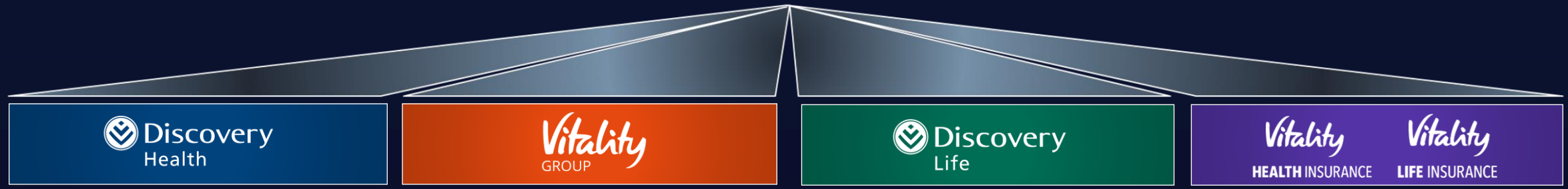
SAMED | 17 NOV 2020

Centre for Clinical Excellence

Building a global clinical capability

Centre for Clinical Excellence

Clinical Exco



Centre For Clinical Excellence

HTA	Clinical Policy	Surgical Risk Unit	Medicines Unit	Clinical Research
Comprehensive review process of published clinical evidence and economic evaluations that guides clinical policy decisions and funding recommendations for Discovery	Development of evidence based clinical funding policies that are credible, consistent and transparent to ensure access to quality, affordable and sustainable healthcare	Drive an integrated strategy aimed at reducing costs and improving quality of care for in and out of hospital procedures, surgicals and devices.	Strategic guidance to the medicines value chain – for the delivery of accessible and affordable, medicines, ensuring quality healthcare and best service experience for our members	Transform clinical and administrative data into usable information that informs business strategy, provider practice and enhances clinical credibility within the premier healthcare system.

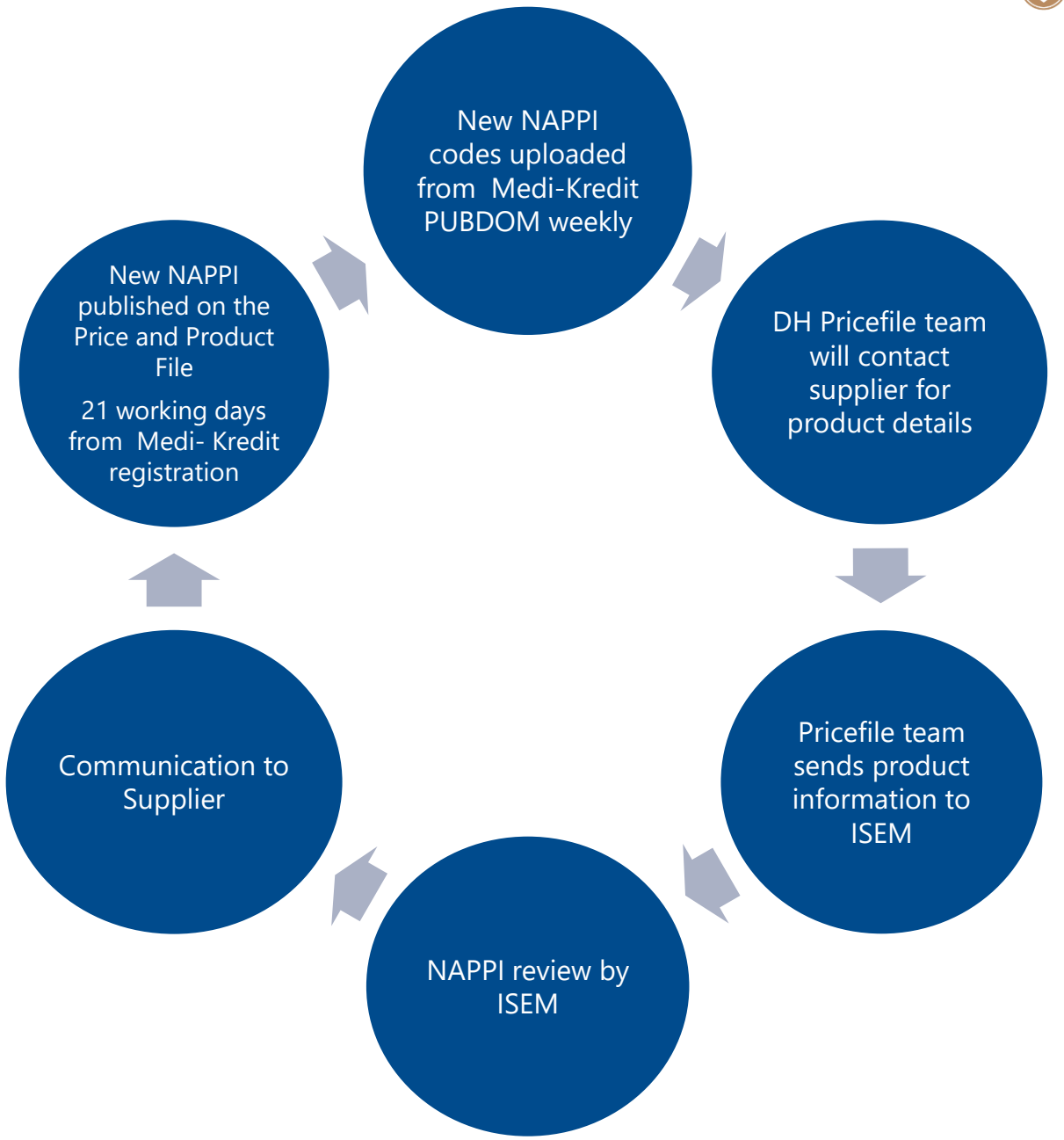
SURGICALS

Life Cycle to list a NAPPI Code and Approval

ISEM = Surgical Risk

Published Surgical NAPPI codes = 557 934

2020 YTD = 21 907 for review



Requirements to enable accurate claim reimbursement

Discovery Health Medical Scheme

Discovery Health (DH) Price and product file custodian

DH require specific information to maintaining product details and prices. This information is not received from Medikredit.

Newly registered NAPPI Codes

Require the relevant price and product information to classify and price products accordingly

- **Not automatically funded**
- DH pricefile team will issue a template for completion once the NAPPI code is registered with Medikredit
  - ISEM and the Health Technology Assessment team assess new products and technologies entering the market for clinical appropriateness and cost effectiveness
  - ISEM will evaluate **M2 products only**

To accurately reimburse claims, suppliers should update their Pricefiles annually with DH

- This ensures that our system is up to date with all your products and their prices
- Without the latest dated price claims could be processed incorrectly. This results in members incurring a short payment and an inconvenience to providers, such as pharmacies and doctors, who have to deal with these short payments.

Processes and Contact details

Classification and listing on the DH Pricefile	PRICE_AND_PRODUCT_FILE@discovery.co.za
Surgical NAPPI queries and approvals	ISEM@discovery.co.za
Price increases/Pricefile updates	ISEM@discovery.co.za
New Health Technology Submission	CPUWatchList@discovery.co.za
Health Provider Queries	HEALTHPARTNERS@discovery.co.za

Discovery

HTA

Health Technology Assessment

Discovery Health

NIRI BHIMSAN

Health Technology Assessment (HTA)

- The ***systematic evaluation*** of properties, effects, and/or impacts of health technology.
- Uses scientific evidence (EBM) to assess the quality, safety, efficacy, effectiveness and cost-effectiveness
- Supports best practices
- Applied to many health interventions – diagnostic tests, medical devices, implanted prostheses, medicines etc.

Is it safe?

Does it improve health outcomes?

Is it cost-effective

Is it affordable?

INNOVATION vs Incremental Benefit

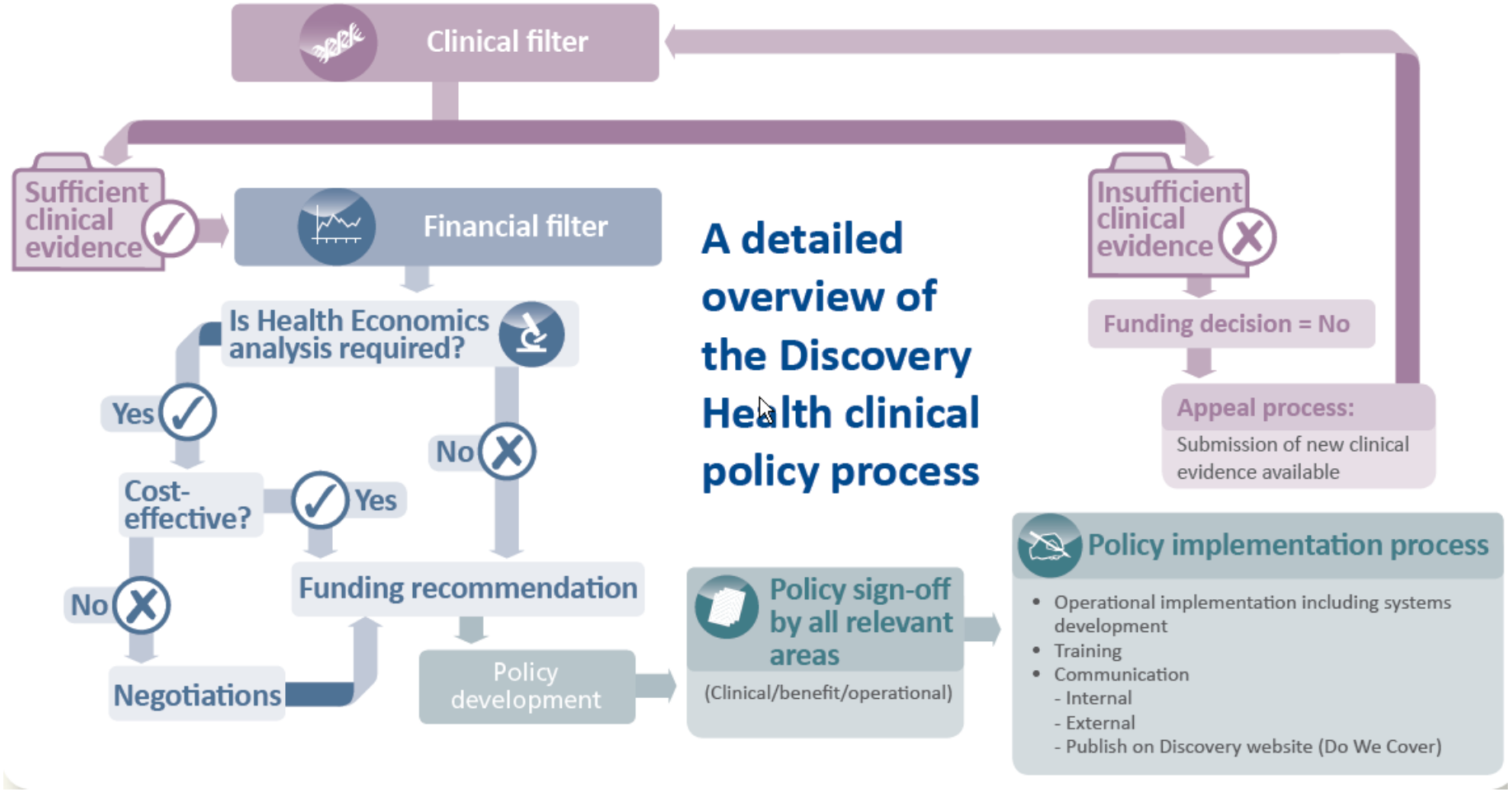
Innovation: Any combination of activities or technologies that break existing performance tradeoffs in the attainment of an outcome, in a manner that expands the realm of the possible. Defined in health care as providing "more for less"—more value, better outcomes, greater convenience, access and simplicity; all for less cost, complexity, and time required by the patient and the provider, in a way that expands what is currently possible.

PROCESS

1. Quality and Quantity of clinical evidence
2. Critical Appraisal of literature
3. Clear unmet need?
4. Cost vs benefit
5. Data analysis – scheme experience
6. Cost-effectiveness, Budget impact

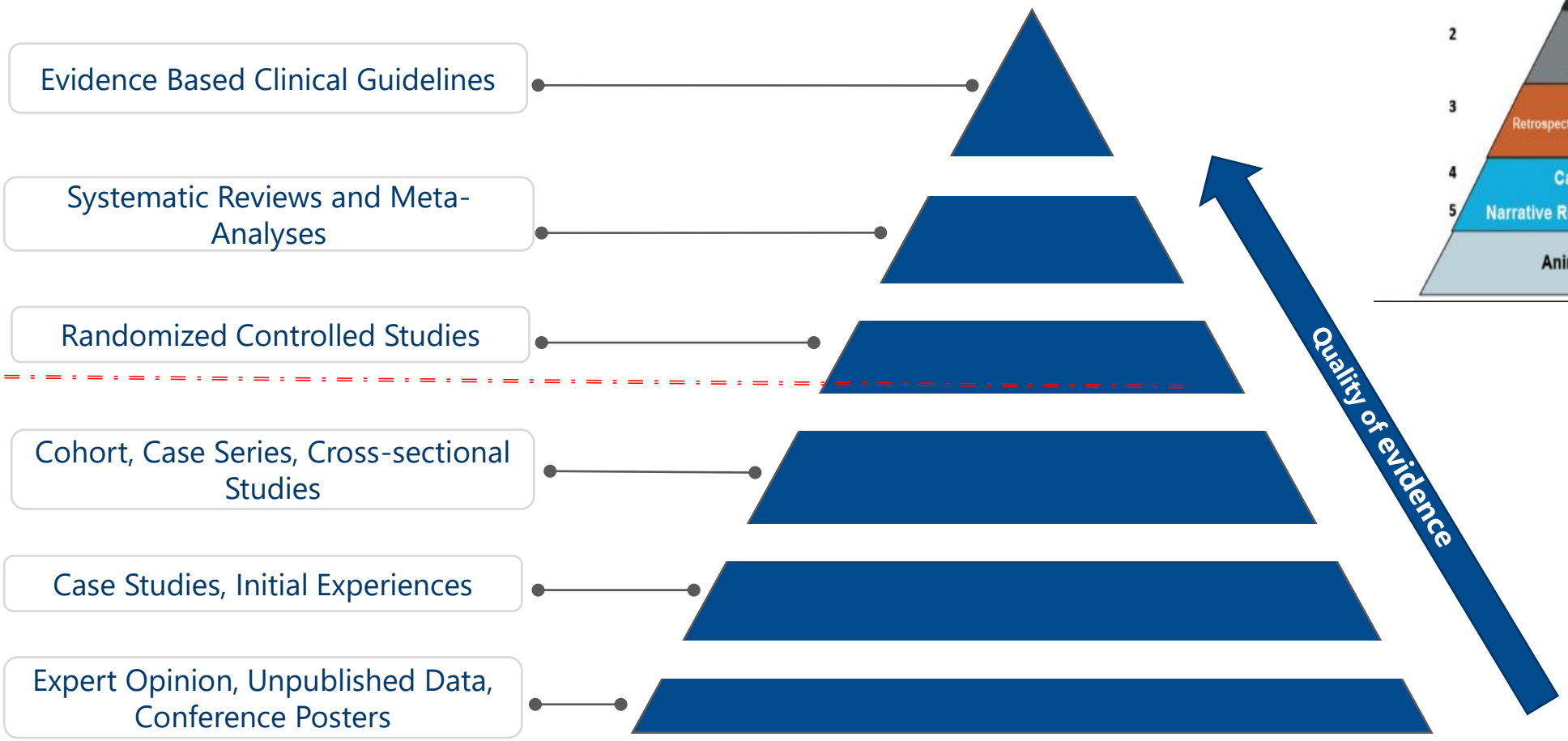
Is the Scheme paying for Value?
Is it affordable and Sustainable

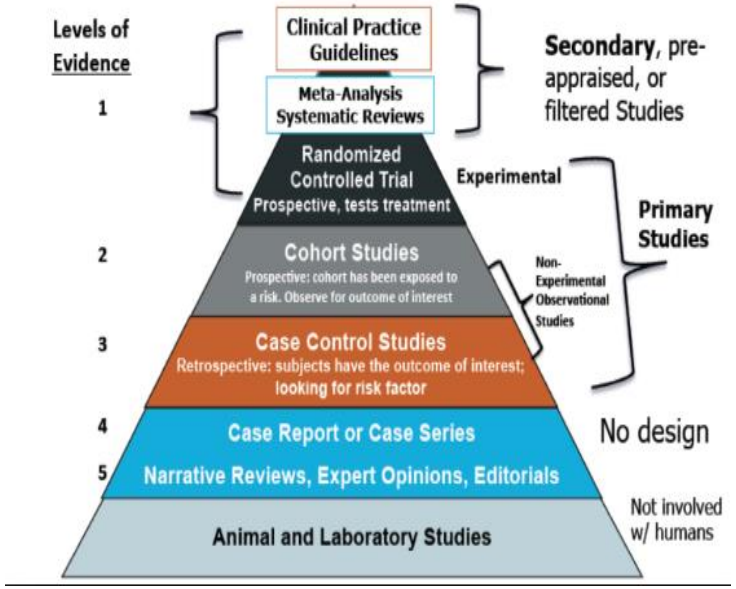
The HTA process for new technology



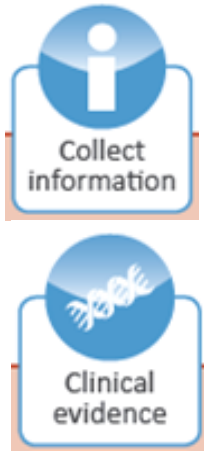
Discovery HTA Process – published in *SAMJ*

Hierarchy of Evidence





Clinical filter



Clinical Filter: Ethical, safe & clinically effective

CCE has developed a thorough and rigorous process for the assessment of new technology (pharmaceuticals, devices, and procedures) or new indications for existing technology.

Functional Components

- Evidence Based Medicine
- Clinical Matrix
- Clinical Information Summary (CIS)
- Clinical Protocols
- Clinical Policy
- Support operational implementation

International Knowledge Database

- Hayes
- Cochrane Library
- Micromedex
- UpToDate

Systematic literature review approach

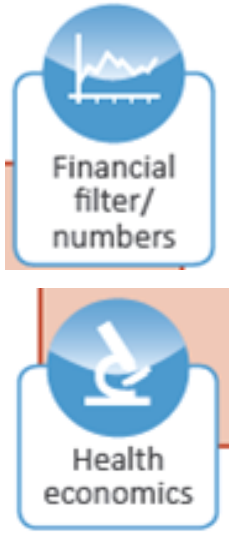
(journals, scientific publications)

External advisors & Associations

- Review & endorsement of national international guidelines & policies
- Consultation Key Opinion Leaders / professional societies
- Review of HTA decisions
- Review of international & public funding decisions

Clinical Matrix

Financial filter and Health Economics (HE)



Financial Filter:

The objective of this filter is to ensure the proposed health technology is responsibly funded

Functional Components

- Evidence Based Medicine
- Clinical Information Summary
- Health Economics models
- Matrix for non cost effective technology

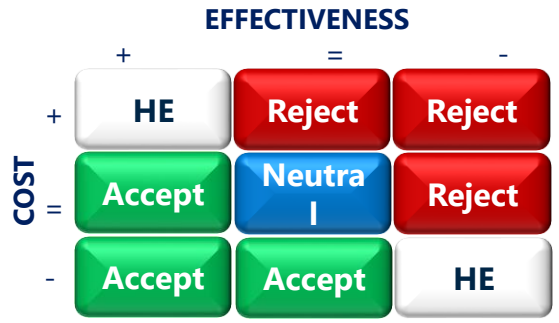
Supporting Technology

Treeage; Excel; Data and reports; Systematic Literature Review (Medical journals), International Health Technology Assessment and International public and private funding decisions.

Financial filter

- Incidence and prevalence of the condition
- Historical and projected costs of the condition and current treatment
- Cost of the new technology
- Cost of the comparator
- Budget impact
- Cost-effectiveness /health economics
- Adverse selection

Matrix



HTA Form

Discovery Health Medical Scheme

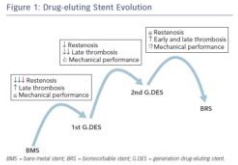
Section C: Clinical information

Brief description of new technology

Clinical indications for new technology

Please ensure that:

- Clinical indications for the use of the technology are clear.
- ***Does the evidence that has been submitted support the indication/s being requested***



Please list alternative therapies/existing comparators* and costs

*(*A comparator is a product/treatment/technology currently available in South Africa that is regarded as the standard of care which performs the same purpose/function as this product.)*

Product Name	Product description	Supplier/Distributor

COMPARATORS:

- Standard of Care
- ***Even if the new technology is different – will it replace the SoC?***
  - ***E.g. Bioresorbable stent***

HTA Form

Section D: Regulatory bodies

International registration
Indicate if this product has international registration. Please attach the certificate to this document where applicable

Country	Date of registration	Registered indication
USA (FDA)		

- Type of Approval
- ***Provide details that have resulted in the FDA approval***
- ***Delays process substantially as information has to be requested.***

Section F: Clinical Evidence

Clinical Evidence supporting this technology
Please attach full text documents such as meta-analysis, systematic reviews, randomized trials and/or other studies that indicate the effectiveness and safety of this product. Clinical evidence should be submitted with the highest level of evidence (e.g. Meta-analysis, RCT etc) at the beginning of this section.

For each clinical trial attached, please supply the following information

Trial (Author, title, publication reference)	**Trial Design** (e.g. RCT, Cohort study, Case series etc)	**Comparator**	**Sample size in each treatment group**	**Outcome measure** (e.g. Re-intervention required, blood loss etc)	**Effect size**

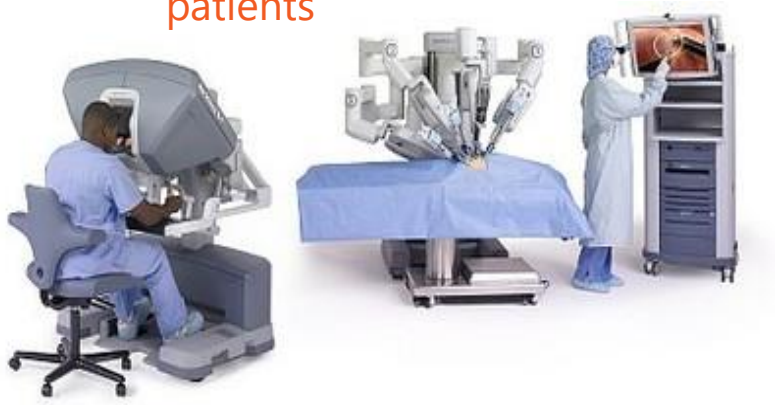
- *Start with your highest level of evidence*
- *Please don't submit animal trials/models*
- *Complete the table comprehensively*
- *Ensure that it ties back to the indications being applied for*

Case Study ROBOTIC SURGERY: Prostatectomies and TAVI Valves

Discovery Health Medical Scheme

BACKGROUND

- Robotic surgery for prostatectomy
- Indications?
- Clinical evidence against comparators
  - ❖ Open Prostatectomy
  - ❖ Lap procedure
  - ❖ Subset of patients? All patients



Does the evidence support the indication/s?

CAPITAL EQUIPMENT

- **Robotic costs exceed R25M**
- Consumables cost per patient high

2013 Procedure Costs

Open R85 000 (95% of procedures)
Lap R120 000 (5% of procedures)
Lowest likely cost ROBOT R150 000

Does the benefit warrant the cost?

BACKGROUND

- Aortic Valve Replacement
- Indications? (1st line/ inoperable/high risk/ intermediate risk)

Clinical evidence against comparators

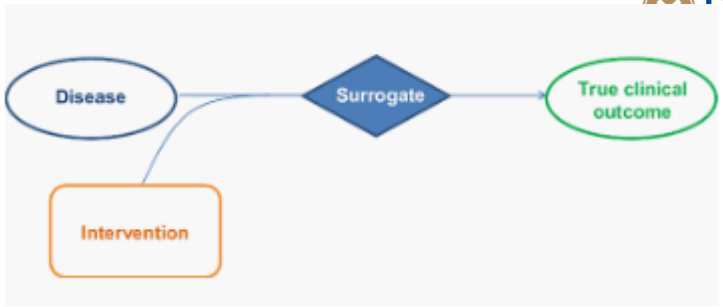
- ❖ Open procedure
- ❖ Inoperable Conservative management/ Standard therapy

VALVE costs

2011
Mechanical Valve ~R22 000

TAVI - R216 600 (2018 newer versions R300 000)

Challenges in the Clinical Evidence



1. Lack of direct comparisons to relevant alternative

- Head-to-head trials often not available
- Comparator in trials may not be relevant in our setting
- Lack of well-designed comparator trials poses a significant problem

2. Measuring relevant costs and benefits

- Vary from country to country (transferability)
- Clinical practice may also vary

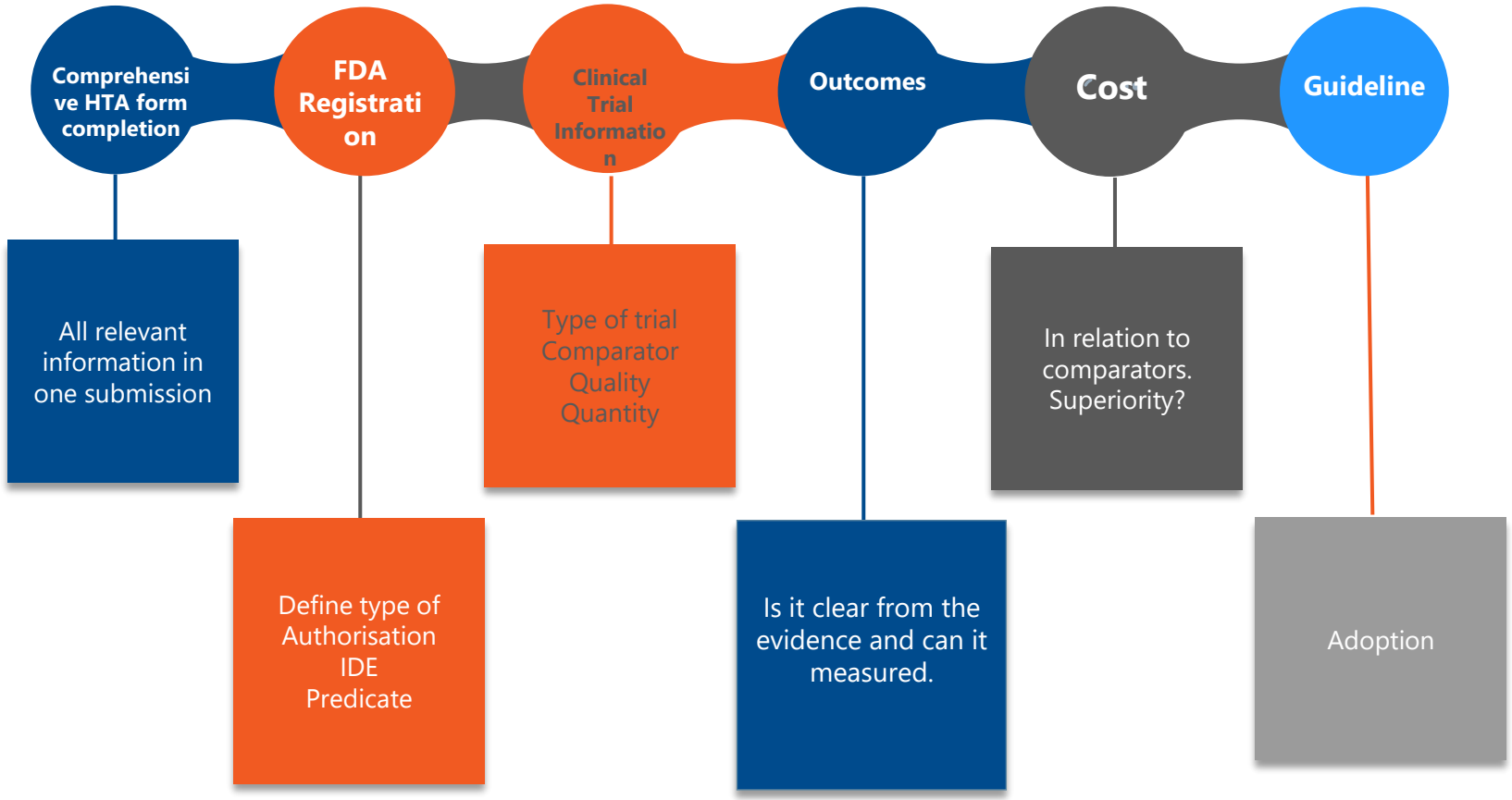
3. Lack of long-term follow-up

- Especially important depending on what the claim is or where the benefit in the outcome is expected (e.g. robotic surgery and cancer outcomes?)
- Decision needed now - can't wait until long-term data is available
- What does it mean in the current context? (can it be applied? Is this the clearer role for registry data?)

4. Superiority of Devices

?

Considerations



CD: What are the main issues and challenges that typically face pharmaceutical and medical device companies during the litigation process? How might they go about addressing these issues?

Greenblatt: Th… dis…

Medical Devices | Policy & Regulation | Clinical Trials | Manufacturing | Legal | M&A | Research | Diagno…

5 takeaways amid new scrutiny of FDA medical device oversight

A slate of FDA actions in recent days has paralleled release of investigative stories taking aim at regulators and manufacturers alike for lax safety standards, in a wide-ranging probe by the International Consortium of Investigative Journalists.

AUTHOR
David Lim
@LimOpinion

FDA Overlooked Red Flags In Drugmaker's Testing of New Depression Medicine

…PECTIVES

…NE 84 (2011), pp.471–478.

Medical Reversal: Why We Must Raise the Bar Before Adopting New Technologies

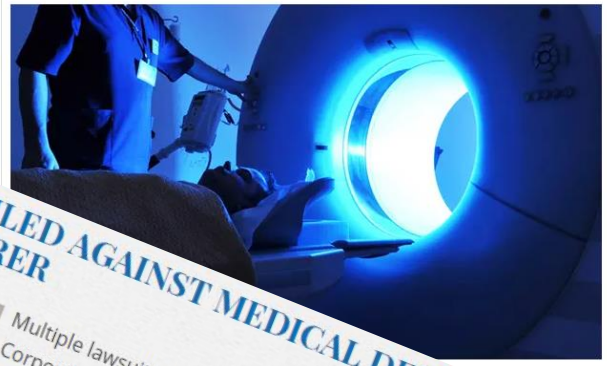
Vinay Prasad, MD,[a] and Adam Cifu, MD[b]*

[a]Department of Medicine, Northwestern University, Chicago, Illinois; [b]Department of Medicine, The University of Chicago, University of Chicago Medical Center, Chicago, Illinois

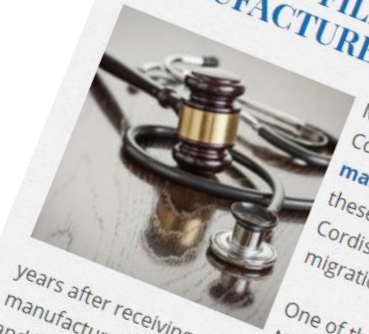
LITIGATION IN THE PHARMACEUTICAL AND MEDICAL DEVICE SECTOR

…he Bleeding Edge: behind the terrifying new Netflix documentary

The $400bn medical device industry is exposed in a horrifying look at a string of products that have wreaked havoc on patients



LAWSUITS FILED AGAINST MEDICAL DEVICE MANUFACTURER



Multiple lawsuits have been filed against Cordis Corporation, a company based in Miami Lakes that **manufactures medical devices**. According to these lawsuits, vascular filters manufactured by Cordis are prone to fracture, disintegration, migration through the blood system…

years after receiving an inferior… manufactured by Cordis… and lungs from… defect… One of these lawsuit… New Jersey…

Discovery

CLINICAL POLICY

Development of evidence based clinical funding policies that are credible, consistent and transparent to ensure access to quality, affordable and sustainable healthcare

LINDIWE PEMBA MBEKENI

Agenda

- What constitutes policy
- What informs policy
- Considerations
- Challenges

What constitutes policy

- Clinical funding policies / protocols

- Baskets of care
  - Consultations
  - Investigations – pathology, radiology
  - Procedures
  - Allied therapies

- Medical supplies
  - Medicines – formularies
  - Devices / surgical

What informs policy

- Legislation
  - Medical Schemes Act
    - PMB defined
    - CDL – algorithm
    - DTPMB
  - Medicines and Related Substances Act
- Standard of care
  - Public sector vs private sector vs international
- Evidence – HTA
- Guidelines
  - Current
  - Level of evidence – EBM principles
  - Local, international
  - Strength of recommendation
  - Quality of the guideline
  - Where it is published
  - Societal vs other group(s)
  - AGREE, GRADE, SORT tools
- Societal recommendations

Considerations

- Policies cover 80% of the population

- Regular review
  - Protocols – annual
  - As required

Challenges

- Local studies – applicability of international references
- Guidelines – EBM principles
- Website publication by clinician groups
- Legislation
  - Outdated
  - Stakeholder understanding

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