

Healthcare guidelines in health behaviour change interventions: Quality appraisal and implementation.

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Abstract

In this position paper, we note that appraisals of health behaviour change interventions (HBCIs) focus on identifying intervention particulars (e.g., techniques, design, theoretical underpinnings, psychological mechanisms, delivery modes) most prominently and consistently associated with desired behaviour change. However, a key aspect of interventions, the implemented healthcare guidelines, do not undergo intensive scrutiny in intervention research. We provide evidence to show that available healthcare guidelines may be flawed, and as such, may result in ineffective interventions and potential harms for guideline and intervention recipients. We therefore argue that HBCIs would benefit from investigating the accuracy and quality of the embedded guidelines, by using established guideline appraisal frameworks, and we provide examples of how this can be, systematically, done.

Keywords: *health behaviour change interventions; healthcare guidelines; healthcare accuracy and appraisal; the Practice Guidelines Evaluation and Adaptation Cycle (PGEAC) framework.*

Risk-taking behaviours, such as substance abuse, unhealthy eating, and lack of exercise, are among the strongest contributors to disease and to total and cause-specific mortality across nations (Kvaavik et al., 2010). Accordingly, health promotion efforts have focused on preventing or reducing risk-taking behaviour through health behaviour change interventions (HBCIs), which

comprise of coordinated sets of activities designed to change health behaviour patterns (Beard et al., 2019). Health psychology research is at the forefront of HBCI development and appraisal (Presseau et al., 2022), with appraisal efforts focusing on establishing components of successful HBCIs. Intervention appraisal research, typically conducted via evidence syntheses, has identified behaviour change techniques linked to change; psychological mechanisms through which behaviour change techniques exert their effect; theoretical determinants of behaviour change; components of cost-effective HBCIs; methodological design, recipient, and environmental/ contextual features associated with successful HBCIs; and optimal ways to tailor and frame HBCI health messaging (Beard et al., 2019; Carey et al., 2019; Michie et al., 2013; Pope et al., 2017; Protogerou & Johnson, 2014; Protogerou et al., 2018). Intervention research has also focused on formative evaluations of HBCIs (e.g., assessment of programme creation, adequacy of theoretical and empirical basis, and cultural adaptation); input evaluations (e.g., assessment of resources, such as funding, staff numbers and training, facilities and equipment); process evaluations (e.g., assessment of recipient experience, acceptability, feasibility, fidelity, dose, and reach); and output evaluations (e.g., appraisal of documentation of measurable products, such as number of sessions, community and staff meetings, extent of content coverage) (Protogerou et al., 2012). In other words, intervention appraisal research has focussed on dissecting the HBCIs: intervention techniques, design, and implementation procedures have been

autopsied down to their minute particulars. Despite these intensive efforts, and while there is evidence for the effectiveness of certain HBCIs under certain conditions (e.g., Protogerou et al., 2020), overall, HBCI effects are small, variable, and not maintained long-term (Willmott & Rundle-Thiele, 2021).

HBCIs: Guideline focus

One key aspect of HBCIs – the healthcare guidelines embedded in them – do not typically undergo intensive scrutiny by intervention developers. Healthcare guidelines, or just “guidelines”, are, “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (Field & Lohr, 1990, p. 38). Guidelines address topics across the health care spectrum (i.e., illness prevention behaviours, diagnosis, and treatment plans), and are expected to enable consistent and effective health care practice, improve health outcomes, and inform health promotion and policy. Guidelines are developed by expert committees and professional societies, and in some places, by independent public bodies with the input of community stakeholders (Garbi, 2021). Most guidelines can be freely accessed through online repositories, such as the US National Guidelines Clearinghouse: <https://www.ahrq.gov/prevention/guidelines/index.html> and Guidelines: <https://www.guidelines.co.uk/>.

Health practitioners, researchers, policy-makers and laypeople alike, rely on guidelines to make decisions to promote health and prevent illness. HBCI developers will typically not generate their own guidelines but use extant guidelines to form the basis for their intervention, its rationale, and messaging (Eccles & Grimshaw, 2004). Then, through HBCI implementation and publication, extant guidelines are bolstered and perpetuated. However, the quality of guidelines has been found

to be variable and often falling short of basic standards (Graham & Harrison, 2005; Florez et al., 2020), with claims that only about half of available guidelines are trustworthy (Iannone et al., 2016). Assessments of guideline methodological quality have often found guidelines to be of low quality, with small or no improvements in quality over time (Kung et al., 2012). Furthermore, evidence suggests that even well-developed guidelines become outdated quickly, with one out of five recommendations being out-of-date within three years of their release, and in need for revision (Garcia et al., 2014; Vernooij et al., 2014).

Reasons behind the development of substandard guidelines, and potential limitations and harms associated with them, have been proffered. Woolf et al. (1999) and Iannone et al. (2016) argue that the most serious limitation of extant guidelines is that they may be flawed—or flawed for some populations—for three reasons: (1) guidelines may not be evidence-based to begin with or based on imprecise, low-quality evidence; (2) guidelines may be heavily influenced by personal beliefs, preferences, clinical experience, and composition of guideline development committees; and (3) guidelines may be known to be sub-optimal for individuals but still recommended to minimize costs, serve certain societal needs, or protect the interests of groups (e.g., industries, funders). The adoption of flawed guidelines has the potential to cause harm, with the greatest potential harms for guideline recipients – that is, the public. Simply stated, flawed guidelines may result in individuals receiving ineffective or harmful care, or to individuals receiving blanket recommendations at the expense of personalized care (Guerra-Farfan et al., 2022). Health care practitioners, especially junior ones, tend to over-rely on guidelines without critically appraising their accuracy (Brichko et al., 2018), which could potentially result in inadvertently advocating/implementing flawed practices). Furthermore, medical malpractice litigation suits have been brought against health

care practitioners who deviate from guidelines (Hyams et al., 1995; Mackey & Liang, 2011). So, while guidelines facilitate the implementation of standardized healthcare, they may also pose constraints to healthcare practitioner autonomy in choosing treatments beyond, or in addition to, standard care, and may contribute to defensive medicine practices (for a description of defensive medicine see Katz, 2019). Auditors, administrators, and managers are also likely to evaluate the quality of healthcare according to whether and to what degree practitioners have implemented (potentially flawed) guidelines to avoid malpractice claims (Zerbo et al., 2020). Furthermore, and more relevant to the present article, flawed guidelines can endanger HBCI-related research. For example, intervention research not complying with extant guidelines may be discouraged and may not get funded, thus halting scientific progress and perpetuating (flawed) guidelines. Embedding flawed guidelines in HBCIs can result in ineffective, wasteful, and potentially harmful interventions.

There is evidence to suggest that HBCIs may have been based on questionable guidelines and we offer the use of dietary fat guidelines as an illustration. In line with the national dietary fat guidelines introduced in 1977 and 1983 by the US and UK governments, respectively, dietary guidance for cardiometabolic health embedded in HBCIs has overwhelmingly and almost universally promoted the reduction of total and saturated fat intake (Estrada et al., 2022; Krist et al., 2020). Dietary fat guidelines were originally based on a theoretical link between fat consumption and coronary heart disease risk, and the goal of those guidelines was to reduce coronary heart disease by reducing overall fat consumption to 30% of total energy intake and saturated fat consumption to 10% of total energy intake (Cohen et al., 2015). Since their introduction, however, dietary fat guidelines have been questioned in terms of their credibility and health promoting effects (see Forouhi et al.'s, 2018 historical account of the origins of dietary fat

guidelines and related controversies). Harcombe (2017) conducted a meta-review of four systematic reviews and where available, meta-analyses, to assess the evidence base of the dietary fat guidelines. The meta-review included evidence from randomized controlled trials (RCTs) and epidemiological studies available to the dietary guideline committees in 1977 (USA) and 1983 (UK); and evidence from RCTs and epidemiological studies available at the time of the meta-review to assess the evidence base in retrospect. Harcombe found that RCT and epidemiological evidence did not support the introduction or continuation of the fat consumption recommendations within the guidelines. In addition, the methodological quality of the reviewed evidence was judged to be so low that it could not be relied on had it provided support for the guidelines. Related, Astrup et al.'s (2020) state-of-the-art review of the effects of saturated fat consumption on health outcomes, risk factors, and mechanisms underlying cardiovascular and metabolic outcomes, found that the totality of the evidence does not support the guidelines' recommendations for limiting consumption of foods high in saturated fat. The review indicated that foods high in unprocessed saturated fat, specifically unprocessed red meat, full fat dairy, and dark chocolate are healthful, not associated with coronary heart disease risk, and need not be avoided.

As mentioned above, the uptake of flawed guidelines may lead to harms or unintended consequences for guideline recipients. Since the introduction of the dietary fat guidelines, fat consumption declined and carbohydrate consumption concomitantly increased, but without the anticipated decline in cardiovascular disease and other diet-related diseases (Dehghan et al., 2017). Some data present a (causal) link between the introduction of the dietary fat guidelines and concomitant increases in obesity and diabetes (e.g., DiNicolantonio, 2014; Hansen, 2013). Other data suggest health risks from avoiding healthy

saturated fat consumption, given that saturated fats contain nutrients necessary for hormonal health, digestive health, and fat-soluble vitamin absorption (Gershuini, 2018), as well as for optimal brain function and mood (LaChance & Ramsey, 2018). Dietary fat guidelines have also led to fear, disgust, and avoidance of fat consumption, which has been found to be involved in the aetiology and worsened prognosis of eating disorders (Nguyen et al., 2019).

Recommendations for effective HBCIs

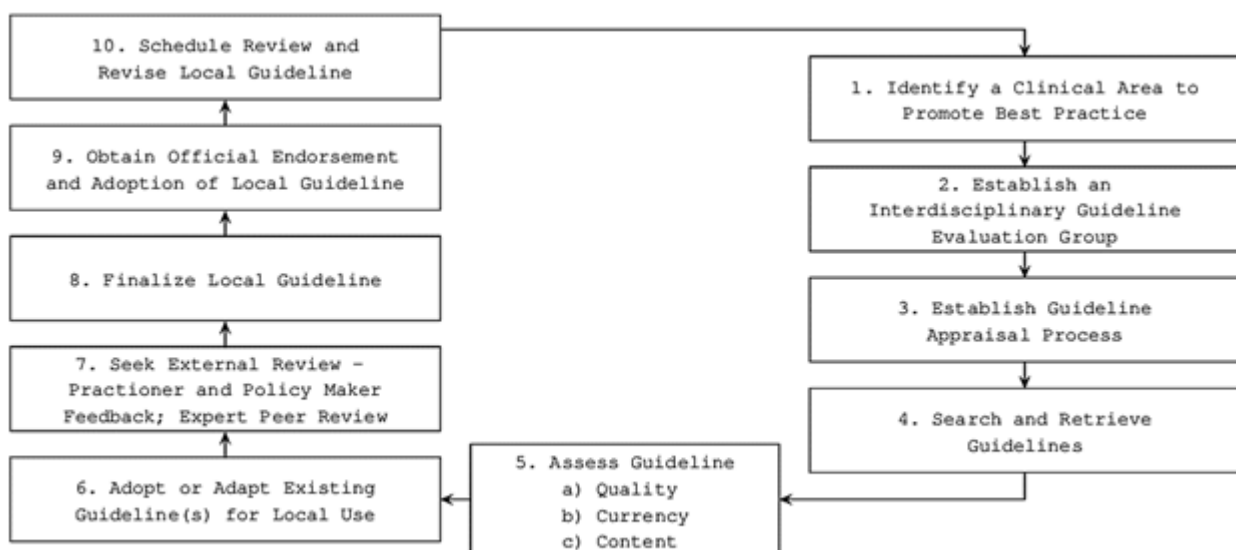
Considering the evidence suggesting that extant guidelines are of variable quality and applicability and in need of periodic revision (Garcia et al., 2014; Vernooij et al., 2014), we advocate implementing a guideline evaluation and adaptation process as an integral component of HBCIs, or as a research endeavour in its own right, alongside HBCIs. A guideline evaluation/adaptation process is particularly pertinent when a guideline is to be implemented in a context or population

outside the one it was originally developed, as this process will facilitate targeting guidelines to local context/population, with increased likelihood of guideline acceptance, uptake, and adherence (Harrison et al., 2010).

While guideline appraisal can take various forms (e.g., reviewing the guideline content through evidence syntheses), we find that HBCIs may benefit from utilizing systematic guideline appraisal frameworks, such as the Practice Guidelines Evaluation and Adaptation Cycle (PGEAC, figure 1) (Graham et al., 2002; Graham & Harrison, 2005) - figure 1). We introduce the PGEAC process below and illustrate it using a hypothetical example with relevance to HBCIs: a research group decides to develop a dietary intervention to prevent or reduce depression in menopausal women. As part of designing the intervention, the research group decides to appraise *antidepressant foods* guidelines for menopausal women (by *antidepressant foods*, we refer to foods to prevent and promote recovery from depression).

1. Selecting a health/risk behaviour to improve using best evidence-based practice. Factors guiding behaviour selection include

Figure 1
The Practice Guidelines Evaluation and Adaptation Cycle (PGEAC: Graham & Harrison, 2005).



behaviour prevalence and associated burdens; concerns about adherence to behaviour and variations in healthcare; relevance and applicability of behaviour to target population/guidance recipients; the existence of relevant evidence-based guidelines; and the likelihood that extant guidelines may achieve what they are meant to.

Example. At this step the research team ascertains *whether* recommending foods to prevent or promote recovery from depression among menopausal women would be a good topic for a healthcare guideline. To answer this question, the research team collects information on depression incidence and prevalence in the population; burdens related to depression (e.g., financial costs, mortality, morbidity); variations in practice in recommending antidepressant foods; costs related to practice variations; the likelihood that a guideline for antidepressant foods for menopausal women would succeed in influencing practice; and the availability of extant evidence-based guidelines for antidepressant foods. Upon reviewing the evidence, the research group decides that having evidence-based recommendations for foods to prevent and promote recovery from depression among menopausal women is a valuable topic for a healthcare guideline and decides to set up a guideline evaluation group.

2. Setting up a guideline evaluation group.

This would be an interdisciplinary group, comprising members with clinical content expertise, methodological expertise (e.g., in literature searches and guideline appraisal skills), HBCI developers, project managers, and members of the target population/guidance recipients.

Example. A panel is convened, involving psychologists, psychiatrists and other healthcare professionals dealing with depressed populations—ideally holding knowledge and expertise in applying dietary approaches to depression; dietitians—ideally holding knowledge relating to antidepressant foods; experts in menopause care; researchers with relevant methodological expertise;

project management/admin staff; and other community stakeholders, such as patient groups, laypeople, and policymakers. Panel members are drawn from across geographical areas (e.g., cities, regions, countries) and across healthcare settings (e.g., public hospitals, private practice, community centres, industry, government). The panel is given the task of formulating a best practice antidepressant foods guideline for menopausal women and a name: the Menopause Moods Taskforce (MMT).

3. Establishing a guideline evaluation process. This step involves deciding on guideline selection criteria and an appraisal instrument. While there are at least 40 guideline appraisal instruments (Siering et al., 2013), the PGEAC framework recommends the Appraisal of Guidelines for REsearch and Evaluation instrument (AGREE: Terrace et al., 2003; Brouwers et al., 2010). The AGREE comprises a total of 23 Likert-type scale items evaluating six guideline domains, those being scope and purpose; stakeholder involvement; rigour of development; clarity of presentation; applicability; and editorial independence. Guidelines are given a standardized dimensional quality score ranging from 0 to 100. The AGREE is validated, translated in many languages, and comes with a user's manual.

Example. Members of the MMT with methodological expertise establish, and transparently document, criteria for selecting antidepressant foods guidelines to appraise. Selection criteria include guidelines that are international, peer-reviewed, written in English, published in the last 5 years, and targeting menopausal women. At this time, MMT members familiarize themselves with the guideline appraisal instrument.

4. Identifying the guidelines. This step involves a systematic search of all relevant guidelines using the selection criteria established in step 3.

Example. Members of the MMT with

methodological expertise apply the selection criteria established in step 3, to a systematic search of antidepressant foods guidelines. The search is conducted electronically on search engines such as PubMed, MEDLINE, Google Scholar, and the World Wide Web, using combined search terms of *practice guideline, clinical practice guideline, standard, statement, consensus, depression, mood, food, diet, nutrients, and menopause*. The systematic search failed to retrieve established antidepressant foods guidelines for menopausal women, though, and as a result, the MMT decides to expand the literature search to scholarly articles. The search retrieves scholarly articles with information on nutrients, supplements, and foods with antidepressant qualities for menopausal women, as well as recommended eating plans.

5. Appraising the guidelines. This step involves systematically appraising the overall quality of retrieved guidelines and the content of guideline recommendations. Using a validated guideline appraisal instrument like the AGREE offers many advantages, such as allowing the evaluation group to establish whether each guideline meets quality criteria; directing the groups' attention to methodological issues; ascertaining agreement/disagreement on raters' scores on the instrument; discussing and resolving disagreements; and calculating overall quality scores to rank guidelines according to quality criteria. As is the case in study quality appraisal (Greenhalgh & Brown, 2017), guideline appraisal is, ideally, conducted by at least two independent raters, to increase reliability assessment. The guideline appraisal process reduces the number of guidelines by revealing the ones that do not meet the minimum quality standards. Still, guideline appraisals by validated instruments are unlikely to provide enough information on the content of recommendations advocated by guidelines. Therefore, the next step would be to conduct a content analysis of the recommendations contained

in the selected guidelines. This could entail one or two evaluation group members, ideally experienced in content analysis, to produce a table, also referred to as the *recommendation matrix* (e.g., Graham et al., 2002, p. 603), comparing the specific recommendations of the guidelines, and the level of evidence supporting each recommendation. The hierarchy/ pyramid of evidence (e.g., see Greenhalgh, 1997) may be used to ascertain the level of evidence in recommendations. The recommendation matrix would be used by the whole interdisciplinary group to discuss the content of the various dietary guidelines under consideration; identify whether the same recommendation is made by different guidelines or whether the recommendations differ; and identify recommendations linked to high levels of evidence or strong evidence. When guidelines contain recommendations supported by evidence of differing strengths, the group may want to select from the various guidelines the recommendations supported by the strongest evidence. In the absence of available guidelines, the evaluation group reviews the evidence from relevant studies, prioritizing those originating from higher levels of evidence (i.e., evidence syntheses and experimental studies).

Example. As the MMT found no established antidepressant foods guidelines for menopausal women, it content-analyses evidence from the retrieved studies. The outcome of the content analysis is a draft narrative and table with nutrients, foods, and supplements with antidepressant properties for menopausal women.

6. Adopting or adapting a guideline to embed in a HBCI. *Adopting* a guideline means choosing the best guideline and accepting all its recommendations "as is". *Adapting* a guideline means taking the best or most appropriate recommendations from more than one guideline and repackaging recommendations into a new guideline. Adaptation is particularly appropriate when guideline recommendations are not relevant

or applicable to the target population, when logistics and available resources prohibit recommendation implementation, or when new evidence supports recommendation modification. In the absence of any formalized published guidelines, or in the presence of guidelines that are outdated and/or of very low quality, the evaluation group may develop recommendations *de novo*. Developing guidelines anew would involve prioritizing drawing information and guidance from high quality systematic reviews and experimental studies (Graham et al., 2002).

Example. Drawing from the content analysis, the MMT formulates its own guideline on antidepressant foods for menopausal women. The guideline advocates the consumption of foods that are the densest sources of nutrients found to be implicated in the prevention of and recovery from depression. The guideline ranks the foods in terms of antidepressant nutrient density (most dense ranked first) and provides guidance for prioritizing foods based on nutrient bioavailability, that is, the proportion of a nutrient that is digested, absorbed, and metabolized. The guideline also provides background information on depression during the menopause.

7. Seeking external review of the guideline.

At this step, the draft of guideline recommendations is disseminated to stakeholders outside the evaluation group for review and feedback. Obtaining this feedback has advantages, such as gauging practitioner and policymaker acceptance of the guideline and identifying potential obstacles to uptake.

Example. The MMT sends the antidepressant foods guideline draft to stakeholders for feedback. Stakeholders could include academic researchers in the fields of psychology, psychiatry, nutrition, and HBCI development; healthcare practitioners (e.g., physicians, nurses, nutritionists, menopause specialists); policymakers; and laypeople, including menopausal women. Stakeholders are asked to indicate the extent to which they approve the draft

guideline, to state its strengths and weaknesses, and areas that might warrant improvement.

8. Finalizing the guideline. At this step, feedback by stakeholders and experts is reviewed and responded to. The guideline is modified where appropriate, and, potentially, pilot-tested. Modifications made to the guideline in response to feedback are documented, with reasons for the changes. Similarly, if the guideline is not modified despite feedback received, the rationale for this is documented.

Example. The MMT reviews feedback on the antidepressant foods guideline and makes changes based on the feedback. The MMT then pilot tests the draft guideline at the private practices of a nutritionist and a menopause specialist. Based on insights from the pilot testing, the MMT documents the process of guideline implementation and identifies factors that facilitate and inhibit implementation; evaluates the perceived utility and acceptability of the guideline; and further revises the guideline.

9. Adoption and implementation of the guideline. In this step, the proposed guideline is formally adopted and embedded in the HBCI. In other words, the guideline guides the formation of HBCI basis, rationale, messaging, and techniques. Furthermore, the guideline may be given “official status”, that is, endorsed by a relevant organization as policy.

Example. The research group develops a HBCI to promote and prevent depression among menopausal women, using the MMT guideline as its foundation. Furthermore, the MMT guideline receives endorsement by a national menopause specialists alliance and is situated on their website, as the recommended foods approach for menopausal women.

10. Scheduling a review and revision of the guideline. Based on guideline survival analyses (e.g., Garcia et al., 2014), healthcare recommendations become out-of-date in about three years, implying that the content/messaging

of a HBCI may also become outdated in that time. Therefore, research and guideline evaluation groups may plan for a process of guideline revision and update or indicate a guideline “expiration date”. Guideline revision may involve a small update based on a new piece of evidence or discussion with key stakeholders, or a larger update, involving undergoing the entire, or parts, of the evaluation cycle.

Example. At this step, the MMT schedules a review of the antidepressant foods guideline in three years. In this three year period, the MMT regularly monitors new evidence syntheses, randomized controlled trials, and other developments pertinent to the guideline to inform its review and revision.

For published examples of PGEAC implementation in healthcare see Mwangi et al.’s (2018) adaptation of clinical guidelines for diabetic retinopathy in Kenya, Wang et al.’s (2020) appraisal of the quality of nursing practice guidelines in China, and Trepanier et al.’s (2022) appraisal of psychology practice guidelines in Canada.

Conclusion

While healthcare guidelines have the potential to improve health outcomes, their beneficial effects are contingent upon a guideline development process that is methodologically rigorous and has considered the best available evidence. Even guidelines developed by expert committees and governmental bodies need to be scrutinized as it has been found that they may be flawed or out-of-date. Flawed guidelines may stand in the way of desired health behaviour change and pose potential harms to guideline recipients. HBCIs developers would therefore benefit from integrating a rigorous guideline appraisal process into their methods to adopt well developed guidelines that can be used with confidence. Alternatively, guideline appraisals could be conducted alongside HBCIs, as research

projects in their own right. Appraisals of extant guidelines can inform clinical and HBCI decision-making on which guidelines are most appropriate for their context and population. Using a systematic and transparent framework for identifying, evaluating, adopting and adapting guidelines, or developing guidelines de novo, is critical as the decisions made based on guidelines affect patients, practitioners, and HBCI developers. Furthermore, a systematic guideline appraisal process like the one described in the present position paper raises awareness of evidence gaps relating to guidelines, fosters interdisciplinarity, and facilitates guideline adoption and implementation given buy-in from involved stakeholders.

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