



National Institute of
Diabetes and Digestive
and Kidney Diseases

**National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), National
Institutes of Health (NIH)**

Kidney Interagency Coordinating Committee (KICC) Meeting

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I. Welcome and Introductions

Andrew Narva, MD, FACP

The goal of the committee is to encourage cooperation, communication, and collaboration across federal agencies involved in kidney research and other kidney-related activities. This KICC meeting focused on patient safety and the reduction of acute kidney injury (AKI), especially injuries associated with medications.

II. Patient Safety and Chronic Kidney Disease

Jeffrey Fink, MD

Among the findings of the 1999 Institute of Medicine (IOM) report, *To Err is Human: Building a Better Health System*, is that at least 44,000 and possibly up to 98,000 people die in the hospital each year as a result of preventable medical errors. Since the release of the report, there have been efforts to reduce medical errors. However, the results have been mixed. For example, an Agency for Healthcare Research and Quality (AHRQ)-funded study tracked adverse events in 61,523 hospitalizations for four common conditions from 2005-2011. While there were improvements in some areas, in others there was no improvement in terms of patient safety.

Patient Safety: Working Definition

An unintended injury or complication that is caused by health care management, rather than by the patient's underlying disease process, and results in disability or harm.

Patients with chronic kidney disease (CKD) can experience many medical events that can disrupt renal function. Many of these events are preventable—and preventing them could slow the progression of CKD in patients and the incidence of end-stage renal disease (ESRD). Treatment of CKD can be complex, with issues such as multiple chronic conditions, appropriate drug dosing, multiple medications, cognitive impairment, and poor health literacy making treatment difficult and contributing to possible lapses in patient safety. This is compounded by the failure on the part of other providers (e.g., emergency room providers, primary care providers) to recognize CKD and take it into consideration during treatment.

An additional challenge is that there is no common set of safety metrics for CKD. For example, AHRQ has developed patient safety indicators (PSI), but they are not particularly relevant for CKD. Such a common set of measures is necessary to evaluate CKD practice.

The Veterans Administration (VA) Patient Safety Cohort explored the rate of general safety events using the AHRQ PSIs by severity of CKD. The cohort included 247,176 veterans hospitalized in 2004 with one pre-hospital measurement of creatinine. About 30 percent of the patients in the cohort had CKD. The study found that while safety events as defined by the AHRQ PSI were relatively rare, the risk of an adverse safety event increased with severity of CKD.

To gain more insight, the researchers developed their own set of CKD-specific patient safety indicators. With these CKD-specific indicators, safety events increased in relation to the risk factors for a safety event (i.e., age > 75, GFR < 30, Charlson Comorbidity Index, cardiovascular

disease). The odds of having a CKD-related safety event were much higher than when using the AHRQ PSIs. Using the CKD-related safety indicators revealed a forty fold increase in prevalence of safety events in the later stages of CKD.

It is important to note that neither the AHRQ PSIs nor the CKD-specific measures address medication errors. A 2001 study of almost 8,000 CKD patients over an 8-month period found that of over 773,000 medication orders, 14 percent were for nephrotoxic medications or medications that require dose modification for CKD patients (i.e., renal relevant), and of these, 13 percent were improperly dosed (Chertow, et al, JAMA, 2001).

The VA Safety Cohort Study also explored the likelihood of multiple safety events over a discrete time in CKD, substantiating the notion that CKD patients are particularly vulnerable to safety events. It was used to look at the likelihood of having a safety event resulting from 1) hyperkalemia; 2) hypoglycemia; 3) medication errors; or 4) AHRQ PSIs over a year or less of observation. The study focused on four medicines: digoxin, atenolol, allopurinol, and glyburide. Of the more than 70,000 veterans with CKD in the study, 18.9 percent had one or more dosing errors. This is an underestimate of medication dosing errors since it only involved four drugs.

Over a period of less than a year, seven percent of the cohort had three or more safety events. Given the limited duration of the study, this has significant implications for the number of safety events over the lifespan of a person living with CKD.

Safe Kidney Care Study

Funded by NIDDK in 2010, the study is designed to explore whether under-recognition of kidney disease affects patient safety and ways to increase recognition of CKD in patients. The study piloted medical alert bracelets intended to increase recognition of CKD. The pilot sub-cohort of 108 patients were offered the bracelet, the second sub-cohort was not. There has never been a randomized trial to evaluate the effectiveness of medical alert bracelets.

The participant demographics reflect the community where the study took place (e.g., Baltimore) and the VA patient population. The majority of the participants were over 65, male, and African American. There was a high incidence of diabetes and cardiovascular disease in the study population. The median number of medicines for participants in the study was 13. While the study population is not the most likely to spend time online, approximately 30 percent of participants did log in to the study's website at least once. Participants were also given a paper diary to record safety events that occurred outside of clinic so they could be tracked by the researchers.

The bracelet states, "Decreased kidney function. For my care please visit www.safekidney.org." It also includes the patient's unique study identity. The bracelets are customized based on the participant's preferences (e.g., type of metal, size). Participants are encouraged to visit the website and register so that the researchers can track their use of the website. Approximately 40

Most Common Drugs Linked to Adverse Drug Events in Kidney Disease

- Antibiotics
- Analgesics
- Cardiovascular meds
- Diabetic meds
- Antifungals
- Neurotropics

percent of the participants that had the bracelet reported that it contributed to a “near miss” in terms of a medical decision that was not appropriate given the patient’s CKD.

The researchers conducted baseline assessments (e.g., self-reported safety events questionnaire, estimation of eGFR, medication prescribed within last 30 days, bacterial skin cultures for staph colonization). Three safety “classes” were identified.

- **Class I**, Patient-reported safety incidents: reported by patient that they attributed to a medication treatment (e.g. hypoglycemia, hyperkalemia, falling).
- **Class II**, Actionable safety findings: discovered during clinical evaluation with the potential to be corrected with modification in a treatment.
- **Class III**, Adverse safety hazards: treatments or consequences of medical care that are not injurious at the time of discovery but represent a threat to a patient’s health.

The first report from the cohort on Class I events found that hypoglycemia was the most commonly reported event. The researchers sought to condition the event on use of pertinent medications (i.e., documenting if the patient was on a medication that could have caused the event) to determine whether it was actually a safety event. For Class II events high hemoglobin and hyperkalemia were the top two events. It is important to note that none of the patients who had high hemoglobin were on any erythropoietin-stimulating agents (ESA), so this did not constitute a safety event.

The researchers are also conducting association analysis (e.g., market basket analysis), which is a way to explore the relation between variables. The metrics in association analysis include:

- Support—the prevalence of individuals with the co-occurrence of a pair of events in relation to the entire sample of individuals;
- Confidence—the likelihood of a consequent event following an antecedent event; and
- Lift ratio—the ratio of the confidence over the expected confidence.

In the analysis, the most commonly reported event among participants with diabetes was hypoglycemia, with falling or severe dizziness as the most common co-occurring event. For patients that experienced falling it was highly likely (69% confidence) that they were also hypoglycemic. A similar analysis was done for 16 other events. Identifying these relationships presents an opportunity for intervention. For example, if a patient has hypoglycemia, the provider can also ask about falling and make appropriate interventions.

To track medication errors in the study cohort, the researchers record all medications, including over the counter medications. Currently, there is no search engine for identifying medication errors related to eGFR. This would have facilitated the process.

Medications were assigned to one of four groups: avoid, adjust, review, and okay. Each medication and dose was recorded along with the participant’s eGFR. The database flags appropriate dosages based on the eGFR. The flags were consistent across different eGFR estimating equations.

The findings from the review of medications indicated that the top medication hazard was aspirin. Many other common medications, which are viewed as relatively safe, were also frequently flagged. This indicates the importance of reviewing medication hazards for patients with CKD. In particular, use of over-the-counter medications should be reviewed with patients.

Discussion

- Dr. Narva asked what federal agencies could do to implement interventions based on the study's findings. Dr. Fink stated that low-cost interventions like the medical alert bracelet can make a difference, especially since patients are seen by multiple providers. There is also a need for common terminology related to safety events and performance measures to assess practitioners and health systems.
- Dr. Flessner asked whether prompts in electronic health records (EHR) are an effective way to prevent medication errors. Dr. Fink stated that there are prompts related to eGFR in the VA's EHR. Dr. Pogach added that there have been studies related to point-of-care decision support and the effectiveness of prompts in the EHR.
- Dr. Flessner asked if EHR prompts are used in the Canadian system. Dr. Narva stated that a Canadian study explored the impact of EHR alerts based on eGFR. The study found that there was no impact on physician behavior, but that the EHR alerts did have an impact on the care provided by pharmacists.
- Dr. Pogach asked whether over-treatment of some chronic conditions (e.g., hyperglycemia, high blood pressure) contributes to increased safety events. Dr. Fink stated that this area needs more study.
- Ms. Ashe-Goins asked if the study was limited to admissions by nephrologists or included all admissions. Dr. Fink stated that the VA Safety Cohort included all admissions.
- Dr. Bartman asked whether patients were adherent in terms of consistently wearing the medical alert bracelet. Dr. Fink stated that patients were surveyed and over 66 percent reported wearing the bracelet 5-7 days per week. Dr. Bartman added that some people are getting tattoos that state their medical conditions.

III. Preventing Acute Kidney Injury in the Community

Thomas Blakeman, MRCGP, PhD

The United Kingdom's (UK) National Health Service (NHS) was launched in 1948 with the guiding principles of universality, equity, and quality. Everyone is eligible for care, which is provided free of charge. Care is based on clinical need and the services are supported through central taxation. Under the NHS, general practitioners (GPs) are independent contractors and serve as gatekeepers to services. The practice team includes GPs, nurses, and health care assistants. EHRs are universally used. Funding is largely based on a capitation fee (the current list size for each GP is approximately 1,700 patients) as well as quality of care payments.

There is recognition that care within the NHS needs to be accessible, clinically effective, and patient-centered; as well as safe, efficient, and sustainable. Both in the UK and internationally, service reorganization is seen as essential in order to achieve high quality chronic illness care.

As a key example, the Chronic Care Model highlights elements of a health system required to achieve productive interactions. These elements include: delivery system design, decision support, clinical information systems, and self-management support.

In 2004, the Quality and Outcomes framework (QOF) was introduced. Based on best available evidence, indicators of quality have been assigned to certain long-term conditions. Practices are then paid for achieving targets derived from these indicators. Clinical information systems comprised of computer templates have been developed to help professionals deliver such care.

There is also an emphasis on supporting patient self-management. This entails:

- Providing meaningful information;
- Monitoring and addressing exacerbations;
- Adjusting medications;
- Improving lifestyle behaviors; and
- Improving access to services, including peer networks and community support.

Chronic Kidney Disease

In 2008, the National Institute for Health and Care Excellence released guidance for the identification and management of CKD in both primary and secondary care. The guidelines provide a platform to support blood pressure control, lifestyle change, and medication management.

Reflecting a focus on vascular health and prevention of disease progression, indicators of quality have been assigned to CKD. There have been various iterations of the CKD domain of the QOF. General practices are then paid for achieving targets derived from these indicators. This includes payment for:

- Establishing a disease register of patients with CKD;
- Ensuring that patients with CKD have their blood pressure controlled;
- Having a urine sample sent to detect proteinuria; and
- Ensuring patients with CKD and proteinuria are prescribed an ACE inhibitor or an ARB.

Quality improvement (QI) work at the University of Manchester (Manchester) has focused on the implementation of a toolkit to support practices that identify and manage patients with CKD—again with a focus on blood pressure control and detection of proteinuria. Manchester has also developed a kidney information guidebook with a focus on helping put CKD in the context of maintaining general vascular health. This was delivered in conjunction with telephone and website support to help signpost people to relevant resources in their local community to support lifestyle change. This has been evaluated through a randomized control trial—a manuscript has been submitted for peer-review publication.

A key issue that has emerged since the introduction of the CKD classification has been what to do with the elderly. Resonating with wider concerns in the literature, qualitative research that was conducted at Manchester highlighted a reticence to discuss a diagnosis of CKD, particularly with patients who are elderly and/or have stage 3a. If discussed, evidence is framed in the form of reassurance (i.e. ‘nothing to worry about’).

Manchester is embarking on further QI initiatives that are person centered and make CKD meaningful for both patient and practitioners. The current gaps in implementation highlight a need to broaden the reasons for discussing the diagnosis and then personalizing the conversation according to need. For example, discussions with a 56 year-old may need to be different than to an 86 year-old housebound woman and her caregiver.

Transforming Urgent/Emergency Care

- Provide better support for self-care, self-treatment options, and a care plan so people know what to do and who to contact in the event of deterioration.
- Help people with urgent care needs get the right advice the first time.
- Provide responsive urgent care services outside hospital.
- Connect all urgent and emergency care services.

Broadening and tailoring discussions around CKD offers the potential to address strains in urgent and emergency care. The demand for urgent care has increased each year and will continue as people live longer with multiple, complex chronic conditions. The current service structure is unsustainable.

In April 2014, a new NHS contract with a focus on vulnerability will be put in place for GPs. It is designed to promote whole-system solutions to prevent avoidable emergency care admissions. Provisions include:

- Provide all patients aged 75 and over with named, accountable GP;
- Give timely access to relevant providers;
- Identify and case manage the most vulnerable patients (top 2 percent of patients);
- Review and improve discharge process; and
- Conduct internal reviews of unplanned admissions.

AKI is common, harmful, costly, and avoidable. It is more common in older patients and those with complex comorbidities, the prevalence of which is greater in areas of socioeconomic deprivation. CKD is reported to be the most consistent pre-existing condition associated with AKI. Hypovolemia associated with any type of insult, including exposure to sepsis and nephrotoxic drugs, is the most modifiable risk factor.

AKI is often the result of poor care (e.g., delayed diagnosis, failure to systematically apply basic care) and can serve as a quality marker. Ensuring that health care providers consider the risk of AKI can drive care in the direction of better outcomes and increased patient safety. A systematic approach to preventing AKI that focuses on the basics of care includes:

- Risk of AKI as a marker of vulnerability to identify those at highest risk (2% most vulnerable);
- Proactive care for the most vulnerable (e.g., annual reviews, episodes of acute illness, post-discharge care);
- Annual disease management reviews (e.g., medication review to identify nephrotoxic potential);

- Social and caregiver support;
- Action plans for patients for management of acute illness (e.g., what to do in the event of flu, urinary tract infection, etc.);
- Better assessment of acute illness by providers; and
- Post-discharge care (e.g., mention AKI in discharge summary, mechanism to ensure GP review, medication review, check renal function, social and caregiver support; action plan).

Dr. Blakeman and colleagues will be conducting a study focused on preventing AKI that will explore implementation of such a systematic approach. The study will evaluate the implementation of these components and also assess clinical and cost effectiveness.

Discussion

- Dr. Kozlovsky stated that the focus on patient vulnerability for improving safety and outcomes is an interesting concept.
- Dr. Flessner asked whether NHS payments to GPs drive implementation of specific processes. Dr. Blakeman stated that the payments are a mechanism to drive implementation. NHS publishes data related to all the core quality markers (see <http://qof.hscic.gov.uk/>).
- Dr. Flessner asked about the diversity of the patient population in the UK and whether it is difficult to engage with patients that do not speak English. Dr. Blakeman stated that he works in an inner city practice and sees patients from a diverse range of backgrounds. His work includes seeing patients that do not speak English multiple times during the course of the day. Use of an interpreter through Language Line is often used during these consultations. How to discuss kidney health in the context of patient-centered care and overall health can be a challenge with these patients, although evidence suggests it can be challenging to make a diagnosis of CKD meaningful for all patients.
- Dr. Watson asked if there is a single, interoperable EHR used across NHS. Dr. Blakeman stated that there are different software systems that submit common data to the NHS.
- Dr. Star asked whether there are other variables (e.g., pneumonia) for vulnerability that would be better than AKI. Dr. Blakeman stated that risk stratification tools are used to identify vulnerability. Dr. Blakeman plans to explore incorporating AKI into these tools. Dr. Narva added that successful reduction of AKI would be a good indication that the systemic approach focusing on vulnerable patients had been successful. Dr. Blakeman stated that this will be the focus of his upcoming research (though note there may be increased coding of AKI in the short term).
- Dr. Narva asked how the criteria for identifying the most vulnerable patients are determined. Dr. Blakeman stated that risk stratification models are used to help GPs identify vulnerable patients with the goal of reducing hospital admissions. The new contract for 2014 that will include a new payment structure has not yet been implemented.

III. Patient Safety in CMS Quality Programs for Patients with ESRD

Joel Andress, PhD

Dr. Andress' presentation slides are available as a [separate PDF](#) document.

IV. Preview of Department of Health and Human Services (HHS) National Action Plan for Hypoglycemic Safety

Leonard Pogach, MD, MBA

Adverse drug events (ADEs) are responsible for approximately 100,000 emergent hospitalizations in older Americans each year. Approximately two-thirds result from just four medication classes (anticoagulants, insulin, oral hypoglycemic, and antiplatelets). In addition, approximately two-thirds result from unintentional overdoses. In response to these findings, HHS formed an interagency working group to develop the National Action Plan for Adverse Drug Event Prevention. The Action Plan focuses on anticoagulants, diabetes agents, and opioids using a four-pronged approach:

- Surveillance;
- Evidence-based prevention tools;
- Incentives and oversight; and
- Research/identification of unanswered questions.

Within the section focused on diabetes agents, there is a focus on the use of the chronic care model to prevent adverse drug events while simultaneously addressing the need to manage comorbid conditions. Data indicate that most adults with diabetes have at least one comorbid chronic disease and up to 40 percent have at least three. Improving diabetes management requires a holistic, patient-centered approach—with patients as partners in deciding treatment goals. Effective participation by patients requires health literacy and numeracy skills. Disabling conditions such as advanced heart failure and cognitive impairment/dementia may make self-care more difficult.

There are opportunities for advancing prevention of hypoglycemic ADEs across multiple domains.

- Safer care (e.g., individualized glycemic goals, shared decision making, evidence-based protocols);
- Patient and family engagement (e.g., shared decision making, patient education/health literacy tools);
- Communication and coordination of care (e.g., multidisciplinary and systemic approach, medication reconciliation, care transition models); and
- Science-driven prevention and treatment (e.g. address inaccuracy of self-monitoring of blood glucose, root-cause analyses for all inpatient hypoglycemic events).

The Action Plan includes recommendations for advancing policy strategies:

- Expand national health care quality reporting measures to include concepts related to multidisciplinary, systemic, and coordinated models of care.
- Adopt health care quality reporting measures that reflect latest advances in science related to prevention of hypoglycemic events.
- Consider payment/coverage barriers that could improve the uptake of evidence-based high-quality ADE Prevention strategies (e.g., patient engagement, health literacy).
- Explore the public reporting of national health care quality measures to include measures specific to hypoglycemic events.
- Take advantage of EHRs to identify patients at high risk of hypoglycemia.
- Address barriers to integrated communication and coordination across health care settings.

Dr. Pogach recommended that the Diabetes Mellitus Interagency Coordinating Committee and the KICC work together to achieve the goals of the Action Plan.

Discussion

- Dr. Narva stated that hypoglycemia and hypotension are major issues for people with CKD. NKDEP materials identify hypoglycemia as a possible indicator of CKD progression. NKDEP's materials are designed to educate providers about the uncertainty in the results of eGFR and UACR.

V. Comparative Short-term Safety of Iron Sucrose vs. Sodium Ferric Gluconate for the Treatment of Anemia in Hemodialysis Patients

Barbara Bartman, MD, MPH

The American Recovery and Reinvestment Act of 2009 called on the IOM to recommend a list of priority topics to be the initial focus of new national investment in comparative effectiveness research (CER). The IOM developed a list of 100 priority topics. In response, AHRQ requested proposals to develop and disseminate valid scientific evidence to inform stakeholder decisions regarding the CER of medical treatment, technologies, tests, procedures, or other clinical interventions. One of the two projects addressing renal disease is the Comparative Effectiveness of Intravenous Iron Formulations in ESRD, which was conducted by Maurice Alan Brookhart, PhD, under AHRQ's Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) program at the University of North Carolina at Chapel Hill.

VI. AHRQ Patient Safety Project

Kendall Hall, MD, MS

AHRQ's Healthcare Associated Infections (HAI) Portfolio supports projects aimed at reducing HAIs, reducing the transmission of multi-drug resistant organisms, and reducing the emergence of multi-drug resistant organisms through stewardship activities. Much of the research has focused on inpatient settings, the ICU in particular, but following the HHS National Action Plan to Eliminate HAIs, the work is moving into the long-term care and outpatient settings, including dialysis facilities.

Optimizing Antimicrobial Use in Dialysis Facilities

(PI: Erika D'Agata, Beth Israel Deaconess Medical Center)

This R18 grant aims to develop, implement, and demonstrate the effectiveness of an antimicrobial stewardship program in dialysis facilities. The stewardship program will combine behavioral and systems change strategies and educational interventions to address three key categories of inappropriate prescribing: lack of following national consensus criteria for diagnosing infection; lack of de-escalation of antimicrobial therapy; and continuing prophylactic antibiotics for access-related procedures longer than 24 hours post-procedure. The researchers will also explore the cost-effectiveness of the stewardship program.

National Opportunity to Improve Infection Control in ESRD

(Contractor: Health Research and Educational Trust in conjunction with University of Michigan Kidney Epidemiology and Cost Center and Renal Networks 11 and 6)

The goal of this project is to develop and test a change package to improve infection control practices to reduce vascular-access infections and blood stream infections in ESRD patients. In Phase 1, worksheets and checklists were developed to assess infection control practices. The worksheets and checklists were based on current guidelines and information gathered from an extensive literature review of best and required infection control practices and vetted through an expert panel. Tools were developed for use by both facility supervisory staff and auditors when observing staff practices (worksheets) and by direct care staff at the dialysis station (checklists). Using the worksheets, evaluators visited facilities to assess compliance with infection control practices and found a striking variation in compliance. Phase 2 is focusing on the development and testing of a multi-component quality improvement change package, including tools like the checklists, facility data reports with benchmarking, and information on improving the culture of safety and patient and family engagement. This project is being conducted in collaboration with the CDC and CMS.

Identifying and Aligning Work System Risk Factors to Reduce HAIs

(Contractor: CNA Corporation in conjunction with MedStar Health)

This project takes a human factors approach guided by a social/technical system model to explore organizational, technological, physical environment, and works systems factors to reduce risks in a large, urban dialysis unit. Four risk factors were identified: work flow/work stress; surface contamination; patient-specific factors; and lack of staff feedback. The intervention was aimed at reducing these risks and included closing the unit between shifts for cleaning, decreasing distractions by reducing early patient entry in the unit, increase environmental services resources, improve communication between dialysis staff and environmental services, and add copper surfaces to high-touch areas. Feedback to staff on monthly HAI rates was also provided.

VII. Adjournment

Dr. Narva announced that the next KICC meeting is scheduled for September 12, 2014.