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Guidelines, Calculators and Clinical Judgement

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A guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk with a risk calculator was published by the American College of Cardiology and the American Heart Association on 12th November 2013 [(1)]. It generated a controversy in the medical [(2)] and lay [(3)] press and was thought by many to overestimate cardiovascular risk and result, if implemented, in massive over prescription of statin drugs.

The event raises questions on **whether guidelines are flawless and whether doctors are bound to abide by them!**

Throughout the history of medicine, great physicians have written instructions to guide their colleagues in their practice. Those *guidelines* reflected the personal experience and judgment of their writers and the knowledge they inherited from their predecessors. With the advent of clinical **randomized controlled trials (RCTs)** in the second half of the previous century, guidelines took a different shape: more accurate, organized and **evidence based**. They came to be written by committees of experts who study the clinical trials done in a particular subject and write instructions based on the results of these trials. The instructions are intended to help doctors in assessing the condition of their patients, estimating their risk and advising about management. They are frequently accompanied by tables, algorithms, calculators etc. With the widespread use of computers nowadays, these guidelines are frequently aided by software applications, which facilitate their use and make them available on computers, tablets and mobile phones which can be carried in the pocket of the user or accessed on the internet anywhere.

Back to the questions:

Are guidelines flawless? Are doctors bound to abide by them?

They are to start with *guidelines* and not *laws*. They are not legally binding. They are meant to help the doctor make informed decisions, not to provide ready made decisions.

Guidelines are based on the results of randomized controlled trials and *on the assumption that your patient is similar to the patients studied or to a group within them to a sufficient degree that justifies treating him in a similar manner and expecting similar results.* But, every individual patient is in fact unique and cannot be precisely represented by patients included in the trials.

Trials are done in different countries (*mostly developed countries, an important point to remember for a doctor practising in a developing country*). They lump together patients of different ethnicities, nationalities, environment, cultures, education, economic level, etc. The studies may have been done ten or twenty years ago and things may have changed since. The results of trials are based on statistical analysis of large numbers of patients who are divided into groups by artificial boundaries according to various parameters (e.g. age, number of cigarettes smoked, etc). The groups are represented by their averages like the mean or median. Your patient is not necessarily represented well by the average used. If he is 60

year old, you may have an instruction, which treat him similar to a 69 year old because he is in the same age group. The risk of a certain condition or the outcome of a certain intervention depends on many factors in each patient. The clinical study cannot take into account all factors that may affect the result. It is almost certain that there are factors in your patient which have not been included in the clinical trials studied. There is not enough trials and guidelines to have a specific guideline for each ethnicity, nationality, culture, level of education, intelligence, economic state, etc.
The following may serve as explanatory examples:

- **CHADS2 score** [4]: It is a guideline on anticoagulation to prevent stroke in patients with nonvalvular atrial fibrillation according to the presence of other risk factors (congestive heart failure, hypertension, age 75 y or above, diabetes and previous stroke or transient ischemic attack). It treats all patients with nonvalvular atrial fibrillation, permanent and paroxysmal, in the same way based on evidence from clinical trials showing similar risk of stroke in permanent and paroxysmal atrial fibrillation [5,6]. But *are patients with paroxysmal atrial fibrillation a homogeneous group?* Is it logical to think that patients who experience one attack every several months, which lasts few minutes carry the same risk of stroke as those who have daily or every few days attacks that last hours [7]? Do we have to treat our patients with paroxysmal atrial fibrillation in the same way regardless of the frequency or the duration of their attacks?
- **Osteoporosis fracture risk calculators and treatment guidelines:** The calculator estimates the 10 year risk of developing a fracture depending on the result of bone mineral density assessment and some other risk factors. There are more than one calculator developed in various places. The WHO one (FRAX) [8] is probably the most widely used. Another calculator (QFracture [9,10]), developed in the United Kingdom, assesses fracture risk regardless of bone mineral density relying on a larger number of other risk factors that are more readily available. Its developers justified this by evidences that most fragility fractures occur in women with normal bone mineral density [11] and that risk prediction algorithms that do not include bone mineral density are almost as good as those that do [12]. However no calculator can be perfect enough to consider all possible factors that affect the probability of developing fragility fractures like balance and coordination, presence of other diseases, drugs, alcohol consumption, smoking, body weight, type of work, home atmosphere, intelligence and education, using a car or public transport and so on. No calculator can take all these into account but you should in your particular patient, especially if you are contemplating long term treatment with potentially hazardous drugs like bisphosphanates.

Guidelines are no doubt very useful. They put you in a better position by giving you an idea on the risks of your patient and the possible benefit of various interventions based on the outcome of randomized controlled trials on thousands of patients. However, it is you who should decide whether your patient could reasonably be considered similar to the average patient included in such trials. Certain characteristics in your patient that may affect his risk or his management and are not included in the guideline or the calculator should be taken into account to decide whether to apply, modify or abandon an instruction, especially if your patient falls near a border between various groups. It is your **clinical judgement** that makes the final decision. The committee who wrote the guideline on the treatment of blood cholesterol that I mentioned in the opening of this article has in fact defended its position by pointing out (among other things) that the guideline included a statement that it *should not be implemented blindly and that doctors should apply the art of the practice in dealing with individual patients*.

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