Assessing pharmacists’ impacts in primary health care: are we asking the right questions?

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Abstract

In some settings, steps are being taken to more fully integrate pharmacists in primary health care as a means of improving the public's health and reducing drug-related iatrogenesis. Yet, evidence of improvement in health outcomes from pharmacists’ inputs is mixed; the diversity of research approaches and methodologies makes it difficult to reach an overall conclusion about it. A detailed review and analysis of two published articles using different methodological approaches to assess the role of community pharmacists in primary health care, but similarly reporting unfavourable findings regarding pharmacists’ impacts, is conducted. The Randomized Controlled Trials (RCT) design did not account for possible within-group differences in the delivery of the pharmacist intervention, and could not ascertain there were differences in pharmaceutical care received by intervention and control group heart failure patients. The RCT did not include an evaluation of pharmacists’ recommendations to physicians. The qualitative discourse analysis did not distinguish between patients’ response to pharmacists’ recommendations and the appropriateness of those recommendations. Researchers face two key challenges in demonstrating pharmacist impacts in primary care. The first is methodological – and relates to the need to identify, measure and evaluate the range and complexity of pharmacists’ work in conducting medication review and pharmaceutical care. The second relates to the differing levels of status and power of two key players in the field of medicines-related health care – the physician and pharmacist – a relationship whose contribution to ‘negative impact’ studies needs consideration. An appeal for ‘methodological creativity’ in pharmacist impact studies is made.

Keywords: pharmacist-impacts; pharmaceutical public health; methodology review; pharmacist-physician relationship

Background

Governments in Canada, Britain and elsewhere are increasingly recognizing the potential of a fuller integration of pharmacists in primary health care as a means of improving the public’s health and reducing drug-related iatrogenesis. For example, the UK “Choosing Health through Pharmacy”1,2 initiative was rolled out to enhance pharmaceutical-related public health and the pharmacist’s role in it. In Ontario, Canada, in 2007 the Medscheck3,4 program was piloted, initially providing cost-free (government funded) pharmacist counselling to Ontarians taking 3 or more medications for a chronic condition, and expanded in 2010 to all residents of licensed long-term care homes, all Ontarians living with diabetes, and to home-bound persons not able to attend their community pharmacy for the service. The growing recognition of pharmacy’s responsibility for the publics’ uses of medicines is also reflected in pharmacists’ evolving role as prescribers – worldwide5; in Canada6,7 the UK8 and the US9.

There are hundreds of individual pharmacist-impact studies examining specific populations (i.e. elderly), specific disease categories (i.e. asthma, hypertension) and various outcomes (humanistic and quality of life, economic, clinical), and it is not my intent to review these here. Published reviews of this literature indicate that, given the variability in patient populations, disease states, and pharmacists’ interventions included – and the varied positive, neutral, and negative findings of individual studies, it is difficult to reach an overall conclusion about the impact of pharmacists’ health care provision on patient outcomes10-13. Holland and colleagues11 provide a most strenuous argument for the need to clarify what is known about pharmacists’ impacts on the public’s health. In their review, Holland et al. examine eight large studies of medication review in older populations. They conclude that “the most successful interventions have been delivered by small numbers of pharmacists working in close liaison with primary care physicians, but that services... set up at a distance from physicians, have either failed to
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deliver clear positive outcomes, or have potentially worsened health outcomes” (p. 92). These authors question the logic of the UK government investment of £40 million for community pharmacist led services1, asserting:

…medication review, like drugs themselves, has the potential to yield benefits, but may also cause harm. The [medication review] intervention delivered by professionals not primarily responsible for prescribing decisions should be considered in the same way as other health technologies and be expected to adequately demonstrate not just effectiveness, but also cost effectiveness before being introduced more widely. At the moment, the jury is still out on this newly promoted form of public health pharmacy (pp. 92-93)11”.

I argue here that two key challenges confront researchers seeking to clarify the impacts of pharmacist efforts in primary care. The first is methodological – and relates to the requirement that research studies identify, measure and evaluate the range and complexity of pharmacists’ work in conducting medication review and pharmaceutical care. The second relates to the differing levels of status and power of the two key players in the field of medicines-related health care – the physician and pharmacist – a relationship whose contribution to ‘negative’ or ‘positive impact’ studies needs to be carefully examined.

In this article, I conduct a detailed critical analysis of two empirical studies taking different methodological approaches to assessing the role of community pharmacists in primary health care, but similarly reporting ‘unfavourable findings’ regarding the role of pharmacists in improving patient outcomes. I summarize how pharmacists’ impacts were evaluated in each study; and re-direct attention to the array of pharmacist activities – and to pharmacist-physician relations that – had they been more closely scrutinized in each study - might have led the authors to different, potentially more positive, conclusions.

Reviewing how we analyze pharmacist-impacts: two illustrative cases

The two studies examined here include a randomized controlled trial of the effectiveness of visits from community pharmacists for patients with heart failure15; and a qualitative discourse analysis of the advice giving role of the pharmacist during consultations for medication review with patients aged 80 or more16. In the following paragraphs, the key design features and results of each study are examination and discussed in detail.

The Holland et al. randomized controlled trial (RCT)15, included 149 heart failure patients in a pharmacist-intervention group, and 144 heart failure patient-controls who received ‘usual care’. The authors’ recognition of the need for specialist personnel to deliver education and self-management intervention to heart failure patients; a shortage of specialist staff, and an abundance and wide availability of community pharmacists motivated the study.

The intervention involved two home visits by one of 17 community pharmacists within 2 and 8 weeks of patients’ discharge from hospital, and included numerous inputs: intervention pharmacists educated patients about heart failure and their medications; they gave basic exercise, dietary and smoking cessation advice; they encouraged completion of simple sign and symptom monitoring diary cards; they removed discontinued medication. Intervention pharmacists were also required to provide recommendations to the general practitioner and the local pharmacist – regarding the need for medication adherence aids15.

Intervention pharmacists had post-graduate qualifications in pharmacy practice or recent professional development in therapeutics. All intervention pharmacists had 7 contact training hours including a lecture on heart failure, heart failure drugs, exercise, diet and smoking cessation; more than half attended two evening training events on communication skills (4 contact hours); 14/17 intervention pharmacists received training in medication review as part of previous trial (14 contact hours), the other 3 received additional medication review training (1 day)15.

The primary outcome was total emergency admissions to hospital at 6 months. The secondary outcomes included mortality; quality of life, medication adherence; a heart failure self care behaviour scale; and primary care activity. The authors reported finding no significant differences in hospital admissions at six months, quality of life, or mortality between the intervention-group patients and heart failure patients who received ‘usual care’15.

In this study, the authors’ aims to understand the impact of pharmacists’ care on an extremely vulnerable patient population is laudable. However, a vision of pharmacists’ care as ‘standardized’ and thus as suitable for a RCT is concerning, and leads to a number of questions pertaining to the design of the study and its findings. Here, I consider the following: a) was the intervention different from ‘usual care’ provided to heart failure patients?; b) in what ways are the study outcomes problematic?; and c) what might an analysis of intervention pharmacists’ recommendations to patients and physicians have taught us about the appropriateness of (requirement for) pharmacists care of heart failure patients?

Question a) suggests a need to examine the standards of practice in pharmacy, specifically, professional autonomy around the delivery of ‘pharmaceutical care’. As with other professional occupations, pharmacy practice involves the provision of standardized and non-standardized services to members of the public17. In this study, patients in the control-group may have encountered pharmacists with similar qualifications to the intervention group pharmacists; and ‘usual care’ for the control group heart failure patients may have been very similar to the care provided to intervention group patients. That is, if good pharmacists deliver pharmaceutical care – a hallmark of the claim to professional status, involving the pharmacist’s
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cooperation with the patient and other professionals in implementing a therapeutic plan that addresses the individual needs of the (heart failure) patient18 – then the ‘intervention’ in the study may have been redundant.

Further, like other health professionals, pharmacists have tremendous autonomy in their everyday delivery of pharmaceutical care. This means that of the 17 pharmacists who participated in the ‘intervention’, the quality and nature of pharmaceutical care delivered to heart failure patients was likely quite variable19. In this study, the impact of variation in the ‘intervention’ was not examined in a systematic way (it is not a feature of the RCT), but it might have been. For example, it was reported that 91% of patients received one or two visits from [intervention] pharmacists19, but differences in outcomes for intervention-group patients who received 1 rather than 2 visits were not assessed.

Thus, the potential lack of differentiation in pharmacy-related services received by intervention- and control-group patients, within-group variation [among intervention– but also among control-group pharmacists], as well as the range and complexity of intervention-pharmacists’ activities suggest the RCT may not be the best methodology to assess the impacts of pharmacist-delivered primary health care.

Question b) is related to the outcomes of the RCT which included no statistically significant differences in hospital readmissions at six months, quality of life, or mortality between intervention-group patients and heart failure patients who received ‘usual care’; and a 17% overall increase in primary care activity in the intervention- as compared to the control-group15.

The reporting of global outcomes in this way (i.e. reporting of differences between intervention and control groups, as is standard in RCT studies) obscures an analysis of the processes that led to the particular outcomes assessed. For example, it could be interpreted that intervention pharmacists’ activities led to necessary primary care – visits to doctors, medication reviews – and sometimes to hospital admissions – and that these actions may have reduced illness and possibly saved lives. Instead, the global outcomes were interpreted as negative, based on an assumption that a successful intervention would reduce heart failure patients’ use of any health care resources.

An additional outcome measured in the study was medication adherence, which was reported to be unusually high in both intervention and control groups1. This finding, too, makes plausible an interpretation that all heart failure patients received similar pharmaceutical care from all pharmacists (intervention, community or hospital pharmacists), or from other health care professionals (physicians, nurses) encountered since their first heart failure incident.

Question c) pertains to the limitation of the RCT methodology to capture and evaluate details such as whether pharmacists’ recommendations to physicians were relevant, whether/to what extent physicians responded to them; and the effects of action/non-action on individual patient outcomes. In this study, it is reported that pharmacists’ home visits to patients with heart failure resulted in 384 recommendations to general practitioners15. These recommendations were made despite the very high levels of adherence mentioned previously - in other words, the recommendations to doctors appear not to have been motivated by patient medication non-adherence. Further, the authors reported that only 51% of recommendations were fully or partly enacted by general practitioners after the pharmacists’ first patient home-visits, while no data were provided as to whether second home-visit recommendations were enacted by GPs15.

This aspect of the study highlights the differing levels of status and power of the two key players in the field of medicines-related health care – the physician and pharmacist – and the uneven playing field in which pharmacists interact with patients. The failure of physicians to follow up on a large proportion of (potentially life saving) recommendations made by pharmacists regarding seriously ill heart failure patients highlights both the discretionary power of the physician as well as the lack of respect shown to pharmacists by physicians (at least in this particular study). Without a clear analysis of the consequences of pharmacists’ recommendations – whether they were appropriate, whether the physician heeded them, and what particular effect was produced as a result of the pharmacist’s recommendation - it seems premature to judge the impact of a pharmacist-led intervention with heart failure patients.

In the second study, Salter et al., examined elderly patients’ responses to advice given by a pharmacist during medication reviews. This is an important study that highlights the value of using qualitative methods to examine the practice of medication review, and to understand it from a patient-perspective. In the article, the authors report that despite finding many opportunities to offer advice, information and instruction, the didactic, pharmacist-initiated and controlled encounter was frequently resisted or rejected by elderly patients and ‘interactional difficulties’ with the pharmacist ensued14. Through analysis of the discourse between pharmacist and patient, the authors rightfully problematize the practice of medication review, and raise questions related to the potential negative impact of certain forms of interaction.

Salter et al. are emphatic about the negative impact of pharmacists’ advice-giving – the major finding and the emphasis of discussion in this article. The authors emphasize the potential harm of (unsolicited) advice-giving on patients’ sense of competence and self-governance, observing that pharmacists

1 The study authors also were interested in the delivery of the intervention by pharmacists. They recorded a selection of pharmacists’ visits to investigate the intervention’s delivery and the pharmacists’ communication skills (p. 2 of 7), reporting that each component of the intervention was delivered, and that pharmacists used good consultation styles (p. 6 of 7)15.

2 In a recent review, it is estimated that general non-adherence is about 20-50%19; whereas Holland et al report adherence levels at ~ 95% for both groups (using mean adherence scores), at baseline, at 3 months and 6 months15.
“provided advice, information or instruction on a constant basis” (p.3 Of 6); and that almost no patient-initiated requests for advice or information were observed16. They reported that in resisting or rejecting pharmacists’ advice, “patients adopted a variety of conversational strategies, including direct or indirect challenges to the pharmacists’ authority and knowledge boundaries” (p. 3 of 6)15. The authors reported that “one of the strongest rebuttals to the pharmacists’ attempts to counsel and give advice was patients’ use of the higher authority of the doctor” (p. 4 of 6)15.

However, in this study there was a failure to recognize the important distinction between patients’ unwillingness to accept pharmacists’ advice from the appropriateness of that advice itself. Its design did not include the identification and classification of the specific drug-related problems identified which would have enabled an assessment of the potential harmful to the pharmacist’s advice. Further, the pharmacist’s drug review and advice may have led patients to seek necessary care that resulted in necessary attention even if, in interaction with the pharmacist, the advice remained unacknowledged or was resisted or rejected.

At the least, the findings from this study, as with the previous one, indicate that pharmacists uncovered numerous problems regarding patients’ medicine regimes. That the patients were uncomfortable with the (unsolicited) input from the pharmacist doesn’t detract from that important conclusion.

**Conclusion**

I have argued that two key challenges need to be addressed in research designed to assess the effectiveness of the pharmacists’ provision of primary care. First is the limitations imposed by a standardization method like the RCT used in a context where professional services are not readily standardized. The assessment of the ‘pharmacist-consultation-as-intervention’ does not provide any means of discerning the diverse ‘inputs’ of an individual pharmacist in consultation with an individual patient. Hence, study findings of differences between patients assigned to intervention and control groups in the trial run the risk of internal validity...a failure to discern that within an ‘intervention’, specific aspects of pharmacists’ work may improve patient outcomes, while other aspects may alienate the patient, or otherwise fail to impact his or her outcomes.

A second key challenge relates to the differing levels of status and power of two key players in field of medicines-related health care – the physician and the pharmacist – whose contribution to outcome studies needs consideration. The importance of this relationship was alluded to by Holland et al. in their review of pharmacist-impact research, where it was observed that successful interventions involved pharmacists working closely with primary care physicians11. In my review here, I have suggested how in future research, if study designs are to distinguish the relevance of pharmacists’ recommendations from patients’ and physicians’ responses to them, very different conclusions about the impact of pharmacists’ involvement in primary health care may be reached.

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