



New Directions
Technology Consulting

University of Pennsylvania Senior and Emeritus Faculty

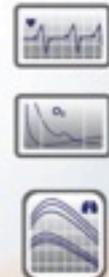
November 17, 2016



*"Drugs don't work in patients
who don't take them."*

C. Everett Koop, M.D.

Former U. Penn Faculty
and U.S. Surgeon General



Introduction and Objective



Introduction: Napoleon Monroe

- Strange name
- Connection to combination products and telemedicine
- More information and contacts at www.mmedhealth.com
- Personal not in the bio
- Disclosure of IP interests

Objective: Provide an introduction to connected medication delivery systems and some thoughts to stimulate discussions

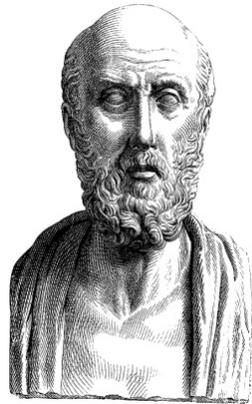
Glossary



Glossary

- ACO: Accountable Care Organization
- AIDC: Automated Identity and Data Capture
 - RFID: Radiofrequency Identification
- Biopharma: specialty pharma
- Combination Product: A drug + a device
- Connected drug delivery product: Telemanagement, Internet of Things
- Plan sponsor, often an employer: Sponsor of insurance program, real payor
- REMS: Risk Evaluation and Mitigation Strategy
- RWE: Real World Evidence
- RWD: Real World Data

Wise Words

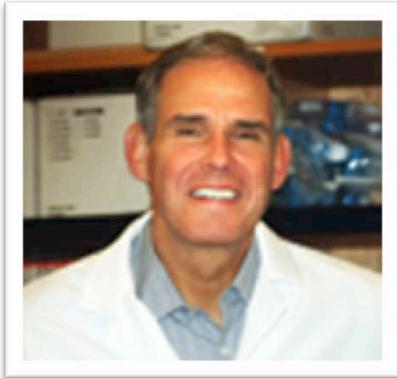


Keep a watch also on the faults of the patients, which often make them lie about the taking of things prescribed.
–Hippocrates



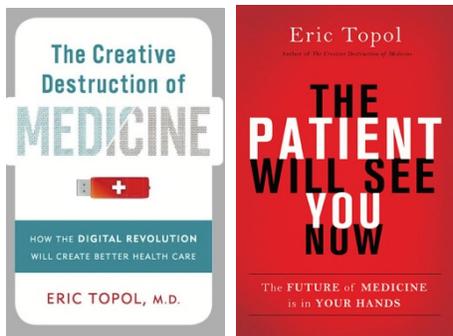
Drugs don't work in patients....

Wise Words (cont'd)



Director, Scripps
Translational Science
Institute; Chief Academic
Officer, Scripps Health

*[Improvements in adherence are] especially noteworthy because only half of patients demonstrate adherence to prescriptions, and **this problem represents an important, if not the most important, reason for failure of management of chronic diseases.***



– Dr. Eric Topol, The Patient Will See You Now, p.128

Medication Telemanagement Possibilities

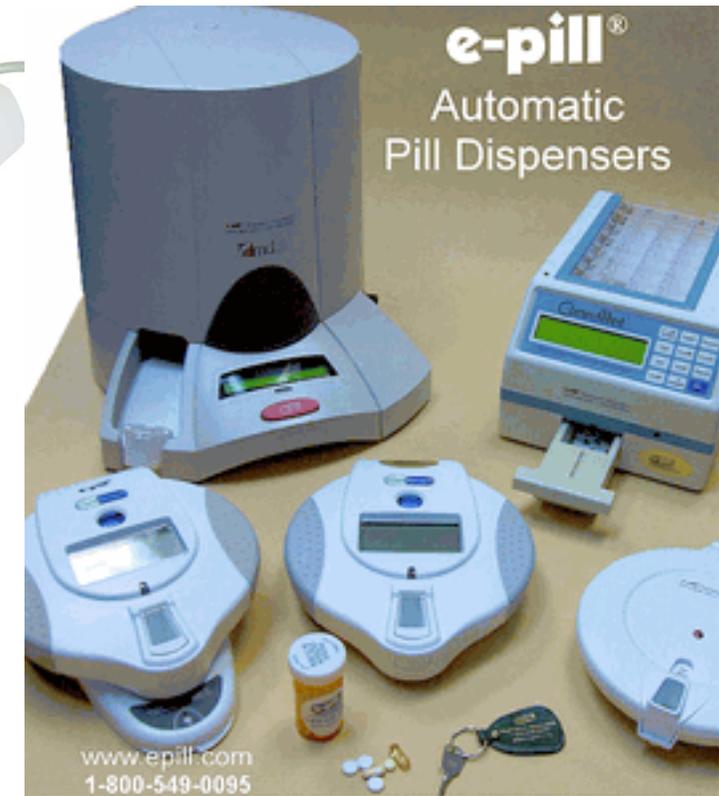


Potential System Elements

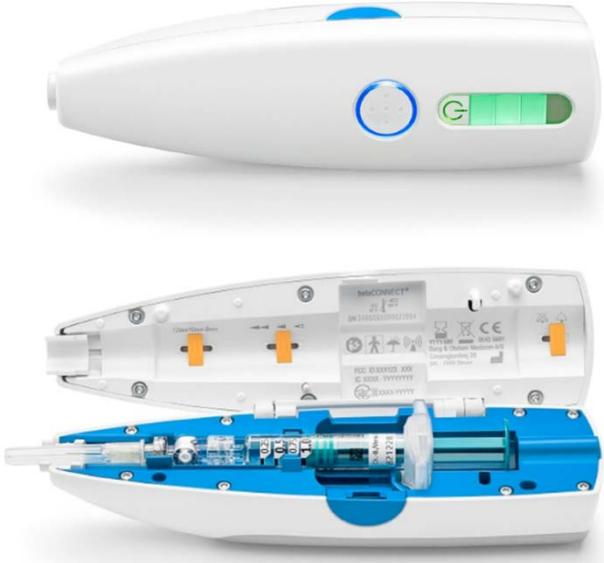
Capabilities for communications of medication telemanagement data through a smartphone or other device with short- and long-range communications capabilities, and delivery of information to caregivers and/or a central monitoring facility operated by medical professionals.

1. A medication container with embedded sensors and AIDC capability
2. Communication device with integrated sensors and applications

Examples: Medication Telemangement



Examples: Medication Telemangement



Best Known Example of Medication Telemanagement



- Controller: Initially dedicated, but will likely become a smartphone
- Communications between and beyond system elements



State of the Industry Prior to 2010



- Little had been done to ensure medication adherence
- Traditionally, pharma was often content with their legacy model and reluctant to offer service
- Biotech and advanced delivery devices SC/IM/IV growing together
- 2005 WHO: more health benefits from boosting adherence to current treatments than developing new ones
- 2010 NEJM annual U.S. medical cost estimates for patients' nonadherence: \$300B
- **2010 Affordable Care Act /Accountable Care Organizations**
- 2012 Capgemini: U.S. revenue loss from medication nonadherence is \$188B. If extrapolated to the global market: \$564B

The Advance of Enabling Technologies



- Explosive growth of **mobile** communications user community. (Dosing often happens outside institutions; social media.)
- Linux/cloud computing **disrupt** the high-cost computing and data-storage models
- Electronic medical records
- Other enablers emerge: Sensors, low-power options, AIDC (RFID/2D barcodes/serialization), predictive analytics, apps., wearables, Internet of Things

Disease and Therapy Trends



- Increasing longevity: Lengthening treatment cycles
- Better diagnosis: Increasing incidence
- Chronic diseases prevalent. Patients have multiple diseases
- Polypharmacy and contraindications complicate adherence
- Biotech, genomics/proteomics: personalization
- Specialty drugs requiring more care in storage / administration than traditional meds
- Medication management
- Biotech parenteral administration
- Home/self **mobile** treatment

Industry Trends



- Orphan disease focus
- More specialty products for cancer and chronic diseases
- Attempts to reduce complexity of treatment, new-product presentations/devices/routes of administration and connectivity
- Suffering from cost pressures and reputational challenges
- Attempts to add value

Biopharma Trends



- Specialty medications face more cost challenges
- Many new parenteral systems introduced
- Many companies already developing advanced and connected delivery systems to help patients manage therapies outside institutional settings and to gather real world evidence (RWE)
- Remote injections present special human factors challenges

Healthcare System Trends



- Increasing costs
- Digitization of information. EMRs can capture RWE if delivery is connected
- Economic restriction of access. ACOs. New payment models. Payor and plan sponsor issues. Higher co-pays. High deductibles. Health Technology Assessments
- Issues around redefining the supply chain to include the patient
- Competitions for concordance (TO BE UNDERSTOOD)

Legislative and Regulatory Trends



- FDA systems and standards for mobile technologies becoming better developed
- FDA Office of Combination Products. Human factors
- Drug Supply Chain Security Act. Serialization
- Cost pressures on healthcare worldwide. Political systems differ
- New payment models evolving
- Demands for RWE

Features of Connected Medication Management



Besides simple reminders to take the medication or prompts to initiate the replenishment process, a connected medication telemanagement system can:

- Automate capture of patient and the medication identity in the patient's hands
- Verify dosing. Inference with all
- Relate quantity of medication available
- Provide medication-condition alerts (e.g., premature degradation, breakage)
- Inform re drug interaction, adverse drug reactions, abuse
- Instruct real-time for proper use and disposal
- Integrate usage data into medical records

Benefits of Connected Medication Management



For patients and all stakeholders:

- Improved outcomes and concordance
- Real-time patient support
- Facilitate communication with and support among healthcare professionals/stakeholders
- Assist in real-time monitoring, diagnosis, counseling, training and feedback and formulation of treatment plan changes. Before, during and after medication administration
- Lower **overall** costs????

What Some are Saying:



- We don't get paid for this
- My time with patients is limited and better spent diagnosing
- I'm already overwhelmed with computer requirements and can't deal with all this unwanted information
- I can't be pinged every time a patient fails to..., or wants to chat
- All this is like electronic medical records. The systems are not built for practice workflow
- What about privacy? How does all this fit into HIPPA?
- Hacking is all over the news. This has to be a security threat
- I've seen some of these toys. They are worthless
- Patients abandon apps because they are a pain for them, as well
- Obamacare is going to be repealed and....

Others are Saying: 'This is an Opportunity!'

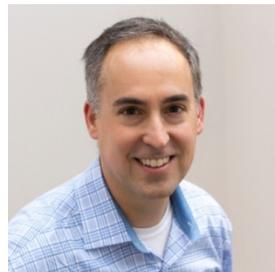


- CMS, hospitals (including ACOs), PBMs, payers (including third-party administrators), plan sponsors, wellness providers, community health centers, pharma companies, individuals, patient advocacy groups...
- Pharmacy chains: There are many of us, we're local, and are in regular contact with patients. We pharmacists can sell devices and our service to other stakeholders
- We have an interest in and can be paid for medication therapy management
- Healthcare as reimbursed is dysfunctional and such innovations as medication telemanagement are essential to improving the system
- We should lead

Penn Innovation



- *The biggest problem in healthcare is how do we get paid for the value of the services we offer. Many innovations are stalled because there is no viable model for payment.*
- *Some aspects of Obamacare may be delayed based upon the election, but CMS intends to move forward with value based purchasing.*
- *Clinical teams will manage high risk situations, but many tasks can be taken over by intelligent systems and lower-credentialed individuals.*



Roy Rosin, Chief Innovation Officer,
Penn Medicine. (Highlights of a phone
interview, November 9, 2016)



QUESTIONS?

Thank You



Contact: Napoleon Monroe

Managing director, New Directions Technology Consulting, LLC

718-427-3038

nap.monroe@newdirectionsconsulting.net

New Directions is the exclusive market developer for the MMed patent portfolio found at

www.mmedhealth.com

mMed is a trademark of New Directions Technology Consulting, LLC. Any other names of companies, organizations, entities, products or services may be the trademarks of their respective owners.

Attribution



Terms of Use

This work is licensed under a **Creative Commons Attribution (CC BY) License**. It is attributed to **Napoleon Monroe**.

Attribution - "CC BY"

This license lets others distribute, remix, tweak, and build upon a work, even commercially, as long as they credit the original author for the original creation.

You must give appropriate credit, provide a link to the license, and indicate if changes were made. You may do so in any reasonable manner, but not in any way that suggests the licensor endorses you or your use. **There are no additional restrictions.**

License: <http://creativecommons.org/licenses/by/3.0/>