Department of Veterans Affairs
Office of Inspector General

Informational Report

Community Based Outpatient Clinic Cyclical Reports

Report No. 10-00627-124 **April 6, 2010**

VA Office of Inspector General
Washington, DC 20420

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Contents

Executive Summary

As requested in House Report 110-775, to accompany H.R. 6599, Military Construction, Veterans Affairs, and Related Agencies Appropriation Bill, fiscal year (FY) 2009, the VA Office of Inspector General (OIG) is beginning a systematic review of Veterans Health Administration (VHA) community based outpatient clinics (CBOCs). The purpose of this report is to describe the study design of the forthcoming CBOC reviews.

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

SUBJECT: Informational Report – Community Based Outpatient Clinic Cyclical Reports

Purpose

As requested in House Report 110-775, to accompany H.R. 6599, Military Construction, Veterans Affairs, and Related Agencies Appropriation Bill, fiscal year (FY) 2009, the VA Office of Inspector General (OIG) began a systematic review of Veterans Health Administration (VHA) community based outpatient clinics (CBOCs) in FY 2009. The purpose of this report is to describe the study design of the CBOC reviews for FY 2010.

Background

The Veterans' Health Care Eligibility Reform Act of 1996 was enacted to equip VA with ways to provide veterans with medically needed care in a more equitable and cost-effective manner. As a result, VHA expanded the Ambulatory and Primary Care Services to include CBOCs located throughout the United States. CBOCs were established to provide more convenient access to care for currently enrolled users and to improve access opportunities within existing resources for eligible veterans not currently served.

Veterans are required to receive one standard of care at all VHA health care facilities. Care at CBOCs needs to be consistent, safe, and of high quality, regardless of model (VA staffed or contract). CBOCs are expected to comply with all relevant VA policies and procedures, including those related to quality, patient safety, and performance. For additional background information, see the *Informational Report for the Community Based Outpatient Clinic Cyclical Reports*, 08-00623-169, issued July 16, 2009.

Review Purpose and Objectives

The purpose of the cyclical reviews is to assess whether CBOCs are operated in a manner that provides veterans with consistent, safe, high-quality health care in accordance with VA policies and procedures. The objectives of the reviews are:

1. Determine if the CBOCs' quality of care measures --- selected Prevention Index (PI) and Chronic Disease Care Index (CDCI) --- are comparable to the parent VA medical center (VAMC) clinics.

2. Determine whether CBOC providers are appropriately credentialed and privileged in accordance with VHA Handbook 1100.19.[1]

3. Determine whether CBOCs maintain the same standard of care as their parent facility to address the Mental Health (MH) needs of Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) era veterans.

4. Determine whether patients who are assessed to be high risk for suicide have safety plans that provide strategies that help mitigate or avert suicidal crises.

5. Determine whether CBOCs are in compliance with standards of operations according to VHA Handbook 1006.1[2] in the areas of (a) environmental safety and (b) emergency management plan.

6. Determine if applicable CBOCs comply with local and selected VHA standards[3] for reusable medical equipment (RME) sterilization and low/high level disinfection.

7. Determine whether the CBOC primary care and mental health contracts were administered in accordance with contract terms and conditions.

8. Determine whether primary care active panel management and reporting are in compliance with VHA Handbook 1101.02.[4]

Study Design

Study Population

The study population consists of all veteran patients who were enrolled in the CBOCs that were not inspected in FY 2009. To identify the study population, we first obtained a list of all VHA CBOCs as of June 30, 2009, from the Planning Systems Support Group's VHA Site Tracking data file. We then excluded the CBOCs inspected in FY 2009 and the CBOCs that were not operational (closed or suspended), leaving a total of 641 (out of 714) CBOCs. In order to ensure that each CBOC would have sufficient performance measure data for review, we included in our review only CBOCs that were open and operational on or before September 30, 2008. Thus, 576 CBOCs were included for this

[1] VHA Handbook 1100.19, *Credentialing and Privileging*, November 14, 2008.
[2] VHA Handbook 1006.1, *Planning and Activating Community-Based Outpatient Clinics*, May 19, 2004.
[3] VA Handbook 7176, *Supply Processing and Distribution (SPD) Operational Requirements*, August 16, 2002.
[4] VA Handbook 1101.02, *Primary Care Management Module (PCMM)*, April 21, 2009.

review. The study population constitutes all patients who were enrolled in these CBOCs for their health care.

Sample Design

Because CBOCs within a parent facility share the same leadership and because our objective is to compare quality of patient care received at CBOCs staffed by VA with that by contracted staff, the sample design consisted of three stages for selecting the probability-based sample of patients with stratification and unequal probability of selection. With probability sampling, each patient in the study population has a known, positive probability of selection. This property of probability sampling avoids selection bias and enabled us to use statistical theory to make valid inferences from the sampled patients to the study population.

The 576 CBOCs included in the review were under 135 VHA parent facility's administrative leaderships, with the number of CBOCs within each parent facility ranging from 1 to 12. We categorized each of the 135 parent facilities into one of the following three strata of staffing type:

- The "Contract" stratum of parent facilities with all its CBOC facilities operated by contracted staff.
- The "VA" stratum of parent facilities with all its CBOC facilities operated by VA staff, regardless if the building is leased or VA owned.
- The "Both" stratum of parent facilities with some of its CBOC facilities operated by contracted staff and some by VA staff.

In the first stage of sampling, we statistically randomly selected 24 VHA parent facilities from the universe of 135 parent facilities, stratified by staffing type. One VHA parent facility was sampled from the "Contract" stratum, 6 from the "VA" stratum, and 17 were sampled from the "Both" stratum.

In the second stage, two CBOCs were randomly sampled from CBOCs within each of the 24 parent facilities if the parent facility operated more than two CBOCs and included all the CBOCs if the parent facility operated two or fewer. For the facilities that operated CBOCs both by contracted staff and by VA staff, one CBOC was randomly sampled from the CBOCs staffed under contract and one from the CBOCs staffed by VA. A total of 47 CBOCs were sampled from the 24 facilities.

The third stage sampling was used for selecting patients from the 47 CBOCs for the patient medical chart review. We randomly selected 50 patients diagnosed with diabetes (ICD-9-CM 250) and independently 75 patients who were 50 years of age or older from each of the 47 CBOCs that had enrolled more than 50 subjects. All patients were included if the CBOC had 50 such patients or fewer. An additional 30 patients with a

service date after September 11, 2001, and who did not have a post-traumatic stress disorder (PTSD, ICD-9-CM: 309-81) clinical encounter during the study period (October 1, 2008 – November 30, 2009) were sampled for chart review. All patients were included if the CBOC had 30 such patients or fewer. This was a complex, multistage sample design that included stratification, clustering, and unequal probabilities of selection.

Methodology

CBOC inspections consist of four components: (1) CBOC site-specific information gathering and review, (2) medical record reviews for determining compliance with VHA performance measures, (3) onsite inspections, and (4) CBOC contract review.

Document Request

We notify the Medical Center Director (MCD) 8 weeks prior to the onsite visit of the CBOCs selected for review. The letter includes instructions for completing an online survey and a list of documents we need to conduct the review. The documents include: (1) CBOC local policies and standard operating procedures (SOPs); (2) list of diabetic patients; (3) list of patients 50 years of age or older; (4) list of OEF/OIF era veterans; (5) list of patients flagged as high risk for suicide; and (6) copies of the CBOC contract and modifications for Primary Care Services, invoices, and payment schedules covering 1st quarter, FY 2010. We request the facility to create a secured SharePoint and place the documents there for our review.

Medical Record Review

For each CBOC, a random sample of 50 patients with a diagnosis of diabetes, 75 patients 50 years of age or older, and 30 patients with a service date after September 11, 2001, without a diagnosis of PTSD will be selected, unless fewer patients are available. We will review the medical records of these selected patients to determine compliance with VHA performance measures.

We will also review 10 patients (unless fewer are available) assessed to be at high risk for suicide to determine if clinicians developed safety plans that included all required elements.

VHA Performance Measures

VA uses two key performance measures to assess the quality of health care delivery, the CDCI II and the PI II. These indices measure the degree to which the VA follows nationally recognized guidelines for the treatment and care of patients. The CDCI II focuses on the care of patients with ischemic heart disease, hypertension, chronic obstructive pulmonary disease, diabetes mellitus (DM), major depressive disorder, schizophrenia, and tobacco cessation. The PI II focuses on primary prevention and early

detection recommendations for nine diseases or health factors that significantly determine health outcomes: pneumococcal pneumonia; influenza; tobacco and alcohol consumption; screenings for colorectal, breast, cervical, and prostate cancer; and cholesterol levels.

This review will evaluate PI II (influenza vaccination) and CDCI II (DM and PTSD screening). Data for the indicators will be obtained from the patient medical record and compared to the parent facilities' results. We will use the same time period, 1st quarter, FY 2010,[5] for comparison with the following exception. Since the VHA only scores influenza vaccination in the third (3rd) and fourth (4th) quarters of the fiscal year, we will evaluate 4th quarter, FY 2009 influenza vaccination.

The Office of Quality & Performance (OQ&P) identifies the cases for review by the External Peer Review Program (EPRP)[6] abstractors. EPRP is designed to provide medical centers and outpatient clinics with diagnosis and procedure-specific quality of care information. It provides a database for analysis and internal and external comparison of clinical care. Data used for these analyses are abstracted from a random sample of both paper and electronic medical records. EPRP data is primarily used for quality improvement, evaluation, and benchmarking with external organizations.

This review will follow the same process used by EPRP to collect the selected performance measure data. It is important to note that when OQ&P identifies cases for review at a VAMC, patients who have been seen in CBOCs are not excluded as long as they meet the VAMC sampling requirements. Therefore, a small number of CBOC patients may be included in the parent facilities' performance measure reports.

Influenza Vaccination

Influenza, also known as the flu, is a contagious disease that is caused by influenza viruses. Influenza viruses infect the respiratory tract (nose, throat, and lungs) in humans. The flu is different from a cold, mainly because the symptoms and complications are more severe. Much of the illness and death caused by influenza can be prevented by an annual influenza vaccination.

Influenza vaccination is indicated for people age 50 years and older, because it is highly effective in preventing influenza-related pneumonia, hospitalization, and death. The VA's influenza immunization period for FY 2009 was from September 1, 2008, through March 31, 2009. VHA collected data from April 1, 2009, through August 31, 2009, to retrieve documentation of Influenza immunizations. It is acceptable if a patient reports influenza immunization was obtained privately if the data is recorded in a progress note, on a problem list, or in the historical event in the patient's medical record. Documentation should include month and year if possible, at a minimum 'fall or autumn'

[5] VHA's comparison dates for Quarter 1, FY 2010, are October 1–November 30, 2009.
[6] The External Peer Review Program is a contracted review of care, specifically designated to collect data to be used to improve the quality of care delivered.

and year. Eligible patients are determined by their age as of September 1 of measurement year.

Diabetes Mellitus

VHA diabetes-specific measures included annual foot examination (inspection, palpation, and sensory evaluation); annual retinal eye examination by an eye care specialist; screening for nephropathy; annual low-density lipoprotein cholesterol (LDL-C) assay; and the percentages of patients with an annual glycosylated hemoglobin molecule (HbA1c). Other measures we did not assess included patients with an HbA1c greater than (>) 9 percent or not done and a blood pressure less than 140/90 millimeters of mercury (mmHg). The indicators we will evaluate are listed in Figure 1.

Diabetes Mellitus Indicators	Definition
Foot inspection	The proportion of diabetics, excluding bilateral amputees, with chart documentation of visual inspection of feet in the past year.
Foot pulse checked	The proportion of diabetics, other than bilateral amputees, with chart documentation of examination of pedal pulses in the past year.
Foot Sensation	The proportion of diabetics, other than bilateral amputees, with documentation of foot sensory with monofilament in the past year.
Retinal eye exam	The proportion of diabetics with chart documentation of a retinal examination by an eye specialist in the past year.
LDL-C measured	The proportion of diabetics with chart documentation of a full lipid panel in the past year.
HbA1c measured	The proportion of diabetics with chart documentation of HgbA1c in the past year.
Nephropathy screening	The proportion of diabetic patients having a nephropathy screening test during the past year or documented evidence of nephropathy.

Figure 1 - Diabetes Indicators

Foot Care. More than 60 percent of non-traumatic lower-limb amputations in the United States occur among people with diabetes. Comprehensive foot care programs can reduce amputation rates by 45 to 85 percent.

Eye Care. Diabetes is the leading cause of new cases of blindness among adults age 20-74, and diabetic retinopathy[7] causes 12,000 to 24,000 new cases of blindness each year. Detection and treatment of diabetic eye disease with laser therapy can reduce the development of severe vision loss by an estimated 50 to 60 percent.

[7] Retinopathy is a general term that refers to some form of non-inflammatory damage to the retina of the eye.

Lipid Profile. Heart disease is the leading cause of diabetes-related deaths. Adults with diabetes are at risk for heart disease death and stroke about two to four times higher than adults without diabetes. Improved control of cholesterol and lipids (high-density lipoprotein, LDL, and triglycerides) can reduce cardiovascular complications by 20 to 50 percent. Patients must have had a full lipid panel in the 12 months prior to the study interval (October 1 – November 30, 2009).

Glucose Control. Research studies in the United States and abroad have found that improved glycemic control benefits people with either type I or type II diabetes. In general, for every 1 percent reduction in HbA1c, the relative risk of developing microvascular diabetic complications (retinal eye, kidney, and nerve disease) is reduced by 40 percent.

Renal Testing. Kidney damage from diabetes is called diabetic nephropathy. It begins long before symptoms appear. An early sign is small amounts of protein in the urine. If the damage continues, the kidneys could fail. Diabetes is the most common cause of kidney failure in the United States. People with kidney failure need either dialysis or a kidney transplant. Evidence supports that screening and early treatment for diabetic nephropathy is associated with a reduced risk and decreased rate of progression to end stage renal disease.

This measure is intended to assess if diabetic patients are monitored for nephropathy. The indicators include: 1) documentation of existing nephropathy, 2) macroalbumin[8] testing, 3) microalbumin[9] testing, or 4) evidence of angiotensin converting enzyme[10] (ACE) inhibitor or angiotensin receptor blocker[11] (ARB) therapy.

In FY 2010, patients who only receive Behavioral Health Care in the VHA with explicit documentation of refusal of VHA Primary Care and that primary care is received in a non-VHA setting will be excluded. Also patients who did not have at least two encounters for diabetes (HEDIS criteria: 250, 357.2, 362.0, 366.41, 648.0) during the past year, or one encounter in the past year and one encounter in the 13-24 months prior to the study interval, will be excluded.

Mental Health

PTSD is a serious and often chronic response to overwhelmingly stressful events. The disorder is associated with increased rates of morbidity, poor health-related quality of life, and functional impairment.

[8] A macroalbumin test evaluates urine for the presence of a protein called albumin.
[9] A microalbumin test evaluates urine for the presence of a protein called albumin.
[10] Medication used to treat hypertension and heart failure.
[11] Medication used to treat hypertension and heart failure.

PTSD is the mental health disorder most commonly associated with combat and is central to VA's mission[12] and therefore, the VA requires regular screening for PTSD. Screening for PTSD is the first and most essential step in identifying and engaging veterans with PTSD. It is crucially important that VA be proactive in identifying new PTSD and intervening early in order to prevent chronic PTSD and its complicating disorders and functional problems whenever possible.

Attention to PTSD in medical settings is the key to providing treatment to this population because primary care, rather than specialty mental health services, is the point of contact with the health care system for the majority of individuals with PTSD. Patients are most likely to present to primary care with unexplained somatic and/or psychological symptoms (such as, case sleep disturbance, night sweats, fatigue, difficulty with memory or concentration).

For the patient to be considered "screened," a standard four-question Primary Care PTSD (PC-PTSD) screen developed by the National Center for PTSD is used.

Evidence of responses to all four questions, summary score, and positive/negative results must be documented in the medical record. Screening must be accomplished annually for the first 5 years after most recent date of service separation from military duty and then every 5 years after the first 5 years. Patients excluded from this measure include those with a recognized diagnosis of PTSD in the past 12 months, as evidenced by at least one clinical encounter or documented moderate or severe cognitive impairment.

A positive response to the screen does not necessarily indicate that a patient has PTSD. However, a positive response does warrant further investigation of trauma symptoms. Patients who screened positive for PTSD should be interviewed to determine the presence of risk factors that would indicate a need for urgent intervention of suicidal ideation.

The indicators for this measure include: 1) patients screened at required intervals for PTSD, 2) positive result of the PC-PTSD screen in the medical record, and 3) suicide risk evaluation completed within 24 hours. Patients eligible for PTSD suicide risk evaluation were screened after October 1, 2008.

Suicide Prevention

A safety plan is a prioritized written list of coping strategies and sources of support that patients can use during or preceding suicidal crises. Safety plans should have patient and/or family input, be behavior oriented, and identify warning signs preceding crisis and internal coping strategies. They should also identify when patients should seek

[12] VHA Directive 2005-055, *Implementation of the National Clinical Reminder for Afghan and Iraq Post-Deployment Screening*, December 1, 2005.

non-professional support, such as from family and friends, and when patients need to seek professional help.

The basic components of the safety plan include: (1) recognizing warning signs that are proximal to an impending suicidal crisis; (2) identifying and employing internal coping strategies without needing to contact another person; (3) utilizing contacts with people as a means of distraction from suicidal thoughts and urges. This includes going to healthy social settings, such as a coffee shop or place of religion or socializing with family members or others who may offer support without discussing suicidal thoughts. (4) contacting family members or friends who may help to resolve a crisis and with whom suicidality can be discussed; (5) contacting mental health professionals or agencies; and (6) reducing the potential for use of lethal means. By following a pre-determined set of coping strategies, social support activities, and help-seeking behaviors, veterans can determine and employ those strategies that are most effective.

We will determine whether clinicians had developed safety plans that provided strategies to mitigate or avert suicidal crises for patients assessed to be at high risk for suicide as described in VA Safety Plan Treatment Manual.[13]

Onsite Inspections

We will be onsite at each CBOC for 1 to 1 1/2 days. As part of the onsite visit, we will inspect the CBOC for environment of care (EOC) issues and emergency management procedures, review CBOC providers' credentialing and privileging (C&P) files and supporting documentation, and interview and discuss their compliance with VHA performance measures.

Environment of Care

EOC is crucial to achieving a safe patient care environment, reducing infection control risks, and improving patient care outcomes. CBOCs must be maintained in a state of cleanliness that fully meets all VHA, Occupational Safety and Health Administration, and the Joint Commission standards. We will conduct EOC rounds at each CBOC to ensure that they adhere to American Disabilities Act, National Fire Protection Association regulations, and infection control guidelines.

Reusable Medical Equipment

Reusable medical equipment (RME) is defined as any medical equipment designed by the manufacturer to be reused for multiple patients. Surgical instruments and other types of RME have been used in medical facilities for many years. Advances in diagnostic and therapeutic medicine have led to sophisticated device designs, which, in turn, have

[13] *Safety Plan Treatment Manual to Reduce Suicide Risks*, final version 8/20/08.

complicated the processes for cleaning, disinfecting and/or sterilizing such types of equipment.

Endoscopic procedures are inherently safe with infection rates in the range of 1 in 1.8 million procedures. Virtually every case of pathogen transmission related to an endoscopic procedure has ultimately been attributed to failure to follow established reprocessing guidelines or to the use of defective equipment. Proper reprocessing of RME is a key component to ensuring patient and staff safety and must be performed to exacting standards.

Manufacturers of RME are responsible for developing instructions for preparing the device for reuse and then conducting tests to validate those instructions. Specific guidelines have been developed by organizations such as the Centers for Disease Control and Prevention and the Association for the Advancement of Medical Instrumentation.[14] Earle H. Spaulding[15] categorized instruments and other patient care items as critical, semi-critical, and noncritical according to the degree of risk of infection involved for each item. By defining the risk, the degree of disinfection and sterilization could be determined. This approach has been utilized by VHA and other institutions to guide their approaches to disinfection and sterilization of patient care instruments and equipment.

VHA facilities are responsible for establishing and maintaining policies and oversight to ensure safe and quality patient care. VHA published two directives to outline processes to ensure quality patient care: VHA Directive 2009-004 "*Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*" and VHA Directive 2009-031 "*Improving Safety in the Use of Reusable Medical Equipment through Standardization of Organizational Structure and Reprocessing Requirements.*" These, as well as the above-cited references and the VA Handbook 7176, provide direction for facilities to develop their policies and programs in the use and reprocessing of RME.

If a CBOC reprocesses RME on site, we will: (1) inspect how and where RME is reprocessed and sterilized, (2) determine if there are SOPs (consistent with manufacturer's instruction) for reprocessing RME, and (3) determine if staff are trained and maintain appropriate competencies for reprocessing and or sterilizing RME.

Emergency Management

We will review each CBOC's local emergency management policy and interview employees to ensure there is a plan in place to address patients who experience a medical or psychological emergency such as heart attack, hypoglycemic events, suicidal or

[14] Association for the Advancement of Medical Instrumentation (AAMI), *Comprehensive Guide to Steam Sterilization as Sterility Assurance in Health Care Facilities*, 2006.
[15] http://www.health.qld.gov.au/EndoscopeReprocessing/module_2/2_1.asp

homicidal ideations. We will also ensure that staff are aware and can articulate the steps outlined in the emergency management plan.

Credentialing and Privileging

All VHA health care professionals who are permitted by law and the facility to provide patient care services independently must be credentialed and privileged. The C&P program is used by medical centers to ensure that clinical providers have the appropriate professional licenses and other qualifications to practice in a health care setting and that they practice within the scopes of their licenses and competencies. The credentialing, but not privileging, requirements apply to all Advanced Practice Registered Nurses and Physician Assistants even though these practitioners may not practice as licensed independent practitioners.

VetPro is VHA's electronic credentialing system and must be used for credentialing all providers who are granted clinical privileges or are credentialed for other reasons. C&P must be completed prior to initial appointment or reappointment to the medical staff and before transfer from another medical facility.

We will conduct an overall review to assess whether the medical center's C&P process complies with VHA Handbook 1100.19. We will review providers' (maximum of five) C&P folders (electronic and paper) and nursing staff personnel folders (maximum of four).

Contract Community Based Outpatient Clinics

Approximately 25 percent of the CBOCs are contracted to provide primary and mental health care. Contracts for CBOCs are administered and monitored by the parent facility. We will review how the contract parameters affect the quality of care veterans receive at the contract CBOC. Quality of care issues need to be considered in the context of the contract that provides the guidelines that the contractor needs to follow.

We will verify that the number of enrollees or visits that are reported is consistent with what is actually supported with collaborating documentation. We will accomplish this by:

- Requesting that the Contracting Officer's Technical Representative provide supporting documentation of tracking methodology for number of enrollees or visits.
- Reviewing invoices for number of enrollees or visits.
- Using the Primary Care Management Module (PCMM) and Data Storage System (DSS) data to verify what was reported.

- Verifying what the VA actually paid by crosschecking with payments made and recorded in the Financial Management System.

The number of enrollees is a critical factor when looking at the number and type of providers assigned to a clinic.

Primary Care Management Module Coordinator

This application that runs on the Veterans Health Information Systems and Technology Architecture (VistA) is the primary means for VHA to track and manage patients in primary care panels. The PCMM Coordinator is responsible for ensuring that the information in the PCMM database is accurate and current. We will be reviewing compliance with VHA Handbook 1101.02 in regards to patient assignment and inactivation of primary care patients from a PCMM panel.

We will accomplish this by:

- Verifying that each patient is only assigned to one Primary Care Provider (PCP) within the VA system. In cases where there are exceptions, documentation should be made available for review.
- Verifying that inactivation is performed if the patient expires or that the patient has not been seen by their PCP in 12 months.
- Using the VHA Support Service Center (VSSC) Web site.

The accuracy of the data in the PCMM database is critical to ensuring that resources supporting primary care are appropriately allocated.

Report Timeline

A report should be issued approximately 60 days after the onsite inspection of the CBOC. The report will cover the inspection of three to four VAMCs' CBOCs, usually two CBOCs per medical center. Each report will cover our findings of the objectives described earlier in this report. The first report will be issued in May 2010 (CBOCs visited in March 2010).

At the end of the fiscal year, we will aggregate the data and report our findings as we compare contract to VA-staff CBOCs, CBOCs to the parent facility, and urban to rural CBOCs. The FY 2010 report will include 47 CBOCs.

(original signed by:)
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Appendix A

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Appendix B

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