

Development of the Australasian Vascular Surgical Audit

Bernie M. Bourke, FRACS,^a Charles Barry Beiles, FRACS,^b Ian A. Thomson, FRACS,^c Michael J. Grigg, FRACS,^d and Rob Fitridge, FRACS,^e Gosford, New South Wales and Footscray, Victoria, Australia; Dunedin, New Zealand; and Box Hill, Victoria and Woodville, South Australia, Australia

Objective: The purpose of this study was to describe the development of the Australasian Vascular Audit that was created to unify audit activities under the umbrella of the Australian and New Zealand Society for Vascular Surgery as a Web-based application.

Methods: Constitutional change in late 2008 deemed participation in this audit compulsory for Society members. The Web-based application was developed and tested during 2009. Data for all open vascular surgery and for all endovascular procedures are collected at two points in the admission episode: at the time of operation and at discharge, and entered into the application. Data are analyzed to produce risk-adjusted outcomes. An algorithm has been developed to deal with outliers according to natural justice and to comply with the requirements of regulatory bodies. The Audit is protected by legislated privilege and is officially endorsed and indemnified by the Royal Australasian College of Surgeons. Confidentiality of surgeons and patients alike is ensured by a legally protected coding system and computer encryption system. Validation is by a verification process of 5% of members per year who are randomly selected. The application is completely funded by the Society.

Results: Data entry commenced on January 1, 2010. Over 40,000 vascular procedures were entered in the first year. The Audit application allows instantaneous on-line access to individual data and to deidentified group data and specific reports. It also allows real-time instantaneous production of log books for vascular trainees. The Audit has already gained recognition in the Australasian public arena during its first year of operation as an important benchmark of correct professional surgical behavior. Compliance has been extremely high in public hospitals but less so in private hospitals such that only 60% of members received a certificate of complete participation at the end of its first year of operation.

Conclusion: An Internet-based compulsory audit of complete surgical practice is possible to create and be maintained by a society of surgeons with a membership of just over 200. The 60% compliance rate for complete data entry has created an immediate constitutional challenge for the Society. Future challenges are to improve total participation to an acceptable level and to ensure accurate data entry via a robust validation system. (J Vasc Surg 2012;55:164-70.)

Audit of surgical outcome is an important method of quality improvement and is becoming an increasing expectation on the part of consumers, funding bodies, and regulators. Although voluntary audits provide useful data, they have been constructively criticized because they are not complete and therefore prone to under-represent poor outcomes.^{1,2} The Australasian Vascular Audit (AVA) was developed as an Internet-based application during 2009

with the aim of amalgamating the existing non-Web-based vascular surgical audits throughout Australia and New Zealand (Australasia is a geopolitical term used to describe the region encompassing Australia and New Zealand). A simultaneous aim was to institute this as a compulsory audit of complete practice to maximize the accuracy of subsequent analyses of the collected data.

The most used audit in Australia over the preceding 10 years had been the Melbourne Vascular Society Audit³ (MVSA), which had operated mainly in the state of Victoria, and this model was adopted for the binational audit. The Vascular Society of New Zealand (VSNZ) counterpart was the vascular module in the Otago Audit.⁴ The VSNZ is a vascular society operative in New Zealand. The AVA commenced operation on January 1, 2010, and is totally funded by the Australian and New Zealand Society for Vascular Surgery (ANZSVS), which is the peak vascular surgical society in Australasia. Most members of the VSNZ are members of the ANZSVS. Vascular surgery is one of the nine surgical specialties of the Royal Australasian College of Surgeons (RACS). Membership of the ANZSVS requires the qualification of Fellowship of the RACS in vascular surgery (FRACS-Vascular) and, since 2010, also requires complete compliance with the AVA. The latter requirement necessi-

From the Department of Vascular Surgery, Gosford Hospital, Gosford, New South Wales^a; Vascular Surgical Unit, Western Hospital, Footscray, Victoria^b; Vascular Services, Dunedin Hospital, Dunedin^c; Box Hill Hospital, Box Hill, Victoria^d; and Australian and New Zealand Society of Vascular Surgery and University of Adelaide Department of Surgery, the Queen Elizabeth Hospital, Woodville, South Australia.^e

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Reprint requests: Charles Barry Beiles, Audit administrator, Western Hospital, Department of Vascular Surgery, 3/30 Fisher Street, Malvern East, Victoria, Australia 3145 (e-mail: barryb2@optusnet.com.au).

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tated a change in the ANZSVS constitution, which was agreed to by 92.4% of those members who responded to a postal ballot sent to all members in late 2008.

The AVA is an "individual total practice audit" of all members of the ANZSVS who perform any open vascular surgical or any endovascular procedure and, at present, captures data and outcomes for that hospital admission. There is a capacity to "piggy back" more extensive audit data such as 30-day follow-up, but that is not a compulsory requirement at this stage. Members are required to enter all procedures performed in all hospitals (both private and public) in which they work. The application also caters for outpatient procedures such as endovenous therapy but the latter are not compulsory. Non-ANZSVS members who perform vascular procedures can use the application, but must agree to be subjected to the audit rules.

The purpose of this article was to outline the development, technical aspects, features, and function of the AVA. By way of example, some results of the data collection for the first year of operation (2010) will also be presented. More detailed results will be presented in future years.

METHODS

After the ANZSVS constitutional change was ratified by the RACS lawyers, approval to develop and use the application was gained from the Ethics Committee of the RACS. In Australia, the Audit gained legal protection from the Commonwealth of Australia "qualified legal privilege" mechanism as a quality assurance activity, with a similar method of national legal privilege operative in New Zealand. Such protection means that any divulgement of a participant's identity (either surgeon or patient) is punishable by a substantial fine and a custodial sentence of up to 2 years. The AVA was granted official RACS endorsement under its Continuing Professional Development program thus fulfilling this aspect of ANZSVS members' recertification requirements. The AVA is indemnified under the umbrella of the RACS insurance policy. The audit complies with current national privacy legislation regarding the collection of health data in situations where it is not practicable to obtain patient consent and when the data are potentially deidentifiable.

Postdischarge follow-up data are not presently collected in the AVA. This was based on previous experience from other audits such as the MVSA where it became apparent that follow-up data entry was poorly performed and inaccurate. This may be included in future versions of the application if groups request it for specific dedicated areas of practice.

Audit rules. A working audit committee was formed with a representative from each state of Australia as well as a New Zealand member to define data fields and mechanisms of data collection. A Web-based interface was adopted as the only method of data entry and, after the fields had been chosen, a software development company was selected by the committee to design the application.

A set of audit rules was drawn up and ratified by the RACS lawyers. These pertained to the use of the AVA, to

the Audit Monitoring Committee (AMC), and to the use of deidentified data.

Members were all issued with a unique and confidential user number. The code linking these numbers with the members' names is securely housed by the ANZSVS and access to the code is restricted to two non-surgeon Society officers (the general manager and the senior executive officer). Neither of these officers has access to the audit data. The AMC is the only committee within the ANZSVS with the power to access the code and, only as defined within the rules, document which pertains to the investigation of an outlier result which has been identified by the statistical analysis. Any request by a third party to access the code must be addressed to the RACS solicitors.

Data entry. Data entry commenced on January 1, 2010. Data are entered via any computer with Internet access. Access to the AVA Web page requires entry of the user number and a password known only to the member. In public hospitals, members may elect to have data entered either by a data manager or by the vascular surgical trainee, in which case a unique hospital code is entered rather than the member's number and a different password is used. It is still the member's strict responsibility to ensure accurate data entry in these situations. If data managers or vascular trainees are entering data, they can only do so for the surgeons who work in their unit. They have no access to the surgeon's data from their other (eg, private) hospitals. When the trainee leaves the hospital to rotate to another institution, the new trainee changes the password.

Data collection. Members enter data on all patients undergoing either open surgical or endovascular interventions at two points in the admission episode: at admission/operation and at discharge. Patients not having a procedure are not entered at all. Although entry of all procedures is compulsory, currently only the following index procedures have been selected for audit:

1. Aortic surgery – ie, aneurysm and nonaneurysmal disease (in-hospital survival).
 - i. Open elective and emergency.
 - ii. Nonfenestrated elective and emergency endoluminal grafts (ELG).
 - iii. Fenestrated endografts.
2. Carotid procedures (in-hospital freedom from stroke/death).
 - i. Open carotid endarterectomy.
 - ii. Carotid angioplasty with stenting.
3. Infrainguinal bypasses (IIB; in-hospital patency and limb salvage).
4. Arteriovenous (AV) fistula for dialysis (in-hospital patency).

Although it is compulsory to enter peripheral endovascular procedures, they were not subjected to societal audit because the AVA only considers in-hospital data.

Data analysis. The data are analyzed by logistic regression analysis to produce predictive models for adverse outcomes. These data are then risk adjusted (where adequate models exist) and risk adjusted funnel plots are used

to identify outliers using 95% confidence limits.⁵ Because this activity is a complete audit loop, an algorithm has been adopted by consensus of the membership to deal with any clinical performance concerns identified by the data analysis. Examination of the case-by-case clinical details by an elected committee will determine if substandard care exists.

Audit Monitoring Committee. The executive committee of the ANZSVS has established an AMC, which consists of four members: the Chairman of the AMC, the immediate past-president of the ANZSVS, the administrator of the AVA (a vascular surgeon with computer skills), and the president or immediate past-president of the VSNZ. These are senior members of the ANZSVS engaged in active vascular surgical practice and elected by the membership. The roles and responsibilities of the AMC are:

- To oversee protection of the collected data.
- To ensure confidentiality of participants (both surgeon and patient alike).
- To monitor the collection of the audit data and to facilitate maximal compliance.
- To prevent misuse of the data (including addressing complaints about misuse of the data).
- To investigate and verify statistical outliers according to a predetermined algorithm.
- To assess applications to determine suitability for participation in the AVA.
- To assess applications to use the collected data for non-audit purposes.
- To oversee the AVA verification process.
- To provide an annual report of the AVA results for the ANZSVS annual general meeting.
- To identify opportunities for performance improvement.
- To identify opportunities for external publication.
- To provide annual certificates of satisfactory vascular surgical audit participation.
- To oversee the disclosure of audit data to a third party at the instigation of a participating member.

Compliance. At the beginning of the next calendar year, members are required to apply for a “Certificate of Participation” by signing a statement verifying that, to the best of their knowledge, they have entered and discharged all patients under their care who have undergone vascular surgical or endovascular interventions during the preceding calendar year. Upon receipt of the application, members are issued with the certificate signed by the president of the ANZSVS. Possession of this certificate is necessary to maintain ANZSVS membership.

Technical features of the Australasian Vascular Audit application.

1. Security and performance:
 - a. Uptime – application and database uptime is >99%.
 - b. Backup services – daily database and application backup.
 - c. Security services – enterprise firewalls, intrusion prevention systems, and anti-virus protection.

- d. Disaster recovery – daily backups to a fully redundant storage area network infrastructure featuring file recovery, data deduplication, redundant block elimination, over the wire encryption, and offsite storage of backup data
- e. Log-on is only permitted by surgeon code and password.
- f. The ability to view reports is determined by the status of the user. Full members of the ANZSVS have the ability to view all reports, and there is the ability to view the user’s outcomes in the four categories of audit in real time compared to the peer group. Non-ANZSVS members who use the application do not have access to the collective data outcomes.

2. Scalability:

The application is capable of handling 200 simultaneous users.

3. Role-based data updates:

Modification of data entered in the discharge/complication form fields after user log-off is only allowed by the administrator. Addition of data is allowed by all users. Deletion of records is only allowed by the administrator.

4. Privacy and confidentiality:

Compliance with privacy legislation is current and patient identifiers are encrypted and the database is securely stored by the server. Confidentiality of patient details is thus ensured. Confidentiality of member’s identity is ensured by the storage of the surgeon code with legal nonsurgeon representatives of the ANZSVS.

5. Data reliability:

Strict data validation criteria prevent erroneous data entry and there is no ability for free text data entry, except for two “comment” boxes in the operation and discharge forms. Drop-down menus allow choices to appear that are based on selections made in previous fields. This diminishes the ability to enter incorrect data.

6. Flexibility:

The application has been designed to allow alterations to the menu choices by the administrator. This has ensured that unusual and uncommon operations can be entered. The application captures all endovascular procedures where appropriate.

7. Validation (auditing the audit):

External validation (a check to see that cases have not been omitted) as well as internal validation (to check that data entered are accurate) is operative. In the initial year of data entry, this consisted of requesting a random 5% sample of members to submit an independently collected list of the index procedures performed at each of their hospitals, together with the name of the operation and length of stay. Validation methods will be upgraded in future years.

RESULTS

Sixty percent of full members received a “Certificate of Participation” for 2010, thus satisfying their constitutional requirements. There are a small number of surgeons who

Table. Raw data for operations audited in 2010

Operation	Total	Outcome measured	Percentage
Aneurysm intact (open)	650	Mortality	2.6
Aneurysm ruptured (open)	196	Mortality	33.7
Aneurysm intact (ELG)	1437	Mortality	1.4
Aneurysm ruptured (ELG)	75	Mortality	22.6
Fenestrated ELG	80	Mortality	7.5
Carotid endarterectomy	2148	Stroke/death	1.7
Carotid stent	199	Stroke/death	1
Infringuinal bypass	1842	Graft occlusion	6.2
Infringuinal bypass	1842	Major amputation	1.4
AV fistula for dialysis	2398	Fistula occlusion	3.1

AV, Arteriovenous; ELG, endoluminal grafts.

have not entered any data, and a larger percentage who have not entered any private data. Most other members partially participated but could not be awarded a certificate. Of the 5% who were audited for validation purposes, 60% responded with the data.

Of all public hospitals, there has been only one unit that has not participated because the surgeons were reluctant to change from a pre-existing audit that has been operative for 30 years. At present, there is no facility to import these data into the AVA and it will be unlikely that this will be adopted for a single institution.

Examples of some specific results from the first year of audit (calendar year 2010). Outcomes for each of the four index procedures are shown in the Table. Most AV fistulas in Australasia are performed as inpatients.

Risk-adjusted outcomes have been obtained for mortality after open aortic and open aortic aneurysm surgery and for amputation after infringuinal bypass. Predictive models were obtained by binary logistic regression with excellent discrimination (c -statistic >0.9) as well as calibration (by goodness of fit showing nonsignificance).^{6,7} Outcomes are displayed for comparison between hospitals or surgeons using funnel plots, with a standardized mortality rate against total operations scatterplot upon which 95% binomial confidence intervals for the adjusted individual crude adverse event rates are superimposed (Figs 1 and 2).

Nonrisk adjusted funnel plots were used to demonstrate comparative performance in occlusion rates after IIB as well as after AV fistula creation for hemodialysis. In a single case, there was an outlier for occlusion after IIB and this will be examined by the audit monitoring committee along the guidelines of the algorithm adopted by the Society (Fig 3).

DISCUSSION

Audit, or self-examination of practice, is the cornerstone of professional development because it investigates and acts on outcomes which have resulted from the enactment of what a professional has gleaned from other components of development such as reading, research, experience, and attendance at meetings designed to improve technique and knowledge.

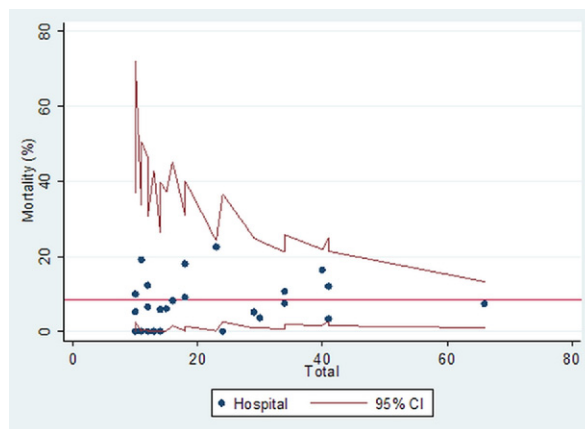


Fig 1. Risk-adjusted funnel plot for mortality after all open abdominal aortic aneurysm surgery for hospitals performing >10 procedures showing 95% confidence interval (CI) around the mean crude mortality rate of 8.4% for this population.

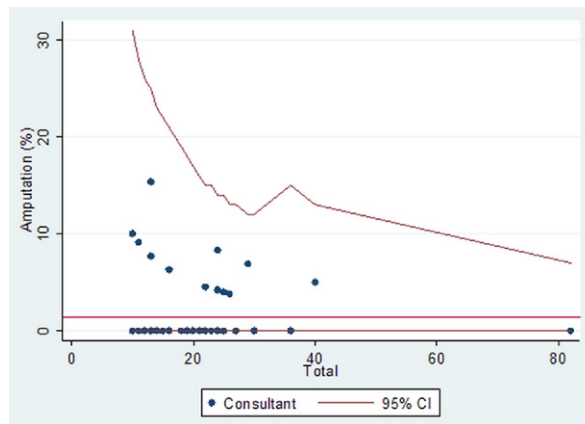


Fig 2. Risk-adjusted funnel plot for amputation following IIB (infringuinal bypass) for surgeons performing >10 cases for the year with 95% confidence interval (CI) around a mean crude amputation rate of 1.4%.

In addition, examination of outcomes with investigation and correction of substandard practice is that component of professional behavior which the public and the regulatory bodies deem most relevant to them.

In Australasia, there is increasing pressure being exerted by national registration and other regulatory bodies for medical practitioners, and in particular surgeons, to justify why they should remain self-regulated. Surgeons wish to maintain this professional freedom because they believe they alone should determine standards and not have these forced on them by third parties, and they resent these outside agencies intruding into the doctor–patient relationship. However, whenever substandard practice gains public attention, the argument is fueled in favor of the regulatory bodies. The problem was eloquently addressed by the Honorable Geoffrey Davies, AO, (an eminent lawyer) to the An-

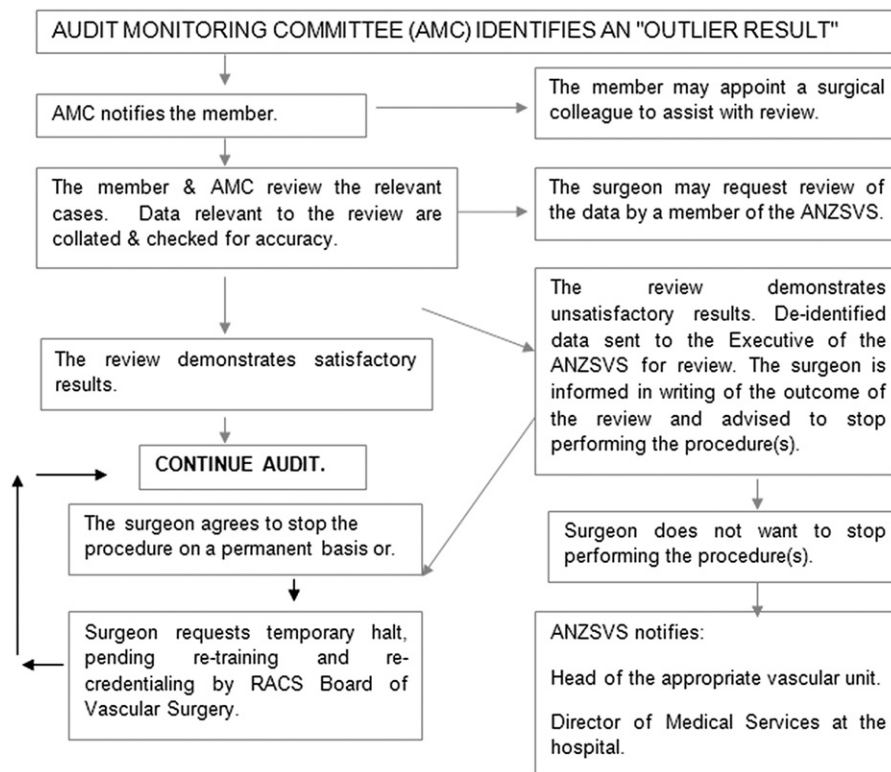


Fig 3. Algorithm for dealing with an outlier. ANZSVS, Australia and New Zealand Society for Vascular Surgery; RACS, Royal Australasian College of Surgeons.

nual Scientific Conference of the Australian Orthopedic Association in Adelaide October 11, 2010. Davies highlighted activities such as the AVA as a benchmark for what is expected by the public to fulfill true surgical professionalism.^{8,9}

The ANZSVS has for many years recognized the importance of audit on a national/binational level. A major breakthrough in the development of such occurred in 2008 when a postal ballot of all full members saw over 92% of respondents vote for a change in the constitution to legislate that participation in Society-endorsed audit of vascular surgical practice would be compulsory for full membership. The ANZSVS has also recognized that voluntary submission of outcome-related data can be biased in favor of good outcomes because of the reluctance to report poor outcomes.² The AVA is a compulsory binational audit involving total practice which is criterion based, verifiable, and peer reviewed, and as such provides tangible evidence to regulators, funding bodies and consumers that self-regulation is being performed through accurate self-examination and in the best interest of patients.

Independent collection of complete, nonfocused outcome-related data with associated risk stratification (as alluded to by Beard²), although ideal, would be beyond the financial means of any group wishing to audit its surgical practice on a national/binational basis. It is unlikely that any government body would provide such resource for any individual group. The ANZSVS has, however, instituted an

honor system whereby members wishing to fulfill their constitutional requirements have to sign an application form stating that their entry data is complete.

In addition to binational Societal benefits, the AVA has many benefits for the individual user. The ability to compare outcomes by surgeon and/or hospital with the membership as a whole is very attractive. Also, there is the ability to conduct unit or personal audit using the reports specifically designed for this purpose. Data can be extracted in the form of a spreadsheet containing every field for each patient. This allows filtering to manipulate data in any form the user requires for any purpose. Participation also allows the user access to deidentified data for research or in the event of an inquiry into one's performance by a hospital or medico legal proceeding. The application provides an instantaneous real-time electronic logbook for trainees that automatically fulfill their logbook requirements to the RACS Board of Vascular Surgery.

An important feature of the AVA is the independence provided by total ownership of the data. This has been possible because the ANZSVS has self-funded the establishment and maintenance costs of the entire process.

It is emphasized that the statistical methods are only used to identify a possible area of concern which is then assessed by experienced clinicians to decide if, after careful appraisal of the clinical circumstances of each patient, there is a real concern about the clinical abilities of the surgeon.

The algorithm allows completion of the “audit loop” and ensures that if clinical inspection by an elected committee uncovers substandard performance, then corrective steps can be followed in a fair and prearranged manner.

The development and implementation of the AVA has been a challenge. Although compliance in the public hospital sector is excellent, that in private hospitals is not to the satisfaction of the ANZSVS at this stage. Some surgeons allow data managers to enter data in public hospitals, but they either do not possess the required minimal computer skills or are not prepared to spend the time to enter their own data in private hospitals. This can occur despite the application’s facility to print data entry sheets from the ANZSVS Web site and have the data entered manually on their behalf. Surgeons who have familiarized themselves do not find this time-consuming except in some isolated regions where the Internet speed can vary. This aspect should no longer be an issue in Australia with the development of a National Broadband Network (already commenced). The reports reflect only discharged patients, so this aspect of data entry requires regular monitoring by the administrator. The audit will only become a robust representation of true outcomes if maximal participation is achieved.

Data validation is vital. It is very important that verification of data entered is performed. Although the method used during the first year of implementation is not very robust, it enabled the administrator to cross-check with data entered in the AVA and allowed conclusions to be made regarding whether complications occurred during admission. This process will be significantly strengthened in future years, involving site visits to hospitals to validate data entry directly.

After 1 year of operation, the ANZSVS glass of complete data entry for the AVA is 60% full and 40% empty. There is cause for high satisfaction that accurate and high-quality data are being collected, but also a realization that the audit aims of the ANZSVS will not be fully realized without maintaining a cultural shift to complete data entry.

CONCLUSIONS

An Internet-based audit of total surgical practice is possible on a national/binational level and has many benefits both for the Society of the members and for individual members alone. A unique feature of this audit is the compulsory nature of the total practice activity. Signed declarations of participation by individual surgeons are an effective means of separating complete from incomplete individual data. The AVA has already gained recognition in the public arena during its first year of operation as an important benchmark of correct professional surgical behavior. The future challenges are to improve total participation to an

acceptable level and to ensure accurate data entry via a robust validation system. Only by meeting these challenges will the AVA become an accurate and credible audit of national/binational vascular surgical practice.

The ANZSVS executive sincerely thanks all members and trainee members who fulfilled their constitutional requirements by fully complying with complete data entry to the Australasian Vascular Audit during its inaugural year of operation. This greatly assists the ANZSVS in its aim to maintain and improve on high-quality care of vascular surgical patients throughout Australasia. The ANZSVS is also grateful for the excellent secretarial and administrative support during the development of the Australasian Vascular Audit (AVA) provided by Ms Abby Richardson (General Manager ANZSVS), Ms Amanda Richmond (past executive officer ANZSVS), and Mr Rhys Smith (executive officer ANZSVS).

AUTHOR CONTRIBUTIONS

Conception and design: BB, CB, MG, RF, IT

Analysis and interpretation: CB, BB, RF, IT

Data collection: BB, CB

Writing the article: BB, CB, RF, IT

Critical revision of the article: BB, CB, MG, RF, IT

Final approval of the article: BB, CB, MG, RF, IT

Statistical analysis: CB

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Overall responsibility: BB

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INVITED COMMENTARY

Jack L. Cronenwett, MD, Lebanon, NH

The Australia and New Zealand Society for Vascular Surgery (ANZSVS) has implemented a regional audit system (Australasian Vascular Audit [AVA]) that received data on 40,000 vascular

procedures by 60% of its members during the first year. This is an extraordinary accomplishment by this Society-owned and financed quality assurance initiative. It has many similarities with the Society