthcare research has grown steadily in the past couple of decades [2]. Qualitative research methodology typically involve interviewing and/or observing people who are central to the research topic. The data produced are usually (though not always) in the form of text, reporting what interviewees said and/or did. The data are then analysed, often by the person who interviewed or observed, leading to the likelihood of subjectivity and bias. Therefore, qualitative studies have often been criticized for lacking rigour, transparency, justification of data collection and analysis methods being used, and hence the integrity of findings [3].

The issue of "judging the quality" in qualitative research has been one of the most debated topics among methodologists and until recently there has been little consensus on what constitutes a good and trustworthy qualitative study [4-9]. Rolfe postulates that three opinions exist in the literature on how best to judge the quality of qualitative research [4]. The first view, although not a popular one, advocates for the adoption and application of positivist terminologies like validity and reliability to describe rigour in qualitative research [5]. The second view (realist), the most popular view among healthcare researchers, rejects the potential applicability of positivist reliability and validity criteria because of differences in the theoretical and philosophical paradigms underpinning quantitative and qualitative research [6,7,10]. This view therefore, promotes the use of alternative terminologies such as dependability, credibility,

conformability and transferability instead of their quantitative equivalents reliability, internal validity, objectivity and generalizability respectively to describe rigour (trustworthiness) in qualitative research. Methodological techniques (explained in detail later) such as the audit trail, member checking, negative case analysis, triangulation, prolong engagement with participants and peer debriefing have also been proposed in the literature to ensure dependability, credibility, and transferability in qualitative studies (Refer to Table 1 for brief description of these terminologies) [6,7,10]. However, not all these strategies are applicable in all types of qualitative studies [8,9]. The third and final view held by some methodologists (interpretivist) have challenged the very idea of having a single pre-determined criterion for evaluating the quality of diverse approaches within qualitative research. Qualitative research encompasses a number of different research methods underpinned by different research paradigms and theories thus making single evaluative criteria impossible to develop and apply [4]. Methodologists belonging to each of these paradigms have their arguments to support their positions. The most important thing to note here is that the term paradigm refers to a discrete set of beliefs and researchers are free to choose any paradigm (constructivist, realist, feminist) but they need to be transparent about the choices that they have made aligning with a specific paradigm and avoid mixing of paradigms. Until recently there has been little guidance available for assessing the guality of published qualitative research, but COREQ (Consolidated criteria for reporting qualitative research) provides a 32 item checklist now widely used by medical and health journals, to aid reviewers [11]. Subsequently two more checklists have been developed based on wide ranging reviews, both producing a 21-item list, one for

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- qualitative studies [12] and another for qualitative research syntheses [13]. However,
- while these papers identify standards for reporting, they do not go into the rationale for
- 3 selecting and undertaking strategies for ensuring rigour.
- Unlike other healthcare disciplines, the subject of "quality" in qualitative research has not been discussed much in the clinical pharmacy discipline. Perhaps this is because
- 6 the quality issue has been discussed extensively in other disciplines, allowing clinical
- 7 pharmacy researchers to rely on the available literature. Being predominantly trained
- within a "positivist" paradigm, pharmacists may find debating this issue "out of their
- 9 comfort zone" or, simply, they may just not be interested. The aim of this paper is not to
- propose another checklist to evaluate the quality of qualitative research but to highlight
- the importance of rigour, present different philosophical standpoints on the issue of
- 12 quality in qualitative research and to discuss briefly key strategies to ensure
- methodological rigour. Finally, an illustration of strategies reported by clinical pharmacy
- researchers in a random sample of papers published recently to show how rigour in
- 15 qualitative research is presented.

Strategies to ensure trustworthiness

- 17 A number of strategies have been proposed to ensure trustworthiness of qualitative
- findings. It has been suggested that at least two of these strategies should be used in
- any particular qualitative study [14]. A brief description of commonly used strategies is
- 20 given below.

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Triangulation

- 1 Triangulation is a widely used method to ensure credibility and conformability of
- 2 qualitative studies [14]. Triangulation involves using at least two related data sources,
- 3 data collection methods or researchers with the aim of reducing inherent bias
- 4 associated with a single source, method or researcher [5]. Triangulation should not be
- seen as a tool to check the validity of data and labeling data as "true" or false" but to
- ascertain the validity of the inferences derived from multiple data sources [15].

Self-description/Reflexivity

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- 8 Self-description and self-reflection is very important in qualitative research to
- 9 acknowledge and reduce researcher bias, a common criticism of qualitative research.
- 10 Self-reflection will enable qualitative researchers to discuss their position within the
- study and how their personal beliefs and past training have influenced the research
- findings [5, 15]. Qualitative researchers should be encouraged to make field notes and
- maintain a reflective journal in order to recognize and make explicit any personal biases
- 14 [15]. Self-description promotes credibility and conformability of research findings

Member checking

- Alternatively known as respondent validation, this is often described as the single most
- important method to ensure a study's credibility [7], and refers to checking of study
- 18 findings and conclusions by the respondents from whom the data (interview,
- observation) were originally obtained [5]. The aim of member checking is to ensure
- 20 dependability and credibility of qualitative studies. However, some methodologists have
- raised concerns about the usefulness of member checking as qualitative data do not
- 22 only consist of interview/observational data but also include field notes, the author's

reflective journal and non-verbal signs which the respondents may not "own as their personal views" [5,15]. Furthermore, study results are often synthesized from data obtained from interviewing/observing a number of participants, making it difficult for individuals to recognize his/her own view. Any forced attempt to accommodate respondents' concerns may make the result more "descriptive" and "close to data", an undesired outcome in almost all of the qualitative research designs [8]. Therefore, member checks should not be seen as a verification strategy to judge accuracy of data analysis.

Prolonged engagement

Prolonged engagement with study participants and community is recommended in order gain their trust and establish rapport [14]. This is likely to enable the researcher to get more in-depth information from the respondents and identify pertinent characters in the community concerning the issue being studied in order to focus on them in more detail and ensure that the research topic is explored comprehensively [14]. Prolonged engagement may promote the credibility of a qualitative study

Audit trail

Audit of decision trails should enable readers to make their own judgments about the quality, transferability and worth of a study [17]. The reader may then follow the authors' decision trail and associate it with their own conclusions which they have drawn from the information provided. Audit of the decision trail involves detailed description of sources and techniques of data collection and analysis (interview/observation),

- interpretations made, decisions taken, and influences on the researcher with the aim of
- 2 demonstrating truthfulness within the findings [17].

Peer debriefing

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Peer debriefing also known as "analytic triangulation" [18], is a method in which the 4 researcher discusses the research methodology, data analysis and interpretations 5 6 continuously throughout the research process with his/her peer who is not directly involved in the research project [7]. Ideally, the peer debriefer should be a skilled 7 qualitative researcher who can meaningfully question the researcher's interpretations, 8 provoke critical thinking, and provide alternative/additional perspectives 9 explanations. Peer debriefing enhances credibility and trustworthiness as it gives the 10 11 researcher an opportunity to ensure that emergent hypotheses, themes or theories are derived from the data and are sensible and conceivable to a disinterested debriefer [18]. 12 For research students, their supervisors can act as debriefers. Other forms of peer 13 debriefing include: presentation of research findings at conferences; regular discussions 14 with an expert qualitative researcher; and presenting preliminary findings to interested 15 groups [5]. 16

Thick description

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Providing rich and thick description is used to obtain external validity (transferability)
[5,14]. It also promotes study credibility as well. It requires the researcher to give
sufficient details about settings, inclusion/exclusion criteria, sample characteristics, and
data collection and analysis methods, so that the reader can evaluate the extent to

- which the conclusions made by the authors are transferable to other settings, situations,
- 2 and populations.

3 A mini-review of strategies used to ensure trustworthiness of qualitative research

4 in Clinical Pharmacy

- 5 To illustrate the points made above, a mini review was undertaken. This explored the
- 6 strategies reported by clinical pharmacy researchers to ensure rigour in their qualitative
- 5 studies, but not to judge the quality of qualitative research which is a relatively broad
- 8 and fiercely debated area. Study selection and data extraction was conducted by the
- 9 first author (MAH).
- Medline was searched to identify qualitative studies using the keywords "qualitative"
- AND "pharmacist" OR "pharmacy" published during 2014 and 2015 in the English
- language. Studies published in non-pharmacy practice/clinical pharmacy journals were
- excluded. A database of the first 30 articles meeting inclusion and exclusion criteria was
- created and finally ten articles [19-28] were randomly chosen using random numbers for
- 15 quality evaluation. The search strategy was not designed to identify all qualitative
- papers in the field of clinical pharmacy but to minimize authors' bias towards study
- inclusion.

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Of the 10 studies reviewed, four studies used individual semi structured interviews, two used focus groups, another two used combinations of both semi structured interviews and focus groups and one used online survey (including open ended questions) as the means for data collection. For data analyses, five studies employed thematic analysis and four framework analysis. Thick description (n=9)

followed by peer-debriefing (n=5) were the most commonly reported strategies used to establish rigour. Surprisingly, only two studies discussed the application of various (member checking, peer debriefs etc.) in relation to establishing trustworthiness/rigour in their studies. Although all the studies described in detail inclusion/exclusion criteria, participant recruitment, participant characteristics and topic guide content, the process of data analysis was not described in detail in almost half of the studies. Only three studies used at least two strategies, excluding thick description, to establish trustworthiness. None of the studies reviewed reported using either member checking or reflexivity to ensure rigour. Although this is a 'snapshot', these findings clearly indicate is that there а need to increase awareness among clinical pharmacy researchers of the importance of demonstrating rigour when publishing qualitative research. Peer-reviewers should also stress rigour, in addition to other aspects of a qualitative study during the peer-review process as it may be that the authors have used strategies to ensure rigour but did not report them. An independent section/sub-section in the methods or discussion section reserved for detailing strategies to ensure rigour will encourage clinical pharmacy researchers to explain these strategies. However, there are certain limitations to the above findings which need to be carefully considered. First, studies were only included from various leading pharmacy practice journals (International Journal of Clinical Pharmacy, International Journal of Pharmacy Practice, Canadian Pharmacists Journal, Research in Social and Administrative Pharmacy, Pharmacy Practice, Journal of American Pharmacists Association), however, studies published in non-pharmacy practice journals were not included, therefore, the findings may not be transferable to qualitative studies published

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by clinical pharmacy researchers in non-pharmacy practice journals which may have different reviewing processes. Second, although the word limit for qualitative research is relatively generous compared to quantitative research, the word limit imposed by journals might have influenced the authors either not to report or abridge the details of the strategies used to ensure rigor and trustworthiness. Finally, all the selected papers have been peer-reviewed prior to publication and the authors' description of methods may have been edited, shortened or removed during the peer review process. Therefore, the above findings are based on what has been reported in the final paper rather than what the authors "intended" to publish.

Conclusion

As with any other research methodology, demonstrating rigour in qualitative studies is essential so that the research findings have the "integrity" to make an impact on practice, policy or both. Although different viewpoints exist in the literature on the issue of quality judgment, it is important for clinical pharmacy researchers to declare their philosophical stance, justify their selection of particular methods in relation to the research question and avoid method slurring. As suggested by Creswell [14], clinical pharmacy researchers should incorporate at least two different strategies to ensure rigour depending on the type of qualitative research design. Clinical pharmacy researchers should also provide detailed accounts of data analysis to enhance the transparency of the research findings and strengthen the conclusions drawn. Failure to undertake rigorous qualitative research has negative implications in terms of its impact on pharmacy practice and policy, future development of pharmaceutical services and most importantly, the qualitative research methodology itself. Since this mini review only

- 1 focused on the strategies employed by clinical pharmacy researchers to ensure
- 2 trustworthiness, future research should explore the quality of qualitative research in
- 3 clinical pharmacy research and, if required, propose recommendations for quality
- 4 improvement. Pharmacy practice journals should also extend their word limits for
- 5 qualitative papers, to allow authors to report methodological processes in detail

6 Conflicts of interest:

7 None declared

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