



New Zealand Hospital Pharmacy Association (Inc)

Te Kāhui Whakarite Rongoā Hōhipera o Aotearoa

NationalClinicalNetworks@tewhatauora.govt.nz

Email title **CKM guidance**

Kia ora tatou

On behalf of the NZHPA, we thank you for the opportunity to provide feedback on the draft Cardiovascular-Kidney-Metabolic (CKM) Guidance. As highlighted, this disease state is increasingly prevalent and disproportionately affects Māori, Pacific people and Indian ethnicities. Additionally, under the umbrella of CVD prevention, the CKM guidance document is a welcome advance towards reducing the burden of CKD. We are enthusiastic about collaborating with healthcare teams to enhance health-related outcomes for these populations.

Our comments and feedback encompass three points:

1. **CLINICAL COMMENTS BASED ON THE MEDICATION THAT WAS DISCUSSED**
2. **NONCLINICAL COMMENTS LOOKING AT NOMENCLATURE AND RELATED ERRORS**
3. **THE IMPACT OF IMPLEMENTATION**

The first two points are addressed jointly.

CLINICAL COMMENTS, NOMENCLATURE AND RELATED ERRORS

1. Commitment to equity in CKM care
 - a. No feedback
2. Definition of CKM diseases
 - a. We note that the definitions of the manifestations of CKM are described in this section with parameters, except dyslipidaemia. For consistency, consider defining dyslipidaemia further in this section.
 - b. It is noted that the definition of Stage 3 Obesity defines a 5-year CV risk score $\geq 10\%$. This differs from the national CVD risk guidelines 2018.
 - i. Differences in national guideline will lead to clinician confusion, and alignment is required.
 - ii. International guidelines adopt a 10-year risk model, which may question the appropriateness of risk extrapolation.
 - iii. We note the reference to the PREDICT tool under section: Clinical Assessments. We invite clarification as to whether this tool can be utilised in the general population or only for patients with a classification of diabetes.
3. Clinical assessments in people with CKM disease
 - a. We wish to highlight the discrepancy in the guidance document regarding repeat CVD risk assessments in the high-risk cohort. Our local (though outdated 2018) guidelines suggest repeated assessments *annually*, and this invites the opportunity to review interventions or assess if targets are met. The CKM guidance states no need to repeat

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as need to optimise treatment. In the practical setting this may lead to missed opportunities for our people.

4. Lifestyle management + interventions for weight loss
 - a. General care: smoking cessation
 - I. Consider adjusting the advice where smoking cessation interventions are offered at *any opportunity* the patient presents, rather than offering it yearly.
 - b. Consider correcting typo: *Phenetermine* to Phentermine.
 - c. We question the inclusion of approximate costs of medicines in a guidance document as this highlights some concerns:
 - I. The pricing of non-funded items varies between pharmacies and may change over time. It would be cumbersome to update medicine costs in a living document.
 - II. These costs can lead to confrontation and disappointment if people are informed of a cost which differs to what the pharmacy charge
 - d. Consider linking medicines or medicine classes to monographs from our national formulary (New Zealand Medicines Formulary) as this contains all the safety and dosing data for health professionals.
 - I. For example, serious risks associated with topiramate include acute myopia, congenital malformations and neurodevelopmental disorders; females of child-bearing potential should be counselled against becoming pregnant while taking topiramate.
5. Management of elevated blood pressure and hypertension
 - a. The following sentence may need rewording: *Strongly consider ACEi or ARB if no hypotension and check BP in 1 month.*
 - I. Is this simply stating that ACEi and ARBs are preferred in CKD over other agents for hypertension?
 - b. We recommend removing advice on selecting one agent over others within the same class. For example, preferentially prescribing ramipril, then quinapril.
 - I. Some cardiology centres use neither of these agents
 - II. Using one or two agents in preference to prescriber preference may lead to drug supply issues and errors with unfamiliar dosing.
 - c. Specific drug considerations:
 - I. Quinapril in combination with a thiazide diuretic is no longer available on the NZ market. The combination antihypertensive agents currently available and funded are losartan/hydrochlorothiazide and candesartan/hydrochlorothiazide.
 - II. Bendroflumethiazide 5mg daily is typically not recommended due to the ceiling effect in achieving blood pressure lowering at doses exceeding 2.5mg daily, while increasing the risk of adverse effects.
 - III. Hydrochlorothiazide is not available as a single agent, only in combination products.
 - d. Subheading Ischaemic heart disease, heart failure or atrial fibrillation

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- I. These are very different entities, and the guidance provided in this section requires further detail or distinction.
 1. For example – we agree that beta blockers can be added at any stage for these conditions in general (unless decompensated HF). While it may be appropriate for patients with IHD or AF to have CCB or TD reduced, patients with HF(rEF) typically should not be on a CCB.
6. Management of dyslipidaemia
 - a. It is uncertain if the statement regarding rosuvastatin being the preferred statin is helpful. Both atorvastatin and rosuvastatin are high potency statins. We feel it is reasonable to trial high dose atorvastatin and ezetimibe as an option over self-funding rosuvastatin.
 - I. There is good evidence that early introduction of ezetimibe leads to lower cholesterol levels faster, and this leads to better outcomes.
 - II. It is reasonable, however, to obtain special authority funding for patients who remain above target despite maximal tolerated statin and ezetimibe.
 - III. Current international guidelines do not state one statin in preference to another. There are some centres where atorvastatin is the preferred first line agent.
 - IV. Please review the statement *‘Maximise rosuvastatin use in Māori and Pacific Peoples given funded and their high CV risk.’* i.e. *“Māori and Pacific People have equity based wider funding access to rosuvastatin”*
 - V. If patients can self-fund alternatives for lipid-lowering treatment, the other alternatives include PCSK9 inhibitors and bempedoic acid. Evolocumab is more readily available than alirocumab, and the maintenance dose of inclisiran is six monthly.
 - VI. The REDUCE-IT trial also demonstrated the benefits of prescription fish oils (as icosapent ethyl) for reducing CVD risk in patients with elevated triglycerides and high CVD risk.
7. Management of hyperglycaemia in type 2 diabetes
 - a. Correct typo *GLp1ra* should be *GLP-1 RA*
 - b. Considerations for specific medicines
 - I. While the pragmatic approach to accessing empagliflozin is appreciated, consider omitting off-licence dosing (12.5mg daily).
 - II. Consider linking medicines to their NZF monographs
 1. Pioglitazone should not be recommended in patients with heart failure. This is not mentioned until further in the section. We feel it should be mentioned earlier.
 - III. A mixture of generic and trade names used. We recommend maintaining consistency by using generic names to avoid confusion. Trade names can often change.
 - IV. Consider an alternative term for *“new starts.”*
8. Management of CKD

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- a. There is a brief mention of spironolactone in the hypertension section but lacks further guidance on the use or place in therapy.
 - b. Avoid information around pricing of drugs (empagliflozin) for concerns already addressed.
 - c. While we agree that the risk of aspirin outweighs the benefit for primary prevention in patients with significant renal disease, evidence suggests that risks outweigh benefits in most patients (a wider population).
9. Management of gout
- a. We generally would recommend the use of colchicine over prednisone for the management of acute gout flares, due to the potential hyperglycaemic effect of prednisone.
10. Calculating CV risk and antiplatelet therapy in CKM disease
- a. Please clarify which PREDICT tool is being used, as there is one for the general population and one for diabetic patients.
 - b. Please clarify which scoring system has been used to assess deprivation and where this is accessible.
 - c. When managing a patient's high cardiovascular risk score who has not been diagnosed with cardiovascular disease, we advocate other pharmacological and non-pharmacological interventions before the use of aspirin for primary prevention.
 - d. Please clarify which aspirin risk/benefit calculators have been used whether these calculators are validated (for which population groups).
 - e. There is growing evidence to support the use of clopidogrel in place of aspirin as the long-term SAPT strategy (SMART-CHOICE 3 trial).
 - f. Correct typo: *ticragrelor* to ticagrelor
 - g. There appears to be multiple time points for reassessing an individual's CVD risk according to which category they fall in (screening vs treatment; low, moderate or high risk). We know this is not done well in practice already, and we wonder if a more simple, consistent, and pragmatic approach could help streamline the process further.
 - h. Review use of word 'Onceified'
11. Screening for CKM disease in the general population
- a. No feedback

THE IMPACT OF IMPLEMENTATION

The CKM guidance document is an aspirational framework that pulls from a wide body of literature and condition-specific guidelines. While we are very supportive in general of this guidance and the improved care it will offer patients, we wonder if guideline implementation will both enhance and complicate our practice in the current climate.

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We envision primary care providers as the champions for initiating the opportunistic screening and treatment for individuals with CKM. Unfortunately, primary care providers are already buried under a myriad of recommendations and mandates. One of the reasons for clinician burnout in primary care is the broad scope of responsibility and numerous metrics that grade our performance. Regardless of our performance-driven tasks for a specific patient visit, we are often competing with the patient's priorities which may differ.

Implementing the guidance will no doubt lead to tremendous advances in CKM detection and treatment. The implementation of these recommendations would require substantial intervention and investment (resource and financial) to prevent widening the gaps in equity and accessing healthcare for our high needs' patients. Secondary care engagement and support from relevant specialists would be particularly important.

As a newly identified syndrome, CKM and its manifestations will no doubt identify many more at-risk patients who require intervention and treatment. There needs to be tools in place that assist in facilitating evidence-based management which are accessible and user-friendly. Resource investment also includes sufficiently trained healthcare providers who are embedded within primary and secondary care, including pharmacists. There is good evidence of clinical pharmacists working within primary care and secondary care outpatient clinics to demonstrate medicines optimization and freeing up other clinical staff time. We invite you to consider this as a strategy to support the implementation of the guidelines.

We hope you find our feedback helpful and thank you for the opportunity to contribute to this important piece of work.

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Dunn, S et al. *The Role of the Clinical Pharmacist in the Care of Patients with Cardiovascular Disease*. Journal of American Cardiology 2015; 66(19).

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