Research Policy of Case Report and Case Series Design

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ABSTRACT

Objectives: This study aims to declare the Research policy of case reports and case series design in pharmacy practice as a new initiative in Saudi Arabia. **Methods:** This article is a narrative review of pharmacy research. Litterateur looked up specific research policies and procedures in pharmacy practice in databases such as PubMed, Medline, and Google Scholar. The time frame for the search was 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 was revised. The pharmacy research committee was formed and consisted of expert members, including clinical pharmacists, pharmacists who specialise 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 topic emphasizes the Pharmacy Research policy of case reports and case series design. **Results:** The Pharmacy Research policy regarding the design of case reports and case series in pharmaceutical care services included several items. This included the advantages and disadvantages of case reports and case series, the steps involved in conducting case report research, and the steps involved in implementing the case series model in pharmacy practice. **Conclusion:** The case report and case series policy in pharmacy is a new initiative that is part of the pharmacy research services and the pharmacy strategic plan. The case report and case series pharmacy policies help a healthcare organisation address its unique drug-related issues. Additionally, the efficacy of the particular drug in treating the particular disease condition. Therefore, in Saudi Arabia, the case report and case series in pharmacy research policy are highly recommended.
Key words: Research, Policy, Pharmacy, Case report, Case series, Saudi Arabia.

INTRODUCTION

The scientific investigation was divided into several steps. First, the research problem to be investigated was determined.[1] The problem derived from any system or disease that was not treated with appropriate medications. Furthermore, the problem occurred unexpectedly as a result of certain questionable medications. The problem could be severe and related to the only drugs required for patients or disease treatment. Furthermore, the side effect was severe for the common use of certain medications.[2-4] As a result, it is critical to document new indications for medications as well as new adverse drug reactions that occur with medications. If new drug-related problems arise, the researcher must collect all necessary information for drug therapy. Assume the pharmacist researcher did not document the case. In that case, the other researcher would be unable to continue validating drug therapy information, making it difficult to avoid future drug-related problems.[2-4] Over the course of several case reports, the other authors may collect all previous case reports with the same objective, summarize them, and compare them to the outcome of the conclusion; that is, cases series of the research design model.[2,3] Furthermore, future recommendations on which types of research design to use in the future. For example, conduct a case-control or cohort study, or proceed directly to clinical trials. Various studies on case reports or case series, as well as their advantages and disadvantages.[2,3] Besides, the majority of previous studies were explanatory reviews.[2-4] Few reports have discussed the case report or case series policy and procedures.[5-9] The authors, who were unfamiliar with the studies, discussed the case report or case series as a research policy locally or in Middle Eastern countries. The topic's current goal was declared research policy of case report design.

MATERIALS AND METHODS

It's a narrative review of pharmacy research was presented. 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 includes 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 centre, 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),[11,12] European Medicine Agency,[16] the American Society of Health-System Pharmacist (ASHP),[17] and World Health Organization (WHO),[14] and other literature.[2,3,24,25] Besides, Equator Network; the library of health research guidelines in observational studies. That includes the CAse REport (CARE) guidelines: consensus-based clinical case reporting guideline development for case study guided of writing policy and procedures.[7-9] The pharmacy research committee was formed and consisted of numerous expert members. This includes clinical pharmacists, pharmacists who specialise in drug information, and clinical research specialists. One member drafted the policy guidelines, another member reviewed and corrected them, and a research specialist revised them three times. The topic covered two areas, including Case reports and case series. The current reviews were reported in accordance with the internationally adopted Appraisal of Guidelines, Research, and Evaluation (AGREE) standard.[26]

Search: Case Report policy[Title/Abstract] Filters: Full text, Practice Guideline, Humans, English

((“case reports”[Publication Type] OR “case report”[All Fields]) AND “policy”[Title/Abstract]) AND ((practiceguideline[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

Case Report: «case reports»[Publication Type] .or. “case report”[All Fields]

Search: Case report policy[MeSH Terms] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English

((“case reports”[Publication Type] OR “case report”[All Fields]) AND “policy”[MeSH Terms]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

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Search: **case series policy** Filters: **Full text, Guideline, Practice Guideline, Humans, English**

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Translations

case: «IEEE Int Conf Automation Sci Eng (CASE)”[Journal:__jid101616229] OR “CASE (Phila)”[Journal:__jid101700477] OR “case”[All Fields]

series: «serie”[All Fields] OR “series”[All Fields]

policy: «policy»[MeSH Terms] OR “policy”[All Fields] OR “policies”[All Fields] OR “policy’s”[All Fields]

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Search: case series report[Title/Abstract] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English

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report[MeSH Terms]: «research report»[MeSH Terms]

Search: case series research[Title/Abstract] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English

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research[MeSH Terms]: «research»[MeSH Term

RESULTS AND DISCUSSION

The primary descriptive reports describe individual experiences in terms of sharing ideas, describing programs, reporting on new treatments, and making observations.[2,4] Descriptive reports DO NOT involve any investigation or scientific principles. The Descriptive reports explain individual

experiences, new programmes, and patient responses to therapy or adverse events are described in the descriptive reports. As with evaluative studies, descriptive reports supplement previously published information on a variety of subjects. In contrast to evaluative studies, descriptive reports do not involve an experimental procedure or an examination of a specific hypothesis.[4]

The Characteristics of Descriptive Reports describe detail the events that transpired and the perceived outcome.[4] Their primary objective is to efficiently incorporate new and innovative information into the literature. Descriptive reports can be written and published quickly. Additionally, these reports may serve as the basis for evaluation studies.[4]

Descriptive Reports may include care reports, case series, pharmaceutical practice descriptions and clinical series that describe the population or programme.[4] For instance, a descriptive report on a programme can educate the professional community about a newly implemented pharmacy programme. In comparison, a descriptive report of a population can be used to describe a group's specific preferences or characteristics.[4]

A case report is a narrative account of a patient's reaction to a novel treatment or medication.[2,4] A descriptive report on a topic related to pharmaceutical practice typically describes a novel procedure or analytical technique. Case reports are used to describe a single patient or a series of patients.

The case report may be observational, consisting of a report of observations regarding the administration of a drug or procedure to a single patient or group of patients without the inclusion of a control group.[4]

The following text contains policies and procedures, as well as flow charts for the design of case reports and case series studies in pharmacy practice.

The following text policy and procedures and flow chart Figures 1,2, for Case report and cases series study design in the pharmacy practice.

Case report design[2-9]

1. Assume the researcher is particularly interested in the case report. Then it is preferable to adhere to the instructions.
2. Conduct a topical search in the preceding litterateur's various databases, including PubMed, Scopus, Web of Science, Google Scholar, and academic Microsoft, science direst, and other databases
3. Become familiar with the pathology and pathophysiology of diseases, as well as the pharmacotherapy or drug treatment of those diseases.

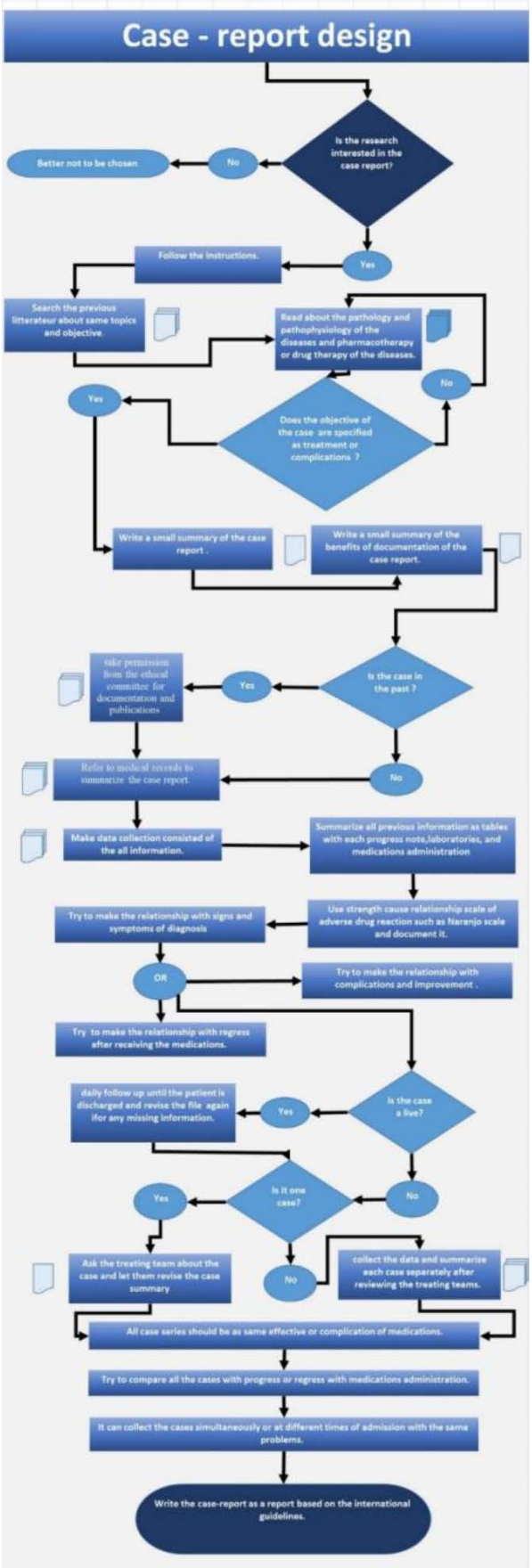

Figure 1: Case Report procedures flow chart.

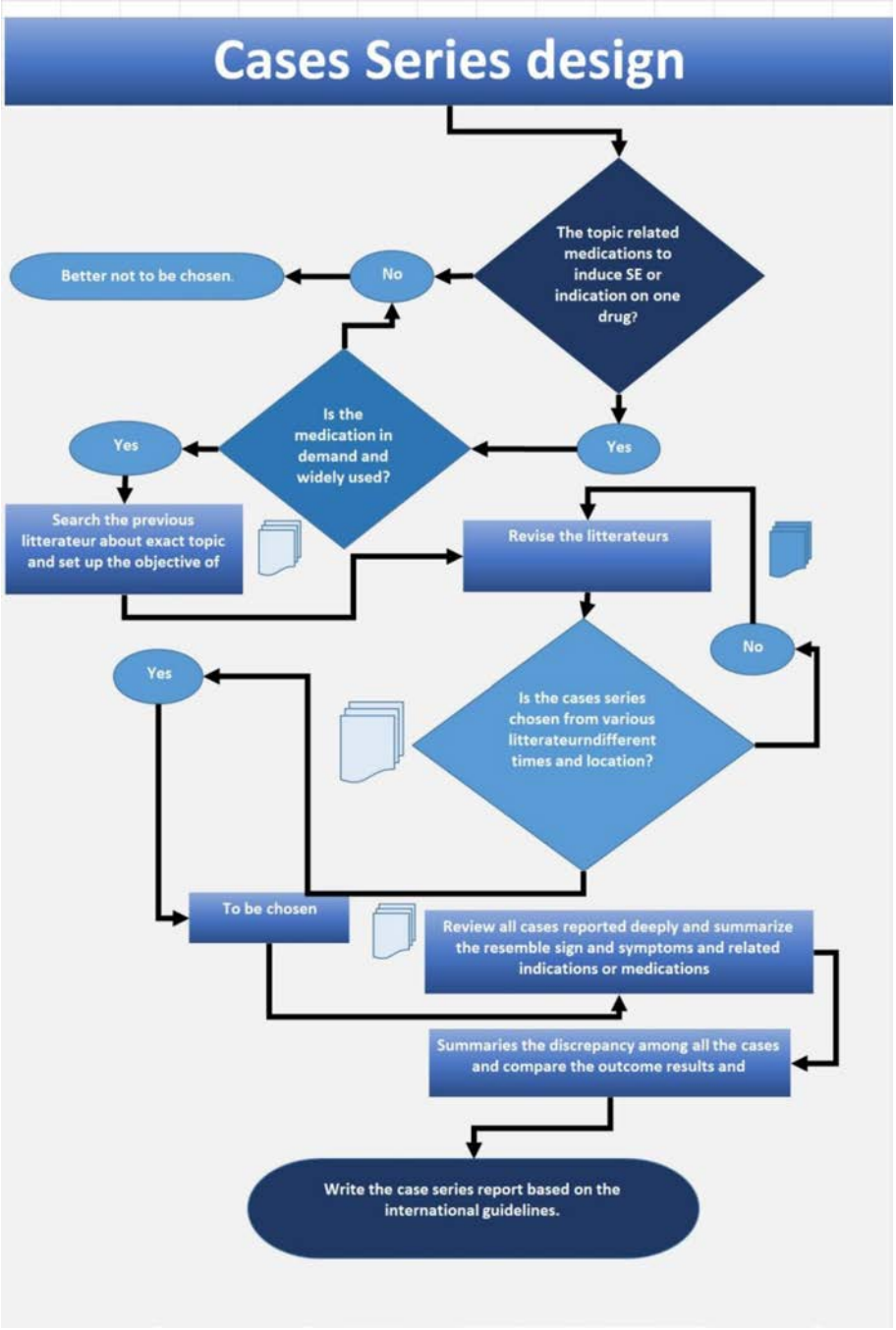

Figure 2: Case Series design flow chart.

4. The case's objective must be specified, such as treatment or avoidance of complications and adverse drug reactions.
5. Write a brief summary of the case report and the advantages of documenting the case report.
6. If the case occurred in the past, permission for documentation and publication should be obtained from the ethical committee.
7. After receiving approval from the ethical committee, summarise the case report using medical records.
8. Create a data collection form that included demographic information, a history of admissions, a history of the presenting illness, an initial diagnosis, and a final diagnosis. Additionally, medication reconciliation at the reach steps in healthcare organizations includes all medications received from the time of admission until the time of discharge from healthcare services, laboratory tests performed during hospitalization, radiology reports, and any additional tests, as well as dated progress reports.
9. Compile all previous information into tables for each progress note, laboratory, and medication administration.
10. Document adverse drug reaction severity using a strength-cause relationship scale, such as the Naranjo scale.
11. Make a connection between the signs and symptoms of diagnosis or complications and the improvement or regress following medication administration.
12. If the case is currently active, attempt to complete all previous steps and monitor daily until the patient is discharged, revising the file again if any information was missed.
13. Inquire about the case with the treating team and allow them to revise the case summary.
14. If there are multiple cases, collect data and summarise each case individually after consulting with the treating teams.
15. All case series should be identical in terms of medication efficacy or complication.
16. Make a comparison of all cases that progress or regress following medication administration.
17. It is capable of collecting cases with the same problem concurrently or at different times of admission.
18. If the case report is written in accordance with the final documentation of the international guidelines for writing case reports or case series[5-8]

Case Series design[2-9]

1. Select the most pertinent topic-related medications to elicit adverse effects or indications for a single drug.
2. It is preferable to select commonly used medications or severe adverse drug reactions for commonly used drugs or server diseases that do not require precise management. Furthermore, there is an urgent need for a solution to the severe problem of pharmacy practice.
3. Conduct a literature search on the subject and establish the case series' objective.
4. The case series should be drawn from a variety of different litterateurs, eras, and locations.
5. Conduct a thorough review of all reported cases and compile a list of comparable signs and symptoms, as well as associated indications or medications.
6. Summarizes the differences between all of the cases and compares the outcomes, findings, and conclusions.
7. Prepare a report on a case series in accordance with international standards

the CAse REport guidelines: consensus-based clinical case reporting guideline.

CONCLUSION

Case reports or case series are primary pharmacy research documents on drug-related issues. The approach encourages pharmacies to increase their reporting of drug-related misadventures. Additionally, the policy initiates steps toward the discovery of new indications for medical care. Therefore, a case report approach in pharmacy organizations is suggested in terms of research and development performance and activities 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; **WHO:** World Health Organization; **ASHP:** American Society of Health-System Pharmacists; **CARE:** CAse REport guidelines; **AGREE:** Appraisal of Guidelines, Research, and Evaluation.

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