Primer on Plain Language Summaries for Advanced Practice Providers With Published Examples and Practical Applications to Practice

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Abstract

Understanding clinical information can be challenging for patients, their caregivers, and other lay audiences because of complex scientific concepts, interventions, procedures and/or evaluated outcomes. It is also challenging for health-care providers to effectively communicate such medical research to patients, which is essential for patients' informed involvement in shared decision-making (SDM). Advanced practice providers (APPs) are on the frontlines of care, often providing detailed and extensive education for patients in and outside of clinical trials. In recent years, scientific researchers, particularly those involved in clinical trial research, have been increasingly using plain language summaries (PLS) to summarize journal publications and conference abstracts in easy-to-read nontechnical language while providing key findings and implications. In this review article, we aim to provide an overview of PLS and show by using published examples, how such communication tools may assist APPs to communicate medical research effectively to patients. This evolving form of scientific communication may be useful to APPs, not only for translating the findings of clinical trials and other health-care research to patients and their caregivers, but also facilitate informed SDM, help them keep up to date on the latest clinical research, and share research perspectives with their care teams.

Clinical and biomedical research help to advance medical knowledge and the development of medicines and treatment interventions, which in turn improves patient outcomes. Clinical research investigators publish their findings on the efficacy and safety of medical interventions in scholarly journals and conference proceedings to transfer knowledge, typically to a targeted

audience or other research colleagues and health-care professionals. This published information is then used to guide treatment decisions and enhance the quality of patient care. Shared decision-making (SDM), as a model of care, has internationally become a centerpiece in health policy and initiatives for the improvement of the quality of health care (European Cancer Organization, 2024; United States House of Representatives, 2010).

Shared decision-making refers to a collaborative approach between health-care providers (HCPs) and patients, in which HCPs communicate and educate patients with the best evidence on the potential benefits and harms of medical care options; the goal of SDM is a mutual and informed selection of the preferred course of action (Elwyn et al., 2012; Elwyn et al., 2010). With the long-awaited, and currently still ongoing, paradigm shift from physician-centric decision making to SDM, there is a demand for the development and use of evidence-based material to aid in the translation of clinical and biomedical research (Stacey et al., 2016).

The approach of SDM is heavily reliant on health literacy, a determinant of health and a skill that can be improved with communication and education (Muscat et al., 2021a). The definition of health literacy was updated in the Healthy People 2030 initiative by the United States Department of Health and Human Services. This updated definition emphasizes that individuals should not only understand health information but also be able to use it effectively to make well-informed decisions. It also highlights the responsibility of organizations in supporting the improvement of personal health literacy (National Institutes of Health, 2021). Advanced practice providers (APPs) include nurse practitioners, clinical nurse specialists, advanced degree nurses, physician assistants, and clinical pharmacists. Advanced practice providers are typically on the frontlines of care, often providing detailed and extensive education for patients in and outside of clinical trials, and are positioned to influence personal health literacy, and thereby active participation in SDM (Faiman & Tariman, 2019).

With widespread availability of the internet starting in the mid-1990s (Fox & Rainie, 2014) came the open access movement, which sought, without barriers, to provide peer-reviewed scientific research to anyone (Edgell & Rosenberg, 2022; Mielke et al., 2020). While open access increases transparency in clinical and biomedical research (Logullo et al., 2023; Tennant et al., 2016), there arises a significant challenge for its understanding by people who do not have the relevant education. Plain language summaries (PLS) of peer-reviewed journal publications and conference presentations (Table 1) have since emerged as a preferred and effective method to engage a wider non-expert audience in clinical and biomedical research (Bredbenner & Simon, 2019; Dormer et al., 2022; Rosenberg et al., 2021).

First appearing in 2010 in the *British Journal of Dermatology*, the communication of clinical research in plain language became the next step in research openness (Dormer et al., 2022; FitzGibbon et al., 2020). The National Institutes of Health (NIH) and a multitude of other government organizations fully support the Plain Language initiative, a Federal directive requiring agencies to incorporate plain language in materials that communicate health information to the public (National Institutes of Health, 2024). The Good Publication Practice (GPP) guidelines, last updated in 2022, now state as a principle to promote transparency that "publications should support communication of scientific information to lay audiences through PLS and other accessible formats" (DeTora et al., 2022). This evolving form of scientific communication may be useful to APPs to translate findings of clinical trials and other health-care research to patients and their caregivers, facilitate informed SDM, help keep up to date on the latest clinical research, and share research perspectives with their care teams.

WHAT ARE PLAIN LANGUAGE SUMMARIES?

Plain language summaries are brief summaries of journal publications and conference abstracts that describe the key findings and implications of scientific research in easy-to-read, nontechnical language (Dormer et al., 2022; Smith, 2021). It has been recommended that the minimum standard of a PLS "should be in the style of an abstract, understandable and readable, free of technical jargon, unbiased, non-promotional, peer reviewed, and easily accessed" (Rosenberg et al., 2021). Plain language summaries first appeared as a requirement

Table 1. Types of Plain Language Summaries

Type	Abbreviation	Description
Plain language summary (text)	PLS	A text paragraph published within an article, usually following the abstract; it shares the article's DOI
PLS of publication	PLSP	A standalone article published with its own DOI; the article summarized is cited as a reference
PLS of abstract	aPLS	A text paragraph summarizing content in a conference abstract; available at conference website or online sponsor platform
PLS (graphical)	None	An infographic within an article, usually following the abstract and text PLS; it shares the article's DOI
PLS (video)	None	A brief (~5 minute) audiovisual video that summarizes the key results reported in an article; it shares the article's DOI

Note. DOI = digital object identifier. Information from Bredbenner & Simon (2019); Taylor & Francis (2024).

for reporting clinical trial results to the public in the European Union's 2014 Clinical Trials Regulation (EU CTR; No 536/2014; Barnes & Patrick, 2019; European Parliament and the Council, 2014); however, the regulation did not proceed to full application until January 31, 2022 (European Medicines Agency, 2023). Plain language summaries are not a requirement for clinical studies in the United States (US); however, the Food & Drug Administration (FDA) has provided draft guidance to assist in their voluntary submission (US Food & Drug Administration, 2017). The EU requirement and US FDA guidance on PLS were driven by suggestions from clinical study participants, patient advocacy groups, and, at some level, also the general public, for increased transparency in the dissemination of information on clinical studies with the goal of building trust and partnership, in addition to patient engagement (Barnes & Patrick, 2019).

Plain language summaries are becoming a valuable addition to clinical and biomedical research publications as they act as a resource to improve the communication of complex medical research, mitigate misinterpretation and misinformation, and enhance communication between HCPs and patients (Bredbenner & Simon, 2019; Dormer et al., 2022; Taylor & Francis News, 2023). With the regulatory mandate of including a lay summary with clinical trial reports in the EU (European Parliament and the Council, 2014) and the potential for similar forthcoming regulations in other countries, PLS in the near future will likely become routine practice in publishing, particularly in the scientific fields of clinical and biomedical research.

Initially, a PLS of a peer-reviewed journal publication only referred to a brief lay summary, approximately a paragraph in length, that accompanied the original publication and shared the same digital object identifier (DOI; Taylor & Francis Group, 2023). Recently, some publishers have introduced a PLS of a publication (PLSP; Future Medicine, 2024; Sage Publications, 2024; Taylor & Francis Group, 2023). A PLSP is a standalone, peer-reviewed, short-form summary that communicates only the scientific evidence provided in the original clinical research publication in easy-to-understand language and infographics focusing on summarizing the primary and secondary endpoints, relevant patient data, and safety endpoints (Sage Publications, 2024; Taylor & Francis Group, 2023). A PLSP is considered an acceptable secondary publication by the International Committee of Medical Journal Editors (ICMJE) and is fully citable with its own DOI (ICMJE, 2024; Sage Publications, 2024). Publishers are encouraging the inclusion of patients and other stakeholders in the development of a PLSP (Sage Publications, 2024; Taylor & Francis Group, 2023), which is also recommended for a PLS (Dormer et al., 2022). Presently, the guidelines for the development and content of a PLSP are evolving as more publishers begin to allow them as a standalone article type.

WHAT ARE THE PURPOSE AND BENEFITS OF PLS?

Originally, the purpose of a PLS was to communicate in an easy-to-understand manner clinical trial results to participants and the general public

who had an interest in trial findings but limited expertise (Barnes & Patrick, 2019). In 2022, the GPP guidelines on PLS extended their mandate to include all publications with clinical information on a marketed product (DeTora et al., 2022), including real-world evidence studies, such as health economics and outcomes research (Dormer, 2022). Dissemination and uptake of PLS is expected to yield societal health benefits of awareness and informed decision making, accelerated trial recruitment, and greater public discussion in the development of medicines and treatment interventions (Penlington et al., 2022). An analysis of data from the US Health Information National Trends Survey (2020) reported 41% of 3,772 adults did not know of clinical trials, and 73% responded that their most trusted source of information was HCPs (Yadav et al., 2022). The call to action by Yadav et al. was to use multimodal approaches to reduce this knowledge gap, including improved patient-HCP communication of clinical trial opportunities. Surveys of clinical trial participants have found that reporting trial results is of considerable importance to participants and is preferred throughout the entire trial process (Innes et al., 2018; Shiely & Daly, 2023).

WHO ARE THE TARGET AUDIENCES OF A PLS?

A PLS is intended for all people who are not experts (nonmedical/nonacademic) but who are engaged in medical care, including patients and their advocates and caregivers, policymakers, and the general public (Gainey et al., 2023; Rosenberg et al., 2021). Physicians and APPs, while formally educated and comfortable in reading and understanding clinical and biomedical research publications in their entirety, may find a PLS useful not only when they are engaging with their patients, but also when time is too short to fully read a scientific manuscript or when the subject matter is not their specialty (Edgell & Rosenberg, 2022).

WHERE CAN PLS BE ACCESSED?

A PLS may be accessed alongside an open access publication at the journal site either directly below the scientific abstract, within the online supplementary materials, or on adjacent or separate online platforms (e.g., social media, dedicated website: https://www.tandfonline.com/topic/article-features/plain-language-summary; Edgell & Rosenberg, 2022; FitzGibbon et al., 2020). Greater accessibility to PLS came in February 2019, when the National Library of Medicine announced that PubMed would display a text-based PLS directly below a scientific abstract when supplied by the publisher (Collins, 2019). However, a study from Open Pharma reported that as of February 9, 2022, only 0.01% of PubMed publication records (n = 31,817,472) were tagged with having a PLS, with just over half having been published in 2021 (Rosenberg et al., 2022). Although the use of this PubMed functionality has been on the rise, approximately 15% of PLS are incorrectly tagged due to a variety of reasons (e.g., included other non-PLS content, such as article highlights or empty content; Rosenberg et al., 2022). Of the correctly tagged PLS, all journals (n = 105) were open access or had open access options (Rosenberg et al., 2022). Thus, it is important that several advances take place to optimize the accessibility of PLS to their target audiences, including having consistent terminology when referring to a PLS (instead of patient lay summary, lay summary, simple summary, trial results summary, nontechnical summary, etc.; Barnes & Patrick, 2019), journals expanding their utilization of PLS, and ensuring correct PubMed tagging (King et al., 2022; Rosenberg et al., 2022). It has also been advocated that a "PubMed for patients" be created as an easily searchable repository of PLS for patients and the general public (King et al., 2022).

WHAT IS THE OPTIMAL FORMAT AND CONTENT OF A PLS?

To date, a multitude of publishers, governments, and various organizations have provided guidance on the format and content of PLS (e.g., Elsevier, Sage Publications, Taylor & Francis, Cochrane Collaboration, European Union Parliament, etc.; European Union Clinical Trials Expert Group, 2021; Gainey et al., 2023; Rosenberg et al., 2021; The Cochrane Collaboration, 2022). Specific to clinical trial research, the EU CTR (No 536/2014) mandates the inclusion of 10 specific elements in a lay summary that must accompany a report of a clinical trial (Table 2; European Parliament and the Council, 2014; European Union Clinical Trials

Expert Group, 2021). Comprehensive guidance on the preparation of a PLS has also been provided by the Patient Focused Medicines Development (PFMD) coalition, an international multistakeholder framework comprised of patient representatives, industries, publishers, researchers, medical communications agencies and public officials, which was established in October 2015 (Boutin et al., 2017; Dormer et al., 2022; Patient Focused Medicines Development, 2022). The PFMD has emphasized that a PLS be prepared in an ethically and responsible manner so that misinformation and misinterpretation are avoided and patient care is not negatively impacted (Patient Focused Medicines Development. 2022). The working group of the PFMD developed 15 ethical principles that were integrated into a 7-step approach for the preparation of a PLS. These principles focus on the application of health literacy principles, considering the target audience, a balanced presentation, the use of inclusive and respectful language, and objective reporting without any promotional intent (Dormer et al., 2022; Patient Focused Medicines Development, 2022).

At least three published studies have examined the usability of a PLS among general practitioners, patients, university students and/or the general public. They concluded that an infographic is perceived to have good usability, although medium-complexity text may provide similar user-friendliness (Buljan et al., 2018; Martínez Silvagnoli et al., 2022; Penlington et al., 2022). In a poster presentation at the annual meeting of the International Society for Medical Publication Professionals (ISMPP) in 2023, the results of an online US survey of 124 patients with cancer and caregivers reported that 86% thought PLS would be moderately to extremely useful as resources to better understand medical information from a scientific journal article (Schuler et al., 2023). Despite being first initiated in 2010 (Dormer et al., 2022; FitzGibbon et al., 2020), in 2025, PLS in journals remain in transition from being nonexistent to slowly developing uniform structure, content, and accessibility. Initiatives led by organizations, such as the ISMPP, are ongoing to determine an optimal PLS format based on perspectives of various stakeholders, including patients, media, HCPs, pharmaceutical companies, publishers, and medical communications agencies (King et al., 2022).

Table 2. Ten Elements That Must Be Included in a Lay Summary Mandated in the European Union's 2014 Clinical Trials Regulation No 536/2014

1. Clinical trial identification
2. Name and contact details of the sponsor
3. General information about the clinical trial
4. Population of trial participants (e.g., demographics and selection criteria)
5. Investigational medicinal products used
6. Description of adverse events and their frequency
7. Overall results of the clinical trial
8. Comments on the outcome of the clinical trial
9. Notification of follow-up clinical trials
10. Where additional information can be found

Note. Information from European Union Clinical Trials Expert Group (2021).

WHAT ARE SOME EXAMPLES OF A PLS?

Clinical researchers studying breast cancer have used PLS to disseminate the results of their studies to a broader audience. Here, we present two examples of a PLSP that summarize (1) a published manuscript of a secondary analysis of two phase III randomized controlled clinical trials (RCTs), PALOMA-2 and PALOMA-3, which included women with hormone receptor–positive/human epidermal growth factor receptor 2–negative (HR+/HER2–) advanced or metastatic breast cancer (ABC/MBC; Rugo et al., 2022) and (2) a published manuscript that reported the findings of a real-world database analysis of African American patients with HR+/HER2– MBC (Rugo et al., 2023).

We have also included an example of a PLS of a conference abstract reporting on the relationship of tumor growth rate with overall survival in a novel analysis of the PALOMA-3 trial (Yeh et al., 2022a). A PLS of a conference abstract can provide several benefits to readers, as well as clinical researchers and study sponsors, including providing up-to-date information on ongoing clinical trials prior to publication of detailed results, quick and credible conveyance of takeaway messages of clinical research, and transparency. When seen by patients, advocacy groups, and/or trial participants, they may also bolster trust, facilitate trial enrollment, and improve the overall clinical trial experience (King et al., 2022; Wilcox et al., 2020).

PLSP of a Secondary Analysis of Randomized Clinical Trials

The secondary analysis of the PALOMA-2 and PALOMA-3 trials, published in 2022 in the journal *The Breast*, presented clinical evidence that palbociclib plus endocrine therapy (ET) compared with placebo plus ET prolonged the time to chemotherapy in patients with HR+/HER2– ABC/MBC in both RCTs, and this was observed across multiple patient subgroups (e.g., those with de novo MBC, those with visceral metastasis; Rugo et al., 2022). The subsequent associated PLSP entitled "The effects of adding palbociclib to endocrine therapy to treat advanced breast cancer: A plain language summary of a study using the PALOMA-2 and PALOMA-3 trial results" was published online in 2023 (Rugo et al., 2024a) and is freely accessible online in the journal *Future Oncology* at https://www.futuremedicine.com/doi/full/10.2217/fon-2023-0407.

Figure 1 shows how the abstract from the original manuscript is translated into an easier, digestible format for the PLSP, specifically answering what the summary is about, what the aim of the original study was, what the results were, and what they mean. The PLSP retains the main objectives of the original manuscript, which were to evaluate time to chemotherapy and progression-free survival across patient subgroups in the PALOMA-2 and PALOMA-3 trials. Throughout the content of this PLSP (Figure 2), terminology specific to the study (e.g., metastatic, cancer, HR+/HER2–) are defined in text boxes; 10 infographics are used to provide easily understandable and unbiased information on ABC/MBC, the meaning of HR+/HER2– breast cancer, how palbociclib and endocrine combination therapy works, the subgroups studied, characteristics of the study populations, the treatments received, and the overall results of the study. Figure 3 shows how complex data described by forest

A) Manuscript abstract

Background

Previous analyses from the PALOMA-2 and PALOMA-3 studies showed that palbociclib (PAL) plus endocrine therapy (ET) prolongs time to first subsequent chemotherapy (TTC) versus placebo (PBO) plus ET in the overall population of patients with hormone receptor–positive/human epidermal growth factor receptor 2– negative (HR+/HER2–) advanced breast cancer (ABC). Here, we evaluated TTC in relevant patient subgroups.

Methods

These post hoc analyses evaluated TTC by subgroup using data from 2 randomized, phase 3 studies of women with HR+/HER2– ABC. In PALOMA-2, postmenopausal patients previously untreated for ABC were randomized 2:1 to receive PAL (125 mg/day, 3/1-week schedule) plus letrozole (LET; 2.5 mg/day; n = 444) or PBO plus LET (n = 222). In PALOMA-3, premenopausal or postmenopausal patients whose disease had progressed after prior ET were randomized 2:1 to receive PAL (125 mg/day, 3/1-week schedule) plus fulvestrant (FUL; 500 mg; n = 347) or PBO plus FUL (n = 174).

Results

First subsequent chemotherapy was received by 35.5% and 56.2% in PALOMA-2 and PALOMA-3 after progression on palbociclib plus ET or placebo plus ET. Across all subgroups analyzed, the median progression-free survival (PFS) was longer in the PAL plus ET arm than the PBO plus ET arm. TTC was longer with PAL plus ET versus PBO plus ET across the same patient subgroups in both studies.

Conclusions

Across all subgroups, PAL plus ET versus PBO plus ET had longer median PFS and resulted in prolonged TTC in both the PALOMA-2 and PALOMA-3 studies. Pfizer Inc (NCT01740427, NCT01942135).

B) PLSP brief summary

What is this summary about?

This is a summary of an article that reported results of a study using data from two phase 3 clinical trials called "PALOMA-2" and "PALOMA-3." Both PALOMA-2 and PALOMA-3 trials included women with HR+/HER2– advanced breast cancer. HR+/HER2– breast cancer means the breast cancer cells of these women have receptors for female sex hormones and little or no HER2 receptors. Both PALOMA trials tested the effect of adding a medication called palbociclib (brand name, Ibrance®) to a hormone therapy. Hormone therapy, also known as endocrine therapy, is a treatment that blocks or removes hormones that cause cancer cells to grow and divide. In both trials, women took endocrine therapy with either palbociclib or a placebo.

What was the aim of this study?

The researchers aimed to see if the results from the PALOMA trials were similar for subgroups of women in the 2 trials. The subgroups in the study included women who shared certain features about their cancer or treatment history, for example, women whose cancer had spread to the liver. For each subgroup, the study compared the results from the 2 treatment groups: (1) women who took palbociclib plus endocrine therapy, and (2) women who took placebo plus endocrine therapy.

What were the results & what do they mean?

The same effect was found in all subgroups. Compared with those who took placebo, women who took palbociclib lived longer without their cancer getting worse (growing or spreading). Also, among women who had chemotherapy after stopping the trial treatment, those who took palbociclib started chemotherapy later than those who took placebo. Because palbociclib slows cancer growth and leads to tumor shrinkage, this may have played a part in starting chemotherapy later. These results show that palbociclib plus endocrine therapy is better at slowing the progression of advanced HR+/HER2– breast cancer than endocrine therapy alone. This can be said for women with different advanced HR+/HER2– breast cancer features and treatment history. Overall, the results support women taking palbociclib with an endocrine therapy if they have advanced HR+/HER2– breast cancer.

Figure 1. Translation of the findings from A) an original manuscript abstract (Rugo et al., 2022)[a] to B) the plain language summary publication (PLSP) brief summary for a lay audience (Rugo et al., 2024)[b].
[a]Reproduced under the Creative Commons CC-BY license.
[b]Reproduced with permission granted from Taylor & Francis Informa UK Ltd.

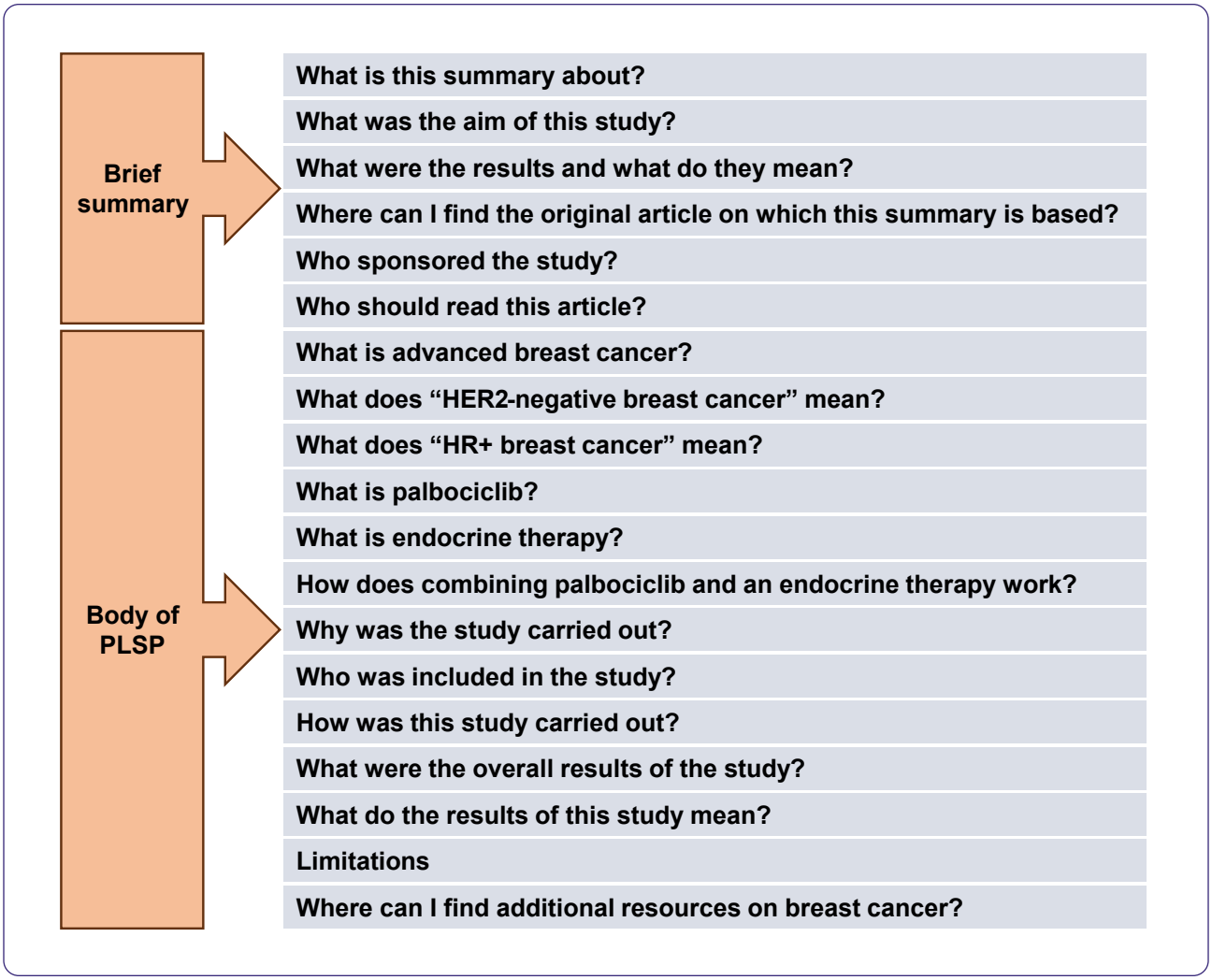


Figure 2. Example of the content of a PLSP (Rugo et al., 2024). HER2 = human epidermal growth factor receptor 2; HR+ = hormone receptor-positive.

plots in the original manuscript are translated into an infographic that presents the data in a readily understandable manner to a nonexpert audience.

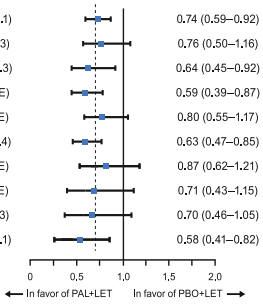
PLSP of a Real-World Database Study

Plain language summaries of publications are not only used to summarize the findings of RCTs but can also be used to describe results of real-world studies. In this example, a retrospective database study evaluated the real-world effectiveness of palbociclib plus an aromatase inhibitor (AI) vs. an AI alone as a first-line treatment in 270 African American patients with HR+/HER2− MBC (Rugo et al., 2023). It was published in 2023 in *The Oncologist*. Overall, the study found that when comparing treatments in real-world settings, among African American patients with HR+/HER2− MBC, palbociclib plus an AI showed improved effectiveness in terms of overall survival and real-world progression-free survival compared with an AI alone.

The subsequent associated PLSP was entitled "Prolonging the lives of African Americans with metastatic breast cancer by adding palbociclib to an aromatase inhibitor in routine clinical practice: A plain language summary of a real-world database study." It was published in 2024 and is freely accessible online in the journal *Future Oncology* at https://www.futuremedicine.com/doi/full/10.2217/fon-2023-1079 (Rugo et al., 2024b).

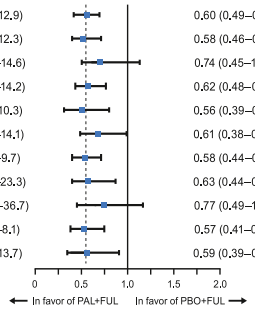
A) Figures in manuscript

Patient Subgroup	n (%), ITT population	mTTC (95% CI), mo		HR (95% CI)
		PAL+LET	PBO+LET	
Overall (ITT) population	666 (100)	40.4 (34.7–47.3)	29.9 (25.6–35.1)	0.74 (0.59–0.92)
DFI ≤12 mo	146 (22)	23.6 (18.3–34.7)	17.0 (13.7–27.3)	0.76 (0.50–1.16)
DFI >12 mo	272 (41)	45.6 (37.5–NE)	30.7 (23.5–39.3)	0.64 (0.45–0.92)
DFI >24 mo	233 (35)	45.6 (45.6–NE)	35.2 (24.9–NE)	0.59 (0.39–0.87)
De novo metastatic	248 (37)	41.1 (36.1–47.3)	33.0 (28.7–NE)	0.80 (0.55–1.17)
Visceral	324 (49)	34.4 (26.9–NE)	24.7 (14.9–31.4)	0.63 (0.47–0.85)
Nonvisceral	340 (51)	45.6 (37.1–NE)	35.2 (28.7–NE)	0.87 (0.62–1.21)
Bone only	151 (23)	40.4 (34.1–NE)	30.1 (21.3–NE)	0.71 (0.43–1.15)
Visceral liver involvement	120 (18)	19.7 (14.6–25.6)	14.2 (6.3–20.3)	0.70 (0.46–1.05)
Visceral lung involvement	253 (38)	47.0 (31.9–NE)	29.5 (18.2–35.1)	0.58 (0.41–0.82)



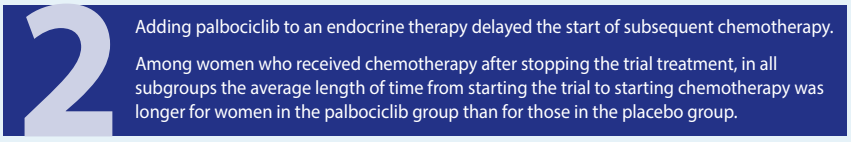
Forest plot of TTC by treatment arm in PALOMA-2, overall and across patient subgroups (ITT population). DFI = disease-free interval; HR = hazard ratio; ITT = intent to treat; LET = letrozole; (m) TTC = (median) time to first subsequent chemotherapy; mo = months; NE = not estimable; PAL = palbociclib; PBO = placebo. Items in bold in the Patient Subgroup column represent stratification factors from PALOMA-2.

Patient Subgroup	n (%), ITT population	mTTC (95% CI), mo		HR (95% CI)
		PAL+FUL	PBO+FUL	
Overall (ITT) population	521 (100)	17.5 (15.2–19.7)	8.8 (7.3–12.9)	0.60 (0.49–0.74)
ET sensitive	412 (79)	19.1 (16.2–21.7)	8.1 (6.9–12.3)	0.58 (0.46–0.74)
ET resistant	109 (21)	10.8 (9.0–15.2)	12.7 (3.2–14.6)	0.74 (0.45–1.20)
Without prior CT in ABC	344 (66)	18.4 (16.0–21.5)	11.9 (7.8–14.2)	0.62 (0.48–0.81)
With prior CT in ABC	177 (34)	14.3 (11.6–20.3)	7.3 (4.3–10.3)	0.56 (0.39–0.81)
Without any prior therapy in ABC	115 (22)	17.1 (12.4–24.4)	11.1 (4.2–14.1)	0.61 (0.38–0.97)
Visceral	313 (60)	15.2 (12.2–17.3)	6.4 (4.4–9.7)	0.58 (0.44–0.76)
Nonvisceral	208 (40)	23.3 (19.1–29.1)	17.0 (8.9–23.3)	0.63 (0.44–0.89)
Bone only	125 (24)	22.7 (15.8–30.0)	19.5 (11.8–36.7)	0.77 (0.49–1.22)
Visceral liver involvement	203 (39)	12.7 (10.4–15.1)	5.7 (3.5–8.1)	0.57 (0.41–0.79)
Visceral lung involvement	162 (31)	16.8 (14.5–20.3)	7.5 (4.2–13.7)	0.59 (0.39–0.87)



Forest plot of TTC by treatment arm in PALOMA-3, overall and across patient subgroups (ITT population). ABC = advanced breast cancer; CT = chemotherapy; ET = endocrine therapy; FUL = fulvestrant; HR = hazard ratio; ITT = intent to treat; mo = months; (m)TTC=(median) time to first subsequent chemotherapy; PAL = palbociclib; PBO = placebo. Items in bold in the Patient Subgroup column represent stratification factors from PALOMA-3.

B) Infographic in PLSP



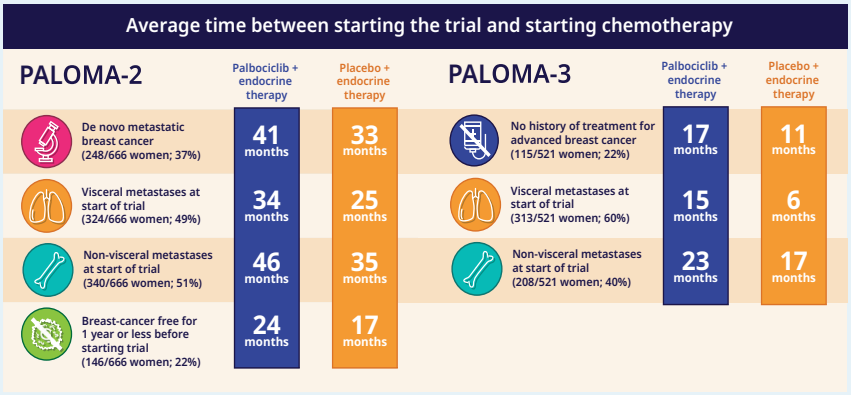


Figure 3. Translation of the findings of A) forest plots on time to chemotherapy by treatment arms from randomized controlled clinical trials (Rugo et al., 2022)[a] to B) an infographic in the plain language summary publication (PLSP; Rugo et al., 2024)[b].

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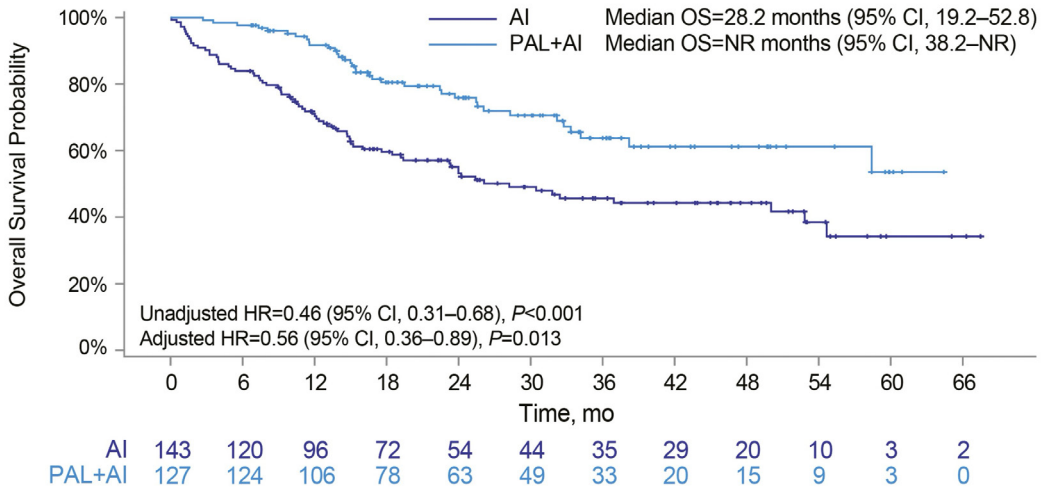
A) Figure in manuscript



Kaplan–Meier curves of OS in African American patients: Unadjusted

B) Infographic in PLSP

The group of African–Americans who were treated with palbociclib with an AI survived longer than those who weretreated with an AI alone:

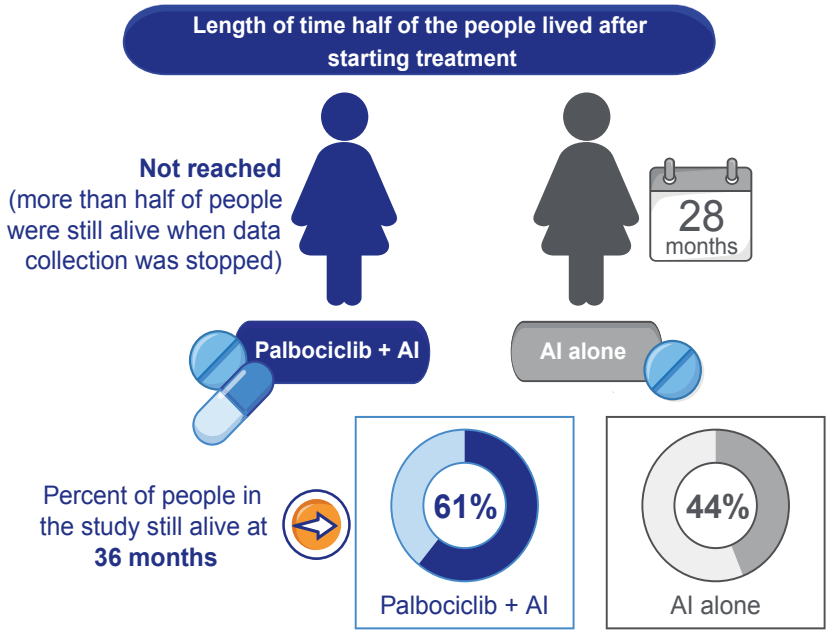


Figure 4. Translation of the findings of A) Kaplan-Meier curve of overall survival by treatment arm from a real-world database study (Rugo et al., 2023)[a] to B) an infographic in the plain language summary publication (PLSP; Rugo et al., 2024)[b]. AI = aromatase inhibitor; CI = confidence interval; HR = hazard ratio; NR = not reached; OS = overall survival; PAL = palbociclib.
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[b]Reproduced with permission granted from Taylor & Francis Informa UK Ltd.

Because real-world evidence studies may be less well known than RCTs among lay audiences, an explanation of their utility and differences in study populations from RCTs is provided in a call-out text box in the PLSP: "Real-world studies help researchers, clinicians, and patients understand how medicines work in routine clinical practice. People treated for cancer in routine clinical practice are often more diverse than people in clinical trials. Real-world studies also include people who are older, more racially and ethnically diverse, have other illnesses (such as hypertension, diabetes, heart disease, etc.) and who have more advanced disease than those in clinical trials."

Similar to the last example, the body of this PLSP contains a series of infographics that provide information on metastatic breast cancer, HR+/HER2− breast cancer, the mechanism of action of palbociclib and AIs to slow or stop cancer cell growth, characteristics of the study populations, the treatments received, and the overall results of the study. Figure 4 shows how a Kaplan–Meier curve of overall survival by treatment type from the original manuscript is translated to "The group of African Americans who were treated with palbociclib with an AI survived longer than those who were treated with an AI alone" in an infographic for a nonexpert audience.

PLS of a Conference Abstract

The original conference abstract presented at the American Society of Clinical Oncology 2022 annual meeting reported that among 393 women with ABC who participated in the PALOMA-3 trial, tumor growth rate measured in two follow-up radiographic scans post-baseline was associated with overall survival (Yeh et al., 2022a). Additionally, the study showed that patients who were treated with palbociclib plus fulvestrant had a significantly slower rate of tumor growth than seen in those who received placebo plus fulvestrant, with some disease characteristics associated with greater benefit and others not related. The authors concluded that tumor growth rate is potentially an early indicator of overall survival, and that the antitumor activity of palbociclib supports the overall findings of the PALOMA-3 trial. Figure 5 shows how the results of the impact of palbociclib on tumor growth rate reported in the conference abstract are translated in an infographic of the PLS. The PLS is entitled "Tumor growth rate as an early indicator of survival in women with advanced breast cancer who were treated with palbociclib" (Yeh et al., 2022b). Currently, this PLS is freely accessible via a company-sponsored webpage (https://doi.org/10.25454/pfizer.figshare.26839795.v1; Pfizer, 2024) but is not a standalone publication. Data in conference abstracts are considered preliminary, and these data may become more finalized when proceeding to publication in a peer-reviewed journal. Therefore, the preliminary nature of the data should be clearly stated, so as not to imply that the information being shared reflects the final data.

Table 3. The 5-Step Process in the "SHARE Approach" for Shared Decision Making

Step 1:	Seek your patient's participation
Step 2:	Help your patient explore and compare treatment options
Step 3:	Assess your patient's values and preferences
Step 4:	Reach a decision with your patient
Step 5:	Evaluate your patient's decision

Note. Information from US Agency for Healthcare Research and Quality (2023).

PRACTICAL APPLICATIONS AND IMPLICATIONS OF PLS FOR APPs

Advanced practice providers provide direct care to patients and often need to hold difficult conversations with them and their caregivers on critical medical care and prognosis (Stein et al., 2022). Reported by APPs in oncology in the US, their top four patient activities include patient counseling, prescribing, treatment management, and follow-up visits (Bruinooge et al., 2018). Excellent communication skills are thus useful for APPs and are recognized as a core competency by national APP organizations (American Academy of Physician Associates, 2024; National Organization for Nurse Practitioner Faculties, 2022; Stein et al., 2022). In a nationwide survey from the Association of Community Cancer Centers and Harborside in early 2020, of 408 oncology APPs, most (80%) reported they were comfortable discussing clinical trials with patients and were involved in the care of trial participants (Braun-Inglis et al., 2022). Ninety percent of APPs reported they should be involved in

Infographic in PLS

- The researchers found that tumor growth rate was highly related to the patient's overall survival.

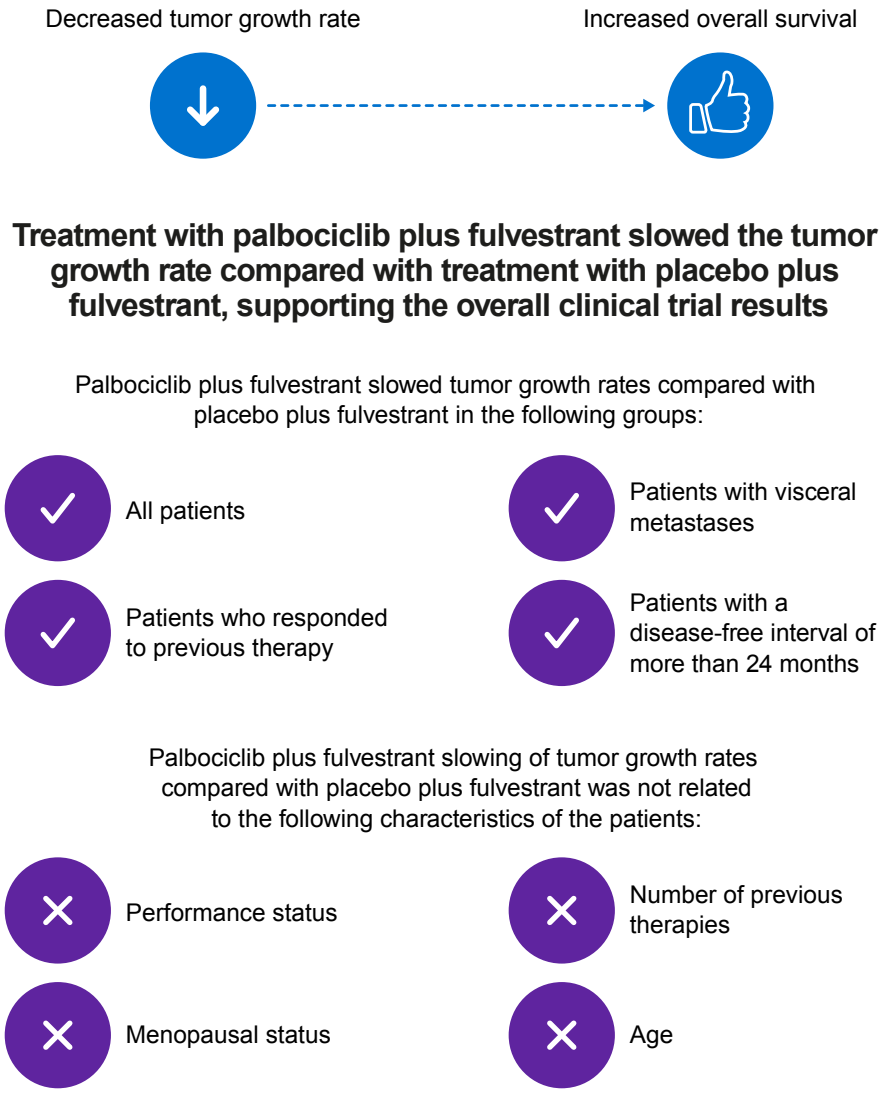

Figure 5. Translation of the data on the impact of palbociclib plus fulvestrant on tumor growth rate presented in a conference abstract into an infographic in the plain language summary (PLS; Yeh et al., 2022a, 2022b).

clinical research, while 73% of APPs wanted to be more involved in research; however, barriers included lack of time, inadequate awareness of trial specifics, and not having a formal role in protocol development and leadership (Braun-Inglis et al., 2022). Plain language summaries represent a potentially valuable tool for APPs to reduce barriers when engaging with patients, participating in clinical research, and interfacing with colleagues. When educating patients regarding clinical trial outcomes, APPs may already be holding an informal PLS exchange in language and documentation. Raising awareness of the existence of published PLS may encourage APPs to seek out and use these tools when engaging with their patients. Plain language summaries also may save time for APPs, helping them keep up to date with the latest clinical research, a key benefit noted in a small study of five participants recruited from professional networking forums or personal correspondence (Edgell & Rosenberg, 2022).

Testing of PLS is considered an endeavor that can generate valuable advice on how to communicate complex scientific information to nonexperts and improve on the future development of PLS, as well as future clinical trials and real-world evidence generation (Collyar et al., 2022; Patient Focused Medicines Development, 2022). Advanced practice providers may have the opportunity to be involved in the preparation of PLS of interest to their practice, use them for patient and team engagement, and test their utility and quality in practice. Testing of PLS may involve using them in their routine patient visits or as a patient engagement tool in a larger focus group, either of which will likely yield constructive feedback to the author team prior to publication and even after publication (Patient Focused Medicines Development, 2022).

Patient-centered communication has been defined as a process that both invites and encourages patients to actively participate in decision making about their care (Langewitz et al., 1998; McCabe, 2004). A PLS may be easily accessed by APPs or patients from an open access journal and then used as a platform for focused dialogue, making care patient-centered (Kwame & Petrucka, 2021; Patient Focused Medicines Development, 2022). A PLS, either as weblink or printed hard copy, can be shared among patients, their caregivers, and families. Effective patient-centered communication has been found among patients to promote health information retention and understanding, improve perceptions of care quality and ensure optimal health outcomes (Kwame & Petrucka, 2021; Stewart, 1995). Recommended by a substantial number of organizations and across multiple disciplines and fields (Warde et al., 2018), use of plain language in health care is a central component of how to enhance patient communication (Hersh et al., 2015). Plain language summaries may be useful to increase health literacy, which is associated with better optimization of individual care (Hersh et al., 2015), while limited health literacy is associated with worse health outcomes (Berkman et al., 2011; Kwame & Petrucka, 2021). The SDM model of care is advancing in its utilization, especially in the cancer care setting, with APPs having a prominent role in multidisciplinary care teams with active participation in patient-centered communication, treatment decisions, and sharing of perspectives on clinical issues and research (Clancy, 2012; Tariman & Szubski, 2015), all responsibilities in which PLS may be integrated.

The US Agency for Healthcare Research and Quality has developed the "SHARE Approach" as a five-step process that can be used by APPs as a tool for SDM during patient encounters (Table 3; US Agency for Healthcare Research and Quality, 2023). A PLSP may be particularly useful in Step 2 as an easily accessible patient decision aid (PDA), an evidence-based tool to assist patients in making informed decisions on their health-care options (Stacey et al., 2024). The content and structure of PLSP align with that of the recommendations for the International Patient Decision Aid Standards (IPDAS) in that they are written in plain language with inclusion of several infographics to visually reinforce key concepts and factually inform on clinical research evidence (Muscat et al., 2021b). A recent Cochrane review of 209 studies including over 100,000 participants has reported that use of PDAs as opposed to usual care helps adults increase their health knowledge, improve risk perception, and actively participate in decision-making (Stacey et al., 2024). Testing and validation of the use of PLS and PLSP as PDAs in the SDM process is warranted in future studies.

CONCLUSIONS

Advanced practice providers are on the frontlines of care, often providing detailed and extensive education for patients in and outside of clinical trials. Plain language summaries represent an evidence-based, peer-reviewed, robust tool that may assist APPs to effectively communicate clinical and biomedical information to patients and thereby facilitate SDM. Since the complex scientific information has already been broken down and key messages of a research article made clear, PLS can serve as a timesaver, allowing for greater discussion and answering of questions, further advancing health literacy, as well as fostering patient-provider relationships. While considerable work is still necessary to uniformly and universally apply PLS routinely to clinical and biomedical research studies, once this is achieved, PLS may evolve to become reliable, high-quality evidence-based aids to promote health literacy, mitigate misinformation, and enhance the SDM process by ensuring patients are informed and confident when making difficult health decisions. Uniform deployment of PLS will likely yield clarity on unforeseen barriers to their utilization. ●

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Ms. Podsada has served as a speaker for Pfizer Inc. Ms. Jones has served as a speaker for Pfizer Inc, Bristol Myers Squibb, Merck, and AstraZeneca. Ms. Ryan is an employee and stockholder in Pfizer Inc.

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