



# Initiation of therapy with a subcutaneously administered antiretroviral in treatment-experienced HIV-infected patients: understanding physician and patient perspectives

Rob Horne, Vanessa Cooper, Martin Fisher

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**Initiation of therapy with a subcutaneously administered antiretroviral in treatment-experienced HIV-infected patients: understanding physician and patient perspectives**

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understanding physician and patient perspectives**

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**Key words:** enfuvirtide, HIV, injectable ARVs, perceptions, T-20, antiretroviral therapy

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## Abstract

**Background and Aim:** Enfuvirtide (Fuzeon) is the first self-injectable antiretroviral (ARV) therapy approved for the treatment of HIV. A study was undertaken to explore the perceptions of injectable ARVs among physicians and treatment-experienced HIV-infected patients and identify potential motivators or barriers to the initiation of injectable ARV therapies.

**Methods:** An empirical study was conducted based on qualitative field research conducted in multiple centres in five European countries and the USA. A purposive sampling strategy was employed, and structured interviews carried out with physicians and patients. Discussion guides for these interviews focused on attitudinal responses to a range of key areas. For physicians these areas included HIV treatment, treatment-experienced patients and their relationships with them and injectable therapy usage, while for patients – some of whom were receiving enfuvirtide therapy – the focus included relationships with their physicians and attitudes towards injectable ARV therapy.

**Results:** Sixty-eight physicians and 43 patients were interviewed. Qualitative analysis of the interview responses revealed a number of recurring themes among physician and patient perceptions of HIV and its treatment. Physicians tended to view injectable ARVs as a last resort, with only limited suitability among treatment-experienced patients and a low level of patient acceptability. In contrast, patients generally perceived the potential value of effective injectable ARV therapy, if recommended to them by their physicians, indicating that its benefits could outweigh the drawbacks associated with its administration.

**Discussion:** This study identified some potential disconnects between physician and patient perceptions of injectable therapy. Our findings emphasize the need for patients to

discuss their treatment goals with their physicians so that they can work together to find the regimen that is most likely to achieve these goals.

## Introduction

Enfuvirtide (Fuzeon<sup>®</sup>, T-20), the first HIV fusion inhibitor approved for the treatment of HIV-1 infection, has demonstrated potent activity against HIV-1 strains that are resistant to all three of the other available antiretroviral (ARV) classes (Greenberg et al., 2002) as well as durable efficacy and a good safety profile in treatment-experienced patients in clinical trials (Arasteh et al., 2004; Eron et al., 2003; Katlama et al., 2003; Lalezari et al., 2003; Lazzarin, 2003; Trottier et al., 2004). Enfuvirtide is also the only ARV to be administered by injection, although a number of investigational agents are also administered parenterally (e.g. PRO140, TNX355).

Although usage of enfuvirtide is increasing, current prescribing rates fall short of the number of treatment-experienced patients who might potentially benefit from this injectable ARV. This suggests that the translation of evidence that demonstrates the efficacy and patient acceptability (Cohen et al., 2003) of injectable ARVs into prescribing practice has been slower than expected, with the risk that some patients may not be getting access to optimum HIV treatment.

The reasons for this are not well understood, but may be due to physician reluctance to prescribe injectable ARVs, patient reluctance to accept them or a combination of both. It is important to understand this phenomenon so that physicians and their treatment-experienced patients can be supported in making informed treatment choices.

For this we need a better understanding of physician and patient perspectives of injectable ARVs, and the challenges they face when translating the evidence of benefit and tolerability from clinical trials into the care of individual patients. Research into the factors influencing treatment offer and acceptance in other chronic medical conditions has highlighted the importance of individual physician beliefs about the medication in the context of the everyday challenges of patient management (Horne et al., 1999). A qualitative study was therefore undertaken as a first step towards designing evidence-based interventions to facilitate optimum use of injectable ARV therapies (including, but not exclusive to, enfuvirtide) in treatment-experienced patients. The primary aim of the study was to explore the perceptions of HIV-treating physicians and treatment-experienced HIV-infected patients regarding injectable ARVs, and to identify the attitudes that might act as motivators or barriers to the initiation of treatment with these therapies.

## Methods

This empirical study was based on qualitative field research conducted in multiple, geographically spread cities in France (Lyon, Paris), Germany (Berlin, Hamburg, Frankfurt, Munich and Nuremberg), Italy (Genoa, Milan, Naples, Rome and Taranto), Spain (Barcelona, Madrid and Valencia), the UK (Leeds, London) and the USA (Los Angeles, New York, Philadelphia and San Francisco). Physicians from HIV centres and hospitals identified through databases available to in-country independent fieldwork agencies were initially approached via telephone and screened for eligibility by independent market research agencies in each of the countries. The study sponsor had no access to the physician databases that were used.

A purposive sampling strategy was employed. To be eligible for inclusion in the study, physicians had to be senior-grade (i.e. consultant/senior registrar) HIV or infectious disease specialists or general practitioners treating HIV-infected patients, with at least 3 years' experience prescribing ARV drugs and at least 15% of patients in their clinic classified as treatment-experienced. For the purposes of this study and throughout this article, "treatment-experienced patients" are defined as patients who have been exposed to (but who have not necessarily failed therapy with) at least eight different ARVs, including those in their current regimen.

Prior to interview and before knowing the objectives of the study, physicians who agreed to participate were asked to invite two or three of the patients in their care to take part in the study. Eligibility criteria for patients were an HIV diagnosis and classification as treatment experienced, as defined above.

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Between 17 January and 18 February 2005, in-depth, face-to-face, 60-minute structured interviews were conducted with physicians and patients by an independent market research agency.

The aim of physician interviews was to explore their approach to managing HIV and, in particular, their approach to treatment-experienced HIV patients, including the different patient types seen and the rationale for treating these patients. Interviews were divided into sections (see Table 1) and included a mix of open- and closed-ended questions to elicit physician demographics and practice details, personal motivations and relationships with patients, and the physician's approach to HIV treatment and influencers of treatment decisions (including patient input). The interview then focused on treatment-experienced patients, including any differences in goals for these patients and approaches to changing therapy. The final section of the interview dealt specifically with patients receiving enfuvirtide, the physician's experience of prescribing injectable ARVs and major barriers to the use of enfuvirtide.

The key areas covered in patient interviews (Table 2) were attitudes to HIV and living with the disease (including the patient's openness about their HIV status), and also the patient's motivation and their involvement with support groups. The patient's relationship with their physician was an important focus of the interview and questions were also designed to reveal how much say the patients had when it came to treatment decisions. The final section of the interview dealt specifically with enfuvirtide/injectable therapies. Patients with experience of enfuvirtide were asked how they felt about injectable therapy, and patients who had not been treated with enfuvirtide were asked whether they had ever been offered enfuvirtide, and if so, why they had not used it.



All interviews were conducted in accordance with the Data Protection Act and carried out by trained medical interviewers. Interviews were transcribed and a qualitative analysis of the content of all transcripts was undertaken by an independent agency.

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## Results

### *Sample characteristics*

A total of 68 physicians were interviewed: ten physicians from each of the five European countries and 18 physicians from the USA. The sample comprised 32 HIV specialists, 35 infectious disease specialists and one general practitioner. The median age of the physicians interviewed was 44 years (range: 30–65) and 62% were male. The physicians had specialized in the treatment of HIV for a median of 6 years and were managing an average of 300 HIV patients. Overall, 78% (53/68) of physicians reported that they had experience of prescribing enfuvirtide.

A total of 43 patients took part in this study – six patients from each of the five European countries and 13 patients from the USA. The median age of the patients was 42 years (range: 29–66) and 65% were male. The average length of time since diagnosis was 12 years (range: 2–22). In the interviewed sample, 37% of patients reported that they were enfuvirtide users, 51% were non-users and 5% of patients were prior users.

### *Physician beliefs*

Analysis of interview transcripts revealed a number of recurring themes among physicians' perceptions. Common themes were generally shared by physicians from all countries, with few obvious inter-country differences. The one notable exception was that in Italy and the UK, physicians appeared to be more influenced by guidelines when it came to the use of new ARVs, compared with the US, where guidelines had little influence on physicians' treatment decisions for individual patients.

## HIV TREATMENT IN GENERAL

In this section of the interview, two recurring themes were apparent among physicians' responses.

*Importance of patient trust.* Physicians who participated in the study were conscious of the high degree of trust that their HIV patients have in them and described being extremely cautious about compromising this trust when making treatment decisions:

I am sure that most of the patients who come here in the practice bring a great deal of human trust with them and don't just see us as technicians...

Some physicians also indicated that they took treatment failure in their patients personally:

Being myself in a failure situation towards them, I feel less detached, less at ease, they are patients for whom I get worried

*Acceptance of patient input in treatment decisions.* Most physicians said that they took patients' concerns and suggestions into account when making treatment decisions; they also provided additional information, time and support if needed to convince patients that treatment decisions were right for them:

I try and make it a partnership between me and the patient, so the decisions about treatment are joint.

## **HIV TREATMENT FOR TREATMENT-EXPERIENCED PATIENTS**

Three central themes emerged from responses to questions in this section of the interview schedule.

*Relationship with treatment-experienced patients.* Physicians reported that their relationships with treatment-experienced patients tended to be stronger than with other

patients, with a high level of trust built up over a long period of time. The strength of the relationship was seen as central to the management of treatment-experienced patients.

...because I know them for so long there is a different relationship there with them, and we trust each other, on both sides

*Guidelines and treatment goals.* Some Physicians felt that currently there are no clear treatment guidelines for treatment-experienced patients, so decisions are based primarily on their knowledge and experience:

... when it comes to first line therapy I follow the guidelines closely, but in the salvage area it isn't as strict and we can decide ourselves more what we want to do, but then I follow what experts are saying

Reported treatment goals for treatment-experienced patients were similar to those of patients at an earlier stage of therapy, although treatment options are more limited:

The goal is the same – the maximal suppression of HIV – but they have to be realistic...

*Expectations of treatment success.* Some physicians admitted that their expectations of treatment success in this patient population were lowered.

When you come to switching treatments or discussing treatment options with treatment-experienced individuals, you may reach a point where you struggle to find a combination which is being both effective and suits the patient's lifestyle.

## **INJECTABLE ARV THERAPY**

Although 78% of physicians interviewed reported that they had prescribed enfuvirtide, most physicians considered themselves to have only limited experience of prescribing and administering injectable drugs. Physicians generally viewed enfuvirtide as an efficacious and novel agent, with clinical need (e.g. failed other treatment options, high viral load, low CD4 cell count) primarily driving its prescription. Key themes that emerged

when physicians discussed their views of injectable ARV therapy centred on problems they linked to injecting and the complexity of preparing the injection, the issues of patient suitability and preparedness and perceptions of low patient acceptability.

*High threshold for prescribing injectable ARVs.* Injectable ARVs were widely perceived by physicians as a last resort for treating HIV infection, with many physicians considering enfuvirtide as a 'reserve' drug, to be used only in cases where no other treatment options were available. Physicians identified a range of 'issues' behind this perception. For some, it was driven primarily by the invasive nature of the injection process itself:

... even when I have to give myself an injection, I don't like to do it.

... there is often reticence on both sides with the fact that it has to be injected...

A number of other physicians also saw the complexities of enfuvirtide administration as a major reason for avoiding its use:

... preparing the injection solution takes more of an effort than swallowing tablets.

It's difficult to manage at home an important injectable therapy...

While others were particularly conscious of the local injection site reactions experienced with enfuvirtide administration:

... it is not dangerous but it is inconvenient and there can be problems on the injection site.

Other physicians rejected the notion that enfuvirtide could be considered a last resort:

I speak with experienced patients a lot about it and keep telling them that if we were to start Fuzeon then it would be before the very last option, because they all say it is the very last option available...

Some physicians made it clear that they were postponing the use of enfuvirtide until other new active agents become available:

I can't do a lot with Fuzeon on its own... which means that I have it at the back of my mind for some but I am waiting...

*Concerns about patient acceptability.* In addition to the issues of injectable ARVs that are outlined above, some physicians perceived a poor level of patient acceptability of this route of administration, for a range of reasons:

... they [injectable ARVs] are too complicated and the acceptance is not high

I have nothing against them [injectables] but I have noticed that patients often reject them.

... some patients are not suitable because we know from the start it is not going to work for them.

For some physicians, this consideration took on a greater importance, in that prescribing an injectable ARV was associated with the fear of compromising the physician–patient relationship. Physicians felt that pushing their patients to take injectable ARVs in this situation risks a breakdown in trust between the patient and doctor.

... it gets to this idea of my losing the patient's trust when he is so strong in his rejection of the treatment, and then if he does use it and it really does all go wrong, just as he thought, then he is not going to trust me...

*Perceptions of limited suitability.* Physicians generally felt that injectable ARVs are suitable only for certain treatment-experienced patients, and that such therapies would be rejected by many patients. Specific types of patient were ruled out by some physicians as candidates for injectable ARVs therapy; former injecting drug users constituted one such group:

The former addicts really don't want to inject.

... the patients here don't want to inject themselves. A lot of them would have huge problems to inject themselves because it would remind them too much of the past or they would be afraid of going back to their old habits, their cravings, the needles...

Patients with a phobia of needles were also highlighted as a group for whom many physicians would not consider enfuvirtide:

... the injection and fear of injections are big blocks for patients.

For some the needle is an issue and even the blood test every few weeks is already a problem – so daily injection is unthinkable for some.

Some physicians expressed the concern that a prescription of enfurvitide would have negative psychological effects on some patients:

There is a psychological dimension ... setting up the treatment is a shock and if it's an injection in addition, it overemphasizes the treatment – they cannot forget anymore that they are treated.

... there are others where it is not at all possible since they are hanging by a thread on to a psycho-social life and it is impossible to get them to inject twice a day...

Socio-economic status, ethnic origin and compliance levels were in addition identified as possible barriers to prescribing injectable ARVs:

... the socio-economic status would be the only thing that might be a problem.

The main characteristics of patients making me to think that Fuzeon is not suitable for them are: social status; ethnic origin, since the Italian language is not understood by everybody, some people from Africa or Latin America hardly understand our language and it's more difficult to give them something if the physician does not trust them; compliance...

... the patient has to have the possibility to learn how to use it and you have to make sure too that they are going to be compliant...

*Need for a high degree of patient preparedness:* Another aspect of injectable ARV therapy is that many physicians made it clear they felt patients need to be both physically and mentally ready to start the twice-daily injection routine:

... they have to be really, really motivated and have the time to prepare the solution and leave it and do all sorts of things. Motivation is the key here.

... we have time to initiate the patient to the treatment, to prepare him psychologically, on the clinical side, social side...

### ***Patient beliefs***

#### **RELATIONSHIP WITH THEIR PHYSICIAN**

A recurring point that was made by interviewed patients was the strong bond they felt they had established with their physicians. Many patients had been seeing the same HIV physician for years and so felt they had built up a particularly solid and close relationship with them over time.

Yes, he knows about me and my story and my daily life... even if not too much in depth... my doctor knows me well enough.

I trust my doctor a lot...

However, across the interviews, patient responses reflected ambivalence towards the role they played alongside their physician in making treatment decisions.

*The physician is 'the expert'.* Some patients indicated an implicit trust in their physicians, given their specialist knowledge of HIV and its treatment, believing that their physician is in the best position to know what treatment is optimal for them. For these patients, treatment decisions were primarily made by the physicians, with relatively little patient input:

They are competent and there is no way I could ever catch up with their knowledge. All I can do is tell them how I am reacting to it.

I am so confident [in him], I leave it to him. I don't want to be totally involved in HIV in my life.

However, other patients were keen to be involved in and take a degree of responsibility for treatment decisions; they felt it is important to research treatment information for themselves:

Before talking with a doctor and discussing my illness, I always prefer to have information in my hand.

I am not like some elderly patients who will always do what the doctor in his white coat says without question, or I am not so credulous that I take all that they say as gospel. I am not like that. I want to be informed.



## ENFUVIRTIDE USERS

For patients who had used enfuvirtide, recurring themes during interviews centred around the down-to-earth approach their physicians had taken in recommending initiation of the treatment, the perceived benefits and drawbacks of initiating injectable ARV therapy, including how drawbacks were managed, and, for the few who had stopped taking enfuvirtide, the reasons behind its discontinuation.

*Clinical rationale for initiating injectable ARV therapy.* Patients with experience of enfuvirtide therapy indicated that their physician had recommended that they initiate therapy with the drug on the basis of a need to improve their viral load or immunological status i.e. based on clinical need:

She told me the therapy was no longer good, that the virus was not decreasing much, and I needed a change.

He told me it was a new medication that would help me to get the viral load down and that it would be used in combination with other products because there was nothing else that was suitable for me.

No enfuvirtide user reported reacting negatively when injectable ARV therapy was recommended to them by their physician.

*Benefits of injectable therapy outweigh its problems.* The enfuvirtide-using patients who were interviewed were generally enthusiastic about the positive effects that initiating enfuvirtide had had on their life:

I mean I was in ICU, I mean I couldn't walk. I was walking with a cane, I was 80 pounds lighter than I am now... I really believe that it is not a cure, but like I said, it's just enough for me to look the way I do now.

I could see how quickly I was back on my feet after I started it, and I am still doing well, and I never spent so long on one combination.

Patients acknowledged the challenges of injectable therapy, but were generally of the opinion that the benefits of enfuvirtide therapy outweighed the difficulties associated with injecting it:

Now I have got something that doesn't have any side effects, I am happy. I would inject myself that many times, I don't care if it hurts and it's painful, because that drug is making me have a life  
It is the efficacy, isn't it? At this moment being undetectable is the most important thing.

*Overcoming barriers: self-management solutions.* Although most patients said they would prefer enfuvirtide to be an oral therapy, they described how over time they had come to accept injection ARV therapy and developed their own routines and techniques to incorporate it into their daily lives.

I didn't know if I would be able to do it or not, but once I did it once, it was fine ... I suppose like anything, you have to get it in your routine, really.

Patients generally indicated that any fear of or difficulties in injecting that they had initially had were overcome with support, such as that provided by nursing staff, and determination:

The district nurse used to come in the morning, and do it every morning. With her patience, she was showing me. She told me the little tricks. How to get rid of the bubbles, what to do, so she helped a lot.

There is no problem with the actual preparation of the product and then with the injecting, I got over that too. Simply like that, you have to, and you hear about it from friends who are diabetic and they get on with sticking themselves.

*Reasons for discontinuing injectable ARV therapy.* The few patients interviewed who described themselves as prior users of enfuvirtide ( $n = 5$ ) indicated they had discontinued its use because of painful injection site reactions, injection difficulty due to lack of fat/lack of suitable sites or because of the complex administration process:

It really hurt. There are bits where you just can't do it... and they told me to try to use the thighs but I don't have a lot of fat there, and I was getting at the skin, and it was a real struggle  
Two per day was too much... it was complex, not very easy to do it... too much for me.

### ENFUVIRTIDE NON-USERS

Transcripts from interviews with patients who were naive to enfuvirtide indicated a general openness to the concept of being recommended injectable ARV therapy if their physician deemed it the best way of improving their health, although a range of reservations about this type of therapy were also raised.

*Willingness to try injectable therapies.* Most non-users of enfuvirtide indicated that they would be willing to start enfuvirtide therapy if it was recommended to them by their physician – since the benefits of effective treatment were seen to outweigh any drawbacks of an injectable ARV.

I trust my doctor a lot, so I don't see why I wouldn't take it.

I always said 'God forbid if I became a diabetic tomorrow.' I'd be in trouble... me and needles... but again, if it's something that would really give a stronger and longer life... yeah, I would consider it.

Efficacy was seen as a key motivator for initiating injectable ARV therapy:

If they could convince me that ... I would definitely be able to maintain an undetectable [viral load] count or I would definitely be able to, you know, function as a normal individual.

If it is going to keep me healthy, then sure...

*Physicians to take the lead in recommending patients start enfuvirtide.* Non-users were generally reticent about requesting enfuvirtide therapy from their physician – rather, they would wait until their physician recommended it to them:

The doctor should give me this info... if another patient tells me about it, then thanks, but this is not an aspirin, a doctor should tell me about it.

A few patients had asked their physician about enfuvirtide, but had been told it was not appropriate for them at that time:

I read about it [enfuvirtide] in one of the HIV magazines, how it is more or less like with diabetes, you inject once or twice a day in the morning or whatever. When I first heard about it, I asked [my] doctor and he said, 'Oh, yes, it is coming out but let's just stay where we are at the moment until we are sure about it.' So, I don't know how good it is, but I wouldn't mind if it would work.

I was pushing my doctor... he didn't want me to do it [start enfuvirtide]. He was feeling it wasn't FDA approved.

*Concerns about additional support.* Although willing to try injectable ARV therapy, some patients had concerns about the need for additional support to inject, particularly if they lived alone:

I am not able to do injections myself, therefore the main problem would be finding someone to help me do that.

I can't imagine what it would be like, to be on Fuzeon therapy if you don't have someone living with you who could help manage the injection site issue because you very quickly run out of sites to do yourself... unless it could be administered much the way insulin is for diabetes.

In addition, some non-users who were former injecting drug users expressed concern about using injectable ARV therapy, since it would remind them of their past:

The fact that it is a twice a day injection... it recalls the past

Some [of the people I know] think badly about it, since it recalls when they were drug abusers... the moment when they contracted the virus due to exchanging needles.

Others indicated their past experiences as an injecting drug user had prepared them for administering injections:

I took drugs for 15 years, so I have no problems with the injection or the needle.

*Other barriers to initiating injectable ARV therapy.* Patients described a range of reservations about initiating injectable ARV therapy. Problems with international travel were anticipated by some:

With injections you would need to be able to explain it when you get to countries where you can't enter. It is more impractical

How do they see these things at airports?

Others were more concerned with being able to administer the injections correctly:

[You would need] Some training classes so we don't walk around looking like some bloody pin cushion if you don't do it right .

Some patients had concerns over the relative 'newness' of enfuvirtide compared with other more established ARVs:

It feels experimental – would the individual be willing to take on new symptoms or new side effects? I would definitely want to be put under observation.

However, only a few individuals indicated they would outright refuse injectable ARV therapy if their physician recommended it. A major barrier for these patients was the inconvenience of reconstituting enfuvirtide prior to injecting.

It takes half an hour before it is dissolved, then forget it! It is much quicker with tablets.

It is not just the 30 minutes, it is all the rest, you have to be sure that the equipment is clean and that everything is disinfected because I have a fear of picking up any other infections and then to do all that takes another 20 minutes.

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## Discussion

One of the main themes highlighted by this study is the particularly strong physician–patient bond identified by interviewed subjects. When making treatment decisions, physicians are cautious of undermining the trust their patients have in them and fear of this is a major concern for physicians recommending enfuvirtide therapy to their treatment-experienced patients.

The findings also suggest that treatment-experienced patients may be more willing to consider an injectable ARV than their physicians believe. This mismatch in perceptions echoes the findings of a survey of HIV-treating physicians and treatment-experienced patients (defined as patients with experience of at least two ARV regimens) commissioned by the American Foundation for AIDS Research (amfAR, 2005). While a majority (79%) of patients in the amfAR survey indicated a willingness to try an injectable ARV if it suppressed HIV and gave them more energy, nearly 68% of surveyed physicians reported having reservations about prescribing injectable therapy. These reservations were mostly compliance related, although most (85%) surveyed patients felt that they would be able to comply with an injectable ARV regimen.

Physicians interviewed for this study seemed to view enfuvirtide as a “last resort”. This tendency – which mirrors the findings of a recent study of UK enfuvirtide usage patterns (Perry et al., 2005) – is likely to limit the effectiveness of this agent compared with if it were prescribed in more favourable settings (Montaner et al., 2004).

Physicians also perceived enfuvirtide to have a poor level of patient acceptability, in contrast to the majority of patients interviewed who conveyed a more positive outlook towards enfuvirtide use, with non-users expressing confidence in being able to initiate

enfuvirtide therapy if recommended to them by their physician. Users did not report reacting negatively at the time their physician recommended initiation of enfuvirtide therapy – however, all had been in poor health at the time of the recommendation, with obvious signs of disease progression, and so were receptive to trying anything that would improve their health status.

The potential disconnects identified in this study could have important implications, given that previous research examining physician–patient relationships in the management of chronic illness suggests that mismatches between physicians' and patients' beliefs and expectations may undermine collaborative care (Campbell & McGauley, 2005).

In spite of an apparent willingness among patients to use enfuvirtide therapy if their physician recommends it, and data to show that initiating enfuvirtide in triple-class-experienced patients before they are at an advanced disease stage achieves impressive virological response rates (Montaner et al., 2004), physicians have reservations about prescribing an injectable ARV. Patient attitudes – of both users and non-users of enfuvirtide – in this study suggest these reservations may be unfounded.

These initial findings should be interpreted cautiously, given the relatively small sample size and the qualitative nature of these analyses. The fact that interviewed patients were recruited by physicians who had already agreed to participate in this study, rather than randomly, may have introduced bias to the results.

This study offers new insights into physician and patient perspectives of injectable ARV and identifies potentially important disconnects between physician and patient beliefs about the optimal use of enfuvirtide. The findings emphasise the importance of open

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discussion of patient treatment goals, perceptions and preferences to achieve concordance between physician and patient views and optimise treatment choices. Although the generalisability of these findings are limited by the qualitative methodology, they justify a more extensive study to quantify physician and patient perceptions and identify the prevalence and consequences of mismatch.

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**Table 1. Summary of interview schedule: physicians**

<p>INTRODUCTION/PHYSICIAN INFORMATION</p> <p>Self-completion sheet: Demographics, practice details</p> <p>Resources for patient support</p>
<p>PERSONAL DRIVERS/MOTIVATIONS</p> <p>Motivations behind career choice, professional objectives, relationships with patients and how these impact on treatment decisions</p>
<p>HIV TREATMENT IN GENERAL</p> <p>Goals of HIV treatment, key influences (including extent of patient input in treatment decisions), frequency and characteristics of patients challenging/refusing recommended treatment options</p> <p>Role play: Physician's approach to changing a patient's therapy</p>
<p>HIV TREATMENT OF TREATMENT-EXPERIENCED PATIENTS</p> <p>Definitions of treatment experienced, relationship with such patients, treatment goals, physician's approach to changing their therapy</p> <p>Self-completion sheet: Adjectives to describe treatment-experienced patients</p> <p>Self-completion sheet: Characteristics of physician's treatment-experienced patients</p> <p>Attitude towards new ARV classes for these patients, factors that influence whether they are used by physician</p>
<p>INJECTABLE THERAPY/ENFUVIRTIDE</p> <p>Experience of and attitude towards injectables in general</p> <p>Experience of and attitudes towards enfuvirtide, factors that influence whether or not it is considered for a patient, hopes and concerns when prescribing enfuvirtide</p> <p>Self-completion sheet: Major barriers to the use of enfuvirtide; how could barriers be overcome</p> <p>Self-completion sheet: Adjectives associated with enfuvirtide</p> <p>Role play: Physician's approach to offering enfuvirtide to their patient</p> <p>Dealing with patients who refuse a recommendation to use enfuvirtide</p>

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**Table 2. Summary of interview schedule: patients**

<p>INTRODUCTION/PATIENT INFORMATION</p> <p>Self-completion sheet: Demographics, time since HIV diagnosis, experience of AIDS-related symptoms, frequency of contact with physician</p>
<p>RELATIONSHIP WITH PHYSICIAN</p> <p>Likes/dislikes about physician, type of information exchanged with physician</p> <p>Self-completion sheet: Adjectives describing physician</p> <p>How patient believes that physician perceives patient</p> <p>Self-completion sheet: Adjectives that patient thinks their physician would associate with them as a patient</p>
<p>LIVING WITH HIV</p> <p>Impact on lifestyle, feelings about HIV and its treatment, familiarity with clinical status, treatment goals, involvement in treatment decisions, involvement in patient support groups</p>
<p>TREATMENT CHANGE AND ENFUVIRTIDE/INJECTABLE ARVS</p> <p>Feelings about and experiences of the treatment change process, exposure to injectable medications, knowledge of and feelings about enfuvirtide</p> <p><i>Enfuvirtide users:</i></p> <p>Extent of discussion with physician prior to accepting enfuvirtide</p> <p>(After viewing product profile)</p> <p>Reservations about/attitudes towards enfuvirtide, impact of initiating enfuvirtide on lifestyle, level of appeal of enfuvirtide</p> <p><i>Enfuvirtide non-users:</i></p> <p>Extent of discussion with physician (if any) and response if enfuvirtide offered</p> <p>Factors that would influence patient to taken an injectable ARV</p> <p>(After viewing product profile)</p> <p>Reservations about/attitudes towards enfuvirtide, potential impact on lifestyle, acceptability to patient/main barriers to accepting, level of appeal of enfuvirtide</p>