ECE 411
Industry Design Practices
Vaccine Monitoring Case Study

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Case Study: Vaccine Temperature Monitoring

- Where does product idea come from?

Thousands may need new shots

By Patrick O'Neill

Because of faulty vaccine storage, many low-income kids may need revaccinating

Multnomah County will likely have to revaccinate several thousand mostly low-income children because vaccines were not stored at proper temperatures during the past three years. State health officials found problems with the temperatures during a federally mandated review of the county clinics' temperature logs…

- Requirements Specification
  - Need, Objective, Background, Requirements
  - First step: interview people
    - Multnomah County Health Department, individual clinics

Needs Identification

1. What are your trying to do? Articulate your goals using absolutely no jargon.

2. How is it done today, and what are the limitations of current practice?

3. What is new in your approach, and why do you think it will be successful?

4. Who cares? If you are successful, what difference will it make?

5. What are the risks and payoffs?

6. How much will it cost? How long will it take?

7. What are the midterm and final "exams" to check for success?
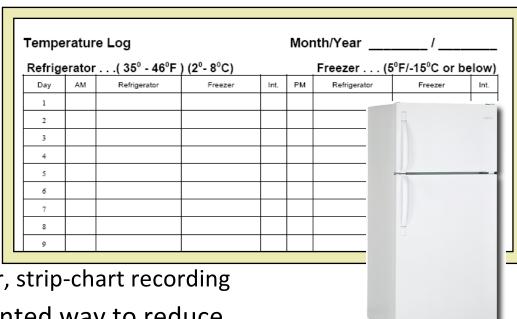
Cost of Improperly Stored Vaccine

- Direct costs
  - Vaccine replacement
  - Revaccination
    - Administrative: Identify and notify clients
    - Labor: Administer vaccine
- Indirect, intangible costs
  - Risk of outbreak
  - Loss of confidence in system

West Virginia: $360K direct costs in period September 30, 2005 - September 29, 2006
-- Robert Fernatt, MS thesis Marshall University, WV.

(West Virginia's population: 1.8M)

Current Status

- Many clinics use ordinary residential refrigerator/freezers
- Rely on manual monitoring
  - Periodic visual inspection
  - Paper record
  - Potential problems
    - Training
    - Human error
    - Restricted to working hours!
- Vaccine freezers
  - Expensive $$$
  - May provide temperature monitor, strip-chart recording
- Need: Inexpensive, easily implemented way to reduce vaccine spoilage due to out of range temperature
- Objective: real-time monitoring, notification, data storage
  - Remote access
  - E-mail or text message alerts
  - Data storage for archival, subsequent analysis
    - Root cause
    - Time out of compliance

Requirements: Constraints

- Permit use of existing refrigerator/freezer units without modification
  - No funds to replace existing units
  - No funds for costly or semi-skilled installation (e.g. drilling, etc)
- Inexpensive
  - Unit cost (in high volume) of < $300
  - Attempt to match price of chart recorders (albeit with more functionality)
- Demonstrate system as soon as possible
- Use "off-the-shelf" open components to build demonstration system
  - Speed development time
  - Reduce expense: no custom hardware
  - Easily supported: no proprietary formats
- SQL Database
  - All data maintained in database (maintenance and traceability)
  - No need to re-invent wheel, ample tools for data display, formatting
  - Standard database technology and data model (tables)
  - Standard query language, interface

Requirements

- Background
  - How many clinics/sites statewide, nationwide?
  - Is internet access available in most clinics?
- Functionality
  - Inputs, Outputs, Functionality
    - Temperature range and accuracy
    - Reporting interval
    - Thresholds for compliance
    - Audible alert desired on site
      - Ability to temporarily suppress sound ("snooze") but not override
      - Visual display → incremental cost (LCD display)
  - Compatibility
  - Standards
- Performance
  - How much data maintained for how long
  - How many sites, freezers, refrigerators

Requirements

- Operational (Physical Environment)
  - Office/clinic environment
  - AC available (powering fridge/freezer), but prefer battery (outages!)
  - Must fit inside freezer/fridge, not take up "too much" space
    - Separate probe, transmitter box? Box placement (on/beside freezer/fridge)?
- Reliability & Availability
  - No on-site technicians
  - High reliability crucial part of application
- Social & Cultural
  - What is social/cultural milieu?
    - Non-technical people (nurses, not nerds)
  - Localization/internationalization
  - Aesthetics
    - Clinical setting (some more "clinical" than others)
- Political (Governmental, Union)
  - Approvals

Requirements

- **Economic**
  - Cost to design
    - 4 students, 6 months
  - Cost to manufacture
    - < $300 (if selling at cost!)
  - Cost of ownership
    - Battery replacement?   Internet access?   Web site hosting?   Power?
- **Energy**
  - AC available, but prefer batteries
  - Single 9V or 2x AA with 1 year life
    - Rationale: size, currently change chart recorder paper more frequently
- **Health & Safety**
  - No sharp edges, no cables to trip over, no possibility of shock
- **Legal**
  - Non-infringing
  - Data encryption
    - No patient-specific data

Requirements

- Environmental
- Maintainability
  - No user-serviceable parts, no regular maintenance aside from battery
- Manufacturability
  - Easily manufactured, off-the-shelf components
  - Rationale: Cost – more manufacturing options, lower costs
- Usability
  - Literally plug & play (no on-site customization, programming, etc)
  - Web site usable without documentation and no training
    - For most common functions
- Documentation
  - Device installation: single sheet
  - Web site user documentation: on-line via web-site
  - Maintainer's documentation!

Modeling

- Physical view
  - System Architecture H/W & S/W
    - Sensing units
    - WiFi access points
    - Data reporting server
    - DB server
    - User interface server
    - Software stack on each piece of H/W
- Entity Relationship Diagram
  - Data Model
  - People, Fridge/Freezers, Clinics, Sites, Organizations
- Interaction View
  - Sensing unit reporting samples to data reporting server
  - Users "installing" new sensing units, accessing historical data/reports
- Use Case view
  - Installing sensing unit "out of the box"
  - Obtaining data on a particular unit
- Activity view
  - Embedded software in sensing unit