North Carolina Department of Health and Human Services

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Adam Sholar
Legislative Counsel
Director of Government Affairs

April 1, 2014

SENT VIA ELECTRONIC MAIL

The Honorable Ralph Hise, Co-Chair
Joint Legislative Oversight Committee on
Health and Human Services
Room 1026, Legislative Building
Raleigh, NC 27603

The Honorable Justin Burr, Co-Chair
Joint Legislative Oversight Committee on
Health and Human Services
Room 307A, Legislative Office Building
Raleigh, NC 27603-5925

The Honorable Mark Hollo, Co-Chair
Joint Legislative Oversight Committee on
Health and Human Services
Room 639, Legislative Office Building
Raleigh, NC 27603-5925

Dear Senator Hise and Representatives Burr and Hollo:

Session Law 2013-360, Sections 12H.28 (a) and (b) require Community Care of North Carolina (CCNC) and the Department of Health and Human Services, Division of Medical Assistance (DMA), to continue to monitor the use of antipsychotic medications for Medicaid recipients under the age of 18 through the Antipsychotics – Keeping It Documented for Safety (A+KIDS) program and to continue to utilize a prior authorization policy for off-label antipsychotic medication prescribing for Medicaid recipients 18 years of age and older through the Adult Safety with Antipsychotic Prescribing (ASAP) program. CCNC and DMA are required to report to the Joint Legislative Oversight Committee on Health and Human Services on the effectiveness of these programs no later than April 1, 2014.

The A+KIDS and ASAP Effectiveness Report produced by DMA and CCNC accompanies this letter. Of note, the report mentions a temporary disruption of certain edits following implementation of NCTracks. The capability is currently scheduled to be added to NCTracks in an upcoming release.

Please direct all questions concerning this report to Dr. Lisa Weeks, Division of Medical Assistance, Acting Assistant Director, Pharmacy and Ancillary Services, 919-855-4305, Lisa.Weeks@dhhs.nc.gov or Dr. Troy Trygstad, CCNC, Vice President, Pharmacy Programs, 919-745-2432, Troy@t2email.com.

Sincerely,

Adam Sholar

cc:

Sandra Terrell	Pam Kilpatrick
Jim Slate	Susan Jacobs
Matt McKillip	Patricia Porter
Sarah Riser	Kristi Huff
Brandon Greife	Theresa Matuala
Joyce Jones	Rod Davis
Robin Cummings	Steve Owen
reports@ncleg.net	

April 1, 2014

Representative Justin P. Burr, Co-Chair
Joint Legislative Oversight Committee on Health and Human Services
NC General Assembly
Legislative Office Building, Room 307A
300 North Salisbury Street
Raleigh, NC 27603

Dear Chairman Burr:

Section 12H.28 (a)-(b) of Session Law 2013-360 directs Community Care of North Carolina (CCNC) and the Department of Health and Human Services, Division of Medical Assistance (DMA) to report on the effectiveness of two programs, "Antipsychotics – Keeping It Documented for Safety" (A+KIDS) and "Adult Safety with Antipsychotic Prescribing" (ASAP). The attached report, which fulfills this legislative requirement, was developed collaboratively among DMA and CCNC staff.

For the A+KIDS program, the report reveals that prescriptions for antipsychotics were reduced as was the occurrence of antipsychotic polypharmacy. It also reveals that a utilization management program can be successfully implemented without causing gaps in therapy and unnecessary emergency room visits and hospital stays. There is less success to report on the ASAP program. That's because despite an initial decline in in the rate of antipsychotic use among adult Medicaid recipients, their utilization rate eventually rose to and exceeded pre-policy levels.

We recommend that A+KIDS program be continued. We also recommend the same for the ASAP program, but that it's continuation be tied to having access to an on-line system and strengthening the management and oversight by DMA and CCNC – two contributing factors that, in my opinion, explain why A+KIDS was so successful and ASAP was less so.

Should you have any questions regarding this report, please feel free to contact Troy Trygstad, PharmD, PhD, my Vice President of Pharmacy Programs. He can be reached at 919-745-2395.

Sincerely,

L. Allen Dobson, Jr., MD
President & CEO

LAD:mtb

Attachment

Community Care of North Carolina

2300 Rexwoods Drive, Suite 200, Raleigh, NC 27607
919-745-2350 919-745-2351
www.communitycarenc.com

cc: Secretary Aldona Wos, DHHS
Dr. Robin Cummings, DHHS
Matt McKillip, DHHS
Adam Sholar, DHHS
Sandy Terrell, DMA
Lisa Weeks, DMA
Torlen Wade
Mark Benton
Tom Wroth
Troy Trygstad
John Thompson
Amy Hobbs

ANTIPSYCHOTICS – KEEPING IT DOCUMENTED FOR SAFETY (A+KIDS)
ADULT SAFETY WITH ANTIPSYCHOTIC PRESCRIBING (ASAP)
EFFECTIVENESS REPORT

S.L. 2013-360, Section 12H.28 (a) and (b)

April 1, 2014

Contributors

Robert Christian, M.D., FAAP, Assistant Professor of Pediatrics and Psychiatry, The Carolina Institute for Developmental Disabilities at UNC Chapel Hill

Joel F. Farley, Ph.D., Associate Professor, UNC Eshelman School of Pharmacy

Jerry McKee, PharmD, MS, BCPP, Regional Dean and Associate Professor of Pharmacy, Wingate University School of Pharmacy

Kathleen Moran, MSPH, Behavioral Health Program Analyst, CCNC

Trista Pfeiffenberger, PharmD, MS, Director of Network Pharmacy Programs, CCNC

Theodore Pikoulas, PharmD, BCPP, Associate Director of Behavioral Health Pharmacy

Charlene Sampson, RPh, Mental Health Pharmacy Programs, Division of Medical Assistance

Brian Sheitman, M.D., Professor of Psychiatry, Medical Director, UNC Healthcare at Wakebrook

Casey M. Thompson-Schwartz, CPhT, Pharmacy Programs Assistant, CCNC

Troy Trygstad, PharmD, MBA, PhD, Vice President, Pharmacy Programs, CCNC

Lisa Weeks, BSPharm, PharmD, Acting Assistant Director, Pharmacy and Ancillary Services, Division of Medical Assistance

Steven Wegner, MD, JD, President, AccessCare

EXECUTIVE SUMMARY

PURPOSE: Pursuant to Section 12H.28 (a) and (b) of S.L.2013-360, Appropriations Act of 2013, the General Assembly has directed Community Care of North Carolina (CCNC) and the Department of Health and Human Services, Division of Medical Assistance, to continue monitoring the prescription and administration of atypical antipsychotic medications to Medicaid recipients under the age of 18 through the Antipsychotics – Keeping It Documented for Safety (A+KIDS) registry and to continue to utilize a prior authorization policy for the off-label use of antipsychotic medication prescribing for Medicaid recipients 18 and older through the Adult Safety with Antipsychotic Prescribing (ASAP) program. This is the required effectiveness report that is to be submitted to the Joint Legislative Oversight Committee on Health and Human Services.

PROGRAMS: The Division of Medical Assistance (DMA) in collaboration with Community Care of North Carolina implemented in April 2011 the Antipsychotics-Keeping It Documented for Safety program (A+KIDS). The Adult Safety with Antipsychotic Prescribing program (ASAP) was implemented March 2012. The A+KIDS program is for Medicaid and Health Choice beneficiaries ages 0 through 17, while the ASAP program is for Medicaid beneficiaries age 18 and older. Both programs capture documentation to support safe use of antipsychotics if:

- An antipsychotic is prescribed without a clinical diagnosis corresponding to an FDA approved indication;
- An antipsychotic is prescribed in an amount differing from the FDA approved dosage for that indication; and if
- The prescribed antipsychotic will result in intraclass polypharmacy defined as combination therapy with two or more antipsychotics outside a 60 day calendar window allowing for cross titration when converting agents.

In accordance with legislative requirements, there are currently no restrictions on the choice of antipsychotic drugs prescribed.

Guidance for the development of the A+KIDS and ASAP programs was provided by psychiatric experts from the four major teaching universities across the state, CCNC staff with specialized training in mental health, and policy staff from DMA. The policy implementation procedures required by DMA allowed stakeholders such as the North Carolina Psychiatric Association, mental health providers, and advocacy entities to provide input prior to implementation about the policies supporting the A+KIDS and ASAP programs.

RESULTS: The A+KIDS Program has increased the quality of care for children and adolescents on antipsychotics while decreasing costs. After consistent increases in outpatient utilization and pharmacy costs for antipsychotic drugs since 2007, claims data shows the A+KIDS program was able to substantially reduce the number of antipsychotic fills for children enrolled in Medicaid and also led to a substantial decrease in the prevalence of antipsychotic polypharmacy for children enrolled in Medicaid. Prior to the program's start, the rate of antipsychotic polypharmacy was increasing. After implementation, there was a

substantial and consistent monthly decrease in overall use of these drugs in children. Along with the decrease in antipsychotic fills and polypharmacy, there was also an increase in the monitoring of glucose and lipids for this population, which is consistent with current best practice guidelines.

The ASAP Program has less restrictive documentation requirements when compared to the A+KIDS program. Antipsychotic prescribing in adults is more frequently done under on-label circumstances and, although severe adverse effects from antipsychotics can occur in the adult population, the threshold for the development of adverse effects can differ greatly compared to the pediatric population. The primary focus of the ASAP program is to ensure patients and/or their guardians are informed about the potential adverse effects of these highly potent psychoactive medications. While there has been a response to documentation of informed consent resulting from the ASAP program, a review of claims data suggests that no significant change overall has occurred in prescribing or drug utilization patterns following implementation of the ASAP program.

KEY LESSONS LEARNED: Some global lessons learned from the implementation of the web-based registry program in children (A+KIDS) include:

- Strong infrastructure, stakeholder involvement, and ongoing support were essential for the successful implementation of this program. In order to reach prescribers and pharmacies across the state, the CCNC structure (along with stakeholder assistance) was heavily relied upon in spreading the word about the program and reinforcing best practice prescribing and monitoring.
- Gradual implementation was vital to the program's success. This gradual implementation allowed time to reach out to high volume providers, educate the community, and minimize disruptions in the acquisition of medication for children and adolescents.
- Pharmacist-Prescriber relationships were essential to making this program run smoothly. Pharmacists effectively communicated with prescribers regarding opportunities to temporarily override the program requirements to ensure minimal disruption to a patient's access to medications while also ensuring that the patient received consistent care and continual safety monitoring.
- There are ongoing efforts underway, but challenges still remain, towards ensuring that the A+KIDS' web-based system becomes a part of the prescriber's clinical workflow. Maximizing automation continues to be a program focus.

There is one additional lesson learned unique to the ASAP program:

- A program designed with broad criteria and multiple exemptions may have little impact on utilization. In order to have a greater impact on off-label use, the program may need to employ tighter criteria with fewer exemptions and overrides, while being implemented in a gradual, staged approach that allows for close operational monitoring.

RECOMMENDATIONS: The following recommendations should be considered:

A+KIDS Program

- Develop incentives for providers. Motivating providers to use the A+KIDS registry has the added bonus of increasing the quality of the clinical information gathered. Possible incentives include:
  - Automatic loading of data from other sources
  - Offering maintenance of certification credits
  - Developing a "Preferred Provider" status that allows for less registry use for those prescribers who consistently follow best practice in safety monitoring
- Develop plans for more active monitoring, and embrace best practice education and awareness efforts around psychotropic polypharmacy prescribing. While decreases in polypharmacy have been observed, continued vigilance and renewed focus on polypharmacy and care coordination for patients with polypharmacy use is warranted.
- Involve stakeholders in all future considerations. Their input and involvement have been essential for the success of the A+KIDS program and should be included in any future program.

ASAP Program

- Develop more refined and directive criteria to address continued off-label use of antipsychotics among the adult population.
- Develop an electronic process for ASAP similar to the A+KIDS registry. This would expand the opportunity for robust program evaluation and may allow incentives for provider participation.
- Develop plans for monitoring psychotropic polypharmacy and continuity of therapy with transitions from facility to community-based care settings and, conversely, from community-based care to facilities.

Preamble: Medicaid pediatric populations have experienced significant growth in the prescribing of antipsychotic medications, particularly second generation or 'atypical' antipsychotic agents.[1,2] Second generation antipsychotics carry a much higher risk of weight gain and metabolic problems, including dyslipidemia and diabetes mellitus.[3-5] Of particular concern, metabolic side effects appear more prominent in children than in adults[6] and are poorly monitored[7,8] despite clinical recommendations.[9] These safety concerns are coupled with evidence that a significant amount of antipsychotic use in children is for conditions where there is limited long-term data to support continued use.[10] In response, many Medicaid programs have adopted prior authorization requirements for patients meeting certain criteria.[11] These policies have been shown to reduce Medicaid spending[12] but may also result in treatment disruptions and unintended consequences.[13] In addition, these policies do not address issues of safety, including monitoring for metabolic side effects. National and state level concerns from the USDHHS Office of the Inspector General, the American Academy of Pediatrics, the American Psychiatric Association, and state Medicaid programs led to the creation of the Antipsychotics – Keeping It Documented for Safety (A+KIDS) and Adult Safety with Antipsychotic Prescribing (ASAP) programs.

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Part 1: Report Introduction

PURPOSE: Pursuant to Section 12H.28 (a) and (b) of S.L.2013-360, Appropriations Act of 2013, the General Assembly has directed Community Care of North Carolina (CCNC) and the Department of Health and Human Services Division of Medical Assistance, to continue monitoring the prescription and administration of atypical antipsychotic medications in Medicaid recipients under the age of 18 through the Antipsychotics – Keeping It Documented for Safety (A+KIDS) registry and to continue to utilize a prior authorization policy for the off-label use of antipsychotic medication prescribing for Medicaid recipients 18 and older through the Adult Safety with Antipsychotic Prescribing (ASAP) program. This is the required effectiveness report that is to be submitted to the Joint Legislative Oversight Committee on Health and Human Services.

Part 2: Timeline of Key Milestones

September 2010:	A+KIDS early policy development begins
December 2010:	DMA A+KIDS policy posted for 45 day public comment period
January 2011:	DMA A+KIDS policy 45 day public comment period ends
March 2011:	Website (www.documentforsafety.org) is released for public viewing; "Document for Safety" provider call center is opened; educational efforts to various NC medical associations and societies about A+KIDS begins; A+KIDS prescriber registration function available
April 2011:	Initial version of A+KIDS registry is implemented for children under 13 years of age (phase I); DMA vendor begins receiving faxed safety documentation
May 2011:	Implementation of A+KIDS pharmacy point of sale (POS) edit; CCNC begins pharmacy calls to provide education on the program and assist with troubleshooting individual claim rejections
July 2011:	Period of unlimited pharmacy overrides is extended (no end date set)
August 2011:	Implementation of phase II – inclusion of NC Medicaid recipients 13-17 years of age; A+KIDS registered providers receive program update and phase II education via email
September 2011:	CCNC education and outreach to providers prescribing antipsychotics for children and/or adolescents but not yet participating in the A+KIDS program
January 2012:	Opportunity for providers to give feedback on A+KIDS program via a web-based survey
February 2012:	NC Health Choice children are added to the A+KIDS Program; CCNC conducts education and outreach to providers prescribing antipsychotics for children and/or adolescents but not yet participating in the A+KIDS program
March 2012:	A+KIDS: Unlimited pharmacy override period ends (now limited to 2 overrides per rolling calendar year); education provided to providers regarding changes to pharmacy overrides ASAP: CCNC pharmacists begin medical and pharmacy provider education for the ASAP program; ASAP education is sent to NCAPA, NC Medical Society, NCHA, NC Medical Board, and NC Neurological Society; ASAP program is implemented; CCNC follow up on individual antipsychotic medication claims is shifted from A+KIDS to ASAP

April 2012:	A+KIDS: CCNC begins outreach to A+KIDS providers making them aware of overrides used for individual patients who need safety documentation ASAP: CCNC and DMA begin pharmacy outreach for high priority ASAP medications; CCNC call center delivers telephone education to top 100 pharmacies by antipsychotic prescription volume
May 2012:	ASAP: Pharmacies surveyed about knowledge of the ASAP program; CCNC re-education to pharmacies with high volumes of ASAP claims rejections
June 2012:	A+KIDS: Registered providers sent email summary of A+KIDS first year in operation; overrides reset (now limited to 2 overrides per rolling calendar year);
September 2012:	ASAP: Overrides reset
March 2013:	A+KIDS: New A+KIDS facsimile form effective; provider notification of individual patient override use ends
July 2013:	A+KIDS and ASAP: NCTracks conversion occurs; A+KIDS and ASAP pharmacy edits are temporarily suspended

Part 3: Directive and Interpretation of Legislative Intent

The legislation as enacted (below) directed CCNC and DMA to monitor and continue the A+KIDS program for children prescribed antipsychotics in Medicaid and Health Choice. The A+KIDS program is a web-based application where providers can register patients, track antipsychotic treatments prescribed over time, and document safety monitoring. The original A+KIDS and ASAP programs were based on session laws that first appeared in 2010 (SL 2010-31) and continued through 2013 (SL 2013-360), requiring continuation of the program and preparation of this report.

Session Law 2010-31 allowed the Department of Health and Human Services to address off-label prescribing of antipsychotics:

SECTION 10.22.(a) 28. *Prior authorization – The Department of Health and Human Services shall not impose prior authorization requirements or other restrictions under the State Medical Assistance Program on medications prescribed for Medicaid recipients for the treatment of (i) mental illness, including, but not limited to, medications for schizophrenia, bipolar disorder, major depressive disorder or (ii) HIV/AIDS. Medications prescribed for the treatment of mental illness shall be included on the Preferred Drug List (PDL). The Department of Health and Human Services, Division of Medical Assistance, may initiate prior authorization for the prescribing of drugs specified for the treatment of mental illness by providers who fail to prescribe those drugs in accordance with indications and dosage levels approved by the federal Food and Drug Administration. The Department may require retrospective clinical justification for the use of multiple psychotropic drugs for a Medicaid patient. For individuals 18 years of age and under who are prescribed three or more psychotropic medications, the Department shall implement clinical edits that target inefficient, ineffective, or potentially harmful prescribing patterns. When such patterns are identified, the Medical Director for the Division of Medical Assistance and the Chief of Clinical Policy for the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services shall require a peer-to-peer consultation with the target prescribers. Alternatives discussed during the peer-to-peer consultations shall be based upon:*
a. Evidence-based criteria available regarding efficacy or safety of the covered treatments; and
b. Policy approval by a majority vote of the North Carolina Physicians Advisory Group (NCPAG) The target prescriber has final decision-making authority to determine which prescription drug to prescribe or refill.

Session Law was updated in 2013 to continue the A+KIDS and ASAP programs, to seek a mechanism to increase the effectiveness of the ASAP program, and to report on their effectiveness.

SECTION 12H.28.(a) of S.L.2013-360 CONTINUE A+KIDS REGISTRY AND ASAP INITIATIVE

Community Care of North Carolina (CCNC) and the Department of Health and Human Services, Division of Medical Assistance, shall continue to do the following:

(1) Monitor the prescription and administration of atypical antipsychotic medications to Medicaid recipients under the age of 18 through the Antipsychotics – Keeping It Documented for Safety (A+KIDS) Registry.

(2) Utilize a prior authorization policy for off-label antipsychotic medication prescribing with safety monitoring for Medicaid recipients 18 and older through the Adult Safety with Antipsychotic Prescribing (ASAP) Initiative.

SECTION 12H.28.(b) No later than April 1, 2014, Community Care of North Carolina (CCNC) and the Department of Health and Human Services shall report to the Joint Legislative Oversight Committee on Health and Human Services on the effectiveness of the programs listed in subsection (a) of this section.

Over the last three decades, point of sale (POS) utilization management has been the primary modality employed by payers to minimize drug expenditures in the United States. Unlike medical or other types of claims adjudication that occur after the provision of a product or service, pharmacy claims are adjudicated prior to the provision of the product to the plan member (otherwise referred to as "point of sale" or POS). As such, pharmacy claims adjudication systems provide a convenient mechanism by which a payer can interact bi-directionally with a pharmacy provider during or prior to the provision of a product (sale), such as filling a prescription medication or delivering a service. A pharmacy "edit," in the form of a claim rejection, or a "stop," is an effective mechanism for preventing a medication from being dispensed until further steps are taken to approve or change the prescription. Historically, these "stop(s)" have been deployed in two general categories: Drug Utilization Review (DUR) and Prior Authorization (PA). DUR tends to be less specific to the payer and more specific to clinical issues, such as alerting the pharmacy to therapeutic duplications, above recommended dosing, and early refills. These DUR alerts can often be overridden at the pharmacy (and as such are referred to as a "soft edit"). In contrast, a PA tends to have specific clinical criteria for coverage approved by the payer and typically cannot be overridden by the pharmacy (a "hard edit"). Prescriber action is required for approval and successful claim adjudication at the pharmacy. Both DUR and PA are now widely deployed across nearly all payers, plans and drug benefits in the United States.

While DUR edits tend to be overridden with very high frequency, PA approval rates are often much lower. Additionally, some medications requiring PA are never filled at the pharmacy, leading to attrition from therapy since the patient may need to wait days for an approval to be requested by a prescriber and approved by the payer or pharmacy benefits manager. These traits of PA make them very effective at minimizing drug expenditure, with the two most common types being: 1) step therapy, which requires a patient to try and fail another product prior to coverage of the prescribed medication and 2) clinical criteria, which requires the patient to have a certain medical condition or meet other pre-requisites (such as testing or lab monitoring) for a particular medication to be covered by a plan.

While effective at minimizing drug costs, these conventional modalities leave much to be desired in the way of improving care delivery and monitoring for patients. However, with the advent of accountable care efforts and the ever increasing role of specialty pharmacy, conventional drug utilization management modalities and methods are likely to be replaced by processes and technical solutions. These solutions meet the future need for managing not the drug budget, but rather the total cost of care through individualized, longitudinal, and interactive drug utilization management programs that balance risk, benefit and cost simultaneously by pushing responsibilities, monitoring and best practice use of medications down to prescribers and pharmacies.

The prescribing practices of significant concern with antipsychotic medications are related to off-label use, including higher than recommended doses and intra-class polypharmacy, with antipsychotic medications in

children/adolescents lending themselves to guidance in terms of safety monitoring. Similar concerns exist for adults, but the long term adverse health outcomes related to overutilization of these medications in children was of primary concern. These concerns led to discussions at the state policy making level, resulting in a proposal for a web-based safety monitoring registry for Medicaid and Health Choice eligible beneficiaries under 18 years of age. The intent of this was to improve the quality of care around the use of antipsychotic medications in these populations, decrease morbidity, and reduce unneeded prescribing of antipsychotic medication for children, while maintaining open access to all antipsychotic medication choices for providers. The registry concept was deemed a "prior safety documentation" process versus a traditional "prior authorization" process. The sole criteria for authorization approval is participation, in that clinicians were not prohibited from prescribing antipsychotic medications on an off-label basis to children/adolescents; however, documentation of evidence-based safety monitoring is a requirement for claims payment.

To facilitate program development, CCNC and DMA partnered to create a safety-based monitoring program which was intended to:

1) Improve the use of evidence-based safety monitoring for patients for whom an antipsychotic agent is prescribed
2) Reduce occurrence of antipsychotic polypharmacy
3) Reduce cases in which the FDA maximum dose is exceeded.

Part 4: A+KIDS Program Description, Implementation, and Evaluation

Program Description

The A+KIDS program is novel in that it retains provider choice in antipsychotic medication selection but still requires documentation of safety monitoring for coverage during claims submission by the pharmacy. Prescribing remains fully within the purview and professional judgment of the prescriber. The documentation is obtained through use of a web-based electronic medication registry. The electronic registry has the functionality to allow prescribers to register patients, track antipsychotic treatment, and document safety monitoring.

The primary goals of the A+KIDS program are to: improve the use of evidence-based safety monitoring for patients for whom an antipsychotic agent is prescribed; reduce antipsychotic polypharmacy, and reduce cases in which the FDA maximum dose is exceeded. It was paramount that the initiative minimize disruption to patient/caregiver and prescriber and pharmacy workflow. Key principles of the A+KIDS program are to be transparent and evidence-based; to include involvement by all stakeholders, including professional associations, advocacy groups, mental health departments, and pharmacy representatives; to preserve open access to all antipsychotics; and to encourage best practices for monitoring of adverse effects.

The A+KIDS program was phased into use in three separate stages to minimize disruption. Provider registration began in March 2011. This was done in advance to ensure high volume antipsychotic prescribers received education and were registered before the official launch of the program. Beginning in April 2011, the system was available for providers to document safety and monitoring information for children ages 12 and younger. Finally, in August 2011, the system was expanded to capture additional safety monitoring data and include adolescents ages 13 to 17 in the program. The program infrastructure and staged approach allowed for significant time to educate and prepare providers and pharmacists for the A+KIDS implementation. In addition, a call center was available 40 hours a week to assist with provider registration, prescription claims denials, and other support needs.

Unlike traditional PA programs, A+KIDS does not restrict access to medications based on criteria related to medication choice, dose, or indication. Instead, the A+KIDS program was designed to enhance patient safety by improving compliance with safety monitoring recommendations, guiding prescribers through a decision making process on risks and benefits of antipsychotic use, and providing a platform for the ongoing tracking of patient adverse effects that can be evaluated at the patient, provider, or drug level. If providers are unable to use the web-based registry, they can use an alternative fax form to submit safety and monitoring documentation, but the system is structured to incentivize use of the web-based tool (web-based authorizations receive longer approval periods than authorizations obtained via faxed documentation). CCNC network pharmacists are available to field any needs regarding specific pharmacy/medical provider education or concerns related to specific patient antipsychotic prescriptions. The system supports standard pharmacy DUR alerts regarding high dose, drug interactions, and therapeutic duplications. A limited number of pharmacy overrides are allowed for each patient so as to prevent disruption in therapy and allow providers time to submit safety documentation before the next prescription fill.

Novel approaches to improving evidence-based prescribing and monitoring of clinical safety for antipsychotic treatments are necessary to improve care. As Medicaid programs struggle with the gravity and complexity of antipsychotic use in children, the A+KIDS program provides a unique approach to improving antipsychotic prescribing in the pediatric population based on widely accepted best practices.

Stakeholder Participation

The policy governing the A+KIDS program was developed by the internal clinical administrative team and reviewed by the Child and Adolescent Psychiatry advisory panel (consisting of providers from all four of North Carolina's medical schools) and the NC DMA Physician Advisory Group. The policy was then posted for the required public review/comment period. Due to the unique design of the A+KIDS program, it was recognized that education to providers, community pharmacies, advocacy groups, and others was critical for the success of this practice shift. Input from stakeholders helped to shape the policy, and stakeholders also assisted with policy education and information dissemination. Educational efforts were essential to the success of the program, including information in news blasts, bulletins, and on website posts from the following groups:

- North Carolina Medical Board
- North Carolina Pediatric Association
- North Carolina Academy of Family Physicians
- North Carolina Hospital Association
- North Carolina Academy of Physician Assistants
- North Carolina Psychiatric Association
- North Carolina Medical Society
- NC Chapter of National Alliance on Mental Illness.

Web-Based Safety Monitoring Portal

The web-based quality and safety monitoring portal requires prescribers to input information regarding each patient under age 18 for whom an antipsychotic agent is prescribed. The application is accessible only to registered providers via www.documentforsafety.org. Information entered into the registry (or submitted via fax) allows for a determination of whether the antipsychotic use is within the FDA's labeling and whether regular safety monitoring is being conducted. Additionally, the information also helps the program's clinical leaders to determine where provider educational needs exist and the scope and nature of potential areas for provider level improvement. Data elements collected include the following:

Antipsychotic Treatment Regimen Details

- Prescriber
- Patient Age
- Medication prescribed – name, dose, frequency of administration
- Primary diagnosis related to antipsychotic therapy
- Specific target symptoms (psychosis, mania, irritability, aggression toward self, aggression toward others, other free text entry).

Adverse Effects and Clinical Assessment Monitoring

Due to the increased association of weight gain, cholesterol abnormalities, and blood glucose dysregulation with antipsychotic agents, specific monitoring (at baseline and pre-determined intervals in therapy) is recommended by several expert panels, including the American Psychiatric Association and the American Academy of Child and Adolescent Psychiatry. In addition, some further monitoring may be necessary for specific cases based upon the clinician's professional judgement and/or expert consultation. The registry asks for the following clinical information:

- Patient height and weight
- Blood glucose and cholesterol levels
- Presence of side effects (sedation, restlessness, other)
- Results of a movement assessment
- Provider assessment of therapy effectiveness
- Parent/Guardian preference regarding continuation of the medication.

Questions within the portal are designed to allow for prompt entry of information by providers – using check boxes, drop-down menus, or brief text fields. While all questions must be addressed in order to successfully complete an authorization, many have answers which include "not applicable" or "not available" enabling a provider to continue through the authorization even if lab results are not available. All information requested is based on existing practice guidelines and supporting clinical evidence. Providers who are familiar with the system report that it takes only a few minutes to enter safety documentation for a single patient.

Program Outreach and Education

Pharmacy Education and Outreach

A list of community pharmacy fax numbers obtained from the NC Board of Pharmacy was used to communicate the initial A+KIDS program information to pharmacies across the state. The same information was faxed to the pharmacies on four different days and times in order to maximize the number of pharmacy employees who received the information, and follow up education was conducted specifically with 126 pharmacies across the state that fill a relatively high number of antipsychotic prescriptions for the A+KIDS population. Follow up education included the DMA policy, explanations of point of sale messaging, and override instructions. Pharmacies were alerted by fax about the program expansion to include Medicaid beneficiaries ages 13-17 and the Health Choice population.

From the start of A+KIDS pharmacy claims processing in May 2011 through March 2012, outreach calls were made by CCNC and DMA staff to pharmacies to follow up on unpaid claims for specific beneficiaries. The current status of the claim was determined by having pharmacy personnel re-run the claim. If the claim was still unpaid because of the alert message "Safety Documentation Required," education about the override process was provided. Once the claim was successfully adjudicated, staff offered to fax the pharmacy an override protocol and the March 2011 Medicaid bulletin that featured an article about the

A+KIDS program. The purpose of the calls was to educate the pharmacies and to prevent delays in patients receiving medications.

Prescriber Education and Outreach

A list of antipsychotic medication prescribers for children was generated using Medicaid pharmacy claims data. The list was shared with CCNC network psychiatrists and pharmacists who worked together to reach out to providers to make them aware of the program and the process of registering. Depending on the number of A+KIDS patients cared for by the prescriber, the CCNC staff communicated information to prescribers either via mail, email, fax, phone, or an in person meeting. Generally, the following tools were offered to prescribers to assist them with their initial use of the registry: 1) a list of their NC Medicaid patients eligible for the A+KIDS program, 2) handouts describing how to register, 3) information about the website, and 4) contact information for people to whom the prescriber could direct questions, concerns, and issues. Contact was made with 240 individual practices/prescribers across the state. In addition to education that was directed toward specific prescribers, the following organizations used their websites, newsletters, and other venues to further educate providers about the A+KIDS program: North Carolina Hospital Association, North Carolina Psychiatric Association, North Carolina Medical Society, North Carolina Board of Medicine, North Carolina Academy of Family Physicians, North Carolina Academy of Physicians Assistants, and the North Carolina Chapter of the National Alliance for Mental Illness.

Throughout the program, prescribers who were registered to use the web-based system received email reminders, and upon login, the registry made them aware of specific patients for whom they had prescribed antipsychotic therapy but were not entered into the registry. Registered letters were also sent to prescribers to make them aware of patients who needed safety documentation. When pharmacy overrides were limited, prescribers were contacted to make them aware that a patient had used either one or two of the available overrides. These communications gave prescribers advance notice allowing the prescriber to know that a patient would be unable to refill his/her medication if the prescriber did not submit safety documentation. Registered prescribers also received periodic email updates containing education about program changes or summaries of program utilization to date.

Provider Support Line

CCNC created a "Document for Safety" provider support call center that is available 8am-5pm Monday through Friday. Support provided by the call center is intended to assist with: prescriber registration, user ID/password issues, patient not found/eligibility messaging, and any other error messages returned during the use of A+KIDS program. The center also responds to general questions and concerns regarding the A+KIDS program. As of March 31, 2013, a total of 1,440 calls were received – the purpose of which fell in one of the following four general categories:

- 508 calls for troubleshooting
- 193 calls for general questions and concerns
- 373 calls for patient registration (patient not found/eligibility messaging and/or authorization concerns)
- 340 calls for prescriber registration.

Provider Survey

In addition to the feedback received through the provider support call center, an electronic survey was sent to 755 registered A+KIDS prescribers in January 2012 soliciting feedback, including ideas for further development of the registry. Ninety (90) responses were received.

The survey consisted of the following four questions:

1. Have you had ongoing problems using the registry? If so, please describe in as much detail as possible.
2. Do you have suggestions for future registry enhancements?
3. There has been a steady chorus of concerns expressed in the national news media and published literature regarding the possible overuse and under-monitoring of antipsychotic medications (the most recent specific to foster children). Given these concerns, North Carolina Medicaid has implemented this registry. Overall, considering both the extra time required of providers and the potential benefits for some children, do you think the registry is worthwhile?
4. Optional - If you have further detailed suggestions or concerns regarding the above topics of the A+KIDS Document for Safety Registry, please provide the best point of contact where you may be reached.

Survey responses were used to identify future enhancements to the registry and training opportunities. Regarding the latter, staff focused on survey responses which suggested that an issue or a problem might exist that could be alleviated by additional training. The majority of providers who responded did not have ongoing problems with the registry. Initially, there were reports of firewall and password issues, but there have been few ongoing reports.

Survey Findings

There were many suggestions for enhancements to the registry:

"The website is very efficient and easy to use. It is hard to get all the lab data but I like that data can be added later if it is not at hand."

Another provider commented:

"[An enhancement would be] access to see who else has been prescribing and view a history. The parents of our Medicaid population don't always remember what has been tried in past. Foster care parents are often more clueless about past medical history or past prescribing."

These suggestions for future enhancements to the registry (i.e., the ability to add lab data at any time and see all antipsychotic medications and prescribers for a given patient) are addressed in the A+KIDS registry version currently under development.

There was also support for continued use of the registry. There were multiple respondents who felt as though they did not need the registry necessarily for their own practice but had seen enough lack of

monitoring in the field to justify the registry, and so were very willing to be a part of it. Some prescribers indicated that they use the data for parental education. See some of the responses below:

"Just having to list the meds is helping to keep child psychiatrists accountable and to explain their rationale for using these medications."

"I am lucky to have trained in a program that was extremely diligent about monitoring for metabolic syndrome in any patient, both adults and children, who were prescribed antipsychotics. I was one of the presenters on the subject at the APA in 2006 so taking an additional step by having to log into a registry and manually inputting data is, honestly, off-putting but understandable given the lack of follow up that some of my colleagues display. I have had patients come to me who have been on antipsychotics for two years and have never had any fasting blood work done and are amazed that we check blood pressure, pulse, height, weight and waist circumference at every visit."

"If the data helps clinical care it is good. I think it does force the doctor to order labs and monitor more closely - again, that is good. There needs to be more way to illustrate how good these meds are for some people – I definitely think this may help weed out unnecessary prescribing. There is a clear role for these meds in some children and we need to be able to prescribe them safely. Maybe you could collect data on what strategies have been effective to prevent the weight gain."

"Yes. I show the parents the area requiring their child's information and explain the safety rationale".

Dashboard

The A+KIDS operations and quality assurance group created a dashboard to continually monitor the program. Based on the findings from the dashboard, which is reviewed monthly, the group:

- Targets education
- Develops outreach activities
- Identifies providers in need of help using the registry
- Identifies providers with excessive use of overrides.

Program Participation and Web Portal Utilization

Data Sources

The following data sources were used to provide the monitoring and evaluation of the program:

Claims: CCNC used both pharmacy and medical claims for NC Medicaid and Health Choice children and adolescents.

Registry Data: Files were provided summarizing all registered providers and antipsychotic authorizations.

Denial Data: The Medicaid fiscal agent provided a daily file which contained all A+KIDS related claims denials at pharmacies statewide.

Override Data: The Medicaid fiscal agent provided a weekly file which contained all A+KIDS pharmacy overrides.

Registry Data Summary

Summary of Registry Usage

- As of 6/4/2013 (including faxes submitted prior to 2/28/2013), a total of 1,650 providers supplied safety documentation resulting in 51,346 unique authorizations for 20,434 patients in the A+KIDS program.
- A total of 640 providers who treat foster care patients provided safety documentation resulting in 6,717 unique authorizations for 2,249 foster care patients.
- Using the web-based registry, 1,042 providers made 43,553 unique authorization requests for 18,794 patients.
- Using the fax form, 1,302 providers faxed in 7,793 unique authorization requests for 5,162 patients.
- 347 of the providers who submitted fax-based documentation have yet to register for the web-based system.
- An additional 1,650 providers have registered but have not submitted any safety documentation (either by fax or the web-based registry).

Summary of Clinical Data

- A little over half of providers (54%) registered five or fewer authorization requests.
- 565 providers submitted safety documentation for 10 or more patients.
- The most commonly requested drug was "Risperdal/Risperidone", making up 41% of total requests.
- "Bipolar Disorder", "ADHD", and "Oppositional Defiant Disorder" were the three most common diagnoses, representing 34% of requests.
- "Aggression towards others", "Irritability" and "Tantrums/temper" were the most common target symptoms, representing 62% of requests.

- 62% of the patients were receiving psychotherapy, with the most prevalent type being "Cognitive Behavioral" (27% of those reported in therapy).
- 36% of patients have been on the medication for over six months.
- Over half (52%) of the medications were first prescribed by an outpatient psychiatrist.

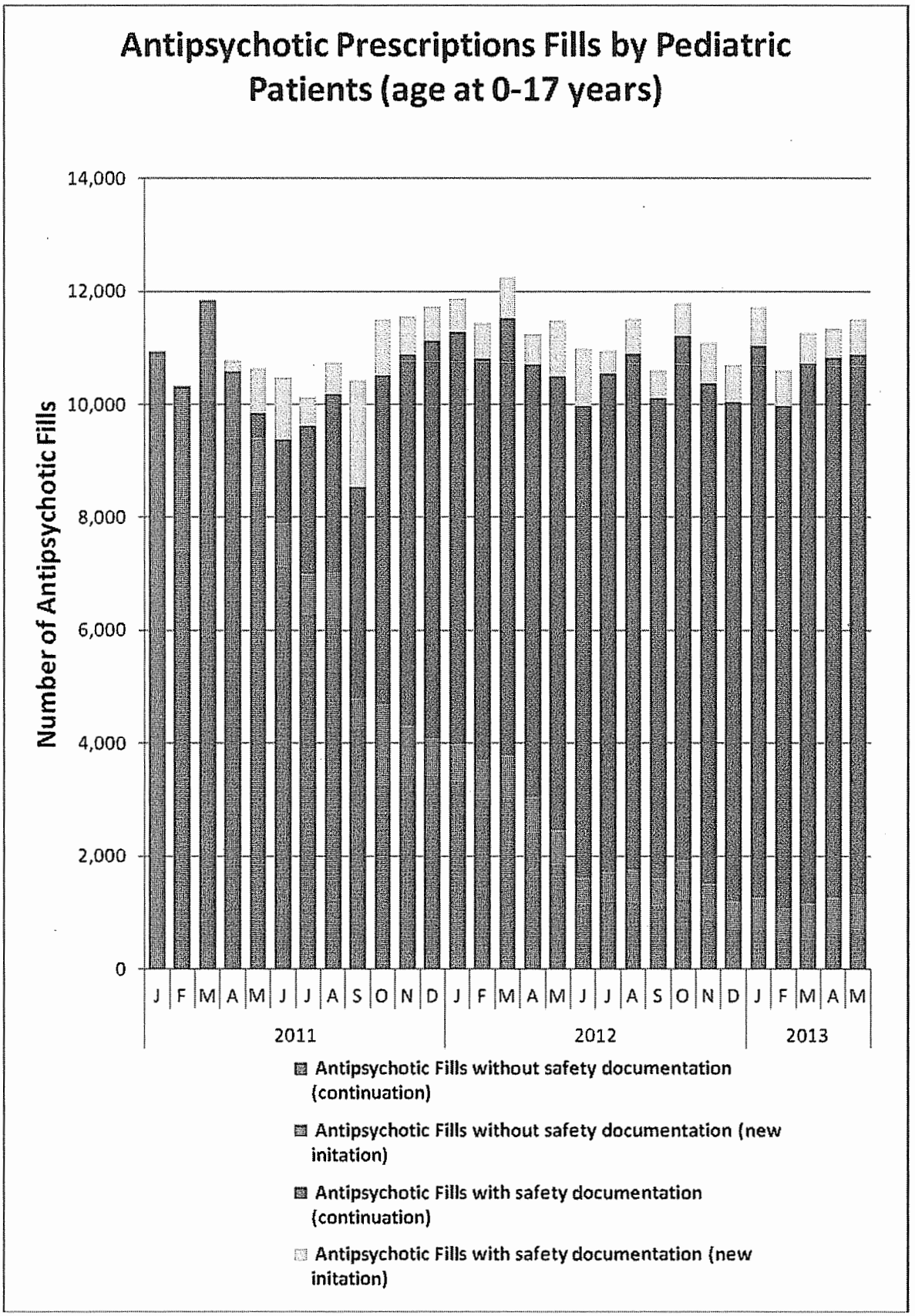
Program Monitoring and Quality Assurance

Operations Dashboard

The operations and quality assurance group from CCNC meets monthly to review a data dashboard to assess the program and address any arising operational concerns and new opportunities for improvement. This dashboard includes the following measures:

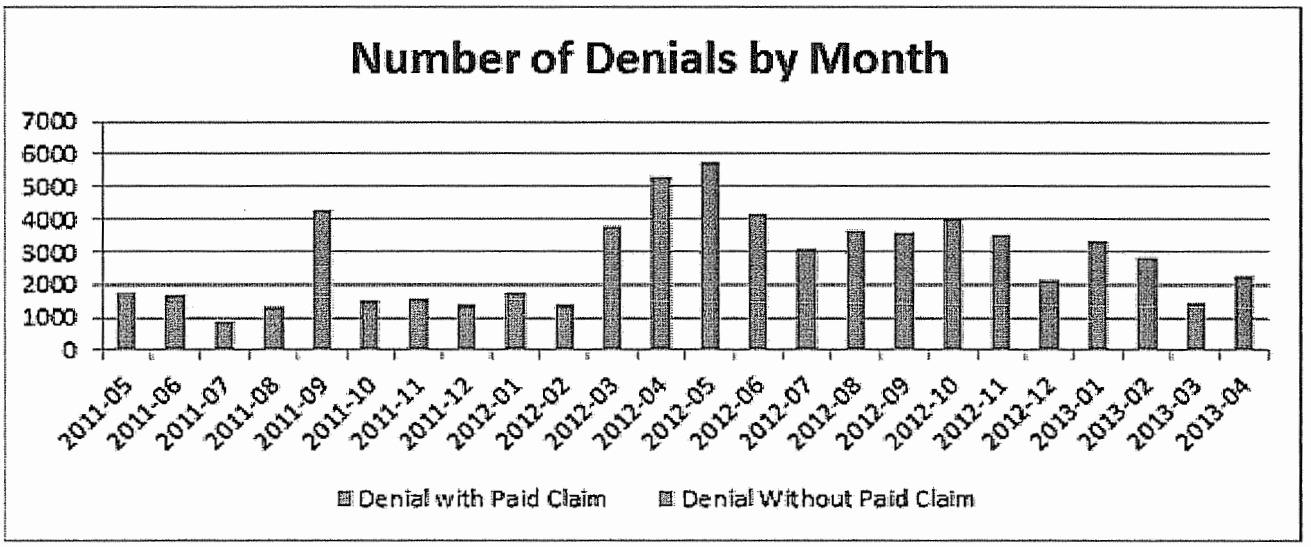
Fills with Documentation

The graph on the succeeding page displays the total number of antipsychotic fills for children and adolescents that have safety documentation. It also further breaks down whether the fill was for continuation of therapy or a new initiation to therapy based on a lack of use in the last 90 days.


Antipsychotic Prescriptions Fills by Pediatric Patients (age at 0-17 years)
Number of Antipsychotic Fills
14,000
12,000
10,000
8,000
6,000
4,000
2,000
0
J F M A M J J A S O N D J F M A M J J A S O N D J F M A M
2011
2012
2013
Antipsychotic Fills without safety documentation (continuation)
Antipsychotic Fills without safety documentation (new initation)
Antipsychotic Fills with safety documentation (continuation)
Antipsychotic Fills with safety documentation (new initation)

Number of Denials per Month

The operations and quality assurance group from CCNC also tracks the ultimate outcome for claims that are initially denied. The chart below details that tracking activity.



Additional Information

The Operations Group looks at information for the program as a whole, but also looks at individual prescribers for areas of potential educational opportunities. Those areas include:

1. Providers with high numbers of unauthorized antispychotic fills
2. Providers who unnnecessarily use the registry for changes that do not affect the authorization (e.g., changes in strength or form of a medication)
3. Providers who use the online system, but unnessarily fax in authorization request forms.

Identified opportuities are directed toward the CCNC networks for provider education, often in a peer-to-peer format.

Children in Foster Care

Ongoing monitoring is also conducted for children in foster care in the A+KIDS registry to assist in program improvement efforts. Children in foster care are treated with psychotropics more frequently than the Medicaid population as a whole (Table 1).

Table 1. Antipsychotic Use in Children in Foster Care

	Number of Children in Foster Care	% of Children in Foster Care	Number of Children in Medicaid Population	% of Children in Medicaid Population
Total Population	12,923		1,029,013	
Receiving at Least 1 Psychotropic Medication	2,636	20.4%	120,585	11.7%
Receiving at Least 1 Antipsychotic Medication	1,207	9.3%	21,512	2.1%

Formal Evaluation of Prescribing, Utilization, and Safety Monitoring

CCNC collaborated with the UNC Eshelman School of Pharmacy, Division of Pharmaceutical Outcomes and Policy to conduct a formal evaluation of the effectiveness of A+KIDS. Their analyses examined how policy and program implementations affected the following:

- Metabolic Monitoring
- Antipsychotic Fills per Day per 1,000 Enrollees
- Number of Antipsychotic Users Per 1,000 Medicaid Enrollees
- Polypharmacy Rates per 1,000 Antipsychotic Users
- Percent of Antipsychotics On- & Off-Label by Age Group
- Mental Health ER Visits Per 1,000 Enrollees Per Month
- Non-Mental Health ER Visits Per 1,000 Enrollees Per Month
- Mental Health Inpatient Admissions Per 1,000 Enrollees Per Month
- Non-Mental Health Inpatient Admissions Per 1,000 Enrollees Per Month
- Mental Health Outpatient Visits Per Enrollee Per Month
- Non-Mental Health Outpatient Visits Per Enrollee Per Month

Metabolic Monitoring

Metabolic Monitoring from the Registry:

In the registry, body mass index (BMI) is entered at baseline and with each follow-up authorization request. Inquiries regarding cholesterol and glucose measurements are made only upon follow up authorizations. Table 2 shows the percent of registry patients who have at least one BMI, cholesterol, or glucose measurement recorded.

Table 2. Percent of Patients with Metabolic Monitoring Recorded in the Registry

	BMI	Glucose	Cholesterol	Triglyceride	LDL†	HDL†
Percent of Patients with Value in Registry	66%	36%	34%	34%	34%	34%

†LDL – Low Density Lipoprotein; HDL – High Density Lipoprotein

Metabolic Monitoring from Claims:

In addition to metabolic monitoring reported by providers in the registry, claims can be used to validate or enhance registry findings. For example, claims data can be used to look at the percentage of patients who received a cholesterol or glucose test over time. While claims data does not provide the results of the laboratory test, it is a helpful mechanism to know how often the standard of care for laboratory testing is being met within the population. As such, Table 3 looks for a cholesterol or glucose measurement claim in the 12 months before and after the first fill of an antipsychotic medication (Table 3).

Table 3. Percent of A+KIDS Patients on an Antipsychotic with Metabolic Monitoring Recorded in Claims

Year Ending	Glucose Screening Percent	Cholesterol Screening Percent
June 2010	52%	27%
June 2011	55%	32%
June 2012	60%	41%

This data shows a 9% and 28% increase in glucose and cholesterol screening, respectively, a year after the A+KIDS program was implemented. A chi-square test was done to see whether the proportion of patients with metabolic screening was higher in 2011 and 2012 than in 2010. For each metabolic monitoring parameter, there was a statistically significant increase in metabolic monitoring in the period after A+KIDS implementation as compared to the period before A+KIDS implementation.

Antipsychotic Fills per Day per 1,000 Enrollees

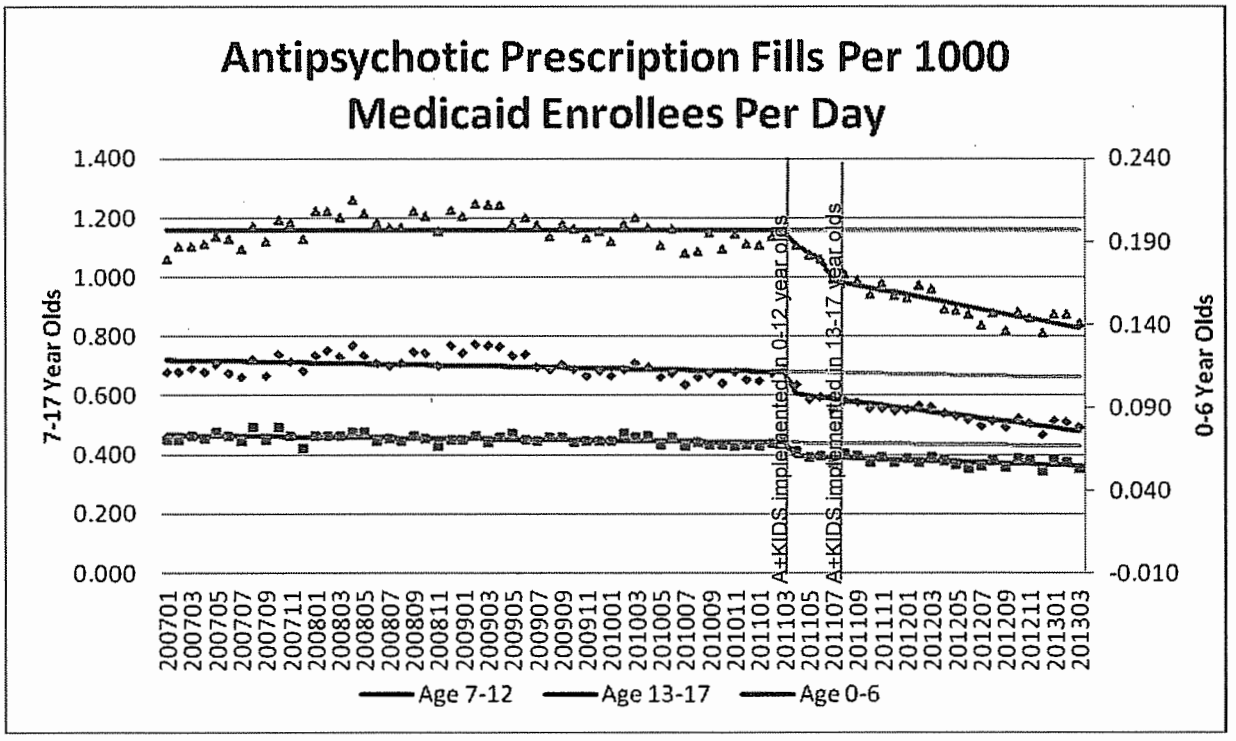
The chart on the succeeding page shows the number of antipsychotic fills per month for every 1,000 enrollees by the three separate age categories: 0-6, 7-12, and 13-17. Each chart is adjusted for the number of Medicaid beneficiaries enrolled each month. Antipsychotic use in children age 6 and under was significantly less than in children at 7-12 or 13-17 years of age. NOTE: The axis denoting this population is listed to the right while the axis for the 7-17 year olds is listed to the left.

Actual utilization for 0-6 year olds, 7-12 year olds, and 13-17 year olds is illustrated as blue squares, red diamonds, and green triangles, respectively. The time-series of actual utilization for each age group is represented as a dark line. In addition, the light shaded line after A+KIDS implementation represents the predicted trend in antipsychotic use had the A+KIDS program not been implemented and the trend continued at the same pace as the period prior to A+KIDS implementation.

Findings 0-6 Year Olds: Antipsychotic use in children 0-6 years of age was slowly but significantly declining prior to A+KIDS implementation. The rate declined at a statistically significant rate of 0.09 prescriptions per 1,000,000 enrollees per day. Following A+KIDS implementation this decline was more rapid at a statistically significant pace of 0.246 prescriptions per 1,000,000 enrollees per day. In addition, there was a one-time decline during the month following A+KIDS implementation equivalent to approximately 7.9 prescriptions per 1,000,000 children 0-6 years of age per day suggesting an immediate policy effect of the A+KIDS program on reducing antipsychotic use in children 0-6.

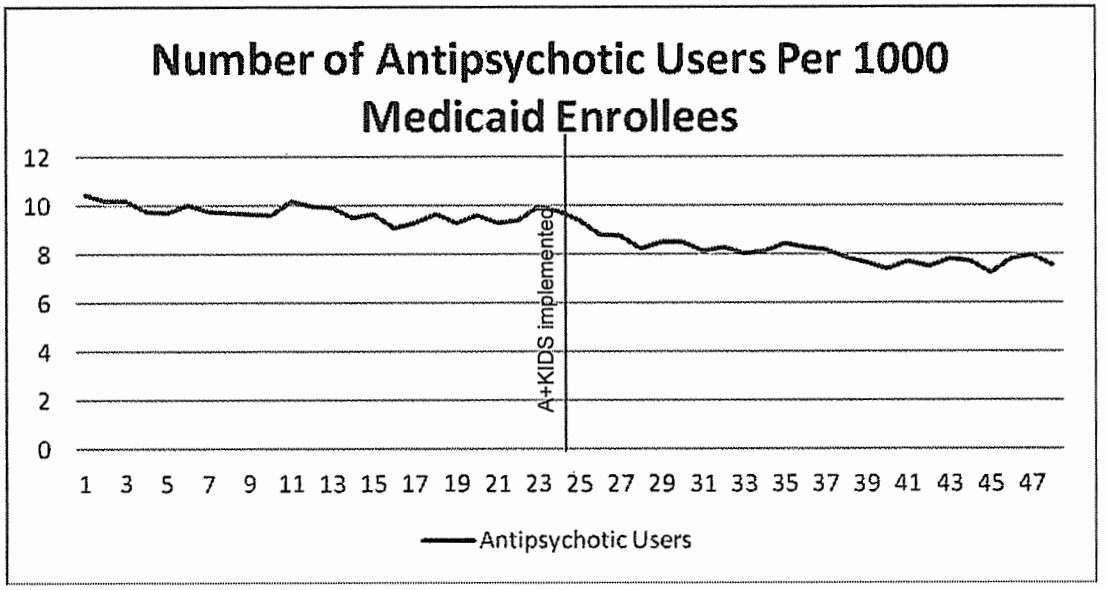
Findings 7-12 Year Olds: In children 7 to 12 years of age, there was a statistically insignificant month-over-month decline in antipsychotic fills prior to A+KIDS implementation equal to 0.8 prescriptions per 1,000,000 children per day. Following A+KIDS implementation, the monthly decline in antipsychotic use was more rapid at 5.4 prescriptions per 1,000,000 children per day. Also, as seen in the 0-6 year old population, there was a one-time decline in antipsychotic use during the month following A+KIDS implementation equal to 69 prescriptions per 1,000,000 children per day age 7-12.

Findings 13-17 Year Olds: Prior to A+KIDS implementation, antipsychotic prescription usage in children 13-17 years of age declined at a rate of approximately 0.03 prescriptions per 1,000,000 enrollees per day. Following the first implementation of the A+KIDS program in April of 2011 when CCNC networks educated prescribers and pharmacies for all children under 13, the rate of antipsychotic use declined rapidly at a pace of approximately 23 prescriptions per 1,000,000 enrollees per day. There was again an immediate policy effect in April 2011 with a one-time decline in antipsychotic use equal to 29 prescriptions per 1,000,000 enrollees per day. In August 2011, the second phase of implementation in 13-17 year olds occurred when a hard edit was introduced requiring safety documentation. This resulted in another decline in the level of antipsychotic use equivalent to a reduction of 63 prescriptions per 1,000,000 enrollees per day. Of note, the decline occurred during the month immediately preceding the pharmacy hard edit and was presumably related to the large provider education effort occurring during that month.



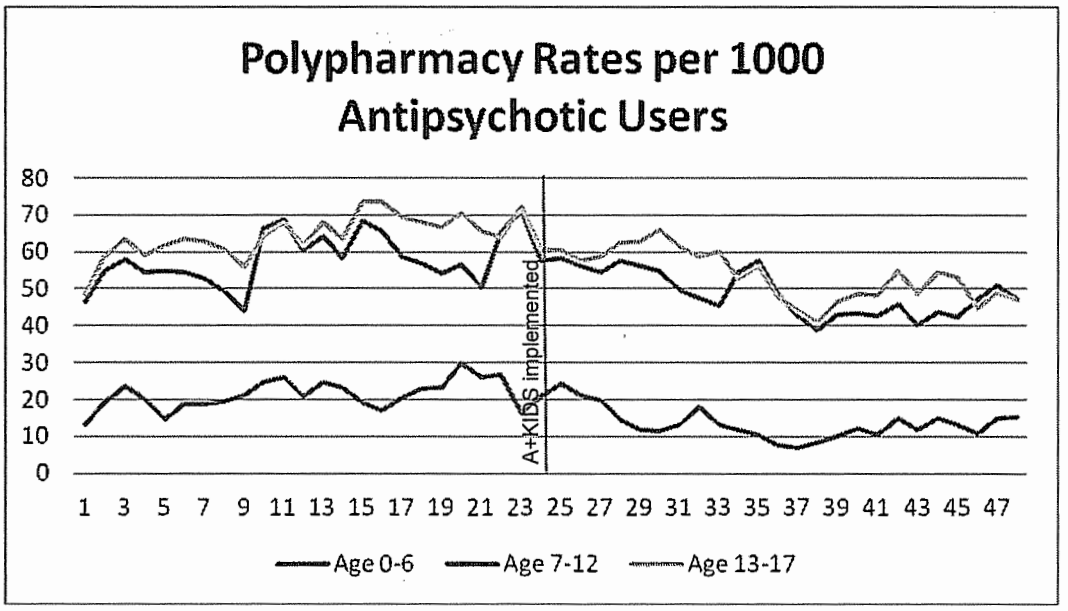
Number of Antipsychotic Users Per 1,000 Medicaid Enrollees

In examining the trends for the number of antipsychotic users age 0 to 17, a decline was noted in the number of patients using these medications from month 1 (April 2009) through month 48 (March 2013). This figure adjusts for the number of Medicaid beneficiaries enrolled in Medicaid each month and is adjusted to 30 day equivalents to account for differences in the number of days in which prescriptions can be filled each month. The month-over-month decline in antipsychotic users appears to strengthen following month 24 when the A+KIDS program was implemented. Modeling the trends in the number of children using an antipsychotic medication, there are 3.09 fewer users each month for every 100,000 children on Medicaid prior to A+KIDS implementation and 6.07 fewer users for every 100,000 children after A+KIDS implementation. In addition, there was a one-time reduction of 5.2 fewer antipsychotic users for every 10,000 Medicaid enrollees immediately after the A+KIDS program was implemented.



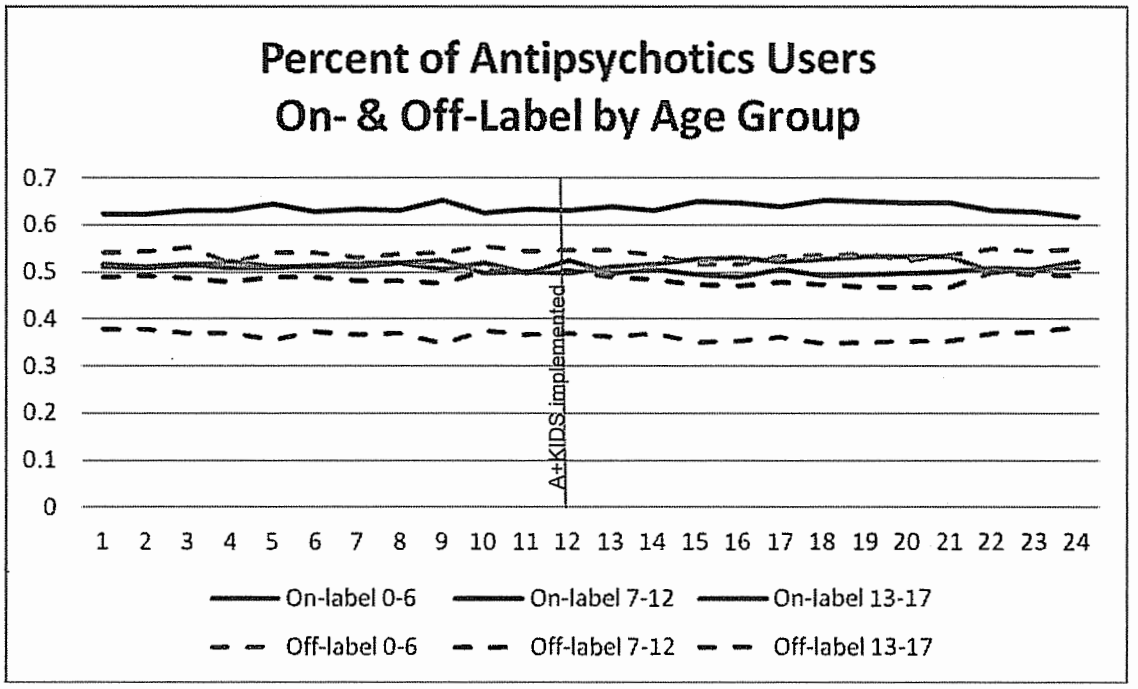
Polypharmacy Rates per 1,000 Antipsychotic Users

Although antipsychotic utilization was decreasing over time prior to A+KIDS implementation, the number of antipsychotic users using two or more antipsychotic medications each month was increasing. The following chart illustrates the rates of polypharmacy (the use of two or more antipsychotic treatments by the same patient) each month, beginning April 2009 and ending March 2013. Prior to the implementation of the A+KIDS program, there was a month-over-month increase in polypharmacy for antipsychotics in each age group. Following the introduction of the A+KIDS program, there was a month-over-month decline in rates of polypharmacy, and these trends have been confirmed to be statistically significant through statistical models. In patients age 0-6, 7-12, and 13-17, rates of polypharmacy increased by 1.46, 3.96, and 4.93 per 10,000 antipsychotic users per month, respectively, prior to A+KIDS implementation. Following A+KIDS implementation, rates of polypharmacy declined by statistically significant rates of 3.57, 6.13, and 7.41 per 10,000 antipsychotic users per month for patients age 0-6, 7-12 and 13-17, respectively.



Percent of Antipsychotics On- & Off-Label by Age Group

In the following table, antipsychotic users were differentiated as either "on-label" or "off-label" users so as to examine the influence of A+KIDS implementation on antipsychotic use for different diagnostic conditions. On-label use was defined as the use of an antipsychotic for one of three FDA approved indications as specified through the following ICD-9 codes: bipolar disorder (296.0-296.1, 296.4-296.8), psychoses/schizophrenia (295, 297, 298), and autism spectrum disorder (pervasive developmental disorder) (299). To be conservative in defining users that are on-label, anyone with an ICD-9 code in any of the 12 months before or after an antipsychotic claim was defined as an on-label user. Any patient without an on-label claim in the 12 months before or after antipsychotic use was defined as an off-label user. Given that this definition requires a minimum of 12 months of observation before and after an antipsychotic claim, data were analyzed only for the 12 months before and after the implementation of the A+KIDS program. After examining on-label versus off-label use, there were similar patterns of antipsychotic use both before and after A+KIDS implementation, and the effect of A+KIDS implementation appeared to be similar in both on-label and off-label users. Of note, rates of on-label were approximately the same as off-label use in children age 0-6 years. On-label use appeared slightly higher than off-label use in children 7-12 years of age and in adolescents 13-17 years of age.

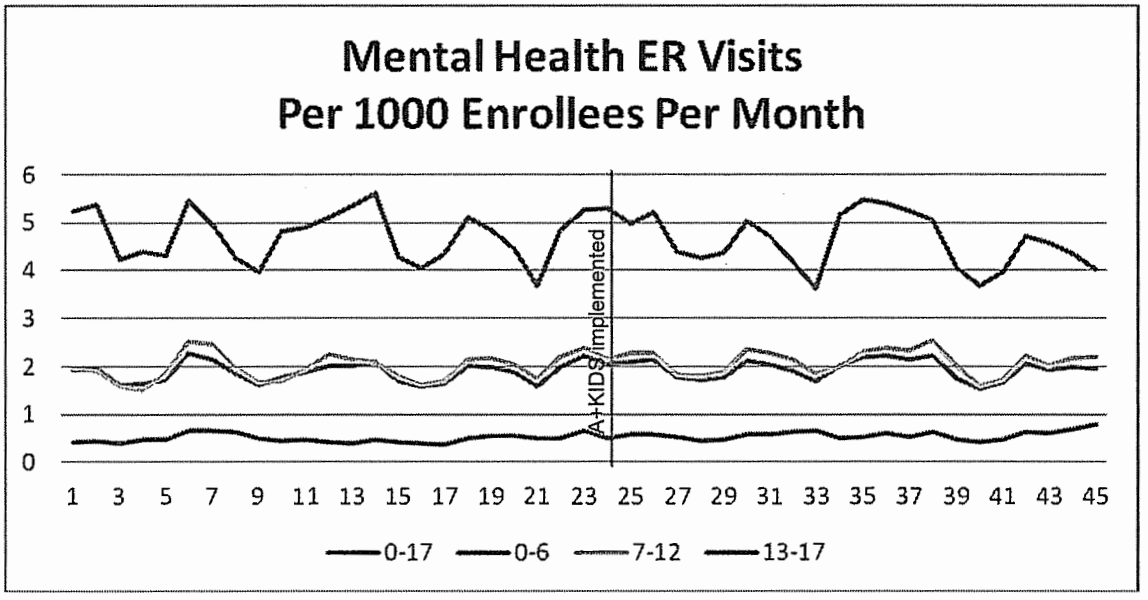


Health Service Utilization

The next several charts examine health service utilization for both mental health conditions as well as non-mental health conditions. Specifically, patterns of use were examined from April 2009 (month 1) through December 2012 (month 45). These data were limited to 45 months of observation due to potential missing data in later months. For this analysis, visits were classified as being mental health related if there are related ICD-9 diagnoses for any of the following: adjustment reactions (300), anxiety (300.0, 300.2, 313.0), bipolar disorder (296.0-296.1, 296.4-296.8), attention deficit hyperactivity disorder (314), conduct disorder (312, 314.2), depression (296.2, 296.3, 300.4, 300.5, 311), developmental disorder (314.1, 315, 317-319), oppositional defiant disorder (313.81), pervasive developmental disorder (299), post-traumatic stress disorder (308), psychoses (295, 297, 298), obsessive compulsive disorder (300.3), tic disorder (307.2), substance abuse (292, 303-305), or unspecified mood disorder (296.9).

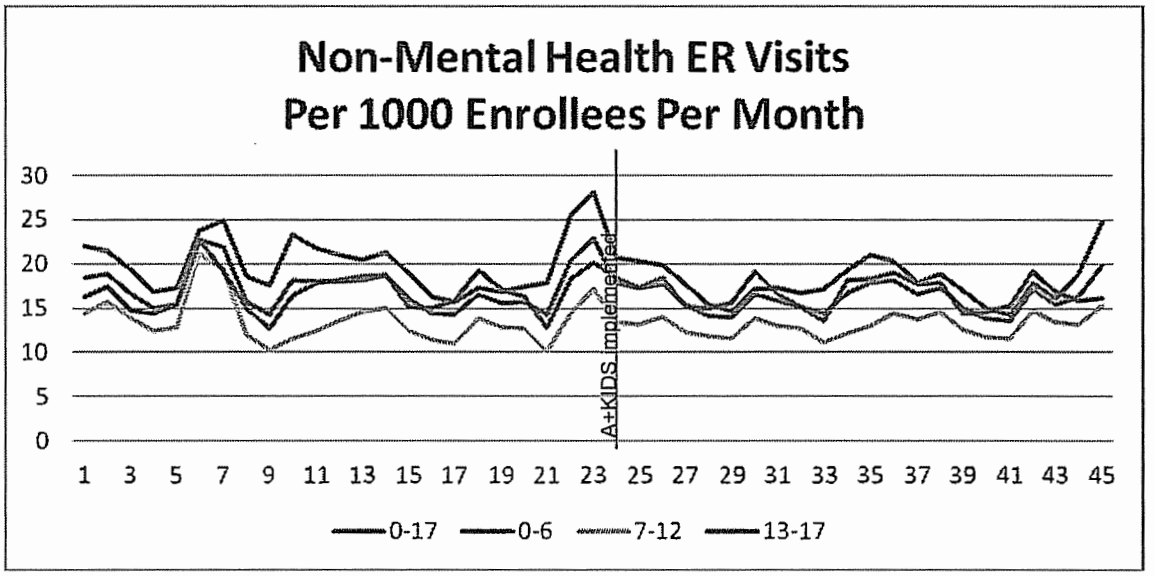
Mental Health ER Visits Per 1,000 Enrollees Per Month

The graph below charts emergency room (ER) visits per month for different age groups. Of note, ER visits for mental health conditions were much higher in children 13-17 years of age. Although ER visits for mental health conditions varied from month to month, there was no statistically significant change in mental health ER visits resulting from A+KIDS implementation in any age group. This suggests no change in ER visits as a result of the A+KIDS policy; however, a lack of claims data beginning in month 30 (coinciding with the Medicaid program shift to mental health managed care) may have artificially lowered this rate of ER usage.



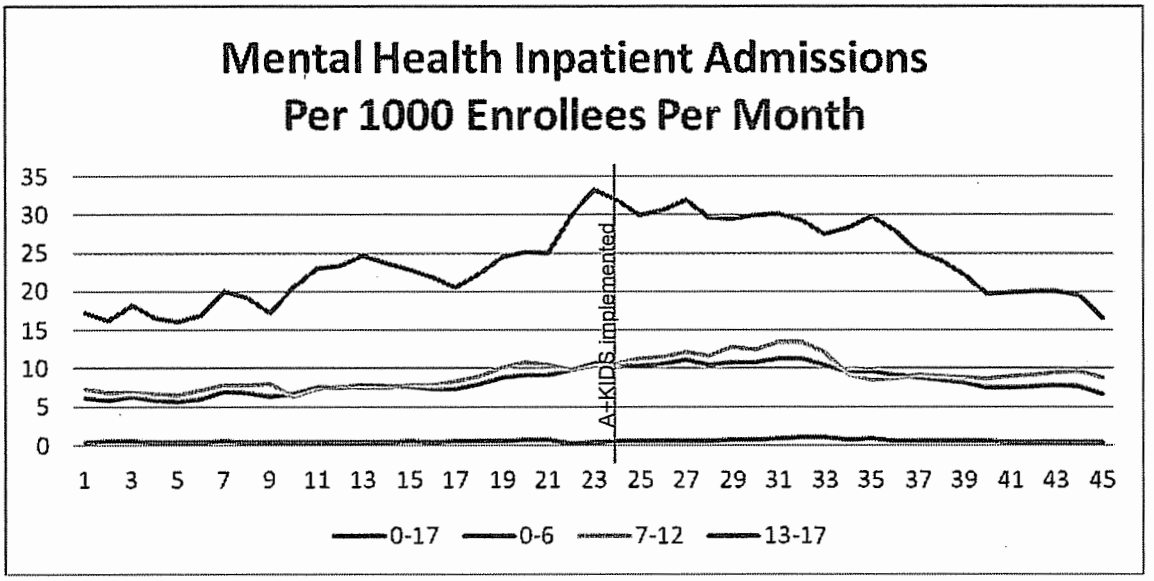
Non-Mental Health ER Visits Per 1,000 Enrollees Per Month

Similar to mental health ER visits, there is significant month to month fluctuation in ER visits across age groups. However, there is no significant change in month to month utilization resulting from the A+KIDS program implementation on non-mental health ER visits.



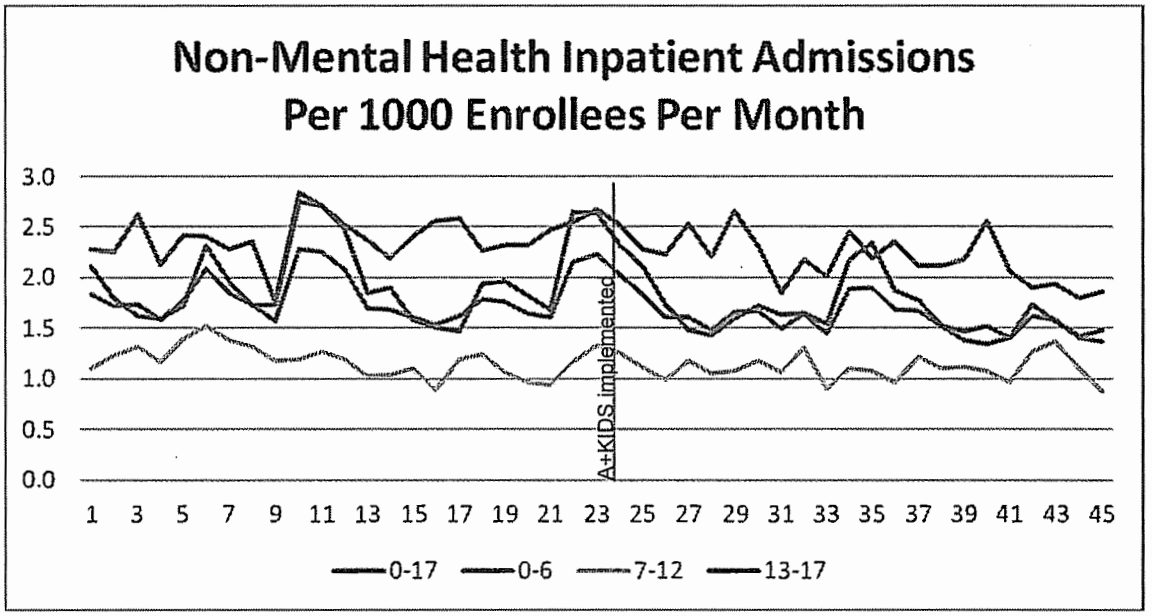
Mental Health Inpatient Admissions Per 1,000 Enrollees Per Month

In examining mental health related inpatient admissions across age groups, there appeared to be a significant increase in mental health admissions per month for each age group prior to A+KIDS implementation, with the highest rate of use being in patients 13-17 years of age. Mental health admissions appear to have leveled off at about month 23 when the A+KIDS program was implemented and then declined further. Although there seems to be a leveling off of inpatient admissions following the A+KIDS program implementation, a lack of claims data beginning in month 30 (coinciding with the Medicaid program shift to mental health managed care) may have impacted the rate of inpatient admissions.



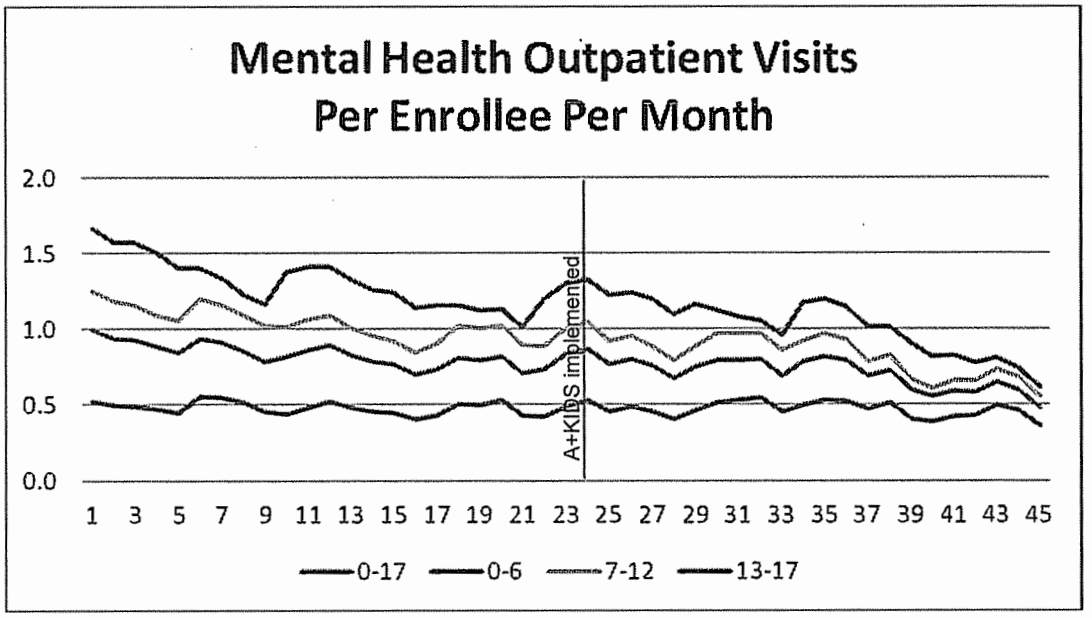
Non-Mental Health Inpatient Admissions Per 1,000 Enrollees Per Month

Non-mental health inpatient admissions show significant variation from month to month for all age groups; however, there is no noticeable trend in rates of inpatient admission for any age group either before or after the A+KIDS program was implemented.



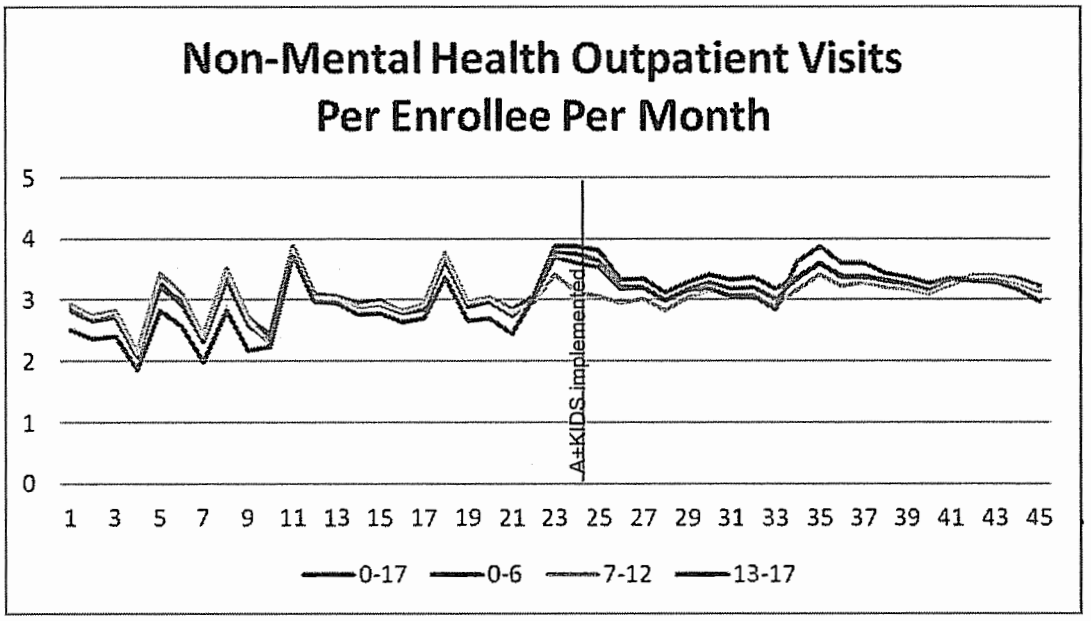
Mental Health Outpatient Visits Per Enrollee Per Month

In examining the rates of mental health outpatient visits before and after A+KIDS implementation, there was a noticeable decline in monthly outpatient visits throughout the observation period. Of note, there appeared to be a higher rate of outpatient visits in older children, with the highest rates in adolescents 13-17 years of age. This decline, however, does not appear to be significantly greater following the implementation of the A+KIDS program in month 24. In particular, there is not a sudden policy effect from the implementation of the A+KIDS program. As with ER visits and inpatient visits related to mental health capitation, the lack of claims data beginning in month 30 may have influenced this trend.



Non-Mental Health Outpatient Visits Per Enrollee Per Month

Although mental health visits were declining throughout our period of observation, non-mental health visits show a pattern of increase in monthly rates both before and after the implementation of the A+KIDS program in month 24.



Future Considerations

Metabolic Data

Metabolic side effects are a major concern for the use of antipsychotics in children. There are currently efforts under way to investigate the prevalence and consequences of these effects. Metabolic monitoring data is used to examine the baseline prevalence of metabolic profiles by a variety of characteristics including age, gender, medication used, primary diagnosis, length of antipsychotic treatment, and type of Medicaid eligibility. This analysis will look at obesity (through BMI data), levels of cholesterol (HDL, LDL, Triglycerides, non-HDL), and glucose to determine if there are specific variables associated with abnormal metabolic levels. Future analyses of the A+KIDS registry will follow children to see how metabolic levels are affected over time.

Preferred Provider Status

Some providers who consistently register their patients and provide appropriate safety monitoring have requested that there be a preferred provider status. The A+KIDS implementation team has considered providing decreased registration requirements (e.g., once per year for all patients rather than twice per year per patient for off-label uses) for providers who are meeting high participation thresholds such as 100% of antipsychotic prescriptions registered online in the A+KIDS registry and 75% of all metabolic data fields completed. This effort would reduce provider burden for a subset of providers and would require limited additional resources if implemented.

Maintenance of Certification

The A+KIDS team has received initial approval from the American Board of Pediatrics to develop a plan for allowing North Carolina-licensed practitioners who use the A+KIDS registry to apply for maintenance of certification (MOC) part 4 credit. This certification is required for physicians to remain board certified within their area of specialty (e.g., pediatrics). If approved by the Board, this would be an attractive way of enhancing provider participation as prescribers could get MOC credit for a quality improvement activity that was part of their daily work routine. The development and execution of this plan will require additional resources.

Part 5: ASAP Program Description, Implementation, and Evaluation

Program Description and Implementation

The Adult Safety with Antipsychotic Prescribing (ASAP) program retains provider choice in antipsychotic selection. Documentation about the primary diagnosis, target symptoms for use of the antipsychotic and confirmation of informed consent about the potential for metabolic and neurologic adverse effects with the drug choice is requested. Unlike the A+KIDS program, all documentation is submitted using a form faxed to a DMA contracted vendor. An option to provide this information via telephone is also available. The vendor then reviews the form for complete information.

The ASAP program launched on March 20, 2012. In essence, it is a prior authorization policy for off label prescribing of atypical antipsychotic agents for beneficiaries age 18 and older. Exempt from the policy are Medicaid beneficiaries that have any of the following diagnoses:

- Schizophrenia
- Schizophreniform disorder
- Schizoaffective disorder
- Delusional disorder
- Brief psychotic disorder
- Shared psychotic disorder
- Psychotic disorder not otherwise specified
- Bipolar disorder
- Major depressive disorder with psychosis
- Tourette syndrome
- Treatment resistant depression (adjunctive treatment)
- Other psychosis

If any one or more of the above diagnoses are found within a two-year claims look back period (done through use of an automated function of the claims processing system), the claim for the antipsychotic medication bypasses all ASAP program requirements. Additionally, the prescriber may write "meets PA criteria" on every antipsychotic prescription or in the comment box for e-prescriptions to authorize the exemption of the above indications. For non-exempt diagnoses, the prescriber must either fill out a fax form or call in the information for the authorization. These authorizations are granted for a period of 12 months.

Override capabilities are a key component of the ASAP program to help ensure interruption of antipsychotic therapy does not occur. To continue processing of pharmacy claims without undue delay, it is important for pharmacy providers to understand the overrides. A robust training effort was done to educate pharmacy staff about how they work. One set of codes is used when the provider indicates that the prescription "meets PA criteria" and a different code when the pharmacist's professional judgment determines bypassing the program requirements for non-exempt diagnoses is appropriate. The latter override edit is an emergency measure and can be used on two unique dates per beneficiary per rolling calendar year.

The primary goal of the ASAP program is to promote informed consent. It is not unusual for the very 'customized' drug regimens sometimes developed for adult patients to result in intra-class polypharmacy and doses that exceed FDA approved amounts. This scenario is more likely when treating the more severe, hard-to-treat cases. As such, the importance of compliance to antipsychotic therapy is continuously stressed during prescriber and patient encounters as is the potential for adverse effects that may result from the sustained use of these agents. In addition, frequent transitions between inpatient facilities and outpatient-based care settings only add to the complexity of achieving and maintaining a stable medication regimen. All of these factors make it critical to inform the patient/guardian about the potential for metabolic and neurologic adverse effects.

Program Outreach and Education

Staff from CCNC networks and DMA, together, educated pharmacies and prescribers about the program prior to its launch. Once the program began, CCNC network pharmacy technicians called individual pharmacies to deliver education and follow-up on claims denials. They also surveyed pharmacies about their knowledge of the program and targeted pharmacies with high numbers of denials for additional education.

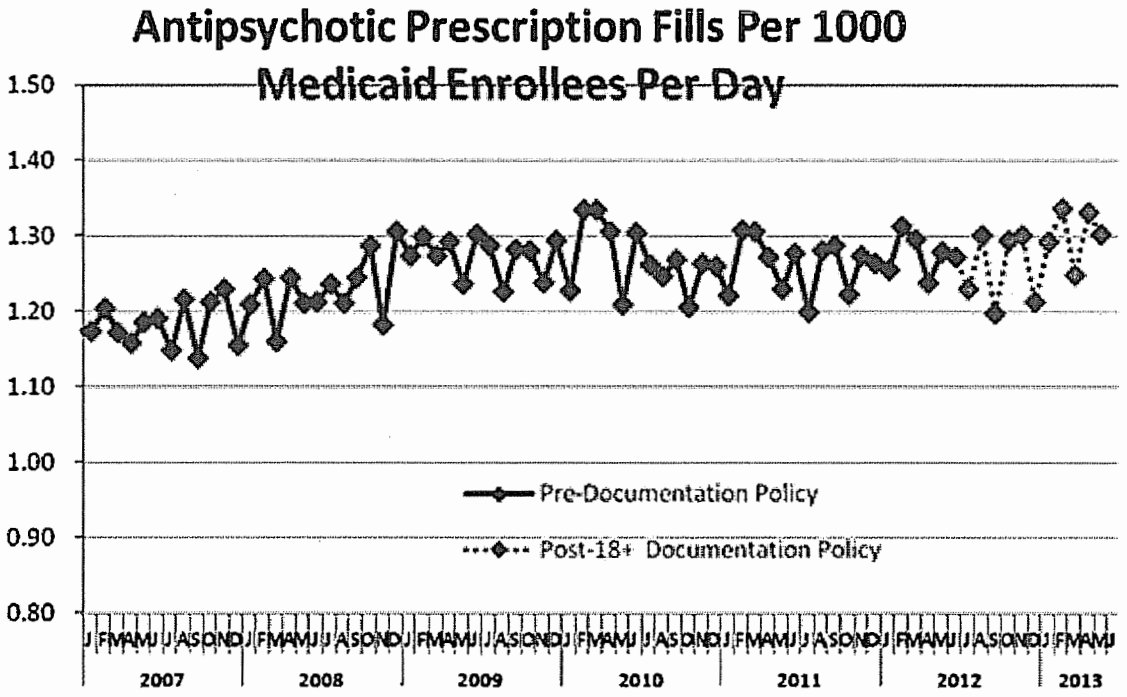
Documentation for the ASAP program is not done using an electronic registry. However, providers may access the www.documentforsafety.org website for information about the program. Providers may also contact DMA.

Provider Support Line

Provider support is available through the "Document for Safety" call center 8am-5pm, Monday through Friday. The center assists providers with general questions and concerns regarding the ASAP program.

Formal Evaluation of Prescribing and Utilization

In the adult population, antipsychotic prescription use was increasing prior to policy implementation at a rate of 1.5 prescriptions per 1,000,000 enrollees per day. Following the implementation of the policy, there was a decline in the rate of antipsychotic use equivalent to 50 prescriptions per 1,000,000 enrollees per day during the initial period of implementation. Following the initial policy effect, antipsychotic use rose to pre-policy levels at a rate of 5.1 prescriptions per 1,000,000 enrollees per day during the year after policy implementation.



Part 6: Lessons Learned

A+KIDS

Lesson One: Successful implementation depends on clinically appropriate policy development, stakeholder involvement, strong infrastructure of CCNC, and ongoing provider support.

The A+KIDS program implementation should be considered a success based on the clear evidence of rapid uptake by prescribers. Within one year, 80% of antipsychotic prescriptions were associated with a registration in the A+KIDS system. There are several key factors that led to this success including: up-front involvement of stakeholders (both clinicians and advocates), ongoing guidance via an advisory board, and leveraging the CCNC network pharmacy and network psychiatry infrastructure for ongoing technical and clinical support. These groups were all instrumental in making providers aware of the program, educating about program changes, and troubleshooting any problems prescribers and pharmacies were having.

Lesson Two: Gradual implementation is essential to getting providers involved and limiting inappropriate denials of medication to a patient.

Allowing providers to register and start submitting safety documentation in the A+KIDS registry a month before there were point of sale edits or "stops" in pharmacy claims processing was essential. When the pharmacy edits were initiated, there were unlimited overrides. The pharmacy was asked to notify the prescriber that safety documentation was needed, but then could override the edit and give the patient the medication. Even with unlimited overrides, about 70% of prescriptions filled were authorized in the registry. When the number of overrides was reduced to two per rolling calendar year, registration rates increased to 80%. The graded implementation of the system over the first year allowed increased uptake without the inappropriate denial of medication to patients.

Lesson Three: A registry program with overrides available can change prescribing and safety-monitoring behavior.

There is clear evidence that the implementation of the A+KIDS program is associated with a significant decrease in the number of antipsychotic fills per day per 1,000 enrollees. This occurred during a time of relative Medicaid expansion in the pediatric sector. Glucose monitoring as measured by the CCNC Quality Measures and Feedback program for this group increased over the time period from program initiation as reported above. Safety and quality increased and costs decreased with the change in behavior by prescribers. Following the implementation of the NCTracks program in July 2013, there has been an extended disruption of the pharmacy edit for A+KIDS. Subsequently there has been a fall-off in registration of antipsychotics within A+KIDS, and there is initial evidence of an increase in antipsychotic prescribing. This provides further evidence of the system's positive impact on prescribing patterns.

Lesson Four: The pharmacist-prescriber relationship is one of the keys to success.

The pharmacist-prescriber relationship was integral to the success. The pharmacy was one of the last mechanisms for reaching out to a provider to alert them to the fact that their patient needed safety

documentation before the patient's overrides were exhausted. The pharmacist-prescriber relationship was important for getting patients the medication they were prescribed in a timely manner.

Lesson Five: Unintended consequences appear to be limited.

As shown above in the evaluation section, there do not appear to be unintended increases in emergency services, either emergency department visits or inpatient stays. This statewide program was able to be implemented to scale without any major unintended consequences and can act as a blueprint for future programs.

Lesson Six: There are multiple challenges to full participation in the program.

There are approximately 20% of antipsychotic fills not associated with an A+KIDS registration. Decreasing this "un-registered" antipsychotic prescription rate will likely require decreasing the number of pharmacy level overrides. The entering of metabolic laboratory data directly into the A+KIDS system is often redundant and out of the normal workflow for prescribers. This is demonstrated by the fact that claims data shows a higher rate of metabolic monitoring than does the provider reported data from the A+KIDS registry. However, there is evidence from the claims data that the A+KIDS project is associated with an upswing in metabolic monitoring as discussed above. It will be difficult to change this reality without the implementation of some of the recommendations below.

ASAP

Lesson One: A program designed with broad criteria and multiple exemptions may have little impact on utilization.

The ASAP program was originally designed using broad criteria and exemptions, with a focus on off-label antipsychotic use in patients *without* severe and persistent mental illness (SPMI). Ample opportunities were provided for emergency overrides at the pharmacy to avoid unintended disruptions in therapy. The broad criteria combined with generous override opportunities created a scenario where the program did not impact utilization in a meaningful way. In order to have a greater impact on off-label use, the program may need to employ tighter criteria with fewer exemptions and overrides, while being implemented in a gradual, staged approach that allows for close operational monitoring.

Lesson Two: Successful implementation depends on clinically appropriate policy development, stakeholder involvement, strong infrastructure of CCNC, and ongoing provider support.

As with the A+KIDS program, a strong policy structure along with stakeholder buy in and the support of the CCNC infrastructure were all essential for a successful implementation of the ASAP program. Each entity has a perspective that is necessary for the development of a high quality and operationally functional program.

Lesson Three: A consistent focus and message around antipsychotic use can impact prescribing practices overall.

Although the ASAP program was implemented almost a full year after the A+KIDS program, the ASAP policy was developed to closely mirror A+KIDS. The policies promote the same thoughtfulness around indications for use, dose amounts, and polypharmacy when prescribing antipsychotics. Informed consent discussions include an inherent assessment of all these areas. Therefore, the education and training for the A+KIDS program assisted with successful implementation of the adult program due to program similarities.

Lesson Four: The pharmacist-prescriber relationship is one of the keys to success.

The pharmacist-prescriber relationship was integral to the success. The pharmacy was one of the last mechanisms for reaching out to a provider to alert them to the fact that their patient needed documentation before the patient's overrides were exhausted. The pharmacist-prescriber relationship was important for getting patients the medication they were prescribed in a timely manner.

Part 7: Program Recommendations

A+KIDS

Build in further incentives for use

As discussed above, registry participation is in part hampered by the currently unavoidable problem that entering data is often out of the workflow for many busy prescribers. Prescribers may have to search for data that they have documented elsewhere to enter into the A+KIDS interface. This presents the biggest challenge in regards to laboratory data. Participation rates for metabolic data entry would likely increase if there were automated uploading of such data elements from the CCNC Provider Portal system which currently houses a large portion of outpatient laboratory data. In a future planned update to the A+KIDS registry, the revised software will show prescribers metabolic data over time in addition to prescriptions and safety documentation from other prescribers treating the same patient. Such enhancements would clearly increase the clinical utility of the A+KIDS platform over time. This is especially true for practitioners who do not have access to an electronic medical record (EMR) system of their own. This recommendation to develop communication between Provider Portal and the A+KIDS registry will require significant resources, but this effort will benefit other CCNC Document for Safety programs. Ongoing consideration of the Preferred Provider and Maintenance of Certification incentives described in the Future Considerations section is recommended.

Consider a stepwise reduction in pharmacy level overrides

The initial A+KIDS program experience demonstrated that the implementation of limited overrides that led to the required communication between pharmacies and prescribers translated into increased rates of antipsychotic prescriptions registered in the A+KIDS system. Eventual reduction to one override per drug per patient per year is likely to increase the overall registration rate. This step should be considered carefully and implemented only after mass communications to Medicaid prescribers, pharmacies, and advocacy groups. The desire for increased antipsychotic registration rates have to be balanced against the risk that a patient will be temporarily denied an antipsychotic prescription due to a prescriber or system level problem.

Develop a method for monitoring and potentially reducing excessive psychiatric polypharmacy

There is considerable national and state level data to suggest psychiatric polypharmacy is a concern for quality and excess cost. Very few psychiatric medication combinations are supported by evidence. While clinical situations may occasionally demand the use of more than one psychotropic, this practice may be an important area for future development using the A+KIDS registry as a base platform. It is recommended that CCNC evaluate this issue systematically using claims data and consider potential undue harms and undue cost burdens from multiple classes of psychotropic medications including antipsychotics, psychostimulants, antiepileptics, and antidepressants. This study could help guide the development of a systematic education and safety enhancement program to reduce unneeded pediatric psychiatric polypharmacy.

Future large changes should be accompanied with appropriate stakeholder involvement

Any major initiative shift or launch should be developed with guidance from stakeholders as with the initial A+KIDS implementation. This includes involving mental health and developmental disabilities advocates as well as major prescriber and pharmacy professional groups. The CCNC pharmacy and psychiatric network should be leveraged to disseminate communications and provide support. Electronic communications should repeatedly announce changes and educate providers prior to and during implementation of new programs or program changes.

ASAP

Consider Enhancements to Policy

Review of the current policy is needed to address continued off-label use of antipsychotics in the adult population. Consideration should be given to tightening the policy to decrease inappropriate off-label uses while avoiding medication disruption for patients who are using antipsychotics for treatment of severe and persistent mental illness, such as schizophrenia.

Develop a method to collect data about safe use parameters

Expand the information requested for an ASAP authorization to include information about the monitoring parameters that are indicative of adverse effects in accordance with standards established by the American Psychiatric Association and current accepted practice standards for the efficacious and safe use of antipsychotics. A baseline evaluation is very important to make determinations about adverse effects occurring from a drug. This additional data would create more opportunities for analysis about the effectiveness of the program.

Future large changes should be accompanied with appropriate stakeholder involvement

Any major initiative shift or launch should be developed with guidance from stakeholders as with the initial ASAP implementation. This includes involving mental health advocates as well as major prescriber and psychiatric professional groups. The CCNC pharmacy and psychiatric network should be leveraged to disseminate communications and provide support. Electronic communications should repeatedly announce changes and educate providers prior to and during implementation of new programs or program changes.

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