Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Informed Consent and Prevention of Disease Progression in Veterans with Chronic Kidney Disease

Report No. 10-03399-51 **December 19, 2011**

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections assessed the extent to which informed consent was documented for veterans with chronic kidney disease who underwent procedures that involved intravascular injection of contrast media, and described efforts to minimize kidney injury. Most patients with significantly impaired kidney function are not under the care of a kidney specialist and may be unaware of the impairment. In the course of their medical care, these patients are particularly vulnerable to interventions that can lead to further decline in kidney function.

We identified patients with pre-existing kidney impairment who underwent cardiac catheterizations or peripheral vascular procedures during April 1-July 30, 2010. Because of their kidney impairment, these patients were at increased risk for complications related to contrast media.

During the review period, 425 patients had complete data and met initial inclusion criteria. These patients had pre-procedure testing that indicated kidney impairment and received at least 100 mL of contrast media. After randomization and exclusion of patients subsequently found to be ineligible, 107 patients were selected for detailed medical record review. These patients needed to be aware of their higher risk of kidney injury in order to give informed consent.

We found that, although 101 patients (94 percent) signed informed consent documents, only 24 of informed consent documents (22 percent) included any information about the risk of kidney injury. Explicit reference to the increased risk of kidney injury associated with contrast media for patients with pre-existing kidney disease was present in only two informed consent documents. However, practitioners evidently were aware of the increased risk of kidney injury because they ordered interventions to mitigate kidney injury in 93% of these high-risk patients.

We recommended that the Under Secretary for Health implement a plan to ensure that patients with chronic kidney disease who are undergoing procedures requiring contrast media be provided sufficient information to give informed consent, in accordance with VHA Handbook 1004.01.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Under Secretary for Health

SUBJECT: Healthcare Inspection – Informed Consent and Prevention of Disease Progression in Veterans with Chronic Kidney Disease

Purpose

The VA Office of Inspector General Office of Healthcare Inspections assessed the extent to which informed consent was documented for veterans with chronic kidney disease who underwent procedures that involved intravascular injection of contrast agents, and described efforts to minimize kidney injury.

Background

Chronic kidney disease (CKD) is common among veterans, affecting approximately 250,000 patients treated at Veterans Health Administration (VHA) facilities in 2010.[1] Although CKD frequently leads to dialysis or death, specific interventions can slow the progression of disease and prevent complications. Because the vast majority of patients with CKD are not under the care of nephrologists, other clinicians must identify patients with impaired renal function and take appropriate action.

In collaboration with the Department of Defense (DoD), VA promulgated a clinical practice guideline to assist primary care clinicians in the management of patients with CKD.[2] Among other steps, the VA/DOD guideline recommends avoidance of nephrotoxins, including contrast agents used to enhance radiographic imaging. Contrast-induced nephropathy (CIN), injury to the kidney caused by contrast agents, typically occurs when patients with pre-existing impairment of kidney function receive intravascular contrast agents. Although CIN rarely causes rapid progression to dialysis, it is associated with prolonged hospitalization and an increased long-term risk of

[1] VA National Patient Care Database.
[2] VA/DoD Clinical Practice Guideline for Management of Chronic Kidney Disease in Primary Care, 2007. Accessed at www.healthquality.va.gov/ckd/ckd_v478.pdf on August 9, 2011.

cardiovascular complications.[3] Further, given the range of available diagnostic approaches in patients with CKD, CIN may be avoided altogether.

Clinicians and patients should jointly evaluate the risks and benefits associated with each potentially harmful procedure,[4] and patients' informed consent should be documented. According to the National Quality Forum, "lack of true informed consent for patients receiving medical and surgical care is a common basis for malpractice cases, increases the chance of a patient safety incident or medical error, and disproportionately affects patients who have more difficulty understanding healthcare information…"[5] VHA requires that patients at high risk for complications give written consent.[6] VHA guidance prepared for radiologists administering contrast agents states that "the definition of high risk is left to each medical center, but must at a minimum include…impaired renal function."[7]

When clinicians and patients together decide that the use of contrast agents is worth the risk, clinicians should take steps to mitigate potential negative effects. Evidence in support of particular measures is limited, but clinicians have been advised to avoid volume depletion and nonsteroidal anti-inflammatory drugs in the management of high-risk patients.[8]

This review examined the extent to which informed consent and efforts to minimize kidney injury were documented for veterans with CKD who received intravascular contrast agents.

Scope and Methodology

We identified patients with Stage 3 CKD who underwent cardiac catheterization or peripheral vascular studies during April 1-July 30, 2010. We obtained information about these procedures from VHA's Clinical Assessment, Reporting, and Tracking System for Cardiac Catheterization Laboratories (CART-CL). Instituted in 2003, CART-CL gathers standardized data from each of VHA's 77 cardiac catheterization laboratories for

[3] James MT, Ghali WA, Knudtson ML, et al. Associations between acute kidney injury and cardiovascular and renal outcomes after coronary angiography. Circulation. 2011;123:409-416.
[4] Paterick TJ, Carson GV, Allen MC, Paterick TE. Medical informed consent: general considerations for physicians. Mayo Clin Proc. 2008; 83:313-19.
[5] National Quality Forum, Implementing a national voluntary consensus standard for informed consent, A User's Guide to Healthcare Professionals, 2005.
[6] VHA Handbook 1004.01. *Informed Consent for Clinical Treatments and Procedures*. August 14, 2009, Appendix A.
[7] VA Online Radiology Guide. 4.1.8. Accessed at vaww1.va.gov/RADIOLOGY/OnLine_Guide.asp on August 9, 2011.
[8] Rudnick MR, TumLin JA. Prevention of contrast-induced nephropathy. In Basow, DS (Ed): UpToDate. Waltham, MA, UpToDate, 2011.

documentation, quality improvement, and research.[9] Procedures are categorized as elective, urgent, or emergent.

Patients with Stage 3 CKD were selected because Stage 3 is the minimum level of impairment generally accepted as defining CKD.[10] These patients account for the majority of patients with CKD who are not on dialysis,[11] and they are usually not under the care of nephrologists.[12] Patients with Stage 3 CKD may be symptom-free, unaware of any impairment, and often have normal or near-normal serum creatinine levels. Patients with the following pre-procedure data in CART-CL were identified for determination of CKD stage and for additional analysis: serum creatinine, age, gender, race, and contrast volume.

We retained only patients who received at least 100 mL of a contrast agent because the CIN Consensus Working Panel determined that "higher contrast volumes (>100 mL) are associated with higher rates of CIN in patients at risk."[13] For patients with multiple procedures during the review period, we analyzed only the first procedure.

Using the pre-procedure serum creatinine level for each patient, we calculated an estimated glomerular filtration rate (GFR) using the 4-variable Modification of Diet in Renal Disease (MDRD) Study equation.[14] CKD is typically defined as a decrease in GFR that persists for at least three months.[15] We anticipated that medical records review would be required to identify patients with a persistent qualifying GFR and retained only patients with a pre-procedure GFR that was at least 30 but not more than 50 mL/min/1.73m^2. We excluded patients with pre-procedure GFR > 50 to increase the efficiency of chart review because these patients were less likely to have a qualifying GFR 90-365 days pre-procedure. We did not utilize GFR estimates reported at each hospital because of variable handling of missing information.

After randomization of patients categorized as having Stage 3 CKD based on pre-procedure testing, patient medical records were examined sequentially. Patients were subsequently excluded if they were found to have been on dialysis at the time of the

[9] Box TL, McDonell M, Helfrich CD, Jesse RL, Fihn SD, Rumsfeld JS. Strategies from a nationwide health information technology implementation: The VA CART STORY. J Gen Intern Med. 2009;25(Suppl 1):72–6.
[10] Levey AS, Eckardt KU, Tsukamoto Y, et al. Definition and classification of chronic kidney disease: a position statement from Kidney Disease: Improving Global Outcomes (KDIGO). Kidney Int. 2005;67:2089-100.
[11] Coresh J, Selvin E, Stevens L, et al. Prevalence of chronic kidney disease in the United States. JAMA. 2007;298:2038-2047.
[12] Abdel-Kader K, Fischer GS, Johnston JR, Gu C, Moore CG, Unruh ML. Characterizing pre-dialysis care in the era of eGFR reporting: a cohort study. BMC Nephrol. 2011;12:12.
[13] Davidson C, Stacul F, McCullough PA, et al. Contrast medium use. Am J Cardiol. 2006;98[suppl]:42K-58K.
[14] GFR = 175 X serum creatinine$^{-1.154}$ X age$^{-0.203}$ X 1.212 [if black] X 0.742 [if female]
Levey AS, Coresh J, Greene T, et al. Chronic Kidney Disease Epidemiology Collaboration. Using standardized serum creatinine values in the modification of diet in renal disease study equation for estimating glomerular filtration rate. Ann Intern Med. 2006. 145:247–54.
[15] VA/DoD Clinical Practice Guideline for Management of Chronic Kidney Disease in Primary Care.

procedure, had no prior testing to confirm CKD in the 90-365 days prior to the procedure, or had a prior GFR > 59 mL/min/1.73m^2. Patient records were selected until a 25 percent sample was achieved.

Three registered nurses experienced in the use of VHA's electronic medical record determined the presence or absence of an informed consent document signed by the patient. Reviewers sought specific language in informed consent documents and progress notes about risks associated with the administration of contrast agents to patients with CKD, and noted the use of iMed or other approved formats.[16] Mention of adverse effects associated with contrast media was not considered acceptable for informed consent unless specific reference was made to kidney injury.

Reviewers also searched physicians' orders, progress notes, and medication records for documentation of pre-and post-procedure interventions related to intravascular volume status, the administration of intravenous fluids or acetylcysteine, and the discontinuation of non-steroidal anti-inflammatory drugs. The absence of informed consent in any record was confirmed by a second reviewer.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Results

During April 1-July 30, 2010, 19,694 patients underwent one or more procedures at VA cardiac catheterization laboratories. After excluding patients with missing data, 425 patients were eligible for analysis (Figure).

The 107 patients randomly selected for review were treated at 37 different facilities. The median patient age of these patients was 70; 75 (70 percent) had diabetes (Table). The median GFR was 44.1 mL/min/1.73m^2 (range, 30.2-50.0).

Procedures included 104 cardiac catheterizations and 3 peripheral arterial studies, which were performed on an urgent or emergent (non-elective) basis for 25 patients (23 percent). The median volume of contrast used during these procedures was 150 mL (range, 100-600); 76 patients received 100-200 mL of contrast, 30 received 200-500 mL, and 1 received > 500 mL. The specific contrast agent used was identified in 97 cases. In each case one of the following isosmolar or low-osmolar agents was used: iodixanol (60), iopamidol (16), iohexol (10), iopromide (6), ioxaglate (4), and ioxilan (1).

[16] In 2005, VHA implemented iMED Consent™, a software program that allows for the electronic signing of informed consent documents. VHA Handbook 1004.01mandates the use of iMED Consent™ to document informed consent. If iMED Consent™ cannot be used, non-electronic Forms 10-0431a or 10-0431b must be used.

Figure. Review Flow and Results

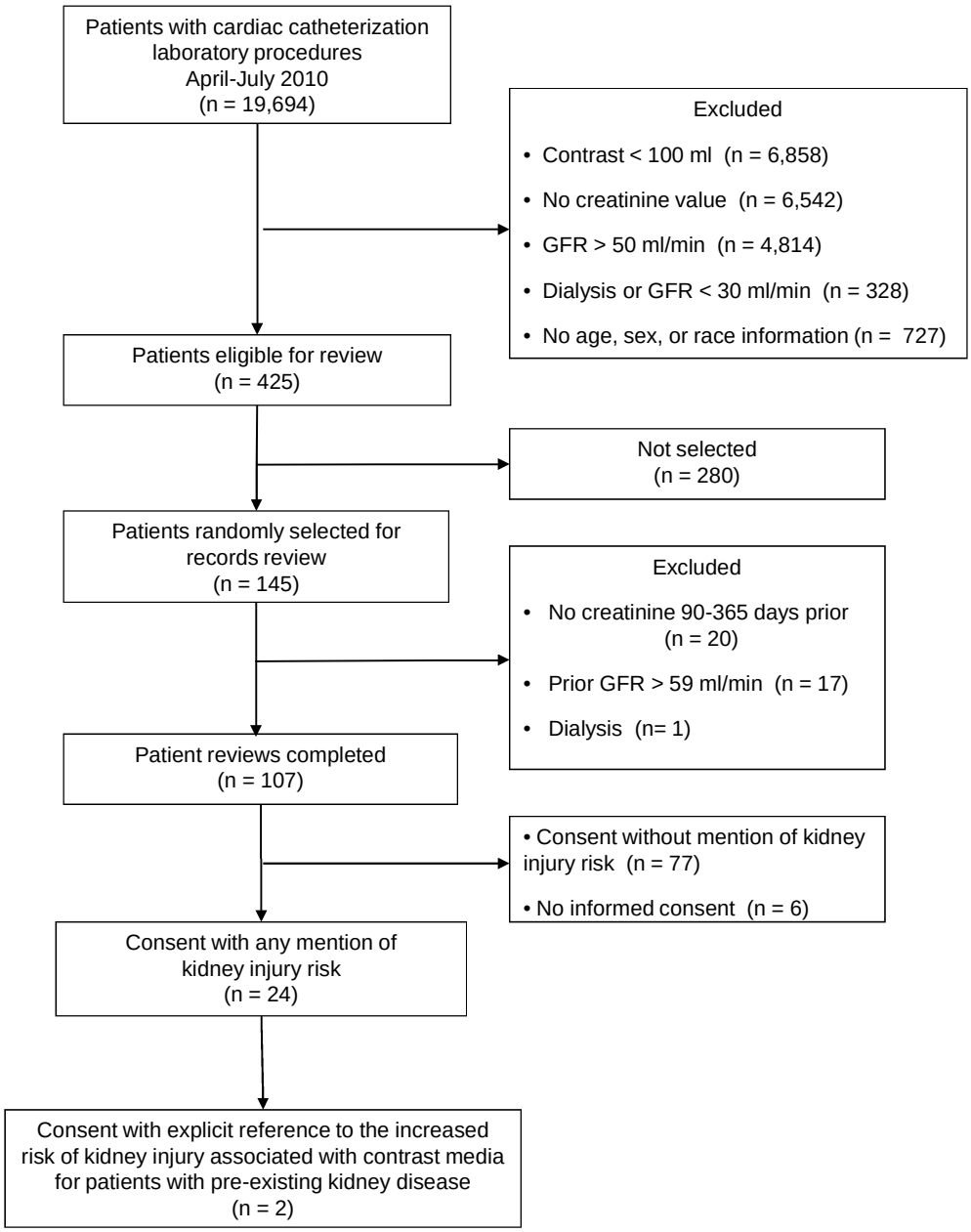

Table. Characteristics of 107 Patients and Procedures

Age, years, median (range)	70 (45-88)
Sex, number male (percent)	103 (96)
Race, number white (percent)	92 (86)
Diabetes, number (percent)	75 (70)
GFR, mL/min/1.73m^2, median (range)*	44.1 (30.2-50.0)
Contrast volume, mL, median (range)	150 (100-600)
Non-elective procedures, number (percent)	25 (23)

*GFR = glomerular filtration rate

Informed consent documents signed by the patient and with any mention of the risk of kidney injury related to contrast media were found for 13 patients. In two of these instances we found explicit reference to the increased risk of kidney injury associated with contrast media for patients with pre-existing kidney disease. An additional 11 patients had informed consent documents that mentioned the risk of kidney injury without reference to pre-existing kidney disease or an association with contrast media. Overall, 24 informed consent documents included some reference to the risk of kidney injury.

We also found for 11 patients some discussion of kidney injury in progress notes, so that a total of 35 of 107 (33 percent) patient records had some documentation of the risk of kidney injury. However, documentation in a progress note does not comply with the VHA Handbook 1004.01 requirement that the patient sign an informed consent form that includes appropriate risk information.

Electronic iMed consent forms were signed by 85 patients. Non-iMed consent forms were signed by 16 patients; in 12 of these instances approved forms were used. We found no documentation of reasons for the use of non-iMed or non-approved consent forms. The two cases with specific language about the risk of contrast media for patients with pre-existing kidney disease involved iMed consent forms at two different facilities.

Ninety-six patients (90 percent) received intravenous fluids immediately before, during, or after procedures. Ninety-three patients (87 percent) received isotonic solutions; 24 (22 percent) received bicarbonate. Three patients received half-normal saline (0.45% NaCl).

Five of the eleven patients who did not receive intravenous fluids had a history of congestive heart failure. Eighty-six patients (80 percent) received acetylcysteine, and for one a nonsteroidal anti-inflammatory drug was discontinued. Overall, 100 patients (93 percent) had interventions to mitigate the risk of CIN.

Conclusion

Patients with pre-existing kidney disease need to be aware of the increased risk of kidney injury associated with contrast media in order to give informed consent. This is information that a person in similar circumstances would reasonably want to know.

We found that, although 101 (94 percent) of 107 patients signed informed consent documents, only 24 (22 percent) of informed consent documents included any information about the risk of kidney injury. Explicit reference to the increased risk of kidney injury associated with contrast media for patients with pre-existing kidney disease was present in only two informed consent documents. However, practitioners evidently were aware of the increased risk of kidney injury because they ordered interventions to mitigate kidney injury in 93% of these high-risk patients.

VA information systems permit modification of informed consent documents to include patient-specific risks. In fact, we found two signed consent forms that included explicit reference to the increased risk of kidney injury associated with contrast media for patients with pre-existing kidney disease. For most patients, however, there was no mention of pre-existing kidney disease or the risk of kidney injury related to contrast media.

Experts recommend that practitioners avoid intravascular contrast media in patients with CKD when alternative approaches are available. This review could not identify CKD patients who had been advised to undergo alternative procedures because of the risk of CIN, and did not evaluate practitioners' decisions to administer contrast media. Whether or not practitioners made appropriate recommendations to patients, however, we found little documentation that patients received the information they would need to make an informed decision regarding the recommended procedure.

Improvements in the informed consent process, including patient-specific risks associated with management options, aligns with VHA's recent initiative to focus on individualized care and empowerment of patients through information and education.[17]

[17] 12 Patient-Centered Care Principles - Under Secretary for Health (USH), accessed on August 15, 2011. http://vaww.ush.va.gov/PACT/12_Patient_Centered_Care_Principles.asp.

Recommendation

The Under Secretary for Health should implement a plan to ensure that patients with chronic kidney disease who are undergoing procedures requiring contrast media be provided sufficient information to give informed consent, in accordance with VHA Handbook 1004.01.

Comments

The Under Secretary for Health agreed with our findings and recommendations. The implementation plans are acceptable, and we will follow up until all actions are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Under Secretary for Health Comments

Department of

Veterans Affairs

Memorandum

Date:

From: Under Secretary for Health (10)

Subject: Health Care Inspection – Informed Consent and Prevention of Disease Progression in Veterans with CKD

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and concur with the report's recommendations. The Veterans Health Administration (VHA) is committed to providing a health care environment that supports respect for patients and protects their rights to autonomous, informed participation in health care decisions.

2. VHA agrees that patients with existing kidney disease need to be aware of risks associated with iodinated radiographic contrast agents. To address the report recommendation, VHA consent forms in iMedConsentTM will be revised to ensure that Veterans with stage three chronic kidney disease are provided sufficient information to give informed consent for clinical treatments and procedures requiring iodinated radiographic contrast agents.

3. Further, the Deputy Under Secretary for Health for Operations and Management will issue guidance that reminds practitioners that signature consent must be obtained and documented for procedures that administer iodinated radiographic contrast agents to patients with stage three chronic kidney disease. These consent forms will include appropriate information on risks associated with iodinated radiographic contrast agents, in accordance with VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures.

4. Thank you for the opportunity to review the draft report. Attached is the complete corrective action plan for the reports recommendation. If you have any questions, please contact Linda H. Lutes, Director, Management Review Service (10A4A4) at (202) 461-7014.

Robert A. Petzel, M.D.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan

OIG Draft Report, Healthcare Inspection, Informed Consent and Prevention of Disease Progression in Veterans with Chronic Kidney Disease

Date of Draft Report: September 30, 2011

Recommendations/ Actions	Status	Completion Date

Recommendation 1: We recommend the Under Secretary for Health implement a plan to ensure that patients with chronic kidney disease who are undergoing procedures requiring contrast media be provided sufficient information to give informed consent, in accordance with VHA Handbook 1004.01.

VHA Comment

Concur

The Deputy Under Secretary for Health for Policy and Services (DUSHPS/10P) will revise consent forms for procedures requiring iodinated radiographic contrast agents to include the following: "Risk of contrast dye induced kidney injury: The risk of kidney injury is increased in patients with pre-existing kidney disease" in the risks section of the iMedConsent™ form (i.e. Section 11). These revisions to the iMedConsent™ form will ensure that Veterans with stage three chronic kidney disease are provided sufficient information to give informed consent for procedures requiring iodinated radiographic contrast agents. Communication with facility Chiefs of Staff, Chief Medical Officers and Clinical Application Coordinators will be initiated when the revised consent forms are available to the field in iMedConsent™.

Further, the Deputy Under Secretary for Health for Operations and Management (DUSHOM/10N) will issue guidance that reminds practitioners that signature consent must be obtained and documented for procedures that administer iodinated radiographic contrast agents to patients with stage three chronic kidney disease. These consent forms will include appropriate information on risks associated with iodinated radiographic contrast agents, in accordance with VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures.

	In Process	December 30, 2011

Veterans Health Administration
October 2011

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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