PUBLIC HEALTH FOUNDATION OF INDIA

ASSOCIATION OF HEALTHCARE PROVIDERS INDIA

Indian Institute of Science

Indian Institute of Space Science and Technology

Certificate Course in

Healthcare Technology (CCHT)

Module 5: Healthcare technology - Regulatory, Policy and Practical aspects

Health technology assessment (HTA)

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HEALTH TECHNOLOGY ASSESSMENT (HTA)

Learning Objectives:

1. Definition of Health Technology Assessment
2. Application of HTA
3. Impact of HTA
4. Case Studies: Infection Prevention
5. Clinical Examples: High Precision radiation Oncology

Overview of Session:

- What is HTA?
- Is HTA a good decision-making tool?
- Components of HTA…
- Cost Benefit, Cost Effective and Cost Utility Analysis
- Medical ethics
- Legal application
- Implementation in Clinical Decision making
- Summary

HEALTH TECHNOLOGY ASSESSMENT

Technological innovation has yielded truly remarkable advances in health care during the last five decades. In recent years, breakthroughs in a variety of areas have helped to improve health care delivery and patient outcomes, including antivirals, anticlotting drugs, antidiabetic drugs, antihypertensive drugs, antirheumatic drugs, vaccines, pharmacogenomics and targeted cancer therapies, cardiac rhythm management, diagnostic imaging, minimally invasive surgery, joint replacement, pain management, infection control, and health information technology.

The proliferation of health care technology and its expanding uses have contributed to burgeoning health care costs, and the former has been cited as “culprit” for the latter. However, this relationship is variable, complex, and evolving. In the US, the Congressional Budget Office concluded that “roughly half of the increase in health care spending during the past several decades was associated with the expanded capabilities of medicine brought about by technological advances”

Few patients or clinicians are willing to forego access to state-of-the-art health care technology. In the wealthier countries and those with growing economies, adoption and use of technology has been stimulated by patient and physician incentives to seek any potential health benefit with limited regard to cost, and by third-party payment, provider competition, effective marketing of technologies, and consumer awareness.

Factors That Reinforce the Market for Health Technology

- Advances in science and engineering
- Intellectual property, especially patent protection
- Aging populations
- Increasing prevalence of chronic diseases
- Emerging pathogens and other disease threats
- Third-party payment, especially fee-for-service payment
- Financial incentives of technology companies, clinicians, hospitals, and others
- Public demand driven by direct-to-consumer advertising, mass media reports, social media, and consumer awareness and advocacy
- Off-label use of drugs, biologics, and devices
- “Cascade” effects of unnecessary tests, unexpected results, or patient or physician anxiety
- Clinician specialty training at academic medical centers
- Provider competition to offer state-of-the-art technology

- Malpractice avoidance
- Strong or growing economies

In this era of increasing cost pressures, restructuring of health care delivery and payment, and heightened consumer demand—yet continued inadequate access to care for many millions of people—technology remains the substance of health care. Culprit or not, technology can be managed in ways that improve patient access and health outcomes, while continuing to encourage useful innovation. The development, adoption, and diffusion of technology are increasingly influenced by a widening group of policymakers in the health care sector. Health product makers, regulators, clinicians, patients, hospital managers, payers, government leaders, and others increasingly demand well-founded information to support decisions about whether or how to develop technology, to allow it on the market, to acquire it, to use it, to pay for its use, to ensure its appropriate use, and more. The growth and development of (HTA) in government and the private sector reflect this demand.

HTA methods are evolving and their applications are increasingly diverse. This document introduces fundamental aspects and issues of a dynamic field of inquiry. Broader participation of people with multiple disciplines and different roles in health care is enriching the field. The heightened demand for HTA, in particular from the for-profit and not-for-profit private sectors as well as from government agencies, is pushing the field to evolve more systematic and transparent assessment processes and reporting to diverse users. The body of knowledge about HTA cannot be found in one place and is not static. Practitioners and users of HTA should not only monitor changes in the field, but have considerable opportunities to contribute to its development.

A. Origins of Technology Assessment

Technology assessment (TA) arose in the mid-1960s from an appreciation of the critical role of technology in modern society and its potential for unintended, and sometimes harmful, consequences. Experience with the side effects of a multitude of chemical, industrial and agricultural processes and such services as transportation, health, and resource management contributed to this understanding. Early assessments concerned such topics as offshore oil drilling, pesticides, automobile pollution, nuclear power plants, supersonic airplanes, weather modification, and the artificial heart. TA was conceived as a way to identify the desirable first-order, intended effects of technologies as well as the higher-order, unintended social, economic and environmental effects.

The term “technology assessment” was introduced in 1965 during deliberations of the GROUP.

Technical information needed by policymakers is frequently not available, or not in the right form. A policymaker cannot judge the merits or consequences of a technological program within a strictly technical context. He has to consider social, economic, and legal implications of any course of action.

Congress commissioned independent studies by the National Academy of Sciences and the that significantly influenced the development and application of TA. These studies and further congressional hearings led the National Science Foundation to establish a TA program and, in 1972, Congress to authorize the congressional Office of Technology Assessment (OTA), which was founded in 1973, became operational in 1974, and established its health program in 1975.

Many observers were concerned that TA would be a means by which government would impede the development and use of technology. However, this was not the intent of Congress or of the agencies that conducted the original TAs. In 1969, an NAE report to Congress emphasized that:

Technology assessment would aid the Congress to become more effective in assuring that broad public as well as private interests are fully considered while enabling technology to make the maximum contribution to our society's welfare.

With somewhat different aims, private industry used TA to aid in competing in the marketplace, for understanding the future business environment, and for producing options for decision makers.

TA methodology drew upon a variety of analytical, evaluative, and planning techniques. Among these were systems analysis, cost-benefit analysis, consensus development methods (e.g., Delphi method), engineering feasibility studies, clinical trials, market research, technological forecasting, and others. TA practitioners and policymakers recognized that TA is evolving, flexible, and should be tailored to the task.

Some Definitions of Technology Assessment

Technology assessment is the systematic study of the effects on society, that may occur when a technology is introduced, extended, or modified, with emphasis on the impacts that are unintended, indirect, or delayed.

Technology assessment (TA) is a category of policy studies, intended to provide decision makers with information about the possible impacts and consequences of a new technology or a significant change in an old technology. It is concerned with both direct and indirect or secondary consequences, both benefits and disbenefits, and with mapping

the uncertainties involved in any government or private use or transfer of a technology. TA provides decision makers with an ordered set of analyzed policy options, and an understanding of their implications for the economy, the environment, and the social, political, and legal processes and institutions of society.

Technology assessment ultimately comprises a systems approach to the management of technology reaching beyond technology and industrial aspects into society and environmental domains. Initially, it deals with assessment of effects, consequences, and risks of a technology, but also is a forecasting function looking into the projection of opportunities and skill development as an input into strategic planning. In this respect, it also has a component both for monitoring and scrutinizing information gathering. Ultimately, TA is a policy and consensus building process as well

Technology assessment is a form of policy research that examines short- and long-term social consequences (for example, societal, economic, ethical, legal) of the application of technology. The goal of technology assessment is to provide policy-makers with information on policy alternatives.

Technology Assessment is a concept, which embraces different forms of policy analysis on the relation between science and technology on the one hand, and policy, society and the individual on the other hand. Technology Assessment typically includes policy analysis approaches such as foresight; economic analysis; systems analysis; strategic analysis etc. … Technology Assessment has three dimensions: the cognitive dimension ─ creating overview on knowledge, relevant to policy-making; the normative dimension ─ establishing dialogue in order to support opinion making; the pragmatic dimension ─ establish processes that help decisions to be made. And TA has three objects: the issue or technology; the social aspects; the policy aspects.

B. Early Health Technology Assessment

Health technologies had been studied for safety, effectiveness, cost, and other concerns long before the advent of HTA. Development of TA as a systematic inquiry in the 1960s and 1970s coincided with the introduction of some health technologies that prompted widespread public interest in matters that transcended their immediate health effects. Health care technologies were among the topics of early TAs. Multiphasic health screening was one of three topics of “experimental” TAs conducted by the NAE at the request of Congress. In response to a request by the National Science Foundation to further develop the TA concept in the area of biomedical technologies, the National Research Council conducted TAs on in vitro fertilization, predetermination of the sex of children, retardation of aging, and modifying human behavior by neurosurgical, electrical or pharmaceutical means (National Research Council 1975). The OTA issued a report

on drug bioequivalence in 1974, and the OTA Health Program issued its first formal report in 1976.

Since its early years, HTA has been fuelled in part by emergence and diffusion of technologies that have evoked social, ethical, legal, and political concerns. Among these technologies are contraceptives, organ transplantation, artificial organs, life-sustaining technologies for critically or terminally ill patients, and, more recently, genetic testing, genetic therapy, ultrasonography for fetal sex selection, and stem cell research. These technologies have challenged certain societal institutions, codes, and other norms regarding fundamental aspects of human life such as parenthood, heredity, birth, bodily sovereignty, freedom and control of human behavior, and death.

Despite the comprehensive approach originally intended for TA, its practitioners recognized early on that "partial TAs" may be preferable in circumstances where selected impacts are of particular interest or where necessitated by resource constraints. In practice, relatively few TAs have encompassed the full range of possible technological impacts; most focus on certain sets of impacts or concerns. Indeed, the scope of HTA reports has been diversified in recent years by the use of "horizon scanning" and the demand for "rapid HTAs," which are described later in this document.

Some Definitions of Health Technology Assessment

We shall use the term assessment of a medical technology to denote any process of examining and reporting properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended (Institute of Medicine 1985).

Health technology assessment ... is a structured analysis of a health technology, a set of related technologies, or a technology-related issue that is performed for the purpose of providing input to a policy decision

Health Technology Assessment asks important questions about these technologies [drugs, devices, procedures, settings of care, screening] such as: When is counselling better than drug treatment for depression? What is the best operation for aortic aneurysms? Should we screen for human papilloma virus when doing cervical smears? Should aspirin be used for the primary prevention of cardiovascular disease? It answers these questions by investigating four main factors: whether the technology works, for whom, at what cost, how it compares with the alternatives (UK NHS National Institute for Health Research Health Technology Assessment Programme 2013).

HTA is a field of scientific research to inform policy and clinical decision making around the introduction and diffusion of health technologies…. HTA is a multidisciplinary field that addresses the health impacts of technology, considering its specific healthcare context as well as available alternatives. Contextual factors addressed by HTA include economic, organizational, social, and ethical impacts. The scope and methods of HTA may be adapted to respond to the policy needs of a particular health system (Health Technology Assessment International 2013).

Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.

There are different types of economic evaluation and they can be distinguished by the outcomes that are considered in each. Cost analysis studies consider the costs associated with the health technologies in question, with the objective to identify the one associated with the lowest costs. These are therefore also called cost-minimisation studies. They implicitly make the assumption that the health technologies under consideration are equivalent in terms of their benefits. Because this assumption is rarely justified, these are now rarely used, with the notable exceptions of burden of illness studies and budget impact analyses. The former are not full economic evaluations because they do not compare alternatives. Instead, burden of illness studies aim to assess the cost of a disease to society. Budget impact analyses, on the other hand, are broader cost analyses that assess the financial impact of adopting a health technology over another in the healthcare system, taking into account the size of the population that would receive it. As such, it addresses the question of affordability, rather than that of value for money.

Measurement of costs and consequences in economic evaluation in HTA

Cost-effectiveness analyses evaluate whether a new health technology provides value relative to other existing health technologies. To assess this, a comparison of costs and consequences (such as health outcomes) associated with all technologies in question is made. The outcomes are typically expressed in life-years gained when adopting a new technology compared with life-years gained with existing technologies.

Cost–utility analyses are essentially cost-effectiveness analyses in which gains in health-related quality of life (HRQoL) are considered and assessed. A commonly used measure of HRQoL is the quality-adjusted life-year (QALY). Cost–utility analyses commonly result

in a relative measure of costs per QALY gained: the incremental cost-effectiveness ratio (ICER). The ICER is then compared to a threshold value below which a technology is deemed cost-effective use of resources, or, put more simply, value for money.

Finally, cost–benefit analyses evaluate both costs and consequences in monetary terms (ie, for example, in euros). For this, it is necessary to assign a monetary value to any consequences associated with the alternative health technologies.

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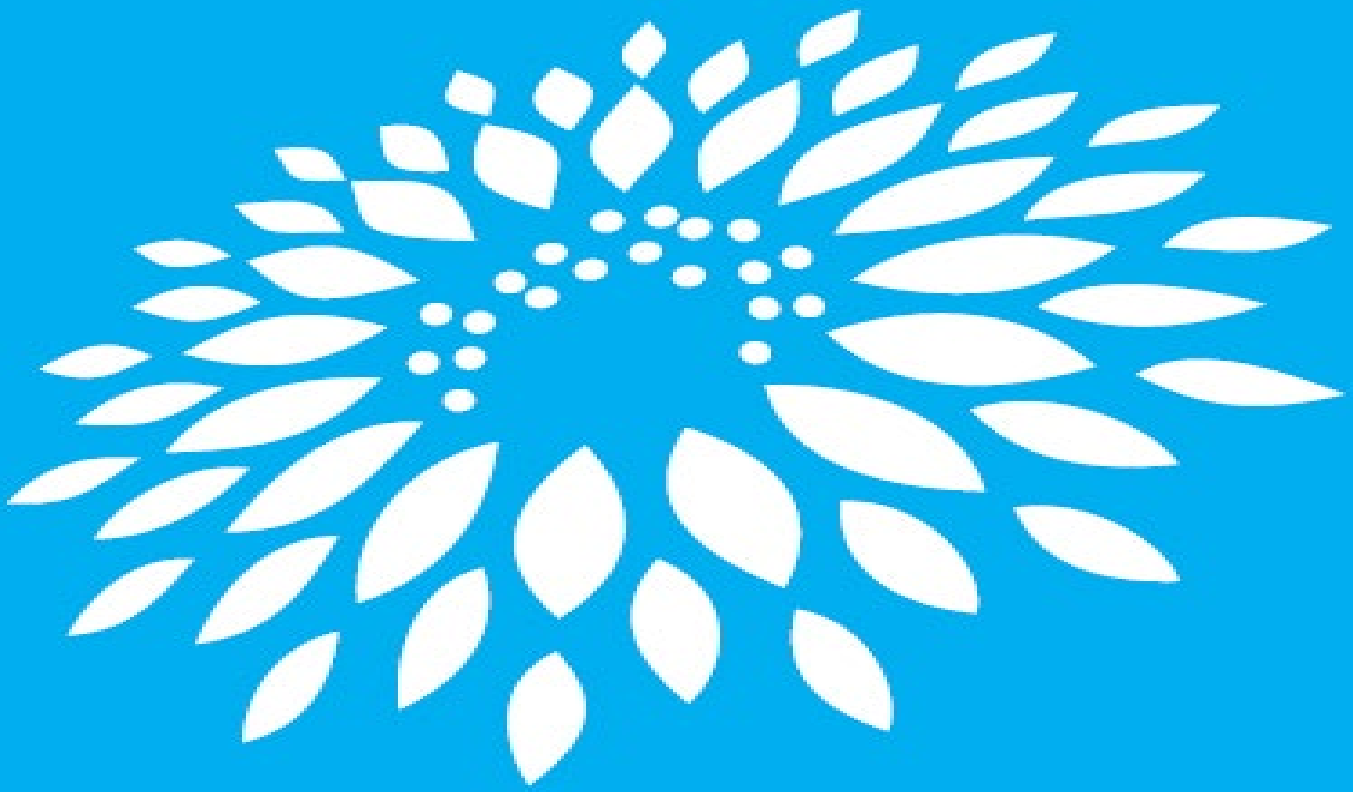
FOOD FOR THOUGHT

- Should I invest in employing Clinical Pharmacists in hospital?

Presentations



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HEALTH TECHNOLOGY ASSESSMENT (HTA)

CERTIFICATE COURSE IN
HEALTHCARE TECHNOLOGY

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Dr Sanjeev K Singh is a pediatrician by training and did his masters in Hospital Management. He completed his PhD in Infection Control.

He worked as a Regional Coordinator at WHO-India in a disease eradication program for couple of years before joining as Chief Medical Superintendent at a 1350 bed university teaching super specialty hospital - Amrita Institute of Medical Sciences & Research Center at Kochi.

He has done his fellowship in Patient & Healthcare worker Safety from University of Virginia and fellowship on Health Technology Assessment (HTA) from University of Adelaide. He is an Improvement Advisor at Institute of Healthcare Improvement (IHI), US. He is a faculty at Indian Institute of Management (IIM), Kolkata (HEMP) and at IIM Bangalore.

Dr Sanjeev is also an Ambassador from India to Society of Healthcare Epidemiology of America (SHEA) and has been adjudged as “Heros of Infection Control” by Association of Professionals of Infection Control (APIC), US. He is the International surveyor at International Society for Quality (ISQua). He was member of Technical Committee at National Accreditation Board for Hospitals, India (NABH) and was responsible in drafting accreditation standards for 3rd and 4th edition. He is presently the Vice Chairman of Research Committee at NABH. He is Chairman of Technical Committee at AHPI (Association of Healthcare Providers of India) and Health Sector Council of India (Government of India). He is member of Drug Safety Council (GOI) and member of National Advisory Body on Occupational Exposures. He is also member of Healthcare Committee at Federation of Indian Chamber of Commerce of India (FICCI) and Secy of AHPI- Delhi-NCR.

CERTIFICATE COURSE IN
HEALTHCARE TECHNOLOGY

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Case Study 1

Should I invest in Pap Smear surveillance for CA Cervix or Human Papilloma Virus estimation

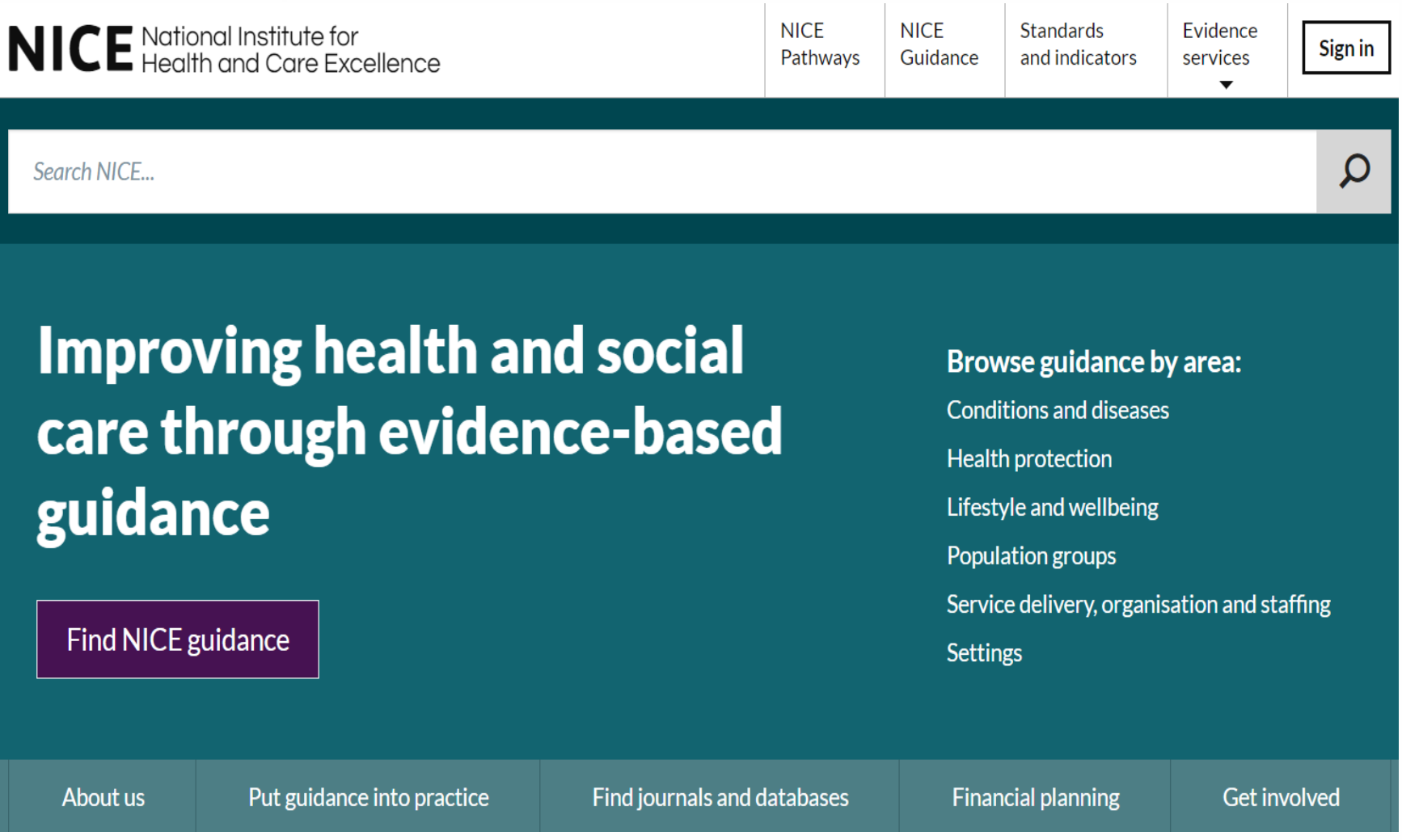
Case Study 2

Should I invest in High Precision Radiation Therapy a) Linear Accelerator b) Cyber Knife

Health Technology Assessment

- "To evaluate the clinical and cost-effectiveness of health technologies including drugs and provide advice arising out of the evaluation"

- "To review and make recommendations as the Authority thinks fit in respect of the services, to ensure the best outcomes for the resources available…"


NICE National Institute for Health and Care Excellence
NICE Pathways
NICE Guidance
Standards and indicators
Evidence services
Sign in
Search NICE...
Improving health and social care through evidence-based guidance
Find NICE guidance
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Health protection
Lifestyle and wellbeing
Population groups
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Find journals and databases
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MTAB

mTAB
Take your research further.

The Government of India is committed to extend healthcare services to its 1.25 billion population as part of India's Universal Health Coverage (UHC) agenda. The Medical Technology Assessment Board (MTAB) to be set as a part of Department of Health Research, Ministry of Health and Family Welfare aims to reduce the cost and variations in patient care, expenditure on medical equipment in directly affecting the cost of patient care, overall cost of medical treatment, reduction in out of pocket expenditure of patients and streamline the medical reimbursement procedures for effective implementation of the Universal Coverage Programme. An Indian delegation visited HiTAP, Thailand to study the complete process of implementation of HTA.

Date: 23-25 January, 2017

Health Technology Assessment (NICE)

Salient Features:

- Evidence in decision making (Systematic Review)
- Cost benefit, effective and utility analysis
- Ethical
- Legal
- Patient Safety
- Societal benefit

Hierarchy for the strength of evidence

Stronger (best)

Weaker

Systematic Reviews of RCTs (*randomised controlled trial – eliminates/reduces bias to give most reliable evidence)*

Results of **single RCTs**

Results of **well-conducted non-RCT** clinical studies

Expert committee reports; clinical experience of respected authorities

Personal **experience and opinion**

Search Strategy

- Potential patient safety practices were identified based on preliminary surveys of the literature and expert consultation.

- Bibliographic databases (e.g., MEDLINE, PsycINFO, ABI/INFORM, INSPEC), targeted searches of the Internet, and communication with relevant experts

Learning Objective

- *To be familiar with international groups conducting systematic reviews of the effectiveness of public health and health promotion interventions*

There are a number of groups around the world conducting systematic reviews of public health and health promotion interventions. Reviews are often published on the group's internet website, and follow guidelines/methods developed by the individual organisation. It is useful to visit each of the organisations listed below to view the different styles of systematic reviews. Reviewers seeking to conduct a Cochrane Review should visit the Cochrane website for more information (http://www.cochrane.org) or contact the Cochrane Health Promotion and Public Health Field (http://www.vichealth.vic.gov.au/cochrane/).

Useful websites of systematic review initiatives:

1. The Cochrane Collaboration – The Cochrane Library:
   http://www.thecochranelibrary.com

   Reviews relevant to health promotion and public health are listed on the Cochrane Health Promotion and Public Health Field website:
   http://www.vichealth.vic.gov.au/cochrane

2. Guide to Community Preventive Services:
   http://www.thecommunityguide.org

3. The Evidence for Practice Information and Co-ordinating Centre (EPPI-Centre):
   http://eppi.ioe.ac.uk/

4. Effective Public Health Practice Project:
   http://www.city.hamilton.on.ca/PHCS/EPHPP/EPHPPResearch.asp

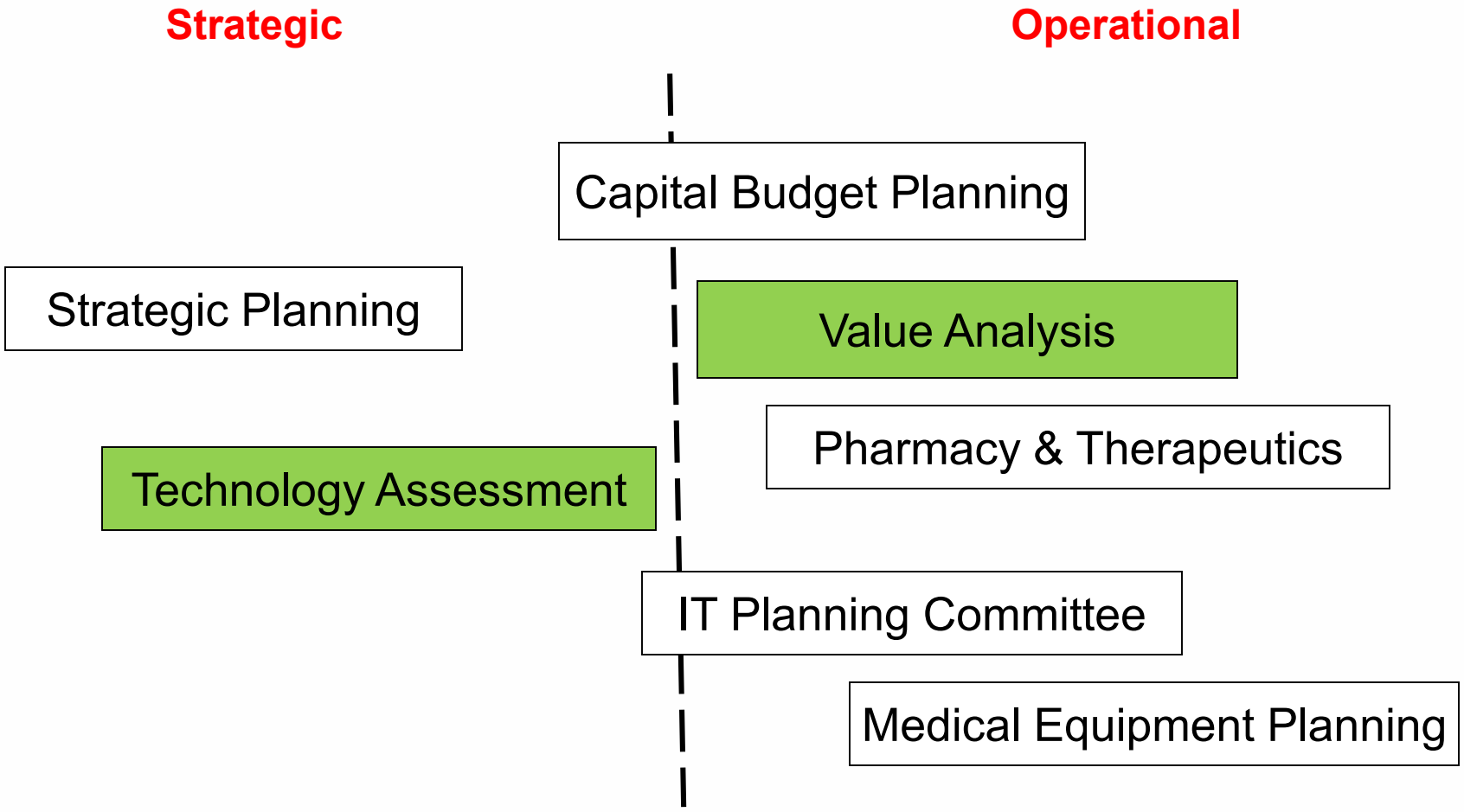
5. Health Development Agency (HDA):
   http://www.hda-online.org.uk/html/research/effectiveness.html
   Note: These reviews are systematic reviews of systematic reviews (not reviews of individual primary studies).

6. Centre for Reviews and Dissemination:
   http://www.york.ac.uk/inst/crd/

Research Questions

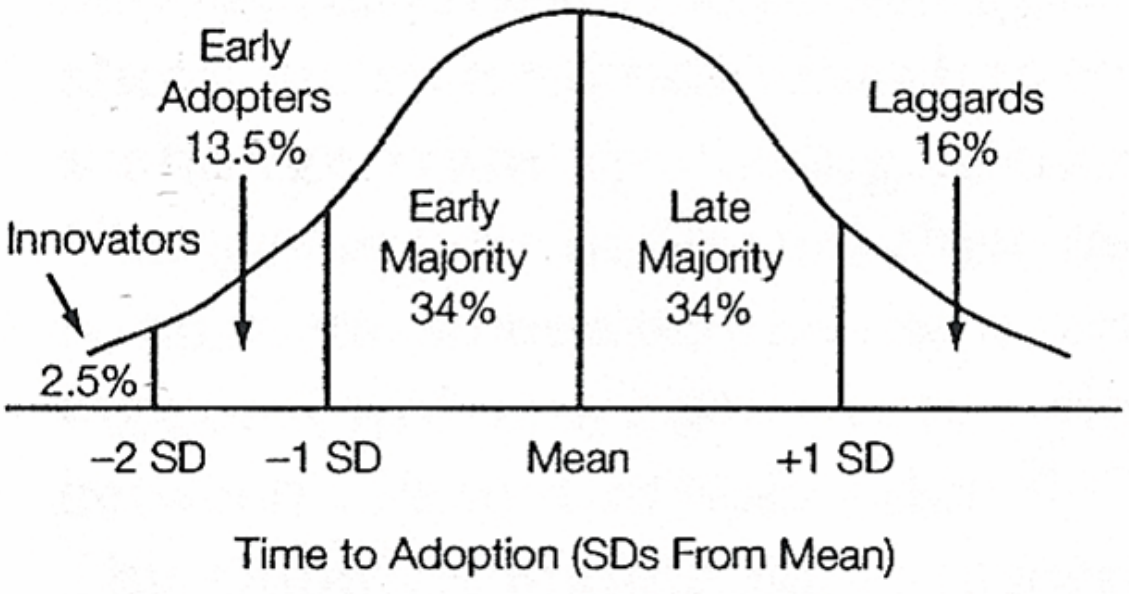
Level	Stem	Research Design
1	What is…? What are…?	Survey Exploratory Descriptive Case study Needs assessment
2	What is the relationship?	Survey Correlational/passive Observation
3	Cause/effect	Experimental Quasi-experimental

Technology-related Processes in Hospitals



Is my Technology Adoption consistent with my Strategic and Clinical Priorities?

Figure 2. Adopter Categorization on the Basis of Innovativeness



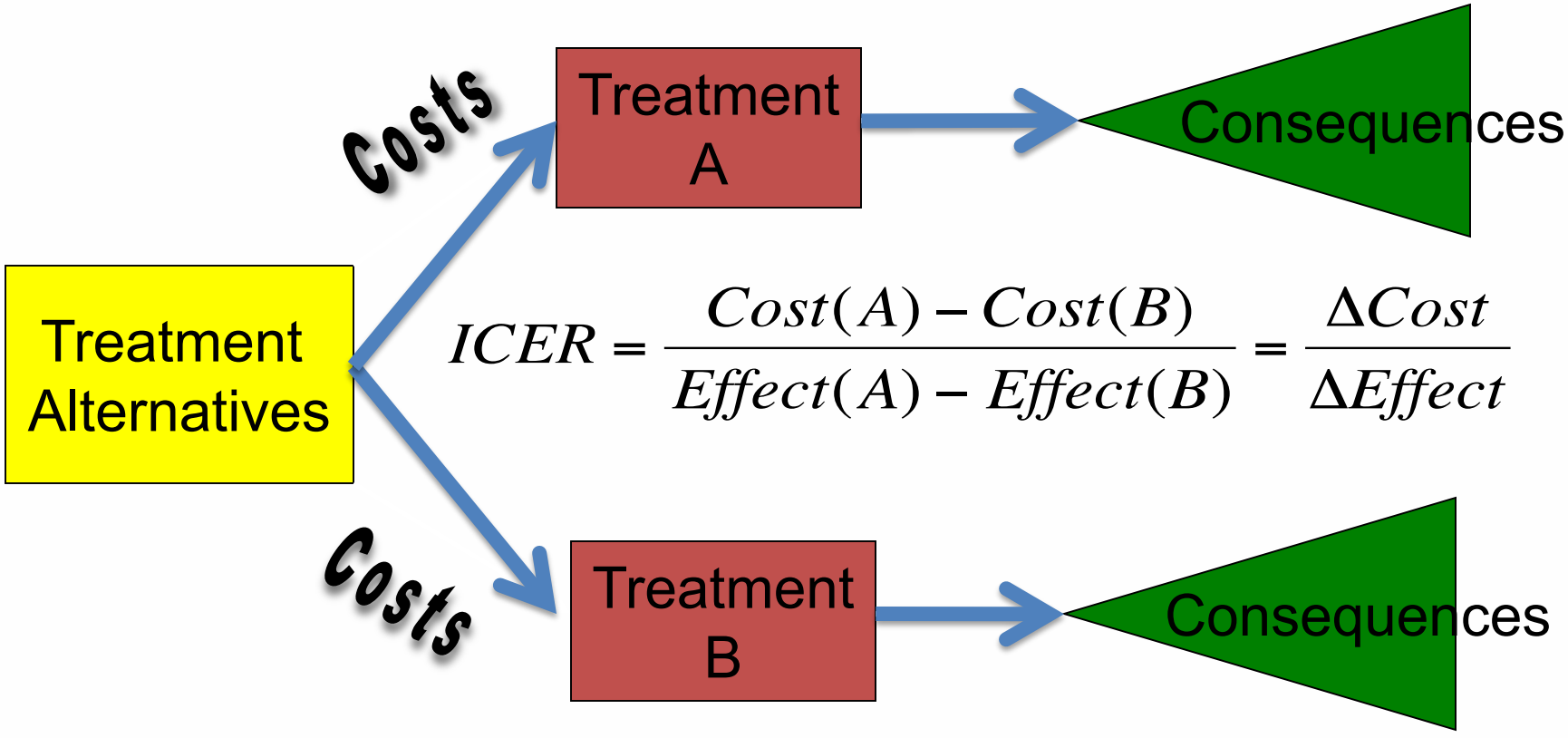
Reprinted with permission from Rogers.[21]

D. Berwick,JAMA, April 16, 2003-Vol. 289, No. 15 (Reprinted)

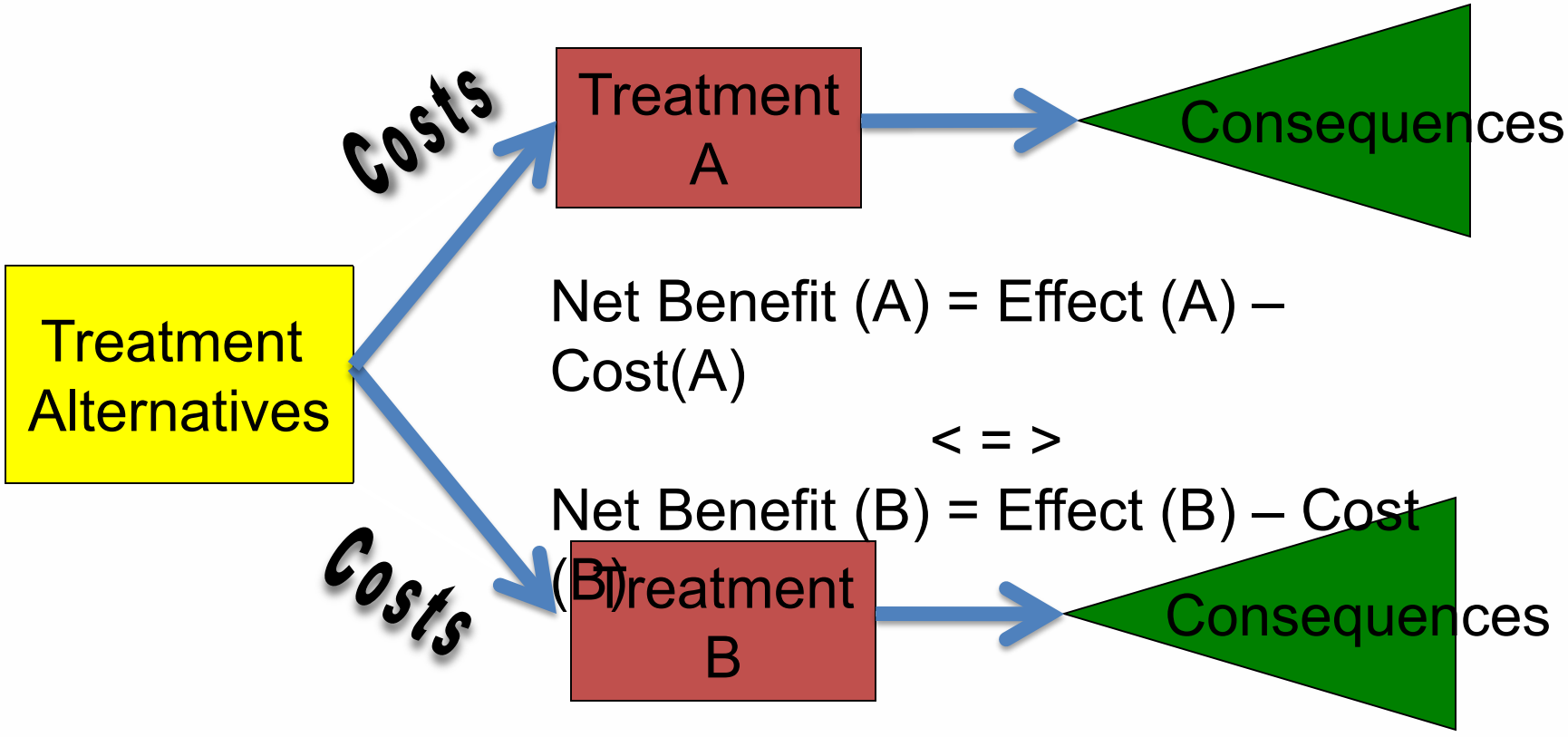
Cost Benefit, Cost Effective & Cost Utility Analysis

Types of Economic Evaluation

Type	Inputs/Costs	Outcomes
Cost Minimization	Monetary terms ($,£,¥,..)	Not considered
Cost Effectiveness	Monetary terms ($,£,¥,..)	Natural units (e.g. mortality, morbidity)
Cost-Utility	Monetary terms ($,£,¥,..)	Utility measures (QALY)
Cost Benefit	Monetary terms ($,£,¥,..)	Monetary terms ($,£,¥,..)



Cost Effectiveness Analysis



Cost Benefit Analysis

Hand Hygiene

Table 12.1. Fourteen studies of practices to improve handwashing compliance*

Study Setting; Practice	Study Design, Outcomes	Handwashing Compliance (unless otherwise noted)†
All medical staff in a neurologic ICU and a surgical ICU in a 350-bed tertiary care teaching hospital in Washington, DC, 1983-84; multifaceted intervention (education, automatic sinks, feedback)[16]	Level 2, Level 2	69% vs. 59% (p=0.005)
Medical staff in 2 ICUs in a university teach hospital in Philadelphia; increase number of available sinks[17]	Level 2, Level 2	76% vs. 51% (p<0.01)
Medical staff in a 6-bed post-anesthesia recovery room and a 15-bed neonatal ICU in a tertiary care hospital in Baltimore, 1990; automatic sink compared with standard sink[14]	Level 2, Level 2	Mean handwashes per hour: 1.69 vs. 1.21 on unit 1; 2.11 vs. 0.85 on unit 2; (p<0.001)
All staff at a large acute-care teaching hospital in France, 1994-97; hand hygiene campaign including posters, feedback, and introduction of alcohol-based solution[18]	Level 3, Level 1	Noscomial infections: 16.9% vs. 9.9% Handwashing: 66.2% vs. 47.6% (p<0.001)

Even when initial improvements in compliance have been promising, long-term continued compliance has been disappointing

The Bottom line…HH

- The implementation of a patient education campaign, when compared to the estimated $5000 per episode cost of each nosocomial infection, would result in an annual savings of approximately $57,600 for a 300-bed hospital with 10,000 admissions annually.
- As others have estimated that the attributable cost of a single nosocomial bloodstream infection is approximately $40,000 per survivor

Leutanbach et al, University of Pensylvania

Avg Length Of Stay

US (Extra ALOS)

- SSI: 11.4days
- BSI: 7.3 days
- VAP: 17.9days
- UTI: 4.3 days

India (Extra ALOS)

- SSI: ?
- BSI: ?
- VAP: ?
- UTI: ?

MMWR Report, 2018, CDC NHSN

Comparative Scenario (Cost)

US (Cost)

- SSI: $ 60,000 – 94,000
- BSI: $ 34,508 - 56,000
- VAP: $ 22500 – 77,000
- UTI: $ 3152 - 6500

India (Cost)

- SSI: ?
- BSI: ?
- VAP: ?
- UTI: ?

MMWR Report, 2018, CDC-NHSN

Cost Effectiveness of IC Prog

Cost Comparision: Infection Expenditure	
Event	Rs
Cost of Training	669
SSI	52808
BSI	37942
UTI	19686
VAP	61140

Cost Parameters

No.	Cost Variables	Costing Parameters
1.	Direct Cost	a) Surgical procedure cost b) Operating room cost c) Anesthesia cost d) ICU and Ward charges e) Medicines f) Lab Investigations g) Radiology Investigation h) Blood Transfusion i) Cross Consultations (if any) j) Any other procedure charges (like dialysis)
2.	Indirect Cost	a) Loss of job days of patient b) Loss of job days of attendants c) Boarding & Lodging cost of attendants d) Miscellaneous charges (like transportation)
3.	Cost of additional LOS	a) Cost involved for extra stay of HAI patients
4.	Opportunity Cost	a) Cost of lost opportunity of admitting additional patients because of occupied beds by HAI patients b) Cost of lost opportunity of doing more surgical procedures because of beds been occupied by HAI patients

Estimated Cost Avoidance - SSI

BI

- No of Surg: 1434
- No of pts infected: 86
- SSI: 6.72
- ALOS: 22 days
- Avg cost: Rs. 52802

AI

- No of Surg: 1404
- No of pts infected: 46
- SSI: 3.27
- ALOS: 10.7days
- Avg cost: 52802

- No of SSI avoided: 40
- Cost saved: 21,12,080

Estimated Cost Avoidance - VAP

BI

- No of Surg: 1434
- No of pts infected: 27
- VAP: 13.71
- ALOS: 32 days
- Avg cost: Rs. 63,645

AI

- No of Surg: 1404
- No of pts infected: 11
- VAP: 4.8
- ALOS: 28.1 days
- Avg cost: 63,645

- No of VAP avoided: 16
- Cost saved: 7,96,782

Estimated Cost Avoidance: BSI

BI

- No of Surg: 1434
- No of pts infected: 38
- BSI: 5.5
- ALOS: 25.3 days
- Avg cost: Rs. 37,942

AI

- No of Surg: 1404
- No of pts infected: 18
- BSI: 3.10
- ALOS: 16.9 days
- Avg cost: 37,942

- No of BSI avoided: 20
- Cost saved: 10,18,320

Estimated Cost Avoidance: UTI

BI

- No of Surg: 1434
- No of pts infected: 21
- UTI: 5.6
- ALOS: 17.2 days
- Avg cost: Rs. 17,686

AI

- No of Surg: 1404
- No of pts infected: 12
- UTI: 3.1
- ALOS: 12.4 days
- Avg cost: 17,686

- No of UTI avoided: 9
- Cost saved: 1,76,860

Global picture of Savings

Total Cost of avoidance	40,24,175
Total Indirect Cost	17,96,050
Additional Cost on LOS saving	57,69,000
Opportunity Cost	84,12,600
Total Savings	**2,00,01,825**

Cost of HAI for each patient ($)

	SSI	CLABSI	VAP	CA-UTI	Total
Direct Cost*	48577 (1056)	13659 (758)	14001 (1272)	4244 (353)	80481 (925)
Indirect Cost#	19568 (425)	7002 (389)	5093 (463)	4257 (354)	35920 (412)
Cost of excess LOS **	67320 (1463)	21384 (1188)	21780 (1980)	4896 (408)	115380 (1326)
Opportunity cost¶					168252 (1933)
Grand Total =					400033 (4596)

With 1 $ of investment;
Return of Investment is 236 $

Cost of Bad Will & Litigation

Variables	Statement	@	Total Amount
Cost of Bad Will	Positive Impact @ 1:9 Negative Impact @ 1:41	50,000/-	20,50,000
Cost of Litigation	1 case / yr	50,000/-	1,00,000
Total (Image cost)			**21,50,000**

Cost of Avoidance of HAI in a year in 1 department	2,00,01,825
Cost of Image on settlement if HAI occurs	21,50,000
Total Cost Saving to work on IPC	**2,21,51,825/-**

Cost Effectiveness

- Estimated Cost of Training & Surveillance: Rs. 82,070 (? Recruitment Cost)
- Total Cost Savings in CVTS: Rs. 1,91,20,192

- Patient Cost is: 59,00,092
- Hospital's Cost is: Rs. 82,070
- Society Gain is: 1,91,20,192

Limitation

- Cost of ill reputation : Intangible ?
- Hidden Costs if any

Comparative Scenario (ALOS)

US (Extra ALOS)

- SSI: 11.4days
- BSI: 7.3 days
- VAP: 17.9days
- UTI: 4.3 days

India (Extra ALOS)

- SSI: 12.2 days
- BSI: 9.9 days
- VAP: 16.5 days
- UTI: 3.4 days

MMWR Report, 2018, CDC-NHSN

Comparative Scenario (Cost)

US (Cost)

- SSI: $ 60,000 – 94,000
- BSI: $ 34,508 - 56,000
- VAP: $ 22500 – 77,000
- UTI: $ 3152 - 6500

India (Cost)

- SSI: 52, 808
- BSI: 37,942
- VAP: 61,114
- UTI: 19,686

MMWR Report, 2018, CDC NHSN

International Journal for Quality in Health Care

Int. Journal for Quality in Health Care

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Advance Access Publication: 16 October 2012

10.1093/intqhc/mzs059

Improving outcomes and reducing costs by modular training in infection control in a resource-limited setting

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Abstract

Objectives. To study the impact of modular training and implementation of infection control practices on all health-care-associated infections (HAIs) in a cardiac surgery (CVTS) program of a tertiary care hospital.

Design. Baseline data were compared with post-intervention (with modular training) data.

Settings. This study was conducted in a cardiovascular surgical unit.

Participants. In total, 2838 patients were admitted in cardiovascular surgical service.

Interventions. Two training modules and online continuous education were delivered to all health-care workers in CVTS unit.

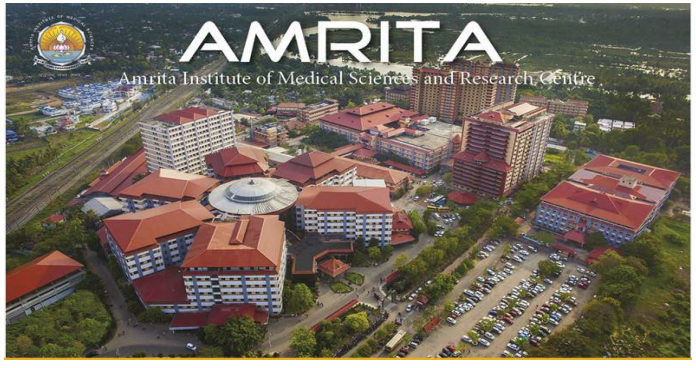
Main Outcome Measures. All four HAIs, such as surgical site infections (SSI), central line-associated blood stream infection (CLABSI), ventilator-associated pneumonia (VAP) and catheter-associated urinary tract infections (CA-UTI), were studied. Additional outcome measures included average length of stay cost of avoidance mortality and readmission rates.

Results. The SSI rate had decreased in the post-intervention phase from 46 to 3.27% per 100 surgeries ($P < 0.0001$), CLABSI had decreased from 44 to 3.10% per 1000 catheter days ($P < 0.009$), VAP was reduced from 65 to 4.8% per 1000 ventilator days ($P < 0.0001$) and CA-UTI had reduced from 37 to 3.48% per 1000 urinary catheter days ($P < 1.0$). For every $1 spent on training, the return on investment was $236 as cost of avoidance of healthcare associated infections (HAIs).

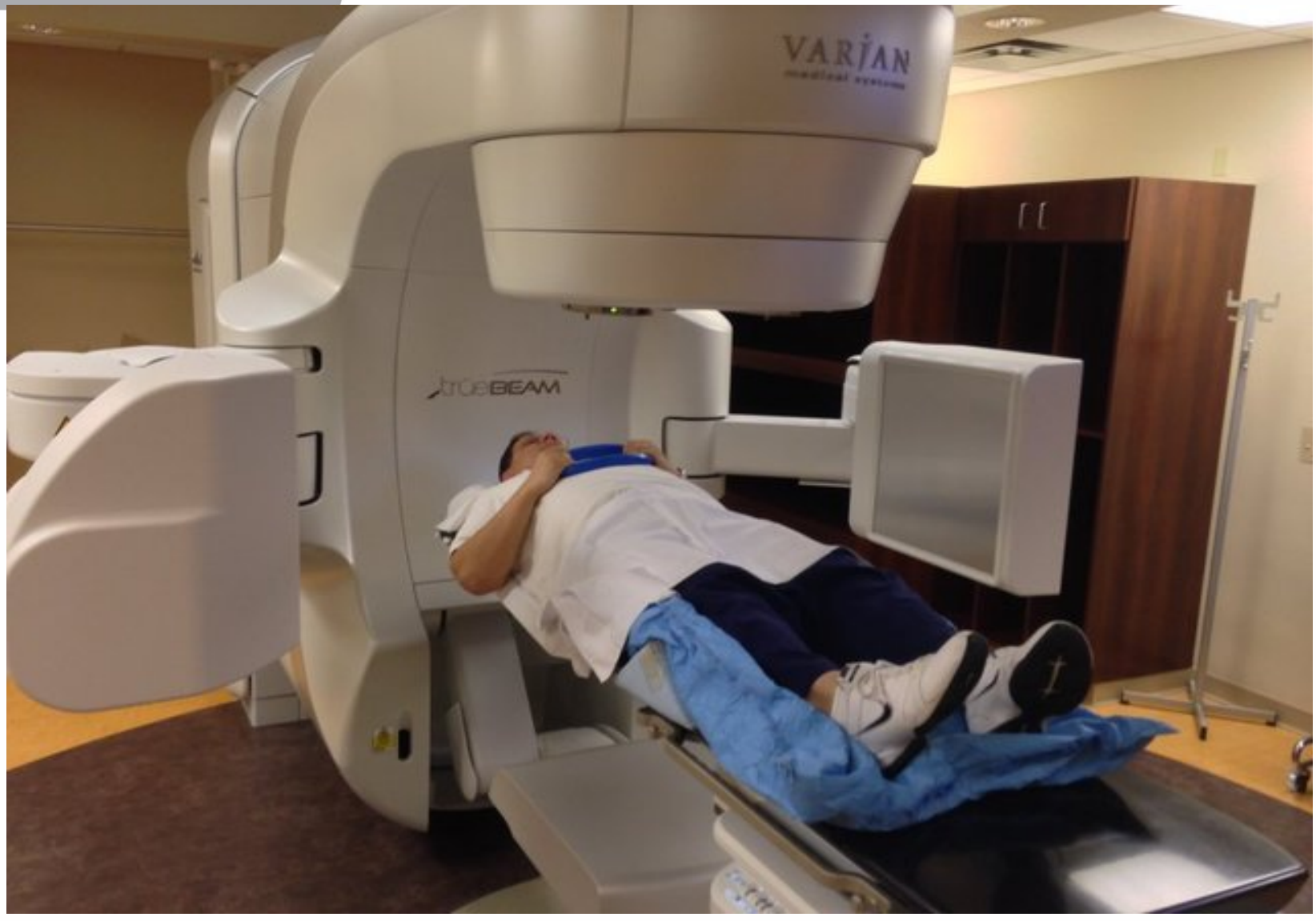
Conclusions. Standardization of infection control training and practices is the most cost-effective way to reduce HCAIs and related adverse outcomes.

Keywords: health-care-associated infections, surveillance, training and hospital cost

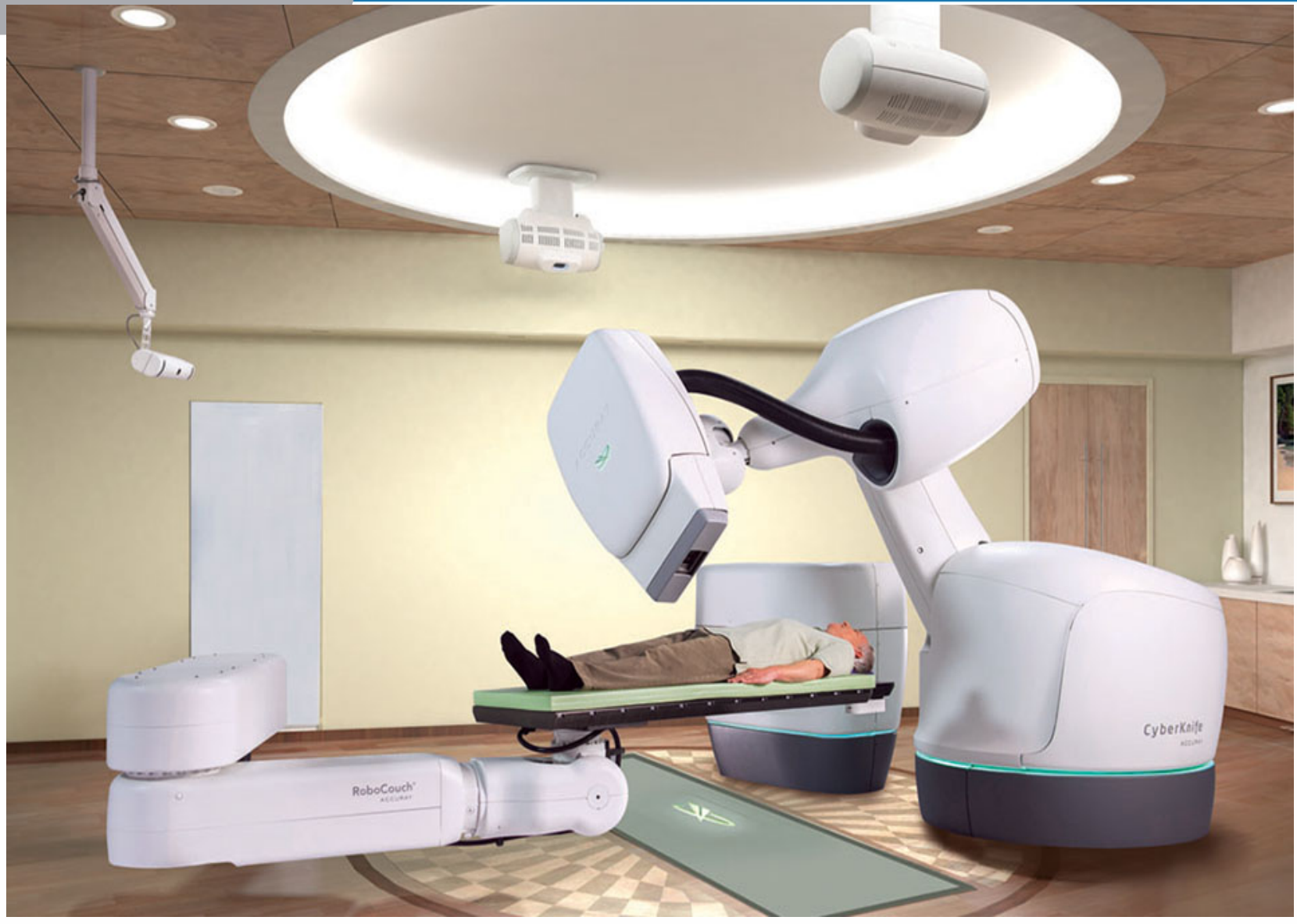
Case Study
Cyberknife vs. LINAC: HTA analysis



COBALT THERAPY



LINEAR ACCELERATOR THERAPY



CYBER KNIFE THERAPY

Systematic review

Electronic Database : Cochrane, PUBMED, Google for website of HTA and Technologies of interest and other relevant public informations.

Keywords :

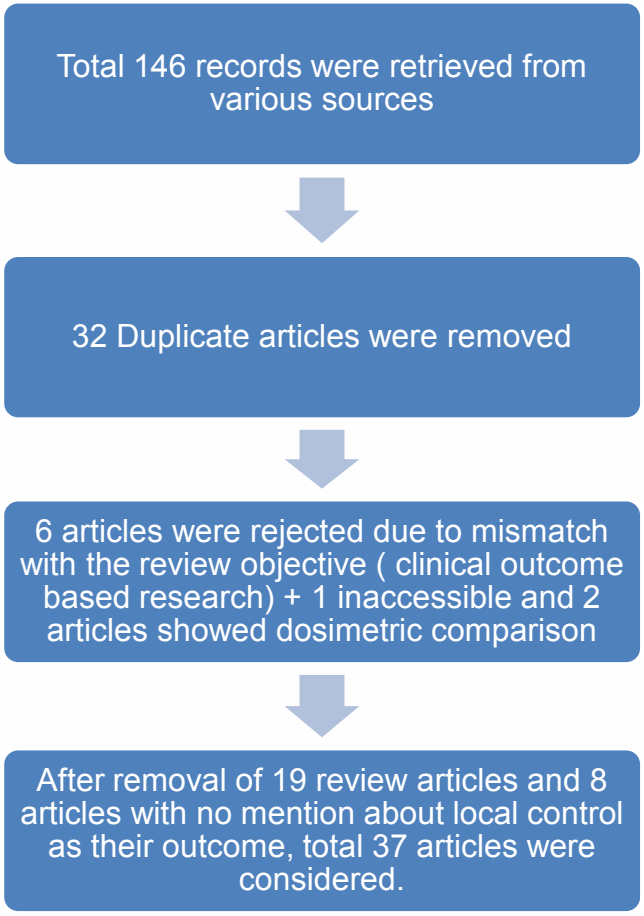
- Comparative Evidence

Cyberknife AND LINAC (68)
Cyberknife AND LINAC AND local Control (11)
Cyberknife AND LINAC AND efficacy(8)
Cyberknife AND LINAC AND effectiveness(6)

Systematic review

Single Arm Evidence
Cyberknife AND local control - Filter-CT, (14)
LINAC AND local control (Filter CT, 36)

Study Flow Diagram



Methodological Quality Assessment

All articles' scientific quality was judged using JBI grade of evidence and CASP cohort studies checklist. The JBI grade of evidence for all articles = *Level 3e- observational study without control group*
Recommended Grade : Level 1a to 1d : Experimental designs.

Data extraction and analysis

Study identifiers, Year of publication, Local control rate and region of exposure were extracted from selected studies.
6 prostate and pelvic region related articles, 9 hepatocellular/liver region related articles, 13 CNS, brain and adrenal system related article and 9 lung carcinoma related articles were identified.

Regulatory Aspects

Being frameless technology, no safety issues are foreseen.
However, from dosimetric analysis, cyberknife consumes more dose amount.

Which could be considered from regulatory point view to ensure patient safety.

Another general recommendation is electronic registration of SRS equipment through ELORA system of AERB,GoI.

Commercial aspects

The precision achievable in Cyberknife could be considered as the only peculiarity for its exorbitantly high cost.
There is only OEM for CK ,Accuray Medical systems ,which is US based company.
Till date, from the AERB information, 18 institutes have been installed with CK. But, no substantial clinical evidence has been produced by any institute.

Organizational aspects

This equipment demands training for using dose planning software dedicated to it.

Given the scenario of Amrita Hospital, there could be recommended a proforma based survey could be undertaken to assess staff's perspectives on undergoing additional training.

Infrastructure requirements are found to have been met by current scenario of the hosptial.

Discussion

Being a hospital based analysis – perspective was set for CEA was “provider’’ perspective.
This means costs which incurred by hospital were only considered for analysis and treatment charges i.e. Cost per patient was ignored as it was considered as income to hospital.

References

- http://www.cadth.ca/en/products/health-technology-assessment/publication/926
- http://portal.dimdi.de/de/hta/hta_berichte/hta225_summary_en.pdf

Clinical Pharmacist

Table 7.1. Studies of clinical pharmacists' impact on ADEs and medication errors*

Study	Study Design	Study Outcomes	Results
Beney, 2000.[18] Systematic review of the roles and impacts of pharmacists in ambulatory settings; reviewed studies included 16,000 outpatients and 40 pharmacists	Level 1A (systematic review)	Levels 1-3 (variety of patient outcomes, surrogate outcomes, impacts on physician prescribing practices and measures of resource use)	Improvement in outcomes for patients with hypertension, hypercholesterolemia, chronic heart failure, and diabetes
Gattis, 1999.[16] 181 patients with heart failure due to left ventricular dysfunction followed in a general cardiology clinic	Level 1 (RCT)	Level 1 (mortality and other clinical outcomes related to heart failure)	16 versus 4 deaths or other heart failure events ($p<0.005$)
Leape, 1999.[13] Medical and cardiac intensive care unit patients at Massachusetts General Hospital, a tertiary care hospital in Boston	Level 2 (prospective before-after study with concurrent control)	Level 1 (ADEs)	66% decrease in the rate of preventable ADEs ($p<0.001$)

Bates et al, Harvard School

CPOE with CDSS (Bates..Harvard)

Table 6.1. Studies of computerized physician order entry (CPOE) with clinical decision support systems (CDSSs)*

Study	Study Design	Study Outcomes	Results
Overhage, 1997.[21] Impact of faculty and physician reminders (using CPOE) on corollary orders for adult inpatients in a general medical ward at a public teaching hospital affiliated with the Indiana University School of Medicine	Level 1 (RCT with physicians randomized to receive reminders or not)	Levels 2 & 3 (errors of omission in corollary orders)	25% improvement in ordering of corollary medications by faculty and residents ($p<0.0001$)
Bates, 1998.[22] CPOE with CDSSs for adult inpatients on medical, surgical, and intensive care wards at BWH, a tertiary care center affiliated with Harvard University	Levels 2 & 3 (two study designs)	Level 1 (ADE rates) and Level 2 (serious medication errors)	55% decrease in non-intercepted serious medication errors ($p=0.01$) 17% decrease in preventable ADEs ($p=0.37$)
Bates, 1999.[23] CPOE with CDSSs for adult inpatients in 3 medical units at BWH	Level 3 (retrospective time series)	Level 1 (ADEs) and Level 2 (main outcome measure was medication errors)	81% decrease in medication errors ($p<0.0001$) 86% decrease in non-intercepted serious medication errors ($p=0.0003$)

Medication Errors

Table 10.1. Studies evaluating the impact of unit-dose dispensing on medication errors*

Study	Study Design, Outcomes†	Results: Error Rates (95% CI)
Hynniman, 1970[23]	Cross-sectional comparison between study hospital and non-randomly selected "comparison" hospitals (Level 3) Errors of commission and omission (Level 2) among doses ordered	Unit-dose system: 3.5% (3.1-4.0%) Conventional distribution systems at 4 hospitals: 8.3% (7.1-9.7%) 9.9% (8.0-12.2%) 11.4% (9.9-13.2%) 20.6% (18.4-22.9%)
Means, 1975[13] Simborg, 1975[14]‡	Cross-sectional comparison of 2 wards within a single hospital over a 60-day period (Level 3) Errors of commission (Level 2) among doses administered during randomly chosen observation periods	Unit-dose ward: 1.6% (1.0-2.5%) Multi-dose ward: 7.4% (6.1-8.9%)§
Schnell, 1976[24]	Prospective before-after study (Level 2) at four Canadian hospitals Errors observed during medication preparation and administration (Level 2)	Before vs. after implementation of unit-dose system: 37.2 vs. 38.5%; 42.9 vs. 23.3%; 20.1% vs. 7.8%; 38.5% vs. 23.1%¶

Table 20.1.2. Systematic reviews of antibiotic prophylaxis*

Study	Trials Included	Surgical Procedures; Antibiotics	Results: Relative Risk of Infection (95% CI)
Gillespie, 2000[36]	48	Long bone fractures; multiple antibiotics	Single dose antibiotic vs. placebo Deep wound infection: RR 0.40 (0.24-0.67) Superficial wound infection: RR 0.69 (0.50-0.95) Urinary tract infection: RR 0.63 (0.53-0.76) Pneumonia: RR 0.46 (0.33-0.65) Multiple dose antibiotic vs. placebo: Deep wound infection: RR 0.36 (0.21-0.65) Superficial wound infection: RR 0.48 (0.28-0.81) Urinary tract infection: RR 0.66 (0.4-1.0) Pneumonia: RR 0.81 (0.41-1.63) Adverse events: RR 1.83 (0.96-3.50) Single dose short-acting antibiotic vs. multiple doses same agent up to 24 hours after surgery Deep wound infection: RR 7.98 (1.01-62.0) Superficial wound infection: RR 4.82 (1.08-21.6) Urinary tract infection: RR 1.81 (1.01-3.23) Single dose long-acting antibiotic vs. any multiple dose regimen lasting more than 24 hours Deep wound infection: RR 1.10 (0.22-5.34) Superficial wound infection: RR 0.57 (0.17-1.93) Multiple doses administered over 24 hours or less vs. longer therapy Deep wound infection: RR 1.1 (0.22-5.34) Superficial wound infection: RR 0.57 (0.17-1.93) Oral vs. parenteral prophylaxis Insufficient data (single underpowered study)
Smaill, 2000[33]	66	Cesarean section; multiple antibiotics	Impact of antibiotic prophylaxis on … -Combined outcomes of fever, wound infection, sepsis and endometritis: Elective Cesarean section: RR 0.25 (0.11-0.55) Emergent Cesarean section: RR 0.39 (0.33-0.46) Unspecified/nonelective: RR 0.37 (0.32-0.42)

Peri-operative Glucose Control

Table 20.4.1. Prospective, before-after study of aggressive perioperative glucose control*

Study	Study Population	Comparison Groups	Results†
Furnary, 1999[20]	2467 diabetic patients undergoing cardiac surgery at a community hospital	968 patients treated with sliding scale SQ insulin (1987-91) 1499 patients treated with CII to target glucose of 150-200 mg/dL until POD 3 (1991-97)	Deep surgical wound infections Unadjusted: 1.9% vs. 0.8% (p=0.011) Adjusted RR 0.34 (95% CI: 0.14-0.74) Mortality: 6.1% vs. 3.0% (p=0.03) Length of Stay: 10.7d vs. 8.5d (p<0.01)

Pre operative and Peri Operative Blood Glucose monitoring and control is equally important as post operative control. Sliding scale blood glucose control mechanism should be avoided.Morbidity, infection rates and mortality would be better with better control

USG Guided Line insertion

Table 21.1. Ultrasound and Doppler ultrasound guidance of central vein catheters*

Study Setting and Population	Year Published	Intervention	Study Design, Outcomes	Relative Risk Reduction (%)†		
				Failed Catheter Insertion	Mean Insertion Attempts Required§	Compli-cations
		Ultrasound				
Tertiary care, teaching hospital ICU[13]	1990	US guidance for IJ CVC insertion without needle guide; concurrent feedback from an US technician	Level 1 Level 2	100[NS]	44	NA
Tertiary care, teaching hospital, CT surgical patients[14]	1991	US guidance (7.5 and 5.0 MHz transducers) for IJ CVC insertion without needle guide	Level 1 Level 2	100	44	83[NS]
Tertiary care, teaching hospital, cardiac patients[11]	1993	US guidance (7.5 MHz transducer) of IJ cannulation for cardiac catheterization and CVC insertion, with needle guide	Level 1 Level 2	100	48	80
Urban, teaching hospital ICU[12]	1995	US guidance (7.5 MHz transducer) for SC CVC insertion with needle guide	Level 1 Level 2	86	48	90
Urban, teaching hospital ED, during CPR[15]	1997	US guidance (7.5 MHz transducer) for femoral CVC insertion without needle guide	Level 1 Level 2	71	54	100
		Doppler Ultrasound				
Tertiary care, teaching hospital, CT/ vascular surgery patients[8]	1994	Doppler US guidance of IJ CVC insertion with probe in the needle	Level 1 Level 2	0	52	0
British hospital, cardiac surgery and ICU patients[10]	1994	Doppler US guidance of IJ CVC insertion with probe in the needle	Level 1 Level 2	-50[NS]	17[NS]	0

Nutritional Support

Table 33.1. Studies evaluating nutritional support*

Study	Study Design, Outcomes	Results (95% Confidence Interval)
Routine protein energy supplementation in adults; systematic review[13]	Level 1A, Level 1	Reduced mortality: OR 0.66 (0.48 to 0.91) Increased body weight gain (%): Oral Sip Feeds: 2.39 (1.80 to 2.96) Oral natural feeds: 5.36 (1.73 to 8.99) Nasogastric feeding: 4.04 (3.15 to 4.94) Percutaneous or enteral feeding, enterostomy: -1.38 (-2.35 to -0.41)
TPN in critically ill patients; meta-analysis[11]	Level 1A, Level 1	No effect on mortality: RR 1.03 (0.81 to 1.31) Complication rate: RR 0.84 (0.64 to 1.09) Complication rate (malnourished subgroup): RR 0.52 (0.30 to 0.91)
TPN in surgical patients; meta-analysis[12]	Level 1A, Level 1	No effect on mortality: RR 0.97 (0.76 to 1.24) No effect on mortality (malnourished subgroup): RR 1.13 (0.75 to 1.71) Major complication rate (malnourished subgroup): RR 0.52 (0.30 to 0.91)
Immunonutrition in critically ill patients; systematic review and meta-analysis[28]	Level 1A, Level 1	No effect on mortality: RR 1.05 (0.78 to 1.41) Reduction in infection rate: RR 0.67 (0.50 to 0.89) Reduction in days of mechanical ventilation: 2.6 days (0.1 to 5.1) Reduction in hospital LOS: 2.9 days (1.4 to 4.4)
Immunonutrition in patients with critical illness and cancer; meta-analysis[29]	Level 1A, Level 1	Trend toward increased mortality: OR 1.77 (1.00 to 3.12) Reduction in infectious complications: OR 0.47 (0.32 to 0.70) No reduction in pneumonia risk: OR 0.91 (0.53 to 1.56) Reduction in hospital LOS: 2.5 days (4.0 to 1.0)

DVT risk & prophylaxis

Table 31.1. Mechanical and pharmacologic preventative measures for VTE

Practice	Type	Description	Comment
Graduated Elastic Stockings (ES)	Mechanical	Fitted hose that extend above the knee	Fitted hose are more efficacious than non-fitted
Intermittent pneumatic compression (IPC)	Mechanical	Devices fitted over lower extremities that sequentially inflate and deflate	
Aspirin	Pharmacologic	Usually 325 mg/d	
Warfarin	Pharmacologic	5-10 mg started the day of or after surgery; adjust to achieve an INR of 2-3	Monitoring of INR needed
Low-dose unfractionated heparin (LDUH)	Pharmacologic	Generally 5000 U subcutaneous bid or tid, though some studies have adjusted dose to maintain PTT at high end of normal	Contraindicated if active bleeding or history of thrombocytopenia; no need to follow coagulation studies (unless adjusted dose is used)
Low Molecular Weight Heparin (LMWH)	Pharmacologic	Dose depends on type of surgery and VTE risk*	No need to monitor coagulation studies

* LMWH dosing: Enoxaparin 20 mg SC daily (moderate risk surgery) or 40 mg SC daily (can go up to 30 mg SC q12h for high risk general surgery, major trauma or acute spinal cord injury); dalteparin 2500–5000 U SC daily; nadroparin 2500 U SC daily; tinzaparin 3500-4500 U SC daily (may be dosed 75U/kg/d for orthopedic surgery).

Cohorting

Table 13.1. Studies of multifaceted approaches with and without "cohorting"*

Study Setting	Compliance	Study Design, Outcomes	Change in *C. difficile* or VRE
725-bed academic medical center in Philadelphia in 1987-88: before-after study of impact of multifaceted intervention (isolation precautions, clindamycin restriction) on *C. difficile*[37]	NA	Level 3, Level 1	Cases of *C. difficile* decreased from 1.47 cases/100 hospital discharges in 1987 to 0.74 cases/100 hospital discharges by the second half of 1988
350-bed acute care hospital in Virginia in 1987-96: before-after study of impact of multifaceted intervention on *C. difficile* infections[23]	NA	Level 3, Level 1	Mean annual new cases of *C. difficile* decreased from 155/year in the before period to 67/year in the after period ($p<0.05$).
840-bed tertiary care center in Brussels in 1989-90: impact of a multifaceted infection control intervention, including cohorting, on incidence of *C. difficile*[28]	NA	Level 3, Level 1	Incidence of *C. difficile* decreased from 1.5 cases/1000 admissions to 0.3 cases/1000 admission (protective efficacy 73%, 95% CI: 46-87%)
Bone marrow transplant unit of a large academic medical center in Texas in 1995: impact of multifaceted infection control intervention on *C. difficile* attack rate[29]	NA	Level 3, Level 1	Attack rate for third week in May was 60%. Following intervention, rate dropped to 17% for remainder of May, 21% for June, and 7% for July ($p<0.05$)

Conclusions

- Practices should support clinical evidence
- Cost factor should be factored in decision making
- Many patient safety practices drawn primarily from nonmedical fields (e.g., use of simulators,

  bar coding, computerized physician order entry, crew resource management) deserve additional

  research to elucidate their value in the health care environment.
- Comprehensive evaluation should base decision support rather then competition

Medical Ethics: HTA

COME (1): Patient Autonomy

J Indian Acad Forensic Med. October-December 2015, Vol. 37, No. 4 ISSN 0971-0973

Review Research Paper

Patient Autonomy and Informed Consent: The Core of Modern Day Ethical Medical

[1]Dasari Harish, [2]Ajay Kumar, [3]Amandeep Singh

Abstract

The UN Charter of Human Rights says: "All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood." In the words of Judge Cardozo, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable". This in complete contradiction to the Hippocratic Oath, which is the Oath taken by most medical graduates in the world.

The most important principle for modern medical ethics is respect for patient autonomy, informed consent and patient confidentiality. The goal of informed consent is to respect patient autonomy and enable him to make decisions regarding his medical care, of his free will, without coercion, after understanding fully what he is consenting for. The Principle of Autonomy, its implications on informed consent and patient care situations will be dealt with in this paper.

Respect the free choice of the patient
Capacity for self determination

COME (2): Beneficence

J Chiropr Humanit. 2009 Dec; 16(1): 44–46. PMCID: PMC3342811
Published online 2010 Apr 1. doi: 10.1016/j.echu.2010.02.006

Beneficence and the professional's moral imperative

Frank Stuart Kinsinger*

Author information ► Article notes ► Copyright and License information ►

Abstract

Go to:

Objective

This article offers a brief discussion of the definition and importance of beneficence in the context of the chiropractic profession.

Discussion

Beneficence is defined as an act of charity, mercy, and kindness with a strong connotation of doing good to others including moral obligation. All professionals have the foundational moral imperative of doing right. In the context of the professional-client relationship, the professional is obligated to, always and without exception, favor the well-being and interest of the client. In health care, beneficence is one of the fundamental ethics. An integral part of work as a professional is the foundational ethic of beneficence. An understanding of this ethic of care compels the individual health practitioner to consider his or her calling to the high standards of professionalism as a moral imperative; one that advocates for high standards and strives for the greater good.

Conclusion

Health care professionals have a duty of care that extends to the patient, professional colleagues, and to society as a whole. Any individual professional who neither understands nor accepts this duty is at risk for acting malevolently and violating the fiduciary principle of honoring and protecting the patient.

Doing good to others
Without exception, favour the well being & interest of the client

COME (3): Non maleficence

JMBR: A Peer-review Journal of Biomedical Sciences
June 2005 Vol. 4 No.1 pp-22-30

Obligation of non-maleficence: moral dilemma in physician-patient relationship

Peter F Omonzejele

ABSTRACT

This paper highlights the principle of non-maleficence from sections of the Hippocratic oath and those entailed in various declarations of medical ethics and conduct. The moral dilemmas associated with adherence or efforts at adherence to the principle were indicated with the use of prepared cases. The centrality of the paper is the moral conflict encountered by physicians in their efforts at maintaining the fiduciary relationship that they have with patients. The concepts of dignity, identity, harm and the definitions of brain death as different from biological death, ordinary and extraordinary health care and the principle of double effect were analysed in an attempt to resolve the moral conflict in physician-patient relationship. Cost-benefit analysis, detriment-benefit assessment and the notion of justice were also brought to bear in the effort to resolve the moral dilemma in physician-patient relationship as it borders on the obligation of non-maleficence.

Intention to avoid needless harm or injury through act of commission or omission

COME (4): Justice

Journal of Medical Ethics 1999;25:394–398

The role of ethical principles in health care and the implications for ethical codes

Alexander E Limentani *East Kent Health Authority, Dover*

Abstract

A common ethical code for everybody involved in health care is desirable, but there are important limitations to the role such a code could play. In order to understand these limitations the approach to ethics using principles and their application to medicine is discussed, and in particular the implications of their being prima facie. *The expectation of what an ethical code can do changes depending on how ethical properties in general are understood. The difficulties encountered when ethical values are applied reactively to an objective world can be avoided by seeing them as a more integral part of our understanding of the world. It is concluded that an ethical code can establish important values and describe a common ethical context for health care but is of limited use in solving new and complex ethical problems.*

(*Journal of Medical Ethics* 1999;25:394–398)

Keywords: Ethical principles; codes of professional ethics; philosophical ethics; medical ethics

Increasingly, many of the moral difficulties in present day health care arise in complex organisations where care is delivered by multidisciplinary clinical teams and influenced by a range of others including managers, boards and governments.[1] This, among other considerations, has led to the recent call for a code of ethics for all health care professions,[5] and follows a number of expressions of concern voiced about the general ethical state of modern medicine.[6] In their recent paper, Dr Berwick *et al* give ample illustration of the diverse and complex moral challenges facing contemporary health care workers, and say they have been encouraged by many to seek a common ethical basis for medical practice.[5]

Their concern is not an esoteric, specialist one; ethics are a central element in the quality of day to day clinical practice and of enormous importance to the care of patients. Even if codes have only a small influence they are likely to be worthwhile. Most ethical codes cover a range of topics. They

Be Fair

COME (5,6,7): Veracity, Fidelity & QOL

Page *BMC Medical Ethics* 2012, **13**:10
http://www.biomedcentral.com/1472-6939/13/1/10

BMC Medical Ethics

RESEARCH ARTICLE Open Access

The four principles: Can they be measured and do they predict ethical decision making?

Katie Page

Abstract

Background: The four principles of Beauchamp and Childress - autonomy, non-maleficence, beneficence and justice - have been extremely influential in the field of medical ethics, and are fundamental for understanding the current approach to ethical assessment in health care. This study tests whether these principles can be quantitatively measured on an individual level, and then subsequently if they are used in the decision making process when individuals are faced with ethical dilemmas.

Methods: The Analytic Hierarchy Process was used as a tool for the measurement of the principles. Four scenarios, which involved conflicts between the medical ethical principles, were presented to participants who then made judgments about the ethicality of the action in the scenario, and their intentions to act in the same manner if they were in the situation.

Results: Individual preferences for these medical ethical principles can be measured using the Analytic Hierarchy Process. This technique provides a useful tool in which to highlight individual medical ethical values. On average, individuals have a significant preference for non-maleficence over the other principles, however, and perhaps counter-intuitively, this preference does not seem to relate to applied ethical judgements in specific ethical dilemmas.

Conclusions: People state they value these medical ethical principles but they do not actually seem to use them directly in the decision making process. The reasons for this are explained through the lack of a behavioural model to account for the relevant situational factors not captured by the principles. The limitations of the principles in predicting ethical decision making are discussed.

Keywords: Ethical principles, Hierarchies, Medical ethics, Analytic hierarchy process

Truthful
Confidentiality
Preservation of Life

Legal

Law related to governing the commissioning of hospital

1. **Society registration Act 1960**
2. **Companies Act** 1956
3. **Urban land Act** 1976
4. **National building code** 2005
5. **Building permit from municipality**
6. Delhi Fire Service Act, 2007
7. Delhi Fire Prevention and Fire Safety Act, 1986
8. **Fire safety rules** 1987
9. **Electricity rules** 1956
10. **Delhi electricity regulatory commission** (Grant of consent for captive power plants) regulations 2002
11. **Delhi lift Act** 1942
12. Bombay Lifts Act,1939
13. **Delhi nursing home registration Act** 1953
14. Bombay Nursing Homes Registration (Amendment) Act, 2005
15. Bombay Nursing Homes Registration (Extension and Amendment) Act, 1959
16. Bombay Nursing Homes Registration Act,1949
17. **Radiation protection certificate** for radiology dept from BARC
18. **Atomic energy regulatory body approval** for radiology / nuclear medicine services under the **atomic energy Act 1962**
19. **Atomic energy** (safe disposal of radioactive waste) **rules** 1987
20. **Indian telegraph Act** 1885.
21. **Clinical Establishments Bill**, 2010
22. BUILDING AND OTHER CONSTRUCTION WORKERS (REGULATION OF EMPLOYMENT AND CONDITIONS OF SERVICE) ACT, 1996 (27 of 1996). http://labour.delhigovt.nic.in/act/details_acts/buliding_other_construction/building/intro.html
23. **The Registration Act,** 1908
24. **THE NATIONAL CAPITAL TERRITORY OF DELHI LAWS** (SPECIAL PROVISIONS) SECOND BILL, 2007
25. Government Buildings Act, 1899
26. Karnataka Medical Registration (Amendment) Act, 2003
27. Karnataka Private Nursing Homes (Regulation) Act, 1976
28. Red Cross Society (Allocation of Property) Act, 1936
29. St. John Ambulance Association (India) Transfer of Funds Act, 1956

Laws governing the qualifications / practice and conduct of professionals

30. **Indian medical council Act** 1956
31. **Indian medical council** (professional conduct, etiquette and ethics) **regulations**, 2002.
32. **Indian medical degrees Act**
33. **Registration of medical practitioners** with state medical councils
34. **Indian nursing council Act** 1947
35. **Delhi nursing council Act** 1997
36. **The ICN Code of ethics for nurses**
37. **The Dentists Act** 1948
38. **The Dentists** (code of ethics regulation) 1976
39. **Dental council of India regulations** 2006
40. AICTE rules of physiotherapy rules
41. **All India council for Technical Education ACT,** 1987
42. **The Apprenticeship Act** 1961
43. Rehabilitation Council of India Act, 1992
44. Rehabilitation Council of India (Amendment) Act, 2000
45. Kerala Anatomy Act, 1957
46. Kerala Co-operative Hospital Complex and the Academy of Medical Sciences (Taking over the Management) Act, 97
47. Kerala Professional Colleges or Institutions (Prohibition of Capitation Fee, Regulation of Admission, Fixation of Non-exploitative Fee and Other Measures to Ensure Equity and Excellence in Professional Education) Amendment Act, 2007
48. Karnataka Anatomy Act, 1957

Law governing storage / sale of drugs and safe medication

49. **Drugs and cosmetic Act** 1940
50. **Drug and cosmetic Act amendment** 1982,
51. **The drug and cosmetics rules 1945** , Amendment 2005
52. **The drugs control Act** 1950
53. **Pharmacy Act 1948**
54. **License for possession and use of Rectified / denatured spirit**
55. **Narcotics and psychotropic substances Act** 1985
56. **Central excise Act 1944** (for permit to use and store sprit)
57. **Retail drug licence**
58. **VAT Act**
59. **Central sales Tax Act** 1956
60. **Sales of good Act** 1930
61. **Adulteration of drugs** (IPC **Sec 274**)
62. **Sales of adulterated drugs** (IPC S**ec 275**)
63. **Sales of drug as different drug or preparation** (IPC S**ec 276**)
64. **Negligent conduct** with regard to poisonous substances (IPC S**ec 284**)
65. **Blood bank regulations** under Drugs and cosmetic (2nd amendment) rules , 1999.
66. Homoeopathy Central Council (Amendment) Act, 2002
67. Homoeopathy Central Council Act, 1973

Law governing Biomedical Research

68. **Breeding of and Experiments on Animals** (Control and Supervision)**Amendment Rules**, 2005.

69. **Reconstitution of Committee for the Purpose of Control and Supervision of Experiments on Animals(**CPCSEA).

Laws governing to management of patients

70. **Drugs and magic remedies** (objectionable) **advertisements Act** 1954
71. **PNDT Act 1994**
72. **Pre conception and prenatal diagnostic techniques** (prohibition of sex selection) Rules, 1996.
73. **MTP Act** 1997
74. **MTP Rules** 1971
75. **Transplantation of human organ Act** 1994
76. **Transplantation of human organ Rule** 1995
77. **Rules for insurance cover** for the sterilization cases
78. **Laws of contract section 13** (Consent)
79. **Birth and death and marriage registration act** 1886
80. **Delhi registration of birth and deaths act** 1969
81. **Indian lunacy Act** 1912
82. **The epidemic disease Act** 1897
83. **Delhi Municipal corporation** (Malaria and other mosquito Borne disease) Bye Law 1975
84. **Lepers act**
85. **Guardians and wards Act** 1890
86. **National guidelines for clinical management** of HIV / AIDS , NACO, Govt Of India.
87. **Manual for control of hospital associated infections** : SOPs, NACO , Govt of India
88. **The Mental Health Act** 1987
89. Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1982
90. Eyes (Authority for Use for Therapeutic Purposes) Act, 1982

Law governing medico legal aspects

91. **Law of privileged communications**
92. **Indian Evidence act** (disclosure of privileged / confidential patient related information before a court of law – under protest)
93. **Law of torts**
94. **Consumer protection Act** 1986
95. Protection of human rights Act
96. **IPC section 52**
97. IPC section 80
98. IPC section 89
99. IPC section 92
100. IPC section 93
101. IPC section 269

Law governing the safety of patients, public and staff within the hospital premises and environmental protection

- 102. **Biomedical medical waste management handling rules 1998** (Amended on 2000)
- 103. **Water (prevention and control of pollution) Act 1974**
- 104. The Water (Prevention and Control of Pollution) Cess (Amendment) Act, 2003.
- 105. The Water (Prevention and Control of Pollution) Act, 1974, amended 1988
- 106. **The Water (Prevention and Control of Pollution) Cess Rules**, 1978
- 107. The Water (Prevention and Control of Pollution) Rules, 1975
- 108. **The Noise Pollution (Regulation and Control) (Amendment) Rules**, 2010 [pdf].
- 109. **The Noise Pollution (Regulation and Control)** (Amendment) Rules, 2006.
- 110. **The Noise Pollution** (Regulation and Control) (Amendment**) Rules,2006**.
- 111. **The Noise Pollution** (Regulation and Control) (Amendment) **Rules, 2002**.
- 112. **The Noise Pollution** (Regulation and Control) (Amendment) **Rules, 2000.**.
- 113. **Business) Rules, 1975 amended 1976**
- 114. **Rules regarding the safe discharge of effluents in the public sewers / drains**
- 115. **DMC sanitation and public health Bye laws**, 1959
- 116. **Air (prevention and control of pollution) act 1981**, amended 1987
- 117. **The Air (Prevention and Control of Pollution) (Union Territories) Rules,** 1983
- 118. **The Air (Prevention and Control of Pollution) Rules**, 1982
- 119. **Environment protection Act** 1986
- 120. **Environment protection Rule** 1986
- 121. **Environment protection** Act 1996
- 122. **Noise pollution control Rules** 2000
- 123. **IPC sec 269** (negligent act likely to spread infection or disease dangerous to life , unlawfully or negligently)
- 124. **IPC sec 278** (making atmosphere noxious to health)

Law governing the safety of patients, public and staff within the hospital premises

125. **No objection certificate from the chief fire officer**
126. **Periodic fitness certification** for operation of lifts
127. **Indian Boilers Act** , 1923
128. **Explosive Act 1884** (for diesel storage)
129. **Petroleum Act** + **storage Rules** 2002
130. **Gas cylinder Rules**, 2004
131. **Rules for provision of safe drinking water**
132. **Rules for provision of uninterrupted power supply**
133. **Prevention of food adulteration Act** 1954
134. **The radiation surveillance procedures** for the medical application of radiation 1989
135. **Radiation protection Rules** 1971
136. **AERB safety code no .** AERB/SC/Med -2 (REV -1) 2001
137. **Insecticide Act** 1968
138. **Arms Act**, 1950
139. **IPC Sec 336** (act endangering life and personal safety of others)
140. **IPC Sec 337** (causing hurt by act endangering life and personal safety of others)
141. **IPC Sec 338** (causing grievous hurt by act endangering the life and personal safety of others)
142. **The Indian fatal accidents Act** , 1955
143. **The cigarettes and other Tobacco products bill 2003**
144. **Prohibition of smoking in public places Rules 2008**
145. **The Indian fatal accidents Act** 1855
146. **The Tamil nadu Medicare service persons and Medicare service institutions Act 2008**
147. Vaccination Act, 1880
148. Vaccination (Repeal) Act, 2001
149. Disaster Management Act, 2005
150. Protection of Human Rights Act, 1993

Laws governing the employment of manpower

151. **Child labour Act**
152. **Citizenship Act** 1955
153. **Employees provident fund and misc provision Act** 1952
154. **ESI Act** 1948
155. **ESI (central) Rules** 1950
156. **Employment exchange** (compulsory notification of vacancies) act 1959
157. **Equal remuneration Act** 1976
158. **Minimum Wedge Act** 1948
159. **Payment of bonus Act** 1965
160. **Payment of Gratuity Act** 1972
161. **Payment of wages Act**, 1963
162. **PPF Act 1968**
163. **TDS Act**
164. Maternity Benefit (Amendment) Act, 2008
165. Workmen's Compensation Act, 1923
166. Workmen's Compensation (Amendment) Act, 2009
167. **Indian Trade Union Act** 1926
168. Industrial Disputes Act, 1947
169. **Shops and factories Act** (for national holidays)
170. **Negotiable instrument Act** , 1881
171. **Persons with Disabilities Act** 1995
172. **SC and ST Act 1989**
173. Weekly Holidays Act, 1942
174. Official Secrets Act, 1923
175. Persons With Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995
176. Karnataka Prohibition of Violence against Medicare Service Personnel and Damage to Property in Medicare Service Institutions Act, 2009
177. Information Technology (Amendment) Act, 2008
178. Information Technology Act, 2000

Law governing to professional training and research

179. **MCI rules for internship training**

180. **National board of examinations Rules for DNB training**

181. **NCI Rules for staring school / college of nursing**

182. **AICTE Rules fir training courses for technicians** (Lab Tech , Radiographers, OT Tech)

183. **ICMR rules governing Medical Research**.

Regulations governing the business aspects of hospital

184. **Charitable and religious trust Act** 1920
185. **Contract Act, 1982**
186. **Income Tax ACT 1961**
187. **Customs Act 1962**
188. **Foreign Exchange management Act** 1999
189. **Insurance Act 1938**
190. **Rules for display of Red Cross Insignia**
191. **Sales of good Act 1930**
192. **Vehicle registration certificate**
193. **Wireless operation certificate from post and telegraphs**
194. **Cable television network ACT** 1995
195. **Gift Tax Act 1958**
196. **Copyright Act 1982**
197. **The Public Liability Insurance Act, 1991**, amended 1992
198. **The Public Liability Insurance Rules, 1991**, amended 1993

Various licenses / certificate required with sanctioning authority

199. **Incorporation of hospital** as Company (Registrar of Companies)
200. **Allotment of land** (State DI/SIDC/Infrastructure Corporation /SSIDC)
201. **NOC and consent under Water and Air Pollution Control Acts** State Pollution Control Board
202. **Approval of construction activity and building plan** (a. Town and country planning , b. Municipal and local authorities ,c. Chief Inspector of Factories d. Pollution Control Board e. Electricity Board)
203. **Sanction of Power** (State Electricity Board)
204. **Boiler Inspection Certificate**(Chief Inspector of Boilers)
205. **Registration under States Sales Tax Act**, and **Central and State Excise Act** (i. Sales Tax Department ii. Central and State Excise Depts.)
206. **General permission of RBI** under FEMA
207. **Form FC-IL - COMPOSITE FORM FOR FOREIGN COLLABORATION AND INDUSTRIAL LICENCE** (http://siadipp.nic.in/download/il-form.doc)
208. **Land, Water, Electricity, Registrations** (Ministry of Environment and Forests http://envfor.nic.in)
209. **Environmental Clearance** (EC) Process in India (http://www.ecprocess.nic.in)

Take Home Message

HTA is a essential path breaking decision making tool

HTA includes:

a) Evidence Synthesis
b) Cost benefit, cost effective and cost utility analysis
c) Ethical Care delivery
d) Legal Care
e) Patient Safety as agenda
f) Societal benefit

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