

## **BHIVA Standards of care online consultation comments**

**7 October 2012**

### **Standard 8: Reproductive Health**

**2 October 2012**

**Paul Decle from Forum Link sent the following message:**

Section 3

Measurable and auditable outcomes

First bullet point

(change)

From...

heterosexual

To...

heterosexual or bisexual

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**2 October 2012**

**Allan Anderson from Positively UK sent the following message:**

Positively UK welcomed the inclusion of the range of choices for conception for couples with HIV and the pathways stated on page 2. However on page 2 we found the statement 'Designated individuals within a trust or network would be helpful', to be too vague, and that a clearer statement that a designated individual in a trust should be identified. While other standards recognised the value of peer and community support, Standard 8 did not include any reference to this. Positively UK's From Pregnancy to Baby and Beyond evaluation report found strong evidence to suggest that peer support during pregnancy is effective in supporting pregnant women through this 'complex' issue, and strengthen relationships between the patient and HIV clinician [http://www.positivelyuk.org/pregnancy\\_and\\_beyond.php](http://www.positivelyuk.org/pregnancy_and_beyond.php). Positively UK would recommend this Standard identifies the value of peer and community support, and encourages clinics to develop links to providers and referrals.

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**2 October 2012**

**Pamela Morrison, IBCLC from Member, Lactation Consultants of Great Britain sent the following message:**

The Standard for Reproductive Health should also include more information on appropriate health care, information and support on infant feeding: either formula feeding for an HIV-positive mother who has a detectable viral load, or for exclusive breastfeeding with maternal antiretroviral therapy for the first six months of life and continued breastfeeding with appropriate weaning foods from 6-24 months for those mothers who have an undetectable viral load and who wish to breastfeed their babies.

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**3 October 2012**

**Karen Fell from Karen Fell sent the following message:**

There does not seem to be any consideration around mothers with HIV feeding their babies. More information and support should be provided to HIV-positive mothers who are on antiretroviral therapy, who have an undetectable viral load and who wish to breastfeed exclusively for the first six months of life and continue breastfeeding with appropriate weaning foods from 6-24 months.

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**3 October 2012**

**Dr Soe Aung from Faculty of Sexual and Reproductive Healthcare sent the following message:**

In Rationale heading paragraph 3:

Likewise, methods such as timed unprotected sexual intercourse for men with HIV who are on successful antiretroviral therapy can be employed to reduce the risk of acquisition of HIV by a female partner who is HIV negative.

Specialist input from Contraceptive and Sexual Health Services can be provided to the discordant couple.

Here is general comment for Standard 8:

BHIVA needs to consider how to manage the logistics of providing urgent health requirements for HIV pregnant women for example offering whooping cough vaccination who are not registered with GP or have chaotic life style.

BHIVA needs to consider healthcare for HIV positive women around post reproductive age (over 50) eg issues around osteoporosis, menopause and HIV medication. Since the advent of Combined AntiRetroviral Therapy(CART)in the mids1990s,HIV infected individuals have enjoyed progressive reduction in HIV associated morbidity and mortality and marked improvements in life

expectancy(Obel N,Om Land.LH,Krong borg,et al Impact of non HIVand HIV risk factors on survival in HIV infected patients on HARRT :population based nationwide cohort study ,PLOS one 2011)

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**3 October 2012**

**Chris O'Connor from Baseline magazine, PLWHIV sent the following message:**

Response to BHIVA standards of Care.

I would like to thank the BHIVA guidelines writing committee, with reference to the standards of care, standard 8, Reproductive Health. Fertility issues and HIV have received minimal attention in the past.

It is a great step forward to see timed unprotected sexual intercourse, for men adherent on ARVs as a option, given the usual parameters. I also applaud the Standard to formalise a 'discussion' around reproductive choice while attending their HIV service. A few specific points however.

It is the singular 'discussion' in the Standard 8 that might be expanded - Canadian guidelines June 2012, (ref below) refer to reproductive health counselling on an 'ongoing basis,' other studies see below state 'regular' discussions on fertility options. One discussion would not cover changing circumstances, new evidence, changing relationships, declining fertility with age, etc.

Who offers the counselling is not specified in Standard 8, I feel it would be helpful, if it stated a 'knowledgeable' health care professional or a trained 'peer' counsellor, as this is an area where personal experience is so valuable. Birth control/conception should also be discussed with HIV positive young people, before they reach HIV adult services.

The 'outcomes' are restricted to heterosexuals, could this not include same sex couples who have a HIV positive or negative surrogate? The Manchester Consortium have pathways to sperm washing at the Royal Womens in Liverpool, in just these circumstances.

I am aware that planning and budgeting for services in the current climate of structural change and financial cutbacks is difficult. However some advances in this area could see costs reduced, eg sperm washing funding should be now relevant for a smaller number of couples and peer support and counselling could be a vital tool in the area of fertility.

Further Discussion

In a wider context and perhaps for the scope of further guidelines - it is the engagement in and content of this 'discussion' that, I feel continues to be a grey area and urgently needs updated guidelines - Pre-conception counselling, informed decisions, safe contraception choices and risks, sub-fertility in positive people and discrimination by fertility services, are all areas that urgently need up to date, evidence based information.

I was at a presentation in Washington this year on Fertility and HIV, presented by Dr Vivian Black, of the WITS reproductive Health and HIV Institute. Part of her talk she looked at contraception use among women NOT trying to conceive and unmet needs in that area.

Patient-provider communication is vital she said, looking at two studies, Badell et al, 2012, (infect Dis Obste Gyenecol, 2012) and Schwartz et al, AIDS Behav, 2011, In the first study, half had only spoke to health worker about contraception in the previous year, and a third had never spoken about contraception. In the second study, only 48% of women in that cohort had discussed non-barrier methods of contraception.

She then looked at consequences. In Schwarz SR, PLoS One, 2012, in South Africa - 62% of pregnancies were unplanned, 53% were efavirenz conceptions and 36% ended in termination. '....an absolute tragedy, these women are in care, coming to a health centre at least four times a year, we are failing these women'

Vivian Black then turning to a UK study: 'Pregnancy outcomes in adolescents in UK and Ireland growing up with HIV', J Kenny HIV Med 2012. Of 42 pregnancies out of 252 women, 81% of these pregnancies were unplanned, over half of sexual partners did not know their status - 33% had detectable viral load during pregnancy and 36% opted for elective termination. One child was delivered HIV positive.

The Standard 8 is long overdue.

In General

There are a number of issues I feel with a pressing need to be addressed and/or updated.

Although 'pathways' to services are welcomed, positive people are still discriminated against in the fertility business. (see Ade Apoola study on IVF clinic discrimination 2002)). Pietro Vernazza recently addressed many of the fears the fertility industry have around dealing with sero-different couples with HIV and Hepatitis C in a presentation at a fertility conference in Stockholm. (see article below)

Scenario based recommendations for the prevention of HIV transmission and maximising conception, eg positive man negative women etc. positive women, negative man, are needed.

A minimum pre conception medical assessment should be consistently offered.

Repeated attempts at trying to conceive increase transmission risk, what investigations and counselling is their for sub-fertile HIV positive people/couples.

What are the chances of conception, natural v assisted, sperm washing v natural, ICSI v IUI or IVF? Many clinics offer ICSI to HIV positive couples, although chances of conception are lower than IVF, is this necessary? (see Vernazza).

Is there a role for PREP for negative partners in a couple trying to conceive – the offer is made in some PCTs but not in others.

In conclusion: The Standards are a great step forward for HIV positive people in negotiating their choices around fertility – I would encourage the ongoing participation of the HIV community in these areas, as their experience I think is unique and invaluable.

Below I attach an article which expands on some of the issues I have touched on above.

Yours Sincerely,

Chris O'Connor

Mob, 0794 151 4335

HIV and the desire to conceive

“What should we now tell patients?” was a question asked from the floor after the presentation in Rome this July of the large HTPN 052 study which showed at least 96% effectiveness against transmission of HIV for couples on treatment with undetectable viral load.

Many HIV affected couples who want to become parents are not waiting for an answer. The vast majority of children born of positive parents are conceived naturally, with or without the help of clinicians

Dr Augusto Semprini the founder of sperm washing in Milan, Italy was curious about what happened to the couples who came for advice and counselling but never went ahead with the process, ‘no shows’ as they are known in the trade. He traced 500 couples - half (250) of them had had children by natural means when they were contacted.

Many of these couples are missing out on advice on how to minimize even a negligible risk and negotiate often difficult choices. Reda Sadki, of the French activist group, Comité des Familles, representing families living with HIV, agrees that in their experience pre-conception counselling is the exception and not the rule, ‘usually a woman turns up at the clinic pregnant.’

That question ‘what do we tell patients was asked by Pietro Vernazza from St Gallen Hospital Switzerland, also one of the authors of the Swiss Statement, which tried to answer this when it was published in January 2008. The Swiss Statement laid out parameters for minimising infection: a stable heterosexual couple with no detectable viral load in the positive partner for at least 6 months, no STDs and timed intercourse. It looked for transmissions, found none and concluded in the above circumstance an HIV positive individual was ‘sexually non infectious.’

The radical challenges of the Swiss Statement have not yet been reflected in clinics says Sadki, ‘We feel that HTPN052 was used in France to discourage couples from attempting natural conception, they said wait till we see what that comes up with. After the Swiss cohort findings, this result is not a surprise to us.’

Once couples are in the consulting room, says Sadki, they can face a lack of reliable information, and can be coloured by a individual clinician’s viewpoint, ‘It is inexcusable for doctors to be reluctant to talk about the risk of HIV transmission in natural unprotected conception, in some cases I think it is

criminal - if a couple then lose the opportunity to start a family. Even a couple who are both positive are recommended to use condoms – it feels as if it's a punishment for being HIV.'

It's not just the clinics that cannot absorb what the risk levels are. "When I ask what do you think transmission risk if you have sex tonight?" says Vernazza, 'the answer ranges from 50% to 100% – way, way above the reality.'

One comparison - the risk of death from passive smoking is far higher than transmitting HIV within the guidelines can be hard to grasp in the real world. Similarly Hepatitis C transmission via vaginal sex has occurred in a handful of cases, yet no national guidelines recommend that heterosexual couples living with Hepatitis C change the way they protect themselves by using condoms.

This is the heart of the matter – balancing risk. HTPN 052 showed that in the one arm that took ARTs immediately and had no detectable viral load, just one couple out of 886 sero converted, compared to 27 HIV transmissions occurring in the arm that delayed ART treatment. Crucially even that one couple, it transpires, could be excluded, as it seems they might have been sero-converting as the trial began.

What does at least 96% protection against transmission mean to couples wanting to conceive? BASELINE asked the trial's lead investigator Myron Cohen. 'It's a huge issue, a negative women and a positive man, it's not 1 in 100 it's not 1 in 1000, is it 1 in 100,000 as some models suggest? To use homogenous numbers is a really bad idea. It's as close to zero as you can get - but it's not zero.'

In the UK, the 2008 BHIVA guidelines state, 'Current evidence supports a more open discussion of this option [timed unprotected intercourse] with the couple to quantify, as far as reasonably possible, the risk in individual cases to enable them to make an informed decision.' So what do HIV doctors in the UK think? Mark Nelson, Chelsea and Westminster 'When I am asked I say there is a very small risk to natural conception, it's not that helpful - I know this is sitting on the fence. But this is the reality. I cannot know if a patient is being adherent to their meds to remain undetectable'.

With freedom comes responsibility, as they say. When the Swiss statement came out many couples living with HIV welcomed it as an opportunity to control their own health and lives. 'We need this discussion about risk and behaviour' says Pietro Vernazza, 'How do we make decisions about our sexual life. If I'm living with a partner and she takes drugs for HIV, I know exactly her adherence. I know exactly her virus. I have been talking with her doctor.' He adds, 'It's a different situation than having sex with a partner who just tells me, "I'm suppressed."'

#### Semen Seeking

However viral load 'fully suppressed' is generally measured in the blood, what about in semen? The Assisted Conception Unit at Chelsea and Westminster say on their website; "... couples ask about the safety of conceiving naturally. Unfortunately, even in men with negative viral loads, semen can still carry HIV ... We therefore strongly recommend that couples wishing to conceive safely continue to have protected intercourse and use sperm washing as a safer alternative."

However French virologists are studying the semen samples of positive men from fertility clinics. The 2010 French expert guidelines say, "Latest data indicates that the phenomenon of persistence of HIV

in semen in men largely disappeared with current treatments.” The report speculates that newer ARTs such as Tenofovir and Abacavir achieved higher penetration in the genital tracts.

At the Necker-Cochin hospital in Paris, the team led by virologist Christine Rouzioux assessed the frequency of detection of HIV RNA in the semen of men on HAART and whose blood viral load was undetectable for at least 6 months from 2002 – 2009. They have found that the prevalence of semen samples with HIV RNA was 3.7% (17/455) over the entire period, but the prevalence decreased between 2002 and 2005 (from 15% to 1%) and no cases were observed since 2005.

Although hindsight is 20:20 it is a sobering thought that the high cost of sperm washing, the lower rates of conception, and the fact that some couples remain childless – may not be necessary in the majority of cases.

#### Fertility Options opening but still limited

Even if more couples continue along the natural conception route there is still a need for assisted conception for sero-different couples. A recent study from Vernazza, presented in Stockholm in July 2011 to fertility experts and about to be published in the journal AIDS, showed that 53 couples - man positive woman negative - offered the option of natural conception using pre-exposure prophylaxis and timed intercourse – 70% conceived a child - usually after 6 unprotected cycles, levelling off at 75% couples pregnant after two years of timed unprotected intercourse. The remaining 25% will need help with conception.

When the sero different couple consists of a positive woman and a negative man other methods of natural conception are available - self-insemination can be done at home, commonly called the turkey baster method. However mother to child transmission has to be addressed, although timely treatment with anti-retrovirals has an exceedingly high success rate.

If you decide to take the sperm washing route, there are three main methods of assisted conception:

- IUI: A sample of washed sperm is placed inside the womb. Usually done when there are no apparent fertility issues.
- IVF: egg is removed from the woman and fertilized by the washed sperm and put back into the womb
- ICSI: Sperm washed but egg injected with a single sperm before re-implantation in the womb

#### Liverpool and Manchester United

Up until now Chelsea and Westminster ACU has been the only UK fertility centre to openly offer HIV couples sperm washing. Now the fertility clinic at Liverpool Royal Women's hospital has opened up a separate unit, and will be offering sperm washing for couples, positive men - negative. (France in comparison has eight clinics across the country and state funded separate laboratory facilities).

Hand in hand with this move are commissioning guidelines, the first of their kind in the UK they say, from the Association of Greater Manchester Primary Care trusts. (see below). The guidelines look at clinical eligibility, age barriers and number of cycles, which will be six IUI cycles a decision based say Manchester as an infection control issue.

The Manchester consortium say they are seeing increased demand for reproductive care for HIV positive couples and are minimizing onward transmission of HIV which they point out would cost £0.5 to £0ne million for ARTtreatment over a lifetime.

The guidelines say that same sex couples are not excluded from access to the programme and would be considered on a case by case basis, for example of a male-male partnership with a surrogate although the NHS will be involved in or responsible for surrogacy arrangements.

The George House Trust in Manchester welcomed the new arrangements, Lynda Shetall: 'From a cost point of view it's a great move as it means that patients don't have to travel to London for treatment . We now have a better process for making decisions more quickly so that eligible patients get access to treatment more quickly.

The decision to use a fertility clinic for a sero-different couple in the UK can be a world of whispers and chasing rumours. Many clinics do not say they offer treatment to men or women living with HIV, unless approached directly. How many cycles are couples are eligible for from the NHS is a post code lottery.

In 2001 the BMJ suggested that UK IVF clinics discriminated against HIV positive men and women. 63% of responding clinics said they would refuse treatment. Also in 2001 Ade Apoola then at the Whittal Clinic in Birmingham said their was IVF clinic discrimination and funding was a lottery.

An article in the Daily Mail recently though carried the headline 'IVF Clinics Could Carry Risk of HIV' quoted Dr Carol Gilling-Smith of the Chelsea and Westminster ACU as saying in a survey she had carried out, only 2 out of 69 clinics had 'separate' facilities for treating HIV positive couples. The paper concluded that healthy tissue was st risk from 'HIV contaminated' samples.

No person or embryo is known to have been infected at a fertility clinic from a HIV sample. 'I don't think this is a helpful article,' says Stuart Lavery of Hammersmith IVF, 'I don't think its necessary to have separate labs, but you do need separate storage.' An embryologist at a london IVF clinics, says 'we are as confident as we can be and follow HFEA guidelines. They emply a double 'Witness' system for handling samples, no more than one sample at in a work area at a time, cleaning down after each procedure.

'With these couples HIV transmission is not the issue - we shouldn't have regulations that take us way from the problem, many fertility centres still say "we are not dealing with this problem." Says Vernazza. He adds that dragging Hepatitis C and B infection into the sperm washing protocols was counter productive, treating frozen, undetectable semen as infectious for HIV and Hep C was not rational he claims.

All hospitals deal with the risks of HIV to both staff and patients on a daily basis according to the HFEA, anyone undergoing IVF would be protected from infection just like all the other thousands of patients going through surgery or having treatment every day



For those couples who decide to go the natural route - for the first time in the UK pre-exposure prophylaxis (PREP) is available for couples wanting to conceive.

Dr Yvonne Gillece, reports that Brighton had experienced an increasing demand for requests to conceive naturally. Now Brighton and Birmingham Heartlands are providing 1-2 doses of Tenofovir pills before and after unprotected sex, at the most fertile time of the month. Again the service is not consistent across the country although in London, St Mary's offer the service Chelsea and Westminster don't.

A 'belt and braces' approach to lowering transmission risk says Gillece, there are huge psychological benefits to PREP for couples who have used condoms for many years says Vernazza. Across the board people don't want to let go of the condom.

END

Pietro vernazza July 3 presentation, Stockholm:

<http://cmwebcast.covr.be/presentations/eshre2011/11090/default.aspx>

The National Aids Trust has a usefull resource, on conception at: <http://www.nat.org.uk/Living-with-HIV/Useful-information/Treatment-care-and-support.aspx>

Manchester Consortium: commissioning guidelines:

<http://www.gmpublichealthpracticeunit.nhs.uk/wp-content/uploads/2010/12/SW-commissioning-policy-v.15-14.01.11-FINAL1.pdf>

Brighton study on PREP for Conception in HIV positive men and negative women:

[www.bhiva.org/documents/Conferences/.../O27YvonneGillece.pdf](http://www.bhiva.org/documents/Conferences/.../O27YvonneGillece.pdf)

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**5 October 2012**

**David Ogden from HIV Pharmacy Association sent the following message:**

Quality Statement

"The management of pregnancy, childbirth... multidisciplinary team (to include obstetrician, HIV specialist physician, specialist midwife, specialist nurse, specialist HIV pharmacist and paediatrician) with expertise in HIV and pregnancy."

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**5 October 2012**

**Nicola Fearnley (on behalf of the Trinity Centre) from Bradford Teaching Hospitals NHS Foundation Trust sent the following message:**

With regards to the the quality statement:

Appropriate timelines for referral to the HIV and pregnancy multidisciplinary team would be:

☑ Within 10 working days from date of the initial HIV-positive result: for an asymptomatic pregnant woman, newly diagnosed HIV positive, booking before the end of the first trimester.

☑ Within 5 working days of the initial HIV-positive result: for an asymptomatic pregnant woman, newly diagnosed HIV positive, booking after the end of the first trimester or if any interventional diagnostic procedures are planned.

☑ Within hours of the initial result: pregnant woman newly diagnosed HIV positive, who has HIV-related symptoms, or is in labour or is within days of her expected delivery date.

We feel this is unclear as to whether it means seen or aware of referral. Also does it mean being seen by the HIV specialist midwife (as would be the case in new diagnoses in our region) within 5 or 10 days of the lab result being available is acceptable ?

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#### **7 October 2012**

**Dr Eric Monteiro from Leeds Teaching Hospitals NHS Trust sent the following message:**

Comment from Eric Monteiro Network Clinical Lead on behalf of North and West Yorkshire Regional HIV Network MDT

It would be helpful for this standard to include a statement on access to Sperm Washing for those serodiscordant couples who, after counselling of their options, wish to conceive by this method. Funding for Sperm Washing is variable within our network and there is confusion amongst some commissioners in the interpretation of HFEA guidelines as the difference between what is for assisted conception and what is for the purpose of prevention of transmission of (HIV) infection. There are also often delays in agreeing further cycles after one that is unsuccessful and with advancing years in the female partner may then also have a problem of infertility due to reduced ovarian function. It would be helpful for the standards to state that serodiscordant should have access to an agreed number of cycles at the outset eg 6 and this would also reduce delays in couples conceiving.

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#### **7 October 2012**

**Lindsay Short from Calderdale and Huddersfield NHS Trust sent the following message: sent the following message:**

Sorry comments put on self management in error.

It would be helpful to have a bit more on sperm washing and access to services for sero discordant couples. In many parts of the country they are assessed by the same criteria as for infertility. This then means that amny couples are not eligible due to existing children for either partner, age etc. It

should be assessed by different criteria as it is for prevention of infection. This results in self funding, not trying at all or taking risks with times unprotected sex

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**7 October 2012**

**Jacqueline Stevenson from African Health Policy Network (Ffena) sent the following message:**

Information and support on contraception and safer conception is currently of major concern, with women participants at the recent Ffena Women conference identifying a lack of information and understanding of safer conception is a particular issue. Much more needs to be done to ensure access to information and services, including improved care pathways where services are not available locally