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## Patient information leaflets on psychotropic drugs: opinions and use by psychiatrists

### AIMS AND METHOD

To assess circumstances and frequency of use, opinions and suggestions for improvement from psychiatrists in a teaching hospital on UK Psychiatric Pharmacy Group patient information leaflets for psychotropic drugs. We also sought information from psychiatrists regarding use of alternate sources of information provision for their patients on psychotropic drugs. A questionnaire was designed, piloted and distributed.

### RESULTS

Sixty-one psychiatrists were approached, of whom 49 (80%) responded. The most common indications for use were when initiating a new treatment and when information is sought by the individual or their carers. The most common reason for not using these leaflets was lack of awareness of their existence. Although 33 (67%) responders were of the opinion that these leaflets were useful for patients, only a small proportion was using them frequently.

### CLINICAL IMPLICATIONS

Our study suggested increasing awareness among psychiatrists to encourage the use of patient information leaflets. Various other themes to improve their use also emerged including easy accessibility to the patient information leaflets, modification in the content and structure, and recording the provision of patient information leaflets in the case records.

Medical practitioners have a duty to explain to their patients the treatment options, expected benefits and side-effects from treatments. The Good Medical Practice guidelines 2006 from the General Medical Council (UK) mention that a registered doctor 'must give patients the information they want or need in a way they can understand'.<sup>1</sup> Providing people with information regarding their treatment is an essential aspect of shared decision-making. Hamann et al have demonstrated that shared decision-making regarding treatment in individuals with schizophrenia increased their knowledge of their illness, improved perceived involvement in medical decisions and increased uptake of psychoeducation.<sup>2</sup>

However, research has shown that only 64% of patients in the UK reported that their doctors gave clear instructions about their treatment always and only 27% reported that their doctors told them about treatment choices and asked for their opinions.<sup>3</sup> Often, information about medications is passed orally to people. It has been shown that the amount of information that is retained following verbal communication alone is very limited.<sup>4</sup>

There is evidence from various studies that patients seek written information on drug treatments.<sup>5</sup> There is also evidence that patient information leaflets provide a useful source of information and reference for patients and carers.<sup>6</sup> Since 1999, following European Union legislation – Council Directive 92/97 EEC<sup>7</sup> – all medicines dispensed within the European Union have been accompanied by printed information written for patients, usually provided as package inserts in the form of patient information leaflets. Medical practitioners cannot assume that individuals read, understand and retain the information provided in these patient information leaflets. Previous reports have clearly shown that not everyone reads this information, many do not understand it and many do not act on the information that is provided.<sup>8</sup>

The Clinical Standards Board for Scotland set out *Clinical Standards for Schizophrenia*<sup>9</sup> in January 2001 that recommended that individuals and their carers be provided with information on antipsychotic drugs and their side-effects when the treatment is initiated or discontinued. Following this, the Pharmacy Department in Royal Cornhill Hospital issued to all the wards and consultants a set of patient information leaflets developed by the UK Psychiatric Pharmacy Group on commonly used psychotropic drugs. This was in addition to standard information leaflets that are included in medication packs. The expectation was that these would be widely used and would be accepted by clinicians and patients.

The aims of our study were to assess the circumstances when psychiatrists used these patient information leaflets, circumstances when they did not use them, frequency of their use, and their opinions and suggestions for improvement. We also wanted to find out if psychiatrists used alternate sources of information provision for people on psychotropic drugs in addition to or in preference to the patient information leaflets under study.

### Method

We developed a questionnaire to survey how these patient information leaflets were being used by psychiatrists in our hospital. Initially, we piloted the questionnaire among five senior psychiatry trainees (senior house officers – year 3 or above). The feedback from the pilot study helped us to modify the questionnaire.

The questionnaire aimed to assess the following main issues regarding the patient information leaflets:

- when do psychiatrists use them
- frequency of use



- circumstances when they are not used
- opinion on the information provided on these patient information leaflets
- suggestions for improvement
- whether psychiatrists used alternate sources for provision of information on psychotropic drugs.

There were 14 items in the modified questionnaire (following the pilot). The majority of the items were statements with tick boxes and the responders were asked to tick the most appropriate statement. Most items also had space for free responses. The responders were asked to use additional space that was provided at the back of the questionnaire with specific item numbers for their free responses if their responses did not fit in the space provided in the main body of the questionnaire. A copy of the questionnaire is available from the authors on request.

We sent the modified questionnaire by internal mail with self-addressed envelopes to all consultants, staff grade doctors and senior trainees (specialist registrars and speciality trainees grade 4) in general adult, old age, substance misuse, psychotherapy, rehabilitation and forensic psychiatry units in Royal Cornhill Hospital, Aberdeen, Scotland. The five senior trainees who participated in the pilot study were not included in the main study. Periodic email reminders were sent to encourage clinicians to complete and return the questionnaire. The reminders were sent as a group email to all participants to preserve anonymisation with an apology if they had already responded. The period of survey was between October and December 2007.

## Results

Of 61 psychiatrists who were sent the questionnaires, 49 (80%) responded. Fifteen (31%) responders have never used the patient information leaflets in question. The most common reason for never having used the leaflets was lack of awareness of their availability (12/15, 80%). The other reasons included 'don't have any; rarely prescribe', 'never felt the need to' and 'patients usually read the leaflets in the medication box'.

As shown in Table 1, most responders (32/49, 65%) used the patient information leaflets both when initiating new treatment and when requested by patients or their carers. Many (31/49, 63%) also used the patient information leaflets when planning a new treatment for their patients. It can also be inferred from Table 1 that 17

responders (35%) did not provide the leaflets even when requested by the patients and their carers.

As shown in Table 2, only about one in five clinicians used patient information leaflets on almost every occasion a new treatment was planned. Also, only about one in four clinicians used these leaflets on almost every occasion when initiating a new treatment. Even when requested by patients or their carers, only about two-thirds of the clinicians offered the patient information leaflets on almost every occasion.

There were 12 responses regarding the circumstances when the psychiatrists would not use the patient information leaflets. The most common reason (5/12) for not using the leaflets for certain individuals was the clinician's perception that the individual would not understand the information provided because of the nature or severity of their mental condition. Other reasons quoted included 'some patients refuse to go on treatment if they read about side-effects', '... might worsen mental state' and 'if patient is likely to manufacture side-effect complaints based on information in leaflet'.

A majority (29/49) of the responders was of the opinion that the information in the leaflet was 'just right' and 33 (67%) responders mentioned that the patient information leaflets were useful to the patients. However, one clinician reported that the information on the leaflets was 'poorly worded, misinformed and scary'.

The suggestions to improve the use of leaflets could be broadly classified into five themes as shown in Table 3.

Twenty-eight (57%) responders used another source of drug information for patients of whom 20 (41%) used them in addition to the patient information leaflets under study. Among the responders, 8 (16%) used exclusively other sources of drug information for patients, whereas 14 (29%) used exclusively the patient information leaflets under study. It was interesting to note that 14% (7/49) did not report using any source for patient information. The most common source (16 responders) for provision of information on psychotropic drugs was from reliable websites including the Royal College of Psychiatrists

**Table 1. Circumstances when clinicians use the patient information leaflets**

Circumstances	Answering yes, n (%)
Planning new treatment	31 (63)
Initiating new treatment	32 (65)
On emergence of side-effects	23 (47)
When requested by patients/carers	32 (65)

**Table 2. Frequency of use (%) by clinicians under various circumstances**

Circumstances	Almost always/ mostly	Sometimes	Seldom	Never
Planning new treatment	21	68	3	8
Initiating new treatment	27	62	6	5
On emergence of side-effects	3	29	38	29
Requested by patients/carers	68	20	6	6



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Table 3. Suggestions to improve the use of patient information leaflets	
Themes	Suggestions
Accessibility	'Leaflets at my desk/office/peripheral clinics' 'Leaflets with secretaries' 'Prominent storage' 'Easy availability'
Awareness	'Increased awareness of their existence and availability'
Content	'More on side-effects e.g. likelihood of them going away' 'Lack of emphasis on important aspects of side-effects and precautions in some side-effects' 'Slightly more information; basically they are just a collection of side-effects' 'Wider indications for drugs that can be used in multiple conditions' 'Simpler leaflets for those with lower IQs and cognitive impairment' 'Wrong information to be corrected'
Structure	'Bigger print'
Use	'Made customisable with community health index/unit number' 'Recording receipt by patient'

(www.rcpsych.ac.uk). Eleven responders used the *British National Formulary*<sup>10</sup> and the *Maudsley Prescribing Guidelines*<sup>11</sup> for providing oral information to patients. Five responders explicitly reported using the services of the hospital pharmacist for provision of information, and four other psychiatrists reported using other unspecified sources of information for patients.

## Discussion

A clear strength of our study is the high response rate (80%) from the psychiatrists involved. The design of the questionnaire enabled them to provide free responses in addition to tick box responses and provided us with the ability to capture a wide variety of responses.

The high response rate indicated the interest among psychiatrists in this area of investigation. It is accepted as good practice for clinicians to discuss with patients their treatment and to provide them with adequate information enabling them to make a balanced decision.<sup>1,2</sup> As expected, most psychiatrists (42/49) were using at least one of the means of providing information to the patients. Thirty-four (69%) clinicians reported using the patient information leaflets under investigation in the study. Of those who didn't use them, the most common reason for not using them was lack of awareness of their existence (80%).

### Improving use of patient information leaflets

To improve the use of these patient information leaflets, as suggested by our findings, clinicians should be made

aware of their existence. It may be necessary to include them in the induction packages for new clinical staff and the clinicians may have to be sent periodic reminders about the presence of these leaflets. It may also be useful to send a reminder to the clinicians each time the leaflets are updated. Even though most clinicians were using the patient information leaflets, they were not using them always. Common reasons were lack of access to the leaflets, individuals' declining the offer of information, clinicians' perception of an individuals' inability to comprehend information and clinicians' opinions that providing information to patients might result in the refusal of treatment, 'generation' of symptoms suggestive of side-effects and/or worsening of their mental state.

Improving access to the patient information leaflets by providing all clinicians with up-to-date leaflets is likely to improve their use. It may be necessary to generate special sets of leaflets for individuals with specific difficulties in understanding the generic leaflets. Also, the emphasis on side-effects may need to change with more information provided on the potential transient nature of many of the side-effects to increase the use of the patient information leaflets among psychiatrists. In addition, patient information leaflets for certain drugs that are used for multiple indications need to be modified and disorder-specific leaflets on drugs may need to be generated to improve their use.

Even though the focus of this study was the opinions and use of the particular patient information leaflets among psychiatrists, we need to remember that patients can receive information from a variety of sources independent of their treating psychiatrists. The increasing role of pharmacists in providing information on drug treatment to people with mental illness is shown in a study by Bell et al.<sup>12</sup>

### Influence on treatment outcomes

If psychiatrists are encouraged to more often give the leaflets to their patients, the next obvious question is whether they have any influence on the treatment outcomes. The evidence from various studies investigating whether they directly influence treatment outcomes is limited and conflicting. However, there is some evidence to confirm that provision of patient information leaflets can improve patient adherence to psychotropic medication. A recent systematic review on this topic<sup>13</sup> demonstrated that educational interventions among people with psychiatric disorders about their medication can have a positive impact on adherence and knowledge. However, provision of written information alone does not appear to be adequate as shown by some studies. Al-Saffar et al showed that combined counselling and written information can have a greater impact on adherence than either of them alone.<sup>14</sup> Peveller et al, in primary care settings, demonstrated that information leaflets did not have any significant effect on adherence either when used alone or in combination with counselling, whereas counselling was shown to have a significant effect on adherence to antidepressant medication.<sup>15</sup> In a review, Koo et al reported that written drug



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information can impact consumers positively and negatively.<sup>16</sup> Various factors are said to potentially affect this including the structure and content of the information leaflet, patient factors and environmental factors.

Our study did not assess the influence of patient information leaflets on patients. We wished to study the use among psychiatrists of an available set of standard information leaflets on psychotropic agents. Psychiatrists have these leaflets at their disposal and can provide patients with information that they believe is reliable. Even though the evidence base to show that the patient information leaflets directly improve the treatment outcomes is weak, psychiatrists are encouraged to use these leaflets as part of clinical governance and good medical practice. More studies are needed that directly study the influence of patient information leaflets on treatment outcomes if we are to encourage increased use of the leaflets among psychiatrists, other mental health and primary care professionals.

We hope to implement the changes suggested in this study to improve the use of patient information leaflets among psychiatrists and revisit the issue again to complete an audit cycle. In the future, we also wish to involve patients in assessing how useful these leaflets are to them.

We accept that as with all questionnaire surveys and especially those that use Likert scales to assess the opinions and frequency of use, there can be biases, such as acquiescence bias and social desirability bias. In addition this study was conducted in a single teaching psychiatric hospital, looking at the use of a particular set of patient information leaflets. This obviously has an impact on whether we can generalise the findings to other settings. We did not perform a reliability or validity test on the questionnaire. However, from the comments and the appropriate responses that we received, we are confident that the questionnaire captured the information that we sought when we planned this study.

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## Declarations of interest

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