

# [Preprint] Plain Language Summaries: A Systematic Review of Theory, Guidelines, and Empirical Research

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# **Abstract**

## **Background**

Plain language summaries (PLS) have been introduced to communicate research in an understandable way to a non-expert audience. Guidelines for writing PLS have been developed and empirical research on PLS has been conducted, but terminology and research approaches in this comparatively young field vary considerably. This prompted us to review the current state of the art on the theoretical and empirical literature on PLS.

## **Main Objectives**

Main objectives were (1) to develop a conceptual framework for PLS theory, and (2) to synthesize empirical evidence on PLS criteria. Major research questions were how theoretical considerations on PLS can be conceptualized and what the empirical evidence of their effects on defined outcomes is.

## **Methods**

We searched Web of Science, PubMed, PsycInfo, and PSYINDEX (last search 07/2021). In our review, we included empirical investigations of PLS, reports on PLS development, PLS guidelines, and theoretical articles referring to PLS. A conceptual framework was developed through content analysis. Empirical studies investigating effects of PLS criteria on defined outcomes were narratively synthesized.

## **Results**

We identified 7,714 records, of which 90 articles met the inclusion criteria. All articles were used to develop a conceptual framework for PLS which comprises six categories each for PLS aims and PLS characteristics. Thirty-three articles empirically investigated effects of PLS on several outcomes, but study designs were too heterogeneous to identify definite criteria for high-quality PLS. Insular studies identified effects of various criteria on

accessibility, understanding, knowledge, communication of research, and empowerment. For most criteria we identified from PLS writing guidelines, we found no empirical evidence.

### **Conclusion and Implications**

Considerable work to establish and investigate PLS has been done, but empirical evidence on criteria for high-quality PLS is scarce. The conceptual framework developed in this review may provide a valuable starting point for future guideline developers and PLS researchers.

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# Introduction

Good research practices include the publication and dissemination of results as well as their honest and transparent communication [1,2]. It is further argued that the public—or at least relevant stakeholders—should have access to research, not only technically but also intellectually [3]. This means that the public needs to be able to understand what the researchers did, what the results mean and which practical implications can be drawn from them [3]. This information is mostly communicated by researchers via scientific publications, which is among other factors further motivated by funding agencies as well as promotion and tenure committees expecting and postulating researchers to publish in high impact scientific journals [4,5]. The target audience of such publications and relevant gatekeepers, namely editors and reviewers of high impact journals, are other researchers. Consequently, this traditional way in which scientific publications are written and published requires researchers to stress the scientific implications of their research. The traditional communication of scientific findings therefore constitutes a scientific ‘bubble’ in which scientists communicate with each other about the meaning of their findings [6]. As is typical for such group formation processes, this bubble results in its own special type of language, shared knowledge as well as implicit and explicit norms which makes scientific communication harder to understand for those outside the scientific bubble [7]. Such a context provides a breeding ground for the evolution of idiosyncratic professional jargon. This lack of plain, easily comprehensible language hinders the public from directly accessing scientific articles.

One viable and ready solution that accounts for the information needs of the public (or of gatekeepers such as journalists) within the current research ecosystem are Plain Language Summaries (PLS)—a lay-friendly summary format of scientific research. Each PLS is thought to provide a brief overview on a study and its main practical implications in a manner that is understandable to laypersons. Various institutions provide some form of lay-friendly

summary formats of scientific studies. Especially institutions in biomedicine have been very prolific in this regard [8]. Still, there is no consensus on PLS criteria (i.e., what defines a PLS and what makes a high-quality PLS). Guidance on how to write PLS is scattered and often relates to specific purposes of the respective institutions that provide the PLS [8]. To evaluate whether a PLS is effective in fulfilling its aim (e.g., to be understandable for laypersons), empirical research on the subject of PLS has been conducted [e.g., 9–14].

To shed light on the status quo of PLS writing guidelines and the empirical research on the effects of PLS on defined outcomes, we present a systematic review of established writing guidelines with their respective criteria and of the empirical evidence on whether PLS are effective in terms of relevant outcomes.

## **Theoretical background**

For the terminology of lay-friendly summaries in the form of PLS, there appears to be no broad consensus yet [8,15]. In the present paper, we consistently refer to ‘Plain Language Summaries’ (PLS), independent from what they are called in the referenced publications. PLS, in this review, are defined as relatively brief textual summaries of scientific publications targeted at laypersons which complement the respective traditional abstracts and summarize the whole scientific article in a balanced, easily understandable manner.

The considerable variation in the terms that are used to refer to PLS [8] may be partly related to the different *aims* that the specific parties (e.g., authors, stakeholders or publishers) pursue with their PLS. On the one hand, some pursue the explicit aim of translating medical evidence into a PLS to enable patients to actively engage in the process of shared decision making [16] or to increase patient engagement in clinical research [17,18]. For these PLS also terms such as ‘clinical trial results summaries for laypersons’ [19,20], ‘patient lay summaries’ [21] or ‘consumer summaries’ [22] are used. On the other hand, publishers of scientific

journals may primarily aim to increase the impact and accessibility of the published articles [17]. They might use terms such as ‘lay summaries’ [e.g., 23–25], ‘translational abstracts’ [26] or ‘lay abstracts’ [e.g., 23]. An overview of the variety of PLS terminology can be found in Shailes [15] for PLS of scientific research in general, and in FitzGibbon et al. [8] for biomedical PLS.

Besides common aims (e.g., increasing the accessibility of research), PLS formats differ in various *characteristics*. Considerable variation exists even for basic formal characteristics, such as the length of the PLS or the language they are written in [27]. For example, the *Journal of Applied Sport Psychology* presets a word limit of 50 words for their ‘lay summaries’ [28] which are expected to be written in English language, while Cochrane specifies a limit of up to 700 words and makes considerable efforts for translating the PLS into multiple languages [29,30]. Similarly to the differences in the terminology used to label the PLS, these differences in text characteristics may be related to the specific aims that the specific parties pursue by providing PLS. If, for example, the aim is to reach out to other researchers to foster interdisciplinary exchange, providing English PLS may be a reasonable choice. Otherwise, if the aim is to reach out to the broader public in a more general way, PLS additionally have to be written in languages other than English, to maximize accessibility. Such differences might not only manifest themselves in varying languages or word limits of PLS, but also in varying recommendations of style or content in PLS writing guidelines (e.g., what the PLS should explain, or whether additional background information or statistical information should be provided). PLS may thus differ considerably in their characteristics, depending on the specific guidelines on which they are based (if at all) and which *criteria* these guidelines specify. Criteria in this context are standards or restrictions of characteristics (e.g., specific word limits or approaches for dealing with technical terms).

In empirical studies on the effectiveness of PLS, such criteria are systematically varied and analyzed with regard to certain defined *outcomes* that are supposed to reflect the aims in terms of measurable, operationalized variables. For example, researchers could investigate the PLS aim of increasing public empowerment by evaluating whether people who read a PLS with plain language explanations of technical terms perform better in a knowledge test about the contents of the summary than people who read a PLS without such plain language explanations.

In sum, theory on the concept of PLS refers to the interconnection of these four main subject areas: PLS serve specific (1) *aims* (e.g., to improve laypersons' understanding of scientific findings) that are accomplished by certain (2) *characteristics* (e.g., use of language) with their related target values or (3) *criteria* (e.g., avoiding technical terms). Criteria can also be subject to empirical investigations (e.g., comparing PLS with different criteria) of certain (4) *outcomes* (e.g., knowledge tests).

In this review, PLS are considered a research subject as well as a service or intervention to make research understandable for laypersons. For this systematic review on PLS research and theory, we will therefore not only synthesize research on the subject using an *ontological* approach by addressing the question of what the topic constitutes and what it distinguishes from other topics (this refers to PLS characteristics). Since PLS are a specific form of 'research translation' service or intervention, our review additionally distills and discusses information from the literature on what a PLS is for (a *finalistic* approach referring to the aims of a PLS), what it should be like to fulfill this purpose (a *normative* approach referring to the criteria of a PLS) and how its effectiveness can be evaluated (a *measurement-related* approach referring to the outcomes of empirical studies on PLS). Thereby, a comprehensive overview of four main subject areas, namely the characteristics and aims of PLS as well as PLS criteria and measured outcomes, is provided. We particularly focus on

existing guidelines and empirical investigations of criteria with regard to defined outcomes, to identify evidence-based criteria for writing PLS.

## Objectives

The aim of this review is to give a comprehensive overview on the current understanding of PLS in the scientific literature and on evidence of their effects on certain defined outcomes. Therefore, we will investigate 1) aims, 2) characteristics, and 3) criteria that are named or defined in the context of PLS, and criteria and 4) outcomes that have been empirically investigated in the context of PLS research and evaluation. On that account, we will systematize theoretical research and empirical evidence on PLS by considering theoretical articles (including literature reviews) and opinion pieces, empirical studies as well as writing guidelines. With that said, the aim of our review is twofold.

First, we intend to establish a conceptual framework of PLS by outlining finalistic, ontological, normative and measurement-related approaches to capturing this research field. More precisely, this means that in the first step, we will synthesize the systematically reviewed literature with regard to four questions relating to the main subject areas of this review:

- 1) What are the *aims* or purposes of a PLS (finalistic approach; i.e., what are PLS for)?
- 2) What are the *characteristics* of a PLS (ontological approach; i.e., what constitutes PLS)?
- 3) Which *criteria*, in terms of values, expressions or degrees of the aforementioned characteristics, define a PLS or are supposed or found to constitute a high-quality PLS (normative approach; i.e., what exactly should PLS be like)?



- 4) Which *outcomes* of PLS are investigated, and how (well) are theoretical aims operationalized in empirical studies (measurement-related approach; i.e., how are PLS evaluated)?

Second, the established conceptual framework will enable us to sum up and integrate the empirical evidence on PLS against the background of this research topic's main subject areas. This does also involve scrutinizing how well the empirically investigated outcomes correspond to the theoretically proposed aims as well as which criteria are listed in guidelines or are empirically investigated. By doing so, we will be able to identify current gaps in the empirical research on PLS, and reflect on what has been achieved so far in providing evidence-based guidelines for writing PLS.

## Methods

### Eligibility criteria

For this review, we searched for scientific publications on PLS (i.e., empirical and theoretical articles) as well as for published PLS guidelines. The term 'PLS', in this review, refers to research summaries that accompany a scientific publication, and that aim to translate published scientific evidence from language that is geared towards expert audiences to language that is geared towards lay audiences. Examples for the accompanied scientific publications are original research reports, meta-analytical studies or clinical study reports. This definition of PLS does explicitly not include popularized science news articles, blog posts or patient-education materials since these are not direct translations of scientific publications but (research) outputs or publications in their own right. In our interpretation, apart from translating the evidence of research articles, the only autonomous scientific contribution a PLS may make is to report the evaluation of risk of bias or putting the reported evidence into perspective (e.g., by highlighting its practical implications or providing

additional background information). This criterion is based on the consideration that evaluating risk of bias is just another way of translating the quality of a scientific finding for a non-expert audience. This audience is expected to have no experience with scientific standards, and additional information on practical implications may help them understand the scientific finding. Finally, with ‘PLS’ we only refer to textual approaches for translating evidence and, therefore, not to infographics, videos or podcasts. Accordingly, we searched for publications and guidelines that investigate, discuss or describe PLS. All three of the following criteria needed to apply to the investigated, discussed or described PLS:

- A. The PLS are summaries of published scientific evidence (i.e., the underlying evidence that is summarized is a scientific study such as a primary study or a systematic review).
- B. The PLS aims at a lay readership.
- C. The PLS uses the same communication format as the original scientific publication evidence (i.e., text).

We included English and German records of the following study types:

- quantitative and qualitative studies or reviews of such studies in which
  - a) characteristics, criteria or aims of PLS are investigated, or
  - b) PLS criteria or guidelines that combine several criteria are developed or evaluated;
- guidelines on how to write PLS;
- theoretical articles (e.g., opinion pieces, theoretical discussions, reviews, editorials, comments) that clearly bear upon PLS characteristics, outcomes or aims, or on PLS writing criteria or guidelines.

## **Information sources and information search**

We systematically searched Web of Science, PubMed, PsycInfo and PSYINDEX (last search on 2021/07/02) using the search terms specified in S1 File. After the first selection process (see below), we performed a backward reference search of included articles. Additionally, we searched the websites of the journals for which we had found that they publish PLS for guidelines on writing PLS, and searched the web for more of such guidelines.

## **Study selection**

In the first step, titles and, if necessary, abstracts were screened to exclude irrelevant records based on the above-mentioned inclusion criteria. In a second step, the remaining potentially relevant records were assessed for eligibility by a full text screening. In both steps, double screenings by two independent researchers were performed (see Fig 1). Discrepancies were discussed, and, if unsolvable, the decision was left to a third independent rater.

## **Data collection process and data items**

MS, MK and AC independently extracted information about the following four subject areas in the form of text passages from the selected reports. Each record was evaluated by one reviewer and information was compiled in tables:

- 1) Aims of PLS: Which aims or purposes of PLS were mentioned?
- 2) Characteristics of PLS: What kind of PLS characteristics were mentioned?
- 3) Criteria for PLS: What information could be found on what makes a high-quality PLS as well as on what makes a PLS different from other types of research summaries?

- 4) Outcomes of PLS: In empirical studies on PLS, which outcomes were examined to investigate the quality of PLS?

After the text passages had been compiled, MS went through all passages again and collated them to the respective original record to ensure proper rendition. Study procedures were not preregistered.

## Analysis

We based our approach for analyzing and summarizing the information from the full texts on qualitative content analysis [31]. As described above, we first extracted information in the form of text passages separately for each of the four subject areas (aims, characteristics, criteria, outcomes) which corresponded to the four approaches of describing the PLS research field from theory. In the next step, we categorized the information that we obtained for each subject area by means of identifying and labeling homogeneous groups of information. Three of the authors (MS, MK, AC) with expertise on PLS each independently worked through the extracted text passages and proposed categories for the subject areas ‘aims’ and ‘characteristics’. The proposed categories and according rationales were discussed by these three authors until an agreement for a set of categories for ‘aims’ as well as ‘characteristics’ was obtained. We then mapped the information about ‘outcomes’ to these agreed aim categories and information about ‘criteria’ to the agreed characteristic categories. For this purpose, the first author (MS) allocated information about PLS outcomes and PLS criteria to one of the previously deduced categories of PLS aims and PLS characteristics, respectively. Afterwards, two other authors (AC, MK) reviewed the categorization and proposed changes in case of disagreement. These cases were discussed until consensus was reached. During and after this process, the final conceptual framework was developed.

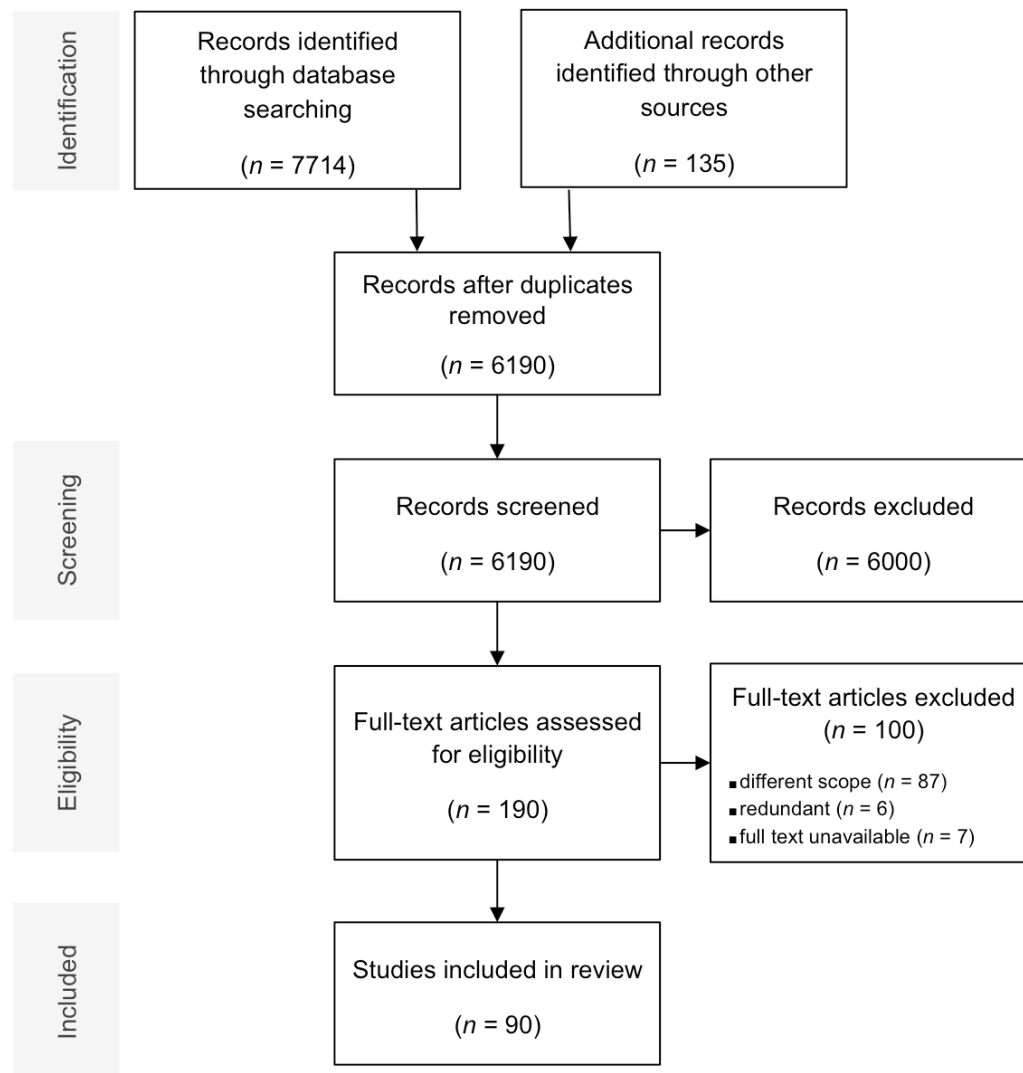
Based on this framework, a narrative review of the empirical evidence on PLS as well as on PLS writing guidelines was performed. Empirical investigations on the effects of PLS on certain defined outcomes were synthesized in detail with a focus on experimental conditions (which were matched with respective characteristic categories), and on outcome measurements (which were matched with respective aim categories).

## **Results**

### **Study selection**

We identified 7,714 records through database searching and 135 records through other sources (see above). After title and full text screening (see Fig 1), we included 90 studies in our review.

**Fig 1. Study Selection Flow Diagram.**

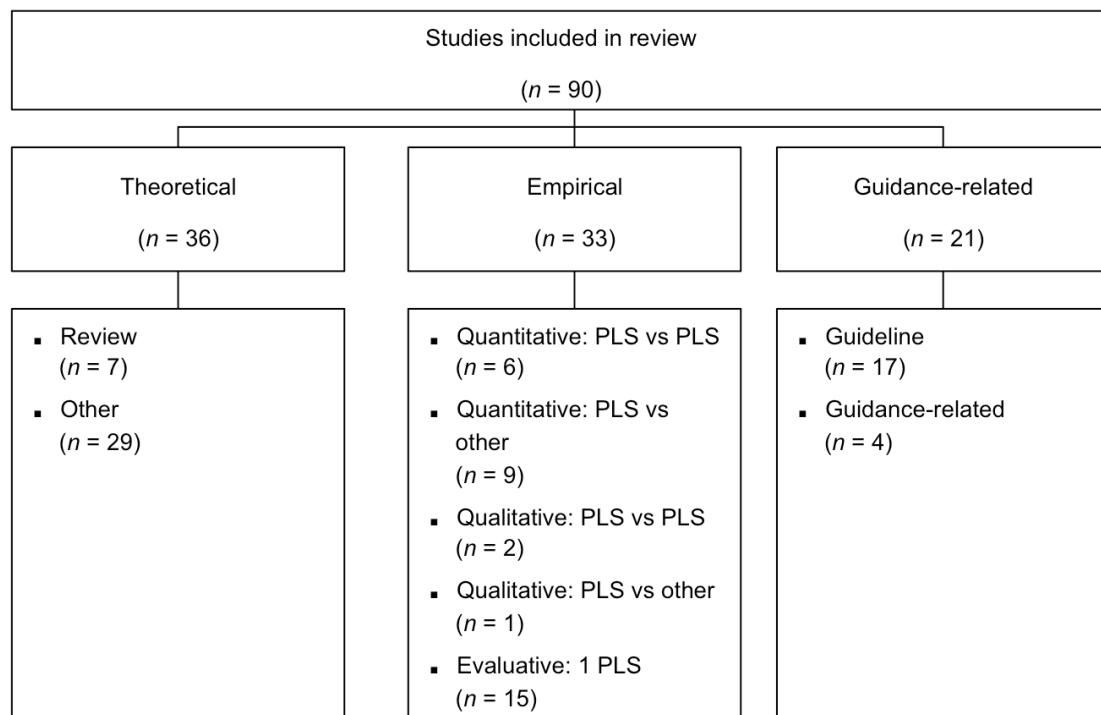


## Study types

Of the 90 included records, 36 (40%) were theoretical and 33 (37%) were empirical articles (see Fig 2). Twenty-one articles (23%) were guidance-related articles. Of the 36 theoretical articles, 7 (19%) were reviews and 29 (81%) were opinion pieces, editorials or comparable articles. Of the 33 empirical articles, 15 (45%) described experiments that quantitatively compared different formats of PLS ( $n = 6$ ) or compared PLS with other summary formats ( $n = 9$ ), 3 (9%) were studies that qualitatively compared different formats of PLS ( $n = 2$ ) or compared PLS with other summary formats ( $n = 1$ ), and 15 (45%) were

studies that evaluated or investigated one specific type of PLS. Of the 21 guidance-related records, 17 (81%) were guidelines and 4 (19%) were other studies related to PLS guidance (e.g., guideline development). All studies are listed in S1 Table.

**Fig 2. Study Types of Studies included in this Review.**



Information about PLS aims, characteristics, criteria and outcomes was extracted from all 90 studies. Specific information about criteria for writing a PLS was extracted in detail from the 17 guidelines. Specific information about empirical evidence of PLS was additionally extracted and summarized in detail from the eight empirical studies that quantitatively or qualitatively compared different forms of PLS.

## Aims of PLS

We firstly investigated all articles to answer the question: Which aims or purposes were mentioned? According to the results of our content analysis, information from the

current literature on the aims of PLS can be divided into six categories which we labeled ‘Accessibility’, ‘Understanding’, ‘Knowledge’, ‘Empowerment’, ‘Communication of Research’ and ‘Improvement of Research’. See below for the description of each category and example quotes from text extractions.

**Aim Category: Accessibility.** This category comprises PLS aims that are geared towards providing laypersons with low-threshold information about research that is easy to find, highly visible, freely accessible, attractive, and appealing to non-experts in general or to specific non-experts such as in teacher training [32]. This also includes the technical accessibility of the file [33].

- Example Text Excerpt: “A key aspect of improving access to knowledge is to ensure not only that the content of the resource is appropriate but also that the format in which it is presented is fit for purpose.” [13, p. 2]

**Aim Category: Understanding.** This category comprises PLS aims that are geared towards providing laypersons with information about research (including research questions, methods and results) that is understandable.

- Example text excerpt: “PLS help to make scientific research understandable [...] by describing complex research using nontechnical language that can be easily understood” [8, p. 2]

**Aim Category: Knowledge.** This category comprises PLS aims that are geared towards increasing laypersons’ knowledge about specific subjects based on scientific evidence.

- Example text excerpt: “[...] evidence summaries are [...] instrumental resources for translating research to inform knowledge” [34, p. 93]

**Aim Category: Empowerment.** This category comprises PLS aims that are geared towards enabling laypersons to make informed, self-determined decisions, and to foster public participation in decision processes.



- Example text excerpt: “Making it more likely that the findings of the research will be used to make a difference to service users’ lives.” [24, p. 2]

**Aim Category: Communication of Research.** This category comprises PLS aims that are geared towards enhancing the communication and dissemination of research by addressing a broad audience. Thereby, the trust in and impact of science on daily as well as political decisions and actions is thought to increase. For example, Phung et al. [35] stresses the interaction of different audiences, and Wada et al. [36] name the PLS as a tool to communicate with project funders.

- Example text excerpt: “The PLS is considered a main building block for dissemination of the review to the end-users of health information.” [37, p. 3]

**Aim Category: Improvement of Research.** This category comprises PLS aims that are geared towards making a contribution to the improvement of research practice in itself, for example through increased transparency, exactness and improvement of writing style as well as through higher engagement in discussions regarding the relevance of research.

Furthermore, PLS are thought to facilitate interdisciplinary communication. They are named, for example, to strengthen public support for the research enterprise [38], enhancing transparency [39], and as an opportunity for science to engage in the media ecosystem [25].

- Example text excerpt: “And plain-language summaries can also be useful to authors when, for example, they need to explain their work in non-technical terms when applying for a fellowship or faculty position.” [40, p. 1]

It must be noted that the first four aim categories are dependent on each other, however they present distinct aims: In order to empower laypersons to make informed decisions based on scientific findings (Empowerment category), laypersons need to have evidence-based knowledge (Knowledge category), which in turn is only possible if they understand the information about the evidence (Understanding category). For that, the base requirement is

that the information is accessible (Accessibility category). Aims of the Communication of Research category represent ideal aims, often pictured as a bridge over the gap between academia and the public, while aims of the Improvement of Research category include effects that these actions have on research itself. These effects are measurable irrespective of a (subjective) PLS reception.

## Characteristics of PLS

We further reviewed the literature on PLS to answer the question: What kind of PLS characteristics are mentioned? According to the results of our content analysis, characteristics of PLS can be organized into six categories which we labeled ‘Linguistic Attributes’, ‘Formal Attributes’, ‘General Content’, ‘Presentation of Results’, ‘Presentation of Quality of Evidence’ and ‘Contextual Attributes’. See below for the description of each category and example quotes from text extractions.

**Characteristic Category: Linguistic Attributes.** This category comprises PLS characteristics that encompass the tone or style of the used language, the choice of words (e.g., handling of jargon and technical terms), or the text difficulty.

- Example text excerpt: “Plain languages summaries [...] are thus diverse in style, words usage, and possibly in literacy requirements.” [41, p. 2]

**Characteristic Category: Formal Attributes.** This category comprises PLS characteristics on the formal level, such as word limits, standardized formulations, prespecified headlines, or inclusion of graphs or tables. This also includes whether a PLS follows a formal structure, for example characterized by the use of headlines and subheadlines or paragraphs.

- Example text excerpt: “Plain language summaries (...) have different word counts depending on the journal.” [42, p. 2]

**Characteristic Category: General Content.** This category comprises PLS characteristics that concern a PLS' content (e.g., whether background information or key messages are included), and the alignment of contents (e.g., a prespecified alignment of introduction, description of methods, results and conclusions).

- Example text excerpt: “The text should provide answers to the essential questions: Who, What, Where, When, Why, How? For example, the reader should easily be able to find answers to questions such as ‘By whom was the research funded, and why?’” [24, p. 5]

**Characteristic Category: Presentation of Results.** This category comprises PLS characteristics that strike the presentation of results in a PLS (e.g., whether an effect size is mentioned, or the way statistical terms are handled).

- Example text excerpt: “Cochrane’s Plain Language Expectations for Authors of Cochrane Summaries (PLEACS) standards recommend that it is not essential to provide numerical information in PLSs, but if there are numbers presented, the presentation should be consistent, comprehensive to the lay population in terms of absolute effects, and framed as natural frequencies [...]” [9, p. 2]

**Characteristic Category: Presentation of Quality of Evidence.** This category comprises PLS characteristics that strike the presentation of the quality of evidence in a PLS, for example whether GRADE-system (Grading of Recommendations, Assessment, Development and Evaluation) results, or authors’ conflicts of interest are reported.

- Example text excerpt: “For example, in current plain language summaries authors use a variety of words to express the strength of the evidence and the magnitude of the effect of the interventions.” [16, p. 495]

**Characteristic Category: Contextual Attributes.** This category comprises PLS characteristics that concern the general context of the PLS, for example the specific process

of drafting, production or publication. These include information on the review process, on technical accessibility and the target group.

- Example text excerpt: “Approaches [...] include [...] paying specific attention to the PLS as part of the editorial process, and/or moving the responsibility of writing the PLS to dedicated writers.” [43, p. 2]

## Criteria of PLS

PLS differ in the specific value of the aforementioned characteristics. We extracted information on PLS criteria to answer the following question: What makes a high-quality PLS? What makes a PLS different from other types of research summaries? More precisely, what values (in terms of expressions or degrees) of the aforementioned characteristics are explicitly named or investigated in the literature on PLS? What values of these characteristics are found or supposed to constitute a high-quality PLS?

We found most information about criteria in guidelines or other guidance-related articles. There were also some empirical studies in which criteria were investigated. Less often, criteria were named in opinion pieces. To give an overview of the current empirical evidence and expert opinion regarding the recommended value of a PLS characteristic, we matched the criteria extracted from the articles to the respectively fitting characteristic category.

Most criteria referred to characteristics of the Linguistic Attributes category [3,6,12,14,19–24,26,34,41,44–67]. For example, in some articles, it was recommended to use active rather than passive voice [14,24,61,66,68], and some articles made more or less specific recommendations regarding the use of jargon: avoid jargon [53,58,63–66,68–71]; use only 2% jargon in the whole text [6]; use only short words or sentences, avoid polysyllabic words, acronyms or abbreviations [17,19,47,52,66,68,70,71]; avoid technical terms [57,64];

avoid potentially misunderstood words [19] or define terms if necessary [17,21,57,66,68,70]. Using technical terms and defining them may be reasonable if oversimplifying terms or concepts leads to inappropriate misleading or inaccurate content [71].

Further, there were many criteria that we matched to characteristics of the Formal Attributes category [14–16,19–23,26,28,39,40,44,48–50,52,53,55,59–61,63,66,71–77]. These included, for example, the exact word limit per PLS, reaching from 50 words [28] to 750 words [58], recommendations on text structuring or the use of headings [20,66,71], or whether visual images should be used [19,22,52,77].

Other often named criteria referred to characteristics of the General Content category [14,19–22,24,26–28,39,40,43,44,47,50–54,57,59–61,63,64,66–71,73,74,76–81]. For example, there were recommendations on the first sentence or paragraph of the PLS: for example, the first sentence should summarize the purpose of the (clinical) trial [81]; the first sentence should make clear to the reader who the summary has been written for and why it has been written [20]; the first sentence should include something that most readers can relate to [57]. Furthermore, recommendations were made as to which information should be included in the PLS: for example, provide answers to the essential questions: Who, What, Where, When, Why, How? [24]; outline three main elements: primary scientific question, what was learned, and why it matters [47] or what should be avoided (e.g., PLS authors should avoid promotional content [19]).

We further identified a range of criteria for characteristics that could be linked to the Presentation of Results category [3,16,19,21,22,26,43,46,48,49,52,55,57–62,68,71,75]. In some articles, it was stated that statistical significance should be clearly explained if required, whereas *p*-values, confidence intervals or standard deviations should be avoided [e.g., 21]; others made recommendations to report sensitivity, specificity, and prevalence in natural frequencies [75]; one article concluded from research with focus groups that numbers should

be completely omitted [48]. It was also stated that outcome probabilities should be presented in multiple ways and with consistent denominators [22]. A guideline by Cochrane included the rule that results of no more than seven outcomes should be reported in the PLS [e.g., 60].

Criteria that we were able to link to characteristics of the Presentation of Quality of Evidence category were only rarely mentioned in the investigated articles [22,60,61,71]. Brehaut et al. [22] specified that risk estimates in PLS needed to be reported with the corresponding level of evidence, and Maurer et al. [71] reported that researchers' conflict of interest statements were published alongside PLS. Further, Cochrane guidelines specified that the overall quality of the evidence should be reported as well as any factors that might affect the confidence in the results (e.g., bias risks such as conflicts of interest [60]).

Lastly, we found criteria that referred to the characteristics of the Contextual Information category [8,14,19,21–23,26,43,46,51–53,55,59,64,72,76,80–82]: For example, there were specifications regarding PLS authorship [8,39,53,72,81], and whether a submission of a PLS is or should be mandatory [17,68,83]. Another main contextual subject was the writing and publication process: There were specifications of where or how the PLS is or should be published (e.g., open access publishing [see 8,72]), some articles including detailed descriptions of how the writing and publishing process of the PLS should look like [65,66,71,77,84]. Occasionally, it was recommended to engage patients or members of the public in the PLS creation process [66,77,84,85]. We found guidelines for writing PLS from a variety of specialist societies such as the American Psychological Association, APA [26], Cochrane [60,61,86] and the Campbell Collaboration [58], from funders of research [66], as well as from scientific journals [49,63,64,68,70]. We also identified guidelines that specifically refer to the clinical trials results summary regulation in the EU [19,54,62] as well as general guidance in writing PLS for scientific writers [23,24,57]. The criteria mentioned in all 17 guidelines are provided in S2 Table.

## Outcomes of PLS

We also aimed to know what kind of outcomes (i.e., operationalizations of PLS aims) are applied in the PLS literature and matched the information we found on defined outcomes of PLS research to one of the aim categories. We analyzed the studies to answer the question: How were PLS investigated (i.e., which outcomes were included) and, consequently, how did the empirical outcomes investigated in these studies correspond with the aforementioned theoretical aims of PLS? In the following, outcomes that are investigated in the PLS literature and their link to theoretical aim categories are summarized.

Many outcomes could be linked to aims of the Accessibility category. In their empirical studies, researchers investigated the readability of the text [6,12,14,20,21,27,41,45,48,87–89], participants' enjoyment or preference of such a text in general [9,10,42,90], participants' satisfaction with text length [12,21,76] or participants' judgement regarding the usability of the PLS [3,11,22,27,52,91]. In order to measure these outcomes, researchers, for example, computed readability indices, such as the Flesch reading ease score [14,41,45,88,89], or participants were asked whether they perceived the information they cared about to be easy to find [52].

We further identified a wide range of outcomes that were linked to aims of the Understanding and Knowledge category. Aims of the Understanding category were investigated by asking participants whether they would perceive the text as understandable and by asking them about their user experience [20–22,27,39,42,48,52,65,76,90]. A typical outcome was to ask how easy or difficult readers found it to read the PLS [e.g., 12], which had to be answered on a Likert scale. We further observed outcomes that cover the objective knowledge gain (Knowledge category) [9–11,13,20,39,42,52,65,87,90,92]. To assess aims of the Knowledge category, researchers typically used multiple choice tests (e.g., “This research

focuses on a) HIV, b) FIV, c) Influenza, d) I don't know" [42, p. 6]) or open-ended questions that referred to the content of the PLS ("What is external cephalic version in breech position - how would you describe that term to a friend?" [90]). Yet other outcomes included whether participants were able to name the purpose of the summary [11], how they judged the effectiveness of a treatment that was described in the PLS [9] or their judgement on the quality of evidence [11].

Even more specific were outcomes that we linked to aims of the Empowerment category [9,11,12,20,22,27,39,52,76]. Readers were, for example, asked whether they would use PLS to make certain decisions (mostly investigated in the context of health care, [e.g., 52]) or they were asked how supported and prepared they felt to make certain decisions [e.g., 22,39] or to evaluate or discuss the subject with others [12,39] after reading the PLS.

In the empirical studies that we found, aims of the Communication of Research category were only examined indirectly [3,11,12,20,27,39,42,48,52,76,92]. Readers were, for example, asked who they think the summary has been written for [20], how important or relevant they perceived the related study or research to be [48] or whether they shared or reused the PLS [76].

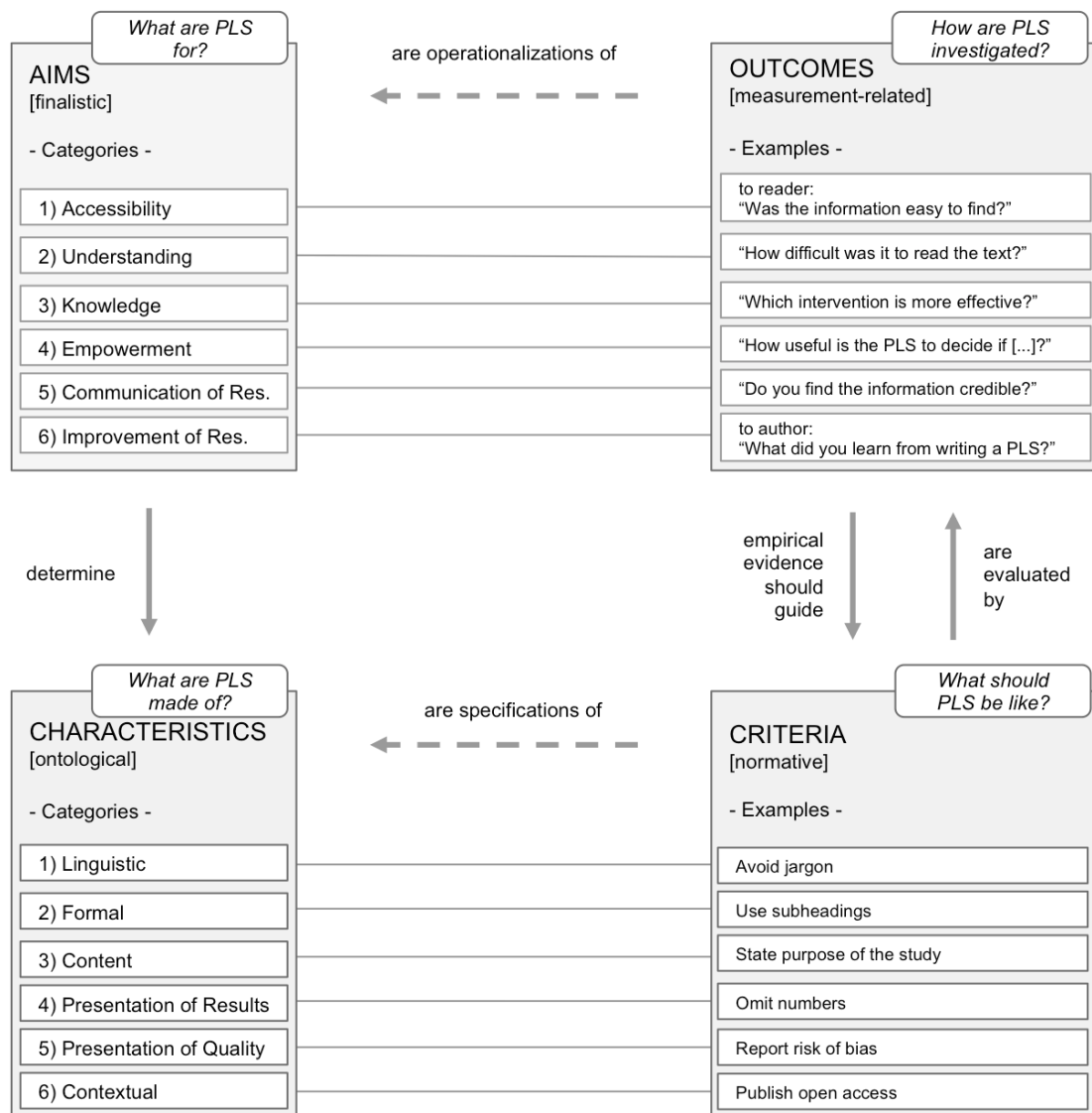
Even less empirical research on PLS included outcomes that related to the Improvement of Research category [45,48,52,65]. One study surveyed PLS volunteer contributors and asked them whether writing PLS improved their skills in writing, editing and time management, and whether it increased their confidence in lay audience communication, enhanced their understanding of the specific scientific literature, or helped in their development as a scientist [65]. This category was also represented in asking PLS readers about the perceived usefulness of science for the public after having read the PLS [48]. One study examined the association between the inclusion of a PLS with trial quality [45].



## Conceptual framework

The derived categories for aims and characteristics as well as their relations with outcomes and criteria are illustrated in Fig 3. This conceptual framework of our synthesis of the PLS literature depicts the four main subject areas of theory and research on PLS. It indicates the main categories of a PLS's ascribed aims and characteristics together with examples of the respective outcomes and criteria, which are operationalizations and specifications of the aforementioned. The finalistic approach, namely, to ask what a PLS is for, determines what it is made of (ontological approach) and thereby, its characteristics. These characteristics are specified by certain criteria which determine what a PLS should be like (normative approach). The eligibility of such criteria is evaluated by analyzing their impact on certain outcomes in empirical studies, which, in turn, guide the development of adequate criteria. Outcomes constitute the operationalizations of aims in empirical studies (measurement-related approach), and thereby, the effect of a PLS on certain outcomes guides the decision as to its suitability with regard to certain prespecified aims.

**Fig 3. Conceptual Framework of Aims, Characteristics, Criteria and Outcomes investigated in PLS Research.**



## Empirical evidence on PLS

In this section, results of the 33 empirical articles on PLS are narratively summarized separated by study type. First, evaluative articles and articles in which one type of PLS was compared to other summary formats are briefly summed up. Second, empirical articles that compare different forms of PLS are described in more detail, matching investigated criteria with characteristic categories and investigated outcomes with aim categories.

## **Empirical articles that evaluated one type of PLS**

We identified 15 empirical articles on PLS that evaluated one type of PLS, for example by investigating how readers reacted to a certain PLS, or how easy they can be found. Researchers evaluated Cochrane PLS that address common health issues [10,43], summaries of studies from the Newcastle Cognitive Function after Stroke cohort [48], consumer summaries of Cochrane Musculoskeletal Reviews [22], lay summaries on how package sizes affect the consumption of food, alcohol, and tobacco [27], lay summaries on open access journal articles [3], lay summaries of pragmatic pediatric clinical trials [18], lay summaries on HDBuzz, a knowledge translation website with a focus on research on Huntington's disease [65], PLS of clinical trials in general [20,93,94], PLS of clinical trials in Japan [95] and PLS posted as 'eLife digests' [57]. There was also one study that investigated how the commitment of volunteer PLS authors can be raised [96] and one study that developed and tested a PLS template in detail [71].

## **Empirical articles that compared one type of PLS to other summary formats**

Ten other empirical articles aimed to investigate the format of a PLS in general by comparing participants' responses after having read a PLS to (the same or other) participants' responses after having read another type of scientific text summary. PLS were compared to scientific abstracts [6,41,88,90,92], infographics [90] or graphical abstracts [42], blog posts [52,97], blogshots [10], podcasts [92], transcribed podcasts [92], Wikipedia articles [52], video abstracts [42], press releases [41], newspaper health articles [89] and systematic reviews with and without summary of findings tables [87]. There were statistically significant indications for the superiority of blogshots over PLS and Wikipedia articles in terms of ease of use, user preference and aesthetical judgement [52]; of videos and PLS over graphical abstracts and scientific abstracts in terms of comprehension, a feeling of understanding and a

feeling of enjoyment [42]; of PLS over systematic reviews with and without summary of findings tables in terms of clarity and accessibility of information [87]; of infographics over PLS in terms of reading experience and user-friendliness, but not of knowledge [90]; and of newspaper articles over PLS in terms of readability [89]. Furthermore, scientific abstracts were found to be less readable [88] and to contain more jargon [6] than PLS, but the amount of jargon in PLS was higher than recommendations for public understanding stipulate [6].

### **Empirical Articles that compared different forms of PLS**

We identified eight empirical articles that investigated specific criteria of PLS by analyzing which criteria have an effect on defined outcomes. There were two qualitative studies that compared different PLS versions and asked readers about their experiences, and six quantitative studies that investigated how different PLS versions affected readers' response patterns (e.g., in knowledge tests). We linked the criteria investigated in these studies to their respective characteristic category and the outcomes investigated in these studies to the respective aim category (Fig 3).

**Qualitative studies.** Ellen et al. [98] investigated feedback of 18 Canadian health system managers and policy makers about PLS of systematic reviews. In their study, they presented three different PLS to each participant and conducted semi-structured interviews. They found that participants preferred structured text (bullet points, tables) with up-front key messages, including details on background, methods and applicability. Also, participants preferred evidence quality ratings (according to the GRADE method) in the summaries. They rather disliked text blocks, unstructured texts and summaries with less background information. Ellen et al. [98] also note that participants preferred a longer, structured PLS format over a shorter, unstructured format, suggesting that readers did not mind longer documents as long as they were well structured and could be easily scanned. The

characteristic categories that were addressed in this study hence were Formal Attributes, General Content, and Presentation of Quality of Evidence.

Glenton et al. [78] developed three different versions of a PLS and conducted semi-structured interviews with 34 members of the public in Norway, Argentina, Canada and Australia. Thereafter, a modified version of a PLS was developed and retested to produce a final version. The preliminary three different versions of the PLS differed in their presentation of results: one version using qualitative statements only, a second version using both qualitative statements and numbers, and a third version using qualitative statements and additionally numbers and symbols in a table. The authors found that most participants preferred the third version. The results of this study showed that participants had problems interpreting effect sizes, confidence intervals and continuous outcomes. The concepts of effect size, intervention effect and evidence quality appeared challenging to understand, along with the difference between a systematic review and an individual study. Partially, the research group was able to improve understanding by adding symbols with explanations for evidence quality and by rephrasing the introduction text about the concept of a systematic review. The characteristic categories that were analyzed in this study were thus Formal Attributes, General Content, Presentation of Results and Presentation of Quality of Evidence.

**Quantitative studies.** In the following studies, criteria of PLS were systematically varied and quantitatively compared with regard to different defined outcomes. The experimental conditions, outcomes and results with the respective characteristics and aim categories are summarized in Table 1 (see S3 Table for a more detailed version).

**Table 1. Quantitative Studies Comparing PLS vs. PLS: Criteria, Outcomes and Results.**

<b>Study (Sample Size)</b>	<b>Criteria</b>	<b>Outcome</b>	<b>Results</b>
Santesso et al. (2015) ( <i>n</i> = 143)	new format vs. current format	knowledge test; comprehension test; usability survey; preference	new > current for all outcomes except comprehension test
Silvagnoli et al. (2020) ( <i>n</i> = 167)	readability level: low vs. medium vs. high	preference	medium > low; medium > high
Alderdice et al. (2016) ( <i>n</i> = 813)	conclusion vs. no conclusion; certain vs. uncertain findings	knowledge test	uncertain findings: conclusion > no conclusion certain findings: no sign. effect
Buljan et al. (2020, BMC Med Res Method.), Trial 1 ( <i>n</i> = 91)	positive framing vs. negative framing	knowledge test, usage of the described treatment; comprehension test	no differences
Buljan et al. (2020, BMC Med Res Method.), Trial 2 ( <i>n</i> = 245)	natural frequencies vs. percentages	comprehension test; preference; knowledge test	no differences
Kirkpatrick et al. (2017) ( <i>n</i> = 60)	original PLS vs. PLS rewritten by author vs. PLS rewritten by writer	understanding survey; reading ease	both rewritten versions > original in reading ease; no further sign. effects
Kerwer et al. (2021) ( <i>n</i> = 166)	PLS with subheadings vs. PLS without subheadings	comprehensibility; knowledge acquisition; credibility; ability to evaluate the study; ability to make a decision	with subheadings > without subheadings for all outcomes

*Note.* Only experimental conditions that investigate PLS criteria against each other are listed; further comparisons (e.g., with other summary formats) are not listed.

Santesso et al. [11] compared a new format of a PLS for Cochrane Reviews to the format that was current at the time of their study. The new format was more structured and results were presented not only qualitatively, but also quantitatively. The criteria that were

tested in their experiment were the differences between the new format and the current format. They cover characteristics of the Formal Attributes, Presentation of Results and Presentation of Quality of Evidence categories. The investigated outcomes cover aims of the Accessibility, Understanding and Knowledge categories: Participants who read the new format performed better in the knowledge-related outcomes and, overall, judged the new format more accessible, while comprehension of the purpose of the summary was low, with no statistical difference between the two formats [11].

Silvagnoli et al. [12] investigated how the complexity of PLS affected the readers' preference for the text format, thereby testing an aim of the Accessibility category. The criteria that were tested in this experiment were three different complexity levels of PLS in terms of readability scores (a Linguistic Attribute characteristic). The results showed that medium-level PLS with a readability that corresponds to a reading age of 14-17 years were preferred most, compared to low-level and high-level complexity PLS [12].

Alderdice et al. [13] investigated PLS of Cochrane Reviews with uncertain findings and certain findings and compared a PLS format with a conclusion to a PLS format without a conclusion (General Content category). The outcome was a multiple choice test that can be linked to aims of the Knowledge category. Only in PLS with uncertain findings, there was a statistically significant difference: Participants who read the uncertain PLS without conclusion performed worse than participants who read the uncertain PLS with conclusion [13].

Buljan et al. [9] conducted two trials that investigated the framing of numerical findings of Cochrane Review PLS. In trial 1, they varied whether results in the PLS were positively framed or negatively framed and in trial 2, they varied whether trial effectiveness and side effects were presented as natural frequencies or percentage scores. Thus, both trials investigated criteria that can be linked to characteristics of the Presentation of Results

category. Outcomes in this study were operationalizations of aims of the Knowledge and Empowerment categories. There were no differences on those outcomes between the experimental groups in either trial [9].

Kirkpatrick et al. [14] compared two strategies to improve the quality of PLS in the National Institute for Health Research (NIHR) Journals Library. They compared original PLS to PLS that were rewritten either by the author of the original scientific publication or by an independent professional writer, both with the help of a guideline. These experimental conditions represent characteristics of the Contextual Information category. The outcomes in this study were perceived ease of understanding (Understanding category) and reading ease (Accessibility category). The results showed that there was no statistically significant difference in terms of ease of understanding, and that both rewritten versions were significantly easier to read than the original [14].

Kerwer et al. [39] compared PLS with subheadings to PLS without subheadings, varying a characteristic from the Formal Attributes category. The investigated outcomes in this study cover aims of the categories Understanding, Knowledge, Empowerment, and Communication of Research. The results of this study show that participants rated PLS with subheadings as more comprehensible and more credible than PLS without subheadings. Subheadings compared to no subheadings were also related to higher knowledge acquisition and a higher perceived ability to evaluate the corresponding study and to make a decision based on the PLS [39].

Summing up the empirical evidence on comparison of different PLS, we note that an effect of specific criteria on outcomes was found in the following cases: PLS are more accessible if they are written on a medium text level [12], and if they are rewritten with the help of a guideline by either the same or an independent writer [14]. PLS impart more knowledge if they are presented with a conclusion than without a conclusion—but only if the



study has uncertain findings [13]. PLS in general impart more knowledge if they are presented in a more structured format [11,39], and participants state that they like PLS better that are structured, use quality ratings and give enough background information [98] as well as PLS that provide results with qualitative statements that are accompanied by numbers and symbols in tables [78]. PLS with subheadings facilitated the communication of research as they were perceived to be more credible than PLS without subheadings. Also, readers' empowerment—their perceived ability to make decisions based on the PLS and to evaluate the veracity of the corresponding study—was higher in PLS with subheadings compared to PLS without subheadings [39].

No statistically significant effects of criteria were found in the following cases: There were no statistically significant differences found in the perceived accessibility between PLS that were rewritten by the scientific author versus rewritten by an independent writer [14] or in the ease of understanding between the original PLS and the rewritten version [14]. There were furthermore no statistically significant effects on understanding and knowledge outcomes between PLS in a general new format versus a current format [11]; on knowledge outcomes between PLS that had a conclusion and those that had no conclusion in cases where findings of the study were certain [13]; between positive versus negative framing of results as well as between reporting results as percentages versus natural frequencies [9].

Interestingly, most of the studies we found investigated their research questions with samples that were not representative for the general public. Furthermore, sample sizes, overall, were comparably small: Four of the quantitative studies investigated samples between  $n = 60$  and  $245$  [9,11,12,14,39]. One exception is Alderdice et al.'s [13] study with a sample of  $n = 813$  [13]. In quantitative and qualitative studies, participants in these samples were often highly educated [12], students [9,13,39], or very selective, such as public reviewers for a studies center [14] or health care managers and policy makers [98]. Only two

studies used samples with members of the (general) public and patients that came from five different nations [11,78].

## **Empirical foundation of guideline criteria**

Comparing the empirical evidence on the effectiveness of PLS criteria with criteria that are mentioned in guidelines (S2 Table, S3 Table), it becomes clear that the empirically investigated criteria only cover a fraction of the entirety of criteria that are mentioned in guidelines. In the Cochrane guidelines on how to write a PLS of a Cochrane intervention review [86], it is argued that these guidelines are built on empirical studies, two of which are also included in this review [11,78]. Due to these studies' holistic approach—testing the whole format rather than single criteria—these studies provide a solid empirical basis for the Cochrane guidelines. However, this approach makes it difficult to deduce the effectiveness of single criteria and to generalize the results to other guidelines. The guideline of the Campbell Collaboration refers to Cochrane and its empirical rationale [58], while the Summary of Clinical Trial Results for Laypersons-guideline is based on general health literacy principles [19]. Other guidelines that we found refer to this document of the EU expert group and provide no further rationale [54,62]. Duke's [24] guideline is presented as a synthesis of various other guidelines and advice for writing PLS. However, in all other guidelines for writing a PLS that we examined, we did not find any (empirical) rationale for the choice of criteria. We conclude that guidelines only rarely provide any empirical rationale for their choice of criteria.

## **Discussion**

The aim of this review was twofold: First, we intended to develop a conceptual framework of the PLS subject in the scientific literature, and second, we aimed to synthesize empirical evidence on PLS by integrating it into the conceptual framework.

To develop a comprehensive conceptual framework, we took into account different approaches that complement each other. Applying a finalistic approach, we scrutinized the aims of PLS reported in the literature. We found that aims can be classified into the categories Accessibility, Understanding, Knowledge, Empowerment, Communication of Research and Improvement of Research. This classification of aims resembles Nutbeam's [99] prominent classification of health literacy levels. This is particularly noteworthy as the majority of articles about PLS that were included in our review stem from medical or public health journals. It is therefore sensible to keep in mind that the PLS literature has a strong focus on PLS of medical research, with the aim to increase health literacy. According to Nutbeam, health literacy can be classified into three progressive ability levels: The first level, 'functional health literacy' refers to the ability to understand health information and to have sufficient knowledge about health risks and the health system. This first necessary level is reflected in our PLS aim categories Accessibility, Understanding and Knowledge. The second level from Nutbeam's model is called 'interactive' or 'communicative' health literacy. In addition to the abilities required in the first level, the second level refers to the ability to actively communicate about a health topic and derive meaning from health information as well as have the necessary social skills to discuss it with others. This second level is reflected in our PLS aim category Communication of Research. Nutbeam's third level, 'critical health literacy' refers to the ability to critically appraise health information and consequently, have more control over health decisions. This third level is reflected in the PLS aim category 'Empowerment'. There are further similarities between our PLS aim categories and theoretical models that describe product user experience. For example, Morville's honeycomb of user experience includes product findability, accessibility, usability, usefulness, credibility, desirability, and value [100]. This and other models for user design [e.g., 101] have already been applied to the particular use in evidence summaries by

Rosenbaum [91], who emphasizes the importance of ‘understandability’ in this context. By taking these theoretical considerations together, we conclude that if a PLS’s purpose is to reach a wider audience for scientific findings, it may not only be important to consider whether it is accessible for this audience at all, but also to take into account the question of *why* we might want to reach a wider audience for scientific findings. Is it because scientists simply want readers to understand what they are doing? Or do they even want to enable them to make certain decisions? Carefully considering such questions and reflecting on the aims PLS are supposed to achieve, ideally, could lead to even more target-oriented research on PLS, which finally improves the development of practical guidelines.

Taking the ontological approach, we strived to evaluate what PLS are constituted of. We found that characteristics that are discussed and evaluated in the current literature can be classified into the categories Linguistics Attributes, Formal Attributes, General Content, Presentation of Results, Presentation of Quality of Evidence and Contextual Attributes. Building upon these categories, we, subsequently, pursued a normative approach to evaluate what a PLS should look like, by reviewing PLS criteria that specify ‘values’ for certain characteristics that belong to those categories. PLS criteria were mostly related to the characteristics of the Linguistic Attributes, General Content and Formal Structure categories. Some criteria were used to *define* a PLS: in this case, they were meant to distinguish a PLS from a text that is not defined as a PLS (e.g., a PLS is a summary of a study that does not use jargon, while a scientific abstract is a summary of a study that does use jargon [23]). Other criteria were used as indicators for the *quality* of a PLS: these criteria were supposed to distinguish a good or serviceable PLS from a rather unhelpful PLS (e.g., not “dumbing down the research” [50, p. 5]). While criteria that we linked to characteristics of the Linguistic Attributes category were similar across articles (e.g., avoid jargon and use short sentences [14,23,57,61]), we observed a considerable diversity in those criteria that we linked to

characteristics of the Presentation of Results category (e.g., report statistics if meaningful for the target group and/or report statistics in natural frequencies [22,52,75], vs. omit any numbers from the PLS [48,49]). Other criteria were highly specific based on the evidence they reported on. For example, the Cochrane guideline for PLS states that quality of evidence should be reported based on the GRADE-approach [60]. This is because the scientific publications that Cochrane PLS refer to—systematic reviews and meta-analyses—are all required to report the quality of evidence based on GRADE. Thus, this criterion makes sense for PLS of original publications that make use of GRADE, but it is of less significance for other PLS.

Lastly, taking a measurement-related approach, we asked which outcomes are investigated to evaluate PLS. Outcomes in empirical studies on PLS mostly related to aims of the Accessibility, Understanding and Knowledge categories. Considering all investigated outcomes, we found that the effects of PLS were mostly investigated in terms of user experience (i.e., how accessible or understandable PLS are perceived to be), and with regard to knowledge gains. Thus, we conclude that the aims of the Accessibility, Understanding and Knowledge categories are well represented in empirical investigations of PLS. However, whether a PLS is accessible and whether readers understand and gain knowledge from it is closely intertwined, and a differentiated operationalization of these outcomes appears challenging. Furthermore, although aims of the Communication of Research as well as Improvement of Research categories were often named in theoretical articles, the effectiveness of PLS regarding these aims was scarcely investigated in empirical studies.

It is hardly surprising that regarding the characteristics, criteria and outcomes, there are much fewer theoretical linking points to be identified than to the aims. These three last components of our framework can be considered as tangible consequences of the (theoretical) aims that are somehow put into practice: The stipulated aims of a PLS determine its

characteristics (what is it?), the standards that are applied (how should it be?), and what will be measured (what can it actually achieve?). In the end, all revert to the primordial aims that ultimately lead to composing a PLS: Characteristics form the mere basis for deriving specific values, the criteria, to reach desired outcomes which are mere operationalization of these aims. Therefore, we conclude that the theoretical basis of PLS to a very large extent can be attributed to considerations of its various aims and purposes.

Against the background of the conceptual framework, we investigated the empirical evidence on PLS. We found eight studies that investigated PLS criteria by either comparing two different PLS formats or by varying specific criteria within the same PLS format. In these studies, effects were observed on outcomes that can be linked to aims of the Accessibility, Knowledge, Understanding, Communication of Research, and Empowerment categories. Here, medium text level and guideline-based PLS were perceived as more accessible [12] and participants preferred such PLS that were structured, that provided background information and qualitative statements on results which were accompanied by numbers and symbols as well as an evidence quality rating [78,98]. Furthermore, PLS with subheadings increased trust in research findings and improved participants' self-reported ability to make decisions [39]. On other outcomes measuring Accessibility, Understanding or Knowledge, however, no statistically significant differences were observed. Changes in the formal structure of PLS only had a significant impact on knowledge if findings were uncertain, but not if findings were certain [13].

In the empirical studies that were included in our review, we did not find outcomes that could be linked to our theoretically proposed aim category Improvement of Research. This means that, although this aim was named in various theoretical articles dealing with the subject of PLS, it does not appear to have been empirically evaluated so far. The criteria we found in the theoretical and empirical articles, though, did resemble all proposed

characteristic categories. However, they were highly heterogeneous and only rarely empirically investigated.

We further observed that some criteria were listed in guidelines very frequently, whereas to our knowledge, they had not been empirically evaluated. For example, most guidelines state that PLS should be written without jargon [19,53,57,58,61–66,68–71]. However, we found no studies that have experimentally varied the use of jargon specifically in PLS to investigate whether its use affects how laypersons perceive PLS. It may be worth considering that a PLS which uses jargon while simultaneously providing explanations for such technical terms by adding a glossary might be easier to read and understand than a PLS in which jargon is replaced by lengthy periphrases.

Furthermore, there are conflicting criteria, for example, some guidelines recommend to omit numbers completely [e.g., 26] while others stress the importance of communicating specific numbers [e.g., 60,61,86], such as risk ratios. These conflicting criteria might result from disciplinary differences or different aims and priorities concerning the PLS (e.g., accuracy vs. plainness). Another important finding is that empirical research on PLS was mostly conducted using small samples of highly educated participants. Of course, when PLS are investigated, the required sample characteristics depend on the target audience. Since PLS are meant to communicate science in a way that laypersons can understand, it appears advisable to investigate an approximately representative sample of the population the PLS is directed at. In contrast, investigating characteristics or the efficacy of PLS in highly educated samples might be fully justified and even desirable if the specific target group of a PLS are researchers from other domains, practitioners, stakeholders or other groups, whose members can be reasonably expected to be highly educated. If this is, however, not the case (e.g., if one wants to reach to the public in general), investigating PLS in highly educated samples imposes a significant threat on the external validity of the corresponding study. Researchers

and providing agencies, therefore, should clearly define and communicate their specific audience and take this adequately into account when evaluating these PLS.

## **Strengths and limitations of the review**

This review has some limitations as well as considerable strengths. The fundamental value of this review, at first, lies in its significant theoretical contribution: the proposed conceptual framework which is based on the exhaustive body of scientific literature on PLS, and which includes four basic approaches to comprehensively describe the research field. This framework can be used to design future studies on the effects of PLS on defined outcomes as well as help develop meaningful PLS guidelines. Second, this is, to our knowledge, the first attempt to map, summarize and discuss the entire current empirical evidence on PLS research. Although a comprehensive statement on the empirical evidence of specific PLS criteria is not (yet) possible, we were able to identify important questions and challenges that may contribute to future research on PLS and, thus, to the improvement of science communication as a whole. Finally, our twofold approach, developing a conceptual framework and reviewing the empirical evidence on PLS, made it possible to integrate the latter into the first, putting single empirical findings on certain criteria into a broader explanatory context.

However, there are two main limitations for this study's evidence contribution. First, there is not yet broad consensus about the term 'Plain Language Summary'. Thus, we cannot fully rule out that there might be literature on lay summary formats that we missed in our search due to the fact that we did not know the respective term that was used, even though we made best attempts to be as thorough as possible in our systematic review. Second, there was high heterogeneity among the outcome measures in the empirical articles we found. Thus, we



were not able to perform a meta-analysis or to combine the empirical results of the studies statistically.

## **Conclusions and future research recommendations**

Considerable work has been done to establish lay-friendly summary formats that not only communicate scientific findings to laypeople but also simultaneously aim to retain as much scientific rigor and accuracy as possible. Our conceptual framework delineates four main approaches related to aims, characteristics, criteria and outcomes of PLS to describe the theoretical and empirical research on PLS, and reveals how they are intertwined in a meaningful way. It thereby constitutes a fertile ground for theory advancement on science communication tools, for hypothesis formulation and testing in empirical studies on PLS, and for writing guideline development. Our findings suggest that in the theoretical as well as the empirical literature, aims of PLS are clearly named and considerably correspond across articles. What's more, there already exists a significant number of valuable and useful guidelines on writing PLS. Also, empirical evaluations of different types and formats of PLS with varying criteria on different outcomes have been conducted in several studies. However, their number is relatively low compared to the amount of theoretical literature which meticulously outlines the aims and specific characteristics of PLS. Consequently, we also observed a lack of empirically evaluated criteria in guidelines. A further major implication of our findings is the need for samples in empirical research on PLS which are approximately representative for the respective target group. Future studies on PLS should therefore consider their target audience and recruit their samples accordingly. More (ideally, randomized controlled) studies that investigate the effects of single criteria on specific outcomes are also needed. Afterwards, fully empirically supported recommendations on how to write PLS can be formulated. Such recommendations may complement current guidelines

which at least partly still lack empirical foundation, as well as form the basis for the development of new guidelines which may be directed at a specific target group or deal with PLS from a certain discipline. Altogether, we believe our review to constitute a suitable starting point both for advancing theory on PLS and for designing and conducting empirical studies on the subject. It is our sincere hope that, in the end, these efforts serve such aims that are meaningful for individuals as well as for society as a whole.

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## **Supporting Information**

**S1 Table. Studies included in this Review.**

**S2 Table. PLS Guidelines and Criteria.**

**S3 Table. Quantitative Studies Comparing PLS vs. PLS: Criteria, Outcomes and Results.**

**S1 File. Search Terms.**

**S3 File. Plain Language Summary about this Review.**

**S 1 Table. Studies included in this Review.**

<b>Authors</b>	<b>Year</b>	<b>Study Type</b>
Alderdice et al.	2016	Empirical
Anstey	2014	Theoretical
Anzinger et al.	2020	Empirical
American Psychological Association	2018	Guideline
Barbara et al.	2016	Empirical
Barnes & Patrick	2019	Theoretical
Barnfield et al.	2017	Empirical
Bredbenner & Simon	2019	Empirical
Brehaut et al.	2011	Empirical
Brown et al.	2012	Theoretical
Buljan et al.	2018	Empirical
Buljan et al. (BMC)	2020	Empirical
Buljan et al. (Trials)	2020	Empirical
Busert et al.	2018	Empirical
Carvalho et al.	2019	Theoretical
Cerejo et al.	2021	Empirical
Cochrane	2020	Theoretical
Cochrane Methods	2013	Guideline
Cochrane Norway	2019	Guideline
Cochrane Norway	2017	Guideline
Coomarasamy et al.	2001	Theoretical

Corneli et al.	2020	Empirical
Dear et al.	2011	Theoretical
Dormer & Walker	2020	Theoretical
Dubé & Lapane	2014	Guideline
Duke	2015	Theoretical
Duke	2012	Guideline
Ellen et al.	2014	Empirical
Expert group on clinical trials for the implementation of Regulation (EU) No 536/2014	2017	Guideline
Ferrar & Conran	2021	Empirical
FitzGibbon et al.	2020	Theoretical
Glenton	2017	Empirical
Glenton et al.	2010	Empirical
Green-Brown & Wigington	2012	Theoretical
Gudi et al.	2021	Theoretical
Halprin	2021	Guideline
Hauck	2019	Theoretical
Jakus et al.	2021	Empirical
Jelicic Kadic et al.	2016	Theoretical
Karačić et al.	2019	Empirical
Kaslow	2015	Theoretical
Kerwer et al.	2021	Empirical
King et al.	2017	Theoretical
Kirkpatrick et al.	2017	Empirical
Koufogiannakis et al.	2016	Theoretical

Kuehn	2017	Theoretical
Kuehne & Olden	2015	Theoretical
Langendam et al.	2013	Theoretical
Linte	2009	Theoretical
Lionbridge	2019	Guideline
Lobban et al.	2021	Guidance-related
Lugaz	2021	Theoretical
Maguire & Clarke	2014	Empirical
Manighetti et al.	2021	Theoretical
Maurer et al.	2021	Empirical
Mellalieu	2018	Theoretical
NIHR	2021	Guideline
Nunn & Pinfield	2014	Empirical
Opiyo et al.	2013	Empirical
Penlington et al.	2020	Empirical
Phung et al.	2020	Theoretical
Pushparajah et al.	2018	Empirical
Rader et al.	2014	Theoretical
Rakedzon et al.	2017	Empirical
Raynor et al.	2018	Empirical
Rees et al.	2017	Guidance-related
Richter	2008	Theoretical
Rodgers	2017	Theoretical
Rosenbaum	2010	Theoretical

Santesso et al.	2008	Theoretical
Santesso et al.	2015	Empirical
Seidel et al.	2017	Theoretical
Shailes	2017	Theoretical
Silvagnoli et al.	2020	Empirical
Simmons	2012	Theoretical
Stricker et al.	2020	Empirical
Suart et al.	2020	Empirical
Taylor et al.	2018	Theoretical
The Steering Group of the Campbell Collaboration	2016	Guideline
TransCelerate Biopharma Inc.	2015	Guideline
Wada et al.	2020	Theoretical
Walker & Dormer	2021	Guidance-related
Whiting et al.	2018	Guidance-related
Zhang et al.	2020	Theoretical
eLife: PLS: Results of reader survey	2017	Empirical
eLife: PLS: How to write an eLife digest	2017	Guideline
“AGU” Tips for Plain Language Summaries	2020	Guideline
“Autism” Manuscript Submission Guidelines	2020	Guideline
“People and Nature” PLS Guidelines	2020	Guideline
“Taylor & Francis” PLS Guidelines	2021	Guideline

**S2 Table. PLS Guidelines and Criteria.**

Guideline	Linguistic Attributes	Formal Attributes	General Content	Presentation of Results	Presentation of Quality of Evidence	Contextual Information
<b>American Psychological Association</b> (“translational abstract”), psychological science	<u>Tone:</u> <ul style="list-style-type: none"> <li>more personal and friendly than scientific abstract</li> <li>do not overstate / oversimplify findings or conclusions</li> </ul> <u>Words:</u> - <u>Sentences:</u> -	<u>Text Length:</u> <ul style="list-style-type: none"> <li>150 - 200 words</li> </ul> <u>Text Structure:</u> - <u>Use of Tables/Visuals:</u> -	<u>Title:</u> - <u>Content structure:</u> <ul style="list-style-type: none"> <li>follow a pattern of introduction, method, results, discussion</li> </ul> <u>Headlines:</u> - <u>Content:</u> <ul style="list-style-type: none"> <li>consider your audience</li> <li>clearly describe investigated problem</li> <li>describe participants only insofar as relevant to the audience; details of the sample only if it is remarkable in some way</li> <li>detailed information about study methods may be summarized or omitted</li> <li>emphasize conclusions that are relevant for the audience</li> <li>try to create a “take home message”</li> </ul>	state the findings in clear, nontechnical language remove any statistics if article contains more multiple studies, summarize contents of all studies	-	<u>Purpose of text:</u> <ul style="list-style-type: none"> <li>clear communication of article content</li> <li>emphasis on article’s value to educated public/professional audiences</li> </ul> <u>Author of PLS:</u> - <u>Review of PLS:</u> - <u>Access:</u> - <u>Context:</u> <ul style="list-style-type: none"> <li>recommendation for PLS as standard feature of each APA journal article</li> </ul>
<b>Cochrane 2013, standards for the reporting of PLS</b> (“Plain Language Summaries”), Cochrane Intervention Reviews	<u>Tone:</u> - <u>Words:</u> <ul style="list-style-type: none"> <li>avoid technical terms and jargon (explain them if unavoidable)</li> <li>avoid long words / words with many syllables / understandable words</li> <li>consider introducing an acronym or short term for repeated use</li> <li>avoid regional terms</li> </ul>	<u>Text Length:</u> <ul style="list-style-type: none"> <li>250 - 300 words</li> </ul> <u>Text Structure:</u> <ul style="list-style-type: none"> <li>use short paragraphs</li> </ul> <u>Use of Tables/Visuals:</u> -	<u>Title:</u> <ul style="list-style-type: none"> <li>restate review title in plain language if possible, otherwise explain terms</li> <li>avoid recommendations</li> </ul> <u>Content structure:</u> <ul style="list-style-type: none"> <li>review question</li> <li>background</li> <li>study characteristics</li> <li>key results</li> <li>quality of evidence</li> </ul> <u>Headlines:</u>	<ul style="list-style-type: none"> <li>present results for all main outcomes</li> <li>use consistent wording across outcomes</li> <li>report findings on harms that are described in the review and state whether they have been fully reported in the included studies</li> <li>it is not essential to provide numerical data</li> <li>do not present</li> </ul>	<ul style="list-style-type: none"> <li>describe overall quality of evidence for each of the main outcomes based on GRADE considerations</li> <li>describe any factor that could affect the confidence in the results</li> <li>provide key reasons for quality of evidence / limitations in lay terms</li> <li>describe if quality of evidence is high</li> </ul>	<u>Purpose of text:</u> <ul style="list-style-type: none"> <li>summary of the review that contains the crucial information in plain language and that will be understood by the general public</li> </ul> <u>Author of PLS:</u> - <u>Review of PLS:</u> - <u>Access:</u> - <u>Context:</u> <ul style="list-style-type: none"> <li>tailor messages across different summary versions of the review</li> </ul>

	<p>(AE / BE)</p> <ul style="list-style-type: none"> <li>▪ use active voice</li> </ul> <p><u>Sentences:</u></p> <ul style="list-style-type: none"> <li>▪ one keypoint / sentence</li> <li>▪ avoid more than two hard words in a sentence unless you can explain them</li> </ul>		<ul style="list-style-type: none"> <li>▪ standard headings</li> <li>▪ consistent order</li> <li>▪ in bold type</li> </ul> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>▪ convey the question addressed in the review</li> <li>▪ shortly describe population, intervention and outcomes in Background section</li> <li>▪ give enough detail on study characteristics (incl. search date and population details)</li> </ul>	<p>numerical data if estimations of effects are imprecise or uncertain</p> <ul style="list-style-type: none"> <li>▪ if numerical data is provided, use natural frequencies for dichotomous outcomes and accompany relative effects with absolute effect estimates</li> <li>▪ explain any statistical term</li> <li>▪ statics, if used, should provide valid, digestible summary of direction, size and precision of the effect estimates</li> </ul>	<ul style="list-style-type: none"> <li>▪ if impact of funding sources on quality of the evidence is considered in the review, include a statement in the PLS</li> </ul>	<ul style="list-style-type: none"> <li>▪ consistent reporting of key messages between PLS, main text, SoF table and authors' conclusions.</li> </ul>
<p><b>Cochrane 2016, Checklist for PLS Review</b>          ("Plain Language Summaries"),          Cochrane Intervention Reviews</p>	<p><u>Tone:</u> -</p> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>▪ avoid or explain acronyms, jargon and technical terms</li> <li>▪ PLS authors can choose to refer to "we" or to "review authors", but be consistent</li> </ul> <p><u>Sentences:</u> -</p>	<p><u>Text Length:</u></p> <ul style="list-style-type: none"> <li>▪ 400-700 words</li> </ul> <p><u>Text Structure:</u> -</p> <p><u>Use of Tables/Visuals:</u> -</p>	<p><u>Title:</u></p> <ul style="list-style-type: none"> <li>▪ if title is difficult to understand, consider re-writing it in plain language</li> </ul> <p><u>Content structure:</u></p> <ul style="list-style-type: none"> <li>▪ What is the aim of review?</li> <li>▪ Key messages</li> <li>▪ What was studied in the review?</li> <li>▪ What are the main results of the review?</li> <li>▪ How up-to-date is this review?</li> </ul> <p><u>Headlines:</u></p> <ul style="list-style-type: none"> <li>▪ use sub-headings</li> </ul> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>▪ explain that results come from a systematic study rather than a single study</li> <li>▪ describe if necessary: why this topic is important; the population; the intervention; the</li> </ul>	<ul style="list-style-type: none"> <li>▪ present results only for the most important outcomes, try not to present more than 7 outcomes</li> <li>▪ if no data was found, present outcomes nevertheless</li> <li>▪ present results consistently (similar words / expressions for similar effects)</li> <li>▪ use the provided standard sentences</li> <li>▪ use absolute numbers (not relative risks, odds ratios, or percentages)</li> </ul>	<ul style="list-style-type: none"> <li>▪ present quality or certainty for each outcome as presented in the SoF table</li> <li>▪ if quality/certainty is not high, avoid strong statements, add modifying statements</li> </ul>	<p><u>Purpose of text:</u> -</p> <p><u>Author of PLS:</u> -</p> <p><u>Review of PLS:</u></p> <ul style="list-style-type: none"> <li>▪ the checklist is intended for use by reviewers of PLS</li> </ul> <p><u>Access:</u> -</p> <p><u>Context:</u></p> <ul style="list-style-type: none"> <li>▪ a template, PLS examples and standardized statements are provided</li> <li>▪ ensure results are reported consistently between PLS and main text / abstract / SoF table</li> </ul>

			<p>comparison group; the outcomes; possible adverse effects</p> <ul style="list-style-type: none"> <li>do not present recommendations</li> </ul>			
<p><b>Cochrane 2019 <sup>1</sup></b>          (“Plain Language Summaries”),          Cochrane Intervention Reviews</p>	<p><u>Tone:</u> -</p> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>avoid research jargon</li> <li>refer to “study” rather than “trial”</li> <li>use name of the outcome and name of intervention instead of “outcome” / “intervention”</li> <li>use words like “parents”, “women”, etc. instead of “participants”</li> </ul> <p><u>Sentences:</u> -</p>	<p><u>Text Length:</u></p> <ul style="list-style-type: none"> <li>see above</li> </ul> <p><u>Text Structure:</u> -</p> <p><u>Use of Tables/Visuals:</u></p> <ul style="list-style-type: none"> <li>if PLS is published outside Cochrane Library, add a simplified version of SoF table</li> </ul>	<p><u>Title:</u></p> <ul style="list-style-type: none"> <li>see above</li> </ul> <p><u>Content structure:</u></p> <ul style="list-style-type: none"> <li>see above</li> </ul> <p><u>Headlines:</u></p> <ul style="list-style-type: none"> <li>see above</li> </ul> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>describe if necessary: why this topic is important; the population / health problem addressed in the review; the intervention and what it was compared to; the outcomes.</li> <li>explain that results come from a systematic study rather than a single study</li> <li>do not present recommendations</li> </ul>	<ul style="list-style-type: none"> <li>see above</li> <li>use standardized qualitative statements when reporting effects of an intervention</li> <li>ideally, use numbers and words; if you use numbers, present them in parentheses after the qualitative statement</li> <li>use absolute numbers (not relative risks, odds ratios, percentages or numbers needed to treat)</li> <li>when presenting continuous outcomes using numbers, refer to the scale</li> </ul>	<ul style="list-style-type: none"> <li>see above</li> <li>presenting confidence intervals is mostly not necessary but it may be useful in some situations (example statement is provided)</li> </ul>	<p><u>Purpose of text:</u> -</p> <p><u>Author of PLS:</u> -</p> <p><u>Review of PLS:</u> -</p> <p><u>Access:</u> -</p> <p><u>Context:</u></p> <ul style="list-style-type: none"> <li>see above</li> </ul>
<p><b>The Steering Group of the Campbell Collaboration (2016)</b>          (“Plain Language Summaries”),          Campbell systematic reviews</p>	<p><u>Tone:</u></p> <ul style="list-style-type: none"> <li>use direct language</li> <li>accessible manner</li> </ul> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>avoid jargon</li> <li>specific terms that are familiar to policy makers and practitioners should be retained</li> <li>verbs: present tense</li> </ul> <p><u>Sentences:</u> -</p>	<p><u>Text Length:</u></p> <ul style="list-style-type: none"> <li>600 - 750 words</li> </ul> <p><u>Text Structure:</u> -</p> <p><u>Use of Tables/Visuals:</u></p> <ul style="list-style-type: none"> <li>text box: “What is the aim of this review?”</li> </ul> <p><u>Form:</u></p> <ul style="list-style-type: none"> <li>no footnotes or references</li> </ul>	<p><u>Title:</u></p> <ul style="list-style-type: none"> <li>headline style</li> <li>summarizing main findings</li> <li>reference to full title at the end of the PLS</li> </ul> <p><u>Content structure:</u></p> <ul style="list-style-type: none"> <li>see “Headlines”</li> </ul> <p><u>Headlines:</u></p> <ul style="list-style-type: none"> <li>use headings and additional subheadings if needed</li> </ul> <p><u>Headlines:</u></p> <ul style="list-style-type: none"> <li>The Review in Brief; What is this Review about?; What are the main findings of this review?; What do the</li> </ul>	<ul style="list-style-type: none"> <li>report the study findings directly and in present tense</li> <li>avoid selective outcome reporting</li> <li>use qualitative statements when presenting the effects of the intervention</li> <li>avoid numbers to increase accessibility</li> <li>qualitative statements: similar words and expressions for similar levels of effect (additional appendix with standardised statements)</li> </ul>	<ul style="list-style-type: none"> <li>included studies: optionally add statement about the quality of evidence</li> <li>results: GRADE reporting system</li> <li>decide whether the size of the effect is important, less important or not important to the user</li> <li>use standardised statements about effect</li> <li>presenting confidence intervals is mostly not necessary but it may be useful in some situations (standardized</li> </ul>	<p><u>Purpose of text:</u></p> <ul style="list-style-type: none"> <li>to make information about main findings available in an easily understandable format</li> <li>to report this information in a consistent way</li> </ul> <p><u>Author of PLS:</u></p> <ul style="list-style-type: none"> <li>study authors submit PLS with final review</li> </ul> <p><u>Review of PLS:</u></p> <ul style="list-style-type: none"> <li>edited by the secretariat, revised version checked with lead study author</li> <li>meta-information reported as last</li> </ul>



			<p>findings of this review mean?; How up-to-date is this review?; What is the Campbell Collaboration?; About this summary</p> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>assessed interventions (i.a.)</li> <li>primary outcomes</li> <li>results for each outcome and analysis of heterogeneity</li> <li>discussion of theory of change (i.a.)</li> <li>quality of evidence</li> <li>implications for policy, practice, research (i.a.)</li> </ul>		statement is provided)	<p>sentence in PLS</p> <p><u>Access:</u> -</p> <p><u>Context:</u></p> <ul style="list-style-type: none"> <li>results should be reported consistently between PLS and main text / abstract</li> <li>a template with suggested wording is provided</li> </ul>
<p><b>Expert group</b> on clinical trials for the implementation of Regulation (EU) No 536/2014 (“lay summary” / “summary of clinical trial results for laypersons”), clinical trial results</p>	<p><u>Tone:</u></p> <ul style="list-style-type: none"> <li>avoid any promotional language</li> </ul> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>avoid jargon / technical / medical / scientific language</li> <li>remove unnecessary / complex words</li> <li>be consistent with use of words and define them</li> <li>explain underlying concepts if necessary</li> <li>avoid ambiguous words / phrases</li> <li>limit use of acronyms, and of abstract or multisyllabic words</li> <li>verbs: use active rather than passive voice</li> <li>texts should be aimed at literacy proficiency level of 2-3 (use metrics to measure text readability)</li> </ul> <p><u>Sentences:</u></p> <ul style="list-style-type: none"> <li>make short and</li> </ul>	<p><u>Text Length:</u></p> <ul style="list-style-type: none"> <li>as short as possible</li> </ul> <p><u>Text structure:</u></p> <ul style="list-style-type: none"> <li>bullet points</li> <li>white space between topics</li> <li>minimum of 12-point font</li> <li>avoid text in all caps or underlining</li> </ul> <p><u>Use of Tables/Visuals:</u></p> <ul style="list-style-type: none"> <li>use visuals to convey critical concepts but limited use of unnecessary images</li> <li>visuals should present one message per image and be clearly labelled with captions</li> </ul>	<p><u>Title:</u></p> <ul style="list-style-type: none"> <li>specific to the trial</li> <li>may be shortened / simplified</li> </ul> <p><u>Content structure:</u></p> <ul style="list-style-type: none"> <li>present general information before the details</li> </ul> <p><u>Headlines:</u></p> <ul style="list-style-type: none"> <li>use headlines and descriptive subheadings to organize information</li> </ul> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>focus on unambiguous, factual information</li> <li>no promotional content should be included</li> <li>avoid overwhelming with too much information</li> <li>describe adverse reactions</li> </ul>	<ul style="list-style-type: none"> <li>describe every study arm and outcome</li> <li>Numbers: follow numeracy principle (links to additional information is provided)</li> <li>report frequencies both in numerical terms and percentages</li> <li>report all outcomes</li> </ul>	<ul style="list-style-type: none"> <li>don't include promotional content</li> </ul>	<p><u>Purpose of text:</u></p> <ul style="list-style-type: none"> <li>EU Clinical Trials Regulation 536/2014 (Article 37): sponsors need to provide summary results in a format understandable to laypersons (research participants and general public)</li> </ul> <p><u>Author of PLS:</u> -</p> <p><u>Review of PLS:</u></p> <ul style="list-style-type: none"> <li>consider including patients, patient representative or advocates to ensure the summary meets its aims; consider help of medical writers with plain language expertise</li> </ul> <p><u>Access:</u></p> <ul style="list-style-type: none"> <li>made available in the EU Portal and Database</li> </ul> <p><u>Context:</u></p> <ul style="list-style-type: none"> <li>provide summary as a minimum in local</li> </ul>

	<p>succinct sentences instead of long and complex ones</p>					<p>language of where the trial took place</p> <ul style="list-style-type: none"> <li>▪ where possible include English version</li> <li>▪ a template with 10 elements that should be included in the summary and suggested wording is provided</li> </ul>
<p><b>Lionbridge (2019):</b> Seven rules for effective communication (“Plain Language Summaries”), clinical trial results</p>	<p><u>Tone:</u></p> <ul style="list-style-type: none"> <li>▪ information should be presented factually and neutrally</li> <li>▪ respectful tone so that study participants do not feel as victims; avoid marketing jargon or overly positive presentation</li> </ul> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>▪ simple and unambiguous</li> <li>▪ avoid polysyllabic words; complex technical terms (unless you explain them); scientific jargon that may be misunderstood or cause confusion</li> </ul> <p><u>Sentences:</u></p> <ul style="list-style-type: none"> <li>▪ active sentences with a subject that executes an action</li> <li>▪ short, simple sentences</li> <li>▪ avoid subclauses and nested sentences</li> </ul>	<p><u>Text Length:</u> -</p> <p><u>Form:</u> -</p> <p><u>Use of Tables/Visuals:</u></p> <ul style="list-style-type: none"> <li>▪ use visual aids such as empty spaces or graphs if it enhances communication with the target group</li> </ul>	<p><u>Title:</u> -</p> <p><u>Content structure:</u> -</p> <p><u>Headlines:</u> -</p> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>▪ content and presentation should be oriented towards language, style and knowledge of laypersons</li> </ul>	<ul style="list-style-type: none"> <li>▪ report absolute, whole numbers</li> <li>▪ report numbers without decimal places or as percentages</li> <li>▪ avoid probabilities or relative risks</li> </ul>	-	<p><u>Purpose of text:</u></p> <ul style="list-style-type: none"> <li>▪ to inform persons with average education level about results and conclusions of clinical studies</li> </ul> <p><u>Author of PLS:</u> -</p> <p><u>Review of PLS:</u> -</p> <p><u>Access:</u></p> <ul style="list-style-type: none"> <li>▪ access to extensive guidelines for writing PLS only for members</li> </ul> <p><u>Context:</u> -</p>
<p><b>TransCelerate Biopharma Inc.</b>  (“lay summary”), clinical trial results</p>	<p><u>Tone:</u></p> <ul style="list-style-type: none"> <li>▪ factual and objective tone</li> </ul> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>▪ avoid superlative and enthusiastic words</li> <li>▪ use neutral language (link to additional</li> </ul>	<p><u>Text Length:</u> -</p> <p><u>Form:</u></p> <ul style="list-style-type: none"> <li>▪ use material that is fair and balanced in terms of formatting</li> </ul> <p><u>Use of Tables/Visuals:</u></p> <ul style="list-style-type: none"> <li>▪ do not use materials that have a commercial</li> </ul>	<p><u>Title:</u> -</p> <p><u>Content structure:</u> -</p> <p><u>Headlines:</u> -</p> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>▪ factual and objective content</li> <li>▪ use accurate, non-misleading information</li> </ul>	<ul style="list-style-type: none"> <li>▪ make only comments on the outcome that are factual in nature</li> <li>▪ do not make inferences or assessments</li> <li>▪ link to additional neutral language guide is provided</li> </ul>	<ul style="list-style-type: none"> <li>▪ include a statement that results are from a single trial and different results may be obtained from other studies</li> <li>▪ include a statement that no therapeutic changes</li> </ul>	<p><u>Purpose of text:</u></p> <ul style="list-style-type: none"> <li>▪ written to be understandable to the general public</li> <li>▪ recommendations to help prepare PLS that are not perceived as promotional</li> </ul>

	<p>guidance is provided)  <u>Sentences:</u> -</p>	<p>appearance</p> <ul style="list-style-type: none"> <li>do not use brand colors / logos</li> <li>be fair and balanced in terms of formatting</li> </ul>	<ul style="list-style-type: none"> <li>include information on efficacy and safety data from the trial</li> <li>do not provide approval status</li> <li>material should be fair and balanced</li> </ul>		<p>should be made based on the results of a single trial without consulting a healthcare professional</p>	<p><u>Author of PLS:</u></p> <ul style="list-style-type: none"> <li>sponsor of trial</li> </ul> <p><u>Review of PLS:</u> -</p> <p><u>Access:</u></p> <ul style="list-style-type: none"> <li>posted to public websites, EU database</li> <li>provided to trial participants</li> </ul> <p><u>Context:</u></p> <ul style="list-style-type: none"> <li>take care that PLS is only provided in a non-promotional context</li> <li>add a statement with link to ClinicalTrials.gov &amp; EU clinical trial register</li> </ul>
<p><b>Duke (2012):</b> How to write a lay summary (“lay summary”), Digital Curation Center collaborating with Patients Participate! project</p>	<p><u>Tone:</u></p> <ul style="list-style-type: none"> <li>do not write to entertain</li> </ul> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>use everyday English words instead of complex words</li> <li>avoid meaningless terms</li> <li>use active voice and second person instead of third person</li> <li>use person-centered language, do not focus on circumstances, illness or disability</li> <li>write in an easily readable style</li> </ul> <p><u>Sentences:</u></p> <ul style="list-style-type: none"> <li>use short and clear sentences</li> <li>avoid complex grammatical structures</li> <li>phrase positively rather than negatively</li> </ul>	<p><u>Text Length:</u></p> <ul style="list-style-type: none"> <li>adhere to convention</li> </ul> <p><u>Form:</u></p> <ul style="list-style-type: none"> <li>break text up into paragraphs</li> </ul> <p><u>Use of Tables/Visuals:</u> -</p>	<p><u>Title:</u></p> <ul style="list-style-type: none"> <li>provide a good and relevant title</li> </ul> <p><u>Content structure:</u></p> <ul style="list-style-type: none"> <li>order the text logically and let it flow naturally</li> <li>adhere to convention</li> <li>provide a first sentence that gives a concise introduction into text</li> </ul> <p><u>Headlines:</u> -</p> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>provide answers to the questions: Who, What, Where, When, Why, How?</li> <li>give concrete everyday examples</li> <li>make sure risks are appropriately communicated (i.a.)</li> </ul>	-	-	<p><u>Purpose of text:</u></p> <ul style="list-style-type: none"> <li>to shortly report research to a general audience</li> </ul> <p><u>Author of PLS:</u></p> <ul style="list-style-type: none"> <li>researchers</li> </ul> <p><u>Review of PLS:</u> -</p> <p><u>Access:</u></p> <ul style="list-style-type: none"> <li>service providers may be responsible for the dissemination of research findings</li> </ul> <p><u>Context:</u> -</p>

<b>Dubé &amp; Lapane (2014):</b> Lay Abstracts and Summaries: Writing Advice for Scientists (“lay abstract” / “summaries”), multidisciplinary	<u>Tone:</u> - <u>Words:</u> <ul style="list-style-type: none"> <li>▪ avoid long / multisyllabic / complicated words</li> <li>▪ do not use acronyms (except commonly known ones)</li> <li>▪ use active instead of passive voice</li> <li>▪ check readability and reading level</li> </ul> <u>Sentences:</u> <ul style="list-style-type: none"> <li>▪ shorten sentences (but avoid choppy writing)</li> </ul>	<u>Text Length:</u> <ul style="list-style-type: none"> <li>▪ depends on purpose</li> </ul> <u>Form:</u> <ul style="list-style-type: none"> <li>▪ check instructions</li> </ul> <u>Use of Tables/Visuals:</u> -	<u>Title:</u> <ul style="list-style-type: none"> <li>▪ state the main impact of your work for your audience with a simple phrase</li> </ul> <u>Content structure:</u> <ul style="list-style-type: none"> <li>▪ organize to make your story clear</li> <li>▪ summarize the most important / relevant information at the beginning briefly</li> </ul> <u>Headlines:</u> - <u>Content:</u> -	-	-	<u>Purpose of text:</u> <ul style="list-style-type: none"> <li>▪ the goal: a summary that is accessible to the public while true to science</li> </ul> <u>Author of PLS:</u> - <u>Review of PLS:</u> <ul style="list-style-type: none"> <li>▪ review from target audience and other scientists of your field</li> </ul> <u>Access:</u> - <u>Context:</u> -
<b>eLife (2017):</b> Plain-language summaries: How to write an eLife digest (“Plain Language Summaries” / “eLife digests”), life sciences	<u>Tone:</u> - <u>Words:</u> <ul style="list-style-type: none"> <li>▪ use words that are understandable to the widest group of readers</li> <li>▪ avoid technical jargon (note that jargon can include common words that are used in a field-specific way)</li> <li>▪ if scientific terms must be used, define each at first use in more everyday-language</li> <li>▪ only use well-known acronyms and do not use more than 3 acronyms overall</li> <li>▪ rather use a few short words than one long one</li> <li>▪ use verbs instead as nouns as much as</li> </ul>	<u>Text Length:</u> - <u>Form:</u> - <u>Use of Tables/Visuals:</u> -	<u>Title:</u> - <u>Content structure</u> <ul style="list-style-type: none"> <li>▪ First sentence: Include something that most readers will be able to relate to</li> <li>▪ Following sentences: Get gradually more specific</li> </ul> <u>Headlines:</u> - <u>Content:</u> <ul style="list-style-type: none"> <li>▪ 4 questions that should be answered: <ol style="list-style-type: none"> <li>1. What background information would someone who is completely unfamiliar with your field need to know to understand the findings in your paper?</li> <li>2. What exact research question did you set out to answer and why?</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>▪ focus on findings highlighted in the title / abstract of your paper; explain them clearly and completely</li> <li>▪ describe methodology with 1-2 sentences</li> <li>▪ always mention which species, type of organism or cells you have studied</li> </ul>	<ul style="list-style-type: none"> <li>▪ avoid hype / exaggeration</li> </ul>	<u>Purpose of text:</u> <ul style="list-style-type: none"> <li>▪ explain findings of a eLife paper to a broader audience</li> </ul> <u>Author of PLS:</u> <ul style="list-style-type: none"> <li>▪ written by editors and writers working together with authors: the author of the scientific paper is asked to answer 4 questions; from that, the eLife Features team writes the digest</li> </ul> <u>Review of PLS:</u> - <u>Access:</u> - <u>Context:</u> <ul style="list-style-type: none"> <li>▪ published in a prominent position</li> <li>▪ some are republished on social media platform</li> <li>▪ encouragement to re-use PLS in other places</li> </ul>

	<p>possible Sentences:</p> <ul style="list-style-type: none"> <li>▪ active sentences</li> <li>▪ all sentences should be shorter than 35 words</li> </ul>		<p>3. What are the most important findings of your paper? (always mention which species, type of organism or cells you have studied)</p> <p>4. Who might eventually benefit from the findings of your study, and what would need to be done before we could achieve these benefits?</p>			
<p><b>NIHR</b> ("Plain English Summaries"), health research</p>	<p><u>Tone:</u></p> <ul style="list-style-type: none"> <li>▪ clearly and simply written</li> </ul> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>▪ avoid jargon, abbreviations and technical terms (provide explanation if you must use them)</li> <li>▪ active rather than passive phrases</li> <li>▪ link to glossary with lay-friendly terms</li> </ul> <p><u>Sentences:</u></p> <ul style="list-style-type: none"> <li>▪ keep short</li> </ul>	<p><u>Text Length:</u></p> <ul style="list-style-type: none"> <li>▪ depends on funding programme</li> </ul> <p><u>Form:</u></p> <ul style="list-style-type: none"> <li>▪ break up the text, e.g. with bullet lists or headings</li> </ul> <p><u>Use of Tables/Visuals:</u> -</p>	<p><u>Title:</u> -</p> <p><u>Content structure:</u></p> <ul style="list-style-type: none"> <li>▪ include, where appropriate, information on: Aim(s) of the research; Background of research; Design and methods used; Patient and public involvement; Dissemination of the findings</li> </ul> <p><u>Headlines:</u> -</p> <p><u>Content:</u> -</p>	-	-	<p><u>Purpose of text:</u> -</p> <p><u>Author of PLS:</u></p> <ul style="list-style-type: none"> <li>▪ strong advice to involve patients, carers and/or members of the public</li> </ul> <p><u>Review of PLS:</u> -</p> <p><u>Access:</u> -</p> <p><u>Context:</u></p> <ul style="list-style-type: none"> <li>▪ links to resources are provided</li> <li>▪ summary will be used on NIHR and other websites to describe the research</li> </ul>
<p><b>American Geophysical Union</b> [several journals] ("Plain Language Summaries"), earth and space science</p>	<p><u>Tone:</u></p> <ul style="list-style-type: none"> <li>▪ language and tone are different from scientific abstract</li> </ul> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>▪ avoid jargon, incl. undefined / excessive acronyms, field-specific terms, obscure / unnecessary long words, words that have different meaning to non-scientists</li> <li>▪ use straight-forward descriptions</li> </ul> <p><u>Sentences:</u> -</p>	<p><u>Text Length:</u> -</p> <p><u>Form:</u> -</p> <p><u>Use of Tables/Visuals:</u> -</p>	<p><u>Title:</u> -</p> <p><u>Content structure:</u> -</p> <p><u>Headlines:</u> -</p> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>▪ develop your take home message by explaining what the research is about, what you found, and why it matters/what the impact is.</li> <li>▪ provide enough context for those outside of your specific area of science will need more context</li> <li>▪ highlight the novelty</li> </ul>	-	-	<p><u>Purpose of text:</u></p> <ul style="list-style-type: none"> <li>▪ to explain your science to broader audiences</li> </ul> <p><u>Author of PLS:</u></p> <ul style="list-style-type: none"> <li>▪ authors of the scientific article</li> </ul> <p><u>Review of PLS:</u> -</p> <p><u>Access:</u> -</p> <p><u>Context:</u> -</p>

			<p>and value of your research</p> <ul style="list-style-type: none"> <li>Think about: What was the research question (in the larger context of your field)? What did your study find? Why does it matter? What's the take-home message?</li> </ul>			
<p><b>Halprin (2021)<sup>1</sup>:</b> Plain Language Summaries Explained in Plain Language, [several journals] ("Plain Language Summaries"), earth and space science</p>	<p><u>Tone:</u> -</p> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>see above</li> <li>define any field-specific terms</li> <li>explain acronyms if they have to be used</li> </ul> <p><u>Sentences:</u> -</p>	<p><u>Text Length:</u></p> <ul style="list-style-type: none"> <li>200 words</li> </ul> <p><u>Form:</u> -</p> <p><u>Use of Tables/Visuals:</u> -</p>	<p><u>Title:</u> -</p> <p><u>Content structure:</u> -</p> <p><u>Headlines:</u> -</p> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>recommendation to use four elements (use 1-2 sentences each): 1) Topic Overview; 2) Paper Overview; 3) Findings Summary; 4) Key Takeaways</li> </ul>	-	-	<p><u>Purpose of text:</u></p> <ul style="list-style-type: none"> <li>see above</li> </ul> <p><u>Author of PLS:</u></p> <ul style="list-style-type: none"> <li>see above</li> </ul> <p><u>Review of PLS:</u> -</p> <p><u>Access:</u> -</p> <p><u>Context:</u></p> <ul style="list-style-type: none"> <li>examples are provided</li> </ul>
<p><b>People and Nature</b> [journal] ("Plain Language Summaries"), human-ecology interactions</p>	<p><u>Tone:</u></p> <ul style="list-style-type: none"> <li>use clear and simple language</li> <li>simple and straightforward style</li> </ul> <p><u>Words:</u></p> <ul style="list-style-type: none"> <li>avoid jargon</li> <li>avoid scientific terms; if you must use a scientific term, explain in clear and simple terms what it is</li> </ul> <p><u>Sentences:</u> -</p>	<p><u>Text Length:</u></p> <ul style="list-style-type: none"> <li>250-300 words</li> </ul> <p><u>Form:</u> -</p> <p><u>Use of Tables/Visuals:</u></p> <ul style="list-style-type: none"> <li>try and include a photo or image, anything that makes you work more accessible and interesting</li> </ul>	<p><u>Title:</u></p> <ul style="list-style-type: none"> <li>plain language title that says what the paper is about in clear terms (a bit like a newspaper headline)</li> <li>short (&lt; 120 characters)</li> </ul> <p><u>Content structure:</u> -</p> <p><u>Headlines:</u> -</p> <p><u>Content:</u></p> <ul style="list-style-type: none"> <li>include any important contextual background or findings that might make your work more relevant, interesting or memorable to the reader</li> </ul>	-	-	<p><u>Purpose of text:</u></p> <ul style="list-style-type: none"> <li>to raise the profile of your work</li> <li>to make it accessible to the widest possible audience</li> </ul> <p><u>Author of PLS:</u></p> <ul style="list-style-type: none"> <li>author of paper</li> </ul> <p><u>Review of PLS:</u></p> <ul style="list-style-type: none"> <li>upload PLS at revision stage with your work</li> <li>will be edited and returned to author if too much jargon</li> </ul> <p><u>Access:</u></p> <ul style="list-style-type: none"> <li>freely available to read</li> </ul> <p><u>Context:</u></p> <ul style="list-style-type: none"> <li>PLS will be added to journal blog, included with the paper</li> <li>encouraged to reuse PLS by posting it on own blog, share on social media</li> </ul>

<b>Autism</b> [journal] (“lay abstract”), all aspects of autism spectrum disorders and related developmental disabilities	<u>Tone:</u> ▪ easily understandable <u>Words:</u> ▪ avoid technical terminology <u>Sentences:</u> -	<u>Text Length:</u> ▪ max. 250 words <u>Form:</u> - <u>Use of Tables/Visuals:</u> -	<u>Title:</u> - <u>Content structure:</u> - <u>Headlines:</u> - <u>Content:</u> ▪ Consider the questions: What is already known about the topic? What does this paper add? Implications for practice, research and policy	▪ avoid reporting of statistics	-	<u>Purpose of text:</u> - <u>Author of PLS:</u> ▪ author of paper <u>Review of PLS:</u> ▪ provide lay abstract as part of submission <u>Access:</u> ▪ will be made widely available to general public and particularly to autistic people and their families <u>Context:</u> -
<b>Taylor &amp; Francis Group</b> [journal] (“Plain Language Summaries”), multidisciplinary	<u>Tone:</u> ▪ as objective as possible ▪ person-centered rather than focusing on the condition/illness <u>Words:</u> ▪ free of jargon ▪ clear language ▪ easy-to-understand language instead of complex words ▪ active rather than passive voice ▪ avoid grammatical structures and abbreviations ▪ if you need to use a technical term, explain it the first time it is used <u>Sentences:</u> ▪ short clear sentences ▪ phrase sentences in neutral language	<u>Text Length:</u> ▪ max. 250 words <u>Form:</u> ▪ continuous prose format <u>Use of Tables/Visuals:</u> -	<u>Title:</u> - <u>Content structure:</u> - <u>Headlines:</u> - <u>Content:</u> ▪ Answer the questions: Why was the study done? What did the researchers do and find? What do the results mean? What is the objective influence on the wider field?	▪ keep statements factual ▪ avoid providing opinions / speculation on study results and significance ▪ priority is that PLS is not misleading	-	<u>Purpose of text:</u> ▪ to communicate the significance of scientific research evidence to a broad evidence <u>Author of PLS:</u> ▪ author of scientific article submitted to journal <u>Review of PLS:</u> ▪ PLS is peer reviewed alongside the manuscript <u>Access:</u> ▪ Open access license is the same as that of the published article ▪ freely available to read on website <u>Context:</u> ▪ submit PLS as part of the manuscript or one year after (then incurring a fee) ▪ submission of PLS with scientific article is optional, but encouraged

i.a. = if applicable; GRADE = Grading of Recommendations Assessment, Development and Evaluation (specific formal process for grading systematic reviews); SoF = Summary of Finding table (standardized form to report results of Cochrane Reviews)

<sup>1</sup> listed are only changes to the version mentioned above

**S3 Table. Quantitative Studies Comparing PLS vs. PLS: Criteria, Outcomes and Results.**

Study [sample]	criteria [characteristic category]	outcome [aim category]	results
Santesso et al. (2015) [ <i>n</i> = 143 members of the public and patients from 5 nations (Canada, Norway, Spain, Argentina, Italy)]	<p>new format vs. current format:</p> <p>- new format: description of effects: qualitative and quantitative (absolute effects, natural frequencies in text; quantitative results in table) quality of evidence: provided in table, according to GRADE text structure: headings, question and answer format content structure: flow of information according to linguistic framework principles</p> <p>- current format: description of effect: qualitative quality of evidence: no criteria text structure: paragraph of text content structure: no criteria</p> <p>[Formal Attributes] [Presentation of Results] [Presentation of Quality of Evidence]</p>	<p>Primary Outcome: <b>A)</b> proportion of participants who correctly answered questions about the benefits and harms of the intervention and quality of evidence (multiple choice test, average of 5 questions)</p> <p>Secondary Outcomes: <b>B)</b> proportion of participants who correctly answered those 5 questions each <b>C)</b> overall correct answers <b>D)</b> comprehension of purpose of the summary <b>E)</b> usability <b>F)</b> ease of understanding <b>G)</b> accessibility <b>H)</b> preference for one format over the other</p> <p>[Knowledge] [Understanding] [Accessibility]</p>	<p><b>A)</b> proportion of participants who correctly answered comprehension questions on average was higher for the new format than the current (53% vs. 18%, <math>p &lt; .001</math>) <b>B)</b> proportion of participants who correctly answered single questions was higher for the new than the current format in 4 of 5 questions (<math>p &lt; .001</math>) <b>C)</b> more correctly answered questions by participants who read the new format compared to participants who read the current format (<math>Mdn = 3</math>, <math>IQR</math>: 1-4; vs. <math>Mdn = 1</math>, <math>IQR</math>: 0-1, <math>p &lt; .001</math>) <b>D)</b> no difference between formats regarding comprehension of the purpose of the study (32% vs. 45%, <math>p = .17</math>) <b>E-G)</b> more participants who read the new format compared to the current format reported that the information was easy to find, reliable, that the summary presented most important effects and the presentation helped to make a decision (all <math>p &lt; .05</math>), no stat. sign. difference regarding ease of understanding <b>H)</b> greater preference for the new format (<math>p</math> unknown)</p>
Silvagnoli et al. (2020) [ <i>n</i> = 167, mostly higher-educated, from UK-based patient]	<p>readability low level of complexity (L1) vs. medium level of complexity (L2) vs. high level of complexity (L3)</p> <p>[Linguistic Characteristics]</p>	<p>preference (score 1-4)</p> <p>[Accessibility]</p>	<p>medium-level PLS with a readability that fits to an reading age of 14-17 years (L2) received highest preference ratings (PLS Psoriasis weighted means: 2.13 (L1) vs. 2.90 (L2) vs. 1.97 (L3); PLS Multiple Sclerosis weighted</p>



association websites and Facebook patient support groups]			means: 2.37 (L1) vs. 2.47 (L2) vs. 2.40 (L3); PLS Rheumatoid Arthritis weightes means: 2.38 (L1) vs. 2.77 (L2) vs. 2.08 (L3), <i>p</i> unknown)
Alderdice et al. (2016) [ <i>n</i> = 813 midwifery students from UK and Ireland]	conclusion vs. no conclusion certain findings vs. uncertain findings <i>[General Content]</i>	proportion of participants who identified the appropriate response to describe the main results of the review <i>[Knowledge]</i>	no stat. sign. difference for conclusion vs. no conclusion for PLS with certain findings (63% vs. 61%; OR 1.13, 95% CI [0.41, 1.50]; RD 2.8%, 95% CI [-3.8, 9.5]; <i>p</i> = .41); stat. sign. more correct answers for conclusion vs. no conclusion for PLS with uncertain findings (45% vs. 37%; OR 1.35, 95% CI [1.02, 1.79]; RD 7.3%, 95% CI [0.60, 14.1]; <i>p</i> = .03)
Buljan et al. (2020, BMC Mes Red Methodol.), Trial 1 [ <i>n</i> = 91, first-year medical students of University of Croatia]	positive framing (i.e., in terms of effectiveness) vs. negative framing (i.e., in terms of ineffectiveness) of health evidence <i>[Presentation of Results]</i>	Primary Outcomes: <b>A)</b> perceived effectiveness of described treatment (score 3-30) <b>B)</b> desire that treatment is offered by family doctor (score 3-30) <b>C)</b> readiness to use the treatment (score 3-30) Secondary Outcome: <b>D)</b> comprehension (brief multiple choice knowledge test, score 0-12)  <i>[Knowledge]</i> <i>[Empowerment]</i>	no differences for positive vs. negative framing: <b>A)</b> <i>M</i> = 15.8 vs. <i>M</i> = 17.3; <i>Mean Difference</i> = 1.53, 95% CI [-0.33, 3.39]; <i>BF</i> <sub>10</sub> = 1.31*10 <sup>-4</sup> <b>B)</b> <i>M</i> = 15.4 vs. <i>M</i> = 16.1; <i>Mean Difference</i> = 0.69 95% CI [-1.00, 2.37]; <i>BF</i> <sub>10</sub> = .036 <b>C)</b> <i>M</i> = 16.6 vs. <i>M</i> = 17.1; <i>Mean Difference</i> = 0.52 95% CI [-1.39, 2.43]; <i>BF</i> <sub>10</sub> = .035 <b>D)</b> <i>M</i> = 9.2 vs. <i>M</i> = 8.6; <i>Mean Difference</i> = -0.51 95% CI [-1.43, 0.35]; <i>BF</i> <sub>10</sub> = 1.81*10 <sup>-4</sup>
Buljan et al. (2020, BMC Mes Red Methodol.), Trial 2 [ <i>n</i> = 245, students of University of Croatia and patients from hospitals or family practices]	presentation of treatment effectiveness as natural frequencies and side effects as percentages vs. presentation of treatment effectiveness as percentages and side effects as natural frequencies <i>[Presentation of Results]</i>	Primary Outcome: <b>A)</b> comprehension (brief multiple choice knowledge test, score 0-2) Secondary Outcomes: <b>B)</b> preference for this type of format for health information (score 1-10) <b>C)</b> perceived effectiveness of treatment for described medical condition (score 1-10)	<b>A)</b> “In Trial 2 we found no difference in CSR PLS comprehension when results were presented as natural frequencies or percentages ( <i>BF</i> <sub>10</sub> = 0.62, Bayesian t-test for independent samples).” (p.1) <b>B), C)</b> “Our study showed no differences in readers’ perceived effectiveness and readiness to use the described treatment [...] when the

		<p><i>[Knowledge]</i> <i>[Accessibility]</i></p>	<p>results were presented as frequencies vs percentages.” (p.6)</p>
<p>Kirkpatrick et al. (2017) [<i>n</i> = 60 members of the NETSCC’s panel of public reviewers]</p>	<p>PLS written with 3 different strategies:  original PLS vs. PLS rewritten with guideline by original author (author revised) vs. PLS written with guideline by independent writer (edited)  <i>[Contextual Information]</i></p>	<p><b>A)</b> ease of understanding (score 1-4) <b>B)</b> reading ease (Flesch reading ease score, 0-100) <b>C)</b> free text comments</p> <p><i>[Understanding]</i> <i>[Accessibility]</i></p>	<p><b>A)</b> no stat. sign. difference in terms of ease of understanding (original vs. edited, 56% vs. 72%; <i>p</i> = .06; author revised vs. original, 61% vs. 56%; <i>p</i> = .81; author revised vs. edited, 72% vs. 61%; <i>p</i> = .22) <b>B)</b> both rewritten versions were significantly easier to read than the original PLS (<i>p</i> &lt; .001); no stat. sign. difference between the rewritten versions (<i>p</i> = .12) <b>C)</b> free text comments: most frequent negative comments (<i>n</i> ≥ 20) on jargon/terminology, title is not clear, insufficient detail, ambiguous language; most frequent positive comments (<i>n</i> ≥ 20): general positive comments, headings useful (only revised and edited versions) rather original than revised / edited PLS: need for headings, less detail</p>
<p>Kerwer et al. (2021) [<i>n</i> = 166 German students]</p>	<p>PLS with subheadings vs. without subheadings  <i>[Formal Attributes]</i></p>	<p><b>A)</b> perceived comprehensibility (score 1-8) <b>B)</b> knowledge acquisition (proportion of correct responses) <b>C)</b> perceived credibility (score 1-8) <b>D)</b> perceived confidence in one’s ability to evaluate the study (score 1-8) <b>E)</b> perceived ability to make a decision without consulting an expert (score 1-8)</p> <p><i>[Understanding]</i> <i>[Communication of Research]</i> <i>[Knowledge]</i> <i>[Empowerment]</i></p>	<p><b>A)</b> higher comprehensibility for PLS with subheadings than without subheadings (<i>M</i> = 6.20, <i>SD</i> = 1.65 vs. <i>M</i> = 5.96, <i>SD</i> = 1.79, residual standard deviation = -.247, <i>p</i> &lt; .001) <b>B)</b> more correct responses for PLS with subheadings than without subheadings (78.68% vs. 75.91%; <i>z</i> = - 2.08, <i>p</i> = .019) <b>C)</b> higher credibility for PLS with subheadings than without subheadings (<i>M</i> = 5.37, <i>SD</i> = 1.58 vs. <i>M</i> = 5.20, <i>SD</i> = 1.65, residual standard deviation = -.135, <i>p</i> &lt; .05) <b>D)</b> higher ability to evaluate for PLS with subheadings than without subheadings (<i>M</i> = 3.70, <i>SD</i> = 1.83 vs. <i>M</i> = 3.51, <i>SD</i> = 1.84, residual standard deviation = -.175, <i>p</i> &lt; .01 )</p>

			E) higher ability to make a decision for PLS with subheadings than without subheadings ( $M = 3.10$ , $SD = 1.76$ vs. $M = 2.78$ , $SD = 1.71$ , residual standard deviation = $-.267$ , $p < .001$ )
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PLS = Plain Language Summary; GRADE = Grading of Recommendations Assessment, Development, and Evaluation; Mdn = median; M = mean; IQR = interquartile range; OR = odds ratio; RD = risk difference; CI = confidence interval; CSR = Cochrane Systematic Review; BF = bayes factor; NETCSS = National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre

*Note.* Only experimental conditions that investigate PLS criteria against each other are listed; further comparisons (e.g., with other summary formats) are not listed.

## S1 File. Search Terms.

Web of Science: last search on 2021-06-28; 4805 articles

TI = ("plain language summa\*" OR "plain-language summa\*" OR "lay summa\*" OR "plain English summa\*" OR "non-technical summa\*" OR "non technical summa\*" OR "nontechnical summa\*" OR "summa\* for layperson\*" OR "systematic review\* summa\*" OR "evidence summa\*" OR "lay abstract\*" OR "plain language abstract\*" OR "plain-language abstract\*" OR "infographic\*") AND TI = ("quality" OR "standard\*" OR "comparison" OR "effective" OR "evaluation" OR "critical review" OR "development" OR "user testing") OR (AB = ("plain language summa\*" OR "plain-language summa\*" OR "lay summa\*" OR "plain English summa\*" OR "non-technical summa\*" OR "non technical summa\*" OR "nontechnical summa\*" OR "summa\* for layperson\*" OR "systematic review\* summa\*" OR "evidence summa\*" OR "lay abstract\*" OR "plain language abstract\*" OR "plain-language abstract\*" OR "infographic\*") AND AB = ("quality" OR "standard\*" OR "comparison" OR "effective" OR "evaluation" OR "critical review" OR "development" OR "user testing"))

PubMed: last search on 2021-06-28; 2495 articles

("plain language summa"[Title/Abstract] OR "plain-language summa"[Title/Abstract] OR "lay summa"[Title/Abstract] OR "plain English summa"[Title/Abstract] OR "non-technical summa"[Title/Abstract] OR "non technical summa"[Title/Abstract] OR "nontechnical summa"[Title/Abstract] OR "summa\* for layperson"[Title/Abstract] OR "systematic review\* summa"[Title/Abstract] OR "evidence summa"[Title/Abstract] OR "non-technical summa"[Title/Abstract] OR "lay abstract"[Title/Abstract] OR "plain language abstract"[Title/Abstract] OR "plain-language abstract"[Title/Abstract] OR "infographic"[Title/Abstract]) AND ("quality"[Title/Abstract] OR "standard"[Title/Abstract] OR "comparison"[Title/Abstract] OR "effective"[Title/Abstract] OR "evaluation"[Title/Abstract] OR "critical review"[Title/Abstract] OR "development"[Title/Abstract] OR "user testing"[Title/Abstract])

PsycInfo: last search on 2021-07-02; 400 articles

3 ("plain language summa\*" or "plain-language summa\*" or "lay summa\*" or "plain English summa\*" or "non-technical summa\*" or "non technical summa\*" or "nontechnical summa\*" or "summa\* for layperson\*" or "systematic review\* summa\*" or "evidence summa\*" or "non-technical summa\*" or "lay abstract\*" or "plain language abstract\*" or "plain-language abstract\*" or "infographic\*").ti. or ("plain language summa\*" or "plain-language summa\*" or "lay summa\*" or "plain English summa\*" or "non-technical summa\*" or "non technical summa\*" or "nontechnical summa\*" or "summa\* for layperson\*" or "systematic review\* summa\*" or "evidence summa\*" or "non-technical summa\*" or "lay abstract\*" or "plain language abstract\*" or "plain-language abstract\*" or "infographic\*").ab. (550)  
4 ("quality" or "standard\*" or "comparison" or "effective" or "evaluation" or "critical review" or "development" or "user testing").ti. or ("quality" or "standard\*" or "comparison" or "effective" or "evaluation" or "critical review" or "development" or "user testing").ab. (1387340)  
5 3 and 4 (287)

PSYINDEX: Datum: last search on 2021-07-02; 14 articles

1 ("plain language summa\*" or "plain-language summa\*" or "lay summa\*" or "plain English summa\*" or "non-technical summa\*" or "non technical summa\*" or "nontechnical summa\*" or "summa\* for layperson\*" or "systematic review\* summa\*" or "evidence summa\*" or "non-technical summa\*" or "lay abstract\*" or "plain language abstract\*" or "plain-language abstract\*" or "infographic\*").ti. or ("plain language summa\*" or "plain-language summa\*" or "lay summa\*" or "plain English summa\*" or "non-technical summa\*" or "non technical summa\*" or "nontechnical summa\*" or "summa\* for layperson\*" or "systematic review\* summa\*" or "evidence summa\*" or "non-technical summa\*" or "lay abstract\*" or "plain language abstract\*" or "plain-language abstract\*" or "infographic\*").ab. (15)  
2 ("quality" or "standard\*" or "comparison" or "effective" or "evaluation" or "critical review" or "development" or "user testing").ti. or ("quality" or "standard\*" or "comparison" or "effective" or "evaluation" or "critical review" or "development" or "user testing").ab. (75303)  
3 1 and 2 (10)

### S3 File. Plain Language Summary about this Review.

#### Plain Language Summary

This text is a Plain Language Summary of our systematic review with the title “Plain Language Summaries: A Systematic Review of Theory, Guidelines, and Empirical Research” from 2021. The authors are Marlene Stoll, Martin Kewer, Klaus Lieb and Anita Chasiotis.

*What was the aim of the review?*

**Background:** Plain Language Summaries (PLS) are short texts that summarize a scientific study and that are written in a lay-friendly language. Because the concept is relatively new, there are different ideas of how PLS should be written and what the purpose of writing a PLS is.

**Research questions:** In this review, we had two aims.

- 1) We wanted to develop a PLS framework that describes the different components of PLS, the purpose of writing a PLS and how PLS can be studied. In order to do so, we brought together all theoretical ideas and guidelines about PLS,
- 2) We wanted to know how, according to current knowledge in research, how PLS should be written to communicate scientific studies to lay people in the best possible way. In order to do so, we reviewed scientific studies that investigate PLS.

*Key message of this review*

A lot of researchers have already thought theoretically about PLS, but there are not many comparable scientific studies on how to write PLS.

*What was the way of working on this research question?*

**What kind of studies were searched?** We searched for articles that studied PLS, discussed PLS, or that gave directions on how to write PLS.

**Which studies were found?** We found 90 articles. All 90 articles were used to investigate research question 1 about the theoretical ideas and guidelines regarding PLS. Ten of the 90 could be used to answer research question 2 about how PLS should be written.

**What did we do with the studies?** In all articles, we searched for information about what the components of PLS are (“PLS characteristics”), how a PLS should be written (“PLS criteria”), what the purpose of writing a PLS is (“PLS aims”) and how we can measure if a PLS is good (“PLS outcome”). We gathered, structured and combined this information into a framework. Also, we summarized scientific studies and their results about how PLS should be written.

*What are the most important results?*

#### **Results for Research Question 1:**

Our framework describes:

- PLS consist of six main characteristics:
  - 1) Linguistic Features (e.g., which kind of words are used)
  - 2) Formal Features (e.g., how the PLS is structured, with or without bullet points)
  - 3) General Content (e.g., what the text narrates)
  - 4) How results are presented (e.g., how statistics are reported)
  - 5) How the quality of the method is presented (e.g., how the PLS reports bias risks)
  - 6) Context Features (e.g., who writes the PLS and where can you find it).

- The aims of PLS can be divided into six categories:
  - 1) PLS should provide access to the content of the study.
  - 2) PLS should be understandable.
  - 3) PLS should give the reader more knowledge.
  - 4) PLS should make possible that readers can use this knowledge, for example, when they are faced with challenges in their daily life.
  - 5) PLS should improve communication between researchers and the public.
  - 6) PLS should improve research as a whole.
- Around these characteristics and aims, a framework can be drawn that includes PLS criteria and outcomes.
- This framework provides people who want to develop a PLS guideline or who want to study PLS with a total overview of what can be considered when talking about or working on PLS.

### **Results for Research Question 2:**

Since the 10 studies we used to answer research question 2 were very different from each other (e.g., some studies used very short and other studies used rather long texts as a PLS), conclusive results were difficult to identify. One reason is that the study authors had different fundamental ideas how a PLS should be written. However, there are insular clues that some PLS may be better than others due to certain features. One study showed that PLS should be written on a medium readability level (rather than a low or high level), another showed that PLS should be structured by headings. Another study showed that PLS should provide background information and report results not only with numbers but also with words that describe the results and another showed that PLS should be written in accordance with a guideline.