- patient satisfaction (I like what he's doing);
- aiding adjustment (I know what I'm doing);
- a defence against unwarranted intrusion (he's only doing this);
- a respect (for rights)—I agree with what he's doing and he has asked me what I want.

In a legal–philosophical sense, consent can be taken as an authorisation (of a proposal to treat), as well as purely an expression of assent (to act). The authorisation implies that there has been an understanding of the nature and consequences of a procedure, and that there has been no coercion. There is, then, not only an agreement between two parties, but also an acknowledgement that a proper legal process has been followed and that no repercussions may follow.

There is a (mis)conception that shared decision-making and informed consent are synonymous; shared decision-making implies an equality in input between patient and doctor; clearly, in most cases, this does not exist. Every medical procedure does not need equality in decision-making at all; some requires little patient input, other than listening to and accepting the advice. A patient may wish that her physician makes all the necessary decisions about management.

There is authority implicit in some patient consent; broad or narrow. Autonomous consent-giving, no matter how enthusiastic or cooperative the patient may be, does not mean lawful consent. This is particularly so when the patient consent-giver is under the legal 'age of consent'. This transfer of authority (to proceed) may not satisfy legal requirements in that geographic region.

Consumerism in the millennium and consent

The ethical responsibilities of the physician in the realm of integrated services is beyond the scope of this article. However, within the legal concept of consent discussed, must come willingness to alleviate pain and suffering beyond the patient's ability to pay.

Physicians with a commercial interest in the business of providing care are subject to the same legal provisions as those in solo practices. Consent to treat does not imply an agreement to over-service.

References

1. Cardozo J. Schloendorff v Society of NY Hospital. In: 125 N, editor; 1914.
2. Skegg PD. Law, ethics and medicine: studies in medical law. USA: Oxford University Press; 1985.
3. Somerville M. Structuring the issue in informed consent. 1981;26:740.
4. Robertson G. Informed consent to medical treatment. 1981;97:102.

Cardiovascular disease risk profile tools and New Zealand—the best way forward?

Pauline Boland, BSc(Hons) OT, PGDip Rehab, NZROT; **Helen Moriarty** MBChB, FRNZCGP

The favourable trends in cardiovascular disease (CVD) mortality rates in New Zealand over the past 35 years may not be sustained due to less favourable trends with smoking and obesity.[1] This is of particular concern for at-risk groups, such as Maori and Pacific people.[2,3,4] This essay sets out to provide two distinct viewpoints on the best way forward and disseminate what these two pieces of research bring to the debate about how to progress this issue.

CORRESPONDENCE TO:
Pauline Boland
Rehabilitation Teaching and Research Unit,
Wellington School of Medicine and Health Science,
PO Box 7343, Wellington South, 6242, New Zealand
pauline.boland@otago.ac.nz

The case for the use of CVD risk profile tools

In 2006 Bannick et al. offered a possible avenue to combat this issue.[5] They described the CVD risk factor status of over 18 000 patients profiled in routine general practice in New Zealand.[5] Patients' CVD risk was assessed and managed using a web-based clinical decision support programme called PREDICT-CVD.[1] The authors conclude that PREDICT-CVD is a practical and effective tool for systematically generating standardised patient CVD risk factor profiles during routine primary care practice. They propose that, when implemented widely, PREDICT-CVD will enable primary care organisations to monitor the CVD risk burden and management in their practice populations using a nationally standardised evidence-based approach.[5]

This descriptive study was cost and time effective, as the data was opportunistically gathered as part of routine risk assessment.[5] The authors did not require training for the clinicians or that they perform extra duties.

One aim of the PREDICT-CVD study is to gather data on Maori, which is a priority in New Zealand legislation.[2,3,4] It can be pragmatic to tread a conservative path and assess whether a relation exists in cheaper studies that provide more rapid answers.[6,7] If a cheaper study confirms that a significant association is likely to exist, then it is reasonable to progress to a more definitive study such as a cohort study or randomised controlled trial (RCT).[8]

This study did not (and could not) measure the efficacy of the intervention. It is complicated by an unknown number of confounding factors[14] and as there is no control group, this study cannot give risk reduction ratios or odds ratios.

The authors did not state how they managed lost or missing data, particularly around ethnicity.[5] This means that poorly recorded or absent data could have influenced the results collected on ethnicity, which appears to be one of the primary areas of interest.

While the authors try to speculate on reasons for variance, they cannot prove or quantify their findings. The authors postulate that, while few patients over 75 were risk assessed, despite their high risk, they may have already been risk assessed using other risk prediction tools. This is speculative and needs to be investigated further as, despite a lesser impact (relative risk) of some factors in advanced age, risk profiles can be useful for predicting CVD events in elderly patients.[15]

An important factor when designing an epidemiological trial is to maximise generalisability.[8,14] Epidemiological studies tend to take place in natural settings, so the study population is more representative of the target population,[8] though the authors acknowledge that their population is not truly representative.[5] The population studied by Bannik et al. were too highly selected to represent either the population of the primary care organisation,[5] or the population of Auckland. This was always going to be the case as their sample was restricted by limited numbers of GP practices with access to the necessary technology. Bannik et al. do not discuss clinician details (e.g. level of experience)[5] or user feedback, even though this is often a factor with implementation of CVD risk profile tools.[16-20]

The case against the use of CVD risk profile tools

In contrast to the enthusiastic recommendations by Bannik et al.[5] about implementation of PREDICT-CVD, Brindle et al.'s well-conducted systematic review provides some sobering observations about CVD risk profile tools in general.[17] They investigated the accuracy and impact of risk assessment in the primary prevention of CVD, by performing a systematic review which gave them the ability to approach the question with unbiased and repeatable methodology.[14] This review found no conclusive evidence that the use of CVD risk profile tools significantly improves patient care.

The authors cast the net wide, with a clear strategy and few limitations to their search. Only randomised controlled trials (RCTs) were considered robust enough to be included, which is a credit in terms of the level of rigour in which they were interested. Conversely, this

It can be pragmatic to tread a conservative path and assess whether a relation exists in cheaper studies that provide more rapid answers. If a cheaper study confirms that a significant association is likely to exist, then it is reasonable to progress to a more definitive study such as a cohort study or randomised controlled trial

The New Zealand Guidelines Group observes that the Framingham risk assessment matrix combines five-year absolute CVD risk estimates with absolute risk reductions achievable with antihypertensive and lipid lowering therapy,[9] so the basis for PREDICT-CVD is backed by evidence from national guidelines.

However, this study was descriptive and opportunistic. The lack of a comparison population means one needs to be cautious about how confidently one can extrapolate recommendations. The original Framingham study[10] on which the PREDICT-CVD tool is based, has been criticised as being biased towards Caucasian men with a risk of underestimation[13] and overestimation of risk in other ethnic groups.[11-13]

limited the number of eligible studies, because although 26 studies were detected which examined the issue of effectiveness, only four were RCTs. This means that many other studies, possibly noteworthy, were excluded.

Systematic reviews rely on the quality of the data they are attempting to appraise and synthesise.[14] This review was dealing with RCTs with poor methodological quality, which affects the validity of the overall findings.

As so few appropriate trials were found, none were excluded due to methodological flaws. The limited population sizes and the acknowledgement that lack of rigour was not necessarily an exclusion criteria (or there would have been no review!), makes the data summarised from this review questionable. No test of heterogeneity was completed, making this a weaker review result.[14] Systematic reviews are often restricted to the inclusion of RCTs, although this concept has been relaxed in areas where such trials cannot be conducted because of practical or ethical considerations.[8]

In health areas where there have been few RCTs, other formal systems for incorporating alternative study designs have been developed. The authors may wish to reconsider their inclusion criteria to incorporate different study designs that may be of better quality than the few poor-quality RCTs they did review. It was not possible to synthesise the results due to heterogeneity and low study numbers, and transferability to a New Zealand–specific context is questionable.

Implications for the New Zealand context

If editors insisted that discussed sections of original articles included a systematic review of the relevant literature, would Bannik et al.'s study[5] endorsing PREDICT-CVD read the same?[21] Despite some methodological challenges, Brindle et al.'s review highlights that there is no conclusive evidence from robust RCTs that the use of CVD risk profile tools significantly improves patient care.[17] There is a message of caution to those involved with implementing PREDICT-CVD across New Zealand; work needs to be done to determine the efficacy and practicality of this tool.[17] The opportunistic and purely descriptive data-gathering design of Bannik et al.'s study[5] leaves more questions than answers, and is not in itself able to definitively support the introduction of PREDICT-CVD across New Zealand.

'The quality of evidence from observational studies is less than from randomised controlled trials because of confounding by indication and other biases related to the effects of unmeasured covariates.'[22] The best reason for evaluating processes of care is if RCTs have previously shown that those processes improve patient outcomes.[23] Brindle et al. have shown that this has not occurred with the use of CVD tools.[17] Bannik et al.'s study[5] does not, by itself, prove that this tool is necessarily better than any other risk profile tool (or no risk profile tool).

Categorical risk factor count approach with CVD is inefficient as it tends to overlook the considerable proportion of persons who were at high risk because of multiple marginal abnormalities,[15] so the use of CVD risk profiles is strongly recommended.[5] How local issues and implementation barriers are addressed will be crucial in determining how effective electronic risk profiles such as PREDICT-CVD will be.[24,25]

A new electronic decision support module (PREDICT-CVD-Diabetes) has been developed, which may provide a way of dealing with under-prediction for this group.[17] This new tool will face the same issues around access to technology and staff up-take as the original PREDICT-CVD. It remains that no randomised evidence to date has shown that informing clinicians and patients of absolute risk of CVD events leads to changes in care or improvement in outcomes.[18]

There has been some criticism of how Framingham-based risk profiles are calibrated.[18] particularly in relation to social and ethnic variables. Low socioeconomic status is known to have an adverse affect on many CVD risk factor levels in New Zealand.[26] The data collected in Bannik et al.'s observational study[5] may contribute to further studies which could be designed to conclusively show a significant effect on outcomes by using a New Zealand–appropriate CVD risk profile tool; this study is forming a building block of preliminary useful information.[4,27] This tool should be employed along with a comprehensive quality-driven programme to specifically target high-risk groups.[28]

It remains that no randomised evidence to date has shown that informing clinicians and patients of absolute risk of CVD events leads to changes in care or improvement in outcomes

References

1. Metcalf P, Scragg R, Schaff D, Dyall L, Black P, Jackson R. Trends in major cardiovascular risk factors in Auckland, New Zealand: 1982 to 2002–2003. NZ Med J. 2006;119:1–16.
2. Sharav VH. Excerpts from David Healy and Joanna Le Noury's article 'Pediatric bipolar disorder: An object of study in the creation of an illness'. [serial on the Internet]. 2007 [cited:[about p.]. Available from: downloaded from http://www.ahrp.org
3. Riddell T, Jackson RT, Wells S, Broad J, Bannink L, Riddell T, et al. Assessing Maori/non-Maori differences in cardiovascular disease risk and risk management in routine primary care practice using web-based clinical decision support: (PREDICT CVD-2) NZ Med J. 2007;120(1250):U2445.
4. Wells S, Kerr A, Broad J, Riddell T, Kenealy T, Jackson R, et al. The impact of New Zealand CVD risk chart adjustments for family history and ethnicity on eligibility for treatment (PREDICT CVD-5) NZ Med J. 2007;120(1261):U2712.
5. Bannik L, Wells S, Broad J, Riddell T, Jackson R, Bannink L, et al. Web-based assessment of cardiovascular disease risk in routine primary care practice in New Zealand: the first 18,000 patients (PREDICT CVD-1). NZ Med J 2006;119(1245):U2313.
6. Kleinbaum D, Kupper L, Morgenstern H. Epidemiolgic research: principles and quantitative Methods. New York: John Wiley & Sons; 1982.
7. Hennekens CH. Increasing burden of cardiovascular disease: current knowledge and future directions for research on risk factors. Circulation. 1998;97(11):1095–1102.
8. Peat J, Mellis C, Williams K, Xuan W. Health science research: a handbook of quantitative methods. London: Sage; 2001.
9. American Academy of Child & Adolescent Psychiatry. Practice parameter for the assessment and treatment of children and adolescents with reactive attachment disorder of infancy and early childhood. J Am Acad Child Adolesc Psychiatr. 2005;44(11):1206–1219.
10. Dawber T, Meadors G, Moore J, FE. Epidemiological approaches to heart disease: the Framingham Study. Am J Pub Health. 1951;41:279–281.
11. Brindle P, Emberson J, Lampe F, Walker M, Whincup P, Fahey T, et al. Predictive accuracy of the Framingham coronary risk score in British men: prospective cohort study Br Med J. 2003;327(7426):1267.
12. D'Agostino SRB, Grundy S, Sullivan LM, Wilson P, for the CHDRPG. Validation of the Framingham Coronary Heart Disease Prediction Scores: Results of a Multiple Ethnic Groups Investigation. JAMA. 2001;286(2):180–187.
13. Brindle PM, McConnachie A, Upton MN, Hart CL, Davey Smith G, Watt GC, et al. The accuracy of the Framingham risk-score in different socioeconomic groups: a prospective study.Br J Gen Pract. 2005;55(520):838–45.
14. Ridgeway R, Guller U. Interpreting study designs in surgical research: a practical guide for surgeons and surgical residents. J Am Coll Surg. 2009;208(4):635–645.
15. Kannel W, D'Agostino R, Sullivan L, Wilson P. Concept and usefulness of cardiovascular risk profiles. Am Heart J. 2004;148(1):16–26.
16. Bonnevie L, Thomsen T, Jorgensen T, Bonnevie L, Thomsen T, Jorgensen T. The use of computerized decision support systems in preventive cardiology–principal results from the national PRECARD survey in Denmark. Eur J Cardio Prev Rehab. 2005;12(1):52–5.
17. Brindle P, Beswick A, Fahey T, Ebrahim S. Accuracy and impact of risk assessment in the primary prevention of cardiovascular disease: a systematic review. Heart. 2006;92(12):1752–9.
18. Scott I. Evaluating cardiovascular risk assessment for asymptomatic people. Br Med J. 2009;338:164–168.
19. Torley D, Zwar N, Comino EJ, Harris M, Torley D, Zwar N, et al. GPs' views of absolute cardiovascular risk and its role in primary prevention. Aust Fam Physician. 34(6):503–4.
20. van Steenkiste B, van der Weijden T, Stoffers HE, Kester AD, Timmermans DR, Grol R, et al. Improving cardiovascular risk management: a randomized, controlled trial on the effect of a decision support tool for patients and physicians. Eur J Cardio Prev Rehab. 2007;14(1):44–50.
21. Montori V, Jaeschke R, Schunemann H, Bhandari M, Brozek M, Devereaux P, et al. User's guide to detecting misleading claims in clinical research reports. Br Med J. 2004;329:1093–1096.
22. Tannen R, Weiner M, Dawai X. Use of primary care electronic medical record database in drug efficacy research on cardiovascular outcomes: Comparison of database and randomised controlled trial findings. Br Med J. 2009;338:1–8.
23. Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schunemann HJ, et al. What is 'quality of evidence' and why is it important to clinicians? Br Med J. 2008;336(7651):995–8.
24. van Steenkiste B, van der Weijden T, Stoffers HE, Grol R, van Steenkiste B, van der Weijden T, et al. Barriers to implementing cardiovascular risk tables in routine general practice. Scand J Primary Health Care. 2004;22(1):32–7.
25. van Steenkiste B, van der Weijden T, Timmermans D, Vaes J, Stoffers J, Grol R, et al. Patients' ideas, fears and expectations of their coronary risk: barriers for primary prevention. Patient Education & Counseling. 2004;55(2):301–7.
26. Simmons D, Harry T, Gatland B. Prevalence of known diabetes in different ethnic groups in inner urban South Auckland. NZ Med J. 1999;112:316–319.
27. Peiris D, Murray J, Scully D, Tilakawardene V, Hetaraka-Stevens L, Stewart T, et al. Cardiovascular risk management at a Maori-led Primary Health Organisation–findings from a cross-sectional audit. NZ Med J. 2008;121(1285):35–46.
28. Whittaker R, Bramley D, Wells S, Stewart A, Selak V, Furness S, et al. Will a web-based cardiovascular disease (CVD) risk assessment programme increase the assessment of CVD risk factors for Maori? NZ Med J. 2006;119(1238):U2077.

ACKNOWLEDGEMENTS

This paper was completed following submission of an article critically evaluating this area, as part of a Research Methods Paper (HASX417), through the University of Otago.

COMPETING INTERESTS

None declared.