How to Turn Your Clinical Practice into Publications that Make a Difference

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Disclosures

• Drs. Clay and Kliethermes have no financial conflicts to disclose.
Upon completion of this session, participants will:

• Gain enhanced understanding of various clinical research design types and how these relate to the level of evidence

• Be presented with a historical perspective on the impact of poorly constructed publications of pharmacists’ research and the implications on inclusion in higher order analyses

• Apply an algorithm to research types to select an optimal publication checklist for maximal impact

• Be introduced to PaCIR, a pharmacy specific reporting checklist
Review of commonly utilized clinical research designs by pharmacists

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Commonly Used Study Designs

Study Designs

- Analytic
  - Experimental
    - Controlled Trials
    - Randomized Clinical Trials
    - Cross-Over Trials
  - Observational
    - Cohort
    - Case-Control
    - Cross-Sectional

- Descriptive
  - Case Reports
  - Case Series
  - Surveys
  - Qualitative
Experimental: Controlled Trials

- A comparison
  - Intervention versus no intervention
  - One intervention versus one or more interventions
- Requires
  - Groups be treated exactly the same except for the intervention(s)
  - Groups to similar
- Design to reduce potential for bias
  - Blind trial: Subject unaware of placement
  - Double blind trial: Investigator and subject unaware of placement
Experimental Controlled Trial

- Randomized Control Trial
  - Gold standard to remove bias potential
  - Comparison groups are randomly chosen
  - Expensive and time consuming

- Crossover study
  - Subjects participate in both groups
  - Occurs after a “washout” period
**Background:** Patients 80 years or older are underrepresented in scientific studies. The objective of this study was to investigate the effectiveness of interventions performed by ward-based pharmacists in reducing morbidity and use of hospital care among older patients.

**Methods:** A randomized controlled study of patients 80 years or older was conducted at the University Hospital of Uppsala, Uppsala, Sweden. Four hundred patients were recruited consecutively between October 1, 2005, and June 30, 2006, and were randomized to control (n = 201) and intervention (n = 199) groups. The interventions were performed by ward-based pharmacists. The control group received standard care without direct involvement of pharmacists at the ward level. The primary outcome measure was the frequency of hospital visits (emergency department and readmissions [total and drug-related]) during the 12-month follow-up period.

**Results:** Three hundred sixty-eight patients (182 in the intervention group and 186 in the control group) were analyzed. For the intervention group, there was a 16% reduction in all visits to the hospital (quotient, 1.88 vs 2.24; estimate, 0.84; 95% confidence interval [CI], 0.72-0.99) and a 47% reduction in visits to the emergency department (quotient, 0.35 vs 0.66; estimate, 0.53; 95% CI, 0.37-0.75). Drug-related readmissions were reduced by 80% (quotient, 0.06 vs 0.32; estimate, 0.20; 95% CI, 0.10-0.41). After inclusion of the intervention costs, the total cost per patient in the intervention group was $230 lower than that in the control group.

**Conclusion:** If implemented on a population basis, the addition of pharmacists to health care teams would lead to major reductions in morbidity and health care costs.

**Trial Registration:** clinicaltrials.gov Identifier: NCT00661310

*Arch Intern Med.* 2009;169(9):894-900
Example of randomized control crossover study
### Observational Studies

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td><strong>Cohort or longitudinal study</strong></td>
<td>- Looks at a defined population with a certain exposure over time and compares outcomes to another group without the exposure</td>
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<td></td>
<td>- Used when multiple outcomes are associated with the exposure</td>
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<td></td>
<td>- The two groups may differ in ways besides the exposure</td>
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<tr>
<td><strong>Case-control study</strong></td>
<td>- Groups defined by presence or absence of an outcome</td>
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<tr>
<td></td>
<td>- Looks backward in time to try to detect possible causes or risks for having or not having an outcome.</td>
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<td></td>
<td>- Estimate the odds of developing the outcome</td>
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<tr>
<td><strong>Cross Sectional or prevalence study</strong></td>
<td>- Observation of a defined population at a single point in time or time interval.</td>
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A PROSPECTIVE COHORT STUDY OF MEDICATION RECONCILIATION USING PHARMACY TECHNICIANS IN THE EMERGENCY DEPARTMENT TO REDUCE MEDICATION ERRORS AMONG ADMITTED PATIENTS

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Abstract—Background: The collection of a complete, verified medication history is essential to patient safety. The involvement of clinical pharmacists has been shown to improve the completeness and accuracy of medication histories; however, to our knowledge, involvement of pharmacy technicians has not been studied. Objective: Our aim was to determine whether verification of medication histories by pharmacy technicians in the emergency department (ED) would result in fewer errors in inpatient medication regimens compared to verification by the admitting physician team. Methods: We performed a prospective cohort study of adult ED patients admitted for continuing care. In the intervention group, medication reconciliation was performed by pharmacy technicians in the ED before the creation of physician admitting orders. In the control group, pharmacy technicians conducted their history taking later, after admission. Initial admitting orders were then compared to the pharmacy technicians' medication reconciliation taken before admission (intervention group) or after admission (control group). Medication discrepancies were classified and determined to be justified or unjustified. Unjustified discrepancies were rated for harm potential. Results: In our cohort of 113 intervention and 75 control subjects, the mean age was 55 years (standard deviation [SD] 16 years); 96 patients (51%) were male. In the intervention group, 566 changes to home medications were observed on admission; 352 (62%) were unjustified. Among controls, 406 changes to home medications were observed; 228 (56%) were unjustified. This difference was not statistically significant (p = 0.0586). The rate of unjustified medication changes per patient was likewise not significantly different (3.14 [SD 2.98] in interventions vs. 3.17 [SD 2.81] in controls; p = 0.9570). The rate of medical errors did not differ between study groups, nor did severity ratings of unjustified changes. Conclusions: Medication reconciliation by pharmacy technicians in the ED did not lead to a significant reduction in unjustified medication discrepancies. © 2015 Elsevier Inc.
Example of a case control study

Assessing the Effect of Pharmacist Care on Diabetes-Related Outcomes in a Rural Outpatient Clinic: A Retrospective Case-Control Study.

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Author information

Abstract

BACKGROUND: The care of diabetic patients in rural areas is complicated by factors such as poor health literacy, cultural barriers, and primary care provider (PCP) shortages. Integrating pharmacist care in diabetes management in these settings may increase access to care and improve patient outcomes.

OBJECTIVE: To evaluate differences in diabetes-related outcomes in patients with type 2 diabetes (T2DM) managed by a pharmacist diabetes clinic compared with patients only managed by PCPs in a rural family medicine clinic.

METHODS: This was a retrospective case-control study. The primary outcome was achievement of hemoglobin A₁C (A1C) reduction ≥0.5%. Secondary outcomes included average A1C reduction, achievement of A1C goal, angiotensin-converting enzyme (ACE) inhibitor/angiotensin receptor blocker (ARB) use, statin use, blood pressure control, and frequency of nephropathy screenings. Patients ≥18 years old with an A1C ≥7% were eligible. Cases included patients established with the pharmacist diabetes clinic. Cases were matched to controls in a 1:1 ratio based on PCP, age (±5 years), gender, and race.

RESULTS: A total of 21 pharmacist-managed patients met inclusion criteria. Cases were significantly more likely to experience an A1C reduction ≥0.5% (odds ratio = 7.51; 95% CI = 1.54-36.81; P < 0.01). Statistically significant improvements were also noted for ACE inhibitor/ARB use, statin use, and nephropathy screenings among cases.

CONCLUSION: Patients managed by a pharmacist diabetes clinic were more likely to experience improved diabetes-related outcomes, including A1C reduction ≥0.5%. Pharmacist care, when added to standard care, can improve outcomes for patients with T2DM in rural areas.
Example of cross-sectional study

Receipt of Overlapping Opioid and Benzodiazepine Prescriptions Among Veterans Dually Enrolled in Medicare Part D and the Department of Veterans Affairs

A Cross-sectional Study

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Background: Overlapping use of opioids and benzodiazepines is associated with increased risk for overdose. Veterans receiving medications concurrently from the U.S. Department of Veterans Affairs (VA) and Medicare may be at higher risk for such overlap.

Objective: To assess the association between dual use of VA and Medicare drug benefits and receipt of overlapping opioid and benzodiazepine prescriptions.

Design: Cross-sectional.

Setting: VA and Medicare.

Participants: All veterans enrolled in VA and Medicare Part D who filled at least 2 opioid prescriptions in 2013 (n = 368,891).

Measurements: Outcomes were the proportion of patients with a Pharmacy Quality Alliance (PQA) measure of opioid-benzodiazepine overlap (≥2 filled prescriptions for benzodiazepines with >30 days of overlap with opioids) and the proportion of patients with high-dose opioid-benzodiazepine overlap (≥30 days of overlap with a daily opioid dose >120 morphine milligram equivalents). Augmented inverse probability weighting regression was used to compare these measures by prescription drug source: VA only, Medicare only, or VA and Medicare (dual use).

Results: Of 368,891 eligible veterans, 18.3% received prescriptions from the VA only, 30.3% from Medicare only, and 51.4% from both VA and Medicare. The proportion with PQA opioid-benzodiazepine overlap was larger for the dual-use group than the VA-only group (23.1% vs. 17.3%; adjusted risk ratio [aRR], 1.27; 95% CI, 1.24 to 1.30) and Medicare-only group (23.1% vs. 16.5%; aRR, 1.12; CI, 1.10 to 1.14). The proportion with high-dose overlap was also larger for the dual-use group than the VA-only group (4.7% vs. 2.3%; aRR, 2.23; CI, 2.10 to 2.36) and Medicare-only group (4.7% vs. 2.9%; aRR, 1.06; CI, 1.02 to 1.11).

Limitation: Data are from 2013 and cannot capture medications purchased without insurance; unmeasured confounding may remain in this cross-sectional study.

Conclusion: Among a national cohort of veterans dually enrolled in VA and Medicare, receiving prescriptions from both sources was associated with greater risk for receiving potentially unsafe overlapping prescriptions for opioids and benzodiazepines.

Primary Funding Source: U.S. Department of Veterans Affairs.

For author affiliations, see end of text.
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Descriptive Studies

• Case Report or Case Series
  • Reporting on an event that occurred in one or more patients
  • Event may be exposure, treatment, reaction, etc.
  • No controls
• Surveys
  • Gain insight into a topic or problem from people who may be vested in the issue being studied.
  • May be cross-sectional (qualitative) or quantitative
• Qualitative Research
  • Explores thoughts, describes experiences using open ended questions that generally are not statistically analyzed
Example of case series

Integration of clinical pharmacists into a home nursing service: a case series

This paper describes a clinical pharmacy service that was developed and piloted within a large home nursing service in Melbourne, Australia, and provides case vignettes that illustrate how home nursing clinical pharmacists can improve medication safety, patient independence and community nurse efficiency.

CONCLUSION

Medication management for home nursing clients can be complex and challenging. Clients, and the community nurses who support them, have limited access to timely clinical pharmacy support under existing practice models. The case vignettes herein illustrate how the integration of clinical pharmacists into home nursing services can support community nurses to provide safe, effective and efficient care and improve client outcomes.
Example of survey study

Survey of collaborative drug therapy management in U.S. hospitals

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Purpose. Results of a survey assessing the extent and scope of collaborative drug therapy management (CDTM) in U.S. hospitals are presented.

Methods. A survey questionnaire was mailed to a national random sample of hospital pharmacies. Pharmacy directors provided data on CDTM activities; their views on support for CDTM, the financial and strategic impact of CDTM, and the effect of state regulations on CDTM practice were assessed using summative Likert-type scales. Logistic regression was performed to assess associations of respondent demographics and hospital characteristics with CDTM use.

Results. The usable response rate was 30.2%. Pharmacists were reported to be engaged in CDTM in 66% of respondents’ hospitals, a significantly (p < 0.0001) greater proportion than reported in a comparable 2003 survey. The most prevalent CDTM activities were ordering laboratory and related tests (59.7% of hospitals), adjusting drug strength (67.9%), and changing the frequency of administration (53.8%). The most commonly reported diseases or treatment areas for CDTM use were anticoagulation (32.4% of hospitals), infectious diseases (44.8%), and parenteral nutrition (32.6%).

Conclusion. From 2003 to 2013, the prevalence of CDTM use in surveyed U.S. hospitals increased significantly, from about 50% to 66%. The 3 most common CDTM activities in 2003 — ordering test results, adjusting drug strength, and changing frequency of administration — were still the most common in 2013 but were allowed at higher percentages of hospitals.

Keywords: attitude of health personnel, cooperative behavior, data collection, drug therapy/standards, interprofessional relations, pharmacists

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Example of qualitative study

RESEARCH

Exploring the expanded role of the pharmacy technician in medication therapy management service implementation in the community pharmacy

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ARTICLE INFO

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ABSTRACT

Objectives: To explore the current roles of the pharmacy technician in the provision of medication therapy management (MTM) and their relation to organizational behavior at “high-performing” community pharmacies within a nationwide supermarket chain. Design: Qualitative research study using methodologic triangulation with the use of semi-structured interviews of key informants, direct observation at “high-performing” pharmacy sites, and responder journals. Setting and participants: High-performing pharmacy sites within a large supermarket pharmacy chain in Tennessee. A high-performing site was defined as a pharmacy that has successfully implemented MTM into its pharmacy workflow. Main outcome measure: Themes related to pharmacy technician roles in the delivery of direct patient care services. Results: A total of 28 key informants were interviewed from May 2015 to May 2016. Key informants included 10 certified technicians, 5 noncertified technicians, and 13 pharmacists across 8 pharmacies in central and eastern Tennessee. Three themes were identified. At high-performing sites, pharmacy technicians were engaged in both clinical support activities as well as nonclinical support activities with the goal of improving clinical service implementation. Several barriers and facilitators were revealed. Conclusion: Within high-performing teams, expanded technician roles to support patient care service delivery were associated with successful clinical service implementation. Future studies should further explore these expanded technician duties, as well as the role of organizational culture, climate, and team dynamics, in the delivery of patient care and clinical services across a heterogeneous pharmacy setting.
Other Types of Studies

• Systematic reviews
  • Comprehensive literature search of studies on a topic that are rigorously assessed for quality, bias, flaws, etc., then synthesized for a balanced and impartial summary based on predetermined criteria.

• Meta-analysis
  • Systematic, objective combining of data from studies through statistical methodology that generates pooled data to answer a research question.
Example of systematic review

The developing role of community pharmacists in facilitating care transitions: A systematic review

Chase D.A. Kooyman, Matthew J. Witry

ABSTRACT

Background: The impact of multidisciplinary interventions to support patients moving from hospital to home have generally demonstrated benefit. However, the role of community pharmacists is still being defined.

Objectives: To review, with the use of the Coleman Care Transitions Intervention (CTI) pillars, the interventions performed by community and ambulatory-care pharmacists for patients undergoing care transitions.

Data sources: The following databases were searched for manuscripts published from 1997 to 2017: PubMed, Cochrane Database, Cinahl, and Embase.

Data extraction: Two authors screened manuscripts for relevancy. Studies were included if they evaluated patient care processes by community or ambulatory-care pharmacists as part of care transitions beyond receiving a discharge summary. Data were abstracted by one author and reviewed by the other.

Results: Twelve studies were included in the review. 8 of which were from the community setting. Each CTI pillar was represented, although to differing degrees. Pharmacists applied their experience in reviewing medications, identifying, and resolving drug therapy problems, and providing education to this new context. Better mechanisms are needed to notify pharmacists of patients undergoing transition, grant access to medical records, and provide appropriate remuneration. The CTI pillars of assisting patients with personal health records and discussing condition red flags were infrequently used, suggesting an area for exploration.

Conclusion: Although these are important structural barriers to address, community pharmacists are increasingly positioned to contribute to care transitions, and there are numerous interventions that can be combined when evaluating new programs.

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Meta-analysis of Interventions to Reduce Adverse Drug Reactions in Older Adults

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OBJECTIVES: To examine the effect of interventions to optimize medication use on adverse drug reactions (ADRs) in older adults.

DESIGN: Systematic review and meta-analysis. EMBASE, PubMed, OVID, Cochrane Library, ClinicalTrials.gov, and Google Scholar were searched through April 30, 2017.

SETTING: Randomized controlled trials.

PARTICIPANTS: Older adults (mean age ≥65) taking medications.

MEASUREMENTS: Two authors independently extracted relevant information and assessed studies for risk of bias. Discrepancies were resolved in consensus meetings. The outcomes were any and serious ADRs. Random-effects models were used to combine the results of multiple studies and create summary estimates.

RESULTS: Thirteen randomized controlled trials involving 6,198 older adults were included. The studies employed a number of different interventions that were categorized as pharmacist-led interventions (8 studies), other health professional-led interventions (3 studies), a brief educational session (1 study), and a technology intervention (1 study). The intervention group was 21% less likely than the control group to experience any ADR (odds ratio (OR) = 0.79, 95% confidence interval (CI) = 0.62–0.99). In the six studies that examined serious ADRs, the intervention group was 36% less likely than the control group to experience a serious ADR (OR = 0.64, 95% CI = 0.42–0.98).


Key words: aged; adverse drug reaction; meta-analysis; randomized controlled trials

Adverse drug events (ADEs), defined as “an injury due to a medication,” are a major public health problem for older adults. A Adverse drug reactions (ADRs), the most
Reporting Guidelines for Research Publications

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“Despite peer review anyone who reads journals widely and critically is forced to realize that there are scarcely any bars to eventual publication”

“The value of research publications is nullified if the published reports of that research are inadequate”
• Contributors of scientific communications to medical journals are responsible for the research designs of their studies, the applicability of the statistical tests used, and the validity of the conclusions drawn.

• “...manuscripts with conclusions of questionable validity are being published in medical journals...”

• “...much work is being done to make the results of studies...more accessible...a considerable amount of misinformation could be disseminated rapidly.”
What is inadequate reporting of research?

• “Reporting research is as important a part of the study as its design or analysis”
  • Failing to publish is a moral hazard and scientific misconduct.

• Sins of Omission and Commission
  • Failing to include crucial aspects of the methods such as the precise details on the interventions themselves (what did the pharmacist ACTUALLY do?)
  • Using indirect rather than direct measures for primary outcome
  • Lack of or incorrect statistical analyses
  • Selective reporting of results
  • Failing to report harms
  • Failing to publish failed interventions
Consequence of inadequate reporting?

JAMA Internal Medicine 2014

*We graded the evidence as insufficient for most outcomes because of inconsistency and imprecision that stem in part from underlying heterogeneity in populations and interventions.*
Key Principles of Responsible Research Reporting

- Present results clearly and without data manipulation
- Describe methods clearly and unambiguously to permit others to confirm findings
- Follow applicable reporting guidelines
- Authorship accurately reflects contributions
- Authors take responsibility for how others use their work when they fail to fully report all aspects of the research
- Funding sources and conflicts of interest must be disclosed
- Decision to publish not based on findings’ degree of agreement with hypothesis or premise
Characteristics of Available Reporting Guidelines

- Provide structured advice on the **minimal** information to be included based on type of research
- Focus on scientific elements
- Should align and complement journal submission requirements
Using Reporting Guidelines to Enhance Research Meaningfulness

- It is not possible to separate research reporting from research conduct completely.
- Reporting guidelines are useful when planning a study (“Is this going to be on the test?”)
- Provide a scientifically accepted outline for instances where more junior researchers are charged with developing initial manuscript
- Order not critical, but the information is!
- If it is in the checklist, make it a part of the manuscript even if the reviewers says no.
  - Refer the reviewer to the checklist
  - Do NOT assume the reviewer has any clue about the checklist (history has proven this to be true...)
The EQUATOR Network
(www.equator-network.org)
Enhancing the QUAlity and Transparency Of health Research

Your one-stop-shop for writing and publishing high-impact health research

Library for health research reporting
The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.

Reporting guidelines for main study types

- Randomised trials: CONSORT
- Observational studies: STROBE
- Systematic reviews: PRISMA
- Study protocols: SPIRIT
- Diagnostic/prognostic studies: STARD
- Case reports: CARE
- Clinical practice guidelines: AGREE
- Qualitative research: SRQR
- Animal pre-clinical studies: ARRIVE
- Quality improvement studies: SQUIRE
- Economic evaluations: CHEERS

See all 411 reporting guidelines

EXAMINE your paper in oncology:

Use reporting guidelines!
Selecting the appropriate reporting guideline for your article

Authors of research articles frequently forget to report details about their study which are important for readers to know. This can delay publication and stop their work being used, cited or replicated. This is a waste of the human and financial resources invested in the research.

Reporting Guidelines and checklists have been developed for a wide variety of research types and study designs which set up the most important things readers need to know about your work.

EQUATOR have created a simple flow chart to help authors, editors and peer reviewers find the most appropriate checklist and reporting guideline.

We have also collaborated with Penelope Research to develop an online wizard based on the chart. Version 1.4 of the online wizard aims to help you find the the most appropriate reporting guideline, and directs you to an online fillable checklist to submit to a journal alongside your manuscript.

If you click on Toolkits or Not sure which reporting guideline to use?
We have also collaborated with Penelope Research to develop an online wizard based on the chart. Version 1.4 of the online wizard aims to help you find the the most appropriate reporting guideline, and directs you to an online fillable checklist to submit to a journal alongside your manuscript.

Find the right reporting checklist to help you plan, write or review medical research.

This free tool will help you work out which reporting guidelines are right for you

The prototype online EQUATOR wizard was piloted by BioMed Central in February 2016. It was embedded in the submission system for four BMC journals and the promising results of a before-and-after analysis were published in Research Integrity and Peer Review in December 2017.

You can also search the EQUATOR Library of Reporting Guidelines, or read more about different study types on the website of Oxford’s Centre for Evidence-based Medicine.
Find the right reporting checklist to help you plan, write or review medical research.

start

This tool was made in collaboration with the EQUATOR Network. Was it useful?

How can we make it better? *
What type of article is it?

- A. Original research
- B. Protocol
- C. Systematic review
- D. Case report
- E. Other
The type of study is often dictated by a multitude of factors, many of which are out of control of the pharmacist. Those elements that are able to be controlled is where the clinical trial design stage is optimized. Use of reporting guidelines when complete parameters are known that will influence study conduct (and thus, design) will enhance the ability of investigator to include the crucial aspects that will be required in the finished publication of the research. PaCIR should complement the primary reporting guideline, regardless of the type of study being conducted.