





## Original Research

# Supporting shared decision-making and people's understanding of medicines: An exploration of the acceptability and comprehensibility of patient information

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### Abstract

**Background:** Patient information may assist in promoting shared decision-making, however it is imperative that the information presented is comprehensible and acceptable to the target audience.

**Objective:** This study sought to explore the acceptability and comprehensibility of the 'Medicines in Scotland: What's the right treatment for you?' factsheet to the general public.

**Methods:** Qualitative semi-structured telephone interviews were conducted with members of the public. An interview schedule was developed to explore the acceptability and comprehensibility of the factsheet. Participants were recruited by a researcher who distributed information packs to attendees (n=70) of four community pharmacies. Interviews, (12-24 minutes duration), were audio recorded, transcribed verbatim and analysed using a framework approach.

**Results:** Nineteen participants returned a consent form (27.1%), twelve were interviewed. Six themes were identified: formatting of the factsheet and interpretation; prior health knowledge and the factsheet; information contained in the factsheet; impact of the factsheet on behaviour; uses for the factsheet; and revisions to the factsheet.

**Conclusions:** The factsheet was generally perceived as helpful and comprehensive. It was highlighted that reading the leaflet may generate new knowledge and may have a positive impact on behaviour.

### Keywords

Patient-Centered Care; Information Dissemination; Patient Preference; Drug Therapy; Health Promotion; Pharmacies; Pharmacists; Qualitative Research; United Kingdom

## INTRODUCTION

Person-centred care, often advocated as a central tenet of healthcare, endeavours to ensure that individuals are adequately educated and supported in a manner which promotes informed decision-making and facilitates management of health.<sup>1,2</sup> It is advised that person-centred care may be achieved via empowerment of patients, carers and communities. Empowerment may be promoted in a number of ways, including by providing support to patients to manage their health and increasing health literacy<sup>3</sup>, which may be defined as "...having the knowledge, skills, understanding and confidence to use health information, to be active partners in their care, and to navigate health and

social care systems".<sup>4</sup>

A key aspect of a person-centred approach, and a focal public health strategy in the United Kingdom (UK) and globally<sup>2,5-8</sup>, is provision of support for shared decision-making (also known as concordance<sup>9</sup>) and engagement in meaningful dialogue between patients and healthcare professionals.<sup>5</sup> Concordance typically centres on the consultation between patients and healthcare professionals and "values the patient's perspective, acknowledging that the patient has expertise in his or her body's experience of illness and response to treatment".<sup>10</sup> However, whilst concordance is perceived to be a central tenet of healthcare, recent evidence outlines the considerable variability in patient experiences.

A systematic review of 63 articles evaluating concordance and patient treatment preferences, highlighted a sizeable variation between a patient's preference for treatment and the actual treatment which was received (concordance value scores). The authors reported that known as concordance value scores ranged from 19% to 97% and hence, it was suggested, that there was a high degree of disparity in the provision of care in relation to patient's preferences.<sup>11</sup>

Patient information may occupy a critical role in facilitating concordance. For example, in the European Union (EU), pharmaceutical manufacturing companies are required to

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include a patient information leaflet (PIL) within all medicines.<sup>12</sup> The legislative directive requires that PILs comprise seven sections: identification of the medicine; therapeutic indications for the product; information which patients need to be aware of prior to taking the medicine; dosage and usual instructions for use; description of side effects; how to store the product; and, date on which the leaflet was prepared.<sup>13</sup>

These stipulations and provisions strive to ensure that the patient is at the forefront of decision-making. Regulation of PILs is perceived to be of considerable importance since they are frequently used by patients as the principal source of information on medicines.<sup>13,14</sup> Whilst legislative frameworks exist to promote patient involvement in taking medicines, a systematic review of 27 articles, published in 2007 on the role and value of PILs to patients has highlighted the challenges faced in drafting information; owed to the variation in patient perspectives with regard to the degree of information that was required in relation to medicines.<sup>15</sup>

Whilst patient information may be used as a means to empower individuals to take ownership of their health and increase health literacy<sup>16,17</sup>, this may prove to be a difficult feat due to the variability in quality of information presented. It has been suggested that creation of leaflets which are understandable may improve patients' knowledge and also, may promote involvement in decision-making.<sup>18,19</sup> Thus, it is of paramount importance to ensure that patient information is presented in a manner which is clearly comprehensible and acceptable to the target audience.<sup>17,20</sup>

Healthcare Improvement Scotland, a national organisation focused on driving improvements in the quality of health and social care<sup>21</sup>, has developed the 'Medicines in Scotland: What's the right treatment for you? Information for patients and the public' factsheet (Supplement 1). The medicines factsheet was developed in response to a recommendation which highlighted the need for greater transparency on information with regard to decision-making and medicines.<sup>22</sup> Similarly, the Scottish Government Chief Medical Officer's Annual Reports 2014-15 and 2015-16, titled 'Realistic Medicine' and 'Realising Realistic Medicine' have highlighted the importance of involving patients in their own healthcare and promoting shared decision-making.<sup>5,7</sup>

In fourteen pages, the A5 size factsheet provides information to support patients in informed decision-making, specifically related to medicines (key sections are presented in Table 1). The factsheet was developed in collaboration with healthcare professionals, public partners, and patient support groups across NHSScotland. In February 2016 the draft medicines factsheet was distributed to a number of stakeholders in NHSScotland to give them the opportunity to share within their local networks (including public involvement groups and third sector organisations) for comment over a 10 week period. Eighty seven responses were received, of which 61% came from patients, public partners/representatives and patient/carer support groups. Various healthcare

professionals responded, including doctors, nurses and pharmacists. The feedback informed the development of the final version of the medicines factsheet which was published in June 2016. The medicines factsheet was available electronically for viewing or download via the Healthcare Improvement Scotland's website. Small numbers of the medicines factsheet were available as hard copy for dissemination at national events.

In an effort to promote engagement, shared decision-making and health literacy, this study sought to explore the acceptability and comprehensibility of the 'Medicines in Scotland: What's the right treatment for you?' factsheet to members of the public. Acceptability<sup>23</sup> will refer to satisfaction of the factsheet, and comprehensibility<sup>24</sup>, to how understandable the factsheet appears. Whilst the initial feedback led to the development of the revised edition, the developers, in consultation with university representatives, perceived a further need to conduct an in-depth study on the acceptability and comprehensibility of the second iteration of the factsheet. The exploration will provide the information required to inform any additional revisions within subsequent editions of the factsheet.

## METHODS

### Design

A pragmatic methodological approach was undertaken whereby semi-structured qualitative telephone interviews were conducted with members of the general public.

### Setting

Four community pharmacies (one city-centre, two city suburbs and one rural) in the North East of Scotland.

### Ethical approval

Ethical approval was granted by the University School of Pharmacy and Life Sciences Research Ethics Panel (Ref: S31) and NHS Health Research Authority East of England – Cambridgeshire and Hertfordshire Research Ethics Committee (16/EE/0461). Management permission for non-commercial research was granted by NHS Grampian Research and Development (2016RG002).

Heading
I have an appointment with a healthcare professional to discuss a problem. How will they decide if a medicine is needed for me?
If I need a medicine, how does the healthcare professional decide which medicine to prescribe?
What is a formulary?
Can I be prescribed a medicine that's not on my health board's formulary?
I have been given a medicine and I'm not sure how to take it. How can I find out how to take the medicine properly?
I don't think my medicine is working. What should I do?
I think I'm experiencing side effects from my medicine. What should I do?
I have heard patients can report side effects to medicines. Where can I get more information on how to do this?
I have medicines I no longer need. What should I do with them?
I am unhappy about my care. How do I make a suggestion or give feedback?

### Sampling and recruitment

Members of the public, who attended four community pharmacies in the local area and presented at the pharmacy counter, were recruited by a researcher (KGS). The inclusion criteria specified that participants were aged 18 years or over and were prescribed at least one medicine for long term use (specified on the basis that they had experienced taking medicines to a greater degree). Based on initial response rates (n=4, 26.7%), the researcher issued further recruitment packs (n=66) in an effort to satisfy the target sample size of 15. The research team initially hypothesised, based on prior research experience, that 15 interviewees may be a suitable target in terms of anticipating saturation. A recruitment pack was presented by the researcher to all members of the public presenting at the pharmacy during the recruitment period. The recruitment pack contained a cover sheet which outlined the study inclusion criteria, a participant information sheet, consent form, demographics form (basic demographics in addition to information on number of prescribed medicines, to serve as a further inclusion screen, and disclosure of any reading/visual impairments), copy of the factsheet and a prepaid return envelope. All participants who returned a consent form and satisfied inclusion criteria were telephoned to arrange a suitable day and time for interview. Participants were required to read the factsheet, and if they wished, to make notes or highlight any areas, prior to the interview. As far as the researcher is aware non-participants were not present during the telephone interviews.

### Data generation

The factsheet explained how an individual's doctor (or other healthcare professional) decides what is the right treatment for them, whether they need a medicine and, if so, which medicine is prescribed. An interview schedule (Table 2 outlines the primary questions) was developed by the research team, with expertise in pharmacy, social studies, technology and health, and social care, and reviewed with one participant. No revisions were made to the interview schedule after conducting the review and thus, the pilot data were included in the main study. A researcher (KGS) with experience in in-depth interviewing conducted the interviews. Each interview was conducted via telephone, audio recorded and transcribed verbatim. Notes were taken where participants did not consent to being audio-recorded. Field notes were not recorded during interviews and transcripts were not returned for member-checking to interviewees.

### Data analysis

Interview content was analysed using an inductive framework approach whereby codes are generated from the data. The approach comprises multiple steps and requires researchers to familiarise themselves with interview content, code relevant aspects of transcripts, develop a working analytical framework, apply the analytical framework to transcripts and charting of the data onto a framework matrix.<sup>25,26</sup> For this study codes were applied to the first six transcripts by one researcher and subsequently, the analysis was reviewed independently

Table 2. Primary interview questions
How do you feel about the patient information leaflet overall?
Did the leaflet improve your understanding of medicines and treatment in anyway?
Did you find the leaflet helpful?
Did you learn anything new?
Is there anything in the leaflet that you did not understand?
Would you change the way you do anything because of what you have read?
Would the leaflet impact on how you discuss your medicines with healthcare professionals?
Would the leaflet impact on how you make decisions about your medicines?
How do you think that the leaflet may be best used to help patients decide on appropriate treatments?
Did you find the leaflet easy to understand?
Are there any aspects of the leaflet that you think may require improvement?

and verified by the second researcher. Discrepancies in interpretation of codes were resolved via discussion. A preliminary framework of analysis was agreed after reviewing the initial six and applied to the remaining transcripts. This was reviewed after analysis of each transcript to ensure adequate coverage of themes. Data were subsequently grouped in Microsoft Excel to identify themes and sub-themes. No minor themes or diverse cases were identified during the analysis.

## RESULTS

The data are presented in accordance with demographics and thereafter each theme and corresponding sub-themes.

### Demographics

Of the 70 recruitment packs issued, nineteen participants returned a consent form (27.1%). Twelve participants were interviewed, a further five could not be contacted via the telephone number provided, one was unable to participate due to time pressures and another was withdrawn from the study as they were unable to complete the interview. Interviews ranged from 12 to 24 minutes. Participants were aged 36 to 85 years and the number of prescribed medicines ranged from 1 to 10. The majority were female (n=7) and did not have a visual or reading impairment (n=8). Seven were recruited from urban pharmacies, and the remainder from a suburban (n=2) or rural pharmacy (n=3).

### Formatting of the factsheet and interpretation

Three sub-themes were identified from the analysis and included: (a) attractiveness of the factsheet; (b) contrast of the text within the factsheet; (c) composition of the factsheet (e.g. good layout; appropriate structure and use of examples). For example, interviewees found the factsheet visually appealing and believed others would be attracted to read it,

"... I liked the pictures, I liked the colours, it was an attractive leaflet I thought so that people would feel attracted to read it" (Interviewee 10).

Recommendation	Quote
Inclusion of a query page	"I think there could be a little more support on if you have queries about this, this or this, in other words at the end a summary or an index and put a sort of page of reference points" (Interviewee 5)
Inclusion of a section on medicines running out	"I suppose it doesn't cover really long term use of medicines, sort of what to do when it runs out" (Interviewee 2)
Inclusion of information on mental health	"... I thought maybe the addition of people believe or feel they have a mental health issue, quite a delicate subject really, but it is not in here" (Interviewee 6)
Inclusion of information on taking multiple medicines	"...many of us as we grow older and the way that primary care is being run is that we are on a cocktail of medicines, you know it is two, three, four, five, six a day and therefore, I think there could be a little narrative in there that could be more helpful, the likelihood of things becoming difficult or having symptoms, that increases with the range of medicines you are taking" (Interviewee 5)
Inclusion of information to assist patients in making choices	"if you pursue something, you don't necessarily need to take no for an answer, straight away if you really feel strongly enough about it" Interviewee 11
Scope for personalisation	"...so you probably would have to be generic and then perhaps with a little secondary sheet which would cover, which covers your particular circumstances" (Interviewee 3)
Inclusion of a section on placebo effects	"...it didn't mention anything about placebo effects, I am not sure whether it should, 'cause I just think a lot of medicines are effective because they are a placebo, you know" (Interviewee 4)
Opportunity for greater promotion of self-care/management	"I think the emphasis could be more equal in the sense that the pamphlet starts from the proposition that the medical practitioner's will be correct, and I don't think they are wrong, but it is not always necessarily the case that the patient should always follow the treatment that has been advised. I think that it is important that patients should understand that they have a responsibility to themselves to understand the risks and benefits and make a decision with the advice of their medical practitioner" (Interviewee 4)
Inclusion of a section on how to use URLs	"...you could give a clue to somebody, maybe an appendix that says, here is a quick way to find URLs" (Interviewee 4)
Greater ethnic diversity in choice of images	"... all the people in it were white and I don't know if that should have been more of a mix" (Interviewee 8)

### Prior health knowledge and the factsheet

One sub-theme was identified from the analysis and encapsulated aspects of 'prior knowledge'. A number of interviewees reported that they had prior knowledge of health processes. This knowledge base was often attributed to either experience with managing a long term health condition and/or occupational background and related expertise,

"...it just kind of confirmed you know what I already thought or knew" (Interviewee 6).

### Information contained in the factsheet

Five sub-themes were identified from the analysis and included: (a) coverage of the factsheet (comprehensive and informative); (b) comprehensibility of the factsheet (language used and use of non-medical terminology; understanding information; difficulty retaining information due to length of factsheet); (c) the factsheet and knowledge (increased knowledge around healthcare and service delivery; generation of new knowledge; nothing new learned); (d) benefits of the factsheet (information may empower; information helpful); (e) critique of the factsheet (content patronising; information self-evident; unclear of target audience; unclear of purpose; complexity of factsheet; unhelpful to those without internet access; information unhelpful personally).

For example, three interviewees felt that the information may empower those who read it providing them with an idea of what to expect from medicines and healthcare practitioners, and problem solving strategies. However, one interviewee reported that they found the information contained in the leaflet both wordy and complex,

"I just felt it was a bit too complex for easy reading, I felt it was maybe a bit wordy" (Interviewee 9).

### Impact of the factsheet on behaviour

Three sub-themes were identified and included: (a) factsheet would be unlikely to impact on behaviour (due to prior knowledge; pre-existing confidence); (b) factsheet may have a positive impact on behaviour (encourage discussions with healthcare professionals; understanding what to do in certain situations; reporting side-effects); (c) factsheet reinforced current behaviour.

For example, interviewees highlighted that the factsheet may promote and encourage discussions with healthcare professionals. Accordingly, it may empower patients and equip them with the knowledge to question treatment,

"...if you have got this booklet saying this is what you can do, this is what you can do then you wouldn't be so bothered about doing it you know" (Interviewee 10).

### Distribution of the factsheet

The most appropriate distribution outlet for the factsheet was identified as the primary sub-theme. For example, interviewees discussed the most appropriate distribution outlets for the factsheet and suggested that it may be useful to make leaflets available in various public places (libraries and electronic displays) along with general practices and pharmacies,

"I would suggest, if you said to me the circulation, I would suggest places like local general practices in the whole of Scotland, libraries, hot points where there are medical, you know these

electronic medical contact points that they have in various public locations, I think it would be excellent to be able to guide people to having access to this book and particularly, certainly having a quantum [sic] of them available in practices, along with pharmacies and the like" (Interviewee 5).

### Revisions to the factsheet

Although some interviewees did not perceive the need for any changes to be made to the factsheet, a number outlined areas which they considered may benefit from revision. These are presented under four sub-themes: (a) clarification of aspects of the factsheet (clarification of purpose and function; clarity of Yellow Card section); (b) wording of the factsheet (rewording to enhance clarity; title revisions); (c) presentation of information in the factsheet (brevity and simplicity; reduction in length; altering of internet URLs); (d) greater emphasis of aspects of the factsheet (inclusive of broad spectrum of healthcare professionals; greater emphasis on conducting a risk benefit analysis; greater emphasis on reading the manufacturer's PIL). For example, a greater emphasis on pharmacists and nurses in addition to general practitioners (GPs),

"...I don't think there is enough, but maybe I am wrong, guidance to say that you may want to initially discuss certain issues with your pharmacist" (Interviewee 5).

### Recommendations for additional sections and further information within the factsheet

Interviewees outlined opportunities to include a number of additional sections and highlighted areas where further information could be provided (Table 3). Due to the variability in responses, these are listed and not grouped into sub-themes.

## DISCUSSION

The research explored the acceptability and comprehensibility of the 'Medicines in Scotland: What's the right treatment for you?' factsheet with the general public. Participants' feedback was grouped into key themes representing their perceptions of the information leaflet along with recommendations for improvement. The themes included: formatting of the factsheet and interpretation; prior health knowledge and the factsheet; information contained in the factsheet; impact of the factsheet on behaviour; uses for the factsheet; and, revisions to the factsheet.

Interview schedules were reviewed by the multi-disciplinary research team in an effort to promote credibility. Steps were also undertaken to ensure the rigour and trustworthiness of data, in terms of both collection and analysis e.g. using established research methods, prior interview experience of researcher conducting interviews.<sup>27</sup> The recruitment from multiple sites, comprising urban and non-urban community pharmacy settings, was a key strength of the research. Whilst the sample size was relatively small and will limit transferability of findings, the

themes identified within the interviews were perceived to have achieved saturation, in that no new themes were emergent. The location (North East of Scotland) of the research may further affect transferability of findings.

Another weakness of the study was that it was evident throughout the interviews that a number of participants had expert knowledge of medical conditions and the processes of the UK health and social care services and this may have impacted the results. For example, it may have been that those with an interest or expertise in health were more likely to be inclined to participate, resulting in a selection bias. Further, younger participants were poorly represented within the interviews possibly because they were conducted during office hours which may have resulted in selection bias. In addition, whilst the research endeavoured to understand the comprehensibility and acceptability of the factsheet, it may be that those with very low levels of literacy were not represented in the study since it would be unlikely that an individual who was unable to read would participate in the research. Moreover, participants were taking long term medicines and this may further limit the transferability of findings.

The formatting of the factsheet was perceived by interviewees in this study to be an important aspect influencing acceptability. Factors included appropriate use of images, headings and layout. These findings are reflected in guidance published by Medicines and Healthcare products Regulatory Agency Committee on Safety of Medicines on the usability of manufacturers' PILs whereby it is stipulated that the following aspects should be considered when developing a PIL in an effort to enhance readability: writing style; typeface; design and layout; headings; use of colour; and use of symbols and pictograms.<sup>13</sup> A systematic review on the readability of PILs concluded that reduced font size and lack of illustrations were often encountered and negatively affected readability.<sup>28</sup> Hence, the visual appeal of the factsheet may be a key factor in influencing an individual's decision to select the leaflet for reading.

Interviewees in this study highlighted that the factsheet may be a source of empowerment in that it may inform decision-making and promote discussions with healthcare professionals however, it should be cautioned that behavioural 'intention' does not necessarily correspond with an intended action.<sup>29</sup> As suggested by John *et al.*<sup>30</sup> in a study on patient evaluation of a factsheet, although patients may feel empowered after reading a factsheet to modify their actions, this may not have any measurable impact on behaviour. This phenomena, termed the 'intention-behaviour gap' stipulates that whilst individuals may feel empowered to engage with a specific behaviour, they may fail to execute the behavior.<sup>29</sup>

Whilst behavioural intention may not lead to enactment of a behaviour, previous research has been positive and has demonstrated the impact of patient information across a series of outcomes. For example, a systematic review on the use of decision aids, including booklets, highlighted that their use improved knowledge of treatment options, how informed they felt, understanding of the risks and benefits associated with treatment and, facilitated greater

involvement in decision-making. Further, they had a positive effect on the patient-healthcare professional relationship, having led to greater communication.<sup>19</sup>

The findings highlight the value of conducting evaluative research on patient information to establish acceptability and comprehensibility to target populations. Whilst evaluation may prove costly, it is a critical factor in ensuring that patients understand and benefit from patient information. In accordance with user-testing protocols which specify receiving feedback over multiple rounds, it may be beneficial to conduct additional diagnostic qualitative research on revised versions of the factsheet.<sup>31</sup> Moreover, the findings of the study also highlight the importance of formatting the information contained within and impact of the factsheet and hence, these categories may be used as a checklist when developing patient information materials in the future.

## CONCLUSIONS

The 'Medicines in Scotland: What's the right treatment for you?' factsheet was generally perceived as helpful and comprehensive. It was highlighted that reading the leaflet generated new knowledge amongst some. In an effort to enhance acceptability and comprehensibility, the factsheet was revised in accordance with some of the recommendations and revisions outlined by participants in this study.

For example, changes included: inclusion of a section for patients to complete on their medicines; changing of tone and wording in areas to ensure that the leaflet was more

patient-centred; inclusion of more information on the benefits and risks of medicines; inclusion of information on how the leaflet may be best used. The updated version of the factsheet, published in March 2017, is available from [http://www.healthcareimprovementscotland.org/our\\_work/technologies\\_and\\_medicines/adtc\\_resources/medicines\\_booklet.aspx](http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/adtc_resources/medicines_booklet.aspx). Further, the findings highlight the value of conducting evaluative research within the target group particularly with regard to appropriate development of patient information.

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## CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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