

Governance of HTA: Early Experiences From Kenya

Dr. Edwine Barasa

Director, Nairobi Programme

KEMRI-Wellcome Trust Research Programme, Kenya

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What is Governance?

*'The **rules** that distribute **authorities, roles and responsibilities** among **actors** and that **shape the interactions** among them... These rules can be both formal Or informal' – Brinkerhoff & Bossert (2014)*

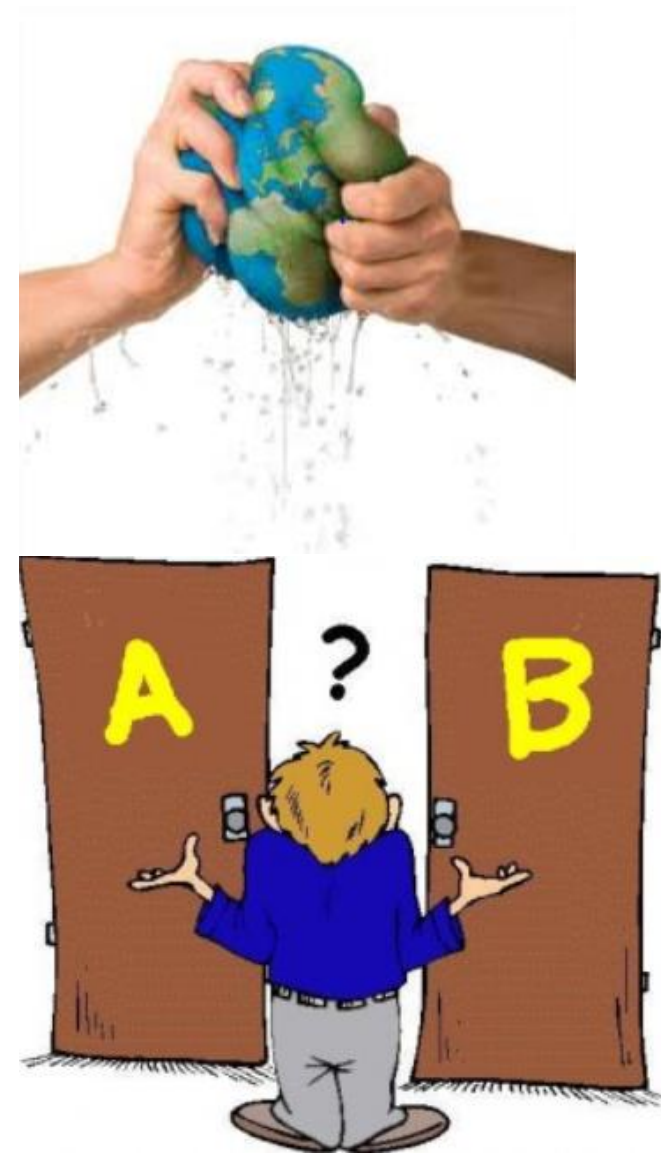
*'...a wide range of **formal and informal processes** for **managing, steering, and rule-making** carried out by health sector decisions makers as they seek to **achieve health policy objectives**' (WHO 2007)*



What is Health Technology Assessment (HTA)

*...it is a **multidisciplinary** process to **evaluate** the social, economic, organizational and ethical issues of **a health intervention or health technology**...the main purpose is to **inform a policy decision making**... (WHO)*

- HTA is a key part of **systematic priority setting processes** in healthcare
- **Priority setting:** the distribution of resources among competing programmes and patients or patient groups



A little about the Kenyan Health System

- Devolved system of governance (National government and 47 county governments)
- National Ministry of Health primarily responsible for policy and regulation
- County governments responsible for service delivery
- Political commitment to achieve UHC by 2022



During the next 5 years, I will dedicate the energy, time and resources of my Administration to the Big Four.

The **Big Four** will create jobs, which will enable our people to meet their basic needs. Jobs will transform the lives of our people from that of hardship and want, to new lives of greater comfort and wellbeing. **And that is the future I have seen.**



#KenyaMbele

Uhuru Kenyatta
PRESIDENT OF THE REPUBLIC OF KENYA

Key Priority Setting Exercises in the Kenyan Health Sector

- **National Health Policy and Strategy formulation** - Kenya health policy (KHP) (15 year cycle) and Kenya health sector strategic plan (KHHSP) (5 year cycle)
- **Service package of health for the public sector** – the Kenya essential package of health (KEPH) –linked to KHP and KHHSP
- **Health programme specific strategies** (5 year cycles) – e.g. vertical programmes (malaria, TB, HIV/AIDs, immunization)
- Annual **budgeting and planning** at the national and county level
- **Essential drugs programme**– Kenya essential medicines list (KEML)
- **National Hospital Insurance Fund (NHIF)** - benefit package development

Fragmented, varying levels of explicitness, evidence based, institutionalization

The Kenya Health Benefits Advisory Panel (HBAP)

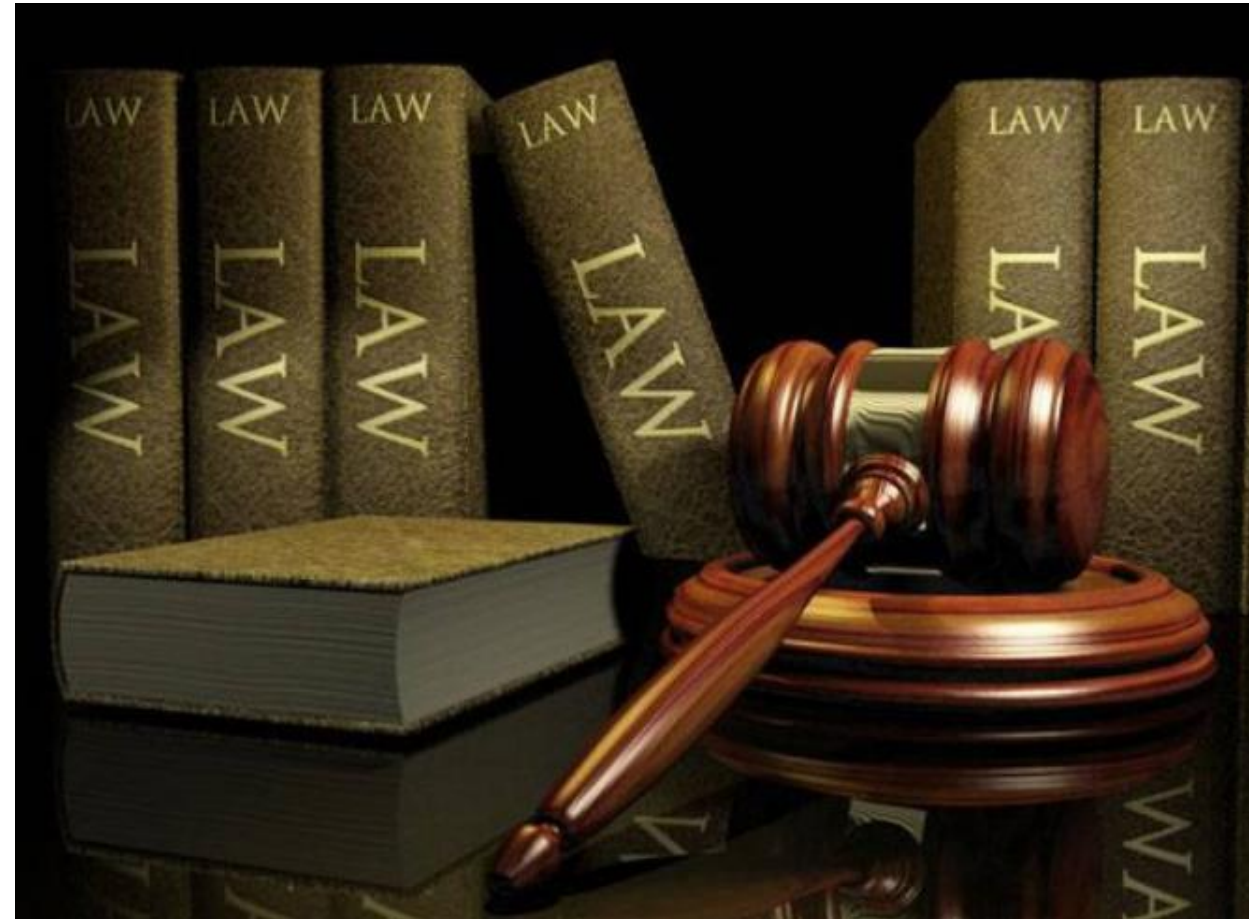
- Appointed by the health cabinet secretary in **June 2018** for 2 years
- Comprised of 14 members with representations from
 - ❖ Academia (health economists, health systems experts, epidemiologists, health professionals)
 - ❖ National (MOH, Treasury) and county governments
 - ❖ Health professional associations
 - ❖ Purchasers
 - ❖ Regulatory authorities
 - ❖ Health civil society
- Among others, to develop a health benefit package for UHC for Kenya

Dimensions of HTA Governance



Governance Dimension 1: Legal and Institutional Basis

- Is the HTA entity, its structures, and roles enshrined in law?
- How are entity board members appointed – is there an explicit legal guidance for appointments?
- Is the entity's role *regulatory* – i.e. decisions must be implemented or *advisory* – i.e. someone else makes the decision?



KENYA GAZETTE SUPPLEMENT

ACTS, 2017

NAIROBI, 23rd June, 2017

PART XII—HEALTH FINANCING

86. (1) The department of health shall ensure progressive financial access to universal health coverage by taking measures that include—

Health finance.

- (g) defining in collaboration with the department responsible for finance, a standard health package financed through prepayment mechanisms including last expense.

8th June, 2018

THE KENYA GAZETTE

GAZETTE NOTICE No. 5627

**ADVISORY PANEL FOR THE DESIGN AND ASSESSMENT OF
THE KENYA UHC ESSENTIAL BENEFIT PACKAGE (UHC-EBP)**

IT IS notified for the general information of the public that the Cabinet Secretary, Ministry of Health has constituted a UHC Health

Benefit Package Advisory Panel for the design of an affordable, responsive health benefit package for the delivery of Universal Health Coverage consisting of the following—

Governance Dimension 2: Mandate

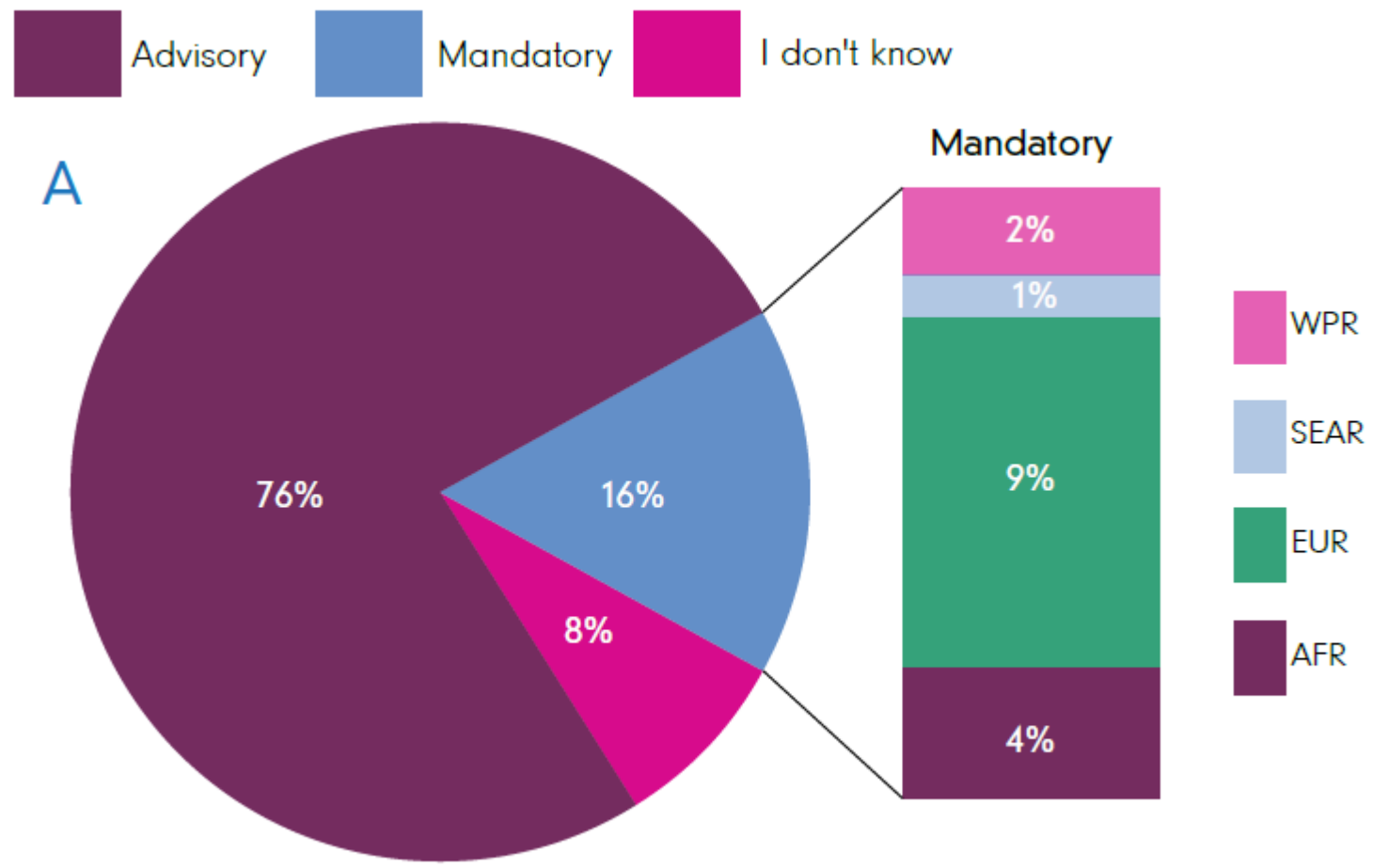
- Does the entity have a clear mandate?
- Does the entity conduct **assessments**, **appraisal** or both?
 - ❖ **Assessment** - analytical process of gathering and summarizing information about health technologies
 - ❖ **Appraisal** - the political process of making a decision about health technologies
- Separation enhances the protection of the scientific assessment from the pressures of interest groups

Functions of the Panel

1. Develop criteria to assess the inclusion and exclusion of services, drugs, commodities in the Kenya Universal Health Coverage-Essential Benefit Package. (UHC-EBP) The criteria should be on critical review of the current International Best Practices.
2. Define an evidence-based benefit package for Kenyans under Universal Health Coverage: (A list of services that should be prioritized and made available taking into account the cost-effectiveness, impact on financial protection, and equity in access across the population).

The law is not clear on whether the Kenya HBAP should assess, appraise, or do both; in practice the panel did both

HTA-related entity's role in policy decision (WHO 2015)



Governance Dimension 3: Independence

- Is the entity **organizationally separate** from the Ministry of Health?
- Is the entity merely part of MOH or does it have its own **autonomous and separate role**
- Does the entity's **head and board members** have **tenure?** - fixed terms or permanent appointments, with removal from office being very difficult
- Are **conflicts of interest** among entity members declared and managed?

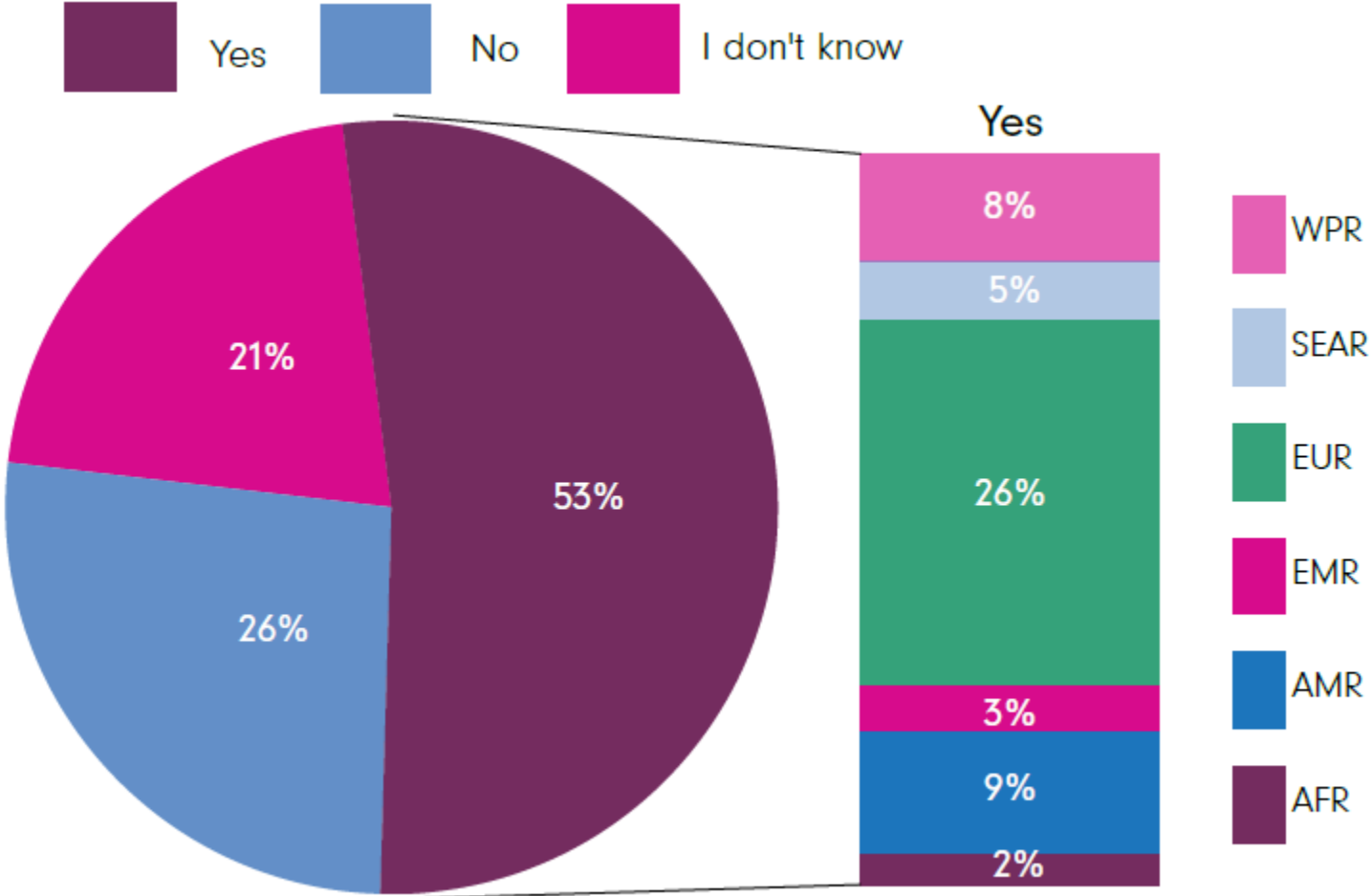


Governance Dimension 3: Independence

- The Kenya HBAP is established as an independent panel of experts that is organizationally separate from the MOH
- **FRAGMENTED APPROACHES:** Even though the Panel has a clear role, this role overlaps/duplicates roles of existing mechanisms within MOH and other entities such as the national hospital insurance fund (NHIF)
- **DECISION SPACE: WHO sets priorities for predominantly donor funded programmes? HIV/AIDS/Malaria/TB/Immunization** - To make systematic decisions, you first have to the remit to make these decisions
- The law is not clear on whether the Panel chair and members have tenure
- Panel has a procedures manual that clearly outlines conflicts of interest declaration procedures



Countries Requiring Conflict of Interest Declaration (WHO 2015)



Governance Dimension 4: Fair and Legitimate Processes

Process is important for both inherent and instrumental reasons

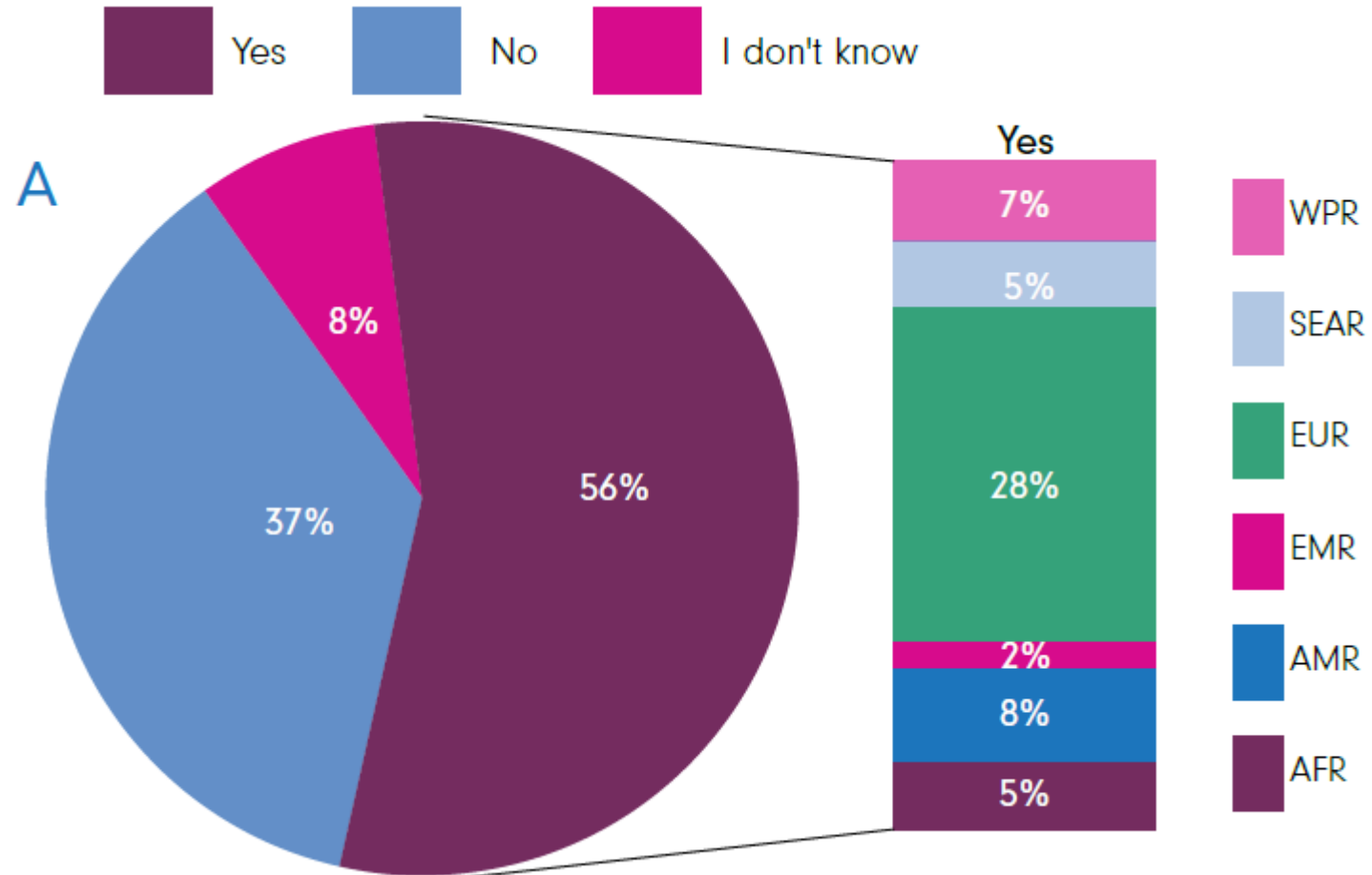
- Among others, fair and legitimate processes are characterized by:
 - ❖ **Deliberative democracy** - deliberation is central to decision-making
 - ❖ Stakeholder involvement
 - ❖ Empowered decision makers
 - ❖ Transparency
 - ❖ Appeals and revisions
 - ❖ Community views
 - ❖ Will the decisions be implemented?



Governance Dimension 4: Fair and Legitimate Processes

- Decisions taken by the Kenya HBAP follow deliberative democratic principles
- The panel composition includes a wide range of stakeholders
- The panel provides for extensive consultations with stakeholders (health professionals, purchasers, government (MOH, MOF), private sector, industry, patient groups in key decisions – nominations of interventions
- A framework for publicity and transparency of decisions and rationales is required
- A frameworks for appeals and revisions required
- Civil society and patient groups engaged; need a framework for wider community engagement

Countries Communicating the Findings of HTA,(WHO 2015)



Governance Dimension 5: Accountability

- **Internal accountability** – are internal answerability requirements effective?
- **External accountability** – are there mechanisms for actors outside the bureaucracy to hold the entity accountable?

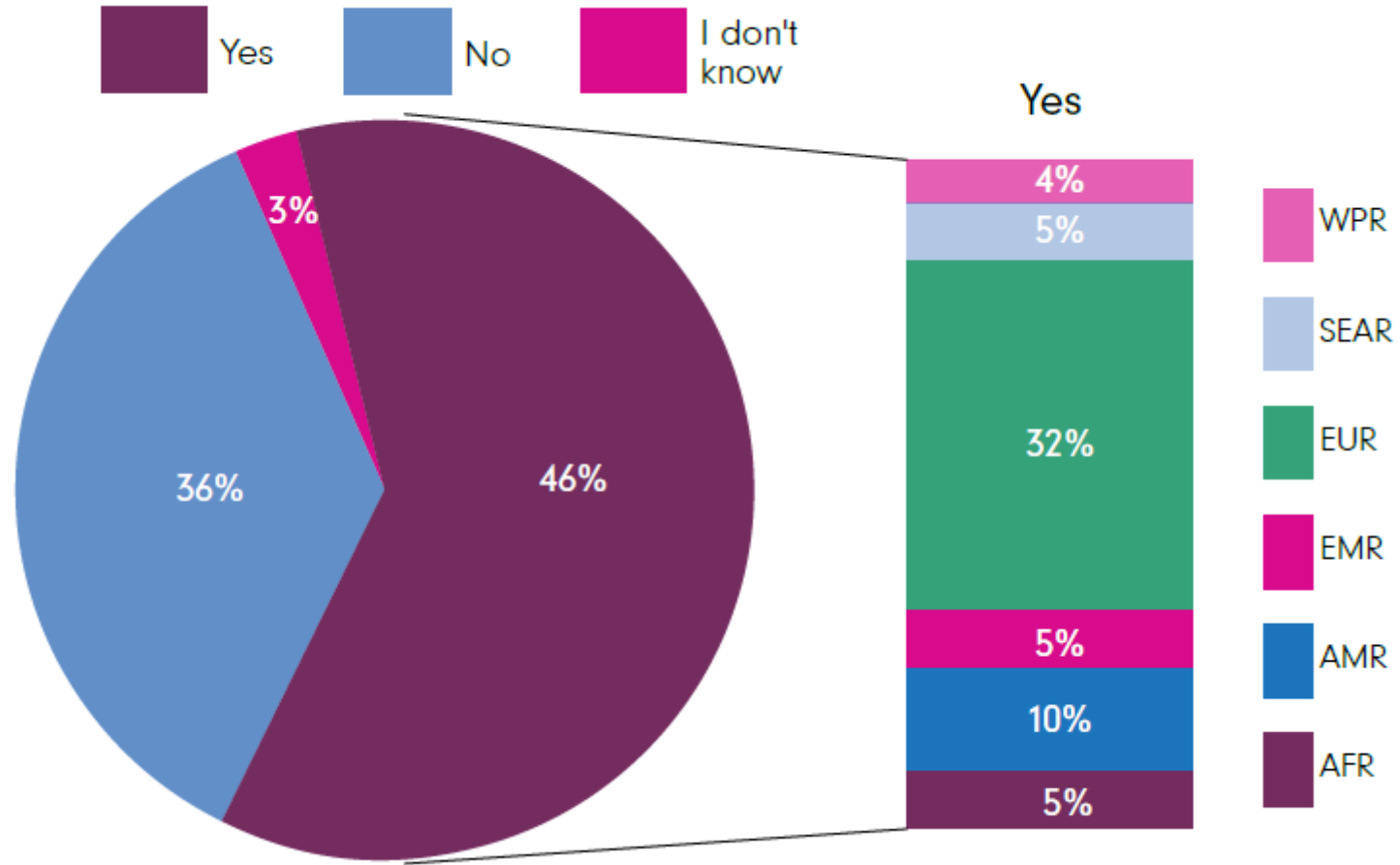


Governance Dimension 5: Accountability

- The Kenya HBAP is answerable to the cabinet secretary (CS) for health
- It receives instructions, approval for work plans, and submits recommendations to the CS health
- The Kenya Health Benefit advisory panel has no mechanism for external accountability
- Procedures and guidelines not public



Transparency: Public Availability of HTA Guidelines (WHO 2015)



Governance Dimension 6: Resources

- Does the entity **have its own resources**, such as building, staff, and budget?
- Is the entity adequately financially resourced?
- Does the entity have adequate technical expertise?
- The Kenya HBAP does not have its own resources (no budget, not staff, no premises) and has relied on partner resources. This makes it difficult for the Panel to discharge its duties and makes it vulnerable to influence
- Has reasonably adequate technical expertise

Thank you