SASCI

South African Society of Cardiovascular Intervention

SASCI SUBMISSION: PRIMARY HEALTHCARE ESSENTIAL MEDICINE LIST
FEBRUARY 2020

A. SOUTH AFRICAN SOCIETY OF CARDIOVASCULAR INTERVENTION

South African Society of Cardiovascular Intervention (SASCI) is an organisation of physicians, scientists and allied professionals with the purpose to advance the development of cardiology and coronary revascularisation and to provide minimally invasive, image-guided diagnosis and treatment of cardiac medical conditions.

It also acts in an advisory capacity to funders; industry; members and the government on matters relating to interventional cardiology. The latter is a branch of cardiology that deals specifically with catheter-based treatment of heart diseases and includes procedures such as angioplasty and Trans Aortic Valve Implantation (TAVI). The society is also a key enabler of CPD accredited education and training in interventional cardiology in South Africa.

Cardiovascular disease is the leading non-communicable cause of death in South Africa, and contributes significantly to morbidity. The way in which the Essential Medicine List (EML) is structured and what benefits it provides will therefore have a direct impact on the cardiovascular health of all in South Africa.

B. THE SIGNIFICANCE OF THE ESSENTIAL MEDICINES LIST ("EML")

The National Drug Policy of 1995/6 ("the Policy") established the Essential Drug List (now referred to as the Essential Medicines List - EML) and stressed on the importance of the EML as being the core (but not the only) medicines to be generally available in the public sector South Africa. The EML is aimed at addressing the needs of the majority of the population.

There is a link between the Primary Health Care EML, and other EMLs, such as the hospital-based EML, in that the standard treatment guidelines should indicate the referral pathways, and primary care interventions, e.g. screening and diagnostics, that would precede referrals.

The absence of the envisaged Essential Medical Device List (called the "Essential Equipment List" or "EEL"), integrated as part of the Standard Treatment Guidelines, also makes it challenging to anticipate treatment costs, and benefits, offered by various treatment options. SASCI would implore the National Department of Health to ensure the incorporation of necessary diagnostics and medical devices required to diagnose and treat patients.

The EML processes should be formalized as per the envisaged regulations undersection 90(1)(d) of the National Health Act, 2003. Such formalization would ensure the following *inter alia*, consistency of review and how analyses such as numbers needed to treat, versus those included in the Policy, such as "*best cost advantage*" are to be considered. SASCI urges the

Department to consider the formalization of the EML and EEL, as part of standard treatment guidelines, including exceptions or deviations in cases where there is, or would be, harm to patients.

C. INTRODUCTION

The National Department of Health issued a call for comments on the Primary Healthcare (PHC) Essential Medicines List and Standard Treatment Guidelines (herein after "PHC EML") on 6 December 2019.

SASCI supports the review of the PHC EML & STGs, and specifically comment on the proposal for amendment of the version of the PHC EML. As a representative body of healthcare professionals in cardiology, SASCI and its members constitutes "healthcare professionals" who should be commenting. SASCI urges that it be listed and included as the formal stakeholder relating to interventional cardiology, and proposes that its operating officer, Mr George Nel, be included so as to facilitate the participate of the profession and specific professionals in any future reviews, or for further details or comments on this, or other EMLs.

D. SASCI'S GENERAL SUBMISSION ON THE EML.

Though the EML as stated in the letter requesting for comment, is aimed for use by doctors and nurse prescribers providing care at primary healthcare facilities to provide access to pharmaceuticals to manage common conditions at this level, conditions treated by SASCI's members start out, and are, and should be, diagnosed at PHC level. It is in the interest of patients that cardiovascular conditions are screened for, diagnosed and treated early.

The EML is important for prioritizing medicines, and placing medicines access within the correct treatment guideline. There however, is a need to find a way of integrating innovative medicines in the healthcare system. New medicines are characterised by improvements in the therapeutic schedules and ease of administration. The availability of a broad range of medicines provides cardiologists with the necessary options to treat widely diverse patient groups. This range of treatment options give healthcare professionals the space to treat patients based on evidence-based medicine, ensuring that all patients have access to appropriate care.

In general SASCI is of the view that the EML documents are well done; well researched with practical clinical guidelines. SASCI reiterates that we strongly believe that PHC should be practised by all doctors at all levels of specialisation in the provision of basic care.

While the NDOH aims to improve access to medicine, the procurement and distribution of medical supplies remains inadequate resulting in stock-outs thereby defeating the very aim of compiling an EML. Perhaps, a provision in the EML that guarantees supply of some sort should be included.

The main frameworks relating to the EML are:

1. Section 90(1)(d) of the National Health Act, 2003, empowers regulations to be made on the EML, and also the Essential Equipment List. No such regulations are however in existence.

2. The National EML Committee (NEMLS) Governance documents, including the Terms of Reference, confidentiality- and conflicts of interest policies and a conflict declaration.

3. The National Drug Policy, 1995, which created, at that stage, the NEDLC (now the NEMLC). It also requires that the EDL/EML be reviewed every two years, and sets the criteria for the EML accordingly:

   (i) Meet the needs of the majority of the population(taking into account the prevalence of CVD in the South African population);
   (ii) Scientific data regarding the effectiveness of a product;
   (iii) Safety and risk/benefit ratio;
   (iv) A preference for single Active Pharmaceutical Ingredients (given the importance of combination medicines in a variety of PHC conditions, this is assumed to no longer be the case); and
   (v) In cases of equivalence, preference to be given to best cost, best researched, best pharmaco-kinetic properties, best patient compliance and reliable local manufacturer.

SASCI proposes that, in the move towards greater emphasis on primary health care, through the implementation of NHI Bill, the adoption of regulations would be important so as to ensure that the criteria set for the governance, development and review of the EML are entrenched in law, as binding. This will provide legal certainty as to the frequency of review, and patient expectations.

E. SPECIFIC COMMENTS ON SELECT PART OF THE PHC EML

SASCI requests that, where an alternative medicine is recommended, this should be supported by appropriate evidence.

The main chapters could conceivably pertain to cardiology were predictably Chap 4 (CV) and Chap 21 (emergencies).

1. Chapter 4

In terms of section 4.6, reference to TC level >7.5mmol/Li for referral SASCI is of the view that, unless this specifically relates to identifying Familial Hypercholesterolemia (FH), much lower levels for treatment should be targeted.

While reference is made in 4.7 to Atenolol. SASCI is of the view that this medication is not readily available and therefore recommends that an alternative of Bisoprolol as it is more metabolically favourable. It is also crucial, in terms of 4.7 to add ACEI to optimise treatment for patients with established CAD irrespective of BP control.

In terms of 4.10, the EML should mention Bisoprolol alternative (see 4.7). Additionally, SASCI recommends that the EML adds dyspnoea as typical and common symptom of angina.

Section 4.11, The sections dealing with NSTEMI and STEMI lack the sense of urgency that should prevail in both these circumstances. Whilst the comments re pain relief etc are valid there should , ab initio, be instruction to make arrangements for immediate referral as soon as the patient is stabilised. Each of these 2 sections should open with this instruction. SASCI is of the view that, the EML should consider immediate referral for primary PCI if interventional centre is available within two hours.

In terms of section 4.13. SASCI proposes that, at first presentation of CCF, a patient should be investigated for the cause with ECG and Echocardiogram. It is critical to have a correct diagnosis in order to institute appropriate management from the beginning: eg LV / pericardial/valve disease.

Crucially, section 4.15, digoxin is no longer considered of value and more importantly it just carries risk of toxicity. SASCI recommends the inclusion of an ECG and an Echo (see 4.13). SASCI recommends that, should consideration be given to future use Angiotensin-receptor/neprilysin inhibitor (ENTRESTO) and IVABRADINE (Coralan) in order to optimise CCF medication in poor responders. This may be more cost effective and/or practical than going to CRT.

2. Chapter 21

In response to sections 21.6 and 21.10, SASCI suggests adding an External pacer in asystole or unresponsive bradycardia.

F. CONCLUSION

SASCI appreciates the opportunity provided to comment on the EML and is available to assist should any further assistance be required.

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