ORIGINAL RESEARCH

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### Australian consensus: Treatment goals for moderate to severe psoriasis in the era of targeted therapies – Considerations for paediatric patients

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#### Abstract

**Background:** Treatment goals have been established in Australia to facilitate the management of adults with moderate to severe psoriasis. The Australasian College of Dermatologists sought to determine if and how these adult treatment goals could be modified to accommodate the needs of paediatric and adolescent patients.

**Methods:** A modified Delphi approach was used. Comprehensive literature review and guideline evaluation resulted in the development of statements and other questions to establish current clinical practices. Two rounds of anonymous voting were undertaken, with a collaborative meeting held in between to discuss areas of discordance. Overall, consensus was defined as achievement of  $\geq$ 75% agreement in the range 7–9 on a 9-point scale (1 strongly disagree; 9 strongly agree).

**Results:** Consensus was achieved on 23/29 statements in round 1 and 17/18 statements in round 2. There was a high level of concordance with treatment criteria in the adult setting. The limitations of applying assessment tools developed for use in adult patients to the paediatric setting were highlighted. Treatment targets in the paediatric setting should include objective metrics for disease severity and psychological impact on the patients and their family, and be based on validated, age-appropriate tools.

For affiliations refer to page 8.

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**Conclusion:** While the assessment, classification and management of moderate to severe psoriasis in paediatric patients aligns with metrics established for adults, it is vital that nuances in the transition from childhood to adolescence be taken into account. Future research should focus on psoriasis severity assessment scales specific to the paediatric setting.

#### K E Y W O R D S

adolescent, Australia, child, consensus, paediatric, patient acuity, psoriasis, quality of life, treatment goals

#### INTRODUCTION

Psoriasis is an immune-mediated inflammatory skin disease with a chronic, relapsing-remitting course. While approximately one-third of psoriasis cases commence during childhood, clinical features and environmental triggers may differ from those in adult patients, contributing to misdiagnosis and undertreatment.<sup>1-3</sup> Differences in clinical presentation compared with adults challenges diagnosis in the paediatric setting.<sup>4,5</sup> Paediatric patients frequently present with disease affecting the face, scalp and intertriginous skin.<sup>2</sup> They experience reduced quality of life, low self-esteem, stigmatisation, and impaired social relationships and reduced school productivity.<sup>2</sup> Anxiety and depression are prevalent,<sup>6</sup> and there is a significant association between childhood psoriasis and obesity, central adiposity and other cardiometabolic comorbidities.<sup>7</sup>

To improve quality of life and avoid potentially serious future complications, early diagnosis and access to effective treatment are critical. As in the adult setting, therapeutic options have expanded to include a number of systemic targeted therapies for moderate to severe paediatric psoriasis.<sup>8</sup> However, real-world data suggest that less than one-fifth of eligible paediatric patients have ever received targeted therapy.<sup>1</sup>

Therapeutic guidance specifically addressing the needs of paediatric patients is limited. A critical review of 33 psoriasis clinical practice guidelines identified only two directed specifically at paediatric patients.<sup>9</sup> Evidence-based treatment algorithms to accommodate the role of approved targeted therapies in the management of paediatric psoriasis have been published in Canada,<sup>10</sup> Germany<sup>3</sup> and Italy.<sup>11</sup> The latter additionally considers the implications of using tools developed for use in adults in the paediatric setting to assess and classify disease severity.<sup>11</sup> However, these guidance papers do not consider quantified treatment targets in the paediatric setting. Australian treatment goals, initially published in 2013<sup>12</sup> and updated in 2023,<sup>13</sup> have been

#### What this research adds

Goals for the assessment, classification and management of children and adolescents with moderate to severe psoriasis in Australian clinical practice align with those developed for the adult population, with the additional requirement to use age-specific tools to better understand the burden of disease on the patients and their family.

This paper expands on these, providing considerations for paediatric and adolescent patients.

#### MATERIALS AND METHODS

The methodology mirrored that of concurrent work undertaken in the adult setting.<sup>13</sup> Briefly, a comprehensive literature search was conducted (Table S1), two of the authors (PF, CB) reviewed the search outputs and considered them in context with published guidelines and consensus opinions,<sup>10,11,14–27</sup> and developed a framework of guidance statements of relevance to the Australian setting. In April 2022 the authors (6 Dermatologists, 4 Paediatric Dermatologists, 2 Paediatric Dermatology Nurses, a Dermatology Registrars, a Junior Medical Officer, a General Practitioner, and a patient representative) were invited to respond to a 43-question survey, which included 29 guidance statements. The authors voted on using a modified Delphi process, by assigning their level of agreement with the statements using a 9-point scale (1 strongly disagree; 9 strongly agree). Consensus was defined as achievement of  $\geq$ 75% agreement in the range 7–9. A medical writer generated an overall strength score (the median score) and a level of consensus (proportion of voters with a score of 7-9) for each guidance statement. All authors discussed the voting results via a hybrid meeting, during which they had the opportunity to review the guidance statements and make suggestions or changes. Following this, a further round of voting took place (November 2022) on an 18-question survey comprising 12 modified and six new guidance statements. At the completion of both voting rounds, final strength scores and consensus scores were assigned to each guidance statement.

#### RESULTS

#### Voting analysis

During voting round 1, participants answered all 43 survey questions and consensus ( $\geq$ 75%) was achieved on 23/29 clinical statements. There was a high level of concordance between the paediatric and adult<sup>13</sup> round 1 voting outcomes (Table 1). During voting round 2, an expanded panel of 16 participants answered the follow-up survey and consensus ( $\geq$ 75%) was achieved on the majority (17/18, 94%) of clinical statements. A detailed summary of the final clinical statements and voting outcomes is provided in Table S2.

#### **Definition and classification**

There was very strong consensus (strength: 8.2, consensus: 90%) that patients could be grouped dichotomously as mild/mild to moderate or moderate to severe/severe and that quantitative metrics (psoriasis area and severity index [PASI], body surface area [BSA], dermatology life quality index [DLQI], physician's global assessment [PGA] and disease in specific high impact sites) could be used to further guide classification based on disease severity. This concurs with the International Psoriasis Council,<sup>19</sup> the recently updated Australian adult treatment targets,<sup>13</sup> and is in concert with guidance found in published paediatric treatment algorithms.<sup>10,11,14,18</sup> However, the group did not reach consensus on the statement that "the definition and classification of psoriasis for paediatric patients should be the same as it is for adults" (5.8, 60%). During re-voting, the statement "PASI and BSA are not validated for use in children and young people" also did not achieve consensus (6.9, 56%), but there was very strong consensus (8.3, 94%) that age-appropriate, validated assessment scales should be used to determine severity when assessing paediatric patients.

#### **Treatment** goals

There was unanimous agreement with the EuroGuiDerm Guideline<sup>23</sup> that the availability of new targeted therapies supports the possibility of attaining higher treatment outcomes and that prior definitions of treatment success

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 Image: Comparison of round 1 voting outcomes: Paediatric versus adult<sup>a</sup> treaters.

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	Number (%) o statements	of
Both voting groups agreed:	23 (80%)	
Both voting groups disagreed:	3 (10%)	
Only the paediatric voting group disagreed:	3 (10%)	
	Voting outcor % consense	nes (score, us)
	Adult	Paediatric
Statements with which both voting g	groups disagreed	l:
There is a strong correlation between PASI and PGA	6.3, 54%	6.3, 60%
Specified criteria for a lack of response/therapy failure	6.7, 54%	5.8, 50%
'Conventional' systemic agents should be first-line when choosing a systemic therapy	5.8, 54%	6.3, 60%
Statements with which only the paed disagreed:	diatric voting gro	oup
The definition and classification of psoriasis for paediatric patients should be the same as it is for adults	6.8, 77%	5.8, 60%
How strongly do you agree with adopting a 'treat-to-target' approach?	7.4, 85%	6.9, 50%
How strongly do you agree with the need for there being options in a treat-to- target approach (e.g. PASI, PGA, BSA, to accommodate the physician's choice of criteria)?	7.8, 92%	7.2, 70%

<sup>a</sup>Data for adult treaters has been sourced from Foley et al, 2023.<sup>13</sup> Abbreviations: BSA, body surface area; PASI, Psoriasis Area and Severity Index; PGA, physician's global assessment.

(for example a 75% reduction in PASI [ $\Delta PASI \ge 75\%$ ] or a 50% reduction in PASI [ $\Delta PASI \ge 50\%$ ] and a DLQI $\le 5$ ) were now outdated (very strong consensus, 7.6, 90%). The concept of adopting a treat to target approach,<sup>20,28</sup> did not achieve consensus in the first-round voting (6.9, 50%). The primary reason was because clinicians managing paediatric patients take a more individually tailored approach to develop personalised care plans. During re-voting, there was unanimous consensus (8.5, 100%) that in the paediatric setting, treatment targets should be patient-centric and based on a composite of outcomes that take the individual's needs into account.

There was some agreement on the need for options for the use of a variety of metrics when considering a treat-to-target approach, but this did not reach consensus (7.2, 70%). The panel identified that subjective perceptions of disease severity may be disproportionate in paediatric patients compared with adults and unanimously agreed (8.6, 100%) that targets for treatment response should include age-appropriate validated scales<sup>29–31</sup> to determine disease impact and account for the burden of treatment on the family and/or carers, which can be substantial.<sup>32</sup> There was agreement (high consensus, 7.7, 80%) that health-related quality of life (HR-QOL) should be accounted for in disease management targets.<sup>23,24</sup> The DLQI and the children's dermatology life quality index (CDLQI)<sup>29</sup> were identified as the most frequently used scales for this purpose in clinical practice.

#### Treatment response criteria

In concert with others,<sup>20,23,24,28</sup> including the recently updated Australian adult treatment targets,<sup>13</sup> and given the availability of new treatments for moderate to severe psoriasis, there was very high consensus (8.0, 90%) that a 90% reduction in PASI ( $\Delta$ PASI90) better reflected a 'clear'/'almost clear' status than did  $\Delta$ PASI75. The group agreed that complete skin clearance (defined as PGA=0) was an important treatment goal from the patient's perspective (very strong consensus: 8.0, 90%).<sup>33</sup>

There was unanimous consensus that treatment modification ought to be considered in patients who have an inadequate response (8.6, 100%) and that treatment

TABLE 2 Treatment response criteria for the paediat	ric setting.
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should be continued in patients who achieve an adequate response (8.1, 81%),<sup>24</sup> noting that in such cases there is a need for ongoing reassessment of treatment suitability. There was very strong consensus (7.7, 90%) that time to onset is therapy dependent, and that during the induction phase of a new treatment, the initial response assessment interval should take this into account.<sup>23</sup> In clinical practice, paediatric assessments typically occur either every 6 months or as directed by the therapy.

In the first-round voting, there was a high level of consensus (7.5, 90%) with the response criteria that are utilised in the adult setting. However, the need to modify the target based on the patient population was discussed, and there was strong agreement that any criteria stated should account for disease severity and psychological impact on the patients and their family, and be based on validated, ageappropriate tools. After revision of the statements, in voting round 2, there was unanimous consensus (8.7, 100%) on the need to consider disease severity and psychosocial impact on both the patients and their family/carer in treatment response criteria. Consensus was reached on criteria for adequate and inadequate treatment responses, matching those proposed in the adult setting,<sup>13</sup> but modified to utilise agespecific tools for HR-QOL impact (Table 2, Figure 1).

#### Management framework

Efficacy, safety and individual patient needs were highlighted as the top three determinants relied on when

Adequate response	Inadequate response
Treatment should be <i>continued</i> <sup>a</sup> in patients who achieve an <i>adequate</i> response	Treatment should be <i>modified</i> <sup>a</sup> in patients with an <i>inadequate</i> response
<ul> <li>An adequate response to treatment is defined as either:</li> <li>Absolute PASI ≤3</li> <li>PGA=0/1</li> </ul>	<ul> <li>An inadequate response to treatment is defined as either:</li> <li>Absolute PASI &gt;6</li> <li>PGA ≥2</li> </ul>
<ul> <li>If neither of these criteria are met an age appropriate QOL measure should also be considered</li> <li>Absolute PASI 3-6 or PGA=2 with one of the following: <ul> <li>Age &lt;4 years: IDLQI<sup>30</sup></li> <li>Age 4-12 years: CDLQI<sup>29</sup></li> <li>Age12-17 years: APso-QoL<sup>31</sup></li> </ul> </li> </ul>	<ul> <li>If neither of these criteria are met an age appropriate QOL measure should also be considered</li> <li>Absolute PASI 3-6 or PGA = 2 with one of the following:</li> <li>Age &lt;4 years: IDLQI<sup>30</sup></li> <li>Age 4-12 years: CDLQI<sup>29</sup></li> <li>Age12-17 years: APso-QoL<sup>31</sup></li> </ul>
<ul> <li>If ΔPASI is being used as the metric, the corresponding criteria are:</li> <li>ΔPASI ≥90</li> <li>ΔPASI ≥75 &lt; 90 AND absolute PASI ≤3</li> <li>ΔPASI ≥75 &lt; 90 AND absolute PASI &gt;3 with age appropriate QOL measure (as above)</li> </ul>	<ul> <li>If ΔPASI is being used as the metric, the corresponding criteria are:</li> <li>ΔPASI ≥75 &lt; 90 AND absolute PASI &gt;3 with age appropriate QOL measure (as above)</li> </ul>

<sup>a</sup>Continuation/discontinuation is modulated by toxicity, contraindications, patient preferences and may also include adding topical therapies, adding other systemic treatment, increasing dose and/or frequency of a treatment, or admission to hospital.

Abbreviations: APso-QoL, Adolescent Psoriasis Quality of Life instrument<sup>31</sup>; CDLQI, Children's Dermatology Life Quality Index<sup>29</sup>; IDLQI, Infants' Dermatology Life Quality Index<sup>30</sup>; PASI, Psoriasis Area and Severity Index; PGA, physician's global assessment; QOL, quality of life.





FIGURE 1 Considerations for paediatric treatment goals for with psoriasis in Australia.

individualising management plans for patients. There was unanimous consensus that targeted therapies should be initiated first-line in cases of severe, active disease (8.6, 100%) and in cases where response to conventional systemic agents is inadequate or they are not tolerated (8.1, 100%),<sup>23,24</sup> but there was discordance (6.3, 60%) with the requirement to use conventional systemic agents before moving onto targeted therapy. Specific considerations in the paediatric setting included the value of patient-reported outcome measures to provide additional relevant information to facilitate individualised treatment plans (7.8, 80%), particularly the use of validated tools to assess the impact on family quality of life (8.6, 100%), and the need for a multidisciplinary team approach in patients with comorbidities (8.5, 100%).

#### DISCUSSION

Paediatric psoriasis places a considerable burden on both patients and their families, but guidance on its assessment and management is limited. The primary aim of this work was to determine whether current Australian consensus treatment goals for adult patients with moderate to severe psoriasis<sup>13</sup> need to be modified to accommodate the needs of paediatric and adolescent patients and, if so, how that could be achieved. Overall, there was a high degree of concordance between the adult and paediatric consensus statements; the key theme of divergence centred largely

on the limitations of applying assessment tools developed for use in adult patients to the paediatric setting.

#### Children are not just small adults

Plaque psoriasis is the most common subtype of psoriasis in children, affecting around 75% of children,<sup>34</sup> with scalp, genital and facial involvement also frequently observed. However, at initial presentation, the distribution, morphology and clinical symptoms of psoriasis differ depending on age and can evolve over time.<sup>35</sup> Infants typically present with 'diaper rash', characterised by sharply demarcated, minimally elevated erythematous plaques involving the inguinal folds. In younger children, erythematous plaques with overlying white scale are frequently observed to be thinner and smaller than in adults, and tend to develop more often on the scalp, face and flexural areas. In school-aged children, disease involvement in the ear canal, upper eyelids and nails is common, while in adolescents, chronic plaque psoriasis resembles that in adults with well-defined erythematosquamous papules or plaques with overlying silvery-white scale.<sup>2</sup> Preliminary diagnostic criteria with sufficient sensitivity and specificity to inform diagnostic accuracy in paediatric patients have been proposed to help guide the clinician {Burden-Teh, 2019 #1934;Burden-Teh, 2022 #1933}.

Group discussion revealed that while classification definitions based on severity are currently viewed as

Modifications for the paediatric setting

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Treatment outcomes mutually agreed with the family as part of an individualised care plan.

Substitute Dermatitis Quality of Life Index with an age-appropriate disease impact score:

- Age <4 years: Infants' Dermatitis Quality of Life Index
- Age 4-12 years: Children's Dermatitis Quality of Life Index
- Age 12-17 years: Adolescent Psoriasis Quality of Life instrument

Use validated tools to quantify impact on the family, particularly for young children.

Be sensitive to the changing needs of adolescent patients.

being the same in adults and children for management purposes, there is limited empirical data to support this, thus raising concern that extrapolations could be made without sufficient data to support them. Opinions on the use of PASI and BSA in children and adolescents were divided. These measures have been validated in adults but do not take into consideration specifics related to paediatric patients, such as the progression of BSA according to age. Scales validated in adults may be of utility in older children and adolescents, but younger children (up to the age of 10 years<sup>36</sup>) have different proportional surface areas making their application in this age group less accurate. The need for user-friendly, validated assessment scales for psoriasis severity assessment in the paediatric setting was identified as a high priority area for further research. In the absence of such scales, the use of PASI and BSA remains applicable for the purposes of clinical decisionmaking,<sup>11</sup> noting that these measures will likely afford less accuracy in children under the age of 10 years.

## Cautions with identifying and scoring disease flares

Psoriasis flares can be provoked by a number of nonspecific factors. In children flares are most frequently associated with stress/anxiety, trauma (Koebner phenomenon) and infections (viral, streptococcal),<sup>3,37</sup> and there is a need to differentiate sudden worsening due to a triggered immune stimulation from an overall progressive disease worsening. In the adult setting PASI and DLQI scores can be used to monitor patients for the occurrence of acute disease flares. For example, in the clinical trials setting criteria such as a single PASI score >5 and/or a single DLQI score >5 have been used to indicate a short disease flare while on treatment.<sup>38</sup> While PGA could be used as an alternative to PASI for measuring disease severity and providing an objective measure of disease response, it is too blunt an instrument to detect disease flares. In the paediatric setting, BSA in combination with consideration of the pattern of disease and sites of involvement may be a more suitable means of evaluating a flare and should ideally be considered before changes to treatment plans are considered.

# Navigating the transition from childhood to adolescence

While there was group consensus that treatment response criteria should include measures of both severity and impact, it was also recognised that impact measurement scales should ideally account for age-related nuances of the population being treated. In younger children, the therapeutic strategy is more likely to focus on providing symptomatic relief, while in older children, concerns about cosmetic appearance may become a higher priority. Similarly, concerns regarding high impact sites are dependent on the individual and their level of body awareness. It is recognised that the transitional period from child to adolescent presents its own unique set of challenges for the clinician.<sup>39</sup> There is a shift in the management dynamic, with a greater need to account for patient disengagement, potential parental conflict, and a widening burden of disease impact encompassing social interactions, schooling, absenteeism, body awareness, sexuality, and stigmatisation.<sup>39</sup>

The CDLQI was adapted from the DLQI to meet the needs of children, however it has been validated for use only in children aged 4-12 years.<sup>29</sup> A 'cartoon' version of the CDLQI is available for younger children, facilitating their ability to self-report; nevertheless, questions remain as to the suitability of the CDLQI as an HR-QOL assessment tool for children outside of the validated age ranges. For children below the age of 4 years, the Infants' Dermatology Life Quality Index (IDLQI) has been evaluated in atopic dermatitis,<sup>30</sup> but not in psoriasis. Given the young age of the patients, consideration could be given to either substituting or combining this measure with a validated family impact measure. A variety of tools exist that quantify the impact of disease on other family members, including the Family Dermatology Life Quality Index (FDLQI)<sup>40</sup> and the Dermatitis Family Impact Questionnaire (DFIQ),<sup>41</sup> but the Psoriasis Family Index  $(PFI-14)^{42}$  is the only tool specific to psoriasis.

The question of how to assess HR-QOL in adolescent patients takes on added importance considering research demonstrating specific issues, such as an increased emphasis on appearance and social acceptance, that are distinct from those of younger children and of adults.<sup>43</sup> Close correlation has been observed between the CDLOI and the DLQI in patients aged 16-17 years with psoriasis, but statistically significant discrepancies in mean scores were found to be caused by differences in questions relating to sleep and sexual difficulties.<sup>44</sup> A validated adaptation of the Skindex questionnaire for use in adolescents aged 12–17 years – Skindex-Teen – is available,<sup>45</sup> but remains underutilised in clinical practice.<sup>43</sup> Similarly, the Teenagers' Quality of Life (T-QoL) instrument measures the secondary impact of skin disease in adolescents (12-19 years) but its validation study was skewed towards patients with acne and only 4% of the study population had psoriasis.<sup>46</sup> A more recent alternative, the Adolescent Psoriasis Quality of Life instrument (APso-QoL), designed for use in daily clinical practice, has undergone preliminary validation in adolescents aged 12-17 years.<sup>31</sup> This new 17-item assessment tool incorporates separate assessment scales for psychosocial impact and physical symptoms and treatment.

#### Management considerations

In the paediatric setting treatment, outcomes are typically mutually agreed with the family as part of an individualised care plan and not based on the achievement of a single metric. Treatment planning should take longterm disease course (paediatric to adolescent to adult) and prognosis into consideration. A proactive approach encompassing education, avoidance of trigger factors, topical therapy including the use of emollients, early management of disease flare-ups, and use of systemic therapies is advocated.<sup>47,48</sup> Educating the patient and family on the chronicity of psoriasis, triggering factors, and treatment modalities are all important adjuncts to prescribing. There is the potential for conflict to arise with adolescents if their views are different to those of their family. Treatment approaches should be discussed with the patient and the appropriate adult responsible for their care. In addition to this, where practicable, reserving time for a discussion with adolescent patients alone creates an opportunity to educate them about their disease and its treatment, and may provide insights that can help resolve these issues.<sup>48</sup>

Treating paediatric psoriasis can be challenging and requires careful compliance to a specific treatment regimen. Several factors need to be considered when selecting a specific treatment, including age, quality of life, severity of psoriasis, location of psoriasis, type of psoriasis, tolerability, safety and patient preferences. The panel felt that there was little role for conventional systemic treatments in paediatric patients, noting that use is associated with unique challenges of conventional systemic therapies in the paediatric setting such as logistical burdens, need for carer support and time off school (or work for carer).<sup>49</sup> There was strong support for initiating targeted therapy first-line in patients with severe disease potential. The rationale for interceding early in the immunologic psoriatic process is driven by the desire to impede 'immunological scar' development to reduce long-term disease burden.<sup>50</sup> More research is needed, with current experience limited primarily because paediatric patients are not being treated early enough.

Paediatric patients with psoriasis are at increased risk of comorbidities including psoriatic arthritis,<sup>51</sup> metabolic syndrome (obesity, diabetes, hypertension, and dyslipidaemia)<sup>7,52,53</sup> and mental health issues (anxiety, depression).<sup>6</sup> Despite reaching consensus that the impact of comorbidities is an important consideration of disease control, Australasian Journal of Dermatology

group discussion highlighted the potential for ambiguity, stressing that it could wrongly imply that a treatment is not adequately controlling disease if it is not also limiting the impact of these comorbidities. The main limitation of this work was that it did not also encompass the management of specific comorbidities. There was unanimous consensus that a multidisciplinary team approach should be undertaken to manage paediatric patients with comorbidities. Clinicians should maintain a high index of suspicion for comorbidities to ensure appropriate management. Detailed reviews and screening recommendations in paediatric patients can be found elsewhere in the literature.<sup>11,15,54,55</sup>

Australian treatment goals have been established for of adults with moderate to severe psoriasis.<sup>12,13</sup> This is, to our knowledge, the first time that specific treatment targets have been expanded to account for the unique considerations for the management of paediatric and adolescent patients with psoriasis. While the assessment, classification and management of moderate to severe psoriasis in paediatric patients align with the metrics established for adults, it is vital that nuances in the transition from childhood to adolescence be taken into account. Future research should focus on psoriasis severity assessment scales specific to the paediatric setting.

#### AUTHOR CONTRIBUTIONS

Conceived the concept of this work and designed the study: Peter Foley, Christopher Baker. Involved in the conduct of the study and contributed to data collection: Peter Foley, Christopher Baker, Amelia James, David Orchard, Monisha Gupta, Patrick D Mahar, Nicholas Manuelpillai, Saxon D Smith, John C Su, Li-Chuen Wong, Gayle Fischer, Morton Rawlin, Gillian Marshman, Murray Turner, Emma King, Robyn Kennedy. Contributed to data analysis and/or interpretation of the results: Peter Foley, Christopher Baker, Amelia James, David Orchard, Monisha Gupta, Patrick D Mahar, Nicholas Manuelpillai, Saxon D Smith, John C Su, Li-Chuen Wong, Gayle Fischer, Morton Rawlin, Gillian Marshman, Murray Turner, Emma King, Robyn Kennedy. Manuscript writing and revision for intellectual content: Peter Foley, Christopher Baker, Amelia James, David Orchard, Monisha Gupta, Patrick D Mahar, Nicholas Manuelpillai, Saxon D Smith, John C Su, Li-Chuen Wong, Gayle Fischer, Morton Rawlin, Gillian Marshman, Murray Turner, Emma King, Robyn Kennedy. Approved the final version of the article: Peter Foley, Christopher Baker, Amelia James, David Orchard, Monisha Gupta, Patrick D Mahar, Nicholas Manuelpillai, Saxon D Smith, John C Su, Li-Chuen Wong, Gayle Fischer, Morton Rawlin,

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#### CONFLICT OF INTEREST STATEMENT

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#### TRANSPARENCY DECLARATION

Peter Foley (the manuscript's guarantor) affirms that the manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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#### SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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