EXPERTISE - NO LONGER A SINE QUA NON FOR GUIDELINE AUTHORS?

Quis custodiet ipsos custodes? – Who will guard the guards themselves? (1)

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Guidelines are traditionally scripted by a panel of experts who are intimately familiar with the topic in question. Practicing physicians inherently trust guideline authors and rarely ever question their expertise, especially when guidelines are endorsed by such venerable societies as the American College of Physicians (ACP) and the American Academy of Family Practitioners (AAFP) and are published in high impact journals such as the Annals of Internal Medicine. The more than 250,000 members of the ACP and AAFP have come to expect that any set of clinically meaningful guidelines has been put together by authors who were selected because of their outstanding skills and expertise pertaining to the topic in question. Thus, there is little if any reason to voice doubt as to the validity of published guidelines

The Free Dictionary defines expertise as "special skills or knowledge acquired by a person through education, training, or experience." For a physician unfamiliar with the experts, there are several simple ways to get a grasp on the quality and quantity of expertise:

1. One can scrutinize the publication list of the experts, to assess how often they have been involved with the guideline topic. Any expert is expected to be well published in the specific area of the expertise.
2. One may take into account an expert's membership in professional organizations pertaining to the subject matter. Obviously, membership and participation in annual meetings demonstrates an ongoing interest in the guideline topic.
3. One may examine whether the physician/scientist has been invited to serve on editorial boards of journals dealing with the topic in question.. Being a member of an editorial board and peer reviewing submissions attest to some expertise pertaining to the guideline topic.

When one scrutinizes the authors of what is called the Joint National Committee (JNC) 8 (2), there is little doubt that most of them were indeed true experts, displaying "skills or knowledge acquired through education, training, or experience" to guide other physicians in detection, evaluation, and treatment of patients with hypertension. Many of these authors have extensively published on hypertensive cardiovascular disease, are members of professional societies and editorial boards of peer reviewed journals on hypertension (Table 1).

Such is unfortunately not the case when canvassing the authors of the recent "Clinical Practice Guideline from the American College of Physicians and the American Academy of Family Physicians" pertaining to "Pharmacologic Treatment of Hypertension in Adults Aged 60 Years or Older" (3). Table 1 compares the authors of JNC 8 with the authors of the ACP/AAFP Guidelines pertaining to publication record on hypertension, membership in professional societies and membership of editorial boards. The highly statistically significant results mostly are self-explanatory. In fact, as per PubMed, 3 of the 7 guideline authors have never authored an article on hypertension and 1 has coauthored a single study only. Moreover, not one of the authors of the ACP/AAFP Guideline is known to be a hypertension specialist certified by the American Society of Hypertension (ASH) or even a member of ASH or of the AHA Council for High Blood Pressure. In contrast, more than half of the JNC 8 authors are certified ASH specialists and even more are ASH members. No ACP/AAFP Guideline author is currently serving'on the editorial board of a journal dealing with hypertension such as Hypertension, Journal of Hypertension, American Journal of Hypertension etc., whereas the JNC 8 authors have a total of 17 editorial board memberships.

In order, not to overlook any hypertension experts we, also examined the individuals who were listed serving on the ACP Clinical Guidelines Committee from initiation of the project until its

approval. If anything, their records of the same expertise criteria is even inferior to those of the authors. One can of course argue that hypertension is a common disorder and those individuals listed as serving on the ACP Clinical Guidelines who are practicing physicians, have treated and continue to treat hypertensive patients. However, the mere fact that you know how and when to prescribe hydrochlorothiazide does not make you an expert in hypertensive cardiovascular disease.

On a somewhat positive note, the authors clearly have extensive know-how as to formalities regarding composition of guidelines and are aware of pertinent rules and regulations. Also, compared with the JNC 8 authors, the ACP/AAFP Guideline authors have a much shorter list of conflicts of interest. By no means are we suggesting that such authorship should consist of experts only, but at a minimum, experts should be part of it or at least extensively consulted. The complete absence of individuals with experience in hypertensive cardiovascular disease makes the ACP/AAFP Guidelines unacceptable to practicing physicians.

To list various deficiencies in the ACP/AAFP Guidelines is beyond the scope of this commentary. Briefly, the authors make very similar recommendations as JNC 8, which depended on evidence that was strong in itself, but not truly relevant to the guideline's most vital question: What is the optimal blood pressure treatment target in hypertensive patients aged 60 or over? Importantly new outcomes evidence and analyses available since JNC 8 was published, appear to have been discounted by the ACP/AAFP Guideline authors. Of concern is that SPRINT-Elderly data or any of the subsequent analyses have been ignored. Clearly these findings are seminal to the above question (4,5).

Of note, the meta-analysis (6) on which the ACP/AAFP Guidelines are based, although supposedly dealing with adults aged 60 years or older, included randomized trials of patients with a mean age of at least 60 years. This means that this meta-analysis (and the resulting guidelines)

were based on findings from numerous patients who were below that age limit. In addition, as pointed out by Bangalore (S. Bangalore, personal communication), one of the issues with the underlying meta analysis pertains to the problematic terminology of "intensive" and "standard". The "intensive" arm of ADVANCE (Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation) (~134 mm Hg) achieved similar BP control as the "standard" arm of ACCORD (The Action to Control Cardiovascular Risk in Diabetes Study Group) or SPRINT (Systolic Blood Pressure Intervention Trial) (133 mm Hg) and therefore combining this in a meta analysis is inappropriate.

Regarding safety, the ACP/AAFP Guidelines fail to identify angioedema as a rare but potentially fatal adverse event of angiotensin converting enzyme inhibitors (7, 8). African American patients are at a particularly high risk of angioedema with this drug class (8, 9, 10). Since the angioedema may manifest itself months after initiation of therapy, not uncommonly neither patient nor physician connect the dots between the antihypertensive medication and periodic swelling of lips, tongue and larynx. Not to even list angioedema as an adverse event is a most troubling omission. We are not privileged to know who selected the authors for the ACP/AAFP Guidelines, nor do we have access to selection criteria. In most US and international guidelines (2, 11, 12) selection has been expertise based. However, as illustrated by ACP/AAFP Guidelines, expertise no longer seems to be a prerequisite, or sine qua non, for authoring guidelines for practicing physicians. If there were selection criteria for the authors of these hypertension guidelines, they must have been other than “special skills or knowledge acquired by a person through education, training, or experience.”

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Table 1: Comparison of publications, Society of Hypertension certification and membership, and Editorial Board Membership (as per 01/2017)

	No. of Publications on Hypertension*	Society certified specialist†	Society membership‡	Editorial Board Membership§
JNC 8 No. of authors=17	39 (5.5-121)	8	12	17
ACP/AAFP No. of authors=6	0.5 (0-2.5)	0	0	0
Associated members ACP/AAFP No. = 28	0 (0-0.75)	0	0	0
2013 ESC/ESH No. of authors=25	98 (40.5-197)	17	18	23

* Median (interquartile range)
† http://www.ash-us.org/Physician-Directory.aspx and http://www.eshonline.org/communities/hypertension-specialist/directory-of-specialists/, respectively
‡ American Society of Hypertension (ASH) and European Society of Hypertension (ESH), respectively
§ Hypertension, Journal of Hypertension, American Journal of Hypertension, Journal of the American Society of Hypertension, Journal of Human Hypertension, and Journal of Clinical Hypertension