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Revising contemporary research methodologies and plugging the loopholes - introducing the concepts of records and interest bias

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Abstract
BACKGROUND: Medical research methodologies is a continuously evolving process and data collection and its reproduction into the study design is still a grey area governed by various human and technological factors and is therefore subject to many errors and glitches. Bias in data collection is an integral part of this procedure. Since ages researchers have tried to define areas of error and suggested and integrated corrections to the same. Here in this study, we describe two such loopholes that are influenced by technology and human behavior.
METHODS: This is an observational study where we went through our previous record books and data entries and also spoke to various previous doctors and paramedical staff to derive conclusions and observations for this study.
RESULTS: We have introduced the concepts of records and interest bias based on our observations and have tried to derive analogy to explain them better.
CONCLUSIONS: Interest and Records bias are an addition to previously classified Reporting and Information bias and are explained here to educate and enlighten researchers who knowing these can practice deliberate methods to mitigate them.
Key words: *Bias, Records, Interest, medical research, reporting*

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I. Introduction

Medical research methodologies have evolved over years to a now near standardized protocol. However data collection and its reproduction into the study design is still a grey area governed by various human and technological factors and is therefore subject to many errors and glitches. Bias in data collection is an integral part of this procedure[1]. Since ages researchers have tried to define areas of error and suggested and integrated corrections to the same[1,2]. Consequently new terminologies have been defined as Reporting and Information bias[3]. However they still have domains which are yet to be clearly defined and incorporate still more definitions to plug additional loopholes. Here in this study, we describe two such loopholes that are influenced by technology and human behavior.

II. Materials And Methods

This study is an observational study, which was based on the observations of the authors while data collection for undertaking medical research. We were carrying out a number of both prospective and retrospective studies wherein we started pouring over and scrutinizing a humongous amount of data from previous record books and software. As a part of this study, we also attempted to speak to various doctors involved in the past record and data keeping. It is during this attempt that we came across certain distinct loophole patterns in data collection and we have attempted to regularize these patterns into discernable and defined nomenclature which we as authors realized was imperative to educate the medical research fraternity and simultaneously educate and create awareness amongst the upcoming young budding researchers about these loopholes so that the same can be mitigated.

III. Results

Record books and software entries of 15 years from 2006 to 2020 were examined in this observational study. Record books comprised of admission and discharge books, operation theatre registers, Injury severity records, disability certificate books, operation theatre logs and anaesthesia logs. Following points were remarked.

1. Admission and discharge books of the year 2009 and 2010 were lost

2. Significant pages from Admission and discharge books from 2011 to 2014 were destroyed due to rodent attack.
3. Operation theatre registers and logs of 2012 to 2014 were incompletely filled and did not carry the details of per-operative findings of the surgery carried out and specimen sent if any.
4. Anaesthesia logs had no mention of operative timings and anesthesia timings from 2006 to 2017.
5. Injury severity records and disability certificate books from 2008 to 2016 were lost in flooding of the document room.
6. Age and family history and complete patient profiling started only from the year 2018 and was missing before that.
7. Illegible handwriting at multiple occasions

Technological and Software related problems were also encountered

1. Central processing unit of many desktop computers prior to 2014 were changed and data backup not taken. Consequently much of data like discharge summaries prior to 2014 which are quite detailed in information, were lost.
2. Previous versions of Microsoft word and excel failed to open in the new systems
3. No uploading of data to cloud based storage and emails to enable them to be universally and eternally accessed.

We also attempted to speak to previous doctors and medical personnel posted previously with this hospital. A total of 16 specialist doctors (surgeons, anesthetists and medical specialists), 30 general duty medical officers and 30 paramedical staff were contacted telephonically.

1. 100 percent of paramedical staff who were frequently involved in register maintenance and data keeping were unaware of research methodologies and their importance
2. As high as 25 percent of specialist doctors and 67 percent of general duty medical officers showed a lack of interest in medical research and consequently did not heed to meticulous data keeping.
3. 50 percent of specialists and general medical officers were either hesitant in the use of computer software or were not interested to do so.
4. Out of the computer literates, 100 percent of all relied on local data keeping in desktop drives without any form of backup

Based on our observations we have attempted to compile our results and draw conclusions from the same.

IV. Discussion

In the classical teaching about research methodologies, we describe the story of the fisherman, the fish and the fishing net to draw relevant analogy to our study[5]. An experiment conducted to find out the distribution of sizes of fish in a lake, a net was used to catch a representative sample of fish. If the fishing net had a mesh size of 1 cm then no fish with sizes less than 1 cm would be found. This is a result of the method of selection (selection bias) from the experiment, there is no way of knowing whether there are any fish smaller than 1 cm.[1,3,5]

Adding to this excellent example of the fisherman and the net, we in our research into the intrinsic factors add to it the perspective of the fisherman with the net. There would be instances where a certain fisherman falls sick or goes on a vacation and is unable to carry out the duties on a certain set of days. But since this activity is his lifeline, his family or an acquaintance may have to relieve him temporarily to carry on. In the good faith the sick fisherman teaches him the tricks of the trade, in our case the research data collection. Now the new ad-hoc fisherman has his own beliefs, interests and skills. He may or may not show involvement to the extent which was required. He may also chose to keep certain juicy fishes for himself, or may decide to sell some of them in the market. Now here there is the analogy of data attrition, wherein the relieving researcher may or may not enter the data into the questionnaire or study design or may decide to start a study of his own. Since research and data collection is often a continuous cohort process, absences on one or any of the researchers may jeopardize the same and so the data collection becomes rather tricky. Data may be missing[4], mis-entered[4], skipped out or at times even subject to manipulation due to low or vested interests of the ad-hoc researcher. It is here that we bring both the concepts of Interest and Record bias.

Extrapolating the classical fisherman analogy into our study, firstly, the fisherman may or may not want to plunge into deeper waters and may just sit on the shores in his zone of comfort. This adds to the component of selection bias in it but also reflects on the mentality of the fisherman (analogous to the researcher), in adding to the loopholes in the study design. In case the study involves a group of researchers, each of them like the fishermen have different motivational levels in their involvement in the study. Some may venture out into deeper waters and some may just be fishing on the shores leading to variations in data gathering process. And there is no true way to place a countercheck on this process, because it is governed by intrinsic human behavior. Plus the fishermen do not necessarily go out to fish simultaneously to keep an eye out on each other and encourage. Similarly all study process and data collection is done often independently and the

motivational and involvement levels of all researchers vary. This is where we introduce the concept of Interest bias. We therefore define Interest bias as a bias that crops up in our study design owing to the varied interest and motivational levels of participating or non-participating; active or potential; researchers, observers, participators or data collectors.

Many of our study designs are retrospective in nature, based on previously recorded data, be it hard copies in the form of books, registers, logs, charts, files or soft copies as computer based or software based data. In these cases many other factors come into play which is imperative to bring out here. For example, while gathering a 15 year data for one of our studies, we found that what started off beautifully with meticulous data keeping in the first two years, reached a pause when we found our certain pages of our registers destroyed due to being eaten by rats. In another study we again found the data of many months missing when a waterlogging washed out the ink in the pages. In yet another study we found the age and family background of the patients missing because the data collector was too shy to ask the subjects so. In the same study we also found a significant amount of data lost because the individual entering the data had a rather illegible handwriting and none of the researchers could make any sense out of it[4]. So much for the meticulous data keeping. In another study where we started to gather a ten year data, we found to our utter dismay that though the data was recorded in a computer software, the files didn't open because the software and the interface were outdated and wouldn't open in our relatively newer updated systems. To summarize, all these add up to what we introduce here is an often unavoidable intrinsic loopholes in data collection and retrieval systems, or else put simply as records bias. We therefore define Records bias as a bias that crops up in our study design owing to differential data or record keeping procedures of participating or non-participating; active or potential; researchers, observers, participators or data collectors.

V. Conclusions

To summarize, Interest and Records bias are an addition to previously classified Reporting and Information bias and have an overlapping domain with interviewer and observer bias but cannot in totality be classified into the same. So we propose here to introduce these additional classifications into the broader subset of Information bias so that researchers may be educated and made aware of the same and it may be an indispensable introspection in undertaking genuine and authentic medical research activities.

It should however be remembered that revising such strategies is a continuous and dynamic process and we need to keep our evolutionary faculties open to facilitate a system where each of us can be either contributors or perpetuators or both in the field of advancing medical research.

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