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RESEARCH

Understandability of statin patient information leaflets in the UK: a mixed-methods cross-sectional evaluation

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Abstract

Background: Statins are the UK's most prescribed medicine and are used more in deprived populations. Patient Information Leaflets (PILs) included in medication packaging may support safe, effective use, but only if they are understandable. Guidance states PILs should have a reading age of ≤13 years, and regulators require that ≥80% of patients answer comprehension questions correctly on them when 'user tested'.

Aim: To provide the first independent evaluation of the readability and comprehension of UK statin PILs.

Design & setting: *Study 1:* Cross-sectional analysis of the reading age of 39/40 of the UK's approved statin PILs.

Study 2: Cross-sectional survey with a representative sample of 517 UK adults aged 40–74.

Methods: *Study 1:* Reading age was assessed using four readability formulas, with additional scores calculated after adjusting for potentially familiar technical terms.

Study 2: Two PILs (atorvastatin [MSN] and rosuvastatin [Ranbaxy]) were randomly selected and user-tested with participants. They answered eight comprehension questions per PIL; responses were double-scored.

Results: *Study 1:* No PIL met the recommended reading age. Median reading age was 15.9 years (15.0 after adjustment). Atorvastatin PILs were least readable.

Study 2: Key messages were poorly understood; for atorvastatin, 5/8 items met the≥80% criterion; for rosuvastatin, 2/8 met it. Key safety and use messages were frequently misunderstood.

Conclusion: UK statin PILs do not meet recommended readability or comprehension standards and are likely to be difficult to understand for many users. Improving clarity and usability is essential to support equitable understanding and safe, informed long-term statin use.

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How this fits in

Statins are the UK's most prescribed medicines, and their PILs are intended as an authoritative source with the potential to counter misinformation and support long-term adherence. Until now, their understandability in the UK had not been independently evaluated. This study showed that UK statin PILs exceed recommended readability levels and that many patients struggle to extract key safety

messages. Clinicians should not assume that PILs reliably support informed use or adherence. They should therefore avoid relying on PILs alone and actively invite questions and address uncertainties during consultations.

Introduction

Statins are England's most prescribed medicine, accounting for 93% of the 99.6 million lipid-regulator prescriptions in 2024/25.[1] They are central to cardiovascular prevention strategies,[2,3] particularly for those aged 40–74. Despite evidence of benefit,[4,5] adherence can be poor; with around half of patients non-adherent within one year of prescription.[6] Public scepticism, amplified by media and online misinformation, may undermine trust and effective prescribing.[7,8]

Patient understanding of statin benefits and risks is central to shared decision-making and informed consent, yet time-limited consultations constrain detailed discussion. Patient Information Leaflets (PILs), supplied with medicines since 1999,[9] are therefore an important source of patient information. If PILs are difficult to understand, they may fail to support informed use and inadvertently contribute to non-adherence.

In the European Union — and, until recently, the UK — PILs are approved by the European Medicines Agency and national regulators,[10] who specify structure and content and require that they be accessible to the widest possible audience.[11] The UK's post-Brexit regulatory processes remain broadly similar,[12] including the legal requirement (since 2005) for manufacturers to involve potential users in PIL development. This reflects concerns about literacy: in England, 15% of adults have literacy skills at or below those of an 11-year-old and a further 28% read at the level of a 12–14-year-old.[13] Literacy is socially patterned,[14] with lower levels in socioeconomically deprived groups, who also have higher rates of statin use.[15] Poorly understood PILs may therefore widen health inequalities.

Evidence from other therapeutic areas suggests regulatory authorisation of a medicine and its PIL may not be sufficient to ensure a PIL is understandable.[16–18] We systematically searched the literature on the understandability of statin PILs (Supplementary File 1). No meaningful evidence was found. Given the widespread use of statins, this was concerning.

Two complementary approaches are commonly used to assess the understandability of PILs.[19] Readability analyses estimate reading difficulty using surface features, such as sentence length and word complexity, typically expressing this as reading age or US school grade (reflecting the origin of this method).[20] The score indicates the reading ability required to understand the text. For PILs, a maximum of 13-years is recommended,[21] commonly expressed as US Grade 8 (key stage 3 in England).

Readability tests allow comparison across documents and large samples, but may overestimate PIL difficulty because some polysyllabic terms are familiar to the target audience (for example "cholesterol"). Contextual adjustment, which excludes such terms, may provide a more accurate estimate, but is rarely used.[22]

The second approach assesses literal comprehension: whether readers can locate, interpret, and apply key information contained within the PIL. This is resource-intensive but important since acceptable readability may not guarantee comprehension because factors beyond surface features can affect it (for example how information is presented).[23] "User-testing" methods, such as the Australian–Sless approach,[24] are thus recommended by regulators. They advise ≥80% of users should answer each comprehension question correctly for a PIL to be acceptable.[11,25]

We conducted an independent evaluation of UK statin PILs by combining readability assessment and user testing, leveraging the former to estimate readability across a large corpus of PILs and the latter to assess comprehensibility among target users.

Our objectives were to:

1. describe the readability of UK statin PILs (study 1);
2. examine factors associated with variation in readability (study 1); and
3. assess patient comprehension of selected statin PILs among individuals from the target population in the UK (study 2).

Method

Study 1: Readability of statin PILs

Design and materials

This study was a cross-sectional analysis of statin PILs.

Five statins are licensed in the UK (atorvastatin, fluvastatin, pravastatin, rosuvastatin, and simvastatin).[26] PILs for all 40 UK products containing one of these statins were downloaded from the Electronic Medicines Compendium (EMC; 27 October 2022). Thirty-nine (97.5%), covering 133 medication strengths (Supplementary File 2), could be prepared for testing (requiring the removal of images, symbols, copyrights, web links). As per the regulator's guidance, PILs contain six sections. We removed section 6 ("Contents of the pack and other information") because patients rate it as of low importance.[18]

Readability assessment

We assessed readability using three established measures assessing different text features: SMOG,[27] Flesch–Kincaid,[28] and FORCAST.[29] Formulae are provided in Supplementary File 3. Consistent with previous studies,[17,22,30] we calculated a composite score for each PIL as the median from the tests. Scores were reported in the original format as US school grade to permit comparison across studies; for interpretability, these were also converted to estimated reading age by adding five. Additionally, we calculated Flesch Reading Ease (FRE; range 0–100, higher scores indicating greater readability).[31] Analyses were conducted in Readability Studio (v2020) using default settings and repeated with contextual adjustment.

For contextual adjustment, a list of words was compiled for exclusion from consideration by the tests. It included statin names (n=14), adverse-event terms (n=1482), and condition-related words (n=78) (Supplementary File 4). Proper nouns were not considered by the software and numerals were treated as monosyllabic.

Analysis

Readability scores were non-normally distributed and so presented as medians with interquartile ranges (IQRs). We reported the proportion of PILs that satisfied the recommended maximum reading age of 13. Mann–Whitney U and Spearman rank tests explored associations between readability scores and PIL characteristics (time since revision,[32] branded versus generic status,[33] and atorvastatin versus other). To limit family-wise error, statistical significance was set at P<0.01. Analyses were conducted in SPSS (v27).

Table 1 Details of PILs selected for user testing (Study 2)

	PIL 1	PIL 2
Characteristics	**Atorvastatin 10, 20, 40, 80mg film-coated tablets**	**Rosuvastatin 5, 10, 20, 40mg hard capsules**
Active ingredient	Atorvastatin	Rosuvastatin
Branded/generic	Generic	Generic
Word count[a]	2019	2410
Flesch Reading Ease score (standard application)	49	63
Authorisation holder	MSN Laboratories Europe Ltd	Ranbaxy (UK) Ltd. (Sun Pharmaceutical Industries)
Last revised date	December 2021	October 2021

[a]Includes titles and all text from Section 1 ("What [medication X] is and what it is used for") through to Section 5 ("How to store [medication X]")

Ltd = Limited. PIL = Patient Information Leaflet.

Study 2: Comprehension of statin PILs

Design, recruitment, and sample size

This study was an anonymous cross-sectional online survey (Qualtrics). To minimise participant burden, only two PILs were tested, with order randomised 1:1.

A sample of UK adults aged 40–74 years was recruited via Prolific in February 2024. Sampling was stratified by age, sex, and ethnicity to reflect UK Census distributions. Full eligibility criteria, approvals, and recruitment are in Supplementary File 5. Participants were informed the study examined the helpfulness of PILs, but not any hypotheses. Participants received £5.50 for participation.

A minimum of 374 participants with complete data was required to estimate, with 95% confidence and ±5% precision, the proportion answering comprehension questions correctly. In the absence of prior evidence for UK statin PILs, the calculation was informed by the comprehensibility of UK PILS for antiseizure medications[17] (Supplementary File 5). Allowing for 30% attrition, the target recruitment figure was ≥486 participants.

Materials

Two PILs were selected from Study 1 by stratifying PILs according to adjusted FRE scores and randomly selecting one from the upper (Atorvastatin film-coated tablets, MSN) and lower quartile (Rosuvastatin hard capsules, Ranbaxy) (***Table 1***).

Procedure and measures

Participants completed demographic questions and self-reported difficulty reading health information. They were then presented with the first PIL followed by eight PIL-specific comprehension questions, and subsequently the second PIL with a further eight questions (Supplementary File 6). PILs remained available and no time limits were imposed.

Questions focused on safe and effective statin use, aligned with regulatory guidance on how to conduct user testing,[11,34] and reflected the key safety messages individual to the medication.[35–39] Questions were bespoke and not necessarily equivalent. Most were scenario-based to reflect how PILs are typically used. Question wording did not mirror phrasing or exact ordering of information in the PILs. Question face validity was confirmed by a GP (JD). Participants responded using free text.

Two attention-check questions – detailed in Supplementary File 8 – were embedded to identify and exclude inattentive respondents, ensuring data integrity.

Analysis

Two trained raters with medical backgrounds (MS, WD) independently coded participants' responses as correct or incorrect using predefined criteria (Supplementary File 7), resolving discrepancies through discussion. Inter-rater reliability was assessed using percentage agreement and prevalence-adjusted bias-adjusted kappa (PABAK) ([40]).

We reported the proportion of participants answering each question correctly with 95% confidence intervals (CIs) and ranked questions by performance. Analyses included only participants with complete PIL comprehension data who passed the attention checks.

Associations between formal education, a history of high cholesterol, and comprehension scores (0–16 correct answers) were explored using two-sided independent-samples t-tests assuming unequal variances. Mean differences and 95% CIs were reported. These analyses were exploratory and not informed by an a priori power calculation. Analyses were conducted in SPSS (v27).

Results

Study 1: Readability of statin PILs

PIL characteristics

The median word count of PILs was 2151 (IQR 1929–2804). Most were for generic products (84.6%). The median authorisation date was July 2014, and the median last revision date was October 2021

(IQR February 2021–January 2022). Of the PILs, 34 (87.1%) were authorised post-2005. Polysyllabic words accounted for a median of 17.2% of text.

Readability

When tests were applied in standard form, no PIL met the recommendation of a maximum reading age of 13 years. Median required reading age was instead 15.9 (median grade = 10.9, IQR 10.6–11.1) (Supplementary File 2). The median FRE score was 54 (IQR 52–59).

After contextual adjustment, readability improved modestly, but still no PIL met the recommended maximum reading age. Median reading age was 15.0 years (median grade = 10.0, IQR 9.6–10.1). The median FRE score was 66 (IQR 65–72).

Factors associated with readability

Readability was not significantly associated with time since authorisation or last revision, nor branded/generic status. However, atorvastatin PILs were less readable than those for others, both before and after adjustment (median grade 11.1 vs 10.1; $P<0.001$).

Study 2: Comprehension of statin PILs

Participant characteristics

A total of 569 participants were recruited. Of them, 519 (91.2%) provided complete data. Two were excluded for failing the attention check, leaving 517 (90.8%). Median age was 51 years (IQR 44–60), 49.5% were female, and 1.9% reported English as a second language; 62.7% of participants held or were studying for a university-level qualification (Supplementary File 8). Nineteen percent self-reported experiencing high cholesterol.

Median survey completion time was 28.2 minutes (IQR 20.8–36.8). Participants with incomplete data did not differ significantly from those with complete data in age, sex, or self-reported literacy.

Inter-rater reliability

Agreement between raters was high (Supplementary File 6). For 15 of the 16 questions, agreement was almost perfect (PABAK 0.81–1.00). Agreement for atorvastatin items ranged from 94.0% to 99.8% (PABAK 0.88–0.98) and for rosuvastatin items from 62.6% to 99.4% (PABAK 0.25–0.99).

Participant comprehension

For atorvastatin, correct response rates ranged from 34.0% to 96.9%, with five of eight questions answered correctly by at least 80% of participants. Supplementary File 6 presents the proportion of participants answering each question correctly alongside the relevant PIL text. The lowest-scoring question (34.0% correct) concerned the increased risk of muscle toxicity in individuals with hypothyroidism.

For rosuvastatin, correct response rates ranged from 42.5% to 82.4%; only two of eight questions were answered correctly by ≥80%. The lowest-scoring item (42.5%) related to maximum dose eligibility.

Participants with, or studying for, a university-level qualification (n = 324) answered more comprehension questions correctly than those without such education (n = 193; mean difference = 0.89 questions, 95% CI = 0.42 to 1.38; t (376.6) = 3.69, $P<0.001$). Participants reporting a history of high cholesterol (n = 101) did not differ significantly from those without such a history (n = 416; mean difference = −0.34, 95% CI = −0.95 to 0.27; t (144.3) = −0.09, P = 0.263).

Discussion

Summary

This study provided the first independent assessment of the understandability of UK statin PILs. Although regulators require PILs to be designed so most users can understand them,[11,25] our findings indicated a significant minority of patients are likely to struggle to extract and correctly interpret key information from them.

In study 1, all 39 UK statin PILs exceeded recommended readability levels, requiring a reading age of approximately 15–16 years rather than the recommended maximum of 13. This was even after

efforts to avoid penalising the PILs for including uniquely familiar polysyllabic terms. Given literacy levels in England,[13] up to 40% of adults may struggle to understand these PILs.

Study 2 assessed the comprehensibility of a PIL for rosuvastatin and a PIL for atorvastatin. Neither consistently enabled ≥80% of participants to answer questions about their key messages, the level regulators consider acceptable. Only 2 of 8 rosuvastatin questions and 5 of 8 atorvastatin questions met this threshold. Several of the lowest-scoring items related to important safety information.

Strengths and limitations

The strengths of study 1 include the systematic identification and analysis of PILs and the use of multiple readability measures with contextual adjustment. Study 2 used a large, demographically representative sample, resulting in narrow confidence intervals around comprehension estimates.

A potential limitation of both studies is that the PILs assessed were from a single point in time and may since have been revised. However, this is unlikely to have materially affected our findings. In Study 1, readability was not associated with time since authorisation. Furthermore, a repeat search of EMC in February 2026 found that most current UK statin PILs (78%) were represented in our original sample. Although many had been updated since 2022, a comparison of a random 10% sample found minimal changes. To evidence this further, Supplementary File 9 showed that 93.3% and 94.6% of the wording in the atorvastatin and rosuvastatin PILs used in study 2 remained unchanged in their updated versions. Most revisions involved the addition of adverse-effect information rather than changes intended to improve clarity. Consequently, any updates were unlikely to have materially altered the understandability of these PILs.

A limitation of study 2 was that it was not feasible to assess comprehension across the full range of PILs examined in study 1. To minimise participant burden, comprehension was assessed using only two PILs selected to differ in their readability characteristics.

Although the study 2 sample was demographically representative, recruitment via Prolific may limit external validity. While Prolific has been shown to generate high-quality, reproducible research data,[41,42] participants with a university degree were overrepresented (62.7% versus an expected 33% in this age group).[43] As higher educational attainment is associated with greater literacy, the comprehension scores observed may underestimate the difficulties experienced by the wider target population. However, the effect of education on comprehension was modest, corresponding to only one additional correct answer on average.

Approximately one-quarter of participants in study 2 reported a history of high cholesterol and may therefore have had prior exposure to statins and their associated PILs. We did not exclude these individuals because 20–30% of statin users switch type over time,[44,45] making exposure to multiple statin PILs common. We found no evidence that participants with a history of high cholesterol had different comprehension scores from those without such a history.

Comparison with existing literature

Our findings aligned with prior research in other therapeutic areas, showing many authorised PILs,[17,46] including those developed after the 2005 introduction of mandatory user testing, fail to meet recommended understandability standards. This suggests a systemic issue.

Implications for research and practice

Despite manufacturers being legally required to involve users in PIL development, our findings suggested that problems with understandability persist. Whether this reflects limitations of user involvement itself or shortcomings in its implementation remains unclear. The lack of transparency surrounding implementation makes its effectiveness difficult to assess. Clearer guidance and reporting requirements may therefore be needed, particularly regarding representative sampling and the minimisation of bias.[47]

The persistence of poor understandability despite regulatory guidance may suggest a need to reconsider more fundamentally what PILs are required to be and include.[48,49] Regulatory templates mandate standard headings and exhaustive content. Pelizzari[50] highlighted this risks pushing PILs to include technical and regulatory styles of writing, which may hinder understanding and engagement among some readers. The UK/EU framework is relatively distinctive in requiring formal user testing of PILs.[51] Future research could compare the understandability of statin PILs developed under different

regulatory frameworks. To our knowledge, such comparative studies of PILs more generally have been restricted to expert assessments of PIL quality or users' ability to locate information, not their comprehension of the information provided.[52,53]

Our findings also highlighted the importance of independent evaluations of PIL understandability, which are rarely funded despite helping identify shortcomings and inform improvement.

For clinical practice, prescribers should be aware that statin PILs may be difficult for a significant proportion of patients to understand. Key safety messages should thus be reinforced, and any reliance on PILs avoided. Actively inviting questions and normalising difficulties reading PILs may help.

The information that may require reinforcement by clinicians is likely to vary across statins and depend on how it is presented within the PIL. Findings presented in Supplementary File 6 suggested that comprehension may be influenced less by where information appears in a leaflet than by how it is presented. In particular, comprehension appeared higher when information was presented prominently and early within a section, and when directive statements, headings, or subheadings helped orient readers to the content that followed.

Finally, recent calls to revise statin PILs[54] to better reflect current evidence on adverse effects[55] present a timely opportunity to also incorporate our evidence on understandability.

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Ethical approval

Approval for study 2 was provided by the University of Liverpool's Institute of Population Health Research Ethics Committee (Reference: 13342). All participants provided informed consent.

Provenance

Freely submitted; externally peer reviewed.

Data

Owing to the condition of approval, the datasets used in this study are not publicly available. Requests for access to the data can be directed to the corresponding author and will be considered on a case-by-case basis.

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