

ORIGINAL RESEARCH

What happens to patients who have their asthma device switched without their consent?

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Abstract**Aims:** To identify asthma patients who have experienced a non-consented switch (NCS) of their inhaler device and to explore the circumstances and impact of these switches.**Methods:** Nineteen asthma patients who had experienced an NCS of their inhaler device were recruited to participate in qualitative, semi-structured one-to-one interviews.**Results:** All 19 participants reported a switch in their asthma inhaler without consultation or approval. There was deterioration in asthma control reported by some participants, many remained unchanged, and two reported better outcomes. Regardless of any change in asthma control, all patients expressed discontent with the NCS. Many felt it had damaged their relationship with their doctor, their confidence in their asthma medication, and their perception of control over their disease.**Conclusions:** These qualitative interviews highlight the need to maintain clear and open communication with patients. Switching of patients' inhalers without their consent may diminish the self-control associated with good asthma management, leave the doctor-patient relationship damaged, increase resource utilisation, and waste medication.

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The aim of asthma management is the control and prevention of symptoms and exacerbations, and the avoidance of environmental triggers and treatment side-effects in order to achieve the best possible lung function and quality of life.¹ Typically, asthma management involves pharmaceutical treatment to achieve these goals. Pharmaceutical therapies for asthma are often broken down into two broad categories:

rescue medicine and preventative medications. More specifically, pharmaceutical therapy for asthma usually consists of short- or long-acting β_2 agonists (SABAs and LABAs respectively) and inhaled corticosteroids (ICS), and in some (usually more severe) cases, add-on therapies such as leukotriene receptor antagonists or immunoglobulin E blockers.² Once a patient and clinician have found a therapy or regimen that works effectively to manage the patient's asthma, that patient may remain on that treatment for a long period of time, often many years. However, it is often necessary to switch asthma medications, sometimes in order to regain or achieve improved asthma control, and at other

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times to contain healthcare costs or work within budget restraints.³⁻⁵

The effective control of asthma symptoms is contingent upon the proper administration and use of asthma inhaler devices, since different types of inhalers require different methods of inhalation.⁶ Previous research has shown that asthma control is better when the treatment has been properly justified and negotiated with the patient, and training in the actuation and use of the asthma device provided.^{1,7} Hence, where a switch in inhaler medication has taken place, it is important that the reason for the switch has been properly explained and an opportunity provided to practice with the new device. Despite this, anecdotal reports have emerged that asthma patients have had their asthma inhaler device switched without their consent. Non-consented switching may leave some patients unable to use inhaler devices and so has the potential to affect symptom control and adherence to therapy adversely. It may also lead to waste through unused prescriptions, and expense related to additional visits to their doctor. In addition, it conflicts with a central tenet of medical practice – the need for informed consent.

We have defined a “Non-Consented Switch” (NCS) here as the substitution or alteration of a delivery device (and medication) without prior approval or knowledge by the patient. Concerns regarding this phenomenon were identified in the USA, where former New York City Public Advocate, Mark Green, has been highly critical of Pharmacy Benefit Managers in Health Management Organisations switching patients’ medication for purely financial reasons.⁸ Lipton *et al.* also reported in 1999 how Pharmacy Benefit Managers exert their influence to change prescribing decisions on cost grounds.⁹ Only one recently published study has documented NCSs or similar practices in the UK.¹⁰

Thomas *et al.* conducted a 2-year retrospective matched cohort study using the UK General Practice Research Database (GPRD) to identify practices where ICS devices were changed without a consultation for more than five patients within three months.¹⁰ Patients whose devices were switched were matched with patients using the same device who were not switched. A total of 824 patients from 55 practices had a device switch and could be matched. Asthma control over 12 months after the switch, assessed using medication volume, hospitalisations, and subsequent changes to therapy, suggested that patients whose medication was switched without their consent experienced more unsuccessful treatment (51% vs. 38%).¹⁰

Aside from these few references, there is no firm evidence from the literature regarding how frequently such switches may be taking place, for what reason, and whether it is perceived negatively by the patient. It is possible that doctors believe a newer medication to be better than a patient’s older medication, but this does not explain why they do not discuss it with the

patient first. The switch may be as innocuous as a change from a branded to generic medication which the physician felt did not require a consultation. Furthermore, under pressure to control costs from local health boards, doctors may attempt to save resources by changing to a less expensive preparation that could be perceived as being so similar as to be equivalent. There is evidence to suggest that treating certain asthma medications as interchangeable on an interclass basis can result in worse control.^{11,12}

The study by Thomas *et al.*¹⁰ did not identify how an NCS could lead to a loss of asthma control after the switch had occurred or what patients do once they receive a new inhaler. Does a non-consented switch trigger a change in behaviour? Is a potential reduction in asthma control the only impact that non-consented switching has on patients? What about those patients who do not experience a reduction in asthma control post-switch?

In order to answer these questions and to gain a better understanding of the circumstances and outcomes of an NCS from the patients’ perspective, we set out to conduct a more in-depth, qualitative study. This study aims, for the first time, to describe patients’ experiences of non-consented switching of medication in order to investigate the potential range of circumstances in which switches happened, and the perception of the impact of the switch.

Methods

Study design

The design of the study was qualitative, using in-depth exploratory interviews.¹³ Qualitative interviews were felt to be an appropriate methodology for investigating NCS experiences, particularly when so little is known about how and why non-consented switches are occurring and the outcomes from a patient’s perspective. Semi-structured face-to-face interviews were chosen as the most appropriate data collection method to understand the impact that the NCS had on patients and their subsequent asthma management. To provide context for the qualitative data, interview participants were also asked to complete a demographic questionnaire, a clinical questionnaire, and a measure of asthma control, the Asthma Control Test™ (ACT).¹⁴

Ethical committee approval was received from Grampian Research Ethics Committee and all participants provided written informed consent before interviews took place.

Participant recruitment

Given the nature and sensitivity of the problem, we felt that it would be naive to try to recruit study participants through doctor practices; most of the non-consented switching had likely originated at physician level. Clinicians may have felt we were directing blame at them, and patients may have been reluctant to enrol if they felt it could damage their

relationship with their care provider.

Therefore, this study recruited patients directly from the community. Recruitment went through a series of stages (see Figure 1). Initially, a series of advertisements were placed in local (Greater London, Glasgow, West Midlands) and national newspapers and on a recruitment website for patient research. The recruitment advertisements asked asthma patients if “you have had your asthma medication changed without your consent, or were given a prescription that you were not expecting.” Interested participants (n=91) were screened to determine eligibility using a detailed screening questionnaire over the telephone. Screening included questions on current medications, when the switch occurred, a description of the circumstances in which the switch took place, and whether or not the switch had been discussed or agreed to beforehand.

Inclusion criteria for the study were:

- reported diagnosis of asthma and currently using an inhaler device
- experience of having an asthma inhaler device changed/switched without their knowledge or consent
- equal to or greater than 18 years of age
- able to read and complete questionnaires
- willing and able to participate and sign written informed consent.

Potential participants were excluded if:

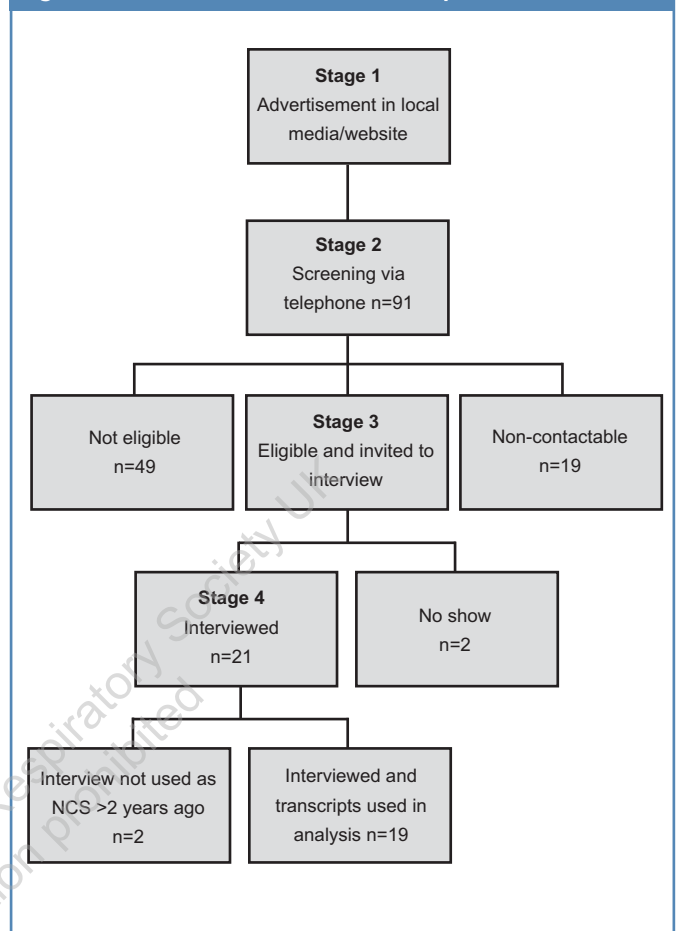
- they were currently involvement in an ongoing clinical study
- had a reported asthma diagnosis with no inhaler device or no switch in inhaler device
- presence of acute illness or other impairment (e.g., visual) that in the opinion of the participant or researcher may interfere with the study requirements
- if a member of their immediate family was a pharmacist or general practitioner.

From the screening telephone call, it was ascertained that a majority of respondents were quickly deemed ineligible, mainly because they had not experienced a switch in medication or the switch had been informed and consented. Where respondents met all screening and eligibility criteria they were invited to participate in a face-to-face interview in Central London at a time and date convenient to them (n=23).

Interview materials and procedure

Prompts and questions for the interview schedule were drafted by the study team (see Appendix 1, available online at www.thepcrj.org). It was recognised that an NCS could potentially occur at many different stages and for different reasons in the process of a patient acquiring their asthma inhaler. Therefore, the interview was designed to explore the circumstances of the inhaler device switch, the impact of the switch on the patient, and to record in detail the actual nature of the switch, including questions on how, when, where, and who initiated the switch. It was important to determine that

Figure 1. Recruitment and interview process.



patients were reporting a genuine non-consented inhaler device switch and not just a change in their medication(s). Participants were shown pictures of the different types of inhalers currently available and they were asked to identify their original inhaler and the one they were switched on to. Following this, participants were asked to describe the different ways in which the switch affected them. This included changes in severity or frequency of symptoms, any need for new prescriptions or unscheduled doctor visits, effect on treatment adherence, effect on relationships with health care professionals, impact on usual activities or work, and any other aspects not otherwise discussed.

Interviews were carried out in London, in quiet, undisturbed rooms. On arrival at the interview, participants were informed again of the study and given the chance to ask any questions or withdraw. Written consent was gained and background demographic and asthma questionnaires were completed. All interviews were recorded and fully transcribed and supplemented with the interviewer's notes. It was intended that all the questions included in the interview guide would be asked at some point in the interview. However, conversations were to develop organically, with the questions to be used as a guide and

not a verbatim script. The interviewer was careful to avoid repeating or re-asking questions to which an answer had already been spontaneously provided.

After the first seven interviews, the authors met to discuss the initial findings from the interviews. On the basis of this, changes were made to the interview guide to focus more on the circumstances of the switch and its impact on the patient's relationship with their doctor. Some of the warm-up questions related to asthma history and perception and general health were dropped and questions on medication type/name and changes in relationship with healthcare professionals associated with the switch were added. Additionally, to help the interviewer ensure that all topics were covered, the sequence of some of the interview questions were rearranged to reflect the order in which the participants were describing their experiences.

Analysis

The analysis was guided by the research question: What were the circumstances and outcomes of the NCS from the patient perspective? Thematic content analysis was undertaken using Framework, an approach developed by the National Centre for Social Research.^{15,16} This provides a systematic thematic way of summarising and classifying data.

A framework was established, working from the interview discussion guide, which was split into five sections: 1) asthma diagnosis/symptoms; 2) daily medication use; 3) doctor/pharmacist experiences; 4) impact of the switch, and; 5) overall conclusion and confirmations. Sub-sections explored or introduced by the participants included: length of asthma diagnosis; types of medications used; asthma severity and restriction on daily life; experiences with health professionals; when the NCS was reported to have taken place; the circumstances of the switch; whether the patient queried the switch or why they felt it occurred; post-switch communication and relationship with health professional(s); tactile differences of actuation of new device; confidence in medication; change in asthma control.

There were expectations that changes in asthma control, medication use, and relationship with health professionals would be affected by an NCS. These beliefs were in part guided by the literature but also partly by our assumptions about the effects. However, as the study was exploratory in nature, we had no idea about the strength or direction of these impacts. Our general hypothesis was that the NCS would lead to negative outcomes and experiences for the patients. Yet, the NCS could easily have led to improvements in asthma control if the physician made the change from a desire to offer a better treatment option but simply forgot or thought it not important to communicate this to the patient.

The first seven interviews were initially open-coded and analysed independently by the two main authors (AL, SD) by reading and re-reading the transcripts and notes, identifying

common categories and salient themes. At this stage, the two authors (AL, SD) discussed and integrated their interpretations until a consensus was reached and a coding framework was agreed.

Discussion points and topics were then entered into a framework chart (using Microsoft Excel) which could be manipulated to facilitate further analysis in terms of comparisons within and between participants. Focus was given to unusual experiences/responses compared to the common experience (negative cases analysis) to aid in the development of the analysis. General issues related to the patient's asthma or health experiences not related or connected to the switch were ignored. The analysis and results from the data were presented to the rest of the study team for feedback and discussion towards the end of the study period and incorporated into the final report.

Results

Profile of participants

Of the 23 respondents invited to interview, two failed to attend and another two participants who attended were excluded because their switch had occurred more than two years previously, with vague or minimal details. In total, 19 participants (5 male, 14 female) who had experienced an NCS of their asthma inhaler were included in the study. The demographic and clinical profile of the participants indicated a good mix of gender, ages, and socioeconomic statuses (see Table 1). However, the small sample size prevented any subgroup analysis from which to make statements about the population attributes and the study qualitative statements.

Themes elicited

Themes were not established *a priori* but did reflect the assumptions of the interview script in that it was believed the NCS would have an impact on patients' asthma and that patients would hold strong feelings about the motives of the parties involved in the switch. There was some overlap between themes, but this was not entirely unexpected since a reported change in one theme – such as an inability to actuate a device – would impact on another i.e. asthma control.

The results are presented here to match the typical chronology of events and are explored as four themes:

- Patient views on the circumstances of the NCS
- Device use post-switch
- Changes in perception of asthma control
- Relationship with health professionals

Table 2 briefly summarises the nature of the NCS that participants experienced. Participants were also asked to make some summary or conclusive statements about their experiences of the NCS; many of these statements draw broad confirmations of impacts across the themes (see Table 3).

1. Patient views on the circumstances of the NCS

Most of the inhaler switches had occurred in the last few

Table 1. Participants' demographic profile.

| Participants (n=19) | |
|-------------------------------------|-------------------|
| Age Mean (std. dev.) | 39.5 (17.4) |
| Gender | 5 male; 14 female |
| Ethnic group | |
| White | 15 |
| Black | 0 |
| Asian | 1 |
| Mixed | 3 |
| Employment status | |
| Full time | 5 |
| Part time | 5 |
| Home maker | 1 |
| Disabled | 0 |
| Retired | 5 |
| Student | 2 |
| Other | 1 |
| Education – leaving age | |
| No formal qualifications | 1 |
| GCSE/ O' Levels (16 yrs) | 4 |
| A' Levels (18 yrs) | 2 |
| Vocational or work based | 1 |
| University degree | 9 |
| Other | 2 |
| Smoker | |
| Yes | 3 |
| Former | 6 |
| No | 10 |
| Satisfaction with current treatment | |
| Very satisfied | 6 |
| Moderately satisfied | 7 |
| Somewhat dissatisfied | 0 |
| Neither satisfied nor dissatisfied | 1 |
| Somewhat dissatisfied | 4 |
| Moderately dissatisfied | 1 |
| Very dissatisfied | 0 |
| Asthma Control Test™ | |
| Range (min/max) | 10 / 25 |
| Not well controlled asthma (5-19) | (n=7) 37% |
| Well controlled asthma (20-25) | (n=12) 63% |

months, and for some participants it had happened very recently or was ongoing at the time of interview. Most participants identified their doctor as being responsible for instigating the switch, but at least a couple identified the pharmacist. In one case, the pharmacist was identified as the source of the non-consented switch and the doctor was understood to be unaware of the switch. In two cases, the source of the NCS was unclear. When participants were asked about why they believed their inhaler had been switched, most mentioned cost issues and many believed the decision was not made in their best interests:

"I think it was the money, it might be the drug company. Is anyone really working on a cure for medication? No. Because then people wouldn't come back and spend

money. That is how I feel. It must come down to money." (P4)

2. Device use post-switch

The NCS related to prescriptions for nine preventer inhalers, nine rescue inhalers, and one person who reported that both had been switched simultaneously. Following the switch, most participants reported that they were not shown how to operate their new device. Many participants gave an account of how they struggled to actuate the new device as effectively as their previous one and some admitted to not using the new device because they were unable to operate it. These respondents either resorted to the use of old inhalers, returned to their doctor, or went without their asthma therapy until someone explained how to use the device.

Participants were asked to comment on whether they felt that they had ever taken too much or too little of the asthma medication as a consequence of the switch. Several participants indicated that they did sometimes take too much, with many remarking on an overuse of medication (especially rescue medication) due to a lack of confidence in the new medication or their inability to actuate the new device effectively. One respondent described his overuse of medication:

"Every time I used it I had to double or triple the dose because psychologically the paranoia of not getting the dose was so strong that I don't think I've ever used a single actuation, ever." (P2)

3. Changes in perception of asthma control

Participants described a range of different outcomes which they attributed to their NCS. Most individuals reported a negative outcome in terms of more asthma symptoms and worse asthma control, but some reported no change in their asthma, and two reported improvements in symptom relief. Of the patients who reported no change or improvements in asthma symptoms, only one felt the experience had been positive overall:

"I had straightaway relief. I was happy with it. I needed it". (P14)

Participants referred to changes in their asthma symptoms including increases in wheezing, difficulty breathing, and reduced ability to perform physical activities:

"I am wheezing more... I am deteriorating.... I am wheezing, even just talking to you... The wheezing wakes me in the night. I live on the second floor of the building and when I walk up, I am knackered at the top". (P7)

These changes in asthma control presented a real fear for many of the participants. For example, one participant commented;

"After a couple of days I went back to the pharmacist and said I am getting quite panicky about it. The only way I can control it [asthma] is using the other inhaler. I don't know what I am going to do. It is a huge issue. I think

Table 2. Circumstances of NCS.

| ID | Age | Gender | Type of inhaler switch | Initiated by? | When | What happened? |
|-----|-----|--------|------------------------|---------------------|----------------------------|---|
| P2 | 40 | Male | Rescue inhaler | Doctor | Approximately 1 year prior | Patient is switched from branded medication to generic. Realises the change when he picks up the medication from the pharmacy. Does not find the actuation or delivery as effective. Uses backup devices until next appointment, where he is switched back. |
| P3 | 62 | Female | Preventative inhaler | Doctor | Approximately 1 year prior | Repeat prescription appointment with no mention of a switch. Collects new device from pharmacy and realises the change upon arriving home. Find the new device awkward and returned to doctor to be switched back the following day. |
| P4 | 57 | Female | Rescue inhaler | Doctor | Approximately 1 year prior | Repeat prescription switched by doctor from branded to generic medication. Patient has trouble using the new device effectively and returns to pharmacy to be shown technique. Asthma worsens and the pharmacist switches her back to old medication. |
| P5 | 58 | Female | Preventative inhaler | Pharmacist | 8 months prior | Went to pick up regular prescription from pharmacist. Pharmacist tells patient that inhaler is not in stock but they have a similar one. Feels compelled to take it as she is leaving on holiday. Was unable to correctly operate the new inhaler device. Doctor was not aware of the switch. |
| P6 | 46 | Female | Preventative inhaler | Doctor | Approximately 1 year prior | Doctor wrote letter telling pt. she would be switched from two to one inhaler. Pt. has allergic reaction on her lips and asthma worsens. Is switched to new medication and proper actuation is demonstrated. |
| P7 | 56 | Female | Preventative inhaler | Doctor | 6 weeks prior | Collected repeat prescription from doctor and attends pharmacy. Arrives home and realises the switch. Goes back to pharmacy to inquire and pharmacist explains that the doctor has switched the inhaler. Calls doctor who confirms that this is going to be her new medication. Asthma is worsening and cannot correctly use inhaler. Waiting for next appointment. |
| P8 | 34 | Male | Preventative inhaler | Doctor | Few months ago | Went for repeat prescription. Doctor told patient they were not prescribing the old inhaler anymore and that the new one is what he had to use now. Patient was not happy with new device and attended a new surgery to be switched back. Collects original inhaler from new Doctor to date. |
| P9 | 54 | Male | Preventative inhaler | Doctor | Few months ago | Collects repeat prescription and notices it is different. Assuming it is similar he tries it for three weeks; asthma worsens. Inquires at pharmacy, and it told the medications are quite different (switched from combination corticosteroid/bet agonist to straight corticosteroid). Returns to doctor and is switched back. |
| P10 | 29 | Female | Preventative inhaler | Doctor | 8 weeks prior | Went for repeat prescription. Picked up at pharmacy and realised the change. Tried to have pharmacist switch her back, then called doctor. Doctor told her the old device was discontinued. Continues to frequent different pharmacies attempting to find the old inhaler device. |
| P11 | 77 | Female | Preventative inhaler | Doctor | 2 years prior | Went to doctor for repeat prescription then to collect at pharmacist. Pharmacist is out of stock and she is told to return in a week's time. Upon returning collects new inhaler and realises a switch has been made. Is unable to work new inhaler and returns to doctor. Is switched to another inhaler and then back to her old one. |
| P12 | 22 | Female | Rescue inhaler | ? | Approximately 1 year prior | Inhaler device is switched from branded medication to generic. Patient does not realise that switch has taken place, until she compares her device with her partner's who is using the same inhaler device as she formerly had been. Asthma is unchanged; no return to Doctor since realisation. |
| P13 | 49 | Female | Rescue inhaler | Doctor | 2 years prior | Collected repeat prescription from Doctor and realises the switch upon arriving home. Uses new device for approximately one week. Asthma worsens and she returns to doctor to be switched back. Doctor says they are the same medication (brand to generic) but complies. |
| P14 | 19 | Female | Rescue inhaler | Doctor & Pharmacist | On going | Collected repeat prescription and told it would be CFC free. Gets medication home and notices the switch. Continues to be switched back and forth from branded rescue inhaler to generic inhaler. Continues to collect prescription from doctor but asks pharmacist to change it for branded name or CFC inhalers (old stock). |
| P15 | 21 | Female | Rescue inhaler | Doctor | 1.5 years prior | Informed on collecting repeat prescription that her old inhaler is no longer being made and is switched. Switch not made in consultation; felt like it was being forced upon her without her consent. Tried unsuccessfully to switch back. Asthma has worsened; patient remains on switched inhaler device. |
| P16 | 28 | Male | Preventative inhaler | Doctor | 2 years prior | Goes to doctor for repeat prescription. Realises the inhaler has been changed when he arrives home. Trusts the switch as his doctor is a family member. Has been using it ever since. Asthma remains the same. |

Table 2. Circumstances of NCS (continued).

| ID | Age | Gender | Type of inhaler switch | Initiated by? | When | What happened? |
|-----|-----|--------|---------------------------------|---------------|----------------------------|---|
| P17 | 22 | Female | Rescue inhaler | Doctor | Few months | Went to doctor for repeat prescription. Asks for same thing and doctor agrees. Realizes the doctor has written something else on prescription. Collects new prescription and see that it is a different device and medication. Has not been back since and find the new inhaler only works for a fraction of the time of the previous medication. |
| P19 | 25 | Female | Preventative and Rescue inhaler | Doctor | Few months ago | Repeat prescription picked up by family member. Told they were switching her from two inhalers (rescue and preventative) to one. Unfamiliar with actuation at first. Asthma has remained unchanged. |
| P20 | 31 | Male | Rescue inhaler | Doctor | Approximately years prior | Attended a new doctor practice after moving. Took in inhaler to 2 show doctor what he had been using while being examined for chest infection. Doctor switched to a new medication without telling him. Asthma remained as well controlled. Continues with new medication for two years despite voiced inconvenience of more frequent refills and more puffs. |
| P21 | 21 | Female | Rescue inhaler | ? | Most recently 2 months ago | Repeat prescriptions change back and forth between generic and branded inhaler devices. Inquires with the doctor as to the reason for the change and doctor passes responsibility on to pharmacist. Asthma is largely unchanged. No major preference for one inhaler over another. |

*ID P1 and P18 were excluded from the study due to the NCS occurring >2 years prior

Table 3. Example summary statements regarding the NCS.

| |
|---|
| "I just wish someone had sat down and told me why, and told me it was a trial run. As it was, you felt, are you testing a new drug?" |
| "I think it was the whole scenario of it being changed and it creates a fear in you – what's all this about? I think first impressions weren't good. I would have done if she had told me, 'I'm going to change your medication'. Maybe then I would have had an explanation and I would have felt different. To give me the opportunity or give me that option or chance, it would take away a lot of the resentment. I just feel that your doctor should tell you and consult with you. If I had had the courage I would have said it to my doctor too. I think I would maybe have given the medicine half a chance if she had discussed it with me." |
| "Why weren't we told? Why wasn't it published in papers? Why didn't the doctor tell us? They must have a list of people that have this medication. Why were we thrown in the deep end? I think they had a cheek with this. Someone could have died with that." |
| "I think the biggest thing is what is done to ensure your understanding? And whether you were shown how to use it." |
| "I didn't feel well – physically and emotional discomfort because you know you don't want to make a fuss. I think one of the most important things first of all is how it was introduced that the switch was taking place. Level of education about the switch and the confidence in being able to go back and say without feeling stupid that this isn't suiting me. I have enough confidence to go back but I still feel apologetic doing so when you shouldn't." |
| "The most important this is that it isn't working. I can feel myself deteriorating. I think that's most important." |
| "The issue of control is very important. You haven't got much of a say in what goes on, as if what you have to say doesn't really count. It has had an impact on me, I used to think that the things I said, the doctor would say I realise what you say and act on it. You can use this because you said so. But now I realise it isn't like that." |
| "I guess it makes you more aware that you have asthma. It's not much in control and with this one." |
| "If I had to choose one main impact, what would it be? I would say that I was nervous. I was quite confident with the inhaler I had and it made me insecure because I didn't know if this would help me as much. If you get sick, it's quite scary. You want to make sure it will fix you quickly." |
| "It was more of a shock that someone could do that and not divulge anything. They just left you." |
| "Well if they want to change the medication, then fine. They are the doctor and I hope they would know what's good for me. It's more about the fact that I wasn't told." |

about it all the time". (P4)

In addition to changes in asthma control, many patients felt as though the NCS affected their sense of personal control over their condition. Some participants talked of being more aware of their asthma and one person described feeling more like a 'sufferer'. Participants talked in terms of feeling disempowered:

"I think it has made me aware that the patient hasn't got any control really. It is out of my hands. I find it scary. Something you use can be taken away". (P8)

And again later this participant commented:

"Your confidence and hopes, you have become so used to something, and it just works and you're quite well most of the time and it's taken away. It can have an effect on your health."

Being in control and being able to control their symptoms were important issues for the patients. A number of participants reported how they regained control of their symptoms by using one of their old inhalers.

4. Relationship with health professionals

In the interview, the effect of the NCS on patients' relationships with their doctor and pharmacist was explored. The participants reported different levels of relationship with their doctors, ranging from, "I am completely satisfied", to, "I don't think they know who I am". This range reflects what would normally be expected in any patient sample. However, the inhaler switches had a clear impact on the doctor-patient relationship. Almost all of the participants said that the switch had impacted on their relationship with the doctor, irrespective of whether their previous relationship had been good or not. Participants talked of being 'angry' and 'upset' or 'shocked' that they had not been told anything about the NCS. Additionally, while the participants mainly experienced a deterioration in their physical functioning (though not always), the participants indicated that the surreptitious nature of the switch was to blame for the impairment in their doctor-patient relationship, not the decline in symptom control:

"If it had been communicated, if it had been a case of, 'have a play around, it does this, it does that', if some quality communication came with it then generally a lot of psychological issues can be dealt with due to the sound communication... Perhaps with communication, with proof and time maybe there would be no issues". (P2)

Some people were frightened by the risk they felt exposed to as a result of the NCS:

"It's like they are putting your life at risk. I wasn't able to do anything about it". (P13)

Even patients who did not experience any deterioration in symptoms raised concerns:

"I could be a guinea pig, that's how I feel... It has definitely affected my relationship with the doctor". (P7)

Some people clearly did not feel comfortable querying the doctor because of the dependent nature of the relationship. One participant even remarked that she was concerned the doctor may remove her from the practice:

"...you're frightened that they will say, 'well find another surgery' ...I'd be frightened of her authority". (P3)

Not all switches were instigated by the general practitioner (GP). A couple of the participants reported that their switch had been initiated by the pharmacist. This had a similar negative effect on the relationship with the pharmacist:

"I wouldn't say it is good at the moment [relationship with pharmacist]. I feel that they are not quite sure what they're giving me sometimes hence the confusion with my current treatment. I think that is where the confusion lies". (P2)

Discussion

This small, exploratory qualitative study mapped the experiences of a group of patients who self-reported that their asthma

inhaler had been switched without their consent. Little is known about the incidence and impact of medication switching and so we aimed to explore the views and outcomes of the switch from the patients' vantage point and made no assumptions about the nature of the switch. The qualitative interviews did provide some answers to the questions of whether or not an NCS leads to changes in asthma control, changes in patient behaviour, and whether the outcomes would be restricted to the physical symptoms of asthma.

Recruitment presented a unique challenge as it was not possible to recruit directly from clinical sites given the nature of the research. This meant that we were unable to confirm the nature of the switch or explore the clinicians' points of view. The recruitment method may have skewed us towards only recruiting those people who had adverse outcomes from the NCS. However, the results indicate that this was not the case, with one participant indicating that they were quite happy with the switch. Therefore, we believe that we managed to achieve a sample that had a fair range of both positive and negative experiences.

A potential study weakness is that the qualitative interviews were based solely on patient recall and it is not possible to verify the accuracy of the patients' reports and if the switch had been truly non-consented. However, given the number of cases that we have identified we believe it is unlikely that all the study participants are mistaken. In addition, during recruitment we excluded a large number of people who responded to the advertisement because we were not convinced that their inhaler switch was non-consented.

The study participants were candid in their discussions and freely offered their take on the circumstances and motive for initiating a non-consented switch, the changes in their medication use post-switch, impact of the switch on perceived asthma control, and how the switch affected their relationship with their doctor or pharmacist.

The switches were reported to be mainly doctor initiated, but at least two were thought to be instigated by the pharmacist. These findings, together with those of Thomas *et al.*,¹⁰ suggests that this is a worrying phenomenon which poses a clinical and emotional risk to patients and their relationship with their health care professional.

Without any consultation to accompany the switch, many participants speculated about the reasons for their own particular circumstances. This quite often led to negative judgements on the underlying reasons for the switch, and led in some circumstances to a negative impact on the doctor-patient relationship. The exact reasons for switching of devices/medications needs to be shared with patients if incorrect assumptions are to be avoided.

In addition, the NCS was reported to have an impact on participants' asthma control. Clinical guidelines highlight the

need for proper training in the use of inhalers. Both the British guideline¹ and NICE guidance² refer to the need to monitor proper usage of inhaler devices, and the US guideline states that medications are not interchangeable on a 'mcg' or 'per puff' basis because newer delivery devices may deliver a greater therapeutic dose to the lungs.¹⁷ All state that whatever device is selected, patients should be instructed in its use and undergo regular checking of inhaler technique. Self-management literature further suggests that proper education regarding use of asthma medication improves adherence and asthma control.¹⁸ When inhalers are switched without the consent of the patient, ensuring effective usage of the new device is not possible. This can then lead to reductions in asthma control, as has been shown by these results and by Thomas *et al.*¹⁰

At the very least, the cases that have been highlighted here demonstrate a breakdown in care for asthma patients. If the consent issue is ignored, it cannot be disputed that these patients have had their inhalers changed and many have experienced a significant deterioration in their asthma as a consequence. These patients reported very poor follow-up care. In many cases, they were left to seek an appointment with a doctor in whom their trust has diminished. Many participants indicated that the biggest impact of the switch on their lives was not physical issues or asthma control, but rather the lack of communication and consultation.

In conclusion, this study has shown the negative impact that non-consenting switching of inhalers can have on asthma patients. Clinicians, practice managers and health boards need to be aware of this impact when considering changes to inhaler devices, whether it is at an individual level, practice level or health board level.

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Conflict of interest declarations

AW was an employee of GlaxoSmithKline during the time the study was being conducted. DP has consultant arrangements with: Aerocrine, Boehringer Ingelheim, Dey Pharmaceuticals, GlaxoSmithKline (GSK), Merck, Sharpe and Dohme (MSD), Novartis, Schering-Plough and Teva. He or his team have received grants and research support for research in respiratory disease from the following organisations: UK National Health Service, Aerocrine, AstraZeneca, Boehringer Ingelheim, GSK, MSD, Novartis, Pfizer, Schering Plough and Teva. He has spoken for: Boehringer. SD, AL, HC, MM, MT have no conflicts of interest.

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Appendix 1. Asthma qualitative interview structure: Topics, questions & queries

Section A: Introduction to asthma diagnosis/symptoms

“Please tell me how many years you’ve had asthma, and how long that you have been taking asthma medication”.

- ∞ How long have you had asthma?
- ∞ How severe would you say your asthma is?
- ∞ What does it restrict you from doing?
- ∞ Does it restrict you in terms of daily activities (housework, going to the shops, etc), and how aware are you of your symptoms throughout the day?

Section B: Daily practice of medication use

Now we would like to ask you a few questions about your asthma medication

- ∞ How satisfied are you with your current treatment for asthma?
- ∞ What medications do you currently use? Which medication was switched- from what medicine/device to what new medicine/device?

Section C: Doctor/Pharmacist; Other

Now we would like to ask you a few questions about your GP (probe for nurse if main clinical contact point)

- ∞ Who is your main point of contact for your asthma care?
- ∞ How often do you see your GP regarding your asthma?
- ∞ How long have you been registered with your current GP?
- ∞ How much trust/faith do you place in your GP?
- ∞ How satisfied are you with the care you receive from your GP?
- ∞ What is your overall impression of your GP?

Now we would like to ask you a few questions about your pharmacist or chemist

- ∞ Do you go to the same pharmacist each time or do you go to the most convenient?
- ∞ Would you say there exists a relationship between you and your pharmacist?
- ∞ How much trust/faith do you place in your pharmacist?
- ∞ How satisfied are you with the service you receive from your pharmacist?
- ∞ What is your overall impression of your pharmacist?
- ∞ Have you ever experienced any problems with your pharmacist?

Section D: Impact of the Switch

Purpose: To explore the patient's experience, views, opinions, and perceived outcomes of a non-consented switch. (*note: reverse chronology may improve recall*)

You told us previously that you have experienced a change or switch in your asthma medication which you weren't expecting. We would like to ask you some questions about this and how it affected you. Just to clarify again we are specifically interested in a change that was made to your asthma medication which you knew nothing about before hand and did not agree to before it happened.

- ∞ When did this switch in your medication happen?
- ∞ Please can you tell us exactly what happened?
- ∞ Have you ever experienced an unexpected change in your prescription for your medication before?
- ∞ Did you inquire about the reason for the switch? What was the response?
- ∞ Why do you think this happened?
 - Who was responsible for switching your medication?
- ∞ Was the change in your medication communicated to you at any point
 - If so how (letter; call; none)?
- ∞ Did you have a follow-up appointment after the change?
- ∞ How did you feel after the switch
 - *Prompts (angry, indifferent, stressed)?*
- ∞ Were you ever shown how to correctly use your new inhaler device? Were you shown how to use your old one? Who showed you?
- ∞ How much personal responsibility do you take for you asthma care? Did the switch have an effect on this?
- ∞ Are you ever uncomfortable about using your inhaler in public? If the new device looked different or you had difficulty using it, did that have an effect on your public usage?
- ∞ Did the change affect:
 - How easy it was for you to use your medication?
 - Your confidence in the medication
 - Your relationship with your doctor?
- ∞ Was the new medication as good as your old medication?
- ∞ How has your compliance with the medication changed following the switch?
- ∞ Do you think your asthma is worse since your medication was switched?
 - If Yes – in what way?

- More symptoms – how
- More trips to Dr/ nurse
- More days off work
- Daily activities – perhaps be more or less physically active?
- Would you be more likely to go out with friends/ family,
- Would you be more likely to go on holiday?
- Change stress/ anxiety levels. Any other ways?
- ∞ What are some of the tactile differences between your old and new device/medication (taste; smell; weight; power of puff, etc.)?
- ∞ Have you ever taken too much (or too little) of your medication? Did this occur before or after the switch?
- ∞ How confident are you in your medication to relieve your asthma symptoms? Has this changed as a result of the switch?
- ∞ What did you do with the medication after the switch- was it binned; did you use the rest of it did you throw out your old inhaler?
- ∞ Did you have to go back to the doctors more than you would have normally, as a result of the switch? (*probe other costing issues*)

Section E: Summary and Conclusions

- ∞ Would anyone like to add anything else to this discussion?
- ∞ Are there any other important issues that we haven't covered?
- ∞ Can you summarize the main points of the interview?
- ∞ What is the single most important impact that the switch has had on you?

Review of information; possibility of additional comments and questions
Confirm answers and clarify important issues