Editorial

Advancing the Quality of Pediatric Antipsychotic Use: Maybe It Takes a PAL

Beginning in 2008, the Washington State Medicaid administration has sponsored a telephone consultation service (Partnership Access Line [PAL]) employing academic child and adolescent psychiatrists to advise primary care prescribers. Initially, PAL staff made recommendations on voluntary requests for psychotropic information/approval of use. Gradually, the program advanced to a mandatory phase in which age-specific and daily dosing were reviewed. The focus then was on stimulant use for the treatment of attention-deficit hyperactivity disorder (ADHD) and the impact of the PAL telephone intervention (Thompson et al. 2009). More recently, the program has turned its attention to the rapidly expanded use of antipsychotics (ATPs), [primarily atypical (second-generation) antipsychotics] in children. This pattern has occurred despite a lack of evidence for treating conditions largely characterized by behavior problems (Olfson et al. 2012) and often involving very young children, particularly among Medicaid-insured youth (Burcu, Safer, and Zito 2016). Washington State's Medicaid program interest in a best practice model for peer review of ATPs no doubt was partly fueled by emerging data on severe short- and long-term adverse events from ATPs (Calarge et al. 2009; Correll et al. 2009; Bobo et al. 2013). In addition, legislative mandates (Congress, 2011) and government accountability reports (GAO, 2012) have encouraged state Medicaid program oversight of pediatric use of psychotropic drugs, in general and antipsychotics, in particular. A major advance in pediatric psychotropic oversight monitoring has been the training of peer reviewers to help the relationship of requester (i.e., prescriber) and reviewer (i.e., adjudicator) to be more collegial and trusting regarding child drug treatment concerns. The state of Washington is not alone in implementing such clinically oriented prior

authorization programs for pediatric use of atypical antipsychotics. In a recent survey of state Medicaid programs, nearly half of these monitoring programs now have adopted the peer review model (Schmid, Burcu, and Zito 2015).

As described in this issue of *Health Services Research* in an article by Barclay et al. (2017), the ATP oversight program to reduce population-based measures of ATP use (youth with ATP dispensings per 100 eligible youth) resulted in a substantial drop from a preprogram monthly level of 0.51 percent in 2008 (when the PAL program was voluntary) to 0.35 percent when a mandatory program was instituted in 2009, to 0.25 percent in 2012 after the use of two or more concomitant antipsychotics was added to the review criteria.

Additionally, the authors collected information on the reviewed ATP regimens and found: (1) dosage above the maximum allowed in this program dropped 57.8 percent among 6- to 12-year-olds and 52.1 percent among 13- to 18-year-olds; (2) most of the 870 mandatory reviews were conducted in either 6- to 12-year-olds (47 percent) or 13- to 18-year-olds (38 percent)—with relatively few reviews among 0- to 5-year-olds (14 percent). Not surprisingly, the great majority of youth included in these reviews were male (70 percent); (3) a substantial proportion of the mandatory reviews (25 percent, 214/870) involved a drug regimen of five or more concurrent psychotropic medications at the time of the review, a level of complexity that raises concerns because of insufficient effectiveness, safety, and tolerability data (Mojtabai and Olfson 2010); and (4) recommendations for changes to the proposed ATP regimen occurred in 55 percent of elective consults and in 33 percent of mandatory consults, suggesting, perhaps, a learning curve on questionable practices and a change in prescribing behavior toward more acceptable practices.

Limitations of the interrupted time series method used in this study are acknowledged by the authors including the absence of a matched comparison state and the possibility that external events independent of the PAL program accounted for the drop in ATP use. Nevertheless, considering the length of time studied (8 years), the large number of reviews (>900 requests were reviewed) and the substantial reduction in ATP prevalence overall—whether reviewed or not—is compelling.

Along with impact study design issues, it is worthwhile to consider the adjudication intervention in itself. There is something remarkable about this state program with respect to developing relationships between reviewers and

Address correspondence to Julie Magno Zito, Ph.D., Department of Pharmaceutical Health Services Research, University of Maryland School of Pharmacy, 220 Arch Street, 12th floor, Room 216, Baltimore, MD 21201; e-mail: jzito@rx.umaryland.edu.

prescribing requestors. Initially, PAL was presented to prescribers as a series of educational seminars in which continuing education credit was an incentive. The degree to which the ratio of reviewers to prescribing physicians (many of whom are primary care providers) and/or the modest population in Washington State relative to other states could influence more personalized and positive relationships and increase the success of PAL is unknown. Also influential is the prominence of recommendations on nonpharmacologic interventions in 86 percent of elective reviews and revisions to requests in 8 percent or limited approval in 25 percent of mandatory reviews—as opposed to outright rejections.

To set these findings in a broader context, two areas will be addressed. First, one must consider the impact of Medicaid oversight in a state-by-state approach. Program differences by state include the criteria for review and the method of oversight. For example, some states deliver automatic flags with letters to physicians and no interruption at the point of service, whereas other states use newer review programs that restrict access at the pharmacy until the request is approved. Programs also may vary in terms of the training and experience of the reviewer. Finally, programs vary in whether findings on the impact of oversight are published either on the web or in peer-reviewed literature.

In Washington State, peer reviewers are highly trained academic psychiatrists. While relatively new, the peer review model appears to reflect the evolving history of Medicaid oversight programs. Many automated oversight programs in the past have been a dismal failure or have focused on cost containment rather than clinical appropriateness and drug safety. Thus, the PAL has partnership at its core with the educational goal of realigning community practice. The approach reflects a dynamic drug information model—one which may change over time as evidence emerges that alters the benefit–harm balance for a given drug or class of drugs, in specific age groups or for particular indications (or off-label). In this way, new information may change decisions on appropriateness according to the particulars of a patient with respect to severity of illness, prior medical history, and data on long-term safety.

PROGRESS IN OTHER STATE PROGRAMS

Two other programs have also published on the impact of prior authorization. The Florida Medicaid program study focused on children less than 6 years of age and enrolled in the fee-for-service program. In a review of 1,424 reviews over 11 quarters (2008–2011), the target symptoms of severe aggression,

impulsivity, and extreme irritability stood out. The program resulted in a 35 percent drop in requests to initiate an ATP across the study period, which may imply that the goal of reduced usage in very young children was achieved, although data on trends in overall usage were not presented. Rates of utilization were not presented, which limits comparison with the present study (Constantine et al. 2012).

A recent study in a mid-Atlantic state with a peer review program (State A) for pediatric antipsychotic (ATP) review used an abutting state without such review (State B) for comparison (Stein et al. 2014). Across 3+years, in a complex “triple difference”-interrupted time series analysis, the analytic method accounted for differences between states, time periods, and rates of antidepressant use. State A findings in 6- to 12-year-olds had a significant ATP prevalence drop while the younger aged group had increased use and the older group had a nonsignificant decrease. Comparisons to the present study are limited by the method employed.

A rough comparison of the ATP use in 6- to 17-year-olds between Washington State and State A in the mid-Atlantic region suggests a 12- to 25-fold greater use in State A and a 7- to 16-fold greater use in mid-Atlantic State B. These large differences in use reflect the consistent West Coast–East Coast differences in psychotropic treatment patterns (Zito et al. 2013) with much lower rates in the West. While it is not clear whether Washington State youth are undermedicated or States A and B are overmedicated, it is clear that such large differences in use for possibly inappropriate treatments demand further explanation, particularly in terms of off-label indications, age of the patients, severity of the reported condition, and specialty of the prescriber. These differences must be understood if progress is to be made to address the concerns highlighted in government reports (GAO 2012) and in academic child and adolescent psychiatry papers (Varley and McClellan 2009). Adjudication within a full integration of primary care and child psychiatry aimed at a best practice model as shown in Washington State could reduce infractions of Medicaid policy.

BROADER ARENA

Besides the need for standardized impact study analytics, it is useful to recall major temporal events in the period from 2006 through 2013. These events highlight concerns about ATP treatment-emergent harm along with the increasing complexity of multidrug regimens (Mojtabai and Olfson 2010).

Concerns have been raised about such use because it is largely off-label; that is, the product labeling was not approved by the Food and Drug Administration either for the purpose of its indication of use or in the specific age group of its use (Roberts et al. 2003). Moreover, while adverse ATP events related to weight gain and subsequent type 2 diabetes were known previously in adults, the safety stakes were greatly raised by the results of a study of Medicaid youth showing a strengthened association to type 2 diabetes mellitus as exposure to ATPs increased (Bobo et al. 2013). Recently, professional voices have been lifted to alert consumers to *choose wisely* regarding antipsychotic use, particularly in children (APA). These developments support continuing efforts to demonstrate the value of Medicaid oversight programs. These can enrich both policy and clinical efforts to improve appropriateness of psychiatric care where the evidence base is weak and changing. Starting with a PAL may make all the difference.

Julie Magno Zito

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