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Stewardship applied to antipsychotics: Development of an antipsychotic stewardship program in inpatient settings for monitoring and optimizing outcomes

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Abstract

Antipsychotic (AP) medications are prescribed for various psychiatric diagnoses that require routine monitoring to ensure optimal use, effectiveness, adherence, and for potentially severe adverse effects. There is currently no comprehensive protocol for institutional supervision of prescribing and monitoring AP. Antibiotics (ABX) are commonly associated with stewardship programs aimed at optimizing use and mitigating harm. These programs have proven to result in positive outcomes in both safety and efficacy parameters for numerous institutions. Given that AP are also associated with significant adverse effects and often misused, the concept of stewardship can be applied to this class of agents to optimize their use and improve overall patient outcomes. The objective of this paper is to provide guidance for the implementation of antipsychotic stewardship programs (APSP) in the inpatient setting. The development of this APSP was designed based on ABX stewardship programs and the Centers for Disease Control and Prevention, Agency for Healthcare Research and Quality, and the American Psychiatric Association practice guidelines on the treatment of patients with schizophrenia. In conclusion, APSPs have the potential to enhance and standardize institutional supervision of prescribing and monitoring practices of AP, leading to improved clinical outcomes and the reduction of adverse effects. APSP teams should be multidisciplinary, consisting of clinicians and administrators, working in conjunction with patients and patient advocates to design individualized recovery plans that consider the individual patient's history and desired outcomes. Monitoring, stewardship interventions, and outcomes should be documented on both an individual and deidentified institutional basis, analyzed, and summarized periodically as measures for quality improvement.

Keywords: antipsychotics, stewardship, monitoring, quality improvement, schizophrenia, bipolar disorder, major depressive disorder, agitation, behavioral disturbance, response, adverse effects

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TABLE 1: Warnings and precautions for antipsychotics use as outlined by FDA-approved product labels

Stroke (cerebrovascular problems) in elderly people that can lead to death.
Neuroleptic malignant syndrome: high fever; confusion; changes in breathing, heart rate, and blood pressure; stiff muscles and increased sweating; these may be symptoms of a rare but potentially fatal condition.
Uncontrolled body movements (tardive dyskinesia) of the face, tongue, or other body parts.
Problems with metabolism, including high blood sugar, diabetes, increased fat (cholesterol and triglyceride) levels in the blood, and weight gain.
Low white blood cell count
Decreased blood pressure (orthostatic hypotension). Feeling lightheaded, dizzy, or faint when quickly arising from a sitting or lying position.
Falls. Feeling sleepy or dizzy due to a decrease in blood pressure when changing position (orthostatic hypotension). Additionally, can slow thinking and motor skills, which may lead to falls that can result in broken bones or other injuries.
Seizures (convulsions).
Sleepiness and trouble concentrating: Do not drive, operate heavy machinery, or do other dangerous activities until the effect of the antipsychotic is known.
Problems regulating increased body temperature. Avoid getting overheated or dehydrated while taking the antipsychotic.
Difficulty swallowing.

Introduction

Psychotropic agents have transformed the care of patients with mental disorders over the past 70 years.[1] Antipsychotic (AP) agents are now indicated and frequently prescribed to patients with various psychiatric diagnoses, including schizophrenia and bipolar disorder and as an adjunct in major depressive disorder. Despite this success, AP are found to be associated with problematic and potentially severe adverse effects. There are no trivial indications for AP, and all use requires careful patient selection following comprehensive baseline assessment, medication choice, medication starting dose and titration, and ongoing monitoring. There currently is no comprehensive framework for systematic supervision of prescribing and monitoring practices of AP to enhance patient safety and efficacy. The current system of AP monitoring is primarily based on each individual clinician's interpretation and compliance with published guidelines and facility policies. As shown in Table 1, the FDA-approved product labels for AP contain warnings and precautions of which patients should be aware and discuss with their health care providers. Adverse effects of AP use include weight gain, sedation, metabolic syndrome, glucose-insulin homeostasis disruption, prolactin elevation, drug-induced parkinsonism, and tardive dyskinesia.[2,3] Dosage adjustments and monitoring for the early appearance of adverse effects can reduce discomfort and the risk for more severe adverse effects to become apparent.[3]

A comprehensive monitoring program, such as an antipsychotic stewardship program (APSP), formalizes the patient-monitoring processes that already exist in various forms and creates a framework that can be successfully replicated in many clinical care settings. Suboptimal AP use contributes to the risk of adverse effects and harmful long-term health consequences, potentially without adequate control of psychotic symptoms.[4] Cardiovascular conditions remain a key cause of death among people treated with AP, suggesting suboptimal monitoring practices delay the identification of high-risk patients and prevent patients from receiving proper management.[5,6] Studies[6-9] show that rates of metabolic monitoring are inadequate and there are significant variations in the monitoring practices of cardiometabolic outcomes in people who use AP, further demonstrating the need for standardized monitoring practices.

To optimize efficacy and reduce harms associated with AP use, AP should be routinely prescribed and monitored following best practices. This situation parallels the use of antibiotics (ABX) with the potential for profound benefits and avoiding serious adverse effects when used appropriately. The Centers for Disease Control and Prevention (CDC)[10] estimates that about 30% of all ABX prescribed in acute settings in the United States are suboptimal or unnecessary. ABX stewardship programs were developed to improve ABX prescribing and monitoring, leading to improved outcomes with minimal harms to patients.[11]

ABX stewardship is a systematic and multidisciplinary approach aimed at optimization and appropriate use of ABX to promote the best clinical outcomes for patients, avoid adverse consequences, and limit the development of ABX resistance.[12,13] Studies[12-14] show that implementation of ABX stewardship initiatives results in positive outcomes, including a relative risk reduction in mortality associated with guideline-adherent empirical therapy and de-escalation to more targeted therapy after cultures are identified. The concept of stewardship, developed initially to optimize the use of ABX, can be successfully applied to AP use with the goal of encouraging optimal use and monitoring to improve efficacy, safety, and tolerability. A clinician-driven inter-

vention that evaluates the patient's comprehensive medical history, previous medication use, indication for an AP, adverse effect monitoring, and rationale for continuing medications long term can improve outcomes and reduce the adverse effects in patients.[2] We provide guidance to develop an APSP, including essential team members and suggestions for implementation.

Methods

A search for meta-analyses and systematic reviews of ABX stewardship programs was conducted on PubMed without restrictions and used to identify the impact of ABX stewardship program interventions.[14-18] The CDC Core Elements of Hospital Antibiotic Stewardship Programs[10] and the Agency for Healthcare Research and Quality[13] Acute Care Hospital Toolkit to Improve Antibiotic Use were employed as prototypes to determine key components that were found to be necessary for the development of a successful ABX stewardship program.

This guidance for APSP implementation in the inpatient setting was based on the experience and recommendations implementing a successful ABX stewardship program in a similar setting. Among all types of psychotropics, it was decided that antipsychotics would be the first agents around which to develop a stewardship program as they have the most potential harms if not prescribed and monitored following best practices. There are some unique differences that require adaptation. For example, mental health clinics have most of their patients seen over an extended period with many interruptions in continuity. The American Psychiatric Association Practice Guidelines on the Treatment of Patients with Schizophrenia have recently been revised and can currently be used to inform individual APSPs algorithms for patient selection, assessment, and monitoring during treatment with AP.[19]

APSP Core Elements

APSP can incorporate the core elements of ABX stewardship as described by the CDC, which may facilitate ease of implementation in health care facilities that have already established an ABX stewardship program due to familiarity of concepts.[10] Those health care facilities without a preexisting ABX stewardship program require additional educational components to introduce the seven core elements of the proposed APSP. These core elements include the following:

- Institutional leadership commitment
- Accountability
- Pharmacist expertise
- Action
- Tracking
- Reporting
- Education[10]

Institutional Leadership Commitment

The buy-in and involvement from senior mental health facility executives is essential to further the goals of the program. The facility administrators need to identify and dedicate the necessary human, financial, and information technology resources that are needed to implement and maintain the APSP. Institutional leadership is responsible for connections with stakeholders and demonstrating that the APSP is supported by the healthcare facility.

Accountability

APSP should have explicitly identified APSP coleaders (we recommend a psychiatrist and pharmacist) that have the authority and resources and are responsible for its outcomes. APSP leaders must have the necessary skills, including leadership, project management, communication, and training in psychiatry and psychopharmacology. Responsibilities and expectations should be clear and explicit to provide accountability for the program.

Pharmacist Expertise

Engagement from pharmacy is essential for ensuring the effectiveness of the APSP. The pharmacy department should identify an experienced pharmacist as coleader of the facility APSP. Pharmacists trained and board certified in the treatment of psychiatric conditions are effective in ensuring the best practices in the use of APs.[20] A board-certified psychiatric pharmacist can serve the organization as a specialist through clinical decision making; implementing best practices; and educating health care personnel, patients, and the public.

Action

The primary APSP intervention is prospective review of AP orders and providing the prescriber feedback to follow best practices as implemented by the facility. AP use for the most common indications and first-line drug choice are routine and should require few prospective interventions. AP monitoring for treatment of emergent problems with adverse effects, efficacy, and adherence are opportunities for increased APSP interventions. Confirming baseline and ongoing documentation should be automated to the greatest extent possible and provide prospective alerts for required time- and event-based assessments.

Tracking

Quarterly reviews of the stewardship program should be performed as a quality assurance measure. See Figure 1. These reviews should include the confirmation of baseline documentation of the rationale to use a specific AP, informed consent including disclosure of potential risks and possible benefits, consideration of the patient's health care beliefs in the recovery plan, and the use of shared decision making to support the appropriateness of the prescribed medication.[21] Ongoing monitoring of APs after initiation should include starting dose and titration as well as the reason for subsequent AP adjustments and their

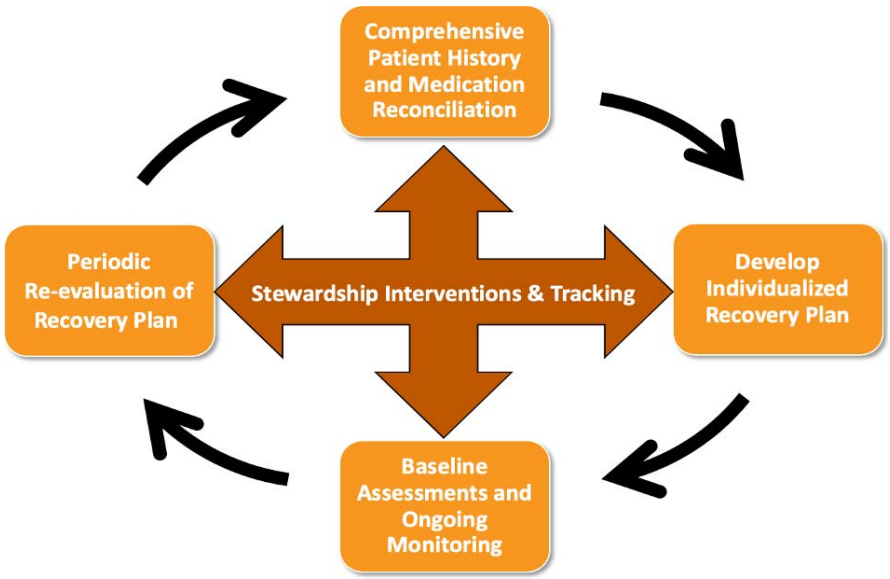

FIGURE 1: Antipsychotic stewardship patient care process

outcomes.[19,22] The rationale for the AP changes may include patient response, adverse effects, dose changes that were planned as part of the titration, added medications, discontinued medications, and changes in route or timing of medications.

Reporting

These reviews should be summarized, analyzed, and reported quarterly at the facility level. More frequent reports would be made as appropriate on an individual patient basis. The intent of the tracking and reports on a facility basis is to provide insight on what is working well and identify potential areas for improvement. The individual patient reporting is intended to ensure best practices are being followed. Criteria for medication use should be monitored in the literature and adjusted periodically to ensure that best practices are being followed. Revisions based on reported outcomes should be implemented following the plan-do-study-act or equivalent problem-solving model.[23,24] Figure 2 depicts the ongoing quality assurance process necessary for a successful program.

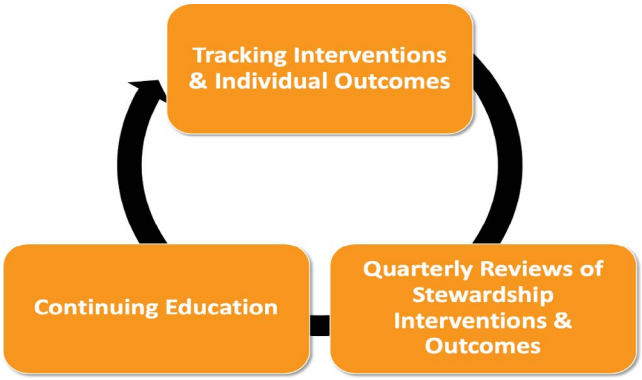

FIGURE 2: Antipsychotic stewardship system quality assurance process

Education

APSP should incorporate a routine education component to review best practices incorporating new evidence on existing drugs, new drugs and their place in treatment, and summarized findings from the quarterly reports. Education programs must include customized components tailored for the unique needs of clinicians, administrators, and stakeholders to encourage continuity of the stewardship initiative.

APSP Team Composition

Overall, clinicians are vital collaborators in stewardship development. Clinician buy-in and support is essential to ensure that best practice guidelines are adopted and adhered to so that the program is successful. See Table 2.

Pharmacist

Pharmacists can support the APSP team by conducting interventions, coordinating data needs, ensuring appropriate use of medications, and serving as a bridge to the pharmacy department. The pharmacist should have board certification in psychiatric pharmacy and the ability to communicate and advise physicians, other clinicians, administrators, and patients in AP use best practices.

Psychiatrist

The psychiatrist should collaborate with the pharmacist to decide the goals of the program. The psychiatrist should see and evaluate patients for clarification or confirmation of diagnoses. Additionally, the psychiatrist should have oversight of prescribing recommendations and settle differences of opinions between the APSP and other prescribers. The psychiatrist should have board certification

TABLE 2: Clinicians and administrators necessary for successful implementation of an APSP

Pharmacists
Physicians
Social workers
Nurses
Patients
Pharmacy and therapeutics (liaison)
Information technology (liaison)
Quality improvement
Other supervisory or regulatory bodies (liason)

in psychiatry and the ability to communicate and advise physicians, other clinicians, administrators, and patients in AP use best practices.

Clinical Social Worker

The clinical social worker provides case management services, individual and group therapy, conducts biopsychosocial assessments and social histories, determines accessibility and patient eligibility for services (including collaboration on access to specialized medication options, such as long-acting injectable AP), assists in coordination and transitions of care, and develops recovery and discharge plans. The clinical social worker should have training in psychiatric conditions and ability to communicate plans with other team members.

Pharmacy Department

The pharmacy department is responsible for processing medication orders and ensuring medications are delivered promptly. Pharmacy can help ensure that prescribing protocols are followed, assist with drug-monitoring protocols, and field drug-related questions. Additionally, pharmacy can collect data on AP use, observe trends in prescribing and dispensing of AP medications, and disseminate information to other clinicians.

Nursing

Nursing is responsible for helping assess patient status, response to interventions, and monitoring for adverse effects. Due to increased direct interaction with patients, nursing is a vital component of the APSP. Nursing preferably will have specialized training in psychiatry and the ability to communicate and advocate for patient needs to both treatment team members and the APSP.

Administrative Support

Administrative support for an APSP is required for the successful implementation and longevity of the program. Suggestions for roles and contributions of various administrators are outlined below.

Executive Leadership

Involvement of executive leadership promotes and supports the goals of the stewardship program. Leadership may also assist in identifying and allocating necessary resources for the APSP.

Pharmacy and Therapeutics (P&T)

The P&T committee oversees the formulary and may endorse prescribing guidelines. The committee may also coordinate incorporation of APSP goals and guidelines with other committees.

Quality Improvement

Quality improvement can ensure compliance with standards and other regulations of regulatory bodies, ensure compliance with quality metrics while promoting rational AP use, and provide resources for interventions to improve AP use.

Information Technology (IT)

IT may aid with data collection and integration of stewardship protocols into operational systems.

Patient-Centered Care

Patient input and involvement is essential in developing a successful, goal-concordant recovery plan. Without patient engagement and buy-in, it is unlikely that an intervention will be successful. Multiple factors should be considered, including the patient's past medical history; history of present illness; social history, including alcohol, tobacco, and substance use; diet; and current and past medications, including all AP, other psychotropics, and all medications for nonpsychiatric disorders. Patient goals, values, and the complexity of the regimen should be considered as well. The health care belief model can be used to understand the patient's perceptions and motivations toward behavior and actions affecting diagnoses.[25] Effective communication is essential in ensuring that patients and providers can engage in shared decision making.[26] Providers should be nonjudgmental, using open-ended questions to elicit patient information, views, and goals and encourage involvement. It is important for patients to believe that they have a condition, that their condition can be treated, and that the benefits of the treatment outweigh any risks. Patients must understand their individual recovery plan, including medication and nonmedication treatment regimens, alternatives to the recommendations, and realistic expectations for the outcome if they participate and follow their recovery plan.

Discussion

AP medications are routinely used to treat psychiatric conditions but have significant adverse effects that require monitoring. The concept of stewardship can be applied to AP use in health care settings to promote safe use and optimize therapy. APSP teams should be multidisciplinary, consisting of clinicians and administrators working in conjunction with patients and patient advocates to design individualized recovery plans that consider the individual patient's history and desired outcomes. The risks and benefits and appropriateness of AP use should be assessed

and monitored routinely for each patient based on the patient's medical and social history, current status, and goals of therapy. Monitoring, stewardship interventions, and outcomes should be documented on both an individual and deidentified institutional basis and analyzed and summarized periodically as measures for quality improvement. APSPs have the potential to improve and standardize prescribing supervision, monitoring, and documentation, leading to improved outcomes of therapy. This document provides guidance for the development and implementation of APSPs in inpatient settings to monitor and optimize patient outcomes while receiving AP therapy.

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