Measuring Clinical Outcomes in General Practice – 2016

1. Introduction

It is incumbent on all medical practitioners to improve the standard of their care, to improve the quality of their medical services, to practise medicine safely and effectively, and to participate in systems of quality assurance and improvement.[1,2] Improving patient health status is the primary goal of healthcare and quality in healthcare is ultimately reflected in patient outcomes.[3]

With general practice being the primary source of front line health care in Australia there has been an increasing drive and action over the last few decades, from both the profession and the Australian Government, to improve the quality of health care provided in general practices, to reduce inequalities in health care and to effectively translate evidence into practice.[4]

Numerous clinical guidelines informed by evidence based medicine have been introduced over this time, along with standards of care and quality improvement programs that have largely addressed the structure and process pillars identified by Donabedian[5] in his framework for examining health services and evaluating the quality of health care. The third pillar, yet to be effectively met both here and internationally, has been in measuring outcomes, i.e. cumulative effects of healthcare on patients or populations, including changes to health status, behaviour, or knowledge as well as patient satisfaction and health-related quality of life.

With health outcomes measurements becoming an important part of assessing the quality of health care, the AMA has developed this position statement to provide guidance on the effective development and appropriate use of outcome measures to ensure that inappropriate outcomes measures are not developed externally and imposed upon general practice.

2. Use of Outcome Measures

Outcome measures are vital tools for medical practitioners to assess the effectiveness of a clinical intervention and standardised measures are the basis on which best practice is

[1] Australian Medical Association, *Code of Ethics*
[2] Medical Board of Australia, 2014. *Good Medical Practice: A Code of Conduct for Doctors in Australia*
[3] Krousel-Wood MA. Practical Considerations in the Measurement of Outcomes in Healthcare. *The Ochsner Journal* 1999. Volume 1, Number 4: pp 187
[4] Dawda P, Jenkins R, Varnam R. Quality Improvement in General Practice. London: *The King's Fund* 2010
[5] Donebedian A. The Quality of Care: How it can be assessed? *The Journal of the American Medical Association*, Sept 23/30, 1988 – Vol 260, No.12

determined.[6,7] Medical practitioners use outcome measures intrinsically to assess when treatment should be changed, referred to another, or discontinued. While outcomes may not be the only measure of quality they by and large provide the ultimate validation of the effectiveness and quality of medical care.[8]

Practical and well-designed outcome measures are fundamental to understanding the benefits and value of specific actions or interventions, and for self-directed learning for continuous improvement in the delivery of and quality of care provided.

Health outcomes are affected by more than just the care provided by clinicians or the personal choices of patients, as social determinants and government policies can have a significant impact. To be meaningful, the right measure for the right purpose must be selected. In general, the broader the perspective required, the greater the relevance of the outcome measure, i.e. national rates of mortality or morbidity. However, the narrower the perspective, the less relevant the outcome measure is, with a process measure relatively more useful.[9]

Quality measures should reflect meaningful health outcomes.[10] Measuring the effects of healthcare on patients or populations will involve assessing changes to health status, behaviour, health literacy, as well as patient satisfaction and health-related quality of life. However, accurately measuring outcomes that can be attributed exclusively to healthcare and that don't have unintended consequences is very difficult, making it essential that any such measures are developed by the profession for the voluntary use of the profession to drive quality improvement and to ensure they are appropriately focussed, measurable, reliable and relevant.

Measuring outcomes typically involves the use of clinical indicators across a number of domains, along with patient reported outcome measures (PROMs) and patient reported experience measures (PREMs). For example, in 2004, the National Health Service (NHS) in England, Wales, Scotland and Northern Ireland implemented the [imperfect] Quality and Outcomes Framework (QOF). The indicators of the framework spanned five domains; clinical, public health, public health-additional services, quality and productivity, and patient experience.

Any use of clinical indicators for the purposes of measuring outcomes must be in line with the AMA position statement on Clinical Indicators which can be viewed at https://ama.com.au/position-statement/clinical-indicators-2012.

Medical practitioners have generally been more comfortable with the use of clinical indicators which measure practice processes and clinical activities, as these are

[6] Krousel-Wood MA. Op.cit.
[7] Roach KE. Measurement of Health Outcomes: Reliability, Validity and Responsiveness. *The Journal of Prosethics and Orthotics* 2006; Volume 18, Number 1S, p 8
[8] Donabedian A. Evaluating the quality of medical care. *Milbank Memorial Fund Quarterly* 1966;44:166-206
[9] Mant J. Op.cit.
[10] Mant J.2001. Process versus outcome indicators in the assessment of quality of health care. *International Journal for Quality in Health Care 2001*: Volume 13, Number 6: pp 475-480

components of care that can be reliably measured and that clinicians have more direct control over. All of the incentives provided under the Practice Incentive Scheme for example, either reflect a practice process or clinical activity.

The purpose of measuring outcomes is an important consideration in their design, their relevance, and thus their value. In order to optimise the performance of the health system, any framework for measuring outcomes should simultaneously pursue three interdependent objectives, known as the Triple Aim: population health; experience of care; and per capita cost.[11] In more recent times, and with greater emphasis on patient-centred care, there has been acceptance that the Triple Aim should be expanded to the Quadruple Aim to include the aim of improving the work life of health care providers as care of the patient requires care of the provider.[12.] In addition to this work, the 10 building blocks of high performing primary care which denote the key elements within the patient-centred medical home may help inform the context of any outcome indicators.

3. Key Concerns

There is an underlying assumption that quality measures positively impact on health outcomes. Yet there is no definitive evidence to support this, particularly within the framework of Bodenheimer's Quadruple Aim.[13,14] The QOF for example cost more than expected, was administratively burdensome adding to increasing work stress for GPs, led to inequities in reward, and did not appear to reduce associated mortality.[15]

One reason for this may be that health care is only one determinant of health. Nutrition, environment, lifestyle, poverty and the social structure of society have been demonstrated to have powerful effects on health as measured by mortality rates.[16] Another may be that the proliferation of quality measures, particularly in the US and UK, and particularly when linked to financial incentives such as pay-for-performance, has led to unintended consequences, such as unnecessary testing, inappropriate prescribing, "cherry-picking" of patients, reduced access to a GP of choice, and a greater focus on the indicator being measured than the patient.[17,18]

Quality and outcome measures may attract new funding streams via incentives, but may not achieve their purpose and may direct policy makers from more thoughtful approaches and useful interventions, such as addressing social determinants, multi-morbidity and the

[11] Berwick DM, Nolan TW, Whittington J. The Triple Aim: care, health, and cost. *Health Affairs* 27, no 3 (2008): 759-569

[12] Bodenheimer T, Sinsky C. From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider. *Annals of Family Medicine*. Vol 12. No. 6. November/December 2014. 573-576

[13] Saver BG. Op.cit.

[14] Bodenheimer T, Sinsky C. Op cit.

[15] Roland M and Guthrie B. Quality and Outcomes Framework: what have we learnt? *British Medical Journal* 2016; 354:i4060

[16] Mant J.2001. Process versus outcome indicators in the assessment of quality of health care. *International Journal for Quality in Health Care 2001*: Volume 13, Number 6: pp 475-480

[17] Saver BG. Op.cit.

[18] Roland M and Guthrie B. Op.cit

provision of individualised care.[19] Caution is therefore warranted when designing and implementing outcome measures. If they are poorly designed or focused, they are likely to be counter-productive, undermine clinician professionalism and erode patient trust.[20]

4. AMA Position

4.1 Purpose and utilisation

The AMA notes that Australia has in place key structural and process components of a quality framework for health care across the nation. These components include professional codes of conduct, standardised professional educational and registration requirements, standards of care and practice, including accreditation against those standards and clinical guidelines, to help drive and ensure the provision of quality care in this country.

Despite the range of national structural and process measures already in place for improving the quality of healthcare provided in Australia the AMA acknowledges that the pursuit of quality improvement is ongoing in the attempt to ensure the provision of the right care, to the right patients at the right time and in a cost-effective manner[21]. There is, therefore, ongoing interest in the development of outcome measures that can be attributed to the quality of care provided in general practice, which is the cornerstone and frontline of Australia's health care system.

The AMA believes that outcome measures are a key component of any objective assessment of the benefit or value to patients of a clinical practice or process. They are a tool with which any participating general practitioner and general practice can review the benefits of the services provided, and the manner in which they are provided, in order to ensure continuous improvement in patient health care and better health outcomes for their patients.

The introduction of any formal selection of outcome measures for use in general practice in Australia must primarily be for the purpose of self-directed GP learning aimed at improving patient health outcomes and the quality of patient care provided in general practice.

4.2 Development and Implementation

The use of outcome measures within general practice must be entirely voluntary, non-punitive, and facilitated through the internal review and effective analysis of practice held data. To ensure the acceptability of outcome measures[22] and that they are appropriately

[19] Hibbert P., Hannaford N., Long J., Plumb J. and Braithwaite J. (2013) Final Report: Performance indicators used internationally to report publicly on healthcare organisations and local health systems. Australian Institute of Health Innovation, University of New South Wales.

[20] Saver BG. Op.cit

[21] Krousel-Wood MA. Op.cit.

[22] Center for Health Policy/Center for Primary Care and Outcomes Research & Battelle Memorial Institute. Quality Indicator Measure Development, Implementation, Maintenance, and Retirement (Prepared by Battelle, under Contract No. 290-04-0020). Rockville, MD: Agency for Healthcare Research and Quality. May 2011.

focussed and used to improve patient health outcomes, they must be developed and agreed by the general practice profession, with input from key stakeholders.

When developing and implementing outcome indicators the following steps should be followed:

1. Select relevant patient groups, care processes or clinical outcomes to be evaluated.
2. Organise a balanced consensus group, measurement team.
3. Conduct a literature search for indicators already developed or data about optimal care available (evidence-based guidelines).
4. Select indicators and standards.
5. Define the measure specification.
6. Operationalise (identify data sources, data collection procedures, implementation plan, and pilot test).
7. Report (statistics, tabulations, data presentation).
8. Apply to the system of quality improvement.

The AMA notes that there is no outcome measure that is perfect for all purposes and that assessment of improvement toward a desired outcome may involve a suite of indicators appropriate for the purpose.

When determining what measures could be utilised to demonstrate progress towards a desired outcome the following factors must be considered:

a) Importance, relevance, meaningfulness
b) Feasibility (driven by availability of data)
c) Accessibility (be appropriate, measurable, and improvable)
d) Reliability (extent to which a measurement with an indicator is reproducible)
e) Sensitivity to change (measure needs to detect change in quality of care)
f) Validity (whether any criteria were rated valid by panels contrary to known results from Random Controlled Trials)

In addition, any formal outcome measures:

- must align with concepts of the medical home model and Bodenheimer's Quadruple Aim;
- must be supported with funding to:
    - facilitate and implement the processes necessary; and
    - encourage ongoing participation; and
    - reward quality improvements as part of a blended funding system i.e. adjunct to FFS and other incentive payments;
- must be aligned to national health strategic goals and priorities; and
- must be subject to ongoing review and evaluation.

4.3 Minimising Unintended Consequences and Preventing Mis-use

The AMA believes that following the processes and conditions outlined above will minimise unintended consequences of the use of outcome measures and help prevent

their mis-use.

Studies have highlighted there are inherent risks with using outcome measures to identify poor or high performers or as the sole basis for pay-for-performance incentives.[23,24]

Judgements made on risk-adjusted comparisons are unlikely to be comparing like with like and as such are unlikely to reveal any reliable information about the quality of care. Risk-adjusted comparisons are highly unreliable as there are many contingencies, such as practice policies, clinical skills and clinical interpretations that can impact the measure. Research has strongly indicated that such factors significantly weaken the link between quality of care and outcomes and can result in oblique information, for example the practitioner or practice with the highest 5% for mortality on a league table will not be among the 5% providing the poorest quality of care.[25]

Poorly designed or inappropriate measures can result in the dysfunctional behaviour of those being assessed and erroneous assessments. Measures that may be effective for quality improvement if used for performance management can lead to mis-directed blame, participant fear, mistrust, resistance, risk avoidance and gaming of data, patient classifications and process of care.[26]

In the quest for ongoing quality improvement, frameworks that are judgement-free and scientifically rigorous could enable GPs and general practices to monitor their own performance, compare themselves with their peers or against past performance and take whatever action seems necessary to improve the quality of care provided and health outcomes for patients.

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[23] Saver BG, Martin, SA, Adler RN, Candib LM, Deligiannidis KE, Golding J et al. 2015. Care that matters: Quality Measurement and Health Care. *PLoS Med* 12(11): e1001902. Doi:10.1371/journal.pmed.1001902

[24] Lilford, R, Mohamed, M, Spielgelhalter D and Thomson, R. Use and misuse of process and outcome data in managing performance of acute medical care: avoiding institutional stigma. *The Lancet*. Vol 363, April 3 2004, pp 1147-1154.

[25] Lilford, R et al. Op.Cit.

[26] Lilford et al. Op.cit.