

Remote Ventilated Patient Management Using Mobile Devices





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)

<u>A Team Effort –</u> The Initial Telemedicine Ventilation Team





- 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

	Average Yearly Exp	penses (in 2014 dollars)	Estimated Lifetime Costs by Age At Injury			
Severity of Spinal Cord Injury			(discounted at 2%)			
	First Year	Each Subsequent Year	25 Years Old	50 Years Old		
High Tetraplegia (C1-C4)	\$1,064.716	\$184.891	\$4,724,181	\$2,596,329		
Low Tetraplegia (C5-C8)	\$769,351	\$113,423	\$3,451,781	\$2,123,154		
Paraplegia	\$518,904	\$68,739	\$2,310,104	\$1,516,952		
Incomplete Motor Functional	\$347,484	\$42,206	\$1,578,274	\$1,113,990		
at Any Level						

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



IVent 201

LTV 1000

Puritan Bennett 840



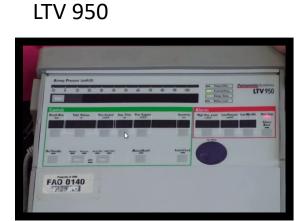




Puritan Bennett 360



Trilogy 100

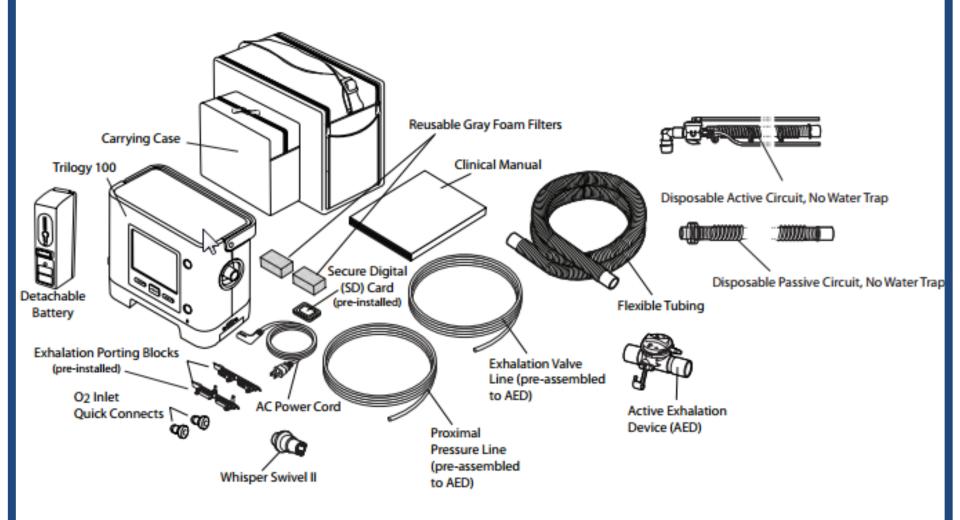


Newport™ HT70 Plus™

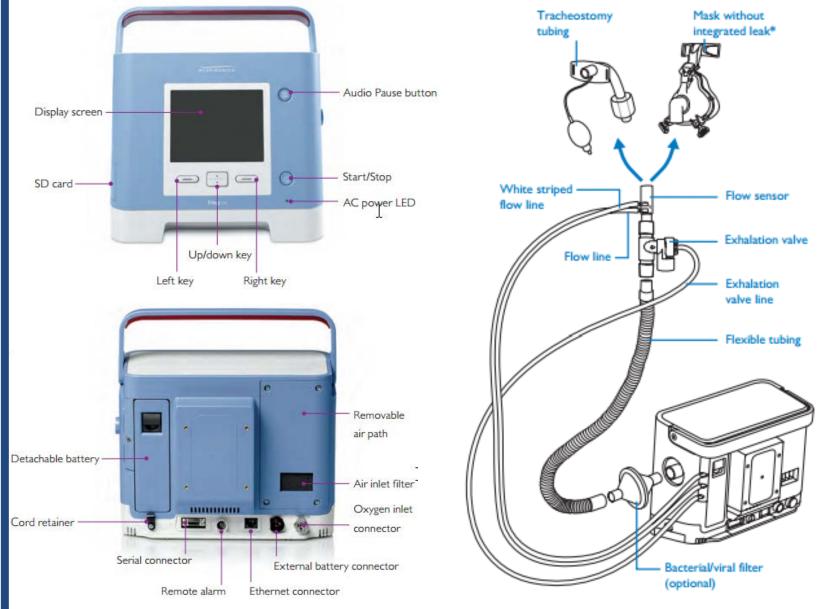


Trilogy 200

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



Adjusting a Trilogy 100 Ventilator (cont'd)



https://www.usa.philips.com/b-dam/b2bhc/us/whitepapers/treating-restrictive-lung-disease-at-home/1061109_TrilogyWrkshpUS_Booklet.pd

"Dialing In" a Trilogy 100 Can Be A Complex Task



Over 200 Setting Options

Parameters

36 Variable

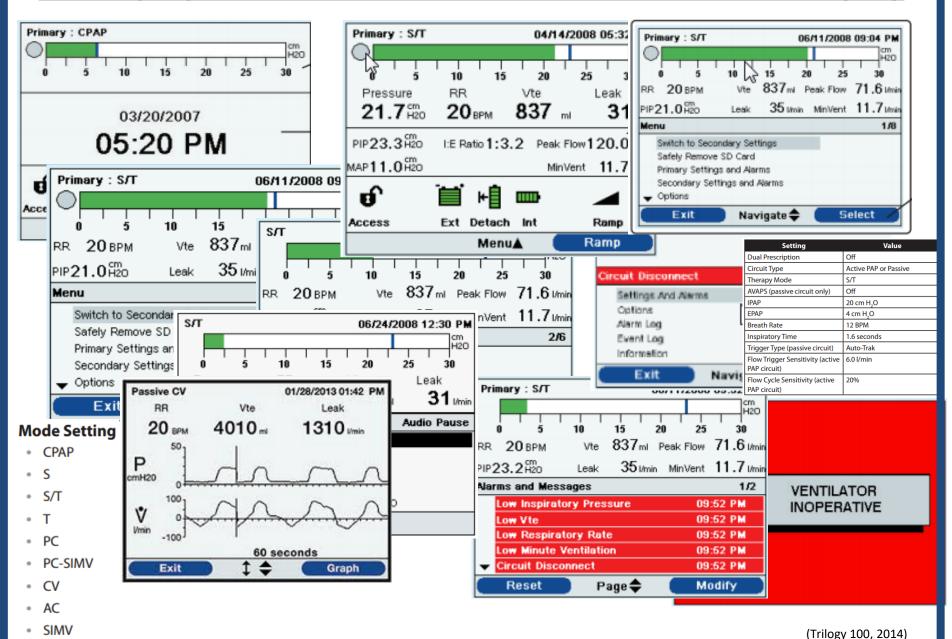
http://www.ahcah.c om/Manuals/Trilogy %20100%20Patient %20Manual.pdf

9 Different Modes

		Therapy Modes								
		CPAP	s	S/T	T	PC	PC-SIMV	cv	AC	SIMV
	Dual Prescription	√	√	- √	√	- √	√	- √	-√	- √
	Circuit Type	√	√	- √	- √	- √	√	-√	-√	- √
	CPAP	- √								
	IPAP		√	√	√	- √				
	AVAPS (On, Off)*		√	√	√	✓				
	IPAP Max Pressure		√	√	√	- √				
	IPAP Min Pressure		√	√	√	- √				
	EPAP		√	- √	√	- √				
	Inspiratory Pressure						√			
	Pressure Support (PS)						√			- √
	PEEP						√	-√	-√	- √
	Tidal Volume		√	√	√	- √		√	√	- √
	Breath Rate			√	√	- √	√	√	√	- √
	Inspiratory Time			√	✓	- √	✓	✓	-√	- ✓
	Trigger Type*		√	√		- √	√		-√	- √
5	Flow Trigger Sensitivity	√	-√	√		- √	√		-√	- √
Parameters	Flow Cycle Sensitivity	√	√	√			√			- √
ē	Ramp Length	√	√	√	√	- √				
2	Ramp Start Pressure	√	√	- √	- √	V				
8	Flex *	√	√							
Therapy	Rise Time		√	√	√	- √	√			- √
يِّ	Flow Pattern							√	√	- √
_	Sigh							√	√	- √
	Circuit Disconnect	√	√	√	√	-√	√	√	√	- √
	Apnea	√	√	√		-√	√		√	- √
	Apnea Rate		-√	√		-√	√		-√	- √
	High Vte*	- √	-√	- √	- √	- √	√	- √	-√	- √
	Low Vte*	√	√	√	√	-√	√	√	√	- √
	High Vti*	√	√	√	√	√	√	√	√	- √
	Low Vti*	√	√	√	√	-√	√	√	√	- √
	High Minute Ventilation	√	-√	√	√	-√	√	√	√	- √
	Low Minute Ventilation	√	-√	√	√	-√	√	√	-√	- √
	High Respiratory Rate	√	√	√	√	-√	√	-√	√	- √
	Low Respiratory Rate	√	√	√	√	-√	√	-√	√	- √
	High Inspiratory Pressure							-√	-√	- √
	Low Inspiratory Pressure							√	√	- √
	DE Tripper Type Elev High Vts :	and I must be			- Habita	ish short	and an electric	ma Tria	T	le not

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!

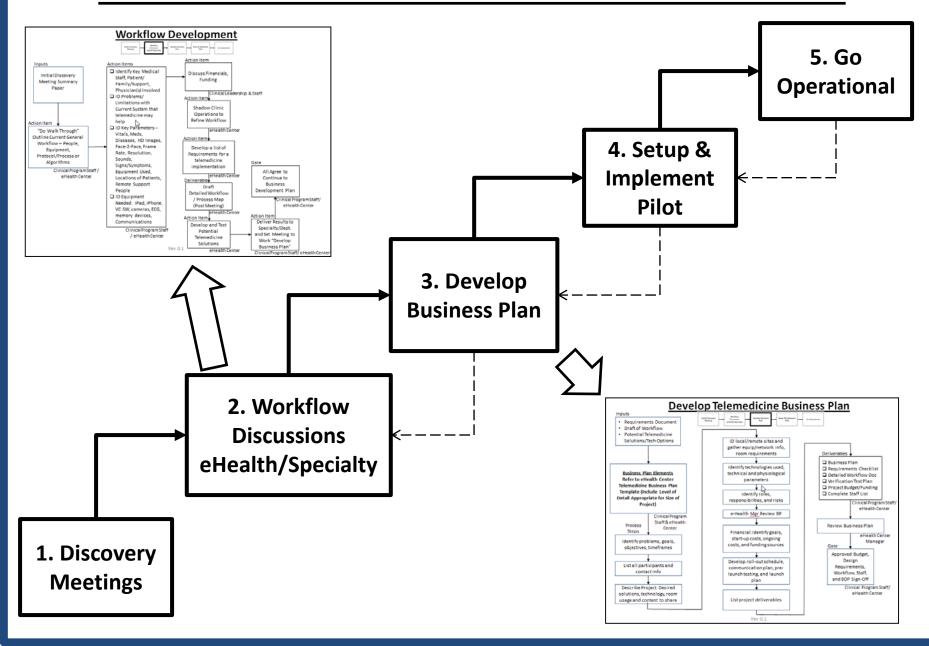
Thinking About Telemedicine? Where Do You Begin?

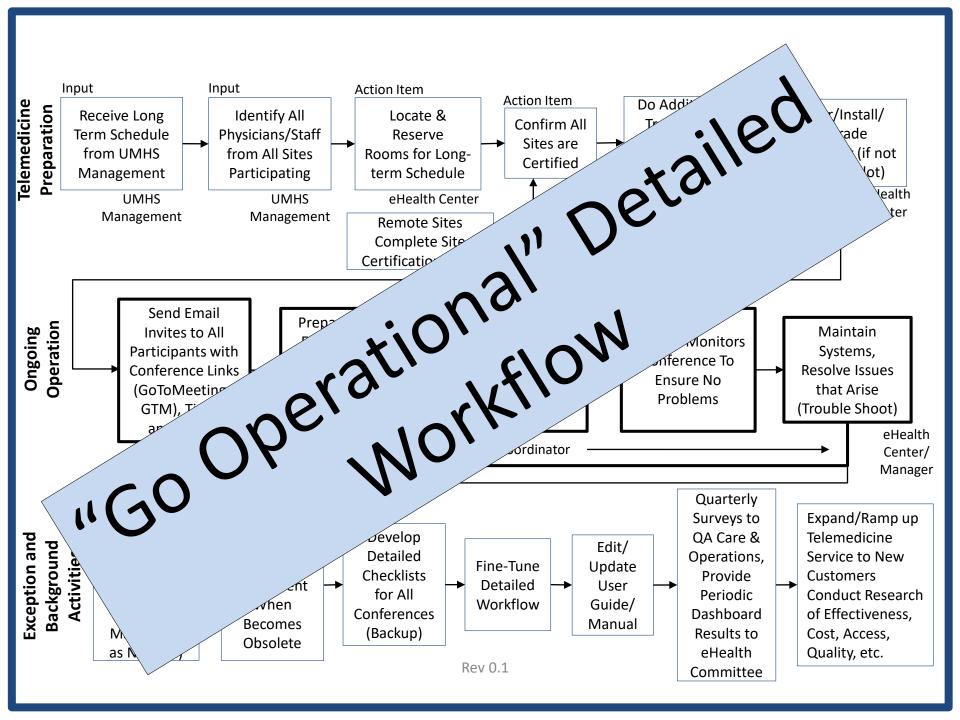
Virtual Health Can Help ...

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





<u>Telemedicine Business Development Plan</u> <u>Template – What do we care about?</u>

- 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/ MRIs/Xrays

- Peripherals
 (Stethoscopes,
 EKG,
 Ultrasound,...)
- Vitals (BP, Pulse, Weight, Temp, SpO2, CO2, Sounds,
- Risks, Costs,...

Glucose..)

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

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

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





Video Conferencing Requirements or "Musts"!
☐Must be <u>HIPAA/HITECH</u> Compliant
☐Must work <u>outside</u> the UMHS <u>VPN</u>
☐Must <u>not</u> be <u>blocked</u> by the UMHS <u>firewall</u>
☐Must work with Apple, Android, and
Windows products what the patient owns
☐Must be <u>easy to use and support</u>
☐Must have <u>adequate resolution</u> to see
ventilator (settings screen) and patient (e.g.
throat, tracheostomy, pressure wounds)
☐ Must leverage UMHS/Patient infrastructure

<u>UMHS vs. Patient Owned Infrastructure</u>

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

	oud & Se	rver Standards	
□ HIPAA	_ S	OC 3	□ ISO 27001
□ SOC 1 Type II	□ F	ISMA	□ITAR
□ SSAE 16		IACAP	□ Sarbanes-Oxley (SOX)
☐ ISAE 3402 (formerly SAS 70 Ty	pe II) □ [edRAMP	□ FIPS 140-2
□ SOC 2, Type II	□ F	CI DS\$/	
Physical Safeguards: 45 CFR §164.310	Requirements		
Safeguard Title	Subsections of §164.3	5 CF	R §164.308 Requirements
Facility Access Controls (AT AND ARD)	§164.310(a)		Subsections of §164.308
Contingency Operations (AAORESSABLE)	§164.310		Q) §164.308 (a)(1)
Facility Security Plan (ADDRESSABLE)	5150	1	§164.308 (a)(1)(ii)(A)
Access Control and Validation Procedures (ADDRESSABLE)	- 3.2	RED) Review (REQUII Onsibility (STANDAR Security (STANDARD) Ind/or Supervision (ADDRESSABLE) Ermination Procedures (ADDRESSABLE) Information Access Management (STANDA) Isolation of Clearinghouse Functions (REQUI	§164.308 (a) (1)(ii)(B)
		(ED)	§164.308 (a) (1)(ii)(C)
Maintenance Records (ADDRESSABLE)		Review (REQUII	RED) §164.308 (a)(1)(ii)(D)
Workstation Use (STANDARD)		ponsi bility (STANDAR	(D) §164.308 (a)(2)
Workstation Security (STAN DAR D)		security (STANDARD)	§164.308 (a)(3)(i)
Device and Media Controls (STANDAB		and/or Supervision (ADDRESSA	ABLE) §164.308 (a)(3)(ii)(A)
Dis posal (REQUIRED)		kforce Clearance (ADDRESSABLE)	§164.308 (a) (3)(ii)(B)
Media Re-use (REQU		ermination Procedures (ADD RESSABLE	§164.308 (a) (3)(ii)(C)
Accountability (AD DR ESS		Information Access Management (STANDA	RD) §164.308(a)(4)(i)
Data Backup and Storage (ADDR)	`	Isolation of Clearinghouse Functions (REQUI	RED) §164.308 (a)(4)(ii)(A)
	_ ()_	Access Authorization (ADDRESSABLE)	§164.308 (a) (4)(ii)(B)
Technical Safeguards: 45 CFN		Access Establishment and Modification (ADDRE	SSABLE) §164.308 (a)(4)(ii)(C)
_		Security Awareness and Training (STANDAR	RD) §164.308(a)(5)(i)
Safeguard Title	W >	Security Reminders (ADDRESSABLE)	§164.308 (a)(5)(ii)(A)
Access Control (STANDARD)		Protection from Malware (ADDRESSABLE	§164.308 (a) (5)(ii)(B)
Unique User ID (REQUIRED)		Log-in Monitoring (ADDRESSABLE)	§164.308 (a)(5)(ii)(C)
Emergency Access Procedure (REQUIRED)	<u>∠</u>)(īi)	Password Management (ADDRESSABLE)	§164.308 (a)(5)(ii)(D)
Automatic Log-off (ADDRESSABLE)	(a)(2)(iii)	Security Incident Procedures (STANDARD	
Encryption and decryption (ADDRESSABLE)	4.312 (a)(2)(iv)	Response and Reporting (REQUIRED)	§164.308 (a) (6)(ii)
Audit Controls (STANDARD)	§164.312 (b)	Contingency Plan (STANDARD)	§164.308 (a)(7)(i)
Integrity (STANDARD)	§164.312 (c)(1)	Backup Plan (REQUIRED)	§164.308 (a)(7)(ii)(A)
Mechanism to authenticate electronic protected		Disaster Recovery Plan (REQUIRED)	§164.308 (a) (7)(ii)(B)
he alth information (ADD RESSABLE)	§164.312 (c)(2)	Emergency Mode Operations Plan (REQUIR	
Person or Entity Authentication (STANDARD)	§164.312 (d)	Testing and Revision Procedures (ADDRESSA	
Transmission Security (STANDARD)	§164.312 (e)(1)	Application and Data Criticality Analysis (ADDRE	
	§164.312 (e)(2)(i)	Evaluation (periodic reviews) (STANDARD Business Associate Contracts (and other Arrangements	
Integrity Controls (ADDRESSABLE)		Written Contract or Other Arrangements (REQ	7 - 177
Encryption (ADD RESSABLE)	§164.312 (e)(2)(ii)	Written contract or other Arrangements (REQ	5 104.308 (0)(4)

Penalties for Violating HIPAA/HITECH

Table 2. TIERS OF CIVIL MONEY PENALTIES (CMP) RELATING TO DEFINED LEVEL OF GUILT				
Violation Category	Potential Cost of Violation	Total CMP for Violations of an Identical Provision in a Calendar Year		
Unknowing	\$100 - \$50,000	\$1,500,000		
Reasonable Cause	\$1,000 - \$50,000	\$1,500,000		
Willful Neglect — Corrected	\$10,000 - \$50,000	\$1,500,000		
Willful Neglect — Not Corrected	At least \$50,000	\$1,500,000		

http://www.the-dermatologist.com/sites/default/files/issues/May2013/Legal%20Ease%20Table%202.png

HITECH GAVE HIPAA

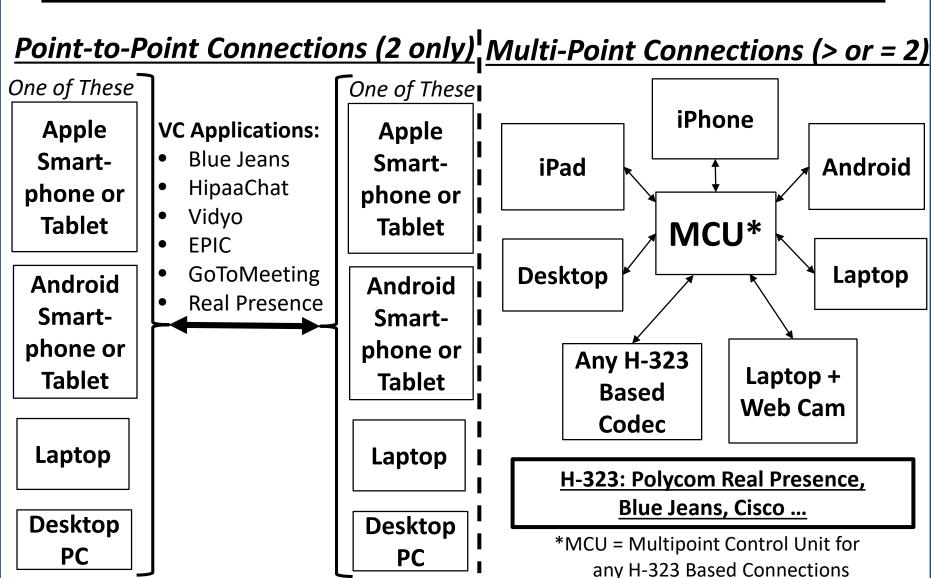
HIPAA Enforcement

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 nullicious harm:
 - \$250,000 fine and/or ten years prison time.
- Again, you can be personally liable!

(Penalties, 2014)

<u>Infrastructure:</u> <u>Point-to-Point vs. Multi-Point Connectivity</u>

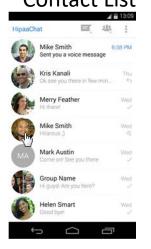


Connecting with the Patient Using HipaaChat

1. Download HipaaChat from App Store

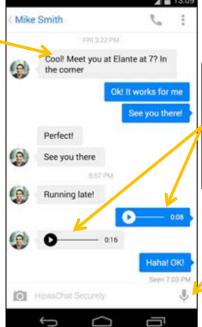


2. Select Patient from Contact List



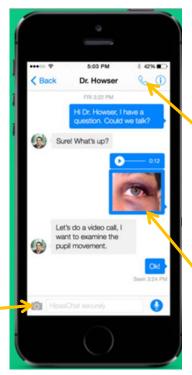
Front/Back Camera Select

Text



Send/Receive Walkie-Talkie Voice Messages

Take a Picture



Open real-time voice communication

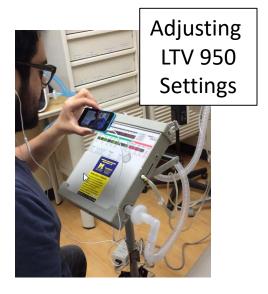
Send Images

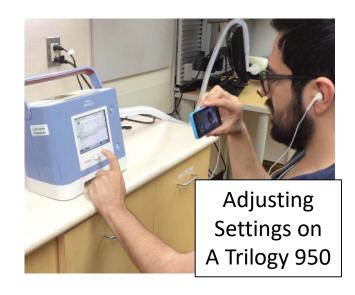
Can People Be Guided Remotely Using Mobile Devices?

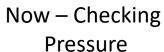
The "Zero Knowledge Ventilator Test"

The "Zero Ventilator Knowledge Test"

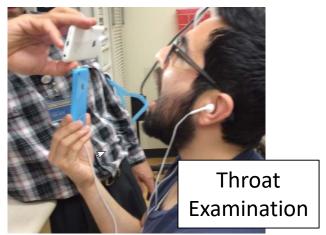




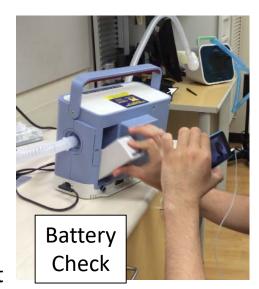






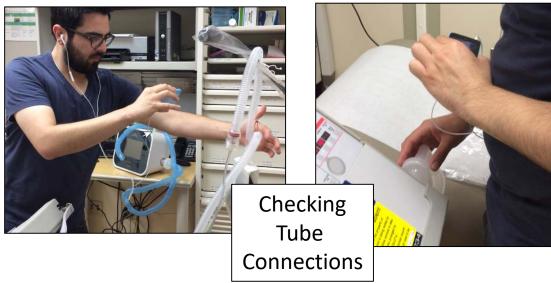


Note: White iPhone is for LED light



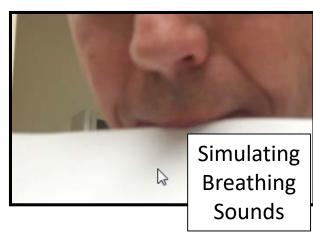
The "Zero Ventilator Knowledge Test"







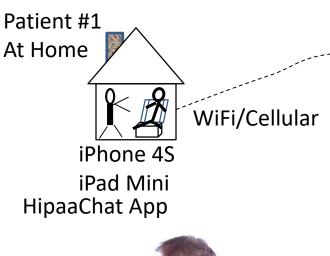


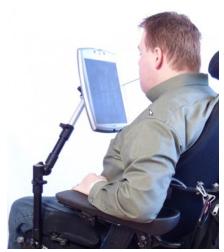


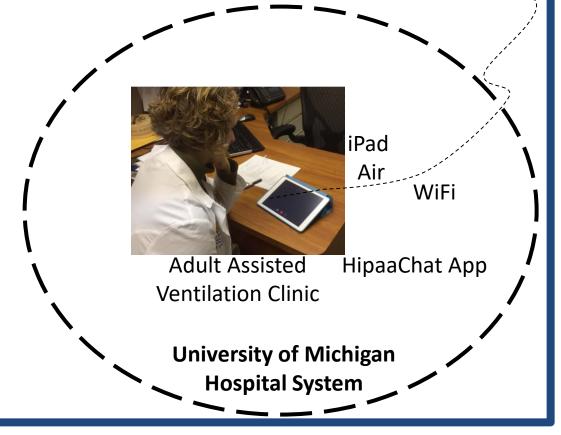
Our First Test Patient ...

- Patient #1 <u>Downloaded</u> 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 <u>Caregiver</u> Was There to <u>Assist</u>
- NP and RT Used an iPad Air

Connecting Clinician to Patient/Caregiver at Home







Internet/Cellular

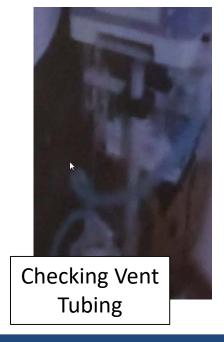
(Patient Image, 2014)

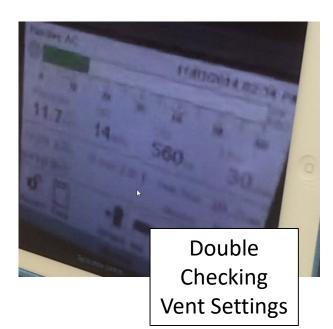
First Patient Results Using an iPad Mini

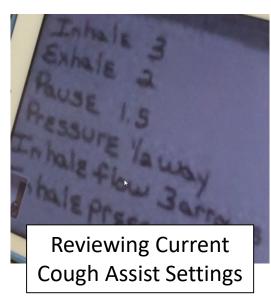




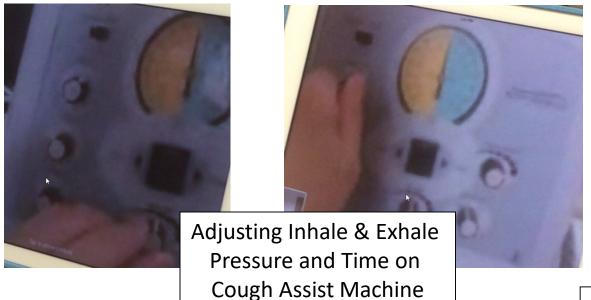








First Patient Results with iPhone 4S





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 **

Current Status

- Workflows being finalized
- Need to <u>Survey Vent Patients</u> and Caregivers to:
 - Determine What Technologies They Own
 - Their Openness to Telemedicine
- Resolve Billing Issues
- <u>Refine Videoconferencing</u> (Lighting, Acceptable Devices, Software/Device Versions, Camera Resolutions, etc.)
- Request Vendors <u>Activate LED</u> on Smartphone/ Tablet for Illumination
- More Research

Research...IRB...Experiments...Publish

	Ventilator Telemedicine Simulation Project Case Script	Case #_		
Case #			'patient' calls vent clinic number (XXX), exp Dr paged to phone # Doctor calls to confirm receipt Doctor and patient agree this is c	lains the asks to have
Patient side stat				
Remote clinician	n		Family Perform	(rapher)
Video observer		-	4iCIII	
Room 'family Videog Equip. Clinici Post-h	and time for case set for case set y' (a UMHS employee) trained and available grapher/ helper trained and available ment in place	eler on P	et up of cases ont scenarios are chosen by raced on it to indicate the actions to be ces an X to indicate their observations. Rando xpressions:	taken. The clinician sees actions
	Z, Ca-	Facial e	xpressions:	mizations include:
Sc Sm	for forearm 'wound'	1 2 3 4 5	Doing fine Acutely sob Wheezing Anxious Coughing	
☐ Wate ☐ Ruler	10r1orearm wound	<u>Trach</u> s	tatus:	
	ute and recording forms		assigned (Randomly generate numbers 1-3 a side. Clinician reads from a distance.)	nd place an X in each trial on the
	an is available for case	1 2	Trach out Trach partially in	(Haig 201

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

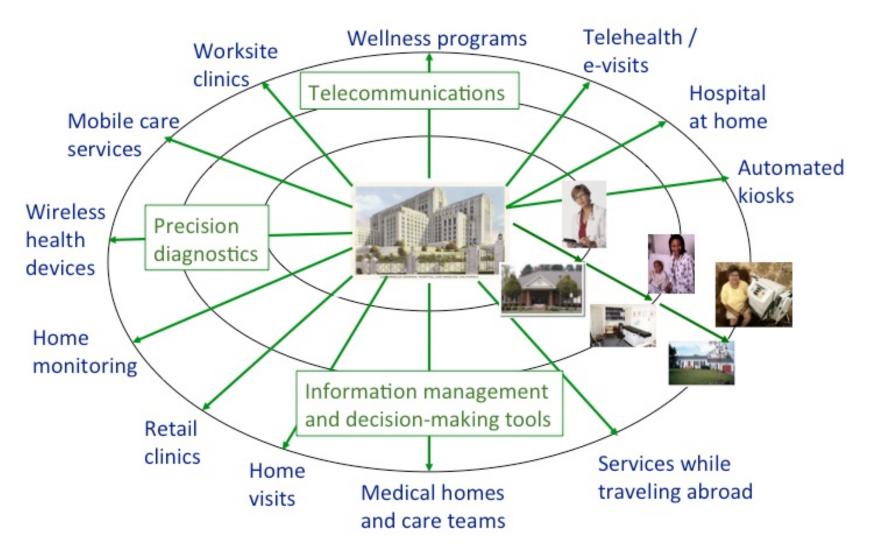
- Teleneurology
- Telestroke
- Inflammatory Bowel Disease
- Neonatology Allegiance
- Bladder Cancer Post-Op Followup
- Teledermatology (Store & Forward)
- Home Speech/Language Therapy
- Pediatric Nephrology ICU
- Partial Nephrectomy Post-Op Follow-Up
- Psychiatry Teleconsultations
- Home Speech/Language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



Retrieved 9/24/15 from http://pharmaceuticalintelligence.com/tag/health-care-budget/

Telemedicine Technology Building Blocks

- Sensors
- Processors
 - LCDs
 - Optics
 - Storage
- Wired/WirelessCommunications
- Software Tools
- Peripherals
 (Stethoscope, US, ...)

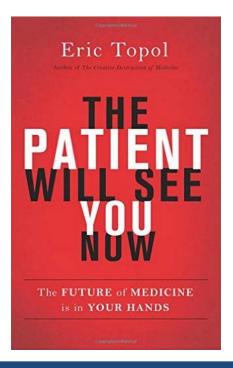
- Algorithms
- Applications
- Networking
 - Cloud
- Materials Science
 - Data Mining
 - Al
 - Analytics
 - Security ...

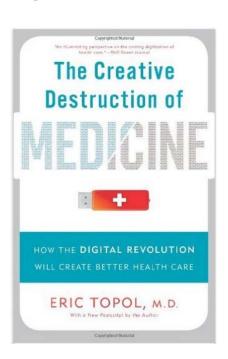
(always last - pacemaker)

"Future of Medicine" Books by Dr. Eric Topol

The Creative Destruction of Medicine

The Patient Will See You Now





Dr. Topol's "The Creative Destruction of Medicine"

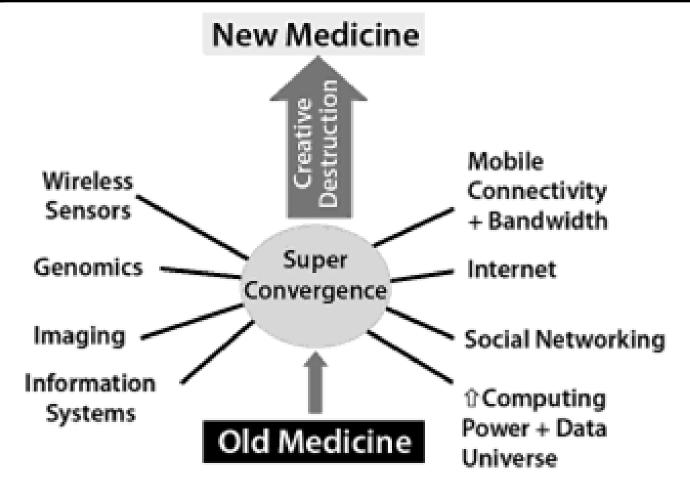
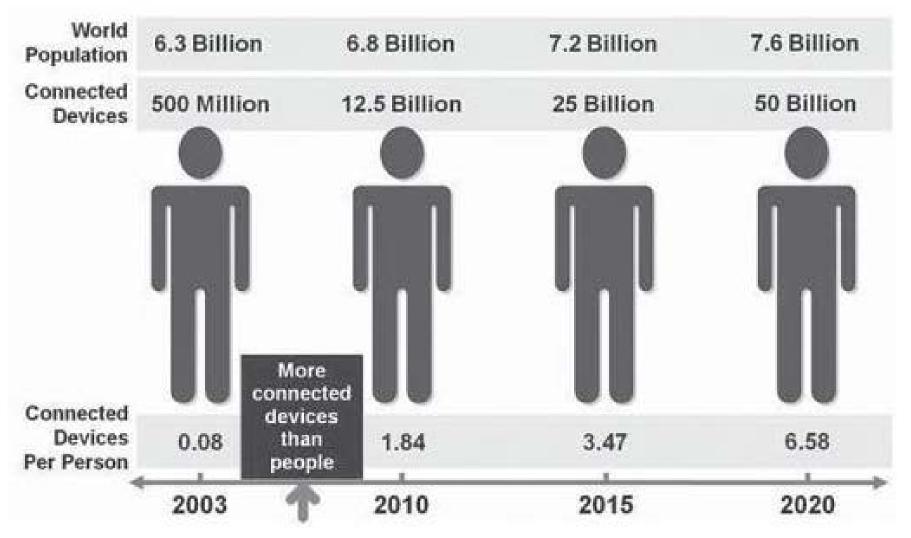


FIGURE INTRO.1: The transformation from medicine today (old, dumbed down) to new, individualized medicine that is enabled by digitizing humans.

Topol, E. The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care 2012, page vii

From Dr. Topol's "The Patient Will See You Now" The Number of Connected Devices Per Person

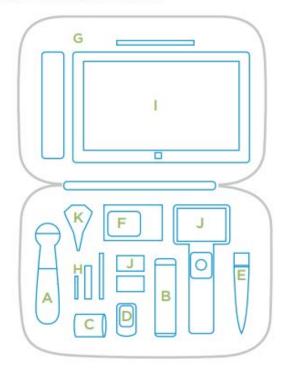


Topol, E. (2015). The patient will see you now: The future of medicine is in your hands. Basic Books, page 11

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
- Opportunity. H Camera Direct wifi SD card
- **Tablet**
- J Multi-Scope
- K Otoscope

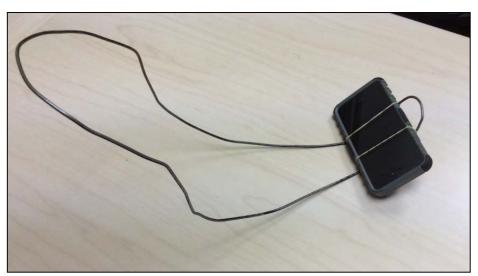


http://www.medweb.com/docs/MedwebDEK.pdf

A Poor Man's Google Glass

(A Prototype: A Wire Hanger and Rubber Band) Joon Change





- 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"

Leveraging the Patient Owned "Infrastructure"







(Ultrasound, 2014)









(Otoscope, 2014)



(Dermoscope, 2014)



(MenPhones, 2014)

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.

<u>Summary: A New Vision For Healthcare</u> <u>The 3 Cares – Eric Dishman, Intel</u>

- <u>Care Anywhere</u> (Home, Work, School, Gym, Car, ... while sleeping)
- <u>Care Networking</u> (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.

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