

**Summer Training at
Department of Health Research, Ministry of Health & Family Welfare
Government of India, New Delhi
(April 3 to June 2, 2017)**

Health Technology Assessment in India

**By
Arvind Bhushan**

**Under the guidance of
Dr. Goutam Sadhu**

**MBA Hospital & Health Management
2016-2018**


Institute of Health Management Research
**The IIHMR University, Jaipur
2017**

CERTIFICATE

This is to certify that **Mr. Arvind of MBA Hospital and Health Management** from The IIHMR University, Jaipur has undergone internship training at **Department of Health Research, Ministry of Health and Family Welfare, New Delhi** from **3rd April to 2nd June 2017**.

The Candidate himself completed the project assign to him during summer training. His approach to the project was sincere and proactive. This summer training is in partial fulfillment of the course requirement recommended for the award of MBA in Hospital and Health Management

I wish him all success in all his future endeavors.



(Col.) Dr. Ashok Kaushik

Dean - Academics and Student Affairs
The IIHMR University, Jaipur



Mentor
Dr. Gautam Sadhu

Professor

The IIHMR University, Jaipur

V.K. Gauba
Joint Secretary to the Government of India
(Department of Health Research)
Ministry of Health & Family Welfare



वी.के. गाबा
संयुक्त सचिव, भारत सरकार
(स्वास्थ्य अनुसंधान विभाग)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Mr. Arvind Bhushan, student of MBA, IIHMR (Jaipur, Rajasthan), has successfully completed the two-month (from 3rd April to 2nd June, 2017) Summer Training Programme in Health Technology Assessment in India, in Medical Technology Assessment Board, Department of Health Research, Ministry of Health & Family Welfare, Government of India.

During the period of Internship, he was found hardworking, professional, punctual and inquisitive.

Department of Health Research wishes him every success in life.


(V. K. Gauba)

Date : 28th June, 2017
Place: New Delhi



वी.के. गाबा

संयुक्त सचिव
स्वास्थ्य अनुसंधान विभाग

एवम्

वरिष्ठ उप-महानिदेशक

भारतीय आयुर्विज्ञान अनुसंधान परिषद

V.K. Gauba

Joint Secretary

Department of Health Research
and

Senior Deputy Director-General
Indian Council of Medical Research



सत्यमेव जयते

भारतीय आयुर्विज्ञान अनुसंधान परिषद

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

भारत सरकार

वी. रामलिंगस्वामी भवन, अंसारी नगर

नई दिल्ली - 110 029

Indian Council of Medical Research

Department of Health Research

Ministry of Health & Family Welfare

Government of India

V. Ramalingaswami Bhawan, Ansari Nagar

New Delhi - 110 029

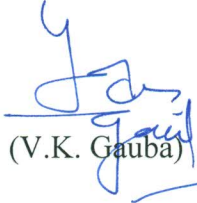
No. ADG (A)/2/2017-Admn-I

Dated: 02.06.2017

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Mr. Arvind Bhushan, student pursuing his MBA (1st year) from Institute of Health Management Research University, Jaipur has completed his summer training in the field of Medical Technology Assessment Board (MTAB) at Department of Health Research, M/o Health & Family Welfare, New Delhi for a period of 2 months w.e.f. 3rd April 2017 to 2nd June 2017.

He was found sincere, hardworking and completed training satisfactory.


(V.K. Gauba)

ACKNOWLEDGEMENT

I would like to extend my gratitude to thank Dr. Soumya Swaminathan DG ICMR, Secretary DHR for providing me an opportunity to work at Department of Health Research, Ministry of Health & Family Welfare, Government of India.

I am thankful to Mr. Vijay Gauba Joint Secretary DHR, Senior DDG ICMR for his keen interest in HTA and his encouragement at various stages of my training period. That helped me boost my interest into the HTA study.

I acknowledge with thanks the kind of patronage, loving inspiration, timely guidance and, the care and concern. which I have received from Dr. Kavitha Rajsekar Scientist D DHR. She helped me during my entire training period as a mentor.

I also thank Dr Laura downey Technical Analyst Imperial College London, Dr Miqdad Asaria and Dr Neethi Rao for their support and constant appreciation in every single work that I did during my training period.

I am extremely thankful to my friend Dr Gaurav jyani who was there with me during my training period and help me for providing me necessary technical suggestion.

Not the last my MTAB team members Dr Oshima Sachin, Dr Shalu Jain, Dr Amir Sohail, Dr Shatvindar Singh and Saagrika Nath Administrative Officer DHR whose presence created a friendly atmosphere and their experiences helped me in my learning.

I also thank IIHMR University, Jaipur for including such needed training programme into the MBA course that is very useful to gain practical exposure to the Industry. I am thankful to my Institute mentor Dr Gautam Sadhu for his support.

Family plays the most important role in everyone's life. I would like to thank my Parents and my younger brother Anupam Kumar. Who are always concern for me. Their concern and faith on me gives me lot of strength.

Section A

About the Organization

Brief History

Initially the Ministry of Health and Family Welfare had four Departments, Each of these Departments was headed by a secretary to the government of India:-

- Department of Health & Family Welfare
- Department of AYUH
- Department of Health Research
- Department of AIDS Control

On August 7, 2014 Department of AIDS Control has been merged with Department of Health & Family Welfare and now be known as National AIDS Control Organization (NACO). Department of AYUSH has been made Ministry of Ayurveda, Yoga and naturopathy, Unani, Siddha and Homeopathy (AYUSH) with focused attention on development of education and research in Ayurveda, Yoga & naturopathy, Unani, Siddha and Homoeopathy systems. Now Ministry of Health and Family Welfare comprises the following two department, each of which is headed by a Secretary to the Government of India :-

- Department of Health & Family Welfare
- Department of Health Research

Directorate General of Health Services (DGHS) is attached office of the Department of Health & Family Welfare and has subordinate offices spread all over the country. The DGHS renders technical advice on all Medical and Public Health matters and is involved in the implementation of various Health services.

About Department of Health Research

Department of Health Research was created under the Ministry of Health & Family Welfare through an amendment to the Government of India (Allocation of Business) Rules, 1962 on the 17th September 2007. The Department of Health Research was formally launched on 5th October 2007 by the Ministry for Science & Technology and Earth Science in a function presided over by the Minister for Health & Family Welfare, in the presence, inter-alia, of the Minister of State for Health & Family Welfare.

Mandate of DHR

1. Promotion and co-ordination of basic, applied and clinical research including clinical trials and operational research in areas related to medical, health, biomedical and medical profession and education through in areas related to medical, health, biomedical and medical profession and education through development of infrastructure, manpower and skills in cutting edge areas and management of related information there.
2. Promote and provide guidance on research governance issues, including ethical issues in medical and health research.
3. Inter-sectoral coordination and promotion of Public-private partnership in medical, biomedical and health research related areas.
4. Advance training in research areas concerning medical and health including grant of fellowship for such training in India and abroad
5. International cooperation in medical and health research including work related to international conferences in related areas in India and abroad.
6. Technical support for dealing with epidemics and natural calamities.
7. Investigation of outbreak due to new and exotic agents and development of tools for prevention.
8. Matters relating to scientific societies and associations, charitable and religious endowments in medicine and health research areas.
9. Co-ordination between organisations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department and for the promotion of special studies in medicine and health.
10. Indian Council of Medical Research.

About Medical Technology Assessment Board (MTAB)

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

Background

Ensuring access to effective and equitable health care for 1.3 billion population of India, within the limited resources involving current spending of just 1% of GDP on public health expenditure, is a great challenge and putting India within reach of the Sustainable Development Goals. Due to heavy out-of-pocket expenses on medical treatment by large proportion of population and rising cost of healthcare without corresponding increase in the government healthcare budget, there is a strong need to have a formal and institutionalized Health Technology Assessment mechanism to prioritize national health spending.

The need to establish a Medical Technology Assessment Board (MTAB) was recommended by 12th Plan Working Group on Health Research and, also by the Planning Commission (Now NITI Aayog) in its 12th Plan document on Social Sector. Department of Health Research, therefore, intends to setup a Medical Technology Assessment Board (MTAB) for evaluation of appropriateness and cost effectiveness of available and new health technologies in the country as part of research governance mandate of the Department.

Aim of the Board: To develop standardized cost-effective interventions that will reduce the cost and variations in patient care, expenditure on medical equipment indirectly affecting the cost of patient care, overall cost of medical treatment, reduction in out of pocket expenditure of patients and streamline the medical reimbursement procedures.

Objective of MTAB

- To support the process of decision-making in health care at the Central and State policy level by providing reliable information based on scientific evidence.
- Develop System and mechanism to assess new and existing health technologies by a transparent and inclusive processes
- To appraise health interventions and technologies based on available data on resources use, cost, clinical effectiveness, and safety
- To collect and analyse evidence in a systematic and reproducible way and ensure its accessibility and usefulness to inform health policy.
- Disseminate research finding and resulting policy decision to educate and empower the public to make better informed decision for health.

Function of MTAB

- Topic Selection (Topic considered of national and state importance will be prioritized according to a pre-defined criterion).
- Allocation of technical analysis on each prioritized topic to an Independent Technical Partner to undertake exhaustive assessment as per defined processes and methods;
- Report on findings will be reviewed by MTAB and
- Final recommendations will be submitted for approval for introduction in the public health system.

Activity At DHR, MOHFW

1. I was involved in the Core Committee meeting regarding the establishment of medical technology assessment board.
2. I was involved in preparing the Framework of the Process Manual for Health Technology Assessment in India.
3. As a member of MTAB team during my training period I participated in Six days training workshop on 'Introduction to economic analysis for Health technology assessment' held from 8 to 13 May, 2017 at the Achutha Menon Center for Health Science Studies, Shree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum. This workshop was organized in technical collaboration with NICE UK (Now Imperial College London, and HiTAP (Health Intervention Technology Assessment Programme) Thailand.
4. As a MTAB team member I participated in a workshop on Systematic Review organized on May 29-30, 2017 at conference hall, DHR to train the scientific staff of MTAB. This workshop was organized in technical collaboration with National Institute of Medical Statistics (ICMR), and Campbell Collaboration.

Exercises done during the Workshop

1) Exercise 1: Statistics for economic modeling

Objective:

- a. To help calculate transitional probability and comparison between conventional and exponential distribution.
- b. To teach basic steps on constructing Markov Model.

2) Exercise 2: Constructing Markov Model

Objective:

- a. To learn about the Markov Model in the worksheet.
- b. To construct a Markov model of dialysis by inserting the values and formulas into the 'HD' and 'PD' worksheet.
- c. To calculate incremental cost-effectiveness ratio (ICER)

3) Exercise 3: Constructing a Probabilistic Model.

Objective:

- a. Select appropriate distribution for all parameters in the model.
- b. Calculate mean, standard error, alpha, and beta for all parameters in the model.
- c. Execute Macro function for the simulation.
- d. To calculate Probabilistic value of Cost-effectiveness and Cost-Utility of renal replacement therapy.

4) Exercise 4: Constructing an acceptability curve

Objective:

- a. To learn and present the result on sensitivity analysis.

5) Exercise 5: Designing a PICO using a case study on Drug Eluting Stents

Objective:

- a. To appraise the clinical and cost effectiveness of drug eluting stents within its licensed indication for the treatment of coronary arterial disease.

A brief about the evaluation

End-stage-renal failure (ESRD) is the irreversible loss of kidney function. When the loss of kidney function reaches the point at which the kidneys fail to support life, then renal replacement therapy (RRT) is required.

There are three major treatment modalities for patients with ESRD. Firstly, hemodialysis(HD), the clearing of the blood from waste products through an artificial kidney, was introduced in 1960, following with renal (kidney) transplantation (RTx). The non-related donor renal transplantation has been possible since 1962 and eliminates the necessity of dialysis as long as graft is not irreversibly rejected by the recipient. Peritoneal dialysis (PD), the removal of waste products through a cleaning fluid in abdominal cavity, was introduced in 1970s. Currently, PD has two main treatment varieties, either with manual exchange of dialysis fluid (CAPD) or with automated exchange of dialysis fluid at night (CCPD).

Although, RRT is among the first medical technologies to be assessed with regard to its costs and outcomes, and has been do so regularly in so many setting so far. Many evaluations have considered the cost-effectiveness of ESRD treatments in a limited fashion e.g. home versus hospital or satellite unit hemodialysis (Mowatt et al 2003), hemodialysis versus renal transplantation (Knoll & Nichol 2003). Few studies were comprehensively compared all treatment modalities and very few conducted in developing countries where healthcare resources and technologies are limited.

This worksheet was developed as part of my PhD work to conduct health economic evaluation comparing value for money of dialysis (CAPD and hospital HD) with palliative medical treatment (current standard practice for UC beneficiaries) in Thailand. Markov model was adopted with probabilistic technique. All costs and outcome data were estimated using societal perspective from various sources e.g. national renal registry, literature (especially the probabilities of the low incidence outcomes i.e. complications, death).

If you have any further queries or plan to adopt this worksheet in any application or publication, please inform me as the following address.

Exercise 1: Calculating Transitional Probability

Year of following up (each cycle)	Interval (years)	Probability of survival (from time zero)	Probability of survival (during each) cycle	Probability of dying during the cycle	Annual mortality rate (during the cycle)	Yearly (transitional) probability of dying
0		1				
1	1	0.839	0.839	0.161	0.18	0.161
5	4	0.708	0.844	0.156	0.04	0.042
10	5	0.530	0.748	0.252	0.06	0.056
	10		0.530	0.470	0.029	0.029
Estimating transitional prob using conventional approach				Estimating transitional prob applying exponential		
Checking	tp(t)	Cumulative Survival		Checking	tp(t)	Cumulative Survival
0		1		0		1
1	0.161	0.839	TRUE	1	0.029	0.971
2	0.042	0.804		2	0.029	0.944
3	0.042	0.771		3	0.029	0.917
4	0.042	0.739		4	0.029	0.891
5	0.042	0.708	TRUE	5	0.029	0.865
6	0.056	0.668		6	0.029	0.840
7	0.056	0.630		7	0.029	0.816
8	0.056	0.595		8	0.029	0.793
9	0.056	0.561		9	0.029	0.770
10	0.056	0.530	TRUE	10	0.029	0.748
11	0.056	0.500		11	0.029	0.727

Exercise 2 Constructing an Economic Model

Parameters

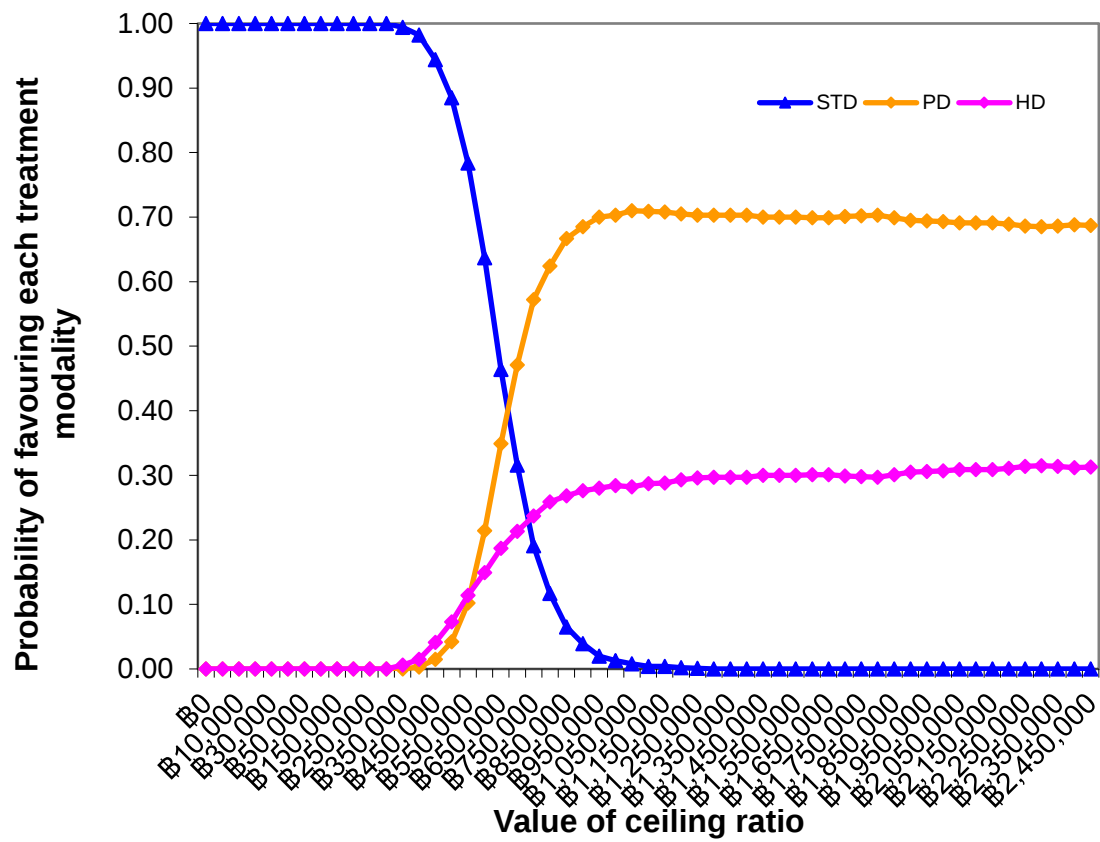
Name	Value	Parameter description
cDC	3.0%	Discounting rate for costs
cDO	3.0%	Discounting rate for outcomes
Transitional probabilities		
pDoNot	0.333	Transitional prob of dying among ESRD patients received paliative care
pComPD	0.329	Rate (per year) of having peritonitis among PD
pComHD	0.270	Rate (per year) of having vascular access related conditions among HD
pHDtoPD	0.006	Prob of switching from HD to PD
pPDtoHD	0.027	Prob of switching from PD to HD
Parametric form of survival data of dialysis cohort, fitting the model using weibull distribution		
cons	-11.18	Constant in survival analysis for baseline hazard
ageC	0.03	Age coefficient in survival analysis for baseline hazard
lambda	0.0001	Lambda parameter survival analysis (depends on chosen mix of above coefficients)
gamma	1.07	Ancillary parameter in Weibull distribution
Resource cost parameters		
Direct medical care costs i.e. direct costs of chronic dialysis or transaplantation		
cPaliative	17,623	monthly cost of paliative care for ESRD patient
cCath	46,667	Cost of catheter implantation
cPD	163.3	Cost of dialysis solution with bag (per set)
SessionPD	3.91	Sessions of PD per day
Set	28	Gauze+cotton+alcohol (per day)
Invest	790	Investigations e.g. BUN Cr Electrolyte chest x ray
cErythro	1,050	Cost of Erythropoietin
dErythro	2.0	Doses of erythropoietin required per patient per week
cVas	21,500	Cost of vacular access
cHD	2,220	Investigations e.g. BUN Cr Electrolyte chest x ray
SessionHD	2.30	Dialysis sessions per patient per week
cChroPD	356,941	medical care cost of chronic peritoneal dialysis
cChroHD	379,832	medical care cost of chronic hemodialysis
cPeritonitis	32,000	Cost of treating peritonitis
cComPD	10,528	Average cost of treatment peritonitis
cComHD	4,028	Average cost of treatment vascular access related conditions
Indirect medical care costs e.g. costs for treating co-morbidities from life-year saved		
cIP	14,919	Unit cost of IP case of university hospitals in Thailand
cOP	1,658	Unit cost of OP visit of university hospitals in Thailand
rIP	0.98	Incidence rate of IP visits for treating of co-morbidities
rER	2.13	Incidence rate of emergency room visits for treating of co-morbidity
rOP	12.85	Incidence rate of OP visits for treating of co-morbidity
cCoMobid	40,164	Total cost of treating co-morbidities
Total medical care cost		
cMedPD1	454,300	Medical care cost of PD in the first year
cMedPD2	407,633	Medical care cost of PD in subsequence years
cMedHD1	445,524	Medical care cost of HD in the first year
cMedHD2	424,024	Medical care cost of HD in subsequence years
Direct non-medical care cost i.e. travel costs, foods, and accommodation		
cIdMDonot	35,245	paid by household of ESRD patients who cannot offord RRT
cIdMHD	32,683	paid by HD households
cIdMPD	4,811	paid by PD households
Indirect non-medical cost i.e. income loss from sick leave or providing informal care (income loss from sick leave		
cPatientHD	40,951	paid by HD households
cPatientPD	2,717	paid by PD households
Total non-medical cost		
cNonMedPD	7,528	Non-medical cost of PD
cNonMedHD	73,634	Non-medical cost of HD
Utility parameters		
uPDnoCom	0.72	Quality of life adjusted factor for PD without complications
uHDnoCom	0.68	Quality of life adjusted factor for HD without complications
uCom	0.60	Quality of life adjusted factor for patients with complications
uPD	0.71	Quality of life for PD
uHD	0.67	Quality of life for HD

Heamodialysis															Peritoneal Dialysis			
Cycle (year)	days	H(days)	Death risk	new HD	HD	SwitchingToHD	HDdeath	Cost	Life Years	QALYs	New PD	PD	SwitchingToPD	PDeath	Cost	Life Years	QALYs	
0	-	-	0.00%	-	-	-	-	-	-	-	1	-	-	-	461,828	1.0	0.7	
1	365	0.045	4.41%	-	0.027	-	-	13,623	0.0	0.0		0.93	-	0.44	374,400	0.9	0.6	
2	730	0.095	4.87%	0.03	0.025	0.001	24,265	0.0	0.0	0.0		0.86	0.000	0.045	336,051	0.8	0.6	
3	1,095	0.147	5.06%	0.05	0.023	0.003	32,777	0.1	0.0	0.1		0.79	0.000	0.043	301,075	0.7	0.5	
4	1,460	0.200	5.18%	0.07	0.021	0.004	39,430	0.1	0.1	0.1		0.73	0.000	0.041	269,426	0.6	0.5	
5	1,825	0.254	5.28%	0.08	0.020	0.005	44,482	0.1	0.1	0.1		0.67	0.001	0.039	240,905	0.6	0.4	
6	2,190	0.309	5.36%	0.10	0.018	0.006	48,166	0.1	0.1	0.1		0.62	0.001	0.036	215,268	0.5	0.4	
7	2,555	0.365	5.42%	0.11	0.017	0.006	50,692	0.1	0.1	0.1		0.57	0.001	0.034	192,266	0.5	0.3	
8	2,920	0.422	5.46%	0.12	0.015	0.007	52,245	0.1	0.1	0.1		0.52	0.001	0.031	171,695	0.4	0.3	
9	3,285	0.478	5.48%	0.12	0.014	0.007	52,967	0.1	0.1	0.1		0.47	0.001	0.029	153,207	0.4	0.3	
10	3,650	0.536	5.58%	0.13	0.013	0.008	53,060	0.1	0.1	0.1		0.44	0.001	0.027	136,708	0.3	0.2	
11	4,015	0.594	5.62%	0.13	0.012	0.008	52,587	0.1	0.1	0.1		0.41	0.001	0.025	121,961	0.3	0.2	
12	4,380	0.652	5.65%	0.14	0.011	0.008	51,674	0.1	0.1	0.1		0.37	0.001	0.023	108,788	0.3	0.2	
13	4,745	0.710	5.69%	0.14	0.010	0.008	50,412	0.1	0.1	0.1		0.34	0.001	0.021	97,026	0.2	0.1	
14	5,110	0.769	5.72%	0.14	0.009	0.008	48,879	0.1	0.1	0.1		0.31	0.001	0.020	86,528	0.2	0.1	
15	5,475	0.829	5.75%	0.14	0.009	0.009	47,142	0.1	0.1	0.1		0.29	0.001	0.018	77,162	0.2	0.1	
16	5,840	0.888	5.78%	0.14	0.008	0.009	45,256	0.1	0.1	0.1		0.26	0.001	0.017	68,806	0.2	0.1	
17	6,205	0.948	5.80%	0.14	0.007	0.008	43,268	0.1	0.1	0.1		0.24	0.001	0.015	61,355	0.1	0.1	
18	6,570	1.008	5.83%	0.13	0.007	0.008	41,218	0.1	0.1	0.1		0.22	0.001	0.014	54,711	0.1	0.1	
19	6,935	1.068	5.85%	0.13	0.006	0.008	39,138	0.1	0.1	0.1		0.21	0.001	0.013	48,788	0.1	0.1	
20	7,300	1.129	5.88%	0.13	0.006	0.008	37,055	0.1	0.0	0.0		0.19	0.001	0.012	43,507	0.1	0.1	
21	7,665	1.190	5.90%	0.13	0.005	0.008	34,991	0.1	0.0	0.0		0.17	0.001	0.011	38,800	0.1	0.1	
22	8,030	1.251	5.92%	0.12	0.005	0.008	32,963	0.1	0.0	0.0		0.16	0.001	0.010	34,605	0.1	0.1	
23	8,395	1.312	5.94%	0.12	0.004	0.008	30,986	0.1	0.0	0.0		0.15	0.001	0.009	30,866	0.1	0.1	
24	8,760	1.373	5.96%	0.11	0.004	0.007												

Exercise 3 Constructing a Probabilistic Model

perspective		0 Probability?						
1								
Name	Value	Parameter description	Distribution	Probabilistic	Mean	SE	alpha	beta
cDC	3.0%	Discounting rate for costs						
cDO	3.0%	Discounting rate for outcomes						
Transitional probabilities								
pDoNot	0.333	Transitional prob of dying (per month) among ESRD patients received palliative care	beta	0.161	0.3330	0.1500	2.95	5.92
pComPD	0.329	Rate (per year) of having peritonitis among PD	gamma	0.008	0.3290	0.5740	0.33	1.00
pComHD	0.270	Rate (per year) of having vascular access related conditions among HD	gamma	0.077	0.2700	0.5190	0.27	1.00
pHDtoPD	0.006	Prob of switching from HD to PD	beta	0.005	0.0064	0.0011	35	5,439
pPDtoHD	0.027	Prob of switching from PD to HD in the first year	beta	0.044	0.0270	0.0054	24	864
Parametric form of survival data of dialysis cohort, fitting the model using weibull distribution								
cons	11.18	Constant in survival analysis for baseline hazard	lognormal	0.00	-11.18	0.24		
ageC	0.03	Age coefficient in survival analysis for baseline hazard	lognormal	0.00	0.035	0.002		
lambda	0.00	Lambda parameter survival analysis (depends on chosen mix of above coefficients)						
gamma	1.07	Ancillary parameter in Weibull distribution	lognormal	0.00	0.072	0.025		
Resource cost parameters								
Direct medical care costs i.e. direct costs of chronic dialysis or transplantation								
cPalliative	17,623	monthly cost of palliative care for ESRD patient	gamma	70,798	17,623	17,623	1.00	17,623.00
cCath	46,667	Cost of catheter implantation	gamma	42,985	46,667	15,275	9.33	4,999.80
cPD	163	Cost of dialysis solution with bag (per set)	gamma	169	163	15.27	114.37	1.43
SessionPD	3.91	Sessions of PD per day	gamma	3.90	3.91	0.33	140.39	0.03
Set	28	Gauze+cotton+alcohol (per day)	gamma	24	28	4.00	49.00	0.57
Invest	790	Investigations e.g. BUN Cr Electrolyte chest x ray	gamma	971	790	238	10.99	71.86
cErythro	1,058	Cost of Erythropoietin per dose	gamma	1,096	1,058	338	9.82	107.70
dErythro	2.00	Doses of erythropoietin required per patient per week	gamma	2,032	2.0	0.13	236.69	0.01
cVas	21,500	Cost of vascular access	gamma	29,296	21,500	7,416	8.40	2,558.00
cHD	2,220	unit cost of HD	gamma	2,705	2,220	981	5.12	433.39
SessionHD	2.30	Dialysis sessions per patient per week	gamma	7.96	2.30	2.46	0.87	2.63
cChroPD	357,775	medical care cost of chronic peritoneal dialysis	sum of parameters above					
cChroHD	380,666	medical care cost of chronic hemodialysis	sum of parameters above					
cPeritonitis	32,000	Cost of treating peritonitis	gamma	33,113	32,000	24,000	1.78	18,000.00
cComPD	10,528	Average cost of treatment peritonitis	sum of parameters above					
cComHD	4,028	Average cost of treatment vascular access related conditions	sum of parameters above					
Indirect medical care costs e.g. costs for treating co-morbidities from life-year saved								
cIP	14,919	Unit cost of IP case of university hospitals in Thailand	gamma	4,304	14,919	14,919	1.00	14,919.00
cOP	1,658	Unit cost of OP visit of university hospitals in Thailand	gamma	477	1,658	1,658	1.00	1,658.00
rIP	0.98	Incidence rate of IP visits for treating of co-morbidities	normal	0.93	0.98	0.04		
rER	2.13	Incidence rate of emergency room visits for treating of co-morbidity	normal	2.07	2.13	0.17		
rOP	12.85	Incidence rate of OP visits for treating of co-morbidity	normal	12.70	12.85	0.44		
cCoMorb	40,164	Total cost of treating co-morbidities	sum of parameters above					
Total medical care cost								
cMedPD1	455,134	Medical care cost of PD in the first year	sum of parameters above					
cMedPD2	408,467	Medical care cost of PD in subsequent years	sum of parameters above					
cMedHD1	446,358	Medical care cost of HD in the first year	sum of parameters above					
cMedHD2	424,858	Medical care cost of HD in subsequent years	sum of parameters above					
Direct non-medical care cost i.e. travel costs, foods, and accommodation								
cidMDonot	35,245	paid by household of ESRD patients who cannot afford RRT (per month)	gamma	15,286	35,245	35,245	1.00	35,245.00
cidMHD	32,683	paid by HD households	gamma	134,210	32,683	54,009	0.37	89,248.34
cidMPD	4,811	paid by PD households	gamma	17,292	4,811	8,400	0.33	14,665.98
Indirect non-medical cost i.e. income loss from sick leave or providing informal care (income loss from sick leave is a major part, accounting for >90% of total cost)								
cPatientHD	40,951	paid by HD households	gamma	33,211	40,951	56,481	0.53	77,901.36
cPatientPD	2,717	paid by PD households	gamma	1,029,630	2,717	4,481	0.37	7,391.13
Total non-medical cost								
cNonMedPD	7,528	Non-medical cost of PD	sum of parameters above					
cNonMedHD	73,634	Non-medical cost of HD	sum of parameters above					
Utility parameters								
uPDnoCom	0.72	Quality of life adjusted factor for PD without complications	beta	0.835	0.72	0.08	21.96	8.54
uHDnoCom	0.68	Quality of life adjusted factor for HD without complications	beta	0.811	0.68	0.10	14.12	6.64
uCom	0.60	Quality of life adjusted factor for patients with complications	beta	0.718	0.60	0.15	5.80	3.87
uPD	0.71	Quality of life for PD	Adjusted for a month period					
uHD	0.67	Quality of life for HD	Adjusted for a month period					

Constructing an Acceptability Curve



Exercise 5 Designing a PICO

A case study on Appraisal of Drug Eluting Stents

Scope

Appraisal Objective

To appraise the clinical and cost effectiveness of drug eluting stents within its licensed indication for the treatment of coronary arterial disease.

Background:

Coronary artery disease (CAD) is a major cause of morbidity and mortality in India. Build-up of material, forming plaques, results in a narrow occlusion of the blood vessels supplying the heart muscle. This in turn results in reduces blood flow and thus supply of oxygen to the heart muscle. Plaques can be unstable and cause symptoms of ‘Unstable angina’, although some people may not experience noticeable signs of CAD. Complete blockage of arteries results in acute myocardial infarction (hear attack) which risk life and lasting damage to the heart.

Risk factors for CAD include smoking, poor diet and lack of exercise. Primary prevention, involving changes in these behaviours may influence the risk of developing CAD. Treatment for CAD and its symptoms include modification of risk factor, such as those for primary prevention and medication. Where these meaures are insufficient, more invasive therapies may be employes. These include surgery to replace occluded arteries, or percutaneous coronary intervention (PCI) to clear or reduce narrowing within vessels.

The number of stents used in India has trebled over the past 5 years, according to the national intervention council (NCI). Almost 5 lakh stents were implanted in 2015 alone. Both drug eluting stents and bare metal stents were added to India’s national List of Essential Medicines in 2015.

The Technology

In PCI, a small elongated balloon is introduced into a patient’s artery (without the need for surgery) and inflated once located at the site of the plaque (lesion), effectively compacting the deposited material against the vessel wall. This procedure, termed percutaneous transluminal coronary angioplasty (PCTA) has been commonly used since the 1980s. Although successful in expanding vessel during the procedure treatment and restenosis re-narrowing of the vessel following treatment. In an adaptation to PTCA alone, tiny metallic mesh tubes can also be guided to the site of the lesion and scaffold the vessel open. Percutaneous coronary intervention

with the use of stents reduces procedural complications and restenosis of treatment vessels. Procedural success rates for deploying these stents are high, complication rates are low and most patients experience improvement in symptoms after the intervention. However, a proportion of patients still experience restenosis following treatment with PCI using stents. Other patients, due to the extent of their CAD, are not suitable for treatment by PCI.

Further modification of PCI technology involves the use of stents that release an antiproliferative agent into the area surround the stents, The agent released from these drug-eluting stents (DES) act to reduce cell migration and growth at the site of the stent and thereby reduce the risk of restenosis, without the toxicity associated with the patient taking a drug which acts systematically.

Economics: Coronary stents account for 20-40% of total procedure costs in private hospitals, and 70-90% in government hospitals. Prices have been reported to range from Rs 23, 625 upto Rs 150000.

The PICO

Intervention	Stent with release of antiproliferative agent.
Populations	CAD Patients
Comparators	a) No Intervention. b) Stent with drug release. c) Balloon catheter without drug.
Outcomes	List here the key outcomes to be considered in the appraisal that are relevant to the disease area. Overall survival, disease-free survival, acute closure can be reduces, restenosis will not occur, Reduced morbidity.
Economic analysis	Provide key elements that should be included in any cost effectiveness analysis, based on the Indian Reference case including: Choice of effectiveness measure? Clinical effectiveness Appropriate time horizon? 10 to 15 years.

	Cost Perspective? Additional drug cost, patient follow up cost, opportunity cost, treatment cost.
Other Considerations	Add other relevant information like Role of budget impact analysis. Building cost, wages cost, equipment cost etc.

About the Project

Health Technology Assessment in India

INTRODUCTION: Technological advancement in the recent decades has remarkably affected the health care setting in a variety of areas to improve health care delivery and patient outcomes, including drugs, antidiabetic drugs, vaccines, pharmacogenomics, cancer therapies, diagnostic imaging, and health information technology (Goodman 2014). Health technology assessment (HTA) is the tool or “any process of examining and reporting properties of a medical technology used in health care setting, i.e., safety, efficacy, feasibility, and cost effectiveness, to examine and access medical properties in order to inform decision and policy maker (Agrawal 2014). It is a multiscientific and interdisciplinary activity delivering input for priorities and decisions in health care system (Kristensen and Sigmund 2007) . Its main purpose is to inform technology-related policy-making in health care, and to improve the uptake of cost-effective new technology (World Health Organization 2011). The HTA information is used for policy and decision making only when performed correctly and reported accurately (Chaikledkaew and Kittrongsiri 2014). This demands a standardize guidelines to conduct HTA and increase transparency of study by allowing reader and user to assess what the analysis have done.

The scaling up cost in primary healthcare setting has been one of the critical areas of discussion among the policy and decision makers in developing countries (Kanjilal n.d.). Considering the huge variation in childhood mortality rate, vaccination and treatment seeking behavior of the population in various states of India, cost effectiveness analysis should be considered at the state level (Gupta et al. 2013)

Literature Review

An affordable healthcare prioritization mechanism in a county like India is essential for achieving the goal of universal health coverage (Kumar et al. 2014). The increasing costs of healthcare intervention, diagnostics and devices, their formal assessment is a must in current health policy in India. There is insufficient resources to provide all health care seekers in all circumstances with the best possible healthcare. With the increasing aging population and technological development in healthcare is producing even increasing demand on health resources. This is particularly crucial in country like India. There is an increasing demand of using HTA information however, in an study it was found that there are various methodological

flaws with HTA studies and a serious attention needed to be given to the quality of reporting and the use of HTA information in the decision making and this problem could be tackled by a standard guideline (Yot Teerawattananon 2008). As countries strive to deliver UHC, the decision process becomes very important and the country faces complex choices in deciding how to invest their health budget to meet the priority health needs. To arrive on a fair and efficient outcome requires a multidisciplinary process to evaluate the social, economic, ethical aspects of health technology (Hill et al. 2015). In recent years a number of guidelines have been produces in different formats. Countries like Australia, Canada, Denmark, Norway, Hungary, England and Wales have developed economic evaluation guideline with different details but similar objective to provide a uniform methodology approach to improve the quality and EE methodology (Drummond et al. 2009) (Yot Teerawattananon 2008).

Purpose: HTA could be utilized in various ways. It can be used for evaluating a technology that is being considered for uptake into practice at the level of healthcare facility or it can be used for evaluating impact of a technology that has already been adopted. As a methodology HTA could have a role in technology application and its impact, including clinical efficacy, cost effectiveness, legal, social, and ethical dimensions (Agrawal 2014)(Kelly and Moore 2012).

HTA in India: India has experienced rapid economic growth and quick transition to middle income state. It has also experiences a consistently growing burden of chronic health problems in line with its growing capital wealth. An evidence informed affordable healthcare prioritization mechanism in low and middle-income country like India is essential for achieving the aspirational goal of universal healthcare (Kumar et al. 2014). While India has the capability to invest more in healthcare, the challenge is to set priorities in a rational way so that any extra investment yield increased health gain (Glassman, Duran, and Sumner 2011). To develop a mechanism to conduct a HTA study in India Government of India has proposed the establishment of Medical Technology Assessment Board under the Department of Health Research, Ministry of Health & Family Welfare.

OBJECTIVE OF MTAB:

1. To support the process of decision-making in health care at the Central and State policy level by providing reliable information based on scientific evidence.
2. Develop systems and mechanisms to assess new and existing health technologies by a transparent and inclusive processes.
3. To appraise health interventions and technologies based on available data on resource use, cost, clinical effectiveness, and safety.
4. To commission the collection and analysis of evidence in a systematic and reproducible way and ensure its accessibility and usefulness to inform health policy.
5. Disseminate research findings and resulting policy decisions to educate and empower the public to make better informed decisions for health.

Proposed Structure of MTAB:

MTAB is proposed to be an Advisory Body under the Department of Health Research (DHR) comprising eminent people from relevant field, like public and private health care provider, academia, researcher, and representative from MoHFW. It will consist of Board, Secretariat, and Technical Appraisal Committee.

Statement of Purpose of Board:

- a) The MTAB will operate as a standing recommendatory body.
- b) The MTAB will consider and approve the recommendation from the Technical Appraisal Committee on all the HTA studies.
- c) The MTAB will submit its recommendations to the MoHFW for further adoption in the Health system of the Country.

Statement Purpose of the Secretariat:

- a) A system for extracting available evidence, gather primary data/information through model projects for improving the health research governance in India and to examine the numerous and heterogeneous health technology providers.
- b) Lead the strategic planning of the establishment of HTA in India as an effective means of priority setting in health.
- c) Supporting the MTAB members and Technical Appraisal Committee members to work on the day to day activities of the MTAB secretariat.
- d) Lead the activities assigned for charter of duties to DHR-MTAB secretariat.

Statement of Purpose of the Technical Appraisal Committee

- a) Operate as a standing advisory committee to Medical Technology Assessment Board.
- b) Receive, consider, and interpret evidence on the clinical effectiveness and cost effectiveness of health technologies referred to it.
- c) Identify the Technical Partners for undertaking HTA studies.
- d) Submit its recommendations/outcomes of HTA studies to the Board.

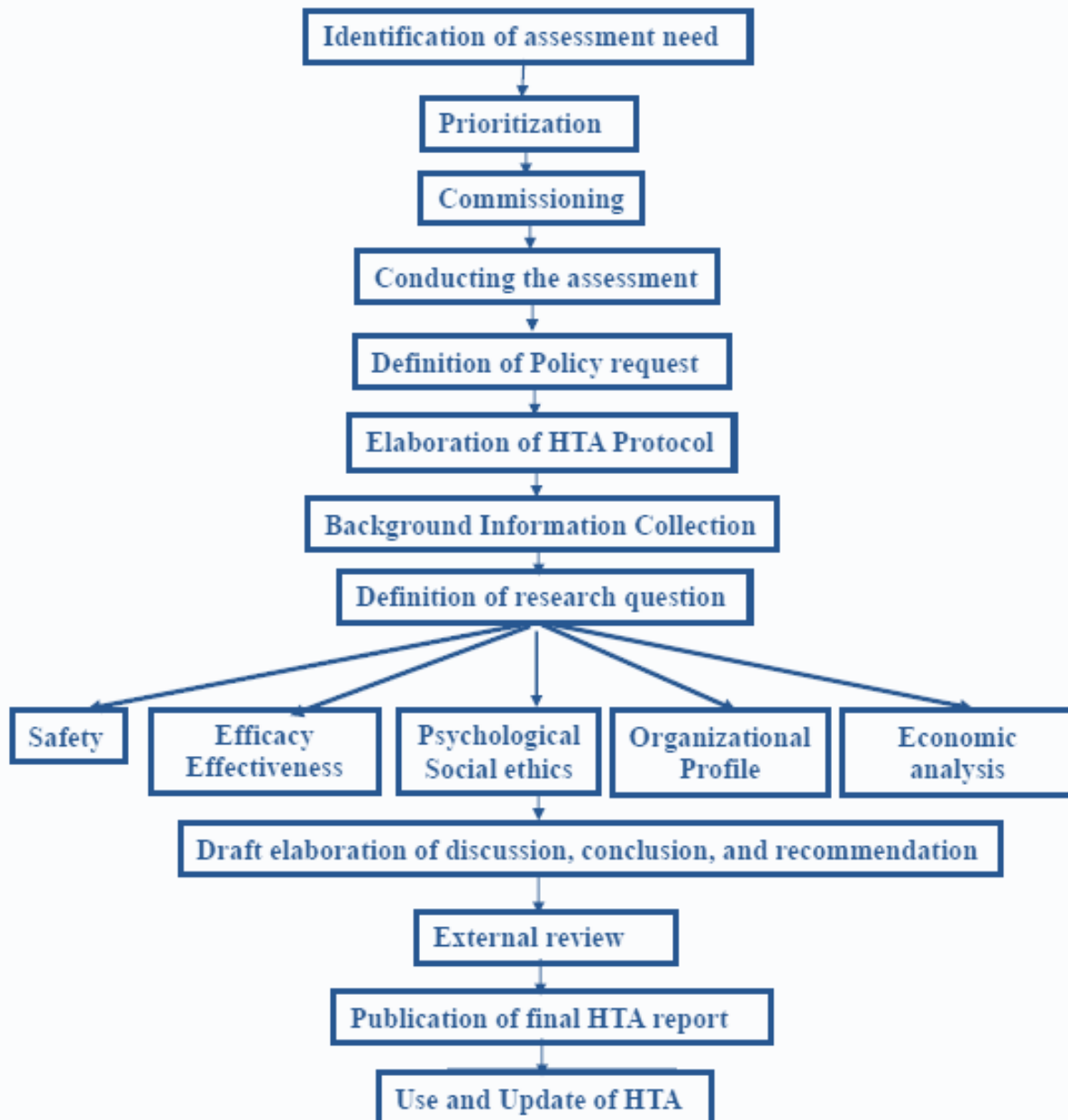
Aim of the training:

- To Understand and Learn the functioning of Department of Health Research.
- To Develop a mechanism to conduct a HTA study in India

Objective:

- To understand the HTA process.
- To do the Economic Evaluation Modeling in India For HTA studies.

Over View of HTA Process



SELECTION AND PRIORITIZATION OF TOPICS

To some large extent topics are determined by the mission or the purpose of the organization submitting the topic (Goodman 2014). A topic could be a medical procedure, a medical device, or a drug.

Horizon Scanning: The urge of prior information about the new technology and health care interventions has prompted the development and evolution of horizontal scanning. It serves multiple purpose (Carlsson 1998; Douw 2003; Harper 1998; Packer 2012).

- Identify HTA topic and information for the priority setting among other HTA study.
- Identify the new technology area and its use.
- Forecast the health and economics impacts of technologies.
- Identify potential social, ethical, or legal implications of technologies.

GENERAL OVERVIEW OF SELECTION AND PRIORITIZATION OF TOPICS FOR HTA

STEP 1: The suggested topics are added to data base. In the first stage all topic are review by the expert committee to ensure it fits the mandate.

STEP 2: Topics that meet the mandate are filtered for appropriateness using a set criteria.

Criteria for assessment of appropriateness of a topic:

Criterion	Definition and Weight	Score	Score Definition
Duplication of effort	Is another organization undertaking a review or considering a review on the same topic? 30	3	No duplication foreseen
		2	Partial duplication is possible, which may allow brokering or collaboration
		1	Another organization is considering this topic
		0	Another organization is currently working on this topic
Need	How important is the policy, purchasing, or practice decision for which this evidence is needed? 40	3	Decision with substantial impact on patient care
		2	Decision with moderate impact on patient care
		1	Decision with limited impact on patient care
		0	No decision to be made in the foreseeable future, or decision with no impact on patient care
Stage of diffusion	Is the technology available in 30	3	Currently approved or in use in Canada
		2	Currently not approved or used in Canada, but likely to be approved or used in the next year
		1	Currently not approved or used, and unlikely to be approved or used in the next year
		0	Currently not approved or used and will not be considered for approval or use in the next year (i.e., not approved in any other countries)

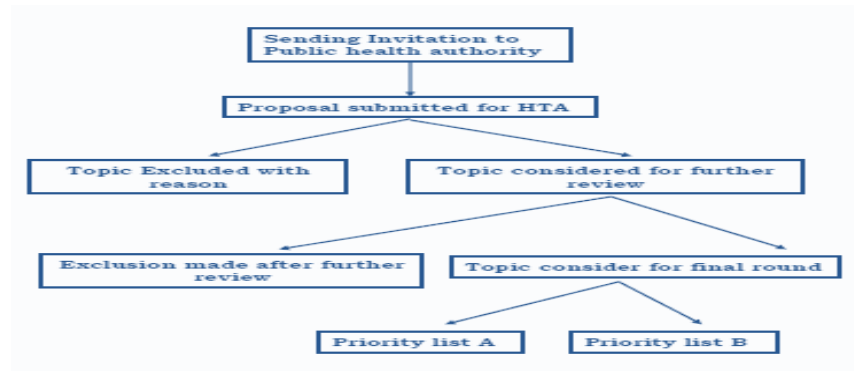
Prioritization Criteria:

Prioritisation considers health benefit, impact on health-related Government policy (Harper, Townsend, and Buxton 1998), impact on health resources, clinical practice variation, and whether DHR can add value by issuing guidance on the given health technology by conducting a formal HTA decision. Prioritisation can be carried out by considering the following criteria:

1. **Population** - The larger the population affected, the more important a technology is for evaluation (Health Quality Ontario 2009).
2. **Disease severity** - Severity of condition impacts on importance of evaluation, takes into account, life expectancy, how far the individual is away from perfect health and health states that incur social stigma (Glassman, Duran, and Sumner 2011).
3. **Potential therapeutic benefit** - Extent to which a new technology claims measurable therapeutic benefit over currently available treatments (Guinness et al. 2005).
4. **Inequity in access and/or utilisation** - The situation of inequality in accessibility to and utilization of health services by region and population (Prinja et al. 2012).
5. **Resource impact** - Potential resource impact of guidance including cost of implementing guidance, any additional service, facilities or staff requirements. HTA can help in managing the unforeseen expenses (WHO 2015).
6. **Availability and relevance of evidence** - Availability and relevance of evidence for conducting HTA (Mobinizadeh et al. 2016).
7. **Health policy priority** - The level of priority of diseases/health problems and proposed interventions. Public or political demand can also influence the priority setting (Agrawal 2014).

Feasibility of implementation - Proposed intervention can be implemented in reality considering social and ethical issues.

FLOW CHART FOR TOPIC PRIORITIZATION



Scoping:

CRITERIA FOR SCORING AND TOPIC PRIORITIZATION

Criterion	Definition and Weight	Score	Score Definition
Clinical Impact	Potential for the technology to have an impact on patient-related health outcomes (benefits and harms) 25	3	Major potential improvement in clinical outcomes
		2	Moderate potential improvement in clinical outcomes
		1	Little potential improvement in clinical outcomes
		0	No expected change in clinical outcomes
Budget Impact	Impact of the technology on health care spending 25	3	Major cost savings or expense (> \$50 M)
		2	moderate cost savings or expense (> \$10 M to \$50 M)
		1	Limited cost savings or expense (\$1 M to \$10 M)
		0	No cost savings or expense (< \$1 M)
Population impact	The size of the population that would be affected by the technology 15	3	Affects 5% or more
		2	Affects from 1% to < 5%
		1	Affects from 0.05% to < 1%
		0	Affects < 0.05%
Jurisdictional interest	The number ^a of provincial, territorial, or federal programs with a CADTH customer (such as hospital, regional health authority, or Ministry of Health) facing a decision on the technology, and which could use the HTA to inform a decision or change 20	3	Interest from ≥ 7 jurisdictions
		2	Interest from 5 or 6 jurisdictions
		1	Interest from 2 to 4 provincial jurisdictions
		0	Interest from < 2 jurisdictions
Equity	The technology has the potential to introduce, increase, or decrease equity in health status 15	3	Major potential to affect equity in health status
		2	Moderate potential to affect equity in health status
		1	Minor potential to affect equity in health status
		0	Will not affect equity in health status

The scoping brief will be used to score the topics under consideration. Weighted scores will be calculated and used to rank the topics. The ranked list will be shared with the committees, and other relevant groups and will be posted on the website.

The final decision about the HTA topics to be undertaken will be done based on the ranked list, the resource needs for the topics will be written on those topics that require an HTA with recommendations. Topics not initiated as an HTA may be considered for an alternative such as Rapid Response, or remain on the list for the next prioritization cycle.

LITERATURE SUMMERY:

The increasing costs of healthcare intervention, their formal assessment is a must in current health policy in India. There is insufficient resources to provide all health care seekers in all circumstances with the best possible healthcare. With the increasing aging population and technological development in healthcare is producing even increasing demand on health resources. There is an increasing demand of using HTA information however, in an study it was found that there are various methodological flaws with HTA studies and a serious attention needed to be given to the quality of reporting and the use of HTA information in the decision making and this problem could be tackled by a standard guideline. As countries strive to deliver UHC, the decision process becomes very important and the country faces complex choices in deciding how to invest their health budget to meet the priority health needs.

It has been seen that the involvement of HTA in health care is increasing with greater transparency, and increasing involvement of stakeholder in HTA. Although some stakeholder may oppose HTA due to inherent interest, Prime movers in healthcare seek to maintain incentive to develop new technologies and healthcare product and services provider seeks short term return on their investment. Companies seek to increase profit through increased sales of the product at high price.

The most crucial obstacle in Indian context is presence of 71% private healthcare market. The government is planning to increase its healthcare expending from 1% of GDP to 3%. The Planning commission constitute a high-level expert group on Universal health coverage with a mandate of developing a framework for providing easily accessible and affordable healthcare to the Indian population. The new reforms when implemented are expected to have far reaching impact on the health system, including pharmaceutical and reimbursement mechanism in India and hence the need for resource allocation mechanism such as HTA.

CONCLUSION:

- Success of HTA study in Indian context will contribute towards the UHC. It will help government identify the lagged area in health system accordingly it will help in the budget allotment.
- It will bring down the out-of-pocket expenditure which at present is 80% in India.
- It will formalize the health care accessibility in rural and urban setting.
- HTA findings will play an advisory role in policy decisions.

SUGGESTION:

- Government should recommend the inclusion of the study of HTA at college level.
- Government Should expand the capacity building and should include health NGOs.
- An HTA Sensitization programme should be conducted to increase public awareness.
- Government should socialize the HTA work and Media should be included.

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