MSAC Application 1344: Australasian College of Podiatric Surgeons' pre-MSAC comments on the ESC Review

The Australasian College of Podiatric Surgeons (ACPS) appreciates the opportunity to provide comments on the ESC Review for the College's Application 1344. Much of the Review commentary appears to be based upon misinterpretation of the College's Application and/or relies upon factual inaccuracies which the College addresses in the body of this Response.

The College has found that this has been a consistent difficulty in progressing this Application.

Similarly, the *Critique of the Assessment Report Submitted to the MSAC,* received by the College in January, contained factual errors and resulting interpretative bias. These were dealt with comprehensively by the College's Response at that time. Much of the College's Response to the *Critique* is also relevant to the ESC Review.

The College is concerned that, despite identifying a number of errors in fact and interpretation in the *Critique* of our Application in January, many of these errors are repeated in the ESC Review. From a process perspective, this is deeply concerning as it impacts significantly the assessment of the College's Application and undermines appropriate and due process.

Given the serious concerns surrounding the approach the *Critique* and ESC Review have utilised, in this response the College outlines for MSAC a contextual review of research difficulties in surgery and a policy review in respect to Application 1344 as well as a specific rebuttal of concerns raised in the ESC Review.

Levels of Evidence in Surgical Intervention.

The *Critique* and ESC Review have highlighted concerns in relation to the level of research that has been presented as evidence to support the College's Application. In its response to the *Critique*, the College highlighted the appropriateness of such research techniques citing the accepted difficulty of conducting randomised clinical trials in the surgical field and difficulties when comparing one discipline to another. This position regarding the clinical evidence has the considered support of a number of highly regarded senior researchers in musculo-skeletal lower limb interventions. These include Professor Hylton Menz, Senior NHMRC Research Fellow, Latrobe University, and Dr Paul Bennet, Faculty of Health, Queensland University of Technology.

In the peer review literature, the ethical and other challenges of RCTs in surgery is reported by Ashrafian[1] and Garas,[2] both who both highlight these challenges for surgery in general, whilst Lim et al[3] highlight the limited support for randomised trials in orthopaedic surgery. The reasons for this are multifactorial: historical, as many surgical procedures developed gradually without trials; patient-related, with many patients not wanting their surgery to be randomly selected; and the fact that operative variability makes standardisation difficult. In the absence of RCTs, it is usual practice to rely on 'lower level' evidence, such as case series and audits, a practice followed in the College's Application.

Podiatric surgeons face the same challenges in trial design as all surgical disciplines. The evidence base for podiatric surgery is stronger than the orthopaedic comparator and there is no evidence that podiatric surgery is in any way inferior to procedures performed by orthopaedic surgeons.

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[1] Ashrafian H, et al (2010) "Evidence Based Surgery", in Athanasiou T, et akl (eds),**Key Topics in Surgical Research and Methodology,** Springer- Verlag Berlin Heidelberg., pp. 12-16

[2] Garas G,et al (2012) **Evidence-Based Surgery: Barriers, Solutions, and the Role of Evidence Synthesis,** World J Surg, 36:1723–1731

[3] Lim HC, Adie S, Naylor JM, Harris IA (2014) **Randomised Trial Support for Orthopaedic Surgical Procedures**. PLoS ONE 9(6): e96745. doi:10.1371/journal.pone.0096745

Clarification of the policy context

The policy context of this Application is important to understand as it points to the relevance and appropriateness of the College's Application. This context is reflected in the following clarification points.

Australian Podiatric Surgeons

- Are trained, licensed and accredited to perform reconstructive foot and ankle surgery.
- Podiatric surgeons have been performing surgery in Australia under state law and regulation since the 1950s and ratification and recognition of their work has occurred in national legislation and regulation over the past 10 years.
- Are recognised and accepted by international peers and health systems.
- Are the only group of surgical practitioners (medical or podiatric) in Australia, USA and UK who currently operate outside their respective national health funding schemes.

Medicare

Medicare provides rebates for medical and surgical services in Australia. These rebates are not limited to provision of services – surgical or otherwise – by practitioners registered with the Medical Board of Australia and oral surgeons and optometrists, for example, receive Medicare rebates.

The effect of Medicare funding is wide-reaching and would increase opportunities for enhanced collaboration in patient management and improved access to health services. Medicare funding would also ensure availability of training opportunities and support sustainability of the surgical workforce.

Podiatric surgeons are not currently included within this policy and practice framework.

Podiatric Surgeons and Medicare

Support and implementation of the College's Application will:

- Normalise the practice of podiatric surgery in Australia.
- Enhance patient safety and access.
- Improve collaboration.
- Improve capacity for monitoring of outcomes.

The ESC Review

The Review, whilst acknowledging many positive attributes of the Application, demonstrates a lack of clarity or misinterpretation of the data and the underlying policy concepts presented above.

The Review highlights some ***Key Areas of Concern*** that are directly addressed below:

Case mix (population)

The College is unclear how the Review reaches the conclusion that the case mix between podiatric surgeons and the comparator cannot be compared especially as, even within the Review, there is a lack of concordance regarding this point and with the data. At one point, the Review states that podiatric surgeons operate on younger less complex patients (p. 15) and then, on the following page, states the opposite – that podiatric surgeons treat predominantly older patients (p. 16).

The data, both from the literature and the ACPS' 2013 National Audit, clearly indicate that podiatric surgeons treat a similar case mix in terms of age and co-morbidities to that of orthopaedic surgeons. This data is described in the ESC *Critique* as 'robust' (p. 26).

Recent data from the ACPS' 2014 Interim Audit again reflects this. A summary of the Interim Audit findings

as reported at an international conference: www.scpod.org/2014-college-of-podiatry-conference-and-exhibition/2015-directorate-of-podiatric-surgery-conference/.

Major elements of the College's 2014 Interim Audit include:

- Migration to an on-line audit tool that further minimises the potential for data entry error and increases the sensitivity of data capture.
- A significant increase in the number of co-morbidities captured when compared to the 2013 National Audit as a result of this increased sensitivity.
- Complications rates remain below rates of foot and ankle surgery complication reported in the literature.
- The total number of procedures increased by 1.5%.

This additional data supports the figures and assumptions underpinning the College's Application.

Patient identification and ongoing monitoring

The Review expresses a key concern that it will not be possible to monitor case mix if the College's Application is successful.

- The College understands that an appropriate administrative mechanism could be put in place to clearly identify which procedures have been performed by podiatric surgeons versus other providers. The College would welcome the opportunity to work with relevant bodies to identify this mechanism.
- Such action will facilitate ongoing monitoring and assessment based on evidence.

Evidence for clinical safety & effectiveness.

The ESC Review does not appear to have referenced the Applicant's Response to the *Critique*.

The College's Response to the *Critique* detailed some significant misinterpretation and errors within the *Critique* in relation to the research data submitted regarding clinical safety and effectiveness. This research data resulted in solid and appropriate evidence that substantiates the safe and quality delivery of services by podiatric surgeons. These significant facts have not being adequately recognised and acknowledged by the *Critique* or the Review. The pertinent section of the College Response to the *Critique* in relation to evidence is provided again at Appendix One for the convenience of MSAC members.

Further, the ESC Review does not acknowledge (unlike the *Critique)* the inherent difficulties encountered in research design. As noted in the *Critique* and above, random controlled trials are difficult to institute when comparing surgical disciplines (p. 15). The Review however does not take this into consideration nor the consequences of this which is that:

- Ongoing reporting of case series, prospective outcome studies and audits is the most achievable trial design for podiatric surgeons within the current funding models; and
- Comparative prospective research is unlikely to occur when comparing competing professions in the private sector.

- The evidence presented in the submission is significant and substantially more extensive than the evidence base for the comparator.
- Based on validated audit data, there is no support for the ESC Report's view that podiatric surgeons are working on less complex conditions.
- The lack of evidence for the comparator is a serious limitation in respect of the current funding model.
- The College has the ability and is willing to commit to undertaking further research regarding safety and efficiency within a common funding model following a positive MSAC recommendation of the Application.

Issues of policy regarding substitution.

The College's Application describes a clinical model that is responsible, collaborative and will involve elements of both additional work and substitution.

Clinical effectiveness

See comments in relation to evidence for clinical safety above.

Further, however, on page 16, the ESC Review noted that 63% of podiatric surgeons' patients elect not to proceed with recommended surgery and questioned why this is the case, indicating concern that this could not be measured. This is actually not the case and, as reported on page 110 of the College's Application, 63% of patients do not proceed with recommended podiatric surgery due to funding issues. This represents a significant concern in respect to unaddressed disease burden in the community.

Other important areas identified by ESC

Economic assessment

The ESC Review, although acknowledging that a cost analysis has been conducted, comments that a full economic analysis has not been performed. In fact a full economic analysis has been performed, in 2008, and the underpinning principles have not altered.

The College has provided a copy of the full economic analysis conducted by Access Economics in 2008 to the MSAC Secretariat and referenced it in our Application. This report, which can be accessed at http://acps.edu.au/cms_files/Podiatric_Surgery_Report220908b.pdf, demonstrates that:

- The use of existing podiatric surgeon workforce on 2008 figures would save the Commonwealth Government $70 million per annum.
- Using orthopaedic surgeons as the comparator, this report analysed Cost Effectiveness Analysis, Cost Benefits Analysis, Disability Life Years, Direct Health Costs and Indirect Costs such as productivity. Podiatric surgeons were found to have higher positive indicators than orthopaedic surgeons across all measures.

Budgetary impact

The ESC Review questions the budgetary impact of the College's Application.

There is no evidence to suggest that the budget assumptions provided in the Application are unreasonable.

Given the timeframes involved in the recruitment and training of podiatric surgeons, ESC's suggestion that there may have been underestimates of podiatric surgeon numbers is unfounded. The College is aware of all future podiatric surgeons currently training in Australia and these are factored into the Application's financial and other forecasts.

Clinical Need and Demand

The ESC Review questions the level of unmet demand and the evidence for need.

Ongoing need for a flexible workforce to address the issues facing the Australian population in delivery of health services is well established. The College has addressed this in the original application and it continues to be evidenced by government reports, including the 2015 Intergovernmental Report (pages 57-63) which highlights the increasing burden that health costs represent. This burden is best addressed through efficiency gains driven by innovation.

The College's Response to the *Critique* outlined:

- Increasing need for surgical services for foot and ankle (Access Economics 2008).

- Concerns about the size of the orthopaedic workforce.
- Ongoing growth in elective surgical waiting lists.

It is not clear to the College how ESC can consider that need and unmet demand are not issues.

Other areas of uncertainty

The ESC Review mentions other areas of uncertainty in respect to the Application.

Clarification of the points raised in this section is as follows:

- The purpose of Application 1344 is multi-layered but encompasses two essential principles:
  - To service growing and currently unmet need in the community; and
  - To normalise the practice of podiatric surgery in Australia and support even greater safety via greater clinical collaboration and access. This is required given the evident casemix diversity managed by podiatric surgeons.
- PASC issues regarding scope of practice and the outcomes of the NRAS review
  The scope of practice of podiatric surgeons has not changed since the creation of the College in 1978. Podiatric surgeons have changed from being regulated and recognised under various state laws however to being recognised within Australian national laws and regulations including the *Health Legislation Amendment (Podiatric Surgery And Other Matters) Act 2004,* the *Private Health Insurance Act 1973*, the *National Health Amendment (Prostheses) Act 2005* and the *Private Hospitals and Day Procedure Centres Amendment (Fees) Regulation 2005.*

  ESC questioned whether it is necessary that MSAC be guided by the outcomes of the NRAS Review or whether it is a quality assurance process. The College supports the latter view.
- Accreditation and training
  The College notes that podiatric surgical training programs are fully accredited under Australian law.
- Guidelines around adverse events & ability to treat severe cases.
  The Review suggests that the College does not have guidelines around adverse events. In fact, the College has developed guidelines for clinical management that mean adverse events are both identified and managed appropriately.
- Impact on Private Health Insurance (PHI)
  Under current legislation, private health insurers have the option to provide funding to podiatric surgeons. At present, podiatric surgeons attract funding for treating patients who are members of various funds including large national funds such as Medibank Private and smaller regional funds such as HBF.

  The ACPS has also undertaken collaborative research with HBF that demonstrates that patients of podiatric surgeons achieve a high level of outcomes across a number of health indicators including achieving a reduction in foot pain, increasing patients' level of physical mobility and improving their perceptions of overall foot health. This significantly improved their quality of life (*Outcomes achieved by Fellows of the Australasian College of Podiatric Surgeons: A collaborative report, 2011-2012,* copy available on request).

Areas of factual clarification

In addition to the errors that have been addressed in the College's Response provided in January, the ESC Review contains some points that are factually incorrect or misleading. These are presented below.

Section 3.1

The ESC Review notes the Application is requesting direct referral from physician or specialist. However the ESC Review fails to acknowledge that the Application also includes referrals to and from general practitioners which is critical to the collaborative care model.

The current lack of podiatric surgeons in the public sector within Australia is not an issue of legal restriction but one of current barriers to access.

Registration with the Medical Board of Australia is not a requirement for MBS funding.

Section 6.0
The Review recognises that rebates are currently paid for foot and ankle services, including surgical services, currently provided by GPs as well as orthopaedic surgeons. The College would highlight that some medical practitioners are likely to be providing these services without relevant surgical training or expertise in direct contrast to podiatric surgeons who spent significant time training and developing an expertise in this area. This is a key point that needs to be highlighted as a current concern in respect to quality assurance.

Section 9.0
The ESC Review suggests that non-inferiority can only be claimed in relation to private patients who are relatively healthy and does not reflect the number of trauma patients treated in public hospitals. However, as MBS data does not collect information regarding public patients in public hospitals, the comparisons made are legitimate and based on comparative evidence.

As highlighted previously, the *Critique of the Assessment Report* incorporated a number of factual errors that are not acknowledged in the ESC Review, some of which are reflected in Appendix One. For example, the *Critique* cites high rates of discontinuation in Bennett 2001: "81.7% of subjects at one month falling to 72.5% at 6 months" (p. 15). The fact is that this study actually reports *exactly the reverse* with a positive response rate of 81.7% at 1 month and 72.5% at 6 months. In addition, it should be highlighted that the study investigated the non-response groups and found their findings to be no different to those of the response group.

This is simply one example of such errors.

APPENDIX ONE:

Comments by the ACPS in relation to the *Critique*'s review of the Application's research data

The *Critique* acknowledges that the research "gold standard" of randomised controlled trials (RCTs) are difficult to institute when comparing surgical disciplines (p. 15). As such, the College is concerned that, when considering the submitted research regarding safety of podiatric surgery, the *Critique* provides a negative view that comparative RCTs have not been cited (p.22).

Secondly the *Critique* suggests that the single arm studies cited are adversely affected by bias. This view ignores that, when bias is identified, acknowledged and appropriately controlled for as in the cited single arm studies, they are appropriate to use in the manner reported. Additionally in the preparation of the application only outcome studies that were published in peer review journals were included to positively address such concerns.

The *Critique* also fails to recognise the research outcomes submitted in the report rely less on generic outcomes, such as the subjective measure of patient satisfaction and the SF36 which is considered insensitive when used in isolation, and more on disease specific outcomes such as functional improvement as a means to compare surgical providers. Reliance on these disease specific outcomes provides substantial intervention focused evidence.

Further, the use by the cited studies of a variety of different instruments to measure the same outcome increases the validation of the research findings rather than diminishes them. Triangulation of findings in this manner is a well established research method applied when RCTs cannot be performed. Similarly the *Critique* cites variation in the two groups of providers' casemix as a confounding factor but does not acknowledge that this variation has been controlled for by a number of the cited studies.

Fourthly the *Critique* reports on measures taken to minimise bias in the reported studies. Of particular concern to the College is the citing of high rates of discontinuation in Bennett 2001: "81.7% of subjects at one month falling to 72.5% at 6 months" (p. 15). The fact is that this study actually reports exactly the reverse with a positive response rate of 81.7% at 1 month and 72.5% at 6 months. In addition, it should be highlighted that the study investigated the non-response groups and found their findings to be no different to those of the response group.

Further critique of the Bennett study was that quality of life improvements were selectively reported. As explained above this PhD study was specifically designed to only use scales that were relevant to its focus in order to reduce response burden and improve participation rates by minimising the burden on the patient. Use of disease specific measures from the Foot Health Status Questionnaire (FHSQ) in this way resulted in the study being more sensitive and providing more meaningful data thereby minimising any potential bias.

The *Critique* also incorrectly states the validated tools used in the submitted research do not have established minimal clinical important thresholds. This is actually not correct as the minimal important difference for two commonly used outcome measures - the Visual Analogue Scale (VAS) and the FHSQ – for foot pathology have been established for some years (Landorf et al, *Journal of Foot and Ankle Research* 2010, 3:7).

Finally, the College acknowledges that podiatric surgeons' casemix may change should MBS funding be approved. However, as identified by the *Critique*, the highly specialised and accredited training of podiatric surgeons *compared to the unknown level of orthopaedic foot and ankle training* ensures that podiatric surgeons are trained to provide safe management of any difference in casemix. This premise is further underpinned by the extremely low rate of complication associated with the outcomes of podiatric surgeons as demonstrated in the College's National Audit.

In addition to this, ACPS members are required to record all cases of surgery for the purpose of peer review and quality improvement. In order to facilitate this, a web-based, real-time audit tool has been

developed with international expert consensus and is used for this purpose. As a result, the level of monitoring available to evaluate the outcomes of podiatric surgery is significantly greater than currently available for other providers of foot and ankle surgery.

The *Critique* comments that 'despite a largely representative sample of participating podiatric surgeons, uncertainty remains whether patient numbers from a one month trial period is appropriate to extrapolate to a one year period' (p.31). This methodology was undertaken recognising some of the data concerns and following discussions with the Department of Health regarding the most appropriate approach. The data aligns strongly with that contained in the College's comprehensive National Audit.

In summary the *Critique* fails to recognise and acknowledge the amount of solid and appropriate research evidence to substantiate the safe and quality delivery of services by podiatric surgeons given the accepted difficulties when comparing surgical disciplines.