Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 15-00359-374

Combined Assessment Program Summary Report

Evaluation of Medication Oversight and Education in Veterans Health Administration Facilities

June 16, 2015

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections evaluated selected aspects of medication management in acute care patients who received a specific class of antibiotics upon discharge from Veterans Health Administration facilities. The purpose of the evaluation was to determine whether clinicians provided appropriate clinical oversight of and medication education to patients discharged with orders for selected fluoroquinolone antibiotics.

We conducted this evaluation at 50 Veterans Health Administration facilities during Combined Assessment Program reviews performed across the country from October 1, 2013, through September 30, 2014. We noted high compliance with Veterans Health Administration policy in many areas, including assessment and identification of learning barriers at admission, provision of written instructions and medication lists to patients at discharge, and documentation of patient or caregiver understanding of medication education.

We identified two opportunities for Veterans Health Administration facilities to improve. We recommended that the Interim Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility leaders, ensure that:

- Clinicians adjust fluoroquinolone doses and/or frequencies consistent with manufacturers' recommendations when patients' estimated glomerular filtration rate values are below targeted thresholds.
- Clinicians providing medication education document the accommodations made to address patients' identified learning barriers.

Comments

The Interim Under Secretary for Health concurred with the findings and recommendations. (See Appendix A, pages 7–9, for the full text of the comments.) 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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections evaluated selected aspects of medication management in acute care patients who received a specific class of antibiotics upon discharge from Veterans Health Administration (VHA) facilities. The purpose of the evaluation was to determine whether clinicians provided appropriate clinical oversight of and medication education to patients discharged with orders for one of three selected fluoroquinolone antibiotics.

Background

The drug class fluoroquinolones includes some of the most commonly prescribed antibiotics in the United States. Fluoride, a known neurotoxin, is a component of fluoroquinolones. These medications have the ability to penetrate the blood-brain barrier and potentially damage the central nervous system. In 2008, the Food and Drug Administration required that manufacturers add a special warning (known as a black box warning) to seven fluoroquinolones because they pose a risk of tendonitis and tendon rupture. VHA maintains three fluoroquinolone antibiotics on its formulary—ciprofloxacin, levofloxacin, and moxifloxacin.

- Ciprofloxacin (Cipro®, Cipro XR®, and Proquin XR®) is used to treat infections of the skin, lungs, and urinary tract. This medication is also effective in treatment of infectious diarrhea.
- Levofloxacin (Levaquin®) is used to treat infections of the sinuses, skin, lungs, joints, and urinary tract, including those resistant to other antibiotics. Like ciprofloxacin, it is also effective in treating infectious diarrhea.
- Moxifloxacin (Avelox®) is used to treat infections such as bronchitis, pneumonia, and sinusitis. It is also used to treat these infections in people who have not improved with other antibiotic treatment or in people who cannot be treated with other antibiotics.

Three areas of concern in fluoroquinolone use are: (a) drug-drug or drug-nutrient interactions, (b) the requirement to adjust the dose and/or frequency for patients with compromised kidney function, and (c) adverse drug reactions.

For patients prescribed levofloxacin and ciprofloxacin, laboratory testing for the level of creatinine in the blood and the subsequent calculation of estimated glomerular filtration rate (eGFR)[1] indicates how well a patient's kidneys are functioning. This information is important since both medications are excreted through the kidneys. Manufacturers of both drugs recommend adjusting the dose and/or frequency for patients whose eGFR is below targeted thresholds of 50 milliliters per minute for levofloxacin and 30 milliliters per minute for ciprofloxacin. Since moxifloxacin is not predominantly eliminated through the kidneys, kidney function is not a consideration.

[1] An estimate of how much blood passes each minute through the glomeruli, which filter waste from the blood in the kidneys.

Adverse reactions to fluoroquinolones include tendonitis or rupture of the Achilles tendon, central nervous system effects (such as drowsiness), and development of antibiotic resistance. Clinicians need to provide medication education that emphasizes precautions, proper administration, and potential reactions so that the patient or his or her caregiver can manage on their own after discharge.

Scope and Methodology

We evaluated fluoroquinolone clinical oversight and medication education in conjunction with Combined Assessment Program (CAP) reviews of acute care VHA medical facilities conducted from October 1, 2013, through September 30, 2014. The study population consisted of inpatients discharged from acute care from July 1, 2012, through June 30, 2013, with an inpatient prescription (original or refill) to take home upon discharge from the facility for one of the following oral fluoroquinolone antibiotics:

- Cipro®/ciprofloxacin 500 milligram tablet
- Levaquin®/levofloxacin 750 milligram tablet
- Avelox®/moxifloxacin 400 milligram tablet

We reviewed facility policies and other documents relevant to the oversight and education provided to patients discharged from the acute care setting with one of the three fluoroquinolones. We evaluated the electronic health records (EHRs) of the sampled patients to determine whether selected elements were compliant with VHA policy and Joint Commission standards. While onsite, we validated and discussed findings with key managers and employees.

Sampling

We used a two-stage complex probability sample design to select patients from the study population for the EHR review. In the first stage of sampling, we statistically randomly selected the 57 VHA facilities scheduled for CAP visits, which we had stratified by the 12 catchment areas of the OIG's Office of Healthcare Inspections regional offices. We excluded seven facilities from the review because they did not provide inpatient acute care services, resulting in 50 facilities that we reviewed.

In the second stage of sampling, we randomly selected 35 inpatients from each sampled facility for our EHR review. If a facility had fewer than 35 eligible patients who met the criteria for the review, we reviewed all patients.

Upon initial assessment, if we noted any of the following situations, we excluded sampled patients from the review:

- No inpatient stay (defined as a stay longer than 24 hours) during the study period
- Not discharged with orders for one of the three oral fluoroquinolone medications

- Discharged to another facility (such as a nursing home, acute care facility, or other) where the facility would administer the medication
- Died prior to the planned discharge

After exclusions, we conducted EHR reviews of 1,648 patients. Of the 1,648 patients, providers ordered ciprofloxacin for 860 patients, levofloxacin for 131 patients, and moxifloxacin for 657 patients.

Statistical Data Analysis

We estimated the VA compliant percentages for each of the quality measures, taking into account the complexity of our multi-stage sample design. We used Horvitz-Thompson sampling weights (reciprocal of sampling probabilities) to account for unequal probability sampling and the Taylor expansion method to obtain the sampling errors for the estimates. We considered a facility compliant with VHA policy and Joint Commission standards if at least 90 percent of its eligible patients met fluoroquinolone requirements.

We presented 95 percent confidence intervals (CI) for the estimates of the true values (parameters) of the study population. A CI gives an estimated range of values (being calculated from a given set of sample data) that is likely to include an unknown population parameter. The 95 percent CI indicates that among all possible samples we could have selected of the same size and design, 95 percent of the time the population parameter would have been included in the computed intervals.

Percentages can only take non-negative values from 0 to 100, but their logits can have unrestricted range so that the normal approximation can be used. Thus, we calculated the CIs for percentages on the logit scale and then transformed them back to the original scale to ensure that the calculated CIs contained only the proper range of 0 to 100 percent. All data analyses were performed using SAS statistical software, version 9.4 (TS1M0), SAS Institute, Inc. (Cary, NC).

Facility-specific review results were reported in 50 CAP reports. For this report, we aggregated and analyzed the data collected from the individual evaluations.

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

Inspection Results

Issue 1: Kidney Function Evaluation and Dose

The Joint Commission requires a pharmacist to review the appropriateness of all orders for medications to be dispensed by the facility. This includes review for existing or potential interactions between medications ordered and food and/or other medications that the patient is currently taking. Pharmacists must also review all medications for current or potential impact based on laboratory values. Because ciprofloxacin and levofloxacin are excreted through the kidneys, clinicians should assess the patient's kidney function prior to starting these medications. We found high compliance with clinicians determining kidney function via laboratory creatinine values prior to prescribing ciprofloxacin or levofloxacin and obtaining a calculated eGFR value.

However, we identified an opportunity for improvement. Of the 860 sampled patients with orders for ciprofloxacin at discharge, 36 had eGFR values under 30 milliliters per minute. We estimated that clinicians had not documented that they adjusted the dose and/or frequency for 30 percent (95 percent CI: 18.45–44.78) of these patients. Of the 131 sampled patients with orders for levofloxacin at discharge, 12 had eGFR values under 50 milliliters per minute. We estimated that clinicians had not documented that they adjusted the dose and/or frequency for 47.8 percent (95 percent CI: 23.15–73.60) of these patients.

We recommended that facility managers ensure that clinicians adjust fluoroquinolone doses and/or frequencies consistent with manufacturers' recommendations when patients' eGFR values are below targeted thresholds.

Issue 2: Learning Needs Assessment and Medication Education

Learning Needs Assessment

VHA requires that clinicians complete an initial assessment of acute care patients' educational needs, preferences, abilities, and readiness to learn within 24 hours of admission.[2] Some facilities established policy requiring a shorter timeframe. For those facilities, we determined compliance with the local policy timeframe for this assessment.

We found high compliance with clinicians completing assessments within 24 hours of admission or sooner if the facility established a shorter timeframe. Clinicians identified one or more learning barriers for an estimated 23.8 percent (95 percent CI: 19.31–29.00) of the sampled patients. Barriers included vision, hearing, cognitive impairment, and other issues.

[2] VHA Handbook 1907.01, *Health Information Management and Health Records*, September 19, 2012.

Medication Education

The Joint Commission requires facilities to provide education and training to the patient based on his or her assessed needs. This includes information on the safe and effective use of medications. A facility must communicate with a patient who has vision, speech, hearing, or cognitive impairments in a manner that meets the patient's needs.

Because these drugs have potential serious drug-drug and drug-nutrient interactions, clinicians need to provide patients or their caregivers sufficient education about the prescribed fluoroquinolone medication to manage on their own after discharge. For the 1,648 sampled patients, clinicians documented several types of medication education. Table 1 below shows the types of medication education documented.

Table 1. Documented Types of Medication Education

Type of Medication Education	Number of Sampled Records	Estimated Compliance 95 Percent CI Limits		
		Percent	Lower	Upper
Detailed education with drug-drug and drug-nutrient reactions	401	24.2	16.27	34.39
Some details regarding the fluoroquinolone	613	31.4	24.82	38.86
General statement about medication education, not specific to the fluoroquinolone	615	42.9	33.59	52.74
No education documented	19	1.5	0.93	2.39

Source: VA OIG

Of the 397 patients identified with one or more learning barriers present at discharge, we estimated that clinicians had not documented medication education that accommodated the identified barriers in 19 percent (95 percent CI: 12.42–27.95) of the EHRs.

We recommended that facility managers ensure that clinicians providing medication education document the accommodations made to address patients' identified learning barriers.

Conclusions

We noted high compliance with VHA policy and Joint Commission standards in many areas, including assessment and identification of potential learning barriers at admission, provision of written instructions and medication lists to patients at discharge, and documentation of patient or caregiver medication education. However, facilities could improve care by ensuring clinicians make needed dose and/or frequency adjustments for patients prescribed ciprofloxacin or levofloxacin. Facilities could also improve care by ensuring that clinicians providing medication education accommodate identified learning barriers and document this in the EHRs.

Recommendations

1. We recommended that the Interim Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinicians adjust fluoroquinolone doses and/or frequencies consistent with manufacturers' recommendations when patients' estimated glomerular filtration rate values are below targeted thresholds.

2. We recommended that the Interim Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinicians providing medication education document the accommodations made to address patients' identified learning barriers.

Appendix A

Interim Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: May 21, 2015

From: Interim Under Secretary for Health (10)

Subject: **Office of Inspector General (OIG) Draft Report, Combined Assessment Program (CAP) Summary Report: Evaluation of Medication Oversight and Education in Veterans Health Administration Facilities (2015-00359-HI-0358) (VAIQ 7595135)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the draft OIG CAP Summary Report: Evaluation of Medication Oversight and Education in VHA Facilities.

2. I concur with the report and the recommendations. Attached is VHA's corrective action plan for recommendations 1 and 2.

3. Should you have any questions, please contact Karen M. Rasmussen, MD, Director, Management Review Service (10AR) at VHA10ARMRS2@va.gov.

Carolyn M. Clancy, MD

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report, CAP Summary Report – Evaluation of Medication Oversight and Education in VHA Facilities

Date of Draft Report: April 22, 2015

Recommendations/ Actions	Status	Completion Date

OIG Recommendations

Recommendation 1. We recommended that the Interim Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinicians adjust fluoroquinolone doses and/or frequencies consistent with manufacturers' recommendations when patients' estimated glomerular filtration rate values are below targeted thresholds.

VHA Comments

Concur

The Office of the Assistant Deputy Under Secretary for Health (ADUSH) for Clinical Operations, will discuss on the Chief Medical Officer/Quality Management Officer (CMO/QMO) call the findings of this report. The purpose of this call is to remind clinicians of the importance of documenting rationale for adjusting or not adjusting doses/frequencies of medications when they exceed the manufacturer's recommendations based on the estimated glomerular filtration rate values.

To complete this action, the Office of the ADUSH for Clinical Operations will provide the agenda as evidence this was discussed on the CMO/QMO call.

Status:	Target Completion Date:
In progress	July 2015

Recommendation 2. We recommended that the Interim Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinicians providing medication education document the accommodations made to address patients' identified learning barriers.

VHA Comments

Concur

The Office of the ADUSH for Clinical Operations will issue reminder guidance to the field and discuss on the CMO/QMO call the importance of documenting the accommodations made to address patients' identified barriers to education.

To complete this action, the Office of the ADUSH for Clinical Operations will provide the issued guidance as evidence that the reminder was sent out to the field.

Status:	Target Completion Date:
In progress	July 2015

Office of Inspector General
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