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‘You feel like you haven’t got any control’: A qualitative study of side effects from medicines

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Abstract

Objectives

An aging UK population and multi-morbidity means patients are receiving an increasing number of medicines. This can lead to greater risk of unintended side effects. The aim of this study was to increase understanding of how people identify and manage side effects from their medicines.

Design

A qualitative interview study with patients who had experienced side effects, recruited from community pharmacies.

Methods

This study examined patients’ experiences of side effects and the impact of these effects on their daily life. Fifteen participants were interviewed - ten females and five males, with ages that ranged between 25 and 80 years, using different types and numbers of medicines.

Results

Thematic analysis revealed six themes; side effect experience, identification, adherence, information use, coping and body awareness. Participants described a wide range of physical and psychological symptoms which had both explicit and implicit impact on their lives. A system of identification based on constructed cognitive processes was common across participants. A variety of strategies were used by participants to cope with their side effects which included information seeking, social support seeking and non-adherent behaviours.

Conclusions

Psychological factors, such as medication beliefs, symptom interpretation and body awareness, contribute to cognitive and behavioural processes used to identify and manage side effects. These processes can have significant impacts on an individual’s decisions about adherence.
**Introduction**

Medicines are frequently the most cost effective and least invasive medical treatments available to individuals. However, a progressively aging population and accompanying multi-morbidity mean there are an increasing number of medicines being prescribed for people by health professionals today in the UK.\(^1\) All medicines have the potential to cause side effects, but the increase in multiple medicine use has contributed to an increase in the risk of unintended harmful effects or adverse drug reactions (ADRs) in the ambulatory care setting. An adverse drug event (ADE) is the harm caused to a patient as a result of medication use.\(^2\) Preventable ADEs are caused by errors in medication that reach the patient and result in harmful effects. While about half of ADEs are preventable, some patients will experience ADEs even when medicines are prescribed/administered correctly. These non-preventable ADEs are categorised as ADRs.\(^2\) The definition of an ADR used by the World Health Organisation (WHO) is “a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function.” \(^3\) An adverse reaction is therefore a damaging and unintended response to a medicine. These responses are sometimes referred to as side effects (SE) and frequently the terms ADRs and SE are used interchangeably in patient information and other contexts. Side effects from medicines can have considerable impact on peoples’ lives. This impact can be significant and extend into many aspects of daily life with physical, economic, social and/or psychological effects.\(^4,9\) Side effects have been identified as the fifth most common cause of death in developed countries.\(^10\) Research conducted into the frequency of side effects has varied across studies with prevalence rates that range
from 0.15% - 30%. Risk factors have been identified such as complex medical history, low income and age which are associated with increased rates of side effects. Research has suggested that older patients and those with low economic status are more likely to experience severe side effects. These risk factors add to the frequent morbidity and mortality associated with side effects. Side effects have a significant impact on public health, placing significant economic burden on stretched healthcare services. The financial burden of side effects on the National Health Service (NHS) can be considerable resulting in increased costs in caring for patients, delays in treatment as well as prolonged hospital stays with one in seven hospital inpatients experiencing severe side effects. Even if a severe side effect episode is successfully resolved patients can experience numerous long term complications. Such complications can be multidimensional in nature with both physical and psychological elements.

Health researchers and healthcare organisations worldwide have realised that side effects are a public health issue which requires strategic attention and effective interventions. However difficulties exist in identifying people who have experienced side effects resulting in recruitment problems for research studies. Therefore, only limited qualitative research has been conducted amongst this population to date. This study sought to add to the literature, providing greater understanding of this topic by focusing on particular perspectives; forming a rich, contextualised picture of individuals’ experiences of side effects through in-depth interviews. Specifically the study aim was to investigate how people identified and managed side effects from their medicines.

Methods

Participants
A purposive sample of participants who had experienced side effects from their medicines were recruited. All participants were pharmacy customers 18 years or over, resident in the UK and proficient in English. The participants were recruited through a survey distributed in community pharmacies to people using prescription or purchased medicines which sought to determine use of information sources to learn about medicine side effects. Ethical approval was obtained from the NHS Research Ethics Service via the Proportionate Review Sub-committee of the NRES Committee North East – Newcastle & North Tyneside 1 (REC ref 14/NE/1053).

**Procedure**

The survey instrument included an invitation to take part in an interview for any respondent with a recent side effect experience. Potential participants indicated their willingness to be interviewed about their experiences of side effects by completing the survey and returning their contact details. Those who reported a suspected side effect experience within the previous six months were selected. All potential participants were contacted by phone/email and arrangements were made to interview them at a time and location suitable for them. Vouchers with a monetary value of £10 were offered to interviewees as an incentive to participate. Recruitment for interviewees was limited to the [Anonymised for review] area and suitable locations were agreed between researcher and interviewees. A list of topic areas and a topic guide was developed which was informed by previous research and the survey data.\(^{18,21}\) Participants were asked to describe how they identified and coped with their side effects and its impact on their daily life. Interviewees provided written and verbal consent before the semi-structured in-depth interviewing began. Interviews were audio-recorded using an Olympus Digital Voice Recorder WS-852 and transcribed verbatim using an Olympus AS-
4000 Transcription Kit. The interview data were then entered into the data management programme NVivo (QSR NVivo 10) to facilitate analysis.

**Analysis**

The interview transcripts were analysed by the first author using thematic analysis. Thematic analysis was chosen as the most appropriate method as it is a flexible research tool that can identify, analyse and organise patterns/themes in the data. The six stages of analysis proposed by Braun and Clarke were followed - familiarisation with transcripts; identification of initial codes which were developed into themes; reviewing these themes and creating thematic maps to identify relationships between themes and sub-themes; further review and refining to establish the key themes. A line-by-line analysis of the transcripts was conducted which involved repeated readings of the transcripts and making initial notes (BO’D). Transcripts were checked by supervisor (JK) and coding was discussed with an expert mentor with extensive phenomenological research experience in health research (AK). The emergent themes were identified, reviewed and refined to create a thematic map (BO’D; AK). Saturation in coding continued until no other emergent themes were being generated at which point recruitment of potential participants for interview was discontinued. Analysis of the interviews led to the creation of main themes and sub-themes which are presented in the Results section. The main themes that were identified are supported with appropriate quotations from the interview transcripts. These distinctive/poignant quotations were selected in line with common research practice and were identified as the most representative of the research findings.4,23

**Results**

The final sample was composed of 10 females and 5 males. Their ages ranged from 25 to 80 years. A response rate for interviews of 9.6% was achieved – 22
potential participants from 230 returned surveys. One participant supplied an incorrect email address and could not be contacted. The remaining 21 were contacted by telephone/email at their preferred times. In total 19 confirmed their agreement to be interviewed; participants were contacted by telephone and arrangements for interview dates, times and locations were made. Fifteen participants were interviewed, by which time saturation in coding was reached and the interviews ceased. The remaining four individuals were contacted, thanked for their participation and advised they would not be interviewed. A demographic summary for each participant, including medical conditions and causative drugs is shown in Table 1.
Analysis identified six main themes: side effect experience, identification, adherence, information use, coping and body awareness. These six main themes and sub-themes are presented in Figure 1.

**Theme 1: Side effect experience**

All the participants related the multidimensional nature of their experience of side effects. They identified a range of physical symptoms which contributed to the somatic experience of side effects:

*P10:* “the one that impacted me the most was the mini-pill reaction..my moods were everywhere..it was making me feel even more agitated and depressed and..just all around horrible”

Most participants described these less obvious psychological symptoms as significant in terms of impact on their lives:

*P7:* “I was really shocked that little tiny patch could do so much to your mental stability and the way that you felt..Yeah cos it was a total nightmare”

Around half of participants also linked their SE experience to explicit economic effects for the individual. These included medication costs, costs of treating SE and work productivity.

Participants also reported that attentional biases towards negative symptoms could facilitate maintenance/escalation of these symptoms:

*P12:* “When I woke up and I was having the breathing issues and I saw just how swollen everything was and I heard my breathing I was very scared. . .I was panicking about it”

Most interview participants indicated the significant impact which medication beliefs had on their side effects experience. These beliefs were extensive in their range and included their attitudes towards their medication, their confidence in their own ability to manage side effects, as well as their perceptions about their health status:
P5: “when I first started taking it for the first fortnight I was getting up with headaches every morning...once or twice I had to take medication...but other then that it’s just get out and get some fresh air”

P6: “this wasn’t life-saving medication that I had to be on there...(pause)..there were options for me”

The mediating effects of a positive doctor-patient relationship on negative medication beliefs were also described by the interviewees. A positive doctor-patient relationship can intervene indirectly in the SE experience, by influencing/altering an individual’s negative medication beliefs. Participants indicated some of the characteristics of a positive relationship which centred on concepts of communication, engagement and accessibility:

P2: “I think that he gave me the opportunity to say...I’m willing to take the risk take this medication because he gave me that opportunity I feel that..I can trust him with other things as well even if there’s something down the road causes another reaction cos he’s very open about it you know”

P8: “Best G.P. in the whole wide world accessible no problem if you need to see him or one of his chums that day”

Theme 2: Identification

Participants described the different processes they used to identify their side effect. These constructed cognitive processes included eliminatory thinking, cognitive linking of medicines to symptoms and acquisition of knowledge:

P1: “It was new so I had been using my other four medicines and they didn’t give me a problem...so I think that’s one of the things that occur to me....This is a new medication”

All participants used the timing of the symptoms to make the causal link between the medicine and the suspect adverse drug reaction. The timing of symptoms onset varied but the sequence of medicine leading to symptoms was common across participants:
P13: “I said to my doctor I took a couple of para-co-codamol and then about five or ten minutes later my face was started coming up like this”

Interview participants used varied information sources – both formal and informal – to find out about their side effects. Interview participants used varied information sources – both formal and informal – to find out about their side effects. These included healthcare professionals (HCPs), patient information leaflets (PILs) or the Internet to find out about their side effects. Past experiences of side effects also influenced participants’ use of PILs. Participants were more likely to read PILs if their medicines were to be taken regularly or for a prolonged period of time:

P6: “unless it was something like an antibiotic that I’d been prescribed for infection or something and then I wouldn’t necessarily bother but something that you’re taking regularly over a long period of time then yeah I would look at the information leaflet yeah”

Theme 3 Adherence

This study found that the medication beliefs of participants had a role in their decisions about adherence. These beliefs ranged from self-perceptions about their abilities to manage the SE, to considering whether the benefits of controlling a chronic condition outweighed the burden of SE and general beliefs that over-prescribing by HCPs is a current issue:

P15: “a side effect is just usually I call it just a mild annoyance...it’s nothing that usually bothers me much usually it’s like silly little headaches”

Theme 4 Information use

All the participants used varied information sources - formal and informal - to find out about side effects. These included HCPs, the Internet and family/friends. PIL use by participants was influenced by their past experiences of side effects:
Participants also described the role of the Internet in the self-management of side effects. All participants considered that the Internet should be used with caution when seeking information on SE. However specific sites – such as NHS Choices\textsuperscript{24} - were identified as being trustworthy. In addition on-line patient forums were specifically identified as useful in offering personal narratives of medical experiences:

\textit{P3: “I got in touch with the association that was linked to my particular issue you know got on to their website and they were brilliant...basically my life savers”}

However participants also described the tendency to over attend to negative information on the Internet:

\textit{P11: “If I wanted to know anything about the tablets I would Google. Usually if I do that I come off and phone the local funeral directors because you always see the bad part of it”}

**Theme 5  \hspace{1em}  Coping**

Interview participants described the coping strategies they used to manage their side effects. They used a variety of strategies which included information seeking, social support seeking and non-adherent behaviours. The majority engaged in information seeking activities, particularly in accessing specialised sources of information:

\textit{P4: “I did go and see the pharmacist down here (pause) he said to me get to your GP I think you’re having a reaction to something you’ve taken”}

Around a quarter of participants also described negative coping strategies which involved cognitive factors such as negative expectations and excessive rumination. Participants also identified the influential role that symptom interpretation can have on coping behaviours. Focus
on symptoms could result in escalation of these symptoms and result in coping behaviours such as sleeping more or pre-planning social outings:

*P7:* “I know that I’ve got at least 10 minutes to find the loo..I look around for loos and stuff like that and I know where they are and then I can run to them if I need to”

Most participants articulated the disparity which can exist between information about side effects risks versus patient understanding and perceptions of side effects risk:

*P14:* “when they gave you the medication they sort of say you may have side effects but it wasn’t explained in a way that you felt you understood or how it should be. It was kind of generalisations”

**Theme 6 Body awareness**

The final theme was linked to body awareness. Many participants indicated that attending to body signals was an essential element of their positive self-care health behaviours:

*P9:* “...cos over the years I’ve learned how my body is, how it works, how it feels and..I’m not a hypochondriac or anything like that. But I know”

*P2:* “I’m very aware of what my body does because the illnesses I’ve had most of my life..so..I don’t play about I know when something is right and wrong”

**Discussion**

This study contributes to research that examines side effects – its goal as a qualitative study is not to generalise but to provide a clearer understanding of individuals’ experiences of side effects. It provided information on the strategies employed by patients to manage SE. These strategies varied greatly and included both cognitive and behavioural responses such as non-adherence; HCP consultation; seeking information from a range of sources and seeking social support. Decisions were made by patients about adherence to their medicines when they experienced side effects. A range of factors influenced these decisions including established
health beliefs; previous SE experiences; cognitive biases; perceived severity of SE; individuals’
coping styles and HCP interactions.

**SE experience: Physical, psychological and economic effects**

The interviewees described a wide range of physical and psychological symptoms which had
both explicit and implicit impact on their lives. The explicit impact was primarily related to
physical symptomology such as stiffness, headaches or rashes. Participants described
the implicit impact of side effects as significant and linked to psychological symptoms. This
pattern of symptomatology is supported by previous research into patient reports of side effects,
which found that these reports generally provide a detailed extensive picture of side effects and
their impact.\(^{25,26}\) In patient reports physical effects are generally the most frequently reported
side effects, with patients reporting more adverse effects than HCPs.\(^{27-30}\) Patients can have
differing levels of susceptibility to psychological effects.\(^{31}\) Previous research supports the finding
regarding the impact of psychological effects with patients describing changes in mood, memory
and/or behaviour as distressing and persistent in nature.\(^{16,32}\)

Participants also linked their SE experience to explicit economic effects for the individual. These
included medication costs, costs of treating SE and work productivity. This supports previous
research into side effects which has also found general economic effects with significant costs to
healthcare services and loss of productivity.\(^{3,26}\)

**SE experience: Attentional biases to negative symptoms**

Participants reported that attentional biases towards their negative symptoms could facilitate
maintenance/ escalation of these symptoms. Research has found that excessive patterns of
attention to negative stimuli play a central role in anxiety and depression disorders.\(^{33,34}\)

Attentional biases can negatively impact on the subjective appraisal and perception of symptoms
in gastrointestinal disorders.\textsuperscript{35,36} This can lead in turn to symptom escalation/persistence and avoidant health behaviours. Attention resources are allocated to symptom-related stimuli over neutral stimuli. This in turn can lead to impaired cognitive processing of the symptom cues, as experienced by the interview participants.

\textbf{SE experience: Medication beliefs}

Interview participants indicated the significant impact which medication beliefs had on their side effects experience. These beliefs were extensive and included their attitudes towards their medication, their confidence in their own ability to manage side effects, as well as their perceptions about their health status. Research has explored the impact that patients’ perceptions and medication beliefs have on their health behaviours. Studies have found that negative medication beliefs can be a factor for non-adherent and information seeking behaviours.\textsuperscript{28,37} The mediating effects of a positive doctor–patient relationship on negative medication beliefs were also mentioned by the interviewees. A patient’s negative medication beliefs could be altered by their interaction with an engaged, accessible HCP with good communication skills.

\textbf{Identification: Constructed cognitive processes}

A system of identifying SE based on constructed cognitive processes was common across participants. These results are supported by research which has identified processes where symptoms are filtered and allocated significance through patients’ cognitive systems.\textsuperscript{36,38,39} Participants also used timing of the symptoms to link SE to their medicine. Previous studies support these findings and established that patients use temporal associations to assess suspected side effects\textsuperscript{8,17,19} a key criteria in professional causality assessments. Also, common across interview participants was the use of aids such as PILs and HCPs to confirm the side effect. This
too mirrors previous research which found that the majority of patients used HCPs, PILs or the Internet to find out about their side effects.20,40

**Adherence: Medication beliefs**

The medication beliefs of participants had a role in their decisions about adherence. These beliefs ranged from self-perceptions on their abilities to manage the SE, to considering whether the benefits of controlling a chronic condition outweighed the burden of SE. Previous research investigating medication beliefs and nonadherence have shown mixed findings. Associations between medication beliefs and non-adherence have been found in a variety of patients – with cardiovascular conditions, HIV and epilepsy.41–43 However other studies involving patients with cardiovascular conditions and asthma found medication beliefs were not related to adherence.44,45 Recent research has found that patients with negative medication beliefs could misattribute symptoms to a medication and consequently decide to stop taking their medication.28,46

**Information use: Formal and informal**

Participants used varied information sources to find out about their side effects. This mirrors previous research which found that the majority of patients used HCPs, PILs or the Internet to find out about their SE.20,40 All participants considered that the Internet should be used with caution but identified on-line patient forums as useful in offering personal narratives of medical experiences. Research has shown that such interactive sites can influence patient health behaviours.48,49 Participants also described the tendency to over attend to negative information on the Internet. These attentional biases to negative stimuli have been identified as potential barriers to effective use of online resources.

**Coping: Strategies**
The interviewees had a variety of coping strategies which included information seeking, social support seeking and non-adherent behaviours. Previous research supports this pattern of coping, with social support seeking being the most common strategy, followed by information seeking. Most of the interviewees engaged in information seeking behaviours. Research has also found that the process of obtaining information may be influenced by an individual’s coping style. The levels of information that patients require varies greatly from those who require detailed medical information to those whose preference is to reduce discomfort by avoiding detail. Many of the participants used negative coping strategies such as negative expectations and excessive rumination. Research has shown that affective cognitions can have significant impact on health outcomes. Cognitive and emotional processes can have a significant role in health-protective and health-risk behaviours.

Coping: Disparity between physician and patient beliefs

Participants identified the disparity which can exist between physician beliefs about side effects versus patient beliefs about side effects. A previous review found that patients had reservations about the overall quality of PILs and changes could be made to improve patients’ understanding of PILs. In addition to confusion about side effects risk some participants described dismissive responses from their HCPs when they discussed their SE. Research studies provide supporting evidence for such dismissive attitudes amongst some HCPs. This disparity between HCPs and patients’ perspectives on SE can lead to decreased SE reporting from patients.

Body awareness: Positive self-care

The final theme was linked to body awareness. Interview participants indicated that attending to
body signals was an essential element of positive self-care health behaviours. Research has defined body awareness as an active process which involves an awareness of and attentional focus on body cues and signals.\(^6^7\) Body awareness has been identified as a complicated construct which can be key to both adaptive and non-adaptive health behaviours. Adaptive body awareness/sensitivity has been identified as occurring in combination with non-judgemental attention to the immediate sensations/effects. Recent research has found that patients who ignored their bodily signals displayed lower levels of physical and psychological health.\(^6^8\) Hypochondriac tendency was reduced in those with high sensitivity to body symptoms that was combined with a non-catastrophising mode of attention.\(^6^9\) To date research has not specifically identified body awareness as a factor in identifying side effects. However this study found that body awareness and an appreciation of how the body reacts in differing circumstances is important in the context of SE from medicines. This suggests that SE could be mediated by adopting a self-focus that directs attention to the effects in a mindful, non-judgmental manner. Further research is required to explore the role of body awareness in SE and potential self-management techniques to manage SE.

**Common Sense Model of self-regulation**

Thematic analysis of the interview transcripts revealed a number of relevant and prominent themes. These emergent themes correspond with an established model of illness behaviour – Leventhal’s Self-Regulation model /Common Sense Model of self regulation (CSM).\(^7^0\) Leventhal’s Self-Regulatory Model (1987) was initially composed of three main cognitive constructs:\(^7^1\)

- **Representations** – representations of the health-related threat which interprets the experience through cognitive representations such as symptoms, social cues, consequences
• Coping strategies – action planning such as avoidance, information seeking, seeking medical attention

• Appraisal - where the success or failure of coping strategies are assessed

Over the years research has found that patients process information about physical symptoms according to their prototypical perceptions about associations between diseases and particular symptoms. Patients use their previous personal health experiences or knowledge of the experiences of others to identify symptoms and use preconceived perceptions about side effects to assist them in labelling and interpreting symptoms linked to the consequences of treatment.\(^{72,73}\) Levanthal’s model has developed into the CSM, identifying a prototype/cognitive schema used by patients to evaluate and assist them in identifying these symptoms as side effects. This specific ADR prototype is composed of five elements/cognitive domains. The five elements are described as identity (symptoms/label); cause; timeline; consequences and cure.\(^{73}\)

Within the CSM factors such as prior experiences with side effects and symptom amplification can lead to misinterpretation of symptoms as side effects of medications. The CSM stresses the central role that symptom interpretation plays in an individual’s health outcomes such as self-management and care seeking.\(^{74}\) The explanatory power of CSM has been improved by the addition of medication beliefs to the model, which could influence patients’ non adherence behaviours when they experience SE.\(^{75}\) In the past this theory has been used as a framework for research in managing chronic illnesses such as psoriasis, rheumatoid arthritis and multiple sclerosis.\(^{76-78}\) However researchers have also suggested that the CSM could be used to assess side effects from medicines.\(^{53}\) This study suggests that a dynamic model such as the CSM could be an effective theoretical framework to investigate how patients identify and manage their side effects.
Limitations of the study

The main purpose of this study was to form a rich picture of individuals’ experiences of side effects. This was achieved through face-to-face interviews however self-selection bias may apply to these interviewees as they signalled their desire to participate from a larger survey sample. It is possible that they were particularly interested in SE as they had experienced significant effects which they regarded as being outside of the common SE experience. However the interviewees had differing ages, education, medical conditions and number of medicines used, which suggests that participants may be likely to have a wide range of opinions and experiences. The use of incentives – vouchers – may have led to bias in recruitment however the vouchers were of small monetary value which reduced their significance. A limitation of this study was related to the inconsistency which can surround theoretical saturation. Saturation in coding was reached after 15 interviews however qualitative studies have reported saturation after just 6 interviews. In this study independent investigators were used to increase the overall reliability of the analysis.

Implications for research

The findings of this study indicate that further research may be warranted in several areas. These include the impact of medication beliefs and body awareness on the SE experience, as well as the challenges involved in effective communication of SE risk. The medication beliefs of interview participants were wide ranging and had a role in their decisions about adherence. Current measures of medication beliefs may not fully capture the wide range of factors inherent in patients’ medication beliefs. Another focus for continued investigation is the role of body awareness in the context of SE. It is possible that SE could be mediated by adopting a self-focus that directs attention to SE in a mindful, non-judgmental manner. Mindfulness training in patients who are most likely to experience SE could be beneficial, however more research is
required to determine if mindfulness techniques could assist these patients. This study also suggests that disparities can arise between information about side effects risks and patients’ interpretation of these risks. Comprehensive information for medicine users needs to avoid ambiguity while clearly imparting the risks and potential impact of SE from medicines.
Communication training for HCPs which focuses on providing such tailored information could improve outcomes for patient-centred healthcare.

Conclusions

This study highlights the complexity in individuals’ experiences of SE and the wide variety of information sources used by patients to confirm SE. It also provided information on the impact of SE on day-to-day life and patients’ attitudes towards medicines and HCPs. Further research is required to establish how best information on SE can be tailored to patients’ needs in a clear, consistent, reliable and useful form and how patients can be assisted to identify SE and engage in meaningful discussions with HCPs about their experiences.

References


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<td>SL 17/18</td>
<td>Asthma</td>
<td>1</td>
</tr>
<tr>
<td>Int15</td>
<td>Female</td>
<td>51-60</td>
<td>Disability</td>
<td>Univ</td>
<td>FS</td>
<td>More than 8</td>
</tr>
</tbody>
</table>
Figure 1 Emergent sub-themes ‘clustering’ to 6 superordinate themes