

Epidemiology as Framework for Conducting Health Research: A Theoretical Overview

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Abstract

Health research is essentially the use of scientific procedure to reveal factual information regarding health phenomena of interest. Since the information revealed through this methodical process is used as evidence for patient care in clinical setting or implementation of population health programs, utilization of the information obtained through irrationally conducted health research can then potentially place risk and harm on those individuals receiving the incorrectly indicated intervention. Then, to rationally conduct health research, epidemiology can be a discipline that gives direction on how to conceptualize ideas and design health studies. Although health investigator needs to be critically cautious at all methodical steps, health research should not be viewed as a far too complicated activity restricted to individuals affiliated with academic or research institutes. Health professionals working on routine health service are also encouraged to participate in research since they can contribute their pragmatic experience and understanding of real practical setting. Translation of research knowledge into practice is also more likely to be achieved by these practitioners. To revise some concepts of health research, especially for professionals working in primary healthcare, this article serves as a theoretical overview of how health research can be conceptualized and conducted from an epidemiological viewpoint.

Keywords : Epidemiology, Health research, Study design, Research method

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1. Introduction

Health research is essentially the use of scientific procedure to reveal factual information regarding health phenomena of interest. The health issue of interest can primarily be the natural history or course of a certain disease in man (Buddingh et al., 1953), which needs description of the etiological process, subclinical disease progression, clinical manifestation, and post-clinical consequences. Questions concerning the ‘cause’ of disease can be further investigated through ‘causal research’, the investigation of factors determining disease occurrence. A single factor or agent can be identified as causing a certain disease, such as the case of ‘scabies’, a skin disease caused by the mite *Sarcoptes scabiei* (Johnston, 2005). Nonetheless, occurrence and course of numerous diseases, especially the non-communicable ones (e.g., cardiovascular diseases, diabetes mellitus), can be influenced by multiple factors (Yusuf et al., 2001). An understanding of associations among factors and causal inference would guide consideration upon which modifiable factors to act, which control or preventive measure is feasible for such disease, and who is the target group. To determine the extent to which a certain health intervention (e.g., medication, therapy) provides useful results under well-controlled conditions, research recognized as an ‘efficacy study’ is needed and the randomized controlled trial is the design of choice. To apply the previously determined efficacious intervention to practice, issues of ‘effectiveness’ and ‘efficiency’ need to be investigated. Effectiveness refers to the extent to which the efficacious intervention shows its intended effect on the result when applied to a defined population in a practical, non-ideal context. Providing the intervention of known efficacy and effectiveness as a health service or program would inevitably require health resource use (e.g., budget, personnel). The efficiency concept focuses on provision of the intervention or service at maximum extent with minimum use of the health resource (Coelli et al., 2005). Given health resource constraints, a healthcare intervention which requires less resource use for its implementation and contributes a net favorable change in health is more efficient than others. Information regarding effectiveness and efficiency of a health intervention would be very important for decision making whether to adopt the intervention into practice. To further assess whether the implementation or practice of the selected health intervention gives rise to the intended result, evaluation is needed. Problems concerning operation or interventional effect can then be further addressed, investigated and identification of a new problem can be

initiated again in a cyclical pattern. This cyclical process, as illustrated in Figure 1, represents all sequential steps of the epidemiological approach in public health practice that health research involves.

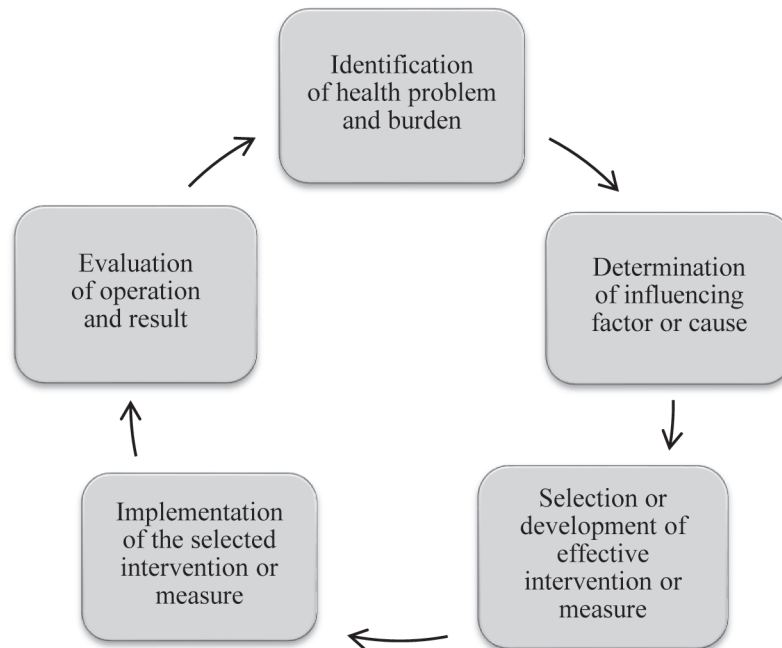


Fig 1 : Cyclical pattern of epidemiological approach to public health practice

Source : adapted from Haveman-Nies, 2010

The information revealed through health research is scientific evidence which contributes to generate hypothesis or either to prove or disprove such hypothesis or scientific theory. Such evidence in health sciences is expected to be well verified due to its potential utilization for decision making in clinical care of individuals or consideration for implementation of population health program (Justham, 2006; Sackett, 1997). The use of the evidence obtained from irrationally conducted health research can possibly impose risk and harm on those individuals receiving the irrationally indicated intervention (Sackett, 1997). Application of illogically conducted health research is thus considered unethical. Researchers must therefore be aware of this consequence and the scientific evidence must be strengthened by rational and methodological planning and implementation,

justified statistical analysis, and responsible research implication (Sackett, 1997; Altman, 1980). Then, to rationally conduct health research, epidemiology is a discipline that gives direction on how to conceptualize ideas and design health studies.

Although the health investigator needs to be critically cautious at all methodical steps of conduct, health research should not be viewed as a far too complicated activity restricted to individuals affiliated in academic or research institutes. Health professionals providing routine health service are also encouraged to participate in health research since they can contribute their pragmatic experience and understanding of real practical settings. Translation of research knowledge into practice is also more likely to be achieved by these practitioners (Tunis et al., 2003). To revise some concepts of health research, especially for professionals working in primary healthcare, this article serves as a theoretical overview of how health research can be conceptualized and conducted from an epidemiological viewpoint.

2. Epidemiology as a framework: organizing ideas of health research through the definition of epidemiology

As earlier mentioned, health research involves a wide variety of scientific inquiries with the intent of answering questions, explaining phenomena, and validating hypotheses or theories related to human health and disease (Fathalla & Fathalla, 2004). With a countless number of research questions requiring investigations in health sciences, a theoretical framework which organizes these concepts of health research is thus needed. A scientific discipline of 'epidemiology' serves as this framework for organizing concepts of health research. Understanding epidemiology would enable investigators to clearly define research questions and objectives, specify elements of design relevant to their context of investigation, identify pertinent data to be collected, and appropriately select analytical approaches.

Prior to further discussion of how epidemiology serves the task of organizing ideas for health research, a definition and general description of this discipline is firstly elucidated. Epidemiology is defined as a discipline which focuses on three main themes: 'study' comprising 'distribution' of health or disease states in a certain population, 'determinants' or factors influencing such states, and 'knowledge translation of the study into practice to prevent and control diseases and health problems' (Last, 2001). The term 'study', in this definition, can be fulfilled generally by means of an investigator's

observation of health-related events or investigator's assignment of intervention to determine its effect on a certain health outcome. The term 'distribution' implies three aspects of analysis including the affected group of individuals (person), geographical location of incident (place), and time point or period of consideration (time). A health event of interest can be influenced by several factors or 'determinants'. Such determinants can range from biological factors (e.g., host immunity, individual's age), physical factors (e.g. exposure to hazardous chemicals, road condition influencing road injury), behavioral factors (e.g., diet, smoking), to social determinants (e.g. socioeconomic status, culture). 'Translation of knowledge into practice of prevention and control of health problems' is explicitly the ultimate goal of epidemiology. Key elements in the definition of epidemiology and additional issues are summarized in Fig. 2

- **Distribution of health event in population**
(*'What' is the health event of interest?*)
 - **Persons** (*'Who' are affected/involved by the event?*)
 - **Place** (*'Where' does the event occur?*)
 - **Time** (*'When' does the event occur?*)
- **Determinant**
(*'Which' factors are involved in the occurrence of event? & 'How' the factors and the event are involved?*)
 - **Variation of influencing factor**
 - Biological factor
 - Physical factor
 - Behavioral factor
 - Social factor
 - Others
 - **Role of factor**
 - Precursor
 - Etiologic factor
 - Intermediate factor
 - Confounding factor
 - Predictive factor
 - Diagnostic factor
 - Prognostic factor
- **Control and Prevention** (*What to be done?*)
 - Selection of pertinent determinant(s) of health event to act upon
 - Evidence-based decision making in healthcare practice or policy implementation

Fig. 2 Key elements in the definition of epidemiology

3. Characterizing the occurrence of a health event through descriptive research

By analyzing the aforementioned definition of epidemiology, elements within the definition suggest how to organize ideas for conducting health research. Prior to investigation, the health event of interest must be well specified. The defined event must also be evaluated on its significance, relevant gap of knowledge to be investigated, and potential implications and applications contributed by the research evidence. It is suggested from the definition that epidemiology is not merely the study of epidemics or infectious diseases, but also a wide variety of health events such as: adverse pregnancy outcomes, congenital anomalies, non-communicable diseases, injuries, psychological disorders, behavioral risk factors, health practice, and others. Epidemiological concepts can thus be applied to innumerable health events to be investigated.

The 'distribution' element of the definition suggests the feasibility of conducting descriptive research. Differently defined study populations (group of 'persons' under study) would reveal similarities or differences of health conditions. Subgroups within a defined population (e.g., various age groups, gender categories) also provide a countless number of distinct health issues to be explored. For instance, diseases such as cervical cancer and ovarian cancer can occur only in females, while prostate cancer occurs only in males, especially those of advanced ages. Different areas (places) also vary in situational or environmental contexts. Tropical diseases, for example, are commonly found in tropical regions but rarely observed in other temperate or frigid regions where environmental contexts are different, especially the temperature. Frequency of disease occurrence can also vary or exhibit specific patterns and fluctuations overtime. For example, incidence of poliomyelitis was found to vary across different latitude (distance from the equator) and different seasons of the year (Dowell, 2001). Seasonal pattern of infectious disease occurrence is also another example (Fisman, 2007). At this stage, it is concluded that descriptive study can be undertaken by an investigator's observation on a certain health event in a defined population—in other words, descriptive study is an observational study with neither an investigator's assigned intervention nor a comparison group. This study design is applied to describe occurrence of health event characterized by a specified group of 'persons' found having or being affected by the occurrence, specified 'place' of the occurrence and point or period of 'time' considered. This kind of research is usually applied for answering questions of 'what' health event or disease and 'to what extent'

(magnitude) it occurs in or affects population health. When descriptive study design is applied to elucidate the clinical profile of a single patient and multiple cases (more than one case) of the same disease, the study can then be recognized as ‘case report’ and ‘case series’ respectively. The epidemiological approach and its link to, descriptive studies explained in this section can be illustrated in Fig. 3

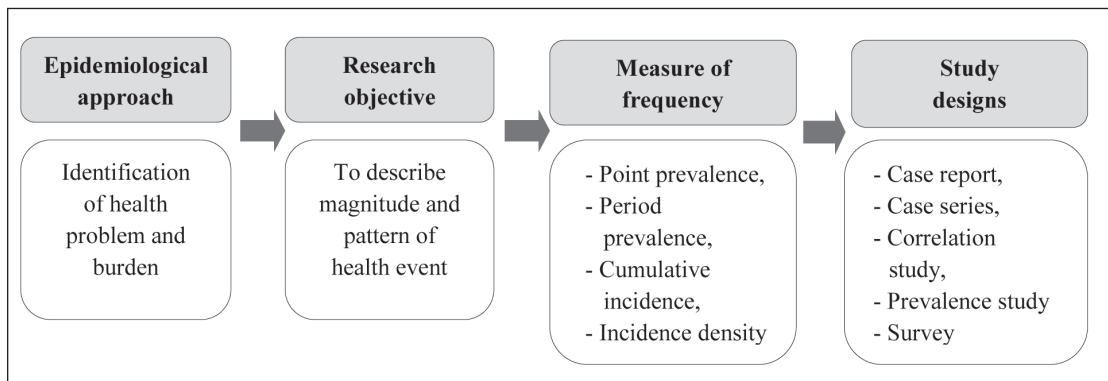


Fig. 3 Describing occurrence of health event through descriptive research

4. Determining the factor influencing the health event: association and causation

In addition to describing population health, the investigator may wish to understand ‘why’ a certain health event or disease occurs. The questions regarding ‘cause’ of health event or etiology of disease are common in health research. This kind of questions tries to address whether a certain factor fully or partially relates to the occurrence of a health event or disease. If existence of the factor is found to significantly contribute to the occurrence of the outcome (the disease or health event) in considerably greater extent compared to the outcome occurrence when the factor is absent, the factor is presumed to be a ‘determinant’ of or ‘associated’ with the outcome.

Nevertheless, ‘association’ does not imply ‘causation’. To further determine that the factor is the ‘cause’ of such outcome, it is important to primarily rule out alternative explanations for the identified association commonly by bias, confounders, random variation, and reverse causality (Kamangar, 2012). After that, the identified association is needs to be discriminated from the non-causal ones and assessment by causality criteria, such as Hill’s causality criteria (Höfler, 2005), is crucial needed prior to reaching conclusion

that the factor causes the outcome (Kamangar, 2012). In some diseases, a single agent is found responsible for their cause, such as *Corynebacterium diphtheria* is a single cause of Diphtheria (Evans, 1976). However, numerous diseases and health events are commonly found to be influenced by several related factors, especially non-communicable diseases (Berrios et al., 1997). Therefore, disease occurrence can be regarded as a result of either single cause or multiple causes, depending on the different nature of pathogenesis or causation.

Health research concerning ‘cause’ of disease or health event is extensively conducted especially in the fields of public health and community medicine, and it is regarded as ‘causal’ or ‘etiologic’ research. The aim of etiologic research is to identify factors associated with a certain health event in a defined population or community in order to ultimately act upon the modifiable ones and improve health. When this theme of causal research is applied to individual patient care, instead of considering the whole population, it is recognized as ‘etiognostic clinical research’ (Miettinen, 2010). Studying the association between a set of existing factors (natural exposure or unassigned intervention) and an outcome of interest can only be achieved by using ‘analytical study designs’– observational study designs with availability of comparison or control group.

Unlike a descriptive study which lacks a comparison group, analytical study designs can potentially allow investigation of a ‘temporal relationship’ concerning time sequence. If the hypothesized independent variable or ‘exposure’ occurs before and likely to influence occurrence of hypothesized dependent variable or ‘outcome’. Three major analytical study designs include cross-sectional study, cohort study, and case-control study. These designs differ in their temporal directions or time sequence of occurrence between exposure and outcome.

In the cross-sectional study, both exposure and outcome statuses are determined at the same point of present time when the study is conducted. In other words, this study does not inherently contain temporal direction. Thus, this design is generally incapable of identifying a temporal relationship or making a causal statement about the study variables. To exemplify this temporal relationship problem, assume that a cross-sectional study finds that obesity is more common among dentists with low back pain than those without ones. Does excessive body weight contributes to low back pain, or does the low back pain limit

physical activity and result in excessive weight gain? Cross-sectional study is typically conducted in the form of survey and usually recognized as ‘prevalence study’ which provides snapshot information on prevalence of both exposure and outcome variables.

In a cohort study, investigator initially ascertains existence of interested exposure among individuals in a group and non-existence of the exposure among those in the comparison group. Non-existence of outcome is also ascertained at the start to ensure that exposure occurs prior to the outcome occurrence. Then, both exposed and non-exposed groups are followed for the same period of time to identify the outcome occurrence. Since the investigator follows the two groups of individuals with probability of developing the outcome forward in time, measure of association in this case is therefore ‘incidence’ of the outcome. If the incidence in the exposed group is found greater than that of the non-exposed group, the exposure is thus associated with increased probability of developing the outcome. When adverse outcome (e.g., disease occurrence, mortality) is considered, the increased probability of developing this outcome implies ‘risk’.

Unlike the cohort study, a case-control study works in the reverse logical temporal direction—starting from the outcome backwardly in time to identify past existence of the exposure. The investigator initially identifies a ‘case’ group of individuals with a disease or outcome of interest and ‘control’ group of those who are free of the outcome. The investigator then investigates for past exposure—which potentially contributed to the outcome occurrence—by means of interview, review of past medical records, or other ways. In this design, relative prevalence of exposure among cases compared to that of the controls is used to identify association. If the prevalence of exposure is higher among controls, the exposure is thus associated with a higher likelihood of having the outcome. The epidemiological approach and link to analytical study explained in this section can be illustrated in Fig. 4

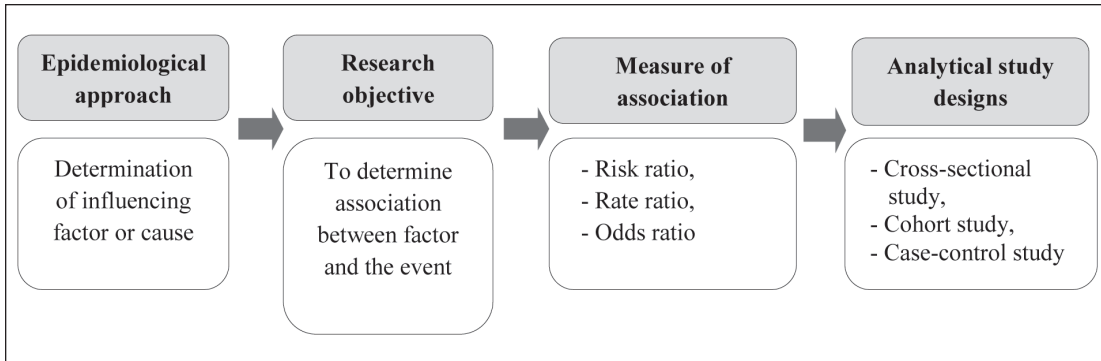


Fig. 4 Determining factor influencing health event

5. Determining the effect of the assigned intervention through experimentation

Apart from studying the existing factors, an investigator may wish to determine effect of a new treatment or preventive intervention on a certain health outcome. In this case, the investigator needs to assign such treatment or intervention to study participants, as the intervention has not been previously implemented or is being implemented in a way which does not serve the scientific investigation of its effect. Since the intervention is intentionally assigned by investigator in a controlled manner, the study no longer belongs to the observational study type but is instead recognized as an ‘experimental’ or ‘interventional’ study. When a experimental study is undertaken in human subjects, the study is generally recognized as ‘trial’ and ethical consideration is a critical issue since the assigned intervention may impose risk and harm to study participants.

When a certain trial is carried out in patients attending a clinical facility, the study is regarded as a ‘clinical trial’ and each patient is a unit of analysis. A clinical trial is principally conducted to determine the effect of a therapeutic intervention (e.g., drug, acupuncture) on improving disease status or prognosis. With this objective, the study can thus be regarded as a ‘therapeutic trial’. It should also be noted that when the trial is instead aimed at evaluating the effect of a preventive intervention (e.g., vaccination, dietary control), the study is then recognized as a ‘preventive trial’.

When the interventional study is instead conducted in a ‘community context’, it can be either a ‘field trial’ or a ‘community intervention trial’. A field trial mainly focuses on evaluating the effect of an intervention to at-risk individuals context, and compared to an appropriate control group. A classical example of field trial is Salk’s poliomyelitis

vaccine trial (Marks, 2011; Meldrum, 1998). In contrast to the field trial, the community intervention trial focuses on assessing the group-level effect of an intervention given to a community (as a whole) compared to another comparable community without such intervention. In this trial, the intervention is ‘assumed’ to be delivered to all target individuals and assessment of aggregate health outcome is focused on instead of evaluating individual health outcomes. A study describing the relationship between fluoride in drinking water and occurrence of dental caries is a classic example of this type of trial (Lennon, 2006). In this case, amount of fluoride intake through water drinking varied among individuals living in the experimental community but all were assumed to receive the intervention. The group-level outcome of dental caries prevalence was compared to that of the control community, to determine whether water fluoridation is effective in improving overall dental caries status in community context. The epidemiological approach and link to the experimental study explained in this section can be illustrated in Fig. 5

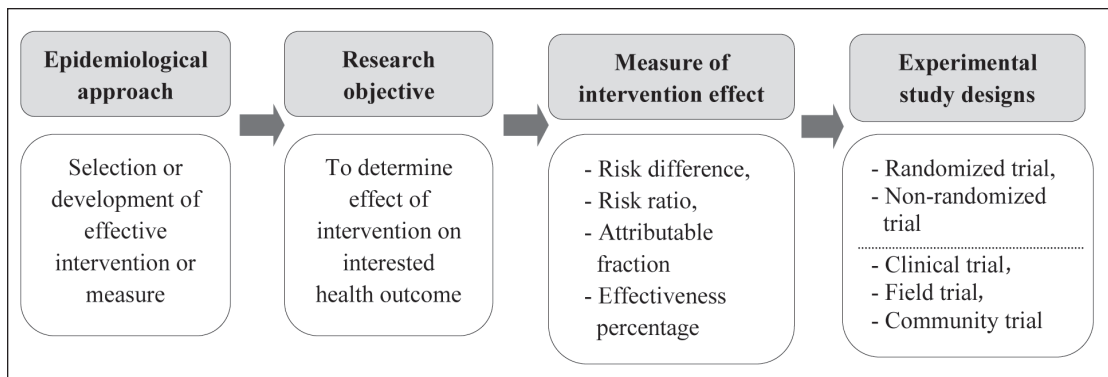


Fig. 5 Determining effect of intervention

It can be summarized at this stage that influence of a single or multiple explanatory factors on an outcome of interest can be investigated either by means of observational study or experimental study. When the explanatory factor or exposure already exists and investigator does not assign any intervention but acts only as an observer, the approach of the observational study is adopted. However, when investigator assigns an intervention to test its effect on an outcome, the approach of the experimental study is instead adopted. The observational study approach plays a major role in causal

research and the health outcome can vary. In contrast, the role of the experimental study approach in health research is rather limited to determining efficacy or beneficial effects of a therapeutic or preventive intervention. The experimental study, which likely places unacceptable risk or harm to study participants, is strictly prohibited due to ethical issue. It is also remarked here that having a comparison or control group is very important in strengthening the evidence of association.

6. Implementation and evaluation of a health program

Making a rational choice of which intervention to be implemented is a critical issue in healthcare practice. Evidence regarding efficacy and effectiveness of an intervention for such decision making can be obtained through efficacy research or trials as earlier explained. Nonetheless, implementing the most effective intervention does not always assure maximum effectiveness in reality since there are several other factors which potentially influence such effectiveness. Examples of these factors are biological variation in the population, protocol compliance of healthcare providers, patient compliance, quality of the related instrument or facility, access to care, and program coverage. These operational factors can also be investigated and improved through health research to improve quality of care or health intervention.

Evaluation of a health program or intervention can be undertaken during the operation (e.g., through action research) or post-implementation period. Health indicators which previously indicate a health problem can again be measured after the intervention has been implemented to assess whether the problem has been reduced. To further improve efficiency of program implementation, health economics and outcome research can also be incorporated to analyze cost minimization, cost to outcome, cost to benefit, and cost to utility gain of the program. Since a health problem is dynamic over time, the cyclical process can then be repeatedly initiated and completed. Health research involving the cyclical framework of epidemiological approach at each sequential step can thus be undertaken to improve healthcare practice.

Conclusion

Health research is the use of scientific method to reveal factual information regarding the health event of interest. Health research involves the cycle of sequential steps starting from problem identification, investigation of cause, selection of appropriate intervention, implementation, and evaluation. Principles of epidemiology can be applied in terms of methodical design of research at all of the mentioned steps. For problem identification, the magnitude of disease or adverse health event must be initially described and later considered whether it is a public health problem. Descriptive study is capable of revealing information for this aim. Moreover, to identify an association which causally influences an outcome by an exposure, analytical study designs with inherent temporal direction would be useful. To further determine whether a certain health intervention brings about the expected result and improves health, the experimental study provides methodical feasibility for such investigation. Studies regarding interventional effectiveness, efficiency, and evaluation also need crucial information from the outcome research which is based on these epidemiological designs. It is therefore recommended that details of these study designs and related analytical approaches should be further studied, especially the epidemiological measure unique to each study design. Novel designs which have been later developed from the basic epidemiological designs mentioned in this article are also interesting for additional study.

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