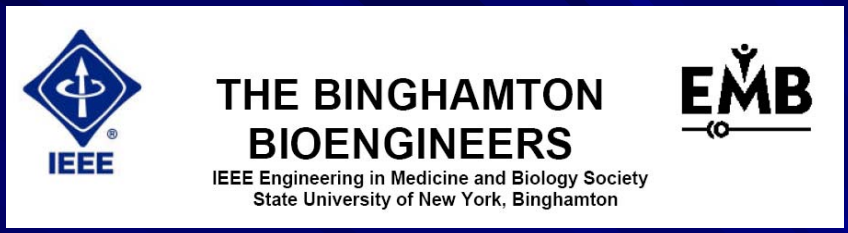



# SUNY - Binghamton University

Binghamton, NY

# Future of Clinical Engineering

March 11, 2005
2:00 pm

Stephen L. Grimes, FACCE
Senior Consultant & Analyst
**Strategic Health Care Technology Associates**
**www.SHCTA.com**

# On the Subject of *Change*

*"It's not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change"*

**Charles Darwin**

*"It's not the progress I mind, it's the change I don't like"*

**Mark Twain**

*"Change is good. You go first …."*

**Dilbert**

# Definition of Clinical Engineering

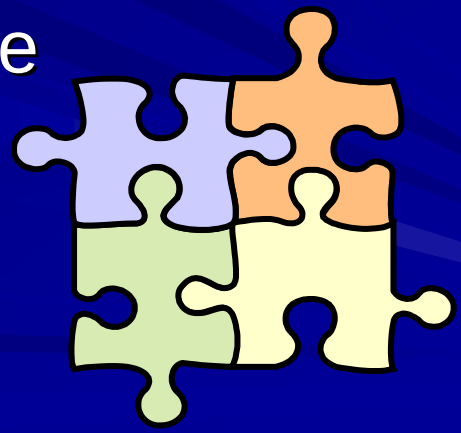
- American College of Clinical Engineering (ACCE) defines a clinical engineer as

  *"A professional who supports and advances patient care by applying engineering and management skills to healthcare technology."*

# Clinical Engineer's Role Considered in "Context"

Future CE role can only be predicted by understanding

- The future developments in healthcare … and the *forces* likely to bring that future about
- Clinical engineering's ability to contribute to future needs with respect to these developments



# Four Primary Forces Affecting Future of Healthcare Industry

- Technological
- Economic
- Regulatory
- Social

# Technological Forces

- Mapping the human genome
- Micro- and Nano- Technology
- Proliferation of computers in medicine
  - Knowledge-based, expert systems
  - Autonomic systems
- Connectivity …
  synergistic effect of interconnecting computers & other medical technology

# Technological Forces

- Mapping the human genome
  - ✓ Ability to screen/ identify individuals who possess genes that predispose them to certain diseases
  - ✓ Focus preventive efforts on those most at risk
  - ✓ Refine our treatments (i.e., ability to develop some treatments that target affected genes while still other treatments can be optimized for an individual patient based on what we know to be effective for someone of their genetic make-up)

# Technological Forces

- Micro- and Nano- Technology

  Technologies designed to be minimally invasive, minimally disruptive, and to closely mimic the body's own natural systems

  - ✓ Nano-particle vectors aid in drug delivery and DNA modification
  - ✓ Micro- and nano-scale devices functioning as artificial organs and surgical instruments
  - ✓ Micro- and nano-sensors under development to serve as probes and detectors at an organ, tissue, cellular or even molecular scale-level..

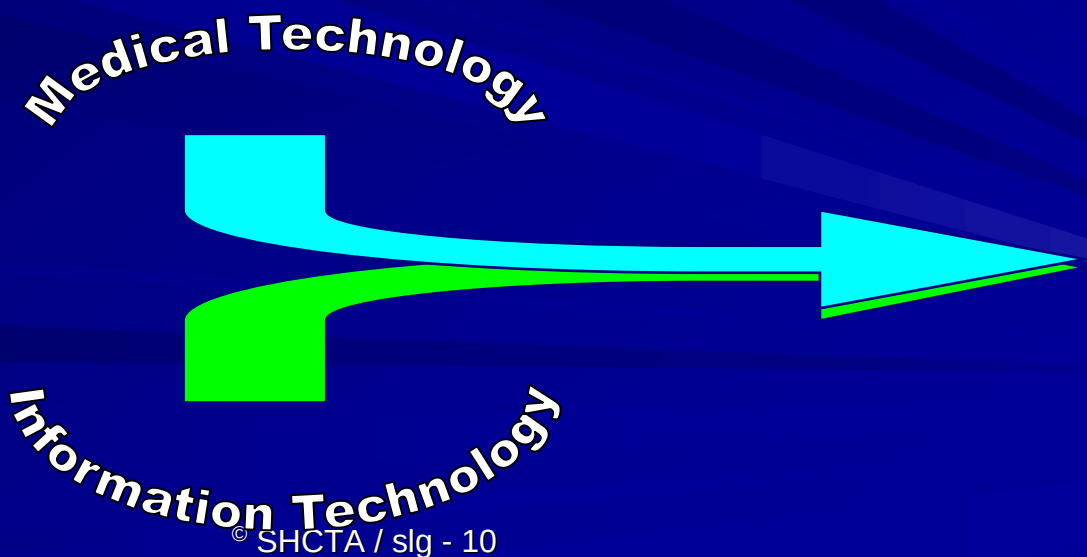
# Technological Forces

- Proliferation of computers in medicine
  *(Processing power doubles every year - Moore's Law 1965 )*
  - ✓ **Knowledge-based, expert systems**
    - designed to collect data and suggest diagnoses and courses of treatment based on "pre-selected rules for decision making within specialized domains of knowledge."
    - advancements have had the added benefit of improving system reliability and incorporating self-diagnostic capabilities
  - ✓ **Autonomic systems** - like involuntary nervous system that allows the human body to adjust to environmental changes, external attacks and internal failures, future autonomic technical systems will
    - be self-aware,
    - adapt to environmental changes
    - continuously adjust to optimize performance
    - defend against attack
    - self-repair
    - exchange resources with unfamiliar systems
    - communicate through open standards
    - anticipate users' actions

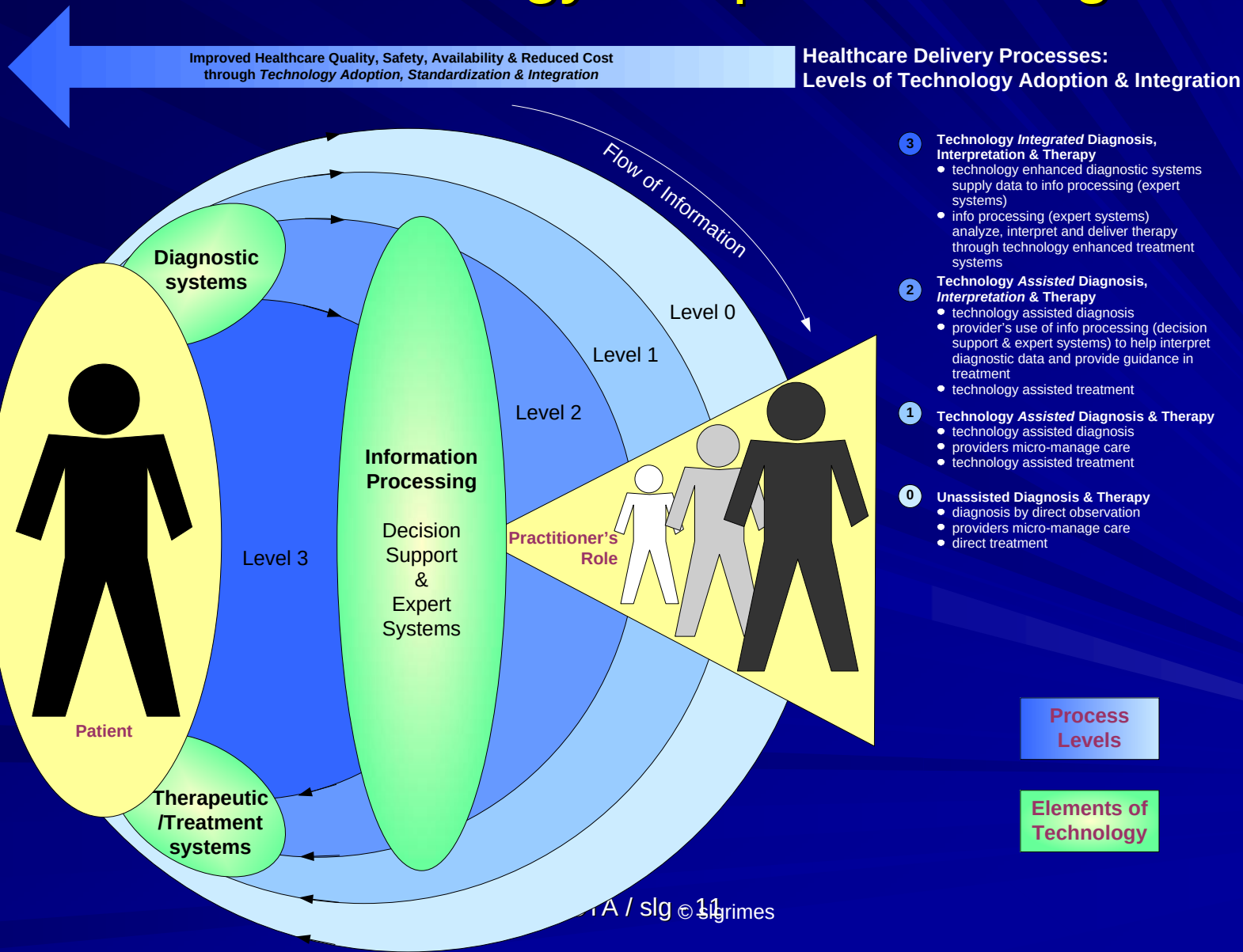
    Autonomic systems enable us to realize benefit of increasingly complex technologies that, without their autonomic abilities, would quickly overwhelm us with their need for management and support.

# Technological Forces

- Connectivity … *and Confluence*
  - ✓ Synergistic effect of interconnecting computers & other medical technology - benefits gained from integrated systems far exceed the benefits available when the individual devices and systems are used in their stand-alone mode.
  - ✓ Networking & Internet bring healthcare resources to any near or remote location and to facilitate medical data and personal (voice & video) communications between a combination of patients, providers and payors



# Healthcare Delivery Processes: Levels of Technology Adoption & Integration



# Economic Forces

- Total US Healthcare industry expenditures
  - ✓ Year 2001 ~ $1.4 trillion (14% of GDP)
  - ✓ Year 2012 ~ $3.1 trillion (18% of GDP)
- Health insurance premiums
  - ✓ from $177 billion in 1991 to $252 billion in 1996
  - ✓ increased by 11% in 2001
- Administrative costs takes 19 to 24¢ out of every $1 spent on US healthcare
- New medical technology accounts for 19% of inpatient healthcare spending between 1998-2002
  - ✓ TCO represents 3.6 to 18.5 times initial technology cost

# Economic Forces

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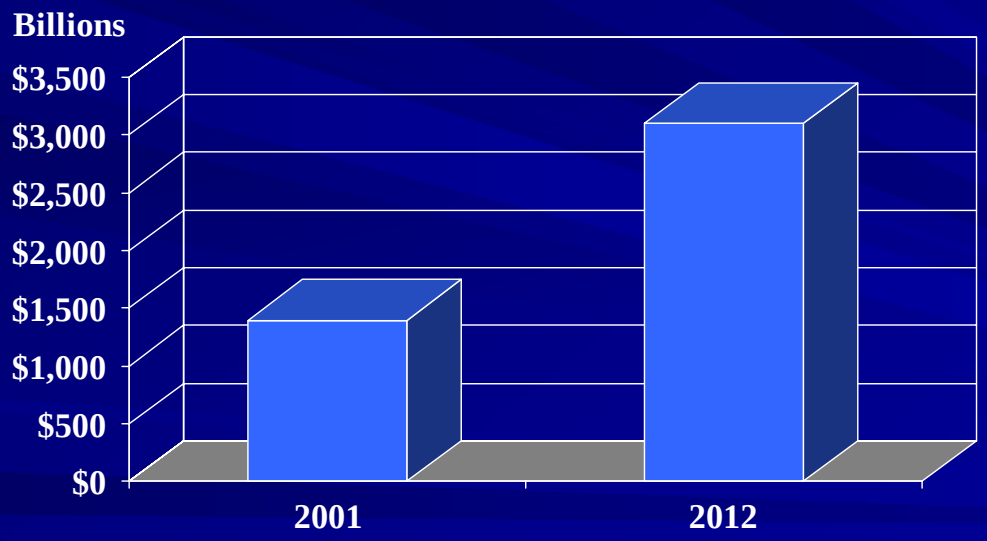
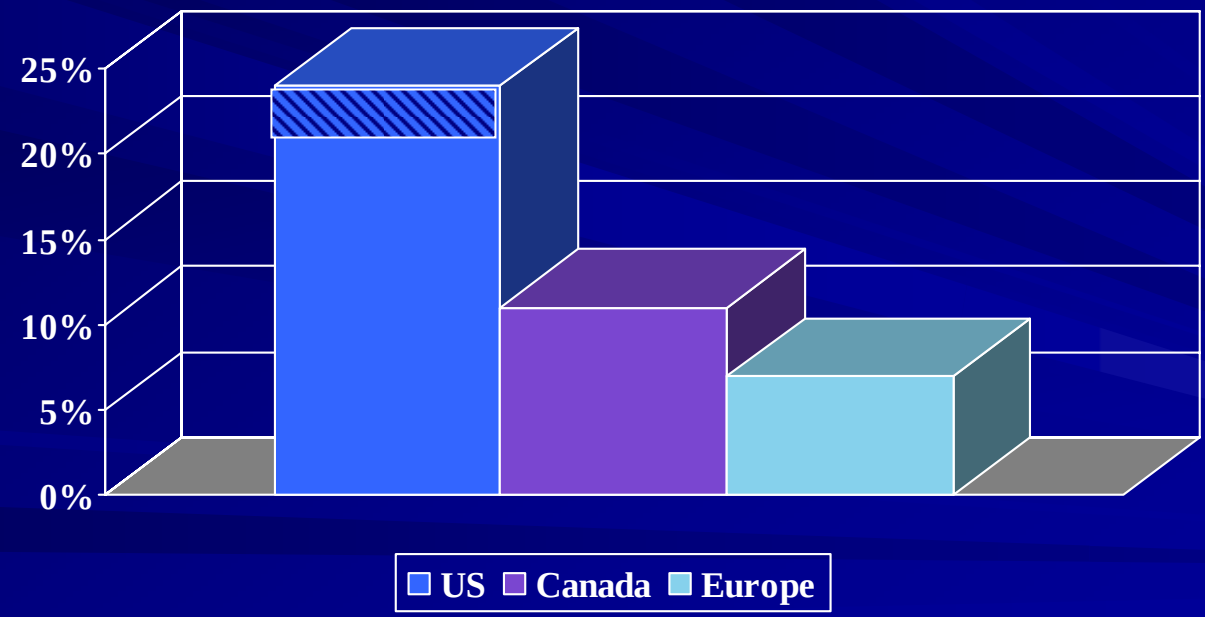


# Economic Forces

- Health insurance premiums
  - ✓ from $177 billion in 1991 to $252 billion in 1996
  - ✓ increased by 11% in 2001
  - ✓ double digit annual growth in premiums continued since 1993

# Economic Forces

- Administrative costs takes 19 to 24¢ out of every $1 spent on US healthcare



# Economic Forces

- New medical technology accounts for 19% of inpatient healthcare spending between 1998-2002
  - ✓ TCO represents 3.6 to 18.5 times initial technology cost

# Regulatory Forces

- HIPAA's Administrative Simplification
  - ✓ Reduce costs by adopting EDI & encourage electronic medical record
  - ✓ Implement security
- IOM reports on Quality and Safety
- Industry efforts
  - ✓ Integrating the Healthcare Environment (IHE)
  - ✓ Leapfrog

# Regulatory Forces

- HIPAA's Administrative Simplification
  - ✓ Reduce costs by adopting EDI & encourage electronic medical record
  - ✓ Implement security
    take necessary steps to preserve integrity, availability & confidentiality of data

# Regulatory Forces

- IOM reports on Quality and Safety
  - ✓ *To Err is Human: Building A Safer Health System* – which suggested as many as 98,000 Americans die annually as the result of medical errors
    - use of increasingly sophisticated & complex technologies is cited as a contributory factor in many errors
    - technology must be recognized as a member of the healthcare team and that among its roles are enhancing human performance and automating processes so as to remove opportunities for humans to make errors
  - ✓ *Crossing the Quality Chasm: A New Health System For The 21st Century* – report detailing a number of major recommendations on "applying advances in information technology to improve clinical and administrative processes." In fact many of the report's main recommendations can be accomplished only through the effective integration of information and clinical or biomedical technologies.

# Regulatory Forces

- Industry efforts
  - ✓ Integrating the Healthcare Environment (IHE)
    - *foundation of the the digital hospital*
    - *vendors adopting standards for interoperability between disparate devices & systems*
  - ✓ Leapfrog Group
    - Major employers & insurance organizations linking reimbursement rates to quality benchmarks

# Sociological Forces

- US Population over 65, between 2011 and 2030, will jump from 13% to over 20%
- Shifting demographics will cause nation's healthcare to shift from *acute, episodic* to *chronic* conditions
  - Now 100 million have chronic conditions accounting for 60% of nation's medical costs
  - In 2020, 157 million will have chronic conditions accounting for 80% of nation's medical costs
- A generation of better informed healthcare consumers will demand effective & affordable care ~ a *quality of life* issue

# Net Impact of Technological, Regulatory, Financial & Social Forces

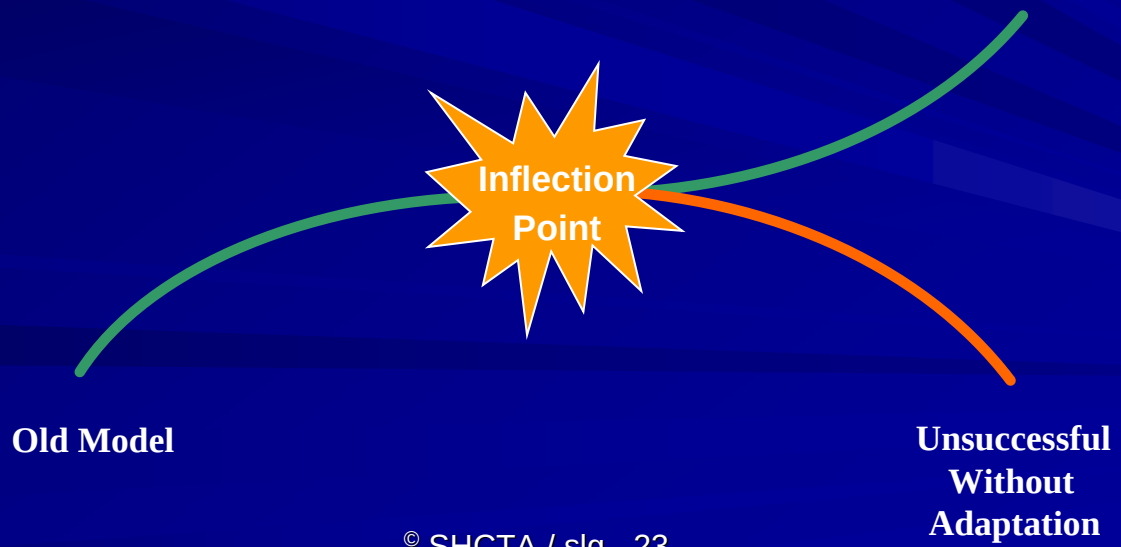
- Healthcare industry will increasingly focus on the long-term treatment of chronic conditions for an aging patient population.
- Population will expect high quality care that is both readily available and reasonably priced.
- Technological advances will facilitate the industry's ability to meet these demands and
- Regulatory pressures will foster better integration of healthcare services & healthcare quality

# Strategic Inflection Points

## Strategic Inflection Point …

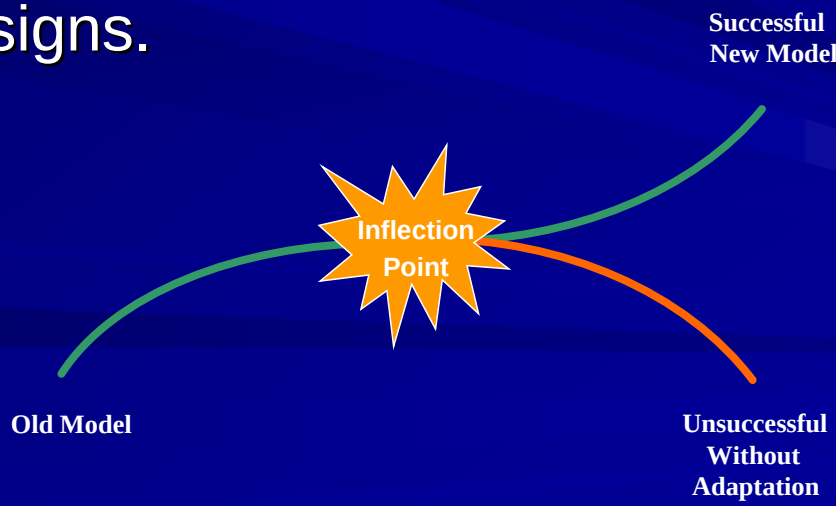
*as defined by Andrew Grove, Intel founder & chairman*

- a term that describes the time in which extreme forces forever alter the landscape of an industry, creating both opportunities and challenges



# Strategic Inflection Points

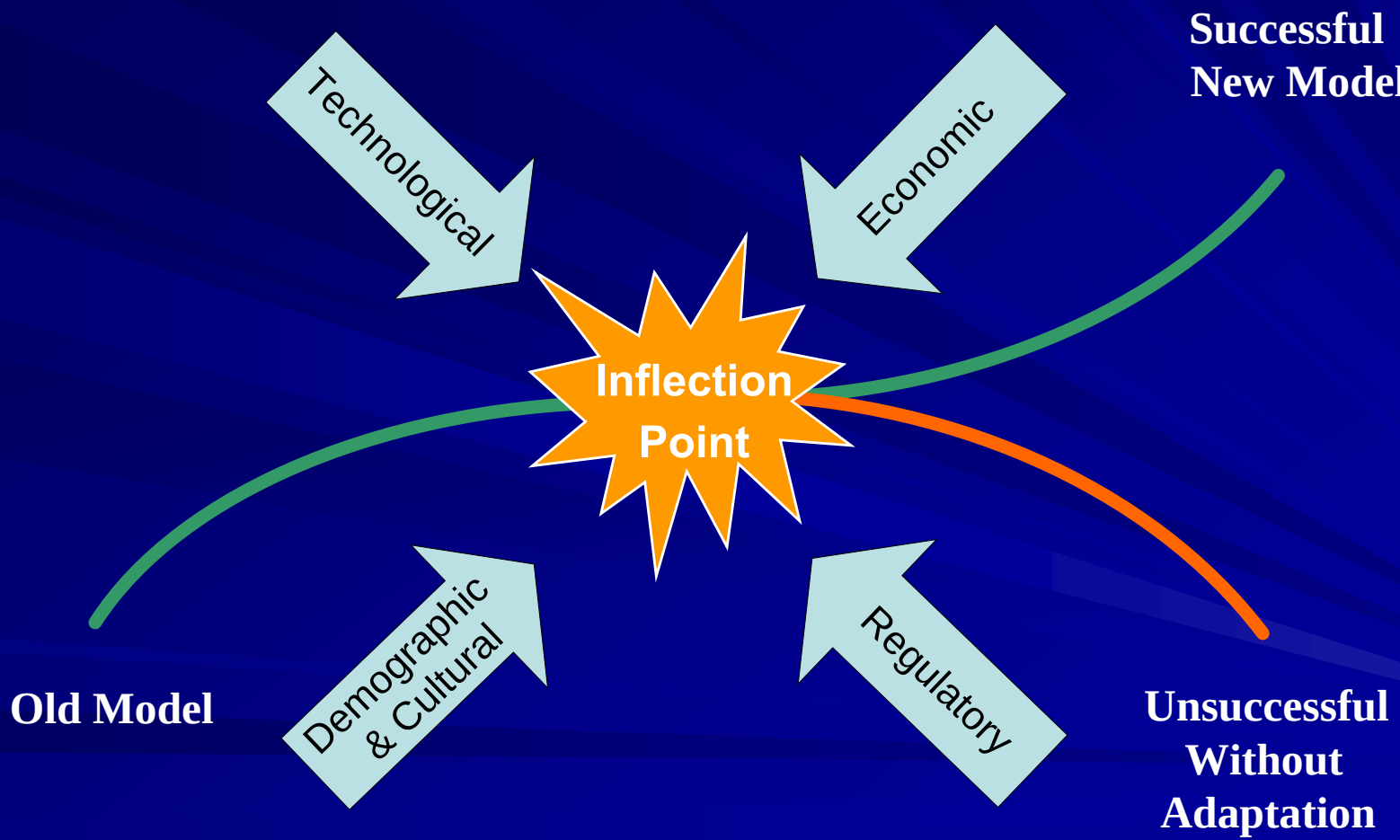
- Businesses and industries progress along at a steady, smooth fashion until hitting a subtle point where the business dynamics force a change in the curvature of that progression.
- At this “inflection point,” the transition is so smooth and subtle that there are no obvious profound, major or cataclysmic signs.



# Strategic Inflection Points

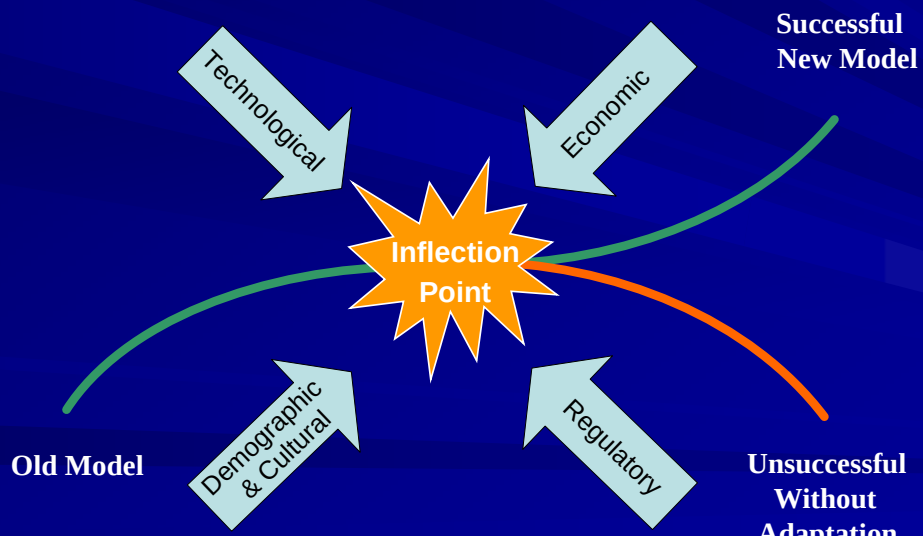
- However depending on the actions it takes, a business will progress through the inflection point along a path to potentially unprecedented heights … or find itself going down the path toward obscurity.
- If a business misses the opportunity and begins the descending branch of the curve, it is exceedingly difficult to reset the progression and correct for the action not taken at the inflection point. It is therefore extremely important to anticipate and act before reaching that inflection point

# Clinical Engineering is at a Strategic Inflection Point



# Clinical Engineering: *Take Action Now!*

- *"If you want to prosper on the other side of a strategic inflection point, you must take action before you get there."*
  Andrew S. Grove, Intel Chairman & co-founder



# Eleven Key Steps Clinical Engineers Must Take to Prepare for their Future Role

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

1. Adopt a systems & process approach
   - ✓ Understand relationships between interconnected devices/systems rather than focusing on discrete devices
   - ✓ Manage processes & systems

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

2. Add basic information technology & telecommunication skills
   - ✓ IT & telecommunications knowledge and skills have become necessary given the convergence of technologies
   - ✓ establish close/integrated working relationships with IT

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

3. Monitor technological, regulatory, economic and other developments (forces) affecting healthcare
   - ✓ developments in emerging technologies, regulatory, and economic issues will have a major impact on healthcare … and should therefore be areas of concern for clinical engineering

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

4. Become conversant in the “business” of technology
   - ✓ Learn to nuances of healthcare economics
     - Cost-benefit analyses
     - Return on investment (ROI)
     - Life cycle cost analyses
     - Total cost of ownership (TCO)

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

5. Plan for the integration of existing and new medical technologies
   - ✓ Time of rapid technological changes
   - ✓ Practical considerations dictate integration of "legacy" technologies with the "new"
     - understand implications of integration
     - develop skills necessary to manage integration process

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

6. Develop systems & infrastructure to support technology in non-traditional venues
   - ✓ Healthcare delivered increasing outside traditional venues (i.e., *moving from "bricks" to "clicks"*)
   - ✓ Delivery of healthcare involves new technologies and poses new challenges for clinical engineers - requires development of new infrastructures

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

7. Closely examine existing clinical engineering services & practices
   - ✓ must continually review services/practices and use of resources
   - ✓ must be prepared to morph to meet healthcare's changing needs …
     - acquire skills as needs dictate
     - discard services for which there is no longer sufficient demonstrable benefit

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

8. Incorporate continuing education
   *Pace of technology revolution is quickening*
   - ✓ on-going education is only hope CEs have of staying relevant
   - ✓ education includes
     - universities
     - continuing education programs offered by professional associations & conferences
     - industry/manufacturer training
     - literature reviews

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

9. Build relationships with other stakeholders
   - ✓ teamwork is critical
   - ✓ identify stakeholders in technology implementation process and establish working relationships with those individuals & groups
     - clinical/medical staff
     - information technology
     - finance
     - materials management
     - risk management
     - quality assurance
     - etc

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

10. Develop a plan to transition from existing to future services … *how to get from "here" to "there"*
    - ✓ acquisition of resources, skills, education (of clients as well as staff)
    - ✓ timetable for smooth transition

# Eleven Key Steps CEs Must Take to Prepare for their Future Role

11. Formulate a vision for clinical engineering within the organization
    - ✓ Must be able to articulate a clear vision
    - ✓ Vision must be aligned with organization's stated mission
    - ✓ Vision must, in any case, promote *quality*, *service*, and *innovation*

# Future Scope of Clinical Engineering Services

# Future Scope of Clinical Engineering Services

## Management & Consulting Services

1. Inventory & Asset Management
   - ✓ accurate inventory is fundamental component of effective asset management
   - ✓ medical devices & systems –
     - basic identifying information
     - location & interconnection with other devices/systems
     - risk assessment

# Future Scope of Clinical Engineering Services

## Management & Consulting Services

2. Strategic Planning …

   *considering technology's ability to improve healthcare quality, safety and availability while reducing costs*

   - ✓ continually work to sharpen their awareness of existing and newly available technologies
   - ✓ evaluate the technical strengths & limitations in the context of the intended applications
   - ✓ apply their knowledge of the environment where the devices or systems are to be used to the appropriate selection and configuration of devices and systems
   - ✓ plan for installation, integration with other systems, training, and on-going service
   - ✓ contribute to cost-benefit and life-cycle cost analyses

# Future Scope of Clinical Engineering Services

## Management & Consulting Services

3. Quality & Safety
   - ✓ adopt quality management system (e.g., ISO 9000, Six Sigma, Malcolm Baldrige or similar)
     - performance criteria for technical systems and processes
     - target goals & objectives (benchmarks) associated with use of technology
     - techniques for measuring progress toward goals & objectives
     - a process for analyzing and improving effectiveness of methods used to achieve goals & objectives
   - ✓ implement a risk management program
   - ✓ provide root cause analysis, investigation, and reporting support when technology and technological processes are involved in adverse outcomes or incidents

# Future Scope of Clinical Engineering Services

## Management & Consulting Services

4. Regulatory & Standards Compliance
   - ✓ Food & Drug Administration (FDA)
   - ✓ Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
   - ✓ Safe Medical Device Act (SMDA)
   - ✓ Integrating the Healthcare Enterprise (IHE)
   - ✓ Health Insurance Portability & Accountability Act (HIPAA)
   - ✓ State & Local Regs

# Future Scope of Clinical Engineering Services

## Management & Consulting Services

5. Vendor Management
   (e.g., medical device manufacturers, service providers

- ✓ evaluate vendors, products and services … recommend those who best meet the needs and standards of the organization
- ✓ insure inclusion of necessary terms and conditions in agreements with vendor and regularly insure vendor compliance with those terms/conditions
- ✓ insure vendor makes available any information, documentation, software, specialized tools, and education necessary to operate or service technology
- ✓ verify integrity of technology supplied
- ✓ monitor vendor quality and integrity of services delivered

# Future Scope of Clinical Engineering Services

## Support Services

6. Education
   - ✓ train medical device users
     - operation
     - basic troubleshooting
     - Security (data integrity, availability & confidentiality)

# Future Scope of Clinical Engineering Services

## Support Services

7. Help Desk

   Similar to IT – provides operational & technical support

   - ✓ rapid response
   - ✓ triage & assign service
   - ✓ remote service

# Future Scope of Clinical Engineering Services

## Technical Services

8. Installation & Integration
   - ✓ configuration & integration of disparate systems (new & legacy)

# Future Scope of Clinical Engineering Services

## Technical Services

9. Upgrades (hardware & software)
   - ✓ more commonplace as owners try to curb costs by staggering upgrades of components
   - ✓ CE must provide advice & assist in upgrade process

# Future Scope of Clinical Engineering Services

## Technical Services

10. Testing, inspection & preventive maintenance
    - ✓ need (and therefore process) changing as technology continues to be more reliable, self-diagnosing, and self-repairing
    - ✓ device users will need training in operation check-out procedures

# Future Scope of Clinical Engineering Services

## Technical Services

11. Repair
    - ✓ will require fewer clinical engineering resources in future due to increased reliability, self-diagnostic and self-repair abilities

# Summary

- Clinical Engineering is at a “Strategic Inflection Point” …
  *Technical, Economic, Regulatory & Social Forces are re-shaping healthcare*
- Clinical engineering must
  - be responsive and reshape its services to meet changing needs
    - or -
  - find itself relegated to diminishing roles while other professionals step in to fill those needs

# Examples of *e*-Health

Moving from
“Bricks” to “Clicks”

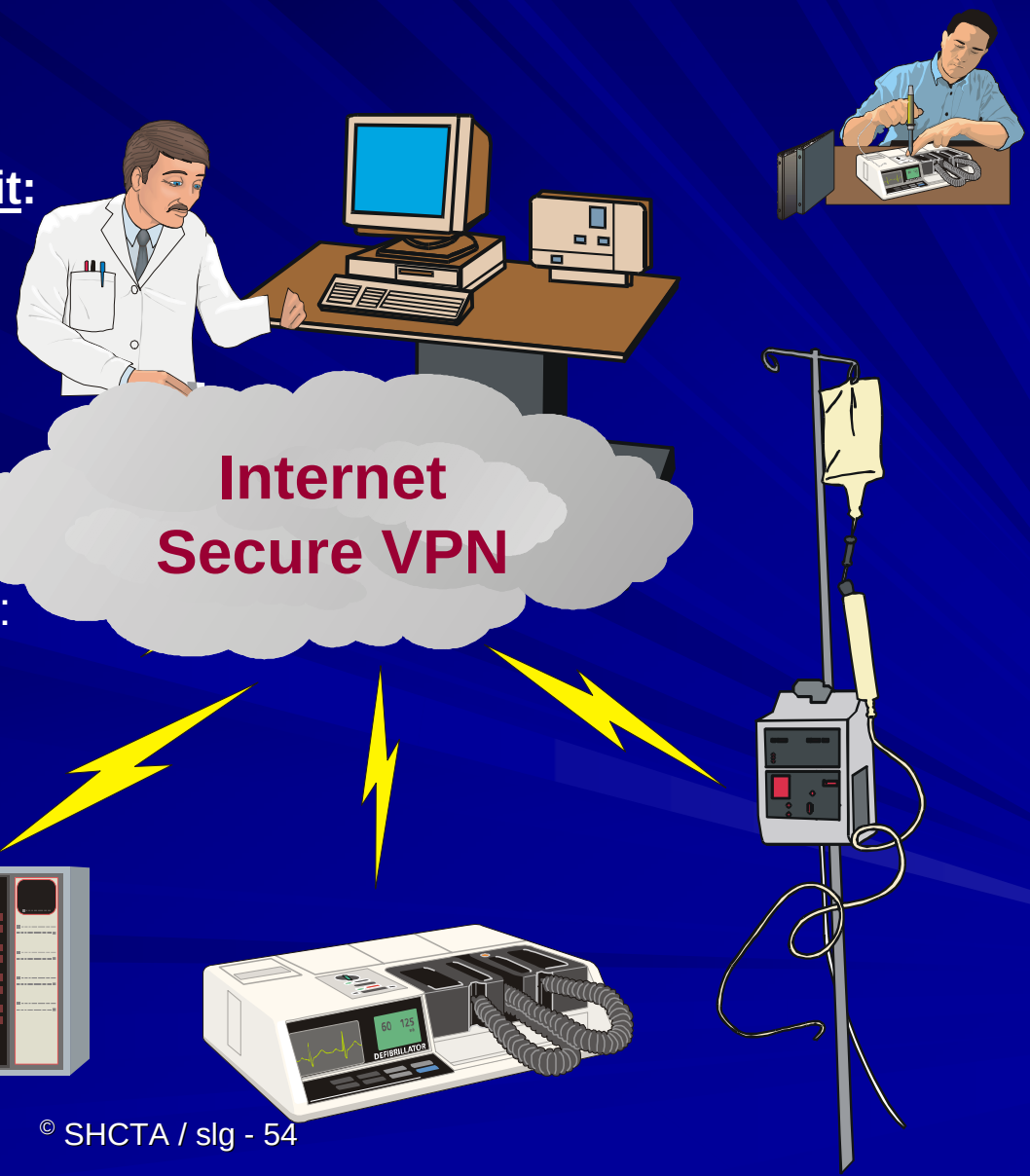
# Remote Access to Medical Devices

**Devices on Internet can transmit:**

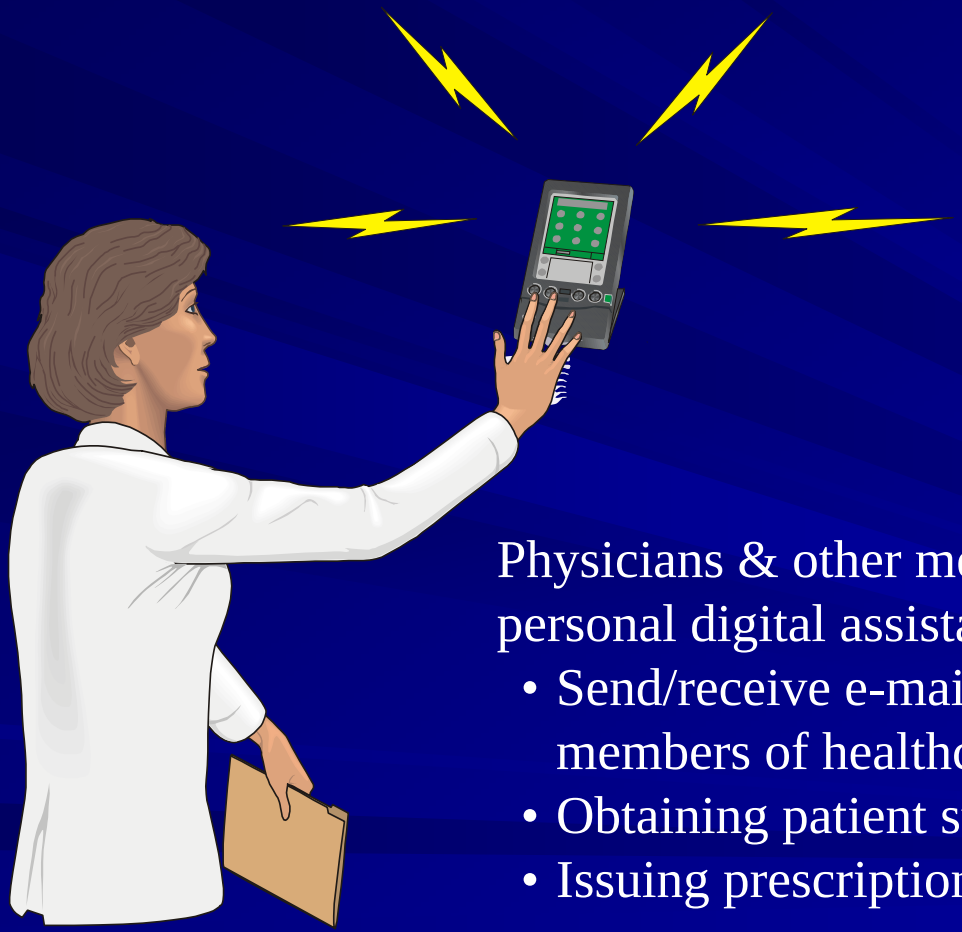
- Location (& patient info)
- Current Status & Settings
- Diagnostics
- Error Codes

**Devices on Internet can receive:**

- Calibration
- Software/Firmware Upgrades
- Diagnostics



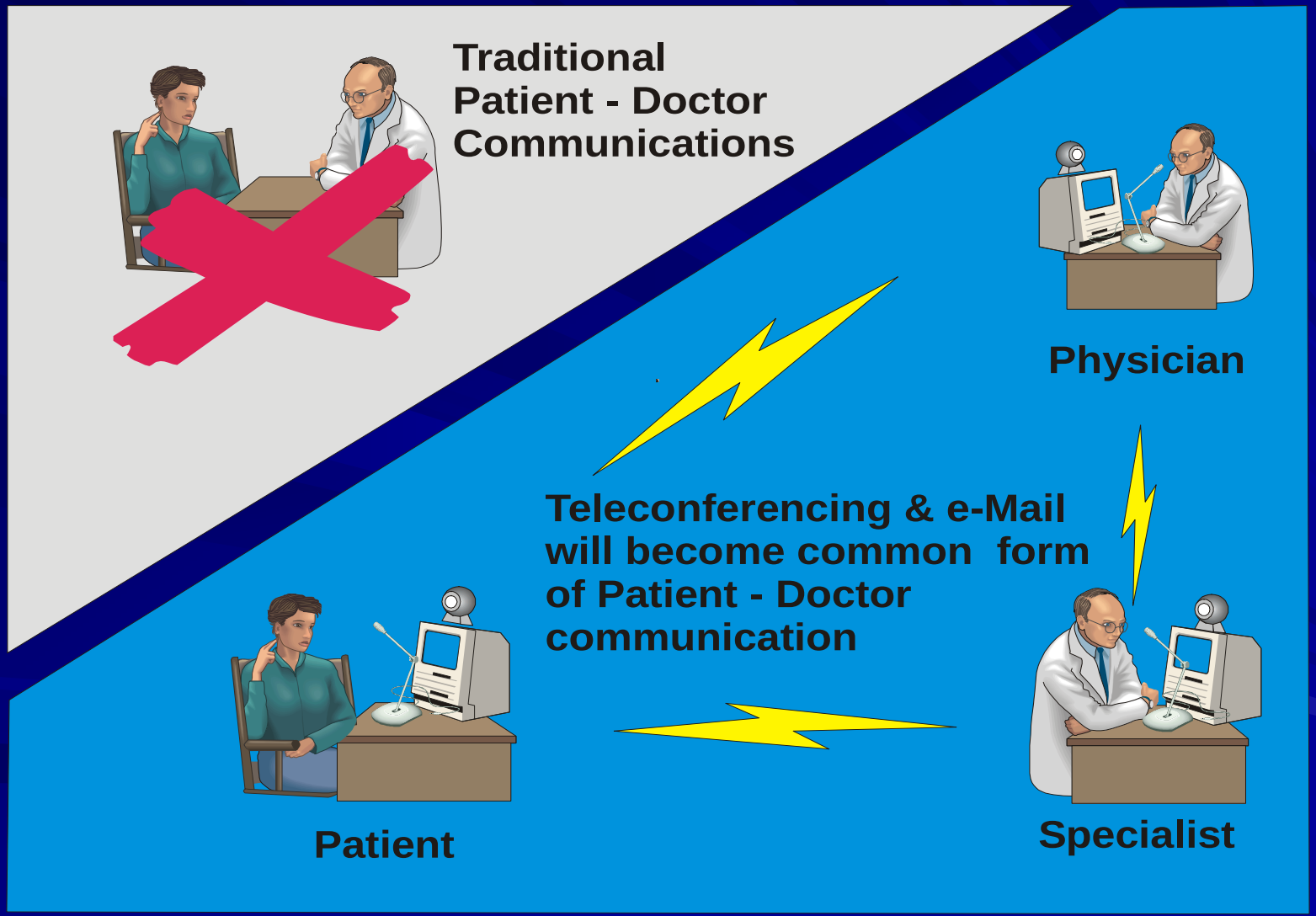
# e-Health: Physician's & Other Healthcare Providers On-line



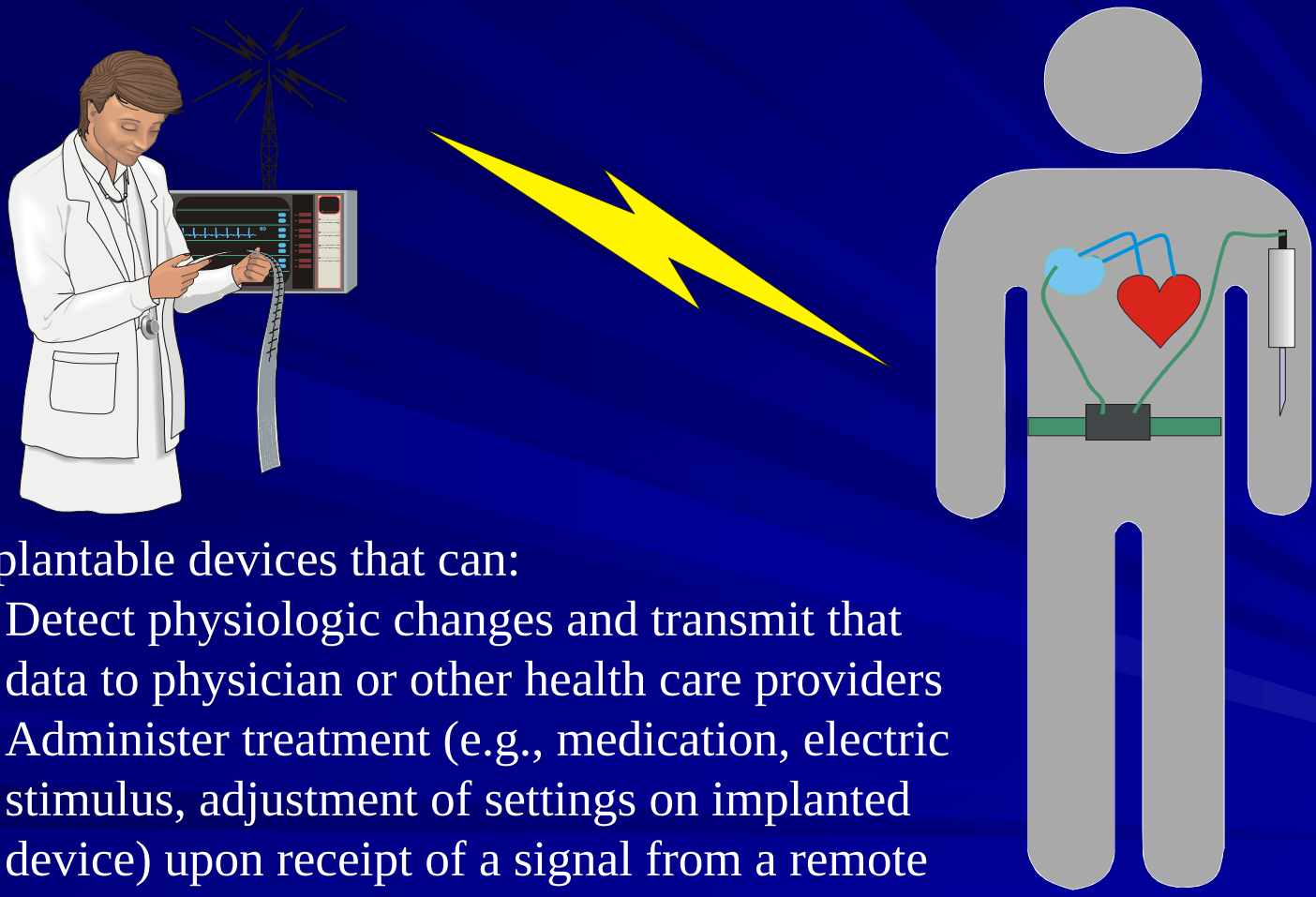
Physicians & other medical providers are using personal digital assistants (PDAs) to:

- Send/receive e-mail with patients and other members of healthcare team
- Obtaining patient status reports, test results
- Issuing prescriptions (less error prone) & orders

# *e*-Health: Telemedicine Provides the "Virtual Office" Visit



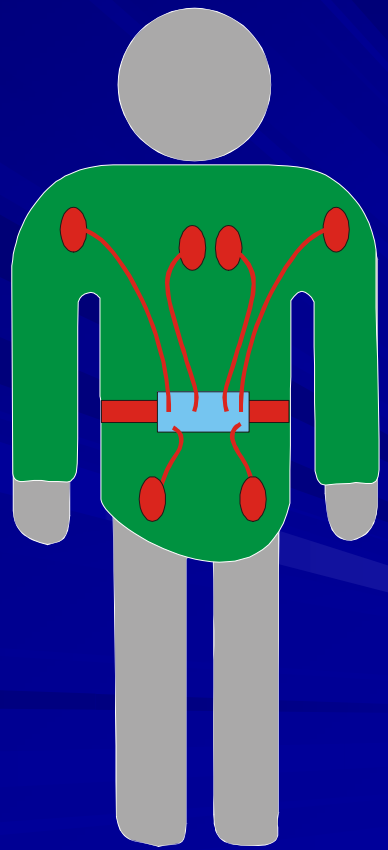
# e-Health: Telemedicine Delivers Remote Diagnostics & Therapy



Implantable devices that can:

- Detect physiologic changes and transmit that data to physician or other health care providers
- Administer treatment (e.g., medication, electric stimulus, adjustment of settings on implanted device) upon receipt of a signal from a remote healthcare provider

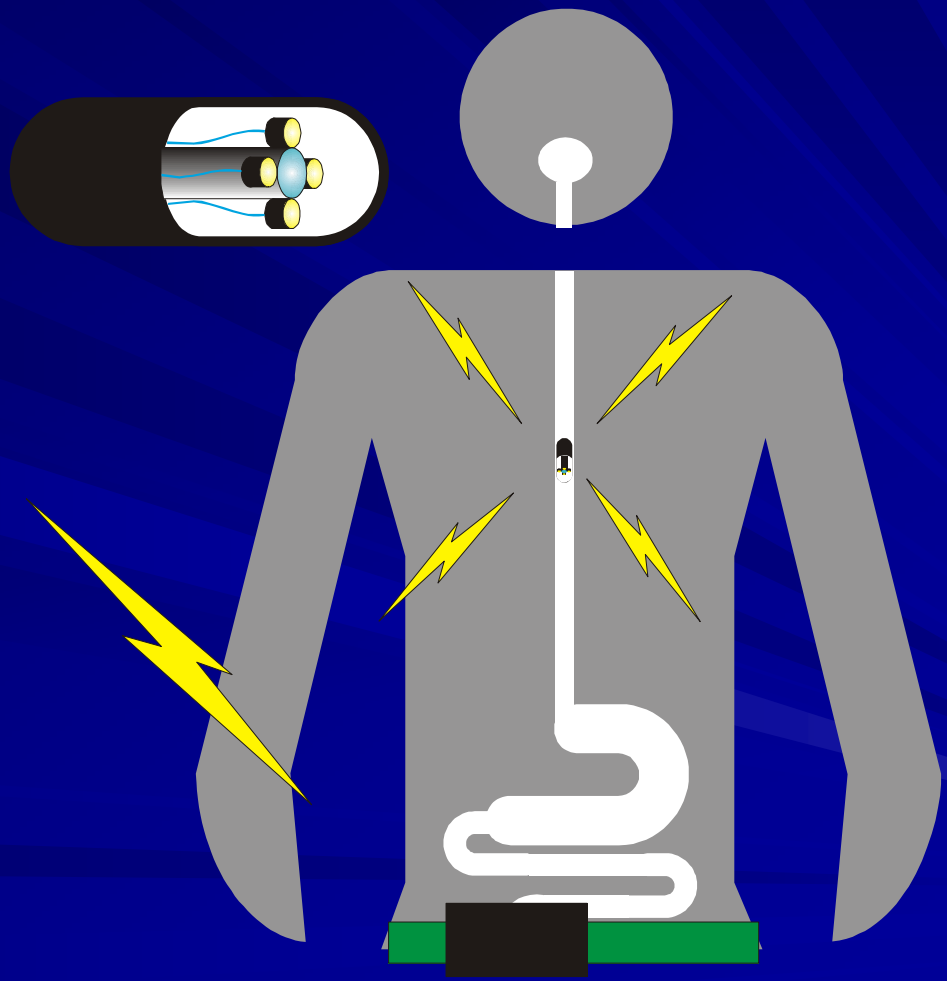
# *e*-Health: Telemedicine Delivers Remote Diagnostics & Therapy



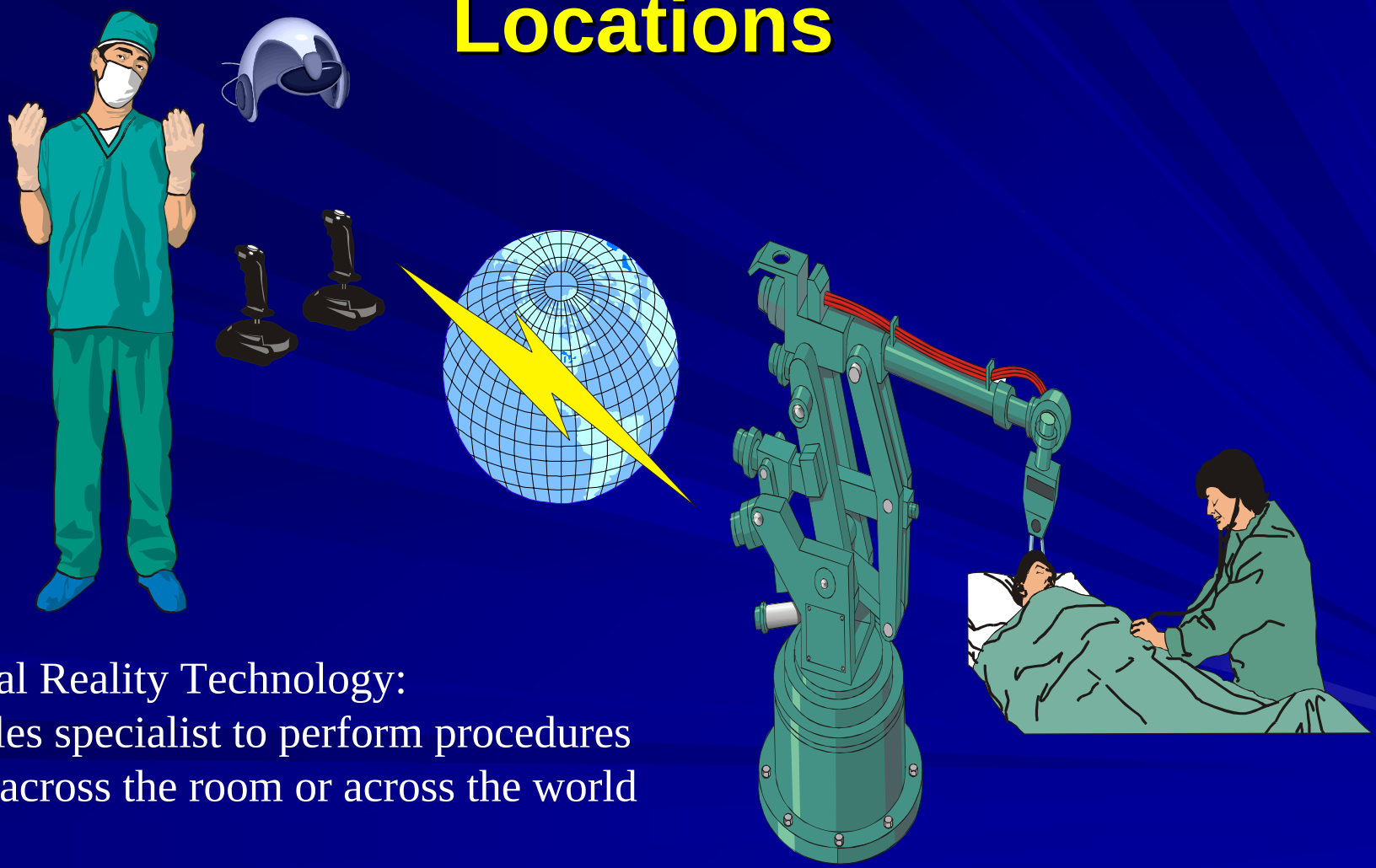
- Clothing with embedded sensors will enable medical personnel to monitor a wide range of physiologic conditions for patients who are known risks
- Problems can be detected and appropriate care initiated often before the patient is aware any problem exists

# *e*-Health: Telemedicine Delivers Remote Diagnostics

Miniature cameras in pill form can transmit and record high resolution images of gastrointestinal



# *e*-Health: Telemedicine Can Deliver Medical Expertise to Remote Locations



Virtual Reality Technology:
Enables specialist to perform procedures from across the room or across the world

# Resources

- American College of Clinical Engineering (ACCE) … www.accenet.org
- Health Information and Management Systems Society (HIMSS) …www.himss.org
- Association for the Advancement of Medical Instrumentation … www.aami.org
- IEEE Engineering in Medicine & Biology …www.ieee.org/embs/index.html

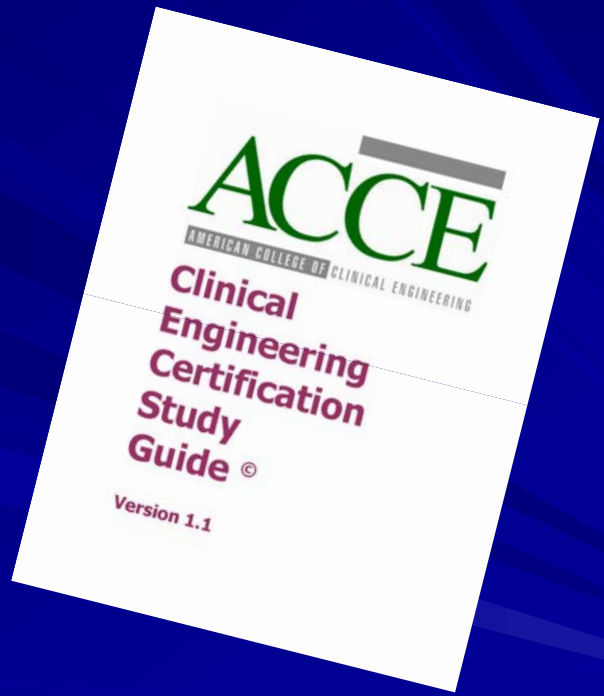
# Clinical Engineering Certification

- Sponsored by AAMI & the ICC for 25 years.
- Suspended in 1999
- Assumed by ACCE in 2001
- ACCE Foundation formed Healthcare Technology Certification Commission and US Board of Examiners for CE Certification
- Body of Knowledge (BOK) Survey Conducted by ACCE in 2000
- Board of Examiners wrote a new exam based on BOK survey results
- The first exam was given in November 2003, the second in Nov 2004
- Exam will be given semi-annually, in June and November from now on.
- Exam consists of 150 multiple choice questions and an oral exam.
- To qualify to take the exam you must have a BS degree in Engineering and three years of CE experience (although there are a few variations on this)

# Resources

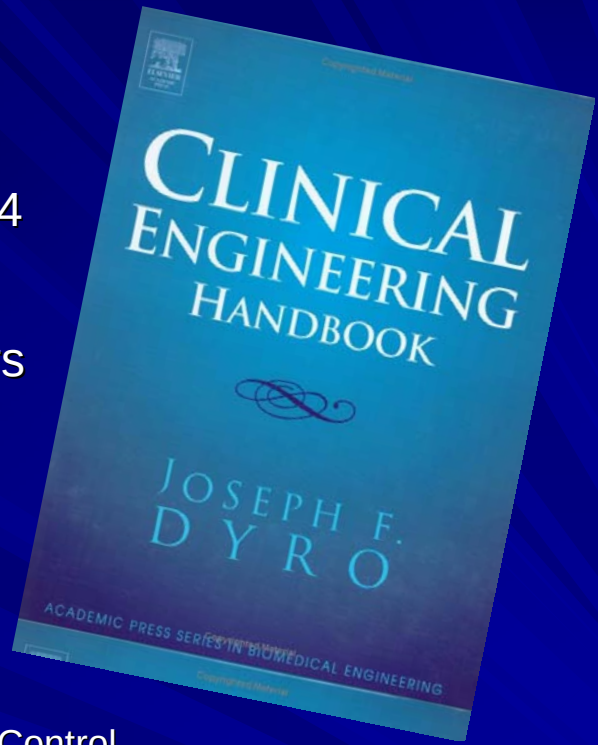
- Clinical Engineering Certification Study Guide
  Copyright: American College of Clinical Engineering (ACCE), 2004
  $30, 104 pages

- Based on Body of Knowledge
  *8 Major Sections, 47 Topics*
  - Management
  - Technology Assessment
  - Regulatory / Quality Assurance Issues
  - Repair / Systems Thinking
  - Risk Management / Safety Issues
  - Education
  - Product Development
  - Miscellaneous Topics



# Resources

- Clinical Engineering Handbook
  Joseph P. Dyro, Editor
  Amsterdam/Boston, Elsevier Academic Press, 2004
  $125




674 pages, 13 Sections, 142 Chapters, 128 Authors

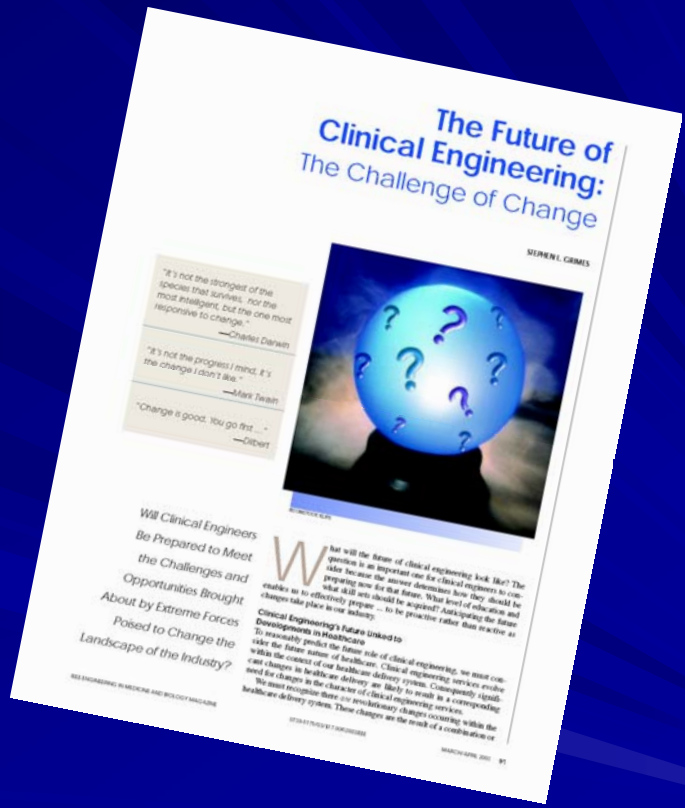
i. Clinical Engineering
ii. Worldwide Clinical Engineering Practice
iii. Health Technology Management
iv. Management
v. Safety
vi. Education & Training
vii. Medical Devices: Design Manufacture, Evaluation and Control
viii. Medical Devices: Utilization and Service
ix. Information
x. Engineering and the Clinical Environment
xi. Regulations, Standards and Law
xii. Professionalism and Ethics
xiii. The Future

# Technology's Limitations

# Questions?

**Thank You!**

THE BINGHAMTON BIOENGINEERS
IEEE Engineering in Medicine and Biology Society
State University of New York, Binghamton

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