

The Next Frontier of Disease Monitoring and Management?



How home-based telemedicine could be transformational for patients with AMD.

BY JUDY E. KIM, MD

Connected health, also known as technology-enabled care (TEC), is a broad term that encompasses concepts such as telehealth, telecare, telemedicine, and cloud-based home monitoring platforms. TEC innovations are evolving at lightning speed. They aim to disrupt traditional care models, improve quality of care and patient outcomes, and provide a conduit for personalized medicine.

The introductions of glucometers and blood pressure monitors decades ago seem almost primitive when compared with the new Apple Watch Series 4 (Apple). The watch, which has received two US FDA clearances for use as a medical device, allows wearers to obtain electrocardiogram readings they can share with their physicians. It can also detect hard falls. When one is detected, it can then initiate an emergency call, if needed.

Technology is making meaningful changes in how medical specialists monitor and manage disease. For retina specialists, embracing this future-forward trend toward personalized connected medicine could mean a transformational shift in how we treat patients with a multitude of diseases, including those diagnosed with wet age-related macular degeneration (AMD).

IMPROVING PATIENT OUTCOMES

Without question, the introduction of anti-VEGF therapy in 2004 revolutionized the treatment of wet AMD; however, there is still a long way to go to achieve optimal long-term VA outcomes, as real-world concerns pose significant barriers.

Both clinical trials¹⁻³ and real-world studies^{4,5} have shown that more than 95% of patients started on anti-VEGF therapy can maintain VA within 3 lines of baseline VA. These

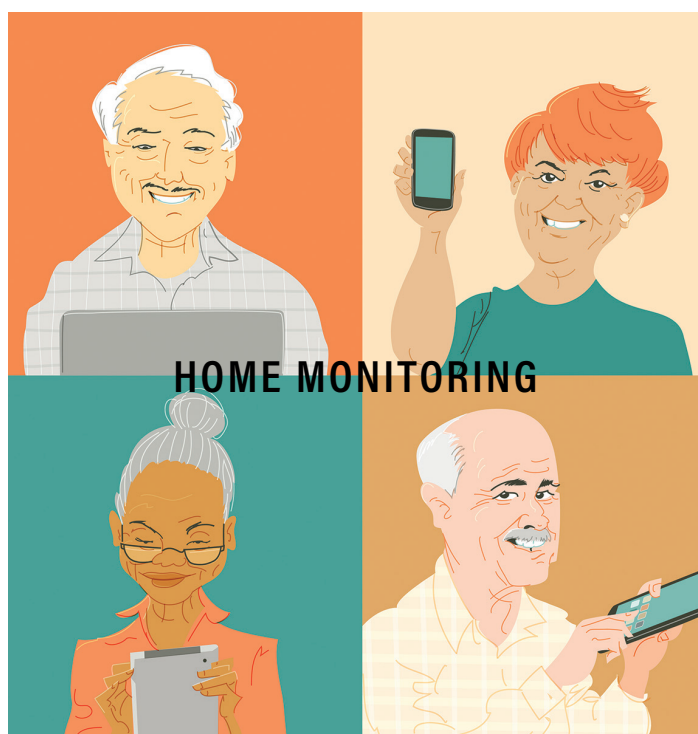
studies confirm that prompt recognition of conversion to wet AMD and subsequent initiation of treatment are essential for good long-term vision outcomes. Furthermore, studies consistently demonstrate that better VA at the time of diagnosis and treatment initiation is the strongest predictor of better long-term VA.

Despite these findings, too many patients are diagnosed with baseline VA worse than 20/40.⁶ Significant opportunity exists to optimize long-term outcomes through earlier detection using technology-enabled home monitoring for those at risk of disease progression.

AT A GLANCE

- ▶ Anti-VEGF therapy revolutionized the treatment of patients with wet AMD, but there is still a long way to go to achieve optimal long-term VA outcomes.
- ▶ A substantial opportunity exists to optimize these long-term outcomes through earlier detection by having those at risk for disease progression use home monitoring technology.
- ▶ Technology-enabled home monitoring has the potential to personalize disease management and improve the patient journey.

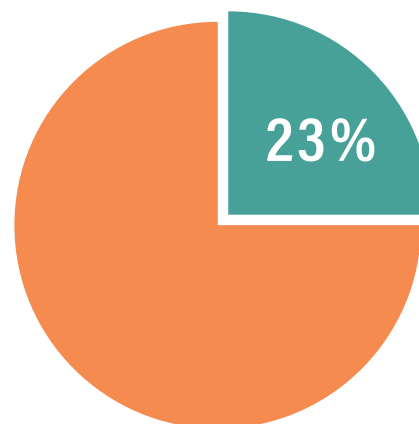
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HOME MONITORING

Call it connected health, technology-enabled care, home monitoring, telemedicine, or remote patient monitoring; the basic concept behind all of these is a health care platform that allows patients to use a mobile device to perform some sort of test and send the results of that test to their health care professionals.

These technologies can benefit anyone. They are particularly useful for older patients, those in remote locations, and those who are chronically ill, but their applications are not limited to these populations.



Telehealth accounts for roughly one-fourth of the health care-related technology market.¹

1. Wearable electronic devices rapidly gaining ground in healthcare information technology industry. PRWeb. May 20, 2015. www.prweb.com/releases/2015/05/prweb12736376.htm. Accessed October 19, 2018.



The expected market value (in billions) of telehealth in 2020.²

2. Telemedicine to attract 7M patient users by 2018. *Becker's Hospital Review*. October 2016.



Americans living in rural areas benefit the most from telehealth applications.³

3. Top 10 statistics regarding telemedicine for 2018. Advance Healthcare Network. February 27, 2018. <http://health-information.advanceweb.com/Features/Articles/Top-10-Statistics-Regarding-Telemedicine-for-2018.aspx>. Accessed October 19, 2018.

DEMOGRAPHICS DRIVING CHANGE

AMD, the leading cause of blindness for individuals older than 50 years, is projected to affect 25 million people by 2020 and as many as 38 million people by 2040.⁷ This is not surprising, given that, by 2030, one in five people in the United States will be of retirement age.⁸

As patients are getting older, the number of ophthalmologists needed to fulfill the demands of their care may be insufficient. A recent report projected a shortage of 6,180 ophthalmologists by 2025.⁹ Furthermore, it is forecast that in the coming years there will be fewer retina specialists relative to the increasing number of patients. TEC

that efficiently and accurately complements our office-based care will allow us to manage this increased patient load while optimizing long-term VA outcomes of our patients with AMD.

A 2018 poll from the Associated Press-NORC Center for Public Affairs Research found that nine in 10 respondents aged ≥ 40 years would be comfortable using at least one form of telemedicine.¹⁰ Evidence also suggests that patients with AMD are receptive to using technologies that allow them to participate in the management of their disease.¹¹ The willingness of patients to embrace technology is especially meaningful

in AMD, where studies have noted a correlation between loss of central vision and decreased independence, increases in depression and risk of fall, and decline in cognitive function.

NEW TAKES ON AN OLD CONCEPT

The concept of home monitoring for patients with AMD is not new—the Amsler grid is a proven, time-tested tool that is easy for patients to use. However, significant limitations of the Amsler grid include poor compliance, low or variable sensitivity, and lack of automated transfer of abnormal results to physicians. These limitations raise questions about

the Amsler grid's utility for patients at risk for conversion to wet AMD.¹²

TEC can help address these limitations. Two TEC options are currently on the forefront of home monitoring in AMD: the mVT app (myVision Track; Vital Art and Science) and the ForeseeHome AMD Monitoring Program (Notal Vision).

The mVT App

This FDA-cleared application is available for use on Apple and Android smartphones. The mVT app is available by prescription, costs \$19.95 per month, and relies on shape discrimination hyperacuity testing. Patients can use the app to monitor themselves for any significant vision changes associated with maculopathy, including AMD. Prescribing physicians are alerted via their choice of portal (email or phone) when changes are detected. The recommendation for testing is twice per week, although the app does not ensure regular use (ie, accountability for compliance rests with the user).

ForeseeHome AMD Monitoring Program

This service, available by physician order, uses preferential hyperacuity perimetry, an application of Vernier acuity, to detect minute differences in the relative spatial localization of two or more objects. The technology has been validated in a multicenter, prospective, randomized clinical trial sponsored by the National Institutes of Health,¹³ which led to its being covered by Medicare and most private insurance with no cost for most patients.

In the AREDS2 HOME Study of 1,520 patients with intermediate dry AMD, 94% of patients who used the ForeseeHome device at least twice weekly maintained 20/40 or better VA at the time choroidal neovascularization was detected, compared with 62% in the standard-of-care arm. Moreover, those in the standard-of-care arm lost more letters (-9 letters) from baseline, on average,

"REAL-WORLD VISUAL OUTCOMES HAVE NOT YIELDED THE RESULTS OBSERVED IN CLINICAL TRIALS; THIS IS THOUGHT TO BE DUE TO UNWANTED FLUID IN THE RETINA WITH UNDERTREATMENT."

than those in the ForeseeHome group (-3 letters) at the time of choroidal neovascularization detection.¹³

When the ForeseeHome device detects threshold changes in a patient's test score, an alert is sent to a designated contact, and an appointment is made for the patient to see a physician. Additionally, monthly reports are emailed to the physician's practice, and test results are available any time via the Notal Vision portal. Alerts can also be sent to patients with the physician's written consent.

ForeseeHome also addresses the need for compliance, as it tracks the frequency of usage. To encourage compliance, the Data Monitoring Center contacts the patient if no results are received for 7 consecutive days.

THE NEXT FRONTIER

Once a patient is diagnosed with wet AMD, many retina specialists employ a treat-and-extend or as-needed regimen with anti-VEGF injections in an attempt to tailor the treatment to the patient's response and reduce treatment burden. Most retina specialists incorporate findings from OCT, VA, and clinical examination when assessing treatment response and making treatment decisions.

Although maintenance of disease-free intervals between treatments is key to optimal wet AMD management and better long-term visual outcomes, we currently do not have a good biomarker to accurately determine disease-free intervals for every patient. Furthermore, real-world visual out-

comes have not yielded the results observed in clinical trials; this is thought to be due to unwanted fluid in the retina with undertreatment.

What if we could truly personalize retinal fluid management while reducing the burden of frequent follow-up visits? What if we could minimize the days with fluid in the retina, gain between-visit knowledge regarding the disease or the treatment response and maintain VA over time? What if patients could image their own eyes on a regular basis with an at-home OCT device to help determine when they should return to their physician for follow-up? What if those OCT images could be interpreted rapidly and accurately using artificial intelligence?

An at-home OCT monitoring program would complement in-office OCT and allow patients to play a larger role in the management of their disease, resulting in more timely and personalized treatment intervals. This could potentially translate to better visual outcomes while reducing treatment burden. The Notal OCT Analyzer (NOA; Notal Vision), currently in development, performs fully automated detection of lesion activity—defined as the presence of fluid in the various tissue compartments when applied to a macular volume scan. In a published clinical trial, the performance of NOA, which uses a machine-learning algorithm, was comparable in sensitivity and specificity to that of retina specialists in detecting abnormal OCTs selected from an image

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repository at a tertiary center.¹⁴

Compact Imaging is developing miniaturized OCT devices and home retinal monitoring based on the company's proprietary MRO (Multiple Reference OCT) technology, and the company recently signed a collaboration agreement with Novartis Pharma stating that Novartis will fund its development of a low-cost home-based monitor to detect disease progression in advanced cases of AMD and diabetic retinopathy.¹⁵ According to Compact Imaging, the technical feasibility of MRO has already been demonstrated, achieving results similar to clinical OCT in a study measuring retinal thickness in healthy eyes. Clinical trials of a prototype system for patients with active AMD or DME are expected to begin in the second half of 2019.

SEIZE THE TECHNOLOGY

The time has come to employ modern home monitoring options in order to better personalize disease management and improve our patients' journeys. The future of teleophthalmology is potentially transformative in patient management. Let's make sure we provide our AMD patients with the best chance at maintaining optimal VA long term. ■

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