PRACTICAL PHARMACOECONOMICS; HOW TO DESIGN, PERFORM AND ANALYZE OUTCOMES RESEARCH pdf

1: HOPE Center Training Programs | College of Pharmacy

Practical Pharmacoeconomics How To Design Perform And Analyze Outcomes Research The positive impacts of real world data on the challenges, demand for healthcare.

This program is not intended for individuals in post doctoral training. However, those enrolled in post doctoral training programs scheduled to conclude by July 1, , who will hold an academic appointment by that time, may apply. Those holding academic rank of instructor or assistant professor, and investigators at the doctoral level with equivalent positions, are eligible to applyâ€"provided the proposed research is neither directly nor indirectly subsidized to any significant degree by an extramural support mechanism. Eligible candidates will have a firm commitment from the university. Applicants must be sponsored by the department or unit in which the proposed research is to be undertaken. Eligible candidates will not have other substantial sources of research funding. Funds must be used to conduct the proposed research. The grant is paid on a quarterly basis to the university on behalf of the applicant, with the understanding that the university will administer the funds. The funds have limited restrictions â€" a characteristic of the program. Funds may not be used to provide fringe benefits or indirect costs. The support of technical assistance may include the hourly wages of a technician; however the funds may not be used to provide fringe benefits or indirect costs for the technician. PhRMA Foundation funds may not be used for indirect costs or fringe benefits. These funds are not transferable. Research Starter Grant Application Checklist Please make a copy of this list to reference during the application process, as incomplete applications will not be considered. General Registration Information 2. Applicant CV or Biosketch 3. Extended Letter This letter is an opportunity to tell us who you are and to describe your career and future plans. Include a synopsis of your career, your professional interests, and your desired career path. The letter should not exceed two single-spaced pages point font. Preliminary studies, as well as results if available , should be included. Detail the research design and methodology. Applicants should use a format similar to the format specified for grants submitted to the National Institutes of Health. A bibliography of major references should be provided, but will not be included in the page limit. The first use of any abbreviation or acronym should be preceded by the full name or description. Clearly identify other principals involved as collaborators in the project, the amount of time they will commit, and the amount of time you will commit. List by titles the funded research projects of each principal, the portion of time committed, and the amount and source of funds for these projects. Identify the amount of intramural support available for the proposed project, and other research efforts by budget categories and amounts. If the school makes the services of a technician available to the candidate, note this. The Advisory Committee that reviews each application places considerable emphasis on the quality of the research and training proposal. In describing the research and training plan, it is essential to document that guidance and departmental support will be available to ensure proper training in the techniques and principles of the specified area. Research Abstract Submit a titled abstract of approximately words concerning the proposed research plan. Budget no specific format required Submit a budget categorizing how grant funds will be used. List any other funding this project will receive, including startup funds for the applicant. Department Chair Provide contact information and a recommendation letter. Additional References Provide contact information and reference letters from up to three individuals familiar with your scientific career. Reprints Submit copies of relevant articles you have published. Letters and third-party materials should not be uploaded by the applicant. The application process will request contact information, including an email address, for your chair, thesis advisor, and additional reference. These individuals will receive a prompt from the application system with instructions for uploading their document s , which will be appended to the application. Based on our policy, we do not provide written reviews.

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2: new methods: outcomes â€“ ISPOR News & Press Releases

The purpose of the column was to respond to health care professionals who want to learn the practical aspects of designing, performing, analyzing and interpreting outcomes research and pharmacoeconomics in their own setting.

Published online Jan This article has been cited by other articles in PMC. However, to date, the use of big data in medicine has not been concretely illustrated across a variety of health economics and outcomes research HEOR. Big data refers to large amounts of information that require new technologies for capture, storage or analysis, due in part to the amount of information, the speed at which it is generated, and its content. Two approaches have been used in formally defining big data [1]: The 3V definition includes volume, variety and velocity [2 , 3]. Smartphones are often used to illustrate the complexity of big data. In addition to providing information that is easily captured as flat files or simple-format records, they can also provide more complex data like geographic location, motion and direction information [2]. In this section, the 4V definition is used to describe big data in terms of its volume, variety, velocity and value. The variety of big data represents the different potential sources e. The velocity of big data relates to the speed at which data transfers occur as well as to the rapidly changing nature of the data due to the sources, formats and categories of the contributing data [1 , 2]. This fourth characteristic of big data has important implications for clinical research and population health research [6]. This special issue focuses on the application to population health research and particularly HEOR. The full-length articles in this special issue draw on one or more of the components of the 4V definition and contribute to our understanding of the role of big data in HEOR. Contributions were sought that addressed important aspects of HEOR, including data sources, measurement, regression modelling and simulation. Additionally, the goal was to include a geographically diverse set of applications to highlight perspectives across institutional, government and health system settings. The articles illustrate innovative, linked data sources and discuss practical considerations for their development, reliability and use in HEOR e. The articles discuss the practical challenges and opportunities with regards to measurement of healthcare cost and utilization using large, complex datasets e. The articles utilize analytic methods and tools that are particularly suited for developing evidence from large-volume datasets. These articles illustrate the use of classification and regression trees for analysing prescribing patterns [12], clustering algorithms for cost prediction [13] and data visualization tools for examining prescription drug fill patterns [14]. Last but not least, the full-length articles in this special issue describe innovative opportunities for linking dynamic simulation modelling DSM with electronic health records [15] and integrating DSM with big data for evidence generation [16]. Together, these articles offer a much-needed snapshot of current data sources, analytic methods, opportunities and challenges. The hope is that future work will offer additional insights and lessons learned to increase our knowledge of the role of big data in HEOR. This knowledge base is important given that observational data, whether used for regression or simulation modelling, are critical to evidence generation in HEOR. We will need to be sure that big data provide more value and not more noise. As we consider the availability of more complex data, we cannot forget what we already know about the importance of study design or the appropriate interpretation of study findings. We cannot assume that more data necessarily means more information. Indeed, as the volume of data increases, it will be important to pay continued or more attention to established concerns regarding measurement, bias, and fallacies relevant to empirical analysis and interpretation. With regards to the role of big data in HEOR, we will need thoughtful data linkages, model specifications, and interpretation to leverage the potential of big data. We will also need richer measures, including environmental measures e. In addition, we should have a clear sense of what may be missing e. The papers in this special issue provide practical, provocative discussions regarding the use of large, complex data in HEOR. We hope that these papers spur continued discussions because the availability of big data is neither a silver bullet nor a temporary distraction. Developments in information technology will support its continued relevance into the foreseeable future. The opportunities for linking clinical, cost and

contextual data, as well as the challenges that arise in this undertaking are welcome developments. They challenge us to continue efforts to improve the conduct and translation of HEOR for real-world impact. Compliance with Ethical Standards Conflicts of interest Dr. Accessed 23 Dec Controlling Data Volume, Velocity and Variety. Accessed 7 Jan Gantz J, Reinsel D. Extracting value from chaos. IDC iView , p. Accessed 16 Dec Accessed 28 Mar Big data and new knowledge in medicine: Realising the value of linked data to health economic analyses of cancer care: Validation of the hospital episode statistics outpatient dataset in England. Calculating total health service utilisation and costs from routinely collected electronic health records using the example of patients with irritable bowel syndrome before and after their first gastroenterology appointment. Using linked electronic health records to estimate healthcare costs: Cost prediction using a survival grouping algorithm: Understanding adherence and prescription patterns using large-scale claims data. Johnson O, et al. Dynamic simulation of health economics outcomes using big data. Specification issues in a big data context: Big data and health economics:

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3: The role of pharmacoeconomics in current Indian healthcare system

Note: Citations are based on reference standards. However, formatting rules can vary widely between applications and fields of interest or study. The specific requirements or preferences of your reviewing publisher, classroom teacher, institution or organization should be applied.

Introduction Before beginning your paper, you need to decide how you plan to design the study. The research design refers to the overall strategy that you choose to integrate the different components of the study in a coherent and logical way, thereby, ensuring you will effectively address the research problem; it constitutes the blueprint for the collection, measurement, and analysis of data. Note that your research problem determines the type of design you should use, not the other way around! Research Design in Social Research. Research Methods Knowledge Base. General Structure and Writing Style The function of a research design is to ensure that the evidence obtained enables you to effectively address the research problem logically and as unambiguously as possible. In social sciences research, obtaining information relevant to the research problem generally entails specifying the type of evidence needed to test a theory, to evaluate a program, or to accurately describe and assess meaning related to an observable phenomenon. With this in mind, a common mistake made by researchers is that they begin their investigations far too early, before they have thought critically about what information is required to address the research problem. Without attending to these design issues beforehand, the overall research problem will not be adequately addressed and any conclusions drawn will run the risk of being weak and unconvincing. As a consequence, the overall validity of the study will be undermined. The length and complexity of describing research designs in your paper can vary considerably, but any well-developed design will achieve the following: Identify the research problem clearly and justify its selection, particularly in relation to any valid alternative designs that could have been used, Review and synthesize previously published literature associated with the research problem, Clearly and explicitly specify hypotheses [i. However, you can get a sense of what to do by reviewing the literature of studies that have utilized the same research design. Also included is a collection of case studies of social research projects that can be used to help you better understand abstract or complex methodological concepts. The Research Methods Videos database hours of tutorials, interviews, video case studies, and mini-documentaries covering the entire research process. Qualitative, Quantitative, and Mixed Methods Approaches. Sage, ; De Vaus, D. Creating Robust Approaches for the Social Sciences. Sage, ; Leedy, Paul D. Pearson, ; Vogt, W. Gardner, and Lynne M. When to Use What Research Design. Action Research Design Definition and Purpose The essentials of action research design follow a characteristic cycle whereby initially an exploratory stance is adopted, where an understanding of a problem is developed and plans are made for some form of interventionary strategy. Then the intervention is carried out [the "action" in action research] during which time, pertinent observations are collected in various forms. The new interventional strategies are carried out, and this cyclic process repeats, continuing until a sufficient understanding of [or a valid implementation solution for] the problem is achieved. The protocol is iterative or cyclical in nature and is intended to foster deeper understanding of a given situation, starting with conceptualizing and particularizing the problem and moving through several interventions and evaluations. What do these studies tell you? This is a collaborative and adaptive research design that lends itself to use in work or community situations. Design focuses on pragmatic and solution-driven research outcomes rather than testing theories. When practitioners use action research, it has the potential to increase the amount they learn consciously from their experience; the action research cycle can be regarded as a learning cycle. Action research studies often have direct and obvious relevance to improving practice and advocating for change. There are no hidden controls or preemption of direction by the researcher. It is harder to do than conducting conventional research because the researcher takes on responsibilities of advocating for change as well as for researching the topic. Action research is much harder to write up because it is less likely that you can use a standard format to report your

findings effectively [i. Personal over-involvement of the researcher may bias research results. The cyclic nature of action research to achieve its twin outcomes of action [e. Advocating for change usually requires buy-in from study participants. Coghlan, David and Mary Brydon-Miller. The Sage Encyclopedia of Action Research. Action Research in Education: Guilford, ; Gall, Meredith. Chapter 18, Action Research. Norman Denzin and Yvonna S. SAGE, , pp. Writing and Doing Action Research. Sage, ; Reason, Peter and Hilary Bradbury. Handbook of Action Research: Participative Inquiry and Practice. Case Study Design Definition and Purpose A case study is an in-depth study of a particular research problem rather than a sweeping statistical survey or comprehesive comparative inquiry. It is often used to narrow down a very broad field of research into one or a few easily researchable examples. The case study research design is also useful for testing whether a specific theory and model actually applies to phenomena in the real world. It is a useful design when not much is known about an issue or phenomenon. Approach excels at bringing us to an understanding of a complex issue through detailed contextual analysis of a limited number of events or conditions and their relationships. A researcher using a case study design can apply a variety of methodologies and rely on a variety of sources to investigate a research problem. Design can extend experience or add strength to what is already known through previous research. Social scientists, in particular, make wide use of this research design to examine contemporary real-life situations and provide the basis for the application of concepts and theories and the extension of methodologies. The design can provide detailed descriptions of specific and rare cases. A single or small number of cases offers little basis for establishing reliability or to generalize the findings to a wider population of people, places, or things. Design does not facilitate assessment of cause and effect relationships. Vital information may be missing, making the case hard to interpret. The case may not be representative or typical of the larger problem being investigated. If the criteria for selecting a case is because it represents a very unusual or unique phenomenon or problem for study, then your intepretation of the findings can only apply to that particular case. Chapter 4, Flexible Methods: Columbia University Press, ; Gerring, John. Past, Present and Future Challenges. Encyclopedia of Case Study Research. The Art of Case Study Research. Applied Social Research Methods Series, no. Most social scientists seek causal explanations that reflect tests of hypotheses. Causal effect nomothetic perspective occurs when variation in one phenomenon, an independent variable, leads to or results, on average, in variation in another phenomenon, the dependent variable. Conditions necessary for determining causality: Empirical association -- a valid conclusion is based on finding an association between the independent variable and the dependent variable. Appropriate time order -- to conclude that causation was involved, one must see that cases were exposed to variation in the independent variable before variation in the dependent variable. Nonspuriousness -- a relationship between two variables that is not due to variation in a third variable. Causality research designs assist researchers in understanding why the world works the way it does through the process of proving a causal link between variables and by the process of eliminating other possibilities. There is greater confidence the study has internal validity due to the systematic subject selection and equity of groups being compared. Not all relationships are casual! The possibility always exists that, by sheer coincidence, two unrelated events appear to be related [e. Conclusions about causal relationships are difficult to determine due to a variety of extraneous and confounding variables that exist in a social environment. This means causality can only be inferred, never proven. If two variables are correlated, the cause must come before the effect. Beach, Derek and Rasmus Brun Pedersen. Causal Case Study Methods: Foundations and Guidelines for Comparing, Matching, and Tracing. University of Michigan Press, ; Bachman, Ronet. Chapter 5, Causation and Research Designs. Sage, , pp. Chapter 11, Nonexperimental Research: Cohort Design Definition and Purpose Often used in the medical sciences, but also found in the applied social sciences, a cohort study generally refers to a study conducted over a period of time involving members of a population which the subject or representative member comes from, and who are united by some commonality or similarity. Using a quantitative framework, a cohort study makes note of statistical occurrence within a specialized subgroup, united by same or similar characteristics that are relevant to the research problem being investigated, rather than studying statistical

occurrence within the general population. Using a qualitative framework, cohort studies generally gather data using methods of observation. Cohorts can be either "open" or "closed. Date of entry and exit from the study is individually defined, therefore, the size of the study population is not constant. In open cohort studies, researchers can only calculate rate based data, such as, incidence rates and variants thereof. Closed Cohort Studies [static populations, such as patients entered into a clinical trial] involve participants who enter into the study at one defining point in time and where it is presumed that no new participants can enter the cohort. Given this, the number of study participants remains constant or can only decrease. The use of cohorts is often mandatory because a randomized control study may be unethical. For example, you cannot deliberately expose people to asbestos, you can only study its effects on those who have already been exposed. Research that measures risk factors often relies upon cohort designs.

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4: Health Outcomes Research and Evaluation Sciences : SLU

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Major types of pharmacoeconomic analysis, formula and application given in Table 1. It witnessed a robust growth from the production turnover of about 1. Medication prices are among the lowest prices in the world. However, the overall expenses associated with medications continue to soar in the country. In rural areas comprised of villages and small towns, primary health-centers and community health-centers are put into service by the state government. On the breadline, the rural population heavily depend on the government funded hospitals for procuring healthcare. In India, allopathic and alternative medicine healthcare practices Ayurveda, Unani, Siddha, and Homeopathy operate side by side. Many patients switch from one practice to another when relief is not adequate. The quality of healthcare services is much better in the urban areas compared with rural areas. Some rural areas might have very minimalistic healthcare. The practice of procuring private healthcare for many people is on the rise. The challenge that the Indian government faces is to make healthcare affordable for the majority of people in the country who cannot afford healthcare. Allopathic medications have a big market in India. As far as the ratio of doctors and nurses to the population is concerned, it is 5. The major issues that govern insurance penetration are the extent and type of coverage. The ironic situation is that the insurers leave out the poor and the ill population as they cannot afford the prepayment schemes. The insurance that people purchase voluntarily accounts for Rs. The cost effectiveness data were used to support the addition or deletion of a drug to or from a hospital formulary. At present, the pharmacoeconomic assessment of formulary actions has become a standardized part of many pharmacy and therapeutic committees. Pharmacoeconomic studies find value in Fixing the price of a new drug and re-fixing the price of an existing drug Finalizing a drug formulary Creating data for promotional materials of medicines. Compliance of requirement for drug license. Introduction of new schemes and programs in hospital pharmacy and clinical pharmacy. Drug development and clinical trials. For every 10, NCE in discovery, ten enter preclinical development, five enter human trials, and only one might be approved. Pharmacoeconomic studies may be planned and conducted at the clinical development stages phases 1 to 3 and post-marketing research stage phase 4. Subsequently, studies may need to be conducted at several stages of pharmaceutical research. It is during this stage that cost of illness studies should be accomplished to aid in deciding whether to further develop the drug and gather background data for future pharmacoeconomic evaluations or not. Cost of illness data may also aid in the development of preliminary models to assess the clinical benefits that must be achieved to have a marketable product. Phase 2 trials In phase 2 trials, the drug is administered to a limited number of patients with the target disease. During this phase, cost of illness studies can begin or continue, as can preliminary development of quality of life and recourse utilization instruments. Models can be refined as more information is available about the clinical aspects of the drug. Phase 3 trials Cost of illness data can be an important factor that can determine the marketability of drugs. In the phase 3 clinical trials, the drugs are administered to the patients similarly as they would be when they are marketed. At this stage, the discussion, planning, and pharmacoeconomic studies are of prime importance. It is recommended that clinical studies presenting pharmacoeconomic evaluation be conducted along with efficacy evaluation of the drugs. Even though pharmacoeconomic evaluations might be time consuming and may delay the new drug application NDA process, they should be done unless the drug is very innovative and has no other alternatives. Phase 4 trials Phase 4 trials consist of the post-marketing phase. Pharmacoeconomics can be applied to retrospective and prospective studies involving the drug. Pharmacoeconomic evaluations provide information about cost and outcomes of drugs in real life settings unlike clinical trials that are conducted in controlled settings. Pharmacoeconomic evaluations conducted during clinical trials give information about the efficacy of drugs,

which in turn provide an approximation to the real world. Pharmacoeconomic evaluations and clinical trials can be conducted in conjunction with each other in several ways: A clinical trial can be designed to test the safety and efficacy of a drug, followed by a pharmacoeconomic evaluation. A clinical trial can be designed to conduct a pharmacoeconomic evaluation. Clinical data collected prospectively in a clinical trial can be used to conduct a retrospective or prospective pharmacoeconomic evaluation. Given the ever-increasing healthcare costs, this evidence needs to be backed by evidence of cost-effectiveness as well. In simple words, evidence comparing the effectiveness of available treatments for a particular disease condition and their related costs need to be presented to the federal body before they are introduced in the market. Australia was the first country to form evidence based guidelines about medication reimbursement on the basis of cost-effectiveness research. Since , the Australian Pharmaceutical Benefit Scheme enforces the production of evidence about economic evaluation of the drug before its introduction in the market. The committee provides recommendations to the health ministry about drug inclusion in the reimbursement list on the basis of evidence about its cost effectiveness. The final decision making by the policy makers about the cost-effectiveness of the drug is determined by the following factors: The importance of the clinical area The availability of alternative treatments The likely effect of listing on the healthcare system and other therapeutic activities The investment of the sponsor in primary research. In spite of this, relative cost effectiveness is an important criterion. The Netherlands also introduced a formal process of economic evaluation in Germany has an institution for economic evaluation research and Spain has regional centers that perform health technology assessment. In Denmark, France, and Italy, pharmaceutical companies provide data about economic evaluation on a voluntary basis. These data when provided are given importance and consideration. A new drug has to be approved for a program based on pharmacoeconomic analysis. The formulary system Formulary creation involves preparing, updating, and using a list of essential medications with their detailed information formulary manual and standard treatment guidelines STGs. A formulary list is an indicator of good pharmaceutical practice and rational drug usage. The formulary consists of appropriate therapies and cost-effective medications which are of a good quality. It is a precise list which makes the process of procuring, storing, distributing, and using the drugs very easy. Availability of cost contained quality drugs: This makes it possible to provide drugs at subsidized rates to people who require them the most. Provision of quality care: Healthcare personnel can be better trained to provide cost effective medications. Usage of cost-effective drugs will also make the practitioners prescribe fewer drugs whose drug interactions and adverse reactions they are aware of. This in turn will improve the provision of quality care as the selection of medication is evidence based. The formulary system, right from the national level to the institutional level, can be strengthened with the help of studies in the areas. It will also help for the rationalization of the drug procurement system in the country and for the practical implementation of the standard treatment protocols. This, instead of saving costs leads to cost inflation. It is necessary to have some mechanism in place, whereby the insurers can strike a contract with healthcare providers and healthcare systems that can help in cost containment,[21 , 22] There is an added need for insurance systems that encourage consumer to contain costs by providing incentives as well as contain their health expenditure. There needs to be further expansion of insurance services other than inpatient services, and more focus should be placed on preventive care and wellness programs. Patients will receive better quality healthcare at reduced costs, and the insurance companies will be able to provide enhanced care to their clients at minimum cost. Indian pharmacy practice and pharmacoeconomics As third largest producer of drugs by volume, Indian pharmaceutical industry has diversity of medicines; yet, brand name prescriptions are the rule of the day. Formulary system is very weak and treatment protocols exist only in theory. The resources are scarce and competing programs are plenty in healthcare. The concept of healthcare insurance is yet to be popularized in the country. Pharmacoeconomics can aid in decision making when evaluating the affordability of and access to the right medication to the right patient at the right time, comparing two drugs in the same therapeutic class or drugs with similar mechanism of action, and in establishing accountability that the claims by a manufacturer regarding a drug are justified.

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Practicing pharmacists in community, hospital, and clinical settings in India can benefit considerably from the application of the principles of pharmacoeconomic into their normal practice settings. Proper application of pharmacoeconomics will empower the pharmacy practitioners and administrators to make better and more informed decisions regarding products and services they provide. Pharmacotherapy decisions traditionally depended solely on clinical outcomes like safety and efficacy, but pharmacoeconomics teaches us that there are three basic outcomes to be considered clinical, economic, and humanistic in drug therapy. It is accepted by all that appropriate drug selection decisions could not be made today based on acquisition costs only. Applied pharmacoeconomics can help in decision making, in assessing the affordability of medicines to the patients, access to the medicines when needed, and comparing various products for treatment of a disease. It will provide evidence contraindicating the promotion of certain types of high-cost medicines and services. Pharmacoeconomics has use in health policy decision making and can be applied by a number of healthcare professionals such as policy makers, primary healthcare providers, health-care administrators, and health managers. Available in large quantities, Indian primary care providers are often bombarded with many new drugs of the same category, in addition to the existing drugs. Introduction of new drugs can confuse the doctors and administrators for the judicious selection and rational use of medicines. When introducing new medications, its outcome should be equal or more effective compared to the existing drug and shall have some economic or related advantage. Evidence about pharmacoeconomics can aid pharmacists and policy makers in the decision-making process about the use of medications and healthcare services. With clinical training about self-medication, Ayush physicians, i. Pharmacological and pharmacoeconomic knowledge is acquired and can be applied in practical prescribing skills. Present qualification of pharmacist in India is Diploma in pharmacy 2-year study, plus h practical training in hospital and B. Pharm 4-year degree program and its curriculum does not provide sufficient information, practice, and knowledge about pharmacoeconomics. To overcome such a dilemma, the government of India introduced a new program in pharmacy education named PharmD , which highlights the principles of pharmacoeconomics in its syllabus. Consequently, we can expect the future M. The development of pharamcoeconomics is at an infancy stage in India at the moment, despite the rapid growth of clinical research. India is an affordable destination for conducting clinical research for many western countries. We hope in India clinical pharmacists including PharmD graduates be more beneficial than conventional pharmacists as they can implement the principles of economics in daily basis practice in community and hospital pharmacy. Footnotes Conflict of Interest:

5: Health Outcomes (Deadline: Feb. 1,) - PhRMA Foundation

This task force will offer practical guidance on how to perform and interpret the results of a VOI analysis in order to guide decisions on additional research and research priorities. Recent developments in metamodelling approaches should reduce the computational and practical burden associated with implementing VOI.

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