

Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Section 1013: Suggest Priority Topics for Research

Request for Comments

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- I. Fund CDC and FDA (or other organizations) to study medication safety in terms of:**
- 1) Developing case definitions**
 - 2) Conducting surveillance using methods other than review of claims databases**
 - 3) Affecting change in patient behaviors**

An example of one approach that could be used is a joint CDC/FDA project which leverages CDC surveillance systems (specifically the National Electronic Injury Surveillance System - All Injury Program) to conduct ACTIVE post-marketing surveillance for adverse drug events. Currently, the FDA predominantly depends on PASSIVE surveillance (MedWatch) or industry reporting of adverse drug events once a drug has been approved.

This system called NEISS-CADES (National Electronic Injury Surveillance System - Cooperative Adverse Drug Event Surveillance) was started in a nationally representative sample of 60+ hospital Emergency Departments in August 2003. After one year of operation, it should be possible to generate national estimates of adverse drug events treated in emergency departments.

The CDC/FDA project has collected approximately 5,000 cases at this point and expects to collect approximately 10,000 cases a year which makes this system robust enough to analyze characteristics of adverse drug events in specific subgroups (such as patients ≥ 65 or children) and adverse drug events associated with specific drugs (such as insulin, coumadin, digoxin, opioid analgesics, and ibuprofen).

Post-marketing adverse drug event surveillance is important to identify the drugs and patients most at risk for medication-related injuries and to monitor progress in reducing medication-related injuries in the future.

II. Vaccinations

- 1) Measurement of effectiveness of methods to improve the rate of influenza vaccinations among high risk children (defined as those having pre-existing medical conditions that place them at increased risk of having adverse influenza-related health outcomes such as physician office visit, hospitalization, and death).
- 2) Measurement of effectiveness of methods to improve rates of influenza vaccination among those aged 50 years and older (particularly among those covered by Medicare).

Background: The Advisory Committee on Immunization Practices (ACIP) recommends annual influenza vaccinations for the two age-and-risk groups mentioned in the two suggestions. Further, these suggestions are based on the idea that annual (regular) influenza vaccinations of the age and risk groups mentioned are often likely to be cost-saving (which is not necessarily true among other age and risk groups). Even if increased compliance resulted in greater costs of vaccination (which includes more than just the cost of the vaccine, such as the costs of administration), there are still likely to be cost-savings.

Potential methods for evaluation: To increase vaccination activities could include (but are not limited to): Holding more influenza vaccination clinics (outside of physician offices), paying doctors a small "bonus" fee for proof-of-vaccination of patients who are members of target groups, establishing databases of targeted age-and-risk groups, which will then be used to send reminders, receive phone calls from CMS-funded phone banks, and other methods to encourage patient compliance with the ACIP recommendations. The effectiveness of these and any other potential measures would be the focus of the above research items.

- 3) Experience from the joint CDC/CMS demonstration project on reducing racial/ethnic disparities among the elderly (READII) suggest that for some providers, particularly those who serve lower socioeconomic status patients, upfront purchase of vaccine may be a barrier to vaccination. To better understand the degree to which this is a barrier, CMS should conduct a study to determine whether providing free vaccine, i.e. avoiding the need for the provider to front the cost until they are reimbursed by CMS, is an effective way to increase vaccination in provider offices.
- 4) Design and implement studies to increase pneumococcal vaccination rates in elderly African Americans and Hispanics whose vaccination rates are substantially lower than elderly whites, even among those with regular doctor visits. Studies should include both developing methods to target providers working with those populations as well as methods to increase patient demand for this vaccine.
- 5) Design and implement studies to increase influenza and pneumococcal vaccination of residents and staff in long term care facilities.

III. Explore the benefits of Medicaid reimbursement for programs designed to prevent secondary conditions among people with disabilities.

According to the U.S. Census Bureau, there are nearly 50 million Americans living with a disability, including physical disability, such as those associated with spinal cord injury, cerebral palsy, or spina bifida; sensory disabilities such as hearing loss and visual impairment; and cognitive conditions like intellectual disability.

Often, people with disabilities become more susceptible to other health problems as a result of their disabling, or primary, condition. Secondary conditions experienced by people with disabilities include pain, fatigue, obesity, isolation, and depression. Because secondary conditions among people with disabilities can be experienced across the life span, reducing them is a public health priority.

For adults with chronic illness and permanent injuries, a growing body of literature identifies health promotion as both effective in improving health and cost-effective compared to treatment alternatives. Yet third-party payers (Medicaid, Medicare, and private insurance) typically do not reimburse providers for health promotion interventions. This is a problem for many individuals with disabilities who have significant health care costs and cannot pay for health promotion programs.

Case Study

Living Well with a Disability is a health promotion and wellness program for people who experience a variety of disabilities. The program is an eight-week workshop that uses goal setting and problem solving as the framework for developing healthy lifestyles. Sessions concentrate on developing tools and skills for healthy living, including healthy communication, managing depression, information seeking, physical activity, nutrition, and advocacy. Participants develop long-term personal health goals that have the potential to improve quality of life while learning to adopt healthy behaviors. Through the program, participants have reported better health, more productive doctor's visits, and fewer trips to the emergency room.

Evaluations of the *Living Well* program demonstrate significant cost savings. Based on data from 1585 participants of the program, implementation has yielded cost savings ranging from \$1.5 to \$2.5 million. Discounting the cost of the program, the estimated net benefit to healthcare payers is between \$538,900 and \$1,588,170. These early data suggest that widespread implementation of a curriculum like *Living Well with a Disability* has the potential to be cost saving by reducing health care costs. To date, the *Living Well with a Disability* has been implemented in 17 states; however, there remains no mechanism for the long-term support of existing state-based *Living Well* programs or for expansion to additional beneficiaries.

Comprising 18% of all Medicaid beneficiaries, 7.5 million Americans with Medicaid qualify for the program because of disability. Average payments for this group are \$10,040 per person, a total that is much higher than for other covered groups. It is therefore beneficial to explore widespread implementation of a program that has shown both improved health outcomes for people with disabilities and substantial health care cost savings.

IV. Clinical Preventive Services

Priorities should be expanded beyond prescription drugs to include those prevention services which have been demonstrated to be effective, address significant burden of preventable disease, and are cost effective to deliver. Evidence for the effectiveness of these preventive services should have been subjected to systematic evidence-based review such as those recommended by the U.S. Clinical Preventive Services Task Force (USCPSTF) and the Community Preventive Services Task Force (CPSTF).

Additional information that can inform the prioritization process can be drawn from the National Commission on Prevention Priorities. This group has ranked the recommended clinical prevention services by their preventable burden on health-related quality of life and cost effectiveness.

Health indicators should be developed for the purpose of demand estimation and cost projections. An important part of planning for a potential increase in demand for preventive services by the frail older population is the process of defining the dimensions of health. Very promising research has developed the GoM (grade of membership) procedure. GoM determine latent profiles (pure types) of health and show the degree to which individuals correspond to the identified profiles.

The new initial visit (AKA the “Welcome to Medicare” visit) is the first preventive medicine visit to be covered by Medicare, but its access is limited to the first six months of Medicare eligibility. Evidence suggests that more time is needed for physicians to deliver US Preventive Services Task Force recommended preventive clinical services (Yarnall et al., *Am J Public Health*. 2003;93:635-641.) A prospective cost effectiveness evaluation would assist CMS to adjust the access limitations or to prioritize the specific services that may be bundled into this one-time visit.

V. Medicare Prescription Drug Benefit

Design and implement studies that would examine the impact of the new Medicare prescription drug benefit on: (1) physician prescribing patterns; (2) consumer demand; (3) adherence to drug regimens, and (4) health outcomes. With the advent of a new prescription drug benefit, there will be questions about whether the provision of this benefit changes the way physicians prescribe and patients use medication, and whether the benefit actually improves health outcomes.

Evaluate the interaction of this federal drug program with state run senior drug assistance programs as well as other drug benefits – retiree or Medicaid. In addition collect and analyze information regarding (1) the benefit; (2) appropriate use of drugs; (3) management of drug therapy.

VI. Promoting early identification of developmental disabilities

Recently the *Federal Register* published notice of the Relative Value Units for 2004, which

includes a change in the billing code for developmental screening¹. This action marks a positive first step in addressing issues related to reimbursement for developmental screening. However, additional efforts are needed to ensure that screening services provided are properly evaluated and offer a level of quality care.

Background

Today, 17% of children in the United States have a developmental or behavioral disability such as autism, mental retardation, or attention-deficit/hyperactivity disorder (ADHD)². Early identification of and intervention to address developmental problems can have a significant impact on a child's well-being, as well as reduce the need for more costly interventions over time. Research has shown that children with autism identified early and enrolled in early intervention programs show significant improvements in their language, cognitive, social, and motor skills, as well as in their future educational attainment.³

The American Academy of Pediatrics (AAP) recommends "all infants and young children should be screened for developmental delays". Additionally, federal mandates require the early identification of and intervention for developmental disabilities through community-based systems. However, numerous factors including cost, time, inadequate training, inappropriate use of assessment tools, reimbursement policies, and the fragmented delivery and integration of services have prevented developmental screening from becoming a routine part of standard child care.

Medicaid insurance provides coverage to approximately 23 million low-income or more than one in four children in the U.S (1996). Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a national Medicaid sponsored program that provides for comprehensive and preventive child health care for individuals under the age of 21 primarily living in poverty. Although EPSDT services, which include an assessment of both physical and mental health development, are mandated, too few children are receiving EPSDT⁴. In addition, the rates, availability, and implementation of screening vary widely among states.

Proposed activity

Phase 1: *Evaluation of existing EPSDT screening services.*

We propose to work with CMS to evaluate how developmental screening is being conducted within the EPSDT eligible population. We will also examine health benefit coverage mandates and Medicaid and SCHIP policies that pertain to early identification by collecting and analyzing health care legislation and regulatory information from states. In addition, this effort could include detailed case studies of selected states (e.g. those with model screening programs, states with less effective programs, etc).

Phase 2: *A demonstration project to develop and evaluate a model program within the EPSDT eligible population for improving developmental screening practices for young children.*

¹ Federal Register: November 7, 2003 (Volume 68, Number 216. 42 CFR Parts 410 and 414.) Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004

² Boyle CA, Decoufle P, Yeargin-Allsopp M. Prevalence and health impact of developmental disabilities in US children. Pediatrics 1994;93(3):399-403.

³ Dawson & Osterling, 1997; National Research Council, 2001).

⁴ National Health Law Program (<http://www.healthlaw.org/pubs/19990323epsdtfact.html>)

The project would help to increase the early identification and appropriate referral of children at risk for or with developmental delays or disabilities. Specifically, the goals would be to:

1. Foster an understanding and appreciation among health care providers and parents of the importance of timely and appropriate developmental screening of young children (0-5).
2. Ensure the timely identification of children at-risk for or with developmental delays and disabilities.
3. Ensure necessary tracking and follow-up of children at-risk for or with developmental delays or disabilities.

The following outlines essential elements for the proposed model developmental screening program:

1. Standard use of recommended screening tool (e.g. Ages and Stages Questionnaire (ASQ) or the Parent's Evaluation of Developmental Status (PEDS)) and standard protocol (i.e. who screened, ages, periodicity, etc.)
2. Use of a customized, electronic age-specific tracking form to insure that all components are met during each well-child visit (using Arizona or New York as a model). The system will provide detailed tracking of screening practices, of referrals to early intervention system, specialist care, and services.
3. Incorporation of anticipatory guidance resources such as Bright Futures Guidelines for health care providers.
4. Development of study procedures, including screening tools, training materials, and community resource guides, to use with participating research pediatric practices.
5. Implementation in pediatric care settings where very young children are most likely to receive care on a regular basis. This setting is the best context for the early identification of young children (birth up to age 5) if screening is systematically integrated into existing standards of care.
6. Utilization of parental expert knowledge. Parents would be encouraged to be active participants in monitoring their child's development and working with their pediatrician to do this.
7. Training for health professionals on topics including:
 - a. the importance of developmental screening and early intervention in relation to child outcomes,
 - b. the description and distribution of a valid and reliable developmental screening tool (either ASQ or PEDS) as well as Bright Futures materials,
 - c. why, how, and when to deliver anticipatory guidance,
 - d. a short billing tutorial related to developmental screening codes,

- e. distribution of a flow-chart mapping the appropriate mechanisms for referral into early intervention programs,
 - f. instructions on implementing the screening protocol for all children they see after the training, and
 - g. receipt of screening forms and parent developmental information and resources (for waiting room or distribution).
8. Implementation of a full screening program for a period of 6 to 12 months, monitor screening and referral rates, evaluate follow-up and enrollment into early intervention services, and assess parental perceptions and outcomes of the process. Screening will initially target the population 3 years of age or younger.
9. Identification of and linkage with appropriate diagnostic and intervention services.

VII. Explore the feasibility of offering a preconception care visit to women intending pregnancy.

Preconception care refers to a bundle of screening and counseling services, delivered in an office visit to women (or couples) before they become pregnant. The bundle consists of the identification and management of conditions known to cause birth defects as well as the promotion of positive health behaviors known to improve maternal, infant, and pregnancy outcomes. If a preconceptional care visit can be included in place of one of the approved prenatal care visits, this care would be at the very least cost neutral and would have the potential to be substantially cost saving by realizing the benefit of the prevention of known causes of birth defects and other adverse perinatal outcomes.

In order to achieve optimal effectiveness, many interventions must be put in place prior to the beginning of pregnancy – hence the term *preconception care*. Such interventions include maintaining healthy weight, stopping smoking, vaccination for certain diseases, avoiding alcohol, the daily use of a folic-acid containing multivitamin, and others.

A list of potential preconception care components (not exhaustive) has been selected to demonstrate the importance of this prevention opportunity (see Table 1). Three selection criteria have been used to develop this list; they consist of 1) strong evidence of effectiveness and the need to begin before conception, 2) the existence of clinical practice guidelines to inform health care delivery, and 3) the existence of surveillance systems to measure risk factor prevalence. Twelve components meeting these criteria have been identified and include promotion of 1) folic acid use and 2) rubella seropositivity; 3) management of preconceptional diabetes and 4) hyperthyroidism; 5) evaluation for the use of anti-epileptic drugs, 6) oral anti-coagulants, and 7) Accutane; 8) management of HIV/AIDS and 9) maternal phenylketonuria; and addressing 10) smoking, 11) alcohol misuse and 12) and obesity.

Table 1. Selected components for a preconceptional care visit

Component of Care	Rationale for Preconceptional Care	Clinical Practice guidelines
Folic acid	Daily use of folic acid containing vitamin supplements has been shown in clinical trials, including randomized controlled trials, and case-control studies to reduce the occurrence of neural tube defects by two-thirds. Optimal protective effect is observed for supplement use from 3 months prior to conception through the first 3 months of pregnancy.	<ul style="list-style-type: none"> •U.S. Public Health Service 1992 • The American College of Obstetricians and Gynecologists (ACOG) 2003
Rubella seropositivity	Observational studies have established that rubella seropositivity prevents the occurrence of the congenital rubella syndrome. Rubella immunization provides protective seropositivity but administration is contraindicated one month prior to conception and throughout pregnancy.	<ul style="list-style-type: none"> •CDC National Immunization Program 2001 •ACOG 2003
Diabetes (preconceptional)	There is a 3-fold increase in the prevalence of birth defects among infants of women with type 1 and type 2 diabetes. Good glycemic control begun prior to conception has been shown in retrospective and prospective cohort studies to prevent the excess occurrence of birth defects.	<ul style="list-style-type: none"> •American Diabetes Association 2004 •ACOG 1994
Hyperthyroidism	Clinical hypothyroidism is treated with levothyroxine. Levothyroxine requirement increases in early pregnancy. Preconceptional serum testing is needed so that dosage can be adjusted to maintain adequate hormone levels needed for neurological development.	<ul style="list-style-type: none"> •American Association of Clinical Endocrinologists 1999 •ACOG 2002
Anti-epileptic drug (AED) use	There are a number of drugs used to control epilepsy (AEDs), and some of them are known teratogens*. Therefore, for women who are being treated with more teratogenic regimes and who are also contemplating pregnancy, it is recommended that, prior to conception, these women have their seizure control regimens changed to include less teratogenic medications.	<ul style="list-style-type: none"> •American Academy of Neurology 1998 •ACOG 1996
Oral anti-coagulant use	Warfarin, a medication used to control blood clotting in venous thrombotic disease and in heart valve replacement, has been shown to be a teratogen. Therefore, to avoid exposure to Warfarin in early pregnancy, medication regimes be switched to a non-teratogenic anti-coagulant before conception.	<ul style="list-style-type: none"> •American Heart Association 2003 •American College of Cardiology 2003 •ACOG 2001
Accutane use	The medication Accutane can provide effective treatment for severe, recalcitrant, nodular acne. Use of Accutane in pregnancy results in miscarriage and birth defects. Thus, a pregnancy prevention program has been put in place to prevent unintended pregnancies among women with childbearing potential who use the medication. Women desiring to become pregnant should stop taking Accutane prior to conception.	<ul style="list-style-type: none"> •Consensus Practice Guidelines 2001
HIV/AIDS	Perinatal HIV infection in infants of HIV positive women can be prevented by treatment of the mother throughout pregnancy. Identification of HIV infection prior to conception provides women (or couples) additional information which can influence the timing of pregnancy onset.	<ul style="list-style-type: none"> •U.S. Public Health Service 2001 •ACOG 2001

Component of Care	Rationale for Preconceptional Care	Clinical Practice guidelines
Maternal phenylketonuria (PKU)	Women with PKU lack an enzyme needed to break down the amino acid phenylalanine (PHE); the resulting PHE overload is neurotoxic to a developing child. Women with PKU are protected from toxic PHE levels by their mothers' enzymes before birth, and by a special low PHE diet in early childhood. Many adult women discontinue this diet during adulthood when the risk of personal complications from affects of PKU lessens. However, cohort studies have shown that women diagnosed with PKU as infants are more likely to have infants with mental retardation. This adverse outcome is prevented when mothers maintain a low PHE diet starting before conception and continuing throughout pregnancy.	<ul style="list-style-type: none"> •NIH Consensus Conference 2003 • (ACOG) 2001
Smoking	Preterm birth, low birth weight, and other adverse perinatal outcomes associated with maternal smoking in pregnancy can be prevented if women stop smoking in early pregnancy. Since only 20% of women who smoke successfully control tobacco dependence during pregnancy, it is recommended that smoking cessation be completed before pregnancy begins.	<ul style="list-style-type: none"> •Guide to Community Services 2001 •U.S. Public Health Service 2000 •ACOG 2001
Alcohol misuse	Fetal alcohol syndrome and other alcohol-related birth defects can be prevented if alcohol binge drinking and/or frequent drinking behavior is controlled before pregnancy begins. Screening and brief behavioral counseling interventions in primary care settings have been shown in clinical trials to reduce alcohol misuse associated with adverse perinatal outcomes.	<ul style="list-style-type: none"> •U.S. Preventive Services Task Force 2004 •ACOG 1994
Obesity	Adverse perinatal outcomes associated with maternal obesity include neural tube defects, heart defects, preterm delivery, diabetes, cesarean section, and maternal hypertensive and thromboembolic disease. Weight loss prior to pregnancy reduces these risks. Since optimal perinatal outcomes are associated with a weight gain of at least 15 pounds for women with obesity, it is necessary that women with obesity complete weight loss prior to conception. Screening and brief behavioral counseling interventions in primary care settings have been shown in clinical trials to promote sustained weight loss for adults with obesity.	<ul style="list-style-type: none"> •U.S. Preventive Services Task Force 2003

*A teratogen is a reproductive toxin that can cause malformations of an embryo or fetus. This can be a chemical substance, a virus, or ionizing radiation.