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# Post Marketing Studies

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# Healthcare System

- Set of activities aimed at promoting, restoring or maintaining health

www.who.int/en/

# Aims of a Healthcare System

- **Improve health** of the target population
- **Meet the expectations** of society providing high quality and effective services, socially and financially acceptable
- **Provide financial protection on costs** in sickness and health

# Healthcare System Aims

## CLINICAL OUTCOMES

Technical Dimension (Safety, Effectiveness, Efficiency, Utility)

Impact on the Health System (organization, economic)

Ethics and Social Acceptance

**VALUE**

**COST**

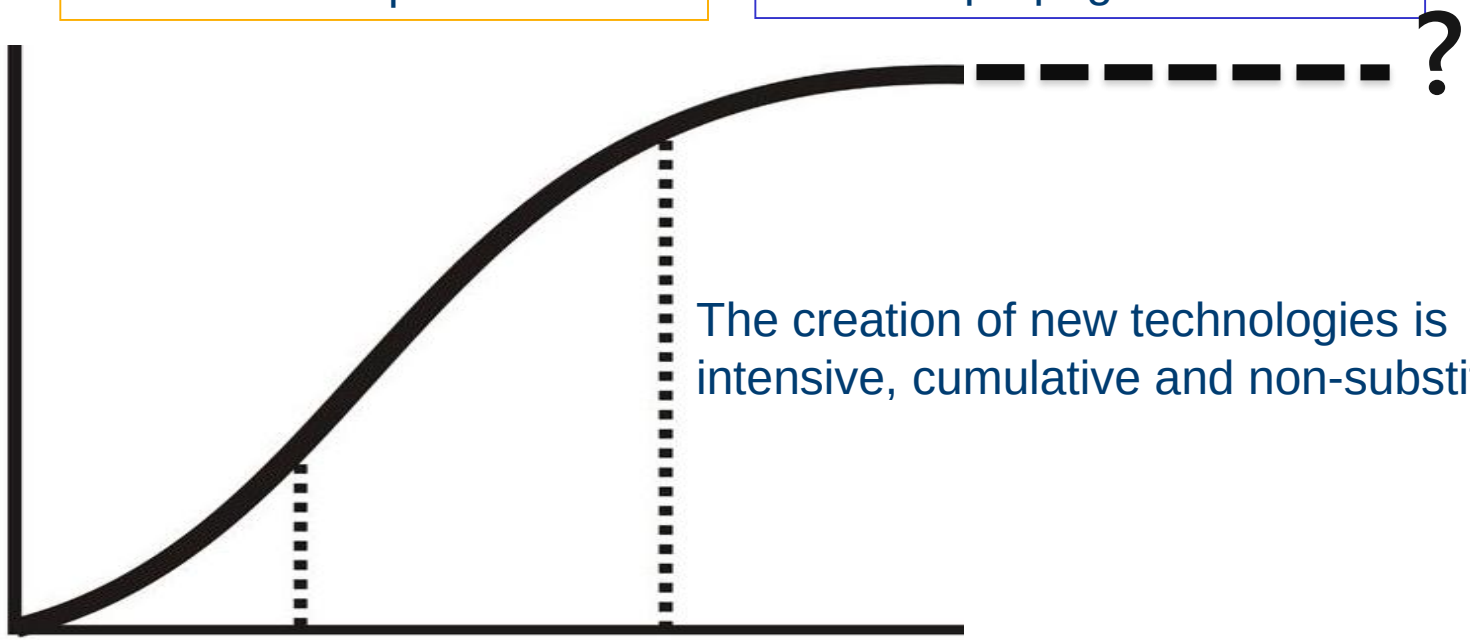
# Healthcare Technology

- Intervention tools including instruments, equipment, drugs, procedures, installations, financing systems, infrastructure and processes applied in diagnosis, treatment or rehabilitation of human health, or that affect access to health services

# Healthcare Product Life Cycle

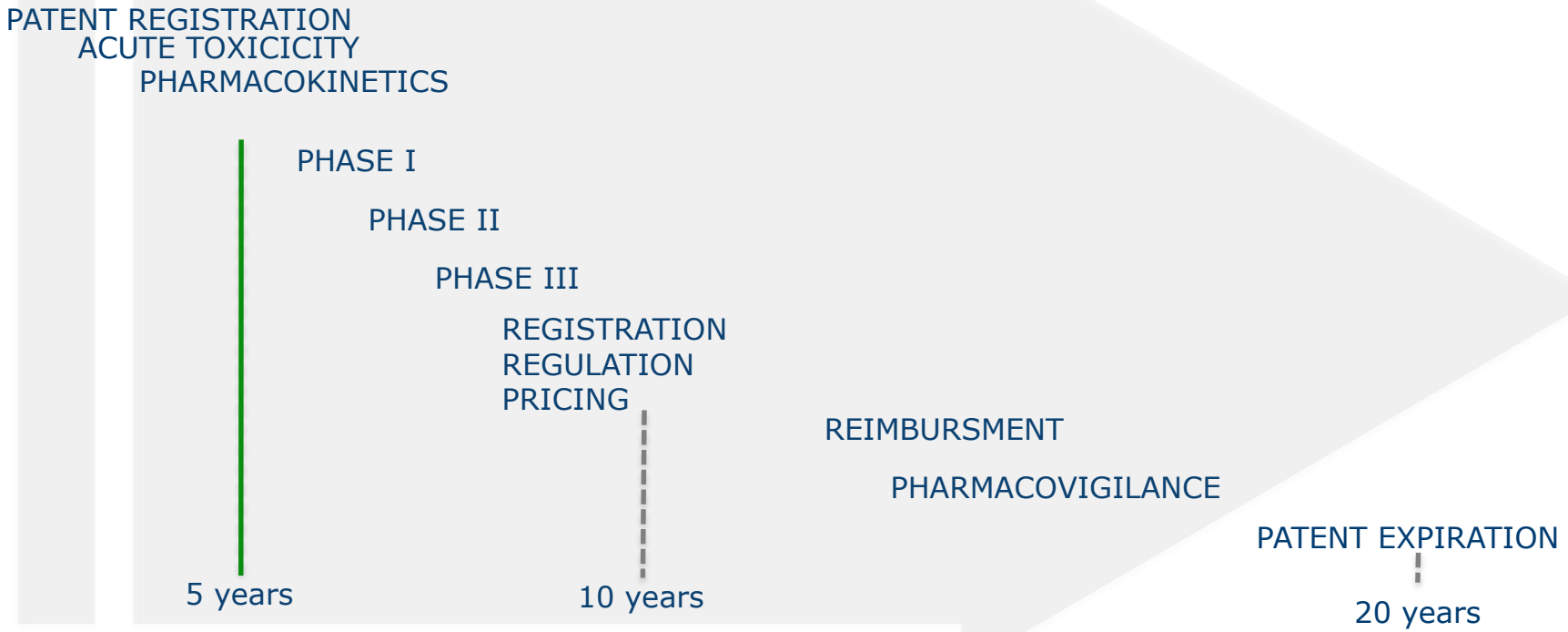
**INOVATION**
development

**ADOPTION**
propagation




The creation of new technologies is intensive, cumulative and non-substitutive.

# New Molecules Development



# Health Technology Incorporation “as it used to be”

- Technological standards ≠ clinical results.
- Technologies proven without effect (or deleterious) x other effective.
- ´Off label` technologies.
- Rapid assimilation, without rigorous evaluation of efficacy, side effects, costs and financial results.
- Supply-induced demand (if available, tends to be used).
- Lack of objective and structured information on new technologies

# Health Technology Incorporation

COMMERCIAL PRESSURE

UNQUALIFIED TECHNOLOGY

**Enthusiasm Convictions**

FORMAL HTA

**USEFUL**

USELESS

**TECHNOLOGICAL INCORPORATION**

“Technical information needed by policy-makers is frequently not available, or not in the right form. (…) Technology assessment identifies policy issues, assesses the impact of alternative sources of action and presents findings.”

*U.S. Congress, 1967*

# HTA development

- XVIII: Development based on disease mechanisms
- 1902: Netherlands initiative
- 1960: Archie Cochrane, multidisciplinary approach, focus on clinical efficacy.
- 1972: Office of Technology Assessment-USA
- 80`s: Increasing costs due to new technologies. HTA organizations in Canada, France, Sweden and USA. Cochrane collaboration

# HTA – INAHTA 2000

- Research-based multidisciplinary analysis that studies **medical, social, ethical and economic** implications of development, dissemination and use of health technologies

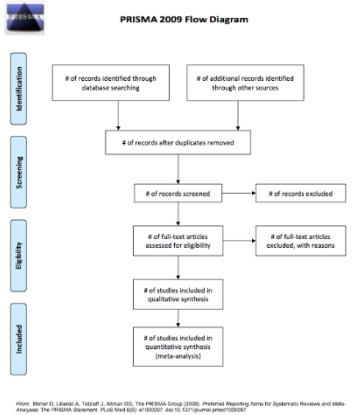
# Systematic Review

- "Prepared under systematic approach to literature, with documented methodology, which minimizes random and systematic errors" (Chalmers & Altman, 1995)

**Cochrane Collaboration**

**Campbell Collaboration**

**Centre for Reviews and Dissemination**



**“many key decision-makers, …, have neither the tools nor the stomach to apply cost-effectiveness analysis explicitly.”**

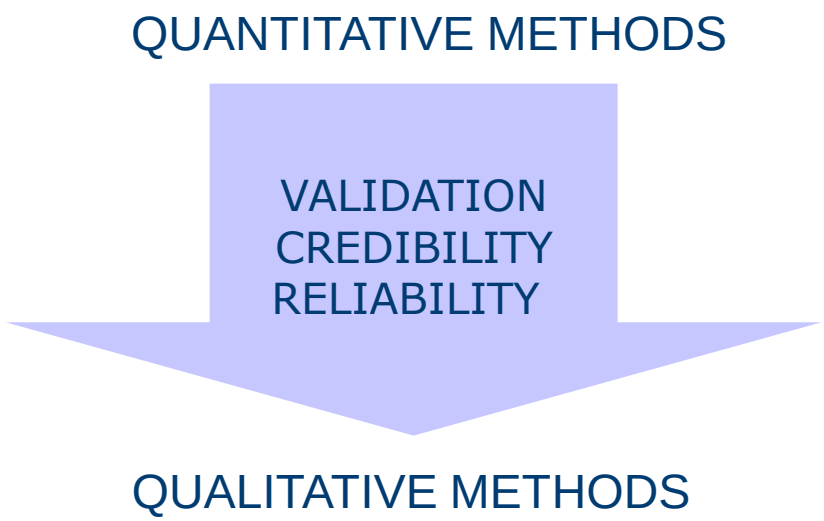
Stirling Bryan, MS, PhD *Director, Centre for Clinical Epidemiology & Evaluation Vancouver Coastal Health Research Institute and Stanford Health Policy Adjunct Associate*

# Health Technology Assessment

- Systematically and research-based approach
- There is no single methodology
- No action field delimitation

# Health Technology Assessment

- Natural Sciences
- Health Sciences
- Social Sciences
- Human Sciences



# Some Remarkable Evidence-Based Decisions

DECISION IN COVERAGE
- Cochlear Implant Release (France, Quebec)
- Laser Myocardial Revascularization Rejection (Norway)

HIGH COST RESTRICTION
- β-interferon in multiple sclerosis (Denmark)
- Ventricular Assist Device (Quebec, Oregon)

CONTROL OF USE
- Routine PSA measures (France, Norway, Quebec)

PLANNING
- Hemodynamic Labs (Quebec)
- PET scan (Quebec)
- MRI (Austria)

ELIMINATION OF USELESS INTERVENTIONS
- Routine Pre-Op Thorax X ray (Sweden, Quebec)

# Phase IV Clinical Trial

- Monitor **effectiveness** and **side effects** associated with **widespread use** over a **long period of time,** related to a new treatment after it has been **approved and is on the market**. Also called post-marketing surveillance trial.

**National Institutes of Health**
**World Health Organization**

# Phase IV Monitored Trial: a moral imperative?

Support product success in a real-world clinical practice.

Main Aims:

- Demonstrate superiority versus **competitive** products
- Attain approval of **new indications** or label changes
- Establish safety and efficacy in **new patient populations** (special population, drug interaction, etc)
- Validate **new dosing or models of administration**
- Improve **physician education** regarding appropriate use
- Conduct **safety surveillance** for targeted endpoints
- To find **new markets** for competitive analysis on the drug or treatment

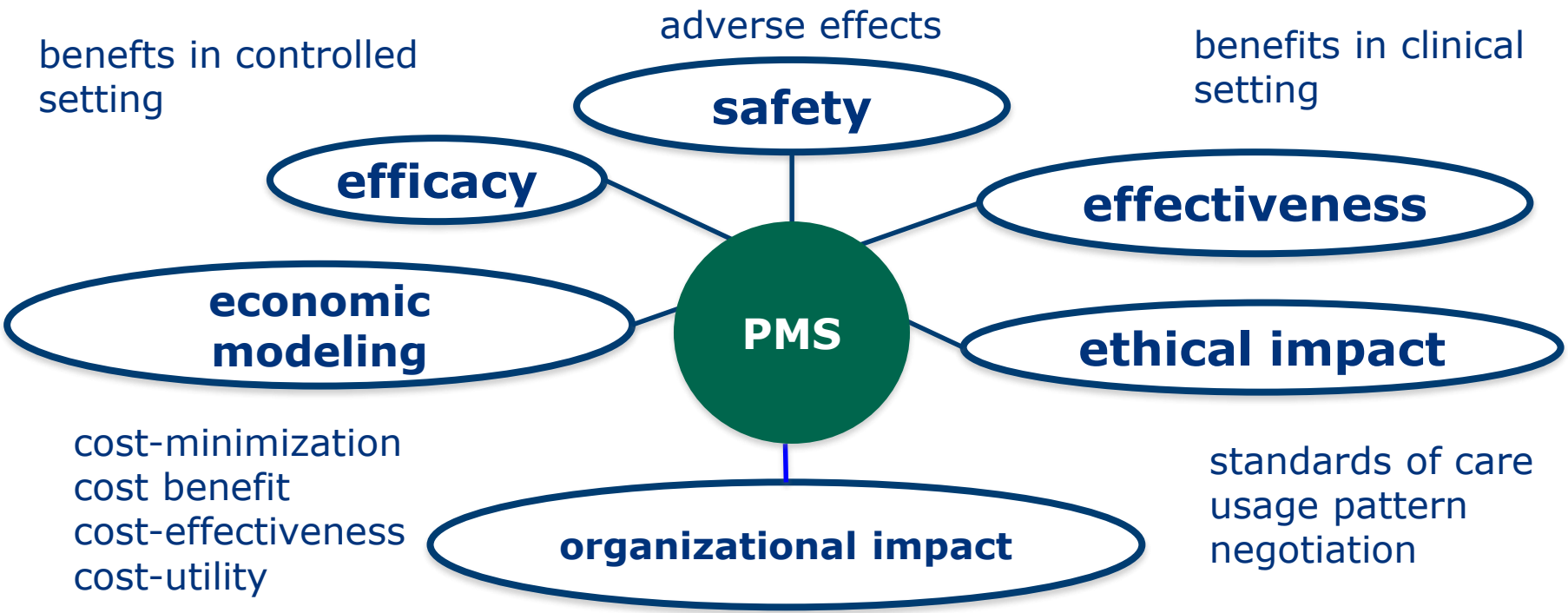
Ecancermedicalscience. 2012; 6: 276.26.

# Postmarketing studies

- Required of or agreed to by a sponsor that are conducted after FDA has approved a product for marketing.
- FDA uses postmarketing study commitments to gather additional information about a product's safety, efficacy, or optimal use.
- Agreements with sponsors can be reached either before or after FDA has granted approval to a sponsor to market a product.

www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/Phase4Trials

# Post Marketing Studies Range



# Postmarketing Surveillance

monitor drug and device safety, including:

- spontaneous reporting databases
- prescription event monitoring
- electronic health records
- patients registries
- record linkage between databases

DATA MINING

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm

# Post Marketing Host Platform Requirements

- Wide recruitment capacity
- Consistent methodology support
- Quick start-up
- Centralized patient management
- Analysis and reporting of clinical data
- Regulatory compliance
- Health economics and quality of care studies
- Structured reference platform

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# Clinical Pathway & Medical Consensus Group

# Clinical Consensus Solution

## Evidence based research team

i. Responsible for going through available clinical evidence for subject and come up with a clinical care proposal;

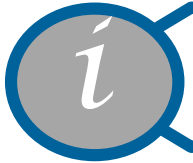
ii. Group of stakeholders and specialists will be brought together to pick apart proposal with the objective of reaching a consensus on the subject.

## Clinical Consensus implementation

i. Create a formal expectation of care quality and value generation, thus decreasing variability;

ii. The creation of policies, pathways, and checklists will utilize the consensus as their one and only source;

iii. Group will have a single language within through all business units.



## Provide best care knowledge

i. Patients, help lines, and physicians will have the optimal care information available.

# Efficiency Studies in the Real World:

# Clinical Pathway Creation Process


## I – Elegibility Criteria:

i. Clinical Relevance
ii. Healthcare Chain Impact
iii. Cost-effectiveness Improvement Opportunity
iv. Timming
v. Social Impact

## II – Development Group:

i. 2 EBCP consultants
ii. 2+ MCO Representatives
iii. 6+ Healthcare Network Representatives (AMS, Next, contracted)

## III – Impact Analisys

i. Patients
ii. Social/Legal
iii. MCO
iv. Providers
v. Market

## IV – Consensus Workshops Call, according:

i. Relevance for Operation
ii. EBCP compliance
iii. Confidenciality
iv. Commmitment with Implementation

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# Efficiency Studies in the Real World: Clinical Pathway Creation Process