Health Technology Assessment : an evidence-informed approach to designing, adjusting and applying Benefits Packages

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Is there is better way to set priorities, rather than letting priorities set themselves?

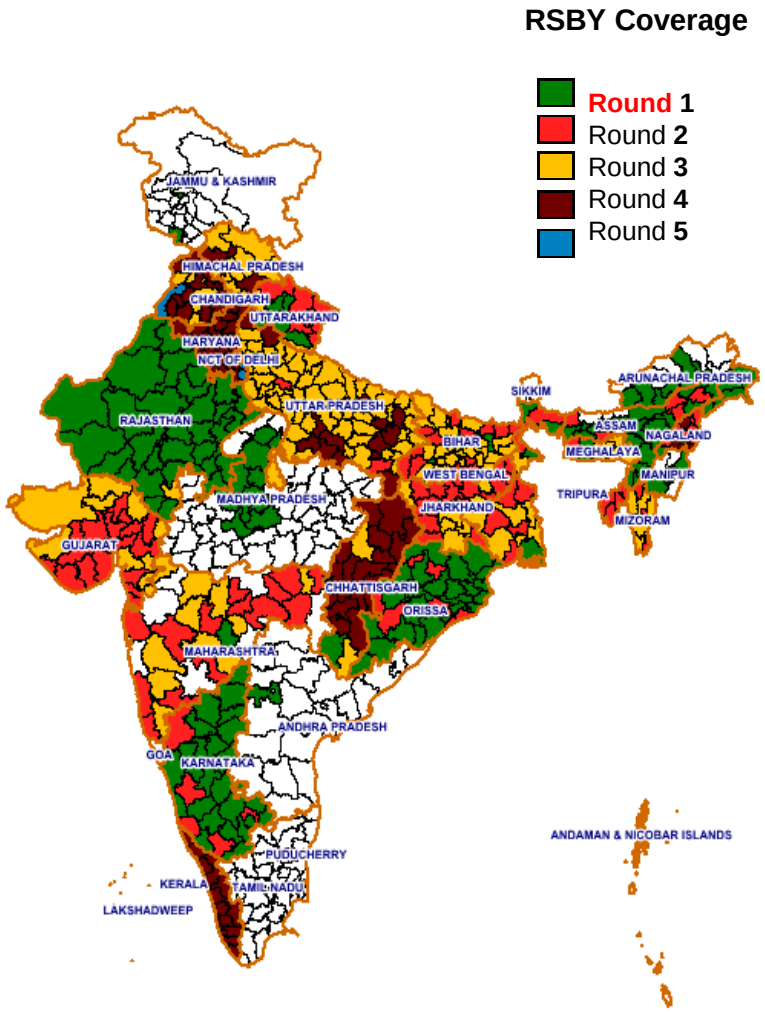
- "Priority setting means deciding *who* is to get *what* at *whose expense* [who is to go without healthcare].. **We must not shrink away from identifying who (implicitly) the low priority groups are**." *Williams (1988)*

Our starting point

- If a country is to meet its commitment to **universal access to a package of services** for its population, *long-term financial sustainability* of providing the listed services is essential.
- To ensure this, a **prioritisation process** to determine the **benefits package** (*who receives what services*) has to be designed, implemented and regularly reviewed.
- A legitimate and relevant process should adhere to a set of **core principles:** *scientific rigour, transparency, consistency, independence from vested interests, inclusiveness of all stakeholders, contestability, timeliness and enforcement*.

HTA is about this priority-setting process and its core principles

Current status of RSBY



Scheme is operational in **398 districts** of **25 States**

- **Fee-for-service reimbursement** for bundles of procedures/interventions in approximately **10,000 network hospitals**: around **60% private** sector & **40% public** sector hospitals.
- During 2013-2014: **250 Million BPL families** in possession of active RSBY cards.
- As on 30th April 2014, more than **38 Million enrollees** had an active smart card & total hospitalization cases were more **7 Million**.

Ref: Rashtriya Swasthya Bima Yojana (RSBY) Operational Manual 16 July 2014.

RSBY Website accessed 4th Oct 2014.

RSBY: an illustration of challenges facing a universal health assurance package

- **ACCESS**: Improving enrolment and increasing access.
- **QUALITY**: Improving quality of care delivered in hospitals.
- **MALPRACTICE/ FRAUD**: Prevention and early detection of inappropriate/excessive treatment.
- **BUDGET CONSTRAINT**: Controlling cost & increasing coverage within the existing budget constraint.

Why do we need HTA?

- **PRIORITY SETTING:**

  WHAT DISEASES/ CONDITIONS need to be covered ?

  WHAT SERVICES (**Public Health**, **Outpatient**: drugs, diagnostics etc., **Inpatient**: procedures, intervention etc.) need to be provided ?

  Need to prioritize what will provide maximum population benefit since **budget constraint prevents everything from being provided**.

- **HEALTH TECHNOLOGY ASSESSMENT:**

  Will identify **clinically effective & cost effective** treatment (drugs, diagnostics, procedures, interventions) suitable for India. Hence help set priorities.

- **BENEFIT PACKAGES**: **WHAT IT SHOULD CONTAIN ?** HTA will guide its design in a scientific, cost effective & transparent manner.

Why do we need Clinical Guidelines?

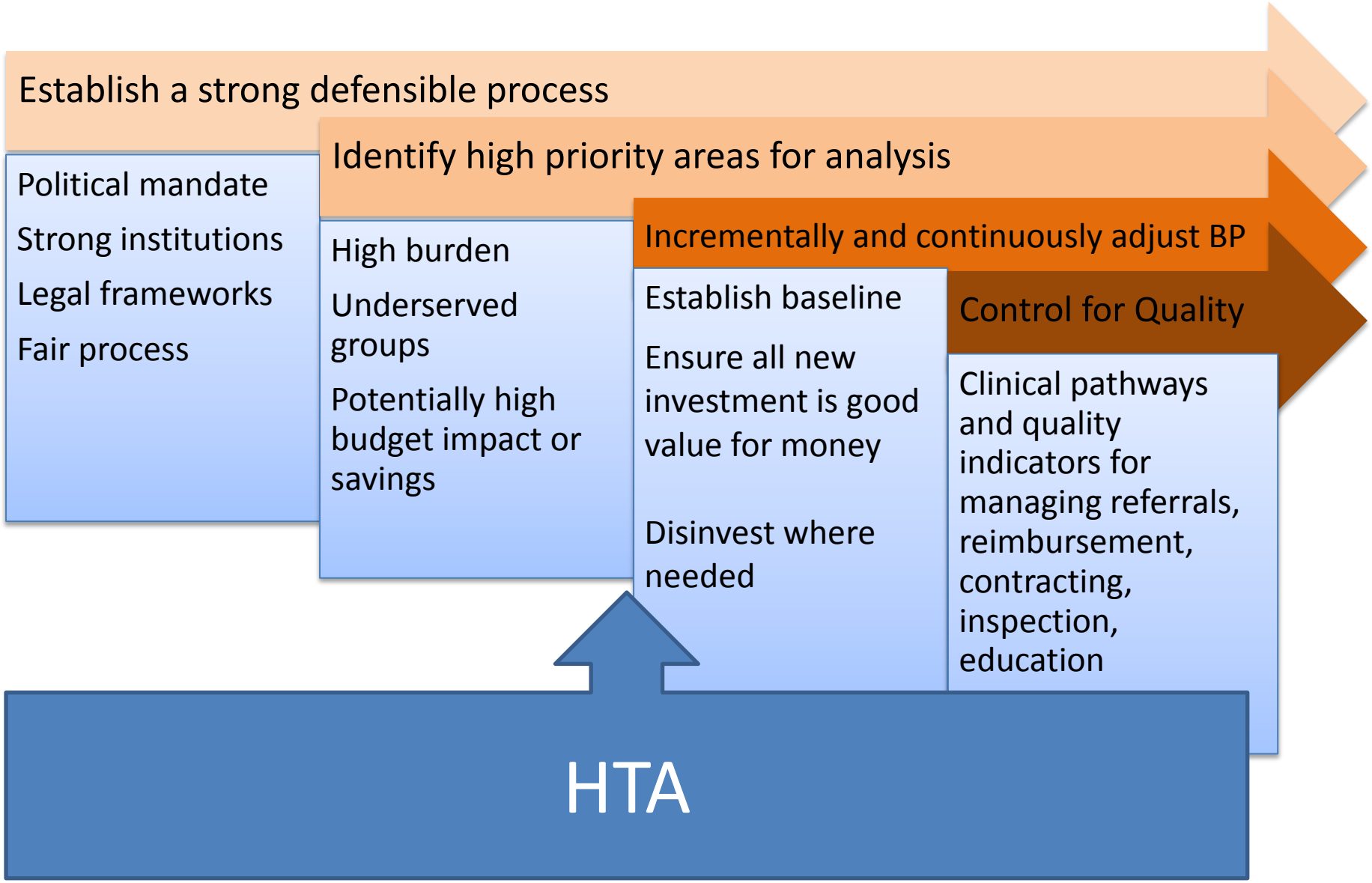
HOW BENEFIT PACKAGES NEED TO BE DELIVERED WITHIN A UNIFIED HEALTH ASSURANCE SCHEME?

CLINICAL GUIDELINES will provide guidance to healthcare provider for provision of clinically & cost effective treatment.

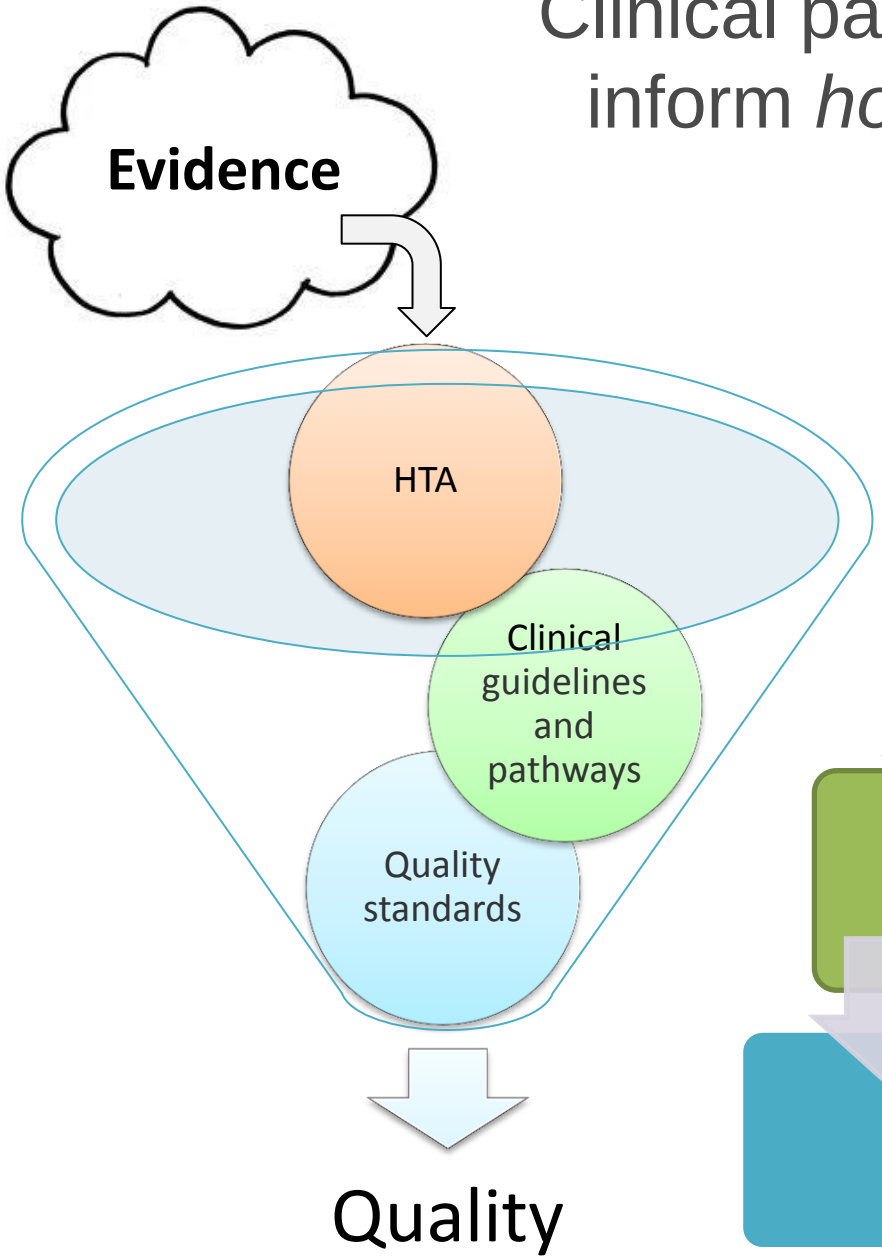
QUALITY STANDARDS: Indicators to monitor and drive improvement.

CLINICAL AUDIT: To guide detection of malpractice/ fraud to prevent delivery of unjustified / unwarranted care.

How can HTA help with benefits package design?



Clinical pathways and quality standards inform *how* benefits package is to be implemented



HTA to synthesise evidence on costs and clinical effectiveness, and compare different options

Clinical guidelines and pathways distilled from HTA and other evidence

Quality standards derived from evidence-based clinical guidelines and pathways

Quality indicators can inform reimbursement, inspection, education..

Identify high priority areas for analysis

- **Prioritise**! Not everything can be subject to HTA
- Target cost-effectiveness analyses to decisions at the margin with *potential for considerable health benefit and/or budget impact*
- *Set out clear criteria* for identifying high priority diseases and interventions, such as:
  - Population size
  - Disease severity
  - Resource impact
  - Claimed therapeutic benefit
  - Policy priority and social consensus
- Include *potential candidates for disinvestment*

What *evidence* is needed to compare interventions in HTA?

- Evidence about what works, clinically (**effective**), and what works better (**relatively effective**)
- To find out what is efficient (**cost-effective**)
- To rank interventions so as to include only those that out-perform others
  - an **outcome measure of 'effectiveness'** that enables needed comparisons (eg QALY or DALY)
  - **costs** (including their scope)
  - an **inclusion/exclusion criterion for technologies** (**threshold**)
  - some **ways of handling technical and clinical disagreements** and absence of evidence or poor evidence (deliberation)
  - some ways of addressing **issues of fairness and justice**

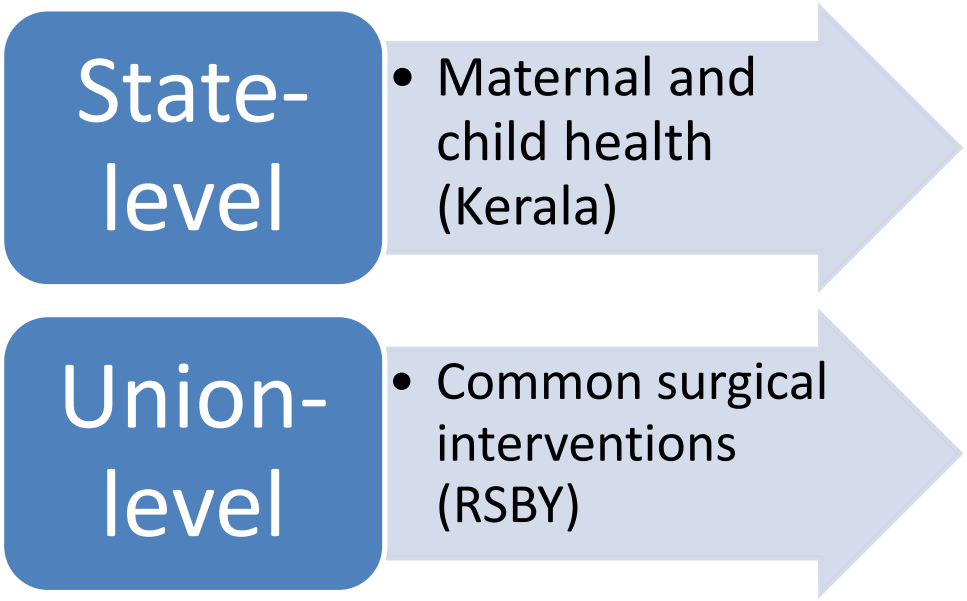
All of this is **'economic evaluation'**

Incrementally and continuously update the benefits package

- Designing/updating the benefits package is an *ongoing process,* not a one-off technical exercise
- Refining the benefits package takes time, and must be *responsive* to changing needs, new technologies and new prices/costs
- Any addition MUST be paid for and made available, to ensure trust is maintained in the process

Control for quality

- Integrate HTA with evidence-based Standard Treatment Guidelines
- Introduce measurable Quality Standards (indicators)
- Align quality framework with reimbursement, e.g.:



Develop the maternal care pathway and the respective measurable Quality Standards

Measure baseline and progress

Name and Address of Institution

Year : **Month:**

S.No. Monthly / Annual	MRD No.	Booked / Unbooked Doctor in charge	Name	Name of husband and Address	Maternal A/N Problems	Date and Time of Delivery	Was labour induced	Sex of Baby Write Male / Female	3rd Stage management	4th stage monitoring (Yes / No)	Blood loss and transfusion	Any Fetal Problems, NICU admission	Any Maternal Complications	Details of Labour, Remarks, Treatment	Conducted by
					Anemia : Diabetes : Heart Disease:				was AMTSL followed?		Blood loss (ml)	Congenital anomalies:	Placenta prev.accreta (detected & managed locally)	Type of delivery	
					Hypertension / pre ecl : Which anti hypertensive?		Type of induction :		oxytocics used with Time Dose Route				Placenta prev.accreta (referred from outside)	Indication	
		Ht :	Age :		Severe Hypertension / Severe Pre ecl : Which anti hypertensive ? Detection treatment interval :					Problems noted:		NICU Admission with indication:	Perineal tear with degree		
		Wt :	Blood group, Rh.:		Did she have HELLP:		Outcome - (vag. del/ cs)		3rd Stage Duration		Blood & Blood Products (quantity)		Cerebro vascular problems	Robson's class	
		BMI(at 1st visit)	Obst. Score : LCB :	Date and time of admission :	Eclampsia : Did she receive MgSO4 :	Presentation :		Wt.:	Manual removal (Y/N)			Still Birth with cause :	Severe maternal morbidity with cause	Special aspects	
			No. of prev CS :		any previous surgery :		Indication for induction	Apgar 1' 5'	Placental Weight		Admission to ICU in same hospital: If transferred for ICU care was it in ALS ambulance		Maternal Death with cause		
			in the same hospital :	Gest.age (wks & days) :	Cerclage :	Episiotomy : (Type)			Did she develop Hypotension?			Neonatal death cause:			
			in other hospitals :		others :		induction del interval		Amount of IV Fluids Used				Any other		

Steps to achieve IMR reduction

Health Department and NRHM to develop clinical guidelines and evolve quality standards

12TH PLAN INITIATIVE

C. Maya

THIRUVANANTHAPURAM: The Health Department and the National Rural Health Mission (NRHM) have launched an exercise to develop clinical guidelines and evolve quality standards to reduce infant mortality rate (IMR) in Kerala, which has remained stagnant for over a decade now.

Kerala's IMR at 12 (per 1,000 live births) is only second to the IMR of Goa and Manipur (IMR of 11). Despite its success story in reducing IMR from 37 in 1981 to 16 in 1991, and further down to 12 in 2011, Kerala's IMR is high given the fact that 99.9 per cent of the de-

of maternal mortality rate by half (MMR 81 per one lakh live births, SRS data, 2007-09) had been two key recommendations for the State in its 12th Five Year Plan projection.

Maternal care

Last year, the Health Department worked together with the National Institute for Clinical Excellence (NICE), U.K., and the Kerala Federation of Obstetrics and Gynaecology (KFOG) for over six months to draw up a 10-point standard clinical guideline aimed at improving the quality of maternal care and thus reducing the MMR in the State. The document was formally released in January this year.

Maternal care management, as per these new quality standard protocols, is currently being piloted in

MANAGEMENT OF NEONATES

TRACK RECORD

- Kerala's IMR remains stagnant for over a decade
- State's IMR is only second to Goa's and Manipur's
- 99.9% of deliveries take place in hospitals

IMR statistics	Major causes of infant deaths in State
1981 – 37*	Prematurity (34.6%)
1991 – 16	Congenital anomalies (28%)
2011 – 12	Sepsis (9.3%)
	Birth asphyxia (8%)

FINDINGS OF IAP STUDY

- Wide regional differences in IMR
- 75% of infant deaths during neonatal period
- Of the neonatal deaths, 59% during first week
- State's maternal mortality rate 81 per one lakh live births

*Per 1,000 live birth

dards to reduce IMR, which could be implemented in our hospitals," a senior Health official said.

The department has sought the expertise of Access Health International, a not-for-profit organisation, which works with governments and provides research and training inputs to improve health care service delivery and processes.

A month-long study done by the IAP last year in four districts in Kerala — Wayanad, Kannur, Ernakulam, and Kollam — to study the exact causes of infant deaths and the recommendations evolved from the same, is the basic document on which the IMR reduction strategies are being based.

Certain problems

The study was launched on the premise that there were certain problems in

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IMPROVING MATERNITY CARE IN

Quality Standards on Post-partum Haemorrhage and Hypertensive Disorders of Pregnancy

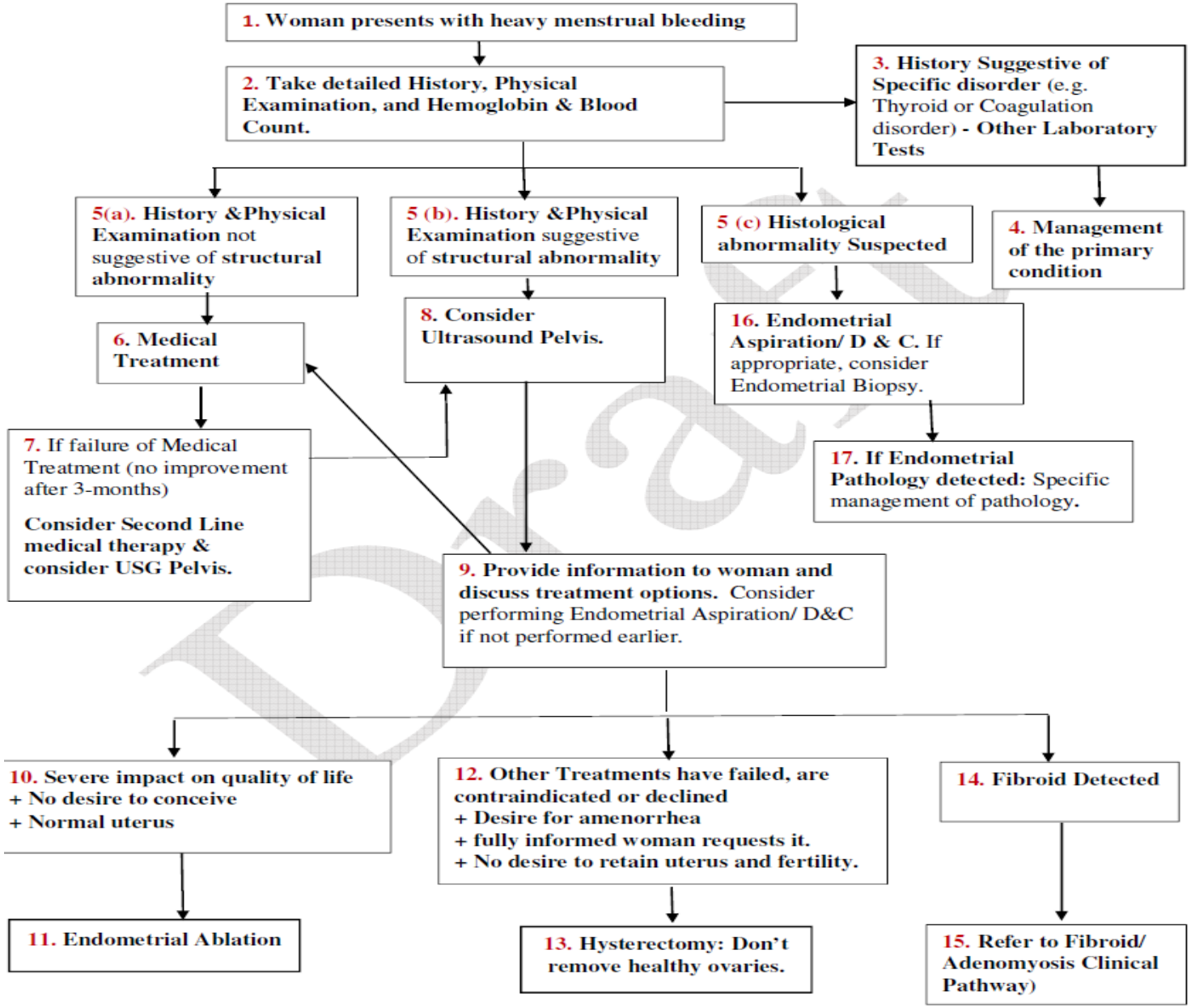
NICE International

Example of RSBY: Clinical pathways

- Presently, healthcare providers & insurers lack clear guidance on most appropriate treatment options: leads to *sub-optimal care & disagreement about payment*
- *RSBY Quality Program*: to provide authoritative & evidence-based clinical pathways and quality standards on identified procedures
- RSBY convened a Committee to **prioritise conditions/ procedures based on high volume, high cost and potential for fraud,** and authorise clinical pathways: starting with *hysterectomy, hemodialysis, cholecystectomy, hernia, hydrocele, appendicitis, pterygium*
  - *E.g. hysterectomy: 2nd most frequent claim (3.7% of all RSBY procedures);10% of RSBY budget at INR 35 crore*
  - *46% of all ob/gyn procedures*

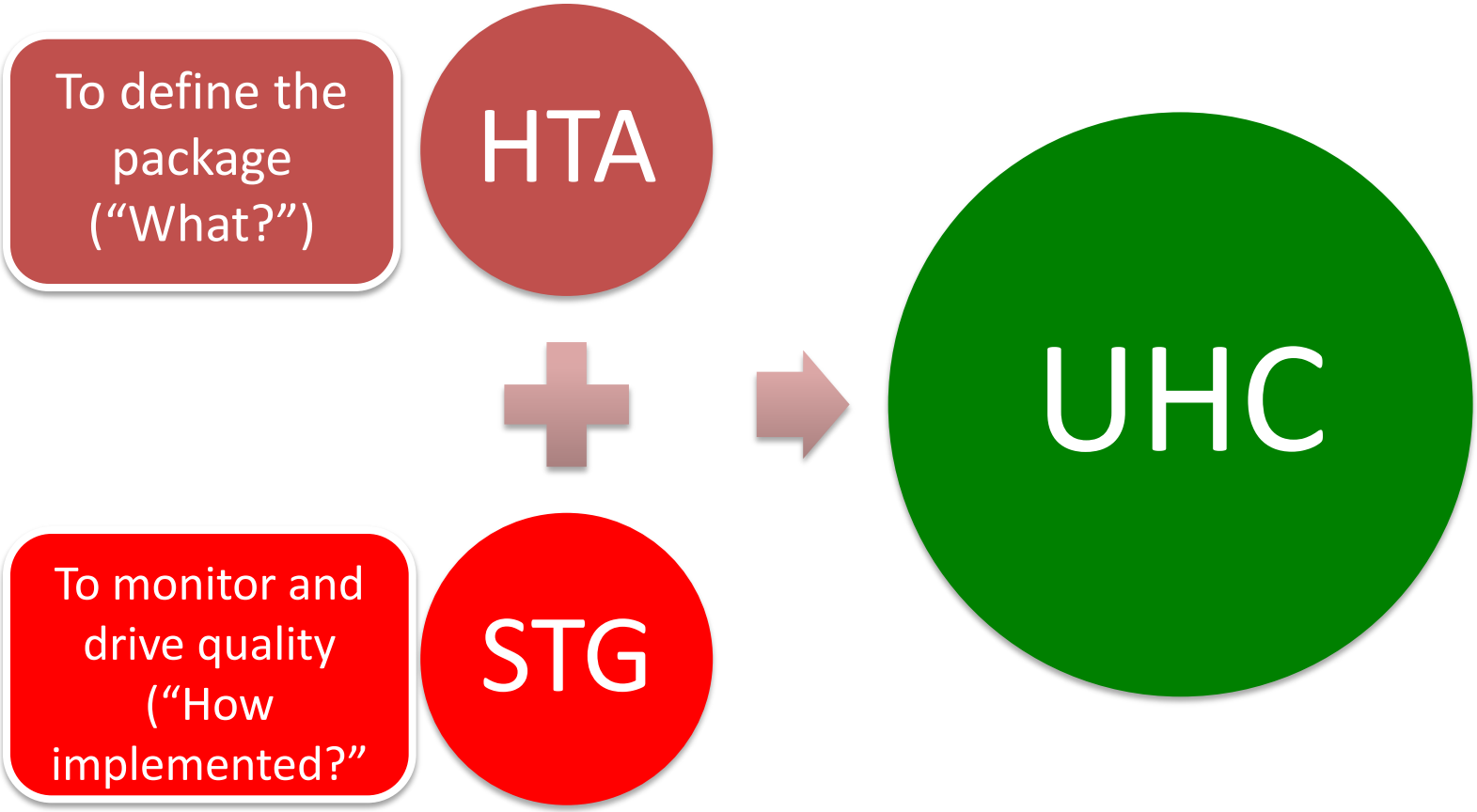
Example: RSBY Clinical Pathways for Hysterectomy

- Formed **topic expert group** (TEG) for hysterectomy
  - Stakeholders: public and private providers, specialists, district level doctors, public health personnel, professional associations, insurance companies and RSBY/World Bank.
- 3 **TEG meetings** in Kerala:
  - **Identified key indications** of hysterectomy.
  - **Reviewed existing standard treatment guidelines** & evidence cited for recommended interventions. *E.g. Heavy menstrual bleeding (NICE, 2007), Guidelines on management of Dysfunctional Uterine Bleeding (DUB), Government of India, Ministry of Health etc*.
  - **Clinical pathway** with clear recommendations for Indian context, drafted with expert consultation and consensus.
  - **Quality indicators** and **pre-authorisation checklist** to inform reimbursement
- **Peer review** by FOGSI (Federation of Obstetrics & Gynecological Societies of India), independent reviewers in UK, with 4th meeting to discuss and incorporate feedback.



Draft Clinical Pathway: Heavy Menstrual Bleeding

Indispensable tools for reaching and sustaining UHC



Conclusion

- All nations successful in achieving and sustaining UHC need HTA and standard treatment guidelines
- Draw on RSBY experience to guide the design and implementation of National Health Assurance Mission benefits package.
- Apply HTA and STGs in India to ensure quality, cost-effective care, and **health for all**.