Important Instructions for Approving Your Edited Manuscript

- This PDF document contains your edited manuscript (text and tables).
- Please respond to my queries within 24 hours.
- Do not generate a new electronic version of your manuscript.
- If you have Adobe Reader (http://www.adobe.com/products/reader.html) or Adobe Acrobat, you may indicate your changes in the file, but you must use Adobe's Comment tool. **Do not make any changes directly in the file using strikethroughs and underscores**. Upload the annotated PDF file to The JAMA Network production system using the encrypted link sent to you in the email.
- If you are unable to use Adobe, indicate clearly all changes by page number and line number. Please include the entire sentence, with your changes clearly marked (in bold, italics, or underline).
- Please verify that the email address we are displaying is accurate and is the one you wish to use for correspondence.
- Please answer all questions and review the manuscript thoroughly.
- If your manuscript contains tables, they will be more readable when they have been formatted; review them for content only, not for bad word breaks or the shapes of the cells.
- If your manuscript has figures, they are being formatted and will be sent to you separately and/or included in the proof that we will send to you for final review.
- The information in your manuscript is confidential. You should not distribute copies of the edited
 manuscript to anyone, except coauthors, without our approval. The news media should not release any
 information about your article until the date of publication. Please contact me if you need to confirm your
 publication date.
- If you have questions or need help coordinating news releases or media attention, contact JAMA Network Media Relations at mediarelations@jamanetwork.org or 312-464-5262.
- Please verify and confirm that all Conflict of Interest disclosure information for you and all coauthors is accurate, complete, up-to-date, and reported accurately and in its entirety.
- Our policy requires that all authors disclose all potential conflicts of interest, including specific financial interests and relationships and affiliations (other than those listed in the author affiliations) as listed are disclosed. Definitions and terms of such disclosures can be found at the journal's Instructions for Authors. Authors should err on the side of full disclosure and should contact the editorial office if they have questions or concerns.
- Please be sure that any funding/support information is complete and accurate, including the role of the sponsor.
- You may order author reprints or eprints online at www.ama-authorreprints.com.

I hope you will be pleased with our editing and the published version of your manuscript. Sincerely yours,

John McFadden Senior Manuscript Editor Phone: 312-464-2479 John McFaddon @iomano

John.McFadden@jamanetwork.org

2 Healthful Diet and Physical Activity for

3 Cardiovascular Disease Prevention in Adults

4 Without Known Risk Factors

- 5 Is Behavioral Counselling Necessary?
- 6 Simon Capewell, MD, DSc¹

1

- 7 Christopher Dowrick, MD, FRCGP²
- ¹Clinical Epidemiology, University of Liverpool, United Kingdom
- ²Primary Medical Care, University of Liverpool, United Kingdom
- In 2014, the US Preventive Services Task Force (USPSTF) issued
- advice focused on individuals with elevated cardiovascular risk factors.¹
- 12 They have now focused on "healthy" adults who do not have hypertension,
- dyslipidemia, obesity, abnormal blood glucose, or diabetes. The current This
- 14 issue of JAMA contains that latest USPSTF recommendation, which.² H
- states as follows: "The USPSTF recommends that primary care professionals
- 16 individualize the decision to offer or refer adults without obesity who do not
- 17 have hypertension, dyslipidemia, abnormal blood glucose, or diabetes to
- behavioral counseling to promote a healthful diet and physical activity.
- 19 Existing evidence indicates a positive but small benefit of behavioral

- 1 counseling for the prevention of cardiovascular disease (CVD) in this
- 2 population. Individuals who are interested and ready to make behavioral
- 3 changes may be most likely to benefit from behavioral counseling. (C
- 4 recommendation)"²
- 5 A healthful diet and physical activity are worthy targets. Indeed, poor
- 6 diet alone accounts for at least 40% of all deaths and disability-adjusted life
- 7 years (DALY). However, the USPSTF statement raises a number of issues.
- 8 These concerns might include intervention heterogeneity, "real-life"
- 9 effectiveness, potential benefits and harms, and the distraction from other,
- more effective prevention strategies for these low-risk individuals, and
- indeed for the wider community.

12

A Diversity of Behavioral Change Interventions

- The USPSTF reviewed over 120 distinct and diverse counseling
- interventions focusing on promoting a healthful diet, physical activity, or
- or web-based materials). Half of the interventions were medium-intensity
- 17 (0.5 to 6 hours of contact time), and a fifth were high-intensity (>6 hours of
- 18 contact time), commonly including face-to-face individual or group
- 19 counselling with follow-up by <u>telephone</u>, email, or text, and typically lasting

Comment [jm1]: At ever cite to reference 4. I have also added (as ref 18, to be renumbered if we keep it) a cite to the updated evidence review published simultaneously with this editorial and with the new recommendation statement in JAMA. We would prefer to cite this new evidence review instead of the older one. However, if it does not contain the relevant info, we'll leave as is. If you have not seen the updated review, I can send you a copy. Please let me know.

- around 6 months. The main behavioral change techniques were diverse, and
- 2 variably included goal setting and planning, monitoring and feedback,
- 3 motivational interviewing, addressing barriers to change, increasing social
- 4 support, and general education or advice. These counseling interventions
- 5 were variously delivered by primary care clinicians, health educators,
- 6 behavioral health specialists, nutritionists, dieticians, exercise specialists, or
- 7 lay coaches. 4,18 The heterogeneity of this intervention was thus further
- 8 increased.

Efficacy, Effectiveness, and Sustainability

- The trials were not powered to report on mortality; however, over 30
- 11 (mostly medium or high-intensity trials) reported on intermediate outcomes.
- 12 Results from the "better quality" trials were selected and then pooled to
- demonstrate modest improvements averaging a 1 Kg 1-kg weight loss, a -
- 1.3_mm Hg <u>decrease in systolic blood pressure</u>, and <u>a -2.6-mg/dL decrease</u>
- 15 <u>in low-density lipoprotein LDL</u> cholesterol. 4,18 Behavioral outcomes, mostly
- self-reported, 4,18 demonstrated an apparent dose-response effect, which the
- 17 USPSTF highlighted.² However, skeeptics might suggest that while modest
- 18 efficacy was probably demonstrated in optimal conditions in selected trials,

5

- "real--«jm2: world» ctiveness, and hence cost-effectiveness, remains
- 2 less certain.
- Furthermore, the absolute reductions in non-fatal and fatal events
- 4 achieved by such behavioral counseling interventions are likely to be even
- 5 more modest, because the probability of early death in these low-risk,
- 6 "healthy" adults is already much lower than in adults with unhealthy
- 7 behaviors.⁵
- The evidence on sustainability was also limited, because few trials
- 9 went beyond 12 twelve-months. Relapse of dietary and activity behaviors
- and regaining lost previous weight are all likely, particularly given the low
- perceived risks and low perceived benefits to the individual. Prochaska's
- 12 Stages of Change model⁶ usefully proposes the stages of pre-contemplation,
- contemplation, preparation, action, maintenance—and relapse. Relapse is
- more likely if the person is stressed, but less likely if new learning is placed
- in familiar context, includes retrieval cues, is leveraged with positive human
- emotions, and, crucially, is linked into societal norms. Our social,
- economic, and physical environment can thus powerfully support healthful
- behaviors,—or undermine them. Furthermore, an excessive focus on
- 19 individual behavior also risks obscuring those very powerful social

Comment [jm2]: To explain this edit and other similar ones, in our style for "quoted" terms where the quote marks indicate a shade of meaning beyond or other than the commonly understood one, we set quote marks on the first mention only.

6

1		C :11 1141_ 0,7	N / C = 1-4 C = = : =	1 1	
1	determinants	or ill nealth	Might focusing	on penavioral	-counseiing oi
1	acterminants	or mi meanin.	THIS I TO COSTIL	, on comandia	counselling of

- 2 individuals to generate modest gains likewise distract attention from other,
- 3 more comprehensive and effective approaches?

The Effectiveness Hierarchy: "Upstream" vs "Downstream" 4

Interventions 5

- Extensive evidence suggests that "downstream" preventive activities 6
- targeting individuals (such as behavioral counseling, 1-on-+1 personal advice 7
- to stop smoking or take exercise, health education, or prescribing primary 8
- prevention medications) consistently achieve a smaller community health 9
- benefit than interventions aimed further "upstream" (for instance, smoke-10
- free legislation, tobacco taxes, alcohol minimum pricing, or regulations 11
- eliminating dietary trans-fats). Indeed, these comprehensive, policy-based 12
- interventions tend to be more powerful, more rapid, and cost-saving. 9,10 13
- Furthermore, these population-wide policies are also more equitable, tending 14
- to reduce disparities; while whereas individual interventions tend to 15
- increase disparities.¹¹ 16
- 17 Useful examples come from recent trends in the United States. For
- 18 instance, smoking prevalence in men has fallen from approximately 80%
- immediately after post World War II to less than 20% **(im3:** today). 19 19





Comment [jm3]: Could we cite a reference as source for this specific data report? Might it already be in the reference section? Please advise.

- 1 This success in tobacco control demonstrates how comprehensive strategies
- 2 have used upstream policies addressing the "3 As": of (1) Aaffordability
- 3 (taxes and price hikes), (2) Aacceptability (notably, smoke--free laws and
- 4 zero marketing), and (3) Aavailability (eg, removing no vending machines,
- 5 licensing retailers, <u>verifying customers'</u> age checks etc). Conversely,
- 6 behavioral counseling in isolation has played only a modest role in tobacco
- 7 control, as in alcohol reduction.¹²
- 8 These principles are likely to be equally relevant when considering
- 9 soda, or junk food. For example, <u>Brandt et al¹³ report</u> the recent, <u>success of</u>
- 10 progressive policies to successfully eliminate toxic industrial trans-<u>-</u>fats from
- the food eaten by Americans; and the potentially achievementing of
- 12 substantial mortality reductions. 13

Adverse Events and Medicalization

- The first duty of a <u>physician doctor</u> is to do no harm—*__primum non*
- 15 *nocere*. Only 14 fourteen of the behavioral-counseling trials reviewed by
- the USPSTF^{4,18} reported on adverse events, mostly injuries and falls.^{4,18}
- 17 None considered medicalization; might engaging a-healthy persons in
- behavioral counselling carry the risk of turning them into a-life-long
- 19 "patients"? The World Organisation of Family Doctors (WONCA)¹⁴
- 20 supports Jamoulle's concept of quaternary prevention, "actions taken to

- identify a patient or population at risk of over-medicalisation, and protect
- 2 them from invasive medical investigations and provide care procedures
- which are ethically acceptable.": 44,15(***jm4:**

4 Over-diagnosis and over-treatment carry serious hazards. 8 Labeling

- 5 individuals as being at risk or as having a disease based entirely on biometric
- 6 analysis can lead to unnecessary fear that which undermines health and well-
- 7 being. In addition to escalating financial and opportunity costs, over-
- 8 treatment can also lead, paradoxically, to under-treatment, by diverting
- 9 attention and resources away from those most severely affected. More
- 10 controversially, should physicians therefore perhaps endorse McCormick's
- suggestion, that family physicians doctors should encourage their patients to
- live lives of "modified hedonism"? **«jm5:** 16» p



omment [im5]: Page

Comment [jm4]: Please

indicate the page number of direct quotes taken from hard

copy sources.

13 Conclusions

14

In conclusion, we paraphrase a recent JAMA editorial by Redberg and

15 Katz¹⁷ on the use of statins for primary prevention of cardiovascular disease:

16 might paraphrase Redbergn and Katz's recent JAMA IM Editorial on statins

17 for CVD primary prevention. ¹⁷-Before recommending any intervention that

18 has potential adverse effects, it is incumbent on clinicians to identify

19 evidence that intervention will lead to a better quality of life, or longer life,

Comment [jm5]: Page number for quoted material.

- or both. Given these potential concerns about behavioral counseling in
- healthy individuals, it is surely in the interests of the medical and wider
- 3 public communities to instead prioritizse "upstream" policies. Let us create a
- social environment for our families and friends that which supports a heart-4
- healthy diet, regular physical activity, and not smoking. 5

Article Information 6

- Corresponding Author: Simon Capewell, MD, DSc, Department of Public 7
- Health, Liverpool University, Whelan Bldg, Quadrangle, Liverpool, 8
- Merseyside L69 3GB, United Kingdom (capewell@liverpool.ac.uk). 9
- 10 **Conflict of Interest Disclosures:** None reported.

References

11

- 1. LeFevre ML; U.S. Preventive Services Task Force. 12
- Behavioral counseling to promote a healthful diet and 13
- physical activity for cardiovascular disease prevention 14
- 15 in adults with cardiovascular risk factors: U.S.
- Preventive Services Task Force Recommendation 16
- 17 Statement. Ann Intern Med. 2014;161(8):587-593.
- Medline: 25155419 18

- 1 2. US Preventive Services Task Force. Behavioral counseling
- to promote a healthful diet and physical activity for
- cardiovascular disease prevention in adults without
- 4 cardiovascular risk factors: US Preventive Services Task
- 5 Force Recommendation Statement [published July 11,
- 6 2017]. *JAMA*. doi:10.1001/jama.2017.7171
- 7 3. Forouzanfar MH, Alexander L, Anderson HR, et al; GBD
- 8 2013 Risk Factors Collaborators. Global, regional, and
- 9 national comparative risk assessment of 79
- behavioural, environmental and occupational, and
- metabolic risks or clusters of risks in 188 countries,
- 1990-2013: a systematic analysis for the Global Burden
- of Disease Study 2013. *Lancet*.
- 14 2015;386(10010):2287-2323. Medline:26364544
- 4. Patnode CD, Evans CV, Senger CA, Redmond N, Lin JS.
- Behavioral Counseling to Promote a Healthful Diet and
- 17 Physical Activity for Cardiovascular Disease Prevention
- in Adults Without Known Cardiovascular Disease Risk
- 19 Factors: An Updated Systematic Review for the US

IED170008.docx 11

- Preventive Services Task Force. Evidence Synthesis No. 1
- 152. AHRQ Publication No. 15-05222-EF-1. Rockville, 2
- 3 MD: Agency for Healthcare Research and Quality;
- 2016. 4
- 5. Ford ES, Bergmann MM, Boeing H, Li C, Capewell S. 5
- Healthy lifestyle behaviors and all-cause mortality 6
- among adults in the United States. Prev Med. 7
- 2012;55(1):23-27. Medline: 22564893 8
- 6. Prochaska JO, Redding CA, Evers K. The transtheoretical 9
- model and stages of change. In: Glanz K, Rimer BK, 10
- 11 Lewis FM, eds. Health Behavior and Health Education:
- Theory, Research, and Practice. 3rd ed. San Francisco, 12
- CA: Jossey-Bass, Inc; 2002. 13
- 7. Guardian Sustainable Business. Ten things we learnt 14
- about behaviour change and sustainability. 15
- https://www.thequardian.com/sustainable-16
- business/behavioural-insights/behaviour-change-17
- 18 sustainability-debate. Accessed June 5, 2017.

- 8. Heath I. Overdiagnosis: when good intentions meet
- vested interests—an essay by Iona Heath. *BMJ*.
- 3 2013;347:f6361. <u>Medline:24162944</u>
- 4 9. Capewell S, Capewell A. An effectiveness hierarchy of
- 5 preventive interventions: neglected paradigm or self-
- evident truth? *J Public Health (Oxf)*. 2017:1-9.
- 7 Medline: 28525612
- 8 10. Masters R, Anwar E, Collins B, Cookson R, Capewell S.
- 9 Return on investment of public health interventions: a
- systematic review. *J Epidemiol Community Health*.
- 2017;0:1-8. <u>Medline: 28356325</u> doi:10.1136/jech-
- 12 2016-208141
- 11. Capewell S, Graham H. Will cardiovascular disease
- prevention widen health inequalities? *PLoS Med*.
- 2010;7(8):e1000320. Medline:20811492
- doi:10.1371/journal.pmed.1000320
- 12. Marteau TM. Will the UK's new alcohol guidelines change
- hearts, minds—and livers? *BMJ*. 2016;352:i704.
- 19 <u>Medline: 26864473</u>

- 1 13. Brandt EJ, Myerson R, Perraillon MC, Polonsky TS.
- 2 Hospital admissions for myocardial infarction and
- 3 stroke before and after the trans-fatty acid restrictions
- in New York. [published online April 12, 2017]. JAMA
- 5 *Cardiol*. Medline: 28403435
- 6 doi:10.1001/jamacardio.2017.0491
- 7 14. Primary Health Care Classification Consortium. World
- 8 Organisation of Family Doctors (WONCA).
- 9 http://www.ph3c.org/4daction/w3 CatVisu/en?wCatID
- 10 <u>Admin=1128</u>. Accessed June 5, 2017.
- 15. Jamoulle M. Quaternary prevention, an answer of family
- doctors to overmedicalization. *Int J Health Policy*
- 13 *Manag.* 2015;4(2):61-64. Medline: 25674569
- 14 16. McCormick J. Health promotion: the ethical dimension.
- 15 Lancet. 1994;344(8919):390-391. Medline:7914313
- 17. Redberg RF, Katz MH. Statins for primary prevention:
- the debate is intense, but the data are weak. *JAMA*.
- 2016;316(19):1979-1981. Medline: 27838702

18. Patnode CD, Evans CV, Senger CA, Redmond N, Lin JS. 1 Behavioral counseling to promote a healthful diet and 2 physical activity for cardiovascular disease prevention 3 in adults without known cardiovascular disease risk 4 factors: updated evidence report and systematic review 5 for the US Preventive Services Task Force [published 6 July 11, 2017]. JAMA. doi:10.1001/jama.2017.3303 7 19. US Smoking reduction since WWII. Au to provide? 8 9

10