

Framework for a national teleretinal imaging program to screen for diabetic retinopathy in Veterans Health Administration patients

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Abstract—Digital retinal imaging with remote image interpretation (teleretinal imaging) is an emerging healthcare technology for screening patients for diabetic retinopathy (DR). The Veterans Health Administration (VHA) convened an expert panel in 2001 to determine and resolve the requisite clinical, quality and training, information technology, and healthcare infrastructure issues associated with deploying a teleretinal imaging system. The panel formulated consensus recommendations based on available literature and identified areas of uncertainty that merited further clarification or research. Subsequent VHA experience with teleretinal imaging and accumulated scientific evidence support nationwide regionalized deployment of teleretinal imaging to screen for DR. The goal is to screen approximately 75,000 patients in the first year of the program, which commenced in 2006. This program will increase patients' access to screening for DR, provide outcomes data, and offer a unique platform for systematically evaluating the role of this technology in the care of diabetic eye disease and routine eye-care practice.

Key words: diabetes, diabetic retinopathy, eye-care delivery, healthcare technology, rehabilitation, screening, telemedicine, teleretinal imaging, VHA, visual impairment.

INTRODUCTION

The Veterans Health Administration (VHA) has almost 5 million patients currently receiving healthcare services

each year at an approximate cost of \$27 billion. The prevalence and rising incidence of diabetes are major challenges for the VHA, in which an estimated 20 percent of the patient population has diabetes mellitus. Prevention of visual impairment and blindness through timely assessment of and early intervention for diabetic retinopathy (DR) is a major healthcare need that the VHA must address.

The prevalence of DR increases steadily with longer duration of disease such that more than 75 percent of patients who have had diabetes for 15 years or more have DR [1–2]. The value of screening for DR is well established for patients with diabetes [3–4]. Such screening is part of routine VHA practice and has established guidelines and performance measures. Achieving timely and appropriate rates of screening for DR remains problematic.

Abbreviations: DICOM = Digital Imaging and Communications in Medicine, DR = diabetic retinopathy, FY = fiscal year, JVNTM = Joslin Vision NetworkTM, TRP = Technology Recommendations Panel, VA = Department of Veterans Affairs, VHA = Veterans Health Administration, VISN = Veterans Integrated Service Network, VistA = Veterans Health Information Systems and Technology Architecture.

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Major barriers to screening include inadequate access to care and patient misconceptions about the value of regular eye examinations (exams) [5]. Indeed, anywhere from 34 to 65 percent of patients with diabetes in the private and public sectors have annual eye exams [6–9]. The VHA has excelled in this area in comparison with the private sector [10]. To further improve this performance in the face of challenges such as increasing patient needs and the geographic distribution of the patient population, the VHA has sought alternative methods for screening and evaluating patients with diabetes for DR and other diabetes-related eye conditions.

In fiscal year (FY) 2000, the U.S. Congress recognized the importance of preventing blindness from diabetes by recommending that the VHA collaborate with the Joslin Vision Network™ (JVN™) (Joslin Diabetes Center, Boston, Massachusetts) to implement a technology-based platform that uses nonmydriatic digital retinal imaging and remote image interpretation (teleretinal imaging) to assess DR. This teleretinal imaging system was an outgrowth of a pilot program developed by the VHA and implemented in FY1999 in collaboration with the JVN™, the Department of Defense, and the Veterans Integrated Service Network (VISN) 1.

Prior to pilot testing teleretinal imaging in other VISNs, the VHA convened an expert panel to address issues of clinical application, quality and training, information technology, and healthcare infrastructure with regard to deployment of teleretinal imaging programs. This article details the recommendations of the panel, identifies remaining areas of uncertainty, and describes the systematic national deployment of VISN-based teleretinal imaging programs.

VHA NATIONAL CONSENSUS CONFERENCE ON TELERETINAL IMAGING FOR DIABETIC RETINOPATHY

On September 5 and 6, 2001, the VHA convened a meeting composed of 27 invited experts who had been selected for their specific expertise in ambulatory care, ophthalmology, optometry, endocrinology, telemedicine, patient safety, health information systems, guideline development, and legal and regulatory issues. The meeting was divided into four panel sessions: (1) clinical care of patients, (2) quality and training, (3) information technology, and (4) healthcare system implications for the use

of teleretinal imaging to screen for DR. The purpose of the meeting was to develop consensus on the clinical, technical, and business processes and infrastructure issues that might confound deployment efforts. In creating its recommendations for the use of teleretinal imaging, each panel focused on ensuring patient safety, developing consistency throughout the VHA, establishing a common platform, and exploring the appropriateness of further VHA investment in the technology.

This meeting allowed experts to consider the issues associated with using teleretinal imaging in DR screening programs. Defining the precise areas for consensus and the related questions that needed to be addressed were primary aims of the meeting. Each of the four panels proposed draft consensus recommendations. A consensus recommendation was only adopted after the participants unanimously agreed. Having arrived at these preliminary areas of consensus, participants then reviewed an initial document that was prepared immediately after the meeting along with a review of the relevant literature. The recommendations were appropriately modified to reflect this literature review.

In March 2002, the recommendations were reviewed by the VHA's Technology Recommendations Panel (TRP), an autonomous body within the VHA that is chartered by the Under Secretary for Health. The TRP reviewed evidence supporting the use of healthcare technologies and provided recommendations to the VHA that reflected the weight of scientific evidence. In accordance with standard TRP procedure, the VHA's Technology Assessment Panel also systematically reviewed the DR screening and teleretinal imaging literature to determine whether the evidence substantiated or refuted the participants' recommendations. The TRP then proposed modifications to the recommendations that were incorporated into the final document.

CONSENSUS RECOMMENDATIONS

Panel 1: Clinical Care of Patients

- Recommendation 1: All patients with diabetes for whom teleretinal images are unobtainable or unreadable must be referred to an eye-care practitioner, ophthalmologist, or optometrist for DR screening.
 - Rationale: This mandate was recommended because a referral for teleretinal imaging is made to confirm or exclude a diagnosis of DR. Media opacities (e.g.,

cornea, lens), miosis (e.g., small pupil), or inability to cooperate (e.g., tremor) may prevent acquisition of an adequate digital retinal image. Given the prevalence of DR and nondiabetic eye diseases and in the interest of patient safety, failure to adequately assess the retina should default to a path whereby the patient is required to have a comprehensive eye exam by an eye-care professional.

- Recommendation 2: The storage and availability of suitably acquired teleretinal images provide a tool for assessing the quality of care received by patients with DR and for communicating this information across the continuum of care.
 - Rationale: In conventional eye-care practices, the diagnosis of DR and the subsequent recording of the ophthalmoscopic findings vary. No standard reporting instrument is used to follow the progress of patients, measure the quality of care, or systematically assess clinical outcomes. Incorporating digital retinal images into the electronic patient record may potentially ensure the accuracy of diagnosis, streamline clinical communication throughout the continuum of care, measure outcomes, and improve standardization of care. When quality assurance programs are included, these benefits can be realized even if images are not transmitted to another location for interpretation.
- Recommendation 3: Centers planning to deploy teleretinal imaging systems should have an implementation plan that details how the system fits into the overall eye-care management plan. Eye-care providers must be included in the formulation of this plan.
 - Rationale: Screening for DR involves eye-care practitioners who take responsibility for all aspects of the diagnosis, treatment, and long-term follow-up of patients. Ensuring continued access to care and integrating this care into the work flow of ongoing eye care rests with eye-care practitioners. To appropriately position teleretinal imaging in the overall eye care of patients and to avoid unrealistic expectations about its use, experts in eye-care delivery should be included in the planning and implementation of these services.
- Recommendation 4: Teleretinal imaging has a place in screening for DR. However, this technology currently cannot substitute for a comprehensive eye exam performed by an ophthalmologist or optometrist.
 - Rationale: Limited evidence supports the assumption that teleretinal imaging improves patients' access to

DR assessments [11]. While teleretinal imaging may increase the number of new cases of DR identified, the potential risk exists that other eye conditions (e.g., glaucoma) may not be detected if teleretinal imaging is applied in place of a comprehensive eye exam. The conferees recognized that teleretinal imaging is being used to screen for DR in situations where eye-care services are otherwise unavailable. Given this clinical paradox, the conferees felt that in the interests of patient safety, reminding the clinicians of the limits of teleretinal imaging was important. This is an area where scientific evidence is urgently needed, given the growing use of teleretinal imaging (see "Areas of Uncertainty").

Panel 2: Quality and Training

- Recommendation 1: Supervision of the person performing teleretinal imaging to screen for DR is the responsibility of a licensed independent practitioner at the image acquisition site.
 - Rationale: The relationships between various practitioners and between practitioner and patient may be altered when teleretinal imaging is used. Several unique models of teleretinal imaging can be used with different designations of practitioners at the image acquisition site and the reading center site. In the interests of patient safety, this recommendation clearly proposes that a designated licensed independent practitioner at the image acquisition site (who need not be an eye-care professional) must take responsibility for the care provided.
- Recommendation 2: The reading of teleretinal images to screen for DR should be performed by or under the direction of an eye-care practitioner at the reading center site.
 - Rationale: No universally accepted training programs, formal licensures, or universally agreed upon scope of practice for reading teleretinal images exist. In the absence of these standards and regulatory frameworks, the conferees felt that patient safety would be maintained if a licensed eye-care practitioner were responsible for reading the images. This practitioner should have formal training and adhere to VHA clinical practice guidelines to ensure a minimum level of quality and consistency in reporting results. If non-eye-care practitioners read teleretinal images for the presence of DR, then careful efforts must be taken to

- ensure their accuracy (sensitivity and specificity) in comparison with care practitioners and to establish inter-rater reliability among members of each practitioner group.
- Recommendation 3: The standards for acquisition and reading of teleretinal images for DR screening should be decided by the local medical center requiring the services along with local eye-care practitioners.
 - Rationale: Timely and appropriate reports of images obtained from DR screening must be provided to the licensed independent practitioners who directly care for the patients. Clear lines of responsibility should also be established for follow-up of imaging results. In some cases, coordination of follow-up may be delegated to the imager. As of yet, no clear guidelines are available for identifying which patient subgroups are most appropriate to screen for DR using teleretinal imaging. Therefore, the local medical center is responsible for judging and implementing the appropriate standards that will govern the clinical reporting of these images. Since no explicit standards or guidelines for report generation times exist, the conferees felt that local medical staff and eye-care practitioners should decide these matters.
 - The conferees felt that the qualifications of the individuals performing teleretinal imaging need not be prescribed as long as such individuals received appropriate training. Local decisions on roles and responsibilities could determine the necessary skill set (e.g., trained technician or clinic nurse). Consensus is lacking on the recommended optimal number of retinal fields that need to be imaged or image quality and resolution in terms of clinical effectiveness and cost-effectiveness. Various studies have reported that one to three retinal fields highly agree with standard fundus photography [12–15]. Similarly, while strong evidence exists that nonmydriatic images are adequate in most cases, whether some patients should undergo pupil dilation and, if so, how they should be identified is unclear.

Panel 3: Information Technology

- Recommendation 1: All image acquisition and management equipment must meet the interface standards of the VHA Digital Imaging and Communications in Medicine (DICOM) conformance statement on DR.

- Rationale: No uniformly agreed upon national standards govern the reliable and convenient transfer of digital retinal images and their associated reports across different information technology platforms. The VHA has developed a conformance statement on similar issues associated with radiological images. Conferees, in conjunction with the Veterans Health Information Systems and Technology Architecture (VistA) development team, agreed that the VHA will produce a DICOM conformance statement on the standards that teleretinal imaging and imaging applications supplied by equipment vendors will be expected to meet. The VHA staff procuring teleretinal imaging equipment should use this statement to guide their purchases.
- Recommendation 2: Images acquired during screening for DR with teleretinal imaging must be transferable to VistA, the VHA's healthcare information system.
 - Rationale: Capturing and transferring digital retinal images to VistA allows those involved in the continuum of care to access specialized diagnostic images. Equipment platforms must be capable of interfacing with VistA. In addition, significant quality of care and clinical risk management implications are associated with storing patient data on disparate clinical information systems that cannot intercommunicate. Mandating VistA image storage capability and compatibility ensures ongoing accessibility of images to VHA clinicians and perpetually safeguards access to patients' images.

Panel 4: Healthcare System Implications

- Recommendation: The effect of teleretinal imaging on clinical workload must be determined.
 - Rationale: By implication, use of teleretinal imaging may also free eye-care practitioners from screening activities and enable them to use their skills more effectively. An additional anticipated benefit of teleretinal imaging to screen for DR is that it will provide eye-care access to patients in remote areas and other locations where access to an eye-care practitioner may be limited. However, no clear data suggest that these benefits are achievable. This recommendation also reflects the lack of clear evidence on the sensitivity, specificity, and interobserver variability of teleretinal imaging use for assessing patients for DR.

Areas of Uncertainty

Detection of Nondiabetic Eye Diseases

While use of teleretinal imaging has been validated in screening for DR, its routine use in place of conventional eye exams may result in missed diagnoses of other ocular pathologies. Limited evidence supports that teleretinal imaging may identify ocular pathologies in addition to DR [16]. However, its accuracy and level of agreement with a comprehensive eye exam is unknown. Whether teleretinal imaging either alone or combined with other eye-exam techniques (e.g., visual acuity, intraocular pressure measurements) can adequately detect DR and other ocular conditions such that it may supplant a comprehensive eye exam in low-risk individuals is uncertain.

Health Services Outcomes

Important issues relevant to the use of teleretinal imaging that require additional data include:

1. The sensitivity, specificity, and interobserver variability associated with different models of teleretinal imaging for DR screening.
2. The number of patients referred to eye-care practitioners after teleretinal imaging assessment, i.e., those for whom assessment is unsuccessful, those needing treatment for DR, and those in whom other significant ocular pathologies are detected.
3. The number of patients who regularly receive comprehensive eye exams for other ocular conditions and for whom teleretinal imaging would be redundant.
4. Whether a specific subgroup of the population exists for which DR assessment can be accomplished through combined teleretinal imaging and periodic comprehensive eye exams.
5. Whether teleretinal imaging results in improved diabetes-related outcomes.

Cost-Effectiveness

The conferees agreed on the importance of evaluating and assessing the appropriateness, effectiveness, and cost-effectiveness of teleretinal imaging in screening for DR.

Clinical Coding

Currently, no agreed upon method exists for coding for DR screening using teleretinal imaging. The VHA is developing codes that may be used for the consistent and accurate tracking of such clinical activity and workload.

Consultation Versus Care

The Joint Commission on Accreditation of Healthcare Organizations has standards relating to the credentialing and privileging of licensed independent practitioners who use telemedicine in different institutions. These standards require that a distinction be made between whether the practitioner is providing consultation or care when using telehealth technologies. No specific guidance with regard to the use of teleretinal imaging to assess for DR is provided.

IMPLEMENTATION OF VHA TELERETINAL IMAGING PROGRAMS

The expert panel recommendations resulted in modifications to the pilot program in VISN 1 and helped determine the nature of further pilot testing in VISNs 19 and 20 between FY2002 and 2004. Evidence from these pilot tests established the appropriateness of using teleretinal imaging technology [11,16]. In addition, other VISNs independently developed local and regional teleretinal imaging systems with similar technologies.

Thus, teleretinal imaging programs to screen for DR reached a significant level of development and acceptance, and the VHA prepared for the next major step in the evolution of this technology. The VHA envisions developing and deploying a nationwide teleretinal imaging system that will be regionalized by VISN and will build on the VHA's robust information technologies for acquiring, transmitting, interpreting, and storing digital retinal images, namely, VistA and the associated electronic medical record (Computerized Patient Record System). A similar system for screening for DR has been established in the United Kingdom. This system uses fixed and mobile retinal imaging systems as well as office-based eye exams and has an established framework and guidelines (<http://www.ncretinopathy.org.uk>).

In January 2005, the VHA invited VISNs to submit applications to obtain funding for the equipment and staff necessary to establish teleretinal imaging programs. Funding for teleretinal imaging technologies includes the purchase of up to six digital retinal cameras per VISN, image acquisition workstations, and a reading center diagnostic display package. The funding will also support personnel to develop and deploy the VISN-wide programs for a 2-year period. Imagers and readers will be trained through remote and "hands-on" supervised training at a

Department of Veterans Affairs (VA) Ocular Telehealth Center. This center is responsible for providing initial training, recertification, and quality improvement services to imagers and readers.

The first program deployments began in Spring 2006. VISNs that received funding were expected to image a minimum of 5,000 patients (or approximately 850 patients per teleretinal imaging camera) within 12 months of commencing the program. Based on the likelihood that most VISNs would participate, the volume of patients imaged in the first year was anticipated to be 75,000 to 100,000. Systematic methods are being developed to code for patient encounters involving teleretinal imaging for DR screening. These codes will provide a resource for subsequent research on the clinical, staffing, technology, and business process issues as well as the identified areas of uncertainty in clinical and health services.

CONCLUSIONS

DR is a leading cause of new blindness in the expanding population of VHA patients with diabetes. Effective medical treatments are available but require timely and appropriate diagnosis of DR. A clinically relevant, cost-effective program to screen for DR using teleretinal imaging may potentially bring specialized services to patients with diabetes who might not otherwise have ready access to them and may reduce the incidence of vision loss as a complication of diabetes.

We described the VHA's systematic approach to developing a teleretinal imaging program, which included identification of and planning for important issues related to clinical application, quality and training, information technology, and the larger healthcare system. The VHA is now deploying a nationwide regionalized teleretinal imaging program that will provide a wealth of information from the large number of patient contacts. This program will also help address the clinical and health service areas of uncertainty related to wider use of teleretinal imaging to screen for DR.

The VHA is the largest integrated managed care organization in the country. It is faced with the challenges of treating more patients while simultaneously improving quality of care, ensuring consistent care between community-based outpatient clinics and medical centers, being accountable for outcomes, providing accurate measures of success, and delivering care at lower costs. Critical to reali-

zing these objectives is the development and application of solutions that use information technology, such as teleretinal imaging, to enhance healthcare providers' effectiveness and provide seamless integration across the healthcare system regardless of provider or patient location.

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