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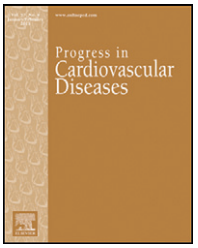

Is the Guideline Process Replicable and, if Not, What Does This Mean?

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ABSTRACT

Increasingly, guidelines determine how medical care will be provided. However there has been limited study of the determinants of the reliability of the guideline process. Guidelines translate evidence into recommendations. If only the evidence determines the recommendations, given the same evidence, different panels of experts should make the same recommendations. That is, the process should be replicable, an essential characteristic of a valid scientific process. The multiple recent cholesterol guidelines, which have considered the same evidence, offer an opportunity to examine guidelines from this perspective. Considerable discordance among the guideline recommendations is evident pointing to an important role for the participants, in addition to the evidence, in the development of guideline recommendations. Guideline recommendations, therefore, appear to be based on both evidence and expert opinion.

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Background and objective

The practice of medicine is now governed by guidelines. The recommendations of guidelines have become the standard of care and, increasingly, reimbursement is linked to adherence. The knowledge base on which trainees are evaluated is the knowledge base defined by guidelines. The knowledge base on which recertification is based is the knowledge base defined by guidelines. To pretend otherwise is to deny the reality that the practice of medicine is now governed to an increasing degree by the paradigm of evidence-based medicine (EBM) and its product-guideline-based care.

We accept that values of EBM do not differ from the classical values of medical care of which the principal one is to ensure the best possible outcome for each individual patient.[1] What is different is that EBM has become a method to decide how that should be determined, a method in which best care for an individual patient is based, to the greatest extent possible, on the results of what has occurred in groups of patients studied under the most controlled circumstances possible—the randomized clinical trial (RCT). The strengths and limitations of the RCT as an experimental tool are not the focus of this essay. Rather, our purpose is to examine this process: the translation of evidence by experts into recommendations.

Statement of Conflict of Interest: see page 8.

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Abbreviations and Acronyms

AHA/ACC = American Heart Association/American College of Cardiology

Apo = apolipoprotein

CCS = Canadian Cardiovascular Society

CHD = coronary heart disease

CKD = chronic kidnet disease

CV = cardiovascular

DM = diabetes mellitus

EAS/ESC = European Atherosclerosis Society/European Society of Cardiology

EBM = evidence based medicine

HDL-C = high-density liipoprotein cholesterol

IAS = International Atherosclerosis Society

JBS3 = Joint British Society

LDL-C = low-density lipoprotein cholesterol

NLA = National Lipid Association

RCT = randomized controlled trial

The interpretation of any single piece of evidence requires the evaluation of the methods and conclusions of the study that generated that evidence. Once there is more than one piece of evidence, whatever there is, must be assembled, evaluated and integrated into a final recommendation by however many individuals make up the panel. Accordingly, guideline recommendations are the outcome of a complex process, a process that has not been studied and validated. If the outcome of this complex process is not automatic, if it is not certain and necessary, then the recommendations that ensue cannot simply be a product of the evidence, but must also be influenced by the participants, by their views and the interactions among them. If so, the recommendations may be evidence-based, but they are not entirely evidence-determined. Therefore whatever emerges is only one of many possible outcomes. If this is the case, the recommendations of any guideline process cannot be assumed to be valid simply because an agreed-on deliberative process has been followed.

Replicability is an essential feature of a scientifically valid process, although this does not ensure that the conclusions are valid, but merely that the process by which the conclusions were reached is reproducible. Accordingly, to assess the replicability of the guideline development process, we will examine the replicability of the recent cholesterol guidelines. These were selected for two reasons. First, in this domain of research, there is an abundance of the highest quality evidence. Many RCTs that are accepted as well designed and well conducted have been performed and several meta-analyses that are accepted as well designed and well conducted have been performed on these RCTs. Second, there are numerous recent cholesterol guidelines, which have been conducted by prominent national and professional groups. The recommendations from these groups have been based on almost the same body of evidence. To the extent their recommendations are the same or similar, the process is replicable. To the extent, they are not, the guideline process is not replicable and one would conclude that the outcome has been determined by subjective as well as objective forces.

Cholesterol guidelines

The recommendations of six recent major cholesterol guidelines were compared. These were issued by the European Atherosclerosis Society/European Society of Cardiology (EAS/ESC) in 2011,[2] by the Canadian Cardiovascular Society (CCS) in 2012,[3] by the American College of Cardiology/American Heart Association (ACC/AHA) in 2013,[4] by the Joint British Society (JBS3) in 2014,[5] by the International Atherosclerosis Society (IAS) in 2014[6] and by the National Lipid Association (NLA) in 2014.[7] Five items were selected on which to compare the 6 guidelines. These selections cover different aspects of the process of care. For each item, we determine whether the recommendations are concordant or discordant and, if the latter, whether in our view, the discordance is significant or not. The issue is not whether the guideline recommendations are concordant with our views but only whether they are concordant with each other: that is, do they or do they not reach the same judgments on the same issues?

Methods to select subjects for primary prevention

All distinguished between primary and secondary prevention and all chose categorical indications for secondary prevention such as symptomatic vascular disease or diabetes or extreme elevations of low-density lipoprotein cholesterol (LDL-C) because all these clinical categories are acknowledged to be associated with subsequent high risk of a cardiovascular (CV) event. Specific definitions differed in some regards, such as when patients with type I diabetes mellitus (DM) were at high risk but these differences were minor. Accordingly, in this regard, the recommendations of all the guideline groups are concordant.

However, considerable discordance was evident in the selection of subjects for primary prevention with lipid lowering therapy. (Table 1) Three of the six guidelines selected subjects for statin therapy for primary prevention based on calculated 10-year risk. The algorithms used differed but their operative features were the same. In SCORE, the algorithm used by EAS/ESC, only fatal CV events were included, whereas in the others, non-fatal events were included as well. All the algorithms used had been validated although not necessarily in the populations to whom they were applied. Thus, the CCS guidelines for a multiethnic Canadian population calculated risk based on the Framingham algorithm, which was developed for a primarily white Caucasian population. Interestingly, none of the guidelines compared the performance of the algorithm they had

Table 1 – Primary Prevention is based on:

Guideline	Primary	Supplementary
EAS/ESC	10 year—SCORE (Fatal CVD)	Risk relative to a normal
CCS	10 year Framinghahm + LDLC/non-HDL-C/apoB in Intermediate Risk	Cardiovascular age
ACC/AHA	10 year pooled cohort equation	Lifetime
JBS3	10 year QRISK2	Lifetime
IAS	Risk up to age 80	
NLA	Risk factor Counting	

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