

PATIENT SAFETY: A FUNDAMENTAL ASPECT OF CLINICAL TRIALS THROUGH A REVIEW OF A STUDY ON CANADIAN ADVERSE EVENTS

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SOURCE:

Article Title –G. Ross Baker, Peter G. Norton, Virginia Flintoft, Régis Blais, Adalsteinn Brown, Jafna Cox, Ed Etchells, William A. Ghali, Philip Hébert, Sumit R. Majumdar, Maeve O'Beirne, Luz Palacios-Derflingher, Robert J. Reid, Sam Sheps, Robyn Tamblyn; “The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada” Canadian Medical Association Journal (CMAJ) May 25, 2004 vol. 170 no. 11 doi: 10.1503/cmaj.1040498

ABSTRACT

Patient safety has received growing attention worldwide sin last decade or two in clinical research. Identification and immediate reporting of an Adverse Event (AE) has always been one of the key parameters to assess and observer patient’s safety in clinical research. Compromise to the patient safety was evident as critical violation of the International Harmonization Conference (ICH) - Good Clinical Practice (GCP) requirements of clinical research.

This review was written after comprehensive and critical assessment of the research conducted by G. Ross Baker et.al. This review provided a synthesis of key principles of identification of AEs and determination of their preventability. It examined detail article structure considering the sample size, research population and relevance to the research topic. The review further critiqued on the article authority and creditability of the journal to authenticate the research. This review also commented on the other relevant advance researches conducted in the area of AEs within clinical research as a detail comparison.

It was concluded in this review that research conducted by G. Ross Baker et.al was critical in terms of improving attention towards patient safety in clinical research and community services.

KEYWORDS

Adverse Event, ICH-GCP, Patient, Safety, Clinical Research

INTRODUCTION

This article review is based on the article, “The Canadian Adverse Events (AE) Study: the incidence of adverse events among hospital patients in Canada” published in Canadian Medical Association Journal (CMAJ) May 25, 2004 vol. 170 no. 11.

This article review begins with a literature review which briefly mentions the research topic focused in original article and other relevant aspects of the literature useful on the same research topic. Then it summarizes the article with key milestones achieved by the authors/researchers.

Further, it briefly analyses the overall structure of the article with the different key structural points talking about the flow of the research. The review also critiques the article through evaluating its authority specifying creditability of the journal in which original article was published and authors. Further it critiques on currency, accuracy, objectivity, stability and coverage of the original article.

This review article analyses the tables and figures in detail of their relevance to the actual objective of the research and relevance to the content of the original article before finally evaluating the article’s accessibility and credibility. This review article also elaborates the details of any recent advanced related topics to the original research.

The review concludes with the overall impression of the article and its usefulness in the research and any space for the improvement. Overall the article was written with clear objective and excellent interpretation of the results from performed research.

REVIEW OF LITERATURE

An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. (ICH GCP Guidance E6, retrieved 2014)

Adverse events in health care are common. Most current knowledge of adverse events is based on reviews of hospital medical records, incident reports by health staff or analysis of administrative databases. These approaches each have strengths, but also inherent biases and weaknesses as many

events will go unreported and unrecorded. Comparatively little is known about adverse events outside hospitals, although some evidence suggests they may be a significant contributor to harm in health care. (Scott IA et.al, 2006)

Patient safety is receiving growing attention in community hospitals. Numerous legal cases and media stories have highlighted the consequences of unintended adverse events (AEs) recently globally. One important indicator of patient safety is the rate of AEs among hospital patients. AEs are unintended injuries or complications that are caused by health care management, rather than by the patient's underlying disease, and that lead to death, disability at the time of discharge or prolonged hospital stays. (Brennan TA et.al, 1991) (Leape LL et.al, 1991)

Health care consumers are a relatively underused source of information about adverse events and about their views about such events. This underuse occurs despite evidence of consumers' capability in noticing adverse events. Patient satisfaction surveys tend not to focus on adverse events so much as problems with interpersonal interactions or the delivery of care, and are most commonly conducted among inpatients. (Agoritas T et.al, 2005)

Therefore, there is a great need to increase awareness and attention towards AEs for the community health and patient safety.

ARTICLE SUMMARY

The purpose of the research article was to incidence of adverse events among community hospital patients in Canada. The original article clearly mentioned what were the research objectives and methodology used for the research and data analysis. The articles expressed that researchers targeted community hospitals to assess community health via wide variety of patients.

The sites selected for the research was excellent selection based on the requirements of the study design. Basic comparison and review of AE incidence with in Canadian community hospitals was done. The aim was to estimate the incidence of Adverse Events among patients in Canadian acute care hospitals. The methods used in this study are based on a protocol developed by the Harvard Medical Practice Study, which examined the incidence of AEs in New York state hospitals in 1984. (Brennan TA et.al, 1991) (Leape LL et.al, 1991)

It was specified in the article that research participants were trained; however delegation of their responsibilities within the research was really not clear. In total 20 hospitals were selected and involved for the research within 5 provinces of Canada. In total 4164 hospital admission samples (patient charts) were reviewed as a part of this research. There was no mention of consenting patient on the use of their data for the research.

This could be a potential ethical issue if not done as a part of research; although it was clear that ethical and institutional review board approval was taken for the research. The data collection was done using 2-stage review process involving patient hospital charts. The aim of the statistical analysis was very

clear to measure incidence of Adverse Events in the samples selected for the research. Kappascore method was used for the statistical analysis

The results of the research were clearly described for patient charts reviewed in the process. Interpretation section was added in terms of traditional approach of discussion. It was readable as extension to the result section rather than actual discussion of the results. Interpretation section was clear enough to explain the results and relevance of the study results with other researchers conducted on same topic. The article concluded mentioning that additional research is needed into the incidence and types of Adverse Events beyond acute care hospital setting. The article has details of peer review and acknowledgement given to the people who participated and supported the research work.

ARTICLE STRUCTURE

The article was original based on the research conducted by the authors G. Ross Baker, Peter G. Norton, Virginia Flintoft, Régis Blais, Adalsteinn Brown, Jafna Cox, Ed Etchells, William A. Ghali, Philip Hébert, Sumit R. Majumdar, Maeve O'Beirne, Luz Palacios-Derflingher, Robert J. Reid, Sam Sheps, Robyn Tamblyn. The article was structured in following main points.

1. Abstract
2. Methods
3. Study Sample
4. Data Collection
5. Results
6. Interpretation
7. Acknowledgement
8. References

Being an original research article it had all the key and relevant sections needed to explain the research and outcomes. Detail subsections and their relativity to each other helped reader to concentrate and understand the article clearly. Article was easy to navigate. The body of article was paragraphed hence the information in each paragraph was easy to access and understand. The study design and methodology was clearly specified in the article.

The abstract was well written with subsections including background, methods, results and interpretation. Tables and figures were preciously used to describe research and outcomes. It was effective way to make readers understand research clearly.

There were sections related to the data collection and statistical analysis which elaborate how the research results were evaluated.

The article was structured through main bold points as discussed below.

- Point 1 –What is Adverse Event (AE)?
- Point 2 – How research in AEs is important in terms of improving patient safety?
- Point 3 – Why patient safety needs improving attention in community?
- Point 4 – Result outcome and relevance to other research on the same topic.

The interpretation was developed towards the end of the article. There were no separate sections for conclusion and discussion. They were combined in section for interpretation. Lack of separate conclusion section did not help readers to conclude article reading with ease.

References were cited in-text and set out clearly in the literature cited section; 18 references were given at the end which was sufficient. However references were not listed in alphabetical order. The overall article's structure was logically developed, with the use of detail paragraphs helping the reader access the main points more easily. The article was a PDF document.

There were links to author, journal, subjects, citations and references which allow the reader to evaluate the articles worth more effectively.

ARTICLE CRITIQUE

AUTHORITY:

The Canadian Medical Association Journal is a peer-reviewed general medical journal published by the Canadian Medical Association (CMA). It publishes original clinical research, analyses and reviews, news, practice updates, and editorials.

CMAJ platforms innovative research and ideas focused at improving health for people in Canada and globally. It publishes original clinical research, analyses and reviews, news, practice updates and thought-provoking editorials. CMAJ has had significant contribution in worldwide healthcare over the last 102 years. In Canada, the journal has played a key role in raising awareness of health and medico-social issues on topics such as the link between sun exposure and skin cancer, the dangers of smoking, contraception, abortion, euthanasia and other topics. It celebrated its 100th anniversary in 2011. (CMAJ, 2014)

The authors' credibility was established in a number of ways. All the authors were from well-known healthcare institutes and have published number of research articles. The lead author G. Ross Baker is a professor of Institute of Health Policy, Management and Evaluation in University of Toronto. The research was supported by Canadian Institute for Health Information and the Canadian Institutes of Health Research. (University of Toronto, 2014)

ACCURACY:

The article targeted community hospitals in the 5 different provinces of Canada covering large geographical area with 20 hospitals. The source of the information in the article was a recent research project supported by Canadian Institute for Health Information and the Canadian Institutes of Health Research. Experienced authors of the article made the article accurate and informative. The accuracy was backed up and supported by a comprehensive, recent reference list with these sources cited in-text to support both the literature review and the research itself. The strict editorial and refereeing processes of the CMAJ also contributed to the article's accuracy.

CURRENCY:

The Canadian Medical Association Journal is a peer-reviewed general medical journal published by the Canadian Medical Association (CMA). This journal publishing research articles since last 102 years. The article was included in volume 170, number 11 of 25 May 2004 while the article was accepted for publication in earlier in 2004. The research review it describes was current and the article cites up-to-date references in the body of the text ranging from year 1991-2003. All the articles referenced were with latest research performed in the AE, patient safety and community health. Therefore the article is current. (CMAJ, 2014).

RELEVANCE:

This was a journal on an academic database, which has high credibility in an academic context. It was written to inform researchers, students and industrial practitioners rather than to entertain or advertise. It would be relevant to these groups but particularly any academic interested in clinical research and in community healthcare generally.

It was easy article to read and understand and therefore useful for all levels of clinical researchers and healthcare professionals. CMAJ's articles describe innovative research and systems that help to advance medical research and to promote community health. The article was clearly a research study targeting community health and aimed to improve awareness of AEs for the patient safety. (CMAJ, 2014)

OBJECTIVITY:

The information in article was objectively developed, well supported with a current research database and with all the latest evidence acknowledged and referenced. The article objective was to study and research incidences of AEs in community hospitals and increase awareness of patient safety. There was no evidence of bias, a fact that was reinforced by the recognition that the article documents research,

which followed the rigorous research processes, and the necessary ethical considerations demanded of such intensely supported research. The supporters were clearly defined on the last page of article. The objectivity is very much clear.

STABILITY:

The article was a source of research work studying incidences of AEs within 5 provinces of Canada and increase awareness of patient safety in community hospitals. The article carefully demonstrated conducted research with the data generated during the research. The article was based on the current research in the patient safety area and backed up with practical evidences published in the recent research; therefore it's stable. The stability of the article can also be judged with the help of the authors and their creditability, expertise and work history. The Canadian Medical Association Journal and its creditability also makes article stable.

ANALYSIS OF GRAPH/IMAGE/TABLE

There were 6 (six) tables and 2 (two) figures were used to elaborate the research work in this article. All tables and figures were clearly titled and linked within the text; detail analysis of each of them is given below. Overall tables and figures were clearly defined and compliment the entire original article.

- Table 1 (page no 1679) - Table 1 shown Screening criteria applied to 3745 charts in the stage I review and the proportion of charts positive for each criterion. Table clearly shown numbers and percentage of charts with criterion.
- Table 2 (page no 1682) – Table 2 shown weighted and adjusted rates of adverse events (AEs), by hospital type. Point estimates and CIs were weighted to account for the total number of charts per hospital and the total number of hospitals per type per province. Whereas adjusted model was developed using backward stepwise logistic regression.
- Table 3 (page 1682) – Table 3 shown degree of physical impairment or disability at discharge resulting from AEs, as determined by physician reviewers, by hospital type.
- Table 4 (page 1683) – Table 4 shown association of AEs with length of stay (LOS), by hospital type. Physician reviewers were asked to estimate, on the basis of their professional judgment, the number of additional days in hospital directly related to AEs.
- Table 5 (page 1683) - Table 5 shown procedures or events to which AEs were related, by service most responsible services such as medicine and surgery for delivery of care at time of AE.
- Table 6 (page 1684) - Table 6 shown studies of AEs in hospital patients. Table was very comprehensive providing data on the studies in hospitals and associated AEs.

- Figure 1 (page 1681) – Figure 1 was flowchart of review process for the Canadian Adverse Events (AEs) Study. It was very clear figure to explain 2 stage approach used for this research.
- Figure 2 (page 1682) – Figure 2 was of timing and occurrence of AEs relative to index hospital admission. It has clearly shown AEs occurrences related to the time.

RECENT ADVANCES RELATED TO THE TOPIC

There were few recent researches conducted on AEs incidences and patient safety in healthcare and community hospitals. Few recent topics are discussed below.

- A study conducted by Aranaz-Andrés JM et.al on “Incidence of adverse events related to health care in Spain: results of the Spanish National Study of Adverse Events” concluded that the incidence of patients with AE related to medical assistance in Spanish hospitals was relevant and similar to those found in the studies from Canada and New Zealand that had been conducted with comparable methodology. Patient vulnerability has been identified therein as playing a major role in generating healthcare-related AEs. These and other recent results indicate the need for AEs to be considered a public health priority in Europe. (Aranaz-Andrés JM et.al, 2008)
- Another study conducted by Masotti P et.al on “Adverse events in community care: developing a research agenda”. The study describes the results of a consensus workshop in which 31 healthcare professionals were asked to identify and rank common adverse events and important research questions relating to community care. Workshop participants were decision-makers and healthcare providers with areas of expertise that included community and home care; acute and primary care; patient safety; medical errors; and health services policy, administration and research. Results include prioritized lists of adverse events, research questions and contributing factors associated with adverse events. (Masotti P et.al, 2007)
- A study was conducted by Robert JA et.al in 2009 on “Self-reported adverse events in health care that cause harm: a population-based survey” concluded that an incidence of self-reported harmful adverse events that was significantly lower than that found by a 2002 Australian survey. Better communication to help patients acquire more realistic risk perception may help reduce harm. Better communication could also increase public advocacy for systems improvement in safety to counter persisting community beliefs that individual action alone can redress the situation.

CONCLUSION

The research discussed in the original article “The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada” was with clear objective and a true research. The content, structure, strengths and limitations of the article were analyzed and critiqued. The article has contributed to the literature in terms of its valuable research of AE incidences in 5 different provinces across 20 hospitals and challenges in awareness of patient safety. The article was very good reference information based on the practical and current research. It had all the details revolving around increasing attention of patient safety, their challenges and usefulness along with certain limitations.

The article expressed detail picture and true data on AE incidences and its effective use which is critical for improving attention to patient safety in community health and healthcare research in current era. The article was very well written and had all the necessary sections to discuss the detail research conducted and outcome obtained. Tables and figures included in the article were accurate, and clear for understanding. It was very useful and informative article for the academic and healthcare researchers. It is suggested to add some more definitive details on the future policies and research directions for the readers and researchers. A conclusion section highlighting key conclusions would be useful in the article.

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