ENGELBERG CENTER for Health Care Reform at BROOKINGS

Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care

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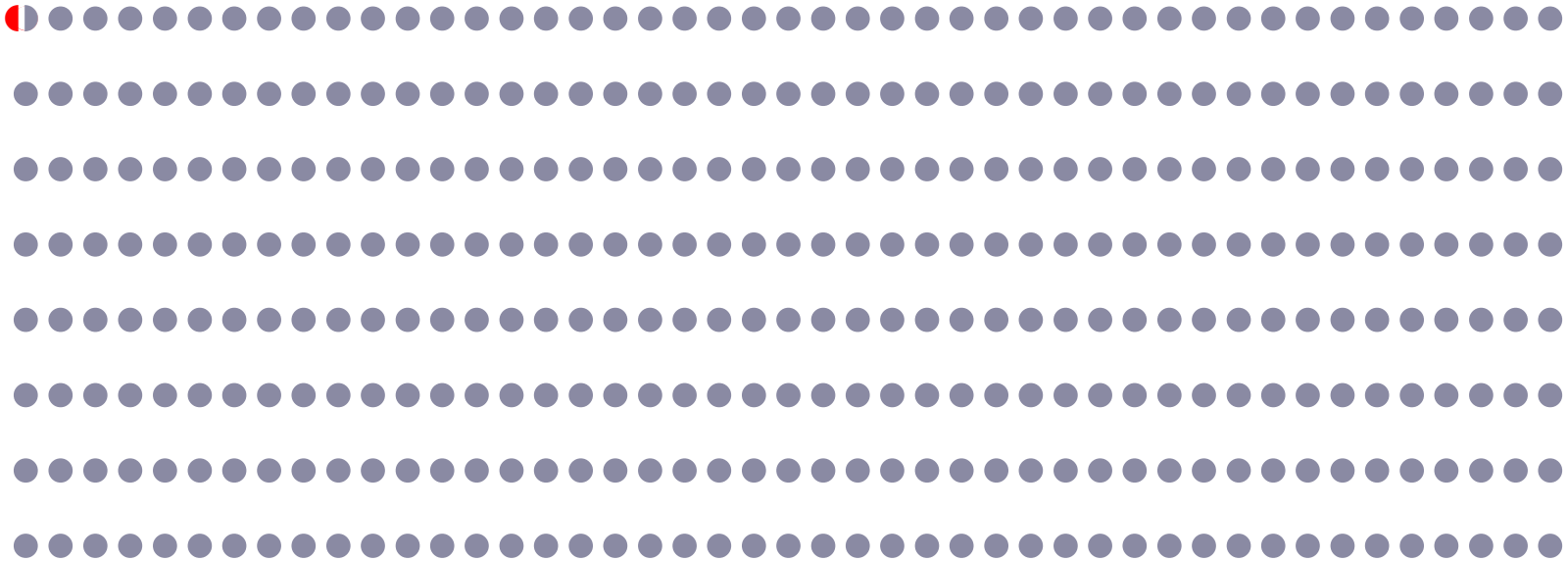
Engelberg Center for Health Care Reform
The Brookings Institution • Washington, DC
May 9, 2013

Innovative Technologies and Nonprescription Medications:
Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care

R William Soller PhD
Professor, University of California San Francisco School of Pharmacy
Executive Director, Center for Self Care
sollerphd.com

Brookings Institute, Washington, DC
May 9, 2013

A Self-care Perspective



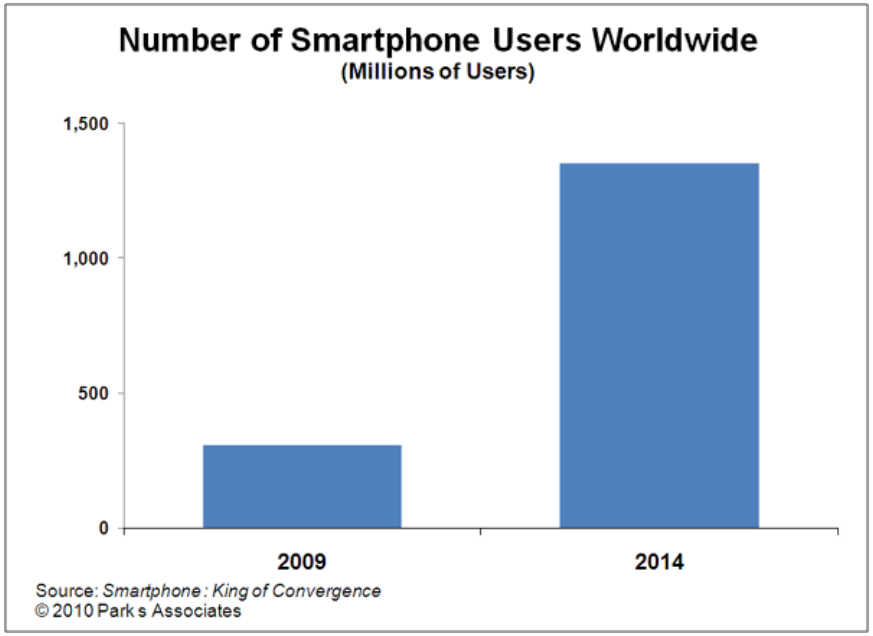
Types of Self-care Activities

BETWEEN doctor visits

- Blood glucose monitoring
- Weight control: CHF, health and wellness
- Self-injection: Coumadin to Lovonox transition
- Self-injection: Insulin
- Self-injection: epinephrine for emergent allergic reactions
- Fertility and pregnancy testing
- Self-management of complex medication regimens

Technology – Embedded in our Lives Now

- Business & Entertainment
- A Parallel Universe
- Mass Market Availability



And more recently…mHealth* Apps

Potential benefits of mHealth:

- Self-monitoring and education
- Self-diagnosis
- Self-selection of products
- Increase therapeutic adherence
- Improve clinical outcomes
- Reduce hospital readmissions
- Improve economic outcomes
- Achieve patient satisfaction

Fits the current policy paradigm for MTM services, ACOs etc.

* mHealth = mobile Health

Certification & Regulation

Happtique™ Your Prescription for Mobile Health

- Operability Standards
- Privacy Standards
- Security Standards
- Content Standards

FDA U.S. Food and Drug Administration Protecting and Promoting *Your* Health

- Under development

http://cdn1.hubspot.com/hub/219577/HACP_Standards_FINAL_2.pdf

In the proximate future…

mHealth Apps as the physician extender

Self-care BETWEEN doctor visits

- Blood glucose monitoring
- Weight control
- Self-injection: Insulin
- Self-management of comple medication regimens
- Management of hypoglycemic episodes

David Jones, M.D.
1 Main Street
New Territory, Sugar Land, Texas

Name: Sandra Lieu Date: 5-9-2013

Address: 9203 Hxy 6 South City: Houston, Texas

℞ *Primus Care Disease Management App for Diabetes*

PRN

Approved by FDA
Backed by a Medical Coding and Billing Protocol
…with incentives (e.g., no co-pays on certain meds or glucose meter sticks)

OTC, Quo Vadis?

Nonprescription Medicines
… in the Era of Consumer Telehealth

Outline

- **Current Approaches to:**
  - Undertreatment
  - Evidence Base for Nonprescription Availability
  - Benefit/Risk Assessment
- **Three Scenarios**
- **Summary**

Undertreatment and Self Care

- **Undertreatment: (Def)**
  - Treatment that is inadequate or inappropriate *
- **Examples**
  - Nicorette — Smoking cessation
  - Oxytrol — Overactive bladder
  - Plan B — Emergency contraception
  - Nizoral — Dandruff
  - Topical Lamisil — Onychomycosis
- **Overtreatment**

* Merriam Webster

Evidence Base & Process for Approval

- **Safety and Effectiveness**
  - Track Record of Parent API

  Triad of Studies

  1. Label Comprehension Studies
  2. Self-selection Studies
  3. In-use Effectiveness Studies (“Actual Use Studies”)

Evidence Base & Process for Approval

- **FDA Benefit/Risk Process for Drug Approval**
  - **Food and Drug Administration**:
    - Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making: Draft PDUFA V Implementation Plan - February 2013. Fiscal Years 2013-2017
  - **Health Policy & Research Sector**
    - Soller, R. W., Chan, P. V, & Shaheen, C. (2011). OTC considerations for expanding access to nonprescription medicines: A critical synthesis of questions from the Food and Drug Administration to its advisory committees on Rx-to-OTC switch. SelfCare, 2(September), 117–138.
    - Soller, R., & Shaheen, C. (2012). The Switch Considerations List: “Considerations for Rx-to-OTC Switch” Refined by a Critical Synthesis of FDA Comments on Expanded Access for Naloxone. SelfCare, 3(November), 121–137.

Nonprescription Medicines
… in the Era of Consumer Telehealth

Outline

- **Current Approaches to:**
  - Undertreatment
  - Evidence Base for Nonprescription Availability
  - Benefit/Risk Assessment
- **Three Scenarios**
- **Implications**

Future Scenarios

Considerations

- Pharmacy work flow
- Cost of Technology
- Cost Shifting
- Type of Technology
- Accessibility
- Efficiency
- Channels of Distribution
- Language
- Monitoring
- Value

Approaches

- Shift intake counseling
- Cloud-based Platform
- To the public/some premium
- Users know the technology
- Paper version/community clinic
- Plug and Play
- Few restrictions
- Easy adaption
- Postmarketing surveillance
- Impact re OTC Drug Facts Label

Future Scenarios

- **Scenario 1: Certain Existing OTCs**
  - **Seamless integration**
    - Many OTCs recommended by physicians
    - Ap
      – a
        - Adherence tracking
        - Dosage reminders
        - Potential DDI interventions
        - Identification on how to handle emergent side effects

mHealth has potential to optimize functionality of the OTC Drug Facts Label

OTC Examples:
- Aspirin
- Stool softeners
- antacids
- cers/PPI
- Oxybutynin

> No/Little change in evidence based approach
> App development & testing is cheap and easy

Future Scenarios

- **Scenario 2: Novel Conditions of Nonprescription Drug Use for Chronic Conditions**
  - **Public Health focus is:**
    - The shifting of risk management to a telehealth nonprescription setting, in order to address:
      - Undertreatment (awareness and access)
      - Overtreatment (better-controlled diagnosis)
  - **Major IT Emphasis:**
    - Self-diagnosis and health condition profiling
    - Compliance with Physician Visits
    - Adherence to Medication
    - Connectivity: Tracking & Reporting

Examples:
- Lipid Lowering
- BPH
- Migraine
- Anticoagulation
- Among others

3. How to take FLOMAX RELIEF

Taking this medicine
- Take one capsule each day
- Take it at the same time each day, after a meal
- Swallow the capsule whole with water
- Do not crush, chew, or open the capsules

Make a note of the date you start taking FLOMAX RELIEF.

After 2 weeks

Breaks the Usual Paradigm of Self-Care with Nonprescription Medicines

Within 6 weeks
You should see your doctor within 6 weeks of starting treatment to confirm that your symptoms are due to BPH.

Every 12 months
You should see your doctor every 12 months to check your prostate. See the doctor sooner if your symptoms change or get worse.

- **No e-based registry**
- **No required reporting of consultation outcomes**
- **Specificity and sensitivity of counseling unknown**

2. Before you take FLOMAX RELIEF

FLOMAX RELIEF should be used only by men who are 45 to 75 years of age.

Do not take the

- You are allerg
  any of the other ingredients of this medicine (listed in Section 6 below)
- You are taking certain medicines prescribed by your doctor (see "Taking other medicines" below)
- You have problems with your heart, liver, or kidneys
- You faint or get dizzy or weak when you sit or stand up suddenly
- You have had your symptoms for less than three months
- You have pain when you urinate, or your urine was cloudy or bloody, at sometime in the last three months
- You have a fever due to an infection of your kidneys or bladder (urinary tract infection)
- You have leaking of your urine which you are unable to control (incontinence)
- You think you have diabetes and it is not properly controlled
- You have had prostate surgery
- You have recently had blurred or cloudy vision and have not been examined by your doctor or optician
- You are about to undergo eye surgery for cataract or glaucoma (see Eye surgery below)

Do not take FLOMAX RELIEF if any of the above apply to you, without first consulting your doctor. If you are not sure, talk to your doctor or pharmacist before taking these capsules.

Reducible to a Structured Survey

…re
taking or have recently taken any other medicines. This includes medicines that you can buy without a prescription, including herbal medicines. This is because FLOMAX RELIEF can affect the way that some other medicines work and some other medicines can affect the way that FLOMAX RELIEF works.

In particular, tell your pharmacist or doctor if you are taking:

- Medicines to lower your blood pressure such as verapamil and diltiazem
- Medicines to treat HIV such as ritonavir or indinavir
- Medicines to treat a fungal infection such as ketoconazole or itraconazole
- Other alpha-blockers such as doxazosin, indoramin, prazosin, or alfuzosin
- Erythromycin, an antibiotic used to treat infections

May 9, 2013 20

		Yes	No	Uncertain
1	Are you allerg (Click here to			
2	Are you curre			
3	Do you have			
4	Do you have			
5	Do you have			
6	Do you faint c			
7	Have you had			
8	Do you have bloody, at son			
9	Do you have (urinary tract			
10	Do you have (urinary incon			
11	Do you think y			
12	Have you had			
13	Have you recently had blurred or cloudy vision and have not been exam			
14	Are you about to undergo eye surgery for cataract or glaucoma?			

- **Computer-based algorithm**
  - Structured survey – self-diagnosis
    - Sensitivity and specificity
  - Online survey accessible:
    - At home, on smartphone
    - In person survey: In store
- **Passing survey criteria yields:**
  - Validated barcode, for scanning at store with valid photo ID
  - May be printed, or sent to email smartphone
- **Gatekeepers:**
  - "Avatar," Sales Clerk, Tech, **or** RPh
- **Triaged only *prn* to RPh for consult**

All Options, with Emphasis on Access

Implications

- **Safety and Effectiveness**
  - Track Record of Parent API

Triad of Studies

1. Label Comprehension Studies
2. Self-selection Studies
3. In-use Effectiveness Studies

Content Comprehension & Operability (Usability)

Self-diagnosis (validated)

Adherence to more than “use directions” on the OTC Drug Facts Label

Health technology has the potential to optimize the full functionality of the OTC Drug Facts Label.

Future Scenarios

Scenario 3: Novel Conditions of Nonprescription Drug Use for Acute Life-threatening Conditions

- **Public health focus**
  - Impact on Public Health Need
- **Major IT emphasis**
  - Selection
  - Caretaker (or Witness)
  - Channel of Distribution

Emergency Care:
- Opioid Overdose
- Asthma
- Allergies

Summary

- Undertreatment is a key driver for OTC drug development.
- Innovative technology has the potential to address under- and overtreatment.
- Consumers are already embedded in the technology of interest.
- Future nonprescription products may be driven by private concerns or the public health concerns.
- Proposed technology approaches can address considerations important to stakeholders.
- Study designs will be modified but in context of the current benefit/risk approach, and triad of studies used now to support switch.
- The proposed technology approach can be built to add significant value to:
  - Improve the functionality of the OTC Drug Facts Label.
  - Tracking and monitoring effectiveness and safety

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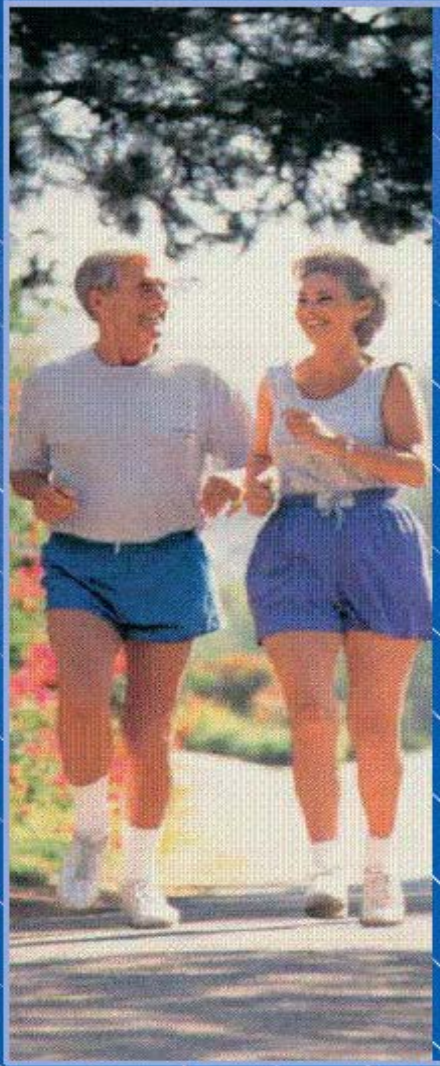
Proposed Mevacor Daily™ Label 2007



MEVACOR™

Lovastatin 20 mg

CHOLESTEROL REDUCER Daily

This Product is only for:

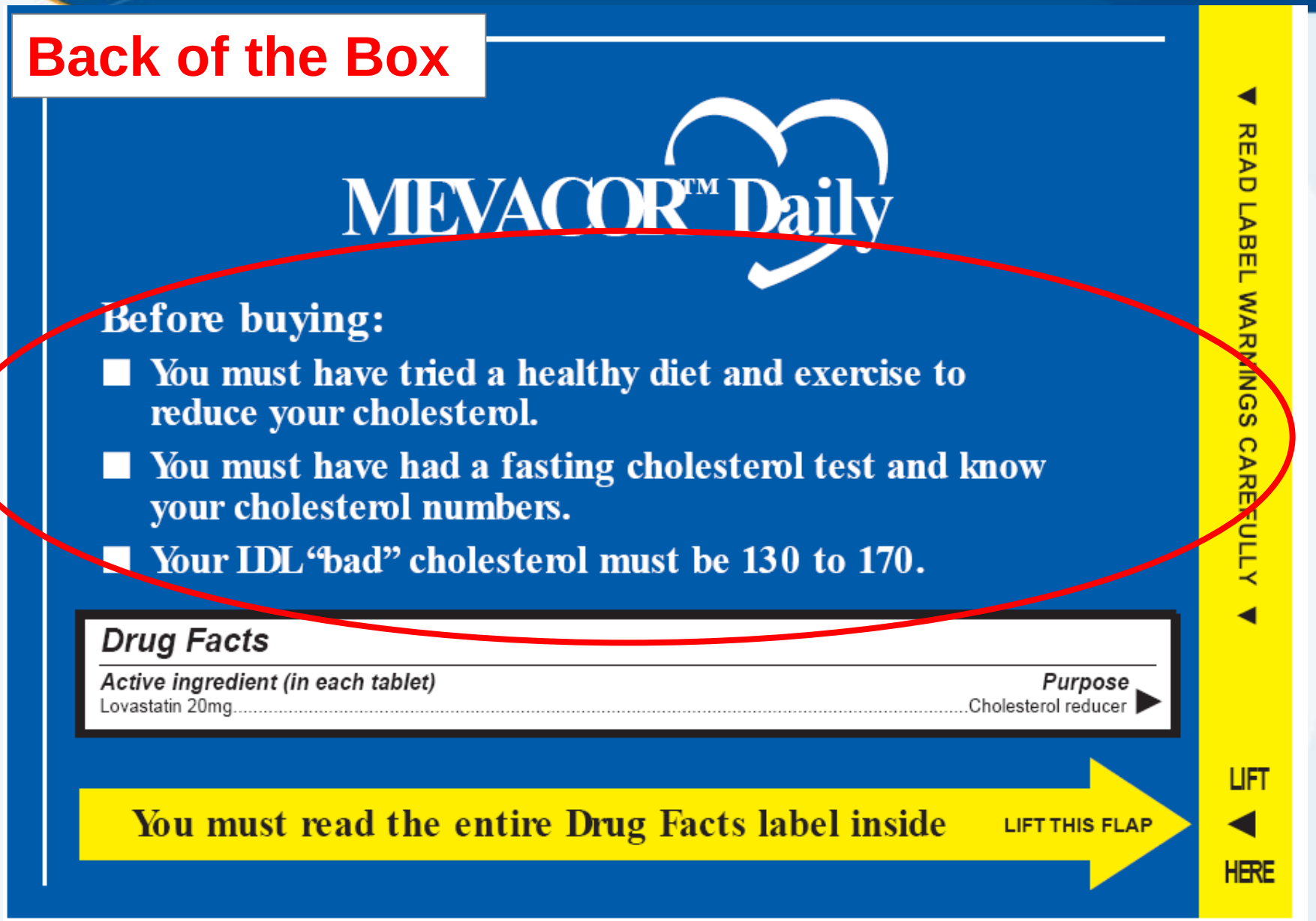
WOMEN age 55 and older

MEN age 45 and older

If you meet these age requirements, read back for more information.

45 TABLETS

Proposed Mevacor Daily™ Drug Facts Label 2007



Drug Facts (continued)

Use To help lower cholesterol, which may prevent a first heart attack.

You must follow the chart below to see if this product is right for you.

This product is ONLY for people who meet ALL OF THE REQUIREMENTS listed below. If you do not meet ALL OF THE REQUIREMENTS, you should not use this product without talking to a doctor.

AGE:

You must be:
- A woman age 55 years or older
- A man age 45 years or older

NO → STOP **DO NOT USE.**
Even with high cholesterol you may be at lower risk and not need this product. Discuss with a doctor.

YES

LDL CHOLESTEROL:

Your LDL "bad" cholesterol is between 130 to 170 based on a fasting cholesterol test within the past year.

NO → STOP **DO NOT USE.**
If your LDL is **lower** you may be at lower risk and not need this product.
If your LDL is **higher** you may need a stronger medicine.
Discuss with a doctor.

YES

HEART DISEASE FACTORS:

You **must have one or more** of the following to take this medicine, because these risk factors increase your chance of having a heart attack:

- high blood pressure or taking medicine to control your blood pressure **OR**
- family history of heart disease: father or brother before age 55, mother or sister before age 65 **OR**
- smoker (smoking increases your risk) **OR**
- low HDL "good" cholesterol 1 to 39

NO → STOP **DO NOT USE.**
If you do not have any of these heart disease factors you may be at lower risk and not need this product.
Discuss with a doctor.

YES

IMPORTANT: You must also read the **entire** label to the right and on the bottom of the package.

Proposed Mevacor Daily™ Drug Facts Label 2007

Drug Facts (continued)

Warnings

Do not use if you know you are allergic to lovastatin

Ask a doctor before use if you

- are taking prescription cholesterol medicines. Do not substitute. This product is probably not strong enough for you
- have LDL "bad" cholesterol 171 to 400. You are at higher risk for heart disease
- are a woman under age 55 or a man under age 45. You may be at lower risk for heart disease
- are a woman with high HDL "good" cholesterol 60 to 200. You may be at lower risk for heart disease
- have liver disease
- have had heart disease
- have had a stroke
- have diabetes

Ask a doctor or pharmacist before use if you are

- unsure of your cholesterol numbers or have not had a fasting cholesterol test within the last year
- taking any of the following, as certain drugs or foods can cause interactions:
  - cholesterol medicines
  - oral antibiotics
  - oral antifungals
  - drugs for irregular heartbeat
  - HIV protease inhibitors
  - cyclosporine (immune suppressant)
  - nefazodone (antidepressant)
  - large quantities of grapefruit juice (more than 1 quart daily)

When using this product, talk to a doctor if there is a change in your health, such as a new prescription medicine or a new medical condition.

Stop use and ask a doctor if you develop any unexplained muscle pain, weakness or tenderness. This can be a sign of a rare but serious side effect.

If pregnant or breast-feeding, or think you may become pregnant, do not use. This product may cause problems in the unborn child.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- this product is only for you if
  - you are a woman 55 years or older or a man 45 years or older and
  - your LDL "bad" cholesterol is between 130 and 170 and
  - you also have one or more of the following heart disease factors which increase your chance of a heart attack:
    - high blood pressure or taking medicine to control your blood pressure or
    - family history of heart disease: father or brother before age 55, mother or sister before age 65 or
    - smoker (smoking increases your risk) or
    - low HDL "good" cholesterol 1 to 39

▼ READ LABEL WARNINGS CAREFULLY ▼

LIFT ◀ HERE

Using Innovative Technologies as a Condition of Safe Use

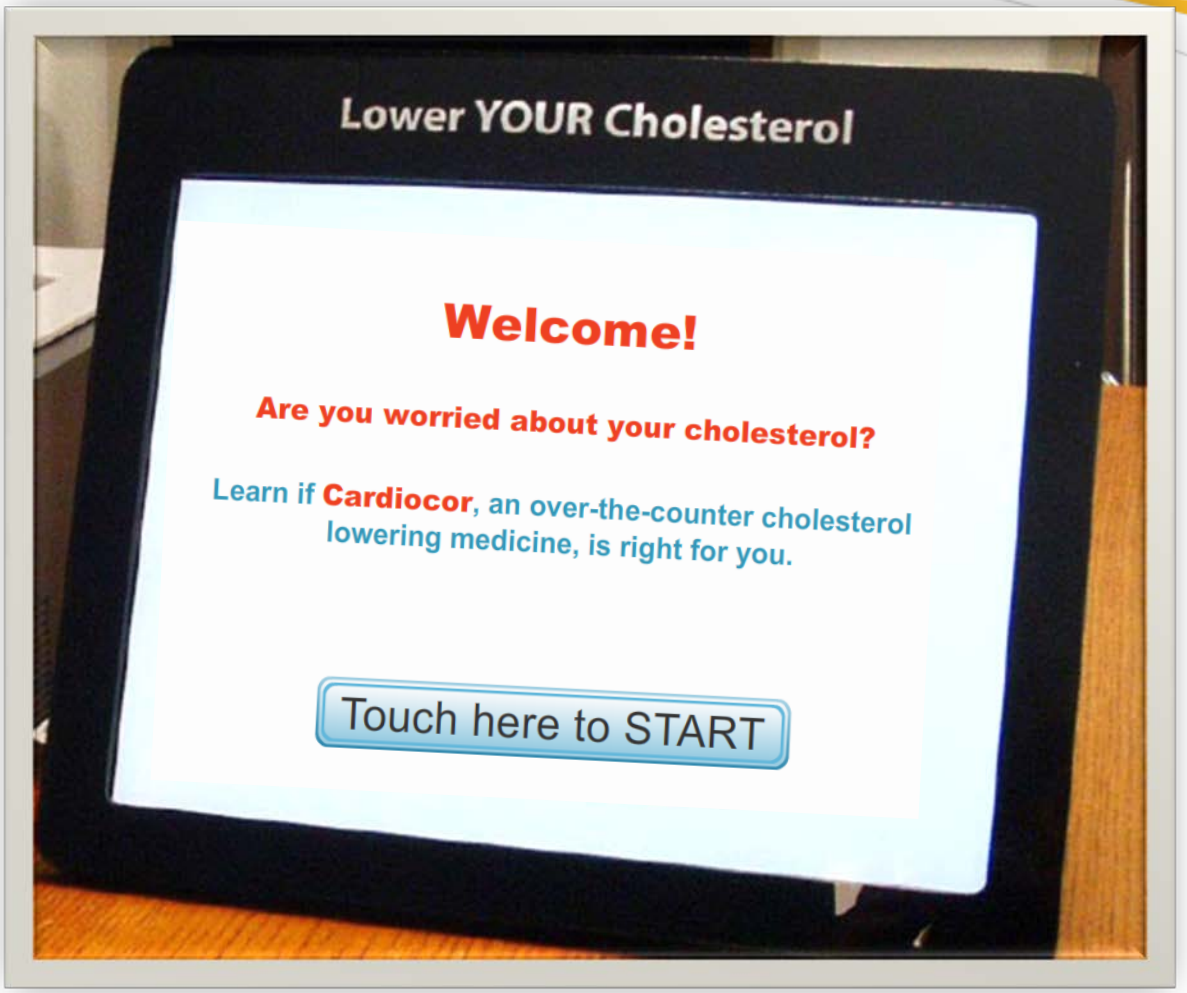
The Brookings Institution
Washington, DC
Thursday, May 9, 2013

Erin Oliver, MS, MBA, RAC
Senior Director, Regulatory Affairs
Global Regulatory and Quality

Can Technology Aid Consumer Self-Selection?

GSK developed a prototype electronic aid to self-selection using:

- a simulated electronic kiosk
- a model drug named “Cardiocor” – an OTC statin for cholesterol reduction
- 9 step self selection algorithm based on the Mevacor- Daily™ Drug Facts label



Are you

Female

Male

54 or younger

55 or older

Have you had a fasting cholesterol test in the past 12 months?

Yes

No

Not Sure

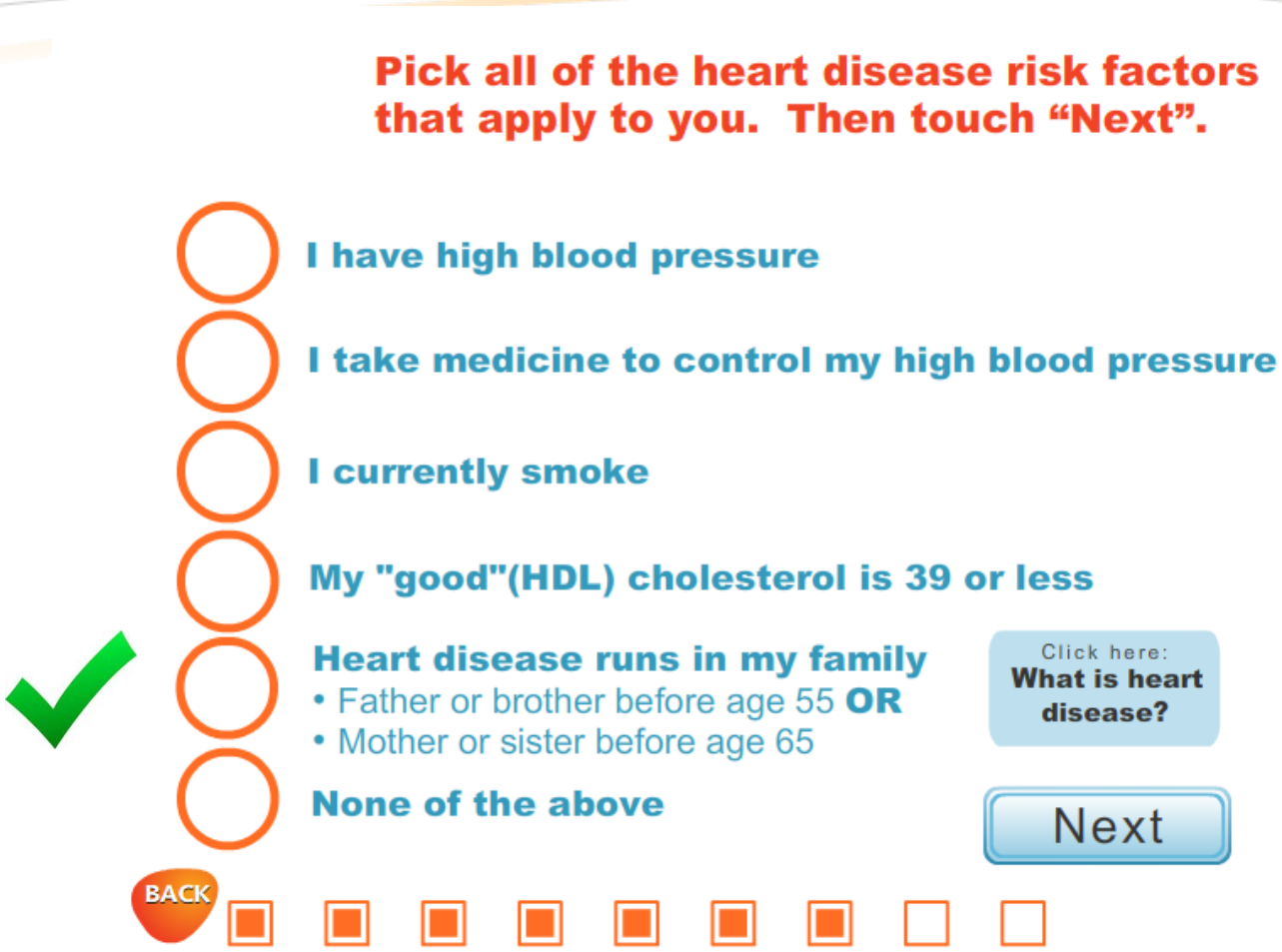
What is your LDL ("bad" cholesterol) score?

- ○ High - more than 170 mg/dL
- ✓ ○ Borderline high - between 130 and 170 mg/dL
- ○ Normal - less than 130 mg/DL
- ○ I don't know my score

Have you tried diet and exercise to reduce your cholesterol?

Yes

No


Pick all of the heart disease risk factors that apply to you. Then touch "Next".
I have high blood pressure
I take medicine to control my high blood pressure
I currently smoke
My "good"(HDL) cholesterol is 39 or less
Heart disease runs in my family
• Father or brother before age 55 OR
• Mother or sister before age 65
None of the above
Click here:
What is heart disease?
Next
BACK

Heart disease is not just one disease. It is all conditions that keep your heart or circulation from working normally. Examples of heart disease include:

- Chest pain - angina
- Irregular heartbeat - arrhythmia
- Narrowing of the arteries - coronary artery disease or atherosclerosis
- Enlarged heart - cardiomyopathies
- Inflammation of the heart's lining – endocarditis or pericarditis
- Aorta or vascular disease
- Heart valve disease
- Heart attack or heart failure

A person who has or has had any of the conditions listed above has heart disease.

Back

I have or have had...

Pick the statement(s) that apply to you.
Then touch "Next"

- Liver disease
- Heart attack or chest pain (angina)
- A stroke
- Diabetes
- None of the above

Next

BACK


Pick the medicines you take or foods you eat.
Then touch "Next"
Prescription cholesterol medications
Oral antibiotics
Oral anti-fungals
Drugs for irregular heartbeat
HIV medicines
Organ transplant medications (For example - cyclosporine)
Nefazodone (medicine in the antidepressant Serzone)
Large quantities of grapefruit juice (more than four 8oz glasses daily)
None of the above
Next
BACK

Cardiocor is right for you!

Cardiocor can help lower your cholesterol and reduce your risk of first heart attack.

Read and follow all directions on the Cardiocor label.

Reprint

Are you

Female

Male

How old are you?

44 or younger

45 or older

Have you had a fasting cholesterol test in the past 12 months?

Yes

No

Not Sure

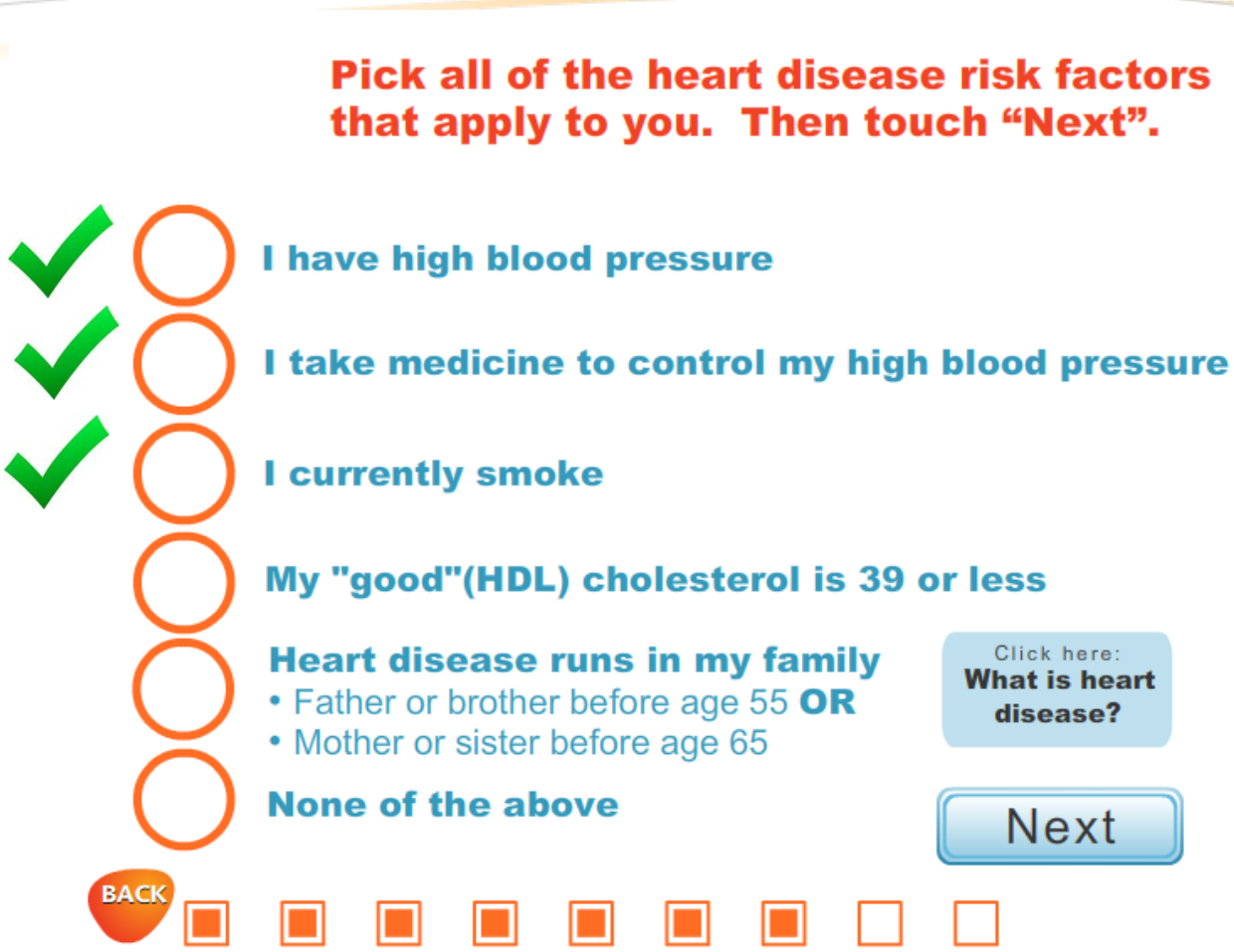
What is your LDL ("bad" cholesterol) score?

- ✓ High - more than 170 mg/dL
- Borderline high - between 130 and 170 mg/dL
- Normal - less than 130 mg/DL
- I don't know my score

Have you tried diet and exercise to reduce your cholesterol?

Yes

No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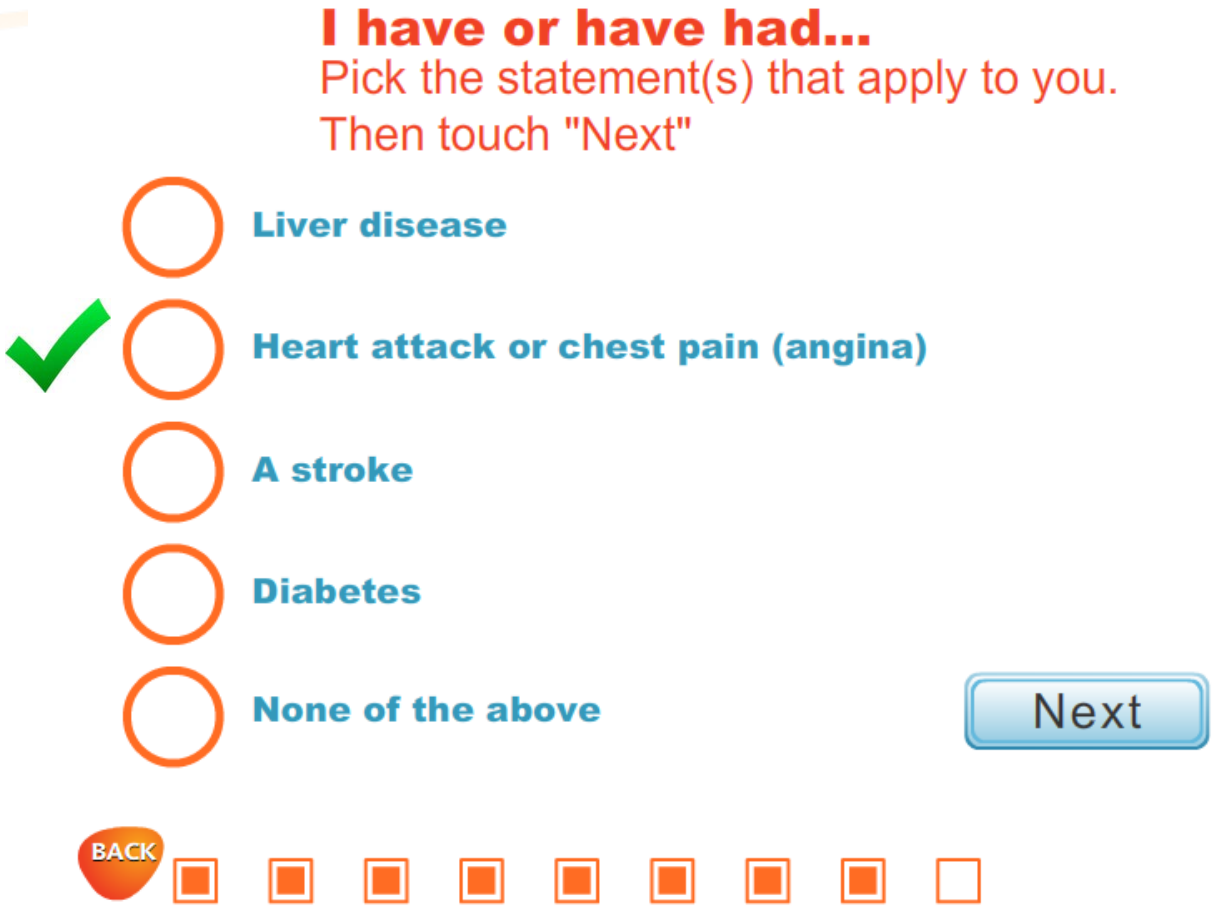
I have or have had...
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Liver disease
Heart attack or chest pain (angina)
A stroke
Diabetes
None of the above
Next
BACK


Pick the medicines you take or foods you eat.
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Prescription cholesterol medications
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HIV medicines
Organ transplant medications (For example - cyclosporine)
Nefazodone (medicine in the antidepressant Serzone)
Large quantities of grapefruit juice (more than four 8oz glasses daily)
None of the above
Next
BACK

Cardiocor is NOT right for you.

Cardicor is right for:

Men 45 or older **OR** Women 55 or older; not pregnant, breastfeeding, or thinking about getting pregnant who

- ...have had fasting cholesterol test in past 12 months
- ...have LDL cholesterol between 130 and 170
- ...have tried to reduce their cholesterol with diet and exercise
- ...have one or more heart disease risk factors
- ...do not suffer from certain conditions
- ...are not currently taking any medicines or foods that could interact with Cardiocor.

To learn more about Cardiocor and how to best manage your cholesterol, talk with your doctor

Reprint

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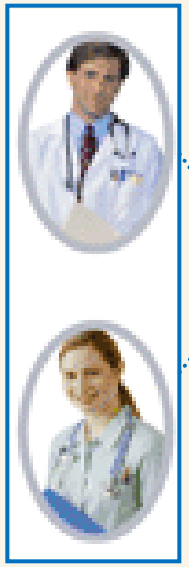
A product of Constant Care, LLC

Why Lilah, Why now…

- Developed from a need identified in our own operations
- Identified multiple needs in other healthcare arenas related to identification and monitoring of health-related conditions
  - Create a product to **empower individuals** to live independently
  - Create a tool to assist healthcare providers in **early identification and response** to change in patients' conditions
  - Create an **exception-based** mechanism to track and trend critical data elements related to chronic conditions
  - Create an **information "hub"** to allow for ease of data sharing
  - **Bridge the gap** in on-going healthcare needs that exists between physician visits



Safety Net For Individuals Requiring Assistance Including On-Demand Video Chat

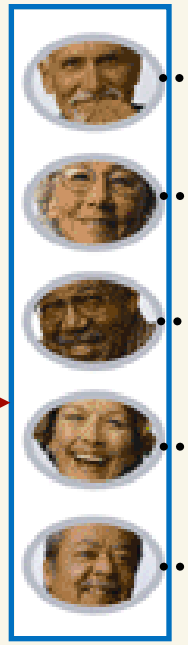
Central Monitoring Hub

Secure Patient Health Stream Portal

Providing Immediate Feed Back to Individuals

Home Monitoring
- Weight
- Pulse Ox
- Temp
- Blood Pressure
- Blood Glucose
- Peak Flow

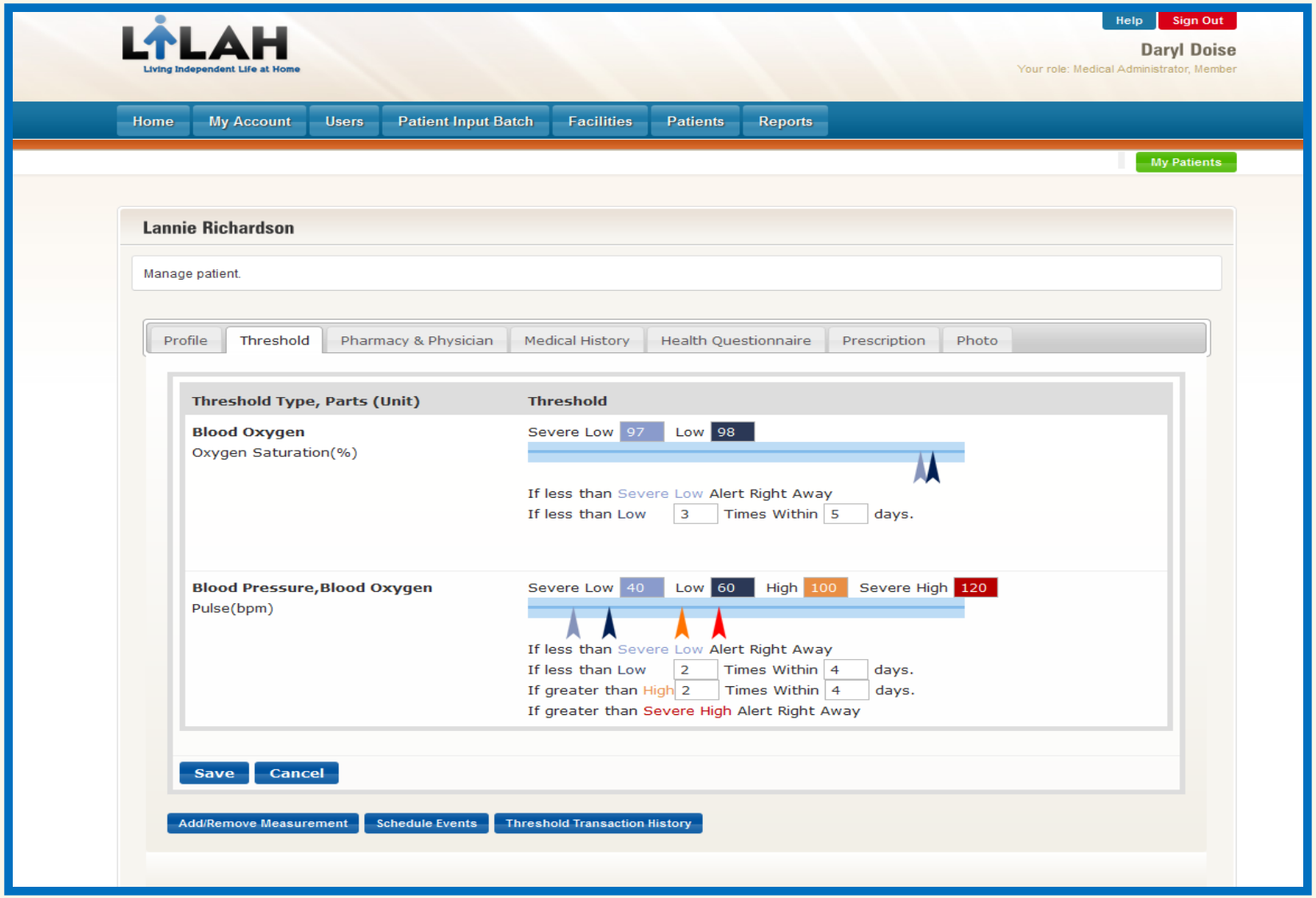
Customizable Health Questionnaire



Possible Role in Conditions of Safe Use

- Address barriers to self-diagnosis due to lack of discrete personal health data.
- Centralized access to individuals' health data
- Evidenced-based tools to aid in determining when to self-manage and when to seek profession help. Sources include: AHA, JNC7, AMDA
- Trend personal health information over time to determine if interventions are working
- Correlate lifestyle choices and medication adherence to fluctuations in personal health data

Establishing Thresholds



Demonstration of patient taking their pulse and O2 saturation with their trended results

Caregiver Notifications

Lilah Patient Alert

alerts@mylilah.com

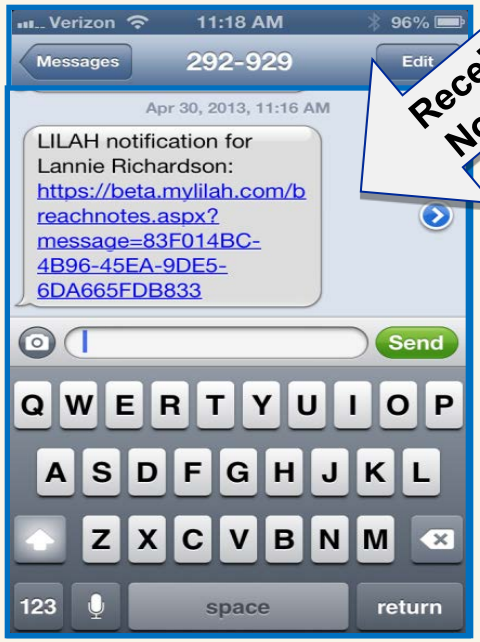
Sent: Tue 4/30/2013 11:16 AM

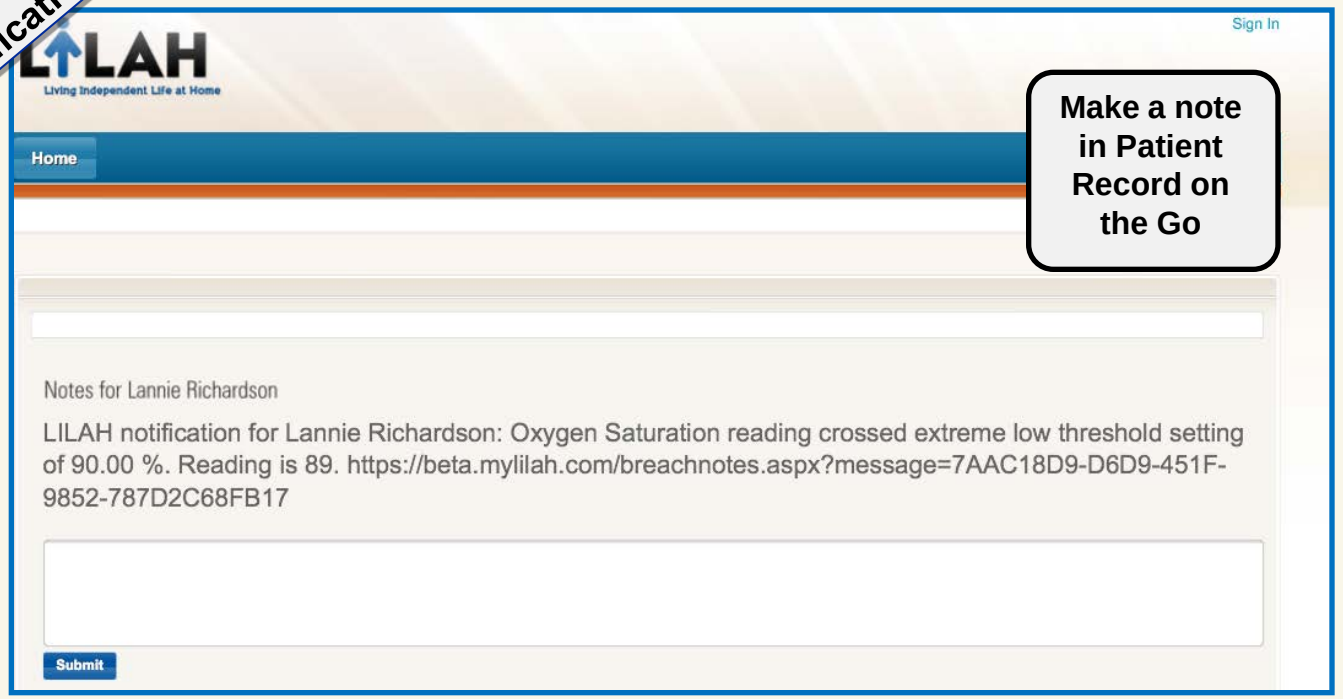
To: Jodi Funderburk

LILAH notification for Lannie Richardson: https://beta.mylilah.com/breachnotes.aspx?message=4FF38598-AB14-4E9F-B335-34BA77101663

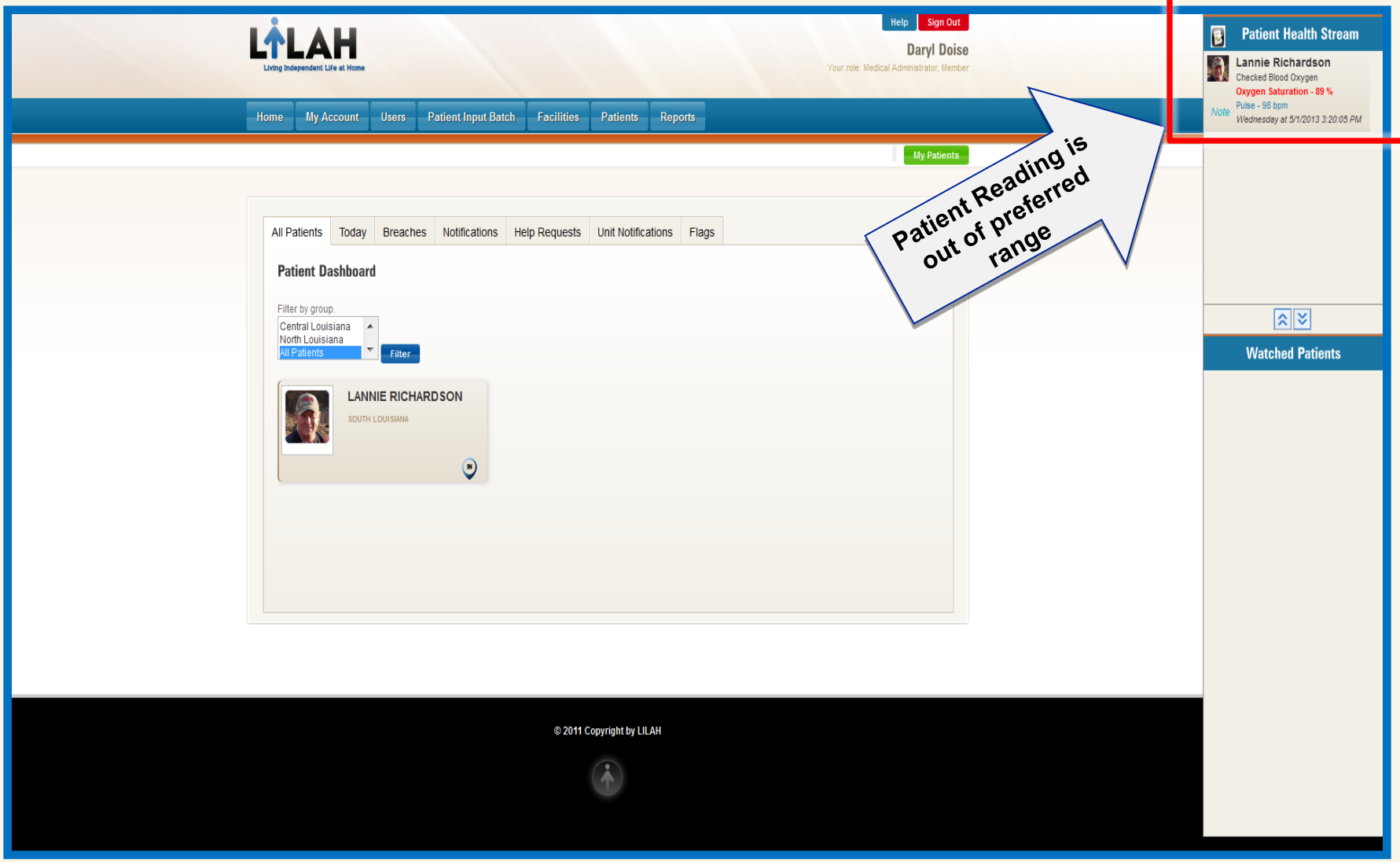
Receive Email Notification

Receive Text Notification





Caregiver Portal Notifications



Demonstration of individual responding to custom health questionnaire

Caregiver Notifications

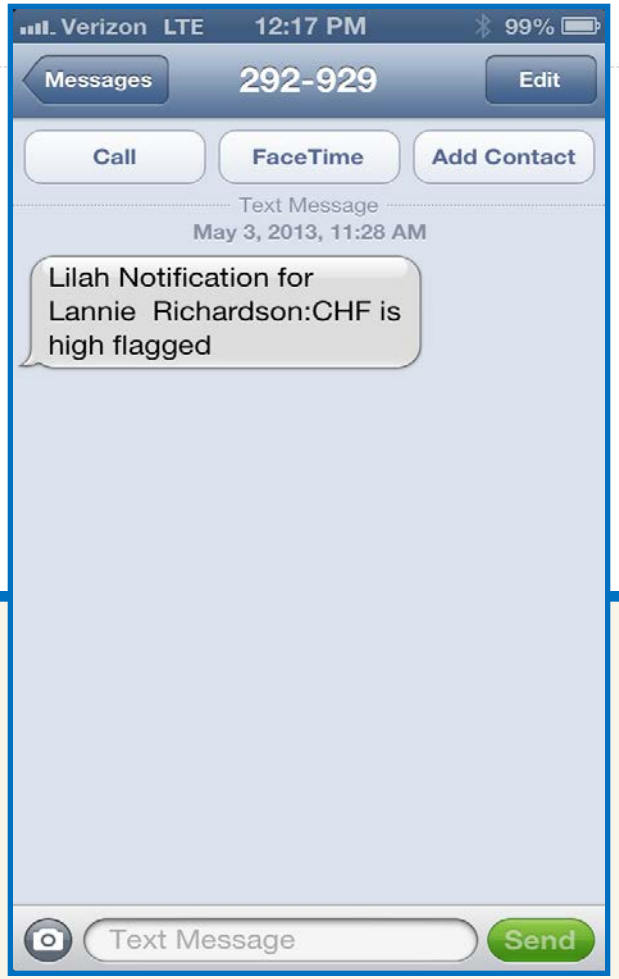
Lilah Patient Alert

alerts@mylilah.com

Sent: Fri 5/3/2013 11:28 AM

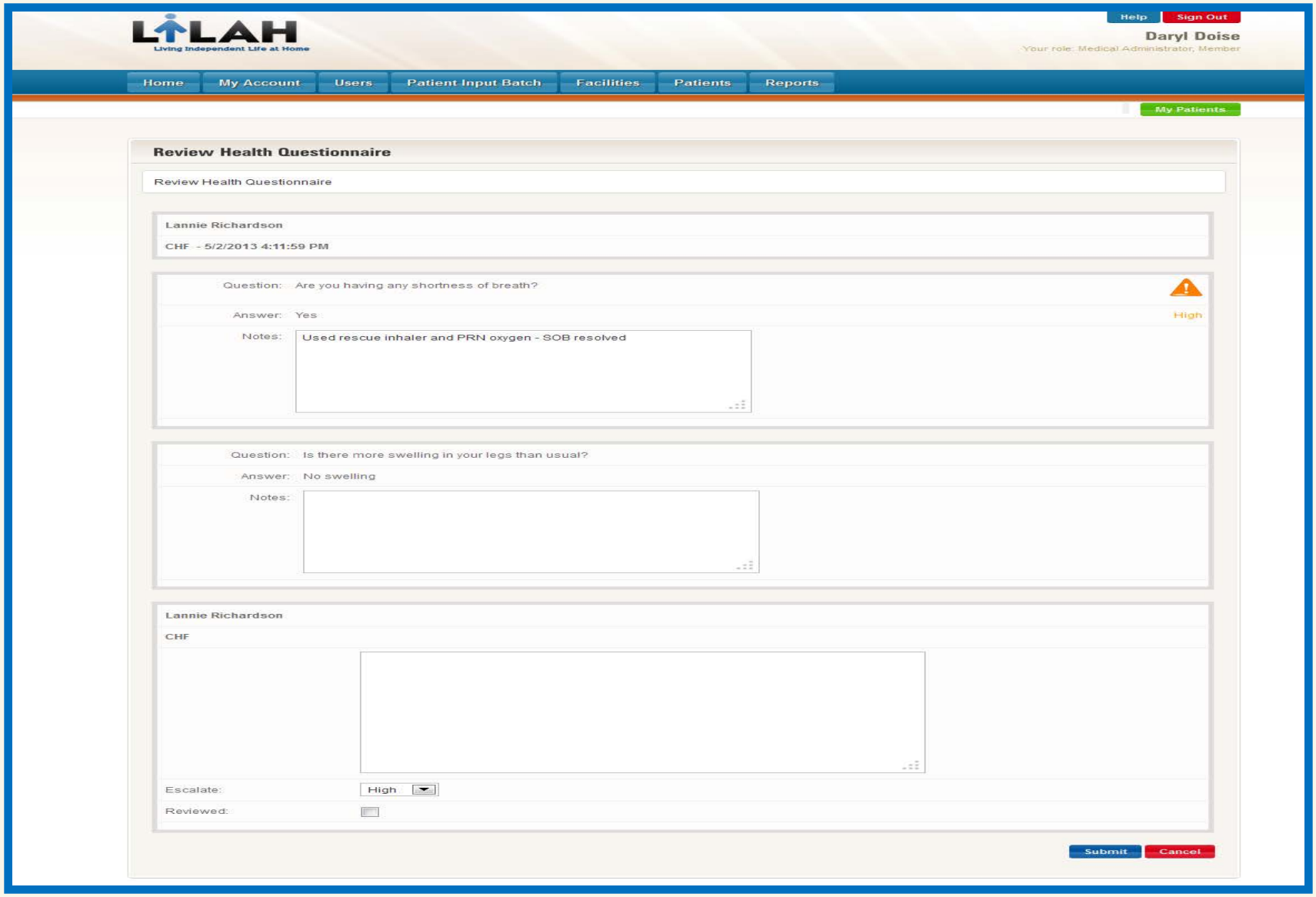
To: Jodi Funderburk

Lilah Notification for Lannie Richardson:CHF is high flagged



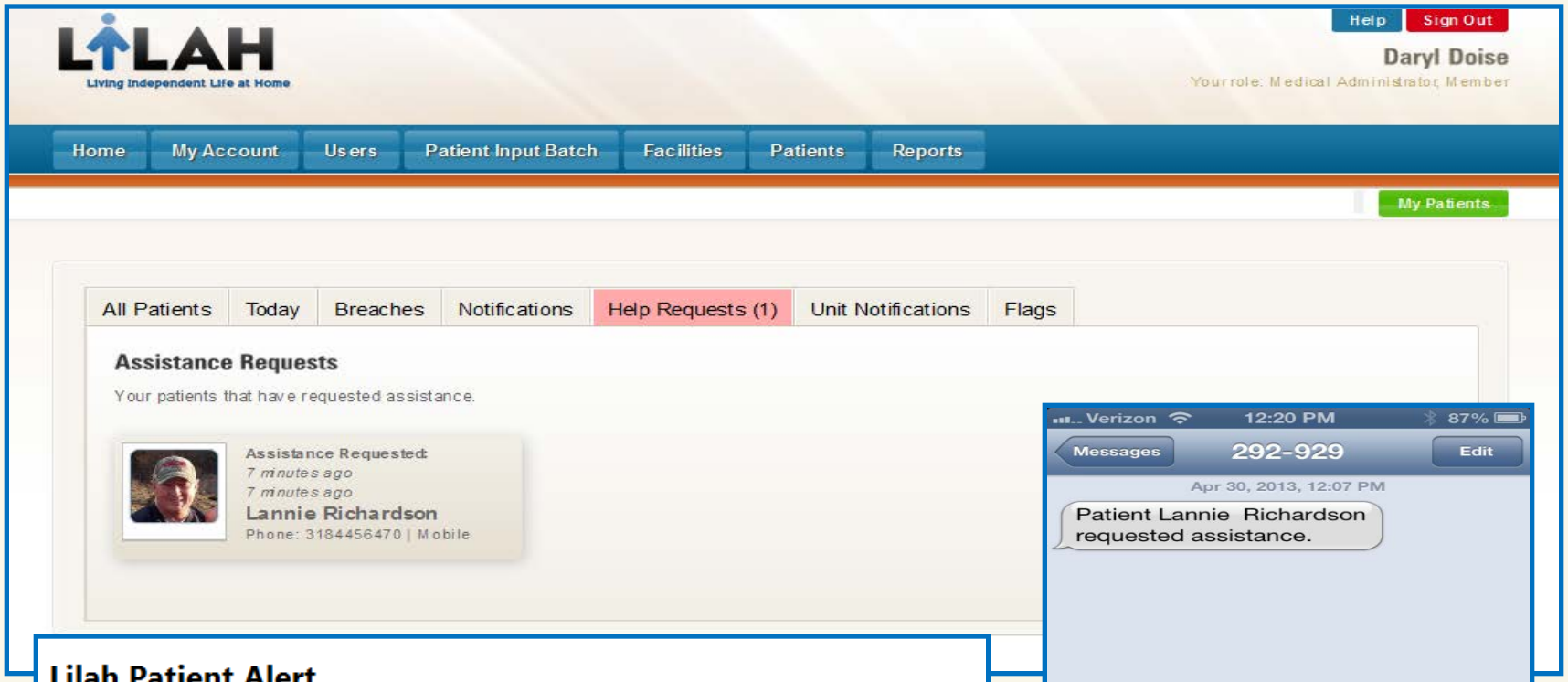
Portal - Health Questionnaire Flag

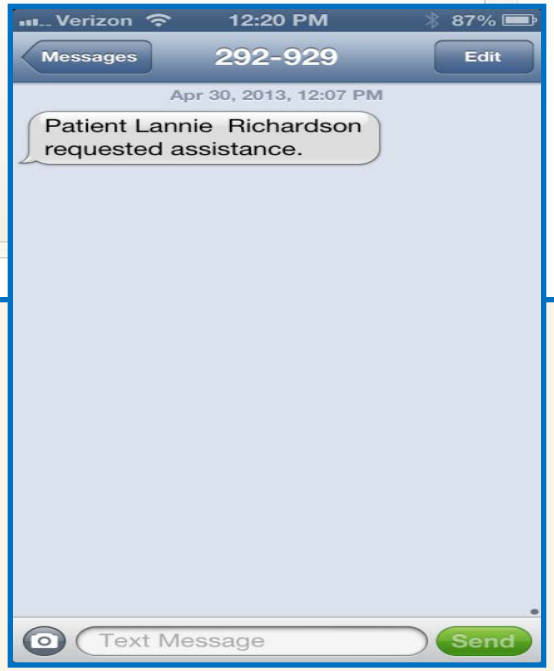
Questionnaire Response Notes

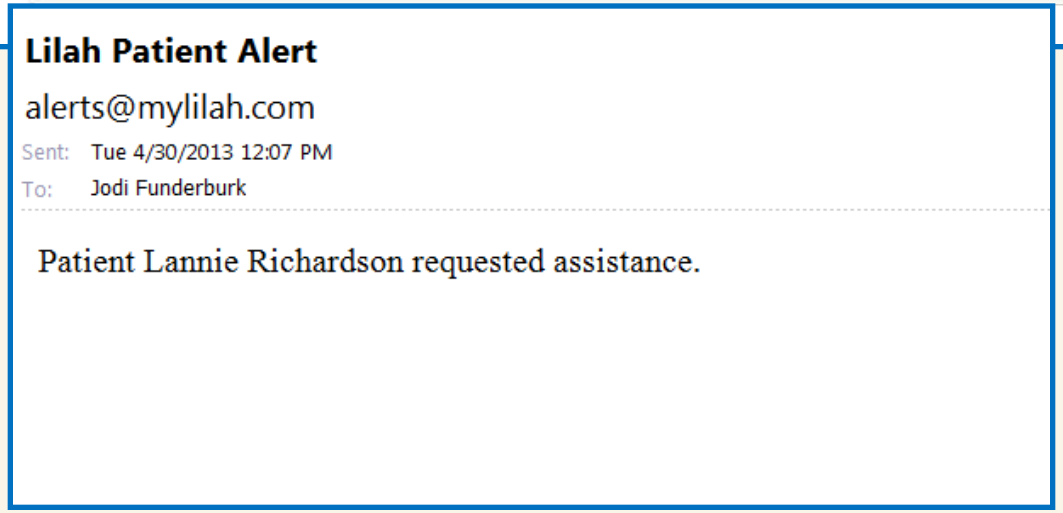


Demonstration of help request initiated by individual

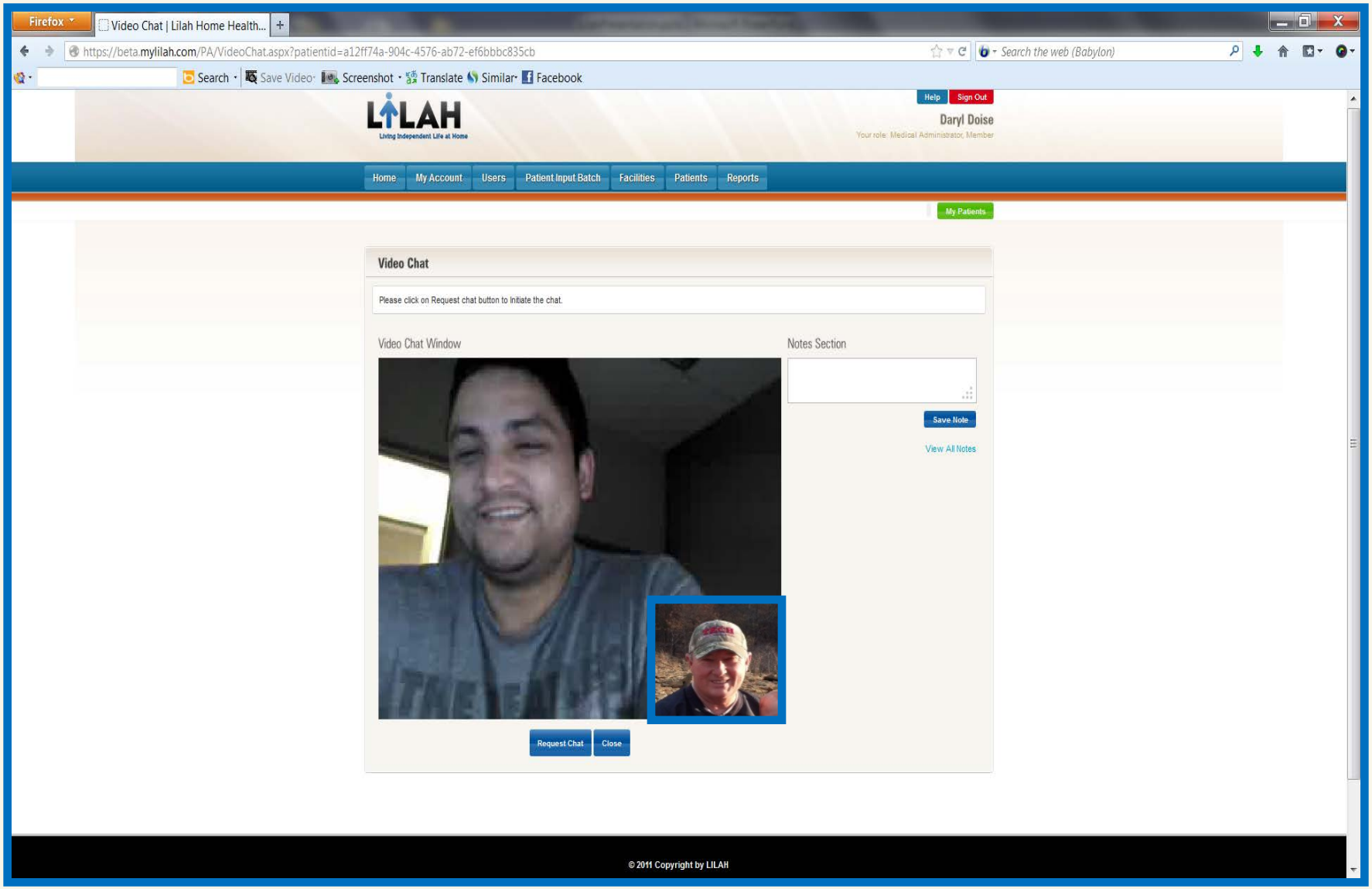
Help Request Notifications







Face To Face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Search
Save Video
Screenshot
Translate
Similar
Facebook
LILAH
Living Independent Life at Home
Help
Sign Out
Daryl Doise
Your role: Medical Administrator, Member
Home
My Account
Users
Patient Input Batch
Facilities
Patients
Reports
My Patients
Video Chat
Please click on Request chat button to initiate the chat.
Video Chat Window
Notes Section
Save Note
View All Notes
Request Chat
Close
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Barriers Encountered Along the Way

- ❑ User Skill Set
- ❑ Literacy Issues
- ❑ Connectivity Issues
- ❑ Patient Engagement

In Development

- Possible partnerships/integration
  - Laboratory Results
  - In-Home Medication Adherence Solutions
- Multi-user model kiosk (or mobile) expanding applications to facility based settings, work sites, pharmacies, and schools (currently pending FDA clearance)
- Biometric devices including, high resolution camera, stethoscope, and otoscope
- Android App for Smart Phones and Tablets
- Multi-Lingual Voice Integration

Thank you …..

LILAH
Living Independent Life at Home

ENGELBERG CENTER for Health Care Reform at BROOKINGS

Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care

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Engelberg Center for Health Care Reform
The Brookings Institution • Washington, DC
May 9, 2013

ROCK HEAL+H

The Brookings Institution

May 9, 2013

ABOUT US

Rock Health is a thought leader for innovation in digital health

We've created an ecosystem of passionate individuals who seek to meaningfully change healthcare through scalable technology

Accelerator

1600+ APPLICATIONS

Research

400,000+ REPORT VIEWS

Events

5,000+ ATTENDEES

HISTORY

2011

Launched at SXSW
March 2011

V1: 15 companies
June-November 2011

2012

V2: 13 companies
January-May 2012

V3: 7 companies (Boston)
June-August 2012

2013

V4: 14 companies
October 2012-February 2013

UNIQUE POSITION

Broad portfolio of 49 startups plus database of 1,600+ applicants spanning every aspect of digital health

Preventive health and wellness

Care management (acute and chronic)

Devices and diagnostics

Payer and provider administration

Data, information and analytics

Telemedicine

Deep partnerships with innovation groups at companies representing multiple aspects of the healthcare system

Genentech

GE

Nike

QUALCOMM LIFE

Quest Diagnostics

UNITEDHEALTH GROUP

ROCK HEALTH

ABERDARE VENTURES

KPCB KLEINER PERKINS CAUFIELD BYERS

MOHR DAVIDOW

Montreux Equity Partners

NEA

HARVARD MEDICAL SCHOOL

KAISER PERMANENTE

MAYO CLINIC Center for Innovation

UCSF University of California San Francisco

Formal relationships with leading venture firms, plus database and contacts with 165 digital health investors

Access to clinical expertise and key opinion leaders at the country's leading medical institutions

We sit at the center of innovation in healthcare

THOUGHT LEADERSHIP

FAST COMPANY

"At Rock Health, they're re-imagining what health care can be.

400,000
Rock Report views

Featured in leading press outlets

THE WALL STREET JOURNAL.

The Economist

Forbes

CNN

Inc.

CNBC

TechCrunch

VentureBeat

GIGAOM

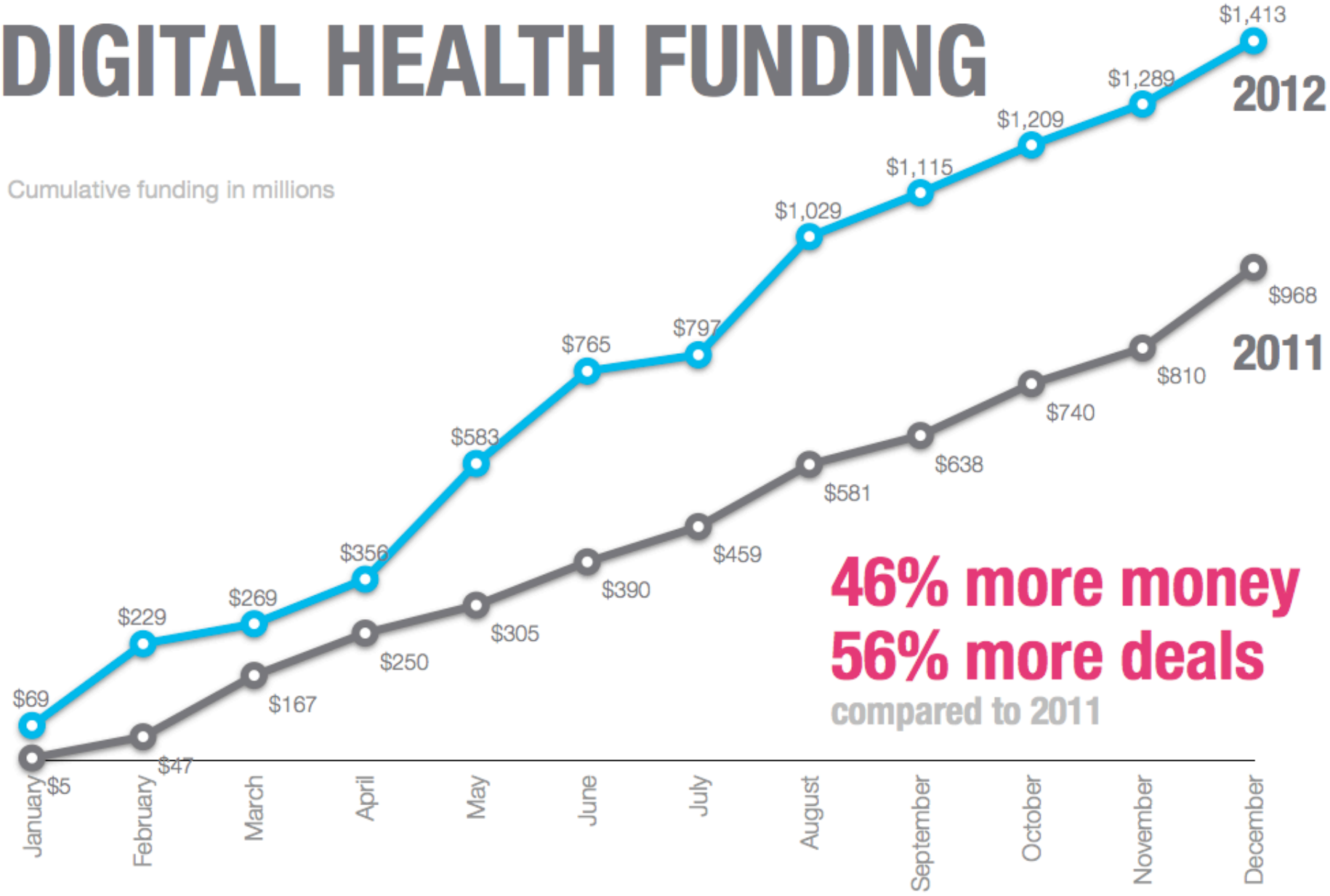
13,000+ followers

3,000+ likes

10,000+ subscribers

25,000+ visits/month

DIGITAL HEALTH FUNDING



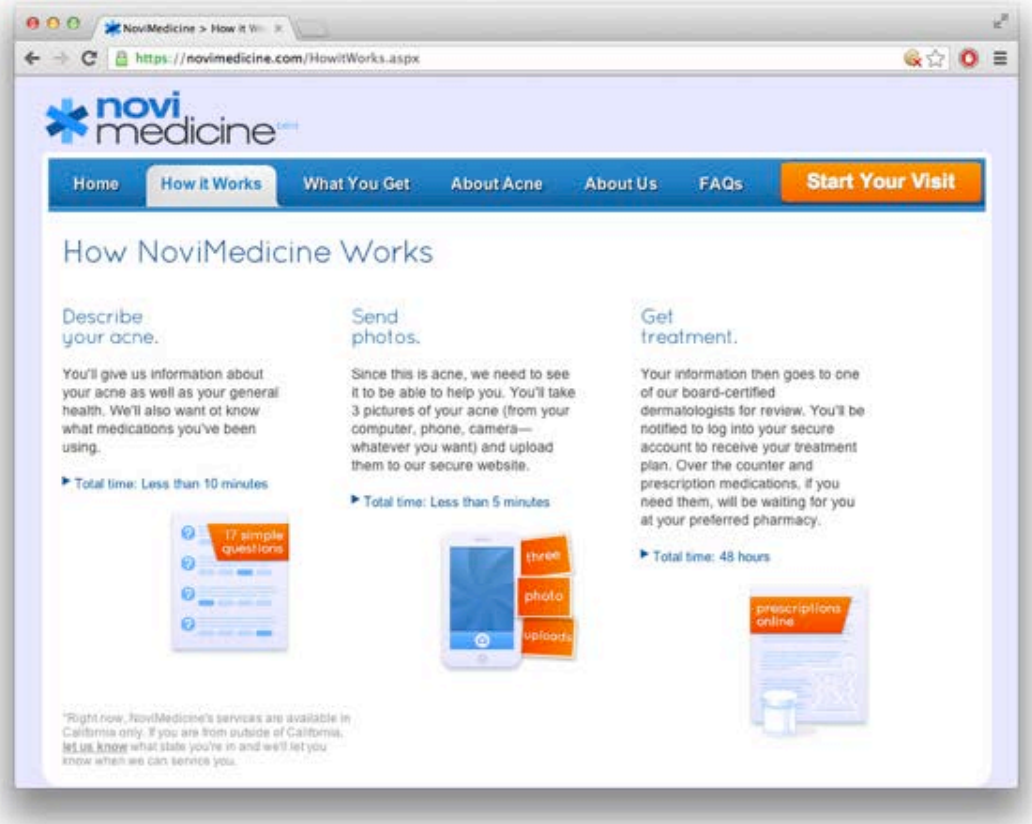
Note: only includes companies that received $2M+ in venture funding

AliveCor

cellscope

NeuMitra

novi medicine



Wellframe

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The Brookings Institution • Washington, DC
May 9, 2013

Learnings Pertinent to FDA's Nonprescription Safe Use Regulatory Expansion Initiative

Farmacia Electronica, Inc.
Donald P. Reitberg, PharmD
dreitberg@prodigy.net
May 9, 2013

How I Came to Be Here Today; Evolution of the Methods:
Started professional career with academic training at

July 1974 - June 1977

B.S. Pharmacy

- Clinical Pharmacy Training Program already well developed in 1977.
- Program is dedicated to remedy sub-optimal utilization of pharmacists in the health care system.
- Behind–the-counter (BTC) distribution has been of continuing interest to pharmacists; this approach could be assisted by computer algorithmic technologies today.
- The profession has evolved to Drug Therapy Management and Collaborative Physician-Pharmacist agreements, but not to behind-the-counter distribution.
- General Accounting Office Reports (1995, 2009) raise many issues regarding safe-use BTC-OTC distribution, so our computer technologies must apply to both traditional OTC or BTC availability.

How I Came to Be Here Today; Evolution of the Methods:
Academia, Post-graduate Training

July 1979 - June 1981
Doctor of Pharmacy (Pharm.D.)
July 1981 - March 1983
Post-doctoral Research and Clinical Fellowship:
Clinical Pharmacokinetics, Clinical Pharmacology, and Clinical Trials Management
Millard Fillmore Hospital Clinical Pharmacokinetics Laboratory

- Learn that mathematical models and computer algorithms are powerful tools and can be continuously updated to improve predictabililty of outcomes in sub-populations.

- Learn that many patients taking serious drugs for serious diseases experience only placebo or no beneficial effects; there is a need for objective and practical tools to help these patients avoid unnecessary exposures to treatment.

How I Came to Be Here Today (Industry, July 1981-present):

Pfizer Pharmaceuticals, Inc. (prescription drug development)
Associate Director
New Drug Development

Glenbrook Laboratories (OTC drug development and support of existing products)
Division of Sterling Drug, Inc.
Director of Clinical Research

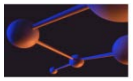
Whitehall-Robins Healthcare (OTC drug development and support of existing products)
Division of American Home Products
Associate Director Clinical Research

SmithKline Beecham Consumer (OTC drug development and support of existing products)
Healthcare
Worldwide Director of Clinical Operations

Novartis Consumer Health, Inc. (OTC drug development, support of existing products, served on CHPA Scientific Affairs Committee)
Vice President of Scientific Affairs, North America

Opt-e-scrip, Inc. (n of 1 RCT test kits to measure efficacy/safety)
Founder, Chief Scientific Officer

Strategic Pharmaceutical Services, LLC (Consulting: clinical pharmacology, pharmacokinetics, Rx-to-OTC switches, regulatory affairs)
President (currently active)



Farmacia Electronica, Inc. (Algorithmic Computer Safe-Use Technologies)
Vice President (currently active)

- **Uncomplicated switches are becoming scarce; more serious symptomatic diseases, more toxic drugs, and asymptomatic chronic conditions are under development by industry for self-care.**
- **FDA responds with Non-prescription Safe-Use Regulatory Expansion Initiative to help assure proper self-selection and self-care without increased & inappropriate population drug exposure.**

Statements made in this presentation are solely the views of Farmacia Electronica, Inc.

Farmacia Electronica, Inc. Background

- Founded in 2009 to create educational systems that help consumers and the health care system minimize risks and enhance the effectiveness of medications.

- Majority of founders are from an ethnic minority. A major focus, therefore, is on technological solutions to assure adequate knowledge and product selection by patients and consumers, regardless of ethnicity or level of education.

- The company developed an initial product and filed for patent protection in February 2011.

- Applications under development are designed to assure that consumers can properly select and use medications, and treatment outcomes can be monitored and improved.

Assumptions Regarding Technologically Assisted Education and Monitoring of Drug Use

- Innovative technologies should be designed to foster an equal opportunity for all consumers, regardless of ethnicity or educational level.
- The technology should obtain consumer feedback and offer individualized re-education to assure proper understanding.
- The technology should continuously improve itself and thereby improve medical outcomes.

How Does Drug-Facts-Label Interactive/ Algorithmic Cloud-based Technology Work?

Consumer uses device to get info about drug for self-selection

1. Enters site and selects ethnicity, language
2. Selects a safe-use candidate OTC drug
3. Talks to a support-person only if needed

Can add mandatory pharmacist-BTC or physician-collaborative approaches

4. Iterative algorithmic distribution system educates consumer
5. System verifies consumer knowledge by asking questions

→Verification is done using a rule-based iterative system in the backend

→ If refill, safety and effectiveness outcomes are monitored

6a. Questions are answered verifying eligibility for initial treatment or refill

→ User gets a coupon or other code documenting eligibility

6b. Questions are answered suggesting possible non-eligibility

→ User is denied purchase and alternative actions are suggested, e.g. physician visit

7. Consumer picks drug from shelf and hands it to cashier with coupon/ code

8. Cashier verifies coupon/ code and if valid, allows consumer to purchase drug

Cloud technology platform tracks each consumer, compiles population data, continuously optimizes methods, & applies system-wide updates

Farmacia Electronica
Technologies Under Development

- Designed to work with any electronic communication device including cell phones in areas where computer technology is not available.

- Assures comprehension of risk-to-benefit relationship, proper product selection and usage by repeated education/questioning in consumer's language and literacy level using any available communication device:

  – Consumer can obtain a verification (bar) code as a condition for purchase or obtain cell phone or other credits as an incentive to take their medications when it is essential to public health (e.g. tuberculosis).

  – Devices as simple as automated cell phone voice (interactive voice reponse-IVR) or text messages can be used to educate and monitor adherence to regimens, side effects and success of treatment.

Farmacia Electronica
Technologies Under Development

- For every refill, the technology monitors each consumer's persistently correct self-selection, their adequate comprehension of labeling, and their efficacy and safety experiences.

- Cloud computer technology can individually track each consumer's experiences regardless of point-of-purchase.

- Technology continuously compiles and statistically assesses population self-selection of drugs, comprehension of proper product usage, and reported efficacy/safety data.

- Continuous improvement of educational content and questions asked are based on collected consumer data.

Advantages of This Approach

- Conserves scarce healthcare resources.
- Using the technology, consumers can take OTC products off the shelf as they always have and self-educate as per the drug facts label.
- In some cases medication may only be purchased if questions have been answered correctly and a bar code or number is presented to the clerk using existing barcode/coupon technology.
- The technology can continuously collect data specific to each consumer from multiple locations and devices using a cloud computer platform.
- Technology can monitor population efficacy and safety.

More Advantages of This Approach

- The system re-educates for refills and collects outcomes data.
- The system can be adapted to multiple interfaces: kiosk, telephone (IVR), browser web page, mobile, smart dispensing device, etc.
- The technology is designed to empower all consumers regardless of ethnicity and education with the ability to provide feedback on their comprehension of drug risks, benefits, and proper usage, and to report actual product usage and outcomes.
- Based on data received, the communication methods are continuously improved to overcome the disadvantages of ethnicity, educational-level and socio-economic background.

Potential Impact on Stakeholders

The benefits to key stakeholders are as follows:

- Consumers can safely gain access to needed medical products and be given incentives (for example, cell phone minutes) for properly taking their medications, (e.g.-tuberculosis).
- Government agencies can support documentable and continuously improving risk management of health care products with greater involvement of minority and educationally compromised populations.
- Private and government healthcare payers can experience reduced overall costs due to automated health care information, distribution and collection.
- Industry can gain market share, decreased litigation risk and possible market exclusivity.
- Providers can reduce medical labor costs via automation and reduce adverse events by assuring appropriate drug selection and use.
- The healthcare system in general can experience cost reductions and more effective use of scarce resources.

Current/Ongoing Programs

- Farmacia Electronica, Inc. is currently pursuing a New Drug Application in collaboration with the US Food and Drug Administration.
- The technology platform under evaluation is designed to assure and document achievement of essential consumer self-selection requirements for a non-prescription drug.
- The technology educates and tests knowledge of the Drug Facts Label and can use existing retail consumer product bar code and coupon technology to assure proper self-selection.
- The company also developed a technology platform for Medication Guides (REMS) prescription products.
- The company is working on systems for use in rural areas and developing countries.

Example: Use of Cell Phones and Texting in Areas with Limited Computer Infrastructure

Please refer to:
http://www.theatlantic.com/health/archive/2013/04/medicine-by-text-message-learning-from-the-developing-world/274656/

- Health communication systems designed for rural, developing countries -- where hospitals are often understaffed and transportation is inadequate -- are being adapted to improve care in U.S. cities.

- Price Waterhouse Cooper estimates that electronic interventions in the U.S. could save $10,000 per diabetic patient per year. The U.S. currently spends $218 billion on diabetes every year.

Example: Remedy of a Serious, Unaddressed Public Health Need

Please refer to:
http://web.mit.edu/newsoffice/2008/tb-cellphone-tt0604.html

- Tuberculosis (TB) kills an estimated two million people every year, and treating the disease requires a strict six-month regimen of antibiotics. If patients abandon treatment early, the TB bacteria survive and can become resistant to antibiotics.

- A novel compliance approach was field-tested in Nicaragua. It combined a paper urine drug testing strip with a simple text message reporting system to ensure drug compliance, and rewarded cell phone minutes in exchange for taking the drugs properly.

- An analogous US technology-enhanced approach could reduce treatment failures and drug resistance by offering incentives to take medications as prescribed.

The potential benefits for all stakeholders in the healthcare system can be profound indeed as we evolve in our relationship with computer technologies.

ENGELBERG CENTER for Health Care Reform at BROOKINGS

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May 9, 2013





NSURE: Perspectives on Consumer Use of Technology to Assist Decision-Making and Self-Care with OTC Products

Julie L. Aker, President & CEO

Concentrics Research

The Brookings Institution

Washington, DC

9 May 2013

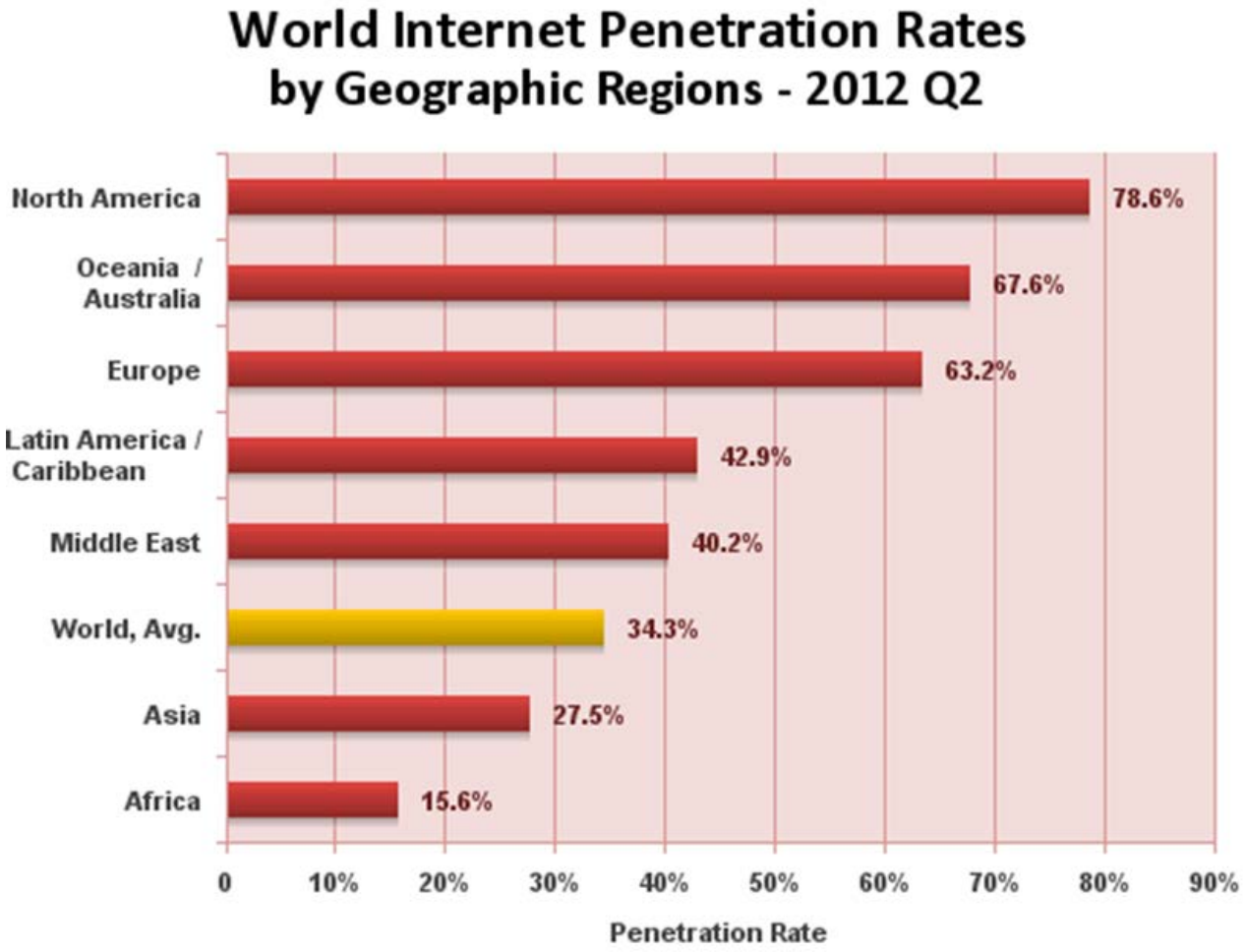
Concentrics Research

How do consumers make decisions about OTC Medications?

Modes of Awareness/Decision-Making	Real-Life	*Technology Assist*
1. Awareness & Relevancy	Advertising Friends/Family	*Advertising* *Education*
2. Motivation to seek the product	Go to the store or check online	*Education (Benefit/Risk, "call to action")*
3. Read label/evaluate	Yes	*Paraphrase, examples*
4. Decision: Is it right for me? (SD/SS)	Yes	*Assisted decision, dx test*
5. Decision: Do I want to purchase it?	Yes	[Value decision]
6. Decision: Do I want to use it?	Yes	*Education and assistance*
7. Decision: Will I choose to comply with the label? (Use)	Yes	*Tracking/tools/progress*
8. Decision: Will I be motivated to continue over time (self-management)?	Yes	*Tracking/tools/progress*

Concentrics Research

Who has access to the internet?



Source: Internet World Stats - www.internetworldststs.com/stats.htm
Penetration Rates are based on a world population of 7,017,846,922 and 2,405,518,376 estimated Internet users on June 30, 2012.

Concentrics Research

How do consumers use technology now?

- 55% of U.S. consumers have a Smartphone (comScore Reports 2013)
- Use of Smartphones by demographic
  - Asians 67%, Hispanics 57%, African Americans 54%, Caucasians 45%
  - Women/Men = ~ 50%

  (Nielsen May 2012)
- How are Smartphones used?
  - 70% to text, 41% to use browsers, 41% to download apps
  - Fastest trend is increase in social networking
  - Fastest growing segment is comprised of ages 55+
  - 1 in 3 people use a Smartphone to download health info
    - More common for those who are sicker, caregivers or have had a change in health

    (Health Populi 2013)

Concentrics Research

How can technology help?

- Before use
  - Further labeling information/detail
  - Self-diagnosis/recognition: the condition (indications) including diagnostic information
  - Self-selection: the indications AND contraindications AND conditional warnings
- During use
  - Self-management
    - Complying with dosing
    - Complying with warnings
  - On-going self-management
    - Motivation to continue
    - Interaction with physician or HCP

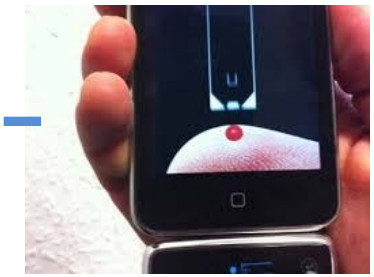
Concentrics Research

Pooled Results: 3 Studies Evaluating Technology-Assisted Decision-Making

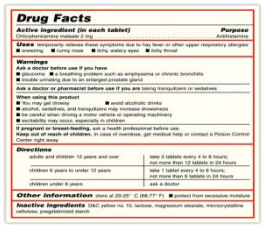
- 3 small pilot studies = 281 subjects
- 3 different types of technology
- *"It was simple and easy to use."*
  - 94% - 100% (all literacy levels)
- *" I understood how to use it."*
  - 86-92% (all literacy levels)
- *"It helped me make decisions about this product."*
  - 86% - 100% correct decisions (with technology when data is known)
  - 62%-73% correct decisions (with technology when data is not known)
  - Generally 20%-40% increases in correct decision-making compared to no tool
- Time to make decision
  - ~80-132 seconds

Concentrics Research

Access = Flexibility

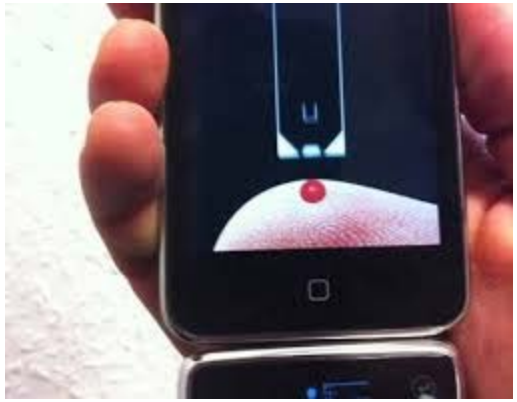


Consumer



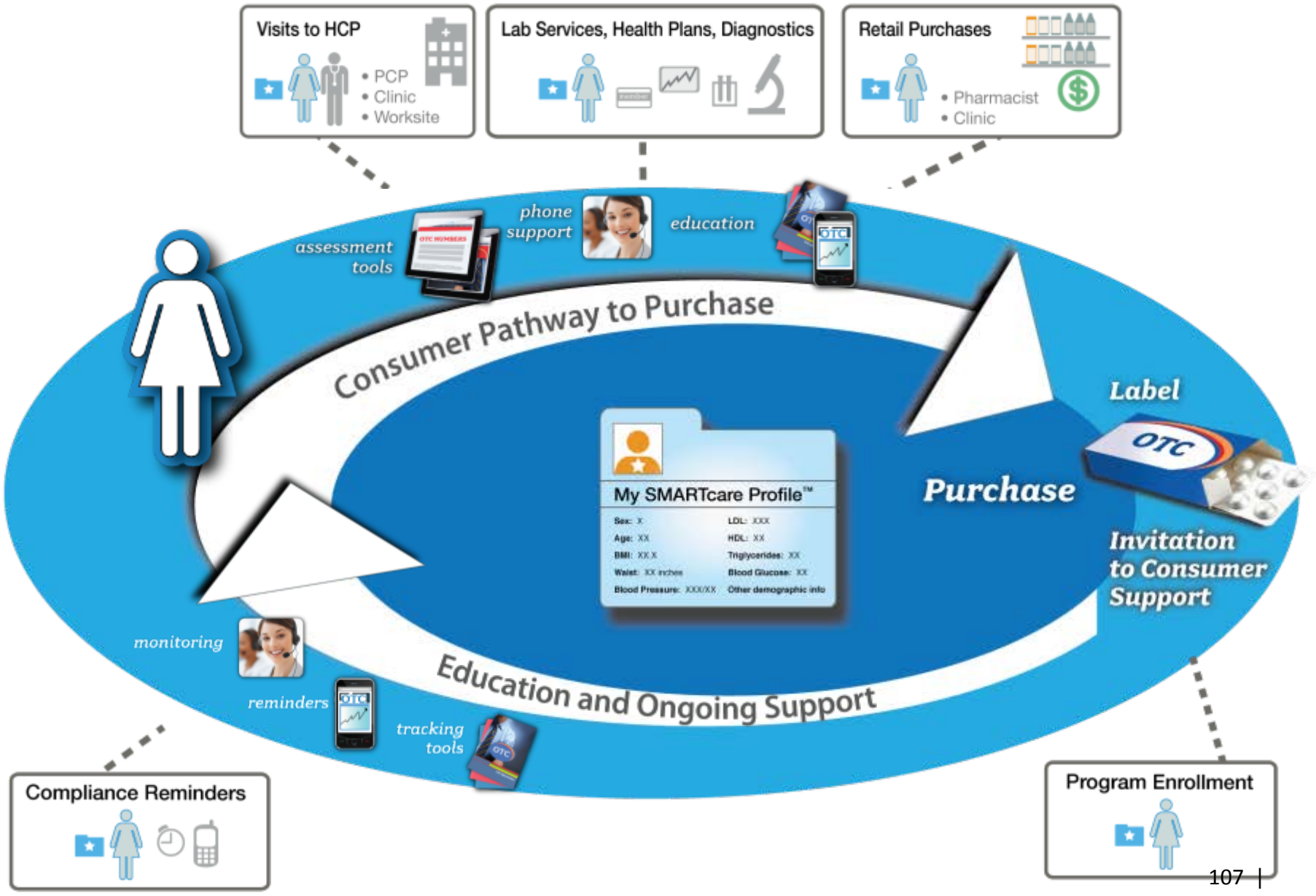
Concentrics Research

Remote Diagnostic tools are in use now

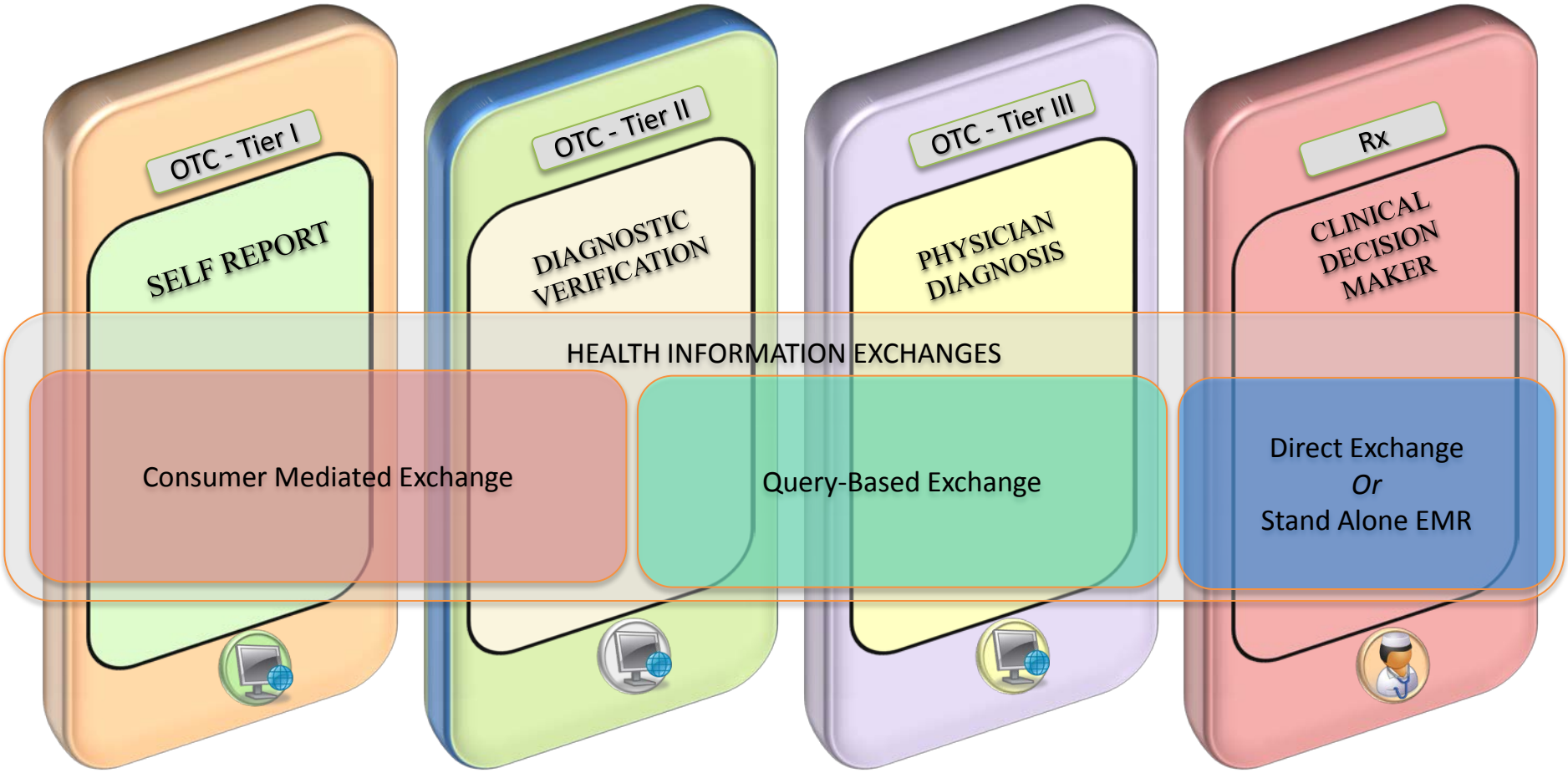


Concentrics Research

Example: Product-specific Decision-Support and Management System



Example: Cross-product Continuum of Information Exchange



Example: Consumer-driven **Health Information Exchange**

Concentrics Research

Summary

- The technology exists today and there are many options
  - To obtain information for decision-making and self-care
  - To exchange information
  - To track progress
  - To interact with HCPs
- Access = flexibility
- Consumers expect a technology-facilitated world which includes healthcare
  - Technology can be used by consumers of varying demographics and literacy
  - Technology can facilitate correct decision-making and long-term compliance

ENGELBERG CENTER for Health Care Reform at BROOKINGS

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May 9, 2013

NSURE: Perspectives on the Role of Technologies as a Condition of Safe Use

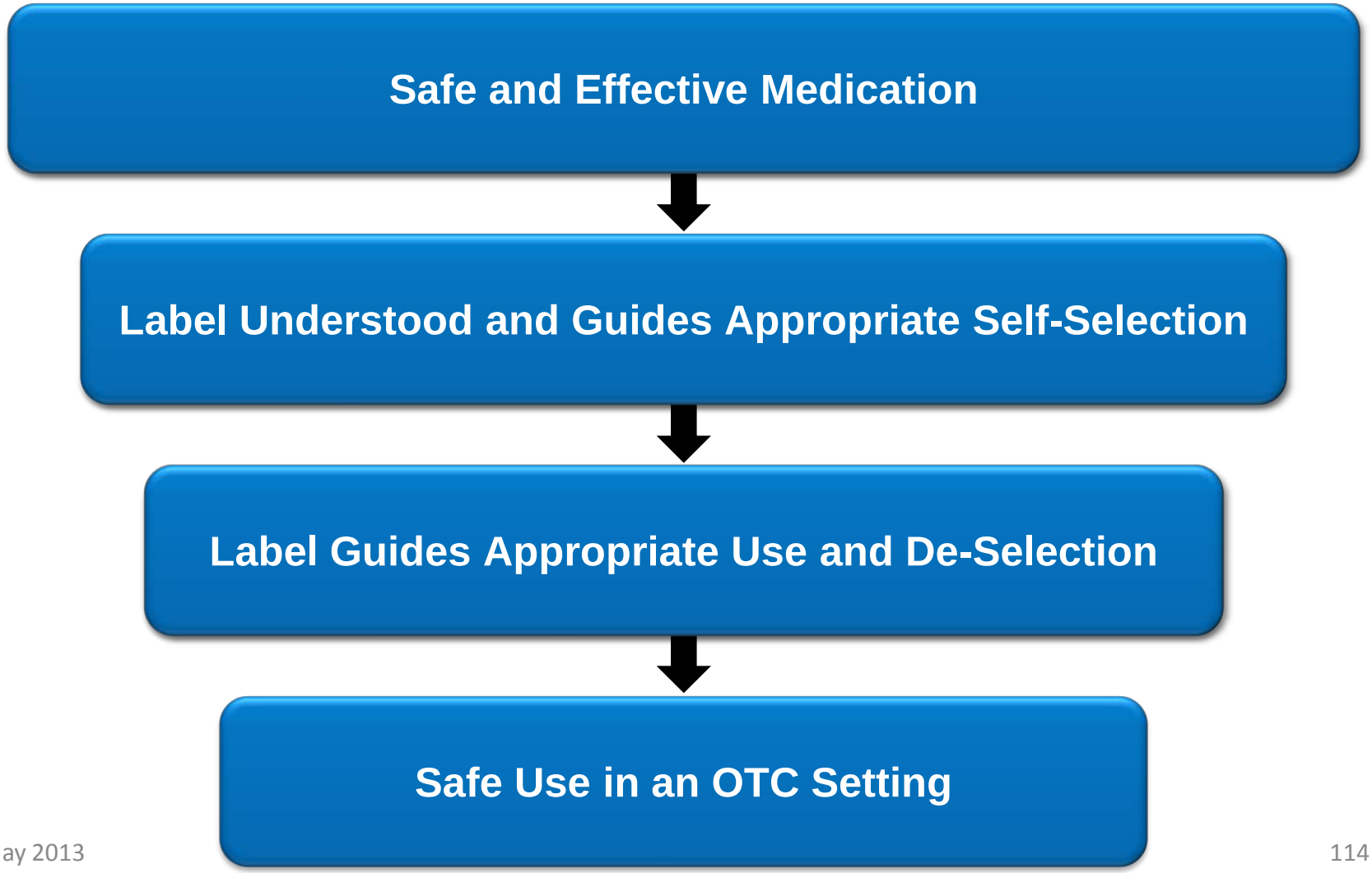
Edwin Hemwall, PhD
Merck Consumer Care

The Brookings Institution
Washington, DC
9 May 2013

Improving Access to Medicines Through Technology Aided Nonprescription Labeling

- Layered approach to OTC labeling safeguards
- Consumer preferences and attitudes
- Product development and testing options
- Points to consider

Self-Management Labeling Safeguards

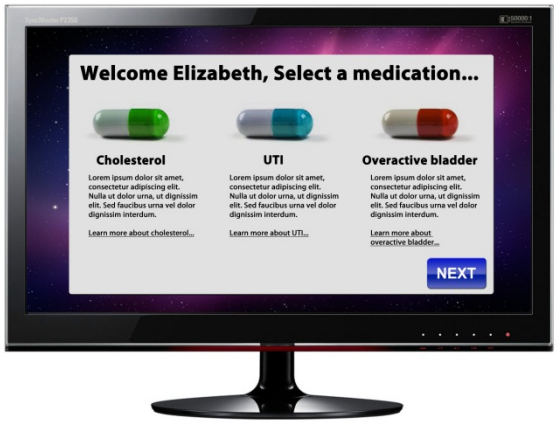


NSURE: Product Development Options

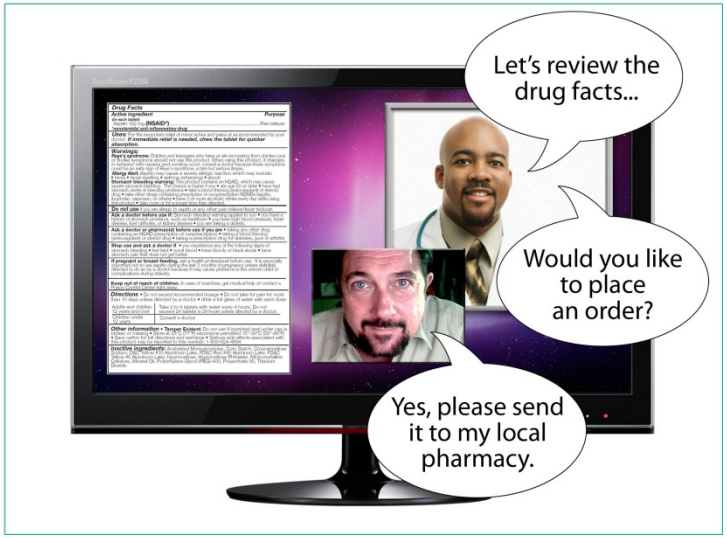
Where can technology help?

- Label understanding beyond Drug Facts alone
- Consumer Self-Selection or qualification
  - Recognition of medical condition and potential to benefit
  - Eligibility to use
  - Diagnostic test
- Driving correct ongoing use
  - Emergent worsening of symptoms or a new condition
  - Monitoring response/effect
  - Recognition of adverse reactions
  - Re-establishing eligibility for continued use

NSURE: Qualification Options



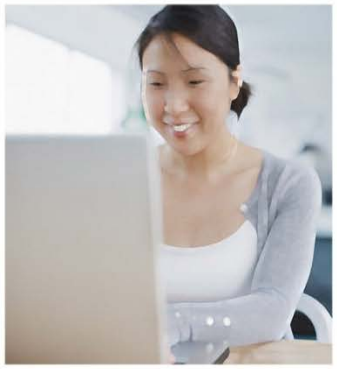
Web



Livechat or videochat

800 number

NSURE: Delivery Options



Token, for in-store collection

Send order to pharmacy

Home delivery

NSURE: Identification Options

Text code or MMS barcode to cellphone

Text code or MMS barcode to iPhone

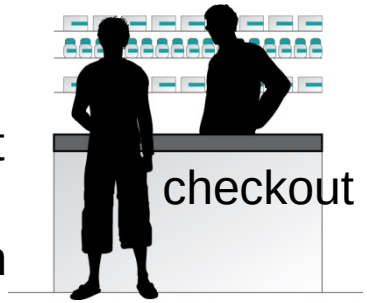
Scan at Speedbuy
- or -
give this code to pharmacist:
GF7TD

Print at home

NSURE: Purchase Options

Speedbuy:
scan at entrance
collect at checkout

Auto-payment with iPhone



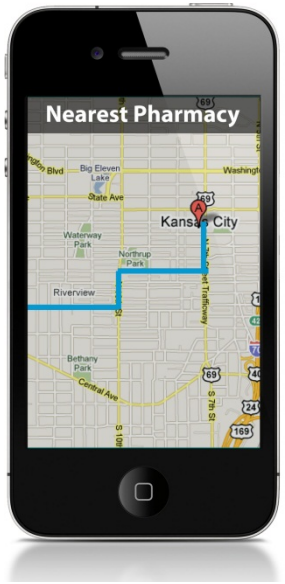
Take token to pharmacist or checkout

Scan token at vending machine

Additional services

Health advice
Medical records
Compliance reminders

auto-payment



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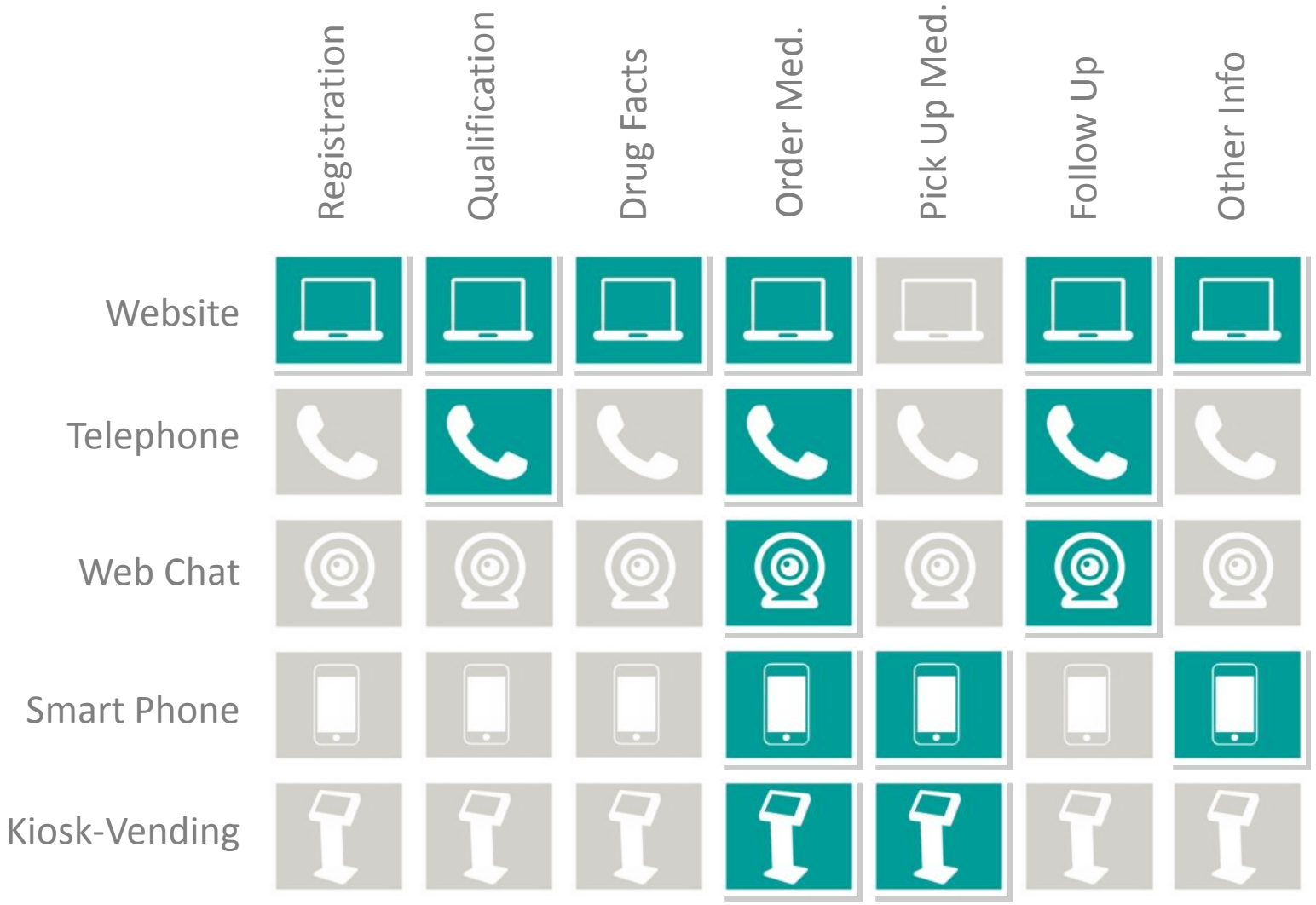
Key Findings From Consumers



NSURE: Product Development

How can we prove that the system works as intended?

- User testing and software validation
- Test consumer behavior employing NSURE system prototypes with standard approaches
  - Label Comp/Self-Selection/Actual Use
  - Simulate or use real home and retail settings
- Multiple studies with iterative process

NSURE: Points to Consider

- Technology continues to evolve but we have the basic tools now
- Potential to send more engaged patients to physicians and other HCPs
- Pharmacists need not be gatekeeper
  - Reduces concerns about time, cost, training, liability
  - Continue to perform valuable advisory role
- Sponsors need incentive to invest
  - Hatch-Waxman exclusivity hinges upon conduct of clinical study necessary for NDA approval

NSURE: Perspectives on the Role of Technologies as a Condition of Safe Use

Questions/Discussion

The Brookings Institution
Washington, DC
9 May 2013

ENGELBERG CENTER for Health Care Reform at BROOKINGS

Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care

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Engelberg Center for Health Care Reform
The Brookings Institution • Washington, DC
May 9, 2013

EVALUATION OF NEW TECHNOLOGIES TO ENHANCE ACCESS BY CONSUMERS TO NONPRESCRIPTION DRUGS

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DIRECTOR, HARBOR-UCLA CENTER FOR CLINICAL PHARMACOLOGY

CONTEXT FOR THE EVALUATION OF NEW TECHNOLOGIES

- Expansion of appropriate access to nonprescription drugs good for individual consumer, good for public health, good for public policy
- Technology a potential asset in expanding access
  - Self-diagnosis
  - Self-selection
  - Longitudinal self-management
- What is the model: Self-care vs adjunctive to physician-directed care

EVALUATION OF NEW TECHNOLOGIES FOR INCREASING NONPRESCRIPTION ACCESS

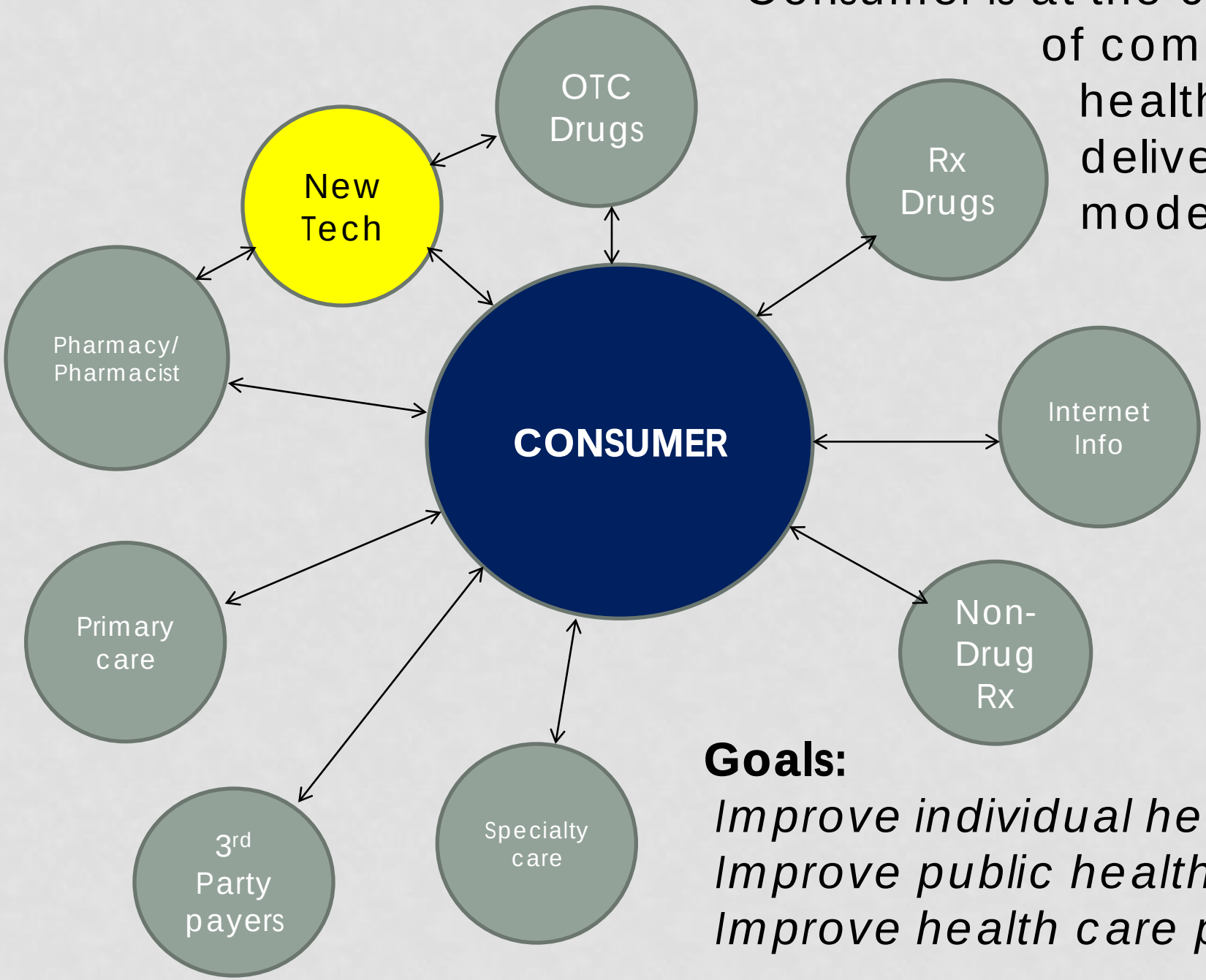
However, technology not an automatic net benefit

- Potential barrier vs traditional OTC
  - Experience with nicotine replacement BTC vs OTC
  - Data driven assessment of justification for barrier
    - Incremental risk reduction or incremental benefit of technology vs decrease access associated with its use
    - Likely require new practices and approaches based on existing consumer research methodologies
- Understand fault modes and their clinical consequences
  - Technological
  - Behavioral
  - Research methodologies – existing, including human factors testing, plus extended field experience

EVALUATION OF NEW TECHNOLOGIES FOR INCREASING NONPRESCRIPTION ACCESS

- Unintended consequences
  - Cost shifts
- Ability to use by “typical” US consumer a design constraint?
  - Segments of population represent a challenge to wide technology implementation: low literacy, elderly, disabled
  - OK if technology designed recognizing that only some consumers will benefit if no adverse impact on others?

Consumer is at the center of complex healthcare delivery model



Goals:

Improve individual health

Improve public health

Improve health care policy

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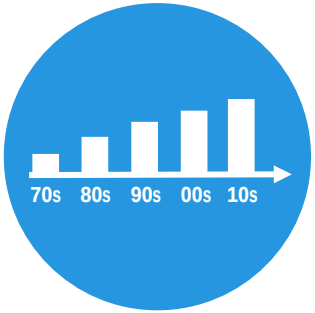
Expansion of Nonprescription Medications: Technology as an Extension of Current Practices

May 9, 2013

Mark Gelbert, PhD, JD, Senior Vice President
Global R&D and Switch, Pfizer Consumer Healthcare

Overview: Expansion of Consumer Healthcare

Non-prescription medicines provide public and individual health benefits



Expansion of OTC medicines has been progressing for decades

Technology plays an important role in guiding consumers

Today's projected application of technology does not require new regulation

Consumer Ability to Self-Diagnose, Appropriately Select and Use Safely Will Drive Expansion of Non-Prescription Medicines

Well-established, proven methodologies

- Label comprehension
- Self-selection
- Actual use

Today's Consumers Are Well-Informed, More Engaged & Actively Manage Health On Their Terms

80%

Of internet users search for health information online[2]

69%

Seek 3-4 different sources before making important health decisions[1]

55%

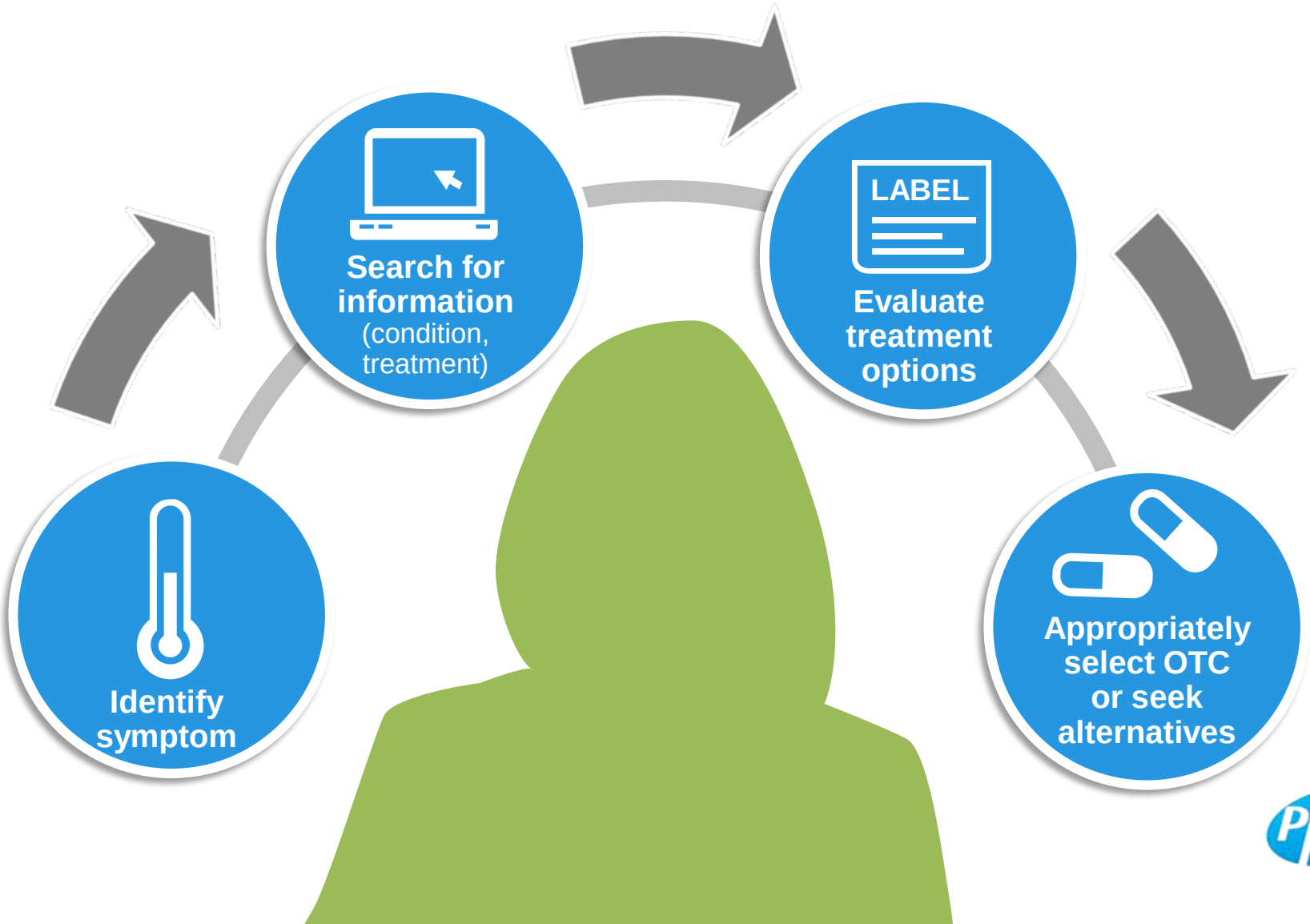
Turn to a virtual experience rather than visit a doctor[1]

50%

Of smartphone users use them to get health information[3]

[1]Yankelovich Health & Wellness Segmentation Study 2009
[2]Pew Internet Project as referenced by Henley Centre HeadlightVision and Yankelovich. "The Futures Company "2011/12 Health and Wellness MONITOR: How to Sell 'Health.'" 2011
[3]Pew Research Center. Mobile Health 2012.

Consumer Journey – Symptom to Treatment



Technology Plays an Important Role In The Self-Care Journey

Currently Available Tools Fall Within the Existing Regulatory Framework

Expanding OTC treatable conditions benefits consumers, society and the healthcare system

Consumer knowledge and behavior should always drive OTC approval

Use of technology is an important part of the self-care journey

No new regulatory framework is needed


Pfizer
Consumer Healthcare

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May 9, 2013

ConsumerReports Health

Consumers want to know about their treatment options

Almost all consumers (91%) want to know about their treatment options (and not just the one recommended by a provider).

Questions:

How will multiple treatment options be presented?

How will non-drug treatment options be presented?

Communicating with Patients on Health Care Evidence,2012, http://iom.edu/~/media/Files/Perspectives-Files/2012/Discussion-Papers/VSRT-Evidence.pdf

ConsumerReports Health

Consumers want to know about risks

- Virtually all consumers (96%) want to know about the risks associated with each treatment option.
- For patients receiving prescriptions for a new drug, 83% had a discussion about the possible side effects with the doctor.

Questions:

How will the risks and benefits of each treatment option be represented?

How will the tools and technologies be tested for their safety and effectiveness for important clinically-relevant and patient-oriented outcomes?

Communicating with Patients on Health Care Evidence,2012, http://iom.edu/~/media/Files/Perspectives-Files/2012/Discussion-Papers/VSRT-Evidence.pdf

Consumer Reports Prescription Drug Tracking Poll, 2012. Available upon request.

ConsumerReports Health

Consumers want to know about costs

- Consumers spend an average of $750 out of pocket per year for drugs they take regularly.
- In the past year, half of consumers (50%) economized on healthcare by cutting corners on a doctor visit, on a medical procedure or test, or on a medicine, or, by seeking out discounts.
- More than half of consumers who spent in excess of $50 per month on medicine asked their doctor about switching drugs in order to save money.
- Recent research by Consumer Reports has found wide variation in the cost (difference of $750 between the lowest-cost retailer and the highest) of five prescription drugs that had recently become available in generic form.
- Almost all consumers (90%) want (their provider to help them) to understand the costs of each treatment option.

Questions: How will comparative costs of treatment options be presented? How will a consumer shop around for the best price?

Consumer Reports Prescription Drug Tracking Poll, 2012. Available upon request.
http://www.consumerreports.org/cro/magazine/2013/05/same-generic-drug-many-prices/index.htm#
Communicating with Patients on Health Care Evidence, 2012.
http://iom.edu/~/media/Files/Perspectives-Files/2012/Discussion-Papers/VSRT-Evidence.pdf

ConsumerReports Health

Consumers do not want ineffective care

- Consumers rank medical evidence higher (71% deem it as “very important”) than provider opinion (61%) and personal preferences (57%) in importance in determining treatment choice.
- Issues with current OTC meds:
  - Overuse/prolonged use: proton pump inhibitors
  - Potential misdiagnosis: overactive bladder
  - Risks outweigh benefits: orlistat (Alli/Xenical)

Question: Will the self-care model exacerbate the propagation of ineffective and/or overused treatments? As exemplified by the American Board of Medicine’s Choosing Wisely project, most professional medical societies recognize the need to bring attention to procedures, tests and drugs that are ineffective and/or overused.

Communicating with Patients on Health Care Evidence, 2012; http://iom.edu/~/media/Files/Perspectives-Files/2012/Discussion-Papers/VSRT-Evidence.pdfhttp://www.consumerreports.org/cro/2012/08/how-to-deal-with-heartburn/index.htm
http://news.consumerreports.org/health/2013/01/should-you-use-botox-or-oxytrol-patch-otc-for-bladder-problems-we-say-maybe-not.html
http://www.consumerreports.org/cro/2012/04/weight-loss-drugs-alli-and-xenical-orlistat/index.htm
http://www.choosingwisely.org/

ConsumerReports Health

Consumers are concerned with the influence of industry

- Two-thirds of consumers we surveyed (65%) *agreed completely* or *somewhat* that pharmaceutical companies have too much influence on the drugs that doctors prescribe.
- Nine in 10 (89%) consumers expressed concern with the practices commonly used by pharmaceutical companies in dealing with physicians.

Questions:

How will the conflicts of interest of the technology owners/investors be disclosed and managed?

Who will determine what the diagnostic criteria are and what the appropriate treatments are?

Consumer Reports Prescription Drug Tracking Poll, 2012. Available upon request.

ConsumerReports Health

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Integrating Technologies as a Condition of Safe Use into Nonprescription Health Care Delivery Systems

James A. Owen, BS Pharm, PharmD, BCPS

Associate Vice President, Practice & Science Affairs

American Pharmacists Association (APhA)

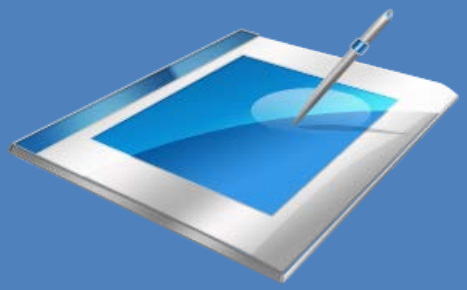
American Pharmacists Association®
Improving medication use. Advancing patient care.
APhA

APhA Perspective

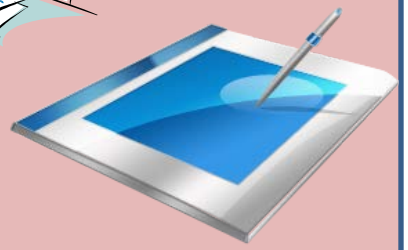
- APhA supports the Food and Drug Administration's (FDA's) efforts to revise the drug classification paradigms for prescription and nonprescription medications to allow **greater access to certain medications under conditions of safe use** while maintaining patients' relationships with their pharmacists and other health care providers.
- APhA sees the new paradigm as an opportunity to:
  - **Expand patient access** and improve public health
  - **Bring back and refer patients** into the health care system
  - **Communicate and collaborate** with medicine

Types of Solutions for NSURE

(*Nonprescription Safe Use Regulatory Expansion*)



Innovative Technology



Innovative Technology & Pharmacist

Pharmacist

Example "NSURE-Like" Example Pilot Program – Epinephrine Auto Injectors

(APhA Anaphylaxis Screening & Prevention Program - ASAP)

Risk Assessment

Education

Patient informed about project & referred to web based technology solution to complete a standardized risk assessment

WEB-BASED risk assessment completed via tablet in-pharmacy or at home via internet web site

Auto-injector INDICATED based on pharmacist review

Auto-injector Rx obtained through CDTM or direct physician consultation

Auto-injector DISPENSED, Patient Educated, Physician Sent Documentation

Auto-injector NOT INDICATED based on pharmacist review

Patient assessment data collected & info sent to Physician

Lessons Learned: "NSURE-Like" Epinephrine Auto Injectors Pilot

(APhA Anaphylaxis Screening & Prevention Program - ASAP)

- **Certain aspects of the potential new paradigm being tested in pilot are limited due to technology limitations**
- **Technology Limitations:**
  - No effective current interoperability of systems – web-based technology to pharmacy systems or EHR/PHR
  - Exchanging information currently requires receiving secure faxes and pharmacy faxing info to physicians or calling physicians
  - Systems are disjointed – rely on different technologies not based on standards – no easy way to share information between providers
  - Lack of capabilities to perform automated information exchange
  - Automated triggers can help to identify patients at risk and increase access to needed therapy – systems to do this are not readily available in marketplace
  - Use of EHR systems to enable connections to Health Information Exchanges is not mainstream in pharmacy practice at present

Lessons Learned: "NSURE-Like" Epinephrine Auto Injectors Pilot

(APhA Anaphylaxis Screening & Prevention Program -ASAP)

- **What can be achieved through the use of technology combined with the pharmacist based on the ASAP pilot program?**
  - Increased access for patients to needed therapy
  - Reduced burden to both the patient and the pharmacist
  - Increased consistency of assessment of patients
  - Increased efficiency
  - Increased simplicity using a web based solution via tablet or home computer (kiosks or other types of technology specific to individual products are not required to implement a technology solution)

Future Technology Workflow Scenario
Option to Facilitate NSURE

Physician Electronic Health Record

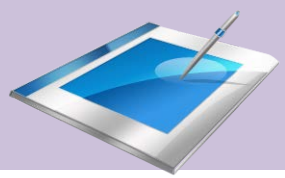
Patient's Personal Health Record

Pharmacist Electronic Health Record

Future Technology Workflow Scenario Option to Facilitate NSURE

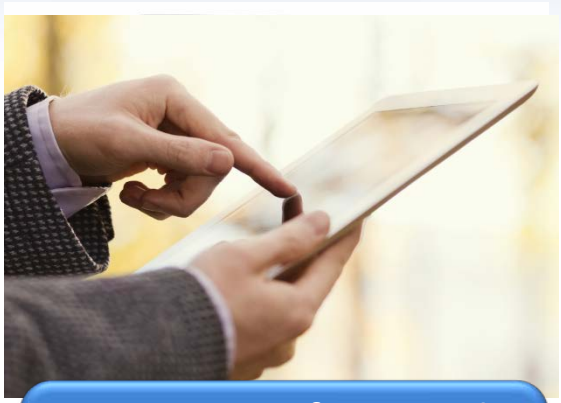
Physician Electronic Health Record

Patient's Personal Health Record



Pharmacist Electronic Health Record

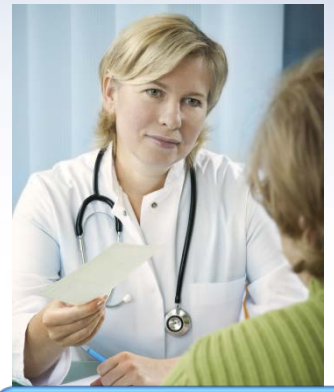
Optimization of Technology to Support NSURE Using Standards



Patient interfaces with **Innovative Technology Solutions**

INFORMATION

PHR



PHYSICIAN EHR

PHARMACIST EHR

Key Provisions for Technology Solutions, Pharmacists & NSURE

- Uniform and standardized processes must be implemented to ensure consistent care for patients
- Integration into workflow is critical for efficiency and effectiveness
- Processes must be standardized and be based upon on consensus-driven, best-practice algorithms developed through evidence-based medicine to provide the best care for patients
- Technology solutions must support efficient and effective documentation, communication and exchange of information using standards based health information technology infrastructure and systems
- Billing mechanisms must be standardized and in place for a viable business model to be effectively implemented

Contact Information

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Pharmacy e-Health Information Technology Collaborative

Session III: Integrating Technologies as a Condition of Safe Use into Nonprescription Health Care Delivery Systems

Shelly Spiro
Executive Director, Pharmacy e-HIT Collaborative

Collaborative Overview

Founding Organizations

- 9 Professional Pharmacy Associations
- Represents over 250K members in all practice settings

Members

- AACP-ACCP-ACPE-AMCP-APhA-ASCP-ASHP-NASPA-NCPA

Associate Members

- Surescripts – NCPDP – RelayHealth – Mirixa – ScriptPro – IQWare- OutcomesMTM

Vision- Mission

Vision

- The US healthcare system is supported by meaningful use of Health Information Technology (HIT) and the integration of pharmacists for the provision of quality patient care

Mission

- To advocate and educate key stakeholders regarding the meaningful use of health information technology and the inclusion of pharmacists within a technology-enabled integrated health care system

Goals

Access	• Ensure HIT supports pharmacists in health care service delivery
Connectivity	• Achieve integration of pharmacists and pharmacies into health information exchanges
Quality	• Advocate pharmacist recognition in HIT programs and policies

Pharmacy e-HIT

Pharmacy e-Health Information Technology Collaborative

Member Login

Home | About Us | Objectives | Membership | News Releases | Links | Collaborative Outreach

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Contact Form

Member Organizations

- Academy of Managed Care Pharmacy
- Accreditation Council for Pharmaceutical Education
- American Association of Colleges of Pharmacy

Webinar - The Roadmap for Pharmacy Health Information Technology Integration in U.S. Health Care

- View the slides

Pharmacy HIT
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shellyspiro Fitch Ratings: EHR Incentive Pay Boosted Hospitals' Bottom Lines lnkd.in/x7z-b8
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Pharmacy e-Health Information Technology Collaborative

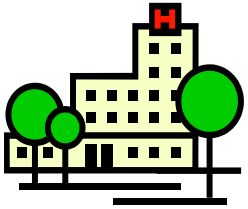
The Roadmap for Pharmacy Health Information Technology Integration in U.S. Health Care

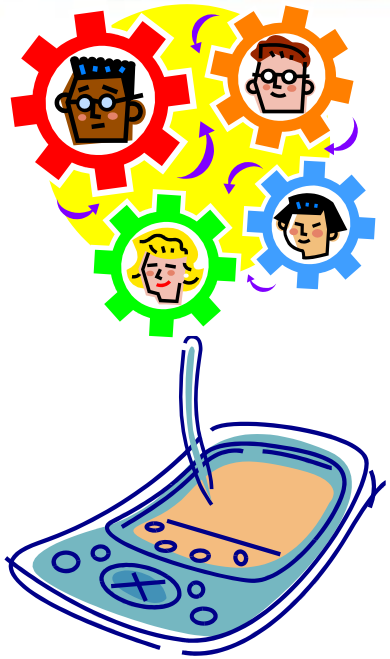
http://www.pharmacyhit.org/pdfs/11-392_RoadMapFinal_singlepages.pdf

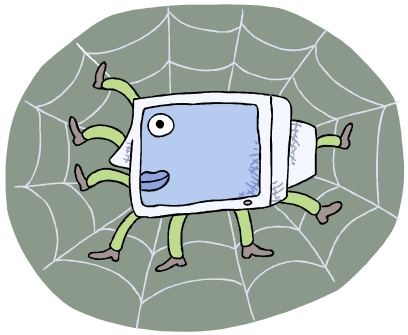
Medication Information Flow

MU -EHR
Physician Office

Hospitals
Clinics - LTPAC



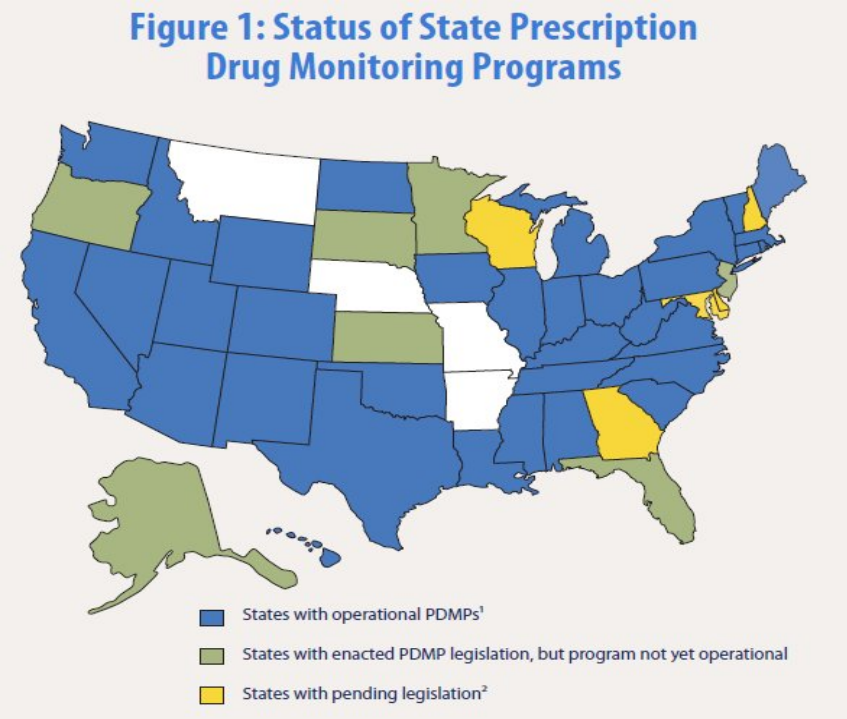




Pharmacy

PDMP and HIE

PDMP and Medication History



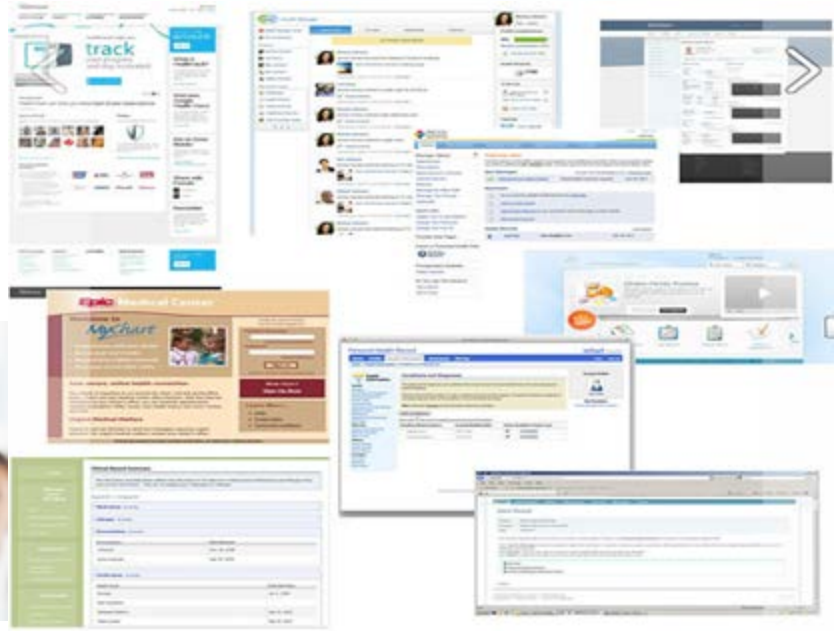
Source:
http://knowledgecenter.csg.org/drupal/system/files/PDMPmap.jpg

Health Information Exchanges

Source:
http://www.google.com/url?sa=i&source=images&cd=&cad=rja&docid=IuPQmSHciitYjM&tbnid=AJVyyBiPUk05nM:&ved=0CAcQjB0wAA&url=http%3A%2F%2Fwiki.siframework.org%2FRelated%2BEfforts&ei=t9iDUdjUMK7A4AOd0YDYCg&psig=AFQjCNFwoCEPHAHU1TZw1w5AM56kAaSlnQ&ust=1367681591849214

Patient Engagement

- ePHR
- Blue Button



9 Popular Personal Health Record Tools

Source:
http://www.informationweek.com/healthcare/patient/9-popular-personal-health-record-tools/232900297

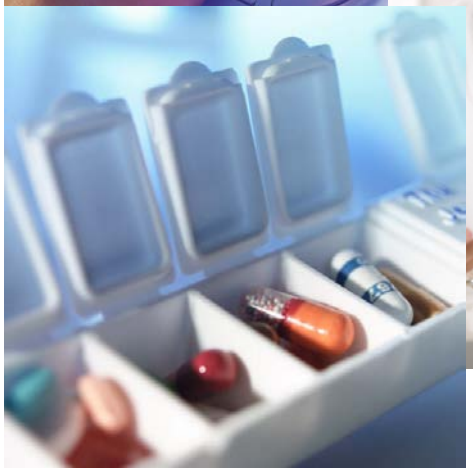
Making Data Useful

What's Different

- SDO's (NCPDP-HL7)
- Portals or HIEs
- Collect – Document - Exchange
- Continuity of care document (CCD) using cCDA
  - Allergies
  - Medication list
  - Immunization
  - Family history
  - Social history (e.g. smoking)
  - Functional status
- Care Coordination (CMR and AWV)

Access-Connectivity-Quality

Pharmacists' clinical services are a critical component of our nation's health care system and can effectively contribute to the meaningful use of EHR.



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