HARDING CENTER FOR RISK LITERACY

Methods Paper

for Developing Fact Boxes

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HARDING CENTER FOR RISK LITERACY

Contents

Preamble

The Harding Center for Risk Literacy at the Max Planck Institute for Human Development in Berlin is an independent research institute affiliated to the Max Planck Society for the Advancement of Science e.V. Further information on the Harding Center and the Max Planck Society can be found at www.harding-center.mpg.de and at www.mpg.de.

The method paper of the Harding Center for Risk Literacy outlines the scientific principles, methods, and tools of the Harding Center used in the production of evidence-based fact boxes, a specific format of health information. The method paper is aimed primarily at scientists, but also at all interested parties as a reference work and is thus intended to guarantee a transparent and comprehensible way of working.

The particular steps of choosing a topic, the scientific processing of these, and the evaluation of certain medical measures depends on both the respective question and the best currently available scientific evidence. Therefore, the method paper is to be understood as a general framework for the development of fact boxes. The respective project-specific procedure is described in detail in the relevant method reports (short reports).

With regard to a cross-institutional standardized approach, the present method paper is oriented to the statements of the German Network for Evidence-based Medicine (DNEbM) in the Position Paper on Good Practice Health Information (Version 2.0) (DNEbM 2015).

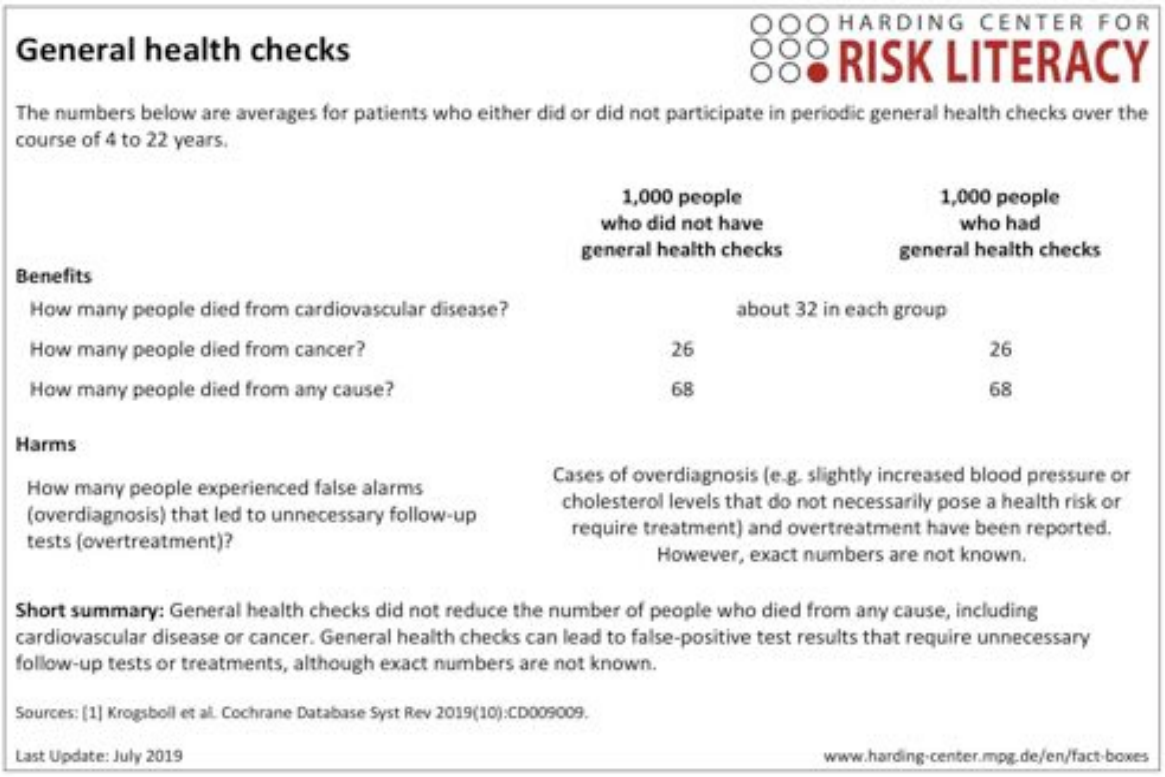
To ensure for an up-to-date working basis, the present method paper is constantly being reviewed for a necessary revision.

For the critical evaluation of the primary and secondary studies used in the particular projects, only sufficiently validated assessment tools for estimating the study quality, so-called critical appraisal tools (CATs), are used, which can be found in the respective method report. The project-specific steps as well as the results of the literature research can also be found in the specific method reports.

Introduction

Fact boxes are a complexity-reducing format of health information. They present the best currently available evidence on a medical intervention in a clearly understandable and transparent manner. The benefits and harms of a medical intervention are compared in tabular form (Fig. 1).

Figure 1: Harding Center fact box on the topic of "General health checks"



General health checks

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The numbers below are averages for patients who either did or did not participate in periodic general health checks over the course of 4 to 22 years.

	1,000 people who did not have general health checks	1,000 people who had general health checks
Benefits		
How many people died from cardiovascular disease?	about 32 in each group	
How many people died from cancer?	26	26
How many people died from any cause?	68	68
Harms		
How many people experienced false alarms (overdiagnosis) that led to unnecessary follow-up tests (overtreatment)?	Cases of overdiagnosis (e.g. slightly increased blood pressure or cholesterol levels that do not necessarily pose a health risk or require treatment) and overtreatment have been reported. However, exact numbers are not known.	

Short summary: General health checks did not reduce the number of people who died from any cause, including cardiovascular disease or cancer. General health checks can lead to false-positive test results that require unnecessary follow-up tests or treatments, although exact numbers are not known.

Sources: [1] Krogsboll et al. Cochrane Database Syst Rev 2019(10):CD009009.

Last Update: July 2019 www.harding-center.mpg.de/en/fact-boxes

(Harding Center for Risk Literacy 2019)

The fact box also contains information on included studies and to which reference group the information in the fact box refers to (e.g., age and gender of the study population) (Fig. 2).

Figure 2: The essential features of a fact box

1) A short summary sentence describing benefits and harms (without making a recommendation).
2) Clear specification of the reference class, age range, timeframe of the study or assessment period, and other facts/caveats that may influence interpretation of the effects.
3) List of the most important benefits and harms (2-4 outcomes each) in the form of statements or questions.
4) Comparison of outcomes between two or more groups, typically between a control and intervention group, and preferably from a systematic review.
5) A measure of the effect for each group, presented as (where possible):

   Frequencies: absolute numbers out of a total sample of 100, 1000, or 10,000

   Continuous scales: mean, mean differences, or median, where appropriate.

   Unquantifiable outcomes: a disclaimer or statement describing the state of evidence.
6) Sources for all information and the date the information was created or last updated.

(according to McDowell et al. 2016: 3)

Fact boxes are not supposed to stand for themselves, they are embedded in an accompanying text. This text is intended to provide readers with brief and easy-to-understand information on the medical intervention focused in the fact box (e.g., early detection or preventive measures, treatment), the disease targeted by the intervention, and the treatment options. A short example for the first endpoint in the fact box can be found in the accompanying text and is intended to help the reader grasp the information from the fact box. An optional line “What other aspects should be considered?” offers the possibility to supplement and explain further study characteristics or study restrictions. Furthermore, the accompanying text reports on the quality of the evidence of the review and the studies included. If the evaluation of the quality of the evidence in the systematic review was carried out according to GRADE, it is communicated for each included endpoint. The corresponding simplified formulations, which are phrased for better understanding in accordance to the GRADE Guidelines (Guyatt et al. 2008), can be found in the internal format template of the fact boxes.

The references to the reported results and all cited literature for the preparation of the accompanying text can be found at the end of each fact box document or on the homepage of the Harding Center, where the fact boxes are published.

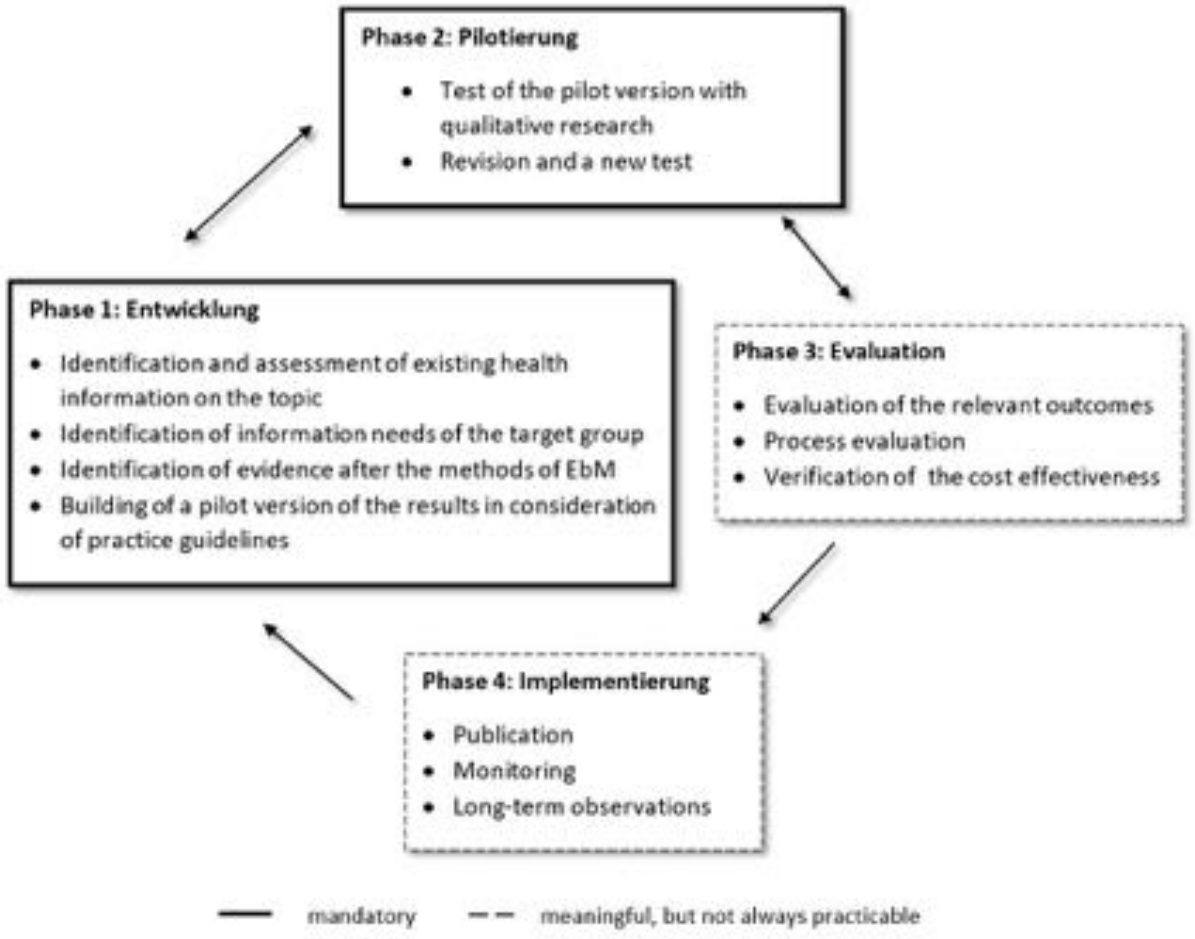
Fact boxes are intended to help people who are not medically or statistically educated to make informed decisions. Decisions are considered to be informed when decision-makers have sufficient knowledge of the benefits and harms of a medical treatment and of treatment alternatives, and their attitudes toward the treatment are consistent with the uptake. In order to assess a decision as informed or uninformed, the dimensions of risk perception, knowledge, attitudes, and uptake of an intervention are taken into account (Marteau 2001).

In this context, several randomized controlled trials (RCTs) by Schwartz et al. (2007, 2009), Schwartz and Woloshin (2013), Rebitschek and Gigerenzer (2018), and McDowell et al. (2019) prove that fact boxes have a positive effect on risk perception, knowledge, comprehensibility, and readability.

The development of the fact boxes follows the methods of evidence-based medicine according to Sackett et al. (1996) and Kunz et al. (2007) and the findings of the guideline evidence-based health information by Lühnen et al. (2017).

To further develop the fact boxes, it is currently being examined to what extent the development and evaluation can be implemented according to the guidance and evaluating complex interventions developed by the Medical Research-Arch Council (MRC) (Craig et al., 2008). The following presentation shows the approach developed by the MRC for the development and evaluation of complex interventions, with a focus on evidence-based health information, modified according to Lühnen et al. (2017) (Fig. 3).

Figure 3: Development and evaluation of complex interventions



(according to Lühnen et al. 2017: 15)

1 Identification of specific information needs

So far, no systematic identification of the information needs of the target groups takes place. However, the identification of information needs by means of qualitative surveys or research into already collected information needs on relevant topics is planned. Currently, specific information needs are raised only in explicitly designated projects. The procedure can be found in the particular project report.

2 Prioritization of topics

The choice of topics and the specification of the question for the fact boxes is based on a variety of criteria. First, it depends on the availability of current Cochrane reviews or other systematic reviews and meta-analyses and, secondly, on the priorities of clients and external cooperatives. If no current systematic review or meta-analysis with sufficient methodological quality (the criteria of evidence-based medicine of appropriate quality) can be identified or if conflicting evidence is available, it is possible to oppose the creation of a fact box on the subject as, amongst other things, the Harding Center is currently not producing its own meta-analyses for creating fact boxes.

3 Systematic literature research

The basis of every literature search is the PICO format, which is elaborated on the basis of the formulated questionnaire. The basis of a fact box is usually a selective literature search. First, a search of a current Cochrane review in the Cochrane library is performed. In the absence of a current Cochrane review, a systematic literature review based on systematic reviews, meta-analyses and randomized controlled trials (RCTs) is performed in the PubMed database and other databases relevant to the hypotheses (e.g., Embase, The Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO etc.). Relevant search terms determined in advance are searched for in the free text as well as in the keywords system of the respective database (e.g., Medical Subject Headings—the so-called MeSH terms), which are combined via the Boolean operators “AND” and “OR.” Filters usually represent the article type’s systematic reviews, meta-analysis, and randomized controlled trials, as well as the limitation of the publication language in English and German. The use of a filter with regard to the publication date depends on the research question.

Inclusion and exclusion criteria are defined individually and as a function of the question as well as the examination objective. Generally, two scientists screen title and abstracts independently and exclude irrelevant results. The full texts are also evaluated independently of each other based on the previously defined inclusion and exclusion criteria. If there are conflicts between the two reviewers, a discussion takes place until consensus is reached.

If existing fact boxes are updated, a search will be carried out from the date of publication of the originally included publications. If the enclosed publication is a Cochrane review, an update of the present reviewed publication will be looked for first. Unless an update is available, a search for systematic reviews, meta-analyses, and RCTs will be carried out in PubMed and other databases relevant for the research (e.g., Embase, The Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO etc.).

Guideline databases such as the Working Group of the Scientific Medical Societies (AWMF) or the Guidelines International Network (GIN) serve as further optional resources for drawing up the accompanying text of the fact boxes. Other resources are the information systems, pages, or registers of the Robert Koch Institute (RKI), the Federal Statistical Office (Destatis), the Institute for Quality and Efficiency in Health Care (IQWiG; gesundheitsinformationen.de), or the Society of the Epidemiological Cancer Registry in Germany (GEKID).

4 Choice of evidence

For the creation of fact boxes, evidence level I studies (systematic reviews and meta-analyses of RCTs or, in some cases, individual RCTs) are used. Here, studies with patient-relevant outcomes (e.g., mortality, morbidity, and quality of life) are preferred. If there are no studies with patient-relevant outcomes (e.g., only surrogate parameters), it does not necessarily mean that no fact box on the subject has been created. On the contrary, the uncertainty regarding patient-relevant outcomes is communicated.

If several current systematic reviews or meta-analyses are available, the one with the highest quality is used. The determination of the methodological quality is described in the following section (5).

If more up-to-date RCTs are identified in addition to systematic reviews, the accompanying text will indicate to what extent they support the evidence of the systematic review(s) or show conflicting evidence. The Harding Center itself does not have the resources to carry out a systematic review or meta-analyses.

5 Critical Appraisal

The literature review for RCTs is carried out using the *Cochrane Risk of Bias Tools* (RoB 2.0) (Higgins et al., 2016) and for systematic reviews using the *AMSTAR 2-Checklist* (Shea et al. 2017). The checklist used can be found in the respective method report.

6 Choice of the outcomes

If possible, patient-relevant outcomes are used to create fact boxes. However, the choice of outcomes also depends on the question and the available evidence. Furthermore, the following criteria are included:

- objective before subjective outcomes
- absolute outcomes before scales
- severe before harmless outcomes
- more frequent before rarer outcomes
- outcomes based on high-quality studies (RCTs)
- outcomes based on a high number of studies or participants (McDowell et al. 2016)

Since a fact box is intended to present the evidence compactly and in reduced complexity, and the format offers only limited space, there is a restriction of two or four outcomes for the presentation of benefits and harms. If, for example, no data is available for the harms because this has not been reported in the studies used, this will be communicated in plain language. When using surrogate parameters, the restriction regarding patient relevance is addressed.

7 Choice and presentation of comparisons

Fact boxes refer exclusively to data from systematic reviews, meta-analyses, or RCTs to always represent a comparison between two or more groups. The intervention group is therefore compared with a placebo or other treatment options (e.g., standard care or no intervention). If there is no data available on the group without intervention or if there has not been a separate search, this will be communicated in the fact boxes (e.g., in corticosteroid injections for knee osteoarthritis: “It is not known how many patients would have suffered side effects if no placebo injections had been given”).

8 Handling numbers and presentation of risks

The benefits and harms of a medical intervention are balanced in fact boxes. By specifying the references and using the past tense, it is made clear that these are study results and thus no individual prediction is possible.

The reference in numbers is always the same for the intervention and control groups. The event frequencies are communicated in absolute numbers. Relative risks are not reported. Which reference value is chosen (100, 1,000, or even 10,000) depends on the study data. It has to be ensured that the indication of integers is possible and that existing statistically significant differences become clear. The absolute change in risk is shown both in the short summary of the fact box and in the accompanying text. Mismatched framing (the presentation of advantages and disadvantages in different formats) is not used. There is no separate search for the natural course of a disease.

For “statistically significant differences,” the numbers for each included group are reported separately. If it is a span of “nonsignificant differences,” the number of controls will be added as “about x in each group.”

9 Consideration of age and gender differences

For many questions, there is currently no differentiation according to age or gender. Any reported age or gender differences in the studies included are at least mentioned in the accompanying text of the fact box. It is further planned to consider gender differences already in the systematic literature research and to report the results in case of existing evidence in different fact boxes.

In fact boxes that do not report gender differences, gender-neutral nouns in the German language are used to implement a gender-sensitive language in the sense of gender mainstreaming so as not to discriminate against intersex or sexless people. If there is no gender neutrality that retains the connotation of the term, the gender star (*) is used. If only male or female persons are meant in the statements, the male or female noun will be used.

10 Adaptation for the target group

So far, there is no systematic adaptation for the target groups. Users are currently only involved in some projects with the help of planned focus group interviews for the user-based verification of fact boxes in the development process. However, the systematic inclusion of the target groups in the development of the fact boxes in the form of user tests was started in the beginning of 2019. In

terms of a simplified presentation to increase convenience, some fact boxes are supplemented by icon arrays (pictograms) to visualize the information. Depending on the objective and the client, videos are created by third parties.

11 Factually appropriate presentation

In the fact boxes and the accompanying text, attention is always paid to neutral language. Worrying and trivializing word choices are avoided. The linguistic appropriateness is checked by the scientific staff and by an internal review. If needed, the content will be discussed with the entire Harding Center team until a consensus is found. The accompanying text of the fact boxes always follows the same structure and is divided into various questions. Abbreviations are largely avoided. If foreign words or medical terms are used, these are explained at first use or the term is given in brackets behind a more familiar term to avoid misunderstandings.

12 Deduction of appraisal and recommendations

As a rule, no evaluations or recommendations are made in the fact boxes. This is guaranteed by a content-wise and linguistically neutral formulation. If recommendations are cited in individual cases (e.g., imaging for back and lower back pain: recommendation of the National Health Care Guideline for nonspecific low-back pain), this recommendation will be clearly marked with the reference.

13 Transparency about responsible employees

The authors of the fact boxes are research scientists at the Harding Center for Risk Literacy. If the creation of the fact box is financed by external clients (e.g., AOK Bundesverband), the corresponding logo or a corresponding remark is located on the fact box. On the homepage of the Harding Center, you can also find information on the qualification of the author(s).

14 Methods of evaluation

A check for content completeness and correctness of the fact boxes is carried out by the resident scientific team. Fact boxes for external cooperation partners are also reviewed by other medical experts. The piloting, for example, by interviewing focus groups, has not yet taken place systematically or has been carried out only by external scientists (Aubertin & Steckelberg 2018), but is planned for the future. The evaluation by means of randomized controlled trials was carried out as

an example for two fact boxes (Prostate Cancer Early Detection and MMR Vaccine). Systematic implementation in the everyday care routine has not been done so far.

15 Publication of fact boxes

The fact boxes are published over multiple means and types of media. It is important to distinguish between fact boxes of the Harding Center and fact boxes for external cooperation partners. Fact boxes of the Harding Center are published on the website of the *Harding Center*. Other possibilities are the *AOK Bundesverband*, the *Bertelsmann Stiftung,* the *Helsana,* and the member magazine of *Viactiv*. In addition, fact boxes will be presented in scientific publications, lectures, continuing education events, trainings, and courses. Individual fact boxes are sporadically published by others such as the Concordia insurance. To date, fact boxes have occasionally been published in the US, UK, Canada, Australia, Brazil, Germany, Austria, Switzerland, Spain, France, Italy, Japan, and South Korea.

16 Statement of conflicts of interest

The Harding Center for Risk Literacy is partly financed by David Harding, hedge fund manager and director of Winton Capital. In addition, there is or has been cooperation with *Bertelsmann Stiftung*; the health insurances *AOK Bundesverband, Helsana, Viactiv*; the *European Research Council*; the *German Football Association*; the *ERGO insurance*; the *German Federal Institute for Risk Assessment* (BfR); the *German Aerospace Center*; *the University of Frankfurt;* and the *Federal Ministry of Justice and Consumer Protection*. Some members of the Harding Center will be rewarded for scientific lectures at national and international conferences. Care is taken here that, as far as possible, no fees are accepted from the industry. There is no cooperation with the pharmaceutical or tobacco industry. The Harding Center pursues various scientific projects with domestic and foreign universities and research institutions (e.g., Microsoft Research). The authors of the fact boxes explain in the accompanying text that there are no conflicts of interest. The persons involved in creating the respective fact box can be found in the method reports, which can be made available on request.

17 Content update of the health information

The aim is to update the fact boxes every 2 years. The update often depends on the availability of the respective Cochrane reviews or other new systematic reviews or meta-analyses. The fact boxes for external cooperation partners have a higher priority regarding updates.

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