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

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

Number of Smartphone Users Worldwide
(Millions of Users)

Source: Smartphone: King of Convergence
© 2010 Parks Associates
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

* mHealth = mobile Health

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

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

Under development

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 complex medication regimens
- Management of hypoglycemic episodes

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**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**

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:
    

• 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.

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
  - Apps create functionality for 'droids'
  - A medicine is a medicine
  - Adherence tracking
  - Dosage reminders
  - Potential DDI interventions
  - Identification on how to handle emergent side effects

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

**OTC Examples:**
- Aspirin
- Stool softeners
- Calcium antacids
- Acid reducers/PPI
- Oxybutynin

**mHealth has potential to optimize functionality of the OTC Drug Facts Label**
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
If your symptoms do not improve after 2 weeks, you should contact your doctor.

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.

Breaks the Usual Paradigm of Self-Care with Nonprescription Medicines

- 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 medicine if:
- You are allergic to 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
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Uncertain</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Are you allergic to tamsulosin or other ingredients in this medicine?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Are you currently taking any prescription medicines?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Do you have problems with your heart?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Do you have problems with your liver?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Do you have problems with your kidneys?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Do you faint or get dizzy or weak when you sit or stand up suddenly?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Have you had symptoms for less than 3 months?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Do you have pain when you urinate or your urine was cloudy or bloody, at some point in the last 3 months?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Have you had a fever due to an infection of your kidneys or bladder (urinary tract infection)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Do you have leaking of your urine which you are unable to control (urinary incontinence)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Do you think you have diabetes that is not properly controlled?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Have you had prostate surgery?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Have you recently had blurred or cloudy vision and have not been examined by an eye doctor or optometrist?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Are you about to undergo eye surgery for cataract or glaucoma?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

- You must have tried a healthy diet and exercise to reduce your cholesterol.
- You must have had a fasting cholesterol test and know your cholesterol numbers.
- Your LDL “bad” cholesterol must be 130 to 170.

Drug Facts

Active ingredient (in each tablet)  Purpose
Lovastatin 20mg  Cholesterol reducer

You must read the entire Drug Facts label inside.
**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:**
- A woman age 55 years or older
- A man age 45 years or older

---

**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.
Even with high cholesterol you may be at lower risk and not need this product. 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 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**

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

Next
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.
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
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
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.
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
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
I have or have had...
Pick the statement(s) that apply to you.
Then touch "Next"

- Liver disease
- Heart attack or chest pain (angina) [Checked]
- A stroke
- Diabetes
- None of the above
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
Cardiocor is NOT right for you.

**Cardiocor 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.
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
Central Monitoring Hub

Secure Patient Health Stream Portal

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

Customizable Health Questionnaire

Providing Immediate Feed Back to Individuals

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


Receive Email Notification
Receive Text Notification
Make a note in Patient Record on the Go
Caregiver Portal Notifications

Patient Reading is out of preferred range
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

Review Health Questionnaire

Lanaie Richardson
CHF - 5/2/2013 4:41:59 PM

Question: Are you having any shortness of breath?
Answer: Yes
Notes: Used rescue inhaler and PRN oxygen - DOB resolved

Question: Is there more swelling in your legs than usual?
Answer: No swelling

Lanaie Richardson
CHF

Escalate: High
Reviewed: 

Submit Cancel
Demonstration of help request initiated by individual
Help Request Notifications

Lilah Patient Alert
alerts@mylilah.com
Sent: Tue 4/30/2013 12:07 PM
To: Jodi Funderburk

Patient Lannie Richardson requested assistance.
Face To Face
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 .....
Innovative Technologies and Nonprescription Medications:
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May 9, 2013
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

Presentation © 2013 Rock Health
Launched at SXSW  
March 2011

V1: 15 companies  
June-November 2011

V2: 13 companies  
January-May 2012

V3: 7 companies (Boston)  
June-August 2012

V4: 14 companies  
October 2012-February 2013

Presentation © 2013 Rock Health
UNIQUE POSITION

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

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

Preventive health and wellness
Care management (acute and chronic)
Devices and diagnostics

Payer and provider administration
Data, information and analytics
Telemedicine

Genentech
GE
Nike
Qualcomm Life
Quest Diagnostics
UnitedHealth Group

Aberdare Ventures
KPCB
Mohr Davidow
Harvard Medical School
Kaiser Permanente

Montreux Equity Partners
NEA
Mayo Clinic
UCSF

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

Presentation © 2013 Rock Health
THOUGHT LEADERSHIP

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

Featured in leading press outlets:

- The Wall Street Journal
- The Economist
- Forbes
- CNN
- Inc.
- CNBC
- TechCrunch
- VentureBeat
- Gigaom

400,000 Rock Report views

FDA 101: A guide for digital health entrepreneurs

13,000+ followers

3,000+ likes

10,000+ subscribers

25,000+ visits/month

Presentation © 2013 Rock Health
DIGITAL HEALTH FUNDING

Cumulative funding in millions

46% more money
56% more deals
compared to 2011

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

Presentation © 2013 Rock Health
How NoviMedicine Works

Describe your acne.
You'll give us information about your acne as well as your general health. We'll also want to know what medications you've been using.

- Total time: Less than 10 minutes

Send photos.
Since this is acne, we need to see it to be able to help you. You'll take 3 pictures of your acne (from your computer, phone, camera—whatever you want) and upload them to our secure website.

- Total time: Less than 5 minutes

Get treatment.
Your information then goes to one of our board-certified dermatologists for review. You'll be notified to log into your secure account to receive your treatment plan. Over the counter and prescription medications, if you need them, will be waiting for you at your preferred pharmacy.

- Total time: 48 hours

*Right now, NoviMedicine’s services are available in California only. If you are from outside of California, let us know what state you’re in and we’ll let you know when we can serve you.
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 predictability 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.
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.
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.
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

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 response-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-educes 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:

• 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:

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

Engelberg Center for Health Care Reform
The Brookings Institution • Washington, DC
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
## How do consumers make decisions about OTC Medications?

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

World Internet Penetration Rates by Geographic Regions - 2012 Q2

- North America: 78.6%
- Oceania / Australia: 67.6%
- Europe: 63.2%
- Latin America / Caribbean: 42.9%
- Middle East: 40.2%
- World, Avg.: 34.3%
- Asia: 27.5%
- Africa: 15.6%

Source: Internet World Stats - www.internetworldstats.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.
Copyright © 2012, Miniwatts Marketing Group
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)
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
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

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Access = Flexibility
Remote Diagnostic tools are in use now
Example: Product-specific Decision-Support and Management System
Example: **Cross-product** Continuum of Information Exchange

- **OTC - Tier I**
  - **SELF REPORT**
  - Consumer Mediated Exchange

- **OTC - Tier II**
  - **DIAGNOSTIC VERIFICATION**
  - Query-Based Exchange

- **OTC - Tier III**
  - **PHYSICIAN DIAGNOSIS**
  - Direct Exchange
    - Or
  - Stand Alone EMR

- **Rx**

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Example: Consumer-driven Health Information Exchange

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

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

Safe and Effective Medication

Label Understood and Guides Appropriate Self-Selection

Label Guides Appropriate Use and De-Selection

Safe Use in an OTC Setting
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

Let’s review the drug facts...

Would you like to place an order?

Yes, please send it to my local pharmacy.

800 number
NSURE: Delivery Options

Send order to pharmacy

Home delivery

Token, for in-store collection
NSURE: Identification Options

- Text code or MMS barcode to cellphone
- Text code or MMS barcode to iPhone
- Print at home

Scan at Speedbuy
- or -
give this code to pharmacist:
GF7TD
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
- Navigation
# Key Findings From Consumers

<table>
<thead>
<tr>
<th>Registration</th>
<th>Qualification</th>
<th>Drug Facts</th>
<th>Order Med.</th>
<th>Pick Up Med.</th>
<th>Follow Up</th>
<th>Other Info</th>
</tr>
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<tbody>
<tr>
<td>Website</td>
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</tr>
</tbody>
</table>

May 2013
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
Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care

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

ERIC P. BRASS M.D., PH.D.
PROFESSOR OF MEDICINE, DAVID GEFFEN SCHOOL OF MEDICINE AT UCLA
DIRECTOR, HARBOR-UCLA CENTER FOR CLINICAL PHARMACOLOGY

THE UNIVERSITY OF CALIFORNIA
UCLA

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

Engelberg Center for Health Care Reform
The Brookings Institution • Washington, DC
May 9, 2013
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
\(^3\)Pew Research Center. Mobile Health 2012.
Consumer Journey – Symptom to Treatment

1. Identify symptom
2. Search for information (condition, treatment)
3. Evaluate treatment options
4. Appropriately select OTC or seek alternatives

Appropriately select OTC or seek alternatives
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
Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care

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May 9, 2013
Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care

Doris Peter, PhD
Associate Director
Consumer Reports Health Ratings Center
dpeter@consumer.org

May 9, 2013
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?

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?


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?

http://www.consumerreports.org/cro/magazine/2013/05/same-generic-drug-many-prices/index.htm#

http://iom.edu/~/media/Files/Perspectives-Files/2012/Discussion-Papers/VSRT-Evidence.pdf
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.pdf](http://iom.edu/~media/Files/Perspectives-Files/2012/Discussion-Papers/VSRT-Evidence.pdf)
[http://news.consumerreports.org/health/2013/01/should-you-use-botox-or-oxytrol-patch-otc-for-bladder-problems-we-say-maybe-not.html](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.choosingwisely.org/](http://www.choosingwisely.org/)
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?

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

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

- A PhA 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.

- A PhA 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

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
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

- **Patient’s Personal Health Record**
- **Physician Electronic 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
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 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
James A. Owen, BS Pharm, PharmD, BCPS
Associate Vice President, Practice and Science Affairs
American Pharmacists Association
2215 Constitution Avenue NW
Washington DC 20037-2985
202-429-7540 (office)
202-638-3793 (fax)
jowen@aphanet.org
www.pharmacist.com
Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care

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

- 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

www.pharmacyhit.org
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 Medication History

Health Information Exchanges

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

Source:
http://www.google.com/url?sa=i&source=images&cd=&cad=rja&docid=1uPQmSHciitYjJ&M&tbnid=AJvvyBiPUk05nM:&ved=OCAcQjBOwAA&url=http%3A%2F%2Fwiki.siframework.org%2FRelated%2FFefforts&ei=t9iDUdjUMK7A4AOd0YDYCg&psig=AFQjCNFwoCEPHAHU1TZw1w5AM56kAaSlmQ&ust=1367681591849214
Patient Engagement

- ePHR
- Blue Button

9 Popular Personal Health Record Tools
Making Data Useful

Data

System Function Usability

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

Slides Prepared by:
Shelly Spiro
Executive Director, Pharmacy e-HIT Collaborative

shelly@pharmacyhit.org
www.pharmacyhit.org
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