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Synopsis of Research Methodologies: A Brief Guide for Pharmacists

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Authors' contributions

This work was carried out in collaboration between all authors. All authors read and approved the final manuscript.

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ABSTRACT

Research is a scientific way of answering questions and testing hypothesis in order to generate new knowledge or validate existing knowledge. Pharmacists, other than their functions in dispensing drugs, they could pursue roles in various areas such as clinical research, research and development, quality assurance, and pharmacy practice research. Every investigation has a study design, types of study design used are dependent on types of questions to be answered and types of research (i.e., qualitative or quantitative research). This review presents a brief overview of general quantitative study designs, sampling methods, data collection, and data analysis. Additionally, qualitative study designs, sampling methods, data collection and interviewing process, qualitative data handling and its analysis.

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1. INTRODUCTION

Research is a scientific way of answering questions and testing hypothesis to generate new knowledge or validate existing knowledge. Research questions can be answered by quantitative measures, or qualitative measures, or both.

The pharmacist could pursue roles in various areas such as pharmaceutical formulation development, clinical manufacture, research and development, quality assurance, project management, regulatory affairs, pharmacokinetics and drug metabolism, medical informatics, marketing, and sales. Hence, pharmacist knowledge about research methodologies is needed as a pharmacist may utilise it in: Basic pharmaceutical sciences, development and testing of new dosage forms or medication-administration modalities. Clinical research, efficacy, safety, and pharmacokinetics/ pharmacodynamics of drugs. Pharmacy practice, research addressing various issues such as the evaluation of new and existing services, workload measurement, pharmaco-economic, pharmacoepidemiology, and quality management. The Canadian Pharmacists Association (CPhA) defines pharmacy practice

research as a component of health services research that focuses on the assessment and evaluation of pharmacy practice.

2. QUANTITATIVE STUDY DESIGNS

Quantitative research is widely used in both the natural and social sciences, including physics, biology, psychology, sociology, medicine, and pharmacy. It uses mathematical measures, models, and hypotheses to come up with results and conclusions.

Quantitative research focuses on gathering numerical data and generalising it across groups of people or to explain a particular phenomenon. It presents the results in numbers, percentages, or frequencies. In other words, quantitative study designs answer the questions: “How often?”, “To what extent?”, “How much?” and “How many?”

Quantitative research design can be classified according to many criteria, such as the purpose of the study, the time which is study is being conducted in, nature of the research and others. Fig. 1 presents the classifications of study designs; also, Table 1 lists the types of study designs according to the researcher action [1].

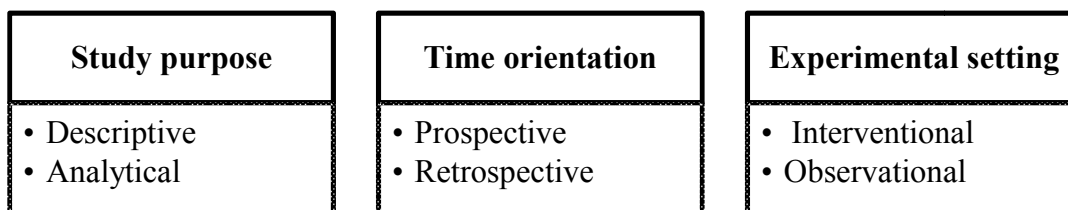


Fig. 1. Classification of quantitative research designs

Table 1. Types of quantitative study designs according to the researcher action

1. Observational studies	2. Interventional studies
A. Case Report	A. Controlled trials
B. Case Series	1. Parallel or concurrent controls
C. Case-control studies	a. Randomised
D. Cohort studies	b. Not Randomised
E. Cross-sectional studies, surveys	2. Sequential controls
	a. Crossover
	B. Studies with no control

3. OBSERVATIONAL STUDIES

Case report: The scientific documentation of a particular clinical observation, rare disease, unusual condition or reaction that was observed by chance is defined as a case report.

Case reports are considered an important resource for new observations and unusual information that may prompt crucial research and advances in clinical practice that may enhance the outcomes of patient management and therapy [2]. Reports involve important scientific observations of those that may be missed or are essentially unnoticeable in clinical trials providing insightful new information that expands our knowledge and trigger new research, which leads to better and safer care of patients. The length of reports or word count generally ranges between 1500 to 2500 words with about 25 references [2].

The format of a patient case report encompasses five different sections, first a precise abstract of 150 to 250 words [3,4]. Secondly, an introduction containing an extensive literature review that supports the justification of the report along with its objective. Third, a description of the patient presentation written in a narrative form, organised in logical order, both accurate and salient. The fourth section is the discussion formed of a detailed explanation and placing the findings within the context of what's known in literature both for comparison and contrast in order to establish a causal and temporal relationship. The session ends optimally with a summary. Finally follows the conclusion section providing a brief conclusion with the recommendations [4].

Case series: To follow a group of patients who have a similar criterion like a diagnosis or a particular treatment over a certain period of time is called case-series studies. It is a descriptive study where no comparison group is presented in the design; hence, no analytical tests can be conducted to draw out results. Likewise as case reports, case series often instigate important agendas of clinical investigation leading to valuable therapeutic applications and scientific paradigms. Initial observations are particularly useful when they fit into a hypothesis with biological plausibility, in which case an important criterion of causal inference already is met [5]. Many clinicians make major contributions by creating such hypotheses based on their clinical observations [6]. Also, case series and reports are crucial in reporting of sentinel events such as

toxicities of therapies post-marketing, the process of pharmacovigilance; a core service by the pharmacist provides at different healthcare settings.

Reporting case series data in a standardised and statistically appropriate manner would allow for proper interpretation of the data available and for future "meta-analyses" combining these case series to produce better estimates of the long-term outcomes. Standardised manner involve as with any clinical study, sharp definition of the inclusion and intervention criteria—sufficient to allow replication of the study is necessary so that potential selection biases can be considered [7]. Avoiding selection of patients for inclusion as much as possible by reporting of consecutive patients is a commonly used desirable design feature. Likewise, precise description of how any treatments were applied (hopefully in a uniform manner) and/or how potential risk factors assessed is critically important to make the report interpretable and generalisable [6,7].

Case series presents often individual patients' characteristics or demographics, their diagnosis, and management. Data of a small case series can be presented as a table and pooled together if needed without the need for individual detailed description [8]. This may occasionally alert clinicians to unnoticed serious clinical events [8]. This approach also enabled authors to develop unique new management algorithms for treating rare serious conditions [9,10]. Furthermore, a case series may have been collected over a specific period of time which should be mentioned in the paper. Case series in which all eligible patients are identified during a study period by researchers is said to be a consecutive case series. Alternatively, a non-consecutive case series is when it includes only some, not all, eligible cases [11].

The format of a case series differs than the one of a case report and more resemble original research articles, it encompasses the following sections: an abstract, an introduction and objective that contain a literature review, a method section describing actions to be taken to investigate problem and how data was collected when and how it will be analysed, followed by a results section showing main data with simple statistics, a discussion of these results compared to literature and finally a conclusion [11].

Case-control: A retrospective study by definition as illustrated in Fig. 2, it is a study that

investigates a certain outcome (cases) compared to samples from the same population without the outcome (controls) in order to detect the risk factors associated with the presence of the outcome of interest prior to its occurrence. It's mainly useful for studying rare conditions and is able to yield a gross amount of information from relatively few subjects. Yet this design major weakness is the increased susceptibility for bias due to mainly its retrospective nature (retrospectively measuring predictor variables) and separate sampling of the cases and controls.

Cohort Studies: A cohort is a group of people that share the same criteria, cohort studies are to follow up certain group for a period of time. In which, people with a risk factor or exposure will be followed up to detect the presence of a particular outcome of interest. Cohort studies could be conducted in a prospective design or retrospective design. Cohort retrospective design differs from a case-control study in the outcome of interest, wherein cohort study sample collected according to the presence of risk factor, while in case-control sample collected based on the presence of the outcome of interest.

Moreover, one can be confused with the difference between prospective cohort studies and case series, the main difference is that a cohort study has a comparison group while case series study does not have a comparison group, it is only a descriptive study cannot be analytical [12].

Cross-sectional studies: A study conducted in a particular period of time to detect phenomena, percentages, or prevalence such as survey studies. In this design, the investigator measures the outcome and the exposures in the study participants at the same time [13]. The classic type of cross-sectional study is the survey where a representative group of people is interviewed or examined in order to find out their opinions or facts. Unlike other observational studies, the participants are selected just based on the inclusion and exclusion criteria set for the study (participants of a cohort are selected based on the exposure status while in case-control studies based on the outcome status). Once the participants have been selected for the study, the participant's variables are measured for outcome and exposure to study the association between these variables. Sampling and data collection occurs simultaneously similar to other characteristics but different on a key factor of interest such as age, income levels, or geographic location.

Although this study design is easy to conduct, non-expensive, and non-time consuming, it is criticised for not being able to generalise results or to derive causal relationships from cross-sectional analysis while it's also highly subject to bias. A further limitation is a need for a large sample size. However, it is extensively used by researchers because it gives an insight into a certain phenomenon, examining a range of variables, where more extensive research can follow later [13].

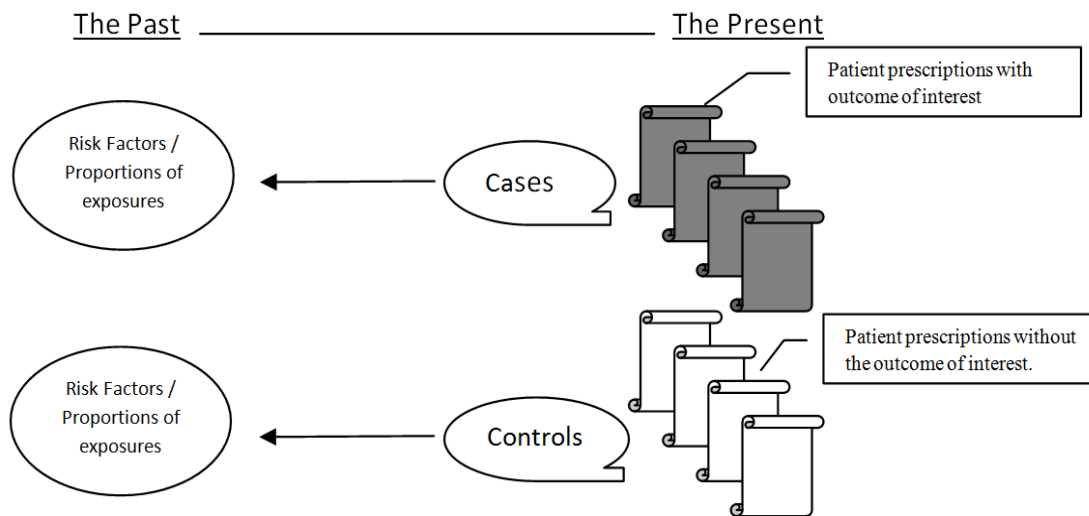


Fig. 2. Case-Control studies the design of prescriptions with specific outcome of interest

4. EXPERIMENTAL STUDIES

Randomised controlled trials: An experiment that divides the sample into groups, however, the samples will be allocated to each group randomly to reduce the bias and strengthen the power of the research. Many random sampling processes are available to put the participant either in the control group (where no intervention is being given) or treatment group (where the intervention to be tested is given), researcher would choose based on the research being conducted to ensure that all participants have an equal chance of being assigned to either group.

Non-randomised controlled trials: Patients allocated to certain groups to receive a particular intervention non-randomly, groups include a control group where the patient is not receiving this particular intervention.

Cross-over experiment: In crossover trials, patients randomly assigned into two group, the two groups of samples will receive the treatments to be investigated in two phases. The first group will take treatment A and the second group will receive treatment B. In phase II, the groups will be switched where the first group is now taking therapy A and the second group is taking treatment B, a model called AB/BA trial.

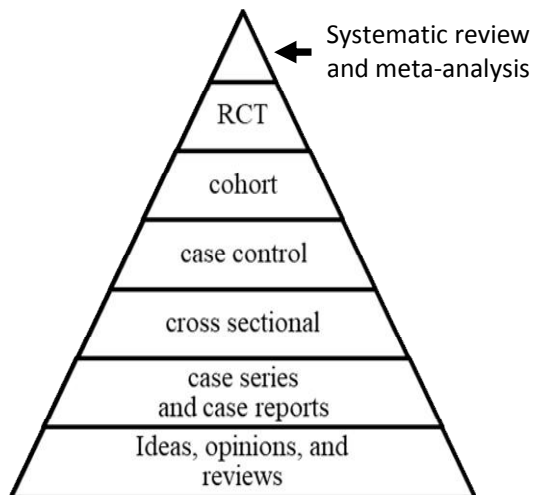


Fig. 3. Strength of evidence of quantitative study designs

Quasi-experiment: A quasi-experiment is a non-randomised study because they cannot be divided, it resembles a randomised controlled trial but without a control group, that there is no group not receiving a treatment. In which, it aims

to detect, measure, or study a phenomenon or causality without randomly assigning subjects to treatment or control, subjects do not have an equal chance to be selected in either group.

With the importance of evidence-based medicine, quantitative study designs differ in the strength of evidence. Fig. 3 shows the hierarchy of clinical study designs in terms of strength of evidence.

5. TYPES OF SAMPLING METHODS IN QUANTITATIVE STUDY DESIGNS

Simply, the sample is a part of a total. The aim of sampling is to represent a larger population since the inclusion of the whole population is inconvenient. Thus, the researcher will study a small group to generate new knowledge about the whole population. Sampling methods vary depending on the probability of sample selection.

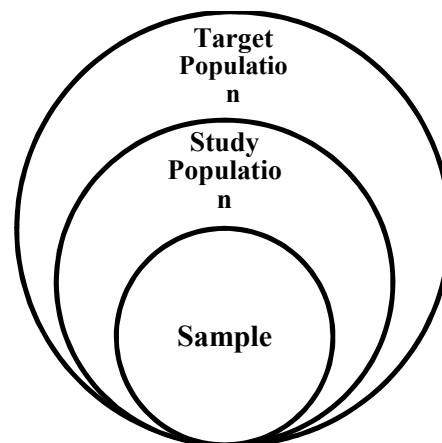


Fig. 4. Sample/population relationship

Non-Probability Sampling: Sampling method where each patient or unit does not have an equal chance to be selected for inclusion in the study. In other words, the researcher will select samples based on a certain criterion, which makes the study prone to bias. Hence, the produced sample will be non-random sample which means it cannot generate knowledge to be generalised. However, it can provide insight and information about certain phenomena. Many types of non-probability sampling available and widely common to be used by researchers such as convenience sampling, purposive sampling, and snowball sampling.

Probability Sampling: Random sampling strategies to ensure that all patients have an equal chance to be selected for the data

collection and analysis, a random sampling step needs to be done. There are several random sampling types:

Simple random sampling: Generate numbers of the pre-numbered files, by using computer software (random number generator) to pick files out randomly. Although it is unlikely to have bias from this sample, there is some probability that the random number happens to select disproportionate numbers of males over females or from specific year over another for example. So even though a simple random sample is taken, that is indeed random, it has some probability that is not indicative of the entire population. So to mitigate that, there are other techniques.

Research Randomizer is a free resource for researchers and students in need of a quick way to generate random numbers or assign participants to experimental conditions. Research Randomizer is a free service offered by Social Psychology Network for researchers, students, and others interested in generating sets of random numbers. Numbers are generated by the use of a sophisticated algorithm.

Systematic random sampling: After giving numbers to the sample subjects, pick the random sample by selects every fixed number assigned by the researcher (choose a subject every K-th number). While this method does take a systematic approach to sample, it is criticised for being not truly random.

Stratified Random Sample: Taking the entire population and essentially stratifying it according to certain criteria, this will assure getting an indicative sample of all different year. However, it is possible to get disproportionate numbers of males over females. Hence, cluster sampling is more convenient.

Cluster random sampling: By dividing the population into mixed clusters, and then randomly select clusters and include all subjects in this cluster regardless. But not common to be used because of its complicated process.

6. SAMPLE SIZE CALCULATIONS IN QUANTITATIVE STUDY DESIGNS

Studies have suggested that if a study has more than one objective, sample size calculation for each objective is required for any designated research, then the largest sample size shall be obtained [14]. Reluctance to go with this way of

calculation will yield a weak study that is not able to provide significant results because of not including the proper sample size. Furthermore, each study design needs its own sample size calculation methods.

To determine the prevalence of a certain disease, for example, it is important to use appropriate precision. Although there is no definite recommendation in the literature for the appropriate precision (margin of error), calculation of sample size should use a proper precision.

A study by (Naing, 2006) suggested that if the prevalence of a certain disease is expected to be more than 10% or below 90%, then precision should be 5%. However, for prevalence above 90% or below 10%, the precision of 5% will not be reasonable [14].

Sample size calculation can be done by using many software programs such as Epi Info™, Raosoft®, PS power and sample size, G* Power, and others. Epi Info™ is a data collection, management, analysis, visualisation, and reporting software for public health professionals. Epi Info™ is a trademark of the Centers for Disease Control and Prevention (CDC). The software is in the public domain and freely available for use, copying translation and distribution.

To yield a representative sample for a known proportion, the equation (1) by Cochran (1963:75) is recommended [15]. Where Z is a constant for the determined confidence of level. For 90% Z = 1.65; for 95% Z = 1.96; for 99% Z = 2.58. P is the expected prevalence or proportion, and d is the margin of error [16].

$$n_0 = \frac{Z^2 P(1 - P)}{d^2} \quad (1)$$

However, for a finite population where the population is small in size, correction to the formula is applied. Equation (2) shows the formula needed to calculate the sample size for such population. Hence, the finite population correction can dramatically reduce the needed sample size for small populations. Where n_0 is the sample size and N is the population size.

$$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}} \quad (2)$$

7. DATA ANALYSIS FOR QUANTITATIVE STUDY DESIGNS

Descriptive statistics summarise the collected data by presenting percentages, frequencies, and measures of central tendency. It does not aim to interpret the data, it aims to give information and insight into the nature of the data. On the other hand, inferential statistics aims to analyse to learn about the data and generalise the sample results to the population, such as regression, variance, and chi-square tests [1].

7.1 Qualitative Study Designs

Quantitative methodology is familiar for all researchers, in which, as the name indicates, it measures certain values, and present the results in numbers, percentages, and ratios, to construct statistical models to come up with an explanation for what is observed. On the other hand, qualitative research methodology distinguished by the nature of the results and the aims of the study. This type of methods deals with the concepts of patients, the patients' mentality and what they feel to present the results in words and statements. In other words, qualitative methods are concerned with answering questions in research began with why? How? What way? Instead of answering to what extent? Or how much?

In general, qualitative research can be defined as a form of social inquiry that delves into how people interpret and make sense of their experiences and toward their environment. Qualitative research is well known for literary sciences and social studies. However, with considering randomised-controlled trials or evidence-based health care as an important aspect of selecting the best therapeutic options. A health-care professional should not neglect the importance of listening and investigating the stories about patients' experiences related to certain therapy. Hence, qualitative research has been integrated into clinical research in the 1970s and 1980s [17], since then, qualitative research methods are gaining more recognition by health specialties [18-20].

Qualitative research enables the researcher in disciplines of health to engage in the social aspects of the patient, questioning their beliefs, gathering information about patients' satisfaction and explore their thoughts, experience, behaviours, and perceptions, identify the

limitations of their management, and find out why a treatment could fail or succeed. In qualitative research, the interview is one of the main data collection tools. It is a very effective way of accessing people's perceptions, meaning, definitions of situations and constructions of reality [21-23].

Based on that and taking into consideration the increasing shift of pharmaceutical care provision toward patient-centred care, information that could be drawn from qualitative approach will provide substantial results that enable healthcare professionals to develop better practices that come up with optimum outcomes and more satisfied patients [24-26].

8. APPROACHES IN QUALITATIVE STUDY DESIGNS

There are varieties of qualitative study designs which differs based on the purposes and objectives of the intended study. However, certain approaches are used commonly in health research such as phenomenology, grounded theory, discourse analysis, and grounded theory [20,27].

Phenomenological approach: As described by the philosopher Edmund Husserl, "phenomenology is the intuitive appreciation of phenomena as they are immediately perceived, without reference to scientific theory or prior learning" [28,29].

To break this up and relate it to the health sciences, one can say, in other words, phenomenology is the study of phenomena. Phenomena may be events, situations, experiences or concepts. Everything around is some kind of phenomena. Hence, one can say that phenomenology studies in-depth description and close analysis of how patients express meanings of their experiences as a first-person point of view. Thus, exploring patients' feelings toward certain therapy, comprehension of meanings of patients' experiences, discovering patients' beliefs of a particular concept, all fall under the umbrella of the phenomenological approach [26,30].

Ethnography: Generally, it is defined as the scientific description of the customs of individual peoples and cultures. It originates from anthropology. Since it investigates people that have something in universal, such religion, region, or experience; it can be applied in

healthcare settings. When a cultural parameter is suspected to have effects on certain population toward particular therapy, a health researcher may choose this approach. Thus, it will help health care professionals to come up with cultural awareness and enhancing the quality of care [20].

Grounded Theory: Development of a new theory by collecting and analysing data of particular phenomena. The more you dig, the more you discover. The main difference with phenomenology is that analysis and results of experiences and meanings are new knowledge which is used to develop new theories about certain phenomena [31].

9. COLLECTING DATA IN QUALITATIVE RESEARCH

Collecting data in a qualitative study comprises direct interaction with patients by conducting one to one interviews or group interviews. It is a very effective approach to access people's perceptions and provides the richness of data. Qualitative interviews have been categorised in a variety of ways, based on the structure of the interview, interviewing can be classified into three types: structured, semi-structured, and unstructured interviewing. Types of the interview can be easily described by the continuum model by Minichiello. The model can resemble a three-spaced triangle where the smaller space, the more structured the interview, and the interviewer cannot yield in-depth information and the interviewee will not be able to speak freely. On the contrary, the lower and more space, the more free and flexible it becomes, however, the more space and unstructured the thicker it gets and the harder it becomes for analysis and comparison. Any interview can fit between the two areas.

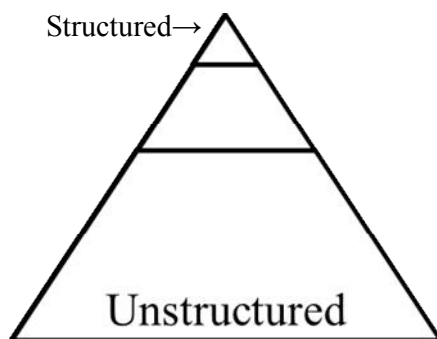


Fig. 5. Interviewing methods

Different interviewing strategies differ in strengths and weaknesses, and they have different purposes in research. Selection of a certain strategy should be in line with the aims and objectives of the research [17,32-34].

Structured Interviews: Pre-prepared questions used to interview the patients, it may consist of pre-established categories to choose from or may have open-ended questions. However, the interview cannot interact with the interviewee, and all patients should receive the exact same questions in the same order [17]. The low flexibility and high limitations and restrictions on the interview process are what makes this type of interviewing strategy a bit weak compared to other strategies. In which, the investigator will not be able to explore the phenomena since no deep explanations were provided [35,36].

Semi-structured interviews: The semi-structured interviews come in the middle of the continuum model, in which the interview conducted with the guidance of an interview protocol or guide. An interview guide involves pre-determined topics or questions about the proposed research. After briefing the interviewee about the research, the interviewer can begin asking the pre-determined open-ended questions. This differs from the structured interview in giving freedom to the interviewer to interact with the patients, ask for elaboration, and change the order, add or edit the questions during the interview. So, the interview guide can serve as a checklist of topics or questions to ensure fulfilling the basic aspects and expectations of the topic to be studied [20,33,36].

The flexibility and convenience of this approach make it a favourable choice for many researchers. However, what gives a strength point to this approach is having an interview guide will guarantee a more comprehensive and systematic interview. Although, consistency of responses from patient to the patient will vary which will affect and reduce comparability, and this considered as a weakness in the strategy [37,38].

Unstructured (In-depth) interviews: If the researcher, or interviewer, has no expectations or unaware about the direction of information that will come up during the interview about the topic, he will conduct a face-to-face interview with a patient with an aim of discussing certain topic, or topics, and start asking question according to patients' answers, and based on interviewee

responses the interviewer will construct questions during the interview. So frankly speaking, there is no totally unstructured interview, as the interviewer does the interview with topics and directions in mind [17,36].

The main advantage of this strategy is that the interview can be matched to the interview answers and responses, which allow gaining as much information as possible. Nonetheless, this can also be considered as a weakness in the strategy, since each interview can go in a different direction and each patient will be asked different questions than the other, which will yield different information. In addition, data analysis is not as easy as other strategies [20,33].

10. SAMPLING IN QUALITATIVE RESEARCH

A sample of the population is selected by either probability or non-probability methods. The different process of sampling between qualitative and quantitative research has been a major confusion point for researchers [39,40]. One cannot just choose based on preferences or haphazardly. In general, quantitative research is aiming to gain as varied information and yet as much information as possible in order to generalise the findings to a defined population. The predictability of random events and the ability to compare these random events make the probability sampling as the best approach for quantitative study [39,41,42].

On the other hand, non-probability sampling is the approach of choice for qualitative research. As going through random sample provides the opportunity for results generalisation, in contrast to quantitative research, random sampling is inappropriate for qualitative studies [43]. The qualitative research is looking for an in-depth understanding and behavioural aspects related to the patients and randomisation is irrelevant for social aspects. Hence, generalisability is not one of the goals of the qualitative research [42].

The concept of choosing a random sample for qualitative research can be explained with a practical example if one wants to drink a cup of tea and started visiting every shop in the street regardless of what does it sell rather than visiting cafés or at least shops that serve food and drinks. One might find a shop offer him a cup of tea if visited all shops, but targeting is more productive [44].

Other than relying on the purpose of the study, the sampling in qualitative research depends on the methodological approach adopted. There are four main types of qualitative sampling: convenience sampling, purposive sampling, quota sampling, and snowball sampling. Below, description of each type briefly followed by the reasons for choosing the particular method for this study.

Convenience Sampling: Simply, it is the selection of cases based on accessibility. The most approachable individual and easy to access will have the privilege to be involved in the study. As the name suggests, this method is most convenient to researchers since it is inexpensive, not time-consuming, and easy to be done. Nonetheless, it is considered a strategy with low credibility. This is attributed to the high chance of having patients involved in the study that does not have much information to contribute well to the study. Obviously, rather than choosing based on a precise rationale; patients picked up merely based on availability [43,45].

Furthermore, convenience sampling may introduce a bias that cannot be taken into consideration during analysis as the investigator was not aware of it. Not to mention the high chance to provoke an argument about being unrepresentative of the population.

Nevertheless, the convenience sample can be the only option in the primary stages of the research before developing the full strategy or when there are no specific characteristics required in patients. That's why it is common to be used despite having drawbacks.

Purposive Sampling: Purposive sampling technique is a non-probability sampling technique which used to choose a sample of participants from a population due to qualities that they possess.

In which, the researcher choose the most productive sample that will fulfill the purpose of the research [42]. There are different types of purposive sampling as shown below [46,47]:

Heterogeneous purposive sampling: Heterogeneous sampling, also known as maximum variation sampling, is a purposive sampling technique ensures to include a wide range of attributes or conditions related to the patients of interest. In which, this used to capture a wide range of individuals with different characteristics

to come up with as comprehensive insight as possible.

Homogeneous purposive sampling: Opposite heterogeneous purposive sampling, this technique's goal is to have a sample that shares certain characteristics like age or sex. Homogeneous sampling is of use for studies that are trying to investigate particular patients with similar features.

Purposive random sampling: To gain the ability to generalise information, randomisation is required to increase the credibility of results. In contrast to probable random sampling, purposive random sampling has a very low sample size. However, randomisation occurs within a certain feature that the patients share.

Snowball sampling: Snowballing sampling, also known as chain referral sampling, usually used for hard to reach patients or for rare diseases. In which, patients who are involved in the research asked for other patients to refer for the researcher to contact them for participation in the study. Hence, recruitment of patients that are not readily accessible to the research done through this technique.

Quota Sampling: In this technique, determination of how many patients to be included in the study occurs a priori. In which, while designing the study, number of patients with specific traits like age, gender, disease condition, or use of a particular treatment is decided. During the sampling process, keep looking for patients in different categories until meeting the determined quotas. This strategy usually considered under the purposive sampling, this is attributed to the fact that both techniques seek to recruit patients based on

defined criteria. However, quota sampling differs than purposive in being more specific in choosing subgroups for each criterion [48].

Nevertheless, researchers tend to choose purposive to achieve a varied approximate number of patients for each criterion rather than a strict number of patients.

11. SYNOPSIS OF DATA MANAGEMENT IN QUALITATIVE RESEARCH

As stated in previous subsections, the qualitative research presents data in words form rather than numbers as in quantitative research. Hence, regardless of the data collection method whether focus-interviews of one-to-one interviews, to have data in a textual form for analysis process, the preceding step is a verbatim transcription of audio-recorded or video-recorded interviews with the observation notes that have been taken during interviews [49].

Commonly, generating data is a debilitating process where it needs a lot of effort to transcribe all interviews. Typically, 30 minutes interview needs work time of almost 5 hours for verbatim transcription, which generates almost 15-25 pages of textual dialogue. Moreover, interviewer taking down field notes and comments about behavioural, environmental, and non-spoken impressions will support the transcription process and will aid in interpretation of audio-records, all of which, will take part in the final transcript of the interviews. Therefore, the amount of generated data in qualitative research is large, which certainly in lines with the number of interviews made and duration of interviews, compared to the amount of data of quantitative analysis [50].

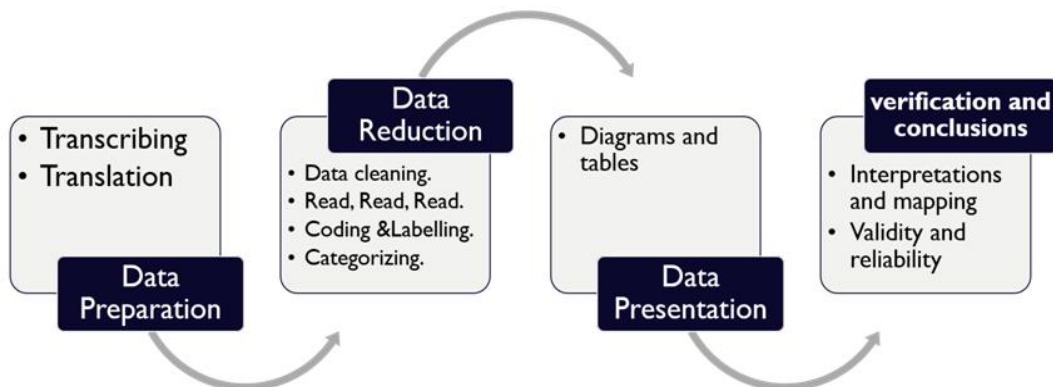


Fig. 6. Qualitative data handling flowchart

Transcribing: Speech conversion into a textual form: In regard to the process of transcribing interview audio-records with patients, there is a limited literature in the health discipline literature even with the increasing interest and use of interviews as a data collection method for qualitative research [51].

Many believe that the collection and organisation of data is an absurd burden, however, although it is an overwhelming task, converting the spoken words into textual form is inevitable to analyse the data. The perfect transcriber of audio-records would be the interviewer himself. Becoming familiar with interview data is crucial for transcription and data analysis later in the process. Therefore, transcriber shall listen very well to the tape before transcribing [49,50,52].

After verbatim transcription of all recordings and numbering of each line in the transcript, transcriber listens to the record while following with the written transcript as a double-checking process in order to correct any errors or missed parts.

Apparently, to ensure the anonymity of participants, interviewees got tags of (patient#1, #2, #3, etc.), where their consecutive transcripts will not include any personal identification said during the interview. Transcripts shall not paraphrase patients' words and include any pauses, laughter, or discomfort expressed by the patients.

Language difference in qualitative research: As qualitative research is the study of meanings for lived experiences of patients. One-to-one interviews are one of the methods for data collection. In order to analyse the data, interviews have to be converted into written words. As stated in previous subsections, in contrary to quantitative research, where presentation takes the form of numbers, the qualitative research presents the results in words form and publication of conclusions and recommendations accompanied by the resulted words [53].

The spoken language is the link between lived experience and meanings expression. Nevertheless, the meanings of lived experiences are not always presented in explicit language, as people tend to use metaphors and narratives [54,55]. Considering the importance of understanding and interpretation of meanings in qualitative research, if the researcher does not

share the same language with patients to be interviewed, the researcher will confront a language barrier that will hinder the phases of conducting qualitative research [56].

Language differences in qualitative research considered as cross-cultural qualitative research [57]. In which, as the word is the tool to transfer meanings, meanings cannot be transferred because of the language barrier which will affect the reliability and validity of the study [53].

On the other hand, healthcare researchers have a profound interest in conducting cross-cultural qualitative research in order to have insight into lived experiences of different populations [57]. Also, research in healthcare settings to seek narratives by patients considered as a valuable source of information [55]. Therefore, cultural differences and language barriers should not stand in the way of research.

Translation influence on qualitative research: Translation is the key to solve the dilemma of language differences to conduct a cross-cultural qualitative research. However, the translation will create a further dilemma that needs to be taken care of, since words and concepts in one language may be understood differently in other languages [53,54].

Translation from a source language to a target language is an interpretive process. Hence, efficient translation is paramount to maintain high reliability and validity of the study. Translator of a healthcare research needs to accurately capture the full meaning of spoken words and be able to comprehend the medical terminology [58].

The translator will be the vehicle that carries the voice of patients to the researcher. As patients will use narratives and might use metaphors to answer the question addressed by the interviewer, many narratives simply cannot be verbatim translated to the target language [55]. The translator might use own words to describe what is being said. Nonetheless, the voice of the patients will be lost since the researcher are dealing with the translator's own words. Therefore, the translator should make sure to preserve the meaning between the original audio-records and the translated data and try not to take over the voice of the patients.

Qualitative Data Analysis (QDA): QDA composed of processes and procedures that transform the collected qualitative data into the

structure of understanding or interpretation of the people and situations that are being investigated.

In another word, QDA is a collection of interpretation processes, where the researcher engages with the data, working with data, cleaning it, organising it, looking for patterns, discovering what is essential and what is to be learned, and decide what is relevant, what can categorise and what can be connected.

There are several ways to analyse qualitative data:

1. Thematic Content Analysis
2. Narrative Analysis
3. Discourse analysis
4. Framework Analysis
5. Grounded Theory

Thematic content analysis: Of all qualitative analysis types, this review will focus on content analysis. The thematic content analysis involves coding and classifying data, to identify relevant words from the transcripts to extract data that is informative and to uncover valuable information hidden in each interview.

In other words, thematic content analysis to transcripts generates themes that reflect the descriptions of participants' experience, analysing the interview data and identify similarities and patterns, coding is then done to the transcripts line by line [59,60].

Steps carried out to conduct the thematic content analysis were as follows:

Step-1: Reading and familiarisation

Browsing through all transcripts, as a whole with making notes. Then read the transcripts, again and again, one by one. Then reading very carefully, line by line.

Step-2: Labeling and coding

Coding step is organising the raw data into categories (sentences, words, phrases), as a step to make transcripts into more meaningful chunks. In other words, breaking qualitative data into smaller parts.

Open coding by marking and labelling every relevant wording and expressions by the patients. Labelling was for actions, activities,

concepts, differences, opinions, processes, and anything relevant.

The decisions about something whether it is relevant to code was to things that it is repeated in several places, surprised the analyst, the patient said that it is important, something similar in reports, something related to a theory or a concept, or any other reason to think it is relevant.

Step-3: From codes to themes

This step was to decide which codes are the most important and to create categories by bringing several codes together.

By going through all the codes created in the previous step, the creation of new codes by combining two or more codes. Codes that are important and similar grouped together to create categories. (i.e., themes). This step was to make the data more organised and to make the data conceptualised.

Step-4: Interpretation

Since categories and the connections are the main results of the study that brings new knowledge from the perspective of the patients, searching for patterns, associations, concepts, and explanations in the data from the labels and categories to decide which are the most relevant and how they are connected to each other.

12. VALIDITY AND RELIABILITY OF QUALITATIVE RESEARCH

Qualitative research is criticised for having a high risk of bias because it is subjected to researchers' perceptions and the researcher is the tool for collecting data. Also, qualitative research does not intend to generalise its findings, but rather to explore certain phenomena and lived experiences, so it is criticised for lacking the element of generalisability because of the small number of patients selected by non-probability (non-random) manners [61,62].

To achieve a high quality of a qualitative research, there are standards applied to assure the quality of results. Validity and reliability are two factors any research should be concerned to assure the quality of the research [63].

The validity of qualitative research increases as the distance between the meanings as

experienced by the patients and the meanings as interpreted in the findings decreases [61]. In which, the validity of the data refers to the extent to which they are an accurate reflection of the phenomena that are the subject of the research [63].

However, as stated by Carswell 2009: "Qualitative validity does not have the meaning used in quantitative research" validity and reliability are two terms usually linked to quantitative research, so they do not make sense in qualitative studies. Hence, qualitative studies use their language to express quantitative terms. As shown in Table 2 [64].

Table 2. Quality concepts of qualitative and quantitative researches

Quantitative research	Qualitative research
Internal validity	Credibility
External validity	Transferability
Reliability	Dependability
Objectivity	Confirmability

Trustworthiness and dependability:

Trustworthiness (or credibility) represents how the findings are close to reality, whether having the complete information from the participants or having the true information from them in order to make meaningful results and results that allow the study to achieve its objectives [61]. There are many techniques for establishing credibility include field experience that is prolonged and varied, triangulation, peer debriefing, interviewing techniques, and member checking [63,65].

Credibility can be approached by making questions generally open-ended to allow respondents to raise the issues that they believe are important and to speak their mind, also some questions were asked repeatedly in a different structure to check the consistency of answers, the role of the interviewer was to explore these questions in greater detail [62]. The data should represent an accurate reflection of the perspectives of the patients on the phenomena of interest.

In a review by Pope and Mays on the subject of qualitative data validation, they recommended a validation strategy in which the findings of the analysis are given back to the participants to see if they regard the findings as a reasonable account of their experience [66].

Dependability and transferability ensure the stability of data and when data can be applied in

other contexts. Hence, documentation of the procedures steps, every step of data collection and analysis is crucial, in details description so the study can be copied in another context [67].

Confirmability represents that the study is free of bias, that the outcomes and interpreted results were influenced by the researcher's concepts. Of the techniques that may be used to strengthen confirmability is data audit by an external researcher not involved in the research process, to examine both the process and product of the research study [65,67].

Quality of translation: In cross-cultural studies, raw data translation from source language is one of the most critical aspects of the quality of the results. Any inaccuracy or compromised authenticity will affect the analysis process which will end up with non-realistic or useless results.

Adoption of a translation algorithm to assure reliable translations, as the translation process can impact on the trustworthiness of qualitative data.

13. CONCLUSIONS

The aim of preparing this piece of literature is to provide a brief guide for direct care providing pharmacists and healthcare professionals in order to demonstrate types of study designs, their data handling, and its analysis in order to boost practice-based research. In summary, every investigation has a study design, it is the architectural blueprint for an investigation. It specifies the stimulus the independent variable and the response (the dependent variable), the time-order sequence of the stimulus and the response, the sampling and allocation procedures for the study units; and the generalised method of analysis. Reflection on the scientific basis of the research question, methodology and methods will enhance the understanding of the research process for future implication.

A type of study design used is dependent on the type of questions to be answered and kind of research (i.e., qualitative or quantitative research). Hence, research question, context, and available resources determine what's most appropriate and practical for the research. All in all, after stating the research questions, review the literature and select an appropriate

framework. Then, design research study using a quantitative, qualitative or mixed methodology. The work will require an appreciation of conceptual, theoretical and practical perspectives regarding the generation and interpretation of data within a discipline. Following that, select sample (sampling method determines the generalisability of findings). Collect data (data can be qualitative, quantitative or both), analyse data using appropriate techniques. Interpret results to disseminate the findings and eventually write and present findings in an understandable language.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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