



## Minutes from the Investigator meeting in Glasgow 8<sup>th</sup> November 2010

Note: The slides from this meeting can be found on the CHIP website

### Status

The current ethical approval status is that 28 centres have approval, and 16 are in progress. We urge all centres to keep us updated on the progress. It is important that the study moves in parallel and the centres are up and running soon.

### Recruitment

#### Conclusion

To meet the enrolment requirements in each site it is important to engage more than one strategy aimed at identifying pairs for enrolment. The different recruitment strategies are:

1. Partnerships are recruited through the regular visit to the sites for the HIV+ person; either via contact by health personal involved with routine care or by others.
2. Partnership identified by the clinic are approached by phone/letter and invited to participate in the study
3. The study is announced in the community and partnerships refer themselves to clinic for participation

*Underneath are further details from the discussion on recruitment strategies:*

If partnership are reluctant to disclose their unprotected sex behaviour to their regularly doctor at the clinic, a solution could be to involve other staff members e.g. the research nurses or nurses, in the clinic in the enrolment procedure and have these staff members to take over the information about the study and the study visits.

Estimation is that approximately 5-10 % of the HIV positive patients in a clinic will be eligibly (having an HIV negative partner with whom they have had unprotected sex with in the last month prior to enrolment) and willing to enrol in study. This means that a great number of patients needs be asked in the recruitments process.

There was a panel discussion with 4 sites representatives presenting their experience with recruitment:

*Sweden/ Andres Blaxhult:* There is a great interest in participating and the PARTNER folder is placed in each file so in 6 months all patients will have had the study presented. Some Swedish patient organisations have been contacted to get them involved in the study.

*UK/Michael Brady:* The danger is that at one point in the next 8 month (until all partnership is recruited) sites will experience recruitment fatigue. To have a community strategy and involve the community can be one of the tools to avoid the fatigue, and have pairs referring themselves through the advertising in relevant magazines.

In his experience, the partnerships seem comfortable disclosing their unprotected sexual behaviour to their doctor and the pairs would be comfortable attending their regularly doctor for study visits.

*Denmark/Lene Pors Jensen:* All the pairs that are interested in the study will be referred to the research nurses and if they enrol, they will have their follow up with the research nurses, thus taking away from the regular doctors any discussion in possible engaging in unsafe sex practise. There will be no clinical notes on their participation in any files at the clinical department.

A practical approach at the Danish site is to list/read all the enrolment criteria to the HIV positive partner as statements (objective transmission of all information), and then the partner can agree to all the criteria at once without being asked directly about having unprotected sex.

*Spain/Antela:* The site have many sero-different partnerships but most of them will have protected sex and the unprotected sex behaviour will be mistakes and unintentionally and will not be happening frequently in the partnership. The site could therefore foresee that the inclusion criteria of unprotected sex within the last month prior to enrolment are too strict and will exclude many sero-different partnerships.

*The general discussion at the meeting*

#### Who should invite partnerships?

Some sites believe that the HIV positive partner's doctor should enrol the pairs, because of the confidentiality between the doctor and the patients. Others sites are in favour of separating the participants from their doctors because they may be reluctant to disclose practicing unprotected sex. The approaches can vary but it is important that each sites/staff member find the way that is most appropriate for the site and for the sero-different partnership.

#### How to invite partnership?

One approach is to give the partners the study information to take home without asking about unprotected sex, and then arrange to have a meeting later with the couple if they are interested in participating. Another idea is to create a list of all the partnership that are interested in participating, but at the moment do not meet the inclusion criteria.

#### Activate the community

It is very important to involve the community, different websites, local NGO's and to get advertisements in magazines to get the community involved in order for the sero-different partnership to learn about the study and to encourage them to participate in the PARTNER study.

We will at the coming investigator TC discuss the different enrolment strategies. We need to learn from each other's experience at this critical stage of the study where everybody is looking for pairs to recruit.

### **The use of rapid test in the Partner study**

A proposal for permitting use of rapid tests without the need for concomitant laboratory testing was discussed. The Executive committee will discuss and decide on this recommendation for use of rapid testing.

After the meeting the executive committee has decided to allow site to use the rapid test as the only HIV testing procedure as long as the sites follow the

### **Update on transmission data**

Alison Rodger updated the investigators on the latest findings regarding transmission. Slides can be found on CHIP web site (her vil også blive et link)

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