



Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 15-01297-368

Community Based Outpatient Clinics Summary Report

Evaluation of Medication Oversight and Education at Community Based Outpatient Clinics and Other Outpatient Clinics

June 18, 2015

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted a systematic review of the Veterans Health Administration's Community Based Outpatient Clinics and other outpatient clinics to evaluate for compliance with selected Veterans Health Administration requirements regarding clinical oversight and education for patients prescribed oral fluoroquinolone antibiotics in the outpatient setting.

The objective was to determine the extent of counseling provided to patients who were prescribed an oral fluoroquinolone antibiotic. This included the care elements of medication reconciliation, patient education, and assessment of the patient's understanding as performed by clinical staff which included physicians, nurse practitioners, physicians' assistants, pharmacists, and nursing staff.

Three areas of concern in fluoroquinolone use are: (1) drug-drug or drug-nutrient interactions, (2) the requirement to adjust the dosage for patients with compromised renal function, and (3) adverse drug reactions.

We performed this focused review at the outpatient clinics of 57 VA medical centers. Our initial electronic health records sample consisted of 2,098 patients who were first prescribed a fluoroquinolone during July 1, 2012, through June 30, 2013.

We estimated that:

- Medication reconciliation occurred and included the newly prescribed fluoroquinolone in 69.0 percent (95% CI: 63.73–73.80) of the electronic health records reviewed.
- Patient education was provided and documented in 83.4 percent (95% CI: 78.40–87.39) of electronic health records reviewed.
- Clinicians documented the patient's (or caregiver's) understanding of the education provided in 85.7 percent (95% CI: 80.95–89.49) of electronic health records reviewed.

We recommended that the Interim Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior leaders, ensure that clinicians consistently:

- Perform and document medication reconciliation at each outpatient episode of care when a new medication is prescribed.
- Provide and document patient education for new outpatient medications.
- Assess and document outpatients' understanding of medication education.

Comments

The Interim Under Secretary for Health concurred with the findings and recommendations. (See Appendix B, pages 9–12, 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 conducted a systematic review of the Veterans Health Administration's (VHA's) Community Based Outpatient Clinics (CBOCs) and other outpatient clinics to evaluate for compliance with selected VHA requirements regarding clinical oversight and education for patients prescribed oral fluoroquinolone antibiotics in the outpatient setting.

The objective was to determine the extent of counseling provided to patients who were prescribed an oral fluoroquinolone antibiotic. This included the care elements of medication reconciliation, patient education, and assessment of the patient's understanding as performed by clinical staff which included physicians, nurse practitioners, physicians' assistants, pharmacists, and nursing staff.

Background

Fluoroquinolones are among the most commonly prescribed antibiotics in the United States and have the unique ability to penetrate the blood-brain barrier and potentially damage the central nervous system. Fluoride, a known neurotoxin, is a central part of fluoroquinolones. In 2008, the Food and Drug Administration required that a black box warning be added to seven fluoroquinolones because they pose a risk of tendonitis and increase the risk of a tendon rupture by three to four times.¹ VHA maintains three types of fluoroquinolones on its formulary—ciprofloxacin, levofloxacin, and moxifloxacin.

Ciprofloxacin (Cipro®, Cipro XR®, and Proquin XR®) is used to treat infections of the skin, lungs, airways, bones, and joints. It is frequently used to treat urinary infections and is effective in the treatment of infectious diarrhea caused by *Escherichia coli*, *Campylobacter jejuni*, and *Shigella* bacteria.²

Levofloxacin (Levaquin®) is used to treat infections of the sinuses, skin, lungs, ears, airways, bones, and joints. It is frequently used to treat urinary tract infections and prostatitis. Like ciprofloxacin, it is also effective in treating infectious diarrhea.³

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 who cannot be treated with other antibiotics.⁴

¹ U.S. Food and Drug Administration, Information for Healthcare Professionals: Fluoroquinolone Antimicrobial Drugs, August 15, 2013. Available from: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126085.htm> Accessed June 27, 2014.

² MedicineNet.com, Ciprofloxacin, Cipro, Cipro XR, ProquinXR. December 12, 2014. Available from <http://www.medicinenet.com/ciprofloxacin/article.htm>. Accessed January 15, 2015.

³ MedicineNet.com, Levofloxacin, Levaquin, December 9, 2014. Available from: <http://www.medicinenet.com/levofloxacin/article.htm>. Accessed January 15, 2015.

Three areas of concern in fluoroquinolone use are: (1) drug-drug or drug-nutrient interactions, (2) the requirement to adjust the dosage for patients with compromised kidney function, and (3) adverse drug reactions. Oral fluoroquinolones need to be taken on an empty stomach at least 2 hours (ciprofloxacin, levofloxacin) to 4 hours (moxifloxacin) before or 2 hours (levofloxacin), 6 hours (ciprofloxacin), or 8 hours (moxifloxacin) after taking magnesium or calcium containing antacids, multivitamins, iron, zinc, and didanosine (antiretroviral) chewable/buffered tablets. The patient will experience a significant decrease in absorption of the medication if taken together. Thus, effective and consistent patient education processes are important aspects of medication management in the outpatient setting.

Medication reconciliation is the process by which the clinical care team maintains and communicates accurate patient medication information. It involves identifying, addressing, and documenting medication discrepancies found in the VA electronic health record as compared with the medication information supplied by the patient. This information, along with any changes such as new medications or dosages made during the episode of care, is communicated to the patient, caregiver or family member, and appropriate members of the health care team.⁵

Communicating with and providing education to the patient, caregiver, or family members regarding updated medication information help to maintain patient-centered medication information that is accurate, safe, and effective. A patient's medication information should cover all medications that will be taken by the patient, how they are to take the medications, and any problems he or she may have or have had in the past.⁶ The patient should also be given written information such as name, dose, route, frequency, and purpose of the medications at the end of the encounter.⁷

Patients are increasingly responsible for managing their own health at home, and effective patient education influences health outcomes and promotes healthy behaviors. The clinical care team needs to assess the patient's learning needs and use methods of education and instruction that are matched to the patient's level of understanding. After providing information on the safe and effective use of medications, clinicians need to evaluate the patient's understanding of the education.⁸

⁴ MedicineNet.com, Moxifloxacin, Avelox, October 7, 2014. Available from <http://www.medicinenet.com/moxifloxacin-oral/article.htm>. Accessed January 15, 2015.

⁵ VHA Directive 2011-012, *Medication Reconciliation*, March 9, 2011.

⁶ VHA Directive 2011-012.

⁷ Joint Commission, *Hospital Accreditation Requirements, National Patient Safety Goal/NPSG.03.06.01*, August 25, 2014.

⁸ Joint Commission, *Hospital Accreditation Requirements, Provision of Care Treatment, and Services/PC.02.03.01*, August 25, 2014.

Scope and Methodology

Scope. The Office of Healthcare Inspections conducted this inspection during CBOC reviews performed in fiscal year 2014. We considered all outpatients at the facility's CBOCs and other outpatient clinics who had an outpatient prescription for a fluoroquinolone antibiotic during the review period of July 1, 2012, through June 30, 2013. We randomly selected 40 outpatients, unless fewer were available, to assess for the focused review objectives.

Methodology. We reviewed facility policies and procedures for the medication reconciliation and patient education of fluoroquinolones prescribed in the outpatient setting. We also evaluated electronic health records (EHRs) to determine if the selected review elements were documented according to the applicable VHA policies and Joint Commission standards. We then validated the findings with key managers and staff.

We used a two-stage complex probability sample design to select patients from the study population for the EHR reviews. In the first stage of sampling, we statistically randomly selected 57 VA medical centers stratified by the 12 catchment areas of the OIG's Office of Healthcare Inspections regional offices. Then we compiled a list of eligible CBOC patients who were assigned to the parent facility for each of the selected 57 VA medical centers.⁹

In the second stage of sampling, we randomly selected 40 patients from each of the 57 patient lists for our EHR reviews. If a VA medical center had fewer than 40 eligible CBOC patients who met the criteria for the focused review, we reviewed all of the patients on the list.

Our initial randomly selected sample consisted of 2,098 patients who were first prescribed a fluoroquinolone during July 1, 2012, through June 30, 2013. The denominators for each issue presented vary based on the number of eligible records for each element assessed in the review. We did not include patients who received their fluoroquinolone medication through the mail or had one-time doses prior to invasive or surgical procedures.

We reviewed the EHRs of all outpatients whose provider ordered original prescriptions for one of three fluoroquinolones during July 1, 2012, through June 30, 2013, specifically ciprofloxacin 500mg tablet, levofloxacin 750mg tablet, and moxifloxacin 400mg tablet.

Statistical Analysis. We estimated the VA compliant percentages for each of the review elements, 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

⁹ Includes all CBOCs in operation before March 31, 2013.

sampling errors for the estimates. We considered a VA medical center compliant with policy if at least 90 percent of its eligible patients met fluoroquinolones requirements.

We presented 95 percent confidence intervals (95% CI) for the estimates of the true values (parameters) of the study population. A confidence interval 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% 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 confidence intervals for percentages on the logit scale and then transformed them back to the original scale to ensure that the calculated confidence intervals 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, North Carolina).

The Office of Healthcare Inspections conducted this inspection during CBOC reviews beginning October 1, 2013, through September 30, 2014. Facility-specific review results were reported in 57 CBOC reports. For this report, we aggregated and analyzed the data collected from the individual evaluations.

We conducted this inspection 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: Medication Reconciliation

We estimated that medication reconciliation occurred and included the newly prescribed fluoroquinolone in 69.0 percent of patients, and 95 percent of the time, the true compliance rate is between 63.73 and 73.80 percent. Thus, the compliance rate was statistically significantly below the 90 percent benchmark.

Issue 2: Patient Education

Documentation of patient education ranged from very detailed entries regarding the fluoroquinolone prescription that included drug-drug/drug-nutrient interactions and side effects to no indication that any education was provided at all. The table below outlines the results.

Types of Education Provided	Number of Sampled Records	Estimated VA Compliance		
		95 Percent Confidence Interval Limits		
		Percent	Lower	Upper
No indication that education was provided	348	16.6	12.61	21.60
General statement regarding medication education not specific to the fluoroquinolone	600	27.6	21.81	34.29
Note mentioned some details regarding the fluoroquinolone	403	19.6	13.46	27.65
Note included drug to drug/drug-nutrient interactions and side effects	734	36.2	28.49	44.60

In accepting documentation of any patient education of medications, we estimated that 83.4 percent (95% CI: 78.40–87.39) of patients had some evidence of receiving medication education or information. The compliance rate was statistically significantly below the 90 percent benchmark.

Issue 3: Patient Understanding

We estimated that clinicians assessed and documented the patient’s or caregiver’s understanding of the education provided in 85.7 percent (95% CI: 80.95–89.49) of EHRs reviewed. The compliance rate was statistically significantly below the 90 percent benchmark.

Conclusions

Of the patients who received newly prescribed fluoroquinolone antibiotics after an outpatient encounter, medication reconciliation occurred and included the newly prescribed fluoroquinolone in 69.0 percent (95% CI: 63.73–73.80) of the sampled EHRs. We also estimated that 83.4 percent (95% CI: 78.40–87.39) of patients had some evidence of the provision of medication education or information and that clinicians assessed and documented the patient’s or caregiver’s understanding of the education provided in 85.7 percent (95% CI: 80.95–89.49) of the sampled 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 perform and document medication reconciliation at each outpatient episode of care when a new medication is prescribed.
2. We recommended that the Interim Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinicians consistently provide and document patient education for new outpatient medications.
3. We recommended that the Interim Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinicians consistently assess and document outpatients' understanding of medication education.

Parent Facilities Reviewed¹⁰

Names	Locations
New Mexico VA Health Care System	Albuquerque, NM
Alexandria VA Health Care System	Alexandria, LA
James E. Van Zandt VA Medical Center	Altoona, PA
Bath VA Medical Center	Bath, NY
Bay Pines VA Healthcare System	Bay Pines, FL
West Texas VA Health Care System	Big Spring, TX
Birmingham VA Medical Center	Birmingham, AL
Boise VA Medical Center	Boise, ID
James J. Peters VA Medical Center	Bronx, NY
Canandaigua VA Medical Center	Canandaigua, NY
Louis Stokes Cleveland VA Medical Center	Cleveland, OH
Harry S. Truman Memorial Veterans' Hospital	Columbia, MO
Atlanta VA Medical Center	Decatur, GA
VA Eastern Colorado Health Care System	Denver, CO
VA Central Iowa Health Care System	Des Moines, IA
John D. Dingell VA Medical Center	Detroit, MI
El Paso VA Health Care System	El Paso, TX
Fayetteville VA Medical Center	Fayetteville, NC
VA Montana Health Care System	Fort Harrison, MT
VA Black Hills Health Care System	Fort Meade, SD
VA Northern Indiana Health Care System	Ft. Wayne, IN
Grand Junction VA Medical Center	Grand Junction, CO
Hampton VA Medical Center	Hampton, VA
Michael E. DeBakey VA Medical Center	Houston, TX
Huntington VA Medical Center	Huntington, WV
Oscar G. Johnson VA Medical Center	Iron Mountain, MI
Lebanon VA Medical Center	Lebanon, PA
Lexington VA Medical Center	Lexington, KY
VA Loma Linda Healthcare System	Loma Linda, CA
VA Long Beach Healthcare System	Long Beach, CA
Miami VA Healthcare System	Miami, FL
Clement J. Zablocki VA Medical Center	Milwaukee, WI
Minneapolis VA Health Care System	Minneapolis, MN
Central Alabama Veterans Health Care System	Montgomery, AL
Tennessee Valley Healthcare System	Nashville, TN
Southeast Louisiana Veterans Health Care System	New Orleans, LA
VA New York Harbor Healthcare System	New York, NY
Orlando VA Medical Center	Orlando, FL
Portland VA Medical Center	Portland, OR
Providence VA Medical Center	Providence, RI
VA Northern California Health Care System	Sacramento, CA
Aleda E. Lutz VA Medical Center	Saginaw, MI
W.G. (Bill) Hefner VA Medical Center	Salisbury, NC
VA Salt Lake City Health Care System	Salt Lake City, UT
South Texas Veterans Health Care System	San Antonio, TX
VA Caribbean Health Care System	San Juan, PR
Overton Brooks VA Medical Center	Shreveport, LA
Syracuse VA Medical Center	Syracuse, NY

¹⁰ This report refers to the CBOCs for these randomly selected parent facilities.

VA Eastern Kansas Health Care System	Topeka, KS
Southern Arizona VA Health Care System	Tucson, AZ
Jonathan M. Wainwright Memorial VA Medical Center	Walla Walla, WA
Washington DC VA Medical Center	Washington, DC
VA Southern Oregon Rehabilitation Center and Clinics	White City, OR
White River Junction VA Medical Center	White River Junction, VT
Robert J. Dole VA Medical Center	Wichita, KS
Wilkes-Barre VA Medical Center	Wilkes-Barre, PA
Wilmington VA Medical Center	Wilmington, DE

Interim Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: May 21, 2015

From: Interim Under Secretary for Health (10)

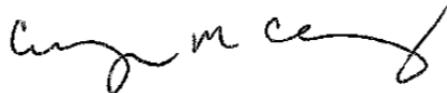
Subject: **OIG Draft Report, Community Based Outpatient Clinics Summary Report – Evaluation of Medication Oversight and Education of Community Based Outpatient Clinics and Other Outpatient Clinics (2015-01297-HI-0406) (VAIQ 7594119)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the draft Community Based Outpatient Clinics Summary Report – Evaluation of Medication Oversight and Education at Community Based Outpatient Clinics and other Outpatient Clinics. I have reviewed the draft report and concur with the report's recommendations.

2. Attached is VHA's corrective action plan for recommendations one through three.

3. Should you have any questions, please contact Karen M. Rasmussen, M.D., Director, Management Review Service (10AR), at (202) 461-6643 or email at VHA10ARMRS2@va.gov.



Carolyn M. Clancy, MD

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report, CBOC Summary Report – Evaluation of Medication Oversight and Education at Community Based Outpatient Clinics and Other Outpatient Clinics

Date of Draft Report: April 20, 2015

Recommendations/ Actions	Status	Completion Date
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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 perform and document medication reconciliation at each outpatient episode of care when a new medication is prescribed.

VHA Comments: Concur

VHA recognizes the role that accurate medication information plays in safe-guarding the health of our Veterans. Clinicians should perform and document medication reconciliation at each outpatient episode of care when a new medication is prescribed. VHA Directive 2011-012 on Medication Reconciliation provides guidance that medication reconciliation should occur at every episode of care and directs each facility to have in place a Medication Reconciliation Point of Contact and a local policy that defines the roles, tasks, and steps of the Medication Reconciliation process.

Medication reconciliation for all medications is currently monitored by the External Peer Review Program by chart review. Over 45,000 charts are reviewed per year. In the table shown on page 2, the two outpatient medication reconciliation monitors (mrec 41 and mrec 27) have shown improvement over the past 2.5 years.

External Peer Review Program (EPRP) Quality Indicator (QI) Description National Data	QI	2013	2014	2015 (YTD)
Home Meds Reviewed with Out Patient or Caregiver	mrec41	78.3% 35,331/45,106	83.8% 40,112/47,831	84.9% 18,457/21,724
Reconciled Med List given to Out Patient or Caregiver	mrec27	63.3% 16,435/25,964	68.6% 17,661/25,739	71.6% 8,516/11,884

To enhance compliance with medication reconciliation, VHA outpatient clinicians require improved medication reconciliation tools and processes. Toward this end, the Office of Quality, Safety & Value (QSV) recently engaged the Veterans Engineering Resource Center (VERC) to design a long-term VA Medication Reconciliation enterprise strategy.

To complete this action VHA will:

1. Develop a medication reconciliation toolkit in partnership with the VERC which will include the medication reconciliation tool, the implementation plan and the educational plan.
2. Educate and train clinicians on the medication reconciliation toolkit. A Medication Reconciliation Education Blitz for VHA clinicians will be conducted when the new tool is ready. This will be completed through national program office calls, community of practice calls, field advisory committee calls and Veterans Integrated Service Network leads operational calls.
3. Implement the medication reconciliation toolkit across VHA clinical programs through the Office of the Assistant Deputy Under Secretary for Health for Clinical Operations. These efforts will be monitored under the partnership of QSV and Pharmacy Benefits Management with collaboration from the VHA clinical program offices.

Status:
In progress

Target Completion Date:
December 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 consistently provide and document patient education for new outpatient medications.

VHA Comments: Concur

It is VHA's practice to provide a Patient Medication Information (PMI) sheet routinely to all patients receiving new prescriptions. The PMI is provided to the patient at the time of dispensing at the VA outpatient pharmacy or by mail for prescriptions filled by the

Consolidated Mail Outpatient Pharmacy (CMOP). Providing patients with PMIs is done consistently but is not documented in the electronic medical record. Pharmacy Benefits Management (PBM) has documented 100 percent rates of packing the PMI with all new medications sent through the mail by the CMOP.

Patient education is an integral, interdisciplinary part of patient care. Use of evidence based education interventions like teach back can be effectively used in time limited clinical encounters to ensure that patients receive information about their new medications that they can understand and act upon.

To complete this action, VHA will:

1. Re-enforce the importance of patient education documentation for new outpatient medications via action #2 of recommendation #1 (Medication Reconciliation Education Blitz for VHA clinicians). These efforts will be lead and monitored under the partnership of National Center for Prevention (NCP), QSV, and PBM with collaboration from the VHA clinical program offices.

Status:
In progress

Target Completion Date:
December 2015

Recommendation 3. We recommended that the Interim Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensure that clinicians consistently assess and document outpatients' understanding of medication education.

VHA Comments: Concur

PMI sheets provided by the pharmacy for patients receiving new medications have been designed to be at a basic reading level for health care consumers.

VHA considers that clinicians assessed and documented the patient's or caregiver's understanding of the education provided approximately 86 percent of the time to be quite beneficial. As a part of the Medication Reconciliation Blitz mentioned above, the importance of the assessment of patients' understanding of any education provided will be emphasized. This tactic is also included and highlighted in the TEACH training that all Patient-Aligned Care Teams (PACT) staff attend.

To complete this action, VHA will:

1. Re-enforce the importance of patient education documentation for new outpatient medications via action #2 of recommendation #1 (Medication Reconciliation Education Blitz for VHA clinicians). These efforts will be lead and monitored under the partnership of NCP, QSV, and PBM with collaboration from the VHA clinical program offices.

Status:
In progress

Target Completion Date:
December 2015

Office of Inspector General Contact and Staff Acknowledgments

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