Comments by Professor John McNeil on behalf of the Monash School of Public Health and Preventive Medicine

The Monash University School of Public Health and Preventive Medicine has been involved in research into safety and quality of care for over 20 years. In 2001 we produced a document entitled 'Improving Safety in Victorian Hospitals" which advised actions in relation to sentinel events, adverse event monitoring and clinical registries . However there was only limited uptake of the recommendations.

In 2005 the School was successful in being awarded an NHMRC Centre of Research Excellence in Patient Safety (funded by the Australian Commission for Safety & Quality in Healthcare). The Centre, known as CREPS, has achieved national prominence for its role in advocating for the measurement of quality & safety, on the basis that "what can't be measured can't be managed' . The focus on measurement of quality has been largely on the development of 'registry science'. This has involved a program of work designed to improve the value of clinical quality registries for monitoring the performance of high significance diseases and procedures in a way that is convincing for clinicians.

As part of the School's work on clinical quality registries we have also contributed to major policy documents including the ACSQHC's "Operating Principles and Technical Standards for Clinical Quality Registries" and "National Framework for Clinical Quality Registries" both of which have received AHMAC endorsement. The School has also published numerous scientific papers related to this topic. The principal author of this submission (J McNeil) has contributed to a range of state based and national committees related to patient safety and is currently a member of the DHHS Patient Safety Committee, the Board of the Victorian Managed Insurance Authority, the Austin Hospital and the Committee of Chairs of Quality Committees of Public Hospitals.

OVERVIEW

We agree that improvements of Safety and Quality require a multipronged approach involving both qualitative and quantitative strategies. Importantly the bodies overseeing patient quality and safety require a series of 'instruments' by which to judge the safety and quality within their own institution. We have likened these to 'probes in the pudding'

At present these probes are principally informed by

1 Sentinel event monitoring and root cause analysis
2 Adverse event reporting
3 Routine administrative data
4 Clinical Quality registries

A variety of other qualitative approaches within each hospital (eg mortality and morbidity meetings' are important but will not be discussed further in this paper.

A brief comment on each of the probes referred to above

1 SENTINEL EVENT MONITORING

The concept of sentinel events is a good one which has proved its value in US hospitals. Sentinel events are essentially 'never events' which should not occur in a well-managed institution because multiple barriers should have been established to prevent their occurrence. . Their occurrence should bring into question the safety culture of an institution and mandate a 'root cause analysis' of sufficient depth to identify underlying causes such as inadequate training o poor resourcing (as opposed to blaming an individual)

To be maximally effective sentinel events should be unambiguous (eg operating on the wrong limb) and their reporting should be mandatory. The Victorian system went off the rails for two principal reasons (a) the inclusion of ambiguous events such as serious drug reactions and (b) the failure to develop a system by which the health system could learn from the outcomes of root cause analyses occurring anywhere in the health system. For example in the US , when inpatient suicides from multiple institutions were analysed together it became evident that hangings from clothes hooks and curtain rails was a common feature. Replacing these with plastic breakable hooks led to a major decline in these events. Such a system for analysing sentinel events has not been developed in Victoria.

Despite the goal that sentinel events should be unambiguous there is still enough of a 'grey area' to make it undesirable to quantify sentinel events. For example in 'wrong limb surgery' one hospital may report only if the surgery is undertaken, whereas another might report a case where the mistake was recognised as soon as the initial skin incision was performed. There it is not typically desirable to compare hospitals by the numbers of sentinel events reported.

2 ADVERSE EVENT MONITORING

Adverse event monitoring has been a mainstay of safety monitoring for many years. Reporting is voluntary, incomplete, inconsistent and the system is overwhelmed with reports of fairly minor clinical significance. No attempt is currently made to include reports from VMIA or the coroner's office. Furthermore resource constraints have meant that they are subject to only cursory analyses with minimal useful feedback to hospitals.

We would recommend that all moderate to serious reports should be coded and analysed by an independent party in order to identify possible system-wide learnings. As with sentinel events , their value is achieved primarily by pooling and learning from specific categories of event occurring across the system.

3 ROUTINE ADMINISTRATIVE DATA

Sentinel events, adverse reaction reports and mortality reviews lend themselves primarily to qualitative analyses. They are not quantitative measures and therefore cannot be used to identify trends, determine whether improvements have occurred or allow benchmarking

comparisons between institutions. They exemplify the adage that 'what can't be measured can't be managed.

In an attempt to introduce measurement into the realm of safety and quality, the first has been to use the data collected routinely for administrative purposes to derive Indices derived from this data include measures such as hospital standardised mortality rates, rates of readmission and rates of return to an operating theatre. More recently it has been suggested that rates of hospital acquired infection or rates of development of pressure ulcers might provide a useful comparison between hospitals, or over time within a single institution. The Monash Department of Epidemiology & Preventive Medicine has been involved in multiple studies investigating the utility of such measures over the last 20 years.

In summary we believe that data from hospital data systems will be fundamental in the future for monitoring safety and quality in hospitals. However the data required to do this will be carefully targeted clinically defined indices rather than the administrative data current used or proposed. It has become apparent that with few exceptions administrative data lacks the accuracy and clinical detail required to provide quantitative information that is credible for clinicians or likely to induce a change in practice. Even relatively straightforward matters, such as differentiating planned and unplanned readmissions, or planned and unplanned returns to the operating theatre involve a sufficiently large 'grey' area that it makes measurement from administrative data quite unreliable .

Hospital standardised mortality ratios derived from administrative data are amongst the most widely used measures of quality in use in Victoria. These measures are highly controversial with most recognised authorities now considering them to be misleading and inappropriate as measures of quality. The principal reason that they are misleading is that the vast majority of individuals dying in hospital die as a result of their underlying illness (in a recent UK study this applied to 97% of deaths). In most of the remaining 3% a difference in treatment h may have made a subtle difference to their progress but it is a relatively rare that poor clinical care causes the death of an individual who would otherwise have survived. Variation due to poor quality care is therefore unlikely to be identified amongst the overwhelmingly larger numbers of deaths occurring without quality issues. Therefore the principal case of a hospital's high HSMRs is likely to be the admission of a relatively high number of patients in the terminal stages of an illness. The approach to adjusting statistically using numbers of comorbidities is quite inadequate .

The perverse nature of HSMRs was seen by an investigation undertaken for the Victorian DHSS in 2014 , looking at the reason for high HSMRs in Victorian Country Hospitals. The reason for the high HSMRs was the fact that in regional communities patients are typically admitted to hospitals for their terminal care, unlike in the city hospitals where this is more commonly managed in a hospice. Big city hospitals typically have a low HSMR for this reason. Also concerning is the potential for measures such as HSMRs to drive perverse behaviours such as unwanted and inappropriate attempts to intervene in terminally ill patients or drive unnecessary referrals to other hospitals.

4 CLINICAL QUALITY REGISTRIES

The Monash Department of Epidemiology & Preventive Medicine has been at the forefront of registry development in Australia for over 20 years. From experience gained with over 20 registries we have developed a registry model that minimises the data-collection burden

while at the same time providing data that clinicians find to be clinically credible. The success of registries as a quality improvement tool in both the US and parts of Europe has spurred interest in registry development internationally.

The basic requirement for a clinical quality registry is a minimum dataset encompassing both process and outcome measures that is collected in an identical fashion from all participating institutions. Outcome measures are typically collected after discharge from hospital at a time when recovery can be judged. The data includes clinical details (required for interpreting the reasons for intervention and to allow basic risk-adjustment) that are not available in routine administrative data. Most registries also collect a number of quality indicators (such as positive margin rates or Apgar scores) that may provide an early warning of quality issues. The development of registries has been made possible by both developments in the handling of large datasets and the widespread adoption of out-out-consent that allows high levels of patient participation.

Registries provide several ways of improving the safety and quality of healthcare but the most important of these is through benchmarking against other similar institutions. Numerous examples attest to the fact that institutions (& individual clinicians) will make strenuous efforts to avoid being outliers and will strive to be amongst the best performers thus driving up quality throughout the system. Safety and quality is further enhanced by providing the opportunity to learn from the best performers, reducing variation, identifying the occasional poor performer, measuring compliance with accepted treatment guidelines and though monitoring the safety of drugs, devices and innovative or high-risk surgery. They are increasingly being enhanced through the introduction of patient reported outcomes.

Registries have their key role in monitoring high-cost high-significance areas of clinical practice where there is evidence of variable treatments or outcomes and where achieving best outcomes will improve quality of life or cost-effectiveness. They are unsuited to conditions such as hypertension, heart failure or diabetes where outcomes occur well into the future. In hospital practice they have found their best application in areas such as trauma, burns, cardiac procedures, cancer, obstetrics and orthopaedic surgery.

A major determinant of the success of clinical quality registries is the governance structure which must involve substantial by-in from leading clinicians. The proper functioning of a registry requires skills in large-data management, biostatistics and clinical practice and is therefore best based in a strong clinical research environment. Given the public interest in such data it is not appropriate for it to be managed by private industry or interests representing only a single specialty. There are many on-going issues to be solved before registries can function optimally and these will require the establishment of a national centre for registry science similar to the NHMRC Centre for Clinical Trials in Sydney.

Although sometimes criticised for their cost the minimalistic data requirements means that they are not large scale data collection exercises. Furthermore a recent independent economic evaluation for the ACSQHC and the Commonwealth identified almost a 3:1 cost saving ratio amongst four registries examined

SPECIFIC RESPONSES TO QUESTIONS RAISED IN DISCUSSION PAPER

With the above comments in mind the following responses, heavily weighted towards clinical quality registries, are proposed

- **What should the department have in place to assure itself, government and the community that robust monitoring of safety and quality, including benchmarking, is in place and working at the hospital and health service level; including strengthening its role in monitoring clinical governance at health services, and further developing the performance management framework to monitor clinical safety and quality in local health services?**

RESPONSE: The essential role of the department is to ensure consistency of data capture throughout the health systems. Unless this guidance is mandated the result will be differences in definitions and approaches to data collection that will negate the value of measurement and benchmarking. Given the key role of clinical quality registries in providing clinically credible benchmarking the department should ensure that such registries are established across the most critical areas of medicine, that they function and report appropriately and that each major health service reports to them. The DHHS should assume responsibility for accrediting clinical quality registries operating in this state and designating those to which reporting should be mandated. DHHS should maintain an overview of their activities

(PS It is important to note that the data that is effective in improving safety and quality is that which is credible to clinicians. Much of the data currently provided from administrative data, whilst appealing to administrators , has little impact at the clinical level).

- **What should be reported to the department, through SoPs or otherwise, regarding safety and quality and how should it use that information, possibly including public reporting?**

RESPONSE: we believe that data from clinical quality registries should eventually be in the public domain. However at the early stages of development of registries this would be inappropriate. Registries take time to reach a level of maturity at which time there is full confidence in the accuracy and timeliness of the data, risk adjustment has reached an agreed level of precision and preliminary analysis has been undertaken of aberrant results to ensure that the appropriate targets for improvement have been identified. The latter is particularly important because in other registries it has been demonstrated that poor results from particular surgeons may be the result of failures elsewhere in the system (eg in anaesthesia or intensive care). Furthermore at present the participation of clinicians in clinical quality registries is voluntary and based on their value as educative and professional support tools. The good will that has led to generally high levels of participation would be dissipated quickly if it was felt that the data was being used unfairly for punitive purposes.

Rather that requiring reporting we advocate that DHHS should require a commitment from registries to adopt strong processes to ensure that quality issues are dealt with quickly and appropriately and that escalation policies are in place and adhered to when recipients of such data make no effort (or are incapable of) addressing them.. DHHS should be represented on the steering committees where they have an overview to provide confidence that such processes are being utilised effectively. The escalation policies should ensure that major quality issues are brought to the attention of hospital administrators at an early stage and it should be the responsibility of hospital boards through their quality committees to respond to matters raised and brought to their attention.

- **Should the scope of the reporting to the department be differently configured in public health services as compared with public hospitals?**

RESPONSE: we believe that reporting to designated clinical quality registries should be mandated for both public and private hospitals. In fact several major private hospitals and private hospital chains already contribute and examine registry data as part of their quality review.

- **What should the scope of the reporting to the department be for private hospitals?**

RESPONSE: for clinical quality registries identical to public hospitals

- **Provide advice on the implementation of the Victorian Health Incident Management System improvement project.**

RESPONSE: see comments above

- **How should the department participate in and provide leadership to the safety and quality agenda, particularly in improvement, including enhanced clinical engagement?**

RESPONSE: clinicians respond best to data that they regard as credible and where they have invested effort in both the collection and governance. At present the clinical quality registries fit these criteria and are probably the most influential sources of information for clinicians (where they exist). The steering committee of existing clinical quality registries include many of Victoria's most influential clinical leaders and this has contributed substantially to their effectiveness. Expansion and sustained support of the clinical quality registry program in Victoria would in our opinion provide the most valuable and tangible demonstration of support for clinicians engaging in quality and safety improvement.

- **How should the department ensure that all boards of public health services and public hospitals are capable of providing appropriate local governance of safety and quality?**

RESPONSE: in keeping with the adage that "what can't be measured can't be managed' , hospital boards and their quality committees find it a difficult challenge to manage quality and safety within hospitals without credible sources of data. Without such data

they must typically rely on anecdotes and reports of individual events which can often be 'explained away'. This is one of the principal reasons that most of the major hospital scandals in Australia have arisen from the action of whistle-blowers. When the performance of individuals is targeted largely on the basis of anecdotes and individual reports it may put a board in a difficult position , for example to be certain that personality issues are not involved.

Individual hospitals cannot be expected to generate such data in isolation and if they did it would probably be fairly meaningless. As an example even the best vascular surgeon is likely to have occasional patients who suffer a stroke after carotid artery surgery. In most cases examination of the details of individual cases of postoperative stroke may well not reveal safety issues. However a benchmarking report demonstrating that a particular hospital has a substantially higher rate of postoperative stroke than other similar hospitals provides convincing evidence that something is amiss.

Again this is an argument for providing boards of management with credible performance data and this calls for greater support of and commitment to the clinical quality registry program. Interpretation of such data for smaller centres could well be made the responsibility of the registry custodians together with the registry's clinical lead.

I hope that these comments are helpful & I would be pleased to provide further detail

John J McNeil