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Abstract

A major goal of nursing and midwifery is the delivery of evidence-based practice. Consequently, it is essential for the quality and safety of patient/client care that policy makers, educators and practitioners are aware of the presence of potential systematic bias in research practice and research publications so that only sound evidence translates into practice. The main aim of this paper is to highlight the need for ongoing awareness of the potential presence of systematic bias in research practice, to explore commonly reported types of systematic bias and to report some methods that can be applied to minimise systematic bias in research.

Key words: Systematic bias, selection bias, confounding variable bias, information bias.

Introduction

In the research process, bias is difficult to avoid completely. A carefully designed study is likely to be relatively free of bias, but its elimination cannot be guaranteed (Siddiqui, 2011). In the attempt to eliminate one particular bias, it is important to be aware that another and different type bias may inadvertently be introduced (Sica, 2006). Researcher awareness of potential bias at all stages of the research process increases the likelihood of implementing considered strategies that aim to minimise bias and enhance the validity (accuracy), reliability (repeatability) and generalizability of quantitative evidence. These criteria are more broadly defined in qualitative inquiry (Azham & Yusof, 2011).

There are two broad categories of error: random error and systematic error. The key difference between the two types of error is that random error occurs by chance and is due to small fluctuations; as such, this type of error can be minimised by increasing sample size (Bruce et al, 2010). In contrast, systematic error, typically referred to as bias, is broadly defined as a factor which will tend to lead to an erroneous conclusion (Daly et al, 1991) and is caused by a feature of the design or conduct of the study (Guyatt and Furukawa, 2008) and remains regardless of increasing the sample size (Bruce et al, 2010).

Repeated measurements of any parameter are subject to fluctuation or random error. The most accurate estimate of a parameter, for example, blood pressure, cholesterol levels, or the heights of classroom children in different schools can be obtained by getting the mean value of a number of measurements. The larger the number of measurements or the larger the sample size, the smaller the random error. The larger the size of the study sample, the more closely the sample means will be dispersed around the true population mean (Bourke and McGilvray,

1975). The focus of this paper is on the type of error referred to as systematic error generally referred to as bias.

Systematic bias can occur in both qualitative (categorical) and quantitative (numerical) research. It can occur during the design stage, when selecting subjects, during data collection, when assessing the data and when reporting results (Arnold, 2011). Systematic bias can have two unfavourable outcomes in research findings. It can create a spurious association where no real relationship exists between two variables or can mask a real association between two variables (Petrie and Sabin, 2010). It is important to be aware that a statistically significant finding does not inform the reader of the presence or the absence of bias (Gerhard, 2008). As such, systematic bias can lead to incorrect conclusions (Bruce et al, 2010). A biased study loses validity depending on the degree of bias present (Gerhard, 2008).

Three of the most commonly documented types of systematic bias are selection bias, confounding variable bias and information bias. The different categorisations of systematic bias should not be considered mutually exclusive and can often overlap.

Selection Bias

Selection bias occurs when subjects are not representative of the population to which the findings will be applied (Petrie and Sabin, 2010). A hypothetical example of selection bias is provided by Colton (1974): a researcher has chosen as a target population, all individuals with rheumatoid arthritis. The researcher's selection of hospitalised patients would not be representative of the rheumatoid arthritis target population to which the findings would be applied, because the majority of patients with rheumatoid arthritis are typically not treated in hospitals but in an outpatient department. As such, only patients with very severe cases of

rheumatoid arthritis requiring hospitalisation would be included in the study. Recruitment by email is another example of how selection bias may occur. This introduces selection bias by excluding potential participants who do not possess or use a computer (McNeill, 1996). The selection of individuals to be included in a study is one of the greatest sources of bias and relates, to a large extent, as to whether the results have generalizability. If the sample studied is a properly conducted random sample from the population of interest, selection bias can be minimised (Daly et al, 1991).

Self-selection or Volunteer Bias

Self-selection or volunteer bias occurs when individuals (self-selectees or volunteers) enrolled in a treatment or control group generally fare better by virtue of their participation in the research study than similar patients in routine medical practice. This is referred to as the Hawthorne effect (McCarney et al, 2007). In addition, people who volunteer/self-select to participate in a study are likely to differ from the general target group in terms of health awareness, education and other factors (Carneiro and Howard, 2011). According to Hernan et al (2004) bias will be present if the study population is restricted to only those who volunteer to contribute. However, there would be no bias if a random sample of the target population were recruited.

Confounding Variable Bias

A confounding variable is a variable that is related to both the outcome variable (e.g. disease) and to one or more of the other exposure variables (Petrie and Sabin, 2010). A confounding variable can create an erroneous relationship between two variables or, at the other extreme; it can hide or mask a real relationship (Daly et al, 1991).

Petrie and Sabin (2010) explain how a variable can act as a confounder, for example, in the study of smoking status on the incidence of coronary heart disease (CHD). It is known that alcohol consumption (confounder variable) is associated with the development of CHD, and that alcohol consumption and smoking are also related (that is, those who consume alcohol are more likely to smoke than those who do not consume alcohol). Thus, unless the study sample is adjusted for alcohol consumption, whereby subjects are matched for this variable, it may confound an apparent relationship between smoking and the incidence of CHD. Commonly, documented confounding variables associated with both the factor (risk) and the outcome (the disease), such as age or gender, can be controlled in the study design through careful matching of age, gender and other relevant factors with appropriate statistical analysis (Daly et al, 1991).

Simpson's Paradox or the Yule-Simpson Effect

Simpson's paradox is a paradox in which an association present in different subgroups groups is reversed when the groups are combined (Wunch, 2007; Tu et al, 2008). According to Petrie and Sabin (2010:69), we should never combine contingency tables from separate studies "for example, consisting of different subgroups, such as males and females, or from different populations...." simply by adding the frequency in analogous tables. If we do so the pooled data might lead to Simpson's paradox"

According to Tu et al (2008) this paradox has serious implications for the interpretation of evidence from research studies. For example, within a population, a higher dose of a drug may be associated with a higher recovery rate. However, when the same population is subdivided into males and females, a higher dose of the drug may actually be associated with lower recovery rates (Kievit et al 2013).

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Information Bias

Information bias can occur in several ways. It includes measurement bias, misclassification of outcomes and inaccurate information which can have an impact on study findings.

Measurement Bias

Measurement bias can arise in several ways. For example, non-response and lack of complete follow up leading to missing items of information can cause measurement bias (Daly et al, 1991). It can also be due to the use of defective measurement tools, for example, when poorly calibrated weighing scales are used to collect measurements (Petrie and Sabin, 2010) or when a non-appropriate tool such as a poorly designed interview form or questionnaire is used. In such studies a pre-designed data collection form should be employed to control for bias (Daly et al, 1991). A pilot study can assist in pinpointing unforeseen difficulties that may occur in the intended study, and allows for the correction of these difficulties before the main study commences (Bourke and McGilvray, 1975).

Misclassification Bias

Misclassification bias may occur when a categorical exposure and/or outcome is misclassified (Petrie and Sabin, 2010). This may arise where there is an element of subjectivity or difficulty in determining classification. Some bias-minimising strategies might include pre-determined criteria pertaining to data classification and data-handling training in the standardisation of methods of classification.

Bias due to Outliers

Outliers are values distinct from the main body of the data. They may be genuine observations or simply typing errors, for example, where the decimal point is erroneously placed in the incorrect place (Petrie and Sabin, 2010). If an outlier is detected, the raw data should be reexamined to check if the outlier is genuine and not a typographical or measurement error. The effect of the outlier can be determined by including and excluding the outlier in the analysis, recording it in the findings, and the outlier should be brought to the attention of the reader.

Survivor and Lead Time Bias

Survivor bias can occur when individuals do not survive long enough to receive treatment, thus introducing an artificial survival advantage amongst healthier subjects receiving the treatment under study (Arnold, 2011). It is explained by Bruce et al (2010) that there is a potential for length-based (prognostic bias) when screening may detect people with less severe disease than the usual route of presenting to a doctor with troublesome symptoms. This can introduce bias because the screened group will, on average, have less severe disease and consequently may appear to have a better outcome. Bruce et al (2010) also refers to lead-time bias where earlier detection through screening may lead to the perception that survival is longer simply because the diagnosis was made earlier than it would otherwise have been through a visit to a doctor.

Observer Bias

Observer variation bias has two components: variation within the observer and variation between observers (Daly et al, 1991). Variation within the same observer is considered to be random but variation between observers can be caused by different criteria (Daly et al, 1991) and is likely to lead to systematic bias. For example, in blood pressure recordings digit preference is evident; that is, a blood pressure of 117/89 is rarely recorded because there is a tendency to have a preference for certain end digit values especially 5 and zero (Daly et al, 1991). Observer reporting bias can also occur when one observer tends to under-report or over-

report a particular variable also termed assessment bias (Petrie and Sabin, 2010). Observer training and the standardisation of data-collection methods prior to the commencement of a study may minimise observer bias.

Participant Reporting Bias

Participant reporting bias can arise when under-reporting socially unacceptable behaviours or disorders such as alcohol consumption or sexually transmitted disease (Petrie and Sabin, 2010). Where under-reporting is anticipated as a result of topic sensitivity, the researcher can reassure participants that the sensitive response is not uncommon (Statistics Canada, 2010).

Recall Bias

Recall bias may occur in retrospective case-control studies as knowledge of being a case (with disease) or a control (without the disease) may affect how an individual remembers their history. For example, patients (with the disease) may be more likely to remember and report events that occurred around the time that the disease first occurred. For example, a relatively young female with a myocardial infarction may be more likely to report the use of birth-control pills than a similar young woman without myocardial infarction. Similarly, a male with prostate cancer may be more likely to report a prior vasectomy (Fletcher and Fletcher, 2005). One strategy to minimise recall bias is to back up the information using multiple sources, such as, through medical records or apply triangulation whereby information is gathered and analysed in more than one way (Curtin and Fossey, 2007).

Central Tendency Bias

Central tendency bias (*over-selection of the neutral option*) can occur when collecting data using a method where respondents are required to select from an uneven number of choices, for example, five graded responses on a Likert scale. Respondents tend to move towards the middle of the scale, which usually depicts the mid-point or no opinion option (Petrie and Sabin, 2010). Whilst only a partial correction it is suggested by (Peacock and Peacock, 2011) that an even number of choices, without a neutral middle option forces the respondent to choose to agree or disagree.

Reverse Bias

This occurs when the disease causes a change in the patient's behaviour causing a reduction in the presence of the factor in the case group (Fletcher and Fletcher, 2005). An example of reverse bias would be cases (with lung cancer) who gave up the factor (smoking). Taking past and present smoking history can minimise this form of bias.

Missing Data, Drop Out and Attrition Bias

Subjects who withdraw or drop out from a study may differ systematically compared to those who remain in the study. For example, in a longitudinal study subjects may leave the study because of loss of interest, improved health, or an inability to continue due to deteriorating health or death. The longer the study the more likely it will have a loss of participants. This introduces information bias and decreases the validity of the study because the remainder of the subjects and their data may not be representative of the target population group (Petrie and Sabin, 2010). Missing data is also a common problem in longitudinal studies when the time between observations is lengthy (Laird, 1988). Missing information can result in biased

estimates and a loss of power (Engles and Diehr, 2003). Choosing an appropriate method for dealing with missing values always requires some knowledge of why the data are missing (Vach and Blettner, 1991). The reasons for missing data in a study should be explored and the influence of missing data on the findings should be examined especially if there is a large proportion of data missing. Dropouts from a study should be carefully categorised and reported in the results (Schulz et al, 2010). Where data is collected by questionnaire, attempts should be made to maximise questionnaire response rates because non-responders may be different from responders in some systematic way (McNeill, 1996).

Confirmatory Bias

Confirmatory bias is giving extra emphasis to information that supports your hypothesis and minimising information that fails to support your hypothesis (Bell and Mellor, 2009). Avoiding this type of bias requires impartiality in all stages of the study including literature review and the collection of information used as data.

Publication Bias

Publication bias is the tendency for authors to submit, and publishers to accept, positive as opposed to negative findings. This threatens the validity of findings available for decision-making. According to Siddiqui (2011), it is estimated that as much as 50% of the literature on a particular topic remains unpublished. One strategy that can be applied to detect publication bias is the application of funnel plots (Sterne and Harbord, 2004), which are widely used to examine bias in the results of meta-analyses. If substantial publication bias is identified, the results should not be pooled in a meta- analysis (Bruce et al, 2010).

Contamination Bias

Contamination bias can arise in randomised controlled trials. The subjects in the control group can, for example, be inadvertently exposed to the experimental group intervention or factor (Arnold, 2011). An example of this type of bias would be a staff communication skills training course where the communication skill in the intervention group unintentionally transfers to the control group. A number of strategies can be applied to minimise this category of bias. One way to minimise contamination bias is to apply cluster sampling, which means to randomise by group, such as all the students in a hospital as opposed to randomise by individual. Henderson and Sundaresan (1982) describe a simplified cluster sampling method. For example, in practice, cluster sampling would be carried out by identifying a geographical area of interest, identifying a group of interest, and random selection of sites (clusters) into experimental and control groups. The analysis of a multi-centre study should always take into account any 'centre effects' by adjusting for centre differences (Petrie and Sabin, 2010). It is well documented that randomisation is a powerful tool to minimise systematic bias (Sica, 2006). The randomised controlled study has the ability to control for factors in a way that ensures that the subjects are similar in every way except for the intervention factor (Daly et al, 1991). However, the randomised controlled trial has its limitations within the nursing and midwifery context. The reason being that the randomised controlled trial, as a study design, does not lend itself to the narrative that is required to be elicited from patients/clients when measuring the human experience of care delivery. Therefore, the qualitative aspect of nursing and midwifery research requires extra special attention in the study design to minimise systematic bias.

Conclusion

In conclusion, an understanding of systematic bias causation facilitates preventing and adjusting for it in research studies (MacLure and Schneeweiss, 2001). Ongoing awareness of

the potential presence of bias in the research process ensures that systematic bias may be kept to a minimum. Such awareness also facilitates a more meaningful critical scrutiny of research results and conclusions prior to submission for publication. Finally, a researcher's goal should be to identify potential bias in the study design and implementation, to minimise identified potential bias where feasible and, where this is not possible, present their study findings in a way that informs the reader of the degree to which any residual bias exists. The extent of bias should be described as it may be of sufficient importance to exercise caution when deriving conclusions from the study findings and translating them into clinical practice.

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