



Crafting Changes for the Future: The Use of Technology to Expand Access to Medications

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As discussed in the first article in this series, the Food and Drug Administration (FDA) seeks to expand access to current prescription medications by making them available as nonprescription (over-the-counter or OTC) medications through certain “conditions of safe use.”¹

Conditions of safe use can include the use of technologies, such as kiosks or mobile applications, or involve consultation with a pharmacist or other health-care provider.²

Conditions of safe use may also be product- or disease-specific (*i.e.*, a pharmacogenomic test designed to predict an individual’s response to a certain medication) or applicable to a number of medications used to treat a specific disease or medical condition (*i.e.*, use of a mobile app to monitor blood glucose and hemoglobin A1C levels in diabetic patients).

This article will discuss some of the current and emerging technologies that may serve as conditions of safe use.



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To ensure the safe and effective use of medication, technology can assist patients with self-diagnosis of a medical condition, self-selection of a medication, and self-monitoring of clinical markers and adverse events. To assist patients with self-diagnosis and self-selection, a kiosk or medical app may gather pertinent information by guiding a patient through a series of questions and answers, ultimately leading to a diagnosis and recommendation for a medication.³

For chronic disease states, technology could assist patients monitor their response by tracking both clinical markers (*i.e.*, blood pressure readings for patients with hypertension) and adverse drug events. To develop effective technology in this regard, industry will

need to appreciate the varying degrees of technical literacy in the patient population, as well as patient reluctance to use such technology for self-treatment.⁴

The second meeting of a three-part series on FDA's Nonprescription Safe Use Regulatory Expansion (NSURE) Initiative and the potential regulatory expansion of nonprescription medications convened in May 2013 at the Engelberg Center for Health Care Reform at Brookings, specifically focusing on the use of technology-enabled self-care to address under-treated diseases.⁵ Participants discussed numerous mobile and electronic technologies that may have a role in expanding patient access to medications, including: (1) the use of interactive text, video and audio to enhance patient

understanding of product labeling; (2) smartphone and tablet mobile health apps that collect health information and use monitoring tools to promote information sharing between physicians and patients; and (3) virtual monitoring of patients to allow health-care providers to observe vital signs, detect warnings, and diagnose medical conditions remotely.⁶

A few of these technologies will be further discussed below, including the use of kiosks, mobile medical applications, and the application of pharmacogenomics.

Interactive Kiosks and Mobile Medical Apps:

For many years, self-diagnostic equipment, such as blood pressure monitors, have commonly been found in the patient-waiting areas of retail pharmacies. In the coming years, however, advancing technology will replace this equipment with interactive kiosks and mobile medical apps capable of gathering, analyzing and storing vast amounts of personal health information.

For example, Rite-Aid recently announced that it will install Higi Stations in more than 4,000 stores in late 2014 and 2015.⁷ Higi Stations are kiosks that provide patients with statistics on their bodyweight, body mass index, blood pressure, and pulse, and store this information in personalized accounts that can be accessed from a personal computer or smartphone.⁸ Using this data, along with "lifestyle" and "community" information gleaned from patient-provided answers and Facebook, Higi assigns an overall health score (between 1 and 999) that users can track and compare to others of the same gender and age.⁹

Other health technology companies are developing devices that can not only provide biostatistics, but can also diagnose diseases and other medical

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conditions, and recommend treatment with medication. One such company, Nanobiosym, currently has multiple applications pending before FDA.¹⁰

Nanobiosym's device, Gene-RADAR, works by analyzing a drop of saliva or blood placed on a disposable chip to look for the presence of disease pathogens.¹¹ The Gene-RADAR is approximately the size of an iPad and requires less than one hour to analyze a patient's sample against DNA and RNA markers to look for diseases such as HIV, malaria, tuberculosis, and some forms of cancer.¹² The device can also provide real-time measurements of disease-specific clinical markers, such as viral load levels and white blood cell counts in HIV, to monitor a patient's response to treatment.¹³ Compared to the current process for obtaining these values, which involves a patient visit to a medical laboratory for a blood draw, analysis of the sample by the laboratory, and interpretation of the results by the patient's physician, the use of these new technologies has the potential to save a significant amount of time and reduce health-care costs.

Medical devices also have the potential to direct patients to appropriate medications, vitamins and herbal supplements. After obtaining information from a patient through an algorithm of questions, and considering the patient's symptoms, vital statistics, concomitant disease states and medications, as well as pertinent laboratory values, a kiosk or medical app located in a retail pharmacy could either recommend a medication or direct the patient to see the pharmacist for additional screening.

Tablet or smartphone mobile medical apps could provide even greater access to medications by expanding availability beyond the pharmacy's location and hours of operation.

Pharmacogenomics:

Kiosks and medical apps may use recent pharmacogenomic advances to provide increased patient access to medications. Pharmacogenomics predicts how a patient's genetics may affect his/her response to drug therapy and delivers personalized medicine.¹⁴ Historically, when prescribing and dosing medications, physicians have been limited to considering factors such as patient age and bodyweight. However, this one-size-fits-all approach has resulted in inconsistent patient responses because of unknown genetic variations. These genetic variations can be responsible for either over- or under-expression of enzymes responsible for drug metabolism and, consequently, affect drug levels in the body.

By analyzing genetic profiles, however, it may be possible to tailor drug selection and dosage to an individual based on gene sequencing, with the goal of maximizing efficacy and minimizing toxicity.¹⁵ Researchers are currently developing tests that can analyze a patient's gene sequence and determine whether that individual would be a proper candidate for a medication. Nanobiosym's Gene-RADAR is once such device.

According to Nanobiosym CEO Anita Goel, Gene-RADAR can analyze a patient's DNA and RNA signatures and recommend which vitamins that patient should take and which OTC or prescription medications would be the most beneficial for her based on her genetic profile.¹⁶ By predicting a patient's response to medication and monitoring the course of therapy, technology developed from pharmacogenomics can ensure the safe and effective use of medications now limited to prescription-only dispensing.

Conclusion:

The focus on technology as a condition of safe use to increase patient access to medications recognizes that health-care providers are not always able to supervise and consult as to disease-state monitoring and medication use.¹⁷ Through accessible placement in retail pharmacies and other institutions, and by assisting with self-diagnosis, self-selection of treatment, and self-monitoring of clinical markers and adverse events, emerging technology can help ensure the safe and effective use of medications.

1. 77 Fed. Reg. 39 (Feb. 28, 2012), pp. 12059-12062, available at <http://www.gpo.gov/fdsys/pkg/FR-2012-02-28/pdf/2012-4597.pdf>
2. *Id.*
3. *Id.*
4. See Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care, Meeting Summary, May 9, 2013, available at http://www.brookings.edu/~media/events/2013/5/09%20innovative%20technologies%20nonprescription%20medicines/nsure_summary_final.pdf
5. *Id.*
6. *Id.*
7. <http://www.drugstorenews.com/article/rite-aid-introduces-interactive-higi-health-stations-across-chain>
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14. Pirmohamed M., Pharmacogenetics and pharmacogenomics. *Br J Clin Pharmacol.* Oct 2001; 52(4) 345-347.
15. *Id.*
16. <http://drugstorenews.com/article/qa-genetic-profiling-anita-goel-nanobiosym>
17. See f.n. 4, *supra*.