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Standardized reporting on studies of psychiatric pharmacist interventions

Brittany L. Parmentier, PharmD, MPH, BCPS, BCPP[1]; Jonathan F. Lister, PharmD, BCPP[2]; Tera D. Moore, PharmD, BCACP[3]; Kristina Reinstatler, PharmD, MBA, BCPP[4]; Ranel Troy Santos, PharmD, BCPP[5]; Gregory H. Payne, MBA, CAE[6]

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Abstract

Reporting interventions thoroughly and consistently in the literature allows for study reproducibility or implementation of the intervention into practice. Although there is currently no standard for describing Board-Certified Psychiatric Pharmacist (BCPP) interventions in the published literature, there are multiple checklists or guides that have been developed for reporting clinical interventions, including the template for intervention description and replication and the pharmacist patient care intervention reporting (PaCIR) checklist, that seek to improve the quality of reporting interventions in the literature. The purpose of this paper is to describe a proposed guide for reporting BCPP interventions in the literature by expanding the PaCIR checklist. Authors use a logic model developed by the American Association of Psychiatric Pharmacists to ensure all elements of the process are addressed in the expanded guide.

Keywords: psychiatric pharmacists, Board-Certified Psychiatric Pharmacist (BCPP), clinical pharmacists, interventions, intervention reporting, reporting guide, outcomes, logic model

[1] (Corresponding author) Clinical Pharmacy Specialist – Psychiatry, The Harris Center for Mental Health and IDD, Houston, Texas, Brittany.parmentier@theharriscenter.org, ORCID: https://orcid.org/0000-0003-3373-0491; [2] Clinical Pharmacist Practitioner – Mental Health, Veterans Affairs Tennessee Valley Healthcare System, Nashville, Tennessee, ORCID: https://orcid.org/0000-0002-6493-7420; [3] Pharmacy Benefits Management Services, Clinical Pharmacy Practice Office, US Department of Veterans Affairs, Washington, DC, ORCID: https://orcid.org/0000-0002-9781-6545; [4] Drug Policy Specialist, University of Cincinnati Health Department of Pharmacy, Cincinnati, Ohio, ORCID: https://orcid.org/0000-0003-0262-7600; [5] Behavioral Health Pharmacist, University of California Davis Health, Sacramento, California, ORCID: https://orcid.org/0000-0002-5045-8365; [6] Director of Strategic Initiatives, American Association of Psychiatric Pharmacists, Lincoln, Nebraska, ORCID: https://orcid.org/0000-0002-8592-7280

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Background

Reporting study interventions is a key aspect of research and publication. Thorough reporting of interventions allows others to reproduce or expand upon the study or implement the intervention in their own practice. All studies in the medical field should have interventions reported in a consistent manner. To address this need and improve the description of interventions in published studies, the first checklist for intervention reporting, the template for intervention description and replication (TIDieR) checklist, was developed and published in 2014.[1]

Although there are many published studies of Board-Certified Psychiatric Pharmacist (BCPP) interventions, there is currently no standard for describing BCPP interventions in the published literature. Authors of a 2020 review of the impact of pharmacists on outcomes for patients with psychiatric or neurologic disorders were unable to complete meta-analyses of the studies due to the heterogeneity of their methods.[2] Another systematic literature review of the impact of psychiatric pharmacists found that only 17.8% (n = 36) of the 202 included articles reported adequate details of the study design, pharmacist training, and collaborators.[3] This problem is not unique to psychiatry as previous clinical pharmacy studies outside of psychiatry have also suffered from a lack of standardized reporting in the literature.[4] In response to this, the descriptive elements of pharmacist intervention characterization

tool (DEPICT) was developed to consistently report pharmacy interventions in the literature.[5] This tool was then updated with DEPICT 2.[6] In 2019, another checklist to enhance pharmacist patient care intervention reporting (PaCIR) was developed using a modified Delphi consensus-building process to improve consistency of reporting, which, in turn, resulted in more studies meeting the minimum requirement for inclusion in systematic review and meta-analysis.[7]

The purpose of this paper is to describe a proposed guide for reporting BCPP interventions in the literature by expanding the PaCIR checklist. Authors use a logic model developed by the American Association of Psychiatric Pharmacists (AAPP) to ensure all elements of the process are addressed in the expanded guide.

Factors That Influence Outcomes

An effective strategy to test the completeness of a reporting guide is to develop a visualization of the system within which the intervention occurs to identify which factors should be disclosed as potentially relevant to the study outcomes. Logic models are 1 such type of visualization and are often used to aid in planning, communicating, and evaluating a program, intervention, or system.[8] These visual representations serve as a tool to demonstrate the relationships between activities or interventions and outcomes. They also show the broader context in which the system operates, which includes assumptions and external influences on the program or system.

The AAPP developed a logic model to describe the impact of psychiatric pharmacists (Figure 1). The foundation of this logic model is that psychiatric pharmacists are being underutilized in the psychiatric workforce despite the significant number of individuals living with psychiatric disorders who need pharmacotherapy. To address this, the intervention of the logic model has 2 parts: a practice intervention and patient intervention. The practice intervention fully integrates a BCPP into the mental health care team to provide direct patient care through face-to-face and/or telemedicine appointments. The BCPP functions at the highest level of clinical practice, often with prescriptive authority through a collaborative practice agreement, scope of practice, or other similar mechanism. This intervention lives under the assumptions that the practice adheres to the psychotropic stewardship model, which promotes the safe and appropriate use of psychotropic medications; the BCPP completes continuing professional development to remain current in practice; and the outpatient practices align with the best practice attribute statements.[9,10] The patient intervention is that the psychiatric pharmacist uses comprehensive medication management (CMM) to treat patients. The ultimate desired result of these 2 interventions is that the outcomes lead to better care, reduced costs, improved patient experience, and improved provider well-being, which represent the quadruple aims in health care. The quadruple aims are a set of goals to improve health systems first developed by the Institute for Healthcare Improvement in 2008 as triple aims and subsequently expanded to include provider well-being to make quadruple aims.[11,12] However, the external influences on the outcomes cannot be forgotten as psychiatric pharmacist interventions are rarely performed without influencing factors. The specific patient population, practice characteristics, and other members of the treatment team are all external influences identified in the logic model.

In order to effectively evaluate the impact of psychiatric pharmacists on the quadruple aims, the core outcome set for psychiatric pharmacists (COS-PP) was developed through a consensus process.[13,14] The COS-PP lists measures and outcomes that help define psychiatric pharmacists' support of the interdisciplinary team in achieving the quadruple aims in health care. These measures and outcomes are depicted in the logic model to show the intermediate steps through which CMM by a BCPP may have an impact on the quadruple aims.

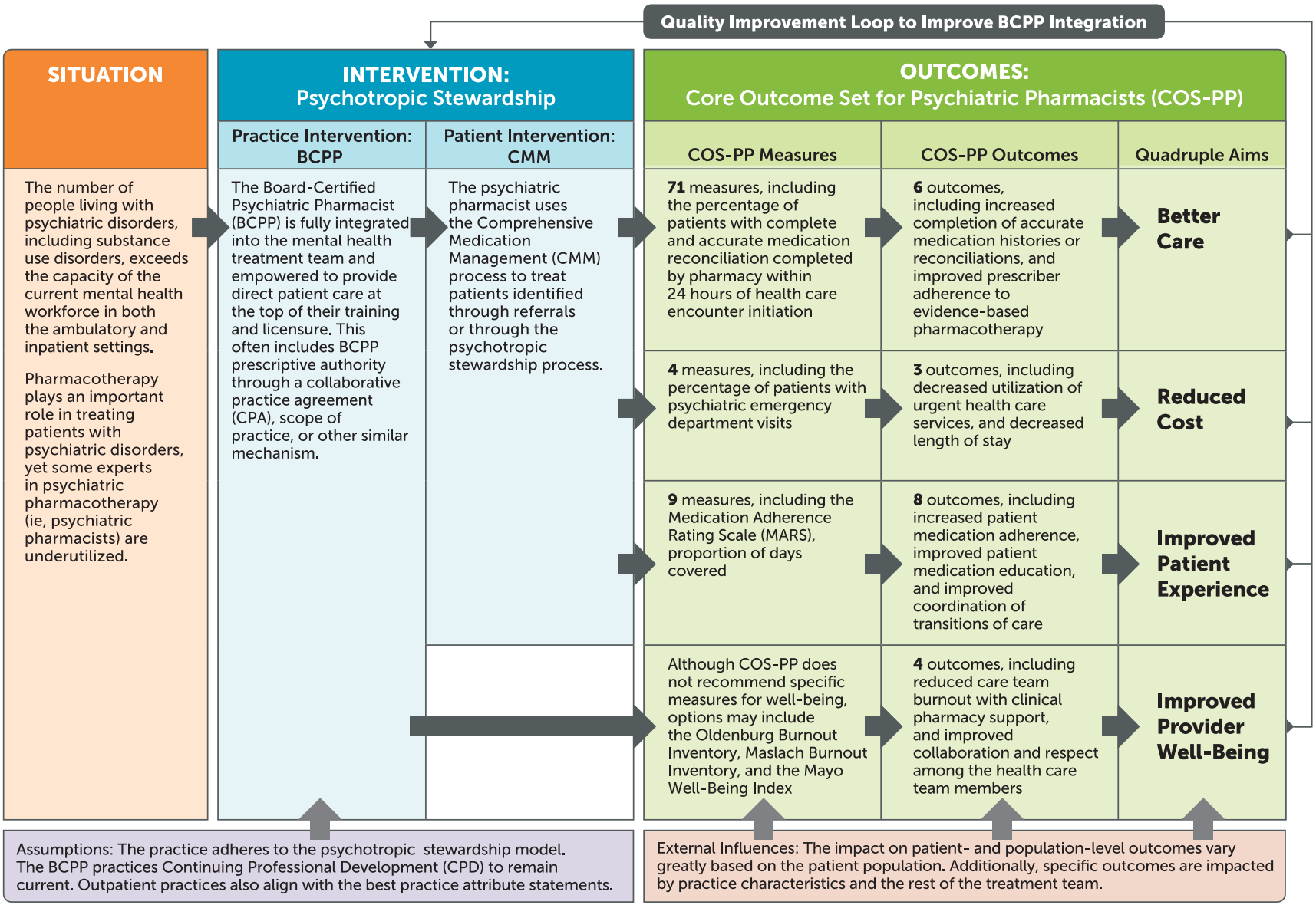
Based on this logic model, study reporting should address the situation, the practice intervention, the patient intervention, the measures and outcomes, the assumptions, and any known external influences.

Pharmacist Patient Care Intervention Reporting

PaCIR was first described in 2019 as an advancement in producing quality reporting of studies involving pharmacist patient care interventions.[7] Authors indicated that using PaCIR could increase the likelihood that studies examining pharmacist-delivered outcomes meet minimal requirements for inclusion into systematic reviews and meta-analyses. The use of PaCIR could also increase successful intervention replication by other pharmacists.[7] In developing PaCIR, authors closely followed key tenets established by the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network, a research publication checklist-creation aid.[15] PaCIR was designed as a secondary checklist to be used in addition to the recommended checklist from the EQUATOR network based on study design. In total, 9 core elements make up the PaCIR checklist and include replicability, patient population, patient/other data sources, environment, delivery, frequency/duration, pharmacist role/responsibility, attribution, and unique attributes. To help provide a future direction for reporting guidelines, in 2021, the American Association of Colleges of Pharmacy endorsed a policy supporting PaCIR with the goal of improving the success rate of replicability and inclusion in analyses.[16]

Expanding PaCIR for BCPPs

The consensus methods used to develop PaCIR resulted in broadly defined elements that were meant to be used in



The **Expanded PaCIR Reporting Guide for Specialty Care** will ensure that published research includes details as reflected throughout the logic model, including measures from COS-PP, intervention details, deviations from the assumptions, and relevant external influences.

FIGURE 1: American Association of Psychiatric Pharmacists logic model for the impact of psychiatric pharmacists[9,10,13]

CRITICAL ELEMENT: For each element below, denote if it is:	Applicable, Present*	Applicable, Absent**	Not Applicable
1. (**Replicability**) Sufficient description of intervention to permit implementation under similar circumstances.			
1a. Trial design (prospective, controlled, randomized)			
1b. Inclusion criteria			
1c. Exclusion criteria			
1d. Patient-level outcomes measured			
1e. Other outcomes measured (e.g., cost, length of stay, medication adherence)			
2. (**Patient Population**) Sufficient descriptors of intervention recipients (and/or population) to assess generalizability.			
2a. The number of patients in final analysis (n)			
2b. The disease states addressed by the study			
2c. Demographics (e.g., age, sex, gender, race, ethnicity, income)			
2d. Method of patient enrollment			
2e. Comparison group			
3. (**Patient / Other Data Sources**) Sufficient description of the source(s) and mechanism(s) by which patient or other data for the intervention were obtained or accessed.			
3a. Type of data source (e.g., assessment tool, insurance, electronic medical record)			
4. (**Environment**) Sufficient description of geographic and/or physical location(s) where intervention occurred, including any necessary infrastructure.			
4a. Treatment setting (e.g., inpatient)			
4b. Facility/Hospital type (e.g., private, non-profit, government)			
4c. Country/State/Urban/Rural			
5. (**Delivery**) Sufficient description of mode(s) of intervention delivery.			
5a. Type of intervention			
5b. Description of delivery of care (e.g., in-person, telehealth)			
6. (**Frequency and Duration**) Sufficient description of frequency, number, and duration of session(s) for the intervention.			
6a. Number of interventions			
6b. Duration of intervention			
6c. Frequency of duration			
6d. Duration of follow-up			
7. (**Pharmacist Role / Responsibility**) Sufficient description of the roles/responsibilities of the pharmacist(s) and others involved in the intervention, including pharmacist-specific skills training.			
7a. All pharmacists and their roles in the project			
7b. Pharmacist prescriptive authority and/or collaborative practice agreement			
7c. All board certifications held by pharmacists (or "no board certifications")			
8. (**Attribution**) Sufficient description of the degree to which the outcomes are directly attributable to the roles/responsibilities of the pharmacist.			
8a. Pharmacist-specific outcomes			
8b. Outcomes related to non-pharmacist collaborators			
8c. Outcomes related to all collaborators			
9. (**Unique Attributes**) Sufficient description of factors not addressed in other elements that may impact replication.			
9a. All non-pharmacist collaborators and their roles in the project			
9b. All board certifications held by non-pharmacists			
9c. Funding sources			

*Author should include section/page/line where reviewer may find it.

**Author is strongly encouraged to include in the methods, discussion, or limitations section of the manuscript why this element is not present.

FIGURE 2: Expanded pharmacist patient care intervention reporting guide for specialty clinical pharmacy practice

conjunction with additional reporting guidelines, such as TIDieR. These original core elements are shown in Figure 2 as critical elements 1 through 9. This paper proposes clarification of those broad elements based on the review of reporting guidelines and consideration of the elements needed to fully describe the BCPP-led interventions using standardized methodology. PaCIR was chosen because it complements existing checklists, it is specific to clinical

pharmacy practice, and it was intentionally designed to improve study reporting so that they can be included in higher order analyses. We sought to expand the PaCIR checklist into a reporting guide to ensure the detailed descriptions of critical elements are included that must be present for acceptance into higher order analysis for specialty pharmacy without the need to rely on additional resources to interpret the PaCIR checklist.

The additional elements reflect specific details identified through analysis of the following:

1. The logic model (Figure 1)
2. Alternative reporting guidelines registered on the EQUATOR Network[15]
3. Standard literature search and research question templates such as PICOT (population, intervention, comparison/control, outcome, and time)[17]
4. *Systematic Literature Review of the Impact of Psychiatric Pharmacists* (Ho et al)[3]

The expanded PaCIR (EPaCIR) checklist (Figure 2) has additional elements following each original critical element to more fully describe the elements of the intervention that will lead to improved reporting standardization in the literature for BCPPs. These added elements are shown as italicized subpoints below the core elements and are intended to disambiguate what should be included in the study description.

Applicability of EPaCIR to Other Pharmacy Specialties

Although the EPaCIR was developed as a reporting guide for BCPPs, it may be applicable to other pharmacy specialties. To the authors' knowledge, no other pharmacy specialties have developed a reporting guide. Authors of a meta-analysis of pharmacist-led interventions to improve medication adherence in older adults used PaCIR to review 39 studies and found that only 15 of the studies (38%) included the frequency and duration and the attribution (2 of the critical elements of PaCIR) in the intervention details.[18] The expanded subpoints of EPaCIR could be used by pharmacists in any setting to guide manuscript development and, thus, improve the reporting quality.

Conclusion

The EPaCIR checklist was expanded from the PaCIR checklist to improve reporting of BCPP interventions in the literature. This reporting guide remains focused on describing the study design. Creation of the manuscript will still involve many other elements beyond the scope of this guide, including completing the primary reporting checklist recommended by the EQUATOR Network and following the International Committee of Medical Journal Editors recommendations. Whereas efforts were made to provide a comprehensive checklist, it may need to be reviewed periodically as practice continues to evolve. For instance, there may come a day when patient populations are described by genomics or when artificial intelligence demands clarity on additional factors. Even if additional factors warrant inclusion in the future, broad adherence to this guide would constitute a major step forward in the quality of reporting of pharmacy interventions.

BCPPs and other psychiatric pharmacists, regardless of board certification, are encouraged to address as many elements of this guide as possible when publishing results of a study of pharmacist interventions.

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