

August 30, 2010

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality
540 Gaither Road, Suite 2000
Rockville, MD 20850

Dear Dr. Clancy:

The pharmacy profession, as represented by the organizations listed below, writes in strong support of the research questions (attached) that were recently submitted to the Agency by the Pharmacy Quality Alliance (PQA). This proposed research seeks to identify the best way to deliver medication therapy management (MTM) services —clinical services, often provided by pharmacists, which have been proven to optimize a patient’s medication therapy. Improved medication therapy management results in improved health outcomes, a better quality of life for patients, and lowered health care costs often due to fewer hospitalizations.

The value of MTM services is well documented. However, more evidence is needed on the comparative effectiveness of different MTM delivery models, the best methods for patient engagement in these services, and the evaluation of these services. The PQA proposal addresses these gaps by proposing research questions related to:

- Which patients benefit the most from MTM services?
- What is the optimal structure and process for delivering MTM services?
- How do we enhance patient engagement in MTM services?
- What methods and performance measures are useful in evaluating MTM services?

Answers to these questions would help to determine optimal structures and processes for providing MTM services to patients. This research would also provide evidence to guide the refinement of statutory and regulatory MTM requirements, and could be used by prescription drug plans as they develop their individual MTM programs. In sum, the results of this research would assist in efforts to optimize the value and cost-effectiveness of MTM services.

Because medications have emerged as the first line of prevention and treatment for a myriad of conditions, the need to provide safe, effective medication management that optimizes patient outcomes has never been greater. Yet research has shown that the quality of medication use is far from optimal. Each year, medication related problems result in untimely deaths and contribute to avoidable costs to the health care system. For example, a 2006 Institute of Medicine report estimated "that there are at least 1.5 million preventable ADEs [adverse drug events] that occur in the United States each year. The true number may be much higher."ⁱ Preventable “medication errors” (errors occurring in the medication-use process) are among the most common medical mistakes, incurring at least \$3.5 billion a year in extra hospital costs alone.ⁱⁱ Poor medication adherence, drug to drug interactions and drug and dosage levels that may not be suitable for certain patient populations are all examples of the need for better medication management.

Congress recognized the need for better management of medication therapy by including an MTM program within the Medicare Part D prescription drug benefit. The evidence produced by this research, which reflects AHRQ’s research priorities, will help CMS refine its MTM policies for Medicare and Medicaid beneficiaries. Additionally, this evidence could be used in the private sector by health plans and employers as they seek to optimize the health of patients that they serve. Finally, this research will help PQA provide specific recommendations to MTM

providers on best practices in MTM.

We, the undersigned organizations, strongly encourage you to incorporate these questions in your research activities and explore this concept that holds so much promise for patients, payors and the entire healthcare system. We would welcome the opportunity to address any questions you may have. Please do not hesitate to contact Kristina Lunner, Vice President of Government Affairs for the American Pharmacists Association, at klunner@aphanet.org or 202.429.7507.

Sincerely,

Academy of Managed Care Pharmacy
American Association of Colleges of Pharmacy
American College of Clinical Pharmacy
American Pharmacists Association
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
College of Psychiatric & Neurologic Pharmacists
Food Marketing Institute
International Academy of Compounding Pharmacists
National Alliance of State Pharmacy Associations
National Association of Chain Drug Stores
National Community Pharmacists Association
Rite Aid Corporation
Safety Net Hospitals for Pharmaceutical Access
Walgreen Co.

Attachment

ⁱ Preventing Medication Errors: July 2006, Institute of Medicine

ⁱⁱ The National Academies Press: To Err Is Human: Building a Safer Health System (2000) Available from http://books.nap.edu/openbook.php?record_id=9728&page=1. Accessed July 29, 2010.



TOPIC NOMINATION FORM

Suggesting a Topic for Effective Health Care Research

The Effective Health Care Program (EHC) researches available health care tests and treatments to determine whether there are significant advantages or disadvantages with different approaches. The results of this comparative effectiveness research can help people make better decisions about what health care they want to have, and can help clinicians and health care purchasers to focus on the best tests and treatments.

[SEARCH FOR EXISTING EHC PRODUCTS](#)

The process of identifying, selecting, and developing important research topics for research reviews or new research is a key aspect of the EHC program. The process is enhanced by strong involvement of stakeholders, maintaining transparency and public accountability, and striving for continuous self-evaluation and improvement. The program uses an established set of criteria to guide the process of topic selection. This form is organized by these selection criteria.

[SEE HOW YOUR TOPIC WILL BE EVALUATED](#)

We would like to understand important aspects of the health care service you are interested in, including to whom it applies, what benefits or harms are of greatest interest, and with what other health care services or tests you think it should be compared. **Your answers to these questions will help us phrase your suggestion as one or more research questions that could be answered through AHRQ EHC comparative effectiveness or effectiveness products.**

[LEARN MORE ABOUT THE EHC PROGRAM](#)

To nominate a topic for research in this program, please fill in the form below as completely as possible and click on “submit” at the end. If you prefer to submit a paper copy, you may print the form and mail it. If you have any supporting documents you would like to include with your nomination, you can include them (if mailing), send them as additional attachments (if e-mailing), or you can upload them while submitting the online form. All topic nominations, including those submitted on paper, will appear in the [Read Suggested Topics for Research](#) section of the Web site. Click [here](#) to view an example of a completed form.

Thank you for participating in the program!

TOPIC NOMINATION

1. Your Nomination –Briefly describe a specific question, or set of related questions, about a health care treatment that this program should consider.

1. Which patients benefit the most from MTM services?

1.1. Which factors, or combinations of factors, are most predictive of the clinical benefit of MTM services?

1.1.1. Disease factors (e.g., diabetes vs COPD ; multi-morbidity vs single disease; recent diagnosis vs long-standing illness)

1.1.2. Patient characteristics (e.g., age, gender, cognitive function, race/ethnicity, education level, health literacy, income)

1.1.3. Medication factors (e.g., number of medications, total expenditures on medications, patient out-of-pocket expenditures on medications, or type of medication [high-risk drugs])?

1.1.4. System factors (e.g., number of prescribers for patient, geographic location [rural vs urban], dual-eligibility for Medicaid/Medicare, undergoing transition in care)?

1.2. What is the relative importance of disease state vs patient characteristics vs socioeconomic vs medication variables in predicting the cost-effectiveness of MTM services? What are the interactive effects of these variables?

2. What is the optimal structure and process for delivering MTM services?

2.1. What are the relative clinical effectiveness and cost-effectiveness of different delivery modes (e.g., telephonic vs face-to-face vs blended)? How does the delivery mode interact with the characteristics of the population in predicting the effectiveness of MTM?

2.2. What is the optimal timing of MTM services relative to events or diagnosis (e.g., initiation of drug therapy; gap in adherence; care transition; time from diagnosis) and what are the most successful approaches to patient enrollment in each of these situations?

2.3. What are the key components of MTM services and how can these be matched appropriately to the needs of the patient (e.g., comprehensive medication review upon addition of new therapy; medication reconciliation during care transition)?

2.4. What is the optimal frequency of follow-up consultations after the initial MTM consultation? Does this vary by disease or by patient characteristic?

2.5. How can MTM services be coordinated with the patient-centered medical home? What MTM services should be provided to physicians versus directly to patients?

3. How do we enhance patient engagement in MTM services?

- 3.1. What reasons are cited by patients for participation in MTM services or for declining an offer for MTM services?
- 3.2. What are the optimal methods for informing patients about MTM services and for extending offers for the services?
- 3.3. To what extent do physician referrals for MTM services affect patient participation in MTM?
- 3.4. What incentives are effective in boosting patient participation/engagement in MTM services?
- 3.5. Are there racial/ethnic or gender differences in participation rates in MTM services? How can we create culturally-appropriate messages to encourage participation in MTM services?
- 3.6. What are consumer preferences for the delivery process of MTM (e.g., telephonic, face-to-face, home visit, web-chat) and how do these preferences vary by sub-population?
- 3.7. How can caregivers and/or family members be appropriately integrated into MTM services?

4. What methods and performance measures are useful in evaluating MTM services?

- 4.1. Which MTM performance measures are most useful for continuous quality improvement of MTM services or for ongoing comparison of MTM programs?
- 4.2. What are the crucial data elements for evaluating MTM programs (e.g., drug claims, medical claims, laboratory data, clinical measurements [blood pressure, pulmonary function], health status) and how can these data elements be integrated most efficiently?
- 4.3. What are the barriers to aggregation of MTM program data across health plans and how can these barriers be overcome in an efficient manner?
- 4.4. What methods are useful for estimating the duration of impact of MTM interventions and how can multiple endpoints be combined in one model for robust evaluation of the duration of effect? Can this multi-variable model be used to identify the optimal timing of follow-up MTM consultations for different sub-groups of patients?
- 4.5. How can health status measurements (e.g., quality of life, activities of daily living) be efficiently integrated into MTM programs for patient management as well as program evaluation? How can assessments of patient experiences/satisfaction be conducted?

2. Does your question include a comparison of different health care approaches?

(If no, your topic will still be considered.)

No

Yes If yes, explain the specific technologies, devices, drugs, or interventions you would like to see compared:

Examples:

- *Calcium versus biphosphonates for the prevention of vertebral fractures*
- *Core needle biopsy versus open surgical biopsy for diagnosing breast lesions*
- *Antireflux medication versus diet and exercise for the control of acid reflux symptoms*

The research would compare different models for assisting patients in managing their medications for chronic diseases. See response to item #1 regarding specific research questions.

3. What patients or group(s) of patients does your question apply to? (Please include specific details such as age range, gender, coexisting diagnoses, and indications for therapy.)

Are there subgroups of patients that your question might apply to? (For example, an ethnic group, stage or severity of a disease.)

Although the research may be pertinent to all patients with chronic conditions, it would be most important to study the effectiveness of MTM services for Medicare beneficiaries with multiple chronic conditions. Medicare Part D benefits include a requirement for prescription drug plans to offer MTM services to Medicare beneficiaries with 2 or more chronic conditions and high drug expenditures. However, we believe that an important aspect of this research is that it will help to identify the patients who would most greatly benefit from the MTM services so that the Medicare requirements for MTM can direct the services to patients in greatest need. This may improve both the effectiveness and efficiency of the Part D benefit.

4. Describe the health-related benefits you are interested in. (For example, improvements in patient symptoms or problems from treatment or diagnosis.)

There is a growing body of evidence that MTM services (including pharmacists' clinical recommendations to patient-care teams) may lead to more appropriate prescribing of medications and improved patient adherence to medication regimens. In turn, the improved use of medications may lead to improved clinical outcomes (e.g., blood pressure, A1c, LDL), reduced incidence of adverse drug-related events and lower rates of hospitalizations, re-hospitalizations or nursing home admissions.

5. Describe any health-related risks, side effects, or harms that you are concerned about.

The risks associated with prospective studies of MTM services should be minimal and can be managed through appropriate coordination of services with the patient's physician(s). If retrospective analyses or evidence syntheses are conducted, there would be no risks to patients.

APPROPRIATENESS FOR EHC PROGRAM

6. Does your question include a health care drug, intervention, device, or technology available (or likely to be available) in the U.S.?

- Yes
- No
- Unsure

7. Which priority area(s) and population(s) does this topic apply to? (check all that apply)

EHC Priority Conditions (updated in 2008)

- Arthritis and nontraumatic joint disorders
- Cancer
- Cardiovascular disease, including stroke and hypertension
- Dementia, including Alzheimer's disease
- Depression and other mental health disorders
- Developmental delays, attention deficit hyperactivity disorder, and autism
- Diabetes mellitus
- Functional limitations and disability
- Infectious diseases, including HIV/AIDS
- Obesity
- Peptic ulcer disease and dyspepsia
- Pregnancy, including preterm birth
- Pulmonary disease/asthma
- Substance abuse

AHRO Priority Populations

- Low income groups
- Minority groups
- Women
- Children
- Elderly
- Individuals with special health care needs, including individuals with disabilities or who need chronic care or end-of-life health care

Federal Health Care Program

- Medicaid
- Medicare
- State Children's Health Insurance Program (SCHIP)
- Other

IMPORTANCE

8. Describe why this topic is important.

Chronic diseases are highly prevalent in the United States where nearly 1 in 2 adults live with at least 1 chronic disease (CDC, 2009). Recent analyses have shown that over 75% of healthcare spending is due to chronic disease and that two-thirds of the rise in healthcare expenditures has been due to the increased prevalence of treated chronic disease. (Partnership to Fight Chronic Disease, 2009). Medications are a key component of treating chronic disease, yet research has shown that the quality of medication use is far from optimal. Congress recognized the need for better management of medication therapy by including provisions for medication therapy management (MTM) within the Medicare Part D drug benefit. Although there are small studies that demonstrate the potential benefit of MTM services, there is a dearth of evidence on the comparative effectiveness of different models for MTM services or the best methods for engagement of patients in these services or for evaluation of these services.

There is a need for better evidence to guide the refinement of statutory requirements, and CMS guidance, for prescription drug plans regarding the provision of MTM services. The current eligibility criteria limit the inclusion of patients to those with multi-morbidity and high drug expenditures. These limitations may preclude enrollment of patients with poor adherence to their chronic medications (since patients who do not refill their medications are unlikely to meet the threshold for drug expenditures), and also preclude enrollment of patients with only one chronic disease. It is possible that some patients who do **not** currently meet the eligibility criteria may benefit from MTM services more so than some patients who are currently eligible.

There is also a need to determine the optimal structures and processes for providing MTM services to patients. Given the wide variety of MTM services being implemented and the uncertainties as to the relative effectiveness of these different MTM models, it is important to generate and/or synthesize evidence on the clinical, economic and humanistic impact of these services. There is also a dearth of evidence on consumer preferences for the structure and process of MTM services. Identifying the “best practices” for provision of MTM services may help clinicians and healthcare organizations to optimize patients’ engagement and providers’ impact in delivering MTM.

9. What specifically motivated you to ask this question? *(For example, you are developing a clinical guideline, working with a policy with large uncertainty about the appropriate approach, costly intervention, new research you have read, items in the media you may have seen, a clinical practice dilemma you know of, etc.)*

Many of the member organizations of PQA are seeking to optimize the effectiveness and cost-effectiveness of MTM services. PQA coordinates a workgroup on MTM services and brings together clinicians, payers and researchers to discuss crucial issues in MTM including how to measure the impact of MTM and the quality of MTM services. This workgroup is limited in its ability to provide specific guidance on the optimal structure and process of MTM due to a lack of comparative evidence on different models of MTM.

Another significant factor that has prompted this recommendation to the Effective Health Care Program is the passage of the healthcare reform act with provisions related to MTM. Congress included an authorization for “MTM grants” to be coordinated by AHRQ (Section 3503), but has not appropriated the funds to carry out the MTM grants program in the current fiscal year. Even if Congress does provide funding for Section 3503 at some point in the future, there will still be great value in having AHRQ’s Effective Health Care Program synthesize the existing evidence on MTM and identify the existing gaps in knowledge. We also believe that there is a wealth of retrospective data from health plans, drug plans and MTM providers that could be analyzed to begin filling the gaps in the evidence base and to identify best practices.

10. Does your question represent uncertainty for clinicians and/or policy-makers?

(For example, variations in clinical care, controversy in what constitutes appropriate clinical care, or a policy decision.)

Yes

No

If yes, please explain:

As noted in items 8 and 9, there is significant uncertainty in how to optimally deliver MTM services and how to structure enrollment and payment policies for MTM.

POTENTIAL IMPACT

11. How will an answer to your research question be used or help inform decisions for you or your group?

The evidence will help CMS refine its policies on MTM for Medicare beneficiaries, and will also be useful to CMS and the states for Medicaid policies regarding medication use. Health plans and employers can also use this evidence to create more appropriate services to optimize the health of patients in the private sector. Furthermore, it will help PQA provide specific recommendations to MTM providers on best practices in MTM.

Describe the timeframe in which an answer to your question is needed.

As soon as possible.

12. Describe any health disparities, inequities, or impact on vulnerable populations your question applies to.

We believe it is important that a research program on MTM services include studies to determine the best practices for engaging different sub-populations of patients in MTM to reduce disparities in medication use and health outcomes.

TECHNICAL EXPERTS AND STAKEHOLDERS

13. Are there health-care-focused, disease-focused, or patient-focused organizations or technical experts that you see as being relevant to this issue? Who do you think we should contact as we consider your nomination?

This information will not influence the progress of your suggestion through the selection process, but it may be helpful to those considering your suggestion for further development. The information is for internal discussion and will not be displayed in the public reading room.

Examples:

- American Heart Association and American College of Cardiologists
- Mental Health America

a. List organizations:

Centers for Medicare & Medicaid Services
Pharmacy Quality Alliance

b. List individual experts:

Julie Kuhle, Iowa Foundation for Medical Care
Brad Tice, PharmMD
Brand Newland, Outcomes Pharmaceutical Health Care
Kim Swiger, Mirixa
William Doucette, University of Iowa
Brian Isetts, University of Minnesota
Lawrence Brown, University of Tennessee
Michelle Ketcham, CMS

NOMINATOR INFORMATION

14. In order to help us to understand the context of your health care question, it would be helpful to know more about you. The answers you give will not influence the progress of your suggestion.

a. Choose a description that best describes your role or perspective: *(you may select more than one)* ***We are a multi-stakeholder organization***

- Patient/Consumer
- Physician
- Nurse/Nurse Practitioner/P.A.
- Pharmacist
- Other Health Care Professional
- Professional Society
- Public Policy-Maker/Legislator
- Continuous Quality Improvement Group
- Health Benefits Plan/Insurance Carrier
- Administrator (Hospital or Other)
- Health Care Payer/Purchaser (Employer, Federal Government, or State Government)
- Health Care Industry (Device, Drug, or Other Manufacturer)
- Researcher

b. Are you making a suggestion as an individual or on behalf of an organization?

- Individual
- Organization

c. If organization, please state the name of the organization: (optional)

The Pharmacy Quality Alliance (PQA) represents nearly 60 member organizations that are mutually dedicated to the improvement of safety and quality in the use of medications. These stakeholder organizations include federal agencies (e.g., CMS, FDA), professional societies, trade associations, health plans, prescription drug plans, pharmacy benefit managers, pharmacy providers, and consumer advocates. The recommendations presented in this form have been reviewed by the PQA workgroup on medication therapy management (MTM) as well as by multiple pharmacy stakeholders.

d. Please tell us how you heard about the Effective Health Care program

e. Your name and contact information: (optional)

Your personal identification will not be displayed in the public reading room, nor will it influence your nomination for Effective Health Care Research. It will only be used to contact you for additional information about your nomination if necessary. It is not mandatory that you provide your contact information, but it is often helpful for us to contact the nominator when we need clarification about a research question.

Your Name: **David Nau**

Your Title: **Senior Director, Research & Performance Measurement**

Your Organization: **Pharmacy Quality Alliance (PQA)**

Your e-mail address: **dnau@PQAalliance.org**

Confirm your e-mail address: **dnau@PQAalliance.org**

May we contact you if we have questions about your nomination?

Yes

No

Thank you for suggesting a topic. If you have answered all of the necessary questions, checked your answers, and are happy with your form, please e-mail the completed form to Effectivehealthcare@ahrq.hhs.gov, or you may print out the completed form and mail it to:

AHRQ Effective Health Care Program
c/o Scientific Resource Center at Oregon EPC
Center for Health Research
3800 N Interstate Avenue
Portland, OR 97227-1110
Attn: Michelle Eder

If you have comments about the form or suggestions for improvement, please e-mail the AHRQ Effective Health Care Program at Effectivehealthcare@ahrq.hhs.gov.

All topic nominations, including those submitted on paper, will appear in the [Read Suggested Topics for Research](#) section of the Web site.