The University of Iowa Older Adults Center for Education and **Research on Therapeutics (Iowa CERT)**

Final Report

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Structured Abstract

Purpose: To make policy-relevant estimates of treatment effectiveness and test interventions to address barriers to optimal therapeutics for older adults in community care settings.

Scope: Whereas clinical practice guidelines exist and departures from optimal practice are well-documented for specific diseases, it is not known whether such guidelines generalize to the elderly with multiple comorbidities. In the limited clinical situations where clinical trial evidence of therapeutic benefit among the elderly is strong, barriers to guideline adherence are more prevalent in the elderly including drug-to-drug interactions, drug-disease contraindications, alterations in decision-making capacities, and compounded adverse event risk due to multiple medications

Methods: Community-based physician and pharmacist research networks and collaborations with state agencies as well as end-users including health plans and patients ensured that stakeholders were involved in all projects. Projects included a study of long-term effectiveness of a collaborative model of hypertension management, database and prospective studies of age disparities in cancer treatments and outcomes, and a longitudinal survey of the effect of the Medicare Prescription Drug, Improvement, and Modernization Act on patient medication safety and access.

Results: The theme of the Iowa CERT was optimizing therapeutics for complex older adults. In the 5 years of the award the Iowa CERT completed 19 projects and over 100 publications. More than two dozen papers addressed comparative effectiveness evidence and methods and over 30 papers evaluated effects of the Medicare Part D program with particular emphasis on its Medication Therapy Management requirement. Project results were translated into tools and fact sheets for providers and patients.

Key Words: comparative effectiveness; decision making; geriatrics; elderly; patient safety /medical error

Purpose

Between 14 and 23% of the elderly receive a medication they should not have been prescribed. Up to 40% of patients do not take their medications as prescribed. Under-use of certain medications like beta blockers or ACE inhibitors is also of concern. Whereas clinical practice guidelines exist and departures from optimal practice are well-documented for specific diseases, it is not known whether such guidelines generalize to the elderly with multiple co-morbidities. In the limited clinical situations where clinical trial evidence of therapeutic benefit among the elderly is strong, barriers to guideline adherence are more prevalent in the elderly including drug-to-drug interactions, drug-disease contraindications, alterations in decision-making capacities, and compounded adverse event risk due to multiple medications. The University of Iowa Older Adults CERTs (UIOAC) offers the CERTs program research expertise for (1) making policy-relevant estimates of treatment effects and cost-effectiveness among subsets of the elderly defined by important characteristics such as function status, co-morbidity, and age and (2) identifying and designing interventions to address barriers to optimal therapeutics in the elderly in community care settings.

The specific aims of the Iowa CERT were to:

- 1. Improve safety and effectiveness of medication use among older adults through intervention and database research projects
- 2. Expand existing collaborations to new partnerships with private and public entitities and
- 3. Educate healthcare providers, patients, and policy makers about therapeutic decision-making in the elderly.

Scope

For all major chronic disease burdens, older adults are less likely to receive guideline-recommended treatments. Yet, because of multi-morbidity, older adults do take a large average number of medications relative to younger adults. For an individual older adult this means that the decision about how to treat their next new health condition is complex: set against their accumulated medications for multiple comorbid conditions, current functional status, and relative preferences for potential health outcomes, there is great uncertainty about the balance of benefit and toxicity from adding a new treatment. Practice guidelines based on randomized efficacy trials leave much uncertainty for individual patients facing such decisions.

Comparative effectiveness research (CER) holds promise for informing these decisions by generating estimates of "real-world" treatment effects through pragmatic trials and observational studies. However, treatment effects are expected to vary across the multiple comorbidities, multiple medications, and functional status of complex older individuals. Observational study designs are powerful CER tools because of their large size, inclusiveness, and the priority they have traditionally placed on identifying sources of treatment effect heterogeneity. Treatment is not randomized in these databases: individuals can often anticipate how their own characteristics, unobserved to the analyst, will affect their net benefit and they use this information to choose whether to take a treatment. Although these unobserved characteristics are often viewed as undesirable "treatment selection biases," with the appropriate mix of social science and biomedical methodologies CER scientists can turn this to advantage. They can harness these individuals' behaviors in choosing to take or not take a treatment in order to reveal the effectiveness of treatments at the margins of practice, where practice guidelines are less helpful. The University of Iowa Older Adults Center for Education and Research on Therapeutics (Iowa CERT) focused through a multidisciplinary lens on understanding treatment effects and decisions among complex older adults. We proposed to focus in particular on improving CVD and cancer outcomes, the two leading causes of death accounting for 57% of deaths among older adults, and on delivery system interventions benefiting older adults, especially a national program, Medication Therapy Management (MTM), that has the potential to reduce treatment complexity and improve patient safety for millions of Medicare beneficiaries.

Methods

We proposed research and education activities to contribute to these outcomes by generating evidence to know what interventions are most valuable for complex patients and implementation through our partnerships with stakeholders including regional and national organizations engaged in MTM quality improvement and statewide practice networks and cancer and CVD consortia.

The aims were achieved by

- funded research projects organized in Working Groups that met monthly and served an advisory function to the projects
- An Executive Committee that met twice monthly for strategic planning, reaction and discussion of CERTs Administration and Education conference calls, review of progress on CERT projects, and to provide peer review for proposed new uses of core resources.
- An Education and Dissemination subcommittee that developed and disseminated tools and Fact Sheets about CERT projects
- A Databases subcommittee that provided data development, documentation, and analytic support for projects
- A Roundtable Discussion Group that met two to four times per year, typically focused on a visiting speaker.

Results

The lowa CERT conducted substantive research related to delivering the best health care to the elderly. This research generated evidence about effectiveness of treatments among older adults in community practice settings and enhanced healthcare provider capacity to deliver high quality care. The individual lowa CERT projects had their own impact in their specific therapeutic or healthcare programmatic areas, including:

- improving Part D program effectiveness through evaluations of emerging Medication Therapy Management program models;
- improving treatment adherence and outcomes through patient-provider symmetry about decision roles;
- improving blood pressure control through patient-physician collaborative management of hypertension;
- reducing the "digital divide" in access to health information and e-Health resources by user-centered design with older adult partners;
- Documenting continued age disparities in receipt of curative and palliative therapies across lung, colorectal, breast cancers and lymphoma; and
- Advancing the methodology for comparative effectiveness research under heterogeneity of treatment effects.

Other Iowa CERT activities included:

- A variety of presentations on CER methods, medication safety issues in older adults, and other topics
- Participation in planning of a CERT meeting with CMS and others on medication therapy management, as well as a CERT Steering Committee session on medication therapy management research
- Membership on the CHAIN editorial board
- Participation in various other CERT workgroups and meetings
- Successful funding of additional grants that leveraged or expanded on CERT-funded work, and incorporated CERT-stimulated partnerships and collaborations

The Center produced over 100 publications (below) and the majority of these included mulitidisciplinary authorship teams.

Publications and Products

Note: This is a more complete list of publications and products than on the CERTs master database (CITT) because our access to this database ended once the new CERTs were announced.

Electronic Resources

lowa CERT tools (http://www.public-health.uiowa.edu/cert/research/factsheets.html) for clinicians and patients to improve safety and appropriateness of medications in older adults, including:

• Clinical Tools:

- Anticholinergic Pocket Reference Card/Anticholinergic Brochure
- <u>A Pharmacist's Guide for Collection of Complementary Alternative Medication and Dietary Supplement Information from Patients</u>
- Tool to Improve Medications in Elderly via Review (TIMER)
- Managing Your Medications

Fact Sheets

- Dementia, Goals of Care, and Personhood: A Study of Surrogate Decision Maker's Beliefs and Values
- Doctor-Pharmacist Team Care Improves Blood Pressure Control
- Inappropriate Medication Use as a Risk Factor for Self-Reported Adverse Drug Effects in Older Adults
- Lipid-Lowering Therapy for the Primary Prevention of Cardiovascular Disease in the Elderly
- Neuropsychological Outcomes of Older Breast Cancer Survivors: Cognitive Features Ten or More Years after Chemotherapy
- Prescription Drug Sample Use and Requests for Lower Cost Prescription Drugs among Medicare Beneficiaries
- Older Adults Think Their Medicines Cause Symptoms but Often Don't Tell Their Doctors
- The Effect of Medicare Part D and Prescription Insurance Type on Medicare Beneficiary Access to Prescription Medicare and Use of Cost-Saving Measures
- **Iowa Personal Health Record (Iowa PHR)**. Web-based Tool. 2011. University of Iowa. https://www.iowaphr.org/

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