INTRODUCTION

As the supply, fit and use of any orthosis is important, to ensure optimal device impact and patient safety, service users must receive sufficient information and advice in appliance application and care. Many hospital trusts and companies within the UK consolidate, supplement and reinforce verbal clinical guidance with leaflets, which form a key part of patient education strategies. To be of benefit, patient information leaflets (PILs) must be readable, understandable, and memorable, and as such, their comprehensibility, quality and sufficiency of content are fundamental. However, British Medical Journal articles indicate that PILs can be inaccurate, inconsistent or confusing for the service user (1).

Knee Ankle Foot Orthoses (KAFOs), are prescribed to support, correct or compensate for deformities or weaknesses around the knee and ankle, minimising, preventing, or protecting against disease progression and pain. While KAFO PILS have been made available to service users, database searches revealed that they had not yet been analysed, highlighting a significant gap in research. Consequently, this study aimed firstly to review and select tools that would be suitable for the assessment of both the comprehensibility and quality of KAFO PILs, and secondly, because one was not available for such a specific topic, to develop an appropriate tool to assess KAFO PIL content sufficiency. Thereafter, the tools selected and developed would be used in the assessment of KAFO PILs collected for consideration.

METHOD

As the application of the tools to KAFO PILs was the focus of this review, an in-depth study of these orthoses and the reason for their prescription was undertaken to ensure that the enquiries raised by the tools were pertinent.

Tool Selection

To accurately assess KAFO PIL comprehensibility, this area was divided into two groups; readability, and design and presentation.

Over 50 formulae are available to assess readability, which is described as the ease of comprehending written material, with each using slightly different methods, such as the number of syllables and characters per 100 words, and the length of the prose. The five most common for assessing readability were selected, being FKGL[1]

[1] Flesch-Kincaid Grade Level

(2, 3), CLI[2](4), FRE[3](3), GFI[4](5) and SMOG[5](6), with each readability formula being run through a number of different calculators such as readable.com. The results were then averaged to provide an overall readability mean for each PIL that was calculated following the assessment protocol set out by Zhou et al (7). The FRE results were excluded from the mean calculation as this tool uses a different scale in its scoring system and instead these results were used to corroborate the findings. The ideal reading age for a PIL was accepted as the Adult British National Average (ABNA) which is 9-12 years old (8).

Design and presentation tools generally review such aspects as imagery and it is accepted that concise, but precise PILs are considered to have a greater effect if visual aids are included, for example, images of how to don a device. The two tools used, Suitability Assessment of Materials, SAM (9, 10), and Baker Able Leaflet Design, BALD (9, 11), were chosen as they analysed PILs in slightly different ways, which was considered to give a more rounded overview to the results.

Whilst a PIL may be considered comprehensible, in that it is well presented and scores appropriately with the readability and design and presentation tools, these do not address, for example, whether the information is accurately and objectively portrayed. For this, quality assessment tools needed to be selected, and DISCERN (12, 13) along with Ensuring Quality Information for Patients 36 (EQIP36) (14), were chosen as they were specifically created for medical literature. These mainly covered three aspects of a PIL, being the content, the structure and any identification data included; for example, whether information is misrepresented or biased, the type of features incorporated, such as logos, and the nature of the information included, such as review dates.

As certain questions within the selected quality and design and presentation tools were not suited to KAFO PIL analysis, they were adopted either with clarifying statements or omitted altogether, with an appropriate score adjustment made. For example, an analysis of paper quality was not possible, as most PILs were collected electronically, consequently this question was omitted and the score modified accordingly.

The tool to assess content sufficiency was created in the form of a checklist, which detailed essential information for the safe, efficient, daily wear and care of a KAFO. This information was identified from the detailed review of KAFO's and their reasons for prescription, published literature, educational materials, and the collected PILs themselves.

[2] Coleman-Liau Index
[3] Flesch Reading Ease
[4] Gunning Fog Index
[5] Simple Measure of Gobbledygook

Guidelines created by the European Commission (15-17) , Medicines and Healthcare Products Regulatory Agency (MHRA)(18) and NHS (19, 20) relating to the production of PILs and which detail such topics as typeface and logos, were all covered by the assessment tools chosen, and therefore a separate analysis of these was deemed unnecessary.

KAFO PIL Assessment

PILs were collected between May and July 2019 through online searches for those already in the public domain and also through direct contact with both UK private and NHS service providers. These were then pseudo-anonymised by redacting identifying material to facilitate analysis without bias.

To avoid the potential for readability result distortion, the anonymised PILs were converted into plain 'text only' documents prior to assessment, however, for all other analyses, the original but anonymised PILs were used.

RESULTS

From the enquiries raised, there were 70 responses, leading to an overall response rate of 24.65%. Of these 70 responses, 24.29% indicated that they did not wish to participate and 27.14% indicated that whilst they provided KAFOs they did not distribute PILs. With leaflets found online added, and duplicates removed, 25 PILs remained for evaluation by this study, which was undertaken with the assistance of Microsoft Excel and Word 2016.

READABILITY

Table 1: Summary of the Number of PILs in each of the Reading Age Levels According to the Averaged Readability Tool Results

Reading age	No. of PILS in each reading age category based on their average under each readability tool					No. of PILs in each reading age category based on their average over all readability tools
	FKGL av.	CLI av.	SMOG av.	GFI av.	FRE av.	
10-11	2	0	0	0	0	0
11-12	4	0	0	0	5	0
13-15	16	11	17	7	16	13
15-18	3	14	8	15	4	12
College or higher	0	0	0	3	0	0

Whilst the averaged readability results varied greatly, all demonstrated a mean score higher than the ideal 9-12 years old ABNA, with 52% rated as 13 to 15 years old and

the remaining 48% as 15 to 18 years old (Table 1). Six PILs did rate within the ABNA reading age in analysis under the FKGL tool, however when these results were averaged with those from the other tools, the ABNA was exceeded. Of these six PILs, five also ranked within the ABNA category under the FRE calculation, but as indicated, the results of this tool were not used in calculating the mean and so they had no impact on the overall average. The readability results identified not only discrepancies in the grading systems between tools, but also in the softwares used to calculate the readability under each tool, in that the result for each software was different for the same tool.

DESIGN AND PRESENTATION

The chosen design and presentation tools, SAM and BALD, looked at this topic from two different perspectives, and no direct comparison between these was possible, therefore it was not appropriate to collectively average their results.

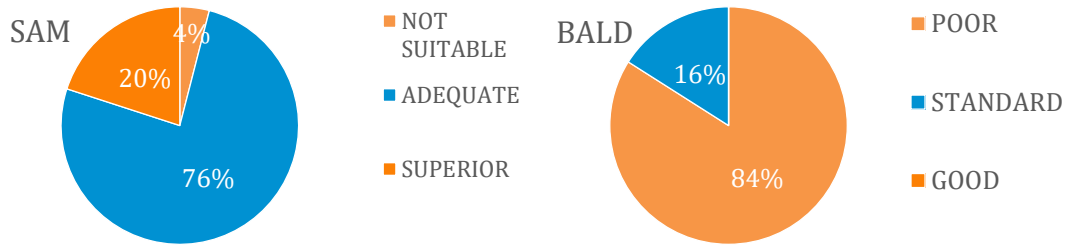

Figure 1: Pie Charts Depicting the Spread of Results under the SAM and BALD Design and Presentation Assessment Tools

Figure 1 demonstrates that SAM rated only 20% of PILS as superior, with 76% being adequate and 4% not suitable. Within these results collective highs and lows were revealed, for example, all PILs scored at least “adequate” in the content section, being whether the purpose of the leaflet was portrayed. Whilst nearly half, 48%, scored “superior” under literacy demands and learning stimulation, 60% of PILs were rated as “not suitable” within the graphics portion.

Figure 1 also demonstrates that under BALD, 76% rated as “poor”, however in all leaflets analysed there were a few positive areas of note, for example, the placing of a positive slant on information, not capitalising individual words or the whole title. However, this tool also identified areas collectively lacking, for example, inappropriate fonts and line spacing as well as the use of a limited colour palette. In some cases there was a marked discrepancy in the findings between the SAM and BALD tools, an example of this being the three PILs that ranked as “superior” in SAM but only rated “poor” within BALD.

QUALITY

As with design and presentation, the quality tool results also could not be collectively averaged as they looked at different aspects which affected the scoring. Generally, PILs scored higher with EQIP36 than DISCERN, but this can be explained by the fact that these tools have different focal points, with 19 PILs each scoring above 50% in EQIP36, but only 3 achieving this under DISCERN.

EQIP36 does not have a word interpretation for its results, but these showed an overall mean score of 55% for the PILs collectively, with the highest scores being achieved in structure, whereas under identification data, 56% of the PILs were either out of date or did not specify a review period. Many failed to adequately portray either the quantitative or qualitative risks with device use, or define the purpose or benefits of device wear.

As with the previous tools, DISCERN identified a large variation throughout the PILs with the collective mean results interpreted as “poor”. Whilst collective benefits included the provision of relevant information, as with EQIP36, the benefits and risks of device use were inadequately detailed, as was the referencing of information, and signposting to other information sources.

CONTENT SUFFICIENCY

Table 2: Percentage of PILs that Provided any Details on Each Checkpoint of Content Sufficiency Assessment Tool

Content Sufficiency Questions	Percentage number of leaflets containing any information (%)
What is a KAFO	76
Device function	96
Device interface	72
How to don/doff	92
How tight to do straps	56
Lock knee if appropriate	44
Footwear	92
Use guidance	96
Skin	92
How to care for the device	96
States do not self-adjust	80
States device only to be worn by person prescribed for	20
Review/How often need maintenance period for KAFO	92

Who contacts who for review appointment	64
States bring KAFO to appointment	28
Device entitlement	56
Contact details/opening times	100
Links to other media sources	28
Specific notes section	12
Leaflet available in other languages	56
When produced/review period for leaflets	76

The results of the content sufficiency tool also emphasised a large variation in the PILs, as seen in Table 2. Whilst the information presented was accurate, no PIL contained all the information expected to be present and at times they were ambiguous or lacking in detail, for example, in many cases there were limited details of user guidance, donning and device care, a wearing-in schedule, an acceptable time for red marks to fade, and device maintenance requirements.

There was some crossover between the tools, for example, leaflet review dates were considered in both the content sufficiency and quality tools. Fortunately, the resultant scores were similar, suggesting any subjectivity in application had been minimised.

DISCUSSION

The average reading age of each PIL was higher than the ABNA, putting this research in line with previous studies relating to other medical PILs (21-30). This suggests that those not capable of reading above the ABNA may struggle to understand the information provided to the service user, potentially prejudicing not only their adherence to the PIL advice but also their ability to make informed decisions(8, 30-35).

Conversely, it must be noted that purely aiming for a low reading age score can result in an infantile, uninteresting or patronising PIL. Consequently a balance must be achieved so that a leaflet is clear as well as informative, be this through sentence structure, for example, the use of bullet points, or the inclusion of other forms of non-written communication, such as images (36-39). It should also be capable of interpretation away from the clinical setting.

The software employed to predict readability determined word difficulty by identifying words over 12 letters or 4 syllables, with the syllable count being affected by grammar and pronunciation. As a result, the software deemed words such as

“accidentally” as difficult, but “maliciously” as not, highlighting a potential flaw in the assessment process, which in turn would impact on the actual readability, and therefore the comprehensibility, of the document. Simplification of words is ideal in order to positively impact readability scores, for example, the use of medical terminology such as “physiotherapy” would have a significant negative effect on scores. Nevertheless other terms for such words could be antiquated or cause confusion, which in itself could be detrimental to actual comprehensibility, even if their use would improve the readability scores (32).

In general the PILs did not exploit the “picture superiority effect” principle, in that memory favours visual images over text or the spoken word (40-43). Visually pleasing PILs have a positive impact on information recall and can help to span the variable reading levels of users (44-47). Discord was apparent between assessment tool criteria and NHS or government guidance, for example, whilst SAM recommends “simple line drawings”, the NHS warns against “clipart”, taking the view that it can undermine the integrity of the distributing organisation (10, 48).

Typography, including font, capital letter use, subheadings, bullet points, use of colour, text consistency, italics and line length can all have a significant impact on comprehensibility and therefore the ultimate PIL score, as well as the user friendly nature of a PIL (35, 42). The majority of leaflets utilised Arial, a sans serif font, being the font recommended by the NHS and certain learning disability organisations as one that can ease readability and, therefore, understanding(11, 49-52). Both tools considered a serif font to be superior, with SAM also scoring a sans serif font highly, whilst BALD distinguished between the two, scoring sans serif poorly (53). Modification of the BALD tool for the assessment of PILs should be considered in future studies, so that those following recommended guidelines are not penalised.

The assessment tools used to consider KAFO PIL quality concentrated on different aspects and had different focus points, which provided a more discerning analysis of the leaflets. EQUIP36 looked at language choice, structure and the qualitative and quantitative nature of the data, whilst DISCERN centred more on the evidential backing to the information contained in the PILs and whether this supported the device user in making their own decisions (12, 14, 54, 55). Unless the results of both tools were considered, a PIL could be inappropriately judged regarding its quality, as orthoses are an under-researched topic and the evidence bank to support the information provided is not readily available. This re-affirmed the need to use multiple tools throughout the study.

The tools identified that a number of leaflets were still in use beyond their review period and in some cases, the same hospital trusts submitted PILs that, whilst similar, had different review dates, suggesting a lack of consistency within organisations. Information contained in PILs should be regularly monitored through review not only to assure KAFO users that they have the most up to date

information, which should include the orthotic department contact details, but also to maintain confidence in the issuing organisation.

The MHRA advocate for concise prose in a columnar format, as a PIL that is too long or poorly laid out can lead to a leaflet not being read, or for the message in the PIL to be missed or misunderstood (1, 36, 56-59). The PILs reviewed for this study varied considerably, both in format and also length, ranging from 2-8 pages, and from 397 to 1246 words, which in itself had an impact on all statistics, including the calculation of readability, because of the number of words available for analysis.

Although it is not a legal requirement for alternative language materials to be available, any disability should be catered for with “reasonable adjustment” under the Equalities Act 2010, for example, visual loss should be accommodated through the availability of larger print text (60). Approximately 8% of the UK population indicate that they do not have English as their first language and 1.6% indicate that they do not speak English well, or at all (18, 61-65). More than half, 56%, of PILs did identify that they were available in other languages, or in braille, which would assist in the prevention of language-based health care discrepancies (61, 64-67).

The disparity in the detail of information contained within the PILs was particularly noticeable in the donning provisions, wearing in guidance, and also the time for skin marking to disappear after device removal, which ranged from “15 minutes” to a “couple of hours”. Whilst there was a general consensus on appropriate footwear, key details, such as the wearing of a sock or interface between the skin and the device, were also missing in 20% of cases. Lack of information in leaflets not only renders them ineffective, but could result in more serious complications, such as skin break down or pressure sores (68, 69).

Contrary to recommendations, some PILs contained details of more than one device, for example, amalgamating KAFO and knee orthosis care, which gives the opportunity for confusion and concern, as well as affecting the impact of the design and presentation along with the quality of the document (70).

Of the PILs analysed, 20% failed to identify that device review was important or even needed. Whilst it is recognised that some provisions, such as the regularity of reviews or maintenance of a KAFO, are related to trust policy and a service user’s requirements, it is important to highlight within the leaflet that regular device maintenance and review is necessary for safe and effective wear.

The majority of leaflets failed to identify reference materials or their information sources, which is inconsistent with MHRA guidance and is another factor which may inhibit the service user's ability to conduct their own research and arrive at appropriately informed decisions (18).

The use of patient test groups for newly created PILs would be beneficial in ascertaining whether the information they contain can be easily assimilated and therefore be of benefit to the service user. However, no leaflet acknowledged whether patient participation had been adopted in their preparation (15, 17, 61).

Limitations

It is important to recognise that the study has a number of limitations.

The 75.35% non-response bias was calculated from the number of responses that were received from direct contact with orthotic departments, whether they supplied KAFO's or not. More detailed statistics on this point were not possible as the reason for a service providers lack of response could not be ascertained, for example whether the departments approached did in fact prescribe KAFOs, or if they did, whether they issued KAFO PILs in support, or indeed, whether the lack of response was due to administrative issues. However, the participant response rate was satisfactory to provide ample information relating to the comprehensibility, quality and content sufficiency of KAFO PILs to enable the study to continue.

The Intra and inter-rater reliability of the tools could not be calculated due to project time constraints and manpower.

The tools chosen for this study were not all used in their original form, in that questions were omitted, or amended with clarifying clauses, to ensure both their appropriateness for this study and also that their standardised application to the PILs was possible. In addition, the tool to assess content sufficiency was created for the purpose of this study and has not been validated.

Recommendations

In line with study protocol, the findings of this study were submitted to those participants who requested them. These were provided in the form of general and individualised recommendations which were divided into the areas of research, being comprehensibility, as split into the two categories of readability and design and presentation, quality, and content sufficiency. Whilst there was some overlap between the categories, it is important that each one should not be considered in isolation, but collectively, to ensure full benefit is obtained from the results.

General recommendations for the design of PILs include:

To maximise comprehensibility, the aim should be to develop a PIL with a reading age between 9 to 12 years old (8). This can be achieved by using shorter sentences, between 15 to 20 words, which are preferably common mono- or bi-syllabic words (15, 32, 61, 70). PIL design and presentation can substantially

influence comprehensibility, through a consideration of, for example, print size (over size 12), type of the font (serif or sans serif), the use of arabic numbers, subheadings, which also improves white space balance, bullet points, which positively affect content density, colour, an active voice (adopting the use of "you", instead of "the service user") as well as labelled illustrations, all of which will help to engage the reader (32, 61, 70-73). In addition, grammatical and spelling errors should always be avoided.

To ensure PIL quality is maintained, treatment aims and effects should be incorporated and a balance should be achieved between the benefits of device wear and associated risks (18, 19, 70). On a practical note, information should be presented in a logical order and a PIL should include details of the author and the prescribing department's direct contact details, the publication and review dates (which should be adhered to), information references as well as further sources for research (55, 72). A place for handwritten notes would enable the leaflet to be personalised, giving a sense of individuality to the information provided.

As the tool developed for content sufficiency took the form of a checklist, this list was the foundation for the essential content recommendations. Practical considerations such as the use of a device interface as well as donning instructions, footwear and skin and device care should be included along with those of a more administrative nature as mentioned above, such as contact details, department opening times, references and information sources.

CONCLUSION

The aim of this study was to assess KAFO PILs obtained from NHS and private clinics within the UK with respect to their comprehensibility, quality and sufficiency of content. This was undertaken with the assistance of nine verified assessment tools and one newly created tool specifically designed to determine any superfluous or missing information. The use of multiple tools standardised the process and limited the subjective influence of the single rater assessment.

The assessment tools revealed a great variation between the PILs, although leaflets that scored lower, generally did so throughout, whereas other PILs consistently scored higher, though not necessarily highly. However, no leaflet fully satisfied all the assessment criteria demonstrating that there was no single PIL that was considered superior although there were areas of collective highs and lows.

A reading age of 9-12 years old should be the aim, with information accurately conveyed without oversimplification to allow a greater proportion of the user group to comprehend the PIL contents. Of the PILs submitted all surpassed this reading age. Common, mono or bi-syllabic words should be adopted with appropriate headings and shorter sentences. Consideration should be given to the print size, typeface,

and the use of illustrations as well as bullet points to maximise the benefits of design and presentation considerations.

To be content sufficient and of quality, essential information should be logically set out and should include, for example, wear and care regimes, risks, benefits and side effects, as well as identification data, signposts to references and further information, along with review and publication dates.

It became clear throughout this research that, whilst a PIL may be visually pleasing and well set out, demonstrating appropriate comprehensibility scores, it may not be of quality or contain adequate information to inform the reader of the safe and effective use and care of their KAFO. Each of the areas analysed in this study therefore, should be considered to ensure the development of a suitably effective PIL.

In providing general and, where requested, personalised feedback, it is hoped that a KAFO PIL producer will be encouraged to promote the development of a leaflet that is as informative as possible and that it will also encourage those that do not yet distribute guidance in PIL format, to consider doing so.

Future Research

Further research is needed within this field, which should begin with the repetition of this study using the PILs then available, but with consideration given to the points raised by this work. The research should be undertaken by more than one researcher so that both the inter and intra-rater reliability of the tools can be ascertained which would enable the data produced to be of more benefit. In addition, consideration should be given to validating the assessment tool prepared for content sufficiency so as to ensure all information necessary for inclusion in a KAFO PIL is incorporated.

Upon completion of any such subsequent research a guide or template should be produced, and KAFO user groups consulted to ensure the efficacy of the resultant leaflet before it is placed into general circulation.

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