



Australian Government

Repatriation Medical Authority

REPATRIATION MEDICAL AUTHORITY

STATEMENT OF REASONS

SUBSECTION 196B(9), *VETERANS' ENTITLEMENTS ACT 1986*

**DECISION NOT TO AMEND THE BALANCE OF PROBABILITIES STATEMENT OF
PRINCIPLES CONCERNING PILONIDAL SINUS**

Instrument No. 28 of 2019

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PART I INTRODUCTION

1. The Repatriation Medical Authority (the Authority) received a request from the applicant, a person eligible to make a claim for compensation under section 319 of the *Military Rehabilitation and Compensation Act 2004* (MRCA), on 1 July 2021. The applicant requested a review, by way of an investigation, of the contents of the Statements of Principles (SOPs) concerning pilonidal sinus (Instrument Nos. 27 and 28 of 2019).
2. At its meeting on 4 August 2021, the Authority decided to conduct a review of the SOPs concerning pilonidal sinus, to determine whether the sound medical-scientific evidence (SMSE) provided a sufficient justification to amend these instruments in accordance with the applicant's request. A Notice of Investigation was published in the Government Notices Gazette of 31 August 2021, advertising a focussed review into 'prolonged sitting' as a factor in pilonidal sinus.
3. At its meeting on 10 November 2021, the Authority decided that the new SMSE, together with the SMSE it had previously considered, was sufficient to justify amendments to the reasonable hypothesis SOP concerning pilonidal sinus (Instrument No. 27 of 2019). However, the SMSE was not sufficient to justify amendments to the balance of probabilities SOP concerning pilonidal sinus (Instrument No. 28 of 2019). Consequently, this statement of reasons, and the associated declaration, address the Authority's decision not to amend the balance of probabilities SOP.

PART II BACKGROUND TO THE REQUEST

Factual background

4. The applicant requested that the Authority consider broadening the scope of the existing factors in paragraphs 9(2)(a) and 9(5)(a) of both SOPs concerning pilonidal sinus. Currently the factors read: 'for pilonidal sinus of the sacrococcygeal region only, driving or being a seated passenger in a motorised vehicle for an average of at least 20 hours per week for a period of at least three months, within the six months before the clinical onset / clinical worsening of pilonidal sinus.'
5. In making his request, the applicant questioned the Authority's decision not to include being seated in ships or vessels in this factor. He stated that 'the movement whilst underway and requirements of watchkeeping whilst at sea require extended periods of time seated for sometimes months at end'.

Ground upon which review was sought

6. The applicant sought a review of the SOPs concerning pilonidal sinus on the ground that being seated for extended periods in ships or other vessels is analogous to being seated in a motorised vehicle, and therefore the factor should be broadened to take this into account. Although the applicant did not provide any material in support of this ground of review, the Authority decided of its own initiative that it ought to review the contents of these SOPs.

PART III EVIDENCE PREVIOUSLY CONSIDERED BY THE AUTHORITY

7. At the time that the SOPs concerning pilonidal sinus (Instrument Nos. 27 and 28 of 2019) were determined, the Authority had before it information including:

- briefing papers prepared in December 2018 by a Repatriation Medical Authority medical researcher; and
- an extensive number of articles published in the peer-reviewed literature.

PART IV NEW INFORMATION CONSIDERED BY THE AUTHORITY

8. The applicant's request was considered. A discussion paper that considered the information supplied by the applicant and other available relevant sound medical-scientific evidence (SMSE) was prepared by a medical researcher for the Authority's meeting held on 4 August 2021.
9. A briefing paper providing a more detailed analysis of the current SMSE was prepared by a medical researcher for the Authority's meeting held on 6 October 2021, as part of the focussed review into 'prolonged sitting' as a factor in pilonidal sinus.

PART V SUMMARY OF NEW AND EXISTING EVIDENCE

10. Among 3 case-control studies considered in the 2019 review, two found significant positive associations with 4 to 6 hours sitting (Bolandparvaz et al 2012¹, Harlak et al 2010²) and one found a non-significant positive association with 6 hours of sitting (Yildiz et al 2017³). In two case series, 44% and 52% of cases reported a sedentary occupation (Sondenaa et al 1995⁴) or a great deal of time spent sitting (Clothier et al 1984⁵). Almajid et al (2017)⁶ did not find a significant risk of recurrence with prolonged sitting.
11. A search for any new SMSE published since the 2019 investigation identified three new case-control studies concerning sitting. Two studies were based on medical record review, so were limited by non-systematic collection of data about sitting times. Kanlioz et al (2021)⁷ found that time spent sitting was significantly different between those with pilonidal sinus and healthy controls. However, the actual difference was not large (median 9 hours versus 8 hours). Faraj et al (2020)⁸ found that students with pilonidal sinus were significantly more likely than controls to study on a hard seat.

¹ Bolandparvaz S, Moghadam Dizaj P, Salahi R, et al (2012). Evaluation of the risk factors of pilonidal sinus: A single center experience. *Turk J Gastroenterol*, 23(5): 535-7.

² Harlak A, Menten O, Kilic S, et al (2010). Sacrococcygeal pilonidal disease: Analysis of previously proposed risk factors. *Clinics*, 65(2): 125-31.

³ Yildiz T, Elmas B, Yucak A, et al (2017). Risk factors for pilonidal sinus disease in teenagers. *Indian J Pediatr*, 84(2): 134-8.

⁴ Sondenaa K, Andersen E, Nesvik I, et al (1995). Patient characteristics and symptoms in chronic pilonidal sinus disease. *Int J Colorect Dis*, 77(10): 39-42.

⁵ Clothier PR, Haywood IR (1984). The natural history of the post anal (pilonidal) sinus. *Ann R Coll Surg Engl*, 66: 201-3.

⁶ Almajid FM, Alabdrabalnabi AA, Almulhim KA (2017). The risk of recurrence of pilonidal disease after surgical management. *Saudi Med J*, 38(1): 70-4.

⁷ Kanlioz M, Ekici U, Tatli F, et al (2021). Pilonidal sinus disease: An analysis of the factors affecting recurrence. *Adv Skin Wound Care*, 34(2): 81-5.

⁸ Faraj FH, Baba HO, Salih AM, et al (2020). Risk factors of pilonidal sinus disease in preparatory school students; a case control study. *Ann Med Surg (Lond)*, 57: 46-8.

12. None of the new studies conducted multivariate analysis, so could have been confounded by obesity, hygiene or other factors. None of the new studies assessed the size of the relative risk. One of the studies (Ekici and Ferhatoğlu 2019⁹) compared cases with and without hypertrichosis and had no healthy control group. They found no difference for those who spent a long time sitting. These studies add only to a small extent to the body of evidence concerning the risk of pilonidal sinus with prolonged sitting.
13. The only study concerning sailors was identified in the previous investigation (Chijiwa et al 2006)¹⁰. This was a case series in which sitting was not specifically examined. However, the authors do state that pilonidal sinus was significantly more common among crew members than other personnel on shore duty. The authors noted that maritime crew tend to gain weight due to the lack of facilities for exercise and because of overeating, the chairs on ships have poor cushioning and bathing on board ships is not easy.
14. The available SMSE provides only limited evidence of a causal association between prolonged sitting and pilonidal sinus, whatever the context in which sitting occurs. It is unclear from the available evidence whether the predominant mechanism for the association of sitting with pilonidal sinus is driving, sitting for prolonged periods, sitting on hard surfaces, sitting on a vibrating surface or a combination of these. Any of these mechanisms could be confounded by obesity or poor hygiene as the studies do not control for these factors. The duration of periods of sitting in studies where this factors was significant was most commonly between 4 to 6 hours as a minimum. There is no specific evidence concerning total duration of exposure required to cause pilonidal sinus, although many of the studies involve occupational sitting (military drivers, students).

PART VI FINDINGS OF FACT

15. In light of the material discussed above, the Authority made the following finding of fact:
 - The body of available SMSE provides limited support for a causal association between prolonged sitting and the clinical onset and clinical worsening of pilonidal sinus. The SMSE provides slightly stronger support for a causal association between driving and the clinical onset and clinical worsening of pilonidal sinus.

PART VII REASONS FOR THE DECISION

16. The Authority was cognisant of the provisions of the *Veterans' Entitlements Act 1986* (VEA), and had particular regard to subsection 5AB(2) SMSE, section 5D injury/disease, and Part XIA.

SMSE is defined as follows:

*"Information about a particular kind of injury, disease or death is taken to be **sound medical-scientific evidence** if:*

(a) the information:

⁹ Ekici U, Ferhatoğlu MF (2019). Obesity, hypertrichosis and sex steroids: are these factors related to the pilonidal sinus disease? *Sisli Etfal Hastan Tip Bul*, 53(3): 263-6.

¹⁰ Chijiwa T, Suganuma T, Takigawa T, et al (2006). Pilonidal sinus in Japan maritime self-defense force at Yokosuka. *Mil Med*, 171(7): 650-2.

- (i) *is consistent with material relating to medical science that has been published in a medical or scientific publication and has been, in the opinion of the Repatriation Medical Authority, subjected to a peer review process; or*
 - (ii) *in accordance with generally accepted medical practice, would serve as the basis for the diagnosis and management of a medical condition; and*
- (b) *in the case of information about how that kind of injury, disease or death may be caused - meets the applicable criteria for assessing causation currently applied in the field of epidemiology."*

17. The Authority noted subsections 196B(7), 196B(8) and 196B(9) and section 196E, which relevantly provide:

196B(7)

If the Authority:

(a) *is asked under section 196E to review:*

- (i) *some or all of the contents of a Statement of Principles;*

[...]

(b) *thinks that there are grounds for such a review; [...]*

the Authority must, subject to subsection 196C(4) and section 196CA in a case where paragraph (a) applies, carry out an investigation to find out if there is new information available about:

- (d) *how the injury may be suffered, the disease may be contracted or the death may occur; or*
- (e) *the extent to which the disease, injury or death may be war-caused or defence-caused.*

196B(8)

If, after carrying out the investigation, the Authority is of the view that there is a new body of sound medical-scientific evidence available that, together with the sound medical-scientific evidence previously considered by the Authority, justifies the making of a Statement of Principles, or an amendment of the Statement of Principles already determined, in respect of that kind of injury, disease or death, the Authority must:

- (a) *[...]; or*
- (b) *make a determination amending the Statement of Principles determined under subsection (2) or (3) in respect of that kind of injury, disease or death; or*
- (c) *[...];*

as the case requires.

196B(9)

If, after carrying out the investigation, the Authority is of the view:

- (a) *that there is no new sound medical-scientific evidence about that kind of injury, disease or death; or*
- (b) *that the new sound medical-scientific evidence available is not sufficient to justify the making of a Statement of Principles, or an amendment of the Statement of Principles already determined in respect of that kind of injury, disease or death;*

the Authority must make a declaration in writing:

- (c) *stating that it does not propose to make a Statement of Principles, or amend the Statement of Principles already determined (as the case may be); and*
- (d) *giving the reasons for its decision.*

196E

- (1) *Any of the following:*
- (b) *a person eligible to make a claim for a pension under Part II or IV;*
 - (ba) *a person eligible to make a claim for compensation under section 319 of the MRCA;*
 - (c) *an organisation representing veterans*
- may ask the Repatriation Medical Authority:*
- (f) *to review the contents of a Statement of Principles in force under this Part.*

Basis for commencing review of an existing SOP

18. It is the applicant's request which prompted the Authority to consider whether to commence an investigation into this particular factor under s 196B(7)(a) of the VEA.¹¹ However, it was the Authority's own consideration of the evidence which ultimately led it to carry out an investigation under s 196B(7)(b) of the VEA.

Basis for amending an existing SOP

19. In forming any view during an investigation, the Authority may rely only on SMSE. Subsection 196B(8) provides that where there is a new body of sound medical-scientific evidence available that, together with the sound medical-scientific evidence previously considered by the Authority, justifies the amendment of a SOP the Authority is required to do so. On the other hand where there is no new SMSE or the new SMSE is insufficient to justify an amendment, subsection 196B(9) provides that the Authority *must* make a declaration stating that it does not propose to amend the SOP and give reasons for that decision.

Reasons for deciding not to amend an existing SOP

20. Together with its own expert knowledge, the Authority took into consideration:
- the applicant's request;
 - the information held by the Authority and obtained during its previous investigations leading up to the determination of the SOPs concerning pilonidal sinus (Instrument Nos. 27 and 28 of 2019);
 - the discussion paper prepared by a medical researcher for the August 2021 meeting;
 - the briefing paper prepared by a medical researcher for the October 2021 meeting.
21. As noted above, the applicant relied on the following ground for seeking a review of the contents of the SOPs concerning pilonidal sinus:
- being seated for extended periods in ships or other vessels is analogous to being seated in a motorised vehicle, and therefore the factor should be broadened to take this into account.

Is there new sound medical-scientific evidence?

22. Since its previous consideration of the SMSE in relation to using prolonged sitting as a factor in pilonidal sinus, new SMSE on this topic has been published. This SMSE is identified and summarised above.

¹¹ It not otherwise being an application within either subsection 196C(4) or section 196CA of the VEA.

Is the available sound medical-scientific evidence sufficient to justify amendment?

23. When considering which factors to include in SOPs for an injury, disease or death, the Authority is required to assess the SMSE against the two standards of proof set out in subsections 196B(2) and 196B(3), respectively. In the case of subsection 196B(2), the Authority must determine a SOP setting out the factors which must as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting the injury, disease or death with service. In the case of 196B(3), the Authority must determine a SOP setting out the factors which must exist before it can be said that, on the balance of probabilities, an injury disease or death is connected to service.
24. It is apparent that the VEA anticipates that the Authority will determine two types of SOP for a particular kind of injury, disease or death: a reasonable hypothesis SOP and a balance of probabilities SOP. Given that 'reasonable hypothesis' is a lower standard of proof than 'balance of probabilities', it is to be expected that the reasonable hypothesis SOP for a given condition will often (but not always) include more factors than the equivalent balance of probabilities SOP for the same condition. Whether a given factor is included in only the reasonable hypothesis SOP, or in both SOPs, will depend on the strength of the causal association which the SMSE shows between the factor and the clinical onset or clinical worsening of the condition.
25. The Authority is of the view that the currently available SMSE (including the new SMSE) is sufficiently strong to include a new factor for prolonged sitting on a hard or vibrating surface in the reasonable hypothesis SOP for pilonidal sinus. This is because the SMSE points to sitting on such surfaces for extended periods as a causal factor for pilonidal sinus, albeit in a limited way. This is sufficient for the factor to be included in the reasonable hypothesis SOP.
26. On the other hand, in order for a factor to be included in the balance of probabilities SOP, the SMSE must show that it is more likely than not that there is a causal association between the factor and the clinical onset or clinical worsening of the condition. In this case, the SMSE does not show that it is more likely than not that sitting on a hard or vibrating surface for extended periods is a factor for pilonidal sinus.

PART VIII CONCLUSIONS

27. Overall, for the reasons set out above, the available SMSE is sufficient to justify the amendment of the reasonable hypothesis SOP concerning pilonidal sinus to include factors for prolonged sitting on a hard or vibrating surface. However, the SMSE is not sufficient to justify the amendment of the balance of probabilities SOP in the same way.

PART IX DECISION

28. The Authority decided at its meeting on 10 November 2021 to amend the reasonable hypothesis SOP concerning pilonidal sinus (Instrument No. 27 of 2019) to include factors for prolonged sitting on a hard or vibrating surface. At the same meeting, the Authority decided not to amend the balance of probabilities SOP concerning pilonidal sinus (Instrument No. 28 of 2019).



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26 November 2021