

## UK-CAB survey: HIV prescribing at London clinics



### Introduction

The UK-CAB is a community advocacy organisation focused on HIV-related treatment issues. It connects more than 500 individual members (membership is free), many of whom are HIV positive and/or work or volunteer in HIV organisations across the UK.

From November 2011 to June 2012, the CAB organised an online community survey about the changes in prescribing of HIV drugs in London that had been introduced in April 2011. [1, 2]

We wanted to know whether the guidelines:

- 1) Were generally safe and effective.
- 2) Were not resulting in reduced care.
- 3) Were being interpreted correctly in clinics.

The survey was partly an additional safety measure so that anyone who was unhappy about their care could have a way to report this. It also wanted to understand how people had experienced these changes.

The survey was publicised on community websites and HIV press. This included i-Base, NAM and THT and included a full page in Baseline magazine. The online survey included 11 questions for all participants and 15 additional questions relating to changing treatment.

The results are summarised in the report below. The summary data from the survey is also available in PDF format.

**We would like to thank everyone who took the time to contribute and share their experiences.**

The UK-CAB Steering Group would also like to thank Mark Platt for help coordinating this survey.

## Who took part?

Over 260 people completed the survey, but this report is based on 226 replies because some people were HIV negative, or were at clinics outside London. As not everyone answered all questions, the percentages in the report relate to the total number of people who answered each question, which is closer to 200 replies for questions 1 to 11, and 40-50 people for questions 12 to 26.

Approximately 85% of respondents were male and 15% were women, with one transgender respondent. About 80% were white (58% white British), 10% were black African and small percentages were black British, Caribbean, Asian, mixed or other. Approximately 75% were gay, 19% were straight and 5% bisexual. The survey attracted mainly older people. Only 5% of respondents were less than 30 years old and no-one was under 20; 27% were between 31-40, 44% were between 41 and 50; 22% were between 51-65 and two people were older than 65 years.

Nearly everyone (96%) was already taking HIV meds, most of whom had undetectable viral load, with half of the sample using home delivery compared to picking up their meds at the clinic. This is important as home delivery, as well as being popular, reduces costs because it means VAT is not due on these medicines.

About 20 clinics were represented although sometimes by only one or two patients. Larger clinics were associated with higher numbers of replies.

## People changing treatment

The main focus of the survey was the impact of the recommendations for changing treatment, and 60% of respondents either didn't change or were not asked to change treatment. So the main part of the survey included 74 people who had been involved in a discussion about changing treatment. Of these, about one-third (22 out of 74) actively asked to change treatment, and two thirds (50 out of 74) were asked by their clinic to change. Two people had their meds changed without being involved in a discussion – these were examples of care that was clearly inappropriate.

Of the 22 people **who asked to change**, nearly all (95%) had an undetectable viral load and most were doing this to manage side effects (12 out of 22) or for other health benefits (5 out of 22), but 4 people were doing this to help save costs.

Of the 52 people **who were asked to change** or changed by their clinic, more than 90% had an undetectable viral. The most common reason that their doctors asked them to change included cost savings and/or new guidelines (mentioned by 36 people). Other reasons given included potential health benefits from better more modern drugs, including reduced pill count and fewer side effects. Some people had been on the same therapy for many years and the guidelines appear to have had a positive prompt for changing from treatments that have not been recommended for many years.

## **Involvement in the choice**

Roughly half of the 52 people asked if they would change agreed to change and half said “no” and continued on their current treatment.

We also asked about how happy people were with the explanations given by their doctor. About half of these people were happy and half were unhappy with the reasons they were given. We thought that this would be the same people who agreed/didn't agree to change in the previous question. Although there was a large overlap between the group questions there were differences. Five people who agreed to change were not happy with their doctors explanation and five who did not agree to change, were actually happy with the reasons that their doctors gave.

Almost half the people who were asked to change treatment (22 out of 52) did not end up changing. These were mainly people who did not agree to the change when they had discussed this with their doctor (17 out of the 22).

Just over half actually changed (28 out of 52), with only four people (4 out of 28) saying that they hadn't agreed to this.

Broadly though, people appeared to have been actively involved in the decision. Remaining on the same combination was as common as actually changing.

## **Treatment outcomes from new drugs**

One of the most interesting set of responses related to people's perception of the impact that a new treatment had on their actual health. Question 20 asked “how has the new treatment affected your health?”.

Again, these are only the responses from 40 people, but over half (57%, 23 people) reported not noticing any difference - that their health was neither better nor worse from the change.

For 27% (11 people), their health clearly improved – the care had made a positive difference in how they felt.

However, six people (15%) thought that their health had got worse. Some of these individuals indicated more complicated health care situations, such as drug resistance and other health issues. Several people who felt worse said they switched straight back to their old combination without any trouble. This option to return to previous drugs, and that every individual drug would still be available to prescribe on an individual basis when this was appropriate, was an important safety measure included in the guidelines.

One interpretation of these results is that the care that was taken in the guidelines to only recommend similar or better treatment for switching, was broadly supported by the clinical results.

However, while more than half of people asked to switch were clearly given the option not to change, 11 people (out of 46) were not given this option and 9 were unsure. This aspect of the survey is important in raising some of the differences between the actual guidelines, which were

based on this being a patient choice, and the way the guidelines were implemented, where some of the cases in the survey highlight poor care and lack of involvement in making shared decisions about care.

### **Statistics and interpretation: percentages and the denominator**

The most important caveat for this survey is that it is a very small sample. This doesn't mean that the results are not important, just that interpreting the results should be done cautiously. It really just tells us a little about a few people rather than a great deal about the London guidelines.

There are lots of reasons, for example, why the people in the study might not be representative of London patients in general.

- The survey might only have reached certain types of people - perhaps those who are already more aware of treatment issues.
- It might have missed the most vulnerable people.
- Or it might have attracted people who were general unhappy, rather than happy with their care.

On the one hand it is reassuring that the survey did not reveal widespread problems. Many responses were from people who supported the guidelines and who understood the reasons behind them and were actively involved in any decision, including one not to change treatment.

On the other hand, some cases of poor care were reported, and many people reported that this was a stressful and unsettling process. Many people did not feel properly informed or engaged, and some people felt pressured in to changing treatment without being given a choice.

Given this survey was well publicised and designed as a safety measure to reach people who had experienced bad care and practice, or whose health had suffered from the change in guidelines, one interpretation is to say that we picked up very few people (perhaps only four) whose treatment had been changed without their agreement and only six who reported worse outcomes.

These cases are still important, and highlight bad care, but the survey didn't show this to be common or widespread. This is a very important point. Some of these people also had more complicated treatment histories, such as changing treatment due to drug resistance.

Looking at this in percentage terms is difficult and shows why the same statistics can be used to tell very different stories. While negative reporting could say 15% of patients thought their health had become worse (6 out of 40 who answered the question), using the number of people starting treatment or who were eligible to switch (probably 3,000 people in London last year) the rate of complications the survey revealed drops to 0.2% (6 out of 3,000). Using the 30,000 HIV positive people this would drop to 0.02%.

Also, the six negative outcomes, included proportionally more people whose answers to other questions in the survey showed that they were not happy with the process or the change, so these views may have influenced the reporting.

Because of this uncertainty over this number, called the denominator, this percentage results

only apply to the survey and not to HIV positive people in London.

News stories often use percentage results that are separated from the numerical (or absolute) results. This can make very negligible findings sound more impressive. So with this survey, the results again relate to a small group. So for example a negative story could publicise the above results as "25% of people forced to change treatment", when the survey really just showed the 11 people out of the 46 who replied, were told that they had no choice. The two conclusions are very different.

Perhaps more surprising, is that the survey prompted a lot of people to take part who were happy with their care, who were supportive of the guidelines and understood the reasons behind them. Most people had either no negative outcomes or this resulted in better care and improved outcomes. So while the change in London policy was widely reported as a negative scare story about using cheap drugs to save money the actual guidelines emphasised optimum choice of drugs based on similar and proven efficacy, individualised care, and switching treatment based on better care with more modern more effective treatment.

However, this is based on a limited group of people, who may not represent the diversity of HIV positive people receiving care in London, including black and minority populations, women and younger people. Although the Commissioners safety evaluation of the survey has not yet been published, an early review of the results indicated that the guidelines were being applied equally, and irrespective of gender, race or likely risk group.

### **Themes from comments: communication and choice**

The space for open comments at the end of the survey was interesting for raising several common themes.

These included:

- 1) The importance of clear communication.

This included better information about what changes were being proposed and why. This was one of the most common and recurring points. Many people were more upset by the process and the lack of involvement that they felt, than with the actual policy or recommendations.

- 2) The importance of a change in treatment being an active choice. By definition this includes the option to say "no". Several of the comments referred to being pressured to change treatment that they were happy with.

*"...patients [...] should be able to access independent support and advice before any changes to treatment..."*

*"I was asked to change but said "no" and they were happy with that".*

This raises issues of people feeling they have the right to choose expensive drugs over cheaper drugs, which has never been a right within the NHS. It also raised the issue of people saying "I have the right to use old, less effective drugs" which is another interesting perspective on freedom of choice. Both these issues were often mixed together.

3) Issues of trust - both good and bad with the doctor. Many people were happy with care but others had felt pressured, or didn't agree with their doctor. A couple of responses said that their doctor did not support the guidelines and this contributed to their views.

*"I trust my doctor"*

*"I felt a pressure and stress in having to change medication [...] that I have been on for three years".*

*"I felt very pressured to change".*

*"The potential change is causing me a lot of stress".*

4) People who were using older drugs who were resistant to using newer better ones.

*"I changed my combination of four years that had given me diarrhoea and my digestive system improved tremendously"*

*"I was concerned {...} because I heard they were trying to get people on cheaper drugs [...] as it turned out I am benefitting from the drug change but I do feel I was coerced into the change..."*

*"I was initially anxious that my regime for 12 years would be changed".*

*"I was taking six pills and it could be one pill".*

This raises the complex issues of why some people continue on older drugs, even when better medicines become available. Often patient choice is a factor in this, and the degree to which this is informed choice.

5) Dissatisfaction and anger based on inaccurate information.

Many of the news reports about the guidelines had contributed to peoples' fears and concerns.

This included the misconceptions that:

- everyone would have to switch treatment
- that the switch was to older worse drugs
- that only the cheapest HIV drugs were being used,
- or that patients had not been consulted.

*"If patients had been consulted there would have been far less of an issue".*

*"I don't have a problem with the changes as I understand the need to save money. However, greater community consultation in advance of the process would have made for a better response and a sense of genuine involvement of PWHIV".*

*"Disgusted and appalled at the changes [...] The first line drugs are nowhere near as good as the more expensive ones previously on offer".*

## 6) Support for the policy and changes.

*"Given cash problems it seems important to save money as long as patient care is not reduced".*

*"I accept that changes might be needed to improve cost effectiveness, but not at the risk of adversely affecting the care of the individual".*

*"I support the changes. The NHS is facing a significant financial challenge [...] the outcome of this process has been acceptable [...]but] there should be no forced change".*

*"Seems like a good idea given the financial problems in the NHS".*

### **Switching drugs: fear about changing treatment delays access to better drugs**

Many of the negative comments, or survey responses where people were unhappy with the process showed an underlying fear of changing treatment.

One aspect of this is very real and shared by most HIV positive people on treatment. Even if we know that a new drug is likely to be better, most of us take a long time making a decision on when and whether we will switch.

This is even the case in some simple examples - such as switching from twice-daily to once-daily combinations.

There is a cultural aspect of treatment that is resistant to change because the certainty of knowing how things are now is often less daunting than the uncertainty of trying something new. So often people put up with side effects for years that would not be a problem with other drugs. Or they continue with side effects because they can sort of manage. This probably undermined most of the frustration and anger that people felt.

This is a difficult dynamic that has its own rationality, perhaps based on a life long anxiety that treatment may one day fail. This is not supported by the numerous studies that show that switching to more appropriate treatment in order to reduce side effects is not only usually safe and effective but results in tangible improvements in someone's quality of life.

The history of advancements in HIV treatment is driven by the development of better, more effective, more tolerable and easier to take drugs and combinations. A reluctance to switch treatment limits the benefits in better quality of life that new medicines offer.

One interesting outcome of the London guidelines was that switching was almost entirely to better drugs: fewer pills, once rather than twice-daily, fewer side effects - and the survey results showed that more people had health improvements than bad outcomes and the vast majority couldn't tell the difference.

## **Generic drugs and the NHS: increasingly important for HIV meds**

A second aspect of switching that will become increasingly important for HIV care in the next couple of years relates to general drug prescription in the NHS.

Approximately 85% of all UK medicines prescribed by the NHS are generic medicines. These are drugs that have exactly the same active ingredients as the original brand-name medicines, but which are considerably cheaper once the original drugs come off-patent. When a company develops a new medicine it gets 15-20 years to exclusively sell and market them. After this period competition from other manufacturers usually dramatically reduces the price.

So when a blockbuster drug comes off patent, the NHS moves to generic versions of the same drugs, unless the companies reduce their prices to match a competitive market. Many of these drugs are still important and effective treatment, and are often safer because of the accumulated data from widespread use. This works for antibiotics, antifungals, cardiovascular drugs (statins etc), painkillers, antihistamines – across the board. This is one of the reasons why the NHS can still continue to provide free care. Although non-HIV patients sometimes complain about this, thinking brand drugs might still be better, this is an issue of better patient information.

The structure for how advocates determine this aspect of “choice” will need to be based on evidence of a medical concern, and this is unlikely to be available for generic medications which are subject to similar good manufacturing practice and quality control.

The medical evidence for taking one additional pill daily is unlikely to support this choice if it is significantly more expensive. While studies generally show a relationship between the number of daily doses and adherence levels, this is not seen when comparing one pill to two pills, or two pills to three, if they are all taken together once-daily.

These issues will become increasingly important for HIV. Generic 3TC is 3TC, generic efavirenz, is efavirenz, generic nevirapine is nevirapine. These three HIV drugs are either already off patent, or will soon come off patent. One issue that is different for HIV care is that fixed dose combinations will not be off patent yet (ie Atripla). If the price difference is significantly reduced by prescribing generic components separately, this pressure will come in the UK, just as it has already occurred in other countries, including Spain, Portugal and Ireland.

So many of the issues that were raised in this survey will be important to highlight in terms of the expectations HIV positive people have for future care.

## **New drugs – access and price**

Where HIV may be different, is that if the newer drugs are proven to be superior to current drugs – it would be important for access to more expensive treatment. Currently though, many new drugs only show they are similar or not worse than existing options, rather than being superior drugs.

This will make widespread access in the UK more difficult, except where there is a clear medical need – such as drug resistance or intolerance – if the companies decide to set high prices. Drug intolerance – basically side effects – have been one of the areas where the London prescribing

policy has increased restrictions on patient care.

Although all HIV drugs can be prescribed, even newer more expensive drugs, this is only on a case-by-case basis, and this had not had a low or easy bar based on side effects.

## Conclusion

- Although this was a small community survey, it is reassuring that it did not find widespread problems as a result of new London guidelines, although it did show some issues of poor care.
- The outcomes of people who changed treatment was far more likely to cause no noticeable difference or actually improve care than have a negative result.
- It is notable that a community organisation was able to run its own evaluation. The CAB survey is one of the few documents to report the outcomes of the changes to London prescribing.
- Although the Commissioners and some clinics have been working towards an audit of the outcomes, this process has been slow and protracted and it is not acceptable that any conclusion or report from the exercise has not be made available. One study from the Royal Free has reported successful clinical outcomes for people switching to atazanavir from older protease inhibitors. [3]
- Poor communication however was a significant issue for many people and patient choice, again for many people, is seen as central to any decision about treatment and care.
- Further change is likely to continue to directly affect the way HIV drugs are prescribed. The economic pressures on the NHS are growing and patents are coming to an end for many of the most widely used drugs. Changes in NHS services should involve HIV positive people and their advocates in all aspects of our care. This will particularly affect the introduction of generic ARVs and access to new drugs.

## Appendix: Additional background to London guidelines

For many years, HIV clinics in London have worked together to buy HIV meds. This is so that they will all pay the same prices. It therefore means that whether someone gets their care at a large or small centre, different drug prices will not affect the choice of treatment. Before this, every health trust had to negotiate a different price with each company for each drug. **Most people assume that the cost of a drug would be the same wherever you are in the UK, but this is not the case.** It is very confusing that one price is not set nationally across the country.

Last year the government froze budgets across the NHS. This meant all services had to find savings equivalent to 4% of their annual budget. For the HIV services in London this meant finding savings of £8-10 million over two years. One strategy was to expand the home delivery service for HIV meds. This saves 20% of the drugs costs as the government charges clinics an additional 20% of the drug costs in VAT. So anyone who has been on treatment a while (not new patients), contributes perhaps £1500 a year to these savings if they have home delivery.

This easily covers the relatively small administrative costs of a courier service 2-3 times a year. This is an optional service. With 25,000 people on treatment, this potentially can save a lot of money, and the savings have been ring-fenced for HIV care.

The other main strategy was to put pressure on drug manufacturers to reduce their prices, especially bulk discounts for the most widely used drugs. London Commissioners have always negotiated for cheaper drugs and as a result has some of the lowest prices in Europe. While the Commissioners are responsible for purchasing drugs, they have no influence on the guidelines for which drug should be used. This is based on a panel of leading doctors representing every London Trust. It also includes pharmacists, community advocates, HIV positive people and other health workers.

In April 2011, this expert group produced recommendations for prescribing guidelines that allowed for the bulk discounts offered by some of the companies. The quality of care and effectiveness and safety of treatment drove the guidelines. Where two similar drugs had large differences in cost, the guidelines simply said that the more expensive drugs should only be used when there is a clear medical reason for this. The mainly resulted in people starting treatment with Kivexa (abacavir + 3TC) rather than Truvada (tenofovir + FTC).

The second area for potential savings involved whether people already stable on treatment should be asked to switch treatment. For a variety of reasons the expert group decided that this was not needed, except in a few cases. There are six boosted protease inhibitors (PIs) and the older drugs tended to be more expensive. Newer PIs are safer, requiring fewer pills, fewer daily doses, and fewer side events. As one of these drugs (atazanavir) was likely to be significantly less expensive, the guidelines recommended this be a choice not just for starting treatment but for switching.

## References and further reading

1. CAB survey for people getting HIV care at London clinics  
<http://www.surveymonkey.com/s/UKCABLondonTreatmentSurvey>
2. The London Consortium Drug Group included lead clinicians from London clinics, HIV-specialist pharmacists, community advocates, HIV-positive people and health commissioners.  
<http://www.londonspecialisedcommissioning.nhs.uk/>  
A slide set summary of the recommendations in PDF and the Powerpoint files are online:  
<http://www.londonspecialisedcommissioning.nhs.uk/documents/371.pdf>  
  
See also: London HIV Consortium issues new guidelines for ARV prescribing.  
<http://i-base.info/htb/14803>
3. Marshall N et al. Switching to atazanavir due to therapeutic tenders: short term outcomes. 18th BHIVA Conference, 18-20 April 2012, Birmingham. Poster abstract P195. Reported in HTB:  
<http://i-base.info/htb/16527>