UNIVERSITY of WASHINGTON

An Introduction to Health Technology Assessment in the U.S. and Canada: Possible Lessons and Implications for Taiwan?

Presentation to:

Workshop on HTA Policy Formation and Implementation

National Yang-Ming University Performance Center

Sponsor: Taiwan Food and Drug Administration

Organizer: Research Center of Health and Welfare Policy, National Yang-Ming University

Co-Organizer: Center for Drug Evaluation

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Acknowledgements

- Research Collaborators:
  - Adrian Towse and Nancy Devlin, Office of Health Economics, UK
  - Sean Sullivan and David Veenstra, University of Washington

Country Populations and Incomes (IMF/$PPP 2010)

- Taiwan—23 million; $35,227
- Australia—23 million; $39,699
- Canada—34 million; $39,057
- South Korea—49 million; $29,836
- UK—62 million; $34,920
- US—311 million: $47,284
  - California: 37 million
  - Medicare (elderly and disabled): 38 million
  - Uninsured: 51 million

Agenda

- **Introduction to Health Technology Assessment (HTA)**
- HTA in the U.S. Health Care System
- HTA in Canadian Health Care System
- Principles of HTA
- Study of HTA in Emerging Markets

Key Messages about Health Technology Assessment (HTA)

- **Evolution**—HTA is not new, but it has nearly 30 years of history—an evolutionary one.
- **Globalization**—HTA is being applied in more and more countries, and the number of competent practitioners is growing--globally.
- **Variety**—How HTA is used varies markedly, but depends on incentives to use the information.
- **Challenge**—HTA operates in the political sphere and its role and performance in any given country will depend on how it is institutionalized and organized.

What is HTA? Some Definitions

- Technology assessment is a form of policy research that examines short- and long-term social consequences (for example, societal, economic, ethical, legal) of the application of technology. The goal of technology assessment is to provide policy-makers with information on policy alternatives (Banta 1993).
- Health technology assessment ... is a structured analysis of a health technology, a set of related technologies, or a technology-related issue that is performed for the purpose of providing input to a policy decision (U.S. Congress, Office of Technology Assessment 1994).

Health Technology Assessment (HTA) – Key Processes/Functions

- Scoping – Identifying and monitoring pre-approval products that will require assessment and appraisal.
- Topic Selection – Post-approval, prioritizing products for assessment and appraisal
- Assessment – Mfrs submit evidence, organization undertakes systematic assessment of the evidence (clinical, economic, budgetary)
- Appraisal – Decision-making committee considers evidence from assessment, input from stakeholders and makes a recommendation for funding/implementation
- Funding/Implementation – Decision by the budget holder to reimburse/cover a product with or without parameters.

Public Sector: Some Do First 3

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Private Sector: Does All Steps

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- Topic Selection – Post-approval, prioritizing products for assessment and appraisal
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- Appraisal – Decision-making committee considers evidence from assessment, input from stakeholders and makes a recommendation for funding/implementation
- Funding/Implementation – Decision by the budget holder to reimburse/cover a product with or without parameters.

Health Technology Assessment: Principle vs. Practice

- In principle, not just about pharmaceuticals
  - In practice, drugs have been the focus
- In principle, not just about costs
  - In practice, it has been about costs and cost-effectiveness (and budget impact)
- In principle, it's a scientific approach to resource allocation
  - In practice, it's often about politics.

Another Separation of HTA Functions

1. **Marketing approval ("Registration")**—usually for drugs and devices, an assessment of benefit-risk balance based on clinical trial or other data
2. **Coverage**—inclusion as a covered service in health plan benefit package
3. **Reimbursement**—establishes plan payment level, perhaps considering "value of money" or budget impact, or via internal (therapeutic) reference pricing or via external (international reference pricing
4. **Clinical guidelines**—use HTA information use to support clinical guidelines in disease areas.

HTA as an Economic Production Process and Economic Good

- The process of HTA can usefully be thought of as a "technology" or production process.
  - As such, one can ask, whether it is **"technically" efficient**, obtaining maximum output given the resources used.
- The output of the process is "information"—a "public" good, in economic jargon. Indeed—a global public good
  - One can also ask whether the the production is **"economically" efficient**, i.e., is it technically efficient, being produced a minimum cost, and in the right quantity?
- Public goods create incentive to be a "free-rider"

Economics says: "public goods" will be undersupplied by private markets. Incentives like patents and subsidies are needed.

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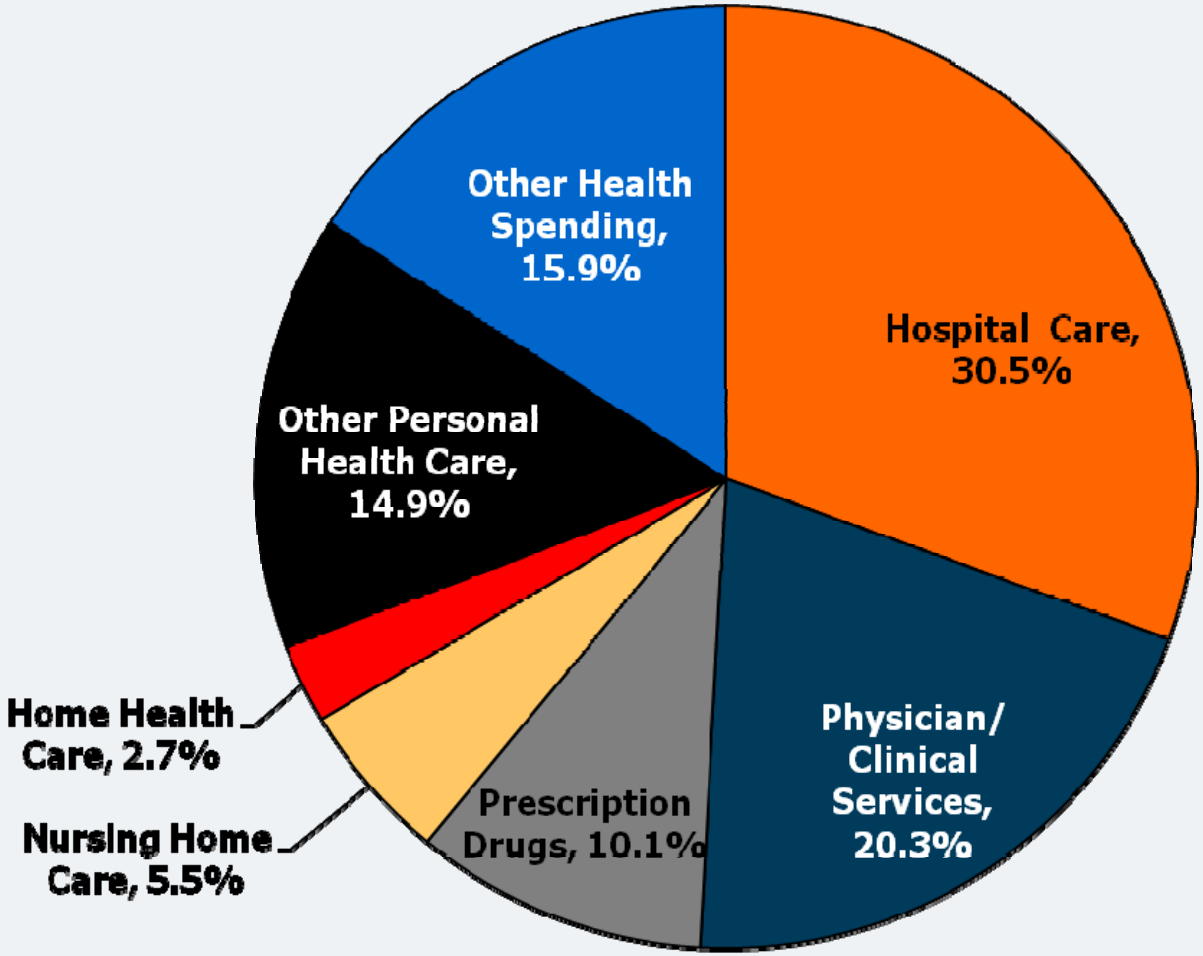
U.S. Insured Distribution, 2011

United States	Number	0 - 150,026,000
Employer	150,026,000	
Individual	14,000,900	
Medicaid	47,375,300	
Medicare	37,583,300	
Other Public	3,683,500	
Uninsured	50,674,300	

United States	Percent	0% - 100%
Employer	49%	
Individual	5%	
Medicaid	16%	
Medicare	12%	
Other Public	1%	
Uninsured	17%	

Source: Kaiser FF. org

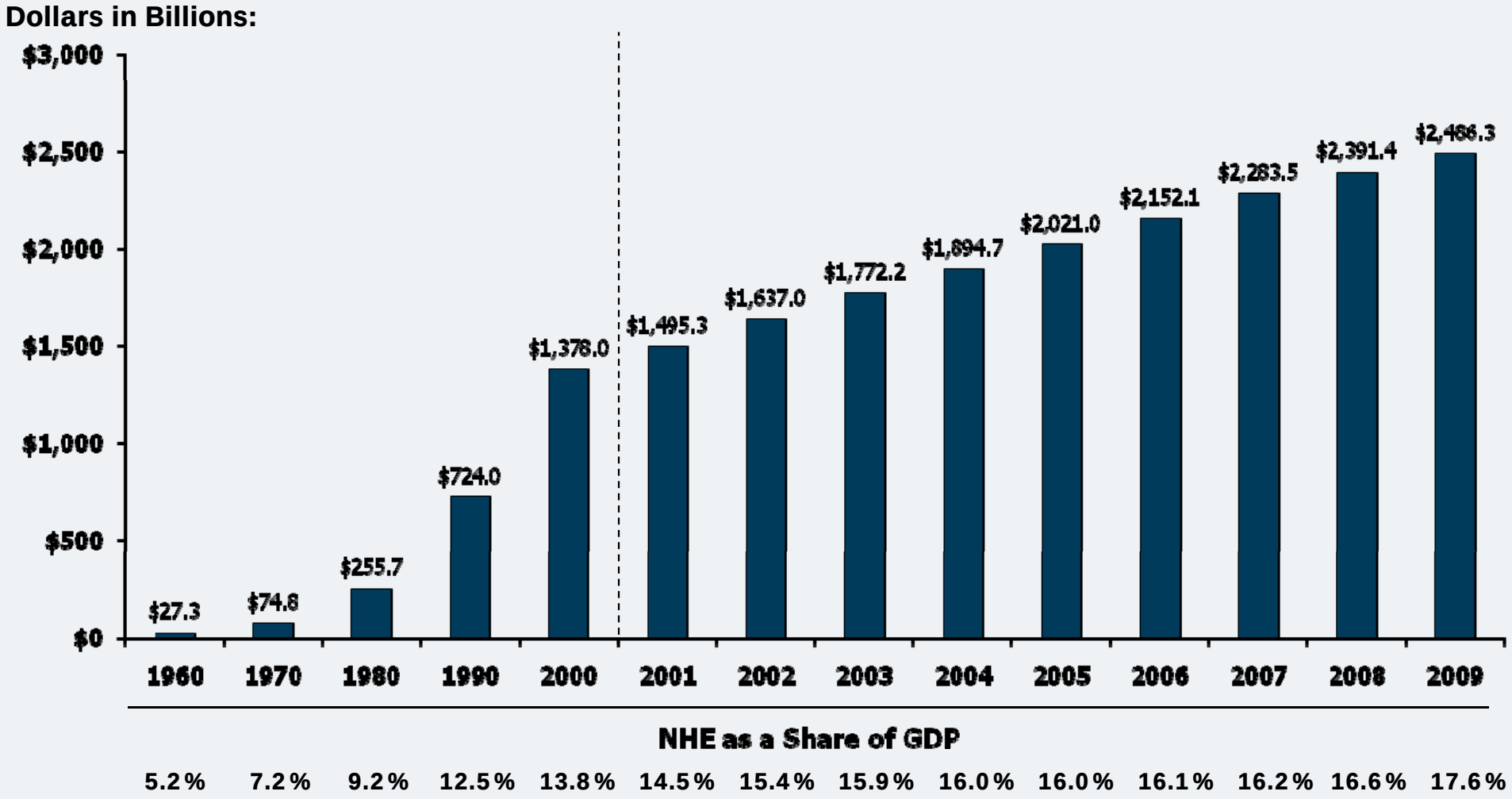
Distribution of National Health Expenditures, by Type of Service, 2009



Note: Other Personal Health Care includes, for example, dental and other professional health services, durable medical equipment, etc. Other Health Spending includes, for example, administration and net cost of private health insurance, public health activity, research, and structures and equipment, etc.

Source: Kaiser Family Foundation calculations using NHE data from Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, at http://www.cms.hhs.gov/NationalHealthExpendData/ (see Historical; National Health Expenditures by type of service and source of funds, CY 1960-2009; file nhe2009.zip).

National Health Expenditures and Their Share of Gross Domestic Product, 1960-2009



Source: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, at http://www.cms.hhs.gov/NationalHealthExpendData/ (see Historical; NHE summary including share of GDP, CY 1960-2009; file nhegdp09.zip).

U. S. Health Care System

- No explicit or constitutional "right to health care"
- No universal coverage
- Insurance coverage is a complicated public/private mix, with a "safety net" that fails too often.
- Described as: "pluralistic", "fragmented", "disorganized," "inequitable", "innovative", "decentralized"….
- No national basic or explicit minimum health care benefit package. (Hence, no need for one national HTA body.)
- Food and Drug Administration review is one form of partial, national HTA
- But plans need not cover FDA-approved products
- And plans can cover some products "off-label"

Two Poles on HTA Continuum

US:
Decentralized;
Little reliance
on formal HTA

UK:
Centralized;
Heavy reliance
on formal HTA

Employer-sponsored health insurance market segments

- Fully or partially insured (approx 150 mill with self-insured)
  - Traditional health insurance plans (e.g. United Healthcare, WellPoint, Aetna,) and closed panel HMOs (e.g. Kaiser, GHC)
  - Have internal/robust HTA programs
- Self-insured companies – With or without administrative services contracts with health plans and/or PBMs (e.g. GM, Boeing)
  - Use HTA programs of the ASO health plan.
- Individual insurance policy – (approx. 14 million)
  - Use HTA programs of the health plan

Government-sponsored (CMS) health care segments

- Medicare (Ages 65+) – (approx. 40 million)
  - MCAC for Part B and medical technology
  - Private health plans for Part D
- Medicaid – (poor and disabled) – (approx. 50 million)
  - State run HTA programs
  - Some supported (assessment) by DERP
- Uninsured – (approx 50 million)
  - 50% pay cash for drug perscriptions

Key U.S. Trends

- Still limited use of CEA in formulary and non-formulary decisions
  - Why? Lack of cost controls in US insurance system

- Growing interest in:
  - **"comparative effectiveness research"**
  - **"real-world" data**
  - **"coverage with evidence development"**

HTA in the US

- Decisions regarding product licensing (FDA) and federal coverage and reimbursement (CMS) are separate.
- Because the US health care system is largely decentralized and privatized, the HTA processes are decentralized and privatized.
  - Adoption, coverage and reimbursement of medical technology is left to the local payers.

HTA in the US - Federal

- Medicare HTA –
  - For non-drug technologies, the Medicare program (Coverage Division) uses the following process:
    - Scopes technologies based on various factors (cost, impact to Medicare, visibility, safety) and then selects technologies.
    - Writes specific questions that determine the scope of the HTA and the search for evidence.
    - Commissions an HTA through a government research organization (AHRQ). AHRQ contracts with an Evidence-Based Practice Center (private vendors and Universities) for the assessment.

HTA in the US - Federal

- Medicare HTA –
  - For non-drug technologies, the Medicare program (Coverage Division) uses the following process:
    - The Medicare Coverage Advisory Committee (MCAC) receives the document, participates in an open hearing and then votes on the STRENGTH of the evidence, but does not make a decision or give a recommendation to Medicare.
    - The Coverage Division within Medicare makes the final coverage decision weighing the evidence and considering the deliberations from the MCAC.

HTA and CEA - Federal

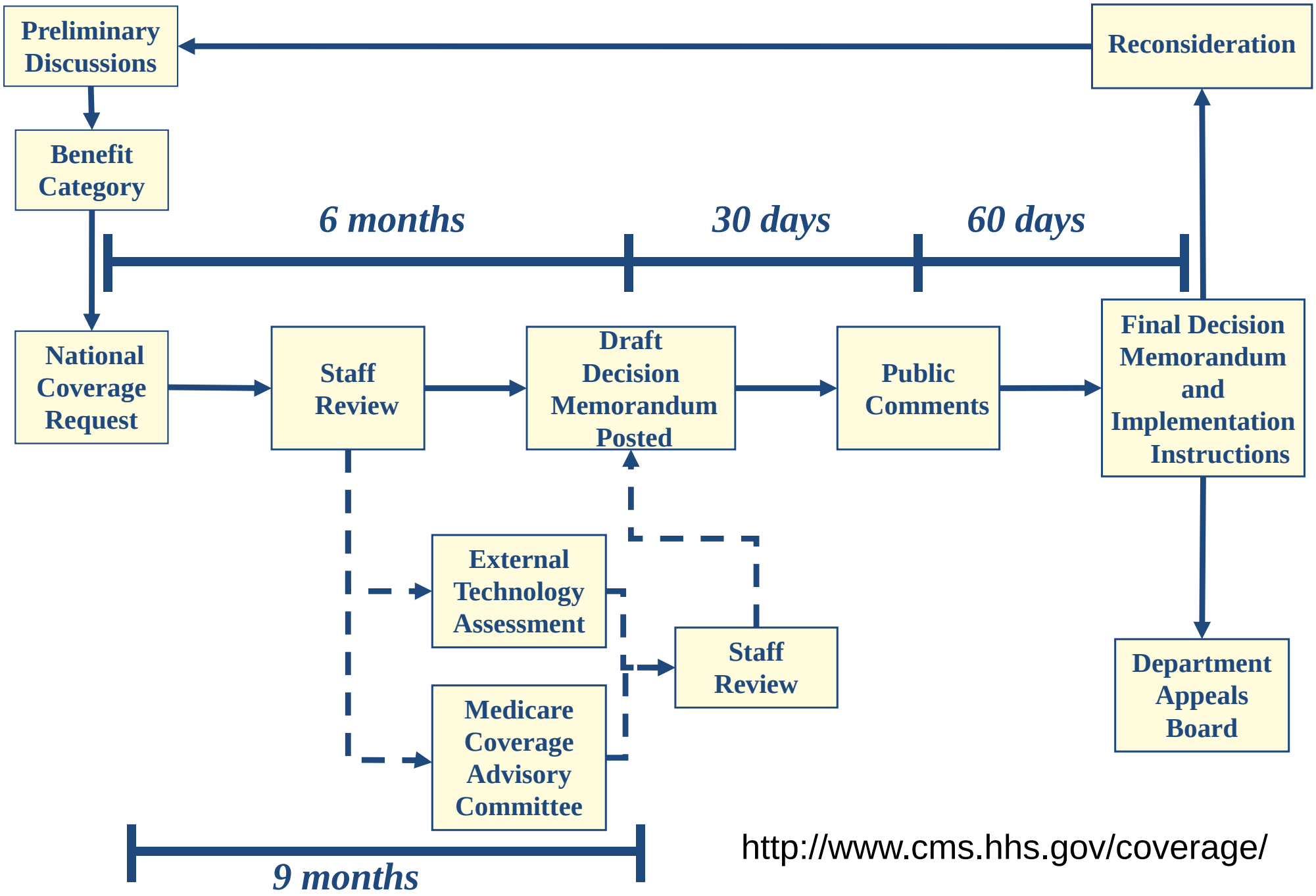
- What is the role of economic evaluations in Medicare program?
  - By Congress – Medicare is prohibited from using CEA data to *make* coverage and reimbursement decisions, but not from informing decisions.
  - Practically – Employees of CMS do review publicly available CEA and budgetary impact data *to inform* coverage and reimbursement decisions. They do not request these data from manufacturers.

CMS/Medicare national coverage decisions (NCDs)

- Reserved for technologies affecting large number of beneficiaries with greatest impact on Medicare
- Inconsistent local coverage policies
- Technology represents significant potential medical advance
- Technology subject to substantial controversy
- Potential for rapid diffusion or overuse exists
- Formal external request

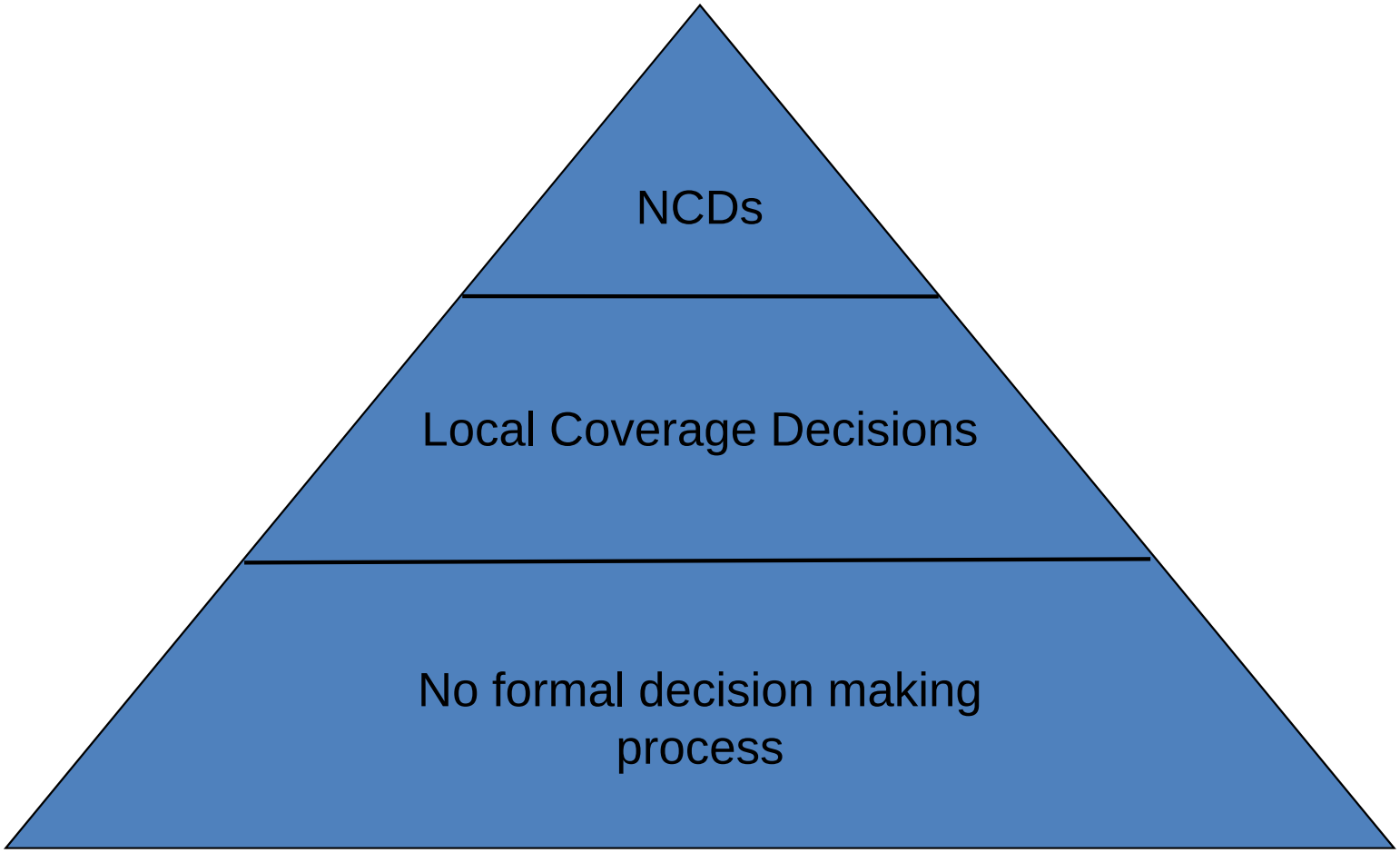
http://www.medpac.gov/publications/congressional_reports/Mar03_AppB.pdf/

MEDICARE NATIONAL COVERAGE PROCESS



http://www.cms.hhs.gov/coverage/

CMS national coverage decisions



Medicare (CMS) - Federal

- **Coverage with Evidence Development (CED)**
  - CMS grants provisional reimbursement of a technology during which time the manufacturer/developer undertakes a study that would address specific evidence gaps. In some cases, the agencies (FDA, CMS, NIH) would be involved in the trial.
  - Purpose – Allowing limited use/reimbursement of the technology during evidence generation.

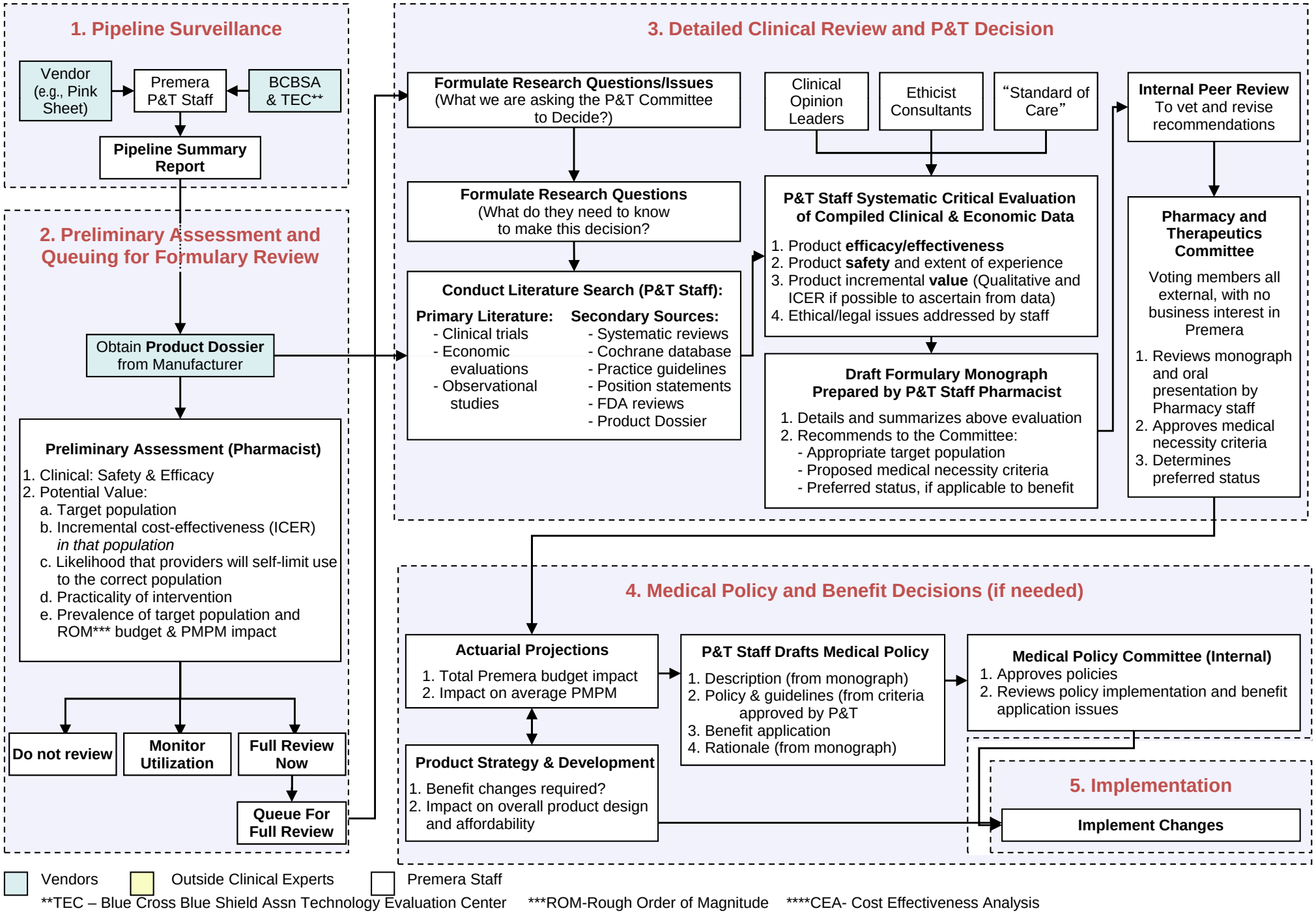
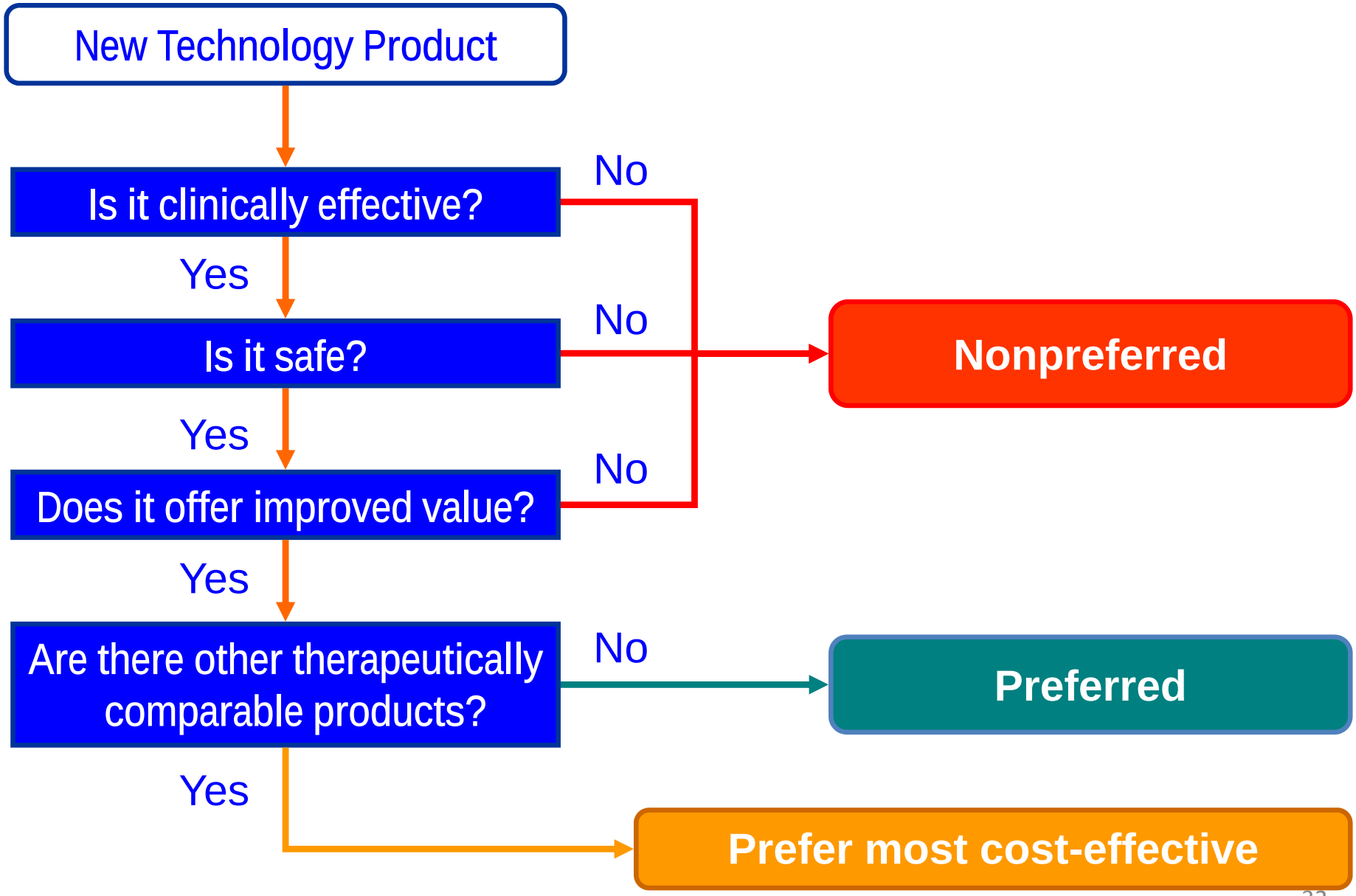


Exhibit A. Enhanced formulary review process for biotech drugs, utilizing AMCP Format submissions.

Watkins, Sullivan Health Affairs 2006

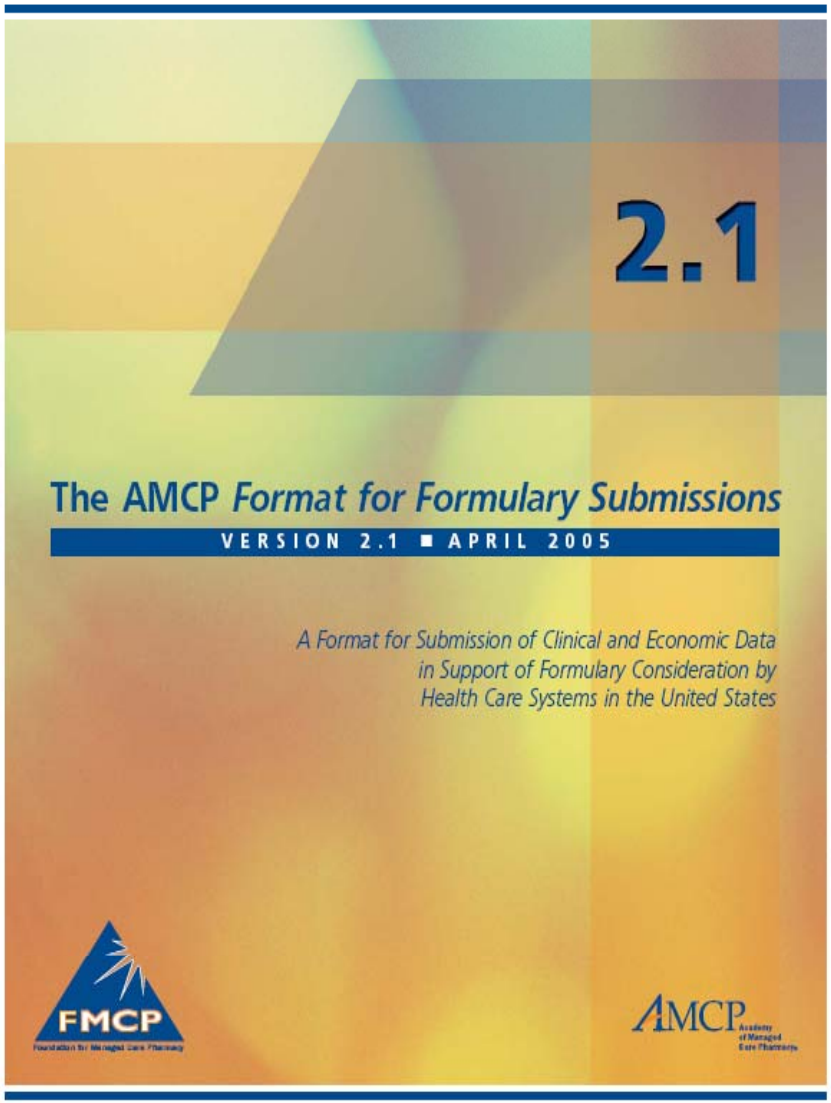
HTA Appraisal Process in US Health Plans



Private Sector HTA Trends

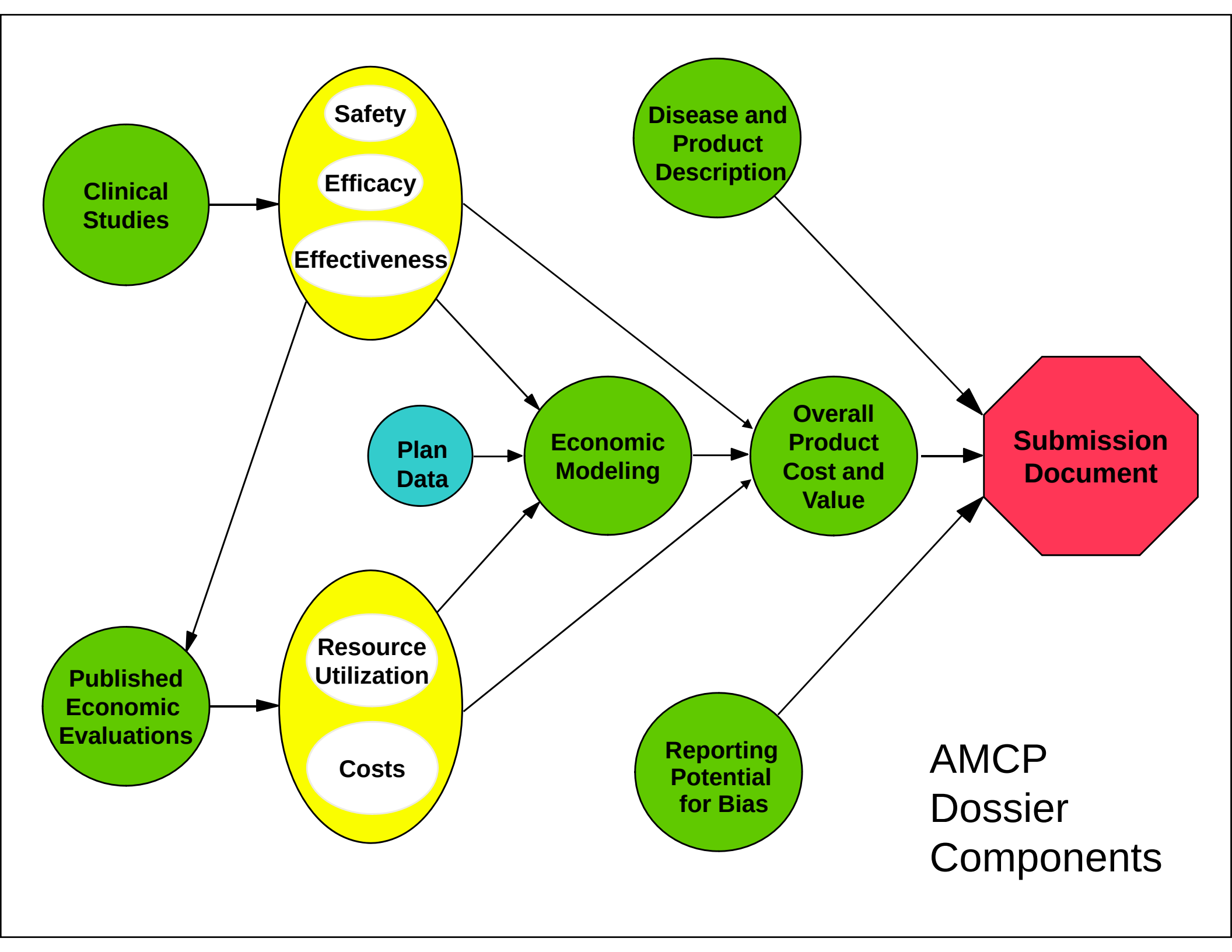
- Plan consolidation in the private market (6 plans = >65% of employer sponsored segment).
  - Economies will allow organizations to build rigorous HTA programs.
  - 2009 Implementation of Wellpoint guidelines is very similar to NICE guidance
- Health plans are routinely scanning the HTA reports of ex-US decision making bodies.
- Non-drug technologies and companion diagnostic/drug combinations are now being reviewed as part of the P/T process in some plans
- Budgetary and financial impact is quite important. These estimates should include
  - Pharmacy costs and medical cost offsets

US Private Sector Guidelines—Academy of Managed Care Pharmacy (AMCP)



Academy of Managed Care Pharmacy (AMCP) Policy on Economic Data for Formulary Decision Making

The AMCP guidelines provide a standardized template for a broad unsolicited request for all product-related information, some of which are not currently available to health plans.


Clinical Studies
Safety
Efficacy
Effectiveness
Disease and Product Description
Plan Data
Economic Modeling
Overall Product Cost and Value
Submission Document
Published Economic Evaluations
Resource Utilization
Costs
Reporting Potential for Bias
AMCP Dossier Components

Health Reform and CER: Patient-Centered Outcomes Research Institute (PCORI)

Responsibilities:

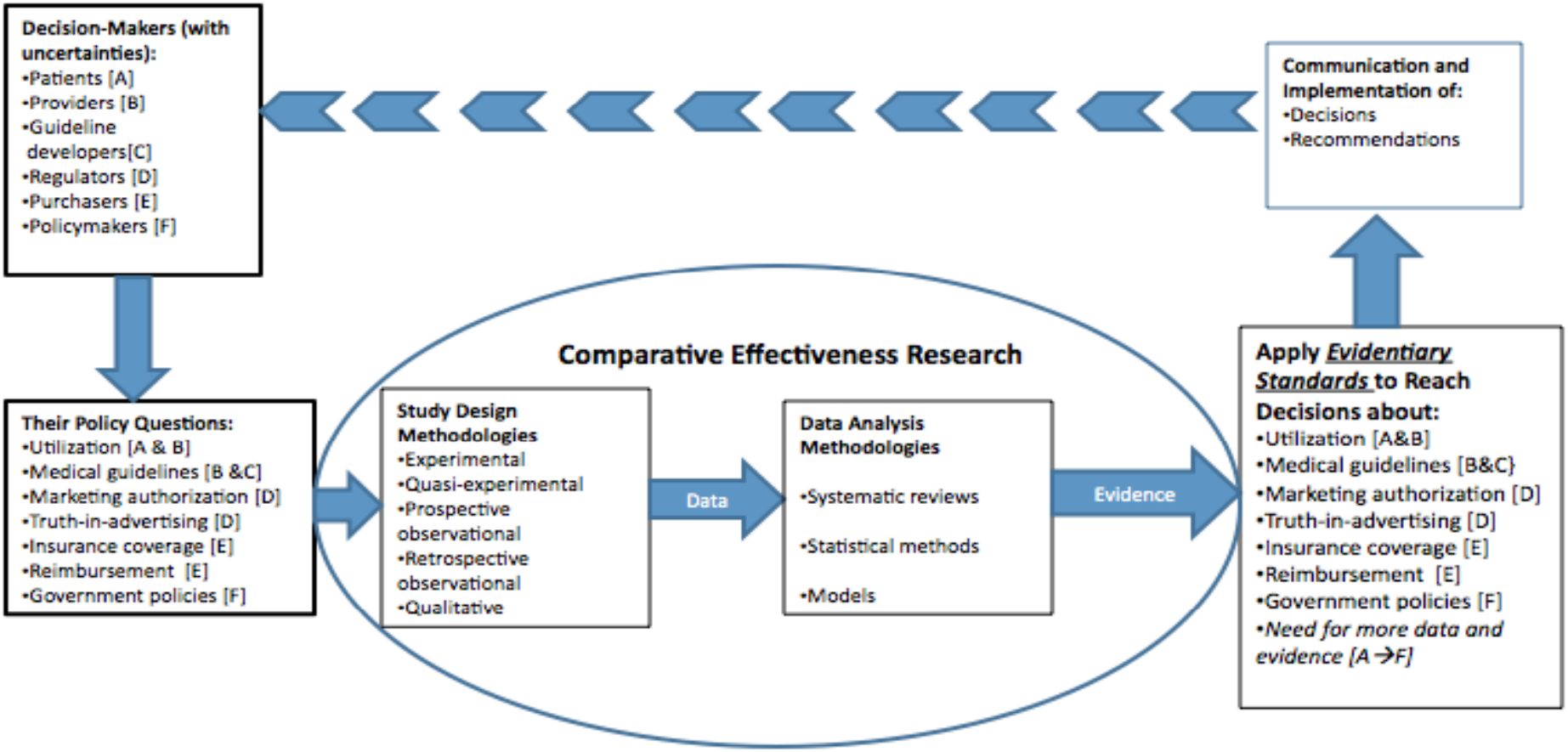
- Setting priorities
- Developing methodological standards
- Communicating research results to decision makers

- **Not allowed to consider cost-effectiveness!**

What is Comparative Effectiveness Research (CER)?

- Compares two or more alternative interventions
- Focuses on effectiveness, or real-world outcomes, as opposed to efficacy, or experimental outcomes
- Aims to provide information to a wide range of decision-makers, including patients, providers, and policy makers.

Comparative Effectiveness Research in the Decision Maker-Evidence-Policy Loop



Question:
The US Pharmacoeconomics Puzzle

- The US has many skilled professionals in pharmacoeconomics, years of production on Health Economics (HE), and the financial resources needed for establishing an HTA. However, the use of HE by payers for decision making is low.
- What are the reasons for this?
- What are the future consequences?

One View: "Economic Evaluation in the U.S.: What is the Missing Link?" (Neumann and Sullivan, ViH, 2006)

- American healthcare is decentralized in organization and financing.
- Value is of concern to decision-makers, but it's use is not explicit.
- Debates focus on the needs for comparative evidence and cost-sharing.
- Economic evidence of value may influence practice guidelines.
- Dramatic shift toward use of CEA "seems unlikely."
- Change is likely to be incremental and use will remain indirect—unless there is a major political shift.

An Incentives Interpretation

The U.S. reality is not surprising given the incentives:

1. The primacy of employer-based insurance which receives a tax-subsidy:

   →Patients are not very price-sensitive in their insurance (i.e., coverage) choices. (A kind of aggregate moral hazard.)

   →Inequitable.

   →Drives the standard of care in system.

2. Elderly are "grandfathered" into the system.

3. Care is rationed to the uninsured, who can usually obtain access the system through the emergency room.

   →They are delayed in their receipt of the standard of care.

Implications of U.S. incentives (1)

- Incentive is to use care as long as
  Marginal Health Benefit > 0.
  →"Flat-of-the-curve" medicine

Payers have limited incentive to make hard choices: they want to keep physicians and patients happy.

Implications of U.S. incentives (2)

- Rationing will remain implicit.
  → Worse outcomes for those with access problems

→ **CEA will play only a very limited role—indirectly in practice guidelines.**

→ Scientific standards calling for CEA from a "societal perspective" can create a norm or standard that influences decision-makers.

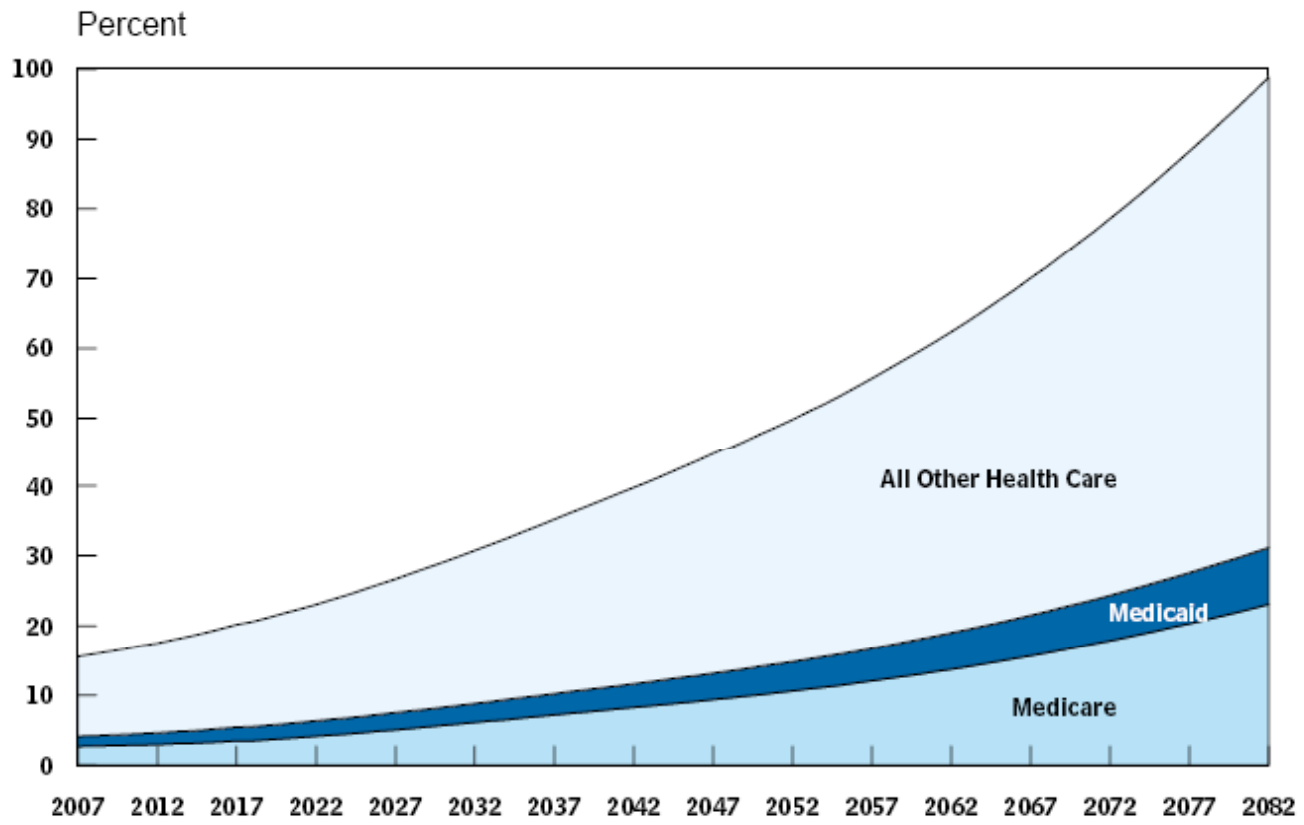
→ Spending will continue to increase, with growing uninsured population.

Modest (to date) HTA Reforms/Developments in the US

- Coordination of evidence development advice to manufacturers between FDA/CMS
  - Early engagement by mfrs (Novartis)
- BCBSA initiative to coordinate the HTA assessment function of member plans
- CER: Broader role of government in generating comparative evidence of technologies
- State heath care authorities establishing robust processes for HTA – Washington State

Things must change!

Spending on Health Care as a Percentage of Gross Domestic Product Under an Assumption That Excess Cost Growth Continues at Historical Averages



Source: CBO, Nov. 2007

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Health Canada:
Canadian Food and Drug Administration

Health Canada Santé Canada

Canada

Health Canada
www.hc-sc.gc.ca

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Drugs and Health Products

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Pharmaceutical Submission and Application Review

Pharmaceutical Submission and Application Review Fees as of April 1, 2011

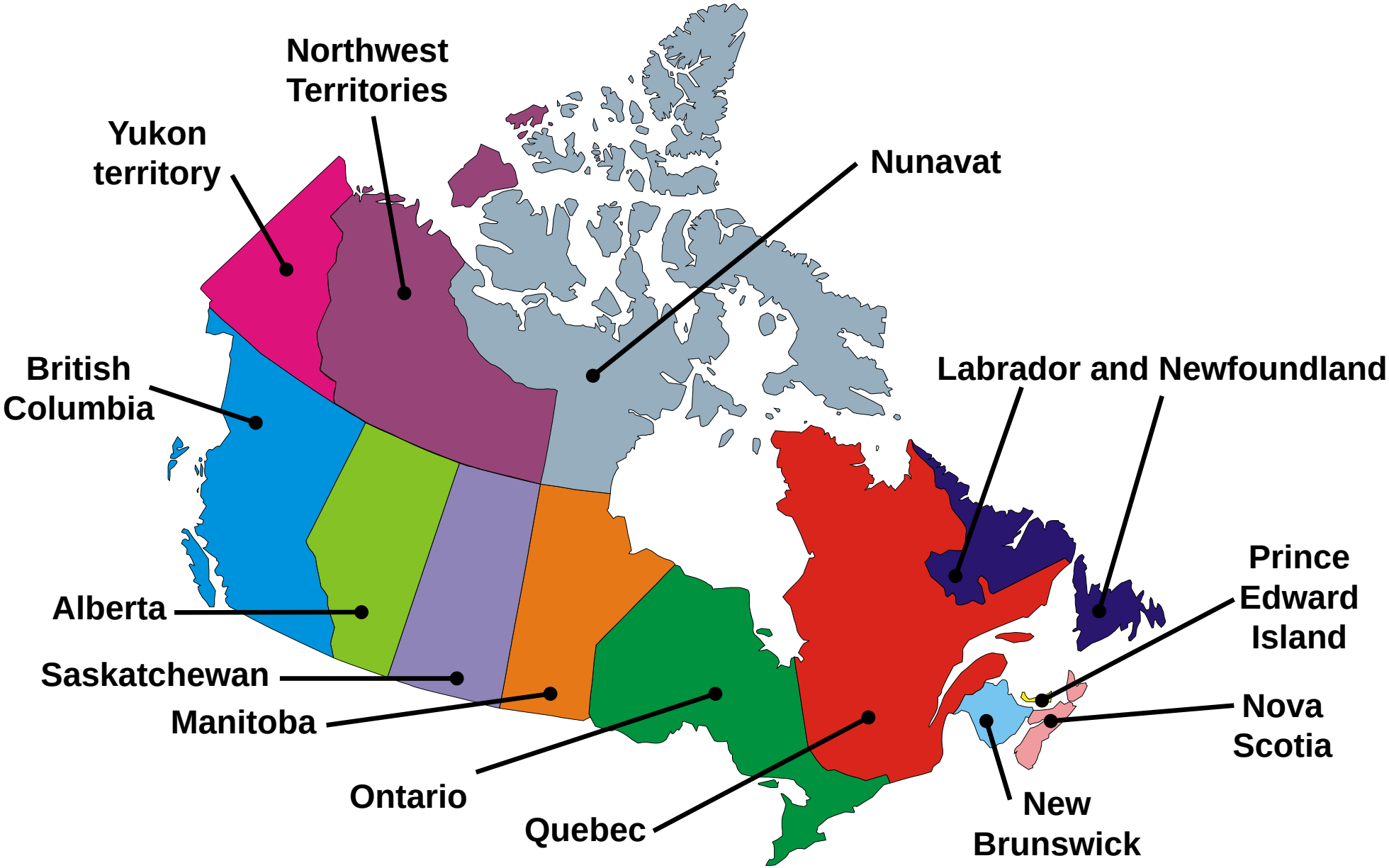
Fee Category	Description	Fee
New Active Substance	Submissions in support of a drug , excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug in Canada and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate, or polymorph.	$303,480

Health Technology Assessment: Canada

Mike Tierney (CADTH) presentation on May 4, 2008 at the PhRMA-ISPOR Symposium, entitled “Evolving Evidence Requirements from a payer’s perspective: Canada”

http://cadth.ca/index.php/en/home

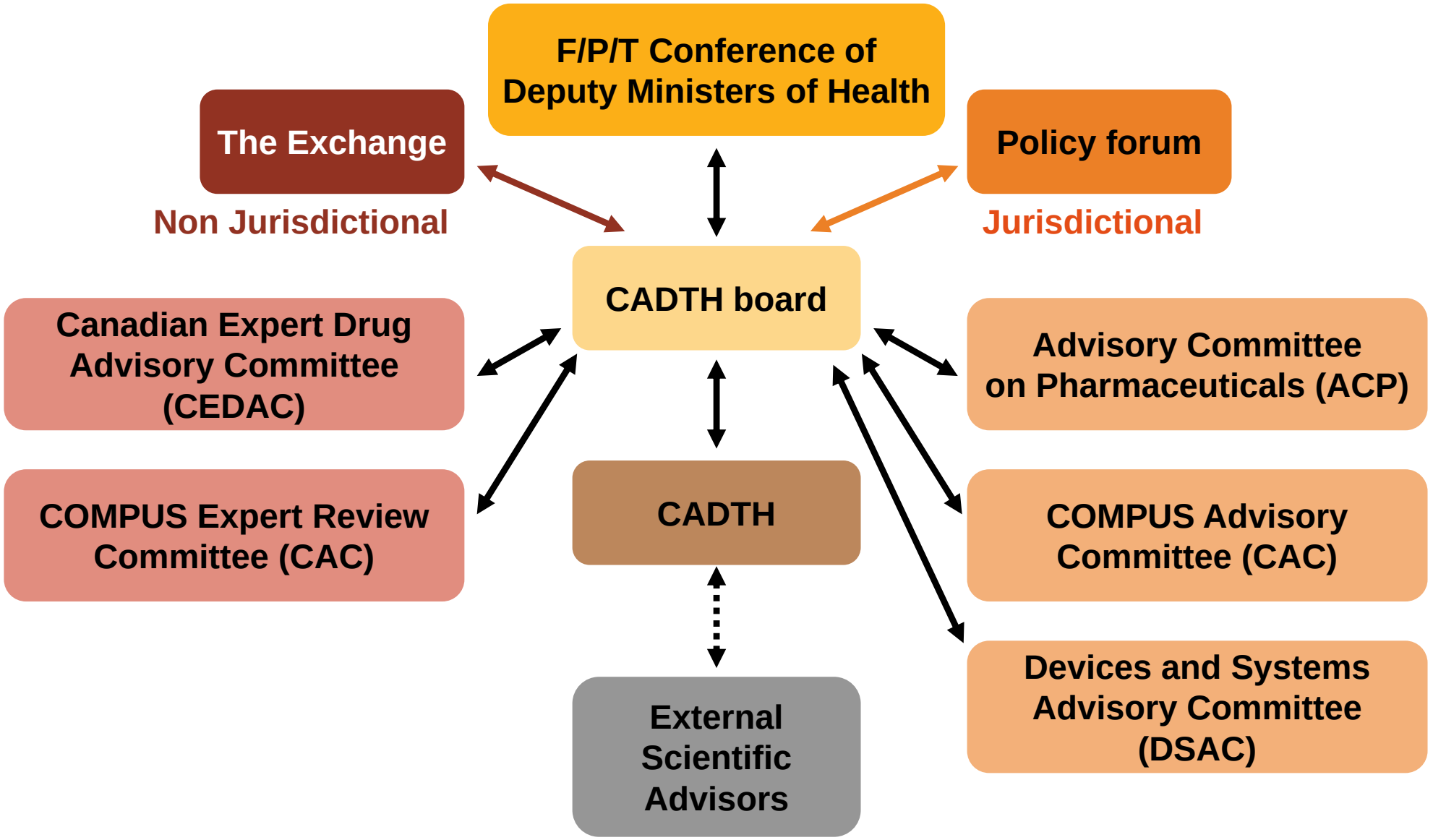
Canadian healthcare – 18 health plan system



Canadian Agency for Drugs and Technologies in Health (CADTH)

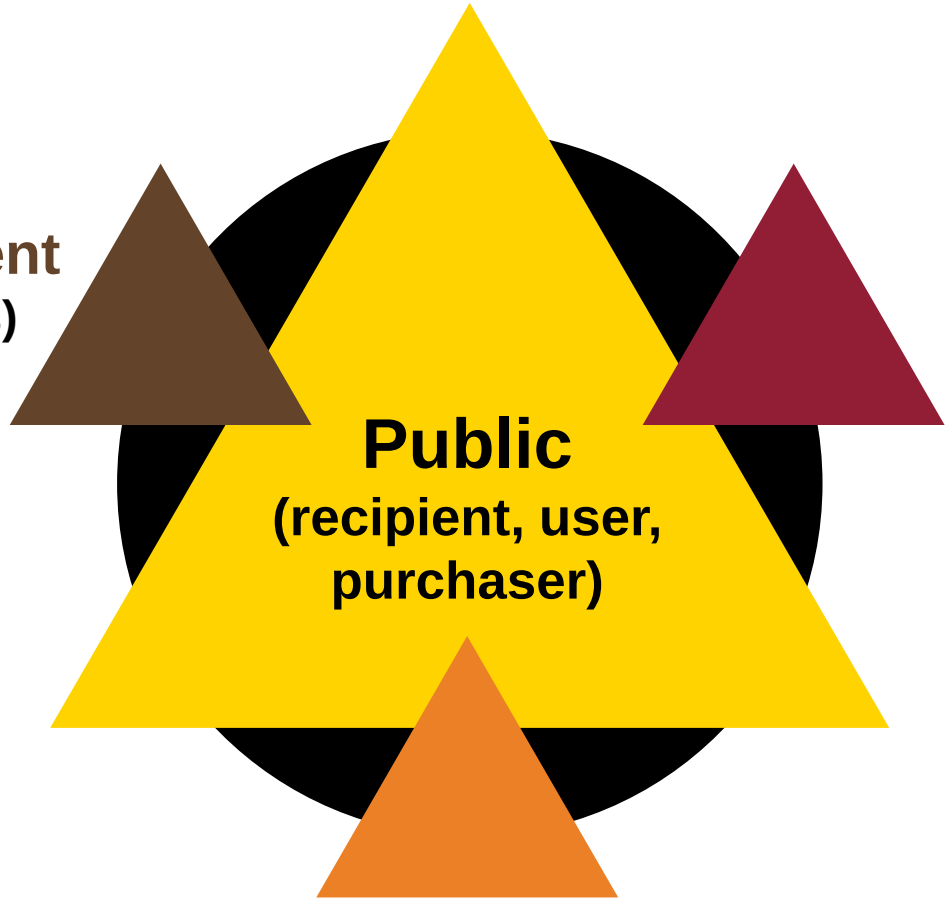
- **Independent, incorporated, not-for-profit agency**
- **Founded in 1989**
- **Funded by the Canadian federal, provincial, and territorial (F/P/T) governments**
  - ***"We need a more coordinated approach across the country to ensure that all Canadians are benefiting from the advances being made in health technology"*** **(Perrin Beatty, Minister of National Health and Welfare, 1989)**

CADTH Governance Committee Structure



Principal stakeholders in health technology management

Federal Government
(regulators)



Provinces/territories
(responsible for health care system delivery)

Health authorities/hospitals
(delegated purchasing decisions)

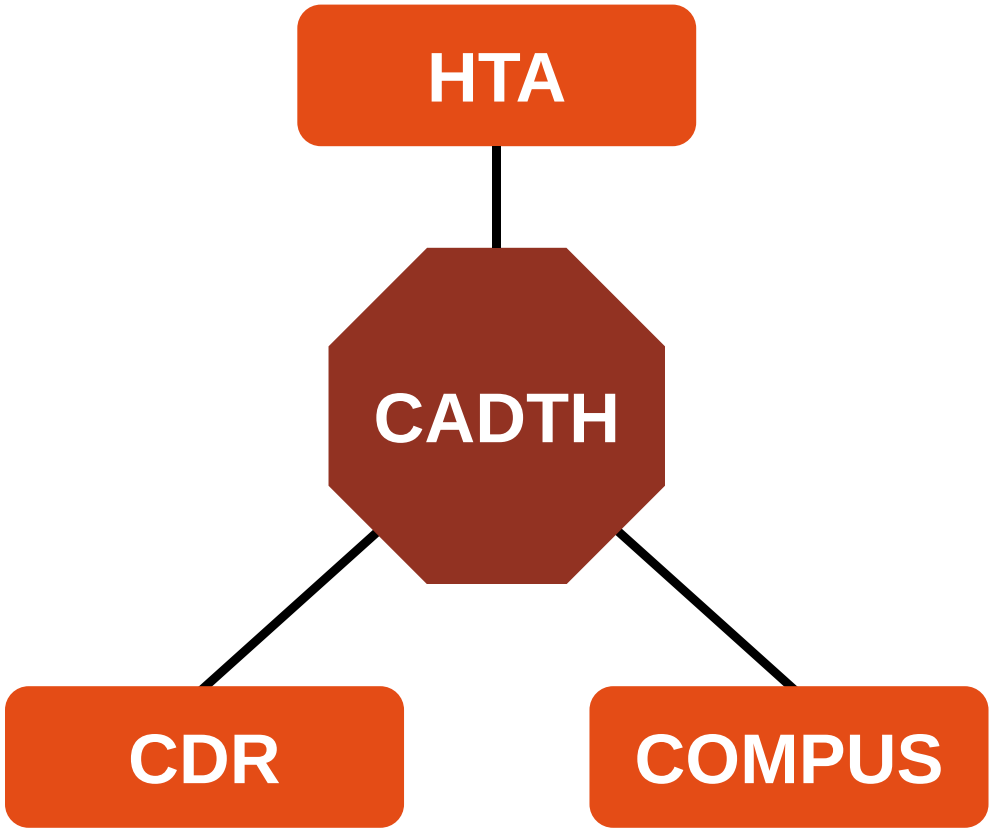
Health care professionals
(health care delivery)

Industry
(designer, tester, manufacturer, information provider)

How does CADTH meet these needs?

CADTH's three core programs

- **HTA (Health Technology Assessment)**
- **CDR (Common Drug Review)**
- **COMPUS (Canadian Optimal Medication Prescribing and Utilization Service)**



CADTH 's Common Drug Review (CDR)

- **A single process for**
  - **conducting objective, rigorous reviews of the clinical and economic evidence for drugs**
  - **providing formulary listing recommendations to the publicly funded drug plans in Canada (except Quebec)**
- **Formulary decisions are made by the drugs plans**
  - **based on CDR recommendation, and plan mandates, priorities and resources**
- **Objectives**
  - **reduce duplication, maximize use of limited resource and expertise, provide equal access to evidence and advise**

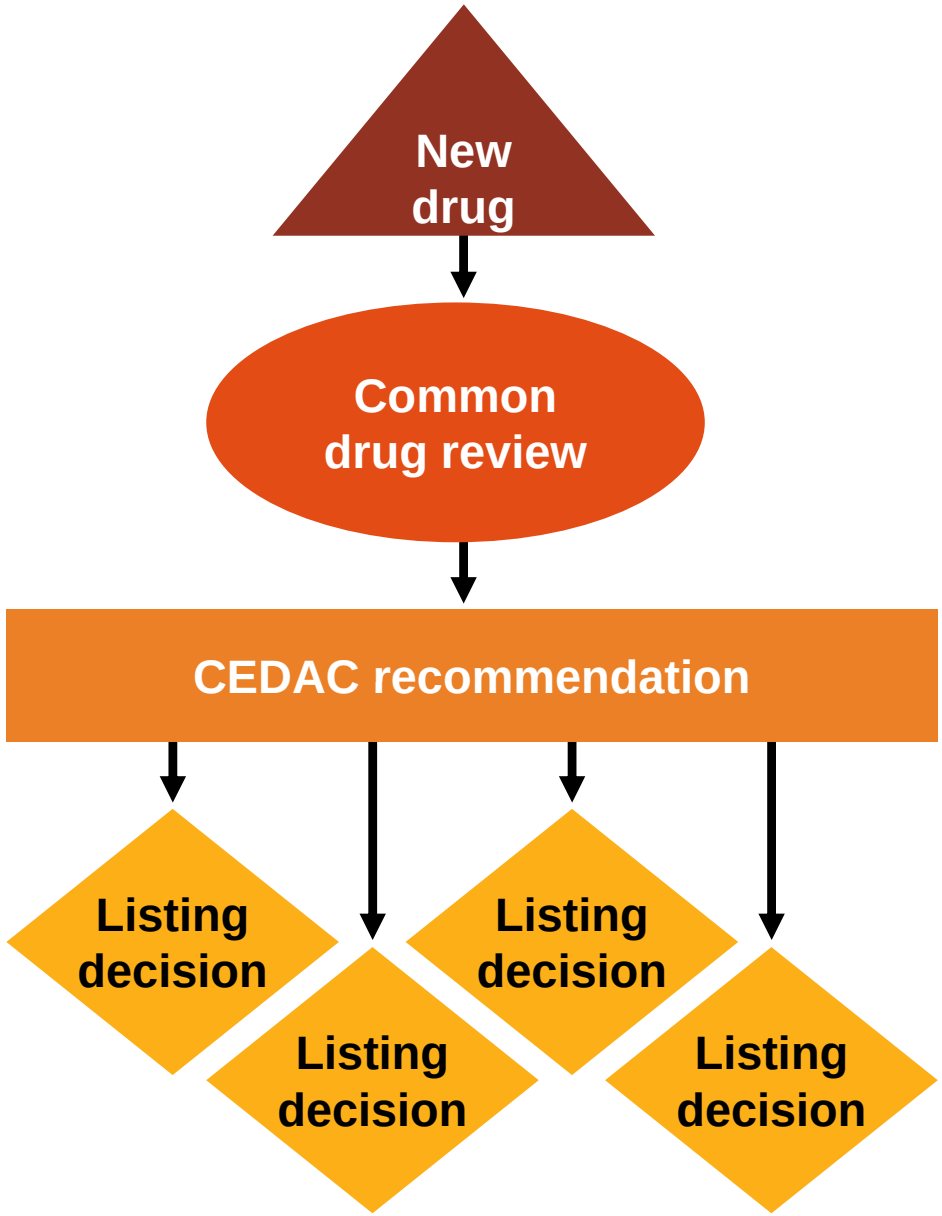
Drug assessment – CDR's role

FEDERAL GOVERNMENT
Approval of new drugs for sale in Canada

CADTH's CDR Program
Evidence-based reviews
Common listing recommendations (CEDTH)

F/P/T DRUG PLANS
Listing/coverage decisions

Common Drug Review (CDR)

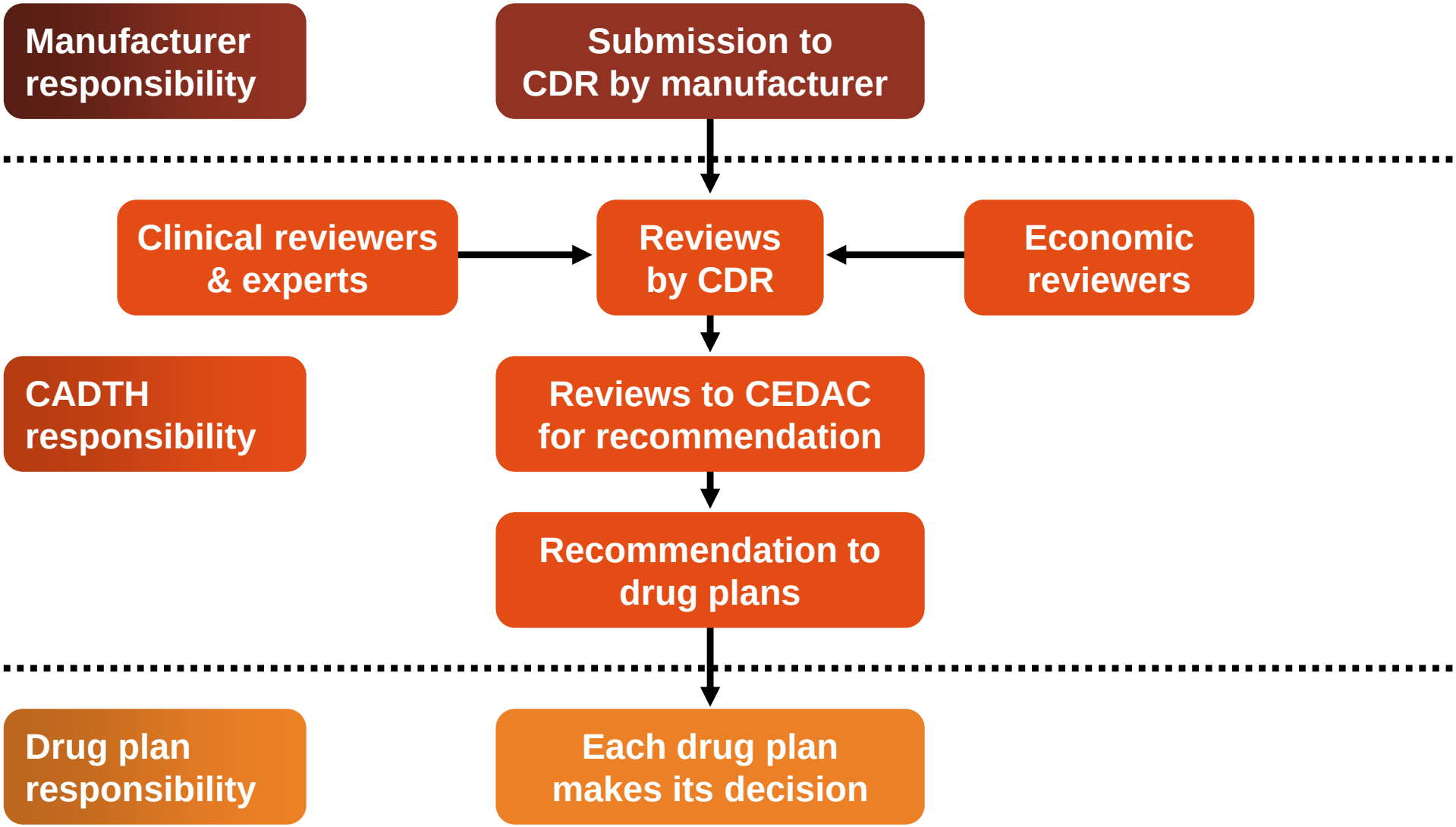


Responsibility

CADTH

Drug plans

CDR process


Manufacturer responsibility
Submission to CDR by manufacturer
Clinical reviewers & experts
Reviews by CDR
Economic reviewers
CADTH responsibility
Reviews to CEDAC for recommendation
Recommendation to drug plans
Drug plan responsibility
Each drug plan makes its decision

CDR reviews

- **Review team**
  - **includes internal and external clinical reviewers, health economics, clinical experts, librarian, review manager**
- **Clinical review**
  - **systematic review of published and unpublished trials**
  - **also includes:**
    - **supplemental issues, background on condition**
- **Pharmacoeconomic review**
  - **critique of manufacturer's economic evaluation**

CDR timelines

- **Total process takes 20–26 weeks from submission to CEDAC recommendation**
  - **1 week to review submission**
  - **9 weeks to prepare reviews**
  - **3 weeks for manufacturer's comments and CDR response**
  - **3–8 weeks to schedule for CEDAC**
  - **1 week to prepare recommendation**
  - **2 weeks when recommendation is embargoed**
  - **1 week to issue final recommendation**

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Essential Elements of a Technology and Outcomes Assessment Initiative (Emanuel, Fuchs, Garber, JAMA, 2007)

1. administrative independence
2. dedicated funding
3. production of objective and timely research
4. use of reliable methods
5. widespread dissemination
6. a governance and organizational structure that lend it legitimacy.

International Journal of Technology Assessment in Health Care, 24:3 (2008), 244–258.

doi:10.1017/S0266462308080343

Key principles for the improved conduct of health technology assessments for resource allocation decisions

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Stockholm School of Economics

Bryan R. Luce
United BioSource Corporation

Peter J. Neumann
Tufts University

Uwe Siebert
University of Health Sciences

Sean D. Sullivan
University of Washington

One Schema for Thinking About EBM, CER, and HTA

Drummond et al.

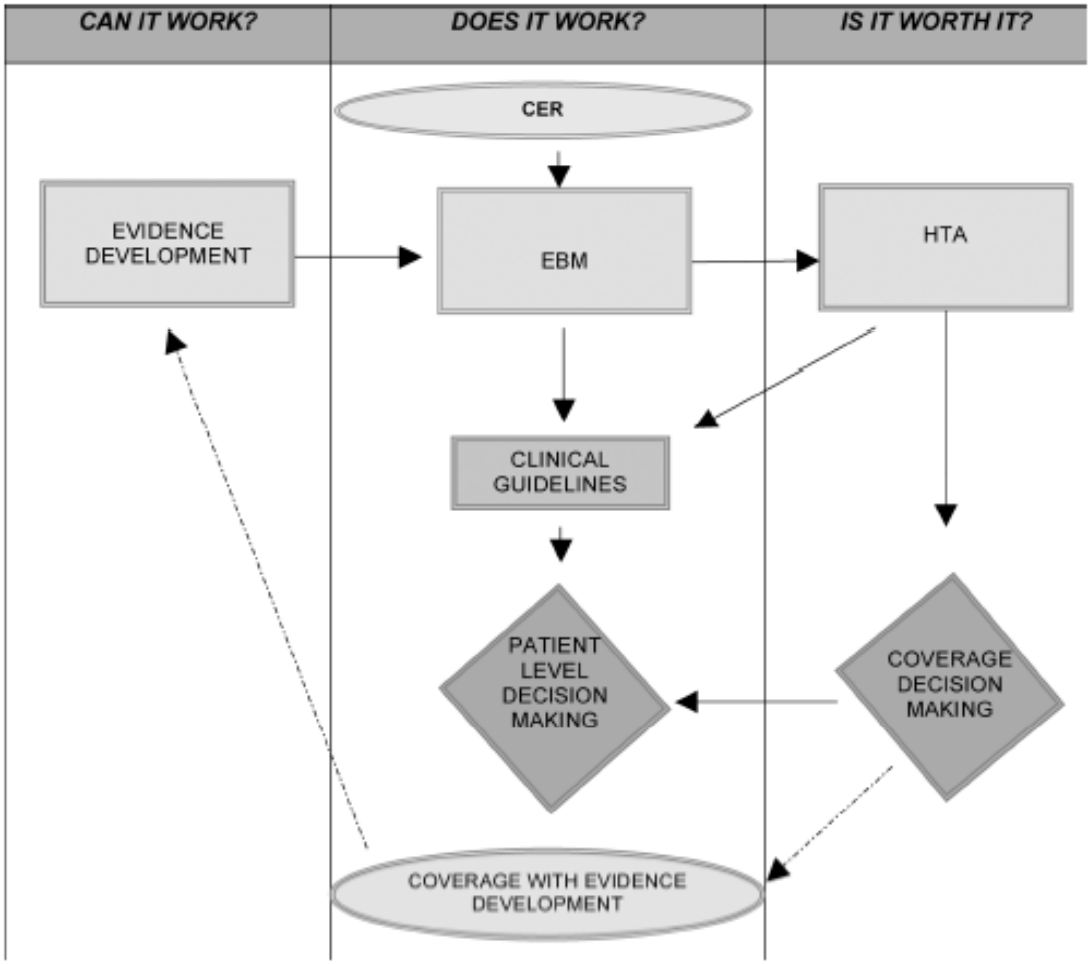

Figure 1. Relationship between EBM, CER, HTA, and related concepts. EBM, evidence-based medicine; CER, comparative effectiveness research; HTA, health technology assessment.

15 Principles of HTA —Drummond et al. 2008

1: The Goal and Scope of the HTA Should Be Explicit and Relevant to Its Use

2: HTA Should Be an Unbiased and Transparent Exercise

3: HTA Should Include All Relevant Technologies

4: A Clear System for Setting Priorities for HTA Should Exist

5: HTA Should Incorporate Appropriate Methods for Assessing Costs and Benefits

6: HTAs Should Consider a Wide Range of Evidence and Outcomes

7: A Full Societal Perspective Should Be Considered When Undertaking HTAs

8: HTAs Should Explicitly Characterize Uncertainty Surrounding Estimates

15 Principles of HTA —Drummond et al. 2008

9: HTAs Should Consider and Address Issues of Generalizability and Transferability

10: Those Conducting HTAs Should Actively Engage All Key Stakeholder Groups

11: Those Undertaking HTAs Should Actively Seek All Available Data

12: The Implementation of HTA Findings Needs to Be Monitored

13: HTA Should Be Timely

14: HTA Findings Need to Be Communicated Appropriately to Different Decision Makers

15: The Link Between HTA Findings and Decision-Making Processes Needs to Be Transparent and Clearly Defined

Key Points from Industry Principles: Combined from PhRMA, EFPIA, and IFPMA Principles for Good Practice in HTA

- HTA should not just be applied to medicines but to all health technologies and interventions. It should be undertaken as part of a broad agenda to improve health care quality and efficiency, rather than used as a cost containment tool. Likewise "silo budgeting," where medicines are put into a separate cost bucket, runs counter to optimising health gains across the system;
- A broad perspective of value should be used including the impact on productivity, and on caregivers and personal time, and societal health priorities, for example in terms of disease burden, should be recognised.
- HTA when applied to determine access to or reimbursement for pharmaceuticals should be kept separate from marketing authorisation.
- HTA should be inclusive, open, transparent and balanced, involving external experts and all stakeholders. It should include rights of appeal. The evaluating body should be independent of the payer.
- Payers should commit to rewarding value. Positive HTA appraisals should attract the budgetary resources necessary to fund use.
- Appraisals should recognise that value emerges through use and additional evidence over the product life cycle and recognise the need to include new data. To this same point, uncertainty around cost-effectiveness has to be dealt with in a flexible way, including the use of in-market data collection, which requires putting in place the necessary infrastructure. A full range of types of evidence including observational data can play an important role. It is important that patients get speedy access to new technologies.
- Patient preferences and needs matter in any choice of medicine. HTA guidance should give clinicians enough freedom to address individual clinical situations. In this context,the incremental nature of innovation should be recognised as should the importance of having multiple treatment options.

Agenda

- Introduction to Health Technology Assessment (HTA)
- HTA in the U.S. Health Care System
- HTA in Canadian Health Care System
- Principles of HTA
- **Study of HTA in Emerging Markets**

The Evolution of HTA in Emerging Market Health Care Systems

A Study by the Office of Health Economics, London and VeriTech/University of Washington, Seattle

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Research OHE Consulting
Office of Health Economics

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- Local researchers Michael Qin, Vanessa Teich, and Ivy Tsai have undertaken research and interviews in China, Brazil, and Taiwan respectively
- OHE / VeriTech would like to thank Stephanie Lane of PhRMA who has been the main industry point of contact for this work and her industry colleagues on the Project Steering Group

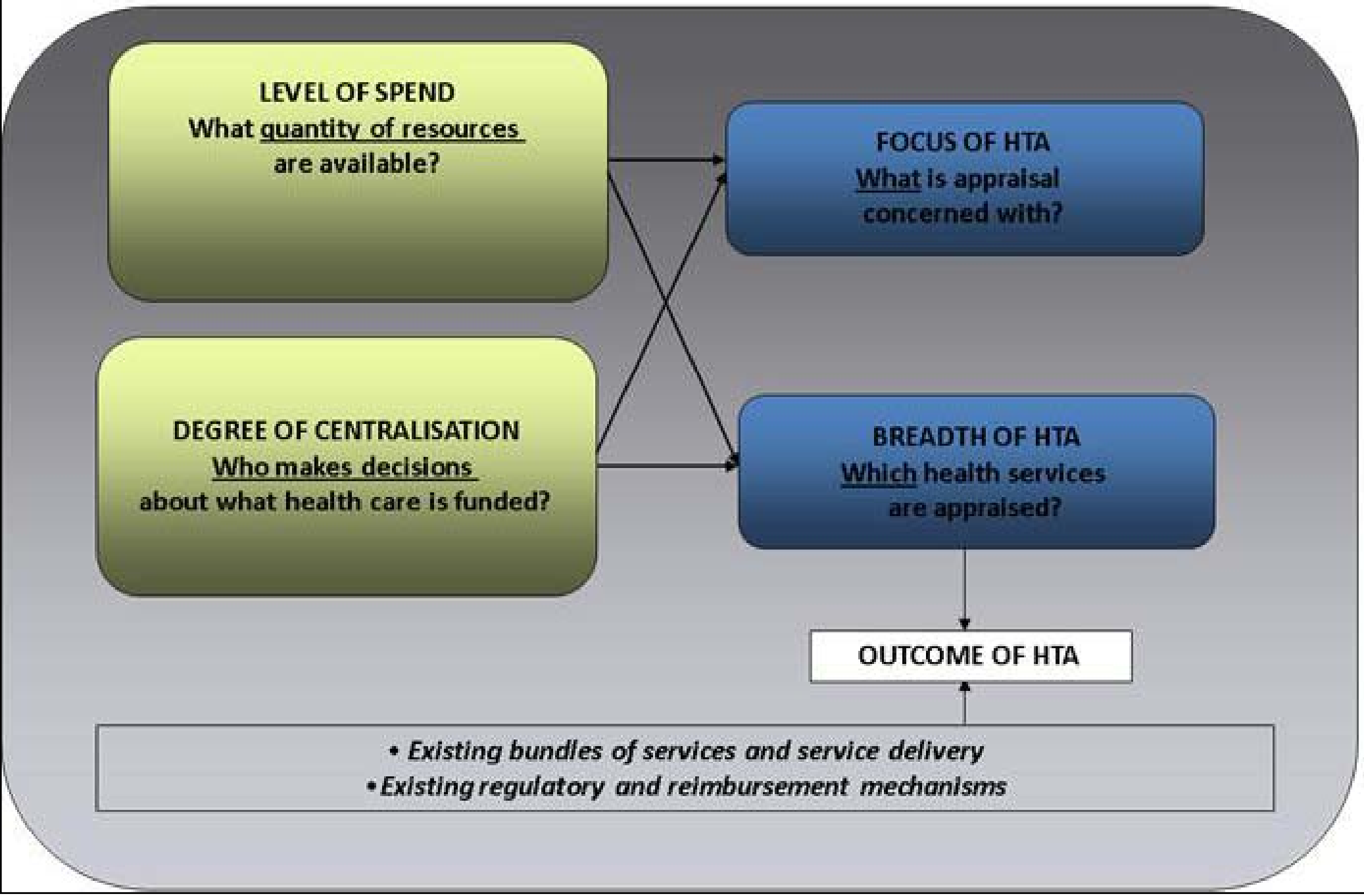
The Objectives of the Study

- To develop a categorisation of health care systems (HCS) which can be accepted by key institutions and experts in the field (WHO, World Bank and academia);
- To develop a categorisation of types of HTA using definitions recognised by practitioners in the field. Inevitably these are based on the experiences of high income countries, but can be expressed in a form that can fit into policy development in relation to the current and future healthcare systems of low and middle income countries.
- To combine these two strands (HCS and HTA) to examine the role for HTA in a health care system dependent on development stage and structure of that health care system;
- To set out these findings in a way that is helpful to understanding the potential role of HTA processes in three markets – Brazil, China and Taiwan

What exactly is HTA?

- EUnetHTA (2008) report:
  - a health technology is ‘any [health] intervention that may be used to promote health, prevent, diagnose or treat disease, or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures *and organizational systems* used in health care’
- We can categorise HTA into three types:
  - **“micro-level” HTA** aimed at appraisal of individual technologies, or groups of related technologies
  - **“micro-level” HTA** aimed at developing clinical practice guidelines or the way in which individual technologies are combined within a delivery system to manage patients efficiently
  - **“macro-level” HTA** which is about the efficiency of the organizational systems or architecture of the health care system

The conceptual model



Health care system typology: two key attributes/variables and levels

LEVEL OF SPEND

What quantity of resources are available?

- Low spend per capita
- Medium spend per capita
- High spend per capita

DEGREE OF CENTRALISATION

Who makes decisions about what health care is funded?

- Out of pocket spend dominates
- Emergence of insurance /collective funding; decisions localised
- Active third party purchasing

Degree of Centralisation

- The extent to which there is third party coverage and so an interest in the use of both “micro” and “macro” technologies that goes beyond the provider-patient relationship that dominates an out-of-pocket spend environment.
- The extent to which there is active rather than passive purchasing by the third party insurer. Related to this is the degree of national level regulation as to what is included in the insurance package offered to enrollees.

HTA typology: key HTA system attributes/variables and levels

FOCUS OF HTA

What is appraisal concerned with?

- **Efficacy/safety**
- **Relative effectiveness**
- **Cost-effectiveness (C-E)**
- **C-E and broader issues**

BREADTH OF HTA

Which health services appraised?

- **Basic preventative services and minimum care packages**
- **New technologies**
- **All technologies/services**

Observations (i)

- *Observation 1: Incomes are growing in emerging markets, but resulting increases in funding for health care are likely to be out-paced by rising demands and expectations. In such situations, HTA may have a role in assisting the health care system to reconcile rapidly expanding demand with more slowly expanding resources. HTA can provide a potential means of handling this in a more explicit and transparent way, and in promoting public debate about priorities.*

Observations (ii)

- *Observation 2: HTA of individual technologies is not a substitute for the reform of health care systems. Where health care systems create obviously bad incentives, this type of micro-HTA is unlikely to compensate for these failings.*
  - HTA should not be approached out of context. HTA should be tied, in a case-by-case way, to what else is going on in the health care system.
- *Observation 3: 'One size fits all' HTA processes and methods are unlikely to be appropriate for emerging markets. There needs to be clarity over the purpose of HTA – and the methods and processes which are adopted need to be fit for purpose.*
  - HTA is not an objective 'tool kit' that is transferable to any setting.
  - "Value" of new drugs varies, and is subjective and based on local preferences and other values.
  - Real value depends in a "second-best" world on the match between costs and the value of all other inputs (hospitals, physician, nurses, equipment, etc.).

Observations (iii)

- *Observation 4: HTA and pricing regulations work hand in hand: the approach to HTA should be appropriate to, and work sensibly in combination with, the particular approach to pricing technologies.*
  - For example, HTA based on reimbursement levels ignores what providers actually have to pay for new drugs. This would tend to under-estimate real-world cost-effectiveness
- *Observation 5: There is no single prescription for HTA methods and processes which will be welfare-increasing in all contexts.*
  - Further, trade-offs between competing objectives are likely if not inevitable; and health care systems may differ in the relative value placed on them, for example, the achievement of equity goals; technical efficiency; cost containment; and patient choice. Every health care system is on a slightly different trajectory: as it develops, and as spending increases, the way that HTA evolves will be a reaction to the possibilities and pressures that new technologies present.
  - The key message is that the relevance and positioning of any role for HTA in a health care system depends on the development stage and structure of that health care system.

HTA and International Reference Pricing (IRP)

- Compliance with good (micro) HTA principles is resource-intensive for governments (and industry.) Countries may "free ride" and some evidence does cross boundaries. However, other evidence does not.
- Alternative "low resource" options such as IRP may be *less* efficient when reference countries have different income levels and willingness to pay for health gain
- Therapeutic RP is also "low resource" as it assumes treatments are the same, rather than looking at evidence
- Efficient local (micro) HTA may be more efficient than IRP and TRP if it respects good HTA principles, and reflects local willingness to pay for health gain.

Final Observation

- The impact of HTA and cost-effectiveness information on health system resource allocation depends on:
  - **Incentives** to use the information
  - Insulation from **political influence**

    (--or at least a fair and workable system of checks and balances.)

Final question for discussion:
What would be "efficient" HTA in Taiwan? From a Taiwanese perspective--Short-term (static) vs. long-term (dynamic)?

Thank you!

Questions?

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