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Implementation of an organisation-wide health literacy approach to improve the understandability and actionability of patient information and education materials: A pre-post effectiveness study

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ABSTRACT

Objective: Limited examples exist globally of coordinated, organisation-wide health literacy approaches to systematically improve the understandability and actionability of patient health information. Even fewer have been formally evaluated. The aim of this study was to use the Patient Education Materials Assessment Tool (PEMAT) to evaluate the effectiveness of an organisation-wide, evidence-based approach to improve the understandability and actionability of patient information materials in regional health service in New South Wales, Australia.

Methods: Two independent raters (blinded to the document version) evaluated pre- and post-implementation versions of 50 randomly-selected patient information materials using the PEMAT, with differences in understandability and actionability analysed using paired samples tests.

Results: Mean (±SD) overall scores for understandability increased significantly by 5% (95% CI 2–8; $p = 0.002$) up to 77%±10%, and mean actionability (±SD) increased significantly by 4% (95% CI 0–8; $p = 0.046$) up to 56%±22%.

Conclusion: These results demonstrate that organisation-wide approaches with standardised processes for staff to prepare, review and store written patient information and education materials can be successfully implemented to address the impacts and risks of low health literacy.

Practice implications: The success of this approach provides a framework for other health organisations to work in partnership with patients to make health information more understandable and actionable.

1. Introduction

Individual health literacy, defined as a person's capacity to obtain, understand and communicate about health-related information necessary to make informed health decisions [1], is now globally recognised as a critical issue for safe and quality care [2] due to the high prevalence of low health literacy [2], and its link with poorer health outcomes and higher healthcare costs [3,4]. To address health literacy, a two-tiered approach is needed that focuses on the interaction between skills and demands; building individuals' capacity to access, obtain, understand, and use health information and services, and also reducing the demands that organisations place on the individual by making healthcare environments less complex and more adaptable [2]. Despite increasing calls for health organisations to take a systematic, coordinated and consistent health literacy approach when designing and delivering healthcare and health information [2], there are few examples of this being achieved to date. Studies consistently show a failure to adopt health literacy universal precautions [5] and considerable scope for improving organisational health literacy [6,7]. The reading level of patient information materials regularly exceeds the skills of patients with lower health literacy [8–10].

Successfully implementing new practices and processes in real world settings can be very challenging, and is often unsuccessful [11–13]. One reason may include that such practices are often implemented in a 'top down' fashion by people external to the organisation. This approach has been criticised for ineffective

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translation to practice and sustained implementation [13,14]. Alternatively, patient care and service delivery benefits are enhanced when initiatives are directly led by the health professionals who will use them [11]. A lack of clear theory-based implementation frameworks, strategies and tools is also likely to result in unsuccessful implementation of evidence-based practices [13,14].

We developed an organisation-wide, evidence-based Health Literacy Framework that uses a systematic and universal precautions approach to address the risks and impacts of low health literacy. The Framework was developed in response to the Australian National Safety and Quality Health Service (NSQHS) Standards that require health organisations to provide information to patients that is easy to understand and use, and to involve patients to develop and review information and materials developed locally. It aims to ensure systems, policies and practices promote clear understanding for all patients and their families and carers, regardless of their health literacy level.

A core component of the Framework is a coordinated, whole-of-organisation system with standardised processes and tools for staff to prepare, review and store plain-language written patient information and education materials that are developed locally. This is commonly referred to as the 'PiP process' (Fig. 1) and is supported by an interactive Patient information Portal (PiP) intranet site and a Patient Information Coordinator who manages the PiP and supports staff to develop resources [15,16]. This process ensures that resources are developed in partnership with consumers, which is now considered best practice for resource development [17,18]. Governance structures require staff to use the above standardized processes to develop patient information and education materials, and a Health Literacy Ambassador (HLA) program has been implemented to train staff to be Health Literacy champions and lead their teams on how to partner with patients to develop plain language materials. Full details of this effort are provided elsewhere [15]. This Framework has been implemented in a regional health service in New South Wales, Australia, and has been used nationally as an example of a coordinated approach to addressing health literacy [2]. However, the effectiveness of this process is yet to be formally evaluated.

1.1. Aims and hypotheses

The aim of this study was to evaluate the effectiveness of the PiP process to improve the understandability and actionability of patient information and education materials using the Patient Education Materials Assessment Tool (PEMAT). It was hypothesised that the systematic and partnership approach would make the patient information and education materials more actionable and understandable.

2. Methods

2.1. Setting

The Illawarra Shoalhaven Local Health District (ISLHD) is a regional health service located in New South Wales, Australia with a resident population of 400,241 people [19].

2.2. Sample size

The mean and standard deviation (SD) for the PEMAT was estimated from published studies [9,20]. Assuming an average PEMAT understandability score of 64.5 and a standard deviation of 17.35, 50 matched samples were required to give 90% power to detect a difference of 0.5 standard deviations using paired samples t-tests.

2.3. Selection of materials

A total of 269 patient information materials were developed by ISLHD staff using the 'PiP process' between July 2016 and December 2017. A web-based random selection tool (https://andrew.hedges.name/e/random/) was used to generate a random list of 50 materials for inclusion in the study. We extracted matched pre- (versions of

Step 1	The author registers the resource on the Patient information Portal (PiP). The resource is required to adhere to plain-English guidelines[a], using standardised templates and images.
Step 2	The author tests for readability using an online readability calculator. A score of ≤6-8 (12-14 years) is required.
Step 3	The author tests the resource with patients (n≥5) and logs feedback using the standardised 'Consumer Information Feedback Tool' (*see Supplementary Materials*). The PiP Coordinator places the resource on the PiP intranet site for staff to review.
Step 4	The author completes the 'Consumer Information Feedback Log' (*see Supplementary Materials*), uses feedback to make changes to the resource, and retests readability to ensure the resource is still meeting the required readability (see Step 2).
Step 5	The PiP Coordinator checks that Steps 1-4 have been completed, files evidence of feedback and modifications in a document management system, and publishes the resource on the PiP intranet site.

[a] Plain-English guidelines were developed from the CDC Simply Put Guide, the AHRQ Health Literacy Toolkit and the NHS Toolkit for Producing Patient Information (Version 2)

Fig. 1. PiP process used to prepare, review and store the written patient information and education materials.

materials that met the criteria for Steps 1 and 2 of the PiP process – see Fig. 1) and post- (final versions of the materials that fulfilled all steps of the PiP process) versions of the randomly selected materials, to make up 100 documents in total ($n = 50$ matched document pairs). The materials were de-identified (i.e. indications of pre- or post-status removed) and put in random order by a research assistant who had no other involvement in the study.

2.4. PEMAT and the material scoring process

The PEMAT was developed by the Agency for Healthcare Research and Quality to assess the understandability and actionability of patient education materials (Shoemaker, Wolf, & Brach, 2014). The PEMAT-P (printed materials) consists of 17 items for understandability and 7 items for actionability, shown in Table 4. Individual items are scored 0 (disagree), 1 (agree), or N/A (not applicable). PEMAT scores are converted to percentages ranging from 0% to 100%, with higher scores indicating the health materials as easier to understand and action [21]. The PEMAT has been shown to be internally consistent, reliable, and valid during its development [22] and has been used widely since its publication [8,9,23–29]. Materials that are more understandable and actionable allow people with diverse levels of health literacy to better understand and interpret the key messages and intended next steps [21]. Previous research has also shown negative correlations between PEMAT scores and readability scores, suggesting that materials with higher PEMAT scores have lower reading level requirements [9,30].

Two raters (YCC and JKS) were trained in the use of the PEMAT tool prior to the scoring process. The raters then scored each material independently following the PEMAT guide. Raters were blinded to the document version.

2.5. Statistical analysis

All statistical analyses were conducted using IBM SPSS Statistics, Version 24.0.

2.5.1. Interrater reliability

Interrater reliability (IRR) was assessed by calculating the intra-class correlation coefficients (ICC) by absolute agreement of PEMAT scores from the two raters. ICC is a well-established and commonly-used statistical method for evaluating IRR for ordinal, interval and ratio data types [31,32]. The four matched scores (pre-PiP understandability, pre-PiP actionability, post-PiP understandability, post-PiP actionability) from the raters were analysed separately. ICC values less than 0.40 indicate poor IRR, and values between 0.40 and 0.59 reflect fair IRR; IRR can be considered good when ICC values lie between 0.60 and 0.74, and excellent for values between 0.75 and 1.0 [33].

2.5.2. Comparing pre-/post-PiP PEMAT scores

The PEMAT understandability score differences were approximately normally distributed (assessed graphically using normal quantile-quantile [Q-Q] plots and histograms), however the differences of actionability scores were not. Thus, both parametric (paired sample t-test) and equivalent non-parametric (Wilcoxon signed rank test) tests were performed to analyse the differences between pre- and post- understandability and actionability scores. The outcome from these analyses were highly comparable with no difference in the conclusions drawn; in the interest of brevity, only parametric test results are reported. An *a priori* significance level of $p < 0.05$ was selected.

3. Results

Two documents that were identical rather than the pre- and post- versions were excluded from the analysis. Data is presented for the remaining 98 materials (i.e., 49 matched document pairs). Materials represented five categories, shown in Table 1. The number of pages of each material ranged from 1 to 24.

3.1. Interrater reliability

The ICC for each of the four scores are shown in Table 2. Given the excellent inter-rater reliability among the two raters among all four scores, the scores from the two raters were combined to get mean ratings for subsequent analysis [32,33].

3.2. Comparing pre-/post- PEMAT scores

The PEMAT scores of the ISLHD patient materials varied widely between documents. Mean (SD) scores for understandability and actionability of the pre- and post-PiP patient information materials are shown in Table 3. A mean increase of 4.69 for understandability ($t_{48} = 3.23$, $p = 0.002$) and a mean increase of 4.25 for actionability ($t_{48} = 2.05$, $p = 0.046$) ratings were observed for the post-PiP versions of the documents.

Table 4 shows the percentages of materials that were rated as meeting the criteria ("agree") for each PEMAT item. Regarding understandability, pre-PiP documents scored highly on several items including providing information without a distraction (98%), use of active voice (96%), having information "chunked" into sections (86%), and use of visual cues to support layout and design (91%). However, fewer made their purpose evident (63%), defined medical terms (67%), provided summaries (5%), and used visual aids whenever possible (38%) with clear captions (20%). The greatest improvements in the post-PiP materials were in the purpose becoming more evident (8% increase), using more common and everyday language (14% increase), and medical terms being better defined (14% increase).

For actionability, most pre-PiP materials performed well on identifying at least one action (87%) and addressing users directly (92%). However, less than half of the materials described explicit steps (36%), provided tangible tools (21%), explained how to use charts (38%) and used visual aids to describe actions (27%). The post-PiP versions showed mild improvements in identifying actions (7% increase), describing explicit steps (5% increase), providing tangible tools (5% increase), and using visual aids (4% increase). A greater improvement was shown in explaining the instructions of charts and diagrams (19% increase), but is only applicable for four materials.

4. Discussion and conclusion

As part of an organisation-wide, evidence-based Health Literacy Framework, ISLHD – a regional health service located in New South Wales, Australia – has implemented a standardised system and process, the 'PiP process', for staff to prepare, review and store written patient information and education materials. Central to this are standardised processes and tools for staff to obtain and use patient feedback to improve health information materials. This study used the Patient Education Materials

Table 1
Types of materials included in the pre-post study.

Category	n (%)
Information about specialist clinics or services	16 (33)
Information explaining medical conditions or medical terms	9 (18)
Instructions for patients about self-management	8 (16)
Ward admission introductions	8 (16)
Information about medical procedures	5 (10)
Other	3 (6)
Total	49 (100)

Table 2
Intra-class correlation coefficients (inter-rater reliability).

	Inter-rater reliability (95% confidence intervals) [ICC(2,2), absolute][a]	Internal consistency [Cronbach's α]
Understandability (Pre-PiP)	0.824 (0.687, 0.901)	0.821
Actionability (Pre-PiP)	0.860 (0.732, 0.924)	0.876
Understandability (Post-PiP)	0.785 (0.590, 0.883)	0.810
Actionability (Post-PiP)	0.854 (0.657, 0.929)	0.884

[a] Calculated using average measures.

Table 3
Changes in PEMAT scores before and after the Patient information Portal process (Paired *t*-test, N = 49).

PEMAT	Pre-PiP Mean (SD)	Post-PiP Mean (SD)	Mean Difference (95%CI)	P Value
Understandability	71.95 (11.81)	76.64 (9.87)	4.69 (1.78–7.61)	0.002
Actionability	52.03 (23.01)	56.27 (21.7)	4.25 (0.09–8.41)	0.046

Table 4
Percentage of "Agree" on PEMAT items among the 49 pairs of documents.

PEMAT items	Agrees (%)[a]		
	Pre-PiP documents	Post-PiP documents	Change
Understandability			
Content			
Makes its purpose completely evident	63	71	8
No distracting information	98	99	1
Word Choice & Style			
Common, everyday language	72	86	14
Medical terms are defined and used only to familiarize readers	67	81	14
Active voice	96	98	2
Use of Numbers			
Numbers are clear and easy to understand[*]	100	100	0
Does not expect readers to do calculation	96	96	0
Organisation			
"Chunks" information into short sections[++]	86	93	7
Sections have informative headers[++]	81	87	6
Presents information in a logical sequence	84	92	8
Provides a summary[++]	5	5	0
Layout & Design			
Uses visual cues on key points	91	96	5
Use of Visual Aids (VA)			
Uses VA whenever possible	38	39	1
VA reinforce rather than distract[#]	76	73	−3
VA have clear titles and captions[#]	20	24	4
VA are clear and uncluttered[#]	90	96	6
Tables are simple with short, clear role and column headings[$]	100	100	0
Actionability			
Identifies at least one action for the user	87	94	7
Addresses the user directly.	92	93	1
Breaks down actions into explicit steps	36	41	5
Provides tangible tools whenever it could help	21	26	5
Instructions and examples for calculations[¥]	100	100	0
Explains how to use the charts, diagrams etc.[§]	38	57	19
Uses VA whenever possible to help take action	27	31	4

[a] Agree(%) in each item was calculated by: (total number of "agrees" from the two raters)/(total number of applicable documents from the two raters).
[*] Not applicable for 43 pre-PiP and 43 post-PiP documents.
[++] Not applicable for 3 pre-PiP and 3 post-PiP documents.
[#] Not applicable for 15 pre-PiP and 13 post-PiP documents.
[$] Not applicable for 45 pre-PiP and 45 post-PiP documents.
[¥] Not applicable for 47 pre-PiP and 47 post-PiP documents.
[§] Not applicable for 45 pre-PiP and 45 post-PiP documents.

Assessment Tool (PEMAT) to evaluate the effectiveness of the 'PiP process' to improve the quality of patient health information and education materials. Results indicate that on average, the understandability and actionability of the patient health information and education materials improved significantly after going through the PiP process. Improvements in PEMAT domains were driven by changes in a select number of items (e.g. items related to word choice and style in the understandability domain; 'identifying actions for users to take' and 'explaining how to use charts, graphs, tables, or diagrams' in the actionability domain). Together, results suggest the PiP process is able to make written patient health information and education materials more understandable and easier to act upon, and provide useful indications as to areas for improvement for the PiP process for the future.

There are few studies that have evaluated systematic approaches to improving the quality and health literacy demands

of patient health materials in a real world clinical setting such as this. Of these studies only one examined outcomes by comparing pre- and post PEMAT scores; Brega et. al. conducted a demonstration of the Health Literacy Universal Precautions Toolkit in 12 primary care practices and assessed whether it resulted in higher quality patient materials after six months [34]. Results showed non-significant changes in the actionability and understandability of materials from pre- to post [34]. This may be because the study was underpowered to detect significant changes, or due to the limited implementation period (6 months), and/or the absence of critical elements for a coordinated and whole-of-organisation approach to support and sustain systematic health literacy practice changes in healthcare (e.g. governance and dedicated human resources). This study also used a 'top down' (researchers introduced pre-developed practices and interventions into hospital systems) rather than healthcare professional-led approach [34].

Although our results indicated statistically significant increases in both understandability and actionability scores pre- to post, these changes are relatively small (4.69% in understandability and 4.25% in actionability). This may be because the entry level status of materials in the current study was quite high; although understandability and actionability scores vary significantly among existing materials, means or median scores for understandability are commonly between 40%–60% and actionability around 50% or lower [8,9,23–25,27,28,35–37]. Pre-PiP materials in this study demonstrated a mean understandability score higher than other studies, with some items showing ceiling effects. There are a number of system factors that may contribute to this positive result. ISLHD uses standardised tools such as plain English guidelines which have been locally adapted from the CDC Simply Put guide [38], the AHRQ Health Literacy Toolkit [17] and the NHS Toolkit for Producing Patient Information [39] which have been successfully implemented at the systems level via governance, dedicated staff resources and a staff intranet site. It is a governance requirement that all materials developed within the health service are drafted using the guidelines and achieve a minimum readability level of Grade 6 to 8 *before* each material is tested with patients (and revised as necessary), put on standardised templates and uploaded to the intranet (Fig. 1). The high entry level status of materials in our study suggests that the systems approach to implementing these guidelines and resources has been successful, and shows that standardised processes and tools to support and guide local developers to independently simplify written information can be effective. Sustained efforts over five years to raise awareness amongst staff of the importance of health literacy are also likely to have played a role in the high entry level status of materials [15].

Nonetheless, refinements according to consumer feedback continued to offer *incremental* improvements to the quality of patient information materials, reinforcing the added value of patient input in simplifying health information. A systematic review of more than 300 articles concerning the involvement of patients in the planning and development of healthcare found that few described or evaluated the effects of involving patients in this process [40]. Of those that did, among the most frequently reported effects of involving patients was the production of new or improved sources of information for patients; the review found that trials of patient information leaflets developed with user involvement were more detailed, readable, and had improved layout and illustrations compared to leaflets developed by healthcare professionals alone. Together with our own, these results attest to the added value of patient involvement in the development of patient information, with our study indicating that structured processes for obtaining and using patient feedback can be implemented at a systems level.

4.1. Strengths and limitations

The PEMAT – an evidence-based tool with proven validity – was used to evaluate the understandability and actionability of materials in this study. However, PEMAT items are limited in that they do not consider the materials' purpose, target audience, or completeness of relevant content. To minimise bias, raters were blinded to the pre- and post- status of the randomly-selected documents and scored all materials independently. We measured IRR using ICC with absolute agreement. This approach examined the consistency and also the correlation of absolute scores between raters, which gave us a more accurate indicator for IRR. Through an intensive training process and the use of the PEMAT guide throughout the rating process, excellent interrater reliability was achieved.

We did not explicitly compare our standardised system and process for staff to prepare, review and store written patient information and education materials to any other systems or approaches. This is primarily because our research did not identify any other whole-of-organisation and systematic approaches either in Australia or internationally. We, therefore, do not know the relative efficacy of this approach compared to others. This is a different, albeit important, question for future research, that can only be answered once other health organisations establish and sustain whole-of-organisation and standardised systems and processes to prepare, review and store written patient information and education materials. Comparing different systems and processes may help to optimise them so that they are maximally efficient, effective and sustainable in routine practice. For example, ISLHD's standardised plain English guidelines were developed from the CDC Simply Put guide [38], the AHRQ Health Literacy Toolkit [17] and the NHS Toolkit for producing patient information [39]). These guidelines do not specifically address actionability. However, tools such as the PEMAT do (e.g. PEMAT items include: "breaks down any action into manageable, explicit steps", "provides a tangible tool whenever it could help the user take action", 'providing a summary'). Subverting the traditional use of the PEMAT so that it can inform the development of materials (rather than evaluation) may be relatively more effective in improving actionability compared to current ISLHD PiP process which generated average post-PiP actionability scores of 60%.

4.2. Conclusion

Our findings support that organisation-wide systems with standardised processes for staff to prepare, review and store written patient information and education materials can be successfully implemented to improve the understandability and actionability of patient health information and education materials. The success of the ISLHD system and implementation can provide a framework for other health organisations to adopt similar universal precautions and systems approaches to work in partnership with patients to make health information and education materials more understandable and actionable.

4.3. Practice implications

Given the significant increase in understandability and actionability of patient information and education materials observed in this study, it is recommended that health organisations take a coordinated, organisation-wide health literacy approach. Specific steps to achieving this goal are detailed elsewhere [15]. Our findings suggest that 'bottom-up', healthcare professional-led approaches, and the inclusion of consumers in the evaluation process worked well in this specific context. New evaluation research designs, such as effectiveness-implementation hybrid

designs [41], may be useful in evaluating both intervention effectiveness and barriers and facilitators to system-wide implementation. Dissemination of findings is integral to ensure replicability and to build the evidence base needed to improve health literacy.

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Conflict of interest

The authors of this article have no relevant conflict of interests to disclose.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.pec.2019.03.022.

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