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RE: *Health Insurance Legislation Amendment (Transparent Patient Outcomes) Bill 2021*

Dear First Assistant Secretary,

The Royal Australasian College of Surgeons (RACS) welcomes the opportunity to provide a submission to this private member's bill by Senator Stirling Griff in relation to legislative amendments of the *Health Insurance Act 1973* in relation to 'Transparent Patient Outcomes'. While RACS supports in principle the need for transparency when examining data and surgical procedures, RACS cannot support this Bill as it stands due to other factors which influence the qualitative measure of surgical health registries in Australia.

RACS is the leading advocate for surgical standards, professionalism and surgical education in Australia and Aotearoa New Zealand. RACS supports the ongoing development, maintenance of expertise and lifelong learning that accompanies the surgical practice of more than 8,000 surgeons and 1,300 surgical trainees and Specialist International Medical Graduates (SIMGs).

As discussed at a meeting between our Chair of the Health Policy and Advocacy Committee (HPAC), Policy and Advocacy Team, and yourself the First Assistant Secretary of the Health Economics and Research Division at the Australian Department of Health on 23 February 2022, RACS is concerned with the introduction of this Bill. Problems which exist to name just a few are; the funding of registries, the lack of risk adjustments, public vs private data, surgical ethics applications with differing state jurisdictions, rural outcomes, and complex procedures. There is reason to believe that if passed, the proposed legislative amendments will have a serious impact on our fellowship and the patients they serve in all regions of Australia.

RACS has consulted with our fellowship within our governance structure including all of our state and territory committees, the Research, Audit & Academic Surgery (RAAS) Division, the Rural Surgery Section (RSS), and the HPAC. We have also reached out to all of our nine Australian and binational surgical specialty societies and associations, and thank them for providing their President's joint signatures in support of our submission.



We present to you our submission written in the format requested by the Australian Department of Health, and we look forward to participating in any possible future meetings and/or hearings.

Sincerely,

Dr Sally Langley
President, RACS

Professor Mark Frydenberg
Chair, Health Policy & Advocacy Committee

Co-signed by:



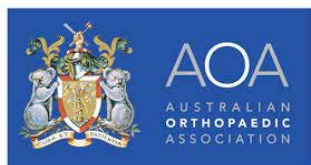
Dr Guy Henry
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Dr Jayme Bennetts
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Dr Peter Subramanian
President, Australian and New Zealand Society for Vascular Surgery



Dr Annette Holian
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Dr Rodney Allen
President, Neurosurgical Society of Australasia



UROLOGICAL SOCIETY
OF AUSTRALIA
AND NEW ZEALAND

Associate Professor Prem Rashid
President, Urological Society of Australia and New Zealand

**Hospital/Facility Level Public Reporting and Senator Griff's Health Insurance Legislation Amendment (Transparent Patient Outcomes)
Bill 2021**

Consultation Input Template

Name/organisation: Royal Australasian College of Surgeons (RACS)

Question	Input (please use more space if required)
<p>1) What is your view of Senator Griff's Bill?</p>	<p><i>RACS is a strong supporter of outcome reporting and audit but is unable to support this Bill in its present form. A broader, deeper and more comprehensive investigation and consultation is required to address the deficiencies in infrastructure, funding, risk assessment, and staffing before there can be derived any confidence in outcome reporting broadly.</i></p> <p>RACS supports the collection and reporting of clinically verified patient outcome data to surgeons as a measure of quality control and improvement. Dissemination of data (both hospital and clinician data) to the public in many of its present forms, whilst improving transparency may lead to unintended consequences.</p> <ul style="list-style-type: none"> • Quality, Accuracy, & Costs: Problems exist with uncertain quality and accuracy of data entry, cost of delivery of the program, and complex ethics and governance processes. There are challenges in utilising surgical registry data for outcome research. Clinical registries in practice are reliant on quality management and investigating outcomes by clinical research. A study into the <i>German Spine Society (DWG)</i> registry revealed a high number of inaccuracies due to the lack of mandatory entries and false entries contributing to incomplete registry data sampled from 17 centres.ⁱ Compliance issues in Australia will have to be paramount with increased oversight of data storage, ownership, and usage. This equates to greater funding. Primary data will need to be entered by appropriately trained and monitored data managers and controlled on secure platforms for the initial processing to ensure appropriate risk/cofactor adjustments. One example of such a platform in Australia is the Secured Unified Research Environment (SURE).ⁱⁱ There are major jurisdictional barriers as well with differing consent processes, and ethics requirements between different states, territories and hospitals in order to implement these registries and it is simply impractical without major legislation changes to substantially simplify this data collection. • Lack of Risk Adjustments & the Risks of Standardisation: Adjustments need to be specialty and case-mix specific. This is challenging for generalised reporting of surgical performance. Inaccuracies

can result in errors as demonstrated in a German studyⁱⁱⁱ within the field of cranial neurosurgery. Healthcare administrators applied standardised quality measurements and reviews on quality indicators (QIs), but concluded that these "proposed QIs for neurosurgery lack scientific rigor and are restricted to rudimentary measures" with neurosurgeons requiring instead to define their own QIs so as to provide the best possible specialty specific patient outcomes. This further highlights the limitations associated with ineffective surgical registry standardisation in absence of clinical consultation for risk adjustments. Surgeons with significant skills and who tackle cases with increased complexity are expected to have worse outcomes, which reflects the underlying patient and case characteristic more than the competence of the surgeon. The ability of the public to interpret this data without appropriate robust adjustment is uncertain.

- **Uniformed Conclusions:** There is a danger in using non risk adjusted data to assess surgical competency e.g., when a surgeon only takes on complex cases that others reject, they may well have higher morbidity and mortality rates. In such circumstances, an incorrect assumption might be that they are not high-quality surgeons. Fundamentally this goes down to issues relating to the completeness of a targeted data set, and appropriate cofactor adjustments. When considering a surgeon in this context, one must in actuality consider the system, for example, the patient's co-morbidity profile, case complexity, referral system, peri-operative care (including the non-surgeon members of the surgical team), post-operative discharge and care in the community. Patient outcomes depend on all these factors and attributing all the outcomes solely on surgical competence is not appropriate. An example of inappropriate conclusions was when Medibank Private reviewed the outcomes of bladder cancer surgery and noted a high readmission rate to hospital within 6 months, publicly releasing this information in the media as a demonstration of poor care by urological surgeons, when in fact readmission within this time frame is actually the standard of care and entirely appropriate. This inappropriate conclusion released to the public led to significant patient harm.
- **Reporting Time-Frames:** The time-frame for reporting outcomes is important, but will the data represent 30-day mortality? Or longer-term mortality and morbidity issues? Are we looking just at immediate peri-operative outcomes or assessing patient reported quality of life outcomes or patient reported experience measures (Patient-reported outcome measures PROMs, and Reported Experience Measures PREMs)?
- **Risk avoidance behaviour:** Surgeons may choose to avoid complex cases in order to "protect" their outcomes data results so patients don't inappropriately determine their competence based on a suboptimal outcome in these complicated cases. This could lead to the flooding of these complicated cases into the public system.
- **Outlier Surgeons:** Inability to define what is an outlier surgeon and how to manage and remediate outlier surgeons without clear qualified privilege for committees examining data.

	<ul style="list-style-type: none"> • Responsibility: It remains uncertain who would be responsible for reviewing the outcome data. RACS has an experienced team that can establish, maintain and analyse audit and registry data, but ultimately the problem at hand is the lack of funding, and the incredibly wide breadth of data collation required from our nine surgical specialities. The data custodians need to be content experts to ensure appropriate analysis. Results from such work could be overseen by an independent expert committee modelled on other Department of Health processes or a health/surgery watchdog. However, this will require a large amount of funding, legislative and infrastructure change. Dogmatic ministerial policy impositions could have the unintended harm of increasing the risk of poor surgical outcomes when the focus becomes data delivery, and not healthcare delivery. • Experienced Surgeons: There are potential training consequences where patients will tend to follow the more experienced surgeons who may have better outcomes, leaving the less experienced surgeons with a far longer time lag to develop their operative experience. As the more experienced surgeons retire, this may leave a significant gap in operative experience to the detriment of the community as a whole. • Centralisation of care: There may be inadvertent centralisation of care, by patients choosing major metropolitan over regional/rural hospitals based on outcome data, disadvantaging smaller and regional hospitals, disrupting the national workforce strategy and taking patients away from all their support services. • Other Quality Measures: Other quality measures that could influence patient outcome are not taken into account – quality of radiology or pathology which is not in the control of the surgeon. • Price Fixing Implications:^{iv} The publishing of fees payable directly to a surgeon may have price fixing implications. In a blended (public and private) Australian healthcare system, the commodification of surgical practice is imperfect outside of fair government regulations. Exposure of fee arrangements may have direct repercussions if the Australian Competition and Consumer Commission (ACCC) investigates issues concerning cartel behaviour, and collusion. It also appears to duplicate the existing Government work in this area to improve price transparency, and would appear to be wasteful from the public resource viewpoint.
<p>2) Does the Bill require any amendments?</p> <p>a) If so, what amendments would be required?</p>	<p>A great amount of work is required from an infrastructure standpoint before a Bill such as this can even be pushed forward to the Parliament. There are a couple of concerns in relation to the amendments suggested. The major areas of concern have been articulated in our previous response.</p> <ul style="list-style-type: none"> • Who is responsible?: There needs to be clarity as to the funding of this initiative, ethics and consent frameworks, how and by whom the data will be collected, and who would be responsible for the collation and analysis? Has the Office of Best Practice Regulation provided feedback on whether this

	<p>amendment to the Act is wise? The economic and logistical barriers of this proposal are "insurmountable" and will place surgeons at risk of reputational harm if inaccurate or incorrect outcome practitioner data is presented. The Bill does not provide any clarity as to where economic and governance accountability actually lies, and what recourse surgeons may have to incorrect data publication.</p> <ul style="list-style-type: none"> • Legal Safeguards: Amendments will result in the addition of s124ZCB(2) under PART VC - QUALITY ASSURANCE CONFIDENTIALITY of the <i>Health Insurance Act 1973</i> providing the Minister additional powers to request the registry. But there is little detail on legal safeguards for surgeons and little commented as to the degree of liability.
<p>3) How could more public reporting of health outcomes data at the hospital/facility level be supported?</p>	<p><u>Support Required</u></p> <p>Public reporting of health outcomes data requires more funding from government to assist the many specialty health registries and which assist the following areas of need.</p> <ul style="list-style-type: none"> • Appropriate funding: There is a major cost and staff issue if databases are to be maintained correctly with accurate independent data entry, appropriate governance, risk adjustment, identification of system issues and oversight of outcomes and results. Governments would have to fund this endeavour which would be a highly expensive undertaking to do properly. • Qualified Privilege: Clarification for qualified privilege and quality assurances are required to protect those who are involved in data collection, and use it in a court case. The Minister already has the discretion to allow release if there is a serious offense like a criminal prosecution as opposed to a civil one. Advice given by the Department is that the draft legislation will have even stronger protection from civil and criminal cases for those who help to provide data. However, QP applications can also be quite arduous. • Surgical Ethics Applications and Differing State Jurisdictions: With respect to registries and surgical ethics applications in many state and territory jurisdictions, the process can be very arduous logistically i.e., The Urological Society of Australia and New Zealand (USANZ) registry regarding ethics took 2 years to complete and better processes are required which would be a complex issue involving all states, territories and health services/hospitals. The Federation structure during COVID has demonstrated the individual approaches of each state as unaligned and at times conflicting. In a recent Australian study, it was concluded that ethics committees across the different states "vary in application, requirement and process for the ethical review and approval for clinical research. This may lead to confusion and delays in the enablement of multicentre research projects" when attempting to enable "multicentre research projects."^v When examining the establishment of the CovidSurg-Cancer

	<p>study during the global COVID-19 pandemic, the research showed that a more “centralized, harmonized application process would enhance collaborative research.”</p>
<p>4) What are the enablers and barriers to more public reporting of health outcomes at the hospital/facility level?</p> <p>a) How could these barriers be addressed?</p>	<p>Enabling factors have been discussed above, but there are numerous barriers which require expert staff and improved risk adjustments which will help improve registries for various specialities.</p> <p><u>Addressing Barriers</u></p> <ul style="list-style-type: none"> • Geography: The Government has released a document addressing medical workforce requirements emphasising the need for a more robust delivery of healthcare to rural and regional areas, and avoiding centralisation. This proposed bill however, is likely to have the opposite effect if released to the public by promoting centralisation. Releasing outcome results to hospitals and surgeons themselves is likely to improve quality and safety by allowing hospitals and surgeons to compare their outcomes to their peers and allowing them to take steps to improve quality where deficiencies arise. This improves the health delivery throughout the country rather than patients, potentially inappropriately, concluding that superior care could be delivered in metropolitan areas further exacerbating the healthcare workforce issue in regional areas. • Complex procedures: How do you measure ‘success’ against improving the quality of life for patients with chronic ailments which may require several surgical procedures over a long period of time? This may lead to surgeons not wanting to take up difficult cases so as to maintain a good ranking, and discriminate against those who do. The Bill fails to account for the complexity of different patient comorbidities, the social determinants of health, and risk assessments to ensure patient safety. • Private Health Insurers (PHIs): PHIs may use the patient registry to discriminate or punish surgeons in absence of risk adjustments, especially in light of the recent Honeysuckle and nib Application to the ACCC, and the issue of managed care. • Profession Discrimination: Other professions like lawyers and barristers do not fall under such scrutiny, nor do GPs and physicians. So, why are surgeons being singled out? • Surgical Teams, not just Individual Surgeons: Any surgical procedure is the product of numerous medical practitioners and other healthcare workers. To focus solely on a surgeon and not to take into consideration nurses, anaesthetists etc. is too simplistic and reductive when it comes to data analysis. Outcomes are achieved by teams not individuals, and according to a recent American study a surgical team is composed of “complex social and technical practices to maintain group cohesion and ensure that routine practices stay on track.”^{vi} Another study shows that diverse teams can demonstrate “superior performance” outside of any inherent systemic prejudices.^{vii}

	<ul style="list-style-type: none"> • Underperforming Surgeons: What is the Department of Health to do with data discovered which indicates a surgeon has been under 'performing' and even how that is to be defined? RACS already has a guide on this called the 'Surgical Competence and Performance'.^{viii} The problems associated with a public registry with data that has not been properly vetted is that surgeons engaged in complex procedures are at the risk of being prejudiced against as underperforming. RACS in unison with the National Boards, and the Australian Health Practitioner Regulation Agency (AHPRA) have pre-existing processes already in play. • Cancer Patients: Oncology is an example whereby cancer patients are required to continually return as part of their treatment, however data samples which have not been properly analysed or risk adjusted may lead to the perception that a surgeon is engaged in an imperfect/flawed medical prognosis or treatment if consultation and hospital stay is ongoing. In actuality, ongoing treatment may be the indicator of good performance. Hence, how would one benchmark appropriate treatments without contradicting more individualised treatment/management regimes for patients? Care is needed when choosing the most appropriate quality performance indicator. <p>Case Study: Rural^{ix}</p> <p><i>"I would be concerned regarding the impact of service provision in smaller centres. I have a colleague who specialises in infected revision arthroplasty and provided a wonderful service for our department taking on these highly complex cases. It means that his joint registry outcomes are far worse than mine. If these figures were published, he may be unable to sustain private practice in town so he would have to cease to do these cases for us. Another issue is that if there is a slightly worse outcome for lower volume surgeons, then generalist in the country would perhaps cease to offer services so country patients would have to travel to city. Furthermore, deprivation and lack of services in the country lead to worse outcomes. I recently asked a full-time subspecialist advice on some really advance dupuytren's cases that I treat routinely. He couldn't provide advice as he just didn't see these advanced cases in his city practice. My outcomes would look much worse since my patients start off far worse since they are deprived early access to care."</i></p>
<p>5) Some mature national clinical quality registries are currently publicly reporting risk adjusted health outcomes data at the clinic/hospital level.</p>	<p><u>Barriers</u></p> <p>Barriers to implementation have been discussed in the previous responses with major barriers being data linkage, and completeness of records. Public reporting improves transparency but does not improve quality. RACS is in favour of individual surgeons and hospitals getting their own data so that can be compared to peers and this leads to quality improvement across the whole national health sector as demonstrated in the Prostate Cancer Outcomes registry which has shown clear improvements in patterns of care, the avoidance of unnecessary surgery and treatment, and improved surgical measures such as surgical margins.</p>

<p>a) What are the enablers or barriers to a more systematic approach to public reporting of mature clinical quality registry data at the hospital/facility level?</p> <p>b) How could these barriers be addressed?</p>	<p><u>Enablers</u></p> <ul style="list-style-type: none"> • Funding of MRFF: Appropriate funding of outcome research using monies from Medical Research Future Fund (MRFF). • Cutting Down on Ethics Red Tape: Streamlined ethics and consent processes across the country and accepted in all state and hospital jurisdictions • Qualified Privilege (QP): QP to all those that sit on committees reviewing the data, especially as it may pertain to an outlier clinician. • Risk Adjustment: Robust, complex risk adjustment including for patient and disease complexity, patient comorbidities, hospital system factors, quality of ancillary services, patient experience measures (PREMs as well as PROMs). • Legal Due Process: Natural justice for surgeons by allowing surgeons to question data and have it formally and independently reviewed before being made public.
<p>6) Could existing national administrative data collections be expanded to provide health outcomes data for public reporting at the hospital/facility level?</p> <p>a) What are the enablers or barriers to expanding existing administrative systems to provide health outcomes data for public reporting at the hospital/facility level?</p>	<p><u>Barriers</u></p> <ul style="list-style-type: none"> • Hospital Data: Hospital collection of data may have punitive effects on an individual surgeon if individual data sets are exposed to the hospital. If surgeons received the data directly, this may incentivize them to improve their quality of healthcare service. State hospitals are already collecting data like this, but private hospitals will be more difficult to collate from. Has the Federal Health Minister consulted with state departments of health? RACS does support in principle the release of hospital level data to the public provided these data sets are valid, reliable and transparent. • Not All Data Sets are the Same: Too much data may hinder the quality of healthcare service. For example, surgical data sets from several specialties will differ from more focused In vitro fertilization (IVF) data sets. Measurable outcomes may result in negative margins for surgeons who may try to control their narrative of practice in order to avoid a negative perception of their performance. • Impact on Retiring and New Surgeons: Data from surgeons who have been working for decades who soon retire, may drive patients away from newer surgeons who are building their practice. Prejudice against certain surgeons may arise due to the lack in quantity of years in practice as opposed to qualitative ability based upon high level training for new surgeons

<p>b) How could these barriers be addressed?</p>	<ul style="list-style-type: none"> • Public Patients: The Bill potentially disadvantages public patients who often are in the higher risk group. Many of these patients still require surgical care, albeit with appropriate consideration of risk – which leaves surgeons willing to take on higher risk cases to public shaming. Staff practitioners like a surgeon cannot choose between which patients they wish to treat, and more often than not based upon their specialist the cab-rank rule will apply. How many patients accessing public hospital services can really exercise choice about which hospital they choose? Unless a person has private health insurance and unlimited time/money to travel for care, choice is limited. What could be the impacts for patients of having access to information but not the ability to act on it? Vulnerable patients will affect the data outcome in the public sector where patients from a lower a socio-economic background with poor health and chronic conditions tend to populate. <p>Addressing Barriers</p> <ul style="list-style-type: none"> • Administrative vs Events Reporting: Administrative data not linked to clinical data can be very problematic. A move towards a continuous improvement model for surgical outcomes may be required. One alternative relates to the Flinders Medical Centre experience of shared values and capacity building focuses on “creating an events-based approach to standardising care pathways and then using trained individuals and audits to, at repeated intervals, assess compliance with those pathways”^x
<p>7) Could the use of the Individual Health Identifier help support public reporting of health outcomes data at the hospital/facility level? (For example, for care that covers more than one episode or provider?)</p> <p>a) What are the enablers and barriers to using the Individual Health Identifier to help support public reporting of health outcomes data at the hospital/facility level?</p>	<p>The Individual Health Identifier (IHI) may need to be linked to MBS items, or the Australian Institute of Health and Welfare (AIHW), and service provider numbers. However, there may be more risks than benefits resulting in the targeting of individual surgeons, and potential restriction of Private Healthcare Insurance coverage.</p> <p>Barriers</p> <ul style="list-style-type: none"> • The use of IHI or Unique patient separation codes: IHI (Medicare) would identify patient related events within the private healthcare system. However, it is the time frame for linking such services to a single episode of care or ongoing care which may be problematic. • Time Limits: The above would require time limits for the co-claims of MBS items, and the time frame will vary depending on the indicated medical issue. • Clustering of MBS Claims: If an incorrect rubric were to be used, such a cluster will lead to more confusion. • Public System: Each admission would result in a Unique ID code for the individual patient. The issue in relation to using these codes are readmissions used to correct an adverse event i.e., How do you connect the primary presentation with the second event?

<p>b) How could these barriers be addressed?</p>	<p>Addressing Barriers</p> <ul style="list-style-type: none"> • Different Facilities and Database Platforms: The issue is compounded by different healthcare facilities using different database platforms – this makes consolidating data and making comparisons difficult. • Patient Consent: The proposed use of an individual's data is beyond the episode of care. Such secondary usage would require informed consent i.e., issues associated with MYHealthRecord whereby this had to be converted to an opt-out system. • Identification Issues & Rural Communities: Whether IHIs are used or not there is a risk of identifying individuals, especially from small facilities/hospitals. The identification is a risk for patients and surgeons especially in the rural setting where hospitals tend to have very few surgeons on staff who can be easily recognised on the street in small communities. • Rural FIFO: The rural setting would be further challenged by the Fly In, Fly Out (FIFO) services and the need to handover care. • Private Sector: For the private system this could be tracked using the Medicare numbers of the patient and the clinician, but this isn't a simple task, and significant access barriers will need to be overcome. <p>Enabler</p> <ul style="list-style-type: none"> • Oversight: One example of an ideal solution would be for the Australian Institute of Health and Welfare (AIHW) to conduct the overall analyse with oversight of various clinical craft groups, and then further oversight by an impartial body of some type.
<p>8) Do you have any further comments?</p>	<ul style="list-style-type: none"> • Escalation of Claims: Advice from our Fellows who sit on committees for various MDOs suggest that in the last two years an escalation of claims has occurred However nothing has changed in quality of practice, but the data may be artificially driving claims

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- ⁱ Bernhard Meyer, Ehab Shiban, Lucia E Albers, Sandro M Krieg., Completeness and accuracy of data in spine registries: an independent audit-based study, *European Spine Journal*. 2020 Jun;29(6):1453-1461. doi: 10.1007/s00586-020-06342-6. Epub 2020 Mar 4.
- ⁱⁱ SURE - Sax Institute - Sax Institute., <https://www.saxinstitute.org.au/our-work/sure/>
- ⁱⁱⁱ Stephanie Schipmann, Michael Schwake, Eric Suero Molina, Norbert Roeder, Wolf-Ingo Steudel, Nils Warneke, Walter Stummer., Quality Indicators in Cranial Neurosurgery: Which Are Presently Substantiated? A Systematic Review, *World Neurosurgery Journal*. 2017 Aug;104:104-112. doi: 10.1016/j.wneu.2017.03.111. Epub 2017 Apr 30.
- ^{iv} Sourced from RACS *Queensland Committee* Submission to the 2022 Bill in question
- ^v Nagendra N Dudi-Venkata, Daniel R A Cox, Nicholas Marso, Lorwai Tan, Peter Pockney, Vijayaragavan Muralidharan, David I Watson, Toby Richards, Clinical Trials Network Australia New Zealand (CTANZ)., Variation in Human Research Ethics Committee and governance processes throughout Australia: a need for a uniform approach, *ANZ Journal of Surgery*. 2021 Nov;91(11):2263-2268. doi: 10.1111/ans.16842. Epub 2021 Apr 13.
- ^{vi} Rachel Prentice., Surgical Teamwork and the Pragmatic Ethics of the Outcome, *Medical Anthropology Journal*. May-Jun 2021;40(4):361-374. doi: 10.1080/01459740.2021.1892666. Epub 2021 Mar 18.
- ^{vii} Lorenzo Cobianchi, Francesca Dal Mas, Peter Angelos., One Size Does Not Fit All - Translating Knowledge to Bridge the Gaps to Diversity and Inclusion of Surgical Teams, *Annals of Surgery*. 2021 Feb 1;273(2):e34-e36. doi: 10.1097/SLA.0000000000004604.
- ^{viii} RACS., Updated Surgical Competence and Performance Guide <https://www.surgeons.org/en/News/News/Updated-Surgical-Competence-and-Performance-Guide>
- ^{ix} Sourced from RACS's *Rural Surgery Section* member and fellow
- ^x Clinical governance report ASERNIP-S 2016 Clinical Governance Frameworks Report, p.18 https://www.surgeons.org/-/media/Project/RACS/surgeons-org/files/position-papers/rpt_2017_05_04_clinical_governance.pdf?rev=6f4cd