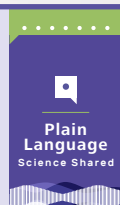


Supporting guidelines and published research evidence



This document provides an overview of the guidelines and evidence that informed the development of the PLS of publications template and the responses to feedback from the PLS of Publications Co-creation Workshop (London; November 28, 2018). Expert opinions from patient partners, representing the target audience, also contributed to the PLS publications template.

POWERING
PATIENT VOICES

Guidelines

Guideline	Comment
<p>IFPMA code of practice 2019. https://www.ifpma.org/resource-centre/ifpma-code-of-practice-2019/ Published September 3, 2018. Accessed April 3, 2019.</p>	<ul style="list-style-type: none">• PLS must be non-promotional, but communication does not equal promotion.• Article 3. Pre-Approval Communications and Off-Label Use<ul style="list-style-type: none">– ‘No pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country.– ‘This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress.– ‘It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences.’• Brand name permitted if it helps patient use educational resource.• Article 7.5.3 - Informational or Educational Items that enhance Patient Care.<ul style="list-style-type: none">– ‘Informational or educational items provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value. These informational and educational items can include the company name, but must not be product branded, unless the product’s name is essential for the correct use of the item by the patient.’

Guideline	Comment
<p>Food and Drug Administration. Manufacturer communications regarding unapproved uses of approved or cleared medical products; availability of memorandum; reopening of the comment period: a proposed rule by the Food and Drug Administration.</p> <p>https://www.federalregister.gov/documents/2017/01/19/2017-01013/manufacturer-communications-regarding-unapproved-uses-of-approved-or-cleared-medical-products.</p> <p>Published January 19, 2017. Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • PLS must be non-promotional, but communication does not equal promotion. – ‘In addition, it has long been FDA policy not to consider a firm’s presentation of truthful and non-misleading scientific information about unapproved uses at medical or scientific conferences to be evidence of intended use when the presentation is made in non-promotional settings and not accompanied by promotional materials.’
<p>Department of Health and Human Services. Clinical trials registration and results information submission: a rule by the Health and Human Services Department.</p> <p>https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission.</p> <p>Published September 21, 2016. Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Brand name use – Requires sponsor to include current and former names that the sponsor ‘has used publicly to identify the intervention, including, but not limited to, past and present names, such as brand name(s)...’
<p>National Institute for Health Research, INVOLVE. Plain English summaries.</p> <p>https://www.invo.org.uk/resource-centre/plain-english-summaries/. Accessed April 3, 2019.</p> <p>National Institute for Health Research, INVOLVE. Make it clear.</p> <p>https://www.invo.org.uk/makeitclear/. Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Brand name use – Not explicitly addressed in these guidance documents, but the principle of using familiar versus technical words is reinforced (generic names may be longer, more complicated, and less familiar to the target audience than brand names). – ‘Avoid wherever possible using jargon, abbreviations and technical terms – if you have to use them provide a clear explanation’; ‘Avoid complicated English or uncommon words’ (‘Never use a long word when a short one will do.’ George Orwell, <i>Politics and the English Language</i>).

Guideline	Comment
<p>TransCelerate Biopharma Inc. Layperson summaries of clinical trials – an implementation guide.</p> <p>http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/02/Implementation-Recommendations_20Jan17_Final.docx. Draft January 20, 2017.</p> <p>Accessed April 3, 2019.</p> <p>Refers to EU CTR No 536/2014 – <i>lay summaries required for all interventional phase 1 to 4 trials with ≥1 EU site; posted 12 months after Last Subject Last Visit</i></p>	<ul style="list-style-type: none"> • Q&A box to prompt shared decision-making <ul style="list-style-type: none"> – ‘Risk of misinterpretation is likely to be reduced when a statement in the lay summary is included to discourage any therapeutic changes before consulting a physician/healthcare professional (PLS: Include direct and specific prompt for the reader to discuss PLS content with HCPs).’ • Operational excellence, eg, need for SOP guidance, resources, updates to global transparency policies. • Archiving PLS. • Need additional distribution systems (ie, posting to EU CTR database is insufficient for all lay summaries). <ul style="list-style-type: none"> – Benefits associated with a multi-sponsor platform (ie, single place for access). – No links to promotional webpages – landing page must be free of any commercial bias. • No IRB review required. • Cultural and regional differences must be considered. • Providing links – recommends referring reader to further information. • Endpoint reporting – prioritise primary endpoints, avoid secondary/exploratory unless adequately powered (perception of cherry-picking, risk of misleading audience).
<p>Multi-Regional Clinical Trials, The MRCT Center of Brigham and Women’s Hospital and Harvard. Return of aggregate results to participants toolkit version 3.1.</p> <p>https://mrctcenter.org/wp-content/uploads/2017/12/2017-12-07-MRCT-Return-of-Aggregate-Results-Toolkit-3.1.pdf.</p> <p>Published November 22, 2017.</p> <p>Accessed April 3, 2019.</p> <p>(50+ stakeholders from patient advocacy, academia, pharmaceutical industry)</p>	<ul style="list-style-type: none"> • Brand name use <ul style="list-style-type: none"> – Examples of PLS provided include both generic and brand names. <p>Example from Harvard/Dana Farber: <i>The purpose of this trial was to evaluate the effectiveness of two treatments taken for 12 weeks, prior to surgery (Vinorelbine (navabine)/Herceptin (trastuzumab): VH or Taxotere (docetaxol)/Carboplatin/Herceptin: TCH) in shrinking the breast cancer tumor.</i></p> <p>Example from Alliance for Clinical Trials in Oncology: <i>All patients in Group A got the common mix of drugs called doxorubicin (Adriamycin®), cyclophosphamide (Cytoxan®), and paclitaxel (Taxol®), which are known as AC+T.</i></p> <ul style="list-style-type: none"> – 2016: If drug names are used, consider including both generic and brand names®. If brand names are not used, help participants find brand names elsewhere. • 2017: If drug names are used, list both generics and where brand names® can be found. ‘Real-world’ examples from industry where PLS of clinical trial results have used both brand and generic names can be found online.

Guideline	Comment
<p>Cochrane. Standards for the reporting of Plain Language Summaries in new Cochrane Intervention Reviews (PLEACS) version 3.0. https://methods.cochrane.org/sites/default/files/public/uploads/PLEACS_0.pdf. Published February 28, 2013. Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Title in PL (PLS 2) • Study population description (PLS 8); disease severity, age, sex. • Results (PLS 10); primary outcome and secondary outcomes 'that are important to patients.' <ul style="list-style-type: none"> – Recommended terms to describe certainty of evidence (PLS 10); uncertain, little, probably, may, will. • Plain-language principles, eg, active voice, avoid jargon. • Plain-language title. • Present information in a consistent order under standard (bolded) headings. • Include study characteristics 'so that the reader can assess the applicability of the information.' • Include funding sources. • Endpoints: all primary and key secondary, acknowledge all patient-centred outcomes. <ul style="list-style-type: none"> – Numerical data: natural frequencies for dichotomous outcomes, mean differences or scales for continuous outcomes.
<p>Centers for Disease Control and Prevention. Simply put: a guide for creating easy-to-understand materials. https://www.cdc.gov/healthliteracy/pdf/Simply_Put.pdf. 3d edition April 2009. Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Font size <ul style="list-style-type: none"> – Use font sizes between 12 and 14 points. Anything less than 12 points can be too small to read for many audiences. Older people and people who have trouble reading or seeing may need larger print.
<p>Plain English Campaign. Guide to design and layout. http://www.plainenglish.co.uk/design-and-layout.html. Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Font size <ul style="list-style-type: none"> – 'Aim for a font size of 12 point. If you are pushed for space, you can go down to 10 point, but don't go below that.' – 'The Royal National Institute for the Blind recommends a minimum font size of 14 point for readers who are likely to be blind or partially sighted. For headings, use a font size at least 2 points bigger than the body text.'

Guideline	Comment
<p>Bristol-Myers Squibb. The universal patient language. https://www.upl.org/ Published March 2017. Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Guidance on visuals (icons, photos, graphics library). • Numeracy recommendations (eg, percentage and normalised frequency, ie, 218 out of 256). • Document suitability – SAM.
<p>National Center for Health Marketing, Centers for Disease Control and Prevention. Plain language thesaurus for health communications, version 3. https://www.orau.gov/hsc/HealthCommWorks/MessageMappingGuide/resources/CDC%20Plain%20Language%20Thesaurus%20for%20Health%20Communication.pdf Draft October 2007. Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Purpose of plain language <ul style="list-style-type: none"> – ‘While the plain language choices given here may not have the specific nuances of meaning that technical terms have, they offer the possibility for better understanding by your audience. With plain language equivalents, it is more important to be understood than to be medically precise.’
<p>Duke M, Patients Participate! project. How to write a lay summary. DCC How-to Guides. Edinburgh: Digital Curation Centre. http://www.dcc.ac.uk/resources/how-guides/write-lay-summary Published December 2012. Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • PLS development guidance, eg, <ul style="list-style-type: none"> – Plain-language principles. – Answer the essential questions: who, what, where, when, why, how? – Person-centred language, eg, ‘people with...’ • ‘Next to no research is available on what makes a good summary and there is a scarcity of evidence of lay summaries and guidelines being tested for effectiveness.’
<p>European Federation of Pharmaceutical Industries and Associations. Reflection paper: EFPIA guiding principles on layperson summary. https://www.efpia.eu/media/25661/reflection-paper-efpia-guiding-principles-on-layperson-summary.pdf Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Guidance on implementing Annex V – aligns with EU expert group recommendations (see below).

Guideline	Comment
<p>European Commission. Summaries of clinical trial results for laypersons: recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use. Version 2.</p> <p>https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf.</p> <p>Updated February 22, 2018.</p> <p>Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Guidance on implementing Annex V. • Covers plain-language principles, readability, numeracy, visuals, non-promotional language, translation. • PLS isn't the only way to communicate with trial participants: recommends acknowledging/thanking them. • For PLS of clinical trial results, need to include all 10 elements of Annex V but can combine/reorder/expand categories if this improves PLS quality.
<p>Salita JT. Writing for lay audiences: a challenge for scientists. <i>Medical Writing</i>. 2015;24(4):183-189.</p> <p>https://journal.emwa.org/writing-for-lay-audiences/writing-for-lay-audiences-a-challenge-for-scientists/.</p> <p>Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Consider scientific terms that have different meanings for lay audiences and choose alternatives. • Inverted pyramid structure. • Templates and forms are helpful. • Provide a process for users to evaluate PLS. • Produce at different readability levels and via different channels.
<p>Cancer Research UK. Style guide for health and patient information pages.</p> <p>https://www.cancerresearchuk.org/about-cancer/about-our-information/style-guide.</p> <p>Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • Consider tone and sensitivity: authoritative and concise, but acknowledging emotional topics, eg, coping with side effects, survival. • Plain-language principles, eg, active voice, sentence length max 16 words, avoid jargon, define technical terms, avoid italics/caps/underlining and use bolding only where helpful for emphasis.

Template element	Reference	Comment
Text	<p>Plavén-Sigraý P, Matheson GJ, Schiffler BC, Thomson WH. The readability of scientific texts is decreasing over time. <i>eLife</i>. 2017; 6:pil e27725. https://elifesciences.org/articles/27725. Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • 709,577 abstracts between 1881 and 2015 in 123 journals. • Readability has significantly decreased (increase in scientific jargon, decrease in familiar words). • Abstracts significantly less readable than full manuscripts (PLS: Extra effort required to make PLS of abstracts). • More authors = significantly less readable.
	<p>Buljan I, Tokalić R, Puljak L, Zakarija Grković I, Marušić A. Identifying optimal characteristics of Cochrane systematic review summary formats: qualitative study and three randomized controlled trials. Oral presentation at Cochrane Colloquium, Edinburgh, 2018. https://abstracts.cochrane.org/identifying-optimal-characteristics-cochrane-systematic-review-summary-formats-qualitative-study-and Accessed April 3, 2019.</p>	<ul style="list-style-type: none"> • RCT of biomed students. • No difference in understanding between positively and negatively framed results text.
	<p>Raynor DK, Myers L, Blackwell K, Kress B, Dubost A, Joos A. Clinical trial results summary for laypersons: a user testing study. <i>Ther Innov Regul Sci</i>. 2018;52(5):606-628.</p>	<ul style="list-style-type: none"> • User testing of PLS (people with differing literacy levels). • Explicit statement as to whom the PLS is for (ie, the public). • Use short and simple sentences. • Delete unnecessary words. • Place key words near the start of the bullet point. • Even high health literacy readers valued the PL text approach (counters assertion that PL text 'too simplistic').
Jargon (technical terms explained)	<p>Raynor DK, Myers L, Blackwell K, Kress B, Dubost A, Joos A. Clinical trial results summary for laypersons: a user testing study. <i>Ther Innov Regul Sci</i>. 2018;52(5):606-628.</p>	<ul style="list-style-type: none"> • User testing of PLS (people with differing literacy levels). • Better understanding of lay terms used first then technical terms (offset in some way, eg, inverted commas or parentheses). • Don't use 'primary finding' – use descriptive terms (eg, symptoms).

Template element	Reference	Comment
Disclaimer box	Raynor DK, Myers L, Blackwell K, Kress B, Dubost A, Joos A. Clinical trial results summary for laypersons: a user testing study. <i>Ther Innov Regul Sci</i> . 2018;52(5):606-628.	<ul style="list-style-type: none"> • User testing of PLS (people with differing literacy levels). • Statement re: putting results of one study in context needs to be highlighted or users may miss it.
Layout	Fearns N, Kelly J, Callaghan M, et al. What do patients and the public know about clinical practice guidelines and what do they want from them? A qualitative study. <i>BMC Health Serv Res</i> . 2016;16:74.	<ul style="list-style-type: none"> • User testing of clinical guideline PLS. • 'Chunking' of text, use of images, bullet point lists, strong colours, clear headings increased visual appeal.
	Raynor DK, Myers L, Blackwell K, Kress B, Dubost A, Joos A. Clinical trial results summary for laypersons: a user testing study. <i>Ther Innov Regul Sci</i> . 2018;52(5):606-628.	<ul style="list-style-type: none"> • User testing of PLS (people with differing literacy levels). • Use colour and bold text for main headings. • Shorter line lengths easier for people with low literacy. • Make the PL title prominent. • Use lay-friendly headings (question format) and subheadings to help users navigate PLS. • Numbering main headings can help users navigate PLS (80% of users preferred numbered headings).
	Santesso N, Rader T, Nilsen ES, et al. A summary to communicate evidence from systematic reviews to the public improved understanding and accessibility of information: a randomized controlled trial. <i>J Clin Epidemiol</i> . 2015;68(2):182-190.	<ul style="list-style-type: none"> • RCT with n = 143 members of the public in 5 countries. • 'New' PLS format (structured, question headings, but no visuals) was better. Understood, easier to use, helped with decision-making than old PLS format (text paragraph). • However, only 65% participants could answer most comprehension questions correctly – not ideal.

Template element	Reference	Comment
Layout	Boudewyns V, O'Donoghue AC, Kelly B, et al. Influence of patient medication information format on comprehension and application of medication information: A randomized, controlled experiment. <i>Patient Educ Couns.</i> 2015;98(12):1592-1599.	<ul style="list-style-type: none"> FDA research – RCT on format/length of patient information leaflet (summary). Better understanding with format that included more white space, visual cues (eg, shading, boxes), chunked text, less content (focus on content most important to patients; 1 page vs 4 pages), plain language text.
Numeracy	Tubau E, Rodrigues-Ferreiro J, Barberia I, Colomé A, et al. From reading numbers to seeing ratios: a benefit of icons for risk comprehension. <i>Psychol Res.</i> 2018. [Epub ahead of print].	<ul style="list-style-type: none"> Promotes use of icon arrays versus just percentages or natural frequencies. 'We analyzed individual risk estimates based on data presented either in standard verbal presentations (percentages and natural frequency formats) or as icon arrays. Compared to the other formats, icons led to estimates that were more accurate...'
	Sirota M, Juanchich M, Petrova D, Garcia-Retamero R, Walasek L, Bhatia S. Health professionals prefer to communicate risk-related numerical information using "1-in-X" ratios. <i>Med Decis Making.</i> 2018;38(3):366-376.	<ul style="list-style-type: none"> HCPs in UK prefer to communicate with patients using natural frequencies. 'The use of the "1-in-X" ratio is prevalent and that health professionals prefer this format compared with other numerical formats (i.e., the "N-in-N*X", %, and decimal formats).'
	Woloshin S, Schwartz, LM. Communicating data about the benefits and harms of treatment: a randomized trial. <i>Ann Intern Med.</i> 2011;155(2):87-96.	<ul style="list-style-type: none"> Challenges use of natural frequency (eg, 1 in 10) as best way to communicate treatment benefit and risk. Their study showed that percentage was best understood and variable frequency the least understood. Percentage + natural frequency was no better than percentage alone.
	Buljan I, Tokalić R, Puljak L, Zakarija Grković I, Marušić A. Identifying optimal characteristics of Cochrane systematic review summary formats: qualitative study and three randomized controlled trials. Oral presentation at Cochrane Colloquium, Edinburgh, 2018. https://abstracts.cochrane.org/identifying-optimal-characteristics-cochrane-systematic-review-summary-formats-qualitative-study-and . Accessed April 3, 2019.	<ul style="list-style-type: none"> Double-blind crossover trial – % versus natural frequencies. No difference in understanding between % or frequencies.

Template element	Reference	Comment
Numeracy	Glenton C, Santesso N, Rosenbaum S, et al. Presenting the results of Cochrane Systematic Reviews to a consumer audience: a qualitative study. <i>Med Dec Making</i> . 2010;30(5):566-577.	<ul style="list-style-type: none"> • User testing of Cochrane PLS. • Absolute numbers and natural frequencies were easy to understand. • Use of symbols can help convey quality of evidence. • Confidence intervals ignored or misunderstood. • Footnotes often not noticed.
Visuals	Fearns N, Kelly J, Callaghan M, et al. What do patients and the public know about clinical practice guidelines and what do they want from them? A qualitative study. <i>BMC Health Serv Res</i> . 2016;16:74.	<ul style="list-style-type: none"> • User testing of clinical guideline PLS. • Negative images highly undesirable. • Simple icons desirable with text descriptor = instant messaging (eg, question mark if evidence is uncertain, green tick = strong evidence); vague icons cause confusion/risk of misinterpretation. • Use colour that leverages people's pre-existing associations with colour (eg, green = go/good; red = stop/bad); Note – need to take cultural colour associations into account. • Pie charts easier to interpret than bar graphs.
	Buljan I, Malički M, Wager E, et al. No difference in knowledge obtained from infographic or plain language summary of a Cochrane systematic review: three randomized controlled trials. <i>J Clin Epidemiol</i> . 2018;97:86-94.	<ul style="list-style-type: none"> • RCTs with university students, consumers, HCPs to compare 3 formats for summarizing Cochrane SR: abstract, text-only PLS, infographic PLS. • All 3 groups preferred infographic PLS – higher ratings for reading experience and user friendliness, but no difference detected for knowledge gained.
	Buljan I, Tokalić R, Puljak L, Zakarija Grković I, Marušić A. Identifying optimal characteristics of Cochrane systematic review summary formats: qualitative study and three randomized controlled trials. Oral presentation at Cochrane Colloquium, Edinburgh, 2018. https://abstracts.cochrane.org/identifying-optimal-characteristics-cochrane-systematic-review-summary-formats-qualitative-study-and . Accessed April 3, 2019.	<ul style="list-style-type: none"> • Double-blind parallel trial – text-only PLS versus blogshot. • Higher understanding by students and consumers of blogshot; consumers preferred blogshot (PLS: Consider visuals, social media blogshot to complement PLS).

Template element	Reference	Comment
Visuals	Raynor DK, Myers L, Blackwell K, Kress B, Dubost A, Joos A. Clinical trial results summary for laypersons: a user testing study. <i>Ther Innov Regul Sci</i> . 2018;52(5):606-628.	<ul style="list-style-type: none"> User testing of PLS (people with differing literacy levels). Consider direction of bars in graphs – increases going up can be associated with improvement (eg, improved control – have bars go up, not down).
	Kasper J, van de Roemer A, Pöttgen J, et al. A new graphical format to communicate treatment effects to patients – a web-based randomized controlled trial. <i>Health Expect</i> . 2017; 20(4):797-804.	<ul style="list-style-type: none"> Icon array (eg, 100 people pictograph) was understood as well as a new format Animating the graphics reduced understandability (PLS: Be careful with animation!).
	Snyder CF, Smith KC, Bantug ET, et al. What do these scores mean? Presenting patient-reported outcomes data to patients and clinicians to improve interpretability. <i>Cancer</i> . 2017;123(10):1848-1859.	<ul style="list-style-type: none"> PCORI-funded study; RCT n = 1163 (patients, HCPs, researchers) on how to present PRO results. Graphs better understood if red threshold lines used to convey 'concerning' scores (better than using green shading or circling scores in red dots) (PLS graphs – consider use of threshold lines). Graphs better understood if direction upwards conveyed 'better' versus 'more'. Note text labels used on graphs. (PLS graphs – use text descriptors on y-axis and direct lines upwards to mean better.)
Q&A box (prompts for 'shared decision-making' action for reader)	Curtis JR, Downey L, Back AL, et al. Effect of a patient and clinician communication-priming intervention on patient-reported goals-of-care discussions between patients with serious illness and clinicians: a randomized clinical trial. <i>JAMA Intern Med</i> . 2018;178(7):930-940.	<ul style="list-style-type: none"> RCT on pre-conversation communication priming intervention. Question primer significantly increased shared decision-making (ie, goal of care discussion) at clinic visit. Question primer significantly increased patient-rated quality of communication with clinician. 'Prompting goal-of-care communication is a high priority...offers opportunities for patients to identify their goals and for clinicians and patients to jointly facilitate goal attainment.'

Template element	Reference	Comment
Q&A box (prompts for 'shared decision-making' action for reader)	Fearns N, Kelly J, Callaghan M, et al. What do patients and the public know about clinical practice guidelines and what do they want from them? A qualitative study. <i>BMC Health Serv Res.</i> 2016;16:74.	<ul style="list-style-type: none"> • User testing of clinical guideline PLS • Provide sufficient information to facilitate shared decision-making • Value and usefulness of PLS increased if link information to action and empower people in their interaction with healthcare professionals.
	Lee K, Hoti K, Hughes JD, Emmerton L. Dr Google is here to stay but health care professionals are still valued: an analysis of health care consumers' internet navigation support preferences. <i>J Med Intern Res.</i> 2017;19(6):e210.	<ul style="list-style-type: none"> • Relationship with HCP and online information; 400 adults. • Consumers want to involve their HCP to help them with information obtained online (PLS: Support patient/HCP relationship through Q&A prompt).
	Buljan I, Tokalić R, Puljak L, Zakarija Grković I, Marušić A. Identifying optimal characteristics of Cochrane systematic review summary formats: qualitative study and three randomized controlled trials. Oral presentation at Cochrane Colloquium, Edinburgh, 2018. https://abstracts.cochrane.org/identifying-optimal-characteristics-cochrane-systematic-review-summary-formats-qualitative-study-and . Accessed April 3, 2019.	<ul style="list-style-type: none"> • Focus groups – students, HCPs, consumers. • Problems with use of evidence in the real world b/c of inefficient communication b/w pts and drs (PLS: Support real-world communication about evidence with Q&A prompt).
	See also...	<ul style="list-style-type: none"> • 'Real world' examples from industry where PLS of clinical trial results include shared decision-making prompts (ie, discuss information with your doctor) can be found online.

Template element	Reference	Comment
Links to other information	Fearns N, Kelly J, Callaghan M, et al. What do patients and the public know about clinical practice guidelines and what do they want from them? A qualitative study. <i>BMC Health Serv Res.</i> 2016;16:74.	<ul style="list-style-type: none"> • User testing of clinical guideline PLS. • Important to provide contact details. • Links to additional information are highly valued.
PLS author credentials	Thon F, Jucks R. Believing in expertise: how authors' credentials and language use influence the credibility of online health information. <i>Health Commun.</i> 2017;32(7)828-836.	<ul style="list-style-type: none"> • Online information seekers reward authors' credentials (higher expertise = more credible, higher integrity) and punish use of technical language (more jargon = less credible, lower integrity). Providing cues on expertise, especially if verifiable, is recommended (eg, PLS: CMPP can be verified for free through the open access ISMPP CMPP Directory). Use plain language – avoid jargon.
	Fearns N, Kelly J, Callaghan M, et al. What do patients and the public know about clinical practice guidelines and what do they want from them? A qualitative study. <i>BMC Health Serv Res.</i> 2016;16:74.	<ul style="list-style-type: none"> • User testing of clinical guideline PLS. • Credibility higher if qualified professionals involved (PLS: cite qualifications and CMPP).
Delivery	Buljan I, Tokalić R, Puljak L, Zakarija Grković I, Marušić A. Identifying optimal characteristics of Cochrane systematic review summary formats: qualitative study and three randomized controlled trials. Oral presentation at Cochrane Colloquium, Edinburgh, 2018. https://abstracts.cochrane.org/identifying-optimal-characteristics-cochrane-systematic-review-summary-formats-qualitative-study-and . Accessed April 3, 2019.	<ul style="list-style-type: none"> • Comprehension by students and patients of CSR results. • Blogshots preferred over a PLS (see below for more information on blogshots).

Template element	Reference	Comment
Delivery	Fearns N, Kelly J, Callaghan M, et al. What do patients and the public know about clinical practice guidelines and what do they want from them? A qualitative study. <i>BMC Health Serv Res.</i> 2016;16:74.	<ul style="list-style-type: none"> • User testing of clinical guideline PLS. • Print versions should be made available.
Assessment readability	Zhou S, Jeong H, Green PA, et al. How Consistent Are the Best-Known Readability Equations in Estimating the Readability of Design Standards? <i>IEEE Trans Prof Commun.</i> 2017;60(1):97-111.	<ul style="list-style-type: none"> • Common readability tools give inconsistent results. • Differences due to how tools assessed hyphens, slashes, numbers, abbreviations, acronyms, URLs, other punctuation and text elements (PLS: do not rely on common readability tools to assess PLS).
	Badarudeen S, Sabharwal S. Assessing readability of patient education materials: current role in orthopaedic. <i>Clin Orthop Relat Res.</i> 2010;468(10):2572-2580.	<ul style="list-style-type: none"> • Audiovisual aids can improve comprehension of patient education materials but most readability tools don't assess them. • Suitability Assessment of Materials (SAM) does but 'is relatively time consuming, inherently subjective and has not been validated as extensively as some of the other readability formulas.'
Assessment document suitability (ie beyond 'readability')	Shoemaker SJ, Wolf MS, Brach C. Development of the Patient Education Materials Assessment Tool (PEMAT): a new measure of understandability and actionability for print and audiovisual patient information. <i>Patient Educ Couns.</i> 2014; 96(3):395-403.	<ul style="list-style-type: none"> • Demonstrated the validity and reliability of using the Patient Education Materials Assessment Tool (PEMAT) to assess 'the understandability and actionability for print and audiovisual patient information'.
	Vishnevetsky J, Walters CB, Tan KS. Interrater reliability of the Patient Education Materials Assessment Tool (PEMAT). <i>Patient Educ Couns.</i> 2018;101(3):490-496.	<ul style="list-style-type: none"> • Demonstrated high inter-rater reliability of the Patient Education Materials Assessment Tool (PEMAT).

Template element	Reference	Comment
Assessment document suitability (ie beyond 'readability')	LeBrun M, DiMuzio J, Beauchamp B, Reid S, Hogan V. Evaluating the health literacy burden of Canada's public advisories: a comparative effectiveness study on clarity and readability. <i>Drug Saf.</i> 2013;36(12):1179-1187.	<ul style="list-style-type: none"> Describes the use of the Suitability Assessment of Materials (SAM) tool and how it considers a 'greater array of health literacy factors than readability tests.' Original SAM document available here: http://aspiruslibrary.org/literacy/SAM.pdf (Validity testing of SAM described in Doak C, Doak LG, Root JH. Assessing suitability of materials. In: Belcher M, editor. <i>Teaching Patients With Low Literacy Skills</i>. Philadelphia: J. B. Lippincott Company; 1996.)
Guidelines for writing PLS	Kadic AJ, Fidarhic M, Vujcic M, et al. Cochrane plain language summaries are highly heterogeneous with low adherence to the standards. <i>BMC Med Res Method.</i> 2016;16:61.	<ul style="list-style-type: none"> Cochrane PLS (n = 1738); adherence to Plain Language Summaries in new Cochrane Intervention Reviews (PLEACS). Not a single PLS adhered to all of the PLEACS items. Guidelines insufficient to ensure quality PLS (PLS: Need trained team and guidelines to support PLS quality).
	Barnfield S, Pitts, AC, Kalaria R, Allan L, Tullo E. "Is all the stuff about neurons necessary?" The development of lay summaries to disseminate findings from the Newcastle Cognitive Function after Stroke (COGFAST) study. <i>Res Involv Engagem.</i> 2017;3:18.	<ul style="list-style-type: none"> Focus group (members of public) reviewed 4 PLS and made following changes: <ul style="list-style-type: none"> Replace jargon Omit numbers Prepare separate glossary Use Q&A layout Include visuals Omit graphs and tables Include a 'quick-read' summary. Recommends collaborating with patients and the public to assess readability and comprehension rather than relying on existing guidelines.

Guideline	Comment
<p>Chapman, S. Pineapples and stethoscopes. The problem with stock images. Evidently Cochrane.</p> <p>http://www.evidentlycochrane.net/stock-images-health-evidence/</p> <p>Published August 31, 2017. Accessed April 4, 2019.</p>	<ul style="list-style-type: none"> • Avoid negative stereotypes ('no more wrinkly hands' for elderly images). • Choose with care, be reflective if image is criticised, but you can't please everyone all the time. • Show diversity in people you feature, be accurate in clinical situations, be respectful and authentic.
<p>Chapman, S. Blogshots – making evidence short and shareable for social media. Evidently Cochrane.</p> <p>http://www.evidentlycochrane.net/blogshots-making-evidence-social-media/</p> <p>Published April 20, 2018. Accessed April 4, 2019.</p>	<ul style="list-style-type: none"> • Blogshots – images, brief information (key message), link to original source are becoming increasingly popular. • Shared on social media. • Used to include quality of evidence (GRADE) evaluation via simple icon, but now not including this (focus audience on key message). • Blogshot template but tailored to different audiences. • Archived and downloadable.
<p>Schrivver K. Plain language in the US gains momentum: 1940–2015. <i>IEEE Trans Prof Comm.</i> 2017;60(4)343–383.</p>	<ul style="list-style-type: none"> • PL has evolved in the last 75 years – focus shifting from how people understand content to whether people trust content. • Most readability formulas are outdated; usability testing is preferred. • PLS works for young and old, experts and novices, English as first or second language.
<p>Patient advocacy views at ESMO 2018; insights gained by Envision Pharma Group staff speaking, with ESMO's permission, to patient advocacy exhibitors</p>	<ul style="list-style-type: none"> • Both brand and generic names should be used (consistent finding from all advocates surveyed). • Layout/visuals matter – PLS template had strong visual appeal – graphics were praised (pure text PLS were not favoured). • Online delivery is required. • Q&A prompt was useful and acceptable, ie, comfortable to discuss PLS with others.
<p>Patient partner PLS reviewers (part of Envision Pharma Group PLS team)</p>	<ul style="list-style-type: none"> • Brand name. <ul style="list-style-type: none"> – 'Can you include the brand name XXX? (it's included in the notes at the bottom of the poster). It's just that many MS patients (and others) will know drugs by brand names rather than the chemical name – YYYY won't necessarily mean much to them.'