Screening Is Not as Simple as It May Seem

We were very interested to read 2 commentaries1,2 on the recent guidelines on lipid screening in children3 because the differences highlighted several important paradigm differences between the authors.

The first is that the guideline and the defense of the guideline reflect an attitude of paternalism toward both primary care physicians and the patient. It is unfortunate that the guideline recommends an intervention without quantifying the benefit or the harm. We recognize that the weight of evidence suggests lipid screening is a good idea, but when a mother asks, “How effective is this? What difference is this going to make?” how is the primary care doctor supposed to answer? Instead of providing the information needed to have a collaborative discussion that would quantify the risks and benefits (such as number needed to screen, number needed to harm), the primary care physician is left to simply answer that it seems like a good idea but no one knows how big a difference this intervention is going to make. In the past, a paternalistic guideline may have been readily accepted, but we are moving toward an era in which patients and families, with increasing health literacy, are expecting to make decisions with the physician in a collaborative matter. A guideline that does not give the physician the ability to explain why an intervention is worthwhile will undermine the authority and credibility of the physician to provide tangible information. I understand that without a specific screening trial which tests these guidelines in a real population, the current evidence does not lend itself to calculating a number needed to screen/number needed to harm, but that should be recognized as a weakness of the guidelines. For harms data, telling a parent that a 2-year trial showed safety when the child may be on a medication for decades is unlikely to be reassuring. It is better to have data. We think guidelines need to reflect that both the primary care physician and the patient would like to know not just if an intervention is effective but how effective it is.

Second, the effectiveness and harms of a guideline cannot be assumed without testing. Guidelines are applied both too aggressively (such as colonoscopy guidelines for cancer screening4) and ignored (such as HIV screening guidelines5), leading to a different outcome than expected by the writers of the guidelines. If a guideline is extrapolated from circumstantial information, the true efficacy and harm of a guideline will differ from the originating evidence. This result will require further studies to see if the guideline actually achieves what was intended with the expected amount of harm. It cannot be assumed from disease-oriented data.

Third, it is very complicated to mandate a new universal screening to an already packed well-child checkup when the intervention has unquantified risks and benefits and will likely trigger an incomplete discussion. There is already not enough time to fully practice preventive care6 or chronic disease management7 in primary care. Looking at other topics in the same issue of Pediatrics, there are articles about tonsillectomy, genetics, child abuse, Lyme disease, and maternal–infant feeding issues. Without enough time or clear information to have a collaborative discussion, there is the potential that this guideline could be implemented in a coercive manner, disrupting the patient–physician relationship, or ignored altogether because it is too time-consuming to explain the guideline and the logistics of a fasting test. This recommendation for screening may simply be placed on the large pile of things primary care physicians should be doing but do not have time to do.

Fourth, the conflict of interest that we are concerned about has little to do with ties to industry. Our concern is that for some of the authors, their careers are focused on lipids. They have a vested interest in highlighting the importance of lipid problems. In the same way that to a hammer everything looks like a nail, to a lipid specialist, managing lipids may seem to take priority over the myriad of issues facing the primary care pediatrician. We also suspect there is a lack of general primary care clinician input. A lipid specialist may not recognize the need to justify a new intervention to a primary care clinician who is juggling multiple priorities.

Guidelines rarely survive their first encounter with the real world, but we would hope that newer guidelines would take into account issues that are important to the practicing physician, not just a mandate for an intervention. Guidelines should be able to help the clinician and patient understand the tangible risks and benefits of a proposed intervention as well as being able to be realistically implemented.

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Conflict of Interest:
None declared

REFERENCES
McCrindle et al are right in that our commentary contained opinions. So did theirs. It may help to highlight areas where we agree and disagree.

We agree that:
1. Childhood lipid levels can identify children at increased risk of atherosclerosis decades later.
2. Clinical trials have shown that treating the 1 child in 500 who has FH can lead to improvements in intermediate outcomes such as coronary atherosclerosis.
3. Trials of whether treating the much larger number of children with high lipid levels as recommended by the proposed guidelines reduces future coronary events have not been done and are unlikely ever to be feasible.

Our areas of disagreement relate both to the aggressive nature of the National Heart, Lung, and Blood Institute guidelines and to the process by which they were produced.

1. We disagree that it is acceptable to make screening recommendations without estimating the health benefits, harms, and costs that might result. Because such estimates are essential for informed decision-making, we disagree that the “guidelines provide clinicians with the necessary evidence … to make their own informed judgment as to the utility and role for these recommendations.”

2. In the absence of randomized trial evidence of clinical event benefits, we disagree with making a “strong recommendation,” requiring a “compelling rationale for an alternative approach” (quoted from Tables 1–3, Evidence Grading System, Strength of Recommendations).2

3. Most important, we disagree that it is appropriate for panel members with extensive conflicts of interest to have leading roles in creating practice guidelines.

Re: Childhood Lipid Screening: Evidence and Conflicts

McCrindle et al titled their response to our commentary, “Bringing Evidence to the Debate.” However, they primarily reiterated the rationale already in the guidelines, rather than bringing new evidence to address our concerns.

One concern was that the guideline did not address the cost-efficacy of its recommendations. McCrindle et al cited studies of the cost-efficacy of screening for the rare (1 in 500) genetic condition familial hypercholesterolemia (FH). However, such a narrowly focused screening program was not recommended in the guideline. The $8700 per year gained that they quote is irrelevant because it refers to a program to screen family members of known FH cases,1 not to the population-wide screening program they recommend, which would be far less cost-effective.

Conflicts of interest among authors of guidelines were discussed in a recent report from the Institute of Medicine (IOM). With the exception of disclosing conflicts, none of the panel’s recommendations were followed (Table).

The panel members, however well-meaning, are only human, and it is unreasonable to believe that the large body of research on conflicts of interest that led to the IOM recommendations does not apply to them. A flawed process led to overly aggressive guidelines in which the strength of the evidence was misrepresented and key evidence needed to evaluate the guidelines was lacking. We can and should do better. Let’s start by following this key IOM recommendation: scientists with extensive conflicts of interest should not be permitted to have leadership or voting roles on guideline panels.
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