PSYCHIATRIC MEDICATION PEER REVIEW PROJECT:

PHASE 1 FINAL REPORT

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October 30, 2012

Overview

The Washington State Health Care Authority (HCA) contracted with the University of Washington Department of Psychiatry and Behavioral Sciences to conduct an antipsychotic medication-prescriber peer review project. We are now half-way through this 2-year long project, having completed 32 consultations from a group of 44 prescribers that were identified by the HCA. The overall goal of this project is to improve adherence and prescriptive practices through safe and effective use of antipsychotic and other psychiatric medications. It was proposed that progress toward these goals would be achieved via identifying opportunities for system improvement as well as through the cumulative effects of the consultations. This report is a summary of our findings thus far, including recommendations based on our experience in performing the case reviews.

Interventions and Techniques Utilized

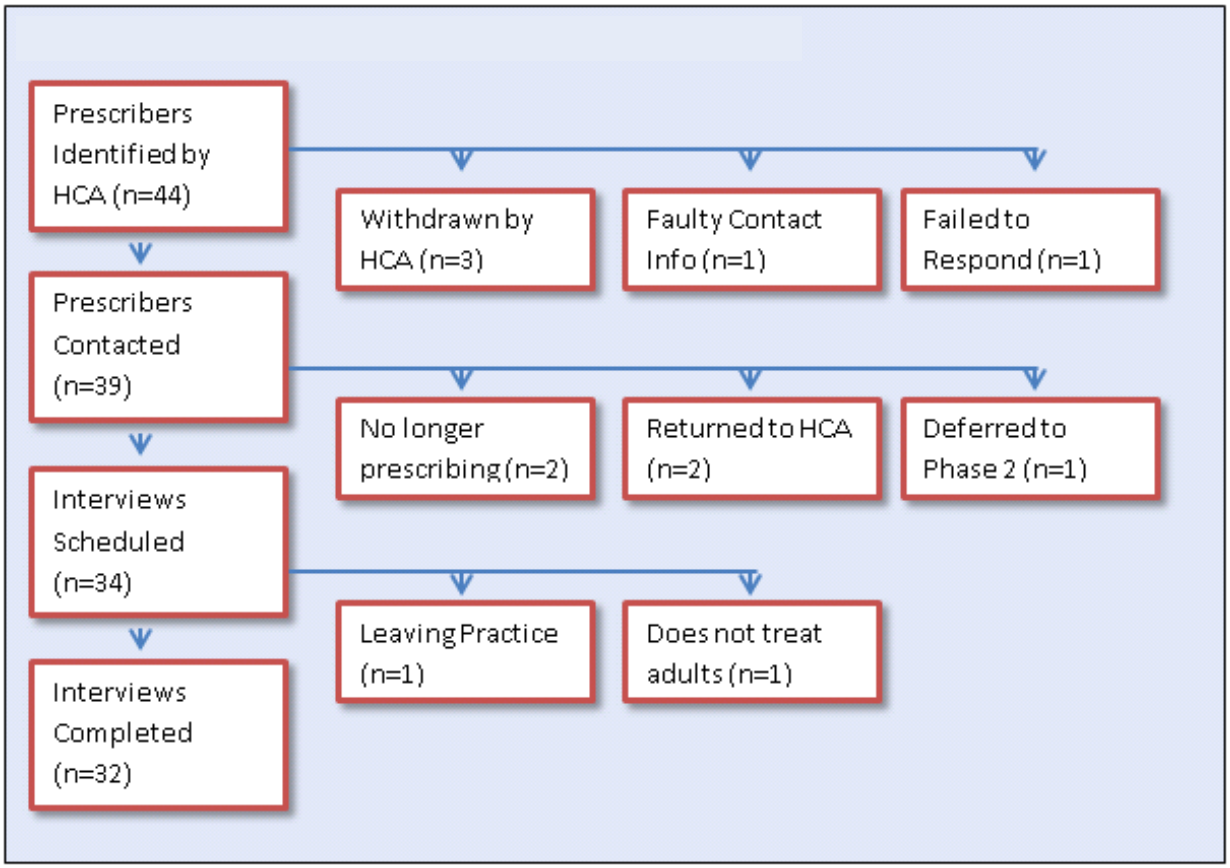
Identifying the Prescribing Providers ("Prescribers") for Consultation: The HCA used an algorithm to identify prescribers to participate in the program. Each prescriber had several patients trigger one or more of the quality indicator flags listed in Figure 1.

Figure 1: Quality Indicator "Flags"

Indicator	Metric
Medication gap	> 7 days (per 6 month review period)
Medication Possession Ratio	< 90% (per 6 month review period)
Psychotropic Medication Dosage	> FDA Maximum
Antipsychotic Polypharmacy	> 2 Concomitant antipsychotics
Psychotropic Polypharmacy	> 5 Concomitant medications

Contacting Prescribers and Scheduling Interviews: Our efforts to contact prescribers and schedule interviews are detailed in Figure 2. For the various reasons illustrated in Figure 2, we required 44 prescriber candidates in order to meet our initial goal of 31 completed interviews (completion rate of 32/44 = 73%). Contacting prescribers for the purpose of scheduling these interviews turned out to be a surprisingly labor-intensive effort.

Figure 2: Flow Diagram for Prescriber Contact and Scheduling



Selecting Patient Cases for Review: Four patients were selected for each prescriber as potential cases for review. These patients were selected by one of the consulting UW psychiatrists (RK) based on the quality indicator flags triggered on their Antipsychotic Medication Reports (AMR) for each patient. The criteria for selecting the patient were (1) the number of quality indicators flagged on that particular patient, (2) diversity of flags chosen for discussion, and (3) flags representative of the prescriber's pattern. Each prescriber was mailed a letter from Jeffery Thompson, MD, Medical Director of the HCA announcing the project, and requesting copies of records for 3 of the 4 patients identified within the letter.

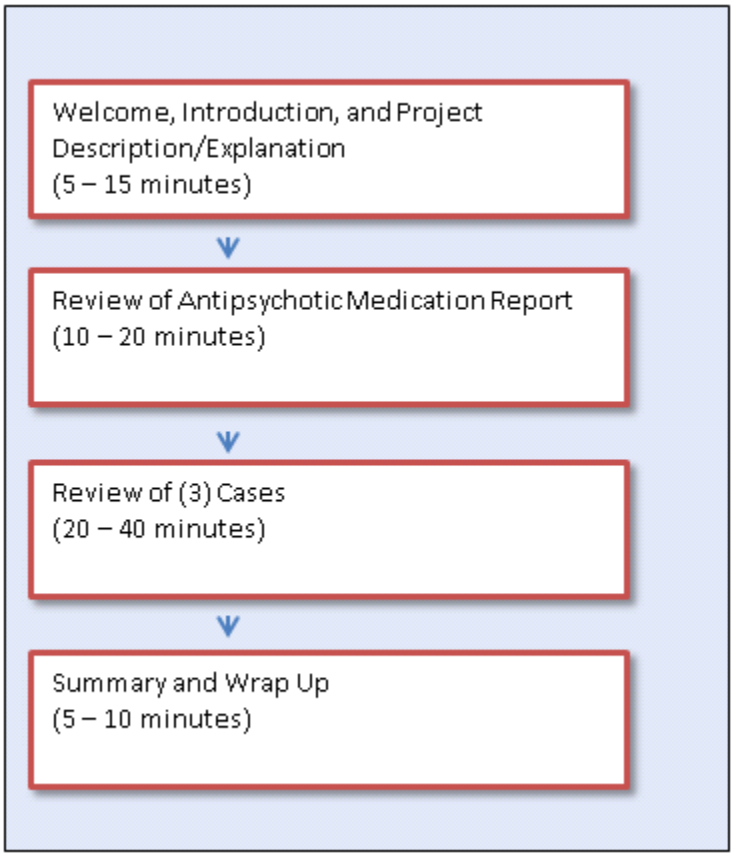
Preparing for the Interviews: The UW team developed ten (10) standard questions to review for each prescriber (Table 1). We created an online survey tool for collecting information during the interviews. Those questions are listed in Table 1. Prior to each interview, the consultants reviewed the antipsychotic medication report (AMR) and the patient records that were submitted. Any discrepancies were noted in the data collection tool for further discussion.

Table 1: Standardized Interview Questions
Introductory Questions:
• Please describe your overall practice type/location (general adult?): • What do you make of the summary data in the report from HCA?
Patient Review Questions :
• Please give us a brief description of this patient's care: • What do you make of the summary data in the HCA report you received? • What is the most challenging aspect of providing psychiatric medication treatment to this patient? • What HAS worked well in providing care to this patient? • What psychopharmacologic issues or questions come to mind with regard to this client? • How can the Health Care Authority help in improving outcomes, safety, and adherence with psychiatric medications?
Wrap up and Summary Questions:
• The Health Care Authority in Olympia is thinking about system-level ways to improve psychiatric patient care – to improve outcomes, safety, and adherence with psychiatric medications. Do you have any ideas that might help to improve care from this level? • Conclusion: How was this consultation experience for you? Do you think it was beneficial?

Conducting the Interviews: We completed 32 prescriber interviews during Phase 1 of the project. Each prescriber was scheduled for a one-hour peer-review consultation with one of two psychiatric consultants (Dr. Ryan Kimmel, MD and Dr. Marc Avery, MD – both faculty at the University of Washington, board-certified in psychiatry, and possess extensive knowledge and experience in the use of antipsychotic medication and the treatment of persons with SPMI). The interviews were generally one-hour long. We chose this length of time as we felt this was the longest amount of time appropriate for the participants' busy schedules. However, this design also required us to focus on just a few clinical issues during the interview. It is important to note that these rather brief interviews comprised neither a systematic evaluation of a prescriber's practice, nor a comprehensive review of any single patient.

All interviews began by welcoming and thanking the prescriber for his/her participation in the project, followed by an explanation of the rationale and goals of the project itself. This explanation took up to 15 minutes, as the activity was new to most participants. Following the introduction, the interviewers moved on to review of the AMR, with special attention to interpretation of the data within the report. As this was often the first time that prescribers had seen information summarized in this way, this too often took considerable time (10 – 20 minutes). The interview progressed to reviewing up to three patients for each prescriber, and then moving on to summarizing the interview. The consultants had considerable latitude in how much time to spend with each element of the interview – with the emphasis placed on opportunities for "teaching moments" during the entire interview process.

Figure 3: Interview Processes and Flow Diagram



Interview Follow-Up with Prescribers: Following the interview, the consultant emailed the prescriber to thank them for their participation and to forward any additional teaching materials that were discussed during the interviews. This often included research reference materials or summary information that we had earlier compiled for the purpose of the project.

Summary of Findings

Prescriber Sampling and Dropout: This report summarizes our findings that resulted from conducting interviews of 32 prescribers from a pool of candidates chosen by HCA. It is important to point out that this group was chosen because of their outlier status within the pool of prescribers – and thus the results of this study cannot be generalized as to represent the entire pool of prescribers engaged in antipsychotic prescribing practices statewide. Furthermore, since we do not have the precise algorithm for selection utilized by HCA – it is difficult for us to generalize patterns across a group. Finally, there was a certain amount of drop-out during the scheduling process (see above) resulting in a 73% completion rate – this likely results in a certain amount of selection bias in the results that we observed.

Prescriber Practice Type: The majority of participants in this project identified themselves as providers from a community mental health center, with some variation. One participant only provided inpatient services. Another was a primary care provider (who did a large amount of mental-health prescribing). Finally, several prescribers noted that their practice had one more specialty focus types: such as dangerously mentally ill programs, or residential programs.

Trends observed, Lessons Learned, Barriers and Successes

General Observations: We must begin our discussion of results by commenting that we were quite impressed by the commitment and dedication we observed in the prescribers on behalf of serving a very ill and difficult to serve patient population. Community mental health care is a challenging occupation, which was underscored by our observations. We were also quite impressed by the level of sophistication of psychopharmacologic knowledge possessed by many prescribers; however, they differed greatly in this extent. Prescribers also differed in treatment philosophies which sometimes colored their medication recommendations.

False Positive and Negative Errors: A primary focus of this study was on the patients identified that triggered one or more of the quality indicator flags. We observed the effect of false inclusion ("false positive") and false exclusion ("false negative") data. Though these effects were mostly minor, we found that it was important to validate these possible sources of errors with the prescribers for the purpose of transparency and accurate use of the reports. A list of false positive and negative errors observed by us is included in Table 2.

A particularly important error came about from the process of attributing patients to a prescriber's caseload. That is – the algorithm that HCA used to identify prescribers is unable to determine whether a patient belongs to one prescriber's regular caseload or another. As clients often get seen by non-assigned prescribers (for a variety of reasons) this algorithm led to database assignment errors in both directions.

Table 2: Observed Sources of False Positive and Negative Errors in the Antipsychotic Medication Report

Source of Error	False Positive	False Negative
Attributing a particular patient to a caseload	Vacation and call coverage, transferred cases, etc.	(same)
Medication GAP, MPR	Starting and stopping medications with clinical approval, use of samples, incarceration, hospitalization, use of stored medication cache.	Medications picked up by third parties. Cheeking, hiding, or inappropriately discarding medications.
AP dose greater than FDA		
Use of 2 or more AP	Switching between medications.	
Use of 5 or more psychiatric medications	Switching between medications.	
Generic Utilization		Use of samples.

Quality Indicator Flags

Table 2a lists the most frequent clinical indicators discussed during our interviews. These indicators were only flagged if they were a focus of our discussions. The polypharmacy and adherence flags were the most frequently discussed – not a surprise as this was the focus of this project. Under-use of clozapine and lack of metabolic lab monitoring with antipsychotic (AP) use was also frequently observed.

Table 2a: Observed Clinical Indicators During Interviews

#	Clinical Concern
47	>=2 AP
42	>=5 psychotropics
25	MPR < 90%
21	AP dose too high
11	Current Gap > 7 days
10	Underuse of clozapine
6	AP without annual FBS
6	AP without annual Lipids
6	Poor medication compliance with provider knowledge
5	Poor medication compliance without provider knowledge
4	LT Benzo and escalating use
3	>= 2 Similar AD
3	>= 2 benzodiazepines
3	AP without appropriate indication

Adherence Flags (GAP and MPR): The HCA has noted that a Medication Possession Ratio of <90% is associated with higher risk of hospitalization, either medical or psychiatric, in the following 6 months. This begs the question of whether some hospitalizations might be avoided through better attention to adherence indicators. We encountered several cases in which poor adherence appeared to be associated with an apparent lack of efficacy (we know from the literature that lack of perceived efficacy is often an important factor in reduced adherence). In some instances however, the provider appeared to prescribe additional medication with a goal of improving efficacy - but improvement with this additional medication was not ascertained (often it was not possible to do so). The net result, however, may have only been more complicated regimens, more side effects, and even worse medication adherence.

Prescribers are often aware of the poor adherence of their patients. Many prescribers were able to identify patient factors that led to reduced adherence. Some of those factors are listed in Table 3.

Table 3: Observed Factors Leading to Poor Adherence

- Poor insight into the diagnosis,
- Poor recognition of the impact of their symptoms on functioning,
- Over-estimation of the impact of potential side effects of the medication,
- Complex medication regimens,
- Substance abuse,
- Complex social issues leading to unstable lifestyle
- Poor follow-up with appointments

We noted that often, when assessing adherence, the prescriber had to depend solely on patient self-report and was unaware of poor patient medication adherence. In these cases, the data from the Antipsychotic Medication Report was viewed as immediately clinically applicable. To address these issues, we also heard of a number of strategies that providers employed. These are summarized in Table 4.

Table 4: Factors Utilized by Prescribers to Improve Adherence
• Active conversations about adherence during med appointments. • More aggressively addressing substance abuse issues • Engaging patients' families, • Moving patients into more structured living situations • Use of long-acting depot medications • Daily medications administration • Medication alerts for late medication pick-ups. • Use of peer services to support adherence. • Engaging other team members in addressing adherence, including case management and pharmacy

Though many of these strategies appeared to be quite effective, their use was quite variable across programs. We felt that many of these strategies could be employed more systematically across all providers. We also noticed that providers varied considerably in their awareness of the importance of adherence treatment strategies, as well as in their awareness of motivational interviewing skills or in medication shared decision making strategies. Some providers lack access to clinical support resources that could help improve adherence. Finally, some providers had apparent barriers to using certain medications that might improve adherence because they required blood draws or injections that were not available at their treatment setting.

Antipsychotic Dosing Flag (>FDA max): In our reviews, we considered whether attention was given to the potential benefit of using antipsychotics above FDA max versus the risk of harm to the patient in the form of side effects. We also were interested in hearing if clinicians observed any benefits following the dose increase. In some, there was good documentation that the current dose worked better than the FDA max dose and the decision seemed rational. In other cases, >FDA max dosing did not appear to correlate medication response. In some cases >FDA max dosing was co-present with antipsychotic polypharmacy. In some cases it appeared that >FDA max dosing was also employed to target symptoms or diagnoses for which the antipsychotic had little likelihood of treating. These types of cases often represented an educational deficit about the mechanisms of the medications and the potential risks of >FDA max dosing, an educational deficit in the treatment of refractory psychotic or mood disorders, or an educational deficit on the treatment of cognitive disorders (dementia, developmental delay, adult autism spectrum).

Antipsychotic Polypharmacy Flag (>2 AP): As there is little scientific literature that supports the simultaneous use of multiple antipsychotic medications, we were concerned that this practice would not have an overall favorable risk/benefit ratio – most likely by increasing exposure to side effects. <u>This flag proved to be the most common opportunity for on-the-spot education during provider interviews.</u>

A frequent reason for 2 AP use was to address sleep problems, as quetiapine is commonly used as a sleeping agent. This medication does not have an FDA indication for insomnia, and the risk of side effects would argue that this medication is not a good choice for off-label use for this purpose. On the other hand, there are few medications available for sedation that have a low risk for dependence, and this medication was sometimes appropriately used for this purpose after failed attempts with other sedatives (such as trazodone or hydroxyzine). In other cases, sub-therapeutic quetiapine (e.g., 50 mg) was used as a hypnotic in bipolar disorder,

depression, and schizophrenia with the thought that it might augment via a mechanism more than just improve sleep.

As was the case with >FDA max dosing, antipsychotic polypharmacy was sometimes unsuccessfully employed for symptoms and diagnoses for which even monotherapy would have a low likelihood of efficacy. Agitation from cognitive disorders, for example, was sometimes labeled “Psychosis NOS” in order justify antipsychotic polypharmacy. This represents an educational deficit in the management, both pharmacologic and non-pharmacologic, of behavioral issues associated with certain cognitive disorders.

Psychotropic Medication Polypharmacy Flag (>5 psychotropics): Complicated psychotropic medication regimens may reduce value by exposing patients to cumulative side effects, increasing the rate of drug interactions (both those known and those unknown), and impair adherence via confusing and complicated daily dosing regimens.

In our review of cases for this project, it was noted that psychotropic polypharmacy regimens were often patient-driven. That is, patients requested medications to treat a variety of symptoms, without a good understanding of the underlying diagnoses. For example, a bipolar patient in a mixed state may have a mixture of depressive symptoms (which might generate a prescription for an antidepressant), manic symptoms (generating prescription for a mood stabilizer), problems with sleep (generating a prescription for a sedative hypnotic), hyperactive and impulsive behavior (interpreted as ADHD and generating a prescription for a stimulant), or excessive daytime sedation from other medications (generating prescriptions for a medication like modafinil). Such pharmacological management is driven by symptoms rather than a good understanding of the underlying disorder. Both patient requests and provider inexperience can contribute to such “symptom-driven prescribing.” In some cases, symptoms seemed to be best characterized as sequelae of psychological or social factors. Prescribers often have few resources to impact such psychological or social issues and may try prescriptions of additional medications to help address the patient’s concerns or distress.

Psychotropic polypharmacy often appeared to be a result of complicated patient profiles – multiple diagnoses, treatment resistance, and numerous life stressors and trauma. The use of multiple medications was sometimes, appropriately, the result of multiple, Axis I diagnoses.

On the other hand, there were also cases of psychotropics that appeared to be added to treat the side effects of other psychotropics. Though antipsychotics have some demonstrated efficacy for certain etiologies of agitation, the agitated patients in our review rarely had a medication removed, even as the agitation persisted and other classes of medications were added. At some point, one has to wonder about the cognitive impact of psychotropic polypharmacy in vulnerable patients who already demonstrate cognitive deficits.

Percent Generic Utilization of Antipsychotic Medication: Compared with the existing, generic, antipsychotic spectrum, most of the recently-released antipsychotics are not a dramatic leap forward in efficacy, mechanism of action, or side effect profile. The value of expensive medications is reduced if there is not a commensurate jump in efficacy. PMAP came at an unusual time for this topic. In 2012, generic versions of ziprasidone, olanzapine, and quetiapine became available. When added to generic risperidone and typical antipsychotics, there is now a much wider armamentarium of relatively affordable antipsychotic medications. Thus, providers may not have to switch medications in order for their Percent Generic Utilization to go up. We

DID observe the occasional use of on-patent delayed-release formulations of medication (for instance one provider's uniform use of Seroquel XR over generic quetiapine).

We also observed an issue related to the use of samples. Community providers often rely on brand-name medication samples for those patients without (or who lose) health care insurance. On one hand, these non-generic meds may keep the patient alive, out of jail, and out of the psychiatric hospital. On the other hand, when a patient has been stabilized for a month on a specific medication, there is some pressure to continue that medication, no matter what the expense, in order to maintain patient health. Moreover, the prescriber sees the patient get better on an expensive medication, perhaps luckily without side effects, and uses this "N of one" to preferentially try the expensive medication, rather than another generic, in the next patient that is doing poorly. This is a system deficit wherein it is easier to get free samples of expensive medication than free samples of a cheap medication.

Recommendations

We organize the section of potential interventions to improve the "value" of pharmacologic treatment according to the primary "targets" of the intervention, focusing on five "P's": Patients, Prescribing providers, Practices (clinics), health Plan (Medicaid), and this Project.

Patients

In our interviews, we only reviewed the prescriber and prescription related documentation. We did not review the overall care plan or any other providers who may have been involved in the patients' care. However, it appeared from our interviews that behavioral strategies to address symptoms, improve self-empowerment, and expand self-management were inconsistently employed, if at all. Many patients appeared to be enrolled in a "prescriber plus case-manager" treatment team – but the degree to which these providers collaborated was unclear.

Recommendations: We recommend efforts that support and promote patient medication education, empowerment, and shared decision making via evidence-based or promising practices such as shared decision making, WRAP planning, illness-management protocols, and medication focused peer services. We encourage the sharing of successful programs between providers, such as the medication-focused care managers in Cowlitz County.

Providers

Though some participants in this project were less than enthusiastic, the majority of providers seemed delighted to have the opportunity to consult and wished there could be more of this type of service. And, despite the rather awkward structure of the interviews and the likelihood of feeling criticized, many quite open to information and accepted the discussions in a collegial and open-minded manner.

- We would recommend that providers have access to peer discussions and/or second opinions in a collegial and non-punitive format. Instead of a consult that was required based on negative performance flags, we wondered if consults could be voluntary or set at a certain frequency based on FTE or caseload size. At any rate, it might still be appropriate to "trigger" consults based on certain clear outliers (such as flag performance > 2 S.D. above mean, use of > 2x FDA max of drugs, etc.). Given the high variability in staffing patterns – it would make sense to offer a variety of consultation opportunities, such as peer-to-peer phone calls, teleconference, and in-person second opinions.

- It is unlikely that one-time consultations will achieve significant behavioral change. Thus, we recommend that a plan for follow up be included in the consultation plan.
- We found a high degree of professional isolation among our group, especially in rural settings. We suggest that a prescriber-peer network system be developed in increase providers' ability to informally discuss cases with one another.
- To reduce the dependence on industry-sponsored education, we would recommend that we consider how to make educational materials more available to our community providers. These might range from written summaries to salient journal articles to archived webinar presentations. These could be made available for HCA providers on topics including motivational interviewing for medication adherence, using depot antipsychotics, clozapine, recommended laboratory tests, rationale behind FDA max dosing, treating refractory bipolar disorder, treating refractory schizophrenia, treating agitation associated with cognitive disorders, treating sleep, appropriate dosing of antipsychotics for mood disorders, risks of antipsychotic polypharmacy, risks of psychotropic polypharmacy, outcomes data when a stable patient is reduced from antipsychotic polypharmacy to monotherapy, the basics of benzodiazepines, medication pricing updates, and framing the newest antipsychotics in light of the existing generics.

Practice

Two of the more significant outlier prescribers worked in unusual practice / clinic structures. The prescriber with the greatest number of flagged regimens and antipsychotic costs is an ARNP who supervises two pharmacists. Per her report, the pharmacists make independent medication changes in the ARNP's name. Two of the cases that we discussed had dramatic polypharmacy without appropriate documentation. This provider seemed to lack substantial psychopharmacology knowledge and was in a position of supervising two pharmacists, whom she noted were directing care. Another provider (a psychiatrist), reported that he practiced with 2 RN nurses who work in a similarly independent manner (though prescriptions and notes required co-signature). We do not know the details of the rationale behind these practice arrangements, but our observations led us to question whether the system is realizing clinical value from these structures.

On the positive side, we did hear of some interesting practice solutions. We were especially impressed by those programs that adjusted staffing and workflow with specific attention to improving medication adherence. These examples were outlined in Table 4, above.

Plan (HCA)

We received a fair number of positive comments about the AMR itself. Many commented that this was the first time they had ever seen such a report and would like to see this data more regularly. They especially liked the list of patients with flagged regimens.

- We would recommend regular AMR reports to providers, including longer-term data to track trends, as well as more real-time data.
- We would recommend that the AMR reports list data in a more descriptive "bell curve" for recipients.
- We would recommend that the AMR break down medication possession ratio by specific medication.

Many providers have used the new Washington State database to look up opiate and benzodiazepine dispensing. They would be willing to use a similar database to look up psychotropics and ER/Hospital visits, especially when those visits led to medication changes.

- Provide physicians and their staff the ability to log on and access the PRISM summaries that were used in the PMAP project.

- Provide education to providers and staff on how to use this resource effectively.
- Consider an automated system to alert providers when medication refills are missed.
- Consider a system to alert providers when patients are hospitalized or visit an ER.

Providers would like to have the ability to look up the labs that have been drawn at other clinics, hospitals, and ERs. This would reduce repeat lab draws and help with real-time psychotropic medication decision-making.

- We encourage progress in expanding electronic access to laboratory information and other critical PHI data for the purpose of clinical decision making.

As documented previously, patients who only have access to non-generic medication samples are likely to end up on these meds after Medicaid is approved.

- Consider a program that puts generic antipsychotic samples in community clinics. While it might be difficult, for example, to have the HCA directly purchase medications which are going to be given to non-Medicaid (or not-yet-Medicaid) patients, one could devise systems to work around this. For example, HCA could provide King County or the Washington Community Mental Health Council with a grant to purchase generic antipsychotic samples and develop a system to be used in community clinics.
- HCA could engage in a project to track the use of antipsychotic samples and test the hypothesis that patients started on samples remain on that medication after Medicaid funding is authorized.

Though clozapine is the only documented intervention to demonstrate significant efficacy and reduced mortality in refractory schizophrenia, many providers have limited access or experience with use of this medication.

- Consider a larger study in Washington State to track the rate (likely very low) of clozapine initiation and identify the barriers.
- Explore variation in clozapine prescribing around the State and learn from successful prescribers of clozapine.
- Consider a provider education program focused on the successful use of clozapine.

Depot medication can be effective for some patients with poor medication compliance and without other structural resources to ensure daily dosing. Many providers have limited access or experience with use of these medications.

- Consider a larger study in Washington State to track the use of depot antipsychotics.
- Consider an educational program to prescribers and/or patients around the benefits of depot medications.

In conducting the PMAP, it was evident that HCA does not have up-to-date contact information for many of the providers to whom it pays for services. For example, we needed 44 provider names to find 32 providers eligible for the project. This lack of contact information impedes the ability of the HCA to contact providers, advertise new programs, provide educational materials, mail Antipsychotic Medication Reports, etc.

- We encourage maintenance of an up-to-date list of all mental-health prescribers working within the state RSN MH system.
- Avoid distributing information using the HCA's secure email program as many providers simply cannot get access. Consider using ordinary email, secure fax, or regular postage.

We noted that the genesis of polypharmacy often occurs with inpatient care – with the outpatient providers "inheriting" the patient with complex medication regimens that were started in the hospital.

- Consider expanding distribution of the AMR to inpatient providers.
- Consider implementing a program to better communicate the intended discharge medication plan (e.g. completing a cross-taper) from inpatient to outpatient provider.

Project

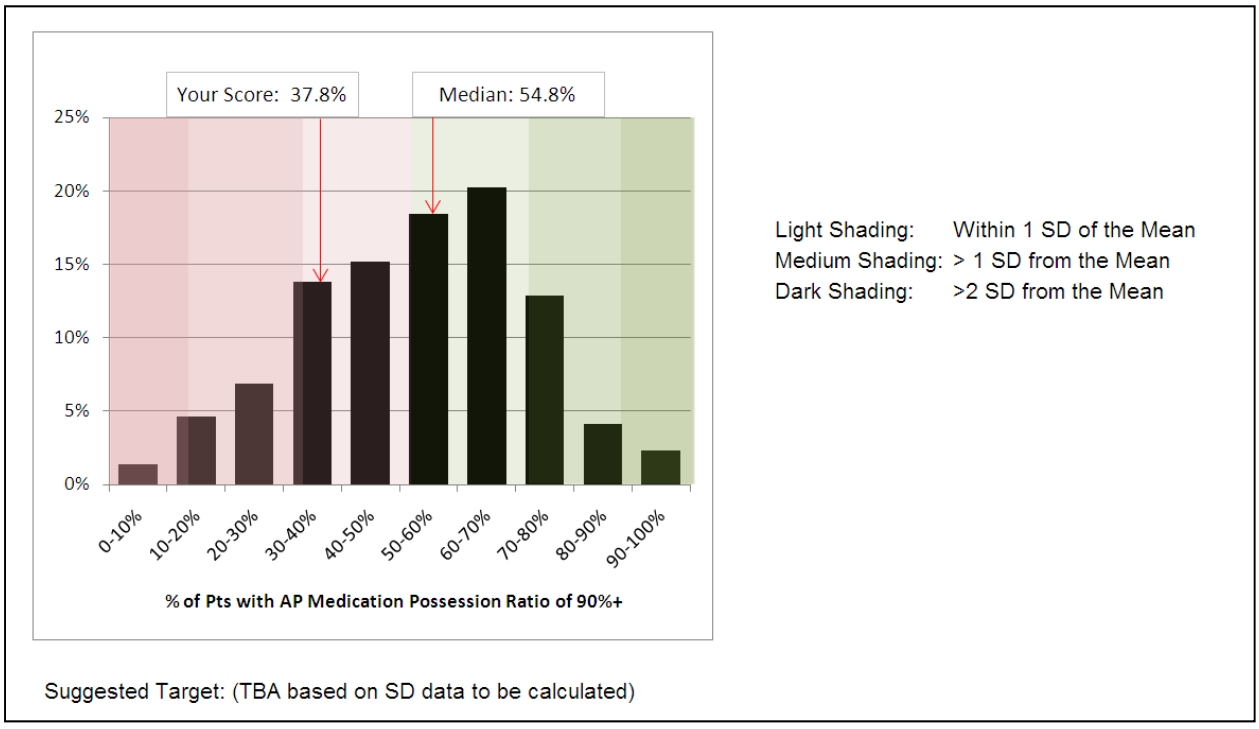
Finally, we would like to comment of improvements that we suggest for Phase II of this project. We base our recommendations of several summary observations:

- Participants often commented that the introductory letters were written with a harsh and critical tone, and did not fully explain the structure and goal of the project.
- Participants found the AMR to be difficult to interpret (or disagreed with the results) – especially the "best prescribers" column.
- The "average prescriber" column seemed like a "low bar" figure for prescribers to compare themselves to.
- We felt the prescriber could have been engaged into the review process more.

Phase II Project Recommendations:

- We suggest that the "welcome" letters be revised to make to tone more collegial, while also being more transparent as to the structure and purpose of the program.
- We suggest that the AMR format be revised to display a bell-curve instead of a bar-graph – with clearly written target (and rationale for calculating the targets). See Figure 4.
- We suggest that the data collected by the project we quantifiable as much as possible, to avoid subjecting interpretations. For instance, we will work to develop an algorithm formula for selecting cases for discussion to replace the more subjective method used in phase 1. We will also review our data collection tool to maximize structured data collection.
- We also suggest considering activating the prescriber more in the review process. For instance, developing a self-review form that the prescriber completes before the interview that documents rationale for Polypharmacy ahead of time.

Figure 4: Proposed AMR Bell-curve



Summary

We are half-way through the two-year peer review project in partnership with the HCA. We have had the pleasure to talk with a number of prescribers who do the difficult work of serving some of our most vulnerable community members – and we hope our efforts have been valuable and useful to them and their patients, while also serving to meet the goals of this project. We look forward to Phase 2 of the study – where we hope to collect additional data and to leverage the lessons and experience gained during this phase of the project.