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Designing IT for Health Care from First Requirements

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Presentation Outline

1. **Health and Information**
2. First requirements
3. Failure to inform
4. Solution

Abstract

- At over three trillion dollars, health care is the largest enterprise on earth.
- It is also the largest, most prolific producer and consumer of information.
- The information revolution, however, has left health care largely untouched.
- I discuss here the main reasons for this paradox and show, using a real-life example, that designing IT solutions for health care is a uniquely challenging task that defies the most cherished notions in modern engineering

Health & Information

- Health/Disease ~ Information/Entropy
  - Intuitive terms,
    - Variable meaning, function of “schools”
  - Hard to quantify
    - More or less healthy, more or less informed
  - Harder to qualify
    - E.g., “good health”, “good information”

Issues

- Most diseases are self-limited (self-cured)
  - Patient P may get better because, despite, or regardless of intervention
  - How can one tell which is which?
- Most health care is provided at home
  - By relatives and friends
  - Without professional supervision
  - How do you know what happens there?

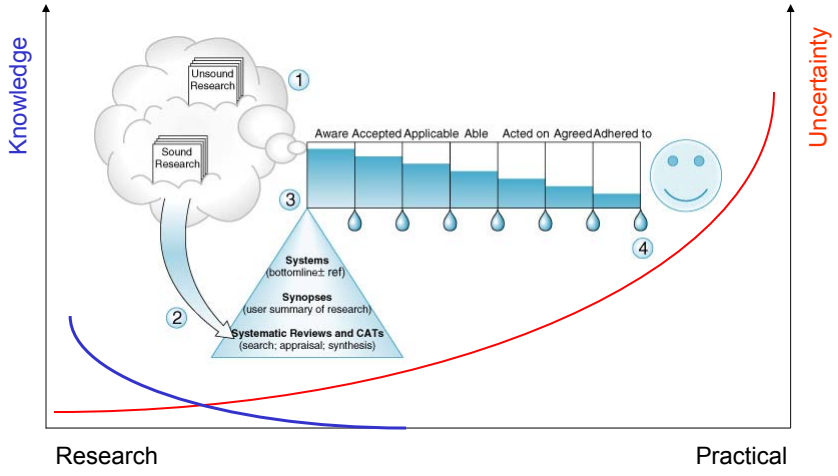
Myths

- Doctors know what the problem is
  - In diagnosing an individual, knowing ALWAYS lapses into opinion
  - Diagnosis contains no knowledge, but pointers to possible medication
  - Drugs are not discovered scientifically; hence, they cannot be prescribed scientifically
- Medicine is logically inconsistent and mathematically incompetent.
- Medical sciences
  - Semiology, etiology, pathology, hygiene,…
    - Unknown to “allied” scientists and technologists
    - Biology is NOT a medical science
      - » Evolution theory has no application
      - » Genetics – immature (the Central Dogma collapsed)
    - Biochemistry is NOT a medical science
      - » Molecules are “inert”
      - » “body chemistry” sounds like “computer metallurgy”
- Medicine cannot use logic

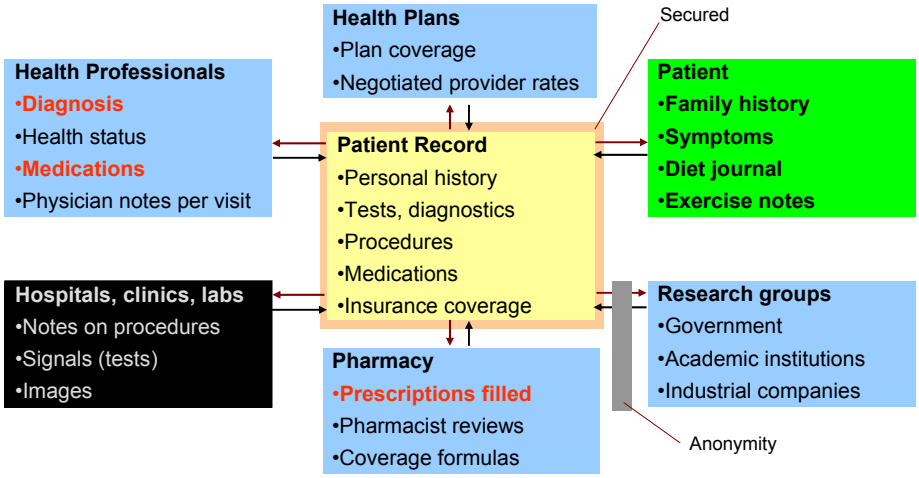
No Help Where Most Needed

- Lack of S&T support for diagnosing
  - No science of feeling (internal sense system)
    - Commonsensical yet science fails to even start
      - » Normal: feeling hungry, thirsty, horny
      - » Medical: Feeling sick, tired, in pain, chilly, depressed
  - No technology for consultation!
    - » Vital sign measurement – PATHETIC!
    - » See your doctor's office equipment (~1920s)

Health care: Trials of One



Tons of data



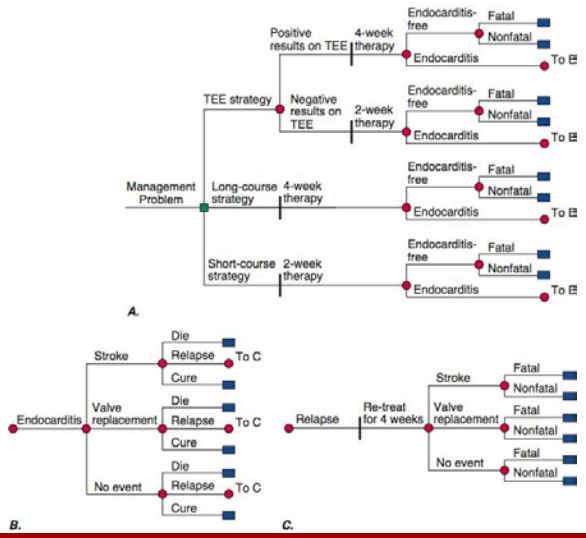
Healthcare and IT

Information technology (IT) is being proposed as a great solution to grave problems in health care, such as [i]:

1. improving individual patient care
2. preventing medical errors
3. reducing health care costs
4. expanding access to affordable care
5. detecting infectious disease outbreaks early
6. improving chronic disease management; etc.

[i] US Department of Health & Human Services, Health Information Technologies, http://www.hhs.gov/healthit/

Compute this…



The Paradox

- Health Care (HC)
  - Largest enterprise on earth > $3 trillion
  - Largest consumer/producer of information
  - Uniquely dependent on information
- Information Technology (IT)
  - has transformed everything
    - from math/logic to manufacturing/shopping
  - has left health care untouched
    - Not even email
- Why?

Efforts so far

- "paperless office" revisited
  - Remember …
- Generic data storage, exchange
  - Mostly admin data (billing, transactions, etc)
- doctors refuse IT
  - Electronic Medical Record barely used
  - They see little value in HIT for patients and themselves

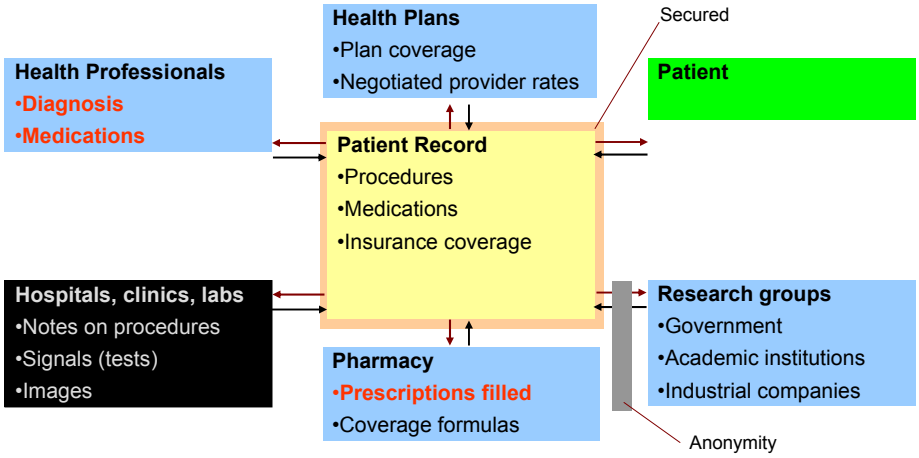
The Noise

- Much ado:
  - Standards: HL7,…. IEEE STD XXX
  - Reports: WHO, NIH, IOM
  - Initiatives: NHII, Infoway, EU Telmed Framework..
  - Billions…
- About nothing
  - See your doctor's office
    - Stethoscope, sphygmomanometer, weight scale…
      - » Circa 1910?
    - Computer – for billing, maybe ECG (1920)

The Problem

- Medical information
  - From the patient - For the patient
- No IT for that information
  - Patients are ignored; “no apps for the pats”
- No means to capture crucial info
  - Adverse drug reactions
  - Health Outcomes, Risk Assessment
- IT provides decision aids for doctors
  - In fact, medical decision is for the patient to make
  - No apps for pats

HIT Applications



Healthcare and Internet

- Security and interoperability issues are often raised to excuse or to explain why all of the above demands have yet to be met.
- It is hard to grasp why healthcare is not fully "wired" in view of the typical data shareable in internet-based clinical- information networks:

Internet Shareable Data

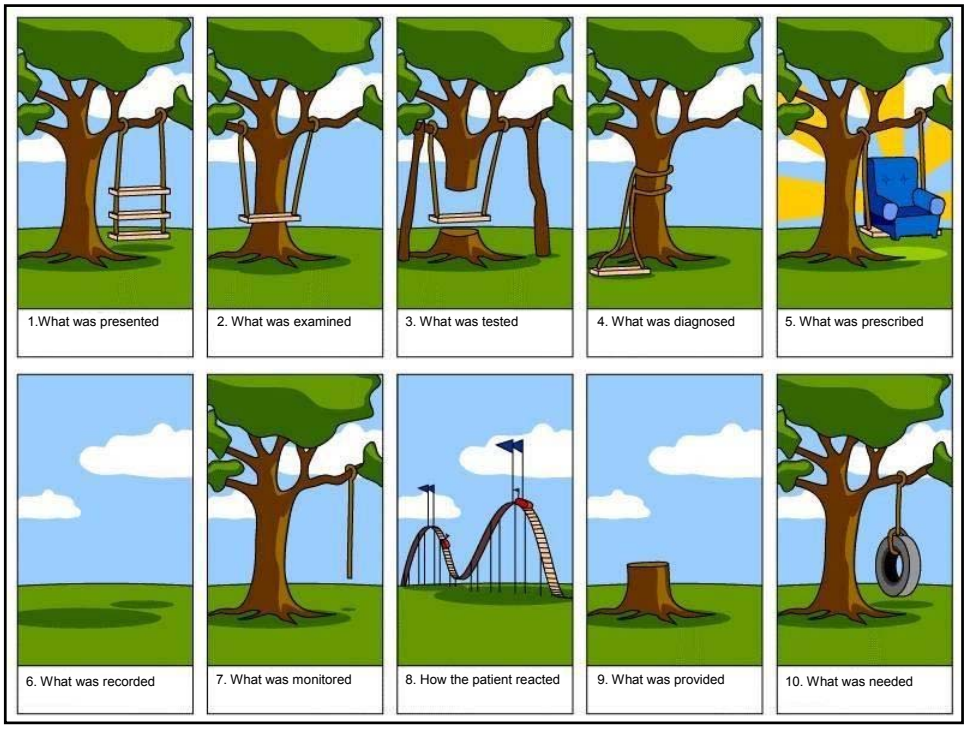
1. Admissions, discharge, transfer notes
2. Bedside chart information (vital signs, nurses' notes)
3. Daily notes by physicians
4. Hospital medication lists
5. Laboratory/diagnostic test results
6. Demographic information on patients
7. Imaging center provides
8. Images (e.g., MRI, ultrasound, X-ray)
9. Transcribed reports

More Internet Shareable Data

10. Voice transcriptions
11. Test results
12. Formulary lists (i.e., lists of reimbursable drugs)
13. Patients' medication lists
14. Billing information
15. Demographic information on patients
16. Insurance information on patients (when applicable)
17. Transcribed, digitized physician notes
18. Payers and pharmacies, etc.

Slow Adoption of IT in Health Care

- The list above indicates the magnitude of the need for HIT.
- The fact that such data is still handled either manually or "generically", by general purpose applications, seems to confirm the suspicion that factors other than IT are involved in slowing the adoption of IT in health care.
  - Money, is the usual suspect, along with
  - the "perverse" incentives insurance-based markets tend to promote.
  - Fear of pioneering – trial & error leads to horror in health care



HIT Claims and Facts

Claim	Fact
Improving health care quality	No
Preventing medical errors	No
Reducing health care costs	No
Increasing administrative efficiency	No
Expanding access to affordable care	No
Improving individual patient care	Not implemented
Early detection of infection outbreaks	No (see SARS, bird-flu)

Who Needs IT in Health Care?

Health Performance		Overall Performance		Overall Attainment	
1.	Oman	1.	France	1.	Japan
2.	Malta	2.	Italy	2.	Switzerland
3.	Italy	3.	San Marino	3.	Norway
4.	France	4.	Andorra	4.	Sweden
5.	San Marino	5.	Malta	5.	Luxembourg
6.	Spain	6.	Singapore	6.	France
7.	Andorra	7.	Spain	7.	Canada
8.	Jamaica	8.	Oman	8.	Netherlands
9.	Japan	9.	Austria	9.	United Kingdom
10.	Saudi Arabia	10.	Japan	10.	Austria
24.	United Kingdom	18.	United Kingdom	15.	United States
72.	United States	37.	United States		

FAQ

- In no other enterprise is the need for IT felt stronger than in health care – yet the information revolution has left health care untouched.
- Doctors are bound professionally to always act in the best interest of their patient, so why are they resisting IT?
  - either IT is “bad” for the patient or
  - doctors are “evil”!

1. Health and Information
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HIT Basic Requirements

- The entire health care system comes down to solving this problem:
  - is there something wrong about what Ms. Pat feels?
  - If yes,
    - what can Dr. Med know about it,
    - what must he do about it, and
    - what may he hope to achieve?
- Diagnosis is the only task doctors cannot delegate and in which they are expected to succeed always.
  - The first requirements for designing a genuine HIT are
    - **help doctors diagnose (R1), and**
    - **help patients decide (R2).**

First HIT Requirements

1. Help doctors diagnose
   - Distinguish which feelings are “medical symptoms”
   - Render examinable what it is not (pain, malaise)
   - Automate testing (theorem-proving)
   - Truth – Proof compatibility
2. Help patients decide
   - What can I know?
   - What must I do? (self-care)
   - What may I hope?
   - Am I really getting better even though I feel worse?
   - Am I really sick even though I feel healthy?

Confusions

- In the early days of computers, many believed that medical expert systems can be readily designed by being given sufficient computing power.
- Engineers fooled themselves into believing that diagnosis is about knowing what might cause Ms. Pat’s symptoms.
  - But diagnosis is mere “opinion” rather than “scientific knowledge.” This much is clearly acknowledged in the advise to seek a “second opinion”.
- Doctors cannot decide on anything without delegation because, unlike airplane pilots, their best interest is not perfectly aligned with that of their patients.

The Problem

- What do doctors want?
  - How does Ms. Jones FEELS today?
  - Does she follows my prescription?
  - Am I doing the right thing?
- What do patients want?
  - Will I get better? When? Why am I feeling worse?
  - Medicine is scientific, only doctors are licensed to know (diagnose) – so, why is my doctor giving me an “opinion”? Can opinion be scientific?

The Problem

- Medical information
  - The patient is THE INFORMER
    - » the ONLY true source of information
  - The patient is THE DECIDER
    - » The ONLY true decision maker
  - There is no IT to support the patient in any way
- Hence: no health IT (HIT)
- WHY?

The Problem

- Medical information (MI)
  - Feelings are not understood scientifically
    - External senses: basis of all science
      - » Colors, sounds, tastes, smells: no scientific grasp
    - Internal senses: not even studied
      - » How can you stand up?
  - Begins with “feeling sick & tired”
    - No scientific grasp of ANY symptom (pain)
    - No scientific grasp of ANY sign (looks pale)
      - » doctors are on their own / left to their (intuitive) devices

Problem Solving

- Information technology
  - What is “information”?
    - Shannon? Wiener? Von Neumann? Bertalanffy?
  - How do you ‘get’ it?
- Information biology?
  - Every thing that lives is PROGRAMMED
    - Has sensors and actuators
    - Behaves ‘intelligently’
      - » Anticipates, fights, resists, endures, tolerates, adapts, evolves, learns, trains…

Why HIT Failed in Medicine?

- Biology refuses to go “informational” – it sticks to chemicals
- There is no science of feelings (internal representation), instincts (autonomy), of symptoms (manifestations)
- Medicine and its aims defies the natural science and its methods

First Requirements

- Do no harm
  - Device quality
  - Data integrity; in context
- Do some good
  - As intended – detect abnormal BP
    - Normative operation; nobody needs METERS
- Be friendly
  - Easy to use (autonomous operation)
    - » Self-corrective operation; error handling/awareness

First Requirements

- Device operation must be
  - Autonomous
  - Distributed
  - Virtual instrumentation
  - Synthetic Instrumentation & Analytic Measurement
- Data must be saved in context
  - Data without data about data is useless in medicine where interference is the rule

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IT Solution Deigned from First Requirements

- A medical technology company – Biosign Technologies Inc. – undertook the seemingly banal task of designing a personal health monitor for hypertension and diabetes.
- Called UFIT™, the system was supposed to record basic data:
  - pulse rate and rhythm,
  - blood pressure, and
  - blood glucose.
- The acquired data was to be charted over time and thus provide information on the "disease-state" of the patient.

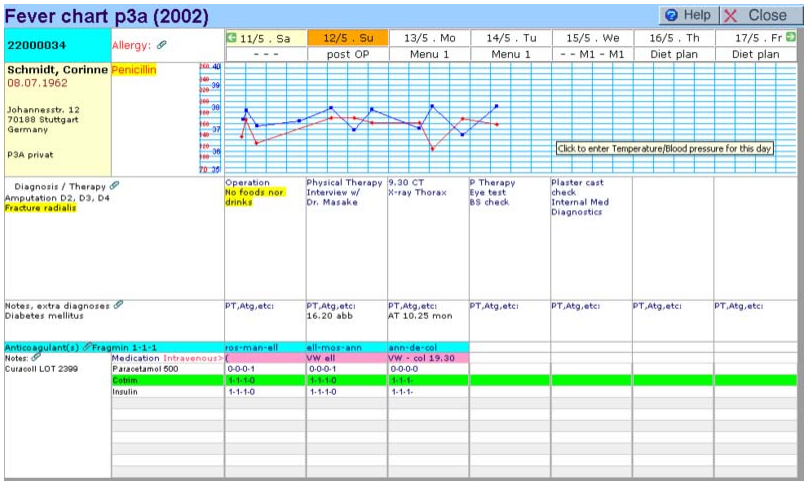
Specification Scenario

- The patient opens a browser, navigates to a certain secured IP address and enters the data provided by the respective meters (manometer and glucometer).
  - P1. Systolic: 140 mm Hg
  - P2. Diastolic: 80 mm Hg
  - P3. Pulse rate: 72 beats per minute
  - P4. Glucose: 98 mg/dl
- UFIT would store the data and display the variation over time (signal) of the four parameters (P1..4).
- As hypertension and diabetes are defined and monitored "by numbers", the variation of the numbers provides information on whether the patient is better (numbers trend down), worse (trend up) or stationary.

Features

- The designers focused on issues such as interoperability (charting and reporting) and security of storage and exchange.
- Facilities such as emailing and alerts were added for convenience.
- Patients could thus present their doctors a well documented “report” on their blood pressure and glucose variation, filled with details such as measurement time and annotations (“feeling much better today, after having two cake slices”) and nicely colored graphs.

Informative?



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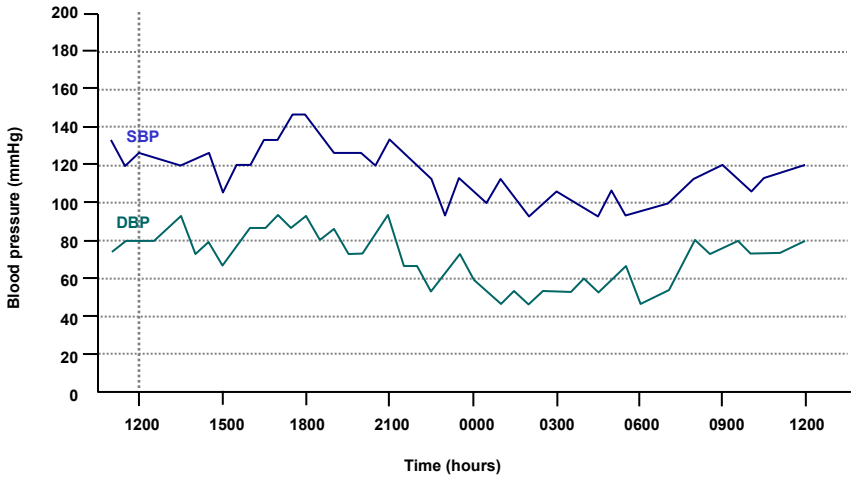

Example

- Get info about one's blood pressure (BP)
  - Precision?
  - Accuracy?
  - Uncertainty?
  - But the INTENDED USE is not to measure BP but to inform one about one's health
    - To measure = to inform?
    - BP is a property of a MEASURED motion (of blood)
      - » How do you measure a measured property that changes with the color of observer's eyes?

Example

- BP = 140/80 mm Hg
  - No physical explanation
  - It is the result of internal REGULATION
    - It is an internally measured property
    - **You measure the measure in which the regulator responds to measurement!!!**
    - Take it several times and it will "regress to the mean"
      - It is not a CONSTANT, but KEPT constant – quasi, sometimes, depending on x^n factors (the sky is blue, had a drink, an angry thought?)
- BP = 90/50 mm Hg – hypertension?

Doctors Were Not Impressed!

- The patients quickly realized that their efforts are useless as the reports did not seem to "inform" their doctors' opinion.
  - If the report confirmed the doctor's opinion, it was discarded as "non-informative".
  - If it contradicted the doctor's expectation, the report was ignored.
- So much for using IT to help patients better inform themselves and their doctors.
- The question was clear: if IT is useless in solving such simple problems – tracking blood pressure and glucose, while patients are unsupervised, then what to expect regarding the much more challenging tasks encountered in health care.

Is it IT helpful?

- Suppose a monitor stored 5 sets of measurements – systolic (SP) and diastolic (DP) pressure, pulse rate (PR), and blood glucose (BG) over five days, one per day

Measurement	***Day 1***	***Day 2***	***Day 3***	***Day 4***	***Day 5***
Systolic (SBP)	122	92	188	101	135
Diastolic (DBP)	88	62	84	83	85
Pulse rate (PR)	62	115	79	138	52
Blood glucose (BG)	84	166	92	177	154
Time (HH:MM)	18:39	21:02	06:17	13:13	13:39

Data about Data

- Before considering the "information" contained in the table, one needs to see if there is enough information "about" that data:
  - Were BP and PR taken when the patient was "relaxed"?
  - Was the pulse regular? Otherwise both BP and PR are meaningless.
  - Was BG taken when the patient was "starving"?
  - Why once per day – that is, why this choice of sampling rate? Does "once per day" means "once, anytime during the day"?
  - Then, of course are the questions about the meters:
    - were they working as they should;
    - their precision and accuracy profile; and
    - did the patient used the same meter to take all those measurements?
- Since we have no data about the instrument use, no data on the patient condition at measurement time, etc., there is no point in even consider how informative such data set might be.

A Diligent Patient

- Suppose now that the patient has followed a strict order – measure four times a day, with the same meters, before eating (BG) and while being most relaxed (BP).
  - Why four times per day?
  - How do we know that the meters did not become defective in between (after dropping the glucometer in the bath tub).
  - Above all, what does "before meals" means to one who does not take a sweet snack for a "meal"?
  - And how do we know the patient was indeed "relaxed"?

Informative Measurements

- Too much **data about data** is missing, without which the "actual data" is irrelevant!
- Should such data be used to inform medical judgment?
  - Definitely not – so doctors are right to ignore such "personal records".
- How about the patients? Should such data be used to inform their decisions?
  - Definitely not – so patients are right to ignore monitoring their state. In this sense, patient "noncompliance" or lack of "adherence" is welcome as a defensive attitude against misinformation.
  - Yet, self-monitoring in diseases such as hypertension and diabetes is required – you cannot manage what you do not measure.
- The dilemma is obvious: you need to measure BP and BG yet you have no tools to ensure those "measurements" are informative.

Suppose …

… we verified the meters before every use for technical performance (precision and accuracy).

- Still, the results are not informative because we need to know whether the measurements were taken in the "**standard conditions**" – otherwise it is like noting that water boils at 72 degrees Celsius without any reference to altitude, purity, etc.

… we confirm the patient was in "standard" state when making the measurement.

- What information could one get now from such a "verified" record?
- What "uncertainty" is being reduced through knowing those numbers?

Normal Thresholds

- Suppose we use a guideline whereby "normal" is SP<140, DP<90, PR<90, BG<120. If a number is above normal we set it to 1, else to zero to obtain, for example SP(0,0,1,0,0). Would this make the record more informative?
- No, not at all. The "normal" values are of statistical nature and therefore we need to know the "number of measurements required" associated with it.
- No guideline tells us that – how many measurements must be made so that the average of our measurements would be statistically equivalent with the numbers used in establishing the "normal" value. As we have no clue on the "normative algorithm", we cannot compare our SP average of 127.6 in table 1 and say it is less than 140 and therefore "normal".

Possible Reactions …

- **Abandon hope** for genuine HIT available for self-care; the money are in the hospitals, for bureaucratic tasks …
- **Address the problem** facing the facts:
  - Hypertension and diabetes are frequent and burdensome (epidemic, costly, etc.), highly morbid (many severe, including lethal complications);
  - They are most responsive to simple countermeasures (a few pills, diet, exercise), prescribed based on "numbers" gathered from easy-to-use devices (BP and BG meters).
  - Monitoring these diagnostic-critical values is not only useful – it is necessary, according to guidelines and best practices. The meters have limited, if any, capacity for recording and charting the numbers, let alone alerting / messaging.
  - Designing an IT solution for monitoring these conditions is unproblematic. Issues such as interoperability, security, and interface personalization can be handled with no less efficiency than elsewhere, including online banking.

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Data Recording

S0: acquire and **store** the measured sample
S1: verify the meter before each use
S2: verify the patient "state" before each measurement
S3: verify the results for "measurement error"
S4: verify the results for "statistical significance"
S5: verify the results for "clinical relevance"
S6: If all checked, store the results in the record.
S7: update the number of measurements required
S8: update the sampling rate (when the next measurement should be taken)

Why a New Device is Needed

- S0 (store the measurement sample) cannot be taken if the measurement is invasive – e.g., strip glucometer, because there is no practical way to store the drop of blood used by the meter.
  - S0 can be taken when using noninvasive meters that use signals (e.g., arterial pressure signal) for indirect measurement (e.g., BP, PR).
  - Ignoring S0 because of practical impossibility (blood drop storage) would degrade the ability to provide data quality assurance (DQA).
  - None of the available meters supply the sample along with the measurement result.
- The patient has to enter the meter results manually as most meters do not use standard device communication protocols.
  - Tests have shown that even professionals make mistakes when entering data; for instance, entering PR of 58 instead of 85 is hard to validate, unlike, say, entering a PR of 18 instead of 81.

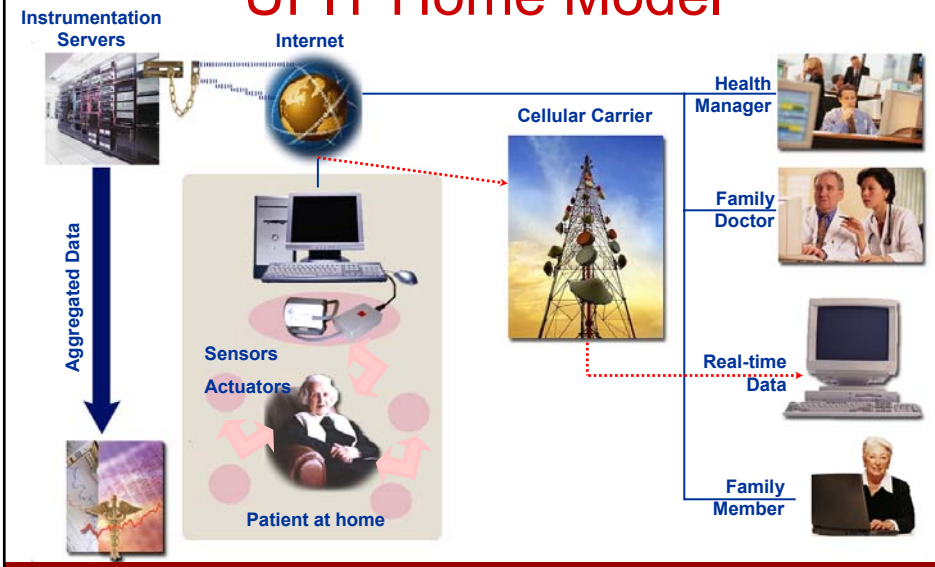
Biosign UFIT®

- Acquires **radial artery pulses** with enough resolution for waveform analysis.
  - The radial artery pulse (RAP) = the right "information source":
    - The most vital of all signals – arterial blood pressure (why the heart beats).
    - Is information-rich – is responsive to anything that "moves" the organism (including thoughts, feelings) = systemic blood pressure.
    - Acquired at the right site: most accessible, and where it is well mixed (elastic and muscular artery components, influenced by central and peripheral factors)
- The HW is "generic", with SW instruments on the server.
- This way S0 and S1 were satisfied
  - measurement samples stored (black box), and
  - the device verified by the server before use and
  - the measurement "piloted" in conformity to guidelines/standards.
- Recently an indirect method for measuring BG from RAP was conceived - still under testing for reliability.

UFIT - More Answers

- S2 posed challenges because medical science has nothing to say about "being relaxed"; scientists seem unable to even approach the issue of "feeling" in a way verifiable by the common sense – as it is required by the scientific method. Methodologies exists for "relaxation", "hunger", "pain", "fever" and such for the purposes of measuring BP and BG according to standards and guidelines.
- Measurement error (S3), statistical significance (S4) and related are handled according to current measurement doctrines.
- S5 (clinical relevance) imposed a re-examination of what measurement means in clinical medicine.

UFIT Home Model



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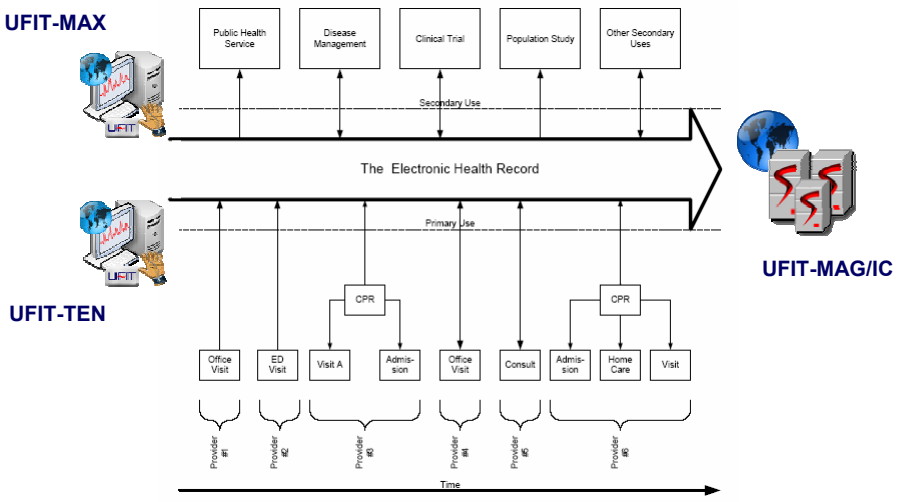

ACKNOWLEDGEMENT

- Thanks to Biosign Technologies Inc. for providing devices, records, processing toolbox, and related documentation on UFIT technology.
- Special thanks to Radu Leca…