HST.S14
Smart Software Design for Healthcare
Unbiased signals – open & affordable technology for resource-constrained healthcare

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The global problems with healthcare

1. **Too few trained medical professionals**
   - **High patient:doctor ratio around the world (up to 50k:1)**
   - **Pyramid training is difficult**
2. **Humans are fallible (medical errors)**
3. **High FP rate inherent in medicine: not scalable**
   - **High FP rate will overwhelm healthcare system**
4. **Compliance**
   - **Lack of evaluation of long term usage**
   - **Humans prefer recreation, not healthy behaviour**
5. **Supply chains are unreliable**
6. **Information is not portable**
7. **Lack of scientific foundation to much of the software**
   - **Look at the flood of 'medical' apps – e.g. sleep**

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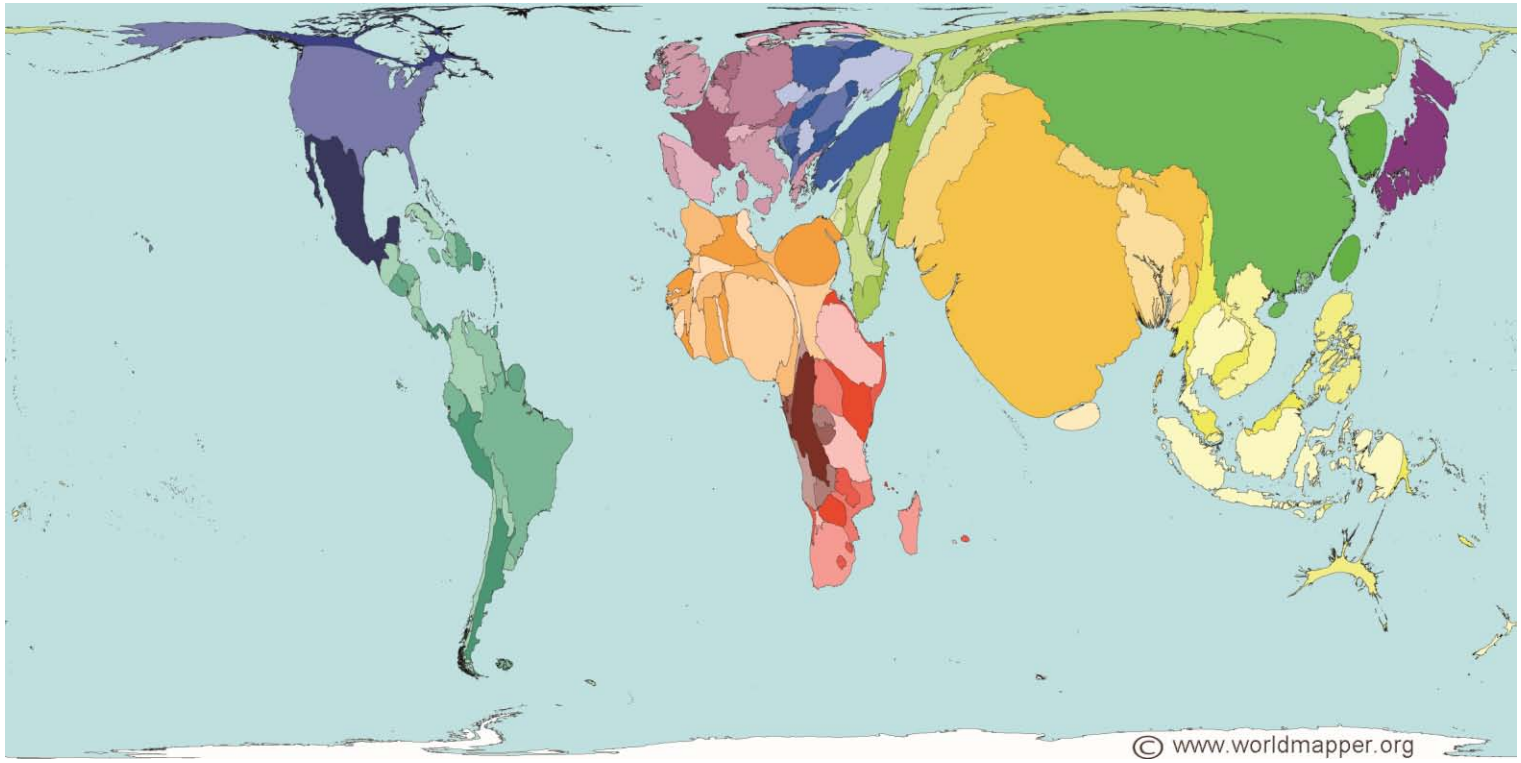
Global Maps: Population 2002

- Each country is drawn in proportion to its relative global population



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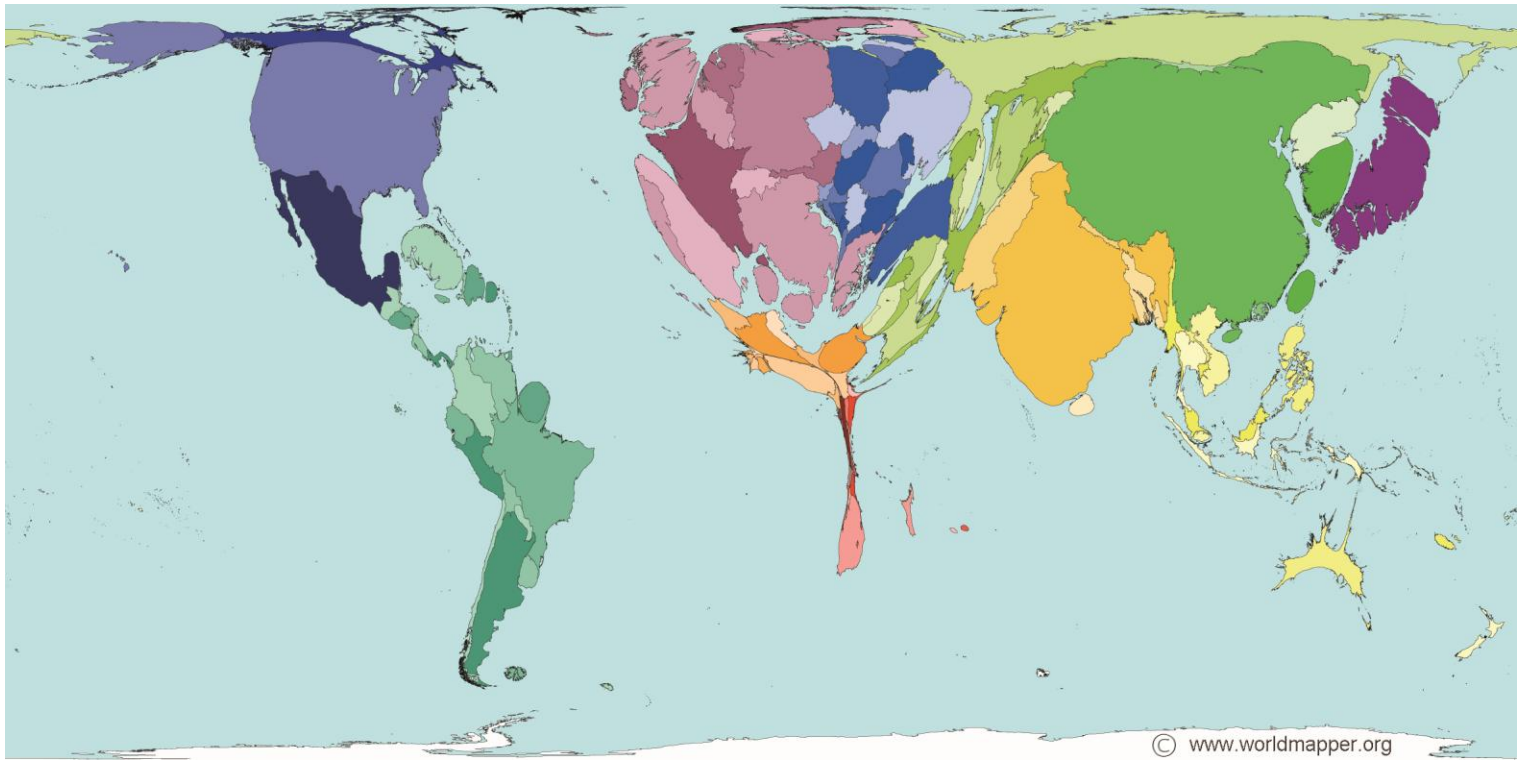
Global Maps: Working Physicians 2004

- Relative proportions of physicians working in each country



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So what if telediagnosis isn't enough?

- **Automate the analysis on the phone**
  - **use signal processing, AI, logic, decision support, etc. to sub for medical professional (more later)**

And/Or

- **If we don't have enough 'doctors' then we can use less well trained users**
  - **Non-colluding non-experts can do a good job if you have enough**
  - **Can even use algorithms + humans,**

And/Or

- **Bootstrap: Use both to train each other in a training reinforcement cycle**

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Dealing with medical errors

This is intimately connected with the first problem …

- **Humans errors rates are ~10-30%**
  - **even when the task is well prescribed and non-vague**
  - **Why don't we use double (or triple)-entry booking keeping?**
    - **Usually only during surgery - See 'the checklist' by Gawande**

- **So use multiple non-colluding annotators to label data**
  - **Experts are not needed – see zooniverse.org**
  - **Bayesian framework can decide on how to weight voters**

- **Also need to incorporate expert systems**
  - **E.g. Drug-drug interaction system**

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Current diagnostic paradigm is wrong

Most medical devices are designed to be:

- **highly sensitive, to ensure we don't miss any events**
- **but not specific; humans expected to post-filter**
  - **E.g. ICU monitors issue false alarms up to 95% of the time**

If we have everyone on the planet screening for 10 diseases every day, with a 1% FP rate ...

we will overwhelm the medical system!

Paradigm change?

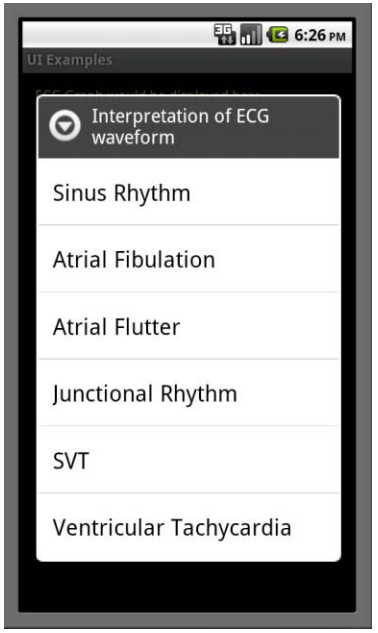
Issue: when collecting data at the source, the data can be extremely noisy, especially when we need it most.

- **Need intelligent algorithms & UI to run at the source of data collection.**
- **User adjusts the recording to get better data, based on 'quality metrics'.**
- **User also annotates the data at source to judge quality and classify**
- **Data is uploaded and back-end AI algorithm is updated to improve the classification.**

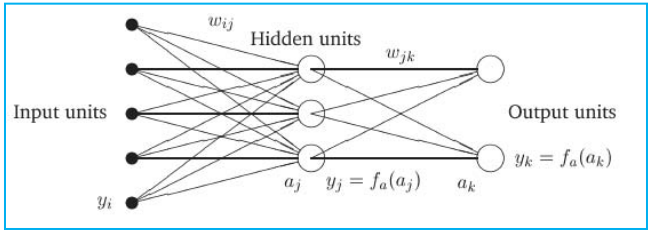
E.g. ECG on a mobile phone

(PhysioNet/CinC Competition 2011)

WHO: Ischemic Heart Disease – predicted to be 2nd largest global burden of disease & injury by 2030



- 1500 12-lead ECGs collected in the field
- Annotated by two trained novices.
  - Expert adjudicated differences
- Signal quality indices calculated on each lead
- Neural net trained on 1000 ECGs to classify the other 500 as clinically useful or not
- Accuracy: 99%/97% train/test (highest accuracy of entrant in in PhysioNet/CinC Competition in 2011)
- Currently working on implementing neural net on phone for auto-screening
- Then automated & semi-automated diagnostic systems can be added



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Compliance tracking?

- Watch out for user fatigue (~ >6 months into pilot)
- Humans prefer not to use medical devices (unless it is life threatening (e.g. glucometers) or recreational .....

- Gomez: 80% DOTS workers not turning up to work
- Use automated activation of chip-on-pill
  - but what if they feed it to the dog?
- Build incentive scheme per Gomez et al.
  - Medication changes body chemistry
  - User has to metabolise drug to reveal an encrypted code
  - Text code in to get phone minutes

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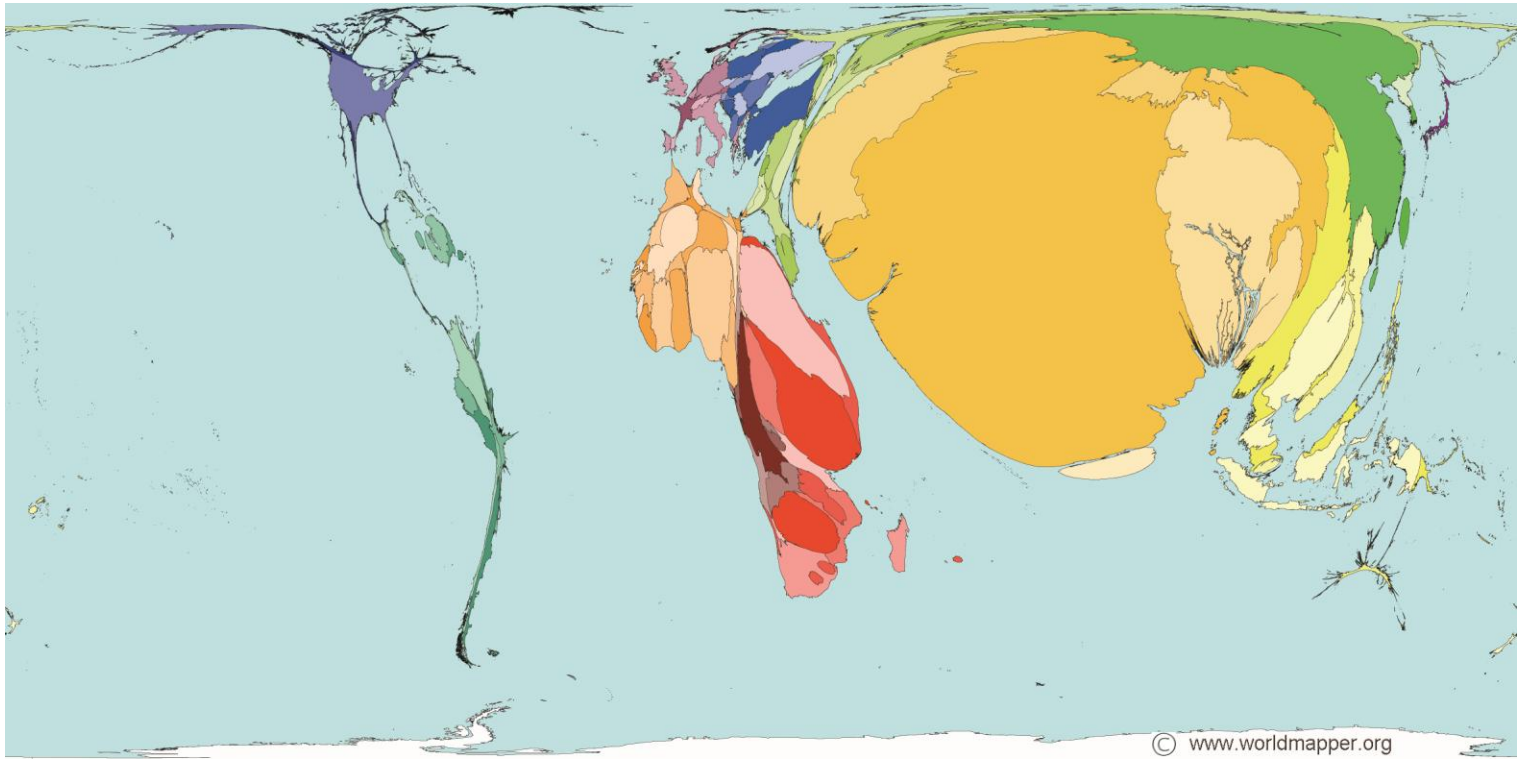
Poor infrastructure

- Relative proportions of global landline telephone faults 2002



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Ad-hoc medical facilities

- Free-market without regulation / standards
- Out of calibration, incorrect supplies, little training

Figure: Freelance X-ray service in Guatemalan highlands
(Device is very old, X-rays developing on washing line!)

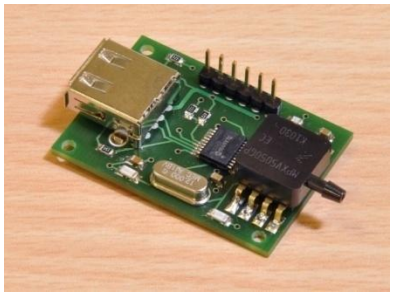
Supply Chain Solution?

Use smart phones, dumb peripherals

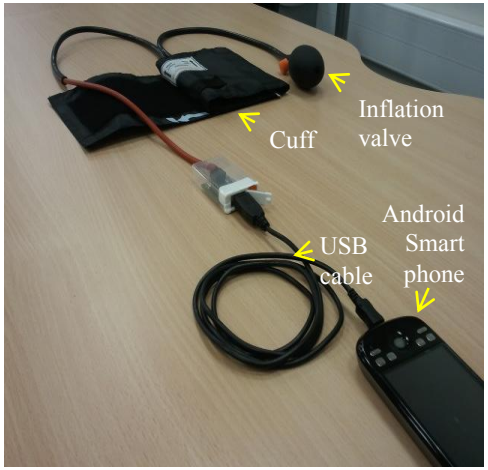
Can you find it on a market?

- **Build cheap (~$5-10) hardware**
- **Try to use low-cost sensors**
- **Avoid wireless transmission components if possible**
  - **USB connector makes pairing trivial**
  - **Supplies power - no battery needed**
  - **Watch out for isolation compliance!**
- **Offload all processing to phone**
  - **Uploads to medical record in one hop**
  - **Can be tune to specific population**
  - **Transparent firmware and software updates over phone network**

E.g.



- **CVD**
  - **New BP monitor plugs into phone to reduce #hops for data**
  - **No wireless transmission components**
  - **USB supplies power – no battery**
  - **<$5 of components**
  - **Can be tuned to specific population**

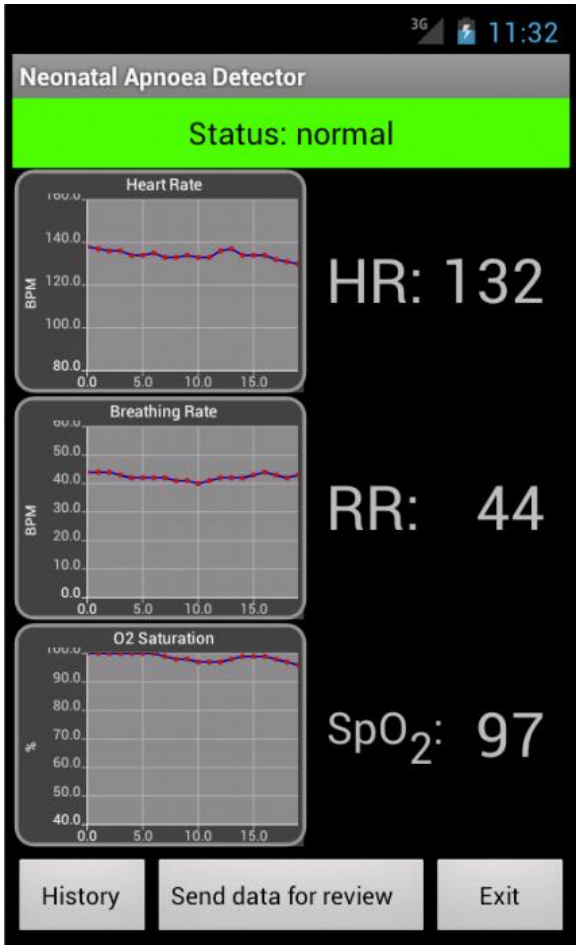


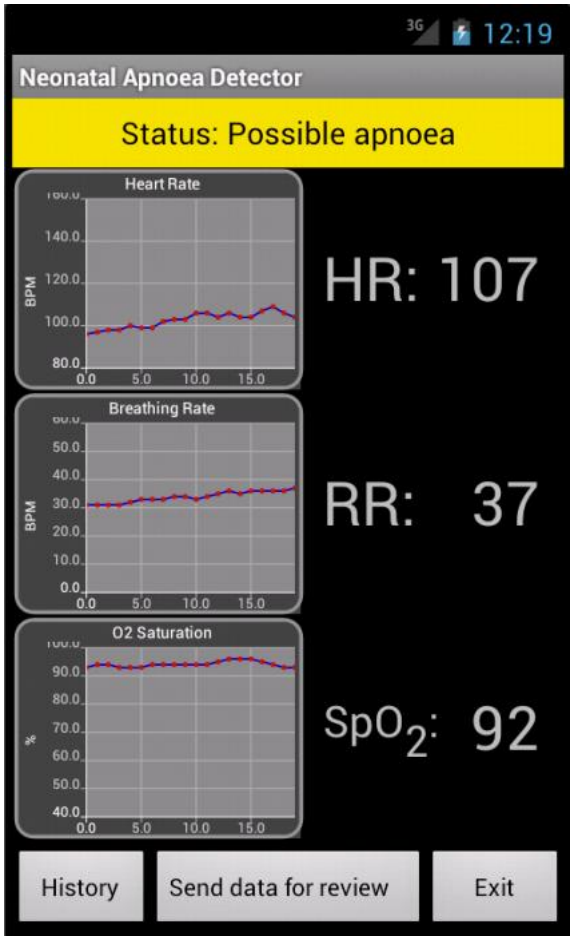
- **Sleep - Use only sensors on phone**
  - **Microphone, accelerometer & camera**
  - **Signals analysed using AI to classify patient**
  - **90% accurate – highly specific!**

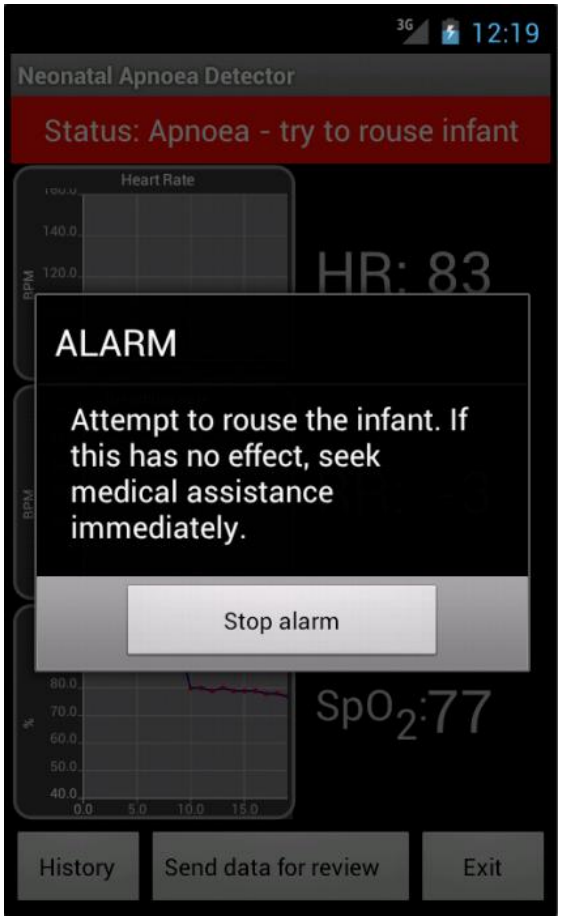
- **Mental Health**
  - **Phone actigraphy & sleep patterns -> schizophrenia**

Apnea monitor:

- Android / USB
- Web connected
- Cost = $15 (Simple circuit/sensors)







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Portable health data?

- **Open EMRs? How to choose a schema?**
- **PHR – IndivoX, MS Healthvault, Google Health, and export formats?**
- **Synchronisation**
  - **Assume store and forward**
  - **How to resolve differences?**
    - **Feedback to user**
    - **Use weighting paradigm – treat per multiple annotator situation**
- **Standard ontolgies**
  - **Coping with different dialects / languages**
  - **Does the software even support your character set?**
  - **Lost in translation?**

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How to evaluate your software?

Can't just look at the software – need to look at the entire system:

- Check compliance with requirements specification - defines what the 'customer' wants
- Check compliance with design specification - defines how you satisfy what the customer wants

- **Begin by using a standard database (e.g. Physionet.org)**
- **Adjudicate annotations / re-label!**
- **Stress test the system using realistic noise**
- **Then build a new database of annotated medical data using your own system (it's always different)**
- **Alpha test in-house (friends/family) then Beta test in the field**
- **Use local teams field who co-design**
- **Conduct a pilot**
- **Publish in peer reviewed journals**
- **Conduct a RCT - Randomised Control Trial**
- **Publish again**

Generic building blocks same for hardware and software

- Essential Requirements
  - Requirements specification: what the customer wants.
  - Design specification - how you satisfy requirements
- Risk and Classification (e.g. Class I, II, III etc)
- Standards (see appendix)
- Testing (RF, current leakage, isolation, defib)
- Approval (510(k)?)
- Vigilance – continual testing and monitoring
- User Reporting – must report problems

Premarket notification: 510(k) Predicate route

- Quickest route to medical device approval is Premarket Notification 510(k)
- Identify ‘predicate’ device(s) that is/are ‘substantially equivalent’ to your device
- Prove equivalence (e.g. BP)
  - Identify a set of patients (normal, hypertension, pre-eclampsia, hypotensive populations)
  - Compare your blood pressure monitor to existing 510(k) cleared device under variety of circumstances
  - Prove differences are no larger than those of predicate device / within tolerance
  - Oddly enough, compound errors are ignored!

Summary

http://sanamobile.org

- **Open Source infrastructure (Sanamobile.org)**
  - **BSD license to allow proprietary plugins / business models**
  - **Universal (multilingual) ontologies**
  - **Portable personal medical record plugs into hospital EMR**

- **Human error reduced through multiple expert adjudications**
  - **Intelligent UI to improve data at source**
- **AI algorithms trained on human annotations:**
  - **Doctors only have to look at a tiny %age of cases**
  - **Reduces costs, offloads it to phone or cloud**
- **Hardware has to use existing supply chains: peer-to-peer**
  - **Low cost/disposable sensors that plug into USB port**

Main learning objectives

1. Due to a lack of trained experts, software needs to be more intelligent, providing decision support, quality feedback on data collection, and automated diagnosis/referral for several patient categories.

2. To develop such algorithms, we often need labelled data. Humans (and algorithms) must label the data together, but they are fallible, so we need to use multiple annotator schemes to adjudicate the discrepancies.

References:

LM Koran - The reliability of clinical methods, data and judgments, New England Journal of Medicine, 1975 - Mass Medical Soc
http://www.nejm.org/doi/pdf/10.1056/NEJM197509252931307

M Imhoff, R Fried, U Gather, S Siebig and C Wrede, Intra-observer and inter-observer variability of clinical annotations of monitoring data, Critical Care 2007, 11(Suppl 2):P437 doi:10.1186/cc5597

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Mindray

Royal Society

www.robots.ox.ac.uk/~gari

Appendices

Appendices – Regulatory links

New FDA mobile app possibilities:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ucm255978.htm

UK

"Guidelines on the Qualification and Classification of Stand Alone Software" has been published as MEDDEV 2.1/6 under Section 2.1 (Scope, field of application, definition) http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf .

MHRA Software Forum
http://www.mhra.gov.uk/Howweregulate/NewTechnologiesForums/DevicesNewTechnologyForum/Forums/CON084987

Design Management Forum may also be of interest.
http://www.mhra.gov.uk/Howweregulate/NewTechnologiesForums/DevicesNewTechnologyForum/Forums/CON114465

US Medical Device Class Definitions

Class I devices are subject to the least regulatory control. They are not intended for use in supporting or sustaining life or to be of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury.[Most Class I devices are exempt from the premarket notification and/or good manufacturing practices regulation. E.g.: hand-held surgical instruments or examination gloves

Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances and require extra special controls. A few Class II devices are exempt from the premarket notification. Special controls may include special labeling requirements, mandatory performance standards and postmarket surveillance. E.g.: powered wheelchairs, infusion pumps.

Class III device is one for which insufficient information exists to assure safety and effectiveness solely through the general or special controls sufficient for Class I or Class II devices. Such a device needs premarket approval, a scientific review to ensure the device's safety and effectiveness, in addition to the general controls of Class I. Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. E.g.: implantable pacemaker, HIV diagnostic tests and automated external defibrillators.

Device Classification". *Medical Devices*. U.S. Food and Drug Administration.
General and Special Controls". *Medical Devices*. U.S. Food and Drug Administration.

Pre-Market Approval (PMA)

Class I: Must only follow FDA general controls, no 510(k) or PMA needed.[2]
Class II: Use the 510(k) process which uses a pre-existing similar device in the market called a "predicate device" for comparison.
Class III: Use the PMA process whereby no "predicate device" exist, such as in a New Drug Application.

Good science and scientific writing is a key to the approval of PMA application. If a PMA application lacks elements listed in the administrative checklist, FDA will refuse to file a PMA application and will not proceed with the in-depth review of scientific and clinical data. If a PMA application lacks valid clinical information and scientific analysis on sound scientific reasoning, it will delay FDA's review and approval. PMA applications that are incomplete, inaccurate, inconsistent, omit critical information, and poorly organized have resulted in delays in approval or denial of PMA applications. Manufacturers should perform a quality control audit of a PMA application before sending it to FDA to assure that it is scientifically sound and presented in a well organized format.

Technical Sections: The technical sections containing data and information should allow FDA to determine whether to approve or disapprove the application. These sections are usually divided into non-clinical laboratory studies and clinical investigations.

Numerous device-specific FDA guidance documents that describe data requirements are available. Study protocols should include all applicable elements described in the device-specific guidance documents.

EU

Council Directive 93/42/EEC provides for four classes, ranging from low risk to high risk.

- **Class I (including Is & Im)**
- **Class IIa**
- **Class IIb**
- **Class III**

The authorization of medical devices is guaranteed by a Declaration of Conformity which is issued by the manufacturer itself, but for products in Class Is, Im, IIa, IIb or III, it must be verified by a Certificate of Conformity issued by a Notified Body.

A Notified Body is a public or private organisation that has been accredited to validate the compliance of the device to the European Directive.

Medical devices that pertain to class I (on condition they do not need to be sterilised or are not used to measure a function) can be put on the market purely by self-certification.

Classification criteria include duration of body contact, its invasive character, its use of an energy source, its effect on the central circulation or nervous system, its diagnostic impact or its incorporation of a medicinal product.

Certified medical devices should have the CE mark on the packaging, insert leaflets, etc.. These packagings should also show harmonised pictograms and EN standardised logos to indicate essential features such as instructions for use, expiry date, manufacturer, sterile, don't reuse, etc.

EU:

EUROPEAN COMMISSION ENTERPRISE AND INDUSTRY DIRECTORATE GENERAL

Consumer Goods, Cosmetics and Medical Devices

MEDDEV. 2.7.1 Rev.3 December 2009 ¯ GUIDELINES ON MEDICAL DEVICES
CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
http://ec.europa.eu/health/medical-devices/files/meddev/2_7_1rev_3_en.pdf

European Legislation

Council Directive 90/385/EEC of 20 June 1990 concerning active implantable medical devices
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
GHTF final documents
SG1/N011:2008 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
SG1N44:2008 Role of Standards in the Assessment of Medical Devices
SG1/N029:2005 Information Document Concerning the Definition of the Term Medical Device¡¨
SG1/N040:2006 Principles of Conformity Assessment for Medical Devices
SG1N41R9:2005 Essential Principles of Safety and Performance of Medical Devices
SG5/N1R8:2007 Clinical Evidence ¡V Key definitions and Concepts
SG5/N2R8:2007 Clinical Evaluation

European guidance documents

MEDDEV 2.10/2 Designation and monitoring of Notified Bodies within the framework of EC Directives on medical devices
MEDDEV 2.12/2 Guidelines on postmarket clinical follow up
NBOG BPG 20091 Guidance on design dossier examination and report content
http://www.nbog.eu/resources/NBOG_BPG_2009_1.pdf
NBOG BPG 20094 Guidance on NB¡¥s Tasks of Technical Documentation Assessment on a Representative Basis
http://www.nbog.eu/resources/NBOG_BPG_2009_4_EN.pdf

International standards

General requirements

ISO 14155-1: 2003 Clinical investigation of medical devices for human subjects - Part 1
ISO 14155-2: 2003 Clinical investigation of medical devices for human subjects - Part 2 Clinical investigation plan

ISO14971: 2007 Medical devices; application of risk management to medical devices.

Biological Evaluation of Medical Devices Series

http://www.aami.org/publications/standards/biotcd.html

Part 1: Evaluation and testing (ANSI/AAMI/ISO 10993-1:2009)
Part 2: Animal welfare requirements, (ANSI/AAMI/ISO 10993-2:2006)
Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity, 2ed (ANSI/AAMI/ISO 10993-3:2003)
Part 4: Selection of tests for interactions with blood (ANSI/AAMI/ISO 10993-4:2002(R)2009 & A1:2006(R)2009)
Part 5: Tests for in vitro cytotoxicity, 3ed (ANSI/AAMI/ISO 10993-5:2009)
Part 6: Tests for local effects after implantation, 2ed (ANSI/AAMI/ISO 10993-6:2007)
Part 7: Ethylene oxide sterilization residuals, 3ed (ANSI/AAMI/ISO 10993-7:2008
Part 9: Framework for identification and quantification of potential degradation products, 2ed (ANSI/AAMI/ISO 10993-9:2009)
Part 10: Tests for irritation and delayed type hypersensitivity, 2ed
(ANSI/AAMI BE78:2002(R)2008; adoption of ISO 10993-10:2002 with national deviation)
Part 11: Tests for systemic toxicity (ANSI/AAMI 10993-11:2006)
Part 12: Sample preparation and reference materials, 3ed (ANSI/AAMI/ISO 10993-12:2007)
Part 13: Identification and quantification of degradation products from polymeric medical devices, 1ed
(ANSI/AAMI/ISO 10993-13:1999/(R)2004)

regulations continued

Part 14: Identification and quantification of degradation products from ceramics, 1ed (ANSI/AAMI/ISO 10993-14:2001/(R)2006)
Part 15: Identification and quantification of degradation products from metals and alloys, 1ed (ANSI/AAMI/ISO 10993-15:2000/(R)2006)
Part 16: Toxicokinetic study design for degradation products and leachables, 2ed (ANSI/AAMI/ISO 10993-16:2010)
Part 17: Establishment of allowable limits for leachable substances, 1ed (ANSI/AAMI/ISO 10993-17:2002(R)2008
Part 18:Chemical characterization of materials (ANSI/AAMI BE83:2006)
Part 19: Physicochemical, morphological, and topographical characterization of materials (ANSI/AAMI/ISO 10993-19:2006)
Part 20: Principles and methods for immunotoxicology testing of medical devices (ANSI/AAMI/ISO 10993-20:2006)
Clinical investigation of medical devices for human subjects - Part 1: General requirements, 2ed (ANSI/AAMI/ISO 14155-1:2003 (R)2008)
Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans, 1ed (ANSI/AAMI/ISO 14155-2:2003(R)2008)
Guidance for ANSI/AAMI/ISO 10993-7:1995, Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals, 1ed and Amendment (AAMI TIR19:1998; TIR19/A1:1999)
22442-1:2007, Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
22442-2:2007, Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
22442-3:2007, Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents

Regulations in China

SFDA: State Food and Drug Administration
www.sfda.gov.cn

Specific regulations for registration of medical devices covered by Decree 16 of SFDA, issued on August 9, 2004 (9 chapters, 56 articles, plus 12 annexes.).

See: Chang Yongheng, "Brief Introduction of Medical Device Regulations in China“ -in Workshop A (Regulatory Model for Development of Device Regulatory Systems: Needs, Barriers and Constraints Associated with National Implementation), 11th Conference of the Global Harmonization Task Force, 'Working Towards Harmonization in Medical Device Regulation‘ Washington DC, 3-4 October 2007

And:
http://www.emergogroup.com/resources/regulations-china

Regulations in India

The Central Drugs Standard Control Organization (CDSCO)

Since 2008, both the Indian Department of Science and Technology and the Ministry of Health have sought to completely restructure the regulations for medical devices.

- Department of Science and Technology: proposed creation of a Medical Devices Regulatory Authority that would operate similar to a division within the CDSCO.
- Ministry of Health: proposed revision of the DCA that would create a Central Drug Authority to function similarly to the U.S. FDA.

To date, neither of these attempts has been successful. In 2009, multiple reports suggested that the Department of Science and Technology had the more favourable suggestion. Based on more recent statements by legislators and other government officials, however, there seems to be stronger support for the Ministry of Health's proposal. Furthermore, India's Prime Minister's Office has reportedly given its sponsorship to the Ministry of Health's idea.

Despite these attempts by other organizations at reforming medical device control in India, the CDSCO is continuing to entrench its own medical device regulation standards. In June 2009, it seemed as if the CDSCO would begin its own form of medical device regulations.

- CDSCO: released Schedule M-III, which provided an official definition for medical devices, outlined a four level medical device risk classification scheme, created a body within the CDSCO to regulate medical devices in India, and more. This notice was approved by the Indian government, but in practice, most medical devices are not regulated.

See here for more information:
http://www.medicaldevices.org/sites/default/files/India%20Medical%20Device%20Regulations.pdf

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