THE ABC’S OF HTA: UNDERSTANDING THE VALUE OF HEALTH TECHNOLOGY ASSESSMENT

Dr. Anna Melissa Guerrero, MPH (HTA)

Department of Health
What if country health systems can afford to pay for every cure invented for all imaginable ills in the world?
RISING HEALTH CARE COSTS ARE BREAKING THE BANK EVEN IN THE RICHEST COUNTRIES
Why cost-effectiveness matters

- Regulatory agencies (FDA, EMEA) only evaluate drugs/technologies based on safety, efficacy, quality.

- No requirement to prove comparative advantage over existing products during marketing authorization → often placebo-controlled.

- ‘Medical need’ clause – not required during licensing.

- Better use of resources -> target investments toward drugs that provide real clinical value.

- Avoid potentially crowding out more effective drugs/technologies (‘disinvestment’).
# Unaffordable new drugs

<table>
<thead>
<tr>
<th>Drug / Indication</th>
<th>Cost per patient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Imatinib</strong> for CML and GIST</td>
<td>Php 1,733,760 per year</td>
</tr>
<tr>
<td><strong>Trastuzumab</strong> for Her2+ breast cancer</td>
<td>Php 3,000,000 per year</td>
</tr>
<tr>
<td><strong>Erythropoietin</strong> for anemia in CKD (dialysis patients)</td>
<td>Php 360,000 per year*</td>
</tr>
<tr>
<td>Imiglucerase for Gaucher’s disease</td>
<td>Php 5,000,000 per year (lifetime)</td>
</tr>
<tr>
<td>Dabigatran for the prevention of ischemic strokes in AF patients</td>
<td>Php 120,000 per year</td>
</tr>
</tbody>
</table>
Price must reflect ‘worth’

“The average monthly price of cancer drugs has doubled over the past 10 years, from about $5,000 to more than $10,000. Of the 12 new cancer drugs approved by the (US) Food and Drug Administration last year, 11 were priced above $100,000 annually. Yet only three were found to improve patient survival rates and, of these, two increased survival by less than two months.”

Kantargian H et al. Making cancer drugs less expensive, The Washington Post
INEQUITABLE CHOICES AND HIGH DRUG COSTS LEAD TO LOST OPPORTUNITIES

- In the UK, a research done by the University of York revealed that for every ‘quality adjusted life year’ (QALY) gained with the Cancer Drug Fund (£230 million), five QALYS were lost across the whole NHS.

- *The Cancer Drugs Fund, Benign or malignant?, The Economist, Jan 24th 2015*
The $1000-a-day pill

*Sovadi* is a wonderful new treatment for Hepatitis C

90 percent cure in 12 weeks!

Price tag of $84,000 per patient

“With a low estimate of 1% prevalence of Hepatitis C in the Philippines, 1 million patients can potentially benefit at the current US list price. This would cost Php 3.7 trillion. Right now, we currently spend Php 136 billion for all drugs.”
The need for HTA in the Philippines

- Large population, limited resources
- Multiple disease burdens – rise of NCDs
- High cost of drugs
- Irrational prescribing
- Variations in access, quality, and costs of care
- Uncontrolled large private system of care
Government budget for health (2010-2015)

Budget in billion pesos

<table>
<thead>
<tr>
<th>Year</th>
<th>Budget in billion pesos</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>24.65</td>
</tr>
<tr>
<td>2011</td>
<td>31.83</td>
</tr>
<tr>
<td>2012</td>
<td>42.08</td>
</tr>
<tr>
<td>2013</td>
<td>53.23</td>
</tr>
<tr>
<td>2014</td>
<td>83.7</td>
</tr>
<tr>
<td>2015</td>
<td>102.18</td>
</tr>
</tbody>
</table>
### Sin Tax

<table>
<thead>
<tr>
<th>Baseline budget of DOH in 2013, before Sin Tax Increment was available</th>
<th>DOH Share from Actual 2013 Incremental Increase in Sin Tax</th>
<th>Sin Tax Incremental increase in 2014 DOH Budget</th>
<th>Available Balance to Frontload UHC in 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>53.2 B</td>
<td>Cigarette: 35.4 B</td>
<td>2013: 53.2 B</td>
<td>44.7 B</td>
</tr>
<tr>
<td>Alcohol: 9.3 B</td>
<td>Alcohol: 9.3 B</td>
<td>2014 (With Sin Tax): 83.7 B</td>
<td>- 30.5 B</td>
</tr>
<tr>
<td>44.7 B</td>
<td></td>
<td>30.5 B</td>
<td>14.2 B</td>
</tr>
</tbody>
</table>
Rising costs of care and the threat of NCDs
Who gets health benefits first?

**Z BENEFITS**
- Colon and rectum CA
- Premature newborn (28-32 weeks AOG)
- Other cancers and blood disorders in children (e.g. retinoblastoma, Non-Hodgkin lymphoma, hemophilia, thalassemia, etc.)
- Pediatric surgical conditions (biliary atresia, omphalocele, gastroschisis, TEF, imperforate anus, Hirschsprung’s Disease, diaphragmatic hernia)
- Pediatric medical conditions such as Kawasaki and Guillain Barre Syndrome (GBS)
- Z Benefits for aplastic anemia, liver cancer and hepatitis C
- Z MIRACLES for orphan disorders/rare diseases (Gaucher Type I, Pompe)
- Ophthalmologic emergency (i.e. retinal detachment)

**SPECIAL BENEFITS**
- Expansion of Z MORMPH (above knee prosthesis (including hip disarticulation), assistive devices: customized wheelchairs for patients with spinal cord injuries and children with cerebral palsy, physical and occupational therapy and speech therapy, specialized medical devices (VP shunts, hearing aids and middle ear implants)
- Early detection for breast and colon CA
- Multi-drug resistant TB
- Geriatric population (senior citizens)
- Palliative care for advanced stages of cancer
- Mental Health (i.e. counseling, among others)
HTA...what is it?
What is HTA?

“A multidisciplinary field of policy analysis, studying the medical, economic, social and ethical implications of development, diffusion and use of health technology”

“... the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.”

- International Network of Agencies for Health Technology Assessment
What are health technologies?

“…drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided.”

- US Office of Technology Assessment, 1978
Scope of HTA

- Pharmaceuticals
- Medical devices, equipment and machines
- Diagnostic tests and procedures
- Medical/surgical procedures
- Rehabilitation
- Interventional procedures
- Public health interventions and programs
Four questions in HTA

(1) Does the technology work?
(2) For whom?
(3) At what cost?
(4) How does it compare with the alternatives?

Milne and Stein in Baker and Kirk 1998. *UK National Health Service R & D Health Technology Assessment Programme*
DIMENSIONS OF HTA

Clinical
- Efficacy
- Safety
- Effectiveness
- Other Outcomes
- Indications
- Population affected

Economic
- Efficiency
- Costs
- Cost-effectiveness
- Cost utility
- Cost benefit

Patient Related
- Social Impact
- Ethics
- Acceptability
- Psychological reactions
- Other patient parameters

Organizational
- Diffusion
- Centralization/
  Decentralization
- Accessibility
- Skills-Routines
- Education-training


Beginnings of HTA

The term ‘technology assessment’ was first coined in the United States in 1965 during a meeting of the Congressional Committee on Science and Astronautics.

The Office of Technology Assessment (OTA) was founded in 1973 with a formal health program established in 1975.
OTA’s impressive range of topics

- Agricultural technology
- Arms control
- Aviation
- Biological weapons
- Business and industry
- Communications
- Competitiveness
- Crime / criminal justice
- Defense technology
- Developing countries
- Education
- Electric power
- Environment
- Forestry
- Fuel
- Genetic research
- Health and health technology
- Information technology
- Law
- Manufacturing
- Nuclear energy
- Oils spills
- Telecommunications
- Transportation
- Waste management
- Workplace safety
**HTA spreads in other parts of the world**

<table>
<thead>
<tr>
<th>Year</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1985</td>
<td>First meeting of ISTAHC (later on INAHTA) in Copenhagen, Denmark</td>
</tr>
<tr>
<td>1985</td>
<td>Dutch government establishes Commission for Future Health Technology</td>
</tr>
<tr>
<td>1987</td>
<td>Sweden establishes Swedish Council on Health Technology (SBU)</td>
</tr>
<tr>
<td>1989</td>
<td>Canada creates the Canadian Coordinating Office for HTA (CCOHTA)</td>
</tr>
<tr>
<td>1993</td>
<td>PBAC (Australia) became the first agency to require pharmacoeconomic evidence for formulary listing</td>
</tr>
<tr>
<td>1993</td>
<td>UK adopted HTA as part of its NHS R&amp;D</td>
</tr>
<tr>
<td>1993</td>
<td>International Network of Agencies for Health Technology Assessment (INAHTA)</td>
</tr>
<tr>
<td>1993</td>
<td>the <em>Cochrane Collaboration</em> was established</td>
</tr>
<tr>
<td>1995</td>
<td>the <em>International Society for Pharmacoeconomic and Outcomes Research (ISPOR)</em> was founded</td>
</tr>
</tbody>
</table>
The HTA movement spreads in other parts of the world

<table>
<thead>
<tr>
<th>Year</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>UK creates the National Institute of Clinical Excellence (NICE)</td>
</tr>
<tr>
<td>2000</td>
<td>European Commission funds ECHTA/ECAHI – European Network in HTA</td>
</tr>
<tr>
<td>2004</td>
<td>Germany creates IQWiG as part of the insurance reform</td>
</tr>
<tr>
<td>2005</td>
<td>the French High Health Authority (HAS) was formed to inform coverage decisions and improve quality</td>
</tr>
<tr>
<td>2006</td>
<td>Thailand establishes the Health Intervention and Technology Assessment Program (HITAP) to inform UHC policy</td>
</tr>
<tr>
<td>2008</td>
<td>Taiwan Center for Drug Evaluation forms HTA division</td>
</tr>
<tr>
<td>2008</td>
<td>South Korea establishes National Evidence-based healthcare Collaborating Agency (NECA)</td>
</tr>
<tr>
<td>2011</td>
<td>HTasiaLink was formed as the first collaboration among HTA agencies in the Asian region</td>
</tr>
</tbody>
</table>
HTA practice predates its popularity: primary scientific research

The first trial on scurvy: James Lind (1747)

On May 20 1747 I took twelve patients in the scurvy, on board the Salisbury at sea. The cases were as similar as I could have them... they lay together in one place..... and had one diet common to them all. To two of them was given a quart of cider a day, to two an elixir of vitriol, to two vinegar, to two oranges and lemons, and to the remaining two an electuary recommended by an hospital surgeon.

The most sudden and visible good effects were perceived from the use of the oranges and lemons, one of those who had taken them being at the end of the six days fit for duty.... The other... was appointed nurse to the rest of the sick.'

_A Treatise of the scurvy_
James Lind 1716-1794
The birth of randomized controlled trials

First published RCT: Streptomycin vs TB

The MRC Trial of Streptomycin 1948

- Defined inclusion criteria
- Random allocation (sealed envelopes)
- Endpoints: All cause mortality
  - X-ray interpretation (observer blind)

<table>
<thead>
<tr>
<th>Ethics</th>
<th>Streptomycin (n=55)</th>
<th>Control (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>4 (7%)</td>
<td>14 (27%) p&lt;0.01</td>
</tr>
<tr>
<td>X-ray</td>
<td>28 (51%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Considerable Improvement</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### CLINICAL TRIALS IN ASIA

<table>
<thead>
<tr>
<th>Region</th>
<th>No. of Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>World</td>
<td>170,209</td>
</tr>
<tr>
<td>East Asia</td>
<td>16,041</td>
</tr>
<tr>
<td>China</td>
<td>5,108</td>
</tr>
<tr>
<td>Japan</td>
<td>3,269</td>
</tr>
<tr>
<td>ROK</td>
<td>5,515</td>
</tr>
<tr>
<td>Taiwan</td>
<td>3,588</td>
</tr>
<tr>
<td>SE Asia</td>
<td>3,514</td>
</tr>
<tr>
<td>Indonesia</td>
<td>246</td>
</tr>
<tr>
<td>Malaysia</td>
<td>675</td>
</tr>
<tr>
<td>Philippines</td>
<td>671</td>
</tr>
<tr>
<td>Singapore</td>
<td>1,291</td>
</tr>
<tr>
<td>Thailand</td>
<td>1,547</td>
</tr>
<tr>
<td>Vietnam</td>
<td>201</td>
</tr>
</tbody>
</table>

Source: Clinicaltrials.gov (5 July 2014)
CLINICAL TRIALS IN THE SOUTHEAST ASIAN REGION

- Only 0.39% of all registered trials are done in the Philippines
- PHL FDA evaluates trials conducted in other countries
- ISSUES:
  - External validity
  - Generalizability

Total no. of studies registered in clinical trials.gov: 170,209
"It is surely a great criticism of our profession that we have not organised a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomised controlled trials."

- Professor Archibald Leman
Cochrane (1909 - 1988)

Source: Cardiff University Library, Cochrane Archive, University Hospital Llandough
The Cochrane Collaboration is an international organization that aims to help people make well-informed decisions about Healthcare by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions.
The Cochrane Collaboration's logo is a blobbogram/forest plot of trials (1972-1991) showing the benefits of antenatal corticosteroids in preventing RDS and deaths among preterm infants.
Over 5,000 reviews produced in 20 years!
Economic Evaluation (EE)

“The comparative analysis of alternative courses of action in terms of both their costs and their consequences”

Requires:
- a comparison of two or more alternatives
- examination of both costs and consequences

The incremental approach: “what is the difference in costs and difference in health outcome of Option A compared with Option B?”
## Types of Economic Evaluation

<table>
<thead>
<tr>
<th>Type of analysis</th>
<th>Valuing resources</th>
<th>Valuing health outcomes</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost minimisation</td>
<td>Php</td>
<td>-</td>
<td>Comparison of ‘equivalent interventions’ with similar clinical effects</td>
</tr>
<tr>
<td>Cost-consequence</td>
<td>Php</td>
<td>Listing of separate consequences with no common valuation</td>
<td>Comparison of health and non health, but without explicit decision rule</td>
</tr>
<tr>
<td>Cost effectiveness</td>
<td>Php</td>
<td>Single indicator of morbidity or mortality</td>
<td>Comparison of interventions with the same measure of outcome (i.e. LYG, deaths)</td>
</tr>
<tr>
<td>Cost utility</td>
<td>Php</td>
<td>Index of morbidity and mortality (QALY)</td>
<td>Comparison of any health care interventions across diseases</td>
</tr>
<tr>
<td>Cost benefit</td>
<td>Php</td>
<td>Php</td>
<td>Comparison of interventions by converting outcomes to monetary units</td>
</tr>
</tbody>
</table>
The ICER:
Is the extra cost justified by the additional health benefit?

\[
\text{ICER} = \frac{\text{Cost}_{\text{new}} - \text{Cost}_{\text{old}}}{\text{Benefits}_{\text{new}} - \text{Benefits}_{\text{old}}}
\]
The cost-effectiveness plane

Threshold = 1X GDP per capita
Php 120,000/QALY

- Less effective and more costly
- More effective and more costly
- Less effective and less costly
- More effective and less costly

NO

YES
The UK NICE Threshold

- £30k: Exceptional (>£30,000)
- £20-30k: Further rationale needed
- £20k: Generally acceptable (£20,000)
NICE: Using HTA in valuing technologies

- **Cost per QALY less than £3,000**
  - Neurosurgery - benign brain tumours
  - Laser treatment for DM retinopathy
  - Folic acid fortification of cereal grain products

- **Cost per QALY £3,000 to £30,000**
  - Neonatal ITU for very low birth weight
  - Rituximab in Rheumatoid Arthritis
  - Haemodialysis

- **Cost per QALY > £30,000**
  - Inpatient detoxification for drug abuse
  - Imatinib in CML
  - Anti-cholinesterases in mild AD

- **More harm than good**
  - PSA Screening
  - Antiarrhythmics after MI
PBAC (Australia): No explicit threshold

QALY “league table”

Source: Towse and Pritchard, 2002
<table>
<thead>
<tr>
<th>Medicines under consideration</th>
<th>ICER (Baht/QALY)</th>
<th>Coverage decision</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>recombinant human erythropoietin</strong> (rHuEPO) treatment in chemotherapy-induced anemia</td>
<td>negative dominant</td>
<td>No</td>
<td>2008</td>
</tr>
<tr>
<td><strong>osteoporosis drugs</strong> (alendronate, residronate, raloxifene) for primary and secondary prevention of osteoporotic fractures</td>
<td>300,000-800,000</td>
<td>No</td>
<td>2009</td>
</tr>
<tr>
<td><strong>atorvastatin, fluvastatin. pravastatin</strong> for primary prevention of cardiovascular disease</td>
<td>negative dominant</td>
<td>No</td>
<td>2009</td>
</tr>
<tr>
<td><strong>galantamine</strong> for treatment of mild-to-moderate Alzheimer's disease</td>
<td>157,000</td>
<td>No</td>
<td>2010</td>
</tr>
<tr>
<td><strong>donepezil, rivastigmine</strong> for treatment of mild-to-moderate Alzheimer's disease</td>
<td>180,000-240,000</td>
<td>No</td>
<td>2010</td>
</tr>
<tr>
<td><strong>adefovir, entecavir, telbivudine, pegylate interferon alpha 2a</strong> for treatment of chronic hepatitis B</td>
<td>negative dominant</td>
<td>No</td>
<td>2011</td>
</tr>
<tr>
<td><strong>simvastatin</strong> for primary prevention of cardiovascular disease</td>
<td>82,000</td>
<td>Yes</td>
<td>2009</td>
</tr>
<tr>
<td><strong>pegylate interferon alpha 2a&amp;2b</strong> plus ribavirin for treatment of chronic hepatitis C subtype 1 4 5 &amp; 6</td>
<td>cost-saving</td>
<td>Yes</td>
<td>2011</td>
</tr>
<tr>
<td><strong>lamivudine or tenofovir</strong> for treatment of chronic hepatitis B</td>
<td>cost-saving</td>
<td>Yes</td>
<td>2011</td>
</tr>
</tbody>
</table>
WHO and HTA

“... all member states should have established a formal mechanism to systematically assess the appropriate use of health technologies and to verify that they respond to the national health program needs.”

- The Declaration of Alma Ata on Primary Health Care, 1978
“HTA is a tool to further advance universal health care in terms of deciding who should be getting which intervention and at what cost.”
Key recommendations of WHA 67.23 resolution on HTA to countries

- Establish **national systems** for HTA
- encourage the **systematic utilization** of HTA in support of **UHC**
- Strengthen **link** between HTA and regulation and management
- Strengthen national **capacity** for regional and international networking, developing national know-how, **avoiding duplication** of efforts and achieving better use of resources;
- **identify gaps** with regard to promoting and implementing evidence-based health policy, on improving related information systems and research capacity, and
- Consider seeking **technical support** and exchanging information and sharing experiences with other Member States, regional networks

Courtesy of Klara Tisocki, WHO-WPRO
HTA and Universal Health Care

Rule VI
HEALTH TECHNOLOGY ASSESSMENT

SECTION 67. Health Technology Assessment

The Corporation shall use Health Technology Assessment (HTA) to examine the medical, economic, social and ethical implications of use of health technology in order to support its benefit and quality assurance policies within the context of actual needs, current standards of medical practice and national health objectives. The Corporation shall do this in partnership with the DOH, academe, government, medical professional organizations and other stakeholders. The outputs of HTA shall be one of the bases for inclusion or non-inclusion of health technologies in the benefit package.

HTA is ingrained in the new National Philhealth Law as a tool for benefit development and the improvement of quality standards.
Institutions conducting technology assessments in the Philippines

MARKETING APPROVAL
- Pharmaceuticals
- Food
- Medical devices
- Biological agents
- Cosmetics

Safety, efficacy and quality

FORMULARY LISTING
- Pharmaceuticals
- Comparative cost-effectiveness
- Budget impact
- Health service impact
- Equity/ethical/social implications

PURCHASING /ACCREDITATION
- Pharmaceuticals
- Diagnostics
- Medical /Surgical procedures
- Professional services
- Sustainability
- Equity
- Affordability
The Philippine National Formulary

A government-approved selective list of medicines that guides:

- The procurement and supply of medicines in the public sector
- Schemes for drug reimbursement by Philhealth
- Medicine donations
- Local medicine production
Formal HTA systems to assess other technologies beyond drugs began in the 1990’s

- HTA was identified by Philhealth as a tool to guide the development of reimbursement policies on medical claims based on the cost-effectiveness of tests and treatments.

- In 1999, the Philhealth HTA Committee was created to guide Philhealth in the selection of health technologies for insurance coverage.
Functions of the Philhealth HTA Committee

- Create a positive list of drugs to complement the national formulary
- Appraise and disseminate clinical practice guidelines
- Evaluate the effectiveness and safety of medical and surgical procedures

However, the Philhealth HTAC has been inactive since 2010 and currently there is no nationally coordinated agency evaluating technologies apart from drugs to guide purchasing by Philhealth.
Revision of the Guidelines for the Philippine National Formulary

In 2011, the National Formulary Committee was reconstituted and renamed as the Formulary Executive Council with 11 new members coming from the academe and the healthcare professional community.

The FEC embarked on a substantial revision of the guidelines of the PNF building on the methods and processes of the previous NFC and considering the inputs coming from the academia, medical community, patient groups and the industry.
First Evidence Review Workshop with WHO (2011)

Second Workshop with the Evidence Review Group (ERG)

Workshop on GRADE and Systematic Reviews with the FEC, ERG and Dr. Antonio Dans (September 2012)
Orientation seminars with hospitals (2013)
Current Process of Drug Inclusion in the Philippine National Formulary

Submission of applications for drug inclusion in the Formulary to the PNF Secretariat

Prioritization of applications by the Formulary Executive Council (FEC)

Assessment of prioritized drug applications

Decision

- Hospitals
- Industry
- Medical associations
- Patient groups

- Local priority – DOH/PHIC, MDGs
- Disease frequency
- Disease severity
- Economic impact to households
- Equity/ethical considerations
Medical economics an important consideration

- In 2013, DOH through the Formulary Executive Council (FEC) began incorporating formal methods of pharmacoeconomic evaluation as part of the decision-making process
  - new costly therapies
  - likely significant budget impact
  - new therapeutic area claiming modest to significant improvement in safety/efficacy
  - different additional benefits to specific subgroups of patients

- A country specific threshold of 1 GDP capita per QALY was recently adopted by the FEC to guide the drug approval process
Rationalizing essential drug prices: The Drug Price Reference Index

- The Philippine Drug Price Reference Index (DPRI) was recently implemented making it mandatory for all DOH health facilities to adhere to a price ceiling (acquisition cost) when procuring drugs listed in the national formulary.

- Being used by PHIC in designing the proposed outpatient drug benefit package that will be implemented in 2015.
Strict criteria used by the FEC in the inclusion of drugs for the national formulary

- **Efficacy and safety** – FDA approval; based on evidence preferably from Level III RCTs, good quality systematic reviews/meta-analysis

- **Pharmaceutical suitability** – Formulations, strengths and pharmaceutical properties; convenience in use/administration

- **Comparative cost-effectiveness** – Clear-cut improvement in length and quality of life relative to its cost versus existing standards

- **Affordability** – Overall sustainability and budget impact to the health system (DOH/PHIC)

- **Public health relevance** – Addresses country needs based on disease ranking/burden and avoidable disease burden; local context

- **Equity/ethical considerations** – Vulnerable/neglected/special populations (i.e. poor, elderly, PWDs, IPs)
Not all about cost-effectiveness

◆ Value judgments will also have to be made on other aspects of care unique to the local setting:

- *Philippine laws*
- *Ethical/social values*
- *Culture*
- *Social acceptability*
- *Feasibility/sustainability*
- *Health system infrastructure/capacity*
The Primary Care Formulary
**ANTIHISTAMINES**

### CETIRIZINE

**Dosage strength**
- Oral: 10 mg tablet (as dihydrochloride)
- 10 mg/mL, 10 mL (as dihydrochloride)
- 1 mg/mL solution, 30 mL and 60 mL (as dihydrochloride)
- 5 mg/5 mL syrup, 30 mL (as dihydrochloride)

**Drug description**
A piperazine-derived, long-acting, second-generation H1 receptor antagonist, which is often better tolerated than sedating antihistamines due to less sedating and less anticholinergic effects.

**Indication**
Perennial and seasonal allergic rhinitis, and other allergic symptoms such as hay fever, conjunctivitis, and chronic idiopathic urticaria.

**Contraindication**
Known hypersensitivity reactions to cetirizine, levocetirizine or hydroxyzine (cetirizine is hydroxyzine's active metabolite) or any component of the formulation; severe renal impairment.

**Dose**
Symptomatic relief of allergy: by mouth, ADULT, 10 mg once daily or 5 mg twice daily (may be increased as necessary to the maximum recommended daily dose of 20 mg); CHILD >6 years, 10 mg/day or 5 mg twice daily; CHILD 2-6 years, 5 mg once daily or 2.5 mg twice daily; CHILD 1-2 years, oral drops, 0.25 mg/kg twice daily.

**Dose adjustment**
**Elderly ≥77 years of age:** Use lower dose (5 mg/day).

**Renal and Hepatic Impairment:**
- For mild-to-moderate impairment, dose reduction is warranted (5 mg/day).
- Contraindicated for severe renal impairment.

**Precaution**
- **WARNING:** May cause CNS depression which may impair physical or mental abilities; patients should be cautioned about performing tasks that require mental alertness, such as operating machinery or driving.
- CNS stimulation may occur with antihistamines, especially in children (caution is advised in patients suffering from epilepsy); children and the elderly (risk of sedation and anticholinergic effects is increased).
- Renal impairment: hepatic impairment; excess alcohol intake, and use of other sedative drugs should be avoided.
- Not recommended for children <12 months, or for breastfeeding mothers (cetirizine is excreted into breast milk).

### DIPHENHYDRAMINE

**Dosage strength**
- Oral: 25 mg and 50 mg capsule (as HCl)
- Inj.: 50 mg/mL, 1 mL ampul (IM, IV) (as HCl)

**Drug description**
A monoethanolamine-derived, first-generation H1 receptor antagonist that exhibits antimuscarinic and pronounced sedative property, with low incidence of GI side effects.

**Indication**
Relief of allergic symptoms caused by histamine release, including rhinitis, cough, conjunctivitis and allergic dermatoses, and anaphylaxis (adjunct to epinephrine).

**Contraindication**
Known hypersensitivity to diphenhydramine or any component of the formulation; acute asthma; neonates, or premature infants (increased susceptibility to antimuscarinic effects); breastfeeding: use of the parenteral form as a local anesthetic.

**Administration**
- Oral: Allergic reactions, by mouth, ADULT, 25-50 mg every 6-8 hours; CHILD >12 years, 25-50 mg every 4-6 hours (maximum, 300 mg daily).

**Adverse Drug Reactions**
Common: Dizziness, drowsiness, dryness of mouth, fatigue, headache, insomnia, malaise, nausea, pharyngitis, somnolence.

Less Common: Abdominal pain, anorexia, arthralgia, chest pain, diarrhea, dyspepsia, dyspnea, elevated liver enzymes, epistaxis, fever, flushing, increased appetite, myalgia, tachycardia, thirst, vomiting, weight gain.

Rare: Dystonias, hemolytic anemia, hepatitis, hypersensitivity, including anaphylaxis and bronchospasm; hypotension, rash, thrombocytopenia.
Antimicrobial Resistance ALERT!
Amoxicillin should not be used for the empiric treatment of Acute Uncomplicated Cystitis and Acute Uncomplicated Pyelonephritis due to the relatively poor efficacy and very high prevalence of antimicrobial resistance.

Contraindication: Known hypersensitivity to penicillins, or any component of the formulation.

Dose:
Community-Acquired Pneumonia, low-risk (CAP-LR), **by mouth**, ADULT, 0.5-1 g three times a day; CHILD, 40-50 mg/kg/day in 3 divided doses (for uncomplicated CAP-LR, the duration of all doses is for 5-7 days). See Clinical Practice Guidelines – CAP for further information.
Dental abscess (short-course), **by mouth**, ADULT, 3 g repeated once after 8 hours.
Endocarditis prophylaxis, **by mouth**, ADULT, 2 g single dose 1 hour before procedure; CHILD, 40-50 mg/kg/day in 3 divided doses (for uncomplicated CAP-LR, the duration of all doses is for 5-7 days). See Clinical Practice Guidelines – CAP for further information.

Choose the agent with:
1. the narrowest spectrum which will cover the likely or proven pathogen(s);
2. the least expensive if efficacy and safety are otherwise equal;
3. the lowest incidence of, or least serious, adverse reactions.
Clinical pathways for common primary conditions

**DIABETES MELLITUS**

- **WITH CLINICAL SYMPTOMS:** Weight loss, polyuria, polydipsia, pruritus vulvae, non-healing wound
- **WITHOUT CLINICAL SYMPTOMS BUT WITH ANY OF THE FOLLOWING RISK FACTORS:** Age ≥40 years old, IGT or IFG or GDM, PCOS, overweight or obese, abnormal waist circumference or waist-hip ratio, first-degree relative with Type 2 DM, sedentary lifestyle, hypertension, history of vascular disease (including stroke, peripheral arterial occlusive disease, coronary artery disease), acanthosis nigricans, schizophrenia, low serum HDL, high serum triglycerides
- **ALL PREGNANT WOMEN** (see section on GDM; screening is by OGTT)

**SCREENING TESTS**

Any of the following tests may be used:

- Plasma glucose
- Two-hour plasma glucose (using 75 g OGTT)
- Random blood glucose

**NORMAL RESULTS**

- FBS <5.6 mmol/L (<100 mg/dL)
- Random/casual blood glucose <7.7 mmol/L (<140 mg/dL)
- Two-hour blood sugar in the 75 g OGTT <7.7 mmol/L (<140 mg/dL)

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**PRE-DIABETES**

- Impaired Fasting Glucose: FBS 5.6-6.9 mmol/L or 100-125 mg/dL
- Impaired Glucose Tolerance: RBS 7.7-11 mmol/L (140-199 mg/dL)

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**DIABETES MELLITUS**

- FBS ≥7 mmol/L (≥126 mg/dL) after overnight fast of 8-14 hours
- 2-hour plasma glucose ≥11.1 mmol/L (≥200 mg/dL)
- RBS ≥11.1 mmol/L (≥200 mg/dL) in patients with classic symptoms

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Universal screening using laboratory tests is not recommended.

All patients seen at the clinic should be evaluated annually for risk factors for type 2 diabetes and pre-diabetes.

Testing should be carried out within the healthcare setting under the supervision of a qualified professional.

The use of the following tests for the diagnosis of diabetes mellitus is not recommended: (1) Urine glucose and (2) Plasma insulin.

IGT: Impaired Glucose Tolerance
IFG: Impaired Fasting Glucose
GDM: Gestational Diabetes Mellitus
PCOS: Polycystic Ovarian Syndrome

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Repeat testing at least annually

Lifestyle modifications and monitoring every 3-6 months
Clinical pathways for common primary conditions

**Communicable diseases**
- Community-acquired pneumonia (CAP) in immunocompetent adults
- Urinary Tract Infection (UTI)
- Tuberculosis

**Non-Communicable diseases**
- Hypertension in Adults
- Diabetes mellitus
- Common poisoning

**COMMON POISONING**
- Caustics: acids
- Caustics: alkali – sodium hypochlorite kerosene
- N-methyl carbamates
- Organochlorine
- Organophosphates
- Watusi (dangerous firecrackers)
- Ethanol
- Cobra bite
- Paralytic shellfish poisoning

**Diarrhea/dehydration**

**Vaccination schedules (EPI)**
International networking and partnerships
Collaboration with NICE International

- The initiative was in response to a direct request for technical support by the DoH Health Secretary during visits to NICE’s HQ in the UK in December 2012.

- 2-year grant by the Rockefeller Foundation with a focus on strengthening priority-setting methods and processes in the Philippines.
UK NICE Scoping activity

With NICE International Director Kalipso Chalkidou and Mr John Appleby from The King’s Fund during a FEC meeting (December 2012)
Experts Committee for the Medicines Access Program for Early Stage of Breast Cancer

Committee Composition:
- Chair
- Relevant clinical specialties
  - Philippine College of Surgeons
  - Philippine Society of Pathology
  - Philippine Society of Medical Oncology
  - Philippine College of Radiology
  - Philippine Oncology Nursing Association
- Representatives of cancer centers
- Representative of patients/carers
  - Philippine Cancer Society

Experts will work on the Areas of Uncertainties:
- Clinical and cost-effectiveness of aromatase inhibitors
- Clinical and cost-effectiveness of trastuzumab
- Role of HER-2 NEU testing / FISH
International activities: Collaboration with NICE International

Health Technology Assessment can inform:

- Listing Delisting
- Procurement Pricing Reimbursement
- Evidence-informed prescribing and use
Networking with HITAP (Thailand)

With Dr. Yot Teerawatannanon and Mr Francis Ruiz (NICE), Undersecretary Valera, the HITAP team, NCPAM, Philhealth, FDA and academic partners during the Second vaccines Workshop (September 2013)
The HTAsiaLink

“The HTAsiaLink is a network to support collaboration between Asian health technology assessment agencies. It focuses on facilitating HTA research by accelerating information and resources sharing and developing an efficient methodology for HTA in the region.”

- HTAsiaLink website
Current developments in HTA

- Creation of standard reference costs for drugs *(drug price reference index)* and common hospital procedures and laboratory services

- National guidelines for conducting HTA and economic evaluation currently being drafted to guide sponsors and researchers tasked to deliver HTA output to the DOH

- Networking with local and international academic partners and HTA agencies/regional partners *(HTAsiaLink, NUS, APEC, ASEAN)*
The Methods Guide for Drugs

- Creation and dissemination of the *Methods Manual for the clinical and economic evaluation of drugs for the national formulary* to standardize the evaluation process and ensure good methodological quality and a transparent/accountable process for all stakeholders.

- The Methods Manual will ensure that HTA principles are used and fitted optimally to the underlying health care system context and the specific requirements needed by PHL decision-makers (DOH and Philhealth).
The Methods Manual will be an elucidation of the Philippine reference case.

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<th>Element of HTA</th>
<th>Reference case</th>
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<td>Defining the decision problem</td>
<td>Scope developed by FEC, ERG and NCPAM</td>
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<td>Comparator</td>
<td>Drug/non-drug interventions currently considered as routine best practice in the Philippines</td>
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<tr>
<td>Perspective on costs</td>
<td>Health care system (funder and private health expenditures)</td>
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<tr>
<td>Perspective on outcomes</td>
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<td>Type of economic evaluation</td>
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<td>Systematic review /meta-analysis (de novo or appraisal of existing)</td>
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<td>QALYs</td>
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<td></td>
<td>Life-years gained, condition-relate events that are valid (if no QALY data)</td>
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<tr>
<td>Source of data for measurement of HRQOL</td>
<td>Patients and/or carers</td>
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<tr>
<td></td>
<td>EQ-5D (Thai study for now; collect Philippine data ASAP)</td>
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<tr>
<td>Source of preference data for valuation of HRQOL</td>
<td>Representative sample of the public</td>
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<td>Discount rate</td>
<td>3.5% for both costs and outcomes</td>
</tr>
<tr>
<td>Other criteria? Weighting?</td>
<td>- equity, affordability, economic impact, variation in practice, implementation factors</td>
</tr>
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</table>
Key messages

- HTA has an important role in charting the course toward UHC in the Philippines

- The ultimate goals of HTA are quality of care, effectiveness and efficiency and equity of the health system

- Long-term local capacity-building for HTA is important while regional and international networking is needed to share and generate evidence to inform coverage decisions

- Robust methods, transparency, participation and integrity in the management of the whole HTA process are key elements to ensure that resource allocation is as fair as possible to all stakeholders
Thank you!