

# Compliance Independence

Passive Wireless Sensor-Tag Workshop  
Robert Matthews CTO WWHI

July 21, 2011



## About the Institute:

# West Wireless Health Institute

- An independent, nonprofit medical research organization *based in San Diego*, launched in March 2009.
- ~ \$100 million in funding to date from the Gary and Mary West Foundation.
- Primary mission: lower health care costs



# Core Functions

## INNOVATE

Commit resources to develop meaningful innovation in health care technology, solutions and business models

## VALIDATE

Champion the clinical and economic validation of specific technologies and solutions

## ADVOCATE

Work to shape the external environment to accelerate the adoption of novel medical technology like wireless health solutions

## INVEST

Evaluation of internal and external opportunities to accelerate and create innovations in health care

## COMMERCIALIZE

Create the capacity to move products and solutions through the initial commercialization process

# State of Health Care Today

Several seemingly inexorable forces:

- Rising costs
- Demographic challenges
- Shortage of doctors

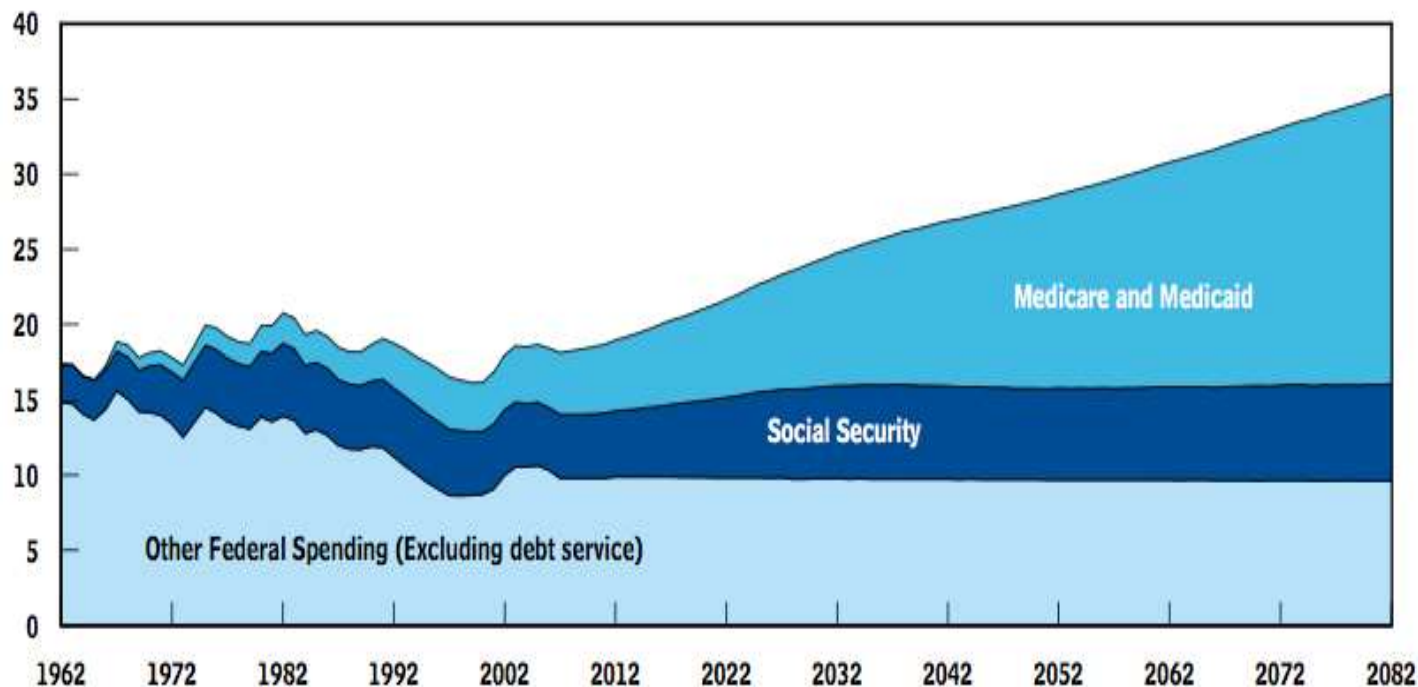


# A fiscal scenario or a social and financial fiasco?

**Figure 1-1.**

## **Projected Federal Spending Under One Fiscal Scenario**

(Percentage of gross domestic product)



Source: Congressional Budget Office.

Note: The figure, from the December 2007 *Long-Term Budget Outlook*, portrays CBO's "alternative fiscal scenario," which deviates from the agency's baseline projections to incorporate some changes in policy that are widely expected to occur and that policymakers have regularly made in the past.

# HEALTHCARE **FINANCE** NEWS

## Healthcare spending unsustainable, says former Fed chair Greenspan

April 09, 2009 | Healthcare Finance News Staff

Greenspan said medicine advanced throughout the 20th century, resulting in the most dramatic longevity increases in history. "This is an unprecedented demographic shift," he said. "When I was a child, high-tech medicine was my physician coming over to me and saying, 'Take two aspirin and call me in the morning.'"

But with the civilian labor force aging and new, expensive treatments gaining in popularity, health costs are increasingly becoming a major drag on the economy. Healthcare costs have been outstripping general inflation for 20 years now, but productivity gains were able to mask much of the problem up until short-term money markets froze up on Sept. 15, 2008.



## Even with reform's savings, Md. health care system 'unsustainable'

By **Bob Graham**

Posted: July 28, 2010

**INSURANCE  
& FINANCIAL  
ADVISOR**

**IFAwebnews.com**

"Our health care system will soon be unsustainable, regardless of these savings, unless we succeed in improving quality while reining in the runaway growth in costs," said the report from the council, co-chaired by Lt. Gov. Anthony G. Brown and Maryland Health Secretary John M. Colmers.

Maryland "must affirm and strengthen its commitment to immediately begin serious and sustained efforts to bend the cost curve and align incentives toward quality, safety and efficiency," according to the council's interim report.

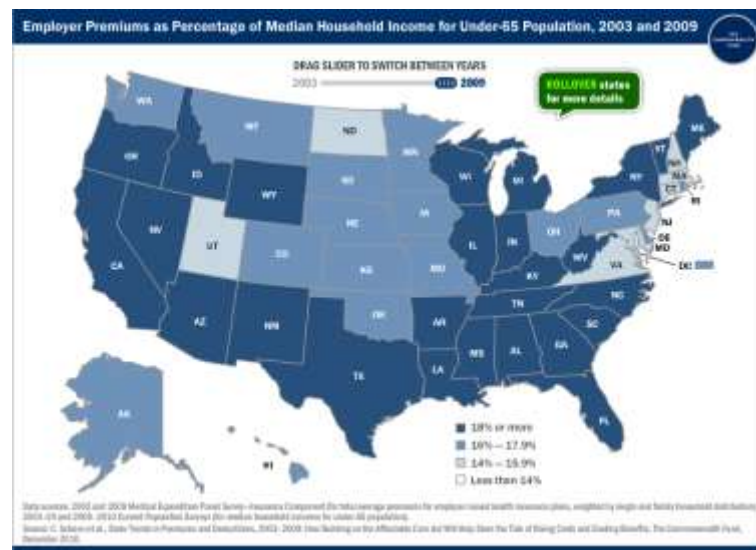
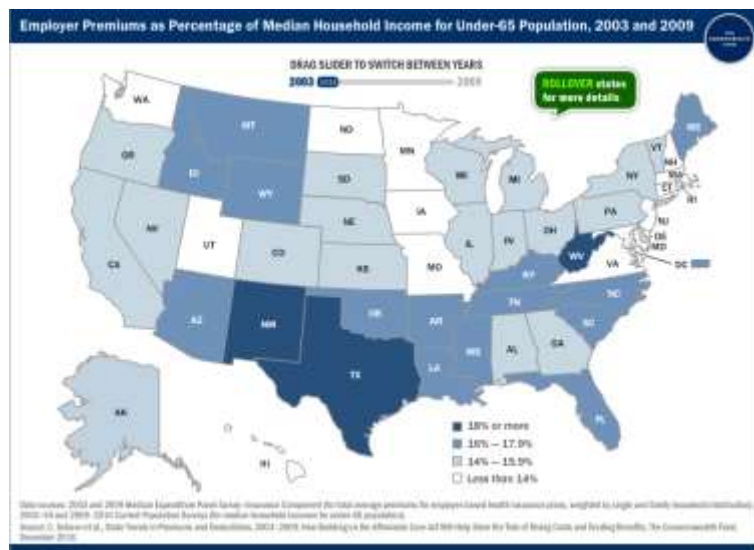


Not many  
will be  
able to  
keep  
coverage

41%  
increase  
2003-2009

71%  
increase  
2010-2020

## Healthcare premiums and deductibles 2003-2009



“The analysis finds that premiums for businesses and their employees increased 41 percent across states from 2003 to 2009, while per-person deductibles jumped 77 percent in large as well as small firms. If these trends continue at the rate prior to enactment of the Affordable Care Act, the average premium for family coverage will rise 79 percent by 2020, to more than \$23,000.” .....*The Commonwealth Fund, Dec 2, 2010*

Status quo  
cannot be  
sustained

# Current health care system is unsustainable

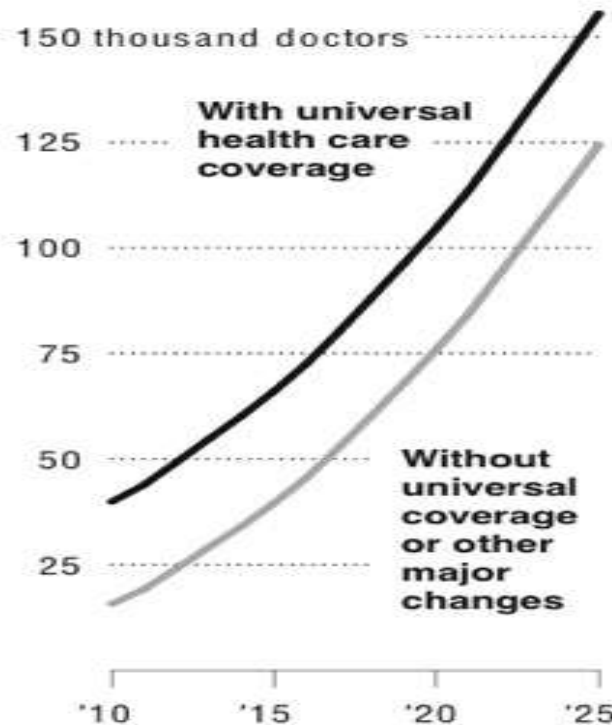


Physicians



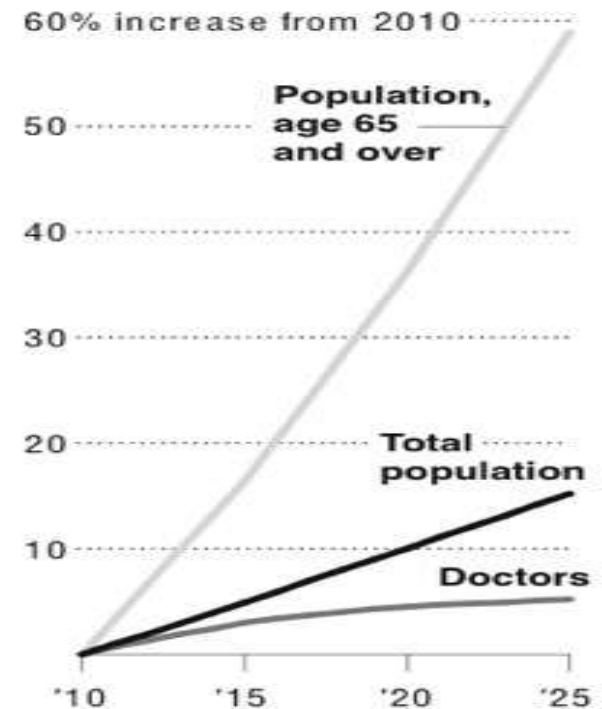
Demand  
for Care

Projected shortfall in number  
of doctors needed



Source: American Association of Medical Colleges

Projected growth in  
population vs. doctors



THE NEW YORK TIMES

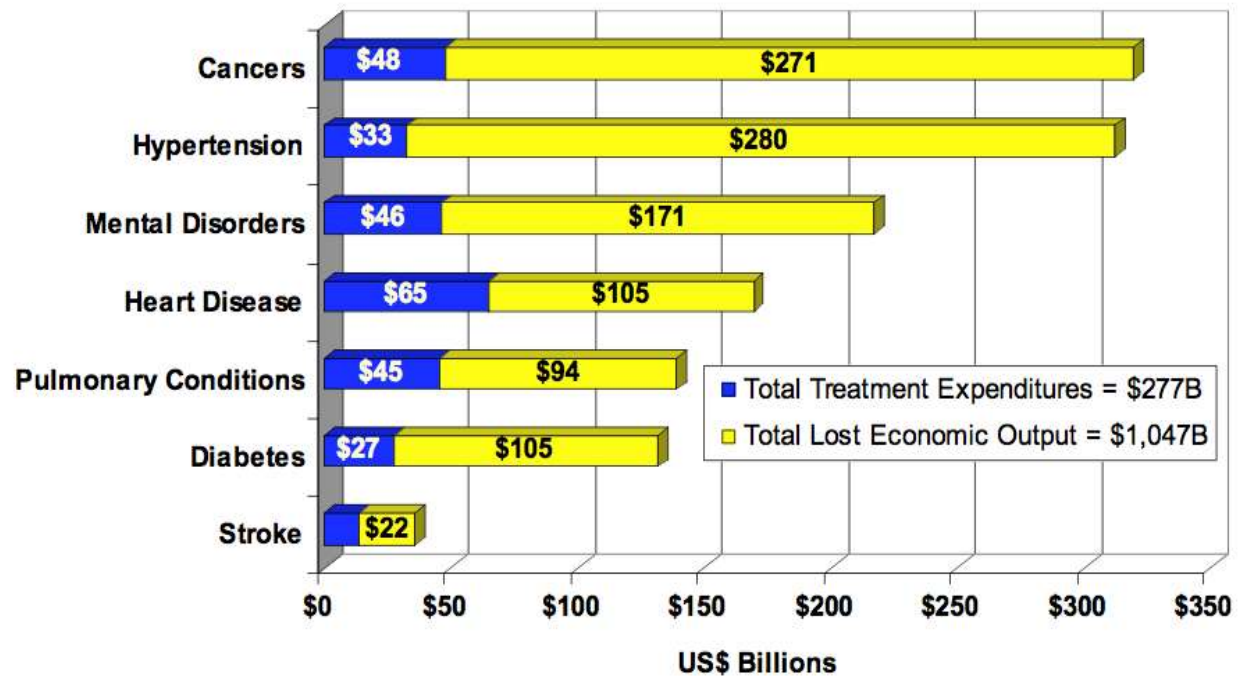


# Chronic Disease Burden

- 20 million Americans have Diabetes
- 20 million Americans have Kidney Disease
- 50 million Americans have Hypertension
- 65 million Americans have Cardiovascular Disease
- 2 of 3 Americans are overweight; 1 in 5 is Obese
- 1 in 5 Americans over 40 will develop Heart Failure
- Chronic diseases account for 96% of Medicare spending
- Complications from chronic disease account for ~75% of overall US healthcare spending!

# Chronic Disease Burden

## Total Economic Cost of Chronic Disease *U.S., 2003*



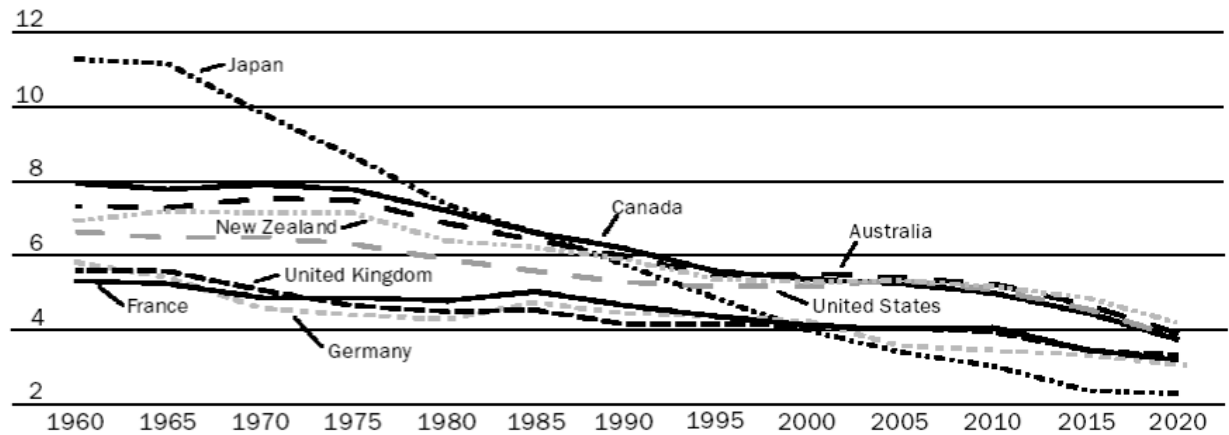
By 2020  
the ratio of  
elderly to  
young will  
be 1-4

# The Graying Populations

## EXHIBIT 5

### Number Of Potential Workers Per Elderly Person In Eight Countries, 1960-2020

Ratio of persons ages 15-64 to persons age 65 and older



SOURCE: United Nations Demographic Indicators 1950-2050 (data diskette, 1998 revision), medium estimate.

SOURCE: United Nations Demographic Indicators 1950-2050 (data diskette, 1998 revision), medium estimate.

1960 1962 1970 1972 1980 1982 1990 1992 2000 2002 2010 2012 2020

5

# Infrastructure Independence

## Infrastructure Independence<sup>SM</sup>

A New Model of Health Care

### Current Model

- low frequency visits
- acute care focused
- appointment driven
- location centric
- high cost

### Infrastructure Independence

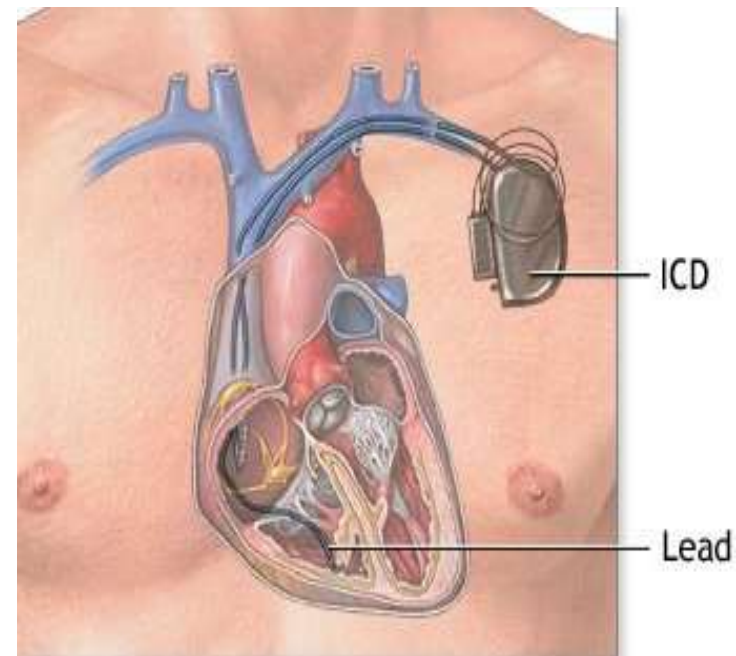
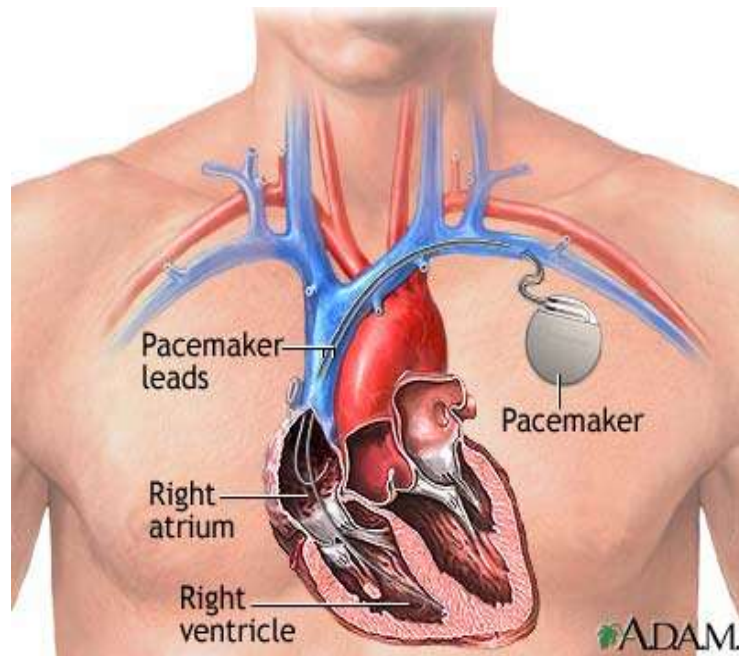
- high touch
- right treatment
- when they need it
- where they are
- lower cost

# Vision

- Present state:** Chronic diseases are episodically diagnosed and intermittently treated, consuming enormous resources driven by exacerbations, clinical decompensations, and complications.
- Future state:** Chronic diseases will be met with continuous care, improving outcomes and lowering costs by prediction and prevention of acute presentations.
- Path:** Near, on, or in-body sensor technology, providing actionable diagnostic information, linked to learning systems and titratable therapies, enabling continuously-tailored, feedback-controlled treatment.

***Replace costly intermittent rescue with continuous and cost-effective care.***

# Prototypical Solution





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- ▶ Digital Infrastructure Task Force
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## ➔ Wireless Sensors May Help Governments Monitor Health of Aging Infrastructure



Mar 13, 2008, By  
Chandler Harris

When the Minneapolis Interstate 35W bridge collapsed on Aug. 1, 2007, sending 88 vehicles and hundreds of people into the Mississippi River - 13

were killed and 100 injured - nobody, including state bridge inspectors, foresaw such a catastrophic event.

The collapse was a sad reminder of the aging U.S. infrastructure, which needs a \$1.6 trillion overhaul over the next five years, according to the American Society of Civil Engineers. Its report graded the U.S. infrastructure as a D in 2005, down from a D+ in 2001. Bridges earned a cumulative C.

U.S. bridges are a pressing concern because stress loads have increased substantially due to a spike in traffic congestion. Since the Minneapolis I-35W bridge was built in 1967, the number of vehicles using the bridge had tripled, according to state documents. Also, truck weight limits have increased nationally, according to the U.S. Department of Transportation (DOT).

The I-35W bridge had been diligently inspected since 1993, and it always passed. Although state officials knew the bridge needed repairs, they had no idea the bridge was in danger of collapse. In January, the National Transportation Safety Board (NTSB) announced the bridge failed due to a design flaw in the gusset plates that connected steel beams; the gusset plates were only half the thickness they should have been. The NTSB investigation found no evidence that

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Report Released on I-35W Bridge Collapse in Minneapolis Last Year

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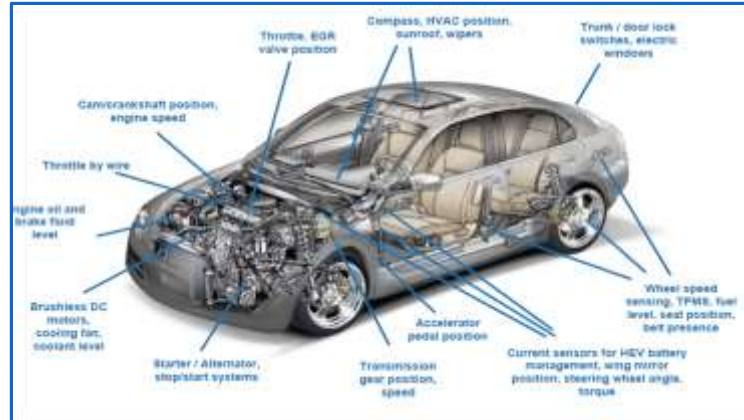
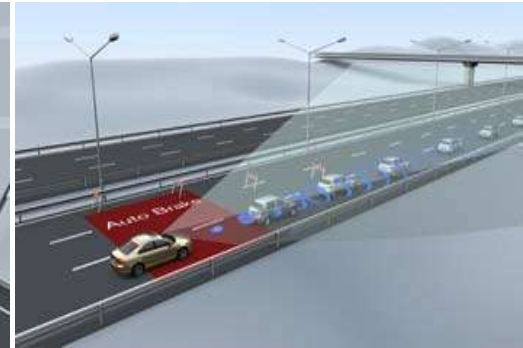
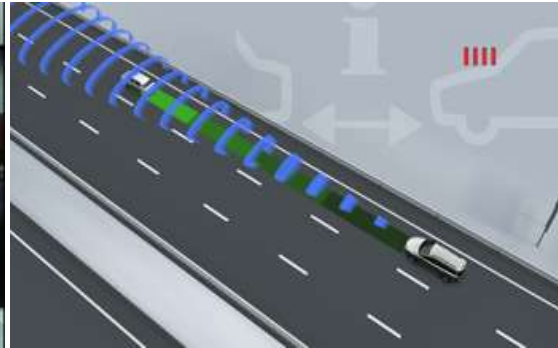
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4G available in over 25 markets and counting.



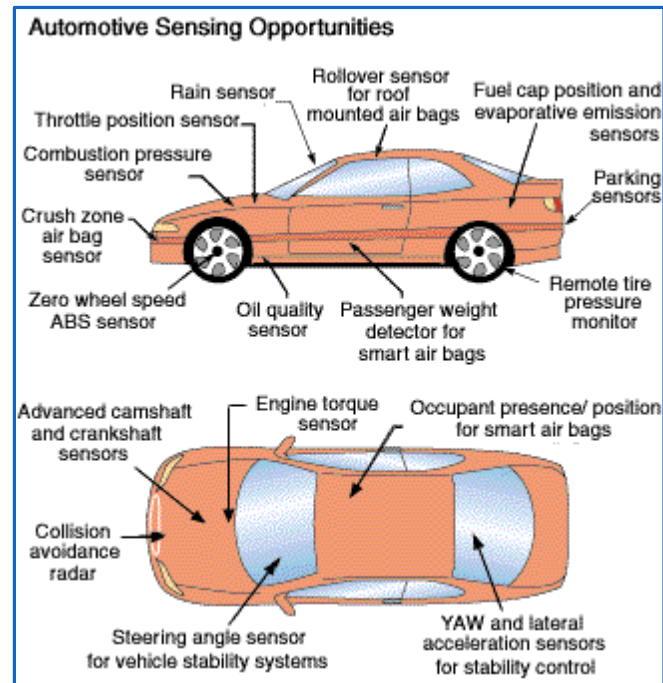
Replay

If we can do  
it for our  
cars...???



If we can do  
it for our  
cars...???

# Electronic Sensors Ensure Safety



- Quick-reaction **crash sensors** activate the front, side, and curtain airbags, and the tension on the seatbelt.
- **Seat occupancy detectors** send a signal to prevent passenger seat front and side airbags from deploying in the event of an accident, if the seat is empty or if a special child's seat is on board.
- **Acceleration sensors** report if the vehicle is deviating off its vertical axis and if it needs to apply the brakes to one, two or three wheels.
- Outside **temperature sensors** send a signal when there is a risk of black ice.
- Engine management system sensors provide information on **exhaust gas quality**, and still others diagnose **the condition of the oil, or amount of oxygen delivered for combustion so that service intervals can be determined more accurately**.
- Height sensors detect the movements of an approaching vehicle and automatically adjust the headlamps to prevent the drivers of oncoming cars from being blinded.
- Anti-pinching sensors in the windows and sliding roof stop them from closing at a pre-defined resistance level to prevent injuries, especially to children traveling in the car.
- Sensors are used in conjunction with the Global Positioning System (GPS) to tell the driver where he or she is at any given moment...



# Wireless Health Care

## Potential to lower costs:

- Shifting to site of care
- Allowing for more frequent monitoring
  - Compliance
  - Disease progression
- Low cost infrastructure
  - Computing / telecommunication costs are lowering
  - Force amplifying doctors
  - Allow for creation of care coordinators



## **Research & Development at WWHI:**

- Patient-centered and guided by needs identified by clinicians, hospitals, and/or health care systems
- Focused on low-cost solutions that meet these needs, including reducing hospital readmissions and ensuring patients have access to the right care at the right time, wherever they live

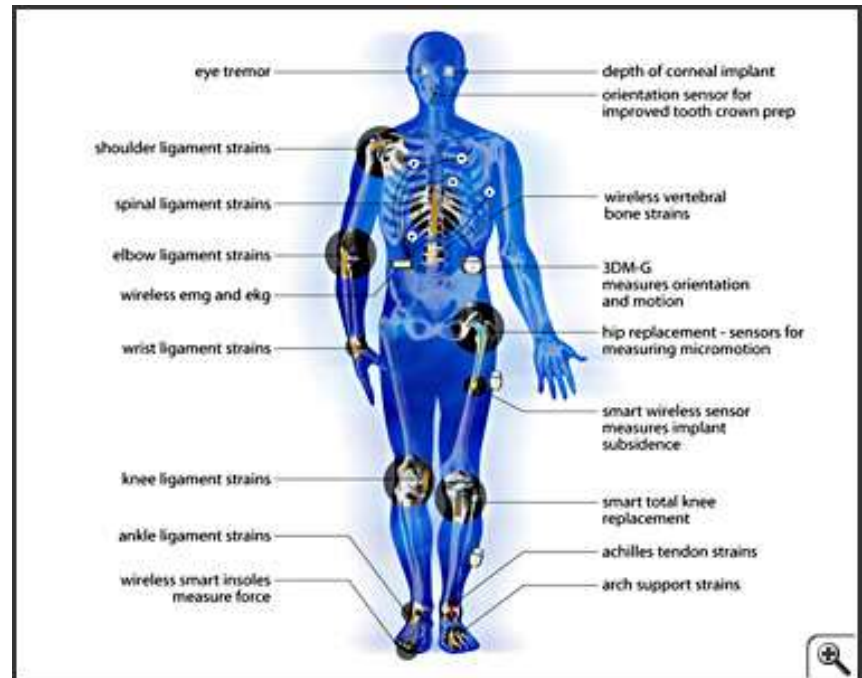
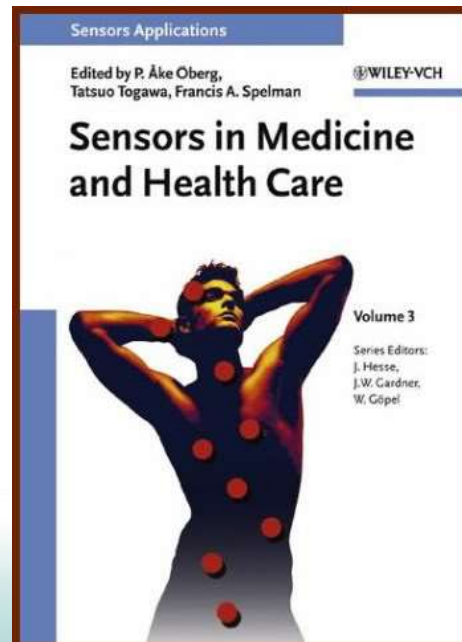
## **Research Team at WWHI:**

- Research at WWHI is focused on creating the next generation of health care innovations, including wireless medical devices that have the potential to significantly lower health care costs.
- The Research team focuses on applied research and is comprised of expert technical staff drawn from around the world.




Shouldn't  
we do it for  
ourselves?

# Electronic Sensors Ensure Safety



# Electronic Sensing for our Human Aging Infrastructure



## Aging In Place Technology Watch

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### Market Research Reports

**Newly Updated (04-05-10) Technology Market Overview Report** [Click here](#)

**Updated (12-10-09) Aging and Health Technology Report** [Click here](#)

**COMMENTS WELCOME!**

### Meet and hear Laurie speak at:

**2010 Silicon Valley Boomer Venture Summit, June 15-16, Santa Clara, CA**

**AARP Orlando@50+, September 30-October 2, Orlando, FL**

**Connected Health Symposium 2010, October 21-22, Boston, MA**

**Digital Health Summit @CES 2011, January 7, 2011, Las Vegas, NV**

### Home

## BeClose Launches New Wireless Home Monitoring System for Aging-in-Place Seniors

Submitted by Laurie Orlov on Fri, 03/19/2010 - 21:43  
[home and remote monitoring](#)

03/19/2010

BeClose™, the new wireless home monitoring system that connects caregivers to care receivers through BeClose.com, announced the commercial launch of their aging-in-place product today during the National Council on Aging and the American Society on Aging's week-long conference in Chicago. The setting was the largest gathering of a diverse, multidisciplinary community of professionals from the fields of aging, healthcare and education.

BeClose works as unobtrusive, wireless sensors placed throughout the home transmit information to BeClose.com, where caregivers can log in to monitor daily activities. The real time information can also be sent to hand-held devices for mobile alerts and the ability to monitor from anywhere.

"BeClose™ allows aging family members to stay in their homes when they feel strongly about maintaining their independence," said Liddy Manson, the Company's president. "Most often the Caregivers are immediate family members, and the Caregivers that we talked to during our product testing phase want the peace of mind that comes from knowing that their loved ones are going through their daily routines successfully. They want this knowledge without constantly intruding on their privacy or calling all the time."

Dr. Mark Hanson, who leads the company's Product Development efforts, is one of the country's leading experts on wireless health and a frequent speaker on the subject of geriatric technology. He added, "unlike cumbersome pendants that rely on the elderly to activate them if something happens, the wireless sensors of BeClose™ provide hands free, continual information about activity in the home -- staying in bed, using the bathroom, doors and windows or other personalized activities you choose

### User login

[Login/Register](#)

### Related News Articles

**Happiness May Come With Age**  
06/01/2010  
More on Gallup poll indicating that after age 50, people get happier as they get older.

**Your Risk of Heart Disease -- 74 is the new 53**  
06/01/2010  
Optimal cholesterol, blood pressure, no diabetes -- means your arteries may be younger than you.

**GE Chief sees Japan as fertile field**  
06/01/2010  
Jeffrey Immelt talks about future GE role in treatment of chronic diseases in the home - in Japan (22% over age 65).

**AARP showing a tech-savvy face to Baby Boomers**

# Pervasive Technologies

Convergence

wireless  
connectivity



ubiquitous  
sensing



cloud  
computing

social  
networks



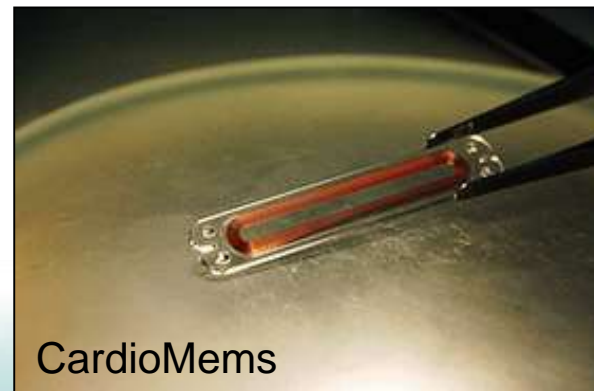
# Ten Targets for Wireless Medicine

Disease	#	Wireless Solutions
Alzheimer's	5 M	Vital signs, location, activity, balance
Asthma	23 M	RR, FEV1, Air quality, oximetry, pollen count
Breast cancer	3 M	Ultrasound aided self-exam
COPD	10 M	RR, FEV1, air quality, oximetry
Depression/ Mood Disorders	21 M	Med compliance, activity, communication
Diabetes	24 M	Glucose, hemoglobin A1C
Heart Failure	5 M	Cardiac pressures, weight, BP, fluid status
Hypertension	74 M	Continuous BP, med compliance
Obesity	80 M	Smart scales, caloric in/out, activity
Sleep Disorders	40 M	Sleep phases, quality, apnea, vital signs

*Some anticipate that by 2014 there will be more that 400 million wireless sensors worn – more than one for each person in the US!*



# Physiologic Sensor Development



# Early stage industry with huge potential

- Against the backdrop of an obviously unsustainable healthcare system to which we have just *increased access*...
- Increased recognition of the wireless healthcare opportunity
  - ...that we have been talking about for 10 years
  - ...that requires risk capital to fulfill its potential
  - ...that in turn requires regulatory clarity and timeliness
  - ...and that then requires a rational business model





## Significant barriers

- **Business model uncertainty being resolved:**
  - Venture (risk) capital – follows real business opportunity
  - Reimbursement issues being solved by cost pressures
- **Regulatory:** “Disclarity” keeping R&D, investment on sidelines
- **Outstanding Legal Concerns:**
  - Privacy – clarity, with consistent interpretation / guidance
  - Liability – whose, for what – tort reform?
  - Interstate medical practice / across state lines
- **Entrenched Health Care Establishment:** shift from hospital and physician as the center to the home/family/patient as center – clear need to align incentives with long-term vision



This week's  
FCC/FDA  
meeting...  
limitations  
in context.

# Moving Forward: Regulatory Clarity

- Current “disclarity” is dampening investment and chilling innovation because of uncertainty around regulation of nonmedical devices (e.g. smartphones)
- In defining regulatory pathways, we should make clear the distinction between *regulated medical devices* that detect and/or treat disease and *ubiquitous, multipurpose nonmedical devices*.

## Medical Facsimile Cover Sheet

Date _____	
TO _____	
Name _____	
Phone _____	
Fax _____	
FROM _____	
Name _____	
Signature _____	
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Fax _____	
Patient Name _____	
Identifier _____	
Medical Record Number _____	
Reason For Release _____	
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# Moving Forward: Aligning Incentives

- Lack of reimbursement for health care innovations such as wireless health solutions have inhibited deployment in non-integrated delivery settings.
- However, **innovations within integrated delivery systems show the way forward:**
  - VHA Care Coordination Home Telehealth (CCHT) program
    - 19% reduction in hospital readmissions and average cost of home care \$1,600 compared to up to \$77k for nursing home care
  - Community Care North Carolina (enhanced medical home model)
    - Estimated savings for FY2006 were \$150-\$170 million relative to what the state (Medicaid) would have spent under previous model
  - Geisinger (ProvenHealth Navigator medical home initiative)
    - Among innovations, patients communicate online with doctors and send health monitoring info including blood glucose and blood pressure
    - Between 2006-2008, demonstrated 20% reduction in hospital readmissions and 18 % reduction in hospital admissions

# THE WALL STREET JOURNAL.

HEART BEAT | JULY 27, 2010

## The Do-It-Yourself House Call

*Insurer-Endorsed Remote-Monitoring Technology Leads Heart Patients to Take Their Readings at Home*

Technology that aims to keep congestive heart failure patients out of the hospital is gaining traction.

The idea is for heart patients to take readings like their weight, blood pressure and other key metrics using wireless and other technologies; the data are then transmitted to a case manager or medical care giver. That way health care givers can catch, and address, warning signs before the patient lands in the ER with shortness of breath or a heart attack. In the past, patients have found such technology difficult to use. But a number of managed-care companies are experimenting with electronic devices meant to make the process easier.

New approaches aim to find problems earlier. A study of 1,450 patients out Tuesday in *Circulation*, a journal of the American Heart Association, showed that implantable defibrillators that wirelessly transmit data on the patient's heart function reduced in-hospital evaluations by 45%. Suspected cardiac events were evaluated in less than two days compared with 36 days.

Another approach being tested by devicemaker CardioMEMS Inc. uses an implantable sensor device to measure pulmonary artery pressure and wirelessly transmit readings to a secure Web site for doctors and nurses. The idea is to detect changes and intervene before the patient has to be hospitalized. The wireless transmitter resulted in a 30% reduction in hospitalization for heart-failure patients, the study of 550 patients released last month showed.



'I was constantly going to the doctor,' said Carolyn Brown of the Bronx, N.Y. 'Now they can tell right away if I am in trouble.'

# One possible solutions stems from Collecting useful salient data in non traditional environments

Many different sensors sensing various environmental and physiological data

Sensors, in, on and off the body:

Salient sensing elements, power, data storage, wireless down and upload.

Receiver:

Wireless down and upload, data Storage, connectivity to the cloud

# Issues around collecting data in non traditional environments

Compliance – if the subject doesn't use the device we won't get any data

Context – if we don't know what they are doing we might miss-understand the data

Artifact – artifacts can and do fool us



# **We will need systems that are “Compliance Independent”**

Ideally the user has to do nothing— no download of data, no changing batteries

The goal is the user forgets they are being monitored

e.g. Sensors in the bed sensing weight, heart rate, motion, pulse ox.

# **We will need systems that are “Compliance Independent”**

Data makes it way to the cloud without  
input from user

Intelligent systems extract useful data

Medical experts use data to manage  
disease

# RFID technology already in use

ID tags for people and equipment  
tracking in hospitals

Some sensors ready. prime time?

# RFID now

## Applications/Solutions

### **Equipment Tracking in Hospitals**



An ActiveWave RFID system can be used to track patients, doctors and expensive equipment in hospitals in real time. RFID tags can be attached to the ID bracelets of all patients, or just patients requiring special attention, so their location can be tracked continuously. ActiveWave RFID technology can also provide an electronic link for wirelessly communicating patient data. An instant assessment of critical equipment and personnel locations

is also possible through RFID technology.

These applications can be combined with ActiveWave access control to allow only authorized personnel to access to critical areas of the hospital.

#### **Benefits of using ActiveWave RFID Systems:**

- ▶ Continuously track each patient's location
- ▶ Track the location of doctors and nurses in the hospital
- ▶ Track the location of expensive and critical instruments and equipment
- ▶ Restrict access to drugs, pediatrics, and other high-threat areas to authorized staff
- ▶ Monitor and track unauthorized persons who are loitering around high-threat areas
- ▶ Facilitate triage processes by restricting access to authorized staff and "approved" patients during medical emergencies, epidemics, terrorist threats, and other times when demands could threaten the hospital's ability to effectively deliver services
- ▶ Use the patient's RFID tag to access patient information for review and update through a hand-held computer

# Patches?

## Diagnostic Sensors Read By RFID-Enabled Cell Phones

by JOSH UMBEHR on May 21, 2007 • 3:20 am



No Comments

Gentag, the leader in wireless sensor technology, is developing a line of medical RFID patches to enable physicians and patients to monitor their health wirelessly. They anticipate that this new technology will simultaneously decrease the cost of health care while drastically increasing patient safety.

By combining RFID cell phones and RFID sensors with cellular networks or the Internet, the consumer will be empowered to read any RFID sensor tag anywhere for almost any application.

A particular focus area for Gentag using RFID cell phones are diagnostic applications. RFID sensors can be integrated into low cost disposable diagnostic devices such as “smart” disposable wireless skin patches or personal drug delivery systems and read directly with a cell phone under existing Gentag/Altivera patents.

The first market application for the smart skin patch is a patient ID and fever onset bandage, integrating Gentag’s proprietary sensor circuit in a disposable skin patch. Applications include





# Patches?

April 20th, 2009

## Medical RFID-Sensor Patch

Posted in [RFID](#) by Melina | [No Comments](#) »

Scientists at the Georgia Institute of Technology recently created a thin, medical patch that uses ultrahigh-frequency (UHF) active RFID sensor tag that's designed to monitor the health and location of its wearers.

The patch is made up of a tag antenna, whose circuit traces and connecting pads are printed on an organic substrate using silver inkjet technology. There's also an IC temperature sensor, battery, and oscillator that are all connected via a silver epoxy.

Since the patch is made of flexible, organic fiber, it can easily be worn using an adhesive backing, or simply sewn into a hospital gown, allowing for a connection to the ECG sensors, which could then wirelessly transmit data from them.

RFID readers could easily be hung on a wall, or embedded in a ceiling, and connected to the internet, using triangulation to pinpoint the location of a patch within 33 feet. With web-based software, such as Google Earth, it would be easy for a computer to display the location of the patch wirelessly.

While the patch is not on the market yet, researchers are currently working with several companies in order to market the RFID medical patch.

**Tags:**

# Problems?

## Study: RFID Tags May Scramble Hospital Equipment



By JR Raphael  
TechNewsWorld  
06/25/08 11:49 AM PT

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**A study cautions that radio frequency chips can interfere with hospital equipment. While researchers identified 22 "hazardous" cases of interference, the head of an RFID industry group says the likelihood of injury is low and the study demonstrates a need for industry standards.**

# Possible PSWT target areas

Smart patient ID

In home/office sensors

On body sensors

Medication compliance

# **ID bracelet or card**

## **(in and out of hospital)**

Once a day (in a USA hospital) a patient is miss identified

Patient ID can contain useful data other than who I am

- Who, what, when
- Allergies, genetic information

Patient ID might also allow for the storage processing of data

- What and when medications were take
- What batch of blood etc

Questions:

Will patient ID tags posse interference risk or health risks

# Bed Sensors

Sensors in the bed could measure various attributes

Pressure – management of bed sores

Weight – identify weight gain (fluid retention)

Heart rate – various diseases

Motion -- various diseases



# Wish list for PWST

- Very Cheap -- cents (disposable)
- Long range (100's ft)
- Provide non trivial power for sensors without risk to patients – how much?
- Buffer power for use whilst not being illuminated
- Store significant amounts of data (both read and write)
- Mechanically flexible
- Reliable/Robust
- Configurable
- Very small
- Easy to integrate
- HIPPA compliant

**Thank you**