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“Introduction of Ethics in Systems Design and Architecture Development"

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Key HIT ethics criteria: Patient Empowerment

1. **Informed Consent:** Opt In/Opt Out under HIE state law – Permission to use particular personal data for specific purposes
   - **Justice**: HIT should give patients the authority to control the sharing and use of their personal health information
2. **Confidentiality:** Privacy protection through HIT
   - **Trust**: Only certified, authenticated, authorized persons have access
   - **Anonymization**: Deidentified patient information cannot be reconstituted
3. **Transparency:** HIT gives easy access to information about one's health and care
   - **Personal Knowledge**: HIT should help educate patients about their health status, risks, care plans, costs and options

Key HIT ethics criteria: Provider Responsibilities

1. **Beneficence:** HIT decision support helps providers deliver high value care to their patients
   - **Risk-Benefit Analysis**: HIT helps weigh and balance possible benefits against possible risks & costs of an action
   - **Non-maleficence:** Self correcting HIT process helps prevent provider errors that may harm patients physically, emotionally, and financially (Do No Harm)
   - **Double-effect:** HIT decision support helps avoid device failure and other unintended consequences
2. **Professional relationships:** HIT helps provider teams collaborate and coordination care to:
   - Minimize errors of omission and commission
   - Continuously increase care value to the patient via CQI processes

Key HIT ethics criteria: Patient-Provider Relationship

Shared Decision Making: HIT enables patient and provider collaborate to create and implement plan of care

- **Autonomy:** HIT supports a patient's right to make his or her own choices
- **Informed Consumer**: HIT helps educate the patient to become an knowledgeable consumer of healthcare with a strong voice in decisions

What is the Definition: Ethics and Technology?

- Deloitte's Keith Darcy:
  - “Technology is the biggest challenge to ethics and compliance in organizations today,”
  - “We have the capacity to do things before we ever consider the ethical consequences.”
- “Computer and information ethics”

  In the broadest sense of this phrase, can be understood as that branch of applied ethics which studies and analyzes such social and ethical impacts of information and communication technology (ICT).

Practice what we Teach:

In an asymmetric world, with the NSA and problems such as Target, etc., we must apply ethical principles to our standards, design, architecture, manufacturing, distribution and sales of products used by the citizen.

Social Ethics of Technology: A Research Prospect

- Richard Devon: “There is no shortage of illustrations of the role of social ethics in technology.”
- Consider the question of informed consent in the case of the Challenger.
  - The launch decision was made in the light of a new and considerable risk, of which the crew was kept ignorant (Boisjoly 1998; and see Vaughan 1996).
  - This apparently occurred again in the case of the Columbia (Ride 2003).
- Informed consent, absent here, is a well-known idea and represents a social arrangement for making a decision.
  - The skywalk of the Hyatt Regency failed because of a design change that was both bad and unchecked (Petroski 1985; Schinzinger & Martin 2000, p. 4).
  - A bad decision is one thing, an unchecked decision means that the social arrangements for decision-making were inadequate.

Ethical Issues: Addressing Federal Standards

- To have a substantive, national discussion:
  - On how the patient is integrated into the system when using EHR, CPOE, HIE, etc.
- To promote trust through our adherence to medical ethics:
  - Autonomy, confidentiality, informed consent, etc.
- To ensure that HIT capability exists at the point of care:
  - Encouraging a dialogue between caregiver and patient as to the extent that protected health information (PHI) affects their privacy and safety,
  - Providing self-correcting capability, so that, use, modification, loss, or misuse will not adversely affect patient care and identify.

Recognizing the Need: Applying ethical principles

- IEEE First Principle –
  - Accept responsibility in making decisions consistent with the safety, health, and welfare of the public
- IEEE-CS/ACM Joint Taskforce on Software Engineering –
  - Shall act consistently with the public interest
- AIChE Code of Ethics –
  - Members shall hold paramount the safety, health and welfare of the public

2014 IEEE/ACM Information Technology Professional Conference at TCF

- Technologists have a responsibility to the citizen to ensure privacy and security of information and to include ethical principles in any design, specification, architecture or tool.
  - Any specification or architecture must include ethical considerations and associated vulnerability and threat scenarios.
- The asymmetric world we live in demands a more thorough approach then we have witnessed.
  - Only by doing so will the industry recognize its responsibility Vis-a-vie consumer risk.

In today's secular, asymmetric world: A search for self-determination

- We see individuals as data points, or sources of information, possibly lacking any human quality, just numbers or letters in a database without any concern for human dignity.
  - Some believe that those who capture data own this information, even when it is very personal information.
- Those who do capture the information believe that it is their right to manipulate, corrupt, or make irrelevant the truth represented by the data.

Loss of Trust: NSA/NIST/Corporate America

- In healthcare and finance, we experience continued breach of our information.
- Hackers and terrorists alike are able to break into and extract our personal information.
- There is a basic problem with all of this manipulation and obfuscation; the Constitution prohibits such actions.

Ethical Principles Absent: An omission example

- "The ZigBee Alliance [23]" is an association of companies working together to enable reliable, cost-effective, low-power, wirelessly networked, monitoring and control products based on an open global standard.
- Thanks to its worldwide adoption, ZigBee specifications often become de-facto standards adopted by the majority of industries.

ETHICS?

Ethics Questioned? Systemic in society

- Office for Civil Rights enforces HIPAA Privacy Rule, it protects privacy of individually identifiable health information:
  - NSA/ACA/FBI/IRS compliance?
- Did NSA show little respect for the truth, by replacing truth with obfuscation
  - NIST/RSA manipulation, control, FISA manipulation, and 4th amendment destruction?
- Are the IHE White Paper statements HIE Security and Privacy through IHE controls for patient privacy undermined by NSA spying?

Patient Privacy & Security At Risk: What is it?

- **KeyHIE, Terms and Conditions:**
  - "Your privacy is of the utmost importance to us."....
- **Universal Authorization (Opt In):**
  - "...medical information may be further released
- **Geisinger Privacy Statement:**
  - "...You wave any and all rights to pursue Geisinger
- **Careworks & KeyHIE Patient Security:**
  - "We are committed to protecting your personal privacy.
- **Full Service HISP to HISP Terms Geisinger/Surescripts (BAA/NPP):**
  - "…the Parties assume no liability for or relating to the integrity, privacy, security, confidentiality, or use of any information
- **MyGeisinger security message:**
  - "...shared with organizations that have agreed to the highest levels of confidentiality

Where have Healthcare Systems Failed?

- 94% Healthcare organizations report breach
- 21 million patients affected by breach
- Approximately 3,000 records stolen per breach
- $2.4 million average price for responding to breach
- Average confidence level 50%
- Street value (identify theft) for identity $50

Potential Loss & Liability: Is Real!

- Cyber terrorist/Hacker Penetration
  - Breach
- Murder by Medical Device
  - Procedure Failure
- Five Rs (Right patient, drug, route, frequency, dose)
  - Insider Threats
- Identity Theft and PHI Corruption
  - Exposure/Loss of Private Key
  - Data Integrity
- Loss of Good Will

HIE Problems Contribute to Loss/Liability

After ONC began to invest over a half billion dollars in statewide HIEs, these problems remain unresolved:

- Complex and expensive
- Prone to error
- Insecure
- Financially unsustainable
- Unable to guarantee privacy protection
- Unable to assure stakeholder cooperation, since providing records is totally voluntary
- Unable to facilitate searching the data
- Disrupt clinician workflows
- Unable to interoperate widely enough

EHR Deficiencies Contribute to Poor Performance & Dissatisfaction

Studies indicate that EHR deficiencies include:

- Difficult to use, hampers productivity, and not interoperable [reference], [reference], [reference]
- Fail to coordinate care and disrupt workflows [reference], [reference]
- Cause information overload [reference]
- Provide immature clinical decision support [reference], [reference], [reference]
- Do poor job with patient education and shared decision-making between patient and clinician [reference], [reference]
- Will ultimately increase costs and make hospital-physician relationships less stable [reference]

Ethical Questions about the Testing Process, S&I Framework

Is it the intent of the SIFC to specify:

- A traceability function that mimics a user at each end of a transaction?
- A traceability function that traverses each path
- A traceability function that demonstrates end-to-end performance?

NO!

Suggested Testing Approach Leveraging Ethical Principles

- We believe our implementation (called RAHN™) requires changes to the specification and standards to incorporate a desktop-to-desktop implementation.
  - This requires construction of a test tool that has knowledge of all software paths, and that links each path to a specification paragraph number.
  - Hence, any failures, errors, omissions, or deviations from specification could be traced back to all SIFC documentation, vendor documentation, and both documentation version control and software release levels along with error history could be coordinated

How do we close the trust gap? We apply ethical principles?

- Trust versus trust
- The clinical encounter, etc.
- The use of Direct Trust versus Direct Conduit (SMTP/MIME)
- Essay: Anatomy of the Deep State, February 21, 2014, by Mike Lofgren
  - http://billmoyers.com/2014/02/21/anatomy-of-the-deep-state/

Where do we see the Implementation of Ethics in Technology

- Distributed systems (telephone network)
  - The customer is authenticated, authorized and certified to ensure person on the other end of the line is the person expected
- Cost to implement (minimal using COTS)
- ROI justification (Simple to use and build)
  - introduction into design, development, testing, and deployment

Who is Affected when Ethical Principles are Breached

- You and me, we are the victims
- Aggregate disclosures:
  - http://www.informationisbeautiful.net/visualizations/worlds-biggest-data-breaches-hacks/
  - Target's credit card breach affected 40 million accounts, and 70 million customers had personal information stolen
  - Adobe Systems said that hackers had accessed personal data for nearly 38 million of its customers: names, encrypted credit or debit card numbers, expiration dates and other information.

Ethical HIT: Summary of Key Points

Enables providers to:

- Prevent and remove harms
- Have adequate knowledge and skills to perform competently
- Do due diligence in evaluating care options
- Balance/weigh the relative benefits and risks of a care plan
- Preserve patient privacy and data integrity
- Make decisions together with patients

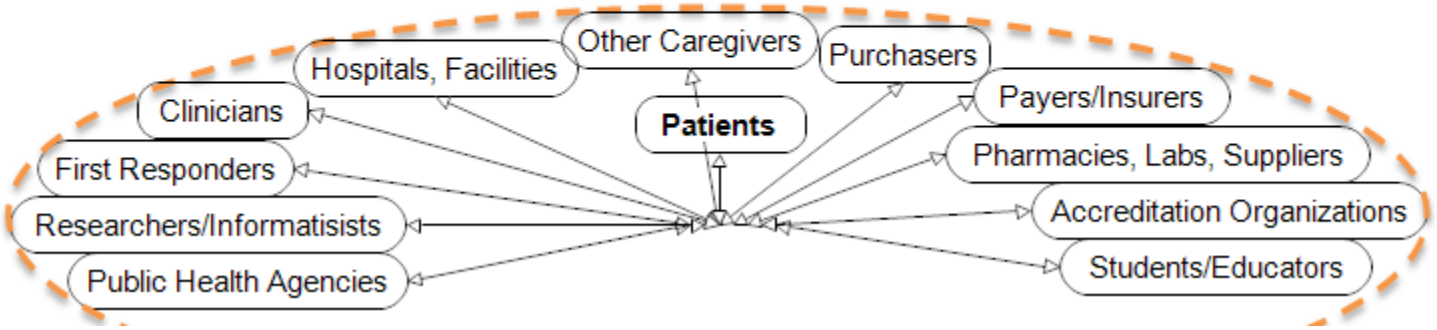
Requires the technology to:

- Enable collaboration and coordination of care planning and delivery
- Provide effective clinical decision support
- Promote discloser of pertinent information regarding benefits and risk to patient
- Encrypt patient data in transit and at rest to protect patient privacy, prevent data corruption, and assure data accuracy

Ethical HIT System

Stakeholder Networks:
Share, study and use healthcare information to support clinical and business decisions

Ethically Enabled Social Network



Stakeholders
Patient-Centric

Ethical HIT System

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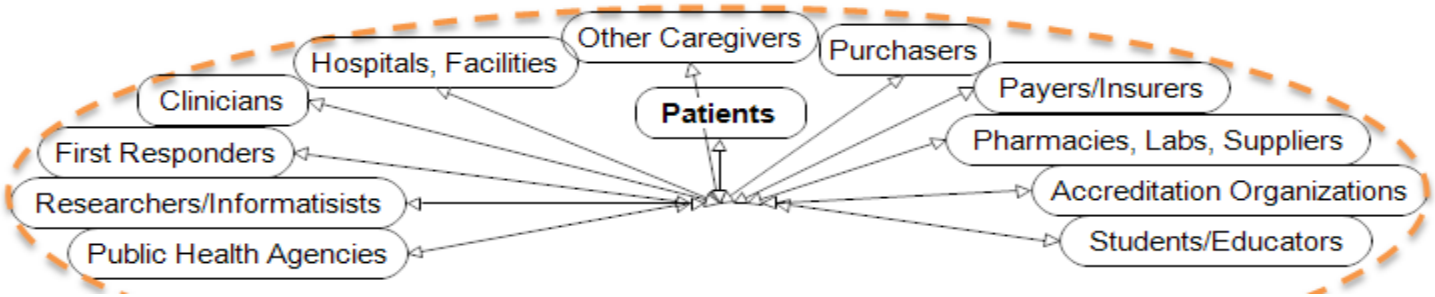
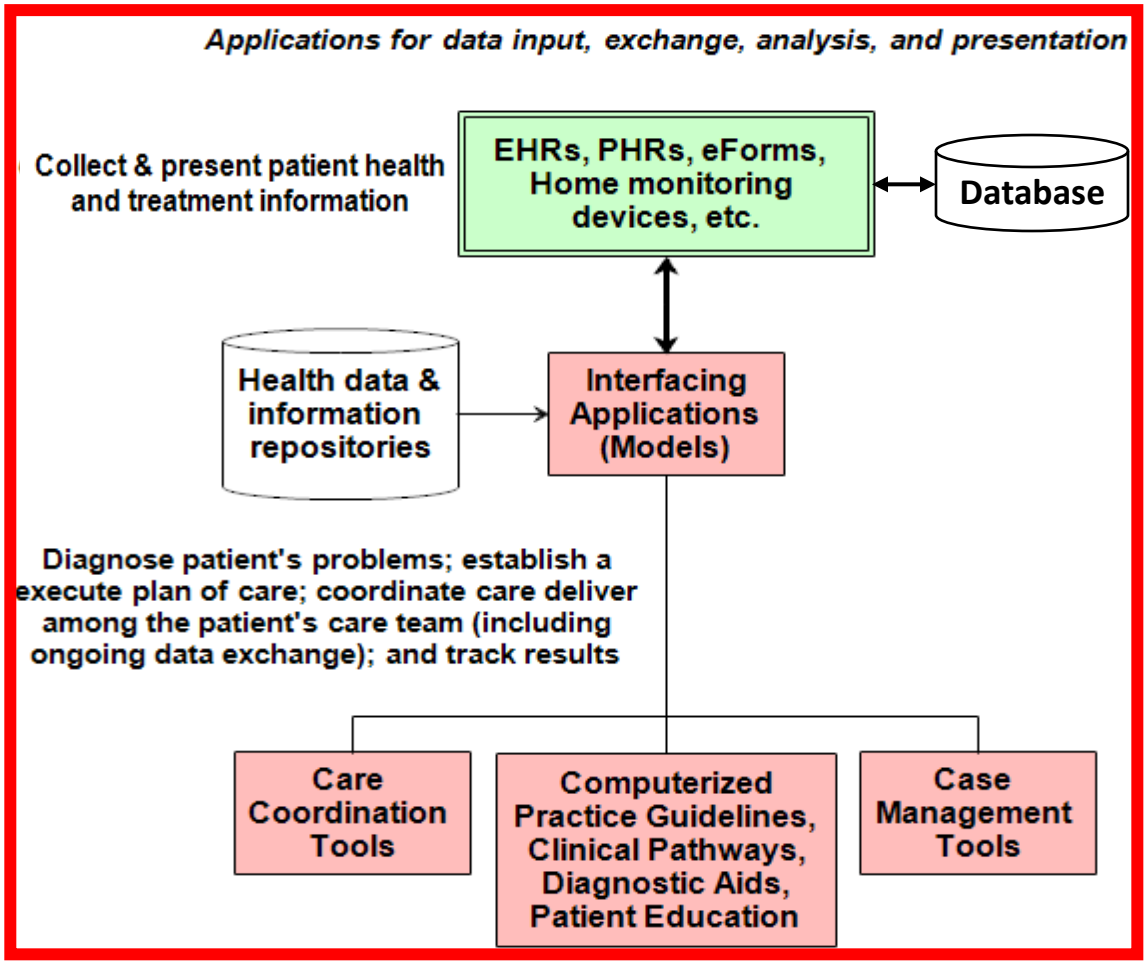


Clinical Apps



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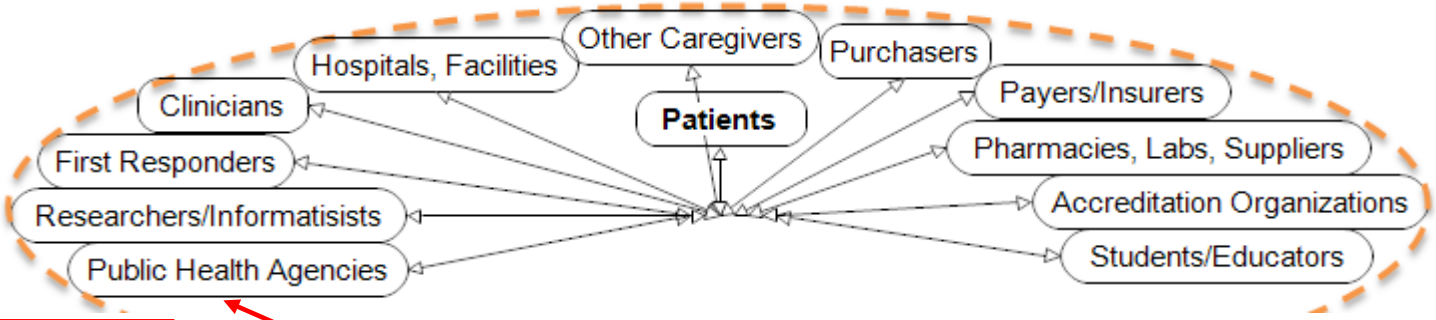
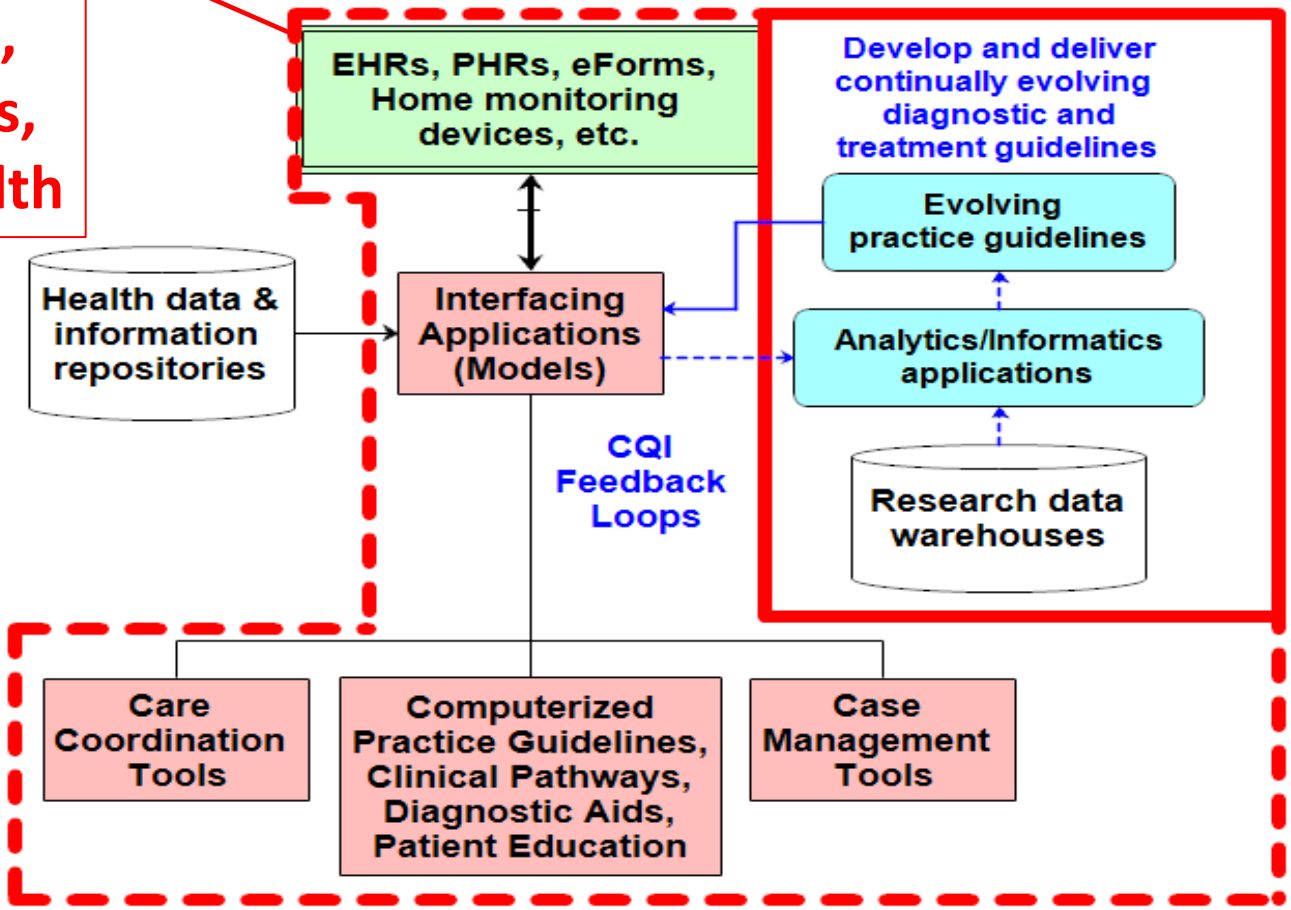


Research, Guidelines, Public Health



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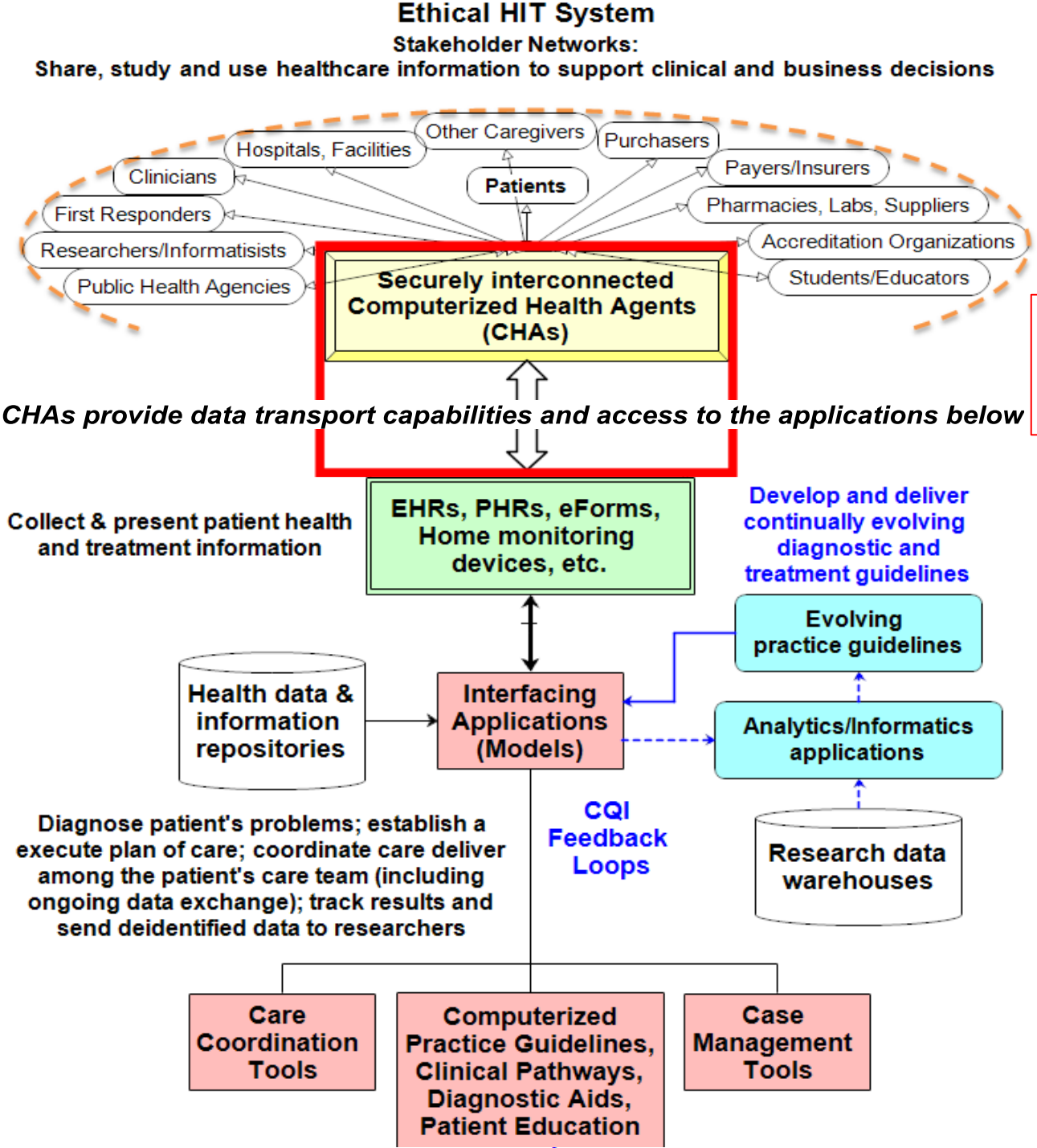
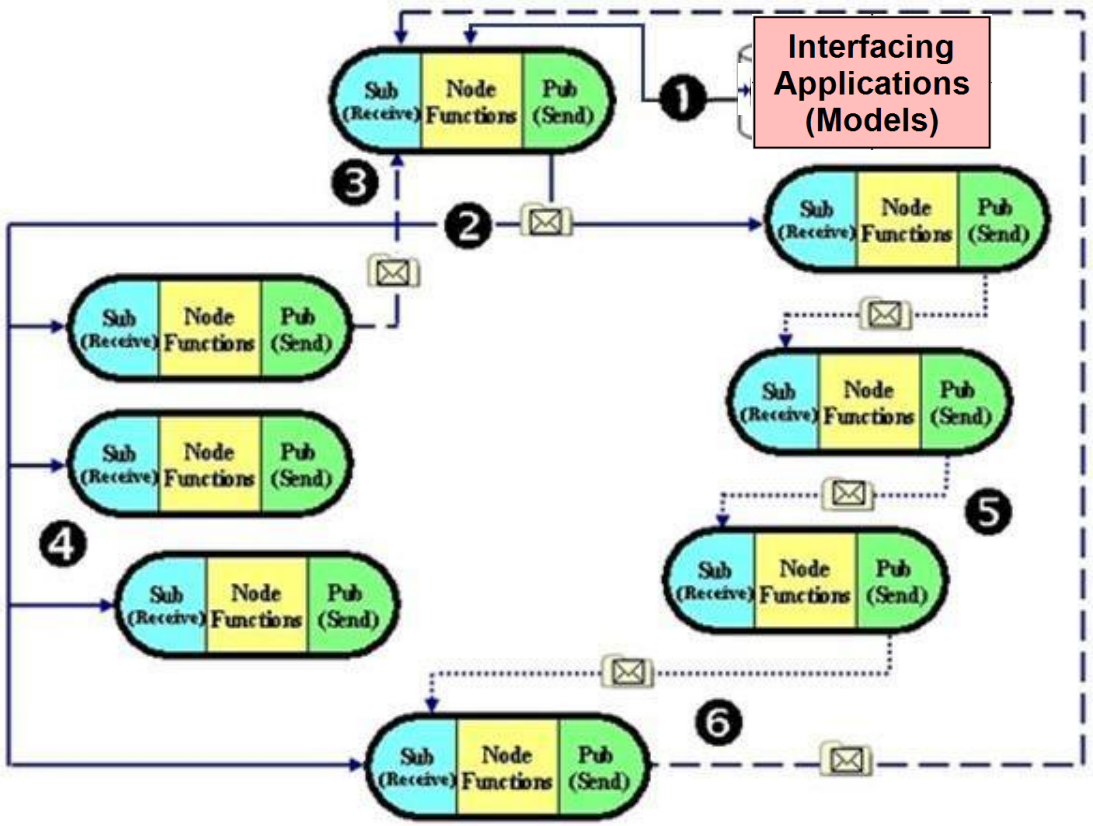
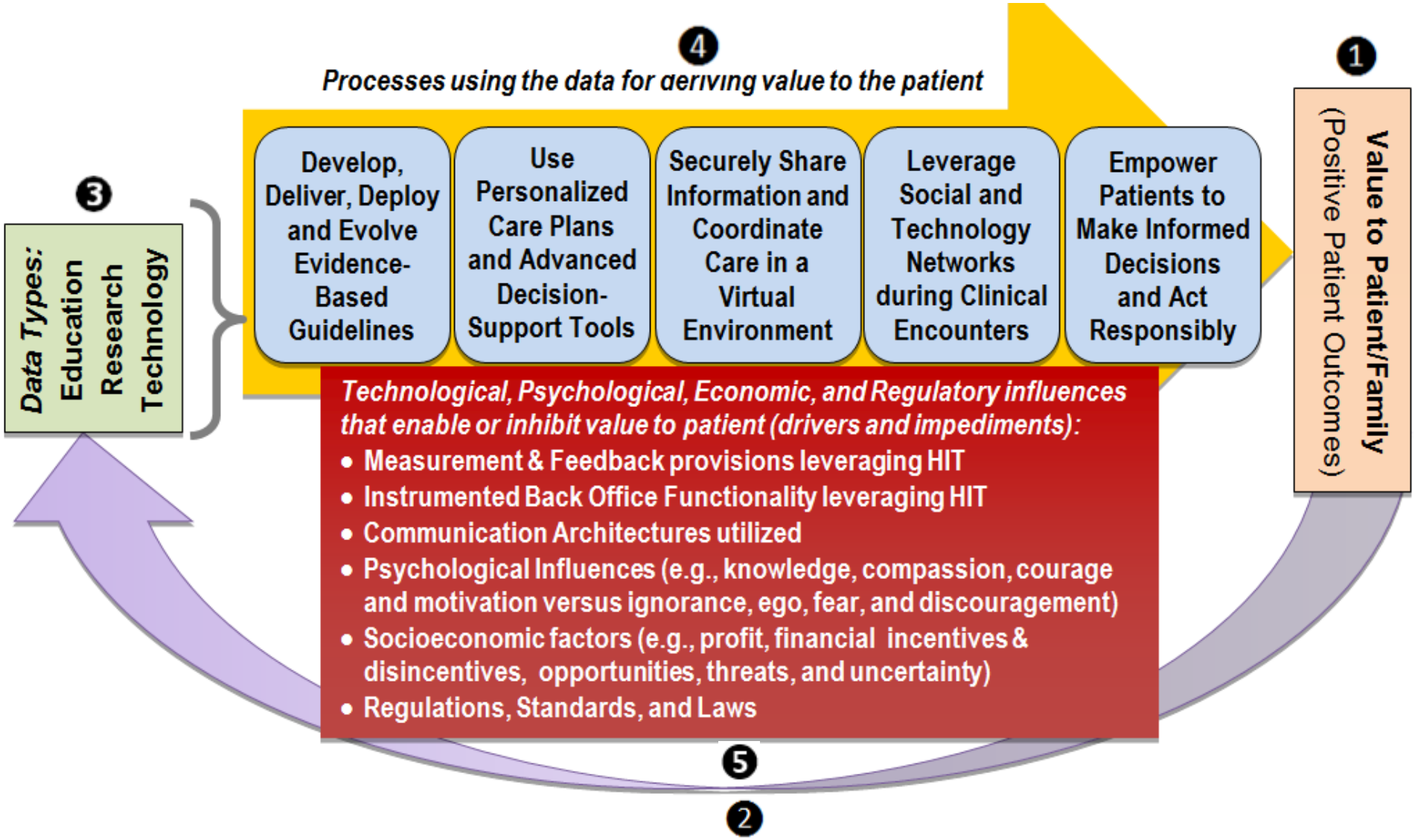


CHAs are Pub/Sub Nodes in a Mesh Node Network



Ethical Value Chain



Basis of Direct RFC-3335 Standard

- Trust is outside of scope
- Simple Interoperability
  - Interoperability problems are not technical
- Specifications arrived by Consensus
  - Protocols are existing protocols, SMTP/SMIME/X.500/LDAP/DNS/XDR
  - Communication takes place between security and trust agents (STA) using Mail Transfer Agents (MTA) between providers (or EHR)
- Applicability Statement 1 (AS1) Encryption
  - Transport independent of content

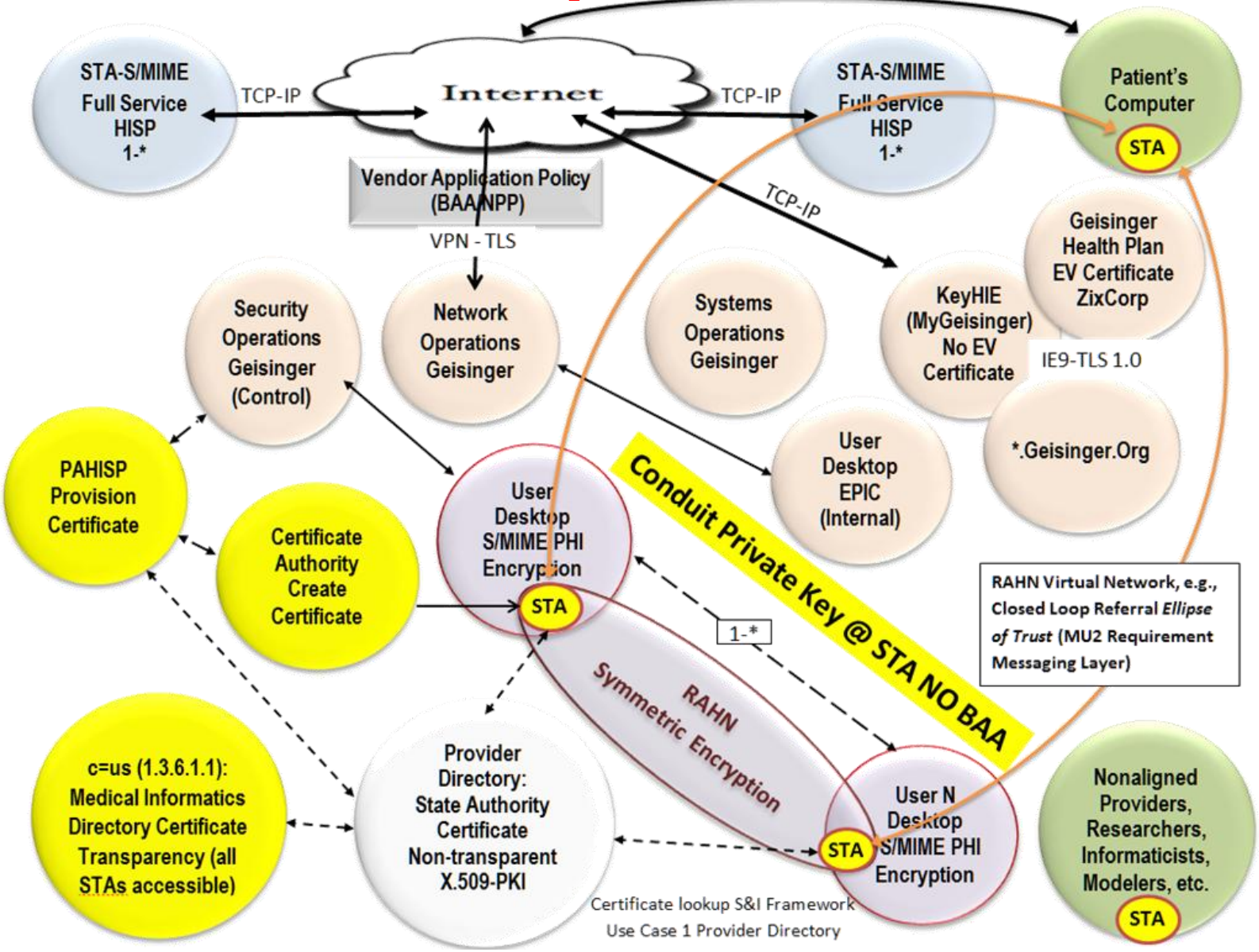
Who cares, the patient doesn't understand any of this?

Role of Provider Directory

- A combined technical and citizen political process (see Directory organization models) that satisfies social network constraints
  - Implemented by a trusted 3rd party that is Non-Government Organization and has clearable Intellectual Property (C=US)
- Each organization will run individual Provider Directories that is authoritative for their own data (Infrastructure)
  - RAHN STA case (1) used for locating certificates; (2) or enables the RAHN layer; (3) promotes ease of use by (N+1) users
  - Use case 1: Logical place to look for CA and User Certificates per X.500, X.509v3 and ISO 21091 standards via LDAPs
- Provides standard set of attributes (schema) for providers formalized in S&I Framework IHE balloting and ISO standards

We need the Committee to review this approach?

PHI World View (What?)



http://wiki.directproject.org/Applicability+Statement+for+Secure+Health+Transport+Working+Version

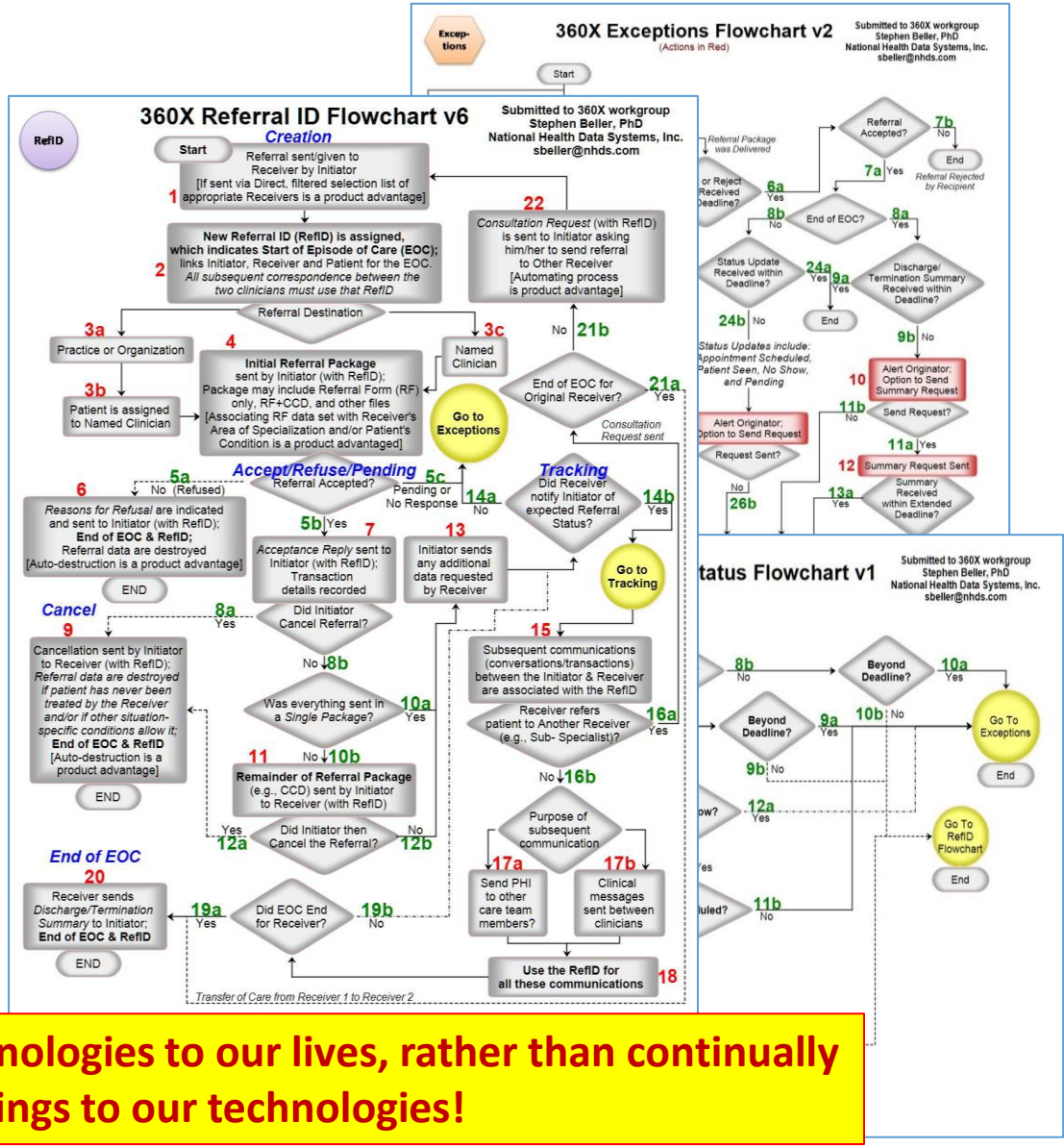
Back

Targets of Opportunity: Build Ethics into the design!

- Traceability – From desktop to desktop institute branch points that provide IP and MAC address for all system that touch the data
- Trust – Individual whose data is used knows who is a trusted recipient (authenticated)
- Tracking – Ensure that the authorized individual or group receives the data, and only them)
- Patient Benefit – If an organization achieves a benefit due to the use of patient data, patient receives remuneration (TBD)
- Rating – Based on past performance, users of data are expected to adhere to the ethical principles, their performance is measured

Workflow Challenges: 360X

- EHR and HIE vendors in the 360X Closed Loop Referral workgroup have been very resistant to dealing with complex clinical workflows:
  - They want to keep the software requirements for handling workflows at a very low level due to the effort required
  - The result is that clinicians have to change the way they work without gaining much benefit, resulting in user dissatisfaction and productivity loss



We should conform our technologies to our lives, rather than continually trying to optimize human beings to our technologies!

Appendix

- Example Code of Ethics

AIChE Code of Ethics

- Members of the American Institute of Chemical Engineers shall uphold and advance the integrity, honor and dignity of the engineering profession by:
  - being honest and impartial and serving with fidelity their employers, their clients, and the public;
  - striving to increase the competence and prestige of the engineering profession; and
  - using their knowledge and skill for the enhancement of human welfare.
- To achieve these goals, members shall hold paramount the safety, health and welfare of the public and protect the environment in performance of their professional duties.