

Patient experiences of switching between different versions of anti-epileptic drugs

Epilepsy Society and Epilepsy Action

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1. Background

1.1 The new MHRA guidance

In 2012 the Medicines and Healthcare Regulatory Authority (MHRA) asked the Commission on Human Medicines (CHM) to develop guidance for the prescribing and naming of anti-epileptic drugs (AEDs).

The CHM brought together a group of clinicians and other scientific advisors to consider a number of published studies on the issue of potential harm for people with epilepsy arising from substituting different versions of AEDs. The group concluded that all AEDs are not the same and problems related to small differences in the bioavailability of different formulations are a clear concern for some drugs. However, they also concluded that for other drugs with a wider therapeutic index and/or high solubility, there are unlikely to be any concerns when switching between different versions. CHM advised that AEDs could be classified into three categories in relation to advice for doctors - about the extent to which consistency of supply must be maintained on pharmacological grounds (i.e. because of their half-life, mode of action and potential to interact with other drugs).

The new guidance, issued by the MHRA in October 2013 in response to CHM advice, placed AEDs in to three categories as outlined in the chart below. This was the first time that such prescribing guidance has been issued for AEDs. The guidance aims to help prescribers, pharmacists and patients decide whether it is necessary to maintain continuity of supply of a specific manufacturer's product.

Category	Advice	AEDs
1	For these drugs doctors are advised to ensure that their patient is maintained on a specific manufacturer's product.	phenytoin, carbamazepine, phenobarbital, primidone
2	For these drugs the need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with patient and/or carer, taking into account factors such as seizure frequency and treatment history.	valproate, lamotrigine, perampanel, retigabine, rufinamide, clobazam, clonazepam, oxcarbazepine, eslicarbazepine, zonisamide, topiramate
3	For these drugs it is usually unnecessary to ensure that patients are maintained on a specific manufacturer's product unless there are specific concerns such as patient anxiety, and risk of confusion or dosing errors.	levetiracetam, lacosamide, tiagabine, gabapentin, pregabalin, ethosuximide, vigabatrin

1.2 The epilepsy care pathway

The primary aim of epilepsy treatment and management is to optimise seizure control while minimising side effects. For most people with epilepsy, seizures will become controlled with AEDs. This is not the case for all individuals, and it can take a long time to achieve. Different health care professionals play different roles in relation to supporting patients to achieve seizure control, as outlined below.



GPs

- Refers patient with suspected first seizure to neurologist
- Monitors ongoing health according to care plan
- Issues prescriptions under neurologist guidance
- Undertakes annual review



Neurologists

- Undertakes specialist assessments
- Diagnoses epilepsy
- Defines and monitor medicine regime



Pharmacists

- Dispenses medicines according to prescription
- Encourages adherence and support renewals
- Highlights adverse drug effects
- Understands withdrawal or AED switch issues

1.3 Initial concerns

Given that the new guidance could potentially have a huge impact on people with epilepsy, we were disappointed that the MHRA did not consult with people with epilepsy or leading patient organisations such as Epilepsy Society and Epilepsy Action before introducing the new guidance.

At a meeting with the MHRA in February 2014, Epilepsy Action and Epilepsy Society outlined our view that having reviewed the evidence-base the MHRA used for their analysis, it is not possible to conclude on pharmacological grounds that there are no significant clinical risks associated with switching between category three AEDs. The CHM themselves note that they could not rule out the causal role of switching in cases where there had been loss of seizure control and worsening side effects around the time of switching.

We also noted that most of the drugs in category three do not have generic equivalents and so any conclusion about their safety to be switched is hypothetical.

Of equal importance is the fact that when developing the new guidance the MHRA did not take account of the non-pharmacological impacts of switching between different versions of AEDs. This includes factors such as psychological impacts of having different medicine, anxiety, confusion, memory difficulties and implications for medicine adherence.

1.4 This report

The MHRA agreed at the meeting in February to monitor use of the guidance and undertake a review after 12 months. Ahead of this 12 month review, Epilepsy Society and Epilepsy Action have undertaken further research into patient experiences of having their AEDs switched which is presented here, along with recommendations for change.

Information on evidence gathering, respondents, terminology and methodology relating to the preparation of this report can be found in the appendix on page 14.

2. Research findings and analysis

In total 624 individuals with epilepsy took part in this research, with 576 of them currently living in the UK. Only respondents living in the UK are used in the analysis.

2.1 Patient experiences of prescribing and dispensing AEDs

65% (374) of UK respondents indicated that their medicines had been switched within the two years prior to undertaking the survey. That is to say that an individual had received a different version of their medicine to the version they had most recently been receiving, either a move between branded original and generic products, or between different generic products of a particular drug.

Of those who received a different version of their medicines, respondents were asked about their understanding of why their medication had been switched. The majority of switches took place in primary care. 38% (142) of respondents who had their AEDs switched reported that the GP had used a generic name on their prescription. This demonstrates that generic prescribing is already used by some GPs. 38% (142) reported that they were told by the pharmacy that their normal medicine was not in stock. This shows that pharmacists are sometimes unable to provide a consistent supply when dispensing medicine. Pharmacists themselves say it is often difficult to guarantee a consistency of supply from the wholesaler.

Some reported switches took place in secondary care. 6% (22) said their neurologist had recommended a change in medicine. This group may include individuals who have in fact received different AEDs (rather than different versions of the same drug). The changes may have been made with the aim of optimising seizure control/reducing side effects. It is also possible that some of these changes may have been between different versions potentially with the aim of saving money.

28% (104) of individuals who had received different version of their epilepsy medicine stated they did not know why their medicines had been changed. Many were unaware that their medicine had been changed until after they had left the pharmacy, with 39% (147) reporting this to be the case. This suggests that health care professionals are not involving patients in the decisions about switching versions of AEDs. It does not adhere to the principles of 'no decision about me, without me'¹, and does not demonstrate the practice of informed consent set out in the NHS Constitution. We acknowledge the possibility however, that in some cases the health care professional may have discussed the switch but the individual might not have remembered, or that it might not have been a productive discussion for the individual.

2.2 Challenging different versions of medicine

We asked respondents who had received a different version of their medicine whether they had challenged this.

Challenging GPs

- 33% (102) asked their GP to make changes to their prescription to ensure consistency of supply.
- A small number of respondents involved their neurologist [8% (25)] or specialist nurse [9% (27)] in contacting their GP about switching their medicine.
- 28% (29) of those who asked their GP to change their prescription were unsuccessful. Again this suggests that in some cases patient involvement in decision making about their care was lacking.

Challenging pharmacists

- 44% (135) asked the pharmacist to change the version of medicine that was dispensed.
- 57% (77) of those who asked their pharmacist to change the version of their medicine were unsuccessful.

The qualitative data from this research suggested that pharmacies based in larger organisations, such as supermarkets or major high street stores, are moving towards stocking a narrower range of medicines. A number of

¹ NHS, ["Liberating the NHS: No decision about me, without me"](#) December 2012

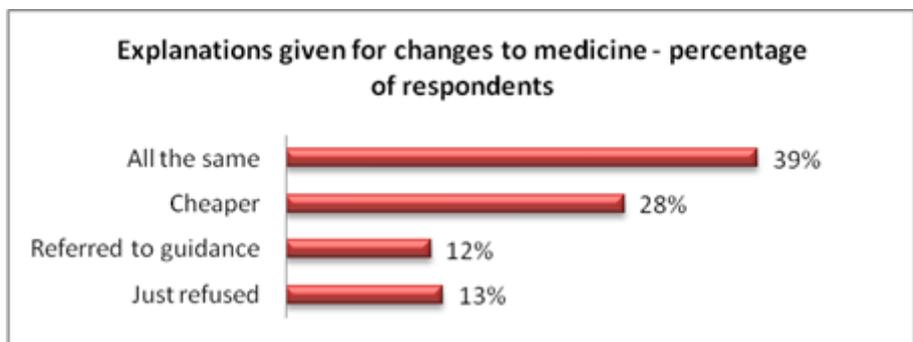
individuals report that where they had previously been able to obtain a medicine at a specific pharmacy, they subsequently had to go to alternative pharmacies in order to obtain the required medicine. This may result in a difficulty for some individuals in obtaining a specific version of a medicine even where it is specified in the prescription. The following comments were made by survey respondents in relation to stock of AEDs in pharmacies:

"Pharmacy has finally agreed to only give me a certain brand thanks to GP intervention; however, they do not keep it in stock for me so I am always left short" (Survey respondent)

"I rang 26 different chemists to find one that stocked it" (Survey respondent)

"I have recently had to change chemists, after a rather unpleasant exchange with the pharmacist. The local Co-op pharmacy took me on, no probs. I found this very distressing. My original pharmacy told me he had been 'carrying me' for 5 years (he made me feel like a criminal). I got my Consultant involved and stuck to Keppra (as it worked). I was too anxious to change." (by email, March 2014)

We asked survey respondents whether they were given an explanation for the switch to their medicine:



- 39% (75) of individuals were told that all versions of epilepsy medicines were the same. This suggests a lack of knowledge among health care professionals about AEDs, and indicates the need for clearer guidance.

"The pharmacy had changed stockist and said that it was still the same" (Survey respondent)

- 28% (53) were told that the new version of epilepsy medicine was cheaper, perhaps suggesting cost being a motivating factor in switching AEDs.

"When questioned my GP confirmed they were going for the cheapest available"

(Survey respondent switched from Keppra to generic levetiracetam—individual experienced breakthrough seizures)

"CCG refused to pay for branded even though that is what was previously dispensed"

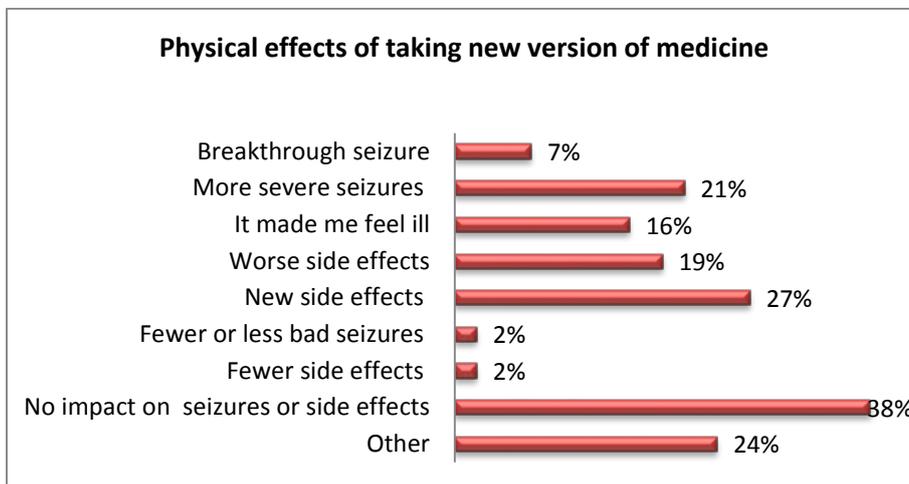
(Survey respondent who had switched from Keppra to generic levetiracetam— patient experienced more frequent seizures of a greater severity and worse side effects)

- 12% (23) were told that the new guidance meant that it was safe to change the version of the medicine. It is worth noting that the guidance is relatively new and the survey asked about a period before and after the guidance was introduced.
- 13% (24) were given no reason for the medication switch, again demonstrating little patient involvement in decision making.

2.3 Physical effects of the switched medicine

13% (47) of respondents reported they did not take the switched version of AED. This is particularly concerning as it has clear implications with regard to seizure control.

We then asked the respondents who took the switched medicine how, if at all, they thought it affected their epilepsy, seizures or side effects. The answers are outlined in the table below (note respondents could 'tick all that apply').



Of the 87% (326) of respondents who took the new version of their medicine, 62% (202) reported some form of negative physical response to the switch of medicine. Negative physical responses included breakthrough seizures, more severe seizures, feeling unwell, worse side effects or new side effects. Other negative symptoms were specified by some respondents, as outlined by the comments below:

"My body almost went into melt down"

"I thought I was going crazy & became sad and withdrawn"

"I felt light headed, physically sick and suicidal"

"My brain feels slower, I can't remember things and struggle to hold concentration"

"Tremors have become a lot worse"

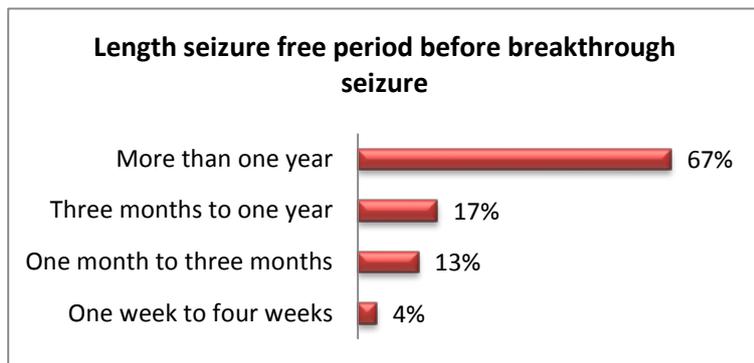
The impact of side effects on people taking epilepsy medicine should not be underestimated. Side-effects of medication can include memory and cognition difficulties, headaches, nausea, slowed mental process, fatigue and impact on mood (for example depression, anxiety). Such side effects can have a huge impact on an individual's life, not least the ability to go to work and socialise.

Of the 87% (326) who took the switched medicine, less than half (38% - 124) of respondents reported that the new version did not affect their epilepsy, or cause seizures or side effects. Less than 2% (6) said that they had fewer side effects and less than 3% (8) said they experienced fewer or less severe seizures. We note that these are retrospective, self-reported outcomes, and is not necessarily proof of a causal link. It might be causal, or might demonstrate the psychological impact of a change.

2.4 Impact on seizure frequency and severity

We explored in more detail the impact switching had on seizure frequency and severity.

21% (68) of individuals who took the switched AED reported that they had more frequent or more severe seizures. 7% (24) of respondents reported a new (or breakthrough) seizure after having been seizure free. The chart below shows the length of time individuals had been seizure free before having a breakthrough seizure.



Of those who had experienced a breakthrough seizure following a switch of medicine, 17% (4) had been seizure free for between 3 months and one year, and 67% (16) had been seizure free for one year or more. Of those experiencing breakthrough seizures, 29% (7) had a seizure within 3 days of starting new medicines, 21% (5) were experienced within one week and 50% (12) after more than one week. We acknowledge this is not evidence of a causal effect, but only suggestive of a correlation. However, it is also worth noting that if the individual feels that it is causal, this might affect the medicine adherence.

The following are comments from survey respondents in relation to breakthrough seizures and switching between versions of epilepsy medicine:

"I fitted within the day after not fitting for years and my son's seizures doubled."

"I started having seizures...tried to stay with it - and they become more and more frequent...finally got them [doctors/pharmacy] to change me back - but it wasn't easy [as it was more expensive]..."

As charities representing people with epilepsy we have a detailed understanding of the impact on the individual of having breakthrough seizures (or having more frequent seizures). This should not be underestimated:

- The one year seizure-free mark is highly significant for people with epilepsy as it often used as the measure for decision making. The most significant legal implication of this measure is the authorisation to drive.
- Having seizures may affect a person's ability to work (for example if their job involves driving or operating machinery).
- The stigma associated with epilepsy and seizures can also negatively impact the employment of people with epilepsy. It is not uncommon to hear about individuals losing their job after having a seizure at work.
- The psychological impact of seizures can be significant. Many people with epilepsy experience extreme anxiety about leaving their house and going out in the community.
- In rare cases seizures can be fatal. Around 600² a year die from sudden unexpected death in epilepsy (SUDEP).

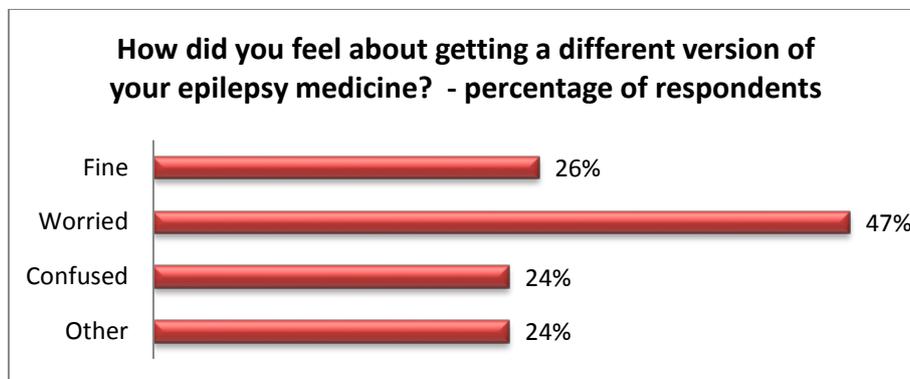
There are also wider costs to the public purse:

- Longer term impact on employment may result in increased welfare costs.
- A change in seizure pattern is more likely to result in ambulance call outs, attendance at A&E departments or emergency admissions to hospital.

² Epilepsy Society, [SUDEP](#)

2.5 Reactions to receiving different versions of medicines

We asked respondents how they felt about receiving a different version of their epilepsy medicine. 26% (96) of respondents stated that they felt fine about the switch, while 74% (265) of respondents felt some form of negative emotion about it. The key terms used by those responding 'other' and providing greater detail were: angry, frustrated, unhappy, uncertain, annoyed, worried, confusing, anxious, terrified, mad, irritated, scared. These terms were used repeatedly by different respondents.

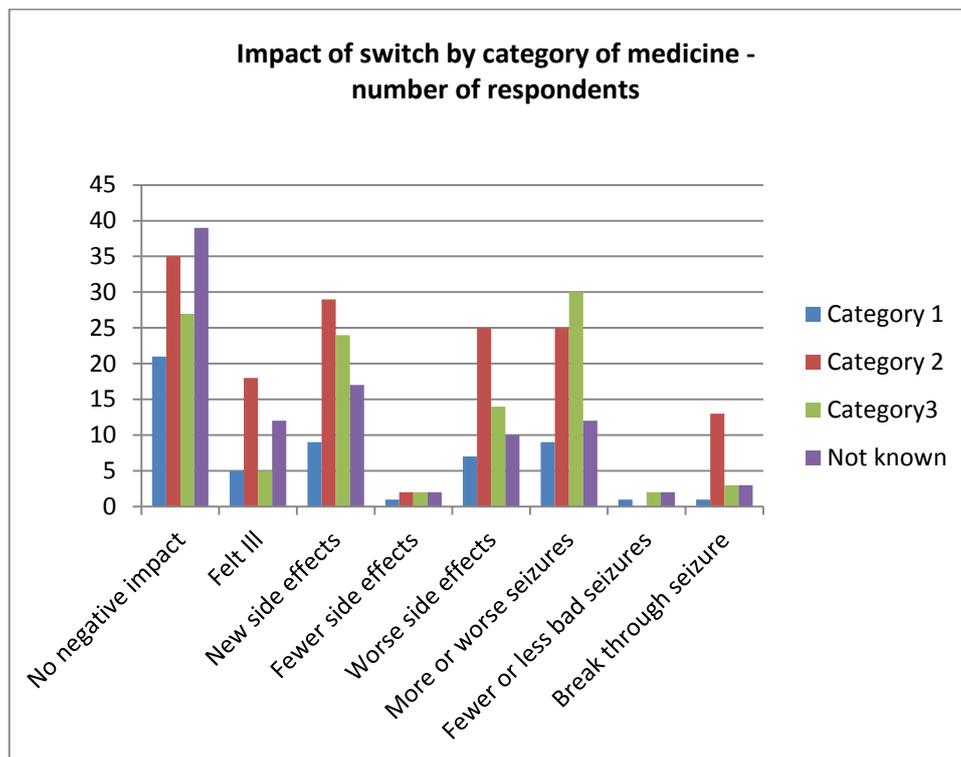


Clearly a large proportion of respondents experienced negative emotions as a result of having their drugs switched. From our experience as charities representing people with epilepsy we know this has a number of implications:

- Stress and anxiety are known seizure triggers. Many people with epilepsy already experience anxiety related to their condition; stress caused by switching drugs may exacerbate this.
- The level of confusion and fear suggests that GPs and other healthcare professionals do not spend enough time discussing the implications of the switch with, and ensuring informed consent from, the patient. .
- Unintentional non-adherence is a well known risk for some groups of individuals with epilepsy. Reasons for this could include forgetting to take medicine; being unable to handle the medicine (physical dexterity) and being physically unable to take the medicine (for example, if they find it hard to swallow tablets, not taking them because they look different, fearing that they will not work).
- A substantial number of people with epilepsy also have memory difficulties. For this group of people changing frequency, colour or taste of a medicine may cause confusion, leading to the wrong number of tablets being taken. Equally, for those with learning disabilities a change in the size or packaging of their medicine may lead to unintentional non-adherence.
- A substantial number of people with epilepsy also have autism or learning difficulties. For someone with autism, it may be distressing if a tablet looks or tastes different to normal. 44% (168) of respondents who had their AEDs switched reported their new medicine looked different and 16% (62) said it tasted different. Neurologists report that people with autism or learning difficulties are more likely to be prescribed category 3 drugs for which the MHRA have concluded that 'no specific measures are normally required and these AEDs can be prescribed generically', and are therefore more likely to have their medicine switched.

2.6 Category of medicine

We also asked respondents which medicines they were taking prior to the switch, and the impact of having the medicine switched. In the table below the impacts of switching are shown against MHRA drug categories:



It is concerning that the majority of individuals reporting a breakthrough seizure after one year of seizure freedom were on category 2 medicines, and a further three individuals were on category 3 medicines. Guidance for category 2 is that a doctor should decide, with the individual, whether it is important to always stay on the same version or whether it is okay to switch between different versions. Under the new guidance category 3 medicines can be prescribed generically.

We looked at the reasons why patients on category 2 AEDs, who report having breakthrough seizures, had their medicine switched:

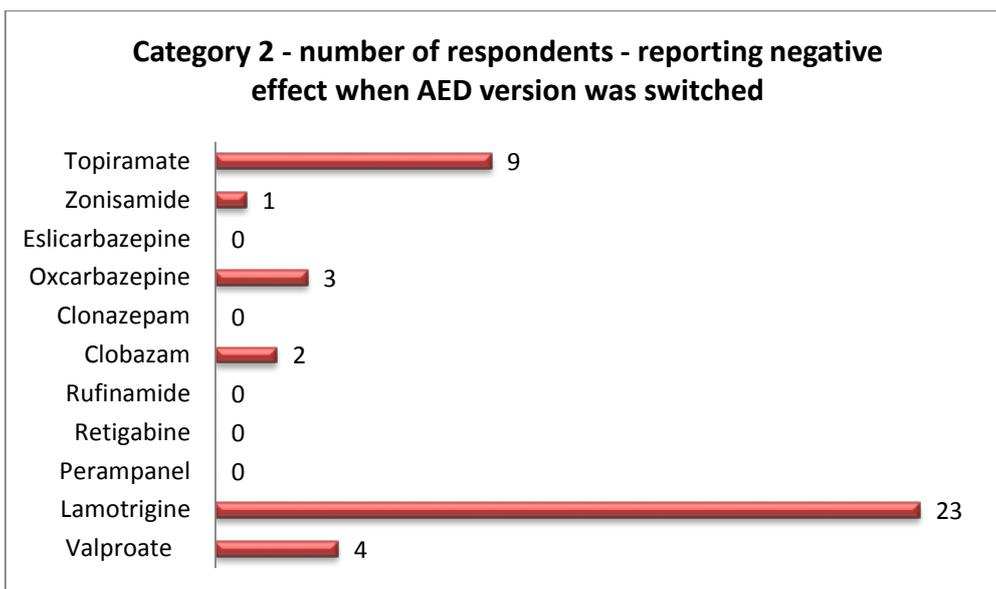
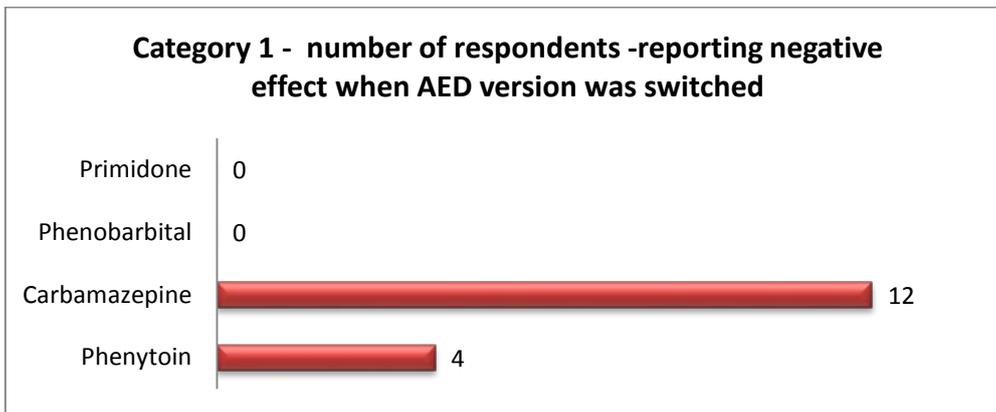
- three of these respondents reported that their neurologist had not specified a particular version of the medicine should be dispensed,
- five said that their GP had not specified the version of medicine, and
- four said that the pharmacist had not had their usual medicine in stock.

The four individuals on category 3 medicines who had experienced a breakthrough seizure said that their medicine was switched because the GP had written the generic name on their prescription.

The table above also shows that the majority of individuals reporting worse or more frequent seizures were on category 2 or category 3 medicines. This is particularly concerning given that under the new guidance there is an increased likelihood of AEDs in these categories being switched. Furthermore, a high proportion of individuals reporting worse side effects, new side effects or 'feeling ill' were on category 2 or category 3 medicines, and therefore more likely to have their medicine switched.

2.7 Versions and brands of drugs switched

We asked respondents to report what version or brand of AED they were taking when their medicine was switched to a different version. The tables below look at the AEDs within each category and the number of respondents reporting a negative physical effect when their drugs were switched (including breakthrough seizures, more severe seizures, feeling unwell, worse side effects and new side effects).



42 respondents in total reported a negative physical effect when a category 2 AED was switched. In particular, Lamotrigine has resulted in negative effects in 23 survey respondents.

It is important to note that for many of the drugs included in category 3, generic versions are not available at present. This applies to Lacosamide and Pregabalin for example.

A total of 36 respondents reported one or more negative response when they were switched to a different version of levetiracetam (Keppra), including three who had a breakthrough seizure. MHRA guidance states that for category 3 medicines there is no need for doctors to ensure consistency of supply in terms of manufacturer. While not generalisable for the whole population taking levetiracetam, this level of response would suggest that further research is required to explore the impact of switching between different versions of levetiracetam.

3. Conclusions and recommendations

3.1 Generic prescribing

This research shows that generic prescribing by GPs is a relatively common reason for individuals with epilepsy having had their medicine switched; 38% of respondents who had their AEDs switched reported that the GP had used a generic name on their prescription. This includes four individuals who experienced breakthrough seizures after having category 2 drugs switched, due to generic prescribing by their GP.

Category 3 of the new guidance states that drugs may be prescribed generically unless there are specific concerns such as patient anxiety, and risk of confusion or dosing errors. Most GPs are not specialists in epilepsy. People with epilepsy repeatedly tell us that their GP does not understand their condition and the associated anxiety or side effects. This means that the new guidance on AEDs is going into a vacuum where there is little, if any, GP information about epilepsy. We also know that in some practices prescribing software may default to generic drugs.

GPs' prescribing habits may also inadvertently contribute to switching. For example GPs may not be aware when a patent ends. If the generic name has habitually been used during the patent period and continues to be used, the possibility of switching at the point of dispensing occurs without intention. Again this highlights a lack of knowledge about AEDs amongst GPs.

We welcome any guidance for GPs which supports consistency of supply in prescribing epilepsy medicine. However, the way in which the current guidance is worded, currently seems to be taken as a green light to continue to prescribe by generic name.

Recommendation 1 – the MHRA should urgently review its guidance, reviewing evidence from patient organisations and professional bodies, to ensure its guidance supports GPs in their role as prescribers. This might include signposting GPs to patient organisation epilepsy information and helplines.

Recommendation 2 – GP prescribing software should incorporate flags for epilepsy medicine to ensure the potential implications of switching between versions are highlighted at the point a prescription is made.

3.2 Generic dispensing

Many of the switching instances reported in our research occurred at the point of dispensing. 38% of respondents who had their medicine switched reported that this was because the pharmacy did not have their normal medicine in stock. This appeared to be a particular problem at pharmacies based in larger organisations such as supermarkets or major high street stores, which are moving towards stocking a narrower range of medicines.

The research also suggested a lack of knowledge among pharmacists and GPs about different versions of AEDs. 39% of individuals who challenged having their medicine switched were told that all versions of epilepsy medicines are the same.

Recommendation 3 – The MHRA should provide guidance for pharmacists on prescriptions and dispensing epilepsy medicine, in association patient organisations and professional bodies. Pharmacists should be encouraged to carry out MURS and make recommendations to the GP where they identify patient concerns.

Recommendation 4 – GPs and pharmacists should highlight the repeat prescription services to people with epilepsy to ensure that they have the best possible chance of a consistent supply from their pharmacist.

3.3 Patient involvement in decision making

Our research presents strong evidence that patients have not been involved in the decision to switch to a new version of AED. 39% of respondents who had their AEDs switched did not realise until after they left the pharmacy.

Furthermore, the high level of negative emotion reported by patients who had received a different version of their medicine suggests that prescribers had not taken into account factors such as patient anxiety into account. Overall, 74% of respondents reported feeling some form of negative emotion about having their AEDs switched.

This practice does not adhere to the principles of 'no decision about me, without me', and does not conform to the practice of informed consent set out in the NHS Constitution. The new guidance from the MHRA includes caveats about patient involvement in the decision to switch a category 2 drug, and notes that patients with particular issues around anxiety should be considered when switching a category 3 drug. We argue this does not go far enough to ensure that patients will be fully involved and informed in changing to their medicine and relies on the GP making a decision about an individual's likely concern about any potential switch, without the onus on the GP discussing it with the individual proactively.

Intentional non-adherence is clearly a risk where individuals are worried about taking a new version of drugs. 13% (48) of respondents reported they did not take the new version of AED. 202 respondents reported some sort of negative physical effect from taking the new version of AED. If an individual thinks that there is a causal link between the new AED and a negative effect, this is likely to lead to non-adherence.

Recommendation 5– the MHRA should urgently review the guidance, with input from patient organisations, to ensure that it promotes patient involvement in decision making

Recommendation 6 – more information should be made available to GPs about wider considerations that are important to people with epilepsy, such as the implications of having a breakthrough seizure, the potential for non-adherence and the potential additional issues for people with co-morbid autism, mental health conditions or learning disability.

3.4 Cost drivers

A drive by CCGs to reduce the amount spent on drugs would appear to be a factor in some of the cases we explored in our research. 28% of survey respondents who had their AEDs switched were told that the reason for this was that the new version of epilepsy medicine was cheaper. This may be a false economy given 62% of respondents who took the new version reported some form of negative physical effect. Most significantly 21% reported increased or worsened seizures and 7% had a breakthrough seizure after having previously been seizure free. Our research also suggested that 13% of people who had their AEDs switched did not take the new version, which has consequences for seizure control. This supports other research suggesting that generic switching can increase non-adherence.³

Lack of seizure control is associated with increased healthcare costs, such as increased likelihood of presenting at A&E or being admitted to hospital as an unplanned admission. For example latest datashows out of every 100,000 emergency admissions, in 298 cases epilepsy will be the primary or secondary diagnosis.⁴ Furthermore 282 cases per 100,000 emergency admissions were individuals with a primary or secondary diagnosis of epilepsy.

Recommendation 7 - Further research should be undertaken by the MHRA into the potential costs and savings of generic switching in epilepsy.

Recommendation 8 – CCGs should review the costs of their emergency admissions and A&E attendances due to seizures, in parallel with a review of AED costs.

3.5 Switching appears to cause adverse reactions including some breakthrough seizures.

³ [Letter to BMJ, Dec 13 'New advice on switching antiepileptic drugs might be a false economy'](#)

⁴ Public Health England – [Public health profiles data](#) -2012/13

Given that the new MRHA guidance enables generic prescribing of AEDs in category 3 (and in some cases category 2), the research shows that a much higher proportion of respondents than might be expected were experiencing a range of adverse effects following a medicine switch. Of those reporting a negative physical reaction (including side effects as well as increased or breakthrough seizures), 42 respondents were on category 2 drugs and 36 were on category 3 drugs. Of these, 23 respondents on category 2 drugs reported increased or worsened seizures, and 13 reported breakthrough seizures. Furthermore, 19 respondents on category 3 drugs reported increased or worsened seizures, with three respondents reporting breakthrough seizures.

This suggests that on both pharmacological and non-pharmacological grounds, the conclusion that certain drugs are 'safe to switch' is not beyond dispute.

Recommendation 9 – the MHRA should take further clinical advice in light of some specific findings from this patient survey- specific concerns regarding lamotrigine and levetiracetam.

3.6 Concerns regarding lamotrigine and levetiracetam

The high number of respondents experiencing adverse effects following the switching of these two particular drugs is a concern. The switching of lamotrigine, as a category 2 drug, should only have occurred where it was felt it was safe to do so and in consultation with the patient or their carer. However, 23 respondents experienced adverse reactions to the switching. Keppra (levetiracetam) is a category 3 drug and as such would be expected to be appropriate for switching, according to the existing guidance. However, 36 respondents reported adverse effects including three individuals reporting breakthrough seizures.

Recommendation 10 – Until further research has been conducted, the MHRA should place levetiracetam and lamotrigine in to category 1. As a precaution these drugs should be placed in category 1 until further research is available.

Appendix 1 - About this research

1. Evidence gathering

A survey was undertaken jointly by Epilepsy Society and Epilepsy Action inviting individuals with epilepsy to share their experiences of switching between different versions of AEDs. Both organisations promoted an online survey to people with epilepsy via links on their web sites, which was available for completion between 26th February 2014 and 13th August 2014.

2. Survey respondents

In total 624 responses were received with 576 of respondents currently living in the UK. Respondents were individuals with epilepsy or the parent/carer for an individual with epilepsy, who elected to complete the survey.

We have also included in the report some evidence gathered from people with epilepsy via emails, helpline phone calls and social media during 2014.

3. Terminology

Most medicines have a generic name and a brand name. The generic name is the name of the active ingredient of the medicine. The brand name is given by the drug company. For example sodium valproate is the generic name and Epilim is the brand name. When referring to different 'versions' within this report we mean versions of the same drug made by different manufacturers.

For the purposes of this report, 'switching' refers to a change between different manufacturers' versions of the same generic drug, for example between different generic versions or between a branded and a generic version.

4. Methodological limitations

It is acknowledged that those completing the survey are more likely than average to have experienced a switch in medicine and that this has prompted them to complete it. It is also likely that individuals who have experienced an adverse reaction to the switch, whether emotionally or physically, are more inclined than others to complete the survey. Consequently, we do not present these results as generalisable to the whole epilepsy population.

Awareness of the survey is likely to have come from accessing Epilepsy Action or Epilepsy Society websites, forums or Facebook sites. This will mean that there are many individuals with epilepsy who were unaware of the survey, particularly those who do not regularly access the internet and social media.

Finally, the self-reporting nature of the survey may have resulted in some bias, as is likely with this form of research. This may include: selective or impaired memory, recalling events that occurred at one time as if they occurred at another time, attributing negative events and outcomes to external forces.