What is Pharmacy Research?

The question of what constitutes pharmacy research emerged at a recent meeting to discuss a pharmacy resident's project. The pharmacists around the table were attempting to clearly define this seemingly straightforward term in the context of a residency project surveying hospital pharmacists about "pharmacy research". Surprisingly, this "obvious" term could not be consistently defined by any of the members present, most of whom were well versed in this type of research. This event triggered a lengthy search to define the enigma called "pharmacy research".

One of our first stops was the Merriam-Webster dictionary. As expected, we did not find the specific term "pharmacy research" in the dictionary. However, a subsequent search for the individual words revealed the following[1]:

> Pharmacy: the art, practice, or profession of preparing, preserving, compounding, and dispensing medical drugs
>
> Research: studious inquiry or examination; especially: investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws

While combining these definitions yields a broad definition, it is limited by the traditional definition of "pharmacy" that the dictionary provides. However, some may consider "pharmacy research", as defined by this combination of definitions, to be synonymous with the more modern term "pharmacy practice research". The Canadian Pharmacists Association (CPhA) defines pharmacy practice research as a component of health services research that focuses on the assessment and evaluation of pharmacy practice.[2] While this definition is clearly unique to the profession, not all research in which pharmacists are involved reflects their practice, nor can it solely reflect the practice of pharmacists, especially in the era of collaborative practice teams. Additionally, research done by pharmacists may address important questions that facilitate improved patient care or service delivery, without specifically advancing pharmacy practice, but still contributing to the scientific literature as a whole. The Canadian Institutes of Health Research (CIHR) lists health services research, which includes the efficiency and effectiveness of health professionals, as 1 of its 4 pillars of health research (the others being biomedical; clinical; and social, cultural, environmental, and population health).[3] However, limiting "pharmacy research" to pharmacy practice research limits the impact and relevance of pharmacists' work to the other CIHR pillars of research deemed to be important to Canadians.

To further refine our definition, we looked to the literature and leading Canadian and US pharmacy organizations for additional insight. An Internet and literature search provided little help with our dilemma. While generally advocating and supporting research, none of these organizations—specifically the CPhA, the Canadian Society of Hospital Pharmacists (CSHP), the American College of Clinical Pharmacy (ACCP), and the American Society of Health-System Pharmacists—have clearly defined pharmacy research. However, both the CSHP and the ACCP have attempted, at least in part, to define "research".

CSHP has published 2 papers discussing institutional pharmacy research, a statement (published in 1995)[4] and a set of guidelines (published in 1997)[5]. The 1995 statement[4] loosely states that "any unknown in the practice field is a potential research idea" and includes the following as research topics for institutional pharmacists:

- basic pharmaceutical sciences, including the development and testing of new dosage forms or medication-administration modalities
- clinical research concerning the efficacy, safety, and pharmacokinetics of drugs
- pharmacy practice research addressing various issues such as the evaluation of new and existing services, workload measurement, pharmacoeconomics, and quality management

The 1997 guidelines[5] are just as vague and incomplete. They state that "the term 'research' can be used to describe many endeavours in institutional pharmacy practice" which may include literature reviews, descriptive studies, and hypothesis-driven research. Neither of the CSHP documents provides the reader with a clear definition of pharmacy research, even though this term is used in the title of both documents. These documents are currently being revised, and we hope that these ambiguities will be addressed.

The ACCP has defined clinical pharmacy as "that area of pharmacy concerned with the science and practice of rational medication use".[6] This definition offers a more contemporary perspective of pharmacy. The ACCP further defines clinical research as "studies of human subjects, including surveys, cross-sectional studies, case-series, case–control studies, cohort studies, first-in-human studies, proof-of-principle projects and all phases of clinical trials".[7] By marrying these definitions (which do not appear in the same document), we can create a broad definition of clinical pharmacy research. However, it is likely intentional that these 2 terms were not presented in a single document, as the ACCP is advocating for increased pharmacist participation in all types of clinical research, not just practice-based research.[8]

It is clear that while we continue to use the term "pharmacy research", it carries no universally accepted meaning. As our group discovered, there is far too much ambiguity related to this term. Perhaps we should consider abandoning it.

Perhaps we also need to re-examine our approach to research as a profession. Instead of undertaking so-called "pharmacy research", we should follow the lead of our US counterparts and

develop a system of pharmacist-researchers and scientists and describe research as any research activity done by pharmacists, regardless of the topic. As health care professionals, pharmacists represent only one aspect of the complex and interdependent health care system. Focusing our energies and resources solely on studying the practice of pharmacy may or may not help in developing our practice, but it will likely add little to the entire health care system. Pharmacists must be involved in all aspects of health research, from basic laboratory investigations to population-based studies. Our unique set of skills and our focus will ensure that we have distinctive research topics. Limiting our contributions to the pillars of health services and clinical research represents a disservice to the advancement of pharmacy and to Canadians.

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CURRENT-OASIS: A Potential Mirage of Numbers

CURRENT-OASIS 7, a 3-year randomized controlled trial, was designed to determine whether a doubling of the loading and initial maintenance doses of clopidogrel is superior to the standard-dose regimen for patients with acute coronary syndrome who have been referred for percutaneous coronary intervention.[1]

In this double-blinded trial, adult patients with non-ST-segment elevation acute coronary syndrome or ST-segment elevation myocardial infarction for whom percutaneous coronary intervention was to be performed within 72 h were randomly assigned to receive double the usual loading dose of clopidogrel (600 mg) or the standard loading dose (300 mg). For the 25 086 patients included in the study, the authors assessed the composite end point of cardiovascular death, myocardial infarction, and stroke as the primary outcome and found no significant difference between a 7-day double-dose regimen and the standard-dose regimen.[1]

Of the study group enrolled, 17 263 patients actually underwent the percutaneous coronary intervention, and the authors performed a subgroup analysis of these patients.[2] The report of this subgroup analysis is the focus of our letter. In our view, the abstract and conclusion of the study report[2] do not adequately represent the results of the study, instead leading the reader to believe that the results are more profound than they truly are.

Our first issue of concern is the unknown. No data are presented for serious adverse events, which would include any untoward medical occurrence that results in death, is life-threatening, necessitates admission to hospital or prolongs the hospital stay, or results in persistent or significant disability.[3] Documentation of serious adverse events should encompass all adverse events that occur during the trial, not only the serious events thought to be related to use of the drug. For example, if there had been fewer serious cardiovascular adverse events in the treatment arm than in the control (standard therapy) arm, but no change in total serious adverse events, then it could be concluded that serious *noncardiovascular* events were occurring more frequently and should be investigated. Information about all serious adverse events throughout the trial would also help to determine the "net effect" of the intervention. We have requested these data from the authors of the original study, but as of this writing (late 2010) had not received them.

Now, for argument's sake, let's say that the serious adverse events are not a factor in assessing the relative benefit of the doubled dose of clopidogrel. There are still some other considerations to be made.

Our second issue of concern is the following statement in the conclusion section of the abstract: "In patients undergoing PCI [percutaneous coronary intervention] for acute coronary syndromes, a 7-day double-dose clopidogrel regimen was associated with a reduction in cardiovascular events and stent thrombosis compared with the standard dose".[2] We think that this statement is misleading. The term "cardiovascular events" implies a much broader meaning than the results actually show. In fact, there were no significant reductions in stroke, ischemia,