Funding Decisions and Alignment with Clinical Guidelines

- A Regulator's Perspective
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- SAMA Conference 2019
- 8th August 2019

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Definitions

"Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." *(Institute of Medicine, 1990)*

"Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. " *(American Academy of Family Physicians)*

Key Elements of a Clinical Guideline

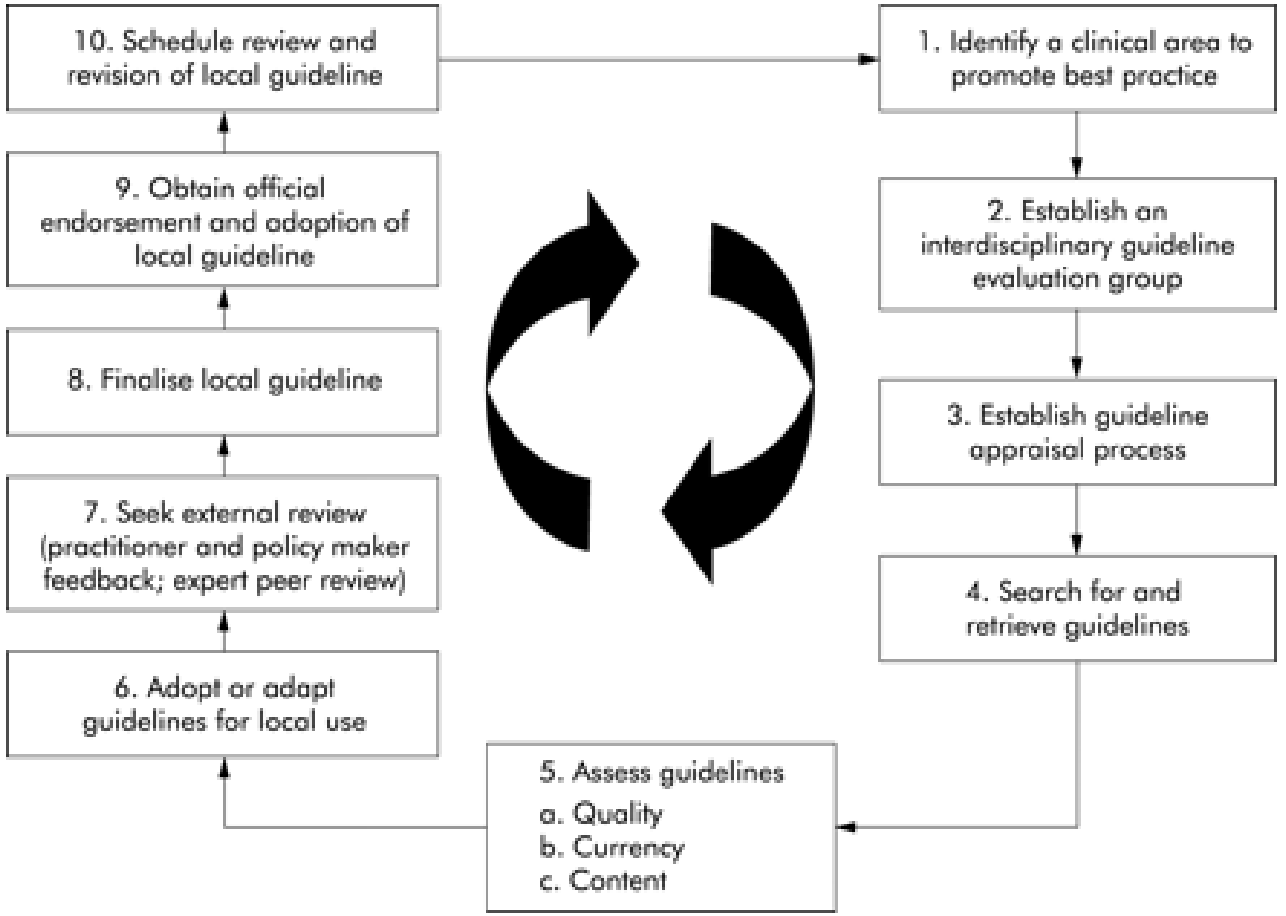
The foundation is a systematic review of the research evidence bearing on a clinical question, focused on the strength of the evidence on which clinical decision-making for that condition is based.

There is a set of recommendations, involving both the evidence and value judgments regarding benefits and harms of alternative care options, addressing how patients with that condition should be managed, everything else being equal.

Key Principles in the Development of CG's

- Establishing transparency;
- Managing conflict of interest;
- Guideline development group composition;
- Clinical practice guideline–systematic review intersection;
- Establishing evidence foundations for and rating strength of recommendations;
- Articulation of recommendations;
- External review; and
- Updating.

Clinical Guideline Evaluation and Adaption: Pickering et al



Challenges associated with Clinical Guidelines in South Africa

- Fragmentation between Public and Private Sector
- Fragmentation within Public Sector
- Fragmentation within Private Sector
- Fragmentation between Service Providers and the Funders
- Fragmentation between Regulators and Regulated Entities
- Lack of standardized manner for development and review
- Poor Integration between local and international processes
- Custodian and Stewardship Role of NDOH

South African Landscape Analysis: Wilkinson et al (2017)

- No formal co-ordination
- No prioritisation
- Different versions
- Poor Quality monitoring (Usability and Credibility??)
- Variations in Methodology

Key recommendations in support of the NHI

- National co-ordination unit
- Development of National Standard Guidelines
- Clinical Quality Standards

Proposed Solutions

- NDOH needs to lead through Stewardship and Custodian mandate
- Eliminate Fragmentation
- Convene all key parties to address the challenges
- Standardise development, adaptation and review processes across the board
- Empower regulatory and co-ordination efforts
- Effectively Manage vested interest and eliminate profit driven Guidelines and Protocols

Regulatory Legal Framework
MSA 131 of 1998 and Regulations

Legal Framework

Regulation 8 (4)

Managed Care Interventions

"(4) Subject to sub regulations (5) and (6) and to section 29 (1) (p) of the act, these regulations must not be construed to prevent medical schemes form employing appropriate interventions aimed at improving the efficiency and effectiveness of health care provision, including such techniques as requirements for pre-authorisation, the application of treatment protocols, and the use of formularies."

Formularies & Protocols

"Protocol" - set of guidelines in relation to the optimal sequence of diagnostic testing and treatments for specific conditions and includes, but is not limited to: clinical practice guidelines, standard treatment guidelines, disease management guidelines, treatment algorithms and clinical pathways.

Schemes – may prescribe treatment protocols and formularies in terms of PMBs to improve their risk management

Formularies and protocols - evidence-based medicine, taking into account cost-effectiveness and affordability

Not offer less than public hospital / facility or below standards published in treatment algorithms for the 25 CDLs and the public sector protocols for the DTPs

Legal framework: What the CMS verifies in respect of clinical protocols & formularies

1. Developed on the basis of evidence-based medicine, taking into account considerations of cost-effectiveness and affordability
2. Clear & comprehensive
3. Limitations & restrictions
4. Clinical review criteria used wrt cost effectiveness to qualify for funding
5. Procedures to evaluate clinical necessity,appropriateness, efficiency, affordability & outcomes
6. Consistent application of clinical review criteria
7. To contain clinical pathway & appropriate exceptions where ineffective or causing harm
8. Programme based on transparent & verifiable criteria
9. Periodically evaluated
10. Provision made for appeals to be lodged.

Prescribed Minimum Benefits

Background

The Medical Schemes Act No. 131 of 1998 introduced prescribed minimum benefits

Regulations developed in terms of the Act were promulgated on 20th October 1999 and came into force on 1st January 2000

Annexure A to the Regulations defines the Prescribed Minimum Benefits

- positive list of 270 diagnosis and treatment pairs that must be provided by each scheme, **without** financial limits in at least one provider setting.
- All emergencies
- List of 26 chronic conditions

Background

Irrespective of option, a Medical scheme must:

Pay PMB's in full

Not require co-payments or deductibles

Not pay PMB's from savings accounts

PMB features (DTPs)

List of 270 conditions listed as a diagnosis with specified severity and related to the specified treatment.

ICD-10 code is associated with each PMB as listed

The DTPs are listed in organ system chapters, e.g. Respiratory system; Gastro-intestinal system etc.

Cover includes: clinical assessment, pathology, radiology and other investigative and monitoring services, acute and chronic medication, surgical management, prosthesis, allied professionals

The DTPs are subject to any limitations specified in Annexure A of the Regulations.

PMB limitations

Scheme rules may dictate that:

Services to be obtained from a DSP: Outside Network **Not paid in full**

No co-payment with **involuntary use** of non-DSP

Formulary to be used: **Deviation: Co-payment**

Benefits may be reduced: **Does not Apply to PMB's**

PMB Features (CDLs)

There are 25 chronic diseases specified in the Chronic Disease List

The chronic disease list differs from the DTPs in having a specific treatment algorithm developed using EBM

The algorithms include entry criteria that determine if a member qualifies for treatment under the specific CDL

PMB Features (Emergency)

- **Emergency medical condition**:
  - “means the sudden and, at the time, unexpected onset of a health condition
  - requires immediate medical or surgical treatment, where failure to provide medical or surgical treatment would result in serious impairment to bodily functions or serious dysfunction of a bodily organ or part, or would place the person’s life in serious jeopardy
- **Code of conduct**:
  - where a medical emergency is provisionally diagnosed, and is not confirmed by additional medical evidence, the scheme will be held liable to cover costs as PMB benefits up to the stage where a PMB condition has been excluded.

PMB features (Treatable cancers)

Explanatory Note 3: Treatable cancers:

- Involve only the organ of origin
- No evidence of metastatic spread
- No irreversible or irreparable damage to originating organ or another vital organ
- Well-demonstrated 5-year survival rate of > 10% for the given therapy of the condition

EBM must demonstrate that specific treatment provide a five-year survival rate of more than 10%

Principles

Must adhere to Evidence-based medicine, cost effectiveness and affordability

Regulations make provision for the use of protocols and formularies

Regulation 15H Protocols and 15I Formularies:

- … must be developed on the basis of evidence-based medicine, taking into account considerations of cost-effectiveness and affordability;
- Provision must be made for appropriate exceptions / substitution……has been ineffective of causes or would cause harm / adverse reaction to a beneficiary, without penalty to that beneficiary.
- ….must provide such protocol / formulary to health care providers, beneficiaries and members of the public, upon request; and

Evidence-based medicine

Funding for PMB is based on integration of best research evidence with clinical expertise and patient's unique values and circumstances

Hierarchy of evidence is used to guide decision-making and funding .

Evidence should be obtained from the highest position (RCT's; Cohort; Case-controlled; Case series; Single case report; Opinions; Animal research, Lab: test tube in-vitro) in the hierarchy.

Evidence alone is never enough - the benefits and risks, inconvenience and costs associated with alternative management strategies must always be traded off in consideration of the patients' values and preferences.

Cost effectiveness

Funding for PMB is also based on Cost effectiveness of interventions:

the gains in overall health relative to the costs of different health interventions in the package must be assessed

Affordability

PMB level of cover is also based on affordability of interventions

When determining affordability, one needs to consider the incremental cost of such intervention on a total PMB package.

- impact of funding interventions as a PMB on the **member contributions and benefits**
- **current and future** impact of funding interventions as a PMB on the **solvency ratio**
- analysis of the impact of funding interventions as a PMB on the **long-term sustainability**

Availability

- Where significant **differences** exist between the **public and private** sector practices, the interpretation of the PMB's should follow the **predominant public hospital practice**, as outlined in public hospital clinical protocols, where these exist

- The technology, medicine or service considered must be **available in the public sector after it was purchased through a tender or buy-out process** (state funded), and not because of research, sponsored treatment trial, or compassionate-use programmes

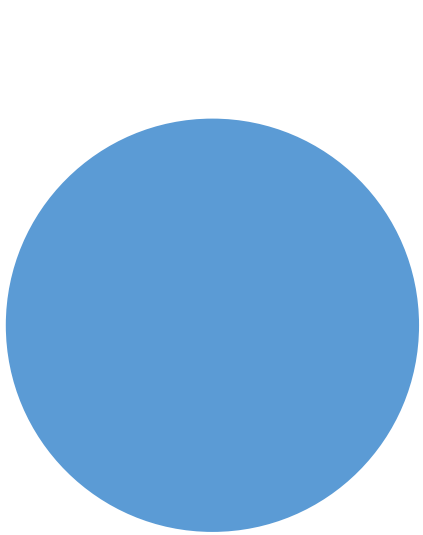
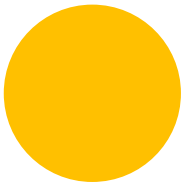
PMB Definition Project

PMB Definition Project

- Set of Clinically based Guidelines
- Strictly linked to the Prescribed Minimum Benefits
- Acceleration of definition of scheme beneficiary entitlements
- Evidence- based; Clinical best practice; Affordability, Cost-effectiveness and Availability still form part of criterion
- Co-ordinated by the CMS with registered clinical expert panels
- CMS has now completed 35 definitions in the past 3 years
- Prioritised conditions where there is disagreements and complaints (Interpretations, Funding decisions, Clinical Appropriateness, Burden of Disease)

Key Funding Decisions: What is covered or not?

- Epidemiology
- Diagnosis and related procedures
- Consultations
- Investigations (Laboratory, Imaging etc)
- Risk Assessment (Staging, Prognosis etc)
- Treatment Options
- Exclusions
- Supplementary Care

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