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DISSERTATION

Submitted in partial fulfillment of the requirement for the award of the degree of

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ON THE TOPIC:

HEALTH TECHNOLOGY ASSESSMENT IN INDIA

Under the Guidance and Supervision of

Dr Athira P. S,

Assistant Professor, NUALS, Kochi

Submitted By:

Aparna Suresh

Register No: LM0321011

LL.M. (Public Health Law)

CERTIFICATE

This is to certify that Aparna Suresh, Reg No: LM0321011 has submitted her Dissertation titled "**Health Technology Assessment in India**" in partial fulfillment of the requirement for the award of Degree of Masters of Laws in Public Health Law to the National University of Advanced Legal Studies, Kochi under my guidance and supervision. It is also affirmed that the dissertation submitted by her is original, bonafide and genuine.

Date: 30/07/2022
Place: Kalamassery, Kochi

Asst. Prof. Dr. Athira P. S
Guide & Supervisor
NUALS, Kochi

THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES

Kalamassery, Kochi – 683503, Kerala, India

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Aparna Suresh

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Dr. Athira P. S

DECLARATION

I hereby declare that this dissertation titled "Health Technology Assessment" has been researched and submitted by me to the National University of Advanced Legal Studies, Kochi, in partial fulfillment of the requirement for the award of Degree of Master of Laws in Public Health Law, under the guidance and supervision of Assistant Professor Dr. Athira P. S, is an original, bona fide, legitimate work. It has been pursued for academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University. I also confirm that all the material which I have borrowed from different sources and incorporated into this dissertation is duly acknowledged. If any material is not duly acknowledged and found incorporated in this thesis, it is entirely my responsibility. I am fully aware of the implications of any such act which might have been committed by me advertently or inadvertently.

Aparna Suresh
Reg No: LM0321011
LL.M., Public Health Law
NUALS, Kochi

Date: 30/07/2022
Place: Kalamassery, Kochi

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Aparna Suresh
Reg No: LM0321011
LL.M., Public Health Law

LIST OF ABBREVIATIONS

ACPM	Advisory Committee on Prescribed Medicines
AETMIS	Agence des technologies et des modes d'intervention en Santé
AHFMR	Alberta Heritage Foundation for Medical Research
AHMAC	Australian Health Ministers' Advisory Council
ANDEM	Agence Nationale pour le De´veloppement de l'Evaluation l'Évaluation Me´dicale
AWMSG	All Wales Medicines Strategy Group
BCOHTA	British Columbia Office of Health Technology Assessment
CADTH	Canadian Agency for Drugs and Technologies in Health
CAHTA/AATM	Catalan Agency for Health Technology Assessment and Research
CaHTIU	Calgary Health Technology Implementation Unit
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
CDE	Center for Drug Evaluation
CDR	Common Drug Review
CETS	Conseil d'évaluation des technologies de la santé
CHEPA	Center for Health Economics and Policy Analysis
CT	Computed Tomography
CTFPHE	Canadian Task Force on the Periodic Health Examination
DCEA	Distributional Cost-Effectiveness Analysis
DH	Department of Health
DHR	Department of Health Research
DISHA	Digital Information Security in Healthcare Act
EACHR	European Advisory Committee for Health Research
ECEA	Extended Cost-Effectiveness Analysis

EIPS	Evidence-Informed Priority-Setting
EQ-5D	European Quality of Life Five Dimension
etc	Et cetera
EUnetHTA	European Network for Health Technology Assessment
GDP	Gross Domestic Product
GIN	Guidelines International Network
HEN	Health Evidence Network
HITAP	Health Intervention and Technology Assessment Program
HRQoL	Health-Related Quality of Life
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
HTAIn	Health Technology Assessment in India
i.e.	Id est
ICES	Institute for Clinical Evaluative Sciences
ICMR	Indian Council of Medical Research
iDSI	International Decision Support Initiative
IHE	Institute of Health Economics
INAHTA	International Network of Agencies for Health Technology Assessment
INR	Indian Rupee
ISTAHC	International Society of Technology Assessment in Health Care
LMIC	Low and Middle Income Countries
MOH	Ministry of Health
MoHFW	Ministry of Health and Family Welfare
MoU	Memorandum of Understanding
MRC	Medical Research Council
MSAC	Medical Services Advisory Committee
MTA	Multiple Technology Appraisal

MTAB	Medical Technology Assessment Board
MTEP	Medical Technologies Evaluations Program
NCCHTA	National Coordinating Center for Health Technology Assessment
NCHCT	National Center for Health Care Technology
NDHM	National Digital Health Mission
NECA	National Evidence-based Healthcare Collaborating Agency
NHP	National Health Policy
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIRRH	National Institute for Research in Reproductive Health
NIRT	National Institute for Research in Tuberculosis
NITI	National Institute of Transforming India
NLEM	National List of Essential Medicines
NPPA	National Pharmaceutical Pricing Authority
OECD	Organization for Economic Co-operation and Development
OMA	Ontario Medical Association
OOP	Out-of-Pocket
OSTEBA	Basque Office for Health Technology Assessment
OTA	Office of Technology Assessment
PAHO	Pan American Health Organization
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PET	Positron-Emission Tomography
PMJAY	Pradhan Mantri Jan Arogya Yojana
PPI	Patient and Public Involvement
PRO	Patient-Reported Outcome
QALY	Quality-Adjusted Life Years

QoL	Quality of Life
R&D	Research & Development
RCT	Randomized Clinical Trials
RRH	Regional Resource Hubs
RSBY	Rashtriya Swasthya Bima Yojana
SBU	Swedish Council on Technology Assessment in Health Care
SDG	Sustainable Development Goals
SMC	Scottish Medicines Consortium
STA	Single Technology Appraisal
STG	Standard Treatment Guidelines
TA	Technology Assessment
TAC	Technical Appraisal Committee
TGA	Therapeutic Goods Administration
TP	Technical Partners
UHC	Universal Health Coverage
UK	United Kingdom
UN	United Nations
US	United States
USD	United States dollar
VATAP	Veterans Affairs Technology Assessment Program
VBHC	Value Based Healthcare
WHO	World Health Organization

TABLE OF CONTENT

CHAPTER 1

1. INTRODUCTION

Past decades have seen exceptional advances technology has made in healthcare, which resulted in breakthroughs in various areas that have helped improve healthcare delivery and patient outcomes. In this era of increasing cost pressure, reforming healthcare delivery and payments, and augmented consumer demands, access to healthcare remains inadequate for millions; technology remains the substance of healthcare. Technology has managed to improve patient access and health outcomes. Nevertheless, the development, adoption, and diffusion of health technology are primarily determined by the policymakers in the healthcare sector. Health product manufacturers, regulators, clinicians, patients, payers, hospital managements, Government, and other stakeholders demand well-grounded information to promote decisions regarding whether or how to develop technology? Whether to allow it on the market? Acquire it, ensure its appropriate use, pay for it, Etc. The incorporation of Health Technology Assessment(HTA) by the Government and the private sector reflects this demand.

Further, the divide between expanding demand for health services and the limited resources is becoming a significant concern. The healthcare decision-making process is highly dynamic and sophisticated. These intricacies paved the way for HTA. Health Technology Assessment(HTA) is a promising and globally accepted tool that enables evidence-based efficient and equitable allocation of resources. Health Technology Assessment (HTA) is a multifarious approach for advising policy in the light of social, medical, economic, and ethical aspects systematically and transparently.

Health technology assessment (HTA) is a domain of scientific research. HTA is used to provide policymakers and clinical decision-makers with well-founded information on the introduction and use of health technologies. For the purpose of this research, health technology is taken to include drugs, medical devices, medical and surgical procedures used in healthcare delivery, the knowledge associated with it, and organizational and support systems within which healthcare is delivered.

HTA broadly includes drugs, medical devices and procedures, and support and organizational systems. It evaluates the safety, efficacy, cost and cost effectiveness as

well as the legal and ethical implications of a new technology.[1] Clinicians must offer their patients the most current care options available while considering which one provides the best use of limited resources.(Barnette 2002)[2]Assessment of the safety, efficacy and the ethical and legal implications of new technologies is necessary to predict patient outcomes. HTA also is a crucial link between introducing a new health technology into the marketplace and integrating it into clinical practice. Licensing of new technology requires evidence about its safety, efficacy, cost, and the like. However, the evidence needed for licensing has little in common with the evidence used to support clinical practice. A primary goal of an HTA is to bridge this gap and ensure that clinical decisions are as evidence-based as possible.[3]

With the increase in the rate at which new scientific advances occur, HTA takes on greater importance. The advances in the technology is largely due to the activities by the university technology transfer offices, which aid the faculty in developing, marketing, and implementing new techniques and technologies. Between 1996 and 2002 there have been a steady increase in patent applications and licenses, from technology transfer offices.(Fleischut, 2005)[4]

Worldwide, governments are faced with various problems in healthcare such as healthcare structure, staff expectations, increased involvement from a diverse pool of stakeholders in decision-making, and the development of expensive medical treatments. Developed and developing countries have adopted health technology assessment alike to guide governments and healthcare institutions in various health decisions. HTA generally comprises structures, replicable and transparent methods to evaluate and compare new and existing technologies based on their safety, efficacy, cost-effectiveness and their potential implications on the governments and the society. Despite being used by a large number of countries, its impacts are still limited compared to its potential to assist health policy.

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[1] García-Altés, A., Ondategui-Parra, S., & Neumann, P. (2004). Cross-national comparison of technology assessment processes. *International Journal of Technology Assessment in Health Care, 20*(3), 300-310. (2004) doi:10.1017/S0266462304001126

[2] National Institute for Clinical Excellence (NICE): symposium on technology assessment. Int J Technol Assess Health Care. 2002 Spring;18(2):159-212. PMID: 12053414.

[3] Ibid

[4] Fleischut PM, Haas S. University technology transfer offices: a status report. Biotechnol Healthc. 2005 Feb;2(2):48-53. PMID: 23393451; PMCID: PMC3564362.

Health Technology Assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technology. It should include medical, social, ethical, and economic dimensions, and its primary purpose is to inform decision-making in the health area. These assessments look at benefits and efficacy, clinical and technical safety, and cost-effectiveness. Informed decision-making comprises coverage and reimbursement issues, pricing decisions, clinical guidelines and protocols, and medical device regulation. The primary purpose of HTA is to inform policy decision making in health care and thus improve the uptake of cost-effective new technologies and prevent the uptake of technologies that are of doubtful value to the health system.[5]

The application of HTA is threefold. Firstly, HTA is employed to evaluate the impact of technology under consideration to be taken up for practical use. Secondly, HTA is used to evaluate the impact of a technology that already exists and is in use. Thirdly, it provides information to enhance the design of the technology itself, also known as early HTA. Typically, HTA covers all elements that play a crucial role in the application and impact of technology, such as cost-effectiveness, clinical efficiency, and social, legal, and ethical facets. Further, HTA also includes health system integration.

This study aims to determine how a scientific evidence-based approach such as the HTA, which primarily focuses on clinical medicine, particularly pharmaceuticals, extends to health policy decisions. The same becomes all the more significant in a country like India, which is committed to achieving Universal Health Coverage(UHC).

1.1 NEED OF THE STUDY

India is one of the fastest-growing economies in the world. Healthcare is one of the frontiers in which the country has achieved considerable advances, and attaining Universal Health Coverage(UHC) is one of the ambitious goals of the Government of India, which is in accordance with the Sustainable Development Goals(SDGs). Universal health coverage means all persons in need of health services get quality

[5] Health Technology Assessment, Available at: https://www3.paho.org/hq/index.php?option=com_content&view=article&id=9229:2013-tecnologias-sanitarias&Itemid=41687&lang=en

health services without undergoing any financial hardship.[6] Though substantial progress can be seen in attaining UHC and SDGs, the healthcare system still faces the challenge of improving healthcare quality and minimizing the economic burden on the household. Public spending on healthcare remains abysmally low, thereby increasing Out-Of-Pocket Expenditure(OOPE), ultimately resulting in health disparities. Further, the increasing disease burden and underfunded healthcare system also pose a challenge to the Indian Government to meet the health requirements of the entire population. India's pluralistic healthcare system comprising about 70 percent private institutions and about only 30 percent public healthcare sector, results in a heterogenous standard of care. Due to this complexity, both the central and state Governments have to budget and allocate public funds constructively to impact health coverage significantly. Also, the public policy adopted should encourage varied providers to provide better healthcare. In order to fulfill these duties, rigorous policy advice based on scientific evidence, optimal utilization and allocation of available resources, and effective governance mechanisms are quintessential in identifying high-value, high-quality health treatments. Health Technology Assessment(HTA) is a promising and globally accepted tool that enables evidence-based efficient and equitable allocation of resources. With the emergence of new drugs and health technologies, often accompanied by exceedingly high price tags, HTA enables health payers and other decision makers to navigate the balance between accessibility and affordability. Various stakeholders are wrestling with the same fundamental questions as to how to make the best use of limited resources and ensure that the prices of these advancements align with their benefits for patients. HTA is an instrument to evaluate clinical and economic evidence to help improve cost containment and quality, ensure effective delivery of care, and rule out the use of treatments or programs that proved to be ineffective.

1.2 SCOPE OF THE STUDY

HTA has various utilities in health technology-related policy and decision making. HTA serves as an input for the pricing and/or reimbursement process as well as a market decision. HTA helps to determine the use of medicines by guiding the physicians or even possibly the patients themselves. Further, apart from clinical

[6] Organization WHO. Tracking universal health coverage: first global monitoring report: World Health Organization; 2015. Available at: https://www.who.int/publications/i/item/9789241564977

guidelines, HTA also assumes a crucial role in developing public health policies. HTA primarily focuses on advising and informing regulatory agencies, payers, clinicians and patients, health professional associations, hospitals, health care networks, group purchasing organizations, and other health care organizations, Standards-setting organizations for health technology and health care delivery, Government health department officials, Lawmakers, and other political leaders, Healthcare technology companies, Investors and companies, and research agencies regarding various aspects of the use and impact of health technologies. For instance, HTA informs and advises the regulatory agencies on whether to allow the commercial use of any drug, device, or other technologies. In the case of physicians and patients, HTA informs them about the use of healthcare interventions. In contrast, when it comes to hospitals, healthcare networks, or the like, HTA advises on the acquisition and management of technology. HTA advice and informs Government health department officials about undertaking public health programs, e.g., immunization, and the lawmakers and other political leaders about policies relating to technological innovation, research and development, regulation, payment, and delivery of health care. Further, HTA informs research agencies concerning unmet needs in the healthcare system and research gaps. This wide range of applications makes HTA a vital tool capable of accomplishing the government's strategic objectives.

1.3 RESEARCH PROBLEM

Research and innovation are continuously introducing new technologies to improve the health of populations effectively. However, not every health technological advancement results in net health benefits. Throughout the history of medicine and health, not every technology has produced the expected results; some proved to be even harmful. However, technologies proven to be effective may require additional resources or distribution of existing limited resources within the health system. Thus, it is necessary to ensure that health technologies are appropriately evaluated, implemented, and prioritized. Health technology assessment (HTA) seeks to inform healthcare policy and decision-making concerning health technologies precisely on these issues. HTA provides scientific evidence based on research on the health effects and broader implications of technology in health care. Thus, there is a need to critically analyze and evaluate HTA to understand its potential to yield efficient and

effective health policy and clinical decisions. Hence it is necessary to examine whether HTA is an effective tool to achieve UHC in India?

1.4 RESEARCH OBJECTIVES

The objectives of this study are as follows:

1. To understand the concept of Health Technology.
2. To study the origin and evolution of Health Technology Assessment.
3. To analyze the relevance of Health Technology Assessment in the international arena.
4. To study the framework of Health Technology Assessment in India.
5. To determine the role of Health Technology Assessment in health policy-making.
6. To determine the challenges of using Health Technology Assessment in India.

1.5 HYPOTHESIS

Health Technology Assessment in India plays a crucial role in effective health policy-making and is a promising tool in helping the Government of India to achieve Universal Health Coverage in line with the Sustainable Development Goals.

1.6 RESEARCH QUESTIONS

1. What is Health Technology?
2. What is Health Technology Assessment?
3. Whether Health Technology Assessment can enhance health policy decision making?
4. Whether Health Technology Assessment in India helps establish a cost-effective healthcare system?
5. Whether Health Technology Assessment is an effective tool to achieve UHC in India?

6. Whether Health Technology Assessment enables priority-setting based on evidence for the efficient and equitable allocation of limited resources?

7. What are the challenges of using Health Technology Assessment in India?

1.7 RESEARCH METHODOLOGY

This research will substantially be doctrinal. The research is descriptive in nature. The researcher has drawn up data from statutes, various books, case laws, guidelines, journal articles, newspapers, reports of international organizations, and all other materials relevant to this study. The Internet was also used to gather information relevant to this research.

1.8 LITERATURE REVIEW

Some journal articles relevant to this study are reviewed hereunder to highlight the research problem and the significance of this research.

1. Andrew Stevens et al. in the article, *Health technology assessment: history and demand*[7] points out three main forces that have driven the recent developments of HTA: rising costs, concerns about the adoption of unproven technologies, and an inescapable rise in consumer expectations.

2. Finn Boerlum Kristensen, in his article, *Health technology assessment in Europe*[8] The author states that the development of HTA is attributable to policy analysis, health economic evaluation, evidence-based medicine, and social and humanistic sciences. HTA as input for policy making, the general framework is set out by policy analysis. Both health economic evaluation and evidence-based medicine set out the methodological framework for analysis done by HTA.

3. Olga Löblová, in the article, *What has health technology assessment ever done for us?*[9] states: HTA works by changing mindsets rather than determining

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[7] Andrew Stevens, Ruairidh Milne and Amanda Burls, *Health technology assessment: history and demand*, Vol. 25, No:2, Journal of Public Health Medicine, pp. 98-101, (2003)

[8] Finn Boerlum Kristensen, *Health technology assessment in Europe*, Vol. 37, No: 4, Scandinavian Journal of Public Health, pp. 335-339, (2009)

[9] Olga Löblová, *What has health technology assessment ever done for us?,* Vol. 23, No:2, Journal of Health Services Research & Policy, pp. 134-136, (2018)

actions. Institutionalization of HTA helps to remove opaque and arbitrary pricing and reimbursement practices. HTA's potential to enhance procedural justice in allocative decisions is a other plausible promise. HTA has predictable upfront costs, which may deter policymakers from establishing HTA agencies, particularly in low-income nations with limited resources. However, it may be premature to abandon this strategy entirely, as less tangible innovative objectives are still necessary.

4. Aris Angelis et al., in the paper, *Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries*[10] set out the idea that comprehensive and systematic assessment procedures characterized by transparency in the selection of evaluation criteria, their significance, and intensity of use could lead to more rational evidence-based decision-making, possibly improving efficiency in resource allocation and raising public confidence and fairness.

5. Hans-Peter Dauben and Alric Rüther in the article, *Health Technology Assessment: Cookbook Medicine with a New Name?*[11] conclude that Today Health Technology Assessment plays a significant role in the decision-making and planning process. HTA reports are slowly gaining informational relevance. HTA reports show the possible user ways to determine the financial restrictions and the additional freedom of action gained in the process.

6. Mark Rasburn et al. in the article, *Strengthening patient outcome evidence in health technology assessment: a co production approach*[12] The author reviewed the existing health technology assessment (HTA) methods in the UK. Also, the study aimed to coproduce propositions to improve patient involvement, the support offered to patient stakeholders, and how committees

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[10] Aris Angelis, Ansgar Lange and Panos Kanavos, *Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries*, Vol. 19, No. 1, Eur J Health Econ, pp. 123-152, (2018)

[11] Hans-Peter Dauben and Alric Rüther, *Health Technology Assessment: Cookbook Medicine with a New Name?* Vol.1, No. 2, HEPAC, pp. 134-139, (2000)

[12] Rasburn M, Livingstone H, Scott SE (2021). *Strengthening patient outcome evidence in health technology assessment: a co production approach*. International Journal of Technology Assessment in Health Care, Vol. 37, e12, pp 1-4, (2020)

identify and consider patient evidence. The study identified factors such as having documented processes, appropriate evidence submission processes, transparent decisions, and proper support to understand and enable meaningful patient and public involvement (PPI) by HTA. HTA working collaboratively with patient stakeholders is found to increase their knowledge and understanding of the barriers faced by patients, thereby enabling HTA to design appropriate solutions to remove them. The stakeholder engagement methods provided better data analysis, improved stakeholder relationships, and supported the development of meaningful conclusions.

7. Pascale Lehoux et al. in the study, *What medical specialists like and dislike about health technology assessment reports?*[13] reveal that Medical specialists play a critical role in the adoption of health technology, and HTA cannot afford to disregard them. A transparent communication between HTA report developers and users could improve policy recommendations.

8. Cyril Benoit et al., in the article, *Health Technology Assessment: The Scientific Career Of a Policy Concept*[14] conclude that The "career" of the HTA concept may be seen as a scientific-knowledge-based institutionalization of a public policy. HTA first needs scientific prerequisites to succeed in a country, such as an organized scientific community working in the health sector and services.

9. Joseph B. Babigumiraa et al., in their research paper *Health technology assessment in low- and middle-income countries: a landscape assessment*[15] found that Formal HTA in the LMICs is limited or non-existent. However, some evidence of informal HTA exists. Formalizing HTA and using existing HTA evidence will enhance the quality of individual and public health and also regulatory, coverage, and reimbursement decisions.

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[13] Pascale Lehoux, Myriam Hivon, Jean-Louis Denis and Stephanie Tailliez, *What medical specialists like and dislike about health technology assessment reports*, Vol. 14, No. 4, pp 197-203, (2009)

[14] Cyril Benoit and Philippe Gorry, *Health Technology Assessment: The Scientific Career Of a Policy Concept*, 33:1, IJTAHC, pp 128–134, (2017)

[15] Joseph B. Babigumiraa, Alisa M. Jennya, Rebecca Bartleinc, Andy Stergachisa, and Louis P. Garrison Jr., *Health technology assessment in low- and middle-income countries: a landscape assessment*, Vol. 7, JPHSR, pp 37–42, (2016)

1.9 CHAPTERIZATION

Chapter 1: Introduction

This chapter seeks to introduce the subject of study while outlining the preliminary requirements such as the scope and need of the study, research problem, method adopted, hypothesis etc.

Chapter 2: Conceptualizing Health Technology and Health Technology Assessment

This chapter aims to elucidate the concept of health technology and HTA. Also the chapter deals with the origin and evolution of HTA.

Chapter 3: Health Technology Assessment: An International Perspective

This chapter seeks to give a detailed idea about the international framework of HTA and also deals with HTA in countries such as Canada, Australia, and England, known for their Health Technology Assessment and often cited as reference countries.

Chapter 4: Health Technology Assessment In India and Its Role in Health Policy Making

This chapter explains the institutionalization of HTA in India, its framework and structure, relationship between HTA and health economics. The chapter also aims to give a detailed analysis on how HTA influences priority-setting, policy and clinical decision making effectively. This chapter also identifies the challenges of using HTA in India.

Chapter 5: Suggestions and Conclusion

This chapter seeks to put forth suggestions in the light of the research conducted and summarize the findings of the study.

CHAPTER: 2

2. CONCEPTUALIZING HEALTH TECHNOLOGY AND HEALTH TECHNOLOGY ASSESSMENT

2.1 HEALTH TECHNOLOGY

Healthcare innovation is one of the most critical battles in the fight to prolong human life. From pregnancy tests to ultrasound scans, Health technology is with you from before you are born. Technology means the practical use of knowledge. Health technology is the practical use of knowledge to enhance and sustain individual and public health. The World Health Organization(WHO) defines health technology as the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures, and systems developed to solve a health problem and improve quality of life.[16] Health Technology in healthcare can be described based on its physical nature, purpose, and diffusion stage.[17]

1. PHYSICAL NATURE

   The term 'technology' is perceived differently by different people. For some, it connotes mechanical devices, whereas it would mean 'information technology' for some. In healthcare, 'technology' assumes a broader meaning. Health technology encompasses drugs, biologics, medical and surgical products, devices, equipment, supplies, public health programs, support systems, and organizational and managerial systems. It is pertinent to note that these categories are not mutually exclusive but interdependent.

2. PURPOSE OR APPLICATION

   Health technology can be described based on their healthcare application as well, i.e.,

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[16] WHO/Europe | Health technology assessment. https://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/policy-areas/health-technology-assessment

[17] Goodman CS. *HTA 101: Introduction to Health Technology Assessment*. Bethesda, MD: National Library of Medicine (US); 2014.

- Prevention involves efforts to prevent disease, reduce the risk of such occurrence, or limit its extent. (e.g., immunization)
- Screening involves detecting a disease, abnormality, or associated risk factors in asymptomatic people.
- Diagnosis involves the identification of the cause and nature of the disease in a person with symptoms (e.g., electrocardiogram, x-ray)
- Treatment is intended to improve or preserve one's health or to prevent further deterioration. (e.g., antiviral therapy, psychotherapy, coronary artery bypass graft surgery)
- Rehabilitation is restoring, maintaining, or improving the function and well-being of a physically or mentally disabled person. (e.g., an exercise program for post-stroke patients)
- Palliation aims to improve patients' quality of life by reducing pain, symptoms, discomfort, and stress associated with severe illness and psychological, social, and spiritual issues. (While palliation is most commonly associated with a progressive, incurable disease, it can be delivered at any stage of sickness and in conjunction with treatment, such as patient-controlled analgesia, depression or insomnia medicine, and caregiver support.)[18]

However, technology does not always fall into just one category. Sometimes technology used for diagnosis may also be used as a treatment process. Also, some technologies combine features of drugs, biologics, devices, or other health technology categories. These are known as 'Hybrid" or "combination" technologies. An example of such a hybrid technology is positron-emission tomography (PET, used with radiopharmaceuticals).

3. STAGE OF DIFFUSION

Health Technologies is assessed at various levels of diffusion and maturity. a healthcare technology may be

- Futuristic, i.e., in a conceptual stage or in the earliest development stages.

[18] Supra note 17

- Experimental, i.e., undergoing laboratory testing using animals or other means.
- Investigational technology, i.e., one that is undergoing initial clinical (i.e., in humans) evaluation for a particular condition.
- Established technology means that which clinicians consider to be a standard approach to a particular condition or indication and diffused into general use.
- Obsolete/outmoded/abandoned technology is the one that is superseded by other technologies or demonstrated to be futile or dangerous.

However, Health technologies do not necessarily develop through these stages in a linear manner because we often see that certain technologies undergo multiple innovations after their initial acceptance into practice. Also another instance often seen is that a technology that was once considered obsolete, may render helpful for a better or may prove effective in an entirely different clinical purpose.

2.2 ORIGINS OF TECHNOLOGY ASSESSMENT

The genesis of technology assessment can be traced to the mid-1960s. The first known documented effort to collect data and use evidence to improve healthcare was introduced 350 years ago by the Swedish Collegium Medicorum. such efforts were employed to distinguish quackery from medicine, control the trade of poisonous drugs, and ban all swindlers who "grease people with their fake, fraudulent, and harmful medicaments." Early technology assessments mainly concerned offshore oil drilling, pesticides, automobile pollution, nuclear power plants, supersonic airplanes, weather modification, and the artificial heart. T.A. was designed to identify the intended effects of technologies and unintended social, economic, and environmental effects.

The term "technology assessment" was introduced in 1965 during deliberations of the Committee on Science and Astronautics of the US House of Representatives. Congressman Emilio Daddario emphasized that the purpose of TA was to serve policymaking: *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 the social, economic, and legal implications of any course of action (US Congress, House of Representatives 1967).[19]

The roots of effectiveness research in western medicine are traditionally traced back to Pierre Louis's Méthode numérique' in Paris in the 1830s. The demonstration that phlebotomy did not enhance survival for pneumonia patients. However, the initial point can be traced back another 80 years to mid-eighteenth-century Britain and the 'arithmetical medicine' associated with Edinburgh medical school graduates. James Lind, for example, famously conducted a controlled trial of six experimental scurvy therapies. Others have referred to Daniel's book in the Old Testament. In the 1800s, there were some important medical discoveries and innovations such as the microscope (in 1695), vaccine (in 1796), stethoscope (in 1816), spirometer (in 1840), ophthalmoscope (in 1850), thermometer (in 1866) and X-Ray (in 1895).

Around the 20th century, Ernest Codman of Boston argued for careful follow-up of patient outcomes. What is now known as health services research in England dates back to the 1930s. It arose partially from epidemiological research, with Glover's results of a 10-fold variance in tonsillectomy in England and Wales being a famous example. However, Glover's work was not pursued further in the United Kingdom until the 1970s and 1980s. His work gained prominence when a rush of research indicated a substantial geographic disparity in general medical admissions and various surgeries (including tonsillectomy, appendicectomy, hysterectomy, cholecystectomy, prostatectomy, and cesarean section). Such discrepancies indicated doubt regarding 'appropriate' rates of treatment in a community, raising concerns about the treatment's efficacy and cost-effectiveness. Randomized controlled trials are the soundest way to answer such problems (RCTs).[20]

In Archie Cochrane's Effectiveness and efficiency: random reflections on health services, published in 1972, Cochrane recognised the lack of evidence of effectiveness for much of health treatment at the time, and he advocated for the RCT as a solution.[21] The introduction of a stunning technology developed by EMI in the

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[19]HTA 101: Introduction to Health Technology Assessment. Available at: https://www.nlm.nih.gov/nichsr/hta101/ta10103.html

[20] Supra note 7

[21] A.L.Cochrane, Effectiveness and efficiency: Random reflections on health services, Nuffield provincial Hospitals Trust. Available at: https://www.nuffieldtrust.org.uk/files/2017-01/effectiveness-and-efficiency-web-final.pdf

UK (CT scanner) and Cochrane marked the very beginning of HTA in 1974. For evaluation of the CT scanner, the policy makers demanded a synthesis of the medical, ethical, organizational, social, and economic implications of this technology, along with a thorough comparison of the alternatives.[22] In the 1970s, Austrian Ivan Illich published Limits to Medicine, in which he described the medical establishment as a major threat to health, and Thomas McKeown in his work The Role of Medicine, which questioned the idea that major improvements in population health were due to advances in medical care. From the mid-1970s to the 1980s, health economics as a distinct academic discipline grew steadily, and studies on differences in health care, successors to Glover's work, got widely recognized.[23]

Further, some historical events also positively contributed to the establishment of HTA: horrific treatments (Thalidomide Scandal and Lobotomy), opinion-based medicine (which was eventually replaced by evidence-based medicine). The research community felt that many questions can be answered by a more structured approach combining safety (what is the risk of the technology known), efficacy (is the technology doing what it is supposed to do), effectiveness (how does it impact patient health health) and cost-effectiveness (what are the costs related to health outcomes). These pioneering perspectives provided the tools for the assessment of both new and existing health care technologies: skepticism, the investigation of variations, RCTs and cost- utility analysis. The most recent addition to the toolkit – systematic reviews – has dramatically accelerated the development of robust HTA.[24]

2.2.2 DEVELOPMENT OF TECHNOLOGY ASSESSMENT

Between the 1950s and the 1970s, technological change was accepted as beneficial and progressive in the industrialized world. However, technology was increasingly blamed for many problems and unexpected consequences. Increasing awareness of these consequences led to the need for greater public and social control of

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[22] A brief history of health technology assessment: A historical ride and present story by Prof. Egon Jonsson
https://www.connectheor.com/a-brief-history-of-health-technology-assessment-a-historical-ride-and-present-story-webinar-notes-speaker-egon-jonsson/

[23] Supra note 20

[24] Supra note 22

technological development, which resulted in the emergence of technology assessment. The adoption of TA occurred in two phases.[25]

In the first phase, TA was adopted by companies, organizations, and narrowly defined interest groups as a goal-oriented tool. It was initially viewed by industry as an analytic discipline to support and determine decisions as to which products and what processes should be developed. TA included tests for safety and efficacy in the form of quality control; and analyses such as program-planning, and budgeting and cost-benefit analysis, to examine economic feasibility of new products. TA was thus the domain of engineers, technicians, and later, economists. During this period, health technology assessment (HTA) also fell under the same ad hoc research grouping like all other industrial technology, and was largely limited to public influence. Hence, during phase one TA and HTA were focused on industrial policy issues.[26]

During phase two emphasis of TA shifted to assessment of consequences, especially when these impacted the public purse. A major turning point in phase-two TA occurred in the commercialization of biotechnology, as concern shifted from internal to external issues, and TA became associated with public policy. Public opinion was uncomfortable leaving the direction of such significant technological change to market forces and policies of laissez-faire, and sent a clear message to this effect through pressure groups and the media. This led to the rapid growth of TA in: (a) non-institutionalized, and (b) institutionalized contexts.[27]

- Non-institutionalized TA and the shift to a more socially-responsive assessment have been attributed to a generalized sense that development should be planned for people. Social movements and pressure groups were key players in the 1980s. There was, for example, the women's health movement in the healthcare sector, particularly concerned about reproductive health issues. Pressure groups, such as patient associations focussing on a particular disease (heart disease, arthritis, Etc.), were influential in requiring technological change. HTA was not an explicit priority of any of these groups

[25] Volume II, Boutros Pierre Mansourian, Global Perspectives in Health, pp 75, (EOLSS Publications, 2009)
[26] Supra note 23
[27] Ibid at 76

but rather a logical response to issues of particular interest. Hence, no single group developed by itself a comprehensive program for TA.

- During the rapid expansion of TA in institutionalized settings, medical or health technology was identified for separately-administered assessment. This transition co-occurred at all levels - provincial, national, and international at an exhilarating rate. Examples ranged from the US Congressional Office of Technology Assessment (OTA) and OECD's special program for the social assessment of technology, the United Kingdom's Parliamentary Office of Science and Technology, and later, the WHO program for regulating drugs and devices, the Foundation for Future. Health Scenarios (STG) in the Netherlands, the Swedish Council on Technology Assessment in Health Care (SBU), and the Canadian Coordinating Office for Health Technology Assessment (CCOHTA); followed by the state-level agencies: Basque Office for Health Technology Assessment (OSTEBA): Conseil d'évaluation des technologies de la santé du Québec (CETS). British Columbia Office of Health Technology Assessment (BCOHTA), the Catalan Agency for Health Technology Assessment and Research (CAHTA/AATM), and others.[28]

Several factors precipitated the establishment of HTA activities. Significant steps in international experience include rapid advances in healthcare research and development; the influence of the medical professional heading most national and international efforts (adding physicians to the growing list of TA experts); and, in particular, rapidly-increasing costs in health care. However, the emerging agencies differed in structure and purpose, depending on the local situation. Furthermore, an agreed-upon theoretical basis for assessment was absent. Consequently, there were (and are) many schools of thought and analysis methods in HTA. It may be inferred that TA has never been a neutral tool: it has developed in various forms, shaped by cultural norms and societal values.

2.2.3 DEFINITIONS OF TECHNOLOGY ASSESSMENT

- Technology assessment ultimately comprises a systems approach to managing technology reaching beyond technology and industrial aspects into society and environmental domains. Initially, it deals with assessment of effects,

[28] Supra note 23, at 77

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 (UN Branch for Science and Technology for Development 1991).[29]

- 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 ─ establishing processes that help decisions to be made. And TA has three objects: the issue or technology; the social aspects; the policy aspects (European Parliamentary Technology Assessment 2013).[30]
- Technology assessment is a type of policy research that looks at the short- and long-term social repercussions of technology use (sociological, economic, ethical, and legal). Technology assessment aims to give information on policy alternatives to policymakers.[31]

2.3 HEALTH TECHNOLOGY ASSESSMENT(HTA)

Health technology has become an essential part of the healthcare system. It is seen as an instrument to tackle the challenges healthcare faces. The development of health technology assessment can help health technologies to have a more significant impact on improving public health. However, technology alone cannot improve the whole healthcare system, and a successful implementation requires a complete understanding “a priori” of the technology capabilities and its application. Moreover, the economic and health policy issues increasingly influence healthcare technology

[29] Supra note 19
[30] Ibid
[31] Banta D, Jonsson E. History of HTA: introduction. Vol. 25(suppl 1), Int J Technol Assess Health Care, pp 1–6, (2009)

solutions, with the aim to keep the healthcare quality high and the costs under control, especially regarding the pharmaceutical sector.[32] Given the complexity of the healthcare environment, the Health Technology Assessment (HTA) has been developed as scientific research capable of supporting health policy decisions. Two driving forces of HTA are increasing budget constraints resulting from the recession; the second is the increasingly demanding policymakers and funders, who demand more evidence for new and existing therapies. Health Technology Assessment originated from "evidence-based healthcare" or "evidence-informed decision making." HTA, in a simple sense, is a structured analysis of health technology. The results of such analysis form the raw material for regulatory, formulary, and reimbursement policy decisions.

HTA evaluates the technical performance, safety, cost-effectiveness, organizational implications, social ramifications, and legal and ethical concerns of a health technology's implementation systematically. Its primary goal is to inform healthcare technology policy-making to increase the adoption of cost-effective new technologies while avoiding the introduction of technologies with dubious value for the healthcare system. HTA's current focus is on promoting effective and efficient health-care systems. As a result, cost-effectiveness analysis is one of the most widely utilized tools for guiding coverage decisions and negotiating prices.

About its breadth and scope, HTA can be divided into micro HTA, which focuses on technologies such as drugs and devices that are considered to be incremental to the health system, and macro HTA, which focuses on elements of the architecture or framework of the health system in general, such as the number, types, and mix of healthcare facilities and health workers in the system.[33]

According to the WHO's global survey on HTA, 80% of countries had a formal HTA process to guide decision-making. They systematically collected data and assessed the effects of a specific health technology or intervention. Meanwhile, nearly half had enacted legislation to legitimize HTA findings in healthcare decision-making, and

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[32] Francesca Iandolo, Pietro Vito, Irene Fulco and Francesca Loia, From Health Technology Assessment to Health Technology Sustainability, Vol. 10, Sustainability, p 4748,(2018) Available at: https://www.mdpi.com/journal/sustainability

[33] Health technology assessment in low and middle income countries: a landscape assessment http://globalmedicines.org/wordpress/wp-content/uploads/2013/12/Babigumira-HTA-2015.pdf

two-thirds had constituted a national HTA organization, department, unit, or committee to produce HTA reports for the Ministry of Health (MOH). HTA has gained international acclaim and has played an increasingly integral role in health policy formulation. The National Institute for Health and Care Excellence (NICE) in the United Kingdom, the Swedish Council for Technology Assessment in Health Care, the Canadian Agency for Drugs and Technologies in Health (CADTH), the Medicare Services Advisory Committee (MSAC) in Australia, and the Veterans Affairs Technology Assessment Program (VATAP) in the United States are few examples of HTA organizations.

2.3.1 BEGINNINGS OF HTA

The systematic development of HTA began in the U.S. with the establishment of the Office of Technology Assessment(OTA). The OTA published its first report in 1976. The OTA inspired many researchers in Europe. As a result, the first HTA agency outside the U.S. was established in Sweden in the 1980s. Later, within about ten years, 14 agencies were established in various countries such as Spain, France, Holland, Belgium, Canada, Poland, United Kingdom, Scotland, Germany, Finland, and Norway. Eventually, HTA agencies were formed in Australia, South America, Turkey, Malaysia, Thailand, China, South Korea, and South Africa. The spread of HTA was facilitated by international organizations such as the World Bank and the WHO. Also, ISTAHC and its successor organization, Health Technology Assessment International (HTAi), and the INAHTA are also significant in this regard. The INAHTA, or the International Network of Agencies for Health Technology Assessment, was formed in 1993 with the object of better cooperation and communication between HTA agencies worldwide. ISTAHC, an international society, is another development that synergized HTA.

Initially, OTA shaped the field of HTA. The OTA examined possibilities for the new field, focusing on methods, efficacy, safety, and cost-effectiveness. The prime method involved in HTA was synthesizing available information, generally called a “systematic review” by the Cochrane Collaboration and others. In addition, these initial reports scrutinized health policies that HTA might influence or use HTA results in their decisions. These issues primarily determined the general shape of HTA programs around the globe. The early results of these reports on efficacy and safety

persuaded the U.S. Congress to establish the National Center for Health Care Technology (NCHCT). NCHCT was the first national agency in the world to deal with HTA. NCHCT advised the U.S. Medicare program on technologies. Other pioneering actions of NCHCT included systematic reviews on selected technologies, developing methods for setting priorities between health technologies, and identifying new and emerging health technologies as candidates for assessment.

Later, when the NCHCT was abolished, the Institute of Medicine (IOM) of the National Academy of Sciences decided to develop a national Council on Health Care Technology to serve in its stead. The Council performed several vital tasks. However, it eventually did not attract sufficient funding and was also dissolved. The IOM has supported the development of HTA in various ways. In addition to developing the Council, a notable move was to form the Committee for Evaluating Medical Technologies in Clinical Use. The main output of the Committee was the development of a rather definitive book on the field of HTA, Assessing Medical Technologies. Since then, HTA has not found a home in the U.S. Federal government, especially after OTA was abolished in 1995. However, several public and private sector developments that followed these events kept the field alive. The recent significant attention to comparative effectiveness in health care in the United States by the Obama administration indicates a much broader support for HTA in the United States. Consensus development conferences, an important activity related to HTA, were also developed first in the United States through the National Institutes of Health. These began in the United States in 1977. The goal was to bring together physicians, researchers, economists, epidemiologists, consumers, ethicists, and so on to seek consensus on the scientific basis of the safety, efficacy, and appropriate conditions for using various healthcare technologies. A panel of experts listens to presentations by leading medical researchers addressing specific questions. After two days of hearings, the panel is sequestered to write a consensus statement, which is read the next day and associated with a press conference. In the early years of HTA, public bodies organized consensus conferences in several countries, including Sweden, Denmark, Finland, France, the Netherlands, and the United Kingdom.[34]

[34] Supra note 25

2.3.2 SOME DEFINITIONS OF HTA

Since the birth of HTA in the mid-1970s, the definition of HTA has also evolved over the years, with varied versions of the definition being used in different organizational contexts. Although the central concepts are consistent across these definitions, the phrasing tends to be cumbersome and technical, which can impede the immediate understanding of those new to the field. Hence there is a need to develop an internationally accepted definition that anyone could easily understand.

- According to WHO Health technology assessment refers to the systematic evaluation of properties, effects and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform policy decision-making.[35]

In 2020 amidst the COVID-19 pandemic, an international joint task force led by the International Network of Agencies for Health Technology Assessment (INAHTA) and Health Technology Assessment International (HTAi) recommended an updated definition of HTA to replace previous definitions. Definition is as follows:

- "*Health technology assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system."*[36]

COVID-19 has revealed the gaps in our present health systems and tested their performance from its inception. The new definition of HTA now explicitly links HTA goals to health system performance and provides a means for bridging gaps. Hence, HTA becomes a tool for strategic planning in the health system and reaffirms the

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[35] WHO/Europe | Health technology assessment. https://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/policy-areas/health-technology-assessment

[36] O'Rourke B, Oortwijn W, et al, the International Joint Task Group The new definition of health technology assessment: A milestone in international collaboration. Vol. 36, Int. J. of Technology Assessment in Health Care, pp 187–190, (2020) https://www.cambridge.org/core/services/aop-cambridge-core/content/view/8A3BA65D279F3FDAA83ADB3D08CF8C17/S0266462320000215a.pdf/the-new-definition-of-health-technology-assessment-a-milestone-in-international-collaboration.pdf

allegiance to resolution 67.23 of the World Health Assembly[37], which has identified HTA as an instrument of sustainable health systems and Universal Health Coverage.

COVID-19 has also exposed the existing inequities in societies. The Human Development Report (2019) has identified the potential of technology to reduce or increase inequity, but this need not be left to chance. By making health equity an explicit goal, this new definition provides a choice to leverage health technology for social convergence rather than divergence. It will encourage HTA producers and users to apply existing equity frameworks and methodological refinements capturing equity dimensions, which would make HTA a tool for determining the impact of health technology on society. Thus, providing a powerful mechanism for HTA users to think beyond cost-containment, safety, and efficacy and address more important questions on the impact of health technology on sustainable, ethical development. Further, by emphasizing the lifecycle approach to technology, the new definition of HTA makes it an evolving process responsive to changing information and contexts. This approach will promote more use of real-world data and evidence and address COVID-related disruptions in HTA research to determine the value of health technology beyond the realms of clinical trials and laboratory experiments. The definition provides scope for adopting flexible frameworks and methods based on local contexts, guided by its normative principles.[38]

Regarding the value, the new definition interprets that the dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organizational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.[39]

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[37] The United Nations, 67th World Health Assembly, Agenda item no: 15.7, Health intervention and technology assessment support of universal health coverage; 2014. Available at: https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R23-en.pdf?ua=1

[38] Mukherjee K (2021). *Relevance of the newly defined Health Technology Assessment: COVID-19 and beyond.* International Journal of Technology Assessment in Health Care 37, e44, 1–2. https://doi.org/10.1017/S0266462321000192

[39] Staniszewska S, Söderholm Werkö S, Mind the evidence gap: the use of patient-based evidence to create “complete HTA” in the twenty-first century, Vol 37, International Journal of Technology

In this updated definition, it highlights the key word of "value" to incorporate all evaluation elements and dimensions, while it gives interpretation of comprehensive dimensions and perspectives.[40] The definition proposes determining the "value of health technology" through a multidimensional framework, using explicit procedures through the best available evidence. This notion reflects a scientific approach and acknowledges "overall value" as a collaborative construct developing through interactions between multiple stakeholders communicating their preferences. It provides the arena for a constructive dialogue between science and policy, a much-needed discussion in times of COVID-19 and beyond.

COVID-19, although a destructive creation of nature, provides an opportunity to adapt and leverage HTA processes creatively and constructively as a tool for health systems transformation and to create value for society at large in the "new normal" post-COVID era. This global consensus in words needs to be converted into global collaborative action now.[41]

Assessment in Health Care, pp 1–7, (2021), https://www.cambridge.org/core/services/aop-cambridge-core/content/view/4C7B0241DCC859611AD4D8FB6E3A56CF/S026646232100012Xa.pdf/mind-the-evidence-gap-the-use-of-patient-based-evidence-to-create-complete-hta-in-the-twenty-first-century.pdf

[40] Supra note 39

[41] Ibid

CHAPTER 3

3. HEALTH TECHNOLOGY ASSESSMENT: AN INTERNATIONAL PERSPECTIVE

In advancing health systems throughout the world, health technology assessment (HTA) plays an essential role. HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system. Health technology is an intervention developed to prevent, diagnose, or treat medical conditions, promote health, provide rehabilitation, or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system.[42]

HTA, from its inception, was involved in the decision-making process in developing products and processes. HTA emerged as groups and institutions and demanded better control of healthcare technologies and their consequences. Rapidly increasing healthcare costs and research prompted the establishment of HTA agencies at the provincial, national and international levels. However, they differed in structures and purposes due to the lack of an agreed theoretical basis for HTA.

HTA found its place in the international arena from the very early days. The health programs launched by the U.S. Office of Technology Assessment gained a steady stream of global visitors and a Swedish Planning and Rationalization Institute of the Health Services (Spri). In 1979, the first international conference on HTA in Stockholm was sponsored by Spri, which encouraged those working in HTA to form a global network or a society. Ultimately the meeting convened in Copenhagen led to the development of an international society known as International Society of Technology Assessment in Health Care (ISTAHC). A journal, International Journal for Technology Assessment in Health Care, was the official publication of ISTAHC. The Annual Meetings of the International Society of Technology Assessment in Health Care (ISTAHC) in 1992 and 1993 involved the exchange of information, development of structured communication, and cooperation of HTA agencies and their activities.

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[42] About HTAi | Health Technology Assessment International (HTAi). https://htai.org/about-htai/

The International Network of Agencies for Health Technology Assessment (INAHTA) was established in 1993 at a meeting held in Paris. The International Network of Agencies for Health Technology Assessment (INAHTA) is a non-profit organization with deep roots in the international HTA community, stretching back to 1993 when the Network was founded. All members are publicly funded, non-profit organizations producing HTA and are linked to the regional or national government. INAHTA has collaboration with the international HTA community and broader global health community.[43] Their collaboration includes organizations such as the World Health Organization, Health Technology Assessment International (HTAi), Guidelines International Network (G-I-N), i-HTS, EUnetHTA, HTAsiaLink, and RedETSA. However, due to some financial reasons, ISTAHC was liquidated in 2003. At its best, ISTAHC had more than 1500 members. Eventually, a new society, Health Technology International(HTAi), was formed in 2003. The HTAi holds annual meetings.[44]

3.1 ISTAHC - INTERNATIONAL SOCIETY FOR TECHNOLOGY ASSESSMENT IN HEALTHCARE

In the early 1970s, many people participated in activities assessing medical technology for health practice and policy. Consequently, an international society was formed for health technology assessment. Discussions concerning international collaboration in the field occurred among HTA groups in the US and Sweden from the late 1970s to 1985.

The first international “journal” or "newsletter" on HTA (The Sorcerers Apprentice) was published by the staff of OTA quarterly from 1981 to 1984. Concurrently,Stanley Reiser and Egon Jonsson planned to publish a scientific journal in the field of HTA from 1982 to 1984. These two publications highly influenced the formation of the International Society; the International Society for Technology Assessment in Health Care (ISTAHC). The aim of the Society was stated as: “. . .encourage research, education, cooperation, and the exchange of information on the clinical and social implications of health care technologies and to foster their optimal use.”[45] The first

[43] The History of INAHTA - INAHTA. https://www.inahta.org/about-inahta/history/

[44] Global Collaboration - INAHTA. https://www.inahta.org/collaboration/

[45] David Banta , Egon Jonsson, Paul Childs, Health Technology Assessment International (HTAi) History of the international societies in health technology assessment: International Society for Technology Assessment in Health Care and Health Technology Assessment International, International

meeting in Copenhagen was to be followed by eighteen annual ISTAHC meetings up to 2003. For almost a decade the Society was fueled by the passion and sacrifices of core individuals committed to HTA.

During ISTAHC's first decade, much of the discussion by the Board initially circulated the aims and objectives of the Society, membership issues, financing, elections, conference planning, how to provide adequate education and training in the field, how to support HTA in developing countries, and how to support research to improve the methodology for assessments. Discussions in the early 1990s continued to focus on some of these issues but also on joint ventures with other societies, collaboration with the WHO and the World Bank, the development of guidelines, assessment of the quality of life, how to provide a forum for agencies in HTA to meet and exchange results (which in 1993 led to the establishment of INAHTA), the formation of a clearing- house for HTAs, how to collaborate with industry, how to reach out to the general public, HTA at the hospital level, and not the least effective dissemination of findings from research, including the impact of HTAs on health policy and practice.[46]

For a long time, ISTAHC consistently grew in membership and funding. However, combined with the cost of running a well-staffed secretariat, the available financial resources were seriously overstretched for all good intentions, and ISTAHC was forced to end its existence in 2003. ISTAHC was reconstituted into a new society, Health Technology Assessment International (HTAi) in 2003. Health Technology Assessment international (HTAi) provides an open platform for global collaboration that leverages collective intelligence to improve health outcomes worldwide. Representing 82 organizational members and more than 2,500 individuals from 65 countries, they are the scientific and professional global society for HTA thought-leaders, researchers, agencies, policy-makers, industry, academia, health-service providers, patients and patient organizations. HTAi will be further discussed in detail in the subsequent section.

Journal of Technology Assessment in Health Care, 25:Supplement 1 (2009),pp 19-20. https://www.inahta.org/wp-content/uploads/2014/04/Banta-et-al_2009.pdf

[46] Supra note 45 at 21

3.2 WORLD HEALTH ORGANIZATION (WHO)

WHO was involved in HTA from the beginning because health technology resulted from health research that could take place anywhere globally, making health technology relevant globally.

The Declaration of Alma Ata on Primary Health Care in 1978 referred to "essential health care based on practical, scientifically sound methods and technologies... " In 1985, the European Office of WHO published several targets for its member states, including one on HTA that stated " ... all member states should have established a formal mechanism to systematically assess the appropriate use of health technologies and to verify that they respond to the national health program needs". Unfortunately, WHO as a whole has never become a strong and consistent supporter of HTA. The European Office had a program related to HTA for several years but actually worked more on quality assurance.[47] Beginning in 2000, the focus was shifted to the development and use of evidence in healthcare decision-making. The Evidence Unit of EURO was revitalized and its resources were expanded. The WHO European Advisory Committee for Health Research (EACHR) was reconstituted to focus on evidence. In addition, a new program, the Health Evidence Network (HEN), was devised to generate evidence on health interventions for the member states. However, during 2007 and 2008, WHO EURO became less active in encouraging evidence-based activities.

By early 1990s, WHO headquarters in Geneva became involved in HTA and took an entirely different path. First, WHO depended on available evidence, particularly on efficacy, in some of its programs, notably essential drugs, diarrheal diseases, tuberculosis, and perinatal problems. However, many guidelines developed by WHO during the 1970s and onward were based more on expert committees' opinions than on systematic review of available scientific literature. This situation began to improve in the early years after 2000. During the 1990s, considerable interest in HTA emerged from certain parts of the office, including an Assistant Director General. Several interesting consultations were held, focusing on the development of national programs or networks of programs and individuals. However, no significant resources were

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[47] Banta, D., & Jonsson, E. (2009). History of HTA: Introduction. *International Journal of Technology Assessment in Health Care, 25*(S1), 1-6. doi:10.1017/S0266462309090321

committed to HTA or similar fields. Regional Offices were urged to become interested in HTA, but few responded. The Regional Office in New Delhi, India, however, did support one international workshop and course on HTA for its members in Bangkok in 1998. Under Gro Harlem Brundtland, Director General from 1998 to 2003, the use of best evidence was strongly supported. [48]

Today, the regional offices support the development of HTA capacity in their Member States through advocacy and raising awareness of the use of HTA in policy development, guidance for best practices and the coordination and collaboration between Member States and established partners. WHO's efforts to broaden the use of HTA has resulted in more tools and resources being available for HTA globally. For example, WHO-CHOICE (CHOosing Interventions that are Cost-Effective) tools have been used to show efficiencies in procurement in different regions of the world, and HTA methods have been applied to find cost-effective interventions to reduce road-traffic accidents in sub-Saharan Africa and South-East Asia. At the country level, WHO-CHOICE information was used in Ethiopia to determine the affordability and financial efficacy of universal health coverage.[49]

Understanding the importance of HTA in support of universal health coverage, resolution WHA67.23 was approved during the 67th World Health Assembly. The resolution recognizes the importance of evidence-based policy development and decision-making in health systems, and HTA's role in sustainable and effective health systems. It also calls for the promotion of HTA within national frameworks, such as those for health system research, health professional education and the establishment of universal health coverage.[50]

WHO recently hosted Decide- Health Decision Hub, a platform established in June 2019 to host a virtual space for collaboration in data-driven health decision-making. "Decide Hub" is One of the prominent initiatives of WHO in relation to HTA. Decide – Health Decision Hub is the global health network for Value for Money. It supports evidence-based decision-making in health to secure value for money across the health system spectrum through collaborative ventures. Decide bolsters collaborations spanning

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[48] Supra note 47

[49] Health technology assessment - Global.
https://www.who.int/health-topics/health-technology-assessment

[50] Ibid

the whole range of data and analytics that identify value for health to help make the best decision the first time. Decide is a meeting space for everyone; networks, projects, data producers, and users. This Hub aims to provide an overarching link for existing networks and practitioners. Decide enables a wide range of partners to work on topical areas pertaining to value in health decisions that include: priority setting, benefits package design, HTA, Capital investment in health, and contract modeling. It aims to create a meeting place and a neutral broker. It seeks to ensure data-driven decisions in all countries and provide a space to access the tools and knowledge to support this process, and to bring together a diverse group of stakeholders to identify gaps and produce new ideas and tools.[51]

The hub will be a helpful platform for HTA, other economic and social evaluations, investment and disinvestment cases, or any other policy territory that needs fair and transparent decision-making. The roundtable endorsed the platform's development and called for all partners to support the WHO in its coordination efforts. The WHO could be a source of strong leadership and sustained support.[52]

Decide is a virtual platform for collaboration. It allows sharing events, activities, and news and publishing blogs. It also serves as a virtual space for open discussions on various aspects of decision-making. Decide, enable access to the collection of tools and instructions deemed best practices by the network partners. Stakeholders can create a profile that displays their work in order to aid them in finding partners for collaboration. It also has provisions to co-produce documents and joint calendars in the interactive working spaces. Hub also gives access to tender requests to locate partners looking for technical skills and capacity building.

3.3 PAN AMERICAN HEALTH ORGANIZATION (PAHO)

As early as 1983, the Pan American Health Organization (PAHO), the WHO for the Americans, began promoting HTA in America. Many national and international meetings and consultations were supported by the Technology Development Unit of the PAHO from the mid-1980s until the early 1990s. PAHO published a Regional Strategy for HTA in 1998. In the mid to late 1990s, PAHO became even more active

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[51] Decide Health Decision Hub https://decidehealth.world/en

[52] Niki O'Brie , Ryan L , Wanrudee Isaranuwatchai, Saudamini Vishwanath Dabak, Amanda Glassman, Anthony J. Culyer, Kalipso Chalkidou, How can we make better health decisions: a Best Buy for all?, 3:1543, Gates Open Research (2020) https://doi.org/10.12688/gatesopenres.13063.2

in promoting HTA as the health sector reform became a significant movement in Latin America. HTA agencies from Spain and Canada formed collaborations leading to workshops on HTA and training many professionals working in the decision-making process in Latin America and the Caribbean. An increasing interest in HTA developed in countries like Mexico, Brazil, Argentina, Uruguay, and Chile.

In 1997, MERCOSUR (Argentina, Brazil, Paraguay, and Uruguay economic initiative) organized a Technical Subcommittee on HTA. In 1998 at the II Summit of the Americas (Head of States and Governments of the Countries of the Americas), Santiago de Chile, April 18–19, the work plan included a chapter on "Health Technology Bridging the Americas." In the year 2000, HTA was included as one of the Essential Public Health Functions in PAHO documents and thinking. PAHO became a member of ISTAHC and promoted the participation of experts from Latin America and the Caribbean in the Annual Meetings. Some academic centers began to carry out HTA studies.[53]

Since 2000, PAHO has redefined the approach to health technology through interaction with the countries in[54] the region and has prioritized the strengthening of HTA programs as part of the new approach. PAHO is promoting and supporting the participation of experts in international conferences and training programs (Ulysses and the distance learning course on Health Technology Assessment, AETMIS); collaborating in the organization of HTA Agencies and Centers in the countries; facilitating access to HTA information and databases, and sponsoring internships in HTA. To facilitate the interaction and communication exchange among the experts, a virtual network(Listserv Group hta@listserv.paho.org) was organized in 2004.[55]

3.4 WORLD BANK

The World Bank has also been active in the field of HTA, sponsoring several consultations and conferences on the subject. More importantly it has included HTA in many of its recommendations to countries concerning their health services. The

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[53] David Banta, Health Technology Assessment in Latin America and the Caribbean, *International Journal of Technology Assessment in Health Care, 25*(S1), pp 253-254 https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/health-technology-assessment-in-latin-america-and-the-caribbean/5D578443361D559A032BF4101D1E8185

[54] Supra note 47

[55] Supra note 51

earliest known concentrated involvement in HTA by the Bank was in China during 1987 and 1988. Other countries that have received substantial support from the Bank to develop HTA include Malaysia, Poland, Romania, and Serbia. Although the Bank has promoted HTA in Russia and has helped develop a substantial body of experts, the government has not responded actively to these attempts.[56]

In Russia, discussions on HTA began in 2009. Until 2013 there were no formal HTA agencies in Russia. However there is an increased demand for HTA as an evidence tool for policymakers due to budget constraints. Nevertheless, there are certain HTA bodies that to some extent, influence policy makers through their publications of pharmacoeconomic studies.

In 2012, significant reforms were initiated that have given rise to the introduction of a Diagnosis Related Group system along with attempts at incorporating HTA (for medicine) into Russian laws. In 2015, the Ministry of Health established a Center for Healthcare Quality Assessment and Control, which serves as the primary official agency in Russia. It is charged with delivering improved processes, guidelines, transparency, and public education to the field of healthcare decision-making. Encouraging though this progress is, it represents only a start. Although HTA now has a formal place in healthcare development strategies, the scholarly research and the associated knowledge exchange networks that connect providers, payers, policymakers, the healthcare industry, health economists, and patients remain underdeveloped. Russia is commencing its health technology assessment journey and should proceed cautiously as it moves toward the valuation of health benefits.[57]

3.5 THE COCHRANE COLLABORATION

The UK Cochrane Center was established in 1992 to facilitate and coordinate systematic reviews of (mainly) randomized controlled trials. That Center became the first Cochrane Center in what would become the worldwide Cochrane Collaboration.[58] The Cochrane Collaboration in 1993, it is a not-for-profit organization whose members aim to produce credible, accessible health information that is free from commercial sponsorship and other conflicts of interest. Cochrane

[56] Supra note 47
[57] Valuing Health States in Russia: A First Feasibility Study
https://www.sciencedirect.com/science/article/pii/S2212109919300421
[58] Supra note 47

Reviews are published in full online in the Cochrane Database of Systematic Reviews, which is a core component of the Cochrane Library. The Cochrane Library was first published in 1996, and is now an online collection of multiple databases.[59] The development and growth of the Cochrane Collaboration has been of great value to the field of HTA, for example, in terms of methodological improvements in searching and grading scientific studies, in access to systematic reviews and other important information, and in fostering a broader understanding of the need for evidence in clinical decision making and in health policy making.[60]

3.6 INTERNATIONAL NETWORK OF AGENCIES FOR HEALTH TECHNOLOGY ASSESSMENT (INAHTA)

The establishment of the International Network of Agencies for Health Technology Assessment (INAHTA) was a milestone in the evolution of HTA as it was associated with increased international cooperation.

INAHTA was subsequently established at a meeting in Paris in 1993, hosted by the French national agency Agence Nationale pour le De´veloppement de l'Evaluation l'Évaluation Me´dicale (ANDEM). There were thirteen founding member agencies from Australia, Canada, France, the Netherlands, Spain, Sweden, Switzerland, the United Kingdom, and the United States. The meeting in Paris and at the 1994 meeting of the network, which followed the ISTAHC Annual Meeting in Baltimore, laid down the framework for the structure and activities of INAHTA.[61] Membership was open to organizations that operated ongoing HTA programs, produced regular HTA reports, provided advice to the government, and received at least 50 percent of their operating funds from public sources. Member agencies offered funds to establish a secretariat at the Canadian Coordinating Office for Health Technology Assessment. A three-person executive board steered the administration of the network. A steady growth in the

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[59] Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions. 2nd Edition. Chichester (UK): John Wiley & Sons, 2019.

[60] Supra note 47

[61] Hailey, D.Development of the International Network of Agencies for Health Technology Assessment. *International Journal of Technology Assessment in Health Care, 25*(S1), 24-27 (2009). doi:10.1017/S0266462309090370
https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/development-of-the-international-network-of-agencies-for-health-technology-assessment/FC9EB7D761D5915AD466ECAD35FC1E15

membership of the network can be seen over the years; there were forty-six members from twenty-seven countries by April 2009. Membership includes both national and regional HTA agencies. At present, there are 50 members. In 1996, the INAHTA secretariat was moved to the Swedish Council on Technology Assessment in Health Care (SBU).

The database of abstracts evolved into the HTA Database, which the Center manages for dissemination and reviews at the University of York in collaboration with INAHTA. By mid-2008, the database included 3690 reports and 949 projects. The INAHTA maintains one-page abstracts (INAHTA Briefs) of their recent HTA reports, which are available on their official website; it also provides information on assessments by members. Output from the network includes guidelines and frameworks on HTA, reports of surveys, and joint projects. INAHTA uses working groups of persons from member agencies to develop these reports and maintain communication between member agencies.

In 2008, INAHTA and HTAi entered into a Memorandum of Understanding (MOU), agreeing to cooperate in the promotion of HTA, organization, and governance, scheduling annual meetings, communication, and joint activities. The MOU essentially outlines activities that have been in place for some time. There have also been long-standing links between INAHTA and assessment networks supported by the European Union. There was an open and constructive relationship with the EUR-ASSESS project INAHTA and the current European network, EUnetHTA, has been a collaborative partner since January 2006. The partnership will allow greater access to draft reports, language translation, and peer reviews and provide the opportunity for joint projects.[62]

INAHTA became a collaborating partner with WHO in May 2007, and the network expects to contribute to mentoring and developing HTA in countries and regions with limited HTA capability. INAHTA has also cooperated with PAHO on promoting HTA in Latin American countries and with the Guidelines International Network in developing evidence tables.

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[62] Supra note 59

INAHTA values collaboration with the international HTA community and broader global health community.[63] Their global collaborations involve the following organizations. First among them is the WHO. INAHTA is a member of the Steering Committee of the Decide Health Decision Hub operated by the WHO. The Decide Hub is a virtual space to support collaboration in data-driven health decision-making through health technology assessment, economic evaluation, investment cases, or any other process developed to encourage fair and transparent decision-making in health.[64] The same was discussed in the earlier parts of this chapter.

3.6.1 HEALTH TECHNOLOGY ASSESSMENT INTERNATIONAL (HTAi)

Health Technology Assessment international (HTAi) is the global, non-profit, scientific and professional society for all those who produce, use or encounter health technology assessment (HTA). The HTAi represents 82 organizations and over 2,500 individual members from 65 countries around the world. HTAi is a member-driven organization, representing a variety of stakeholders who have interests in HTA. These stakeholders include researchers, policy makers, industry, academia, health service providers, agencies and patients, and they contribute to balanced conversation around HTA across different areas of practice and jurisdictions.[65]

HTAi's mission is to provide a key forum for those from the worlds of health care, academia, and business interested in the science, development, and application of HTA. To support and promote the development, communication, understanding, and use of HTA around the world as a means of promoting the introduction of effective innovations and effective use of resources in health care. A Memorandum of Understanding between INAHTA and HTAi was originally signed in Montreal in 2008 and renewed in 2021.[66]

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[63] Global Collaboration - INAHTA. https://www.inahta.org/collaboration/
[64] Supra note 63
[65] About HTAi | Health Technology Assessment International (HTAi). https://htai.org/about-htai/
[66] Supra note 63

HTAi's STRATEGIC PLAN 2020-2025: A BRIEF OVERVIEW

VISION: To continue to be the leading global Society for all stakeholders engaged in the production and use of HTA in decision-making. MISSION: To promote the development, communication, understanding, and use of HTA around the world.[67]

STRATEGIC GOALS

The strategic goals aim to expand and grow the presence of HTAi globally through their membership, knowledge sharing, and information dissemination through partnerships. Also, to advance scientific knowledge, support capacity development, and ensure continued financial stability and good governance.[68]

The main focus of HTAi involves developing effective member strategy, partnership, interest group, business development, capacity building, and policy forum strategies.

HTAI 2022 ANNUAL MEETING UTRECHT, NETHERLANDS

HTAI 2022 annual meeting held at Utrecht, Netherlands, called for a lifecycle approach to determine the value of medicines, devices, and other health services that have grown over recent years. Due to the challenges of innovative and novel technologies, disconnected and disparate stakeholders and data requirements, public expectations, and achieving patient-centric health systems. Lifecycle, here, refers to the lifecycle of health technologies. It conveys the idea that HTA needs to explore the value of health technologies from an early stage of development throughout their maturation; as various stakeholders go through the learning curve, indications shift, technological improvements transpire, or parallel developments render the technology obsolete. Such dynamics defy the notion that HTA could be a one-off undertaking.[69]

A lifecycle approach aims to support better reimbursement decisions and more appropriate use of health technologies while encouraging efficiencies. As such, it has been suggested that a lifecycle approach would promote continuous dialogue and the exchange of knowledge between all stakeholders while ensuring that better outcomes

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[67] 2020-2025 Strategic Plan, Developed by the Strategic Planning Working Group in consultation with the Society Membership Approved by the HTAi Board of Directors January 2020 https://htai.org/wp-content/uploads/2019/08/HTAi_strategic-plan_2020.pdf

[68] Supra note 67

[69] 2022 HTAi Annual Meeting. https://www.htai2022.org/

for patients are central to the activities of HTA bodies as they meet their remits.[70] However, the realization of this approach has been slow. Some HTA organizations have recently started implementing the lifecycle approach more actively in their daily practice. For instance, Health Technology Wales uses the lifecycle approach for non-drug health technologies more explicitly.

In contrast, the Canadian Agency for Drugs and Technologies in Health refers to the lifecycle approach in their promotion of Health Technology Management or implements elements of a lifecycle approach such as regular reassessments in their (French) HTA program (Haute Autorité de Santé). Finally, a lifecycle approach may support a more active contribution to disinvesting obsolete and/or non-effective health technologies.

For the health technology assessment (HTA) community to transition and for individual HTA bodies to find their place in a more proactive, global ecosystem that considers whole system value, key questions must be urgently addressed with stakeholders across the lifecycle. The key questions are: What are the implications for the position and role of HTA in healthcare decision-making at a global level and the potential for HTA bodies to participate across the whole lifecycle of health technologies? How does a lifecycle approach to HTA contribute legitimacy, relevance, and public confidence in healthcare decision-making? What are the implications of taking a lifecycle approach for setting HTA priorities and ensuring the sustainability of the HTA process? How can unmet medical needs influence HTA priority setting, and which elements of unmet medical needs should be considered? What does effective and efficient integration of stakeholder perspectives look like in a lifecycle approach? What are best practices in terms of interaction between different healthcare authorities, and how do they perceive different types of evidence over the lifecycle of health technologies? How do other stakeholders such as innovators and patients feel this interaction between healthcare authorities, and what improvements do they seek?[71]

Building on initiatives from a variety of HTA bodies and previous HTAi Annual Meeting and Policy Forum, the HTAi 2022 Annual Meeting offers a global platform

[70] Supra note 69
[71] Supra note 68

to deepen awareness of the consequences of a lifecycle approach to HTA from pre-market, market approval, post-market, and disinvestment; improve knowledge of suitable methods and processes; strengthen connections across stakeholders, and prioritize activities.

3.6.2 GUIDELINES INTERNATIONAL NETWORK (GIN)

The Guidelines International Network (GIN) is an international not-for-profit association of organizations and individuals involved in the development and use of clinical practice guidelines.[72] GIN is a network of organizations and individuals interested in evidence-based guidelines and has one of the world's largest international guideline libraries. Founded in November 2002 and formally incorporated as a company and a Scottish Charity in February 2003, GIN seeks to improve the quality of health care by promoting systematic development of clinical practice guidelines and their application into practice, through supporting international collaboration.[73] Three principal aims:

- Providing a network and partnerships for guideline organizations, implementers, researchers, students and other stakeholders.
- Assisting members in reducing duplication of effort and improving the efficiency and effectiveness of evidence-based guideline development, adaptation, dissemination and implementation.
- Promoting best practice through the development of opportunities for learning and building capacity, and the establishment of high quality standards of guideline development, adaptation, dissemination and implementation.[74]

A Memorandum of Understanding between INAHTA and GIN was signed at the INAHTA Congress in 2009.[75]

3.6.3 i-HTS (formerly EuroScan)

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[72] CPG Partnerships & Collaborators - American Academy of Otolaryngology Head and Neck Surgery. Available at: https://www.entnet.org/quality-practice/quality-products/clinical-practice-guidelines/cpg-partnerships-collaborators/

[73] About GIN - GIN. Available at: https://g-i-n.net/about-gin/

[74] Supra note 73

[75] Supra note 63

International HealthTechScan (i-HTS) is a collaborative network of HTA agencies for the exchange of information on important emerging new drugs, devices, procedures, processes, and settings in health care. The members of i-HTS aim to establish a permanent network among agencies and organizations in the field of HTA to:

1. Evaluate and exchange information on new and changing technologies.
2. Develop the sources of information used.
3. Develop applied methods for early assessment.
4. Disseminate information on early identification and assessment activities.

All i-HTS members are members of INAHTA.

A Memorandum of Understanding between INAHTA and EuroScan (now i-HTS) was signed in 2009.

3.6.4 EUnetHTA

In 2004, the European Commission and Council of Ministers targeted Health Technology Assessment (HTA) as "a political priority", recognising "an urgent need for establishing a sustainable European network on HTA". A Commission call was answered in 2005 by a group of 35 organizations throughout Europe, led by the Danish Center for HTA (DACEHTA) in Copenhagen which led to the activities of the EUnetHTA Project.[76]

EUnetHTA supports collaboration between European HTA organizations that brings value at the European, national, and regional level through:

- The facilitation of efficient HTA resource use.
- The creation of a sustainable system of HTA knowledge sharing.
- The promotion of good practice in HTA methods and processes.[77]

The consequent activities of the European Network for Health Technology Assessment (EUnetHTA) were organized through establishment of the EUnetHTA Collaboration 2009, the EUnetHTA Joint Action 2010-2012, EUnetHTA Joint Action 2 2012-2015 and EUnetHTA Joint Action 3 2016-2020.

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[76] History of EUnetHTA - EUnetHTA. Available at: https://www.eunethta.eu/about-eunethta/history-of-eunethta/

[77] About EUnetHTA - EUnetHTA. Available at: https://www.eunethta.eu/about-eunethta/

The EUnetHTA Joint Action (2010-2012) refined the collaboration structure and tools with attention to global developments in the field. EUnetHTA Joint Action 2 (2012-2015) extended this by strengthening the practical application of tools and approaches to cross-border HTA collaboration, further supporting and refining a system of collaboration in HTA. These two Joint Actions have proven the ability of national HTA organizations to work together and produce valuable products. EUnetHTA Joint Action 3 (2016-2021) developed the final phase of establishing a permanent HTA working structure for Europe, and was succeeded by EUnetHTA 21 (2021-2023), which will build on the achievements and lessons learned from the EUnetHTA Joint Actions and focus on supporting a future EU HTA system under the HTA Regulation.[78]

The EUnetHTA 21 joint consortium is led by ZIN (The Netherlands) and includes the following HTA agencies: AEMPS (Spain), AIFA (Italy), AIHTA (Austria), GBA (Germany), HAS (France), INFARMED (Portugal), IQWIG (Germany), KCE (Belgium), NCPE (Ireland), NIPN (Hungary), NOMA (Norway) and TLV (Sweden).[79]

3.6.5 HTAsiaLINK

HTA agencies are relatively new in Asia. Health technology assessment (HTA) helps provide information regarding resource allocation, including selecting healthcare benefits packages and essential medicines lists. Unfortunately, several factors including, but not limited to, lack of awareness, lack of local epidemiological data, disjointed efforts in research, and the late introduction of the field of pharmacoeconomics, Asia and other regions of the Global South lack the capacity for conducting HTA.[80]

In 2006, the Health Intervention and Technology Assessment Program (HITAP) was established in Thailand. In 2008, the HTA division was established in Taiwan Center

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[78] Supra note 76

[79] Supra note 77

[80] Teerawattananon, Y., Luz, K., Yothasmutra, C.,et al., HISTORICAL DEVELOPMENT OF THE HTAsiaLINK NETWORK AND ITS KEY DETERMINANTS OF SUCCESS. Vol. *34*(3), *International Journal of Technology Assessment in Health Care, pp* 260-266, (2018). doi:10.1017/S0266462318000223 https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/historical-development-of-the-htasialink-network-and-its-key-determinants-of-success/A21CDC7B77F3DC0E86C3374E8B346BBC

for Drug Evaluation (CDE) and the National Evidence-based Healthcare Collaborating Agency (NECA) was founded in Korea. Soon after the establishment of HTA in CDE, HITAP and CDE started collaborations. In June, 2010, HITAP and NECA delegations met at the Health Technology Assessment International (HTAi) annual conference in Dublin, Ireland and agreed on the need for collaborative networking among the regional health technology assessment (HTA) agencies and collaborative research. Finally, a consensus among three organizations (CDE, HITAP, and NECA) and individual researchers from Malaysia and Japan on potential collaboration among HTA agencies meeting in Thailand, 4th September, 2010, initially reached an agreement to distribute an HTA newsletter among agencies in the region. In January, 2011, during the international symposium and workshop for the Asian value for a QALY, hosted by NECA in Seoul, the agreement was reached on establishing the HTAsiaLink and undertaking collaborative research thereafter. The founding organizational members are CDE, HITAP, and NECA.[81]

Its establishment marked a significant step in the diffusion of HTA in the region. The network began with three agencies interested in setting up a collaborative platform for mutual benefit. Over the years, the network grew in membership and in terms of the depth and breadth of economic and health systems research conducted by network members within the region. The network's functions have evolved from a platform for sharing research findings to becoming a vehicle for sharing awareness about the usefulness of HTA evidence in priority settings. The network has been involved in strengthening the capacities of countries that currently have expertise in HTA and introducing HTA to countries where it is a nascent field and has not yet been recognized as a tool for policy-making. HTAsiaLink's historical development offers insights on how collaborations can nurture new initiatives in different countries, how they can benefit HTA development in countries, and lessons on developing a regional HTA network where most countries are low- and middle-income countries (LMICs).[82]

HTAsiaLink also focuses on promoting HTA utilization, developing an efficient methodology for HTA, and encouraging HTA evidence implementation for Universal Health Coverage. HTAsiaLink Annual Conference is the representative academic event that facilitates the exchange of HTA knowledge and experience among member

[81] HTAsiaLink Annual Conference. Available at: https://htasialink.org/about/history.html
[82] Supra note 80

agencies and identifies the development plan for the network next year. Hosted by the member agency annually designated by the HTAsiaLink Board, the conference also functions as the capacity building platform where junior researchers from the member agencies present their study and obtain productive comments from international experts and peers. Around 34 agencies from 17 different countries voluntarily join the network with the common objective of HTA competency improvement.[83]

3.6.6 RedETSA

Launched in Rio de Janeiro in June 2011, the Health Technology Assessment Network of the Americas (RedETSA) is a non-profit network made up of ministries of health, regulatory authorities, health technology assessment agencies , collaborating centers of the World Health Organization/Pan American Health Organization (WHO/PAHO), and educational and research institutions in the region of the Americas. RedETSA has 19 countries represented by 39 institutions, with the aim of strengthening and promoting the health technology assessment process in the Americas, allowing the exchange of information, to support decision-making on the regulation, incorporation, use and substitution of said technologies. The Network conducts meetings and training plans from a distance.[84] The main objectives of RedETSA are:

- Identify the status of HTA at the national, subregional, and regional levels, as well as the priorities for its use in order to facilitate cooperation between countries and institutions through networking;
- Facilitate access to information and the exchange of knowledge on STDs through the Network, through the Regional Platform for Access and Innovation for Health Technologies (PRAIS);
- Strengthen the skills of human resources in STD in health systems;
- Promote good practices for STD;
- Promote cooperation with other HTA networks (national, sub-regional and global);
- Reduce information asymmetry, helping to improve decision-making processes;

[83] HTAsiaLink Annual Conference. Available at: https://htasialink.org/about/overview.html
[84] What is RedETSA? Available at: https://redetsa.bvsalud.org/que-es-redetsa/

- Stimulate the consolidation of existing local ETS networks and the synergy of these networks with RedETSA.[85]

3.7 HEALTH TECHNOLOGY ASSESSMENT IN CANADA

Canada is sparsely populated with a population density of 4 per Km^2. Life expectancy at birth is 82.2 years. Canada spends USD 4900.48 per capita per year on health which is 10.70% of GDP. Canadian Health Technology Assessments are coordinated by government agencies. In Canada, HTA has evolved to include a combination of national and local initiative, reflecting a decentralized healthcare system.

For over 40 years, Canada has had a publicly funded, national healthcare system designed to ensure residents receive "reasonable access" to "medically necessary" healthcare services, regardless of their ability to pay. However, unlike many of its European counterparts, Canada's system is decentralized, comprising 13 separate provincial and territorial health insurance plans. Guided by common values (e.g., equity and solidarity) and responsible for meeting basic coverage standards, these plans determine how best to organize, manage, and deliver health care within their jurisdictions. Decisions regarding which new technologies to include in the basket of publicly funded services, therefore, rest with individual provinces and territories, and the role of the federal government remains primarily limited to premarket approval and, in the case of patented pharmaceuticals price regulation.[86]

Canada's history in health technology assessment (HTA), a field developed to support purchasing or coverage decisions, reflects the decentralized nature of the country's healthcare system. Its roots predominantly exist at the provincial level, with the establishment of the Conseil d'evaluation des technologies de la sante (CETS) (now called the Agence des technologies et des modes intervention en Sante [AETMIS]) in Quebec 20 years ago. Around the same time, a joint committee representing the federal, provincial, and territorial ministries of health identified HTA as one of its key priorities. It announced the creation of a national, independent HTA body called the Canadian Coordinating Office of Health Technology Assessment (renamed the Canadian Agency for Drugs and Technologies in Health (CADTH) in 2006). Funded

[85] Supra note 84

[86] Devidas Menon, Health Technology Assessment in Canada: 20 Years Strong?, Vol 12, International Society for Pharmacoeconomics and Outcomes Research (ISPOR), pp14-19,(2009) Available at: https://www.valueinhealthjournal.com/article/S1098-3015(10)60057-5/pdf

by the provincial, territorial, and federal governments, its mandate is to provide impartial, evidence-based information on the clinical and economic implications of drugs and other health technologies (including devices, procedures, and systems) to the 13 public insurance plans. Since then, HTA has played an increasingly important role in technology coverage policy in Canada.[87]

3.7.1 CANADIAN HEALTHCARE SYSTEM

Canada's health system is a unique combination of public financing and private provision. With the significant government role in financing health services, health technology assessment (HTA) has found a ready audience as a form of policy research. In addition, Canada has been a leader in HTA and is entering a phase of deepening and maturation of HTA activities. Canada's healthcare system is marked by an enduring combination of public financing and private provision. By 1961, agreements were in place with all provinces, and 99 percent of Canadians had free access to the health services covered by the legislation. By 1966, most Canadians were insured for physician services through various private or public insurance plans.[88]

Healthcare is a provincial responsibility under the Canadian Constitution; the federal role is limited to health care financing, health protection, and environmental health. Although all Canadians are insured for health services, 13 different health care systems exist, one in each province and territory and a federally managed one for aboriginal peoples. The present universal health insurance system originated from concerns that existed at both federal and provincial levels. They realized that insurance, particularly for hospital services, was essential to improve the lives of Canadians.

Provinces were offered a federally subsidized program in return for ceding the collection of personal and corporate income taxes to the federal government during the aftermath of the second world war. However, the provinces rejected the same. This disagreement continued, and in 1956, both provincial and federal governments agreed to a financing scheme involving equal federal and provincial shares. By 1958,

[87] Supra note 86

[88] Battista, R., Côté, B., et al.,Health technology assessment in Canada, Vol. *25*(S1), *International Journal of Technology Assessment in Health Care,* pp 53-60. (2009). doi:10.1017/S0266462309090424

a federally subsidized, provincially administered hospital insurance program was in place. This pressured the Saskatchewan government to establish a comprehensive, publicly funded medical insurance program in 1961.[89]

Later Canada's comprehensive Medicare system was created, with federal contributions conditioned on four criteria: services were to be comprehensive, benefits were to be universally available, coverage was to be portable from province to province, and the system of insurance was to be publicly administered. All provinces had joined the scheme by January 1, 1971. Despite provincial variation, Canada's current healthcare system represents a balance among government direction, consumer choice, and provider autonomy. Universal health insurance, administered by provincial governments on a shared-cost basis with the federal government, covers inpatient and outpatient care in hospitals, ambulatory care and, in some provinces, prescribed medications and appliances.[90]

In the Canadian healthcare system, hospitals are autonomous corporate bodies administered by a board of directors. Here the patients are free to consult the medical practitioner of their choice. The payment model adopted for reimbursing the physician is fee-for-service. Their fee schedules are determined by negotiations between provincial medical associations and ministries of health.

In Canada the diffusion of healthcare technology is determined largely by the health care system's overall structure. Factors promoting or limiting the system's expansion have significant effects on technology diffusion. Among these structural factors, autonomy of both hospitals and physicians is the main force favoring technology acquisition and use. Fee-for-service remuneration, making the physician a quasi-entrepreneur in a publicly funded system, often creates incentives for practitioners to adopt and use technology. Hospitals' pursuit of institutional development and physicians' pursuit of professional development combine to favor the rapid uptake and diffusion of innovative health care technologies. Countering

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[89] Nicola Allen, Stuart R. Walker, Sam Salek, Lawrence Liberti, Health Technology Assessment (HTA) Case Studies: Factors Influencing Divergent HTA Reimbursement Recommendations in Australia, Canada, England, and Scotland Vol 20, Value in Health, pp 320-328, Available at: https://www.valueinhealthjournal.com/action/showPdf?pii=S1098-3015%2816%2930019-5

[90] U.S. Congress, Office of Technology Assessment, Health Care Technology & Its Assessment in Eight Countries, OTA-BP-H-140 (Washington, DC U.S. Government Printing Office, February 1995).

these expansive forces are several funding and management mechanisms, the most important of which is the global budget formula used to fund hospitals.[91]

3.7.2 CANADIAN HEALTH TECHNOLOGY ASSESSMENT

The majority of HTA activity in Canada originates from four government-operated agencies: the Conseil d'Évaluation des Technologies de la Santé du Québec (CETS); the Canadian Coordinating Office for Health Technology Assessment (CCOHTA); the British Columbia Office of Health Technology Assessment (BCOHTA); and the Health Technology Assessment Unit of the Alberta Heritage Foundation for Medical Research (AHFMR). Other agencies, such as the Calgary Health Technology Implementation Unit (CaHTIU), along with hospitals, perform regionally and locally focused Health Technology Assessment.

Emergence of HTA in Canada took place in a relatively favorable environment; which is attributable to several factors such as positive predisposition of the physicians, patients, management, and likely the paucity of Canada-based health technology developers and producers. Although the situation is somewhat less simple with pharmaceuticals, Canada's historically low levels of expenditure on research and development, coupled with the proximity of the United States, so that new technologies are available relatively quickly, meant that HTA could emerge as policy-relevant research to assist governments in spending public resources optimally, rather than as an adjudication mechanism between promoters of technologies and those expected to pay their costs.[92]

The CTFPHE, or the Canadian Task Force on the Periodic Health Examination, is an early example of organized technology assessment in Canada. However, it proved to be ineffective. Canada's first operational technology assessment body was established in Quebec in 1988, known as CETS. CETS was mandated to promote, support, and produce health care technologies assessments, counsel the Minister of Health and Social Services, and disseminate its syntheses and summaries of available knowledge to all the key constituencies of Quebec's health care system.

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[91] Supra note 90

[92] Supra note 88

In 1989, shortly after CETS' creation, an interprovincial symposium on technology assessment was organized to bring together federal and provincial officials and academics. At this meeting, federal and provincial governments agreed to jointly establish and fund the Canadian Coordinating Office for Health Technology Assessment (CCOHTA).[93] CCOHTA later became the Canadian Agency for Drugs and Technologies in Health (CADTH) in 2006.[94] In 1991 British Columbia established the British Columbia Office of Health Technology Assessment (BCOHTA), with an annual budget of $350,000. The BCOHTA is mandated to promote and encourage assessment research in policy and planning activities at the government level and policy, acquisition, and utilization decisions at the clinical, operation, and government levels. It sought to examine, more specifically, the interactions of health technology with society. Government funding for BCOHTA ceased in 2002 when the government made major cuts to its operating budget.[95]

The provinces of Alberta and Saskatchewan also established technology assessment. An HTA Program was established in the Alberta Department of Health in 1993 and then transferred to the Alberta Heritage Foundation for Medical Research in 1995. It was transferred to the Institute of Health Economics (IHE) in 2006, where it is currently situated.[96] In Ontario, the Center for Health Economics and Policy Analysis (CHEPA) at McMaster University is funded by the provincial government, the university, and other sources. In 1992 the Institute for Clinical Evaluative Sciences (ICES) was established at the University of Toronto as a joint venture of the provincial government and the Ontario Medical Association (OMA).[97] In addition to the establishment of a number of HTA organizations, the culture of HTA has diffused relatively rapidly across Canada.

3.7.3 NATIONAL EFFORTS TO INCORPORATE HTA

Established as the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) in 1989, CADTH originated as an independent, not-for-profit government organization aimed at improving coverage decisions to ensure appropriate and

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[93] Supra note 90
[94] Supra note 88
[95] Supra note 88
[96] Ibid
[97] Supra note 90

cost-effective healthcare for Canadians. CADTH provides health care decision makers in Canada with objective evidence to help them make informed decisions regarding the optimal use of drugs and medical devices in the healthcare system.[98] CADTH exists to support evidence-based, coherent, fair, and transparent decision making on the adoption and use of health technology.[99] For over 30 years, it has aspired to help policymakers, clinicians, and patients make better decisions relating to medical, dental, and surgical devices, procedures, and programs; pharmaceuticals; and diagnostic tests. They have become experts at objective assessment and evaluation.

CADTH, Canada's national HTA agency, remains the largest producer of HTA in the country. Governed by a board representing the federal, provincial, and territorial ministries of health (not including Quebec), CADTH conducts assessments on technologies deemed to be of national interest. Specifically, potential technologies (including devices, systems, and existing drugs) are identified by the various levels of government and forwarded to one of two CADTH committees, depending on their type: the Advisory Committee on Pharmaceuticals or the Devices and Systems Advisory Committee. Only a handful of the devices, systems and existing drugs that comprise Canada's healthcare system undergo formal reviews of their clinical and cost-effectiveness. However, this is not the case for new drugs.[100]

In September 2003, Canada launched the Common Drug Review (CDR) process, a voluntary initiative for provincial and territorial plans. Housed at and managed by a directorate within CADTH, the CDR undertakes HTAs of new drugs to provide listing recommendations to all drug plans. Consequently, it represents an effort to reduce duplication and maximize the consistency and the quality of assessments used to aid decision-making across the country.

Common Drug Review provided a pan-Canadian approach for HTA, commissioned and approved by the Conference of Federal/Provincial/Territorial Deputy Ministers of Health to review new drugs and new drug indications. The Pan-Canadian approach "assesses the impact of new technology and provides advice on how to maximize its

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[98] Who We Are available at: https://www.cadth.ca/who-we-are

[99] CADTH 2018-2021 Strategic Plan. Available at: https://www.cadth.ca/sites/default/files/corporate/planning_documents/CADTH_2018-2021_Strategic_Plan.pdf

[100] Supra note 86

effective utilization in the future." Shortly after this, financial contributions to CADTH by the federal government increased exponentially. Although it may be argued that such a funding commitment is, in itself, an indication of the value of HTA to policymakers across the country, there have been relatively few formal attempts to examine, on a national level, exactly how it is used in decision-making.[101]

The CDR process broadly comprises three steps. A submission is prepared by the manufacturer in accordance with explicit submission guidelines and sent to the CDR Directorate. A Review Team (consisting of in-house and contracted reviewers and external experts) is assembled to draft a report based on clinical and economic evidence provided by the manufacturer and identified through independent literature searches. The report is then reviewed by the Canadian Expert Drug Advisory Committee (CEDAC) (a national, appointed body of physicians, pharmacists, other healthcare professionals, and a member of the public), which evaluates the comparative therapeutic benefits and cost-effectiveness of the drug relative to accepted therapy and makes one of three funding recommendations to participating plans: list without conditions ("yes"), list with conditions, or do not list ("no"). Lastly, each plan considers the recommendation separately, which independently makes its own final decision.[102]

The strategic goals of the CADTH strategic plan 2018-2021 were to close the gap between evidence, policy and practice, Adopt a life-cycle approach to health technology assessment and Anticipate health system and health technology trend, and develop agile management strategies.[103] Brian O'Rourke, BSc (Pharm), PharmD, president and CEO of the Canadian Agency for Drugs and Technologies in Health (CADTH), summarized his view of HTA organizations around the world, "If you've seen one HTA, you've seen one HTA. We all differ based on our governance, whether we're part of government or not-for-profit, how we're funded, the transparency that we have, and the scope of work. Some are specifically focused on devices and some are specifically focused on drugs and some have a much broader portfolio covering both and even public health interventions." O'Rourke considers CADTH to be more of a full-service HTA agency, evaluating pharmaceuticals, medical devices, medical,

[101] Supra note 86
[102] Ibid
[103] Supra note 99

dental, surgical devices, procedures, programs and diagnostics—basically, any clinical intervention where there is a need for evidence to support a reimbursement of that particular intervention.[104]

3.7.4 EFFORTS AT LOCAL LEVEL TO INCORPORATE HTA

Out of 13 provinces and territories, three ministries of health have created and invested considerably in HTA initiatives designed to meet their specific needs. These initiatives include the AMIS, the HTA unit at the Institute of Health Economics (previously housed within the Alberta Heritage Foundation for Medical Research [AHFMR]) and the Medical Advisory Secretariat within Ontario's Department of Health and Long-Term Care comprise government-funded HTA bodies whose sole role is to produce assessments for policymakers in Quebec, Alberta, and Ontario, respectively.[105] In Alberta and Ontario, their work is supplemented by university-based programs, which hold grants from the health ministries to conduct HTAs and build HTA capacity in the two provinces. On a more local level, some hospitals in Quebec and regional health authorities in Alberta have established their own HTA units to produce information required for specific technology acquisition and management decisions.

OTHER CANADIAN APPROACHES: HTA IN BRITISH COLUMBIA

HTA in Canada extends beyond CADTH, as a recent survey identified 44 different HTA organizations within Canada. One such example is the University of British Columbia's Therapeutics Initiative. In 1994, the British Columbia Ministry of Health, concerned about both the increased use of prescription medications and the introduction of new (and often expensive) drugs, partnered with independent academic researchers at University of British Columbia to establish the Therapeutics Initiative created an outcomes-based, decision making framework that supports responsible funding decisions in the province, using published literature, Cochrane Collaboration meta-analyses, and scientific material presented by the pharmaceutical industry.[106]

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[104]Michele Clearly, The State of HEALTH TECHNOLOGY ASSESSMENT - ISPOR. Available at: https://www.ispor.org/docs/default-source/publications/value-outcomes-spotlight/march-april-2020/feature_state-of-hta.pdf

[105] Supra note 86

[106] Supra note 99

The information from these stakeholders helps contextualize the national CADTH recommendations for British Columbia. As with many HTA organizations, orphan drugs pose a significant challenge here. The evidence associated with the regulatory approval of most orphan drugs is very sparse, creating a lot of uncertainty for public and private payers. Yet, evaluation of how these types of drugs and disruptive technologies support patient outcomes is consistent with the core values of the Canadian system.[107]

With multiple HTA organizations spread across the country, Canada has been a vigorous user of HTA. HTA's influence has been most identifiable through the inputs of HTA organizations into the policy process at provincial government levels, but increasingly, hospitals are developing HTA competencies and capacity. Public engagement has been modest and the overarching policy environment of Canada's health system is such a significant determinant of the system's functioning and the use and diffusion of technologies that practitioners and individual providers have been relatively unengaged and arguably only indirectly affected by HTA.[108]

Further, the HTA stakeholders perceive the need for a framework to strengthen collaboration and cooperation across regions and between stakeholder groups within the HTA network. This need is perceived as more pressing than that for more explicit decision making frameworks that connect evidence, even though the quality of the evidence is perceived as important. Canadian HTA is a strong advocate and early adopter of participatory decision making practices, which may explain that the focus of stakeholders is on the linkages that strengthen inclusive participation. Solidifying the function of the HTA process in Canada is critical currently.[109]

Yet another critical feature of HTA in Canada is the participation of patients and the public in its process. Most Canadian HTA programmes include patient or public members on project specific working groups established for an HTA, on standing expert or advisory committees that make recommendations, or on both. In a 2013 HTA of alternatives to seclusion and restraint for psychiatric patients, patient

[107] Supra note 104

[108] Supra note 86

[109] Wiesława Dominika Wranik ,Ronaldo-Raul Székely ,Susanne Mayer ,Mickaël Hiligsmann &Kei Long Cheung, The most important facilitators and barriers to the use of Health Technology Assessment in Canada: a best–worst scaling approach, Vol 24, Journal of Medical Economics, Pp 846-856, (2021) https://doi.org/10.1080/13696998.2021.1946326

members were recruited through mental health organizations. In this instance, the direct involvement of patient representatives helped to integrate patients' perspectives during discussions, obtain feedback on HTA results and enhance credibility and confidence in results. In some jurisdictions, patient representatives are members of expert committees that have the mandate to provide recommendations on the funding and use of health technologies, while in other jurisdictions patients' perspectives are presented by public members during expert committee deliberations. At CADTH, two patient members sit on the expert committees with the additional responsibility of summarizing and presenting patient group input during deliberations for each medicine under review. While there are variations across programmes, the inclusion of patient or public members helps ensure that patient relevant information is included within deliberations.[110]

An important challenge, however, is identifying people to fill this role, and most committees have developed criteria by which to recruit and select members. There is general agreement that patient or public committee members should represent the broad perspective of the people who may use or have a need for a health technology under review. To be meaningful, committees must deliberate with knowledge of a variety of patients' experiences, including experiences over time and within different aspects of their lives. At CADTH, for example, patient members are selected for the expert committee based on their demonstration of personal knowledge of, experience with and understanding of issues related to cancer and its management, among other qualifications. Patients or public members can effectively bring this perspective to deliberations; however, in order to do so they must also have the confidence to express their opinions and encourage a discussion that reflects the patient perspective as part of a highly technical conversation with other members, clinical experts, researchers and decision makers.

3.8 HEALTH TECHNOLOGY ASSESSMENT IN UK

The United Kingdom consists of four countries namely, England, Scotland, Wales and Northern Ireland. The UK has a constitutional monarchy, and a single sovereign body governs all four countries. Northern Ireland has regional independence but does not

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[110] Karen M. Facey, Helle Plough Hausen, Ann N.V. Single, Patient Involvement in Health Technology Assessment, pp 256-257, (Springer Nature Singapore Pte Ltd.,2017)

have a federal relationship. Whereas, Wales and Scotland have a degree of administrative devolution of limited significance, even though it has led to some differences as to how health services are organized.

Healthcare in the United Kingdom is publicly funded and generally paid for by taxation. However, tha UK also has a private healthcare sector. The UK has a government-sponsored universal healthcare system called the National Health Service (NHS), which was founded in 1946 and it is responsible for the public healthcare sector of the UK. The NHS consists of a series of publicly funded healthcare systems in the UK. It includes the National Health Services (England), NHS Scotland, NHS Wales, and Health and Social Care in Northern Ireland. Citizens are entitled to healthcare under this system but have the option to buy private health insurance as well. The UK's healthcare system is one of the most efficient in the world, according to a study of seven industrialized countries.[111] The Commonwealth Fund report looked at five performance areas- quality, efficiency, access to care, equity, and healthy lives; the Netherlands ranked first, closely followed by the UK and Australia. The UK performed well regarding the quality of care and access to care. Regarding access to care, it is stated that: "The UK has relatively short waiting times for basic medical care and non-emergency access to services after hours, but has longer waiting times for specialist care and elective, non-emergency surgery."[112]

HTA has long been a policy priority in the UK. Health technology and health technology assessment (HTA) gained increasing attention in the NHS during the reforms that took place beginning in 1990 as part of a more comprehensive NHS Research and Development (R&D) strategy. The strategy promoted a knowledge-based health service with a robust research infrastructure and the capacity to review its needs critically. HTA is the largest and most developed of the programs within the strategy. It has a formal system for setting assessment priorities involving widespread consultation within the NHS and a National Coordinating Center for Health Technology Assessment based at the University of Southampton, the UK has been highly active in the HTA research programme of international reputation. The Strategy supports related centers such as the UK Cochrane Center and the NHS

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[111] Josh Chang, Felix Peysakhovich, Weimin Wang, Jin Zhu, The UK HealthCare System - Columbia University. Available at: http://assets.ce.columbia.edu/pdf/actu/actu-uk.pdf

[112] Ibid

Center for Reviews and Dissemination. A hallmark of the HTA program is substantial public participation. The UK has made a significant commitment to HTA and to seeking effective means of reviewing and disseminating the evidence.[113]

Over the last decade, three key HTA users have emerged: the National Institute for Health and Clinical Excellence (NICE) in England, the Scottish Medicines Consortium (SMC) in Scotland and the All Wales Medicines Strategy Group (AWMSG) in Wales. These institutions through the development and application of scientific methods has led to the UK's approach to health technology assessment becoming internationally renowned as transparent, robust, and inclusive. Moreover, the UK has been successful in controlling pharmaceutical expenditure, which as a proportion of total health spending has remained stable, at around 12%, and one of the lowest levels seen in OECD countries. International surveys also reveal that the UK provides relatively quick access to most new medicines, although at a rate slower than some European countries such as Germany, Denmark, and the Netherlands. However, looking forward, the UK, like many other countries, is facing several important challenges and opportunities when introducing new technologies.[114]

In the UK, HTA has broadly focused on two issues:

- Clinical effectiveness – how do the health outcomes of the technology compare with available treatment alternatives?
- Cost-effectiveness – whether these improvements in health outcomes commensurate with the additional costs of the technology?[115]

3.8.1 THE DEVELOPMENT OF HTA IN THE UK

The early 1970s saw an increasing concern on the effectiveness of the British health services, especially in relation to their considerable cost. During this period a number of organizations became involved in HTA. The Medical Research Council (MRC)

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[113] Woolf, S., & Henshall, C, HEALTH TECHNOLOGY ASSESSMENT IN THE UNITED KINGDOM, *16*(2), Int J Technol Assess Health Care*, pp* 591-625. (2000). doi:10.1017/S0266462300101175

[114] Michael Andersona, Michael Drummondb, David Taylorc, Alistair McGuirea, Paul Carterd, Elias Mossialosa, Promoting innovation while controlling cost: The UK's approach to health technology assessment, Vol 126, Health policy, pp 224–233, (2022). https://doi.org/10.1016/j.healthpol.2022.01.013

[115] Rebecca Taylor, Rod Taylor,What is health technology assessment? Available at: http://www.bandolier.org.uk/painres/download/whatis/What_is_health_tech.pdf

funded a large number of high-quality clinical trials that were done as a part of research and not for strategic purposes such as policy making or improving healthcare quality. Other sources of HTA included industry, charitable organizations, universities and medical centers, and the Department of Health (DH).

In the early 1980s, the DH commissioned a study of heart transplantation's effectiveness and cost-effectiveness, which was widely regarded as one of the best examples of HTA of its era. later, the launch of the R&D Programme marked a shift in emphasis away from the NHS as a passive recipient of new technology to a knowledge-based health service with a robust research infrastructure and competence in critically reviewing its own needs. The most significant expenditure of the R&D Programme was funding for original research, mainly clinical trials, based on national health priorities. However, the R&D Programme showed an increasing commitment over time to synthesizing information on health technology into policy-oriented reports. In addition, the R&D Programme undertook to coordinate HTA-type research whatever its source, to ensure the appropriate use of the results and to avoid wasteful duplication.[116]

However, due to insufficient funds, the need for priority setting, commissioning studies, assessment of the results from studies, and disseminating results was recognized, and the National Coordinating Center for Health Technology Assessment (NCCHTA) carried out the same on contract. Additionally, the contracts undertaken by independent evaluation groups for the National Center for Health and Clinical Excellence (NICE) for the technology assessment are managed by NCCHTA. NICE was established as an NHS special health authority in 1999, and is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. NICE was established to produce national guidance on specific health technologies, including both drugs and medical devices, and clinical practice. It has subsequently assumed the responsibilities of the Health Development Agency and is now structured across three different centers: the Center for Public Health Excellence, the Center for Health Technology Evaluation, and the Center for Clinical Practice.[117]

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[116] Drummond, M., & Banta, D. (2009). Health technology assessment in the United Kingdom. *Int. J of Technology Assessment in Health Care, 25*(S1), 178-181. doi:10.1017/S0266462309090618

[117] Supra note 115

The R&D Programme established the UK Cochrane Center in 1992 to facilitate and coordinate systematic reviews of controlled clinical trials. The worldwide Cochrane Collaboration was developed through this center. In addition, the Programme also established the NHS Center for Research and Dissemination at the University of York in 1993. The two centers were intended to serve complementary roles. The Cochrane Center was to focus on investigator-led, continuously updated reviews of all trials in particular areas. The York Center was to respond in a relatively short period to pressing problems faced by decision-makers by drawing on all relevant research, including primary research and the work of Cochrane groups.[118]

3.8.2 SCOPE AND ACTIVITIES OF UK HTA

NICE is responsible for assessing the clinical and cost effectiveness of new health technologies in England. It has programs for drugs, devices, diagnostic procedures, and public health interventions. Except for the Interventional Procedures Program (which considers only clinical evidence), all the other programs consider clinical and cost effectiveness. When assessing new technologies NICE will commission an external review of the evidence, usually undertaken by an independent academic center. For single technology appraisals (STA), the independent academic center will critique the manufacturer's evidence submission and cost effectiveness model.[119]

The Health and Social Care Act (2012), in April 2013, introduced a number of structural changes into the NHS in England. The result of this is that NICE has a more significant role in the healthcare system and has initiated a major new programme focused on standards in the social care sector. Additionally, NICE has been given the status of a non-departmental government body (NDGB), meaning that even though NICE is accountable to the Department of Health (DoH), they are operationally independent from the government in power. Finally, the Act also reiterated the legal obligation for commissioners to fund guidance published by NICE through its technology appraisals and highly specialized technologies programme. The DoH is responsible for referring technologies to NICE that have a significant health benefit,

[118] Supra note 116
[119] Supra note 114

impact on other health-related government policies or where NHS resources are used inappropriately.[120]

There are similar bodies in other parts of the UK, including the SMC in Scotland and AWMSG in Wales, which assess health technologies. Both SMC and AWMSG evaluate pharmaceuticals. The remit of AWMSG is complementary to that of NICE, only including the assessment of new drugs that are not on the 12-month work program of NICE. Further, NICE guidance can supersede AWMSG recommendations.[121] In contrast, the scope of SMC is not explicitly complementary to NICE on a case-by-case basis. Till date, SMC has chosen to support several MTAs undertaken by NICE, likely because these assessments are exceptionally resource intensive. The arrangement in Northern Ireland is that the local Department of Health endorses NICE guidance unless it is not found locally applicable.[122]

NICE bases its recommendation, primarily on an assessment of the incremental cost-effectiveness ratio of a new technology and how this compares to their cost/QALY threshold. The central feature for appraising technologies that NICE, SMC, and AWMSG utilize is the calculation of the incremental cost per quality-adjusted life-year (QALY) gained, over and above the current standard of care, and to compare this with a decision-making threshold. The QALY is intended to provide a generic measure of 'health gain' and combines data on the extension of and quality of life. Quality of life is estimated using health utilities, representing preferences for different health states. NICE will only accept indirect utility estimates when patients are asked to fill in a quality of life questionnaire, which is then converted into a health utility value. SMC will accept both indirect and direct health utility estimates when patients are asked their preferences for different health states directly using choice experiments such as a standard gamble or time trade-off. The decision-making threshold is intended to represent the opportunity cost of the current NHS budget constraint. Therefore, by comparing the incremental cost per QALY

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[120] Tim Wilsdon, Eva Fiz and Artes Haderi, A comparative analysis of the role and impact of Health Technology Assessment: 2013 -Final Report Available at: https://media.crai.com/sites/default/files/publications/A-comparative-analysis-of-the-role-and-impact-of-Health-Technology-Assessments-2013.pdf

[121] Varnava A, Bracchi R, et al., New medicines in wales: the all wales medicines strategy group (awmsg) appraisal process and outcomes. Vol.36, Pharmacoeconomics, pp 613–24, (2018). Available at: https://link.springer.com/article/10.1007/s40273-018-0632-7

[122] Supra note 114

gained of a given health technology with the threshold, an assessment can be made of whether adopting the new technology will generate more QALYs than would be lost from the treatments displaced under the budget constraint. Ultimately, the determination of a threshold is essentially a value judgment.[123]

Another difference between SMC and NICE is that the local commissioning bodies in England, and health boards and trusts in Wales and Northern Ireland are legally required to make technologies recommended by NICE available to patients whereas, SMC recommendations are advisory. Hence NICE is more open to legal challenge than SMC. NICE processes are therefore more robust and include a longer timeline for appraising new technologies; which varies depending on whether it is a STA or MTA.

ASSESSMENT OF MEDICAL DEVICES IN THE UK

There has been much greater activity in the assessment of novel pharmaceuticals than of medical devices in the UK. There are several reasons for this. First, the expenditure of devices may not be so visible, in so far as some devices represent a small component of the cost of (say) a complicated surgical procedure. Secondly, whereas there is often a formal procedure, at national or local level, to approve drugs for inclusion on a formulary or approved 'list,' the same is not often the case for devices. Thirdly, there are a number of particular characteristics of medical devices that make their economic assessment more challenging. These include the relative lack of controlled clinical studies estimating relative treatment effect, the incremental nature of innovation in devices, the impact of the user 'learning curve' for devices, more dynamic pricing, and the broader organizational consequences of adopting a new device. In response to these challenges, the Medical Technologies Evaluations Programme (MTEP) was introduced by NICE in 2010. Whereas, the SMC and AWMSG are yet to introduce a similar programme dedicated to the evaluation of medical devices.[124]

[123] Supra note 114
[124] Ibid

3.9 HEALTH TECHNOLOGY ASSESSMENT IN AUSTRALIA

Australia is a federation that comprises one commonwealth, six states and two territory governments. Coordination of public healthcare delivery is the responsibility of the health minister of the Australian, state, and territory governments. They are supported by the Australian Health Ministers' Advisory Council(AHMAC), a committee of the heads of health authorities in each jurisdiction.[125] A distinctive feature of Australian healthcare is the diffusion of responsibilities between governments, particularly regarding the provision of healthcare, which is combined with a substantial private section (private insurance/private financing).[126] The Australian Government's contributions include the two national subsidy schemes, Medicare and the Pharmaceutical Benefits Scheme (PBS).[127] Medicare was established in 1984. It is Australia's universal health insurance scheme, and it provides universal access to healthcare to all, regardless of ability to pay. PBS subsidizes payments for a high proportion of prescription medications bought from pharmacies. The PBS has a dominant place in influencing the use of pharmaceuticals in Australia.[128]

3.9.1 INTRODUCTION AND DEVELOPMENT OF HTA IN AUSTRALIA

At the forefront of the HTA revolution, in1992, Australia became one of the first countries to require HTA evidence to be submitted to decision-makers when considering the reimbursement of procedures, diagnostic tests and medical devices in Australia.[129]

The HTA process is conducted by a number of bodies, the most prominent being the Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services

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[125] Hailey, D. The history of health technology assessment in Australia, *25*(S1), *Int. J of Technology Assessment in Health Care,* pp 61-67, (2009). doi:10.1017/S0266462309090436

[126] Hansoo Kim, MSc, Joshua Byrnes, PhD, Stephen Goodall, Health Technology Assessment in Australia: The Pharmaceutical Benefits Advisory Committee and Medical Services Advisory Committee, Vol. 24, Value in Health, pp 6–11, (2021). Available at: https://reader.elsevier.com/reader/sd/pii/S221210992030666X?token=274573BBB5938DED2E6D53E8A1E9DD70DB79D19322677835BF3B9E92792076BB909A5B5CB6513945502E6F8934A09EB6&originRegion=eu-west-1&originCreation=20220706071251

[127] Supra note 125

[128] Ibid

[129] Ibid

Advisory Committee (MSAC).[130] The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent committee composed of experts responsible for assessing all pharmaceutical technologies that will be recommended for inclusion in the Pharmaceuticals Benefits Scheme (PBS). The assessments are based on a clinical and cost-effectiveness analysis and may, under some circumstances, consider indirect costs and social gains as part of the assessment. The regulatory approval is undertaken by the Therapeutic Goods Administration (TGA) in consultation with the Advisory Committee on Prescription Medicines (ACPM), and the HTA recommendation follows this approval.

Once a medicine or medical device is granted regulatory approval by the Therapeutic Goods Administration (TGA) it can be marketed by the sponsor, and purchased by patients. However since most patients cannot afford the expense of many new medicines and devices, they must wait until it is reimbursed by the Government, which requires it to undergo Health Technology Assessment (HTA).[131]

However, in 2011 parallel processing was introduced as part of the Memorandum of Understanding between the Department of Health (DoH) and Medicines Australia. This means that the regulatory approval process undertaken by the TGA and assessment by the PBAC can occur in parallel. This is an essential step towards a faster process and improved accessibility. However, PBAC recommendations are not made public until TGA outcomes are known. Prices are negotiated within the Pharmaceutical Benefits Pricing Authority (PBPA), which considers the HTA recommendations from the PBAC regarding the cost-effectiveness of the new medicine. PBAC does not assess medicines funded through the state government. The result is that medicines, predominantly dispensed in the hospital, may receive immediate funding from the state government without an HTA.[132]

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[130] PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA, The New Frontier - Delivering better health for all Australians Inquiry into approval processes for new drugs & novel medical technologies in Australia Available at: https://parlinfo.aph.gov.au/parlInfo/download/committees/reportrep/024755/toc_pdf/TheNewFrontier-DeliveringbetterhealthforallAustralians.pdf;fileType=application%2Fpdf

[131] Supra note 130

[132] Jonas Hjelmgren, Fredrik Andersson, Fredrik Berggren, Health Economic Guidelines—Similarities, Differences and Some Implications, Vol 4(3), Value in Health, pp 225- 250, (2001). Available at: https://reader.elsevier.com/reader/sd/pii/S1098301511700304?token=50AD6F4FF2B1A4128C03800339704EF2A7FDDD9A5719F84FC2D117A433D36EB3AF203A821EDEB0E67A8CB18A94AAFC02&originRegion=eu-west-1&originCreation=20220708070530

One of the strengths of federal HTA processes in Australia is the national consistency in the availability of new technologies through the direct link between assessment and public funding; however, the independence of the medical and pharmaceutical approval processes has raised a number of additional issues. As the PBAC and MSAC operate independently, there is the potential for inconsistency in methodologies, outcome measures and, more broadly, in what thresholds of evidence are used.[133]

Another strength of the Australia HTA process is that the evaluations of reimbursement submissions are independently performed by academia and other independent groups in Australia.The early adoption of HTA by the Australian government has resulted in an increased capacity of competent health economists or HTA specialists compared with other jurisdictions. However, there has been a reluctance by both agencies to adopt contemporary HTA practices, in particular in the case of economic evaluation techniques. For example, probabilistic sensitivity analyses are not required in the assessment of economic uncertainty by either committee. However, the introduction of the Medical Research Future Fund in Australia has now established a funding mechanism that may enable PBAC and MSAC to influence or shape the public funding of HTA research in Australia. [134]

[133] Gisselle Gallego & Anthony Harris, Evaluation in a disconnected healthcare system: problems and suggested solutions from the Australian HTA review, Vol. 10:6, Expert Review of Pharmacoeconomics & Outcomes Research, pp 615-617, (2010) DOI: https://doi.org/10.1586/erp.10.74

[134]Supra note 126

CHAPTER 4

4. HEALTH TECHNOLOGY ASSESSMENT IN INDIA AND ITS ROLE IN HEALTH POLICY MAKING

Historically and culturally, India is a land of diverse healthcare practices, including traditional and alternative medicine, such as Ayurveda, Unani, Homeopathy, yoga, and Siddha, along with allopathic medicine. Further, India is one of the countries with a very high out-of-pocket (OOP) healthcare expenditure. Over decades, India has made strides in improving its indicators on healthcare; however, public expenditure on health remains low, with high out-of-pocket expenditure and substantial variation in health outcomes across the country.[135] The OOP expenditure typically includes doctors' consultation fees, diagnostic tests, the cost of medicines and medical appliances, and hospitalization costs. The extensive OOP spending on healthcare results in financial catastrophe. The Indian government sees the achievement of UHC as a tool to reduce the catastrophic OOP health expenditure and ensure affordability and accessibility to essential healthcare for the entire Indian population. Only in the recent past, the Indian government unveiled the largest health insurance scheme in the world, the Ayushman Bharat – Pradhan Mantri Jan Aarogya Yojana.

Further, the states must make decisions for allocating resources regarding what to provide, to whom, and how much. Informed Policy decisions regarding health resource allocation, i.e., clinical effectiveness studies, cost-effectiveness studies, budget impact studies, and ethical, social, and political feasibility studies, require a systematic process for generating policy-relevant evidence. This systematic process falls under the broad umbrella of health technology assessment (HTA).

HTA is the international gold standard for using health economic principles to assess evidence for cost, clinical effectiveness, safety, and equity comparatively to provide evidence as to whether an intervention is a cost-effective investment within a given health system and to assist in the prioritization of health resources.[136] HTA is a

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[135] Reddy KS, India's Aspirations for Universal Health Coverage. Vol. 373(1), N Engl J Med., pp 1–5, (2015) DOI: 10.1056/NEJMp1414214

[136] Gavin Surgey, William Reuben, Fatima Suleman, Kalipso Chalkidou, Jacqui Miot, and Karen Hofman, Introducing health technology assessment in Tanzania. Vol 36, Issue 2, Intl J of Technology Assessment in Health Care, pp. 80 - 86,(2020). DOI: https://doi.org/10.1017/S0266462319000588

multidisciplinary process to systematically evaluate the clinical, social, economic, organizational, and ethical issues of health intervention or technology so that the intervention offering maximum health gains from limited or scarce resources can be selected.[137]

The momentum for prioritizing spending on healthcare has been building over years. Discussion of HTA in India began to move beyond academia and into official government policy after the 12th Five Year Plan and NHP. 2017. These marked a significant shift in the Government's commitment toward a more effective resource allocation for health. As a result of commitment to UHC and access to quality healthcare, the Planning Commission, now NITI Aayog, set up a High-Level Expert Group to examine what UHC would entail. To proceed with the evidence-based decision-making for healthcare, the Planning Commission laid down the mandate for HTA under the Department of Health Research (DHR) in the Ministry of Health and Family Welfare, Government of India.[138] Accordingly, a Medical Technology Assessment Board was to be set up and, over the last couple years, the DHR has developed a structure to introduce HTA in making resource allocations at the national level, coordinated by the HTA India Secretariat or, HTAIn.[139] The strategic position of DHR in terms of functional linkage to MoHFW and the National Institute of Transforming India (NITI) Aayog- the strategic policy making arm of the central Government and several other regulatory bodies, implies that all factors leading research toward policy making are favorably aligned.

4.1 INDIAN HEALTHCARE SYSTEM AND HEALTH TECHNOLOGY ASSESSMENT

India, home to one of the world's largest healthcare systems, is undergoing a triple transition - economic, demographic, and epidemiological - presenting challenges and opportunities as it seeks to transform its health sector. Another feature of the Indian

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[137] Shankar Prinja, Kavitha Rajsekhar, Vijay Kumar Gauba, Health technology assessment in India: Reflection & future roadmap, Vol.152, Indian J Med Res, pp 444-447, (2020). DOI:10.4103/ijmr.IJMR_115_19

[138] Planning Commission India. Twelfth Five Year Plan (2012–2017) Social Sectors. Available at: https://niti.gov.in/planningcommission.gov.in/docs/plans/planrel/fiveyr/12th/pdf/12fyp_vol3.pdf

[139] Dabak, S.V., Mehndiratta, A.,Pilasant, S., *et al.* Budgeting for a billion: applying health technology assessment (HTA) for universal health coverage in India. Vol. 16, *Health Res Policy Sys***,** 115 (2018). https://doi.org/10.1186/s12961-018-0378-x

healthcare system is that it includes the public and the dominant private sector. Health systems worldwide attempt to achieve three fundamental aspirations: accomplishing good health, improving system responsiveness, and adequate financial risk protection. Health systems also focus on attaining equity in access to health services, effectiveness in delivering services, efficiency in resource use, ensuring that health services are affordable, and improving access to services. Since independence, successive Indian governments have remained committed to these goals, whose aspirations to achieve health for all, highlighted by principles underlying the Bhore Committee Report in 1946 "assuring the distribution of medical benefits to all, irrespective of their ability to pay…".[140] Similarly, now these global goals highlight the broad commitment made by the current Government of India to attain UHC and align the national health policy agenda with the SDGs.[141]

The achievement of UHC is an ambitious feat, especially during the rising burden of non-communicable diseases in India and infectious diseases (including COVID-19) and malnourishment. The Indian Government's GDP (%) health spending is similar to other low- and middle-income countries but lower than such countries. Therefore, prioritizing resources based on evidence becomes essential for improving efficiency and getting the maximum value for money. An evidence-informed affordable healthcare prioritization mechanism in low- and middle-income countries (LMIC) such as India is essential for achieving the aspirational goal of universal healthcare. Considering the increasing costs of healthcare interventions, diagnostics and devices, their formal assessment is a cornerstone in informing current health policy in India. Priority setting is crucial in an increasingly constrained economic environment. While India can invest more in healthcare, the challenge is to set priorities rationally so that any extra investment yields increased health gain.[142]

The Government of India shifted its focus toward the concept of HTA. The main reasons for focusing on HTA. First, new health technologies, particularly drugs, are

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[140] RESURRECTING BHORE Re-emphasizing a universal health care system - Cehat. https://www.cehat.org/cehat/uploads/files/a8.pdf

[141] Sakthivel Selvaraj, Anup K Karan, Swati Srivastava, et al, India Health System Review, Vol. 11(1), Health Systems in Transition, pp 216, (2022)

[142] Mrityunjai Kumar, Fiona. C. Taylor, Maulik Chokshi, Shah Ebrahim, John Gabbay, Health technology assessment in India: The potential for improved healthcare decision-making, Vol. 27(3), The National medical journal of India, pp 159,(2014). http://archive.nmji.in/archives/Volume-27/Issue-3/08-27-3-MS.pdf

the main driver for the increase in healthcare expenditure worldwide.[143] Therefore, assessing technologies' economic and health impact is central for health systems working under pressure to offer the benefits made possible by scientific research while maintaining equitable access and financial sustainability. Second, HTA is one of the most visible attempts by health systems to promote fair priority-setting, which includes the informed comparison of different policy options based on clear criteria that are systematically and consistently applied in different cases.[144]

In India, HTA, via a viable HTA system, would help in the decision-making process for allocation and proper utilization of resources. It will provide more transparency related to treatment options for different patients with the same disease. HTA provides evidence about the effectiveness and affordability of newer drugs and technologies by comparison of the risks and costs, therefore, providing information about the indications of use for a newly introduced health technology to medical practitioners. The other applications for HTA in India include supporting the development of a pricing strategy for newer drugs and technology for the entire nation or state, thereby helping provide value-based pricing for the drugs and technology. Additionally, it will support the preparation of clinical practice guidelines for maximum efficiency of interventions. HTA assists the Government in priority decision-making and purchasing health services from the private health sector. It is beneficial for providing evidence related to equity and social justice, which are essential areas to focus on while making decisions regarding priority-setting for allocation of resources.[145]

Health technology assessment (HTA) has emerged as a national-level formal process that influences priority setting and is now considered a successful mechanism.[146] HTA is adopted to address inequitable and unaffordable health care problems and move toward a more effective allocation of resources. Decision-making for resource allocation is often consensus-based nationally and at a state level. Due to India's

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[143] Corinna Sorenson, Michael Drummond, and Beena Bhuiyan Khan, "Medical Technology as a Key Driver of Rising Health Expenditure: Disentangling the Relationship," Vol. 5, ClinicoEconomics and Outcomes Research, pp 223-34, (2013).Available at: https://www.dovepress.com/getfile.php?fileID=16250

[144] Daniel Wei Liang Wang, Health Technology Assessment, Courts, and Right to Healthcare, 1st ed, Routledge,(2021).

[145] Rajwar E, Parsekar SS, Pundir P, et al. Latest developments and scope of Health Technology Assessment in India: Tapping into the future [version 1; peer review: 1 not approved] F1000Research 2022, 11:464 https://doi.org/10.12688/f1000research.109924.1

[146] Supra note 142

federal structure, and a significantly greater share of public health funding coming from State Governments, states are essential stakeholders in healthcare decision-making. The introduction of the National Health Mission (NHM), under the Ministry of Health and Family Welfare (MoHFW), improved the process of decentralized participatory decision-making. While this process included a detailed situational analysis, the selection of interventions and programs to be subsidized are still heavily guided by their effectiveness rather than cost-effectiveness or broader impact on social and ethical dimensions.

The MoHFW has further demonstrated support for evidence-based decision-making through the development of Institutionalized National Health Accounts, evidence-based standard treatment guidelines, and the establishment of a dedicated HTA body, HTAIn (previously called Medical Technology Assessment Board (MTAB)). HTAIn falls under the oversight of the Department of Health Research within the MoHFW and is tasked with developing a robust HTA system to assist decision-makers nationally and at a state level. Additionally, HTAIndia is also responsible for informing the public of HTA findings.[147]

4.2 HEALTH TECHNOLOGY ASSESSMENT IN INDIA (HTAIn)

Evidence-based decision-making in a pluralistic society like India is a challenging task. The journey of HTA institutionalization in India began in 2017 with the 'Health Technology Assessment Stakeholder's Consultative Workshop,' which was jointly convened by the Department of Health Research (DHR), Government of India, International Decision Support Initiative (iDSI), and Indian Council of Medical Research (ICMR) to raise awareness about HTA in India. To facilitate the process of transparent and evidence-informed decision-making in the health field, the Government of India set up the Health Technology Assessment in India(HTAIn). HTAIn is an institutional structure established under the DHR, Ministry of Health & Family Welfare(MoHFW) in 2017.

HTAIn is vested with the responsibility to analyze evidence related to clinical effectiveness, cost-effectiveness, and equity issues relating to the deployment of

[147] Kim MacQuilkan, Peter Baker, Laura Downey, et al., Strengthening health technology assessment systems in the global south: a comparative analysis of the HTA journeys of China, India and South Africa, Vol. 11, Global Health Action, pp 1654-9880, https://doi.org/10.1080/16549716.2018.1527556

health technologies such as medicines, devices, and health programs through HTA in India, in turn helping in evidence-informed decision-making for efficient use of existing health resources and provide people affordable, accessible and quality healthcare.[148] immediate goals of HTAIn are: to inform government health department officials about undertaking public health programs, research agencies about evidence gaps and unmet health needs, hospitals and other healthcare organizations and help in decisions regarding technology, acquisition and management, clinicians and patients about the appropriate use of healthcare interventions for a particular patient's clinical needs and circumstances.[149]

The mandate of HTAIn includes: maximizing health in the population. Reducing OOP, and reducing inequity. HTAIn also supports the decision-making process in healthcare at both the Central and State policy making levels by providing reliable information based on scientific evidence[150] and appraising health interventions and technologies based on available data on resource use, cost, clinical effectiveness, and safety. It seeks to develop systems and mechanisms to assess new and existing health technologies through a transparent and inclusive process. HTAIn collects and analyzes evidence systematically and reproducibly and ensures its accessibility and usefulness to inform health policy decisions to educate the public to make better-informed decisions for health.[151] Hence, it could be a valuable tool in taking India towards Universal Health Coverage.

Presently, Health Technology Assessment in India (HTAIn) is a fully functional institution mandated with the responsibility of HTA-related activities to facilitate transparent and evidence-informed decision-making in healthcare. Considering the expanse and complexity of the Indian healthcare system, despite the substantial progress made, there is a long journey ahead for institutionalizing systematic priority setting and using HTA in India.[152]

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[148] Annual Report 2019-20 - DHR. Available at: https://www.dhr.gov.in/sites/default/files/DoHR%20Annual%20Report%202019-20.pdf

[149] HTAIn - NIRT. Available at: https://www.nirt.res.in/html/hta.htm

[150] HTAIn | Department of Health Research - Government of India. https://dhr.gov.in/health-technology-assessment-india-htain

[151] About us | Department of Health Research - Government of India. Available at: https://dhr.gov.in/about-mtab

[152] Report: International Symposium on Health Technology Assessment and Side Meetings with Partners. Available at: https://www.hitap.net/en/documents/182992

4.2.1 HTA FRAMEWORK IN INDIA

HTAIn comprises five core bodies, namely, the Secretariat, the Technical Appraisal Committee(TAC), Regional Resource Hubs(RRH), Technical Partners(TPs), and the HTAIn Board. The Central and State Health Ministry or Government Healthcare Provider/Agency that are directly or indirectly involved in the health sector in India are the user department. They come up with the topic for HTA study with a clear policy question depending upon likely usage of certain health technologies for programmes or projects of healthcare. User department(s) give their topic(s) to the secretariat. The topics are prioritized and allocated to an appropriate TP/Resource hub to conduct the HTA study. The TAC and stakeholders appraise HTA proposals as well as the outcome of the study. After that, the outcome is forwarded to the user department. Secretariat is the point of coordination for TAC, TP, and the user department.

THE SECRETARIAT

HTAIn Secretariat or Secretariat is a DHR-in-house body coordinating between the User Department, TAC, and TP/ Resource Hubs. The Secretariat coordinates between User Departments, TAC, TPs/ Resource Hubs, and the Board.[153] Secretariat consists of Scientists, Economists, Health Policy Analysts, Financial Consultants, Project Managers, Data Entry Operators, and Multi-Tasking staff. It provides necessary assistance to the TP/ Resource Centers wherever required.[154]

Secretariat takes the topic from the user department, prioritizes it, identifies the potential TP, and allocates the topic to them to conduct an HTA study. It keeps monitoring the study's progress and provides necessary assistance to the TP wherever required. Secretariat can also undertake topics for HTA analysis in certain situations. Besides that, Secretariat conducts all the TAC and Stakeholders consultation meetings in DHR and ensures transparency at all stages of HTA by consultation and regular updates from the Technical Partners and Resource Centers.[155] The Secretariat takes up

[153] Health Technology Assessment in India (HTAIn) - Framework. Available at: https://htain.icmr.org.in/index.php/about-us/framework

[154] DoHR Annual Report 2019-20, DEPARTMENT OF HEALTH RESEARCH Ministry of Health & Family Welfare Government of India New Delhi, Available at: https://www.dhr.gov.in/sites/default/files/DoHR%20Annual%20Report%202019-20.pdf

[155] Health Technology Assessment in India (HTAIn) - Background. Available at: https://htain.icmr.org.in/about-us/background

the topic(s) for assessment from the user departments, prioritizes it, identifies the potential TPs, and allocates the topic to them to develop the research proposal and present it to the TAC, and later conduct the HTA study. The Secretariat monitors the study's progress and provides necessary assistance to the TP wherever required. The Secretariat can also initiate topics for HTA analysis in certain situations. The Secretariat organizes all the TAC and Stakeholders consultation meetings and the meeting of the Board in DHR. It ensures transparency at all stages of HTA by consultation with stakeholders and regular updates.[156]

THE TECHNICAL APPRAISAL COMMITTEE (TAC)

The Technical Appraisal Committee (TAC) is a multidisciplinary body with experts drawn from different areas viz economists, clinicians, researchers, social scientists, health policy experts, etc. There may be co-opted members in the TAC depending upon the study under consideration by HTAIn.[157] An eminent person invariably heads the Committee. It ensures the appraisal of the study at different stages, viz., topic selection, allocation, proposal development, outcome report, and recommendations. TAC does the quality assurance and provides overall stewardship to the HTAIn.[158] Till 31st January 2020, sixteen TAC meetings have taken place in DHR regarding the appraisal of the HTA proposals submitted by the TP and discussing potential challenges HTAIn may face in the Indian scenario, such as perspective, equity issues, and availability of evidence.[159]

REGIONAL RESOURCE HUBS(RRH)/RESOURCE CENTERS

Regional Resource Centers or Resource Centers are the technical partners that are upgraded to the Resource Centers to become an extended arm of the HTAIn Secretariat. DHR will provide the requisite workforce to these Centers to bridge the gap between Central and State Governments, assist in capacity building, support a bunch of States located in the vicinity, and undertake the studies allocated to them by the Secretariat. The mentor of the Centres would liaise with the officials of the State Governments and sensitize them about the need for Health Technology Assessment (HTA) for any health intervention. Presently, the following Regional Resource Hubs

[156] Supra note 153
[157] Supra note 155
[158] Ibid
[159] Supra note 154

are in place: i. Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh. ii. Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum iii. National Institute for Research in Reproductive Health (NIRRH), Mumbai iv. National Institute for Research in Tuberculosis (NIRT), Chennai v. Regional Medical Research Center (RMRC), Bhubaneswar vi. Indian Institute of Public Health (IIPH), Shillong vii. Indian Institute of Public Health (IIPH), Gandhinagar viii. Kalam Institute of Technology (KIT), Hyderabad ix. National Institute of Epidemiology, Chennai x. Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry. xi. All India Institute of Medical Sciences, Rishikesh xii. State Cancer Institute and King George Medical University, Lucknow xiii. National Center for Disease Informatics and Research, Karnataka xiv. Indian Institute of Public Health, Hyderabad xv. National Institute of Virology, Pune xvi. All India Institute of Medical Sciences, Jodhpur.[160]

TECHNICAL PARTNERS

Technical Partners are Institutes of the Central/ State Government identified by the HTAIn Secretariat concerning their expertise, capacities, and previous experience in HTA/ Multi-centric/ Operational research. Technical Partners are the research conducting body for HTAIn with their existing capacity/workforce. TP will undertake the HTA study allotted to them and ensure consistency and uniformity with the Process Manual through regular interactions and by making a template available for each stage of the 'Assessment.' The outcome reports of the studies conducted by technical partners are submitted to the HTAIn Secretariat for approval from the TAC and Board. [161]

THE HTAIn BOARD

The HTAIn Board is the highest decision-making authority of HTAIn that appraises the TAC-approved Outcomes/ Recommendation. The Board consists of Government officials, Policy experts, Clinicians, etc. If required, the Board may seek clarification on any aspect of the study through comments.[162] The Board may also look into the

[160] Supra note 155
[161] Supra note 154
[162] Ibid

gaps in evidence and instruct for further research i.e The Board can identify the areas that require further research.[163]

4.2.2 PROCEDURES INVOLVED IN HTAIn

HTA must be rooted firmly in research and scientific method. It employs principles of benefit-harm assessment and economic evaluation to identify beneficial and safe health technologies and allows assessing their incremental cost- effectiveness ratios. It must incorporate appropriate methods to assess benefits, harms and costs, safety and address the issues of generalisability and transferability. All key stakeholder groups should be included in the HTA process. Currently, an HTA undertaken by HTAIn, RRHs or TPs typically takes six months to one year or more for completion, followed by report publication and policy brief.[164]

The various steps of HTA are as follows; the User Department will send their topic(s) to the Secretariat according to their priority area with a clear policy question to conduct an assessment to address those questions. After prioritization Secretariat presents the topics to the TAC, and a suitable Technical Partner/ Resource Centers is identified and those topic(s) are allocated to conduct the study. The respective TP/ Resource Centers then come up with a study proposal containing the policy question(s), objective(s), research question(s), methodology, timeline, workforce required, and the estimated budget. The proposal is submitted to the TAC, and the TP/Resource hubs are called to present the same before the TAC in the TAC meeting held at DHR. After appraisal and approval of the proposal by the TAC, the TP/ Resource Centers are allowed to conduct the HTA study. After completion of the study, the outcome report and recommendations are made to the TAC again for appraisal and approval recommendations. Once the TAC approves the outcome report, it is submitted to the Board for final approval. TP/Resource hubs may also be called to present the outcome before the Board. The recommendations made by MTAB would be used to inform health services provided by the Government like the National Health Programs, the National Health Protection Scheme (formerly RSBY), the National List of Essential Medicines (NLEM), State-specific Health Insurance Packages, etc.[165]

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[163] Supra note 155
[164] Supra note 145
[165] Supra note 154

4.2.3 HTA STUDIES IN INDIA

The User Department will send their topic(s) to the Secretariat according to their priority area with a clear policy question to conduct an assessment to address those questions. After prioritization Secretariat presents the topics to the TAC, and a suitable Technical Partner/ Resource Centers is identified, and those topic(s) are allocated to conduct the study. The respective TP/ Resource Centers then come up with a study proposal containing the policy question(s), objective(s), research question(s), methodology, timeline, workforce required, and the estimated budget. The proposal is submitted to the TAC, and the TP/Resource hubs are called to present the same before the TAC in the TAC meeting held at DHR. After appraisal and approval of the proposal by the TAC, the TP/ Resource Centers are allowed to conduct the HTA study. After completion of the study, the outcome report and recommendations are made to the TAC again for appraisal and approval recommendations. Once the TAC approves the outcome report, it is submitted to the Board for final approval. TP/Resource hubs may also be called to present the outcome before the Board. The recommendations made by MTAB would be used to inform health services provided by the Government like the National Health Programs, the National Health Protection Scheme (formerly RSBY), the National List of Essential Medicines (NLEM), State-specific Health Insurance Packages, etc.[166]

Some of the topics completed under the HTA in India are: Health Technology Assessment of Intraocular Lenses for treatment of Age-related Cataracts in India, Cost Effectiveness of Safety Engineered Syringes for Therapeutic Use In India, Health Technology Assessment of Strategies for Cervical Cancer Screening in India, Health Technology Assessment of Long Acting Reversible Contraceptives in India, Health Technology Assessment of Hemoglobinometers. Studies Approved by TAC include: Rapid Health Technology Assessment for incorporating TrueNat as a diagnostic tool for tuberculosis under RNTCP in India, Evaluation of Pulse Oximeter as the Tool to Prevent Childhood Pneumonia related Mortality and Morbidity, Cost effectiveness analysis Hypothermia detection devices (BEPMU, Thermo Spot and fever Watch) for premature and low birth weight neonates in India, Health Technology Assessment of Uterine Balloon Tamponade for Management of Postpartum Haemorrhage in India”,

[166] Supra note 154

Health Technology Assessment of Portable automated ABR Neonatal Hearing Screening Device-Soham.[167]

Some of the ongoing Multi-centric studies include A multi-centric Costing of Health Services in India Phase I, National EQ-5D Quality of Life threshold validation Study in 8 States, DIAMOnDS-Oncopathology Services.

4.2.4 THE HEALTH TECHNOLOGY ASSESSMENT BOARD BILL, 2019

Subsequent to establishing HTAIn in 2017, in 2019, the draft HTA Board Bill was introduced to constitute an act to institutionalize the structure and functioning of the HTAIn body. For comments and suggestions draft Bill was placed in the public domain and is currently under consideration by the Department of Health Research. The Bill has been proposed to institutionalize the structure and function of the HTAIn body. The Bill is to provide for the constitution of a Board for providing evidence related to cost-effectiveness, clinical- effectiveness, and safety of medicines, devices, vaccines, and health programs using Health Technology Assessment (HTA) studies for decision making. It will evaluate the affordability, appropriateness, and cost-effectiveness of the available and new health technologies in India. It will work on maximizing health, reducing out-of-pocket expenditure, and reducing inequality so that maximum people can access quality healthcare at minimum cost in the country.[168]

The Bill is devised to provide for a board's constitution for providing evidence related to cost-effectiveness, clinical effectiveness, and safety of medicines, devices, vaccines, and health programs using Health Technology Assessment (HTA) studies for decision making. It will evaluate the affordability, appropriateness, and cost-effectiveness of the available and new health technologies in India. It will work on maximizing health, reducing out-of-pocket expenditure, and reducing inequality so that maximum people can access quality healthcare at minimum cost in the country.[169]

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[167] Health Technology Assessment in India, Department of Health.(ppt) Available at: https://nhm.gov.in/New_Updates_2018/Innovation_summit/6th/Health_Technology_Assessment_in_India_Deptt_of_Health_Research.pptx

[168] THE HEALTH TECHNOLOGY ASSESSMENT BOARD BILL (2019) A BILL. https://htain.icmr.org.in/images/pdf/Call_for_comments_and_suggestions_on_the_HTAIn_Board_Bill_2019.pdf

[169] Ibid

NEED FOR THE ACT

The Act would institutionalize the framework and functioning of HTAIn. In addition to innovative health tools reaching the patients faster, it will also boost innovation and improve the healthcare sector's competitiveness, accounting for 10% of GDP. Health technology assessment will inform prioritization, selection, distribution, management and introduction of interventions for health promotion, disease prevention, diagnosis, treatment and rehabilitation, an opportunity to develop a comprehensive HTA strategy based on an existing foundation.[170] Establishing a functioning system will create a policy demand for HTA outputs which may be linked to the precise decision-making requirements of UHC policies. It would enable central gap analysis findings in the health research domains based on disease burden. The Act would introduce new technologies after due validation at different levels. Also, the Act would enable the institution to carry out budget impact analysis and allocation.

The Bill has five chapters and 22 sections elaborating the powers and functions of the Board, Duties of the TAC and Secretariat, the procedure for sanctioning financial assistance, finance audit/ accounts, and miscellaneous.

The Bill states that the Board to be a National Advisory Body for providing robust evidence for decision-making on (i)Health Technologies and Interventions, (ii)Clinical, public health, and social care guidelines, (iii)Quality evaluation in the health and social sector for implementation in public health and social care sectors in Central and State Governments further the Bill empowers the Board, inter alia, to include the authority to (i) consider and ratify the suggestions and recommendations produced by the Technical Appraisal Committee; (ii) identify major interdisciplinary areas of research for undertaking research; (iii) evolve nationally coordinated programs in various identified areas to promote evidence-based research; (iv) provide an overall direction/ guidance in using the evidence.[171]

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[170] Supra note 167

[171] Ibid, at Sec 7(1) & (2)

4.3 HEALTH TECHNOLOGY ASSESSMENT IN INDIA: EVIDENCE INFORMED PRIORITY SETTING AND HEALTH POLICY MAKING

Health policy decisions are becoming more important because the opportunity costs of making inadvertent decisions continue to grow, particularly in countries like India, where the health sector is underfunded. The gap between the production of scientific evidence and its use to inform the decision-making process has been acknowledged globally and is pronounced at levels of policy integration in India.[172] An examination of health policy makers in the UK and Canada (as seen in chapter 3) concludes that systematic reviews could promote effective policy making by identifying relevant information for decision-making. Further, a finite health budget indicates that policy makers are faced with difficulty in deciding the choice of technology and prioritization of health services.

Given the need to reconcile the ambitious goal of UHC with limited resources, a robust priority-setting mechanism is required to ensure that the right trade offs are made, and the impact on health is maximized. Regardless of what UHC for India will eventually look like, the roles of publicly-funded health insurance and public or private health providers, and what specific budget is or will be allocated to health, health budgets are ultimately finite. Decisions will be needed to be made about which interventions or services to be funded to provide maximum benefit to the population. Even the world's wealthiest countries cannot ensure all health services to all their citizens, and for India, home to one-sixth of humanity, the challenge is even more significant.[173]

India is formally committed to institutionalizing HTA as an integral component of the EIPS process. A robust HTA mechanism requires a skilled cadre of local professionals adept at commissioning and generating policy-relevant HTA research, developing and utilizing rigorous technical, transparent, and inclusive methods and processes, and a solid multisectoral and transnational stakeholder appetite for the use of evidence to inform policy. Given the recent establishment of the HTAIn and the nascent introduction of HTA into the Indian healthcare system, there is a presumed absence of

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[172] Supra note 142

[173]Report by NICE International, as part of the international Decision Support Initiative (iDSI) The Current Status of Priority-setting and Health Technology Assessment for Universal Health Coverage in India https://f1000research.com/documents/8-824

HTA-specific local skills and expertise. The government of India approached the International Decision Support Initiative (iDSI), a global network of health, policy and economic expertise, to support a National program for targeted capacity building for HTA and evidence-informed priority-setting(EIPS).[174]

Priority-setting is required to provide a comprehensive range of key services, which are well aligned with other social goals, to which all people should have access. The question then arises: How comprehensive is comprehensive? Definitions and indicators of essential health services and financial protection have recently been suggested to guide countries in implementing UHC. Policy-makers then must decide what health services to provide, for whom, and at what price and quality.[175]

Priority-setting is the allocation of finite health budgets among different health interventions, services, and groups of patients or individuals, and priority-setting always occurs, whether or not, by the explicit action of the policy-maker. An active priority-setting is essential if a country is to achieve and sustain UHC. Hence, decision-makers must follow a process that considers scientific and economic evidence alongside social values and is accountable and defensible by being inclusive, transparent, and shielded from conflicts of interest.[176]

4.3.1 EVIDENCE-BASED PRIORITY SETTING

Priority-setting or prioritization refers to determining the priority to be assigned to a service, a service development or an individual patient at a given time.[177] Priority-setting is about deciding what to fund and weighing the trade-offs between various options in the whole process. Every health system sets priorities and are

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[174] L.E. Downey, S. Dabak, J. Eames, et al., Building Capacity for Evidence-Informed Priority Setting in the Indian Health System: An International Collaborative Experience, Vol. 1, Health Policy Open, pp1-6, (2020), https://doi.org/10.1016/j.hpopen.2020.100004

[175] Chalkidou K, Glassman A, Marten R, Vega J, et al., Priority-setting for achieving universal health coverage. 1; 94(6), Bulletin of the World Health Organization, pp 462, (2016). Available at: https://apps.who.int/iris/bitstream/handle/10665/271913/PMC4890204.pdf

[176] Hernandez-Villafuerte, K., Li, R., Towse, A. and Chalkidou, K. (2015) International Decision Support Initiative (iDSI): Mapping of priority-setting in health in 17 low and middle countries across Asia, Latin America, and Africa. OHE Occasional Paper. Available from https://www.ohe.org/publications/international-decision-support-initiative-idsi-mapping-priority-setting-health-17-low.

[177] Shahabi, Saeed, et al. “Prioritizing Solutions to Incorporate Prosthetics and Orthotics Services into Iranian Health Benefits Package: Using an Analytic Hierarchy Process.” PLoS One, vol. 16, no. 6, Public Library of Science, 2021, p. e0253001.

reflected in the technologies and services paid for and the investments made in training and infrastructure.

In the context of health systems, priority-setting is about the allocation of resources to innovative high-cost medicines or new vaccines and their introduction in public health programs; prevention or primary care; the training of community workers or specialists; about deciding which population subgroups ought to receive subsidized care; even about complex policy interventions such as schemes for remunerating providers. In the case of specific drugs or surgical procedures, establishing priorities concerning human resource capacity, infrastructure investment, provider payment, or premium setting for service delivery also requires systematic consideration of available evidence. While such evidence may be more readily available in the case of pharmaceuticals, policy-makers still need to address two broad sets of issues when considering more complex service delivery and policy interventions. These are: first, the relative effectiveness of rival alternative interventions and, second, the value to be placed on the outcomes for each alternative.[178]

Prioritization is needed because healthcare claims (be they for needs or demands) are more significant than available resources. To prioritize a process may also refer to allocating resources to maximize its health impact within a defined budgetary constraint (major hurdle in our system). Another way for prioritization is to rank order interventions to inform decision-makers of all the pros and cons of implementing the ranked health interventions. Since budgets are negotiated between health and finance departments, showing the potential value and affordability of different programs can also help increase budgetary allocations for different priorities.[179]

Priority-setting may differ according to the population's requirements for implementing the health intervention or the disease burden that needs to be targeted. The prioritizing levels can be broadly categorized as macro-level (e.g. National), meso-level (e.g. State/Provincial), and micro-level (e.g. local community). On the basis of the scale of the impact of healthcare interventions/services, prioritization is of two kinds: explicit and implicit. On a more comprehensive understanding, explicit prioritization involves priorities that are well-defined and precise with clear-cut

[178] Supra note 175

[179] Health Technology Assessment in India - A Manual Available at: https://htain.icmr.org.in/images/pdf/htain%20manual.pdf

boundaries of action, while implicit priorities are usually more flexible in their scope of action.

Whether implicit or explicit, driven by local players or global donors, priorities become established even in settings where the institutions, data, and technical expertise for doing so effectively and fairly are weak or nonexistent. Thus the question is not whether to set priorities rather how to improve priority setting processes. When prioritization is done When prioritization is done explicitly, those who make the decisions are more likely to be known and accountable. Positive and negative lists for surgical procedures and technologies; price controls and reimbursement regulations for drugs and devices; investing preferentially in training and remunerating family doctors; all belong to a lesser or greater extent in this category of explicit priority-setting. [180]

Such explicit prioritization mechanisms can target different types of interventions (prevention versus treatment) such as; levels of the health system, geographies; different services; different population groups, diseases, or technologies, among others.

On the other hand, implicit methods, though complex to describe, may be ad hoc or rely on semi-explicit strategies such as peer benchmarking or oversight or devolving responsibility to the local provider through budgetary or regulatory controls. For example, without a clear benefits package, services provided rely on the clinical judgment of individual physicians. Further, explicit priority-setting processes can be challenged. In an explicit process, it is clear who made the decisions, the criteria used, whether the criteria used were met, what evidence was considered and whether the evidence was adequately assessed, whether appropriate values were employed, who was consulted, and whether those giving advice had significant conflicts of interest and how the various trade-offs were made.[181] Furthermore, it is easier to improve the explicit prioritization process than implicit prioritization. Significant global efforts have been made to inform global and domestic decisions in health, one among them being the WHO's CHOICE initiative and its essential medicines list.

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[180] Supra note 175

[181] Ibid

The most obvious beneficiary of a national priority-setting mechanism would be the MoHFW with regard to UHC, in that HTA can provide a robust process for deciding what interventions to be included in an assured health benefits package (the "what" of UHC) and for updating the package, and that evidence based clinical guidelines and standards can help define how these interventions should be implemented in clinical practice (the "how" and "for whom" of UHC). Evidence-informed priority-setting processes and decisions occurring at the Union level, particularly within the framework of national government priority-setting institutions(HTAIn), could also substantially impact policy in states and public institutions across India.[182]

Institutionalization of quality-focused priority-setting for public providers, for instance, through evidence-based guidelines and quality standards, could at the same time both form the basis for the regulation of the private sector and incentivize private providers to improve quality to remain competitive. The latter is well demonstrated in Kerala, where NICE International has provided technical assistance to the state government and NHM in developing evidence-informed quality standards to reduce maternal mortality. The experience of NHM Kerala and NICE International suggests that elements of local implementation of priority-setting processes has occurred in at least three directions: (1) across patient population, (2) across Indian states (as NHM Odisha and Bihar have sought to learn from the Kerala team in conducting maternal mortality audits), and (3) from State-to-Union level.[183]

4.3.2 HEALTH TECHNOLOGY ASSESSMENT IN INDIA: EVIDENCE TO POLICY

The term ‘policy’ remains ambiguous. One of a plethora of definitions applies according to the setting in which it is used. A restrictive view sees policy as the norms issued by the governmental institutions. These can be equivalent to laws since they are the tools by which the government implements policy. The term policy can also refer to the rules which govern the functioning of the health system in general, including those issued by both governmental and non-governmental institutions (i.e. self-governing institutions, sickness funds, professional associations, etc.). *Healthcare*

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[182] Supra note 173

[183] Vlad I, Paily V, Sadanandan R *et al.* Improving quality for maternal care - a case study from Kerala, India[version 1; peer review: 3 approved], Vol.**5**:166, *F1000Research,* (2016). https://doi.org/10.12688/f1000research.7893.1

policy is a narrower term that refers to the courses of action that deal with health services financing, provision and governance. It may be deduced that policy can include rules to guide actions at any health system level, whether or not they are legally binding.[184]

The primary purpose of health technology assessment (HTA) is to assist those who make vital decisions regarding allocating scarce healthcare resources. Even though developing effective methods for conducting HTA has received much attention, much less emphasis has been placed on ensuring that those conducting HTA are sufficiently connected to and viewed as significant by those making resource allocation decisions.

Those conducting HTA must have a good interface with regulators since the clinical evidence generated during the regulatory process is often used in the subsequent health technology assessment. For example, the manufacturer must undertake at least two well-controlled clinical trials to obtain approval for pharmaceuticals to enter the market. These will typically be randomized controlled trials (RCTs), comparing the new drug with placebo or other active therapy. However, in the case of medical devices and procedures; the evidence requirements tend to be lower for devices, partly because of the relative difficulty in conducting RTCs conducted for regulatory purposes may be considered sufficient to demonstrate a beneficial change to show efficacy. However, they may not be related to outcomes experienced by the patient, such as fatal and non-fatal myocardial infarctions. This potential mismatch of evidence requirements has led to several initiatives exploring the difference of perspective between regulators and payers to harmonize evidence requirements.[185]

An HTA compares the outcomes obtained from the new technology with those obtained using the current standard of care in a particular jurisdiction where the decision is being made. In addition, those conducting HTAs favor clinical studies

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[184] Velasco Garrido, Marcial, Kristensen, Finn Børlum, Nielsen, Camilla Palmhøj. et al., Health technology assessment and health policy-making in Europe: current status, challenges and potential. World Health Organization. Regional Office for Europe. pp 53-60 (2008). World Health Organization. Regional Office for Europe, European Observatory on Health Systems & Policies Available at: https://apps.who.int/iris/handle/10665/107911

[185] Vol.1, *Juan E. del Llano-Señarís* and *Carlos Campillo-Artero,* Health Technology Assessment and Health Policy Today: A Multifaceted View of Their Unstable Crossroads, pp 3-14, Springer International Publishing A&G, Switzerland, 2015

conducted in a 'real world' setting, measuring clinical outcomes of direct relevance to the patient.[186]

Health policy-making in India is segmented horizontally and vertically across many different agencies and departments. Constitutionally, *health* is defined as a subject under the jurisdiction of state governments. However, the Central Government also plays a crucial role in making resources available in design and technical support. Additionally, ministries such as Defense, Labor and Railways may run their hospitals and health facilities to provide services to their respective constituencies. Further, closely allied functions such as pricing drugs and devices are governed by ministries other than the Health Ministry at the central level. Thus, there are multiple potential users for HTA in India at the state and central levels, including health departments, insurers, procurement agencies, hospital administrators and providers. Each of these policy-making agencies represents potential users of HTA evidence to improve priority-setting within their respective functional contexts. There are myriad ways in which HTA evidence can be used to strengthen the priority-setting process at each level of the decision-making space in the Indian health system.[187]

Countries worldwide have various organizational mechanisms for HTA use within their health systems. For instance, the United Kingdom has national HTA agencies that support policy-making for the entire country. India, as a federal system with shared responsibilities for healthcare decision-making, multiple systems of medicines and a large private sector, presents challenges and opportunities for the creation of a unique model of HTA use. There are several ways that HTA may inform critical healthcare decision-making in India, both in the public and private sectors.

Ways in which HTA influence Governmental policies and decisions are:

- The strategic purchases of services from the private sector can be facilitated using HTA: Priority-setting decisions concerning what to purchase, from whom and at what price are essential for strategic purchasing. In India, the dominant healthcare provider is the private sector, strategic purchasing of services from them is one of the vital strategies of the government to achieve

[186] Supra note 185

[187] Neethi V Rao, Laura Downey, Nishant Jain, Rama Baru, Francoise Cluzeau,Priority-setting, the Indian way, Vol. 8(2):020311, J. Glob Health, pp 1-7, (2018) DOI: 10.7189/jogh.08.020311

UHC in India. The PMJAY, for example, reimburses up to a limit of INR 500,000 (7700 USD) for delivering health benefits by private hospitals. HTA can provide valuable input into the design of the PMJAY benefits package by prioritizing high-value interventions to maximize health outcomes and financial risk protection. While the limitations of poor governance or lack of regulatory oversight on private healthcare providers cannot be overcome by HTA alone, it provides rational grounds for negotiating appropriate terms for strategic purchasing to policy-makers.

- HTA helps to Incorporate value-based pricing for devices and drugs: Evidence can be used to support value-based pricing by incorporating the cost-effectiveness of drugs and medical devices in the price-setting process. Regulatory approval for drugs in India is primarily based on the three criteria of quality, safety and efficacy. In addition, India imposes price control on a select set of drugs and devices through the National Pharmaceutical Pricing Authority (NPPA). The price control policy and the patent regime have contributed to some of India's lowest prices for drugs. Price control policies for essential drugs are necessary to ensure affordability in a country that remains largely poor, with over 70% of healthcare costs being paid out-of-pocket. In addition to the domestic market, India as the 'pharmacy of the developing world' also affects the availability of affordable medicines globally. However, stakeholders often criticized the current pricing negotiations for leading to perverse incentives. Value-based pricing incentivizes innovation and drug development instead of barriers and benefits all parties. However, determining the value of drugs and devices may be challenging given the widespread misuse of medication in India and the lack of data on treatments and outcomes. Developing a systematic evidence-based priority-setting architecture will require the development of a data infrastructure that enables tracking of pharmaceutical use and healthcare delivery and, in turn, checks irrational drug use and malpractice. With stronger regulation and increased public investments, value-based pricing supported by HTA can help improve access to medicines.[188]

[188] Supra note 187

- There are two ways through which HTA can help to improve quality of care. First, HTA can inform the development of cost-effective standardized care pathways. Second, HTA can be used to inform reimbursement criteria for purchasing clinical services, thereby improving care by requiring HTA-informed quality standards to be met. The government of India is exploring policy instruments to incentivise accreditation and standardized care pathways to institutionalize health service quality. HTA can assist in the process of development of contextually relevant clinical guidelines that may be used for accreditation or other regulatory instruments such as payment for performance. The use of HTA ensures that standards are evidence based and have the buy-in of appropriate stakeholders, facilitating compliance.[189] This is especially crucial in a diverse health system such as India with multiple systems of medicine including Ayurveda, Unani and Homoeopathy. When adequately enforced, these standards increase the consistency and reliability of healthcare.
- HTA influences regulation of healthcare provisions: The involvement of HTA strengthens the power of government agencies to regulate the price, quality, and distribution of health services across the system by providing levers. In India, medical technology, pharmaceuticals, diagnostics and hospital industries wield a strong influence on public policy and practice. Utilizing the evidence to support regulatory actions in the interest of larger policy objectives minimizes this influence. On the basis of their "value" or "utility" in the health system, HTA can help with results-based financing for health interventions in the public or private sector.

  Since the 'value' of any health intervention is only relevant within the context of the care pathway and target population, HTA can help design appropriate outcomes and quality indicators to ensure payment is adjusted to performance. There is an increasing interest in including patient-reported outcome measures (PROs) in clinical studies, specifically those in tandem with economic evaluation or as part of an HTA, PROs include measure like patient satisfaction and their health-related quality of life(HRQoL) which capture specific treatment effects that are not captured by the main clinical outcomes.

[189] Supra note 187

Moreover, since quality of life(QoL) measures focus on treatment effects that primarily impact the patient's well-being, their relevance becomes important for HTA studies.[190]

Established HTA agencies are increasingly building policy linkage between HTA and healthcare quality regulation. India has had the opportunity to learn from such HTA agencies worldwide and incorporate those pathways at an early stage.

- HTA helps in achieving policy convergence and cooperation: HTA helps to measure how efficient a given health intervention is compared to all reasonable alternatives. HTA evidence on the efficiency of the government health programs can be used to help rationalize interventions at state or national levels. While each program is laudable in its own right, an evidence-based assessment of the effectiveness and efficiency of low-cost pharmacies in the country could enhance the policy design and promote complementarity and convergence between government schemes/programs.[191] Furthermore, HTA can also facilitate improved health policy cooperation between state and central governments by enhancing the efficiency of resource allocations and identifying areas of complementarity. Given the increased fiscal devolution from the center to the states, this becomes more significant.

- Another application of HTA is inclusion of equity and social justice concern in health policy decision making. HTA provides a mechanism to systematically incorporate evidence on health inequities, ethics and implementation challenges into priority-setting that is best suited to the relevant population context. Additionally, the institutional use of HTA in public policy-making can serve as a long-term mechanism to increase public participation and build accountability among citizens, policymakers, and health service providers.

4.3.3 ECONOMIC EVALUATION IN HTA

At the core of HTA stands the question: "Is this health technology worth investing in compared to other things the health system could do with the same resources?".

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[190] Supra note 179
[191] Supra note 187

Health economic evaluations address this question by bringing together diverse sources of evidence within a single analytical framework, often referred to as analytical decision models. HTA employs the principles of economic evaluation to identify the most cost-effective health technology.[192] Attempts to value health states face a multitude of difficulties. Economic evaluations of health care interventions play a vital role in resource allocation decisions. Economic evaluation refers to the comparative analysis of alternative courses of action in terms of their cost and effectiveness.[193] The health economic evaluation aims to explain the relationship between the costs and consequences of a given health technology compared with one or more relevant existing alternatives for screening, diagnosis, and treatment or rehabilitation purposes. This will contribute information about whether the technology is cost-effective from a societal perspective[194]

Economic evaluation can assist the priority setting process in the healthcare sector in deciding on the best use of resources. The basis for economic thinking and economic analysis is the concept of opportunity costs, which states that the real cost of a healthcare program's implementation is not the number of dollars appearing on the program's budget but rather the health outcomes achievable in some other healthcare program which has been forgone by committing the resources to the first program.[195]

HTAs are used to support critical policy decisions. HTA topics usually include a research question that requires an economic evaluation to assist decision makers in formulating evidence-based policies for incorporating or excluding health technologies into the health system. The purpose of the economic analysis, in a health technology assessment (HTA), together with the other relevant questions, e.g. clinical ones, is to provide information to improve decision making in the healthcare sector concerning priority-setting between different health technologies emerging, new and existing ones. The overall role of economic analysis in the HTA study is to provide

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[192] Supra note 179

[193] Cost Efficiency & Cost Effectiveness of Cataract Surgery at Malaysian Ministry of Health Ophthalmic Services Available at: https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.517.4466&rep=rep1&type=pdf

[194] Chawla S et al., Health technology assessment: a tool for evidence-based decisions for quality health care in India, Vol. 9(5), Int J Community Med Public Health, pp 2316-2319, (2022). DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20221258

[195] Drummond MF et al. Methods for the Economic Evaluation of Health Care Programmes. (2nd ed), Oxford Medical Publications, Oxford University Press, Oxford, 1997.

information about the necessary resource consumption from the use of health technologies compared with the health outcome obtained.[196]An economic analysis is the comparative analysis of alternative courses of action regarding their costs and consequences.[197]

There exist four types of economic analysis that can be relevant to consider as part of an HTA: cost-minimization, cost-effectiveness, cost-utility, and cost-benefit analysis. Identifying various types of costs and subsequent measurement and monetary valuation is, in principle, similar across these four types. Cost minimization analysis is the simplest form of economic evaluation, which assumes that the health advantages emanating from the use of the health technologies being compared are identical. In cost-effectiveness analysis, the costs and consequences arising from using the health technologies are identified, measured, valued and compared. The implications are assessed in natural units, e.g., mm Hg reduction in systolic blood pressure, cases prevented, deaths averted, and life years gained.[198]

The cost-utility analysis differs from the cost-effectiveness analysis in that the consequences are measured and evaluated as quality-adjusted life years (QALYs). Therefore the years of life gained are quality-adjusted with health-related quality of life to assess QALYs.[199] It is argued that health in particular is an important independent argument in the welfare function. Hence, the obvious measure for interpersonal comparison in the health care sector would be based on a quantifiable, commensurate measure of health benefit. In other words, some notion of effectiveness that is quantifiable and amenable to comparison across individuals would be a suitable starting point. An immediate candidate is the QALY measure largely as it may be used as a commensurate instrument that may be applied to any health care intervention.[200] This sort of analysis makes it possible to compare outcomes of interventions across different activities in the health care setting, where natural units

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[196] Finn Børlum Kristensen, Mogens Hørder and Peter Bo Poulsen , HEALTH TECHNOLOGY ASSESSMENT-HANDBOOK, pp 96-120, 1st ed, Danish Institute for Health Technology Assessment, (2001)

[197] Supra note 195

[198] Supra note 194

[199] Downey L, Rao N, et al. Identification of publicly available data sources to inform conduct of Health Technology Assessment in India [version 2; peer review: 3 approved], Vol. 7:245, F1000Research https://doi.org/10.12688/f1000research.14041.2

[200] Michael Drummond, Alistair McGuire, Economic Evaluation in Health Care Merging theory with practice, pp 2-14, Oxford University Press Inc., New York (2001)

of outcomes are otherwise different.[201] An economic evaluation of the benefits of new technology is based not only on health gain versus monetary expenditure required but also on its effect on the quality of life of the treated population. The priorities of healthcare resource allocation in the developed world are founded on broadly utilitarian principles (i.e., maximization of total utility in the population, often measured in terms of quality-adjusted life years [QALYs]). However, the same may be at odds with the philosophical and ethical preferences of the Indian population.[202]

Cost-benefit analysis is the broadest kind of economic evaluation where both the costs and outcomes are measured and valued in monetary terms. Hence net gain can be calculated directly.[203]

Economic evaluation provides evidence on ways to maximize health benefits within a given budget, accounting for the societal value of health. It, however, does not generally provide information about the distributional value of health-related benefits in a given setting. Therefore, apart from comparing the health and economic consequences of available policy options, HTA also assesses the feasibility of implementing social, legal, and ethical aspects.[204] An equity study will evaluate social factors such as the impact on out-of-pocket expenditure, catastrophic medical costs, and poverty rates to ensure that the proposed health technology supports the principles of distributive justice. Equity analysis can be carried out through mathematical programming, measuring the distributional cost-effectiveness analysis(DCEA), or extended cost-effectiveness analysis (ECEA).[205]

The term inequity goes beyond measurable differences in health status to incorporate moral and ethical dimensions, all the organizational, legal and ethical issues are assessed with the help of stakeholders' negotiation. A health technology assessment is just as good as the evidence that goes into it. As emphasized in the sections above, for

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[201] Supra note 199

[202] Hass B, Pooley J, Feuring M, et al., Health technology assessment and its role in the future development of the Indian healthcare sector, Vol. 3(2), Perspect Clin Res, pp 66-72, (2012). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3371551/pdf/PCR-3-66.pdf

[203] Supra note 199

[204] Supra note 179

[205] Weinstein MC, O'Brien B, et al. Principles of good practice for decision analytic modeling in health-care evaluation: Report of the ISPOR Task Force Good Research Practices—Modelling Studies, Vol.6(1), Value Health, pp 9–17, (2003) Available at: https://www.valueinhealthjournal.com/article/S1098-3015(10)60128-3/pdf

HTA to assist decision makers in priority setting, evidence inputs that go into assessing clinical effectiveness, cost-effectiveness, equity and financial sustainability should be of highest standard: reproducible, comprehensive, and based on transparent and validated sources.[206]

4.4 CHALLENGES TO HTA IN INDIA

Sustained use of evidence-informed priority-setting has transformational potential for India's health systems by increasing government policy's legitimacy, authority and accountability. However, HTA alone cannot provide a panacea for all the deficiencies within the Indian health system. There remain several challenges to institutionalizing the use of priority-setting tools like HTA in health-policy making in India. HTA in India is faced with several challenges that should be identified and dealt with.

The primary challenge pertains to the gross deficiency in the human resource and institutional capacity to undertake HTA studies in India.[207] A robust HTA mechanism requires a skilled cadre of local professionals adept at commissioning and generating policy-relevant HTA research, developing and utilizing rigorous technical, transparent, and inclusive methods and processes, and a solid multisectoral and transnational stakeholder appetite for the use of evidence to inform policy.[208] Given the establishment of the HTAIn and the nascent introduction of HTA into the Indian health system, there is a presumed absence of HA specific local skills and expertise. For example, local technical professionals play an essential role in producing HTA evidence; however, there is a marked absence of health economists with expertise in HTA in India. This poses an imminent challenge to the country's successful generation and deployment of HTA evidence.[209] Further, limited human resource capability also needs to be addressed in the field of mathematical modeling, health

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[206] Supra note 179

[207] Prinja S, Chauhan AS, Gupta I et al., A Systematic Review of the State of Economic Evaluation for Health Care in India. Vol.13(6), Appl Health Econ Health Policy, pp 595-613 (2015). Available at: https://hsrii.org/wp-content/uploads/2016/06/AHEHP-2015-Systematic-review-economic-evaluation_FINAL.pdf

[208] Li R, Ruiz F, Culyer AJ, et al.,Evidence-informed capacity building for setting health priorities in low-and middle-income countries: A framework and recommendations for further research. [version 1; peer review: 2 approved]. Vol. 7, F1000Res, (2017) Available at:https://f1000research.com/articles/6-231/v1

[209] Supra note 174

economics, and evidence synthesis, requiring considerable investment in skill-building

The next challenge is the complexity of the Indian healthcare system itself. Healthcare in India is largely financed through out-of-pocket payments and state government spending comprises approximately 66% of total public sector spending. The predominance of the private sector in the Indian health system combined with distributed decision-making moderates the impact of governmental agencies such as HTAIn. In a mixed health system such as India's, where the private sector provides over 70% of the care, all decisions taken by the Government will inevitably impact the private provision of care. As such, all uses of HTA will impinge on regulation and incentivization in the healthcare market, whether public or private. This brings challenges associated with lobbying and the inevitable push-back on decisions contrary to the interests of organized interest groups, particularly in the private sector.[210] Furthermore, India suffers from issues related to neglect of primary care, medical malpractice, shortage of trained health professionals and poor implementation of regulations.[211] Strengthening the public sector, the Government's regulatory will and building a healthy public-private working relationship is essential to ensure the long-term relevance and effectiveness of HTA-based decision-making. This requires a solid commitment to transparency and public accountability, accompanied by legislative support to protect against conflicts of interest.[212]

Another challenge is the data and technical requirements as a result of the rapid development of data infrastructure. Like any other low- and middle-income country, India faces a lack of data on costs and quality of life-related to health. The main reason is that healthcare data are often not recorded and are rarely digitized. One of the solutions is to digitize the recordings and make a collective data repository. The MoHFW aims to set up a National eHealth Authority to enable, organize, manage, and store patients' electronic health records and has introduced a draft bill titled the "Digital Information Security in Healthcare Act" (DISHA) in 2018 in this direction. It

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[210] Supra note 146

[211] Bang A, Chatterjee M, Dasgupta J,et al., High level Expert Group Report on universal health coverage for India. (2012). Available at: http://uhc-india.org/reports/executive_summary.pdf

[212] Supra note 146

is essential, however, that digitized innovation considers data policies and patients' rights.[213]

Also establishing the National Digital Health mission (NDHM), which aims to build the backbone necessary to support the integrated digital health infrastructure of the country, is a step in the right direction. VBHC will make manufacturers share performance and outcomes data with providers and help accelerate patient access to technologies that can demonstrate improved value and outcomes.[214] Critical gaps in the existing data infrastructure in India crucial for conducting HTA are data on the costs of delivering healthcare services and the lack of a quality-of-life tariff for the Indian population.[215]

Another challenge is the lack of a regulatory framework, which is affected by India's unregulated, uncoordinated, and diverse healthcare market.[216] The HTAIn Board Bill is still pending before the parliament. Further, the Bill only discusses the board's composition and does not have provisions relating to evidence synthesis or procedure for preparing HTA proposals. India, with its hybrid healthcare system, where there is a wide availability of low-cost alternative treatments (homoeopathy and Ayurveda) and locally manufactured drugs and devices, alongside imported treatments, another concern is minimal clinical and economic evidence available on these generic medicines and alternative treatments. Because HTAIn is a centralized framework and health financing lies with the states, much of the demand for assessments should come from the latter. Several states have their health insurance schemes. Nevertheless, there are existing wealth inequalities among states in their healthcare budgets, and most of

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[213] Shilpi Swami, Tushar Srivastava,Role of Culture, Values, & Politics in the Implementation of Health Technology Assessment in India: A Commentary Vol.23(1), VALUE HEALTH, pp 39–42, (2020). Available at:https://reader.elsevier.com/reader/sd/pii/S1098301519351678?token=D8CC6E5F840BE8FB6FAE7167F313D5778DC0B9F209323AB5B5640F6FB72644DDEF6E21C62E09D75281D8C636B8C4CF82&originRegion=eu-west-1&originCreation=20220727073912

[214] Health Technology Assessment of Medical Devices in India: Key Considerations for Value Assessment Frameworks. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/htain-inforgraphics-for-creative-support-team.pdf?_=1658907755891

[215] Shankar Prinja, Laura E. Downey et al., Health Technology Assessment for Policy Making in India: Current Scenario and Way Forward Vol. 2, PharmacoEconomics Open, pp 1–3, (2018) Available at: https://doi.org/10.1007/s41669-017-0037-0

[216] Supra note 213

these schemes are restricted to a prescribed list of tertiary-level treatments and do not cover preventive interventions.[217]

The next challenge relates to the ethics and transparency of the HTA system, particularly concerning conflicts of interest. This challenge is not unique to the Indian context. To guard against this, the DHR and MTAB will have to ensure the governance of evidence generation in India and safeguard it from vested interests. Established measures to tackle such challenges include using written conflict of interest policies, publication of process and methods manuals for transparency of decision making, publication of summary reports that inform final recommendations, and multi-representative stakeholder involvement ensuring inclusiveness and scrutiny of decision making.[218] Considerations of health inequities and social justice may also be especially challenging given the exceptional diversity of India.

Other challenges identified include the need for consensus building among stakeholders, the need to raise awareness about the value of HTA, and the development and enforcement of HTA policies and guidelines.[219]

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[217] Supra note 213

[218] Supra note 174

[219] Joseph B. Babigumiraa, Alisa M. Jennya, Rebecca Bartleinc, Andy Stergachisa, and Louis P. Garrison Jr., Health technology assessment in low- and middle-income countries: a landscape assessment, Vol. 7(1), J*ournal of Pharmaceutical Health Services Research*, Pp 37–42, (2016). https://doi.org/10.1111/jphs.12120

CHAPTER 5

SUGGESTIONS AND CONCLUSION

The Indian health system represents a unique case of a diverse population with distributed policy-making authority. In India high out-of-pocket expenditures demonstrate the excessive reliance on the private healthcare system in India and indicate that UHC is yet to be achieved. Though the Indian government is promoting UHC and implementing several schemes such as Ayushman Bharat to ensure access to healthcare, the situation in India has not improved. It is necessary to adopt instruments of priority-setting such as HTS to this context. HTA can increase the quality and cost-effectiveness of healthcare provision through iterative practice and evolution.

This research has outlined how decision makers in India can use HTA to increase the return on their investments. Institutionalizing HTA may help to achieve policy objectives while underlining the overarching challenges to a systematic evidence-based priority-setting. Compared to other internationally established HTA agencies, the EBH-based HTA process in India is still in its infancy. The empowerment of HTA in India is a crucial step which can significantly bring down the out-of-pocket spending on healthcare by an average Indian citizen, thereby helping to achieve UHC in India.

Despite the need to use the existing resources to maximize health for every rupee spent, evidence-based decision-making in a pluralistic society such as India is challenging. It is essential to adopt a framework that encompassess and embraces diversity. Thus, HTAIn could foster such decision-making if it acknowledges diversity related to religion, cultures, and politics and works toward reducing inequalities and focusing on socio-economically disadvantaged groups.

It is significant to note that beyond the instrumental uses of HTA, as explained in this research, the iterative utilization of policy-oriented study has conceptual and symbolic relevance for the stakeholders across the spectrum. Institutions like HTAIn make criteria for decision-making explicit and allow systematic, periodic stakeholder input into policy-making, hence increasing transparency and public accountability. Additionally, this strengthens the legitimacy of the policy-making procedure by

giving faith to the citizenry that their interests and values are considered while designing the health system. Institutional evidence in public policy-making can help improve overall health system performance and put India on the trajectory of achieving universal health coverage.

SUGGESTIONS

1. SETTING-PRIORITY:

   Amid significant budgetary challenges, active and explicit priority-setting processes are becoming increasingly important. Embedding HTA to priority-setting decisions at the national level is the key. HTA principles and methods are not exclusively for decision-making between individual technologies and interventions but also in the broader context of public healthcare, assured health benefit plans under several insurance schemes, clinical guidelines, and quality standards to guide the implementation and regulation of services across public and private sectors.

2. COLLABORATIVE APPROACH:

   In a culturally and socio-economically diverse country such as India, collaboration is vital in leveraging technology and resources to fulfill health needs. Thus, for HTA to succeed, multi-representative stakeholder involvement is crucial. In India, where there is such diversity in the health system's stakeholders, only a multi-stakeholder participation can ensure buy-in of priority-setting and decision-making processes. This diverse pool of stakeholders includes the Central Government and state governments, public and private providers; public and private payers; an active domestic devices and pharmaceutical industry, and the general public, donors and other development partners. Their technical assistance can foster a multi-stakeholder approach, thereby bolstering in-country capacity. Efforts to institutionalize evidence-informed priority-setting supported by development partners, can help to improve accountability, efficiency and quality in both public and private sectors.

3. TRANSPARENCY:

   A methodological and robust evaluation, created from the substantial evidence available may not be trusted by public, industry, academic community, and/or policy-makers if the same is conducted and the results are not clearly reported in a transparent manner. Clear and transparent economic evaluations can also improve the transparency of the decision-making process. As for India, a full HTA report of the HTA undertaken must be made available online. Using a comprehensive reporting template would ensure a clear and transparent analysis report.

4. EVIDENCE ON EFFECTIVENESS

   The randomized controlled trial (RCTs) rank highest in the credibility of the evidence. Hence, evidence on effectiveness should be taken from a systematic review and meta-analysis of RCT. Where RCT evidence is absent; the same must be taken from the next highest study design, i.e. quasi-experimental studies, cohort studies, case reports etc., providing optimum justification.

5. STRUCTURED GOVERNANCE

   To comprehend the HTA agency's purpose, structure and goals, there should be a clear mandate, governance structure makes the duties and responsibilities of the agency clear. It defines the appropriate groups to which it is accountable in instances where HTA is used to guide decision-making. This would ensure that individuals and committees act in line with their mandated objectives, be held accountable for transparent decision-making and use their knowledge and resources to benefit those they are responsible for, free from conflicts of interest. Further, a regulatory framework on this behalf also would confer legal authority on HTA structure and their reports.

Evidence-based priority-setting in LMICs, such as India requires sustained political commitment and cooperation from all key stakeholders. Several challenging decisions regarding resource allocation must be made to attain UHC; these decisions can be taken to promote effective and equitable healthcare delivery using the evidence-based and transparent HTA processes. Stakeholders participation in identifying HTA topics and conducting research will enhance the use of HTA evidence for decision making.

Health systems and programs must be designed to yield value for money to accelerate the progress towards achieving UHC. efficient and equitable healthcare provisions can be ensured through evidence-based and transparent HTA processes. Therefore, the established HTA framework in India must utilize its total capacity to guide government and policy-makers in an explicit priority setting that ensures that available health budgets are spent after weighing all options and coming to a fair and just conclusion.

For HTAIn to flourish transparently, the political pressures should fade. Physicians should be made aware of the methods of HTA to help them make evidence-based rational decisions. HTA has emerged globally as a powerful tool for institutionalizing the use of evidence in decision making for health policies. Adapting appropriate HTA strategies in India to contextualize global knowledge, support transparent and accountable decision making, and promote health equity is prudent.

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