

Aug 2017

“ROLE OF HEALTH TECHNOLOGY ASSESSMENT IN FUTURE PROOFING HEALTHCARE”

SINGAPORE HEALTHCARE ENTERPRISE RISK MANAGEMENT
CONGRESS, SINGAPORE
17 AUGUST 2017

Eric Woo, Regional Director

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Why People Call On ECRI Institute?

- ▶ Independent and research driven international nonprofit
- ▶ Strict conflict of interest rules
- ▶ World class experts improving patient care, mitigating decision risk on technology & providing cost avoidance solutions
 - Federally certified patient safety organization and evidence based practice center - Agency for Healthcare Research and Quality (AHRQ)



Our Founder

Dr. Joel Nobel (1934-2014)



Healthcare Technology

- ▶ Heavy investment in technology is a prerequisite for providing modern patient care. But the hospital's responsibilities do not stop with the one acquisition decision—evolving technology needs regular attention
- ▶ Important to centralize responsibility for developing and overseeing consistent technology management policies and practices, instead of treating technology as a diffuse function that clinical and support departments may not recognize as important

▶ AAMI Survey

Biggest mistakes made by organizations when investing in new technology

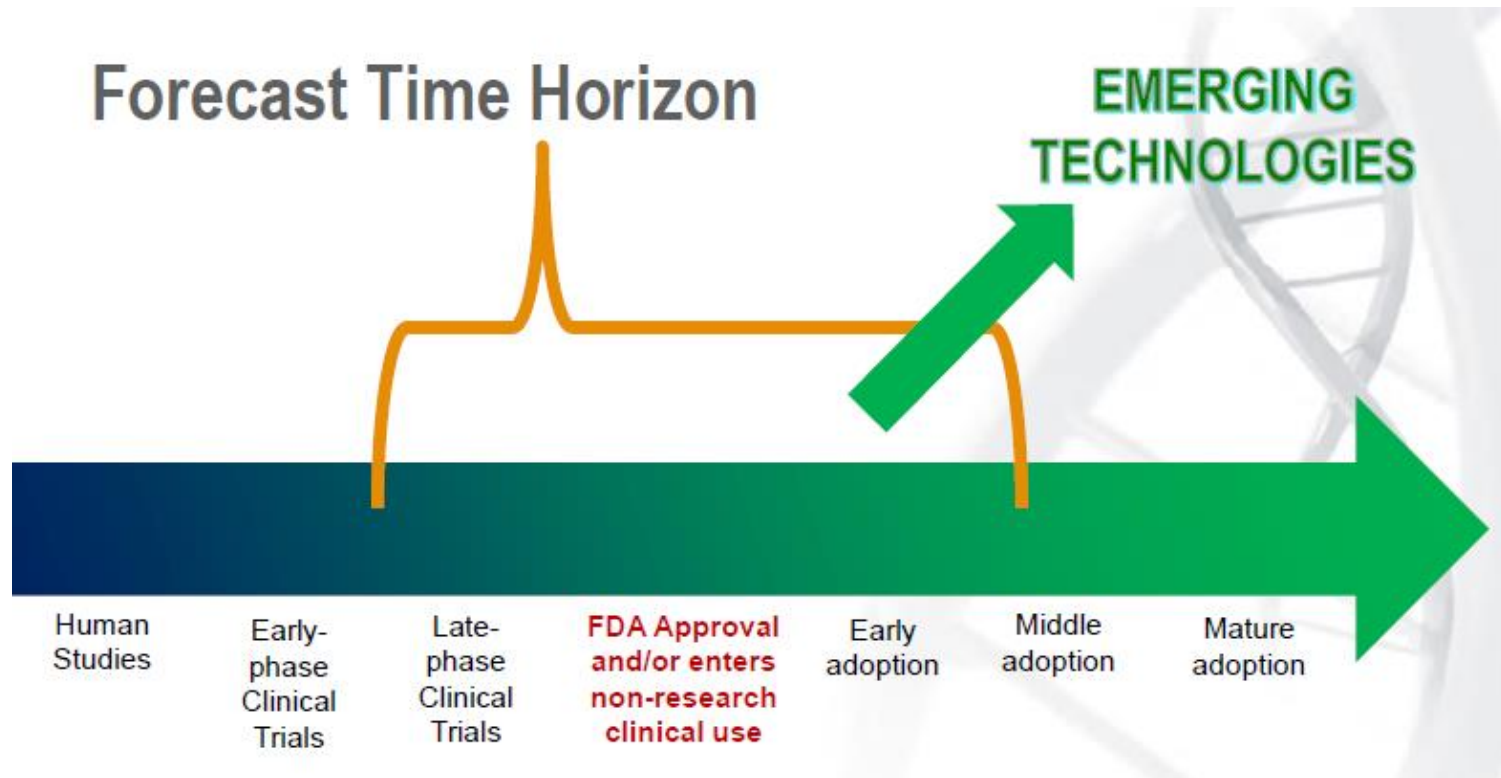
1. Not including all relevant staff in decisions: 67%
2. Basing the decision solely on price: 35%
3. Not investigating the "cost of ownership" thoroughly enough: 32%
4. Not doing a proper technology assessment upfront: 31%
5. Making purchase decisions based on the preference of a single clinician: 26%

Horizon Scanning for Technologies

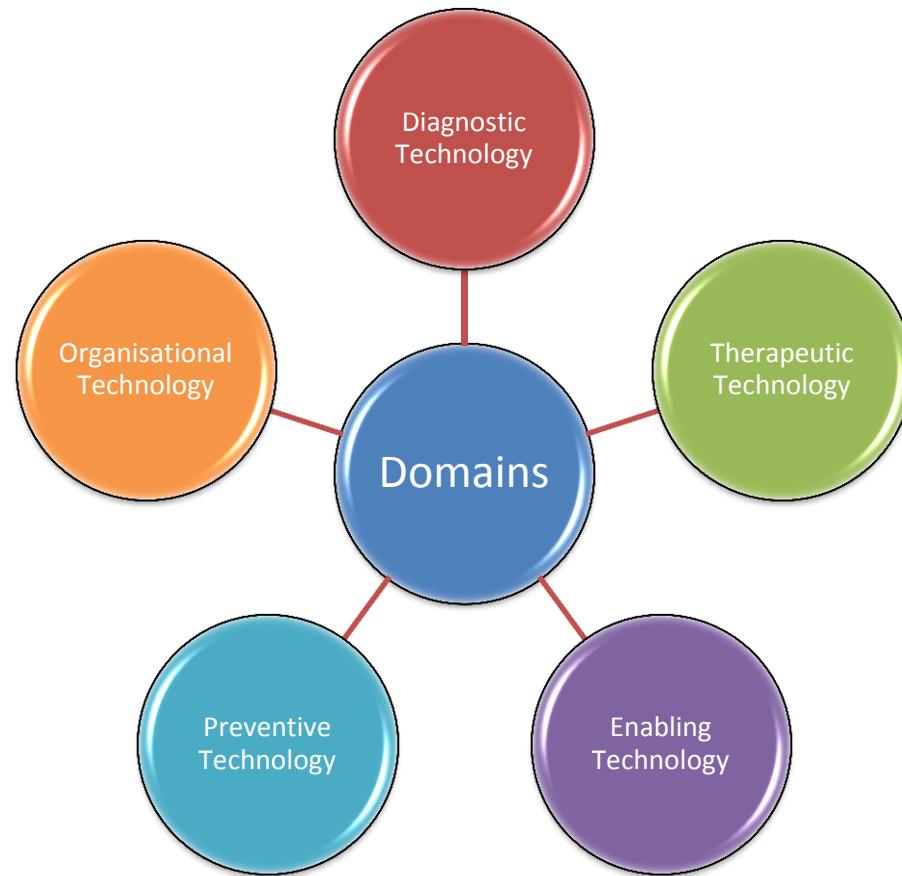
Purpose

- ▶ Intended to aid strategic planning for emerging technology adoption and policy making, to forecast which target technologies have the highest potential for impact
- ▶ To prepare for change in indication or use of an existing technology
- ▶ Hospitals and health facilities use horizon scanning information for 3-5 year technology acquisition plans, to better know how their existing or planned clinical service lines may be affected or disrupted by new innovations

Horizon Scanning Approach



Typical Domains to Watch



Diagnostic Technology

- ▶ Identifying diseases and other conditions, e.g. nanotechnology and point-of care diagnostics
- ▶ Nanotechnology is the science of understanding and manipulating materials on a near molecular scale (nanometre), offers several developments that can increase the efficacy of disease diagnosis and screening



What is on the horizon?

- ▶ One variation uses embedded carbon nanotubes to detect the presence of universally accepted biomarkers associated with particular a disease or illness, by monitoring changes in electrical resistance
- ▶ Then used to identify blood-borne biomarkers that may be indicators of diseases such as breast cancer or HIV, reduces the cost of a traditional laboratory-based test
- ▶ “Nanomedicine” is still at an early stage, has the potential to make the diagnosis of disease across the developed and developing world affordable, allowing treatment to be initiated sooner and with more precision, stopping the development of conditions and associated complications

Therapeutic Technology

- ▶ Used in the treatment of disease and injury, such as MIS (minimally invasive surgery)
- ▶ MIS and non-invasive procedures target to reduce pain, trauma, hospitalisation/stay time, recovery time and post-operative complications
- ▶ Progress in non-invasive therapies includes newer applications of microwave, laser and ultrasound, to support the treatment of complex conditions such as cancer, obesity and scoliosis with more flexibility and precision
- ▶ Developments have been through progress in fibre optics, imaging, and specialised surgical instruments, including robot-assisted surgery such as the da Vinci Surgical System

What is on the horizon?

- ▶ Increasingly sophisticated techniques, e.g. combining magnetic resonance imaging (MRI) with ultrasound to treat previously inaccessible areas
- ▶ Advances in robotics - surgery will become computer assisted with human guidance to begin with but gradually guided by AI (artificial intelligence)
- ▶ Nanorobotics also allow for the possibility of minimally invasive targeted surgery and drug delivery

When is this coming? *(...in another 10-20 years maybe?)*

- ▶ [Link to Video: Prometheus C-section scene](#)



Enabling Technology



- ▶ Mitigate the impact of disease or disability, such as mobile technology, wearable health monitors, and assistive technologies
- ▶ Devices which enable users and physicians to track and monitor vital signs have become increasingly portable
- ▶ Conventional health monitoring technology required patients to be connected via cables to obtrusive and power-consuming hospital-based equipment, is now being replaced by “smart gadgets” such as watches, bracelets, headsets, sensory clothing and chips
- ▶ By functioning as a patient engagement tool, health monitors have profound implications for the management of long-term conditions

What is on the horizon?

- ▶ Worn-on or close to the body devices fitted with micro sensors and actuators, capable of monitoring, processing and analysing real-time biodata on existing conditions such as cholesterol or blood glucose levels, and general health indicators such as heart rate, body fat percentage or sleeping habits
- ▶ Should current trends continue, wearable health monitors will become commonplace in a range of clinical settings, including hospitals, residential care and in homes.
- ▶ More discreet monitors will become available, and “epidermal electronics” – devices that fuse directly with the body in the form of adhesive skin patches, temporary tattoos or implantable chips

Preventive Technology

- ▶ Reduce the risk or severity of illness and injury, such as genomics (“genetic medicine”)
- ▶ Traditional healthcare focuses on diagnostics and treatments, now coming together with products and services centred on prevention and wellness, some resulting from recent advances in genomics and proteomics
- ▶ Developments in genomics may also result in more personalised medicine and treatment for the general population
- ▶ Many legal and ethical issues surrounding genomics (including privacy, data and security) need to be addressed

What is on the horizon?

- ▶ Genomic technologies will allow the use of genetic testing to inform practice and policy, and guide public health research into health disparities
- ▶ Genetic manipulation could become a core focus for preventive medicine, extending high-quality life beyond current upper limits with the absence of illness and chronic disease
- ▶ From birth, patients will be assessed against a full continuum of risk in attracting illness and disease (e.g. by using a single chip) and will be assigned a complete profile of risk factors

Organisational Technology

- ▶ Supporting alternative health and social care delivery configurations and organisational design, such as integrated big data
- ▶ Data and information, both for and about patients and service users, are crucial components of high-quality care, and the volume of information used and generated is increasing
- ▶ Effective management and analysis of the available data could result in drastic organisational changes, by integrating the range of devices and applications available to create a seamless network of information, facilitating the shift towards more person-centred care

What is on the horizon?

- ▶ Traditional separations between acute, primary, community and home settings will become more integrated as a result of information management, using the internet as a platform to store and share information
- ▶ Modern mobile and computing technology will become normal interfaces for people to interact with care services
- ▶ Sophisticated data collection and analysis, using a wide range of biomarkers, combined with increasing computer processing capabilities and developments in artificial intelligence, will enable individualised evidence-based care

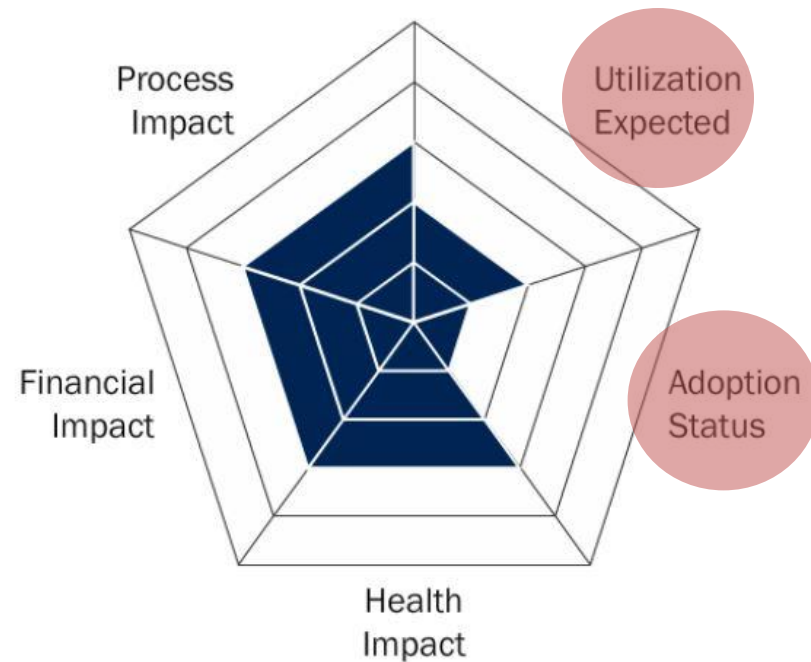
Forecasting Impact of Technologies

► Utilization Expected

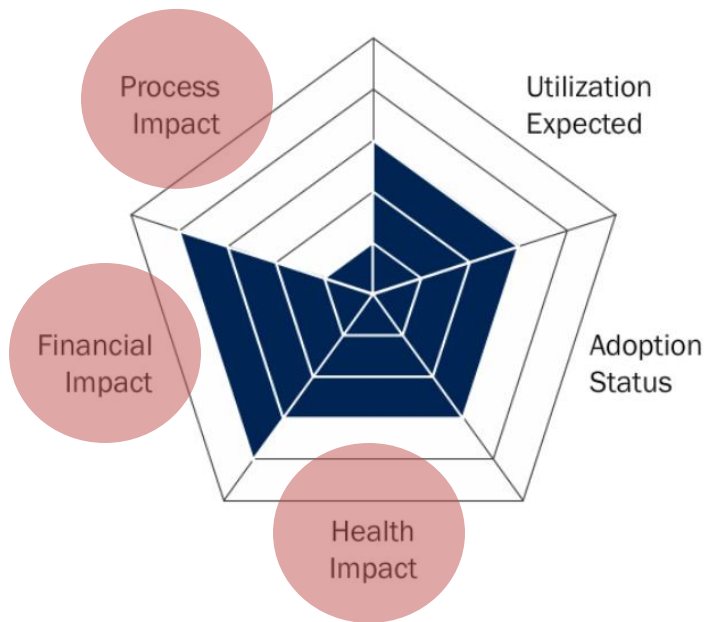
The extent to which the technology is expected to be used in the mature stage of its life cycle.

► Adoption/Diffusion Status

Indicates where this technology currently lies on the adoption timeline



Forecasting Impact



► Process Impact (Staffing/Care)

The extent to which the technology or service is expected to affect the operations of healthcare providers involved in the care of patients receiving the technology or service.

► Financial Impact (Payer/Provider Cost Impact)

The extent to which diffusion of the technology is expected to increase or decrease the cost of care for patients who receive that technology or service.

► Health Impact

The extent to which the technology is expected to improve the health and/or quality of life (QOL) for patients who receive it.

Computed Tomography with Computer-aided Detection for Lung Cancer Screening

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HEALTH TECHNOLOGY FORECAST

Ratings and Rationales of Potential Impact

Note: The following ratings and comments reflect the opinions and consensus of an expert panel convened by ECRI Institute to review information on this topic.

Anticipated Utilization: 1 (Expected to be used by 0% to 20% of eligible patients)

Clinical guidelines recommend low-dose computed tomography (LDCT) to screen high-risk patients for lung cancer; however, they are silent on enhancing LDCT with computer-aided detection (CADe) systems. Some manufacturers report that the slow initial adoption is unlikely to change without extra reimbursement or new clinical data showing that CADe improves outcomes or cost-effectiveness of LDCT. Over time, more radiologists might adopt software that automatically tracks changes to radiologist-identified lung nodules to facilitate lung cancer screening. However, that assumption would depend on ultimate patient demand for LDCT screening.

Estimated Adoption Status: 3 (Early adoption occurring – 0% to 25% of facilities that would be expected to adopt have adopted)

Before July 2012, the U.S. Food and Drug Administration (FDA) required companies to submit marketing applications for CADe software products under its premarket approval (PMA) application process. FDA granted Siemens AD (Munich, Germany) a PMA for its syngo LungCAD product in October 2006. Since the change, FDA has not granted 510(k) marketing clearance to any software products that fully meet its definition of CADe: automatically identifying suspect lung nodules for radiologist review (i.e., second reader mode).

Potential Health Impact: 2 (Expected to make a small improvement to patients' health and/or quality of life)

Few data are available to evaluate the potential effect of adding CADe to LDCT in lung cancer screening programs. Several professional societies recommend LDCT lung cancer screening for certain older smokers and former smokers at highest risk of developing lung cancer. However, these guidelines generally do not address the addition of CADe to LDCT.

Potential Financial Impact: 2 (Expected to have a small financial impact)



Emerging Technology

- ▶ [Link to Video: An implant for monitoring blood pressure in heart failure - ECRI's Research Findings](#)



ECRI Institute's Top 10 C-Suite Watch List

A graphic with a colorful, abstract background of overlapping squares in shades of blue, green, and red. The text '2017 TOP 10 HOSPITAL C-SUITE WATCH LIST' is overlaid on the left side. '2017' is in large red font, and the rest is in dark blue/black font.

2017 TOP 10 HOSPITAL C-SUITE WATCH LIST

- 1 Liquid Biopsies:**
The New Wave of Genetic Testing? _____
- 2 Opioid Addiction:**
Can Technology Predict Risks of Addiction and Relapse? _____
- 3 The Belly of the Presurgery Beast:**
An Initiative to Improve Outcomes and Costs of Abdominal Surgery? _____
- 4 Right-sizing Your Hospital:**
Is It Time to Refresh Your Purchasing and Implementation Processes? _____
- 5 Seeing the Disinfecting Light:**
Will Compact Deep Ultraviolet-C LEDs Zap Infection Rates? _____
- 6 Pepper, the Emotional Robot:**
Do You Have a Spot for Artificial Intelligence on Your 2017 Payroll? _____
- 7 Robotic Surgery:**
Could a Pricey Patient-repositioning Table Improve Workflow and Outcomes? _____
- 8 Adjusting the Endoscopy Picture:**
Is a New Imaging Technique a Better Way to Visualize Tissue Malignancies? _____
- 9 Crohn's Disease:**
Will Immunotherapy and Stem Cell Therapy Rescue Patients with Moderate-to-severe Symptoms? _____
- 10 Sticking It to Diabetes:**
Will Novel Vaccines Prevent or Cure Type I Diabetes in Children and Adults? _____

Diving Deeper with HTA

Health Technology Assessment (HTA)

- ▶ Health technology assessment (HTA) is the systematic analysis of the evidence for safety, efficacy, effectiveness, costs, cost effectiveness, and the ethical and legal implications of healthcare technologies.
- ▶ Comparative effectiveness review, systematic review, rapid review, evidence-based medicine



Health Technology Assessment (HTA)

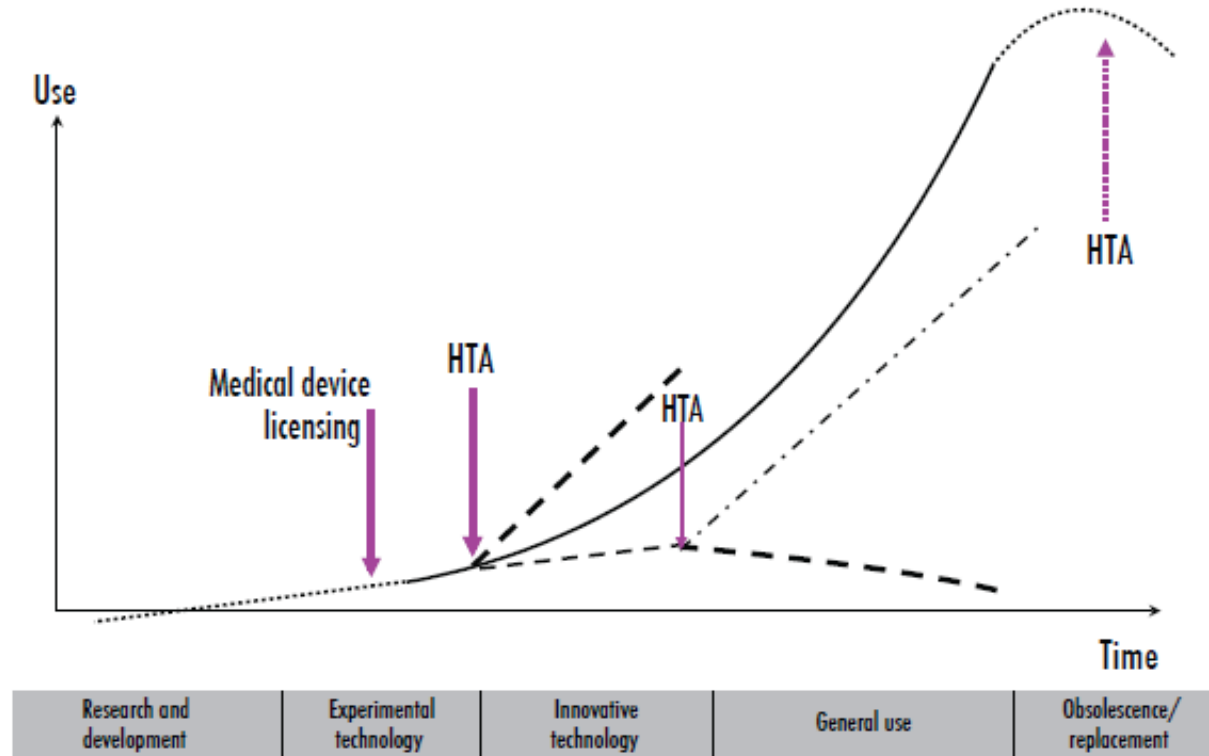
- ▶ *HTA is “the systematic evaluation of properties, effects, and/or impacts of health-care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policy-making in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods”*

<http://www.htai.org/>

<http://www.inahta.org/>

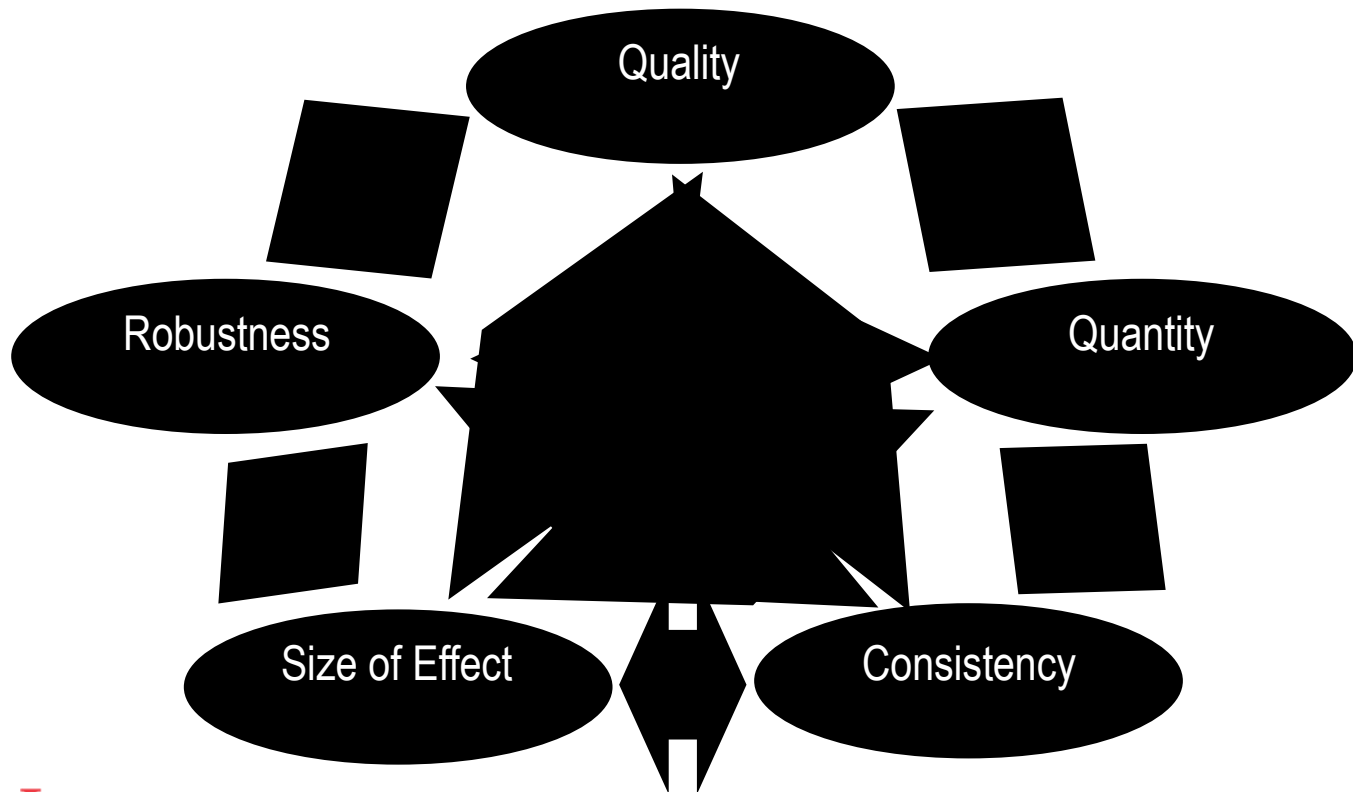
Health Technology Assessment (HTA)

- ▶ HTA and diffusion of health technologies



Health Technology Assessment (HTA)

- ▶ Not all evidence is created equal!



Is HTA Always Done the Same Way?

- ▶ Uses a variety of methods
 - Methods range from rapid *systematic* narrative reviews to highly *sophisticated statistical and modeling approaches (research synthesis)*
 - Depends upon the available literature (new technology can present a challenge because of limited evidence)
 - Budget and time constraints

THE EVIDENCE — META-ANALYSIS



Author	Journal	Studies	Patient no.	Repair type	Recurrence	Chronic pain	Complications	Return to Work (days)
EU Hernia Trialist (2002)	Hernia	25	4165	Lap vs Lichtenstein	No difference	Lap < Open	More serious Cx in lap	N/A
Memon (2003)	British Journal of Surgery	29	5588	Lap vs Open	No difference	N/A	Lap < Open	Lap < Open
NICE Guidelines (2004)		37	5560	Lap vs Open mesh repair	No difference	Lap < Open	No difference	Lap < Open
Schmidt (2005)	Surgical Endoscopy	23	4550	Lap vs Open	No difference	Lap < Open	Lap < Open More serious Cx in lap	Lap < Open
Kuhry (2007) (Systemic review)	Surgical Endoscopy	23	4231	TEP vs Open	No difference	N/A	No difference	Lap < Open
O'Reilly (2012)	Annals of Surgery	27	7161	Lap vs Open	Lap > Open	Lap < Open	No difference	N/A
Koning (2013)	PLOS ONE	13	5404	TEP vs Lichtenstein	No difference	No difference	No difference	N/A
European Hernia Society Guidelines (2009/2014)	Hernia	8 (FU >48mths)	2399	Lap vs Lichtenstein	No difference	No difference	N/A	N/A

Health Technology Assessment (HTA)



13-Step Research Process

1. Establish the HTA team, addressing potential for financial bias/other COI
2. Formulate the topic/define relevant PICOTS (based on prelim. literature searches)
 - a) Patient population
 - b) Intervention
 - c) Comparators
 - d) Outcomes of interest
 - e) Time frame
 - f) Setting
3. Formulate and refine key clinical questions
4. Create analytic framework

Health Technology Assessment (HTA)



5. Define types of study design needed to address key questions
6. Identify external reviewers of draft HTA
7. Refine search strategies
8. Search for and retrieve evidence
9. Extract data, perform quality assessment of individual studies
10. Conduct evidence synthesis, including rating of strength of evidence for each question and meta-analysis as appropriate
11. Evidence interpretation and drafting of HTA report
12. Internal and external review of draft report (including manufacturers)
13. Address reviewers' concerns/finalize report

Health Technology Assessment (HTA)

Domain	Description of applicability of evidence
Population	<ul style="list-style-type: none">• What do the study participants look like?• Are there important differences between study participants and the target population?
Intervention	<ul style="list-style-type: none">• What were key characteristics of the intervention?• How do they compare to those in routine use ?
Comparators	<ul style="list-style-type: none">• Do comparators reflect best alternative treatment?
Outcomes	<ul style="list-style-type: none">• What outcomes were most frequently reported?• Do the measured outcomes reflect the most important clinical benefits and harms?
Timing	<ul style="list-style-type: none">• What was the duration of reporting? Was the duration of reported effects clinically meaningful?
Setting	<ul style="list-style-type: none">• What was the geographic and clinical setting of included studies?• Is this reflective of the settings in which the intervention will typically be used?

Why Payers and Providers need HTA

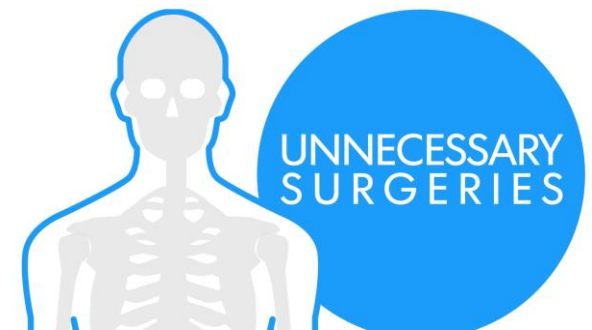
- ▶ To help control wide variations in practices among clinicians locally, regionally and nationally
- ▶ To **control costs** and better match resources with needs
- ▶ To make **informed purchase decisions about health technology**
- ▶ To reduce duplication of services

Challenges in Assessing Effectiveness of New Technologies:

- ▶ Hospitals/clinicians offering more and more technology-based services
- ▶ Manufacturers developing more and more products
- ▶ Systematic review/HTA assessment output never enough
- ▶ Large number of topics means that some will be evaluated in lesser depth
- ▶ How to support decision-making when the evidence isn't there?

Implications of Improper Decision Making (No HTA):

- ▶ Inappropriate technology
- ▶ Excess technology
- ▶ Unnecessary technology
- ▶ Distorted consumer expectations
- ▶ Patient harm
- ▶ Increased costs



Current State of HTA

- ▶ Provides critical input to payers, providers, policy makers and patients
- ▶ Largely based on evidence synthesis of published research
- ▶ Gaps in evidence common: few studies, poor study design and reporting, inconsistencies across studies, use of surrogate rather than patient-oriented outcomes, inadequate length of follow-up
- ▶ “Evidence is insufficient” – most decisions have to be made in the absence of good evidence

Future Directions for Health Technology Assessment - 5 Key Trends

- ▶ Impact of Patient Centered Outcomes Research and Comparative Clinical Effectiveness Research
- ▶ Use of Electronic Clinical Data – Big Data
- ▶ Challenge of Genetic Tests
- ▶ Move from Post market to Pre market Environment
- ▶ Use to identify potential risk of technology adoption

What HTA Organizations will Expect – CER and PCOR

- ▶ Emphasis on CER/PCOR sets a higher evidence Demand bar, this may curtail product diffusion in some cases, as newer, more effective and safer products are approved
- ▶ Demonstrating value means providing HTA organizations (and payers and providers and clinical practice guideline developers) with evidence of superior comparative effectiveness, ideally utilizing patient centered outcomes
- ▶ Patient centered outcomes need to be part of the entire product development life cycle – don't wait until the post market phase

Electronic Clinical Data – Big Data

- ▶ Captured routinely by providers, but up to now, only rarely formally used for HTA
- ▶ Includes “big data” from EHRs and registries
- ▶ Outcomes data that is mostly used indirectly in HTA, depends on whether analyses of this data are published
- ▶ We expect to see more instances of EHR data used to supplement HTA

How Could we Use Electronic Clinical Data in HTA?

- ▶ Answer key questions not addressed by published studies
- ▶ Detect rare harms of treatment: most studies too small, but ECD-derived research may be sufficiently powerful to detect and estimate their likelihood
- ▶ Explain heterogeneity of treatment effect: ECD data on individual patients may explain why treatments work for some, but not all patients
- ▶ Predict clinical impact of the uptake of a new treatment
- ▶ Predict impact of phasing out of an outdated treatment

Electronic Clinical Data in HTA, cont.

- ▶ Determine whether a treatment used in a local or different population gets different results or harms are from patients studied in a published clinical trial
- ▶ Overcome selective outcome reporting bias (publication bias) when investigators measure an outcome but choose not to include data on that outcome in the published report

Pitfalls of Using ECD in HTA

- ▶ ECD collected outside the structure and oversight of a research study
- ▶ Subject to bias from many causes – need to assess risk of bias and exclude data at high risk of bias
- ▶ Controversy about of using ECD for research purposes without explicit patient consent forms

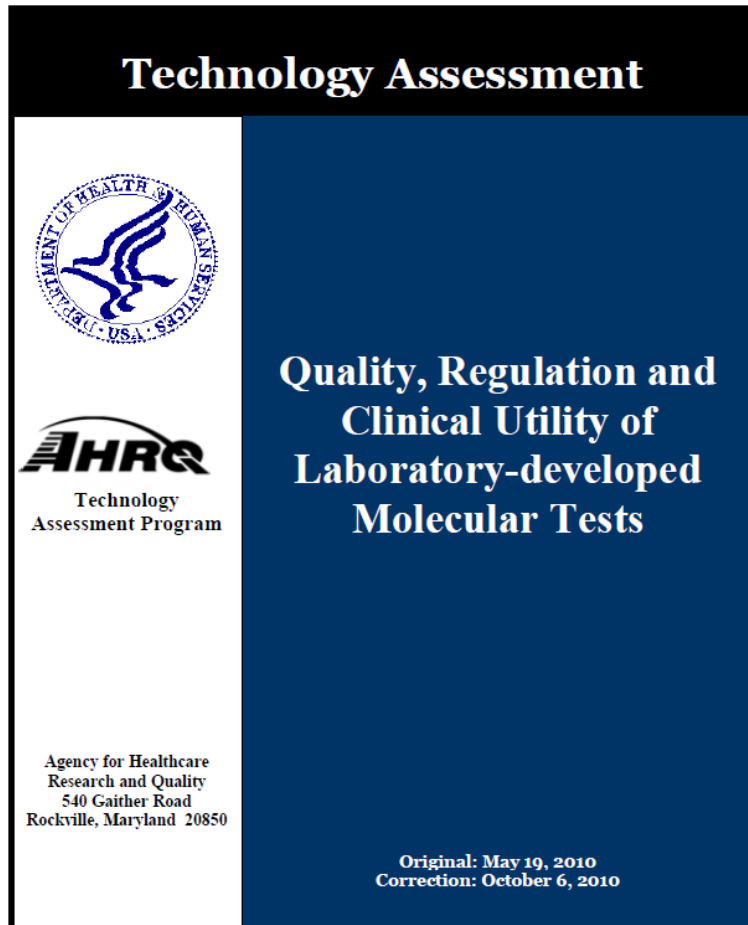
Personalized Medicine

- ▶ Genetic/genomic testing
- ▶ Companion diagnostic tests/biomarkers for cancer specialty drugs

Genetic Tests and HTA

- ▶ 19,000 tests in use for 3,500 conditions and growing
- ▶ Payers and providers uncertain about the value of specific tests – evidence for clinical utility missing
- ▶ Many tests for mutations currently do not change patient management
- ▶ Individual payers spending 100s of \$ millions annually; total spend \$25 billion per year by 2020

ECRI Evidence-based Practice Center



- Sun F, Bruening W, Uhl S, Ballard R, Tipton K, Schoelles KM. **Quality, Regulation and Clinical Utility of Laboratory-developed Molecular Tests.** Technology Assessment. Agency for Healthcare Research and Quality 2010.
- Sun F, Bruening W, Erinoff E, Schoelles KM. **Addressing Challenges in Genetic Test Evaluation.** Methods Research Report. Agency for Healthcare Research and Quality 2011.
- Sun F, Schoelles KM, Coates VH. **Assessing the utility of genetic tests.** J Ambul Care Manage. 2013 Jul-Sep;36(3):222-32

Laboratory Developed Tests Create Dilemmas for reimbursement

- ▶ Currently, the vast majority of clinically available molecular diagnostic/genetic tests are Laboratory Developed Tests (LDTs). FDA has generally not enforced applicable regulations with respect to LDTs.
- ▶ US AMA Current Procedure Terminology coding (316 molecular pathology services codes) is still not comprehensive or specific enough
- ▶ Without this specificity in coding, payers can't effectively assess and monitor the tests' clinical utility, safety, or other impacts
- ▶ In many cases, payers are reimbursing for tests without specific reimbursement policies in place for those tests

What are HTA organizations looking for?

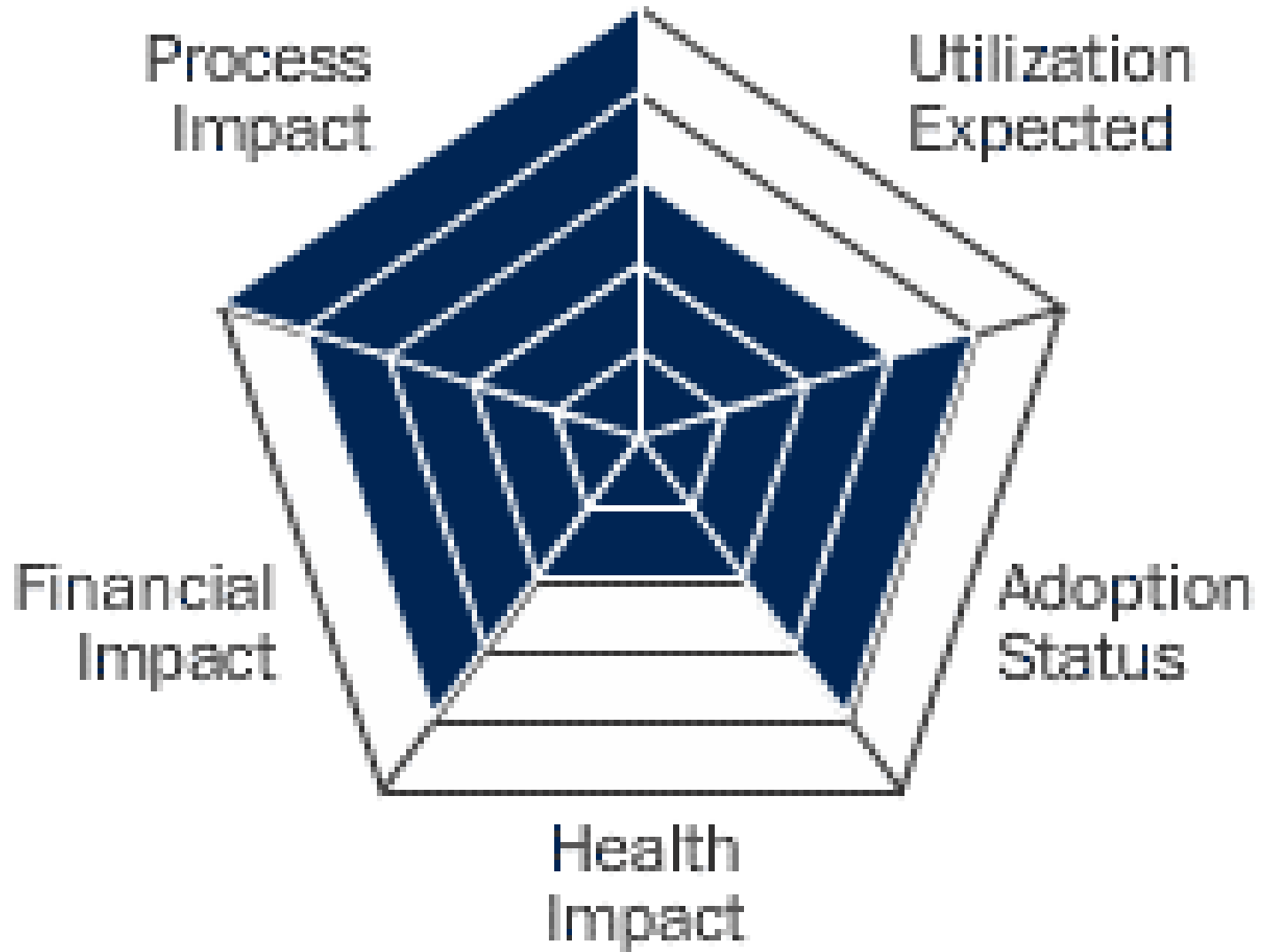
- ▶ Data on *analytic validity*
- ▶ Data on *clinical validity*
- ▶ Data on *clinical utility*
- ▶ From high quality prospective studies published in peer-reviewed journals vs reports presented at meetings, or summaries on company websites or Markov models and cost effectiveness analyses

Genetic Tests – Major Priority for HTA

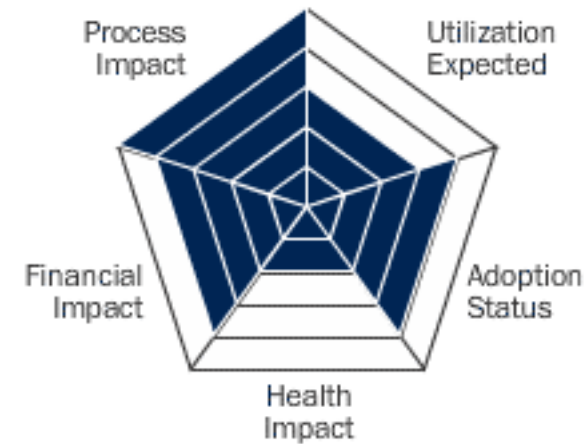
- ▶ Genetic tests have great potential to improve care
- ▶ Concern remains about the quality, safety, effectiveness, cost, and ethical implications of many diagnostic tests, especially genetic tests
- ▶ Inaccurate test results may mislead clinicians to make wrong decisions and potentially cause harm to patients
- ▶ Tests without clinical utility do not lead to improved outcomes but could impose unnecessary burdens on patients and society
- ▶ Clinical utility can sometimes be inferred from evidence of clinical validity, but payers may be less willing than patients/providers to consider indirect chains of evidence linking patient outcomes to testing

HTA Moving from Post market to Premarket

- ▶ Especially for medical devices, increasing emphasis on looking at ways to assess evidence before regulatory clearance



What about using HTA in RISK Management? Case Example



Anticipated Utilization: 3 (Expected to be used by 40% to 60% of eligible patients)

Utilization varies by procedure and could exceed 60% of indicated patients for technically challenging procedures

Estimated Adoption Status: 4 (Middle adoption – 25% to 75% of facilities that would be expected to adopt have adopted)

Potential Financial Impact: 4 (Expected to have a substantial financial impact)

Systems typically cost between \$600,000 and \$2.5 million in the United States with **annual maintenance costs exceeding \$120,000**. Hospitals must recover their investment through realizing procedural efficiencies such as reduced complication rates and shorter lengths of stay. **Longer procedures could reduce the number of procedures performed daily, reducing revenue stream and efficiency.**

What about using HTA in RISK Management? Case Example



Potential Health Impact: 2 (Expected to make a small improvement to patients' health and/or QOL)

Recent prospective, comparative studies have found no statistically significant differences in clinical outcomes between open and robotic-assisted surgery for prostatectomy (Yaxley et al. 2016, Haglind et al. 2015) or hysterectomy (Cohn et al. 2016). Other investigators (Masson-LeComte et al. 2013, Lee et al. 2013, Lim et al. 2013) have suggested that robotic-assisted procedures have longer procedural times but comparable outcomes to laparoscopic procedures; thus, patients are **under anesthesia longer**. Length of stay and **recovery times may be shorter** for some patients during robotic-assisted surgery than length of stay and recovery times during **open surgery**.

What about using HTA in RISK Management? Case Example



Potential Process and Infrastructure Impact: 5 (Expected to have a dramatic process impact) if robotic **surgeries take longer than open or laparoscopic surgery**, operating room scheduling may be more complicated. Hospitals using the technology also **must ensure that surgeons and clinical support staff have adequate training** in use of the robotic technology for specific procedures and that they **have sufficient volumes of patients to maintain proficiency and good patient outcomes**.

ECRI Institute. Da Vinci Robotic-assisted Surgery for Performing Laparoscopic Procedures. Plymouth Meeting (PA): ECRI Institute; 2017 May 12. (Technology Forecast). Updated 12th May 2017

The Trial of a Trial

THE TRIALS OF A TRIAL

One Publication's Journey from Library to Technology Assessment

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Conclusions

- ▶ Adoption of new technology often outpaces the evidence of its effectiveness (eg, genetic tests)
- ▶ Higher evidence bar for reimbursement of new technology
- ▶ Findings are perishable: as new evidence emerges, HTAs must be revisited
- ▶ Where the evidence is incomplete or does not yet exist, forecasting/horizon scanning should be used in conjunction with HTA
- ▶ Forecasting/horizon scanning and HTA are essential tools for determining the *value* of new technology

**Thank You.
Questions?**

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