Remote Ventilated Patient Management Using Mobile Devices

Armando Kurili
Clinical Specialist

Brian Smith
Virtual Health Support Analyst
WHAT HAPPENED ONLY 20 YEARS AGO
WHAT HAPPENED ONLY 10 YEARS AGO

• iPhone
• Facebook
• Twitter
• Airbnb
• Hadoop
• iCloud
Let Me Breathe!
Remote Ventilator Management

Julie Hanley & Armando Kurili
(Adult Assisted Ventilation Clinic - University of Michigan Internal Medicine)

Brian Smith & Steve Jordan
(Virtual Health Support Analyst)
# A Team Effort – The Initial Telemedicine Ventilation Team

### Adult Assisted Ventilation Clinic Team Members
- Robert Sitrin, MD & Director
- Kristy Bauman, MD
- Julie Hanley, NP
- Armando Kurili, RT

### Virtual Health Team Members
- Andrew Haig, MD & Director
- Noura Bashshur, Manager
- Steve Jordan, Operations
- Brian Smith, Engineer
- Michael Gates, Admin
Adult Assisted Ventilation Clinic Mission

Intervene and triage ventilation patients at home or in the clinic to resolve their problems and avoid:

- Unnecessary trips to the ED
- Costly hospital admissions – complex patient so tend to admit to be safe
- Excessive treatments
- Time consuming and logistically complex travel to the clinic or patient’s home
The Clinical Ventilator Support Team

- Physician (MD)
- Nurse Practitioner (NP)
- Registered Nurse (RN)
- Respiratory Therapist (RT)
- Caregiver/Nurse at Patients Home
- Patient’s Family
Background on NMD and SCI Patients

- 276,000 SCI patients in the U.S. in 2014, 38,000 SCI’s at or above C4 – many 100% mechanical ventilator dependent (Jones et al., 2015).
- Number with NMDs hard to estimate (>30 types - Deenen et al., 2015).
- Cost for three (ALS, DMD, and DM) = $2.26B annually (Larkindale et al., 2014).

Estimated Lifetime Costs for Patients with Spinal Cord Injuries

<table>
<thead>
<tr>
<th>Severity of Spinal Cord Injury</th>
<th>Average Yearly Expenses (in 2014 dollars)</th>
<th>Estimated Lifetime Costs by Age At Injury (discounted at 2%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First Year</td>
<td>Each Subsequent Year</td>
</tr>
<tr>
<td>High Tetraplegia (C1-C4)</td>
<td>$1,064,716</td>
<td>$184,891</td>
</tr>
<tr>
<td>Low Tetraplegia (C5-C8)</td>
<td>$769,351</td>
<td>$113,423</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>$518,904</td>
<td>$68,739</td>
</tr>
<tr>
<td>Incomplete Motor Functional at Any Level</td>
<td>$347,484</td>
<td>$42,206</td>
</tr>
</tbody>
</table>

ALS = amyotrophic lateral sclerosis, DMD = Duchenne muscular dystrophy, and DM = myotonic dystrophy

DeVivo et al. (2011) and converted to 2014 dollars by Spinal Stats (2014).
Some Causes of Neuromuscular Respiratory Failure

- Spinal Muscular Atrophy (SMA)
- Multiple Sclerosis (MS)
- Poliomyelitis
- Duchenne Muscular Dystrophy
- And ~30 Other Causes of Neuromuscular Respiratory Failure
The Need for Mechanical Ventilation

• Breathe for People That Have Lost All Ability to Breathe On Their Own
• Get Oxygen Into The Lungs and to cells, tissues, and organs
• Remove Carbon Dioxide from the Body
• Help People Breathe Easier
Many Types of Ventilators


LTV 950

Trilogy 100

Trilogy 200

Puritan Bennett 360

Newport™ HT70 Plus™


Puritan Bennett 840

LTV 1000

IVent 201

Esprit
Set-up and Adjusting a Trilogy 100 Ventilator ... Read the Instructions!

Adjusting a Trilogy 100 Ventilator (cont’d)

“Dialing In” a Trilogy 100 Can Be A Complex Task

Over 200 Setting Options


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<table>
<thead>
<tr>
<th>9 Different Modes</th>
<th>Therapy Modes</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>CPAP</td>
</tr>
<tr>
<td>Dual Prescription</td>
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<tr>
<td>Circuit Type</td>
<td>✓</td>
</tr>
<tr>
<td>CPAP</td>
<td>✓</td>
</tr>
<tr>
<td>IPAP</td>
<td>✓</td>
</tr>
<tr>
<td>AVAPS (On, Off)*</td>
<td>✓</td>
</tr>
<tr>
<td>IPAP Max Pressure</td>
<td>✓</td>
</tr>
<tr>
<td>IPAP Min Pressure</td>
<td>✓</td>
</tr>
<tr>
<td>EPAP</td>
<td>✓</td>
</tr>
<tr>
<td>Inspiratory Pressure</td>
<td>✓</td>
</tr>
<tr>
<td>Pressure Support (PS)</td>
<td>✓</td>
</tr>
<tr>
<td>PEEP</td>
<td>✓</td>
</tr>
<tr>
<td>Tidal Volume</td>
<td>✓</td>
</tr>
<tr>
<td>Breath Rate</td>
<td>✓</td>
</tr>
<tr>
<td>Inspiratory Time</td>
<td>✓</td>
</tr>
<tr>
<td>Trigger Type*</td>
<td>✓</td>
</tr>
<tr>
<td>Flow Trigger Sensitivity</td>
<td>✓</td>
</tr>
<tr>
<td>Flow Cycle Sensitivity</td>
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<tr>
<td>Ramp Length</td>
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</tr>
<tr>
<td>Ramp Start Pressure</td>
<td>✓</td>
</tr>
<tr>
<td>Flex *</td>
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</tr>
<tr>
<td>Rise Time</td>
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<tr>
<td>Flow Pattern</td>
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<tr>
<td>Sigh</td>
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<tr>
<td>Circuit Connect</td>
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<tr>
<td>Apnea</td>
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<tr>
<td>Apnea Rate</td>
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<tr>
<td>High Vte*</td>
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</tr>
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<tr>
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</tr>
<tr>
<td>Low Vti*</td>
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</tr>
<tr>
<td>High Minute Ventilation</td>
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<tr>
<td>Low Minute Ventilation</td>
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<tr>
<td>High Respiratory Rate</td>
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<tr>
<td>Low Respiratory Rate</td>
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<tr>
<td>High Inspiratory Pressure</td>
<td>✓</td>
</tr>
<tr>
<td>Low Inspiratory Pressure</td>
<td>✓</td>
</tr>
</tbody>
</table>

* AVAPS, Trigger Type, Flex, High Vte and Low Vte settings are only available with the Passive circuit type. Trigger Type is not available with the Passive circuit in CPAP mode. High Vti and Low Vti settings are only available with the Active circuit with PAP.
Managing Screens and Parameters Can Be Challenging
Mechanical Ventilator Summary:

Assembling, Setting Ventilator Modes and Parameters, and Trouble Shooting a Problem are Complex Tasks – Now Add the Fact That Your Patient Can’t Breathe!
Thinking About Telemedicine? Where Do You Begin?

Virtual Health Can Help ...
Virtual Health Mission

Support UMHS Clinical Specialties to Integrate Telemedicine Capabilities Into Their Clinical Workflows to Improve and Enable Remote Patient Care
Clinical Telemedicine Consultation Process

1. Discovery Meetings

2. Workflow Discussions eHealth/Specialty

3. Develop Business Plan

4. Setup & Implement Pilot

5. Go Operational
<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Cameras, Microphones, Speakers, Software</th>
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<tbody>
<tr>
<td>Problems</td>
<td>Networking, Firewalls, NAT</td>
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<tr>
<td>Patient Needs</td>
<td>Bandwidth</td>
</tr>
<tr>
<td>Project Mgmt</td>
<td>Packet Loss</td>
</tr>
<tr>
<td>Workflows</td>
<td>Frame Rates</td>
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<tr>
<td>Quality</td>
<td>Resolution</td>
</tr>
<tr>
<td>Goals</td>
<td>Echos/CTs/MRI/MRIs/Xrays</td>
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<tr>
<td>Consent</td>
<td>Peripherals (Stethoscopes, EKG, Ultrasound,..)</td>
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<tr>
<td>Schedule</td>
<td>Vitals (BP, Pulse, Weight, Temp, SpO2, CO2, Sounds, Glucose..)</td>
</tr>
<tr>
<td>Legal/Billing</td>
<td>Risks, Costs,..</td>
</tr>
<tr>
<td></td>
<td>Site Certification</td>
</tr>
<tr>
<td></td>
<td>Training</td>
</tr>
<tr>
<td></td>
<td>Support</td>
</tr>
</tbody>
</table>

**Telemedicine Business Development Plan Template – *What do we care about?***

- Stakeholders
- Problems
- Patient Needs
- Project Mgmt
- Workflows
- Quality
- Goals
- Consent
- Schedule
- Legal/Billing

- Cameras, Microphones, Speakers, Software
- Networking, Firewalls, NAT
- Bandwidth
- Packet Loss
- Frame Rates
- Resolution
- Echos/CTs/MRI/MRIs/Xrays
- Peripherals (Stethoscopes, EKG, Ultrasound,..)
- Vitals (BP, Pulse, Weight, Temp, SpO2, CO2, Sounds, Glucose..)
- Risks, Costs,..
- Site Certification
- Training
- Support
THREE PROBLEMS AREAS

1. Patient/Caregiver Problems

2. Ventilator Problems

3. Remote Telephone Support Problems
Patient/Caregiver Problems

- Patient respiratory changes
- Blood clots
- Airway Mucus / Can’t cough)
- Infections
- Pressure Wounds
- Bruises other wounds
- Acute Resp. Distress Syn. (ARDS)
- Pneumothorax
- VAP (Vent-Associated Pneumonia)
- Oxygen Toxicity (O2 High)
- Lung Damage
- New or Inexperienced Caregiver
- Deciding when to go to the ED
- Unsure how to adjust ventilator settings
- Difficult to travel to clinic 1 or 2 hours away and 100s of miles
- Telephone support & guidance is all based on verbal exchange
- New problems with patient or ventilator
- How do you describe sputum color and viscosity?
Ventilator Problems

- Battery Changes
- Leaks in the tubing or connections
- Incorrect settings
- What is causing alarms to trigger???
- High pressure blocks
- Difficult to debug tube leaks over the phone
- Replacing filters, batteries, SIM card
- Complexity of Modes and Parameters
Telephone Only Remote Support Problems

- Does patient/caregiver description match what clinician perceives?
- Is the caregiver adjusting settings correctly on vent or cough assist devices?
- How do you check patient’s throat?
- How do you examine bruises/sores?
- Guiding caregiver through a new procedure.
Telephone Limitations

- **Uncertainty** without seeing
- Caregiver **description** vs. clinician **perception**
- Clinician **guidance** vs. caregiver **execution**
- Difficult to guide caregiver through **steps** (e.g. ventilator adjustments – which screen?)
- **Difficult to adjust** multiple interacting variables
- Picture is worth a 1000 words – but more time required in verbal interaction to accomplish tasks

Blindfolded Image retrieved on 11/ http://travelnursingblogs.com/companies-and-contracts/
The Proposed Solution

- Leverage patient owned technology – smartphones, tablets, laptops, or desktops
- Use video conferencing to create a “window” into the patients/caregivers remote home environment
So You Want to “Skype”? Finding Video Conferencing Solutions

Many Options …

Vidyo
Cisco Jabber
Lync
Skype
AdobeConnect
GoToMeeting
Polycom Real Presence Mobile
Blue Jeans
Lifesize
HIPAAChat
WebEx
Facetime
VSee
GoToMeeting

Many Options …
Video Conferencing Requirements or “Musts”!

- Must be **HIPAA/HITECH** Compliant
- Must work **outside** the UMHS **VPN**
- Must **not** be **blocked** by the UMHS **firewall**
- Must work with **Apple, Android, and Windows** products ... what the patient owns
- Must be **easy to use and support**
- Must have **adequate resolution** to see ventilator (settings screen) and patient (e.g. throat, tracheostomy, pressure wounds ...)
- Must **leverage UMHS/Patient infrastructure**
UMHS vs. Patient Owned Infrastructure

Our ACO has 120,000 Medicare Beneficiaries ...

120,000 Patients X $300/Smartphone = $36,000,000!

Obsolete in a year or so!
HIPAA/HITECH Cloud/Server, Physical, Technical, & Administrative Requirements

Cloud & Server Standards

<table>
<thead>
<tr>
<th>Physical Safeguards: 45 CFR §164.310 Requirements</th>
<th>Subsections of §164.310</th>
<th>Technical Safeguards: 45 CFR §164.308 Requirements</th>
<th>Subsections of §164.308</th>
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<tbody>
<tr>
<td>Facility Access Controls (STANDARD)</td>
<td>§164.310(a)</td>
<td>Access Control (STANDARD)</td>
<td>§164.308 (a)(1)</td>
</tr>
<tr>
<td>Contingency Operations (ADDRESSABLE)</td>
<td>§164.310(a)(ii)</td>
<td>Unique User ID (REQUIRED)</td>
<td>§164.308 (a)(3)</td>
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<tr>
<td>Facility Security Plan (ADDRESSABLE)</td>
<td>§164.310(b)</td>
<td>Emergency Access Procedure (REQUIRED)</td>
<td>§164.308 (a)(5)</td>
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<td>§164.310(b)(ii)</td>
<td>Automatic Log-off (ADDRESSABLE)</td>
<td>§164.308 (a)(5)(A)</td>
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<td>Maintenance Records (ADDRESSABLE)</td>
<td>§164.310(c)</td>
<td>Encryption and decryption (ADDRESSABLE)</td>
<td>§164.308 (a)(5)(B)</td>
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<td>Workstation Use (STANDARD)</td>
<td>§164.312</td>
<td>Audit Controls (STANDARD)</td>
<td>§164.308 (a)(5)(C)</td>
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<td>Workstation Security (STANDARD)</td>
<td>§164.312 (c)(1)</td>
<td>Integrity Controls (STANDARD)</td>
<td>§164.308 (a)(5)(D)</td>
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<td>Device and Media Controls (STANDARD)</td>
<td>§164.312 (c)(2)(iii)</td>
<td>Mechanism to authenticate electronic protected health information (ADDRESSABLE)</td>
<td>§164.308 (a)(6)</td>
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<td>Disposal (REQUIRED)</td>
<td>§164.312 (c)(2)(iv)</td>
<td>Person or Entity Authentication (STANDARD)</td>
<td>§164.308 (a)(7)(A)</td>
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<tr>
<td>Media Re-use (REQUIRED)</td>
<td>§164.312 (e)(1)</td>
<td>Transmission Security (STANDARD)</td>
<td>§164.308 (a)(7)(B)</td>
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<td>Accountability (ADDRESSABLE)</td>
<td>§164.312 (e)(2)</td>
<td>Integrity Controls (ADDRESSABLE)</td>
<td>§164.308 (a)(7)(C)</td>
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<tr>
<td>Data Backup and Storage (ADDRESSABLE)</td>
<td>§164.312 (e)(2)(i)</td>
<td>Encryption (ADDRESSABLE)</td>
<td>§164.308 (a)(7)(D)</td>
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</table>

HIPAA/HITECH Regulations!
### Penalties for Violating HIPAA/HITECH

**Table 2. TIERS OF CIVIL MONEY PENALTIES (CMP) RELATING TO DEFINED LEVEL OF GUILT**

<table>
<thead>
<tr>
<th>Violation Category</th>
<th>Potential Cost of Violation</th>
<th>Total CMP for Violations of an Identical Provision in a Calendar Year</th>
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<tbody>
<tr>
<td>Unknowing</td>
<td>$100 – $50,000</td>
<td>$1,500,000</td>
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<tr>
<td>Reasonable Cause</td>
<td>$1,000 – $50,000</td>
<td>$1,500,000</td>
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<tr>
<td>Willful Neglect – Corrected</td>
<td>$10,000 – $50,000</td>
<td>$1,500,000</td>
</tr>
<tr>
<td>Willful Neglect – Not Corrected</td>
<td>At least $50,000</td>
<td>$1,500,000</td>
</tr>
</tbody>
</table>

**HIPAA Enforcement**

**CRIMINAL PENALTIES**

- Knowingly or wrongfully disclosing or receiving PHI:  
  $50,000 fine and/or one year prison time
- Commit offense under false pretenses:  
  $100,000 fine and/or five years prison time
- Intent to sell PHI or client lists for personal gain or malicious harm:  
  $250,000 fine and/or ten years prison time.
- Again, you can be personally liable!

(Penalties, 2014)
Infrastructure:
Point-to-Point vs. Multi-Point Connectivity

**Point-to-Point Connections (2 only)**
- **Apple Smartphone or Tablet**
- **Android Smartphone or Tablet**
- **Laptop**
- **Desktop PC**

**VC Applications:**
- Blue Jeans
- HipaaChat
- Vidyo
- EPIC
- GoToMeeting
- Real Presence

**Multi-Point Connections (> or = 2)**
- **iPhone**
- **iPad**
- **Android Smartphone or Tablet**
- **Desktop**
- **Laptop**
- **Laptop + Web Cam**

**Any H-323 Based Codec**

**H-323: Polycom Real Presence, Blue Jeans, Cisco ...**

*MCU = Multipoint Control Unit for any H-323 Based Connections*
1. Download HipaaChat from App Store
2. Select Patient from Contact List

Video Conference
Front/Back Camera Select
Open real-time voice communication
Send Images

Text
Send/Receive Walkie-Talkie Voice Messages
Take a Picture

(HipaaChat, 2014)
Can People Be Guided Remotely Using Mobile Devices?

The “Zero Knowledge Ventilator Test”
The “Zero Ventilator Knowledge Test”

Turning Off Alarm on LTV 950

Adjusting LTV 950 Settings

Adjusting Settings on A Trilogy 950

Now – Checking Pressure

Note: White iPhone is for LED light

Throat Examination

Battery Check
The “Zero Ventilator Knowledge Test”

“Dialing In” On A Trilogy 100

SIM Card Directions

Checking A Bruise

Checking Tube Connections

Simulating Breathing Sounds
Our First Test Patient ...

- Patient #1 Downloaded HipaaChat, Enabled Cameras, Entered Clinic’s Phone # & Email Address ... Then Called Us to Check His Setup

- 100% Mechanical Ventilator Dependent

- Uses a Mouth Stick to Control His iPhone 4S and His iPad Mini Held in a Special Rack Near His Face

- His Caregiver Was There to Assist

- NP and RT Used an iPad Air
Connecting Clinician to Patient/Caregiver at Home

Patient #1
At Home

iPhone 4S
iPad Mini
HipaaChat App

Internet/Cellular
WiFi/Cellular

University of Michigan Hospital System
Adult Assisted Ventilation Clinic
HipaaChat App
iPad Air

(Patient Image, 2014)
First Patient Results Using an iPad Mini

Talking Face-to-Face

Catching Up!

Checking Tracheostomy

Checking Vent Tubing

Double Checking Vent Settings

Reviewing Current Cough Assist Settings
First Patient Results with iPhone 4S

Adjusting Inhale & Exhale Pressure and Time on Cough Assist Machine

Examined Tongue And Throat**

Able to Observe Leg Spasms Visually

Checked Nail Bed & Capillary Refill**

We Were Able to See His Home Environment **

We Were Even Introduced To His Dog **

** Not actual images, used (Some Images, 2014)
Current Status

• **Workflows being finalized**

• Need to **Survey Vent Patients** and Caregivers to:
  – Determine What Technologies They Own
  – Their Openness to Telemedicine

• Resolve **Billing Issues**

• **Refine Videoconferencing** (Lighting, Acceptable Devices, Software/Device Versions, Camera Resolutions, etc.)

• Request Vendors **Activate LED** on Smartphone/Tablet for Illumination

• More Research
“Ventilator Telemedicine Simulation Project” Case Script
Some Other Telemedicine Projects at UMHS

- Remote Second Opinions (RSO) – many specialties
- Telemedicine Home Pharmacy Management
- HomeMed Infusion Pump Roll-Out and Training
- Teleophthalmology Remote/home Consultations
- Variety of Survival Flight Telemedicine Projects
- Infant Oximetry – Pediatric Cardiology
- Pediatric Critical Care Consultations
- Pediatric Congenital Heart Patient at Home Follow-Up
- State Initiative for Telehealth - Peds Epilepsy
- NeuroSport Concussion Teleconsultations

- Teleneurology
- Telestroke
- Inflammatory Bowel Disease
- Neonatology – Allegiance
- Bladder Cancer Post-Op Follow-up
- Teledermatology (Store & Forward)
- Home Speech/Language Therapy
- Pediatric Nephrology ICU
- Partial Nephrectomy Post-Op Follow-Up
- Psychiatry Teleconsultations
- Home Speech/Language Therapy

... quite a few more
Disruptive Models and Technologies in Medicine
Disruptive Business Models in Medicine

A new ecosystem of disruptive business models must arise
# Telemedicine Technology Building Blocks

- Sensors
- Processors
- LCDs
- Optics
- Storage
- Wired/Wireless Communications
- Software Tools
- Peripherals (Stethoscope, US, ...)
- Algorithms
- Applications
- Networking
- Cloud
- Materials Science
- Data Mining
- AI
- Analytics
- **Security ...**
  (always last - pacemaker)
“Future of Medicine” Books by Dr. Eric Topol

• The Creative Destruction of Medicine

• The Patient Will See You Now
FIGURE INTRO.1: The transformation from medicine today (old, dumbed down) to new, individualized medicine that is enabled by digitizing humans.

<table>
<thead>
<tr>
<th></th>
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<tr>
<td>6.3 Billion</td>
<td>500 Million</td>
<td>0.08</td>
<td>1.84</td>
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<td>6.8 Billion</td>
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<td>7.6 Billion</td>
<td>50 Billion</td>
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</table>

Medweb Telemedicine Kit $2500!

A Abdominal Ultrasound
B Eye-Fundus Scope
C Episcope
D Bluetooth Pulse Oximeter
E Ultrasound Gel
F Digital EKG
G Bluetooth Stethoscope
H Camera Direct wifi SD card
I Tablet
J Multi-Scope
K Otoscope

FFMI Opportunity

http://www.medweb.com/docs/MedwebDEK.pdf
A Poor Man’s Google Glass
(A Prototype: A Wire Hanger and Rubber Band)

- Remote Trouble Shooting
- Remote Education
- Hands Free for Performing Tasks Under Observation and Immediate Feedback
- New Infusion Pump Rollout Trouble Shooting and Training
- Remote Vent Patient Care and Adjusting Vent/Cough Assist Devices
- Show Someone “How To”, Then Have Them Show You That They Know “How To”
More People Have Cell Phones Than Toilets, U.N. Study Shows

Out of the world’s estimated 7 billion people, 6 billion have access to mobile phones. Only 4.5 billion have access to working toilets.

Phones vs. Thrones
Smart Toilets: Doctors in Your Bathroom

Toto's new Intelligence Toilet II monitors weight, blood sugar levels, and other vital signs, transferring data to your computer for analysis via WiFi.

Summary: A New Vision For Healthcare

_The 3 Cares – Eric Dishman, Intel_

- **Care Anywhere** (Home, Work, School, Gym, Car, ... while sleeping)
- **Care Networking** (From Social Networking to Remote Second Opinions)
- **Care Customization** (Population vs. Individual)

__The 8-Ps:__

Prediction, Prevention, Personalization, Participation, Price, Population, Performance (Quality/Speed), Process (Reliability)
Thank You.
References

- Haig, A. (2014). Experiment Test Cases for Remote Mechanical Ventilator Management (not publically available yet)