

Better Decisions for Better Health: Priority-setting and Health Technology Assessment for Universal Health Coverage in India

A narrative summary

Prepared by NICE International

As India is launching the ambitious National Health Assurance Mission (NHAM) to ensure guaranteed health services to all its population, it needs to decide which interventions (from drugs, diagnostics, devices to public health interventions) it will cover in order to provide maximum benefit to its population. Even the world's richest countries cannot assure all health services to all its citizens; and for India, home to one sixth of humanity, the challenge is far greater.

The estimated cost of India's plans for universal coverage under NHAM is 1.6 trillion rupees (\$26 billion) over the next four years¹. Though the health budget may increase, it will still remain finite, and the key will be to ensure every rupee spent on health is utilized in the best possible way.

Under NHAM, the government plans to provide a core package of assured health services. Initially this is expected to include 50 essential drugs, a defined package of diagnostics and about 30 AYUSH (Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopathy) treatments. Certain primary, secondary and tertiary services are also expected to be available at differential prices to users according to ability to pay. The Government will however need to evaluate regularly which new services, drugs, or technologies to be added or removed. Determining these priorities will not be easy. For instance, how do we choose between buying 5,000 infant warmers, or stents for cardiac patients, or drugs for someone with cancer?

However difficult these choices are, they still need to be made since not taking a decision also amounts to a decision that someone else will decide. The choice will then become dependent on the discretion of the treating doctor, or maybe influenced by industry or some other vested interest.

How can policy makers make evidence-based choices to ensure finite health budgets prioritize services that provide greatest benefit to the people? This is called "priority-setting"; in other words, it is making better decisions for better health.

¹ As per Reuters report quoting a senior official in the Ministry of Health, 30 Oct 2014.
<http://in.reuters.com/article/2014/10/30/uk-india-health-idINKBNoIJoVN20141030>

In the following narrative summary, we provide an account of the substantive discussions that took place in the recent workshop in India organized to raise awareness on this important issue of priority-setting. NICE International, a not-for-profit arm of the UK's National Institute for Health and Care Excellence (NICE) hosted the workshop in Delhi on 10th & 11th October in conjunction with the Ninth Forum of Government Sponsored Health Insurance Schemes in India (co-hosted by the World Bank and the Ministry of Health and Family Welfare, Government of India).

Presentations from the event and background material are available [here](#).

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The Inaugural: Making sure the rupee goes the longest way

Mr Lov Verma, Union Secretary, Ministry of Health & Family Welfare shared India's progress since Independence in improving population health. He said that priority-setting is important for India as the country is at a crossroads, and that the Medical Technology Assessment Board (MTAB) created under the Department of Health Research will have an important role in priority-setting.

The National Health Assurance Mission will see healthcare as an entitlement for all. But, what should our priorities be? There are so many competing interests and it's important we use evidence to decide.

Mr Lov Verma, Union Secretary, Ministry of Health & Family Welfare, India



Dr. V M Katoch, Secretary of Department of Health Research (DHR) shared that DHR had reviewed various global models and found the NICE model closest to their thinking. This had led to signing of a Memorandum of Understanding with NICE in order to build HTA expertise in India. He also shared that recently a question had been raised in parliament on how the Indian Government decides which health technology to adopt.

Welcoming the views of both previous speakers, Prof Ranjit Roy Chaudhury, Chair of the expert group advising the Health Ministry on the NHAM, reiterated the need to take informed decisions when spending public money.

“Make sure the rupee goes the longest way”.

Prof Ranjit Roy Chaudhury, Adviser MoHFW, India

Sir Andrew Dillon, Chief Executive, NICE, affirmed NICE's commitment to work with Indian partners.

“NICE is committed to its partnership with the Ministry of Health and Family Welfare, under the Memorandum of Understanding with the Department of Health Research and is working closely with health assurers in India to ensure that public and private providers can deliver high quality, cost-effective healthcare for all.”

Sir Andrew Dillon, Chief Executive, NICE, UK

Mr Marshall Elliot, Head of DFID India, also confirmed DFID's commitment towards supporting India in its journey towards better care for all citizens.

The inaugural concluded with Dr Somil Nagpal sharing that the World Bank team was delighted to co-host the workshop with the Ministry of Health and Family Welfare and NICE International; as India is planning UHC, priority-setting matters more.

Dr Francoise Cluzeau, Associate Director, NICE International, remarked that NICE's partnership with Indian state and national agencies goes back a number of years. NICE has provided technical assistance to the Government of Kerala for the development of quality standards in maternal care; and currently is supporting the development of evidence-informed pathways and standards for improving care under the Rashtrita Swasthya Bima Yojana (RSBY).



The experience of NICE in priority-setting for universal health coverage in the UK

What has been the experience of NICE in providing authoritative guidance and standards to the National Health Service (NHS) in England? How does it guide the most cost-effective ways to improve population health? What can India and UK learn from each other?

A key component of the MOU signed between DHR, Ministry of Health and Family Welfare and NICE in 2013 was “strategic and technical cooperation with regard to evidence-informed healthcare policy and practice”. The workshop provided an opportunity for this exchange.

“Everywhere in the world, policymakers have to make difficult choices about how best to use their resources to improve people’s health, and involving the stakeholders in this process is crucial to making better decisions.”

Sir Andrew Dillon, Chief Executive, NICE, UK.



Sir Andrew Dillon, Chief Executive of NICE, recalled NICE’s journey from working on a single programme on the clinical and cost-effectiveness of new drugs in 1999, to 2014 where it now works on an array of programmes including the development of clinical guidelines and quality standards in health, public health, and social care. Sir Andrew said: “Every pound spent on one patient is not spent on another patient, thus we need to make best use of available resources to best serve the whole population”. At the heart of NICE’s work is bringing together science and social value judgments, and reconciling competing interests of

stakeholders: “Any one stakeholder is no more or no less important than any other stakeholder in any NICE decision”.

Dr Kalipso Chalkidou, Director, NICE International, emphasised the importance of governance and process in evidence-informed priority-setting and reiterated HTA is *not* merely a technical or technocratic exercise focused only on technologies (narrowly defined).

“HTA is not just about drugs, but everything the health system delivers... HTA is not cost containment, but ensuring every rupee delivers maximum health benefit.”

Dr Kalipso Chalkidou, Director, NICE International



If we spend money on expensive cancer drugs, have we enough money for wheelchairs to bring the patient to hospital? If we adopt a new technology, what will be displaced? There is always an opportunity cost. Hence, science-based decisions are essential for achieving and sustaining UHC. As India launches NHAM, “the world will be looking to India, how you will set up the World’s biggest Health Assurance scheme”. An evidence-based approach will set an example for other countries to follow. Dr Chalkidou further reiterated that for an evidence-based approach, it’s critical to establish a strong governance mechanism, robust processes, and a transparent approach ensuring the involvement of all stakeholders.

International experiences: using evidence to inform decision-making through the patient pathway

The panel on international experiences had experts from Thailand, Turkey, South Africa and China share their experiences on using an evidence-based approach to decision making. The panel session was chaired by Mr Manoj Jhalani, Joint Secretary (Policy), Ministry of Health & Family Welfare,

“We need to use whatever resources we have in the most cost-effective manner.”

Mr Manoj Jhalani, Joint Secretary (Policy), MoH&FW, India

Dr Inthira Yamabhai, Researcher, HITAP (Health Intervention and Technology Assessment Program, Thailand) shared the Thai experience of priority-setting in public health. Thailand established universal health insurance coverage in 2002 after recovering from the economic crisis of 1990s. It established HITAP in 2006 with the objective of balancing the increased demand for covering high-cost health interventions and the need for greater efficiency in the



healthcare system. A strong civil society movement had advocated for an evidence-based and transparent approach to UHC, and HITAP was established with the vision to ensure appropriate health interventions and technologies for the Thai society.

HITAP established robust processes for HTA, which included consultations from various stakeholder groups

for topic selection; systematic review of clinical and cost-effectiveness evidence; evaluation of results by a multi-stakeholder appraisal committee; and dissemination of results and recommendations. HTA is used in Thailand to inform coverage decisions on which services are to be included in the UHC benefits package, and the National List of Essential Medicines. HTA has informed not only listing of drugs, but also influenced pharmaceutical price negotiations by laying bare the expected health gains from drugs and devices against the price, using the best available evidence. For example, Thailand has been able to negotiate a forty-fold saving on the use of angiotensin inhibitors as a result of a defensible and acceptable HTA process. Dr Yamabhai reiterated that the HTA process must be systematic, participatory and transparent for it to be successful. She added that the HTA organization needs to be semi-independent and neutral with a strong code of conduct, producing high quality, evidence-based products delivered in a timely manner. Strong political will and commitment are also critical for a successful HTA program.



Dr Salih Mollahaliloglu, Minister Consultant, Ministry of Health, Turkey, spoke on Turkey's experience in priority-setting in primary care. Equity, quality and access were the key considerations during the priority-setting process for primary care in Turkey. The methods utilized included HTA of proposed interventions, and the development of health benefits packages and evidence-based clinical guidelines for implementation support. This was achieved by multi-stakeholder engagement which included involvement of non-governmental organizations, and consultations with national and international experts. Dr Mollahaliloglu also shared that in Turkey, cost-effectiveness is considered especially for drug licensing and caps are set for drug prices against European benchmarks.

“HTA is important for both Ministry of Health and Social Security Institute in Turkey”

Dr Salih Mollahaliloglu, Minister Consultant, Ministry of Health, Turkey

The South African experience on HTA was then presented by Prof Fatima Suleman, Chair of National Pricing Committee in South Africa. Prof Suleman spoke on how HTA and clinical guidelines influenced the availability of drugs and also the pharmaceutical pricing in South Africa. In South Africa, drugs are included in the essential medicines list (EMLs) and standard treatment guidelines based on their quality, safety, effectiveness, and cost. The essential medicines list was initially developed in the 1990s with a primary focus on equity, establishment of a universal package of care and removal of irrational medicines. An evidence based approach was introduced which was strengthened in the subsequent decade. In the 2000s, there was a greater use of pharmacoeconomics which led to the development of a guideline for pharmacoeconomic evaluations. The evidence based approach used included review of comparative effectiveness, comparative safety and direct and indirect costs of drugs. The example set by EML has influenced other medical schemes in South Africa working towards Universal Health Care to adopt a similar evidence based approach. Prof Suleman concluded by stating that it was essential we build capacity in people to be able to defend evidence based-decision making.

“South Africa now considers both clinical and cost effectiveness for inclusion of drugs in its Essential Medicines List (EML)”.

Prof Fatima Suleman, Chair of National Pricing Committee, South Africa



Prof. Kun Zhao, Director, China National Health Development Research Center then spoke about how evidence based clinical pathways were used in China to address the problem of over- and under-use of certain health interventions. For example, in China, too many unindicated vitamins, hormones, antibiotics and intravenous injections are prescribed whereas nursing care is underutilized, especially for chronic diseases. To address this, in rural China, a pilot study on evidence-informed clinical pathways linked to a payment reform (with the

support of NICE International) was carried out. The overall goal of the study was to regulate the health provider's behaviour; improve quality of health care services and improve efficiency of public health care funds utilization. CNHDRC are now collecting data to assess the impact of the intervention on reducing over-treatment and improving health outcomes

In the ensuing discussion, Sir Andrew remarked that a critical mass of enthusiastic skilled people at national level can achieve an enormous amount. Mr Manoj Jhalani concluded the panel discussion by stating that there are many lessons to be learnt, and in particular praised the Thais for doing exceedingly well in providing high quality UHC with 5% GDP spending on health.



What can active priority-setting and HTA do for India? Successes, challenges and lessons

The panel on experiences and perspectives from India was chaired by Dr Nerges Mistry, Director of Foundation for Research in Community Health. The session began with a presentation by Mr Rajeev Sadanandan, Director General (Labour Welfare) & CEO of RSBY (Rashtriya Swasthya Bima Yojna). Mr Sadanandan spoke on an evidence-informed approach to designing, adjusting and applying health benefits packages.

During his presentation, Mr Sadanandan questioned whether there is better way to set priorities, rather than letting priorities set themselves? For a country to meet its commitment towards ensuring universal access to a package of services for its population, long-term financial sustainability was essential. He emphasized that a prioritization process to determine the benefits package (who receives what services) is required, and the designed package will need to be reviewed regularly. To achieve this objective, a legitimate and relevant process is required which will adhere to a set of core principles which includes scientific rigor, transparency, consistency, independence from vested interests, inclusiveness of all stakeholders, contestability, timeliness and enforcement.

Mr Sadanandan added that while designing benefit packages, difficult decisions have to be made, and HTA can serve as a useful tool to guide these decisions. RSBY and other health insurance schemes in India experience challenges in ensuring access and quality of healthcare and in limiting malpractice. The NHAM will also face similar challenges. Hence, the “NHAM needs to prioritize what to provide, even if it has a huge budget”. It needs to base its decision on evidence, and a transparent process is required. The hardest choice will be disinvesting from existing packages that are not cost-effective.



“No matter what resources you have, you always need to make choices”

Mr Rajeev Sadanandan, Director General (Labour Welfare) & Joint Secretary

Mr Sadanandan then spoke on the need to integrate HTA with evidence-based standard treatment guidelines and the requirement for measurable quality standards to monitor the quality of healthcare delivered. He shared the work done in Kerala State on development of quality standards for improving maternal and newborn care, and the current work on development of clinical guidelines for seven procedures covered by the RSBY scheme, that are most used and with high potential for abuse (e.g. hysterectomy). Both activities were inspired to different extents by the NICE model, and both were completed with the technical assistance of NICE International. He said that the RSBY experience will guide the design and implementation of the NHAM benefits package. There is a plan to develop pathways for more conditions and improve the mechanism as NHAM rolls out.

Following Mr Sadanandan’s presentation, there was a panel discussion on experiences from across India. Dr Vakkanal Paily, Consultant Obstetrician from Kerala, provided an overview of how quality standards for postpartum haemorrhage, modelled on the NICE multi-stakeholder process, were developed with NICE International support and now were being implemented in Kerala. Dr P. Boregowda, Executive Director, Suvarna Arogya Suraksha Trust (SAST) spoke on the study trip by a SAST team to NICE, which inspired the development of clinical guidelines for oncology and cardiology, comprising 70% of all claims made to SAST. Mrs Meeta Rajivlochan, Commissioner, Municipal Administration in Maharashtra, outlined details of the pay-for-performance initiative undertaken in Maharashtra. Under this initiative healthcare providers adhering to defined quality standards were paid 10-15 % additional reimbursement.



Prof Mala Rao, Professor of International Health, University of East London shared her experience from the Kerala primary health centre pilot. She highlighted the importance of priority-setting by giving an example of screening interventions for depression which were prioritised in Kerala since depression contributed to a high disease burden in the State.

How can good work from different parts of India be implemented nationally? The panel consensus was that we need to learn from everyone, both across India and across the world, and then adapt and contextualize.

The principles and methods of active priority-setting: evidence and governance

Dr Prathap Tharyan, Director, South Asian Cochrane Network & Centre and Professor for Evidence-Informed Healthcare & Health Policy at Christian Medical College, Vellore shared the work being done by the South Asian Cochrane Network.

The Cochrane Centre undertakes systematic reviews of studies in order to answer a clearly formulated clinical question, and disseminates the findings to help policymakers and clinicians make decisions. Dr Tharyan shared examples of how their systematic reviews have guided healthcare policy. For example, a systematic review on the drug primaquine for preventing relapse after infection with Plasmodium Vivax malaria influenced the inclusion of primaquine in the national program on control of vector-borne disease in India.



The examples highlighted a need for evidence to be contextualised, including consideration of epidemiology as well as implementation in the local setting. In 2009, a committee recommended that all children should receive deworming if they reside in an area endemic for worm infestation in India. Subsequently, in 2012 a systematic review found that such interventions showed little evidence of benefit on children's

physical health or school attendance. This raised a need for health planners to review the deworming policy, in light of the new evidence, and underscores the general principle that clinical guidelines should be regularly updated.

Dr Tharyan also shared details of an HTA carried out in CMC Vellore, comparing nucleic acid testing (NAT) plus serology versus serology-only testing for detecting HIV. A well-defined process was followed to review scientific evidence for incremental benefits, cost-effectiveness, and affordability. The HTA results were then appraised by a committee which viewed it through the prism of CMC Vellore's ethos and values. In view of the legal, moral and ethical implications, the committee decided to recommend NAT plus serology screening of blood donors at CMC Vellore.

“HTA process is now institutionalized – so when you have difficult decisions, [we] don't need to fight.”

Dr Prathap Tharyan, CMC Vellore

Finally Dr Tharyan stressed the importance of disseminating and translating evidence, so that decision makers can access it and become aware of its implications. He also informed that he was working towards bringing evidence-based medicine into AYUSH through

Cochrane, and shared an example of a systematic review done for Ayurveda interventions used for treatment of rheumatoid arthritis.

“Knowledge translation is important – researchers need to work with policymakers”

Dr Françoise Cluzeau, Associate Director, NICE International

After the Indian experience, there was a deep dive session on the principles and methods of active priority setting in UK by Dr Amanda Adler, Chair of NICE Technology Appraisal Committee B. Dr Adler shared case studies from NICE highlighting how it considers cost-effectiveness and social values in healthcare priority-setting given the fundamental issue is that we can't spend the same money twice. In England, regulators inform whether a technology *can* be used, whereas NICE tells whether it *should* be used in the publicly-funded National Health Service, after carrying out clinical and cost effectiveness studies. These decisions are made by multi-stakeholder Technology Appraisal Committees and Dr Adler shared examples of some of the complex decisions made. She spoke about the drug vinflunine for bladder cancer treatment which was associated with a high administrative cost making it cost-ineffective even if it was free. This underlined the point that all direct and indirect costs need to be accounted for in a cost effectiveness analysis.

Though NICE appraisals have for the majority of times approved interventions to be adopted by the NHS, Dr Adler shared how NICE has frequently been challenged in the media and sometimes even misreported. For example, many cancer treatments have been found to be cost-ineffective during NICE appraisals and the media has portrayed that NICE is preventing access to life prolonging medicines. However the difficult decisions taken by NICE are now



increasingly being accepted by different stakeholders, including patient organizations since NICE follows a defensible and transparent process based on scientific principles. This has led to the pharmaceutical industry in becoming more willing to engage in the HTA process, and also to extend discounts through Patient Access Schemes. Dr Adler concluded with a quote from the Cancer Research charity in the UK: “Patients must get access to the most effective cancer treatments quickly ... And the pharmaceutical industry needs to price in a realistic way, based on the potential benefit of the treatment.”

Discussion on actionable roadmap for priority setting & health technology assessment in India

The second day of the workshop was extremely interactive and comprised two small-group, role-play exercises. In the first exercise, participants had to decide from the given seven choices (ranging disposable diapers for incontinence, to an educational intervention for diabetes, a drug for advanced colorectal cancer, and others) which treatments or services they would prioritise for inclusion in a health benefits package. A fixed budget was provided which was insufficient to fund all the interventions. The exercise endeavoured to make participants reflect on what factors were important to them while making these decisions, and triggered a discussion on the following key questions:

- How to decide whether to prioritize specific populations or diseases?
- How to decide which healthcare interventions, technologies and services to cover?
- How to ensure this process adheres to some fundamental principles (transparency, insulation from vested interests, and basis on scientific evidence?)

At the end of the exercise, each group shared its recommendations and rationale behind the choices made. The most common rationale conveyed by participants was that they considered both the cost, and clinical effectiveness of the various options, and removed options that did not appear cost-effective. One difficulty was that the exercise had not made available information about the cost or benefits of relevant, alternative choices (comparators) for a given condition or population. Thus it was not really possible to determine whether the listed intervention for malnutrition, for example, was the most cost-effective way for managing malnutrition. Priority setting requires all relevant and available competing choices to be presented and considered.

Participants also expressed that the clinical benefit of the interventions was presented in varying units, which made comparison very difficult between, for example, a cancer



treatment or a maternal-child health intervention. The units ranged from height gained in centimeters, to preterm birth avoided, to life years (LY) gained, to quality-adjusted life year (QALY) gained. This highlighted the need to create a robust, common measure which allows comparison between different interventions, populations and disease conditions.

The QALY is one such measure which reflects health gains from an intervention both in terms of life extended and improved quality of life; it is used by NICE and HITAP to compare between different interventions, in order to inform their adoption as well as disinvestment in their respective health systems. Investing in a particular intervention for one disease area will always mean less money left to be invested in another disease area, thus it is extremely useful for a decision-maker to be able to identify these tradeoffs using a common measure of health gains across the whole population.

If quality of life is chosen as the common unit, how can India assess quality of life reflecting the context and preferences of the Indian population? Can such data be adapted from what other countries have developed even if the validity may be lower? Dr Inthira from Thailand shared that HITAP had also initially borrowed quality of life measures from other Asian countries, until Thailand developed its own dataset through studies within the Thai population; as did CNHDC in China who have used quality of life measures from Japan.



In addition to reviewing the cost-effectiveness of interventions, some groups made choices through a social prism and prioritised children and pregnant mothers. Others considered equity and prioritized the marginalized and poor. Most groups chose a mixed set of interventions balancing both preventive measures and treatment options. These various social value judgments within the decision-making process also meant that when one group that tried to create an objective scoring system for ranking the different interventions, this did not work too well as the group ended up disagreeing on the rankings!

The exercise underscored the key point that priority-setting can never be entirely objective, and at some point people have to make subjective decisions. What matters is that there is a robust, participatory and deliberative process; and the evidence presented will need to be contextualised to the local settings, taking into account the preferences and social values of the Indian population.

“India may not face the problem of deciding at the margins as the NHS does, but the NHAM needs to recognise the data gap, and invest in this for 2 years down the line when the packages will need to be revised.”

Mr Rajeev Sadanandan, Director General (Labour Welfare) & Joint Secretary

The second exercise in the workshop required the participants to discuss in groups how they will prioritize which interventions to include while updating the benefits package in the context of the national health assurance scheme, and how will they support its implementation. The key points shared by the participants were that burden of disease will help inform which interventions need to be prioritized. Participants suggested that existing benefit packages under various insurance schemes could be mapped as a starting point. It was however pointed out that the existing benefits packages in India are more focused on tertiary care management.

Access, equity, cost-effectiveness (efficiency) and quality were recommended by the participants to be the key considerations while designing the health benefits package. An institutional mechanism was suggested for regularly updating the benefits package which can perhaps be a National mechanism with State representation. Challenges in making decisions were discussed which included the limited availability of data, and influence from groups with vested interests. To counter this, a wide stakeholder representation was suggested for decision making. For effective implementation, a strong political commitment and governance structure was suggested. Since Indian States have varying internal capabilities, varying mentorship and support in implementation was anticipated to be required.

How can HTA be utilized to strengthen primary care and its role as a gatekeeper? This will be the crux of the healthcare paradigm shift in India.

Dr Santhosh Kraleti, ACCESS Health International

Care pathways linking primary, secondary and tertiary care were suggested to support implementation, especially since effective primary and secondary care can serve as gatekeepers in curbing unnecessary use of tertiary care. Evidence-informed quality standards, such as those developed in Kerala with the support of NICE International, were also suggested as a tool for monitoring implementation and driving best practice; and a robust IT system was recommended to monitor the quality measures identified.

Mr Rajeev Sadanandan said that the Government recognizes HTA requires an institutional mechanism to be put in place. Other mechanisms like monitoring systems, costing systems etc. will also need to be developed in parallel. The workshop concluded with specific requests to NICE International for ongoing support.

“It’s time to start the journey now. NICE International can support Indian organizations like the Department of Health Research in building indigenous capacity for HTA. Work with us, build this capacity in institutions.”

Mr Rajeev Sadanandan, Director General (Labour Welfare) & Joint Secretary
