CHAPTER GROUP RESPONSE TO PUBLIC CONSULTATION FEEDBACK: PREVENTION GUIDELINE

REVIEWER OVERVIEW

#	TYPE	TYPE
1	Individual Reviewer (*2 partial completed surveys- included)	13
2	Reviewer on behalf of an organisation (*1 partial competed survey - included) *Northern Health, The Australian Orthotic Prosthetic Association, Royal Darwin Hospital, Australian Podiatry Association, Foot Forward, APP HRFG	6
	Answered	19*
	Skipped	0

BACKGROUND

QUESTION	STRONGLY AGREE		AGREE		NEITHER AGREE OR DISAGREE		DISAGREE		STRONGLY DISAGREE		TOTAL
You are involved with the care of patients for whom this draft Australian prevention guideline is relevant.	63%	12	21%	4	16%	3	0%	0	0%	0	**19**
There is a need for a new Australian prevention guideline in this population.	47%	9	47%	9	5%	1	0%	0	0%	0	**19**
The rationale for developing a new Australian prevention guideline on this topic is clear in this draft guideline.	63%	12	32%	6	5%	1	0%	0	0%	0	**19**
									Answered		**19**
									Skipped		**0**

METHODOLOGY

QUESTION	STRONGLY AGREE		AGREE		NEITHER AGREE OR DISAGREE		DISAGREE		STRONGLY DISAGREE		TOTAL
I agree with the overall methodology used to develop this draft Australian prevention guideline.	37%	7	53%	10	11%	2	0%	0	0%	0	**19**
The search strategy used to identify international guidelines on which this draft Australian prevention guideline was based is relevant and complete.	37%	7	53%	10	11%	2	0%	0	0%	0	**19**
The methods used to determine the suitability of identified international source guidelines upon which this draft Australian prevention guideline were based were robust.	42%	8	42%	8	16%	3	0%	0	0%	0	**19**
I agree with the methods used within this draft Australian prevention guideline to interpret the available evidence on this topic.	32%	6	58%	11	11%	2	0%	0	0%	0	**19**
The methods used to decide which recommendations to adopt, adapt or exclude for the Australian context were objective and transparent.	26%	5	63%	12	11%	2	0%	0	0%	0	**19**
									Answered		**19**
									Skipped		**0**

RECOMMENDATIONS

QUESTION	STRONGLY AGREE		AGREE		NEITHER AGREE OR DISAGREE		DISAGREE		STRONGLY DISAGREE		TOTAL
The recommendations in this draft Australian prevention guideline are clear.	39%	7	56%	10	6%	1	0%	0	0%	0	**18**
I agree with the recommendations in this draft Australian prevention guideline as stated.	17%	3	72%	13	6%	1	6%	1	0%	0	**18**

The recommendations are suitable for people living with diabetes-related foot disease.	22%	4	72%	13	6%	1	0%	0	0%	0	**18**
The recommendations are too rigid to apply for people living with diabetes-related foot disease.	6%	1	6%	1	22%	4	61%	11	6%	1	**18**
The recommendations reflect a more effective approach to improving patient outcomes than is current practice.	11%	2	39%	7	44%	8	6%	1	0%	0	**18**
When applied, the recommendations should produce more benefits than harms for people living with diabetes-related foot disease.	44%	8	50%	9	6%	1	0%	0	0%	0	**18**
When applied, the recommendations should result in better use of resources than current practice allows.	33%	6	28%	5	33%	6	6%	1	0%	0	**18**
I would feel comfortable if people living with diabetes-related foot disease received the care recommended in this draft Australian prevention guideline.	39%	7	50%	9	11%	2	0%	0	0%	0	**18**
									Answered		**18**
									Skipped		**1**

IMPLEMENTATION OF RECOMMENDATIONS

QUESTION	STRONGLY AGREE		AGREE		NEITHER AGREE OR DISAGREE		DISAGREE		STRONGLY DISAGREE		TOTAL
To apply the draft Australian prevention guideline may require reorganisation of services/care.	17%	3	33%	6	39%	7	11%	2	0%	0	**18**
To apply the draft Australian prevention guideline may be technically challenging.	0%	0	44%	8	39%	7	11%	2	6%	1	**18**
The draft Australian prevention guideline may be too expensive to apply.	11%	2	11%	2	39%	7	39%	7	0%	0	**18**
The draft Australian prevention guideline presents options that will likely be acceptable to people living with diabetes-related foot disease.	17%	3	67%	12	6%	1	11%	2	0%	0	**18**
									Answered		**18**
									Skipped		**1**

FINAL THOUGHTS

QUESTION	STRONGLY AGREE		AGREE		NEITHER AGREE OR DISAGREE		DISAGREE		STRONGLY DISAGREE		TOTAL
This draft guideline should be approved as the new Australian prevention guideline.	33%	6	44%	8	22%	4	0%	0	0%	0	**18**
This draft Australian prevention guideline would be supported by the majority of my colleagues.	39%	7	44%	8	17%	3	0%	0	0%	0	**18**
If this draft guideline was to be approved as the new Australian prevention guideline, I would use or encourage their use in practice.	44%	8	44%	8	11%	2	0%	0	0%	0	**18**
									Answered		**18**
									Skipped		**1**

SPECIFIC COMMENTS ON RECOMMENDATIONS

#	RECOMMENDATION	REVIEWER TYPE	REVIEWER COMMENT RECEIVED	CHAPTER GROUP RESPONSE	MANUSCRIPT CHANGE (& PAGE NUMBER IF CHANGED)
1	Recommendation 1	Organisation	Recommendation does not seem to address the PICO question - (PICO speaks to prevention, whereas the recommendation speaks to detecting risks). The evidence behind effective prevention is lacking, but evidence that PAD and LOPS increase risk for DFU is high - and thoughts are quality of evidence is not low. Perhaps reword to clarify?	We agree, however, due to the adaptation methodology employed by this guideline we are somewhat constrained by the source guidelines questions, and the recommendations addressing those questions. In saying that we also believe the issue the reviewer raises in terms of mismatch between the quality of evidence for the two parts of this recommendation, we addressed satisfactorily in the Summary of Justification to adapt section and have downgraded the overall quality of evidence rating for the recommendation accordingly.	N
2	Recommendation 1	Individual	Have you considered providing assessment templates?	We agree this would be a great resource however this was outside the scope of the guidelines development protocol and any funding to develop clinical assessment templates. However, we do refer the reviewer to the IWGDF risk stratification system (Table 5) and the clinical pathway (Figure 2) we have developed that helps the reader categorise ulcer risk and may partially address the reviewer's request.	N
3	Recommendation 1	Individual	Specific examples for patient education ie: use X to dry well between toes	Thank you for your suggestion. We have now added more specific example information into the 'Considerations for the Australian context: Recommendations 3,4 & 5',	Y, page 18
4	Recommendation 1	Individual	I agree screening is used widely in current practice	Thank you for your comment.	N
5	Recommendation 1	Individual	Clarification of who should be performing tenotomies: orthopaedics? Pod surgeons? Vascular?	In the recommendations related to surgical procedures, we have now clarified that procedures should be performed by "suitably qualified professionals who are able to demonstrate competence in the procedure and registered with the appropriate regulatory body".	Y, pages 27-28
6	Recommendation 2	Individual	regular screening assists with recognising deterioration in the feet earlier. Self-care can be difficult for some with diabetes due to physical limitations	We thank the reviewer for their comment. We have now added a statement advising patients seek	Y, page 15

				support from others to apply recommendations in this guideline, if unable to perform these themselves.	
7	Recommendation 3	Individual	Agree totally	Thank you for your comment.	N
8	Recommendation 4	Individual	Agree	Thank you for your comment.	N
9	Recommendation 4	Organisation	need options for people with retinopathy or poor mobility to also check feet	We agree and please refer to our response to a very similar suggestion in point 6.	Y, page 15
10	Recommendation 4	Individual	"use emollients to lubricate dry skin" the wording may be a little misleading and encourage patients with diabetes to apply moisturiser between the toes which is not recommended due to the risk of interdital maceration which can lead to tinea pedis and ulcerations. I would prefer a clarifying statement to say not to put emollient between the toes	We agree and clarification has been made to 'Considerations for the Australian context: Recommendations 3,4 & 5', stating to use emollients to lubricate dry skin but not between the toes.	Y, page 18
11	Recommendation 5	Individual	dependent on motivation of person with diabetes and physical limitations with use of temperature checking device	We agree with the comment and refer the reviewer to existing statements on motivation and adherence considerations for temperature monitoring in the Considerations for the Australian context (p31-32).	N
12	Recommendation 5	Organisation	need to consider the patients learning style	A sentence has now been added to acknowledge the importance of providing education tailored to individual learning styles.	Y, page 18
13	Recommendation 6	Individual	I would suggest further definition of 'medical grade footwear' - I believe that standard footwear that is of appropriate fit and style to accommodate foot shape/deformity, is suitable for many people. The 'medical grade footwear' terminology potentially leans to specially made footwear that is not readily available.	We refer the reviewer to the extensive medical grade footwear definitions in the glossary of terms stating that medical grade footwear can be pre-fabricated or custom made and definitions for those types of medical grade footwear as well (p69-71).	N
14	Recommendation 6		dependent on motivation of person with diabetes	We refer the reviewer to a very similar comment in point 11.	N
15	Recommendation 6	Organisation	unrealistic, no suitable measuring device, burdensome to patient	We thank the reviewer and suggest these points have already been extensively addressed and considered in the guideline within the summary of justification section for this recommendation (p29-32).	N
16	Recommendation 7	Organisation	Change the term 'custom-made insoles' to 'custom-made foot orthoses'. This reflects ISO terminology and terminology used by private health insurance funds, the NDIA, state equipment schemes and other funding bodies. Furthermore patients/clients need to be educated on visual inspection of orthoses, not just footwear. Orthoses with poor fit or degradation present risk to the diabetic foot.	The term 'custom-made foot orthoses' has been adopted as suggested. A general statement about accessing funding has been added. A statement recommending inspection of the integrity of orthoses has been added.	Y, pages 6, 22, 24-25, 40, 45, 51-52
17	Recommendation 7	Individual	Implementation of trauma prevention with use of aids will assist greatly	A statement to this effect has now been added into the discussion on recommendation 7.	Y, page 25

18	Recommendation 7	Organisation	Access to MGF is expensive with limited qualified pedorthotists and few footwear style options.	We agree. We refer the reviewer to existing and new statements in the discussion for recommendation 7 that aims to provide consideration for options and funding.	Y, page 25
19	Recommendation 7	Individual	Access to Medical grade and custom footwear is limited and expensive. Lots of work around access to these devices at a coal face, and therefore a preventative, level and not just through Tertiary Hospital settings, post an ulcerative event, is required	We agree and refer the reviewer to the above very similar comment in point 18.	Y, page 25
20	Recommendation 8	Organisation	Consistently refer to (semi) rigid orthoses. This terminology could also be used in recommendation 7.	The terminology used in this specific recommendation is as per the IWGDF guidelines and the specific literature.	N
21	Recommendation 8	Individual	Access to orthoses of any description at Primary Health care level is again expensive. Patients need to be self funded currently unless they are seen in a GP superclinic setting, numbers of which are limited. Funding access via Medicare to enable eligible people to obtain a device as prescribed by a Podiatrist would be beneficial to this outcome.	Agreed and we refer the reviewer to a similar comment in point 18. We would though highlight that these guidelines used the GRADE system (as did IWDGF) to consider and balance the available evidence along with general Australian applicability and feasibility issues (including costs) to develop this and all evidence-based recommendations. This then is further considered as the balance of effects for the recommendation and in turn the strength of the recommendation to use. In this case the strength of the recommendation is rated as weak because of these considerations. Otherwise how each Primary Health Care region accesses or implements the recommendation is outside the scope of guidelines.	N
22	Recommendation 9	Organisation	As with recommendation 1; the recommendation does not address PICO question (which addresses prevention, whereas the recommendation speaks to reducing risk factors e.g peak pressures). suggest revising judgement to include recommendation but with a caveat it doesn't actually address the PICO question	We thank the reviewer for their comment. We have reviewed this and still believe that the PICO question has been appropriately addressed in context of the literature. The question asks what specific orthotic (including footwear) intervention is effective for preventing a foot ulcer and the recommendation suggests to prescribe medical grade footwear (with demonstrated plantar pressure relieving effects) to prevent a recurrent foot ulcer.	N
23	Recommendation 9	Organisation	Expand this recommendation to include the provision of orthoses. In the justification of this recommendation, it was noted that the panel identified the role orthoses have in	The use of orthoses has been addressed in recommendations 7 & 8 and we refer the reviewer to those recommendations instead.	N

			reducing the risk of foot ulcers. This should be reflected in the wording of the recommendation		
24	Recommendation 9	Organisation	access and cost is a restrictive issue, guidelines should contain funding options	A general statement about accessing funding has been added to the relevant 'Considerations for the Australian context' section. Otherwise we refer the reviewer to similar comments in points 18, 19 and 21.	Y, pages 24-25
25	Recommendation 10	Organisation	no mention of consideration of PAD before commencing treatment	We thank the reviewer for their suggestion. A statement has been added to reflect that the level of risk should be considered when selecting treatment, in particular PAD and referred the reader to the PAD guideline.	Y, page 26
26	Recommendation 10	Individual	"Treat... any fungal infection on the foot"; This does not specify between skin and nail. Nail fungal infections are very difficult to clear in people with diabetes. It is often not feasible due to mobility of patients to reach the toes, duration of treatment (Daily for 6-12mnths) and low success rates of every clearing it. Fungal nails rarely cause pathology in people with diabetes provided that the nails are kept thin (if they arent then subungual wounds can occur) therefore management rather than treatment is often advised. I would like to say that i fully support treating fungal skin infections as there is significant anecdotal and recorded evidence of fungal skin infections leading to ulcerations therefore fungal skin infections should be treated.	We thank the reviewer for their observation, however, we believe this is suitable in context of considering ulcer risk in this population and the available evidence.	N
27	Recommendation 11	Organisation	should we include this recommendation for which there is very limited access	We have in the discussion that access to services may be a barrier, and may not be suitable for all individuals, however, as there is evidence to support the use of this intervention, we have included it. Otherwise we refer the reviewer to a similar comment in point 21 in which we addressed access issues.	N
28	Recommendation 11	Individual	Develop a pathway for this to occur outside of the Tertiary Hospital setting but that is still funded through Medicare. Utilise Podiatric Surgeons to perform the procedure - this speciality are best placed to access the biomechamics of the foot post surgical and limit the potential of other mechanically induced pathologies	Thank you for this suggestion, however, as per similar comments in point 21, unfortunately this is not in the scope of this project. We do highlight though that we have developed a one-page clinical pathway incorporating all recommendations which may be of some use (Figure 2).	N
29	Recommendation 12	Individual	Potential foot surgeries are mentioned, if applicable. Yet, the subject of heel height in shoes is not mentioned, despite Achilles Tendon lengthening being considered. Even zero drop anatomically lasted, protective sports	We thank the reviewer for their observation and have adopted the evidence available based on the guideline methodology. We are	N

			shoes are a good starting point for unloading an overloaded forefoot, when in the wrong shoes.	unaware of peer-reviewed trials or other studies investigating such suggested footwear to prevent ulcers, whereas there are studies for Achilles tendon lengthening.	
30	Recommendation 12	Organisation	Could be rewritten as consider orthopeadic review	In the recommendations related to surgical procedures, we have clarified that procedures should be performed by “suitably qualified professionals who are able to demonstrate competence in the procedure and registered with the appropriate regulatory body”.	Y, pages 27-28
31	Recommendation 12	Individual	Imbed Podiatric Surgery in this process. The Biomechanics of these surgeries and the post surgical outcomes are at the forefront of the surgical approaches taken by this specialty	We refer the reader to a very similar comment in point 5 and 30 above.	Y, pages 27-28
32	Recommendation 14	Organisation	Expand recommendation to include "orthoses" i.e. "any increase in weight-bearing activity should be gradual, ensuring appropriate footwear and/or orthoses are worn"	We thank the reviewer for this good suggestion. We have now altered recommendation 14 to include footwear “and / or prescribed offloading device(s)”	Y, pages 7, 31-32, 46
33	Recommendation 14	Organisation	footwear appropriate for what?	We thank the reviewer for their comment. We have reviewed this and believe this is clear in context of the recommendation.	N
				Answered	11
				Skipped	8

OVERALL COMMENTS/FEEDBACK				
#	REVIEWER TYPE	REVIEWER COMMENT RECEIVED	CHAPTER GROUP RESPONSE	MANUSCRIPT CHANGE (& PAGE NUMBER IF CHANGED)
1	Organisation	I suggest the prevention guidelines table 5 explicitly state that: “ Involves at a minimum (but is not limited to): Screening for LOPS with a 10-g Semmes Weinstein monofilament (20) or if unavailable, use of the Ipswich Touch Test (21) and screening of vibratory sensation with a tuning fork or biothesiometer/neurothesiometer, if the monofilament testing is negative does not show LOPS.	We thank the reviewer for their suggestion. Table 5 is a reproduction of the IWGDF original document. Therefore its contents are reflective of this source.	N
2	Individual	As technological advances have changed, including in footwear & orthotic industries, it is now possible to help prevent foot ulcers and pressure lesions, as well as offloading the at risk/diabetic foot. Many of these changes have been seen in the field of orthotic and shoe sole “therapy”. When the first rocker footwear, Massai Barefoot Technology (MBT) of Switzerland arrived in Australia in 2004, commercially produced rockers were a new concept. This original “unstable” rocker because TGA approved as medical grade footwear here in Australia. In the intervening 17 years, many commercial copies and adaptions have been brought to market worldwide. It is also an integral feature of offloading CAM walker boots. Medical Grade footwear traditionally contains heel height (referred to as drop in the sports footwear industry) as well as in the shoes insole/footbed. E.g. Dr Comfort of USA specifically markets depth/wide footwear to the diabetic market with the in-shoe footbed being approximately 6mm in heel height. As we know with ulcers of the forefoot, heel height in shoes/orthotics is not ideal. Under Prevention Recommendation 12, potential foot surgeries are mentioned, if applicable. Yet, the subject of heel height in shoes is not mentioned, despite Achilles Tendon lengthening being considered. Even zero drop anatomically lasted, protective sports shoes are a good starting point for unloading an over-loaded forefoot, when in the wrong shoes. As well, proprioceptive facilitating orthotics are now available which work specifically to switch on foot intrinsics, while also offloading heel and forefoot. A model for diabetes also contains a material called Celliant in the top cover, which is clinically proven to increase oxygenation of tissues.	We thank the reviewer for their observation. As previously mentioned in point 29, we adopted the evidence available based on the guideline methodology. We are unaware of peer-reviewed trials or other studies investigating such suggested footwear to prevent ulcers, whereas there are these studies for Achilles tendon lengthening.	N
3	Individual	I welcome the use of this tool in guiding everyday practice.	We thank the reviewer for their kind comment	N
4	Organisation	The authors have done a great job addressing limitations for geographical rural/remote and Aboriginal Torres Strait Islander people but a lot is lost in text and repeated. ? Separate dot point summary of issues/challenges facing this subgroup to facilitate easier uptake?	We thank the reviewer for their suggestion and agree to some extent that there is some repetition, however, we believe that addressing the considerations to the Australian context for each recommendation is important, as there may be some clinicians only referring to a specific	N

			recommendation and not reading the guideline in its entirety. Thus, we have included considerations for those living in rural/remote regions of Australia and for those who identify as an Aboriginal and Torres Strait Islander person for each recommendation for this reason.	
5	Organisation	AOPA is pleased to see DFU guidelines take a holistic and well-evidenced approach. Our suggestions for the recommendations promote consistent use of terminology and ensure the recommendations accurately reflect the justifications provided. Orthoses were cited numerous times throughout the guidelines as an important feature in diabetic foot care. If the guidelines are to be used to help inform best-practice, programs and services, the recommendations need to clearly reflect the justifications.	We thank the reviewer for your comment. We have reviewed your comments and are satisfied that they are addressed in the revised paper. For example, to improve consistency and be applicable to the Australian context / terminology, we have changed the term 'custom-made insoles' to 'custom-made foot orthoses'.	Y, pages 6, 22, 25, 40, 45, 51-52
6	Organisation	It is really good to see the recognition of Aboriginal and Torres Strait Islander people in these guidelines. We should all be aiming at best practice interventions and these guidelines cover this. However it is important that it documented that many of the suggested prevention strategies (ie temperature testing, the use of medical grade footwear) are not realistic for many regional and remote patients, and I think this is clearly documented.	We thank the reviewer for their kind comment.	N
7	Individual	Thank you for completing this valuable and extensive body of work	We thank the reviewer for their kind comment.	N
8	Individual	Thank you for the great work and effort you have put in this document. It is much appreciated.	We thank the reviewer for their kind comment.	N
9	Individual	I think the off-loading/footwear section is where Australian care lacks-particularly when it comes to the time delays/patient-associated/Medicare funding costs of accessing medical grade footwear/specialist custom-made footwear. As a clinician, this is where I stumble-I don't know who I can access/put patients in touch with to get them	We agree and we refer the reader to our response in point 21.	N
10	Individual	Overall I support this draft and am very happy with it. I am being pedantic and would be happy with the draft in its current form to be our guidelines. I feel that in recommendation 4 the wording could be misleading and lead to potential harm. I also felt that recommendation 10 was not based off clear evidence/is actually feasible based on my clinical experience and readings of current evidence in regards to onychomycosis.	We thank the reviewer for their kind comments. In recommendation 4, we do not believe that these instructions on foot self-care will lead to any potential harm, therefore, no changes have been made. We refer the reviewer to the IWGDF prevention guideline and systematic reviews (see below) for a summary of the evidence surrounding recommendation 10. Bus SA, Lavery LA, Monteiro-Soares M, Rasmussen A, Raspovic A, Sacco ICN, et al. Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update). Diabetes Metab Res Rev. 2020;36 Suppl 1:e3269. van Netten JJ, Raspovic A, Lavery LA, Monteiro-Soares M, Rasmussen A, Sacco ICN, et al. Prevention of foot ulcers in the at-risk patient with	N

			diabetes: a systematic review. Diabetes Metab Res Rev. 2020;36 Suppl 1:e3270. van Netten JJ, Sacco ICN, Lavery LA, Monteiro-Soares M, Rasmussen A, Raspovic A, et al. Treatment of modifiable risk factors for foot ulceration in persons with diabetes: a systematic review. Diabetes Metab Res Rev. 2020;36 Suppl 1:e3271.	
11	Individual	Great interpretation of the IWGDF guidelines and not adopting some that would be impractical and difficult to implement in Australia (such as patient centered temperature testing)	We thank the reviewer for their kind comment.	N
			Answered	11
			Skipped	8