Research Policy on Case-control and Cohort Study Design in Pharmaceutical Care

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ABSTRACT

Objectives: This study explores the Research Policy of Case-Control and Cohort Study Design in Pharmacy Practice as a new initiative in Saudi Arabia. **Methods:** This article is a narrative review of pharmacy research. Litterateur researched specific research policies and procedures in pharmacy practice using a variety of databases, including PubMed, Medline, and Google Scholar. The period covered for the search is from the 1960s to October 2021. The terms used are in the English language and encompasses narrative reviews, systemic reviews, meta-analyses, and guidelines. The search term includes all hospital and community pharmacy-related services. Besides, there are national and international guidelines for conducting general research in hospital practice. The pharmacy research committee was formed and comprised numerous expert members, including clinical pharmacists, pharmacists specializing in drug information, and clinical research specialists. A member drafted the policy's guidelines, which were then reviewed and corrected by another member. The research specialist made the third revision. The subject emphasizes the Pharmacy Research Policy for the Case-Control and Cohort Study Model. **Results:** The Pharmacy Research policy for the Case-Control and Cohort Study Design in pharmaceutical care services consisted of several components, including the advantages and disadvantages of Case-Control and Cohort Study Design and the steps involved in conducting Case-Control research, and the steps involved in conducting Cohort Study research in pharmacy practice. **Conclusion:** The pharmacy research policy for the Case-Control and Cohort Study Design is a new initiative as part of the pharmaceutical care services. The pharmacy policy on Case-Control and Cohort Studies aims to improve pharmacists' research abilities in healthcare institutions. Additionally, the new tools for documenting and validating adverse drug reactions. Therefore, the Case-Control and Cohort Study research policies in pharmacy are recommended for implementation in Saudi Arabia.
Key words: Research, Policy, Pharmacy, Case-Control, Cohort Study, Saudi Arabia.

INTRODUCTION

The case report and case series had good documentation of multiple cases occurring at the same time or at different times.[1-3] In the past, the risk and outcome of case reports were used without any control to compare them. For instance, such a drug may cause severe adverse drug reactions in a single case report or a series of cases documented by multiple authors. Another compiles all previous drug and adverse drug reaction statements.[1-3] The case-control study examined the relationship between outcome and risk factors in groups of cases who had an outcome and compared them to a control group that did not work.[1,3,4,5] Then, review the history of exposure to the risk factors. The control group did an excellent job of avoiding risk factor exposure. For instance, drug A-induced side effect B and compared with drug A did not induce side effect B. Both groups received drug A, but the outcomes varied according to whether a side effect was present or absent. Case report or case series and case-control are all advantages of the research design model. The risk factors were previously exposed, and there is a determination of future risk factors.[1,3,4,5] Cohort studies are similar to case-control studies. However, it may be able to quantify risk factors in the future by monitoring risk exposure.[1,3,5,6] For instance, if drug A caused side effects, B examined the patient's history of receiving the same medication with and without side effects and calculated the correlation between them. It could monitor two groups of patients currently receiving drug A and track the occurrence of side effect B and its absence in patients who received the same drug A. Numerous guidelines discussed the case-control or cohort design as a research model, outlining its benefits and drawbacks.[1-6] However, the policies and procedures governing the design of case-control and cohort studies are rarely well documented.[7-9] Without prior knowledge of any publications, the authors discussed the current topic locally or in Middle Eastern countries. The purpose of this review is to establish the policy and procedures for conducting research using the case-control and cohort study models in pharmacy practice.

MATERIALS AND METHODS

It's a narrative review of pharmacy research. Litterateur searched for specific topics related to research in pharmacy practice in a variety of databases, including PubMed, Medline, and Google Scholar. The time frame for the search is from the 1960s to October 2021. The terms

used were in English and included narrative review, systemic review, Meta-analysis, and guidelines. The policies were limited for the previous ten years. In a search term, all hospital or community pharmacy services are included. Inpatient pharmacy, outpatient or ambulatory care pharmacy, satellite pharmacy, extemporaneous preparation, repackaging units, pharmacy store, drug information center, and clinical pharmacy services were among the pharmacy services available. Furthermore, the National and international guidelines for general research in hospital practice.[10-23] The Saudi Food and Drug Authority (SFDA), the European Medicine Agency,[16] the American Society of Health-System Pharmacists (ASHP),[17] and the World Health Organization (WHO),[14] and other literature.[1,2,24,25] Aside from that, the Equator Network is a library of health research guidelines based on observational studies. That includes Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies guided by writing policy and procedures,[7-9] which were developed by a committee of pharmacy researchers. Clinical pharmacists, drug information pharmacists, and clinical research specialists are among those who work in this field. A second member and the research specialist reviewed and corrected one member's policy draft guidelines. The topic consisted of various organizational topics, including a Case-control study and a cohort study. The covered. The current reviews were reported following the adopted international Appraisal of Guidelines, Research, and Evaluation (AGREE).[26]

Search: pharmacy research policy[Title/Abstract] Filters: Full text, Humans, English

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report[MeSH Terms]: “research report”[MeSH Terms]

Search: case-control policy[Title/Abstract] Filters: Full text, Guideline, Practice Guideline, Humans, English

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policy[MeSH Terms]: "policy"[MeSH Terms]

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report[MeSH Terms]: "research report"[MeSH Terms]

Search: case-control research[Title/Abstract] Filters: Full text, Guideline, Practice Guideline, Humans, English

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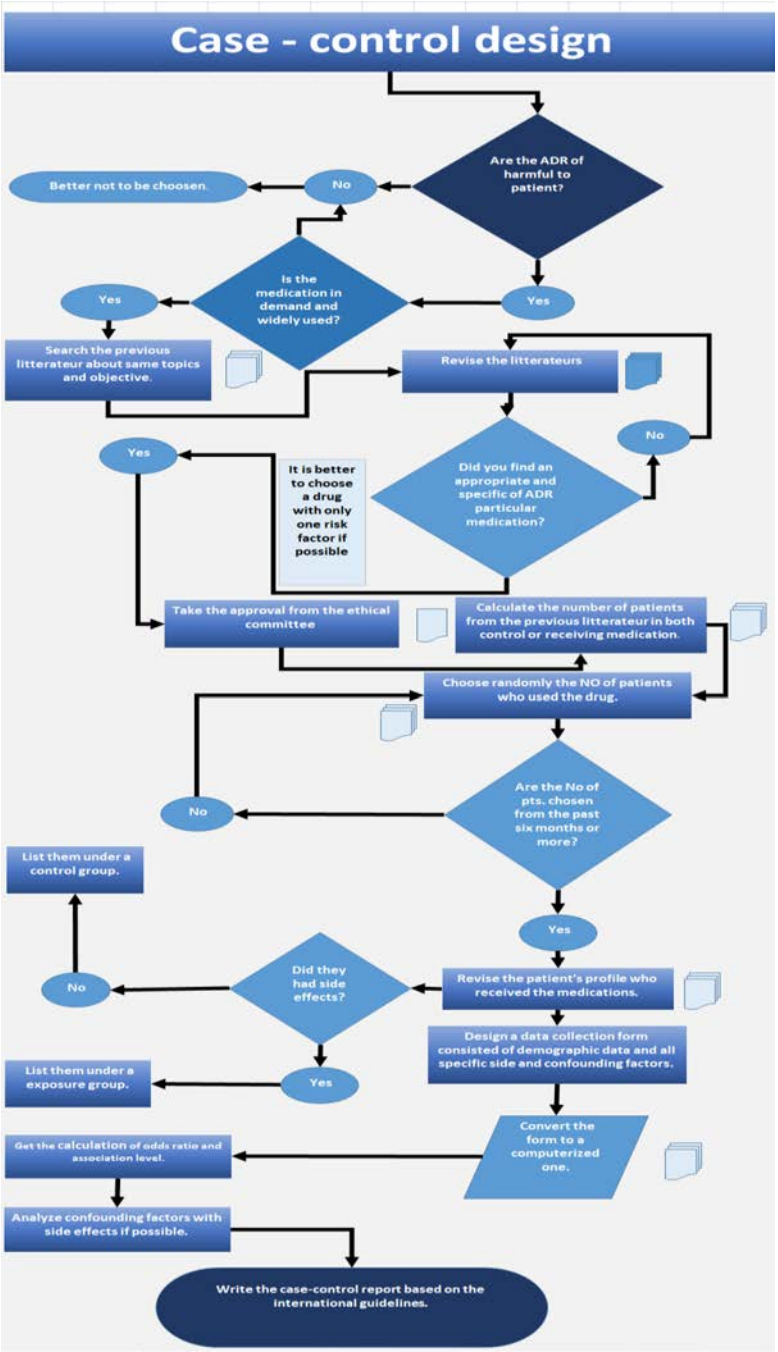

Figure 1: Case control procedures flow chart

RESULTS AND DISCUSSION

Case-control studies are used to evaluate a specific event and the environmental factors that contribute to it.[3-5] For instance, in ovarian cancer, investigators would collect data on all patients with the disease over a specified period and compare them to a similar group without the disease in a case-control study. For example, one observation could imply that patients with ovarian cancer used oral contraceptives at a higher rate than those without cancer; thus, an

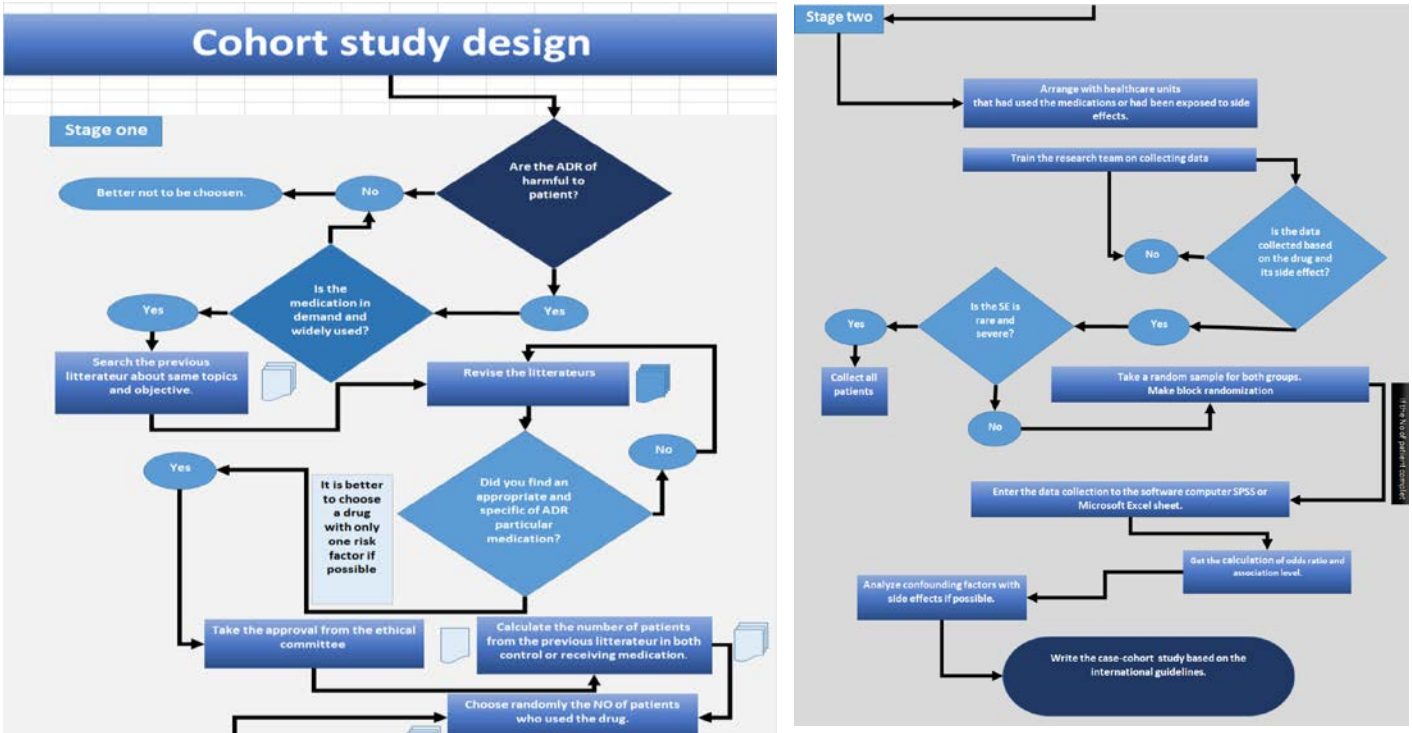

Figure 2: Cohort study procedures flow chart

association between oral contraceptive use and ovarian cancer could exist.[3-5]

Case-control studies are designed to ascertain the relationship between disease states and exposure to various risk factors.[3-5] The design is observational; a group of participants (cases) with a particular disease (feature) is compared to a similar group of participants (non-cases) who do not have the disease (features). The advantages included being quick and inexpensive (inexpressive and straightforward to perform), requiring fewer subjects than cross-sectional studies, being the most efficient design, and being more helpful in studying rare diseases. Additionally, it is capable of evaluating multiple risk factors. On the other hand, disadvantages include reliance on records to determine exposure status and difficulty selecting control groups. Apart from the difficulty in determining which variable should be used to match a case to a control (age, sex, etc.), there is a possibility of bias (selection/classification/etc.) and difficulty in ensuring that both groups receive equal exposure to all factors.[3-5]

Cohort observational studies are similar to case-control studies, with the exception that they examine the effects of a particular type of therapy.[3-5] Cohort studies frequently assess the effects of a drug on a given population and compare them to the effects of the agent on a similar population that does not receive it. For instance, the cohort observational design could be used to investigate the association between oral contraceptive use and ovarian cancer. In this case, the investigators could compare patients who use oral contraceptives to a similar group who do not use them to determine any differences in adverse events. The cohort design is frequently used in conjunction with the case-control method to confirm results. In addition, the cohort approach can be used explicitly following the case-control process's association of a drug with an event. Cohort Research. (A retrospective cohort study (historical) and a prospective cohort study). A retrospective cohort study collects data from patient records and does not follow up on patients as a prospective study does.[3-5]

The Cohort Study's objective is to ascertain the relationship between various factors and the development of disease states.[3-5] It is observational in nature and compares the group of subjects exposed to the factor of interest (drug A) to the group that is not

exposed (drug B or placebo). That is either retrospectively or prospectively followed. The cohort study examines the development of relatively common diseases and has shorter biological etiologies. Numerous advantages exist for cohort studies. For example, it is ethically sound, and subject matching is possible. It is capable of determining the timing and directionality of events. Additionally, eligibility criteria and outcome assessments can be standardized, the administration is simpler and less expensive than with RCTs, and the study design is the strongest among observational studies. On the other hand, the disadvantages were that the controls might be difficult to identify, blinding is difficult, randomization is absent, the study cannot be conducted in the case of a rare disease, large sample sizes, or extended follow-up is required. Bias (selection/information/categorization).[3-5] The following suggested policy and procedures and flow chart Figures 1,2, for Case-Control and Cohort study design in the pharmacy practice as follows.

Case-control design[1-5,7-9]

1. Identify the most significant or most severe adverse effects of commonly used medications that are most distressing to patients.
2. It is preferable to select medications that are in high demand and widely used by patients.
3. Search previous litterateurs who addressed the same subject and objective.
4. Revise the litterateur and select the adverse effects of particularly appropriate and specific medication. It is preferable to use a single drug for a single risk factor if possible.
5. Obtain approval from a healthcare organization's ethical committee.
6. Determine the total number of patients in the previous litterateur who were either in control or receiving medication.
7. Using a random number, determine the number of patients who used the drug in the preceding six months or more.
8. Revise the patient profiles of patients who received medications and experienced adverse events as an exposure group and patients who did not experience adverse events as a control group.
9. The design data collection form included demographic information and all relevant secondary and confounding variables.
10. Convert the traditional data collection method to one that is computerized.
11. Calculate the odds ratio and the level of association.
12. If possible, analyze confounding variables with side effects.
13. Prepare a case-control study following international standards.[7-9]

Cohort study design[1-3,5-9]

1. As stage one, repeat the previous 13 steps on case control.
2. Make arrangements with healthcare units that have used the medications or have encountered adverse effects.
3. Train the research team on collecting data using the case-control study's previous data collection method.
4. The research team member collects data on the drug and its side effects.
5. If the adverse effect is rare but severe, gather all patients. If there is a common adverse effect, a random sample should be taken from both groups, and it is preferable to use block randomization for both the control and exposure groups.
6. After completing the number of patients, enter the data collection into the SPSS or Microsoft Excel spreadsheet software.
7. Calculate the odds ratio and the association level.
8. If possible, analyze confounding variables that have side effects.
9. Prepare a case-cohort study in accordance with international standards.[7-9]

CONCLUSION

Case report and cohort study design policies and procedures are beneficial for monitoring both short- and long-term drug therapy. It encourages pharmacists to document medication management complications and raises pharmacists' awareness of the voidability of drug morbidity and mortality. The current study's policies and procedures address critical issues in pharmacy practice and are highly recommended for implementation in pharmaceutical care services.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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Consent for Publications

Informed consent was obtained from all the participants

Ethical Approval

This research was exempted from research and ethical committee or an institutional review board (IRB) approval.

https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

ABBREVIATIONS

KSA: Kingdom of Saudi; **SFDA:** Saudi Food and Drug Authority (SFDA); **WHO:** World Health Organization; **ASHP:** American Society of Health-System Pharmacists; **STROBE:** Strengthening the reporting of observational studies in epidemiology; **AGREE:** Appraisal of Guidelines, Research, and Evaluation.

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