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Conducting Record Review Studies in Clinical Practice

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ABSTRACT

Clinical record review or chart review is a previously recorded data to answer clinical queries. Such a study can be used to answer specific clinical questions in a relatively easy and less resource intensive manner. But these studies may be constrained by the limited information retrievable and inadequacy of records. Various types of data sources may be available for conducting such reviews (like case charts, computerized registries, etc), each with specific strengths and weaknesses. The procedure usually consists of drawing up the research question, identifying the appropriate data source, devising a data extraction plan, extracting the data, checking for errors, data analysis, and appropriate archiving and dissemination of the findings. The ethical aspects in such studies primarily pertain to issues of informed consent and confidentiality. This paper provides a broad overview of how to go about a clinical record review, and serves as a ready reference for those who would like to undertake such record reviews.

Keywords: Chart review, Ethical issues, Methodology, Procedure, Record review

INTRODUCTION

Clinical record review is a process aimed at obtaining retrospective data to answer clinical queries. It is also known by other names like 'retrospective data analysis', 'clinical chart review', 'chart review' and so on. It is a useful method when data has been recorded in case notes or a structured database and an analysis of the data elements needs to be done. It entails studying data that has already been recorded and involves summarizing the data, subjecting it to appropriate statistical analysis and drawing inferences. It has been widely used in various clinical disciplines like medicine [1], pediatrics [2], orthopedics [3], psychiatry [4],and dermatology [5], to name a few. Record reviews have extended and consolidated the scientific evidence base by evaluating disease characteristics and course over time as well as treatment outcomes [6,7]. The other reasons for carrying out a clinical record review could include determining the appropriateness of diagnoses, problem identification, treatment and care planning, and to assess adherence to guidelines' standards [8,9].

There are specific differences and challenges in performing clinical record reviews as compared to prospective studies. Prospective studies are able to plan what data to gather and how to obtain the information. Gathering selected data may be sufficient for prospective studies where primary data gathering is based upon a hypothesis. Record reviews, on the other hand, are based upon information that is already available in the form of records. If particular information is not recorded reliably, then it cannot be used for record reviews. Hence, prospective studies can have a more focused approach compared to record reviews. Also, data gathering can be more systematically standardized in prospective studies, than in record reviews. Broadly, prospective studies seem to be more appropriate to demonstrate causal relationship, while record reviews may be more helpful in finding associations.

Conducting a record review has several advantages. This kind of study requires less effort and time compared to prospective studies. It is therefore less resource intensive. It enables assessment of a large sample at limited cost. It enables easy collection of information which is routinely recorded. It minimizes recall bias for an event in the past. It also reduces the need for intrusion into patients' time for assessment as part of the study. For some types of data, record review may be the most feasible type of study. For example, knowing the prescription trends of a particular medication in a country [10]. On the other hand, record reviews have certain disadvantages. Variation in the manner in which data has been gathered and recorded in the charts limits the extraction and interpretation of the variables. Some records may be incomplete or lost in the course of time, leading to missing data. Also, records may not have been stored in an easily retrievable manner restricting the extent to which they could be utilized further.

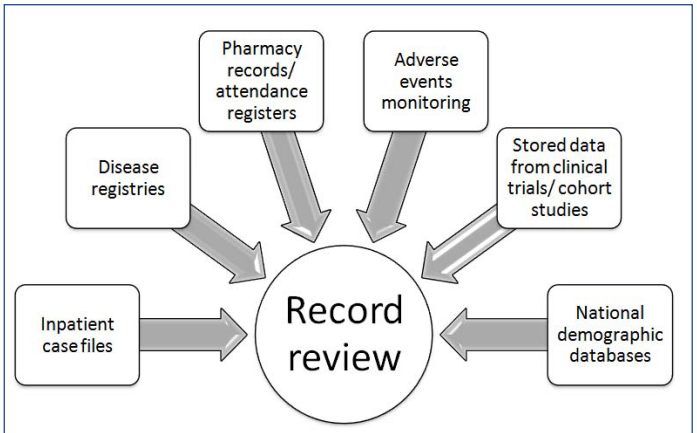
This paper deals with record reviews conducted in clinical practice and delves into the various data sources that can be utilized, the methodology for conducting a review, the utility and applications of such reviews and ethical aspects pertaining to these reviews.

DATA SOURCES

A variety of data sources can be utilized to collect information for a record review [Table/Fig-1]. These sources could be in the form of hard copies of case notes and case files, manually entered registers, and computerized databases [11-14]. Data sources can include case notes, inpatient case files, attendance registers, nursing records, pharmacy records, disease registries (like cancer registries), laboratory records, adverse event monitoring systems, clinical trial information, national demographic records and so on.

Each type of data source presents unique opportunities and challenges. Inpatient case files may provide a detailed account of the patient's symptoms and evolution of the disease, but may be exhaustive and require time consuming data extraction by trained staff. Disease registries on the other hand provide robust data about the demographic and clinical presentation of diseases. However, these data sources require good reporting services to be a valid representation of the disease in question. Outpatient attendance registers and pharmacy records may contain certain details of a large sample of a variety of patients, but they usually provide information about a very limited number of variables. The national demographic databases (for events such as suicide, etc) are reservoirs of information about a large population, and are representative of the community sample. But these extensive repositories require permissions and clearances before use for academic purposes. Also, sifting through such large databases may require extensive and dedicated computing time.

The type of data source would determine the extent and type of information that can be gleaned from it. The selection of the data source is based upon both convenience as well as the requirements of the clinical query. Certain extensive data sources may require significant resources and large organizational supports



[Table/Fig-1]: Data sources for clinical record review

Formulating the clinical question to be answered through the record review. For example, "which medication regimen is associated with better adherence to treatment and follow up among patients with diabetes."
Identifying the appropriate data source that can answer the clinical question (clinical case records, registration entries, adverse event monitoring systems, investigation report filing systems etc) • Assessment of the data source in terms of accuracies and completion • Consideration towards ethical aspects of handling data
Devising an instrument to extract the data from the case records. • Deciding upon which variables would be coded and how they would be entered (coding plan). • A manual may be prepared defining the various terminologies
Extraction of the data in accordance with the instrument devised and definitions agreed upon beforehand. If two or more raters code the data, then inter-rater reliability can be evaluated. A small subsample (approximately 10 percent of the total) can be reassessed to check agreement with the previously coded data, to detect inaccuracies if any.
Analysis of the data using appropriate statistical methods. Analysis can range in complexity from semi-quantitative measures for qualitative data, to hierarchical multivariate quantitative analysis.
Dissemination and archiving of results to expand the scientific evidence base.

[Table/Fig-2]: Process of clinical record review

for processing. On the other hand smaller databases may provide information about a limited sample. Also, some data may be missing or become non-retrievable with any type of source, depending on the manner of recording and storage of data. Hence pragmatic and practical considerations quite often determine the usefulness of a data source for purposes of answering a clinical query.

PROCESS OF CLINICAL RECORD REVIEW

The process of clinical record review involves multiple steps [Table/Fig-2]. The exact procedure and protocol needs to be modified in accordance with the type of study, nature of the data source and local constraints [15-18]. Some of the basic and commonly followed steps are as discussed as under: Formulating the clinical question. The first and foremost step is to clearly formulate the clinical question which needs to be answered through the record review. For example, what are the characteristics of patients attending a psychosexual clinic, which medication regimen is associated with better adherence to treatment among adult diabetes patients and so on. The clinical question can broadly follow the 'PICO' model, wherein it is useful to state beforehand the patient population being studied; the intervention, investigation or the characteristics of the sample under study; the control population or condition if any; and the outcome of interest. The more precise the clinical question, the less vague are the results. It must be noted that preliminary and descriptive studies might use a less defined population or control condition to answer their clinical query.

1. **Identifying an appropriate data source.** The identification of an appropriate data source that can answer the clinical question is the next major step. Data sources can include clinical case records in the outpatient or inpatient service, registration entries, adverse event monitoring systems, investigation report filing systems and so on. Each type of data source has inherent strengths and weaknesses which should be evaluated before its selection. The data source should also be assessed for accuracy and completion, which will determine the usefulness and generalizability of the data. Ethical aspects of data usage should be given due consideration; and appropriate clearances should be obtained.

Common errors	How to avoid?
Not specifying the data source clearly *The study was conducted using records from medicine department of a tertiary care centre*	Specifying the data source clearly *Records of the admission register of patients admitted to the inpatient medicine department of a tertiary care centre were used for the study.*
Not specifying what elements of the data were extracted *Relevant data was extracted from the records*	Clearly mention the elements of the data extracted from the records *Data was extracted from the records using a structured instrument and included age, gender, procedures conducted, duration of hospital stay and complications due to the procedure.*
Not specifying who extracted the data *Data was obtained from the records*	Specify who extracted the information with regard to their expertise in the field. *Data was extracted from the records by trained psychiatrists who were familiarized with the electronic health system of the institute.*
Not stating how inter-rater agreement was established *The information was extracted by four of the study investigators*	Stating clearly how inter-rater agreement was achieved *The data was extracted by four investigators. The investigators coded the data independently. A subset of the sample was coded by the all the investigators to check for inter-rater reliability. The cronbach alpha value was 0.833.*
Not specifying ethical aspects *No mention at all*	Mention the relevant ethical aspects in context *The study had waiver of informed consent as per guidelines of the Institute Ethics Committee. and indentifying information was not disclosed.* *Or, approval was obtained from the Institute Ethics Committee.*

[Table/Fig-3]: Common shortcomings while reporting record reviews

2. **Devising a data extraction instrument.** A well-designed instrument to extract data from the case records to answer the clinical query is of immense importance. It is necessary to agree upon which variables are to be extracted and how the coding is to be done before the data extraction occurs. A manual may be prepared defining the various terminologies and enumerating the operational definitions for the coding process.
3. **Extraction of the data.** Data extraction should be carried out in accordance with the instrument devised and the definitions agreed upon beforehand. The person/people in-charge of coding the data should be clearly specified. In case data is extracted from technical or subjective case notes, it should be ensured that the data extractors have sufficient expertise. Preferably, two raters can be used to extract the data, and it is advisable to present an estimate of the agreement among the raters. Some differences are likely to crop up when subjective data is being extracted by different raters.
4. **Re-evaluating a small dataset.** A small subsample (approximately 10% of the total sample) can be reassessed to check agreement with the previously coded data and to determine the pattern and extent of inaccuracies, if any. This is especially useful when dealing with large data sets where cumulative inaccuracies may translate into substantial absolute values of discrepancy and limit generalizability of results.

5. **Statistical analysis.** Analysis of the data should be conducted using appropriate statistical methods. Analysis can range in complexity from simple semi-quantitative measures for qualitative data to hierarchical multivariate analysis. Excellent statistical software programs are available for carrying out computations in minimal time. It is prudent to involve a trained statistician while dealing with large datasets and conducting complex statistical analysis
6. **Dissemination of findings.** After conducting the record review, it is important to archive and disseminate the results. This is useful to bolster the scientific evidence base on the subject studied through the record review. The results of the record review, even if negative, or challenging to the existing views, should be made known.

Quality assessment of record reviews is another important research consideration. Presently there are no uniform guidelines for reporting of chart reviews as compared to the ones developed for reporting meta-analysis (PRISMA) and randomized controlled trials (CONSORT) [19,20]. Yet, various methods have been suggested for the assessment of quality of record reviews. These have included checklists to assess the various methodological aspects of record reviews [21,22]. Briefly, checklists contain elements like representativeness of the sample, tackling inconsistent data, avoiding misclassification bias, declaration of conflict of interest of the authors and so on. Abstraction methods and tools have been devised for accurately retrieving data from chart reviews [21,23]. It has been suggested that vague definitions, imprecisely worded research questions, and poor initial data collection can impair the quality of the information gathered from the record reviews [23].

APPLICATIONS OF RECORD REVIEWS

Record reviews have found widespread application in the clinical setting and include:

1. **Knowing the clinical characteristics of diseases –** Record reviews and clinical chart reviews have been utilized to know the characteristics associated with a disease or a health condition [24]. The characteristics could be demographic, such as age, gender, socio-economic status, etc; or clinical, such as frequency of symptoms, incubation period and so on. Laboratory, histological and imaging results can also be utilized. Such types of record reviews usually depend upon clinical case notes.
2. **Studying the course and outcome of diseases over a follow up period** – Information about the course of the disease can be obtained from the follow up and progress notes of the patient over a period of time [25]. Data from such records data may not cover detailed examination or symptom evaluation. However, it may indicate trends towards over-all outcome and incidence of severe complications or adverse events during the course of treatment. It may also document which kind of interventions work better.
3. **Attributes of patient population availing a service–** Record reviews can also analyse the characteristics of subjects attending a particular treatment service; both inpatient, as well as outpatient [26]. This may help in guiding policies and making amendments to the services provided, keeping in view the features of the clinical populations served.
4. **Adverse events monitoring** – Surveillance about health conditions and medication side effects can be obtained from record reviews [27]. For example, phase IV drug trials are contingent on the reporting of adverse events with a pharmacological agent.
5. **Surveillance on health issues and indicators** – Hospital and other records can serve as markers of trends in various disorders [28]. This is helpful in providing surveillance data so that preventive measures can be undertaken. For example, a rise in low platelet counts in hemogram samples may indicate the possibility of an emerging dengue epidemic. Microbiology reports of specific pathogens like acinetobacter can point towards the outbreak of hospital acquired infections.
6. **Medical errors –** Medical records can also be utilized to investigate medical errors so that corrective action can be taken subsequently. Medical errors can stem from multiple sources including mistakes in prescription, erroneous judgment, and deviation in dispensing medication. An analysis of records may help to decipher what went wrong and what measures could be taken to minimize such errors in the future [29].

The application of record reviews for clinical purposes may be varied. The above are some representative scenarios. Factors which contribute to a successful and relevant record review include a genuine clinical need, good availability of records and research enthusiasm.

ETHICAL ASPECTS OF RECORD REVIEW

Informed consent and patient confidentiality are the important ethical issues relating to record reviews [23,30,31]. Usually when data is collected and stored in medical records, it is not done so with the explicit intention of further use in research in most situations. Hence, there is no a-priori informed consent for the use of data in a subsequent record review study. Using such data without the consent of patients for research may be considered ethically questionable by some authorities. There is the possibility that confidential data of the patient may be dealt with and possibly misused, which may jeopardize the doctor-patient relationship. Sensitive data about the patient may fall into hands of those not directly involved in patient care or those not bound by the requirement of patient-doctor confidentiality. For example, data about HIV status of a patient may be accessed in a study of gynecological surgery outcomes, the unwanted disclosure of which may lead to difficulties and distress for the patient. Hence, caution should be exercised while using information from records.

In the scenario of record reviews, following certain principles can help in ethical conduct of the study. Firstly, only that much information should be extracted and coded as is required for answering the research question. Usually, informed consent is not required beforehand; if no more than routine clinical information is used for the analysis. Secondly, any identifying information from the data set should be removed by data controllers before further usage and analysis. The data (both variables and their values) may be coded into alpha-numeric format for concealment with few designated persons having the coding key. For example, the variable of high blood pressure can be coded as ABC001, with values of 0 or 1 representing having hypertension or not. Thirdly, safeguards must be in place for appropriate and ethical use of the data. Confidentiality clauses may be explicitly specified for those who do the data extraction. It should be ensured that data, especially in electronic format, are accessible to authorized personnel only, and appropriately archived or deleted. Fourthly, due consideration should be given towards seeking ethical clearance from an Institutional Review Board (IRB) before starting data collection, especially while dealing with sensitive information. Many IRBs have policies of exempting certain types of record reviews, but this should be clarified prior to conduct of the study.

Whether to trace the subject/ patient to disseminate the clinical findings poses another ethical question (especially those which are potentially beneficial for the subject/ patient in question). It may be prudent to weigh the risks and benefits to the patient in such situations. But in most situations it would be appropriate to restrain the enthusiastic tracing of patients by research investigators, especially when formal informed consent has not been obtained.

COMMON SHORTCOMINGS TO BE AVOIDED WHILE REPORTING RECORD REVIEWS

There are certain potential areas where errors may crop up in record reviews. The clinicians and researchers may inadvertently miss out important components while reporting record reviews. Some of these are summarized in [Table/Fig-3]. It may be acknowledged that the description of methodology while presenting the final findings of the review is often constrained by the limited space available for the manuscript in the journal of publication. Yet, a clear description of the methodology encompassing the crucial points should be presented in a coherent manner.

For addressing the shortcomings of chart reviews, there is a need for standardized objective assessment measures for their reporting. The reporting of randomized controlled trials and systematic reviews has benefitted from the use of guidelines and brief checklists [32]. It can thus be surmised that reporting of chart reviews may benefit from the development of standardized reporting guidelines in the future.

CONCLUSION

Record reviews are useful tools for gathering data about medical and surgical illnesses, investigative procedures and their outcomes. The effective utilization of record reviews for seeking answers to specific clinical questions requires adequate planning and use of appropriate data sources. Record reviews offer several advantages in their conduct but their results should be interpreted keeping in view their limitations. Ethical issues, especially those pertaining to confidentiality of records, need to be taken into consideration. Appropriately conducted record reviews can help in effectively expanding the scientific knowledge base, and can provide information which may not be available through other means.

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