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Research article

What constitutes evidence-based patient information? Overview of discussed criteria

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ABSTRACT

Objective: To survey quality criteria for evidence-based patient information (EBPI) and to compile the evidence for the identified criteria.
Methods: Databases PubMed, Cochrane Library, PsycINFO, PSYNDEX and Education Research Information Center (ERIC) were searched to update the pool of criteria for EBPI. A subsequent search aimed to identify evidence for each criterion. Only studies on health issues with cognitive outcome measures were included. Evidence for each criterion is presented using descriptive methods.
Results: 3 systematic reviews, 24 randomized-controlled studies and 1 non-systematic review were included. *Presentation of numerical data, verbal presentation of risks* and *diagrams, graphics and charts are based on good evidence. Content of information and meta-information, loss- and gain-framing* and *patient-oriented outcome measures* are based on ethical guidelines. There is a lack of studies on *quality of evidence, pictures and drawings, patient narratives, cultural aspects, layout, language* and *development process.*
Conclusion: The results of this review allow specification of EBPI and may help to advance the discourse among related disciplines. Research gaps are highlighted.
Practice implications: Findings outline the type and extent of content of EBPI, guide the presentation of information and describe the development process.

1. Introduction

Evidence-based patient information (EBPI) can play an important part in supplementing and reinforcing information provided by clinicians within consultations. EBPI can also be used outside consultations especially for subjects where consultations do not necessarily occur, e.g. information on screening procedures.

Most patients want more information and a greater share in decision-making, though, proportion of people wanting active involvement varies within and between countries [1,2] or medical conditions [3]. In a survey in eight European countries 51% of the sample opted for the shared decision-making model, whereas 23% said that the patient should decide and 26% assigned the role of main decision-maker to the doctor [4].

Evidence-based patient information is a prerequisite for informed choice. Evidence-based patient choice intends to incorporate science and rigour of evidence-based medicine with the personal values of consumers and patients. The information has to be easy to understand and should give information on the benefits and harms of treatment options, diagnostic or screening procedures. Patients and consumers have the (ethical) right to get such information.

Decision aids facilitate patient involvement in decision-making and improve decision quality. Furthermore, decision aids show promise to prevent over- or underuse of medical interventions [5].

Despite various initiatives to improve the quality and availability of health information, the information needs of patients and the public are not adequately met yet. Health professionals tend to overestimate the amount of provided information [6]. In addition, there are concerns about the quality and usefulness of much printed and electronic consumer health information [7,8]. Recent studies have shown that decision aids are frequently not evidence-based even though they might be labelled as evidence-based [9].

There is as yet little discussion as to what can be expected of EBPI. It is important to define what basically comprises EBPI and how the information should be presented. In addition, the special needs of the target groups have to be considered in the development process of EBPI.

Steckelberg et al. [10] provided an overview of criteria for EBPI, which is available in German language only. Trevena et al. conducted a systematic review on communicating with patients about evidence [11].

This article provides an update and extension of our previous work [10]. It intends to support developers of EBPI, and might be helpful for consumers who want to judge the quality of existing EBPI.

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The main objectives of this overview were to identify categories for EBPI and to survey the underlying evidence for each criterion.

2. Methods

The methods consist of two predefined phases: phase 1: update of the pool of categories for EBPI and phase 2: identification of the evidence of categories and criteria.

2.1. Phase 1

A primary systematic search was conducted to identify all criteria for EBPI to revise the pool of categories. The search in the Cochrane database of systematic reviews, PubMed, PsycINFO, PSYNDEX and the Education Research Information Center (ERIC) was limited to systematic reviews and reviews published in English or German for the period from November 1, 2004 to February 28, 2009.

2.2. Phase 2

Criteria are described for considering studies to identify the evidence of categories and criteria.

2.2.1. Types of studies

Systematic reviews and randomized-controlled trials (RCTs) published in English or German.

Studies with less than 40 participants were excluded. Sample sizes of studies on categories of EBPI are often rather small. Since validity of such studies is limited, we decided to only include studies with at least 40 participants in order to not exclude too many studies.

2.2.2. Types of interventions

The interventions consist of the different categories. Categories with examples are: content of information and meta-information (e.g. benefit and harm of the intervention), quality of evidence (QOE) (e.g. symbols for presentation of QOE), patient-oriented outcome measures (e.g. mortality, quality of life), presentation of numerical data (e.g. absolute risk reduction (ARR), number needed to treat (NNT)), verbal presentation of risks (e.g. verbal descriptors, i.e. common or rare risk of side effects), diagrams, graphics and charts (e.g. bar chart, pie chart), loss- and gain-framing, pictures and drawings (e.g. line-drawings, cartoons), patient narratives (e.g. use of personal stories to present evidence, symptoms or diseases), cultural aspects (e.g. content of pictures), layout (e.g. font style and size, bolded headings), language (e.g. plain language, mother-tongue), development process (e.g. involvement of patients, consumers in EBPI development process).

We considered studies which tested the interventions in printed, web-based and audiovisual information material, excluding verbal only communication and educational programs.

2.2.3. Types of outcome measures

Outcome measures focusing on cognition were included: knowledge, comprehension, understanding, recall, risk perception, and readability.

Studies that only measured affective, behavioral, economic, or health status outcomes were excluded. If studies assessed different outcomes, only the cognitive ones were considered. The development process was not restricted to the defined outcome measures.

2.2.4. Search methods for identification of studies

A systematic literature search was undertaken to identify evidence for each category. Two authors (MB and AS) searched the Cochrane database of systematic reviews, PubMed, PsycINFO, PSYNDEX and ERIC (from November 1, 2004 to February 28, 2009). The search strategies were developed from the first publication of this review [10]. Search terms for the new categories were added without limits of dates of publication.

Search strategies were tailored to the relevant databases using medical subject headings (MeSH) and keywords (Box 1).

The titles and abstracts of all articles were screened by two investigators (MB and AS). Full articles were examined if the abstract met the inclusion criteria. Reference lists were screened. Disagreements were solved by discussion (Box 1).

Box 1. Search terms.

Symbols; numbers; letters; visual display; graph*; chart*; pictogr*; ARR; RRR; NNT; diagram; Patient Participation [MeSH]; Probability Theory [MeSH]; Risk Assessment [MeSH]; Data Display [MeSH]; Sensitivity and Specificity [MeSH]; Communication [MeSH]; Communication Barriers [MeSH]; Persuasive Communication [MeSH]; Comprehension [MeSH]; Language Tests [MeSH]; Health Knowledge, Attitudes Practice [MeSH]; Information Services/standards [MeSH]; Information Services/statistics and numerical data [MeSH]; Quality Assurance, Health Care/standards [MeSH]; Biomedical Research/standards [MeSH]; Cultural Competency [MeSH]; Cultural Characteristics [MeSH]; Consumer Participation [MeSH]; Personal Narratives [Publication Type]; Anecdotes as Topic [MeSH]; patient participation; risk assessment; sensitivity; specificity; communication AND barriers; persuasive communication; comprehension; plain language; non patronizing AND language; language AND measurement; language AND assessment; readability; cultural characteristics; cultur* AND compet*; consumer participation; personal narratives; narratives; testimonial*; narration; framing AND data; risk communication; involve*; Patient Education as Topic [MeSH]; Patient Education Handout [Publication Type]; Health Education/methods [MeSH]; Communications Media [MeSH]; Teaching Materials [MeSH]; Information Dissemination [MeSH]; Consumer Health Information [MeSH]; Decision Support Systems, Clinical [MeSH]; Evidence-Based Medicine [MeSH]; patient education; health education; teaching materials; consumer health information; decision support systems; evidence-based medicine

2.2.5. Critical appraisal, data extraction and analysis

We extracted key information from all included publications. Extracted data included sample size, participants, interventions, controls and outcome measures. The quality of the included studies was assessed using the SIGN-checklist for systematic reviews [12] and the EPOC-checklist for RCTs [13].

Two authors (MB and AS) assessed the quality and analyzed all papers. Differences in assessment of publications were solved by discussion.

Due to heterogeneity of interventions, study participants and healthcare settings descriptive data analysis was carried out.

3. Results

3.1. Phase 1: Pool of categories

The existing pool of categories was enlarged and specified. The final pool contains the following categories:

1. Content of information and meta-information.
2. Quality of evidence.
3. Patient-oriented outcome measures.
4. Presentation of numerical data.
5. Verbal presentation of risks.
6. Diagrams, graphics and charts.
7. Loss- and gain-framing.
8. Pictures and drawings.
9. Patient narratives.
10. Cultural aspects.
11. Layout.
12. Language.
13. Development process.

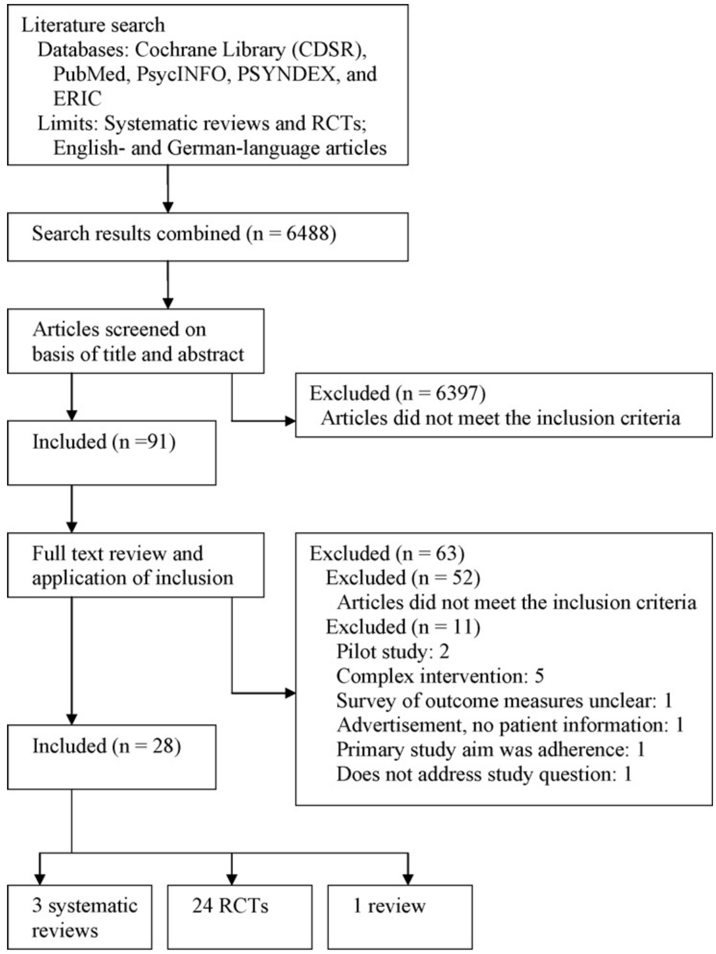


Fig. 1. Flow diagram of study selection (phase 2).

3.2. Phase 2: Study selection

Three systematic reviews and 24 randomized-controlled studies met the inclusion criteria and were included. One additional review was included after reference tracking. See flow diagram Fig. 1.

3.3. Descriptions of studies

The characteristics and outcomes of included studies are shown in Table 1. Excluded studies with reasons for exclusion are shown in Table 2.

Table 1
Characteristics of included studies.

Study	Methods	Participants	Intervention	Outcome
Akl et al. [27]	Randomized-controlled trial	84 participants of a community health education program (mean age: 59.6 years), USA	Symbols compared to numbers and letters for the representation of strength of recommendation (SOR) and quality of evidence (QOE)	Understanding
Almashat et al. [30]	Randomized-controlled trial	102 students (mean age: 19.7 years), USA	Vignettes and a debiasing questionnaire compared to vignettes with control questionnaire	Framing effect
Austin et al. [49]	Randomized-controlled trial	101 emergency department patients with lacerations (mean age: not reported), USA	Comparison of discharge instructions with or without illustrations	Comprehension
Braun et al. [66]	Randomized-controlled trial	86 students and non-students (mean age: 32.7 years), Germany	3 versions of package inserts that varied with regard to the personal nouns used (a generic masculine version and two gender-neutral ones)	Recall
Brotherstone et al. [52]	Randomized-controlled trial	318 participants (aged 60–64), United Kingdom	Written information leaflet with illustrations compared to a written (standard) information on bowel cancer and screening procedure	Understanding
Delp and Jones [50]	Randomized-controlled trial	234 emergency department patients with lacerations or parents/guardians of children with lacerations (mean age: 20.6 years), Michigan/USA	Wound care instruction sheet with cartoon illustrations compared to wound care instruction sheet without cartoon illustrations	Comprehension
Edwards et al. [29]	Systematic review	People facing real life decisions about whether to undergo screening	Personalised risk information (oral, written, video or electronic media) compared to generalised risk communication interventions	Knowledge of risk, accurate risk perception
Edwards et al. [28]	Systematic review	People attending consultations for themselves or their children or using materials communicating risk	Risk communication interventions	Knowledge, risk perception

Table 1 (*Continued*)

Study	Methods	Participants	Intervention	Outcome
Ghosh et al. [44]	Randomized-controlled trial	150 women at increased risk for breast cancer (mean age: 60.2 years), 88% white, 70% some college education, Minnesota/USA	Risk presentation (probability) with a bar graph alone compared to a bar graph with frequency format diagram. Each patient's 5-year risk estimate of invasive breast cancer was calculated using the Gail model	Risk perception
Hawley et al. [45]	Randomized-controlled trial	2412 internet user (mean age: 49 years), 82% white, well educated, USA	Comparison between different graphs (pie chart, bar graph, pictograph, sparkplug, clock graph, table) for presentation of treatment risk and benefit information	Verbatim and gist knowledge
Knapp et al. [53]	Randomized-controlled trial	67 primary care patients (mean age: 79.3 years), United Kingdom	Full-sized pictograms (9×9 cm) compared to smaller pictograms (3×3 cm)	Interpretation of pictograms
Kools et al. [54]	Randomized-controlled trial	99 participants (aged 20–60 years), Netherlands	Instructions for asthma devices with line-drawings and captions compared to original instructions	Recall
Kools et al. [68]	Randomized-controlled trial	46 students (mean age: 19 years) (1st-year undergraduates), Netherlands	12-pages text with graphic organizers (on the top of each page) compared to a standard text about asthma	Comprehension
Leiner et al. [55]	Randomized-controlled trial	206 parents/caretakers of paediatric patients receiving polio vaccines (mean age: not reported), Texas/USA	Vaccine information video (animated cartoon) compared to a printed vaccine information sheet (VIS)	Knowledge
Mansoor and Dowse [51]	Randomized-controlled trial	120 HIV-positive out-patients (aged 26-40), English or isiXhosa-speaking, black, no antiretroviral therapy on chronic co-trimoxazole therapy, South Africa	A simple, shorter patient information leaflet incorporating pictograms and text compared to a standard PIL (longer, more complex, no pictures) on co-trimoxazole therapy	Knowledge
Mazor et al. [57]	Randomized-controlled trial	600 (317) patients with anticoagulant therapy (mean age: not reported), Massachusetts/USA	3 video versions (narrative evidence, statistical evidence and combination of narrative and statistical evidence) compared to usual-care (control)	Knowledge
McDonald et al. [58]	Randomized-controlled trial	113 community-dwelling adult women (mean age: 42.6 years), English or Spanish-speaking, Connecticut/USA	Pamphlets with educational format (storytelling/narrative vs. factual). All versions use pictures	Knowledge
Murphy et al. [56]	Randomized-controlled trial	187 adolescents at risk of HIV/AIDS (aged 15–19 years), USA	Simplification of the HIVNET prototype (simplified text with illustrations) compared to the standard version. Reading grade level was simplified from 8.4 to 5.1	Comprehension, recall
Muscatello et al. [46]	Randomized-controlled trial	543 participants (mean age: not reported), New South Wales/Australia	12 modified (one or more changes) graphs compared to the original graphs	Comprehension
Nilsen et al. [70]	Systematic review	Healthcare consumers (or professionals) involved in decisions about health care	Ways of involving consumers to participate in patient information material (printed, audio-visual and electronic information that is intended to help patients to make informed decisions about healthcare) compared to no consumer involvement or different methods of involvement	Knowledge
Sansgiry et al. [67]	Randomized-controlled trial	225 Spanish-speaking consumers of over-the-counter (OCT) medications (mean age: 38.9 years), Texas/USA	A bilingual (English and Spanish) OCT-patient information leaflet compared to the old label version and the new FDA label format	Knowledge
Sudore et al. [65]	Randomized-controlled trial	205 English and Spanish-speaking people (aged >50), California/USA	A redesigned advance directive (5th grade reading level, >14 point font, graphics) compared to a standard advance directive (12th grade reading level, 12 point font)	Knowledge
Trevena et al. [11]	Review	Patients making healthcare decisions	Different presentation formats/methods (numeric, absolute risk reduction, relative risk reduction, graphical, pictures and text words) compared to no method or each other	Understanding, knowledge, comprehension
Walker et al. [69]	Randomized-controlled trial	363 participants with rheumatoid arthritis (mean age: 62 years)	Arthritis Research Campaign (ARC) booklet with a mind map compared to the standard ARC booklet	Knowledge
Yates and Pena [64]	Randomized-controlled trial	200 adult emergency medicine patients with head injuries (aged: 38–48 years), New Zealand	A short, simplified head injury advice sheet compared to a standard sheet	Comprehension
Zikmund-Fisher et al. [43]	Randomized-controlled trial	1704 internet users (mean age: 50 years), USA	Survival curves (5 or 15 years) compared to mortality curves (5 or 15 years)	Comprehension
Zikmund-Fisher et al. [31]	Randomized-controlled trial	1393 internet users (mean age: 49 years)	Comparison of different communication formats: risk presentation with text alone, text with pictograph, total risk and incremental risk	Perceived likelihood
Zikmund-Fisher et al. [32]	Randomized-controlled trial	659 women with risk of breast cancer >1.66% estimated by the Gail model (mean age: 59 years), USA	Comparison of different presentation formats for risks of side effects: pictograph vs. numeric text, total vs. incremental risk, 100 vs. 1000 persons as denominators	Risk perception, gist knowledge

Table 2
Excluded studies.

Study	Reason for exclusion
Boer et al. [14]	Advertising of health products
Braun et al. [15]	Intervention: complex intervention
Dowse and Ehlers [16]	Primary study aim adherence
Fagerlin et al. [17]	Does not address study question
Fuchs and Hippius [18]	Intervention: complex intervention
Hinshaw et al. [19]	Pilot study
Hoffmann et al. [20]	Intervention: tailored complex intervention
James et al. [21]	Survey of outcome measures unclear
Lipkus and Klein [22]	Intervention: tailored complex intervention
Schwartz et al. [23]	Intervention: complex intervention
Wilson et al. [24]	Pilot study

3.4. Risk of bias in included studies

Critical appraisal of systematic reviews showed high quality. Results of critical appraisal of RCTs are shown in Table 3.

3.5. Evidence of categories

3.5.1. Category: Content of information and meta-information

The ethical guidelines of the General Medical Council (GMC) define principles for the content of EBPI [25]. The guidelines describe how patients have to be informed before therapeutic, diagnostic or screening interventions.

Patients have to be informed about the purpose of the intervention, uncertainties about diagnosis and prognosis, and the options for treating or managing the condition, including the option not to treat. Furthermore, they must be given the probabilities of potential benefits, risks, likelihood of success or failure, side effects, and false-positive/false-negative results.

In addition, it is demanded to consider criteria of transparency, so-called meta-information [7], which supplemented the GMC criteria. Information should be given about the authors, sponsoring, financial dependencies, aim of the publication, sources of information, publication date of the information itself and also about the background information, references for further information and additional support or patient organizations.

3.5.2. Category: Quality of evidence

Patients prefer information which is given with an honest assessment of whether or not interventions are known to be effective [26].

A large number of taxonomies are used to rate quality of an individual study and the strength of recommendation if based on a body of evidence. However, the diversity of these scales rather confuses than enhances perception.

One randomized-controlled study was included [27]. Akl et al. [27] evaluated health care consumers' understanding and preferences for symbols vs. numbers and letters for the representation of strength of recommendation (SOR) and QOE. Understanding was measured with correct interpretations of the used grading formats. In addition, they evaluated health care consumers interest in receiving information about the SOR and the QOE using a seven-point Likert scale (−3 "strongly disagree" to +3 "strongly agree"). Participants expressed a strong preference to be informed about the QOE (mean Likert scale rating = +2.50; 95% CI, 2.26–2.73).

Symbols were superior to numbers for the presentation of the SOR (understanding: 74% vs. 14%), but were not preferred by the participants due to the grading system which is well known by American students. Understanding was high for symbols and letters for the presentation of the QOE (91% vs. 95%).

The standardization of systems of grading the QOE and SOR should be supported. There is a need to balance simplicity and clarity. However, the meaning of the presentation type must possibly be learned by the intended audience.

Until then developers of EBPI should ensure that a clear explanation is readily available for the presentation which is used.

3.5.3. Category: Patient-oriented outcome measures

Patients should be informed about two key factors when weighing new information about the effectiveness of a treatment: the quality of the evidence supporting its use and whether the evidence focuses on patient-oriented outcomes or disease-oriented outcomes.

No study was found which evaluated the impact of patient-oriented outcomes in patient information material.

Missing evidence for patient-oriented outcomes should be communicated, if patient-oriented outcomes were not considered.

3.5.4. Category: Presentation of numerical data

The way numerical data is presented, the framing of data, affects understanding and decision-making. This category comprises various aspects like presentation of risks, results and diagnostic tests.

Two systematic reviews [28,29], three randomized-controlled trials [30–32] and one review [11] were included.

Edwards et al. [28] reviewed existing literature on risk communication in genetics and described the effects on key outcomes for clients. As a result risk communication interventions achieve some benefits for consumers on cognitive outcomes, e.g. knowledge and risk perception, but counselling and psychosocial interventions appeared to be more effective.

Edwards et al. [29] reviewed the literature to assess the effects of different types of personalised risk communication about screening tests. In three studies the interventions showed a trend towards more accurate risk perception (fixed effects OR 1.46 (95% CI, 1.13–1.88)). Three other trials with heterogeneous outcome measures showed improvements in knowledge with personalised interventions. But there was insufficient data from the included studies to report odds ratios on knowledge. There is little evidence that personalised risk communication (whether written, spoken or visually presented) promotes or achieves their effects by enhancing informed decision-making in consumers.

Almashat et al. [30] studied the use of a debiasing questionnaire to prevent the framing effect for young adults on hypothetical decisions. The participants read a set of three medical treatment vignettes that presented information (i.e. mortality vs. survival frame) in terms of different outcome probabilities (i.e. cumulative probability, interval probability, life expectancy) under either debiasing or control conditions. The debiasing technique involved participants listing advantages and disadvantages of each treatment prior to decision-making. The control group was given a questionnaire with questions regarding stress, dental hygiene, and physical fitness. The participants had to choose a treatment option after answering one of the questionnaires.

The framing effect was demonstrated in the control group in two of the three vignettes. The debiasing group successfully avoided the framing effect for both vignettes; e.g. the cumulative probability vignette, control participants were more likely to select the risky choice in the survival frame (OR 7.64) and less likely to select the risky choice in the mortality frame (OR 0.30). In the intervention group, the odds ratio for selecting the risky choice was 0.60 (95% CI, 0.34–1.08) for the mortality frame, and 1.69 (95% CI, 0.90–3.18) for the survival frame.

A debiasing questionnaire may be a helpful aid for patients and consumers to concentrate on given information. On the other hand

Table 3
Risk of bias.

	Was the allocation sequence adequately generated?	Was the allocation adequately concealed?	Were baseline outcome measurements similar?	Were baseline characteristics similar?	Were incomplete outcome data adequately addressed?	Was knowledge of the allocated interventions adequately prevented during the study?	Was the study adequately protected against contamination?	Was the study free from selective outcome reporting?	Was the study free from other risks of bias?
Akl 2007	unclear	unclear	unclear	unclear	yes	unclear	unclear	no	yes
Almashat 2008	unclear	unclear	unclear	unclear	yes	unclear	unclear	yes	yes
Austin 1995	unclear	unclear	unclear	yes	yes	yes	unclear	yes	no
Boer 2006	yes	unclear	unclear	yes	yes	yes	yes	yes	no
Braun 2007	unclear	unclear	unclear	unclear	yes	yes	yes	yes	no
Brotherstone 2006	unclear	unclear	unclear	unclear	yes	yes	yes	yes	no
Delp 1996	yes	yes	unclear	yes	no	yes	yes	yes	no
Ghosh 2008	unclear	unclear	yes	yes	yes	yes	yes	yes	no
Hawley 2008	unclear	unclear	unclear	unclear	yes	yes	unclear	yes	no
Knapp 2005	unclear	unclear	unclear	unclear	yes	yes	unclear	yes	yes
Kools 2006a	unclear	unclear	unclear	yes	yes	yes	yes	yes	no
Kools 2006b	unclear	unclear	unclear	yes	yes	yes	yes	yes	no
Leiner 2004	yes	unclear	yes	yes	yes	no	yes	yes	yes
Mansoor 2007	unclear	unclear	unclear	yes	yes	unclear	yes	yes	yes
Mazor 2007	unclear	unclear	yes	unclear	yes	yes	yes	yes	yes
McDonald 2006	yes	unclear	unclear	yes	yes	yes	yes	yes	no
Murphy 2007	yes	unclear	unclear	yes	yes	yes	no	yes	no
Muscatello 2006	unclear	yes	unclear	unclear	yes	yes	yes	yes	yes
Sansgiry 2007	unclear	unclear	unclear	unclear	yes	yes	yes	yes	no
Sudore 2007	yes	yes	yes	yes	yes	yes	yes	yes	no
Walker 2007	unclear	unclear	yes	yes	yes	unclear	no	yes	no
Yates 2007	unclear	yes	unclear	yes	yes	unclear	yes	yes	no
Zikmund-Fisher 2007	unclear	yes	unclear	unclear	yes	yes	yes	yes	no
Zikmund-Fisher 2008a	unclear	unclear	unclear	yes	yes	yes	yes	yes	yes
Zikmund-Fisher 2008b	unclear	unclear	unclear	unclear	yes	unclear	unclear	yes	unclear

yes no unclear

presentation styles, that affect patients' decisions, should not be used in EBPI.

Zikmund-Fisher et al. [31] assessed participants subjective reactions to different communication formats for medication side effects, using a 2 × 2 factorial design to independently vary risk framing (total risk vs. incremental risk) and number of graphs (single graph vs. a sequence of two graphs). Participants indicated their perceived likelihood of experiencing each side effect using an 11-point (0–10) scale. Incremental risk framing had a significant effect on perception of likelihood of experiencing side effects. Effect sizes ranged from $d = 0.15$ for judgements of the likelihood of strokes to $d = 0.39$ for perceived likelihood of experiencing more colds. No effect was shown for using a two-graph sequence compared to a single pictograph. Participants with higher numeracy scores perceived significantly less risk.

Zikmund-Fisher et al. [32] examined whether using pictographs, incremental risk formats, and varied risk denominators influence perceptions and gist (general impression) knowledge of side effects in an online decision aid. Tailored estimates of the risks of five side effects were presented in a three factor design: risk

Table 4
Examples of presentation of numerical data.

1. Presentation of numbers	
Natural frequencies: 5 out of 100.	5 out of 100 correspond to 5%. Percentages are often misunderstood [33].
Comparability of numbers: 1 out of 100; 5 out of 100; etc.	Comparisons between two likelihoods will be more accurate if they are presented as 5 out of 100 vs. 25 out of 100, rather than the formally equivalent representation of 1 out of 20 vs. 1 out of 4 [34].
2. Presentation of risks	
Comparison of health-risks with everyday risks: 150 out of 1000 male smokers, who just turned 50, will die within the next 10 years: thereof 2 will die from colorectal cancer, 1 from prostate cancer, 30 from lung cancer, 35 from cardiovascular diseases and 4 from accidents [35].	The additional presentation of everyday risks allows comparing risks [35].
3. Presentation of results	
Absolute risk reduction (*ARR*): Uptake of colorectal screening reduces colorectal cancer mortality by 0.1 percent points.	The presentation of absolute risk reduction leads to better understanding compared to relative risk reduction [33].
Relative risk reduction (*RRR*): Uptake of colorectal screening reduces colorectal cancer mortality by 20%.	The presentation of relative risk reduction leads to an overestimation of intervention effects [36,37].
Number needed to be screened (*NNS*): About 1000 people would have to take part in colorectal cancer screening with occult blood test every 2 years for 10 years, to prevent 1 death caused by colorectal cancer.	The presentation of number needed to treat (NNT), NNS and number needed to harm (NNH) is comparable to ARR regarding comprehensibility [36].
Confidence intervals: About 1000 people would have to take part in colorectal cancer screening with occult blood test every 2 years for 10 years, to prevent 1 death caused by colorectal cancer. It might as well be about 700 or else 3000, who would have to take part in screening [38].	Confidence intervals communicate uncertainty of data [39].
4. Presentation of diagnostic tests	
Test results: Of 1000 pregnant women who are 40 years of age, 10 will have children with Down syndrome. If all 1000 women were tested, 9 of the women with Down syndrome babies would test positive for the condition, and 1 would test negative. Of the 990 women whose babies do not have Down syndrome, 394 would test positive, and 596 would test negative.	When the information on diagnostic tests is presented as frequencies rather than single event probabilities (e.g. 0.01), it is immediately obvious, that a positive test result carries much less diagnostic certainty [34].

information displayed either in pictographs or numeric text, risk reported either total or incremental risk with or without tamoxifen, and risk estimates used 100 or 1000 person as denominators. Incremental risk formats consistently lowered perceived risk of side effects but resulted in low knowledge when displayed by numeric text only. Adding pictographs, however, produced significantly higher comprehension levels.

Trevena et al. [11] reviewed studies which examined different formats of presentation of probabilistic information in order to improve patients' understanding of evidence. Based on one study it is suggested that natural frequencies or event rates are better understood than probability formats with varying denominators. Two other studies indicated that changes in risk are better understood if absolute risk reduction or relative reductions with baseline risk formats are used.

Cognitive psychology provides insight into the best ways to present risks and benefits to promote understanding and minimize interpretation bias.

Table 4 gives examples and practical recommendations.

3.5.5. Category: Verbal presentation of risks

The use of verbal descriptors is an effort to facilitate communication about risks with consumers. A guideline of the European Commission established five verbal descriptors for the probabilities of medication side effects (very common, common, uncommon, rare, very rare) with assigned frequencies [40].

One review [11] was identified, that included two relevant studies.

Patients have a more accurate perception of risk if probabilistic information is presented as numbers rather than words [11].

As already shown in the previous review, consumers significantly overestimate the risk of side effects when interpreting verbal descriptors [41,42]. Table 5 shows consumers' perception of verbal descriptors. Consumers were asked to estimate the probability (as a percentage) of having a side effect from a prescribed drug from one of the five qualitative descriptions.

Therefore risks should be presented numerically or else numerically and verbally.

3.5.6. Category: Diagrams, graphics and charts

Diagrams, graphics and charts are commonly used to visually display numerical information, e.g. bar graph, pie chart, table.

Four randomized-controlled trials [43–46] and one review [11] were included.

In an internet-administered survey Zikmund-Fisher et al. [43] assessed participants' comprehension of four graphs showing data of treatment outcomes. Participants received either a survival curve showing 15 years worth of data, an abbreviated survival graph showing only 5 years worth of data, or one of two analogous mortality graphs. Comprehension was surveyed. They observed a significant difference in people's ability to correctly identify the most effective treatment. While 94% of participants viewing the survival graphs accurately interpreted the graphs, this percentage dropped to 85% among those viewing the mortality curves. In addition, comprehension of mortality graphs was generally at least as good as, and often better, than comprehension of survival

Table 5
Example of verbal descriptors [42].

Qualitative descriptors	EU assigned frequency	Mean frequency estimated by participants (n = 200)
Very common	>10%	65% (24.2)
Common	1–10%	45% (22.3)
Uncommon	0.1–1%	18% (13.3)
Rare	0.01–0.1%	8% (7.5)
Very rare	<0.01%	4% (6.7)

Values are mean (SD).

graphs. The number of years of data in the survival curve can change beliefs about treatment effectiveness.

Ghosh et al. [44] evaluated whether patient education regarding breast cancer risk using a bar graph, with or without a frequency format diagram, improved the accuracy of risk perception. Overall, 72% of women overestimated their risk of breast cancer in the pre-visit questionnaire. Accuracy of risk perception improved after the intervention (bar graph group, 19 to 61%; bar graph with frequency format group, 13 to 67%). Results were not significant. But the difference was significant for women who inaccurately perceived very high risk ($\geq$50% risk), inaccurate risk perception decreased significantly in the frequency format group (22 to 3%) compared with the bar graph only group (28 to 19%).

Hawley et al. [45] evaluated the ability of six graph formats to impart knowledge about treatment risks and benefits in a hypothetical medical decision-making scenario (bar graph, pictograph, modified pictograph (sparkplug), pie chart, modified pie chart (clock graph) and table). Perception of the graph formats and two different types of knowledge were assessed: verbatim (specific numerical) knowledge and gist (general impression) knowledge. Participants who saw the table were most likely to have adequate verbatim knowledge (67% vs. 18–62% for other formats, $p < 0.001$), whereas those who viewed the pie chart more often had adequate gist knowledge (68% vs. 57–65% for other formats, $p < 0.05$). Among participants with lower numeracy, tables and pie graphs produced the most correct answers for verbatim and gist knowledge, followed by pictographs in both cases.

Muscatello et al. [46] tested modified statistical graphs compared to the original graphs to improve comprehension by non-experts. Comprehension rate (CR) was defined as the prevalence of correct answers to the tasks and categorized according to the following scale: 0% to <20%, very low; 20% to <40%, low; 40% to <60%, moderate; 60% to <80%, high; and 80–100%, very high. One or more modifications were made to improve comprehension of the statistical information depicted in the graph. Different categories of changes were made and combined, e.g. changing graph type, including a footnote or removing independent variables. The modifications with the most benefit for a single task were: changing a pie chart to a bar graph (changed CR from low to very high), changing the y axis of a graph so that the upward direction represented an increase rather than a decrease (changed CR from low to high), including a footnote to explain an acronym (changed CR from very low to low), and making the y axis of two adjacent graphs match (changed CR from moderate to very high). The modification of removing a layer from a stacked layer graph and adding a footnote reduced the comprehension rate from very high to high.

Trevena et al. [11] reported that patients can understand survival curves, when given more than one opportunity to do so. This result was based on one study. There is also some evidence in two studies that vertical bar graphs with numeric estimates may be the best way to graphically represent probabilities.

There is only little consensus regarding which methods for conveying information to patients are most likely to achieve the necessary level of understanding.

Table 6 gives examples and practical recommendations.

3.5.7. Category: Loss- and gain-framing

The presentation of information is either framed focusing on gain or on loss or on both.

No study was found that assessed the defined outcome measures. But some studies tested the persuasiveness of gain- and loss-framing regarding a desired behavior, e.g. uptake of screening.

The ethical guidelines explicate that the information given to the patients should presented in a balanced way [25].

3.5.8. Category: Pictures and drawings

The utilization of written text in combination with pictures in health communication is thought to be helpful for patients, especially for those with limited literacy. The category pictures and drawings comprises cartoons, pictures, pictograms, drawings and photographs.

Eight randomized-controlled trials [49–56] were included.

Austin et al. [49] examined comprehension of patients given written discharge instructions with or without pictures. The median number of correct responses was 5 out of 10. Patients who received text plus pictures were 1.5 times more likely to give five or more correct responses compared to the control group (65% vs. 43%, $p = 0.033$). In addition, they found that this was especially pronounced among nonwhites, patients with no more than high school education, and women.

Delp and Jones [50] evaluated printed instructions for caring wounds at home for patient with lacerations. The control group were given just text and the intervention group received the same text plus pictures (like comic drawings). The pictures illustrated the textual information. Participants were interviewed by telephone a series of questions about information in the handout 3 days later. The percentage of people who correctly answered all wound care questions when comparing patients who were given the illustrated version and the text version differed significantly (46% vs. 6%). A subset analysis of those patients who had less than high school education demonstrated a more pronounced difference between the groups.

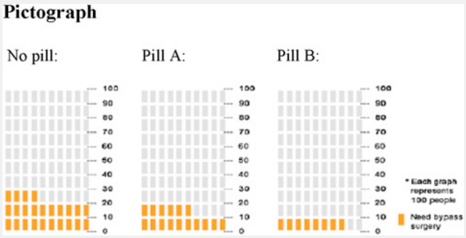
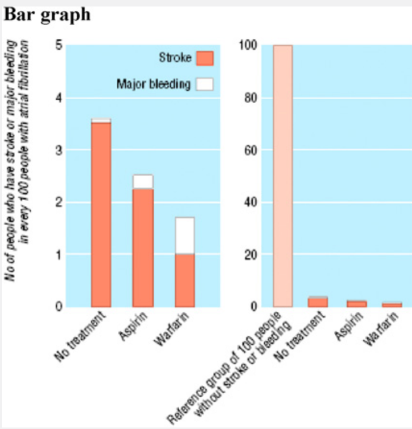
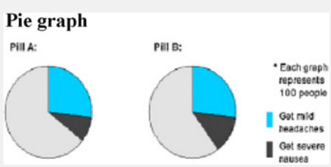
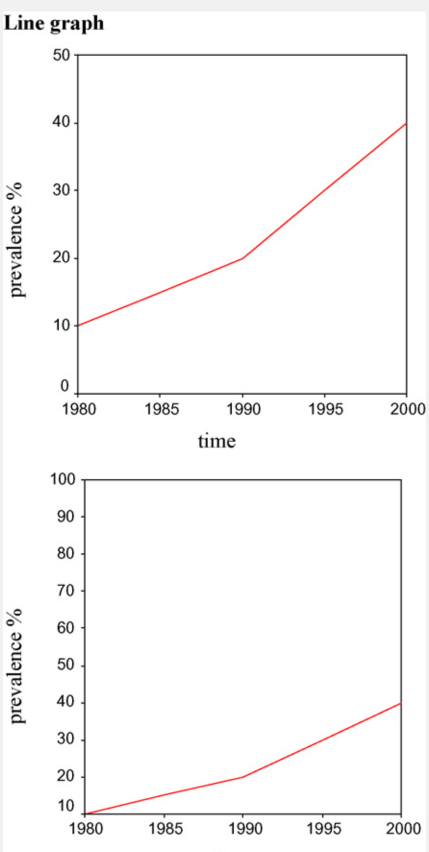
Mansoor and Dowse [51] evaluated two different patient information leaflets on co-trimoxazole therapy compared to standard care with any printed information. The interventions consisted of a short, simple version with pictures and a more complex version. A significant higher mean percentage of correct answers for medical knowledge were assessed for the patient information with pictures compared to the others (76% vs. 43% and 50.9%). This may be an indicator that pictures enhance knowledge. However, some important information was unknown by all participants.

Brotherstone et al. [52] studied the effectiveness of visual illustrations in improving peoples' understanding of the preventive aim of flexible sigmoidoscopy screening. The illustrations represented the removal of polyps and the polyp-cancer process. Three hundred and eighteen people were invited to participate and got information material with illustrations or the control information material. Only 65 out of these were interviewed. The illustration group had 84% good understanding compared to the only-written group with 57% good understanding. Therefore the results suggest that only the meaning contained within the illustrations has an advantage regarding recall.

Knapp et al. [53] examined the correct interpretation of medication pictograms and the effects of pictogram size on understandability among older people. The participants had to interpret the pictograms at two times. They were told the correct meaning after their first interpretation. Participants were more likely to correctly interpret pictograms that were larger (9×9 cm vs. 3×3 cm) at both times. Participants viewing the large pictograms correctly interpreted at mean 3.1 pictograms at the first interview and 5.0 at the second interview. The control group received scores of 2.0 and 3.6, respectively. However, in the second interview only 5 out of 10 pictograms were correctly interpreted.

Kools et al. [54] evaluated the additional presentation of seven line-drawings (visualizing the instructions) with textual instructions for two medical devices (11 instructions for the inhaler chamber and 26 instructions for the peak flow meter). Some

Table 6
Examples of diagrams, graphics and charts.

	Hawley et al. compared different formats which showed the effect of different drug interventions on bypass surgery. Pictographs achieved adequate levels of verbatim and gist knowledge across numeracy levels [45]. Pictographs are also used with faces or stick-figures. A drawback of pictographs is that they require more space than numerical presentations [34].
	Different representations of the same benefits of treatment: the reduction after treatment in the number of people who have a stroke or major bleeding looks much larger on the left, where the reference class of 100 patients who have not had a stroke or bleeding is not shown [47]. Bar graphs are well understood by patients and consumers. In addition, bar graphs are perceived to be helpful [48].
	Pie graphs are used to show the increased risk of headaches and nausea caused by taking pills. People who viewed a pie graph achieved more gist knowledge, especially those with low numeracy levels. However, the effect on verbatim knowledge was much smaller [45].
	Line graphs are used to display, e.g. cumulative risk. Scaling of line graphs influences risk perception. The larger the area under the curve the higher the risk is estimated. Line graphs are effective for communicating trends in data [48].

textual instructions served as captions below the line-drawings. It was expected that the line-drawings improve understanding of the instructions and the effect would be stronger for the inhaler chamber. Regarding the number of correctly recalled propositions of the inhaler chamber instruction the text with picture group outperformed the text-only group (6.04 vs. 4.81 correct propositions).

Leiner et al. [55] compared a four-page non-illustrated leaflet with a video-tape of animated cartoons explaining the need for a polio vaccine. Both versions were available in English and Spanish and contained the same information. Results showed statistically significant higher post-knowledge scores for the animated cartoon group. Furthermore, 30% of this group responded to all questions correctly while none of the printed group did so.

Murphy et al. [56] examined two versions of consent a form for a HIV vaccine trial. A simplified, picture-based version was compared to the HIVNET prototype with adolescents at risk of HIV. The simplified version contained modification in vocabulary, grammar and sentence structure and added illustrations. A comprehension test and interview with recall questions were conducted. The simplified consent group scored (significantly) higher on comprehension with mean scores of 15.29 (out of 19) compared to 13.62. 63% of the participants of the intervention group answered at least 16 items correctly; in the standard group only 32% answered at least 16 items. Participants of the simplified consent form were also able to recall more items than the control group. However, it is unclear which factor, the illustrations or the simplifications, lead to the better scoring. Six of the seven items for which the simplified group scored significant better had pictures to illustrate the concept.

There is some indication that pictures enhance knowledge und comprehension, especially for instructional advices (medication pictograms). But there are differences for the various types of pictures. Clear and simple drawings which support textual information should be preferred. More research is needed to examine which kinds of pictures are most beneficial regarding different target groups.

3.5.9. Category: Patient narratives

Patient narratives (also called testimonials or described as using a narrative or storytelling format) are used to educate (education programs) and to support patients (DA).

In contrast to a statistical message patient narratives present a definite experience not a probability of an experience. Patient narratives are typically considered as more concrete, familiar and vivid. They are expected to make information more memorable, realistic and comprehensible.

Two randomized-controlled studies were identified [57,58].

Mazor et al. [57] designed three versions of an educational video depicting a physician talking with a patient about anticoagulant medication management (with warfarin). The versions differed in the presentation of the key points. The physician used anecdotes about patient experiences, referred to scientific evidence using lay language or used a combination of both. These video interventions were compared to usual-care. The relevant outcome knowledge was measured by a baseline and post-intervention questionnaire. The participants who watched any video showed greater gains compared to those in the control group ($p < .001$). None of the video versions were superior compared to the others.

McDonald et al. [58] evaluated a storytelling format compared to a factual format to teach women about myocardial infarction symptoms. Four groups used different pamphlets in English and Spanish. No differences were found regarding the primary outcome. Women in both groups identified significantly more symptoms after reading the pamphlet compared to baseline data. However, the English-speaking women reported more symptoms than the Spanish-speaking women ($p < .007$).

Regarding cognitive outcomes no beneficial effects for the use of a storytelling format or additional narratives were found.

3.5.10. Category: Cultural aspects

Health information tries to get the attention of a broad audience. Up to now little attention has been given to cultural differences. These differences are observably in cultural aspects (e.g. religiosity) and dimensions (e.g. uncertainty avoidance, masculinity vs. femininity) [59].

No study was found. Studies that examined language related aspects were considered in the category Language.

Following ethical responsibility it is supposed that cultural aspects should be considered by developing patient information material.

3.5.11. Category: Layout

The layout of EBPI can facilitate reading and supports comprehension. Many recommendations and instructions exist to design written patient information.

Nevertheless no study was identified comparing information materials which only vary in layout and design.

The Harvard School of Public Health offers a concise compilation (including aspects of type, spacing, lines and design) [60].

It is recommended to use a readable type style (generally a serif type in 12 point size) and an appropriate space between lines (1.2–1.5 spacing) printed on paper that provides contrast between the paper and the text (no words on shaded or patterned background). The lines should be left-aligned with an appropriate length (maximum of five inches) and splitting of words across two lines should be avoided. Relevant aspects and recommendations for the overall design are:

- be consistent,
- provide a guide for finding key information,
- clearly label all illustrations and charts,
- offer explanations and make legends clear,
- place charts as close as possible to explanatory text,
- avoid wrapping text around illustrations,
- use consistent and easily recognized headings, and
- signal main points with bold or highlights.

3.5.12. Category: Language

Language means a system of spoken sounds or conventional symbols for communicating thoughts or ideas. Language facilitates the exchange of information, but people differ in their abilities to admit and process information. Language may a be barrier for people in search of information and knowledge. Therefore, the intended audience, including their use and handling of language, must be considered. Several aspects describe this category and build the following criteria.

Six randomized-controlled studies [64–69] for different criteria were included.

3.5.12.1. Criterion: Plain language and readability. Explicit communication is recommended to enhance health literacy and understanding of medical issues. A key communication strategy is to use plain language [61]. Plain language is a way of organizing and presenting information so that it makes sense and is easy to read. Plain language is defined as a simple, clear, conservational style and one that presents information in a logical order [62]. The consideration of using everyday words and examples, explanation of technical terms, avoidance of long and complex sentences, avoidance of gender-specific terminology, and writing in active voice is recommended.

The NIH Plain Language Coordinating Committee recommends a 4th–8th grade reading level for public information materials [62]. Written materials for people with limited literacy skills should generally be at 5th grade level or lower [63].

Yates and Pena [64] investigated understanding of medical information in emergency medicine patients to assess differences in comprehension between a standard head injury advice sheet (750 words, 4th grade Flesch Reading Grade Level) and a more structured, simplified one (371 words, 4th grade Flesch Reading Grade Level). 84.5% of the participants had a reading level of high school or above. Lower literacy groups were hardly represented. Median comprehension score for the standard form was 9 (out of 10), and for the simplified form 10 (out of 10).

Sudore et al. [65] evaluated a redesigned advance directive (5th grade reading level with redesigned layout and graphics) compared to a standard form (12th grade reading level). Pre- and post-knowledge was assessed as a secondary outcome. English and Spanish versions of both forms were provided. The participants had a mean literacy score of 24.6 that implied an adequate literacy (>9th grade reading level). The knowledge was improved in both groups, but the redesigned form did not result in greater knowledge gains. Participants answered a similar number of knowledge items correctly (71.2%, redesigned vs. 70.8%, standard form). However, more participants preferred and wanted to take home the redesigned advance directive.

Braun et al. [66] examined fictitious package leaflets that varied with regard to the personal nouns used. A generic masculine version and two gender-neutral ones were compared to assess recall. Female and male participants recalled a similar amount of details in all three text versions. However, male participants rated the generic masculine version as more comprehensive compared to the gender-neutral versions.

Plain language is recommended, but studies showed only marginal effects. One reason may be that the included participants did not present the target audience.

3.5.12.2. Criterion: First language. The first language (also mother-tongue) is the language a human being acquires in early childhood. But one can have two or more languages, being a native bilingual or multilingual. The proficiency of a language has an impact on comprehension and understanding of information.

Sansgiry et al. [67] evaluated bilingual Product Information Labels (PILs) compared to currently available label formats in a sample of Spanish-speaking consumers. Mean scores for product knowledge from PILs among Spanish-only speakers differed significantly from mean scores of old (CI, 4.50-8.63, $p < 0.05$) and new label formats (CI, 4.17-8.25, $p < 0.05$).

Bilingual materials provide an opportunity to receive information and may foster knowledge gain for a broader audience.

3.5.12.3. Criterion: Comprehension enhancing tools. To comprehend a text, the text information should become part of the reader's personal knowledge base. Readers need to cognitively encode the incoming information by maintaining coherence in their mental representation of the content. Graphical organizers such as network maps, hierarchical tree diagrams or matrices try to clarify or highlight relations among the macro level concepts in the text. They may foster the comprehension of the thematic structure and the organization of information in the memory of the reader.

Kools et al. [68] examined the effect of graphic organizers on the comprehension of a health education brochure text. The graphic organizers were graphically depictions of relations among concepts in a text. Participants read a text about asthma with or without graphical organizers. A questionnaire with open-ended questions was developed to measure objective comprehension. Individual scores were transformed into percentages of the maximum possible score. The graphic organizer group had better comprehension (57.2% vs. 43.8%, $p < 0.01$). The findings suggest that systematic placement of graphic organizers encourages readers to learn the whole picture rather than only facts.

Walker et al. [69] determined the knowledge gain of a booklet compared to a booklet with a pictorial mind map. Both groups showed a significant increase in knowledge (mean increase 6.56 vs. 6.45), but there was no significant difference between these groups. Mind maps seem to be a helpful method, but were not superior. However, mind maps should be a support for people with low literacy skills, but only a few of these people participated in the study.

The beneficial effect depends on the used tool. Graphic organizers highlighting hierarchical relations seem to improve comprehension, but this effect was not shown for mind maps.

3.5.12.4. Criterion: Non-alarmist and non-patronizing. A non-alarmist [26] and non-patronizing [10] use of language is discussed and recommended. However, no study was found that examined these aspects.

3.5.13. Category: Development process

It is expected that the involvement of consumers in the development process has beneficial effects, since patients' and consumers' ideas and information needs are incorporated.

One systematic review was identified [70].

Nilsen et al. [70] assessed the effects of consumer involvement and compared different methods in the health care domain. One aspect is consumer involvement in the development process of patient information material. Two studies were included which compared patient information material with consumer consultation to those without consumer consultation. The involvement or consultation of consumers resulted in patient information material that had more illustrations and was more readable. Based on one study there is moderate quality evidence that consultation of consumers before developing patient information material can improve knowledge of the patients.

4. Discussion and conclusion

4.1. Discussion

The evidence for the categories for EBPI is quite heterogeneous. Some are supported by good evidence, e.g. presentation of numerical data or graphical presentations. Others, like content of information, derive from ethical guidelines. Some categories have not yet been studied, e.g. cultural aspects. This review is the first which summarizes the evidence of categories and criteria for EBPI.

Our review has limitations. Many studies evaluated various outcomes. Because understanding and comprehension of information are prerequisites for informed patient choice, we only included cognitive outcomes. Our search was limited to RCTs and systematic reviews, as we searched for efficacy trials. Therefore, we did not consider formats which showed positive effects within qualitative studies. In addition, we focused on the context of health information. Therefore, findings from cultural studies and the like were not considered. The quality of included studies was heterogeneous, sometimes poor. Further systematic reviews should be performed on single categories to allow inclusion of multitude of outcomes in RCTs and also studies beyond RCTs.

The development of EBPI requires consideration of the target audiences and their special needs, e.g. those deriving from the

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cultural background. Culturally relevant tailoring is discussed, but has not yet been tested within the context of patient information. It remains unclear which cultural aspects are relevant and should therefore be considered. Culturally competent approaches have been examined in educational programs for diabetes. Anderson-Loftin et al. included ethnic beliefs, values, customs, food preferences, language, learning methods and health care practices in the development of their program [71]. Study results showed significant positive changes in BMI and dietary behaviors, whereas metabolic parameters were not affected. Therefore, relevance of effects is questionable. Furthermore, Nollen et al. tested culturally sensitive patient information and found no differences in smoking cessation [72]. According to the authors this might be due to the heterogeneity of the addressed ethnic group.

In the rapidly growing field of health communication, narrative approaches are emerging as a promising set of tools [73]. Sometimes the use of narrative approaches is expected to persuade consumers in order to achieve health-behavior changes. This is in contrast to the aims of EBPI.

Fagerlin et al. studied the influence of anecdotes in patient information on decision-making [74]. When the content and number of the narratives were adapted to the statistical data (e.g. bypass surgery cures angina in 75%, three anecdotes describing success and one describing failure of treatment) the effect on treatment choices was significant. Participants receiving anecdotes which were representative of the statistical information were more likely to choose bypass surgery compared to those who received one anecdote about successful and one about unsuccessful experiences (41% vs. 20%). In addition, the latter study showed that the presentation of statistical information using a pictograph reduced the undue influence of anecdotal reasoning in hypothetical treatment choices on balloon angioplasty and bypass surgery.

Framing of information in either gain or loss is also used to support health-behavior. The persuasiveness of gain- and loss-framed messages for encouraging disease prevention behavior was assessed [75]. Gain-framed messages were significantly more persuasive than the loss-framed ones. However, a balanced presentation of benefit and harm is required for EBPI [25]. In the context of patient information Almashat et al. studied the effect of mortality vs. survival framing regarding treatment choice. Participants were more likely to select the risky choice in the survival frame than in the mortality frame [30]. Trevena et al. also reported that the framing of information in terms of either benefit or harms can affect patient preferences [11].

4.2. Conclusion

The results of this review allow specification of EBPI and may help to advance the discourse among related disciplines. Research gaps are highlighted.

4.3. Practice implications

The results of this review are useful for developers of EBPI. Findings outline the type and extent of content of EBPI, guide the presentation of information and describe the development process. However, depending on the qualification of the developers of EBPI, additional guidance may be needed. A manual that contains detailed guidance on the complex process of developing EBPI is still lacking. Further research should address this gap. The Medical Research Council proposed a framework for the development and evaluation of complex interventions [76]. Since so far, no instruments have been developed to evaluate EBPI, the categories may be helpful to guide evaluation of EBPI.

Conflicts of interest

We have no conflicts of interest to declare.

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