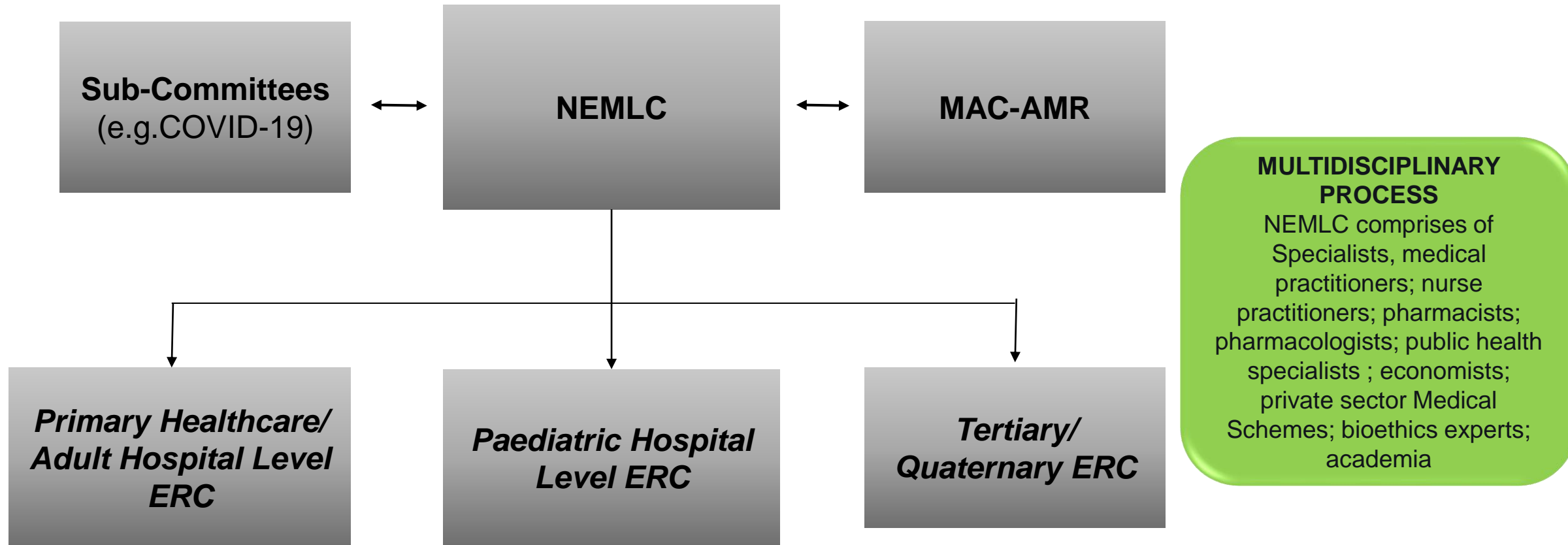# The Medicine Selection Process and NEMLC
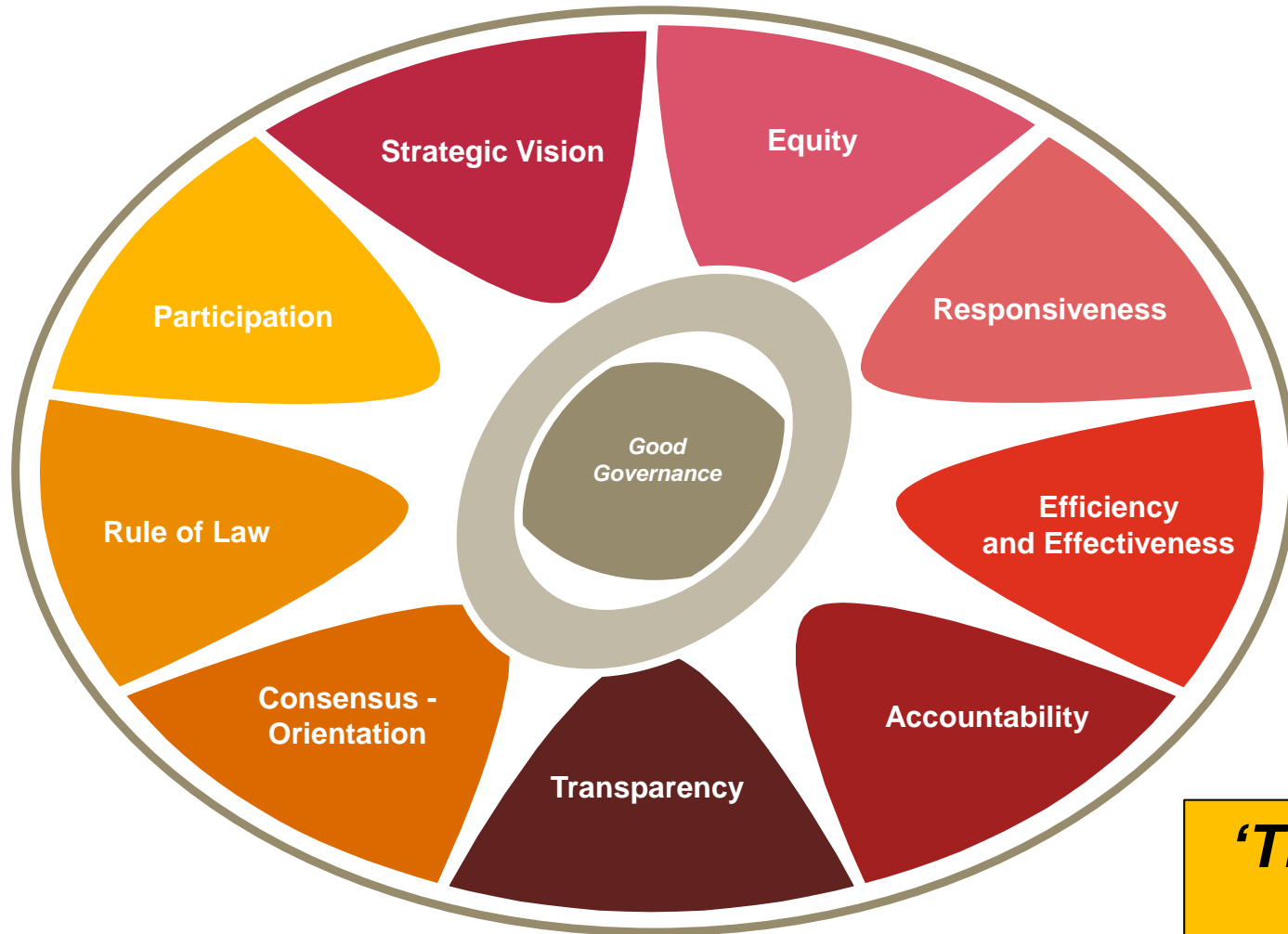
Dr Jane Riddin

Essential Drugs Programme

EDP aims to ensure that **"affordable, good quality essential medicines are available at all times in adequate amounts, in appropriate dosage forms, to all citizens"**

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Sub-Committees        ◄──►    NEMLC    ◄──►    MAC-AMR
(e.g.COVID-19)
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MULTIDISCIPLINARY PROCESS
NEMLC comprises of Specialists, medical practitioners; nurse practitioners; pharmacists; pharmacologists; public health specialists ; economists; private sector Medical Schemes; bioethics experts; academia

Primary Healthcare/ Adult Hospital Level ERC

Paediatric Hospital Level ERC

Tertiary/ Quaternary ERC

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Good Governance In Decision Making

Good Governance wheel showing: Strategic Vision, Equity, Responsiveness, Efficiency and Effectiveness, Accountability, Transparency, Consensus - Orientation, Rule of Law, Participation, with Good Governance at the center.

Conflict of interest: Preserving selection decisions against undue influence is of paramount importance

'There is no such thing as a free lunch'

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Selection Criteria

1
Need: Public Health Relevance

- Priority health diseases and conditions - burden of illness and injury
- Local epidemiology

2
Quality, Safety & Efficacy & Effectiveness

- Product registered in terms of the Medicines Act
- Evidence of efficacy, safety and

3
Cost & Affordability

- Affordability of medicine, compared to current standard of care
- Within budgets of providers of health care

4
Implications for Practice

- Pragmatic considerations
- Feasibility (e.g. adherence)
- Acceptability

- Used to formulate a well-defined question

P	Patient, population or problem
I	Intervention
C	Comparator (current standard of care)
O	Outcome

Evolution of Decision-making

GOBSAT	EBM (Evidence-based Medicine)	HTA (Health Technology Assessment)

GOBSAT

Good Old Boys Sat Around a Table

Systematic Reviews
RCTs
Cohort Studies
Case-Control Studies
Case Series
GOBSAT

Relationship of EBM and HTA

EBM

Evidence Based Individual decision Making

Evidence Based Guidelines and policies

HTA

Outcomes analysis → Economic analysis → Cost-effectiveness analysis → Ethical/ Legal Analysis

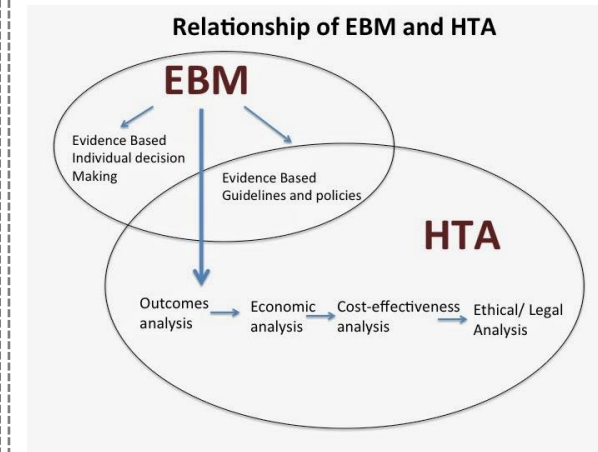*NDoH template for medicine reviews was developed in collaboration with Cochrane SA*

Rigorous process of transparent, multi-layered, evidence-based decision making
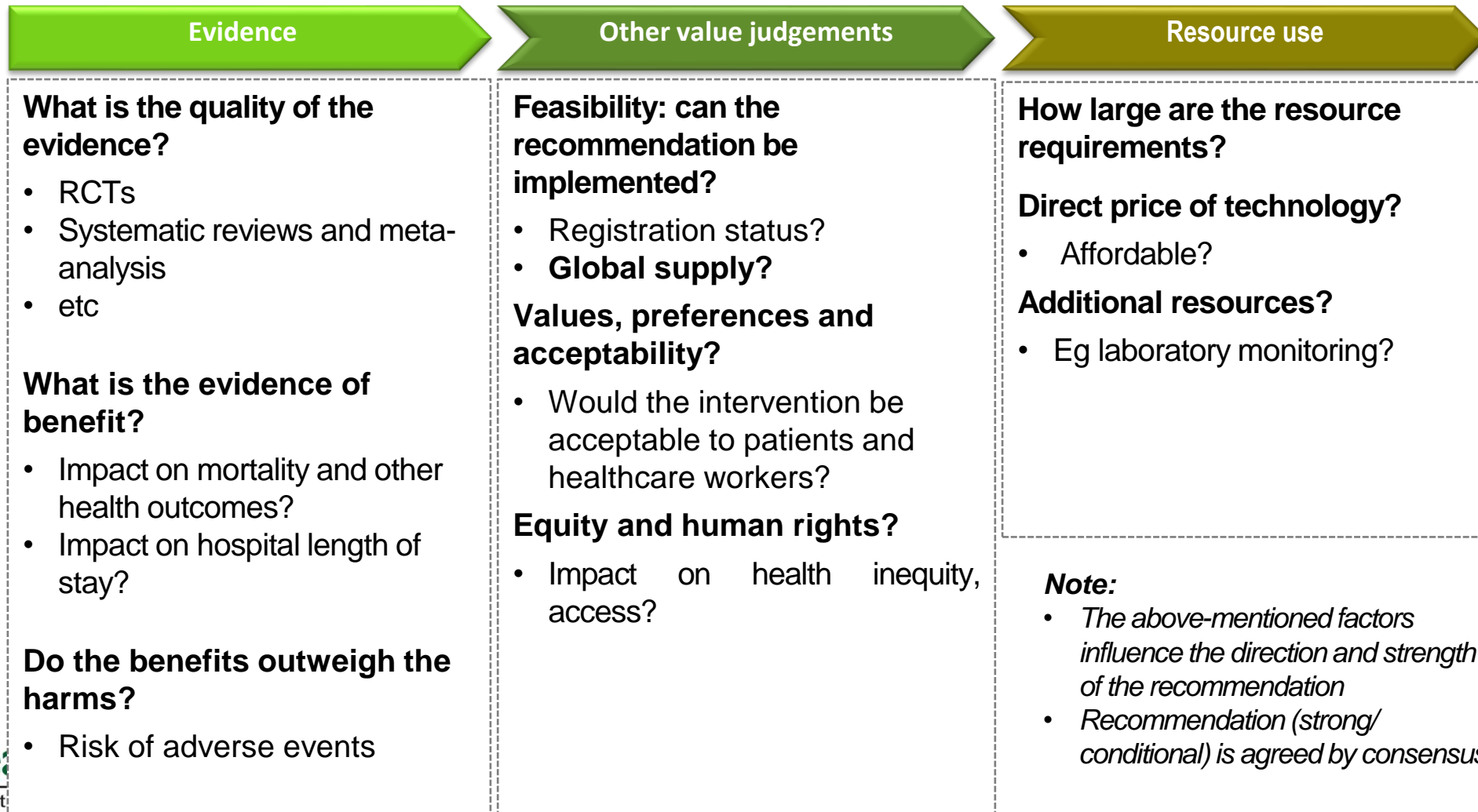
Evidence to Decision (EtD) framework

A strong existing process:
example Evidence To Decision framework

Rapid evidence review – example of factors within the framework

Evidence	Other value judgements	Resource use
What is the quality of the evidence? • RCTs • Systematic reviews and meta-analysis • etc **What is the evidence of benefit?** • Impact on mortality and other health outcomes? • Impact on hospital length of stay? **Do the benefits outweigh the harms?** • Risk of adverse events	**Feasibility: can the recommendation be implemented?** • Registration status? • **Global supply?** **Values, preferences and acceptability?** • Would the intervention be acceptable to patients and healthcare workers? **Equity and human rights?** • Impact on health inequity, access?	**How large are the resource requirements?** **Direct price of technology?** • Affordable? **Additional resources?** • Eg laboratory monitoring?

Note:
• *The above-mentioned factors influence the direction and strength of the recommendation*
• *Recommendation (strong/ conditional) is agreed by consensus*

Progress of Pharmacoeconomics in Decision Making

International price comparisons

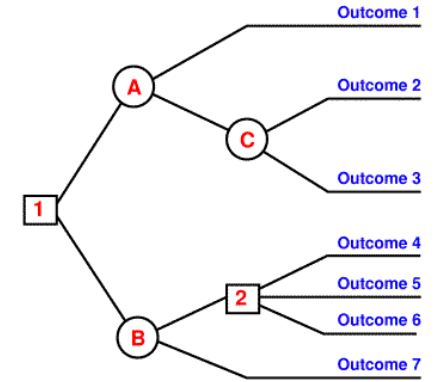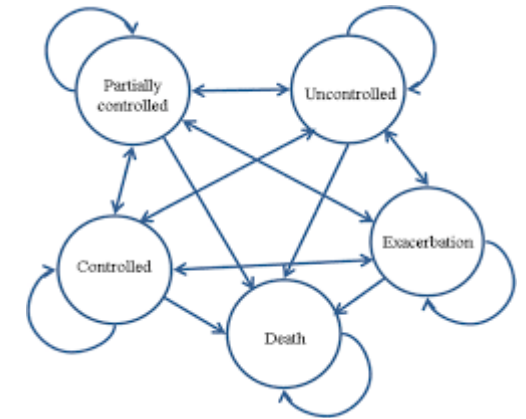| COST COMPARISON	COST MINIMISATION	CEA, CUA, BIA (modelling)

Budget = R40.00

Option 1 = R39.95

Option 2 = R99.95

A

B

Budget
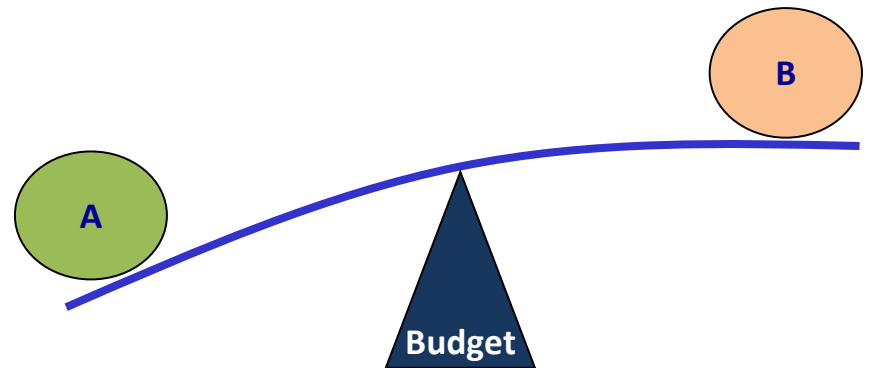
Option A comparable to option B in terms of efficacy (& safety)

- Decision   ◯ - Uncertainty (external event)

health

Department: Health

REPUBLIC OF SOUTH AFRICA

2030 NDP

8

Process Map for Revision, Dissemination and Implementation of STGs and EML

1 — Planning

- List of conditions
- Review of National ABC Analysis (Expenditure and Volume)
- Departmental Guidelines
- Call Up Notice to Pharmaceutical and Therapeutics Committee (PTC) and Stakeholders
- External Comment

2 — 1st Review

- PTC Submissions
- External Consultation
- Reviewer compiles chapter
- Literature Review
- Market Intelligence (Availability & Price)
- Technical Expert Committee Peer Review
- Meta-analyses / Health Technology Assessments / Randomised Controlled trials
- Pharmacoeconomic Analyses

3 — 2nd Review

- National Essential Medicines List Committee (NEMLC)
- External Comment
- Comments compiled and investigated
- Peer Review by Technical Expert Committee
- NEMLC approves amendments

4 — Editorial

- Editing – Essential Medicines List extracted from Standard Treatment Guidelines

5 — Measure and Evaluate

- Provincial ABC Analysis and Drug Utilisation Review

Thank you