Review of the evidence for the UK national guidelines on safer sex advice.

The Clinical Effectiveness Group of the British Association for Sexual Health and HIV (BASHH) and the British HIV Association (BHIVA)

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Scope and Purpose

This document provides further detail on the evidence used and the issues considered in developing the UK National Guideline on Safer Sex Advice. The objective of the Guideline document is to provide guidance for practitioners in Level 3 Genitourinary medicine (GUM) services (Tier 5 in Scotland) on safer sex advice provided in sexually transmitted infection (STI) and HIV management consultations. The value of simple advice giving is unproven, so evidence based guidance on the format and delivery of advice as part of a combination prevention approach is included. The guideline consists of:

- Recommendations on the format and delivery of brief behaviour change interventions deliverable in GUM clinics.
- Recommendations on the content of safer sex advice given to individuals at continued risk of STI.
- The components of a combination prevention approach to be applied
- Additional advice to be provided for those living with HIV, or from groups with higher rates of HIV incidence.

Much of the guidance is applicable in other sexual health and general practice settings, including HIV care services. Issues relating to implementation of behaviour change interventions in clinics, such as designing service structures and care pathways or the competencies required in different multidisciplinary staff groups, will be addressed in British Psychological Society (BPS) Good Practice Guidelines[1]. Safer sex advice and individual behaviour change interventions provided within clinics are elements of a combination prevention approach that may also include group and community based behavioural interventions, structural and social changes and biomedical interventions including post-exposure prophylaxis following sexual exposure (PEPSE), pre-exposure prophylaxis (PrEP) and early initiation of antiretroviral therapy. Each of these issues is complex and in some cases contentious and the guideline includes recommendations on the application of these interventions to the individual only. The scope of these guidelines does not include the structure, development and implementation of a comprehensive combination prevention strategy, or policy development.

Identifying candidates for safer sex advice and other prevention interventions

The majority of published studies are concerned with the efficacy of interventions applied to groups already considered 'high risk' such as those suggested above. The selection of subjects for published intervention studies has been based on predefined demographic criteria, such as being a man who has sex with men. No systematic reviews, meta-analyses, or original studies describing methods to systematically target potential candidates for interventions were found. One descriptive study outlines the use of some brief risk assessment tools in clinic practice to ascertain potential candidacy for interventions[2]. However there is no validated system currently available for the assessment of risk of STI that can be applied routinely to clinic attendees. At present the selection of patients for advice and behavioural interventions should be based on demographic group and individual history taking to identify recognised risk factors[3-4]. Guidance on eliciting risk factors will be detailed in the BPS Best Practice Guidelines[1]. Those at increased risk may include:

- adolescents [3 5-6]
- people from, or who have visited countries with high rates of HIV and/or other STIs[3 6]
- men who have sex with men (MSM) [7 6]

(Women not using contraception: A review of 83 identified studies showed that the use of hormonal contraceptive use was positively associated with cervical chlamydial infection but not with other STIs. However, the quality of this evidence is poor and this group are not included in the guideline[8])

Also individuals with a history of:

- frequent partner change or sex with multiple concurrent partners [6 7]
- early onset sexual activity [6]
- previous bacterial STI[5 9]
- attendance as a contact of STI[4 10]
- alcohol or substance abuse (the use of recreational and stimulant drugs has been associated with HIV seroconversion in MSM[11-12] although a history of intravenous drug use (IVDU) has been associated with a lower risk of acute STI[7])

A range of other demographic and behavioural factors may be used to identify groups believed to be at risk of poor sexual health outcomes, although compelling evidence of elevated risk of STI compared to other populations in the UK is lacking or mixed; these include prisoners[13], sex industry workers[14] [15]and their clients [16], looked after and accommodated adolescents[17], and those with poor

mental health[18-19] or learning disability. Sexual compulsion and addiction is recognised in men and women[20-21] and is associated with increased sexual risk in gay and bisexual men[22-23] and lesbian and bisexual women[24].

Recommendation
Sexual history taking should be structured to identify risk factors for sexual ill health, sexual practices and behaviours and opportunities for brief behaviour change interventions (Evidence level IV, C).

Evidence for behaviour change interventions

Do behaviour change interventions work?
There is high level evidence that behaviour change interventions can increase condom use and reduce partner numbers. There is also biological end point evidence showing reduction in STI incidence[25-26] but no statistically significant end point evidence for a reduction in HIV incidence. The evidence base is limited by significant methodological problems in evaluating outcomes in many populations[27]. An HIV specific review and synthesis of 18 meta analyses showed typical interventions produced a 34% increase in the odds of condom use (with the weakest effect in adolescents and strongest effect in MSM), a 32% reduction in the odds of unprotected sex (weakest in injecting drug users and strongest in people living with HIV) and a 15% reduction in number of sexual partners (with the strongest effect amongst MSM)[28]. A systematic review of HIV prevention behavioural interventions for high risk USA populations across a variety of settings identified factors associated with efficacy at reducing HIV risk behaviours[29]. A wide range of different interventions delivered in different clinical and community settings have been shown to be effective[30-31].

In adolescents, systematic reviews of interventions deliverable within primary care found four randomised controlled trials (RCTs) of moderate to high intensity counselling interventions showing modest reduction in laboratory diagnosed STI incidence. There was no evidence of substantial harm and no evidence of inadvertent increases in number of sexual partners or number of sexual occasions[32-34]. A previous review identified nine clinic based RCTs that evaluated interventions focussed upon adolescents[35]. However a systematic review of non-clinic based peer-led interventions in adolescent sexual health education shows no evidence of reduction in STI incidence or increases in condom use[36]

A systematic review of evaluated HIV prevention interventions amongst MSM found clear evidence of the efficacy of individual, group and community level interventions implemented in a variety

of settings, reducing the odds of engaging in UAI by 43%, 27% and 35% respectively[37]. In a USA sample of MSM undergoing HIV testing an RCT of a single session personalised cognitive counselling (PCC) delivered by paraprofessionals showed a greater reduction in high risk sexual behaviour among MSM repeat testers[38].

In people living with HIV, meta-analysis of HIV prevention interventions showed that overall they are efficacious in reducing unprotected sex and avoiding STIs[39].

Cost-effectiveness:

In MSM, meta analysis shows that behavioural interventions to reduce sexual risk in MSM are cost effective[40], but there is limited cost effectiveness data directly applicable to other risk groups or other STIs[41]. No data on the provision of interventions in GUM clinics or data comparing interventions in clinics with community based prevention interventions was found. Local protocols on the selection and prioritisation of candidates for various levels of intervention and the interventions provided should be based on the relative prevalence of infection in different risk groups outlined above, staff competency, training capacity and local financial constraints. There is sufficient evidence to recommend that access to intensive behaviour change interventions, at least for those at the highest risk of STI and HIV, should be available in all GUM clinics.

Using behaviour change interventions in routine consultations

Behaviour change interventions in routine consultations with GUM clinic patients can be effective at reducing STIs and increasing condom use[42,43]. Currently available evidence does not permit a conclusion on the minimal length and intensity of an effective intervention. Overall intervention format, or length, was not associated with effectiveness[44], but the minimal intervention shown to have an effect to date is greater than that currently likely to be routinely delivered to all attendees in the UK GUM clinic setting[43] NICE Guidance and cost estimates[45-46] are based on the provision of a single session of 15-20 minutes, but the most robust evidence applies to multi session interventions. The minimal intervention shown to reduce STIs and increase condom use in heterosexual GUM clinic attendees is two sessions each of 20 minutes, with the greatest observed effect in adolescents and those with prior STI[25]. A more extended course of 10 sessions reduced unsafe sex in MSM[26]. A brief (US) clinic based safer sex intervention for heterosexual African American men delivered by a lay health advisor reduced subsequent STIs, increased condom use and decreased number of sexual partners in a randomised controlled trial[47]. A similar RCT amongst African American women reported

that in terms of brief interventions, skills building interventions were more effective than information interventions[48]. Such interventions are unlikely to be routinely delivered to all at risk attendees in the UK GUM clinic setting given the need for training and competing demands on resources. However, condom use errors are directly associated with STI rates and are reduced with both experience and the provision of instruction[49-50]. Condom use also increases in the control arm of a number of studies in which advice alone was provided, suggesting that giving safer sex advice may be an effective intervention. For some individuals, increasing communication skills to enable successful negotiation of condom use may also be required.

It is not possible to provide definitive recommendations on the design, scope and content of effective interventions to be used in a UK GUM Clinic. However, broad themes identified in one or more meta analyses, systematic reviews or RCTs suggest that successful interventions:

- draw upon a theoretical base (often models of social cognition)[28-29 43 51]
- are developed through extensive formative research[43] and are holistic in focus and specific in their design[39]
- are 'active' rather than 'passive'[52-53] and are enhanced to include skills building or 'behavioural counselling' rather than simple information giving[29 32 43 48]: these skills may be technical (e.g., condom use), personal skills (e.g., relaxation) or interpersonal (e.g., communication)[29].
- may include individual or group based interventions focussing on individual risk-based counselling, or a tailored risk reduction plan[32]. The individual delivery of the intervention (rather than group level) appears to have greater effect[39-40]
- are associated with greater intervention exposure complexity[40], the intensity of delivery[39], and with multiple delivery methods[29]
- are usually most effective if delivered by health care providers or counsellors[39] and in places of routine care
- delivered by experts induce more[53] change than those delivered by non experts[54]
- delivered by non-community members induce more change than community members[36 54]
- when associated with the use of information, behavioural skills arguments, behavioural skills training and HIV counselling and testing *increase* behavioural change, but when associated with threat inducement and normative arguments *decrease* behaviour change[54]

Motivational Interviewing

Brief behaviour change interventions applicable within clinics may include, but are not exclusively, Motivational Interviewing (MI). Meta analysis showed MI to be more effective than advice giving in the treatment of addiction, with effective interventions as brief as 15 minutes[55]. It is a collaborative, person-centered form of guiding to elicit and strengthen motivation for change[56]. It may be used to make the pre contemplative client significantly more likely to start to contemplate change than those receiving any other intervention[57]. Effect was shown to increase with an encounter of longer duration and further sessions, but diminished over time, as with other behavioural interventions. One-off interventions may have some residual effects after 12 months of follow up[58]. In general practice MI was no more time consuming than giving advice[55]. There are few published trials of the use of MI in sexual health: one large RCT of HIV negative MSM[26] found that 10 sessions of one to one counselling using motivational intervention techniques over six months, plus three monthly maintenance sessions, reduced the rate of acquisition of HIV by 15.7% (Not significant) and the rate of self reported unprotected anal sex with a partner of unknown or positive HIV status by 20.5% over a 48 month follow up, compared to a control group. However, a RCT of two sessions of MI to reduce sexual risk and improve contraceptive uptake showed no effect[59]. Case studies suggest that MI may be useful in giving consistent change messages and improving the client's commitment to changes such as reduction in partner numbers, and participation in treatment, in the management of sexual addiction and compulsivity[60]. A randomized controlled trial of learning methods showed that proficiency in delivering MI can be achieved with training over one and a half days with ongoing coaching and feedback, but a single lecture or workshop or self directed learning is not effective[61]. It may be preferable to work towards creating a cultural change in services, whereby all staff are trained to incorporate behaviour change interventions such as MI in their routine practice.

A pragmatic approach to the organization of behaviour change interventions involves enhancing the delivery of safer sex advice routinely given by all staff across clinics using a recognised brief behaviour change strategy, such as (but not exclusively) motivational interviewing. More detailed but brief (15-20 minute) one-to-one interactive interventions using the same techniques and also delivered by clinic staff should be provided in line with NICE Guidance to those at increased risk as listed above and tailored, intensive behavioural interventions involving two or more sessions

should be provided to those at the highest continuing risk of acquisition and transmission of STIs including HIV. Good Practice Guidelines developed by the British Psychological Society (BPS) will provide detail on the implementation of behaviour change interventions within services.

Recommendations

Intensive multi-session, evidence based behaviour change interventions targeting individuals and focussing upon skills acquisition, enhancing communication skills and increasing motivation to adopt safer sexual behaviours should be available directly or by referral in all GUM clinics (Evidence level Ia, A).

Motivational interviewing techniques should be used as part of an intensive course of risk reduction counselling in MSM at high risk of HIV infection (Evidence level Ib, A).

Brief (15-20 minute) evidence based behaviour change interventions targeting individuals and focussing upon skills acquisition, enhancing communication skills and increasing motivation to adopt safer sexual behaviours using techniques such as Motivational Interviewing should be provided as part of routine care of those at elevated risk of STI and HIV in GUM clinics (Evidence level Ib, A).

The delivery of safer sex advice, including condom demonstration, based on the characteristics of effective brief behaviour change interventions, should be part of the routine care of all those at continued risk of infection/transmission in GUM clinics (Evidence level III, B).

The provision of accurate, detailed and tailored information on safer sex should form part of all sexual health consultations (Evidence level IV, C).

Motivational interviewing should be provided by clinic staff who have gained competency in its provision through training. (Evidence level IV, C).

<u>Intervention delivery</u>

Computer delivered interventions may offer consistency ('intervention fidelity') and reduce the demand on human resources. A meta analysis of randomized controlled trials of computer assisted behaviour change interventions to prevent HIV[62], looking at the

outcomes of unprotected sex or condom use, showed a statistically significant effect (Cohen's d=0.259, equivalent to an OR of 1.54) on condom use and unsafe sex comparable to the effect measured in the meta-analyses of human delivered interventions discussed above [28 52]. Interventions were delivered on-screen, via the internet or as printed materials. The effect was independent of target group, but was more effective when delivered to single sex groups, when individualized and when based on a Stages of Change theoretical model. A Cochrane review including 15 studies[63] of interactive computer-based interventions (ICBI) for sexual health promotion found that ICBI had significant moderate effects on sexual health knowledge and were slightly more effective for this outcome than face-to face interventions. Smaller effects were observed for self-efficacy, safer sex intentions and sexual behaviour. Computer assisted interventions have also been demonstrated to reduce the number of male sexual partners and the number of unprotected sex acts with partners of unknown status in HIV positive MSM attending outpatient clinics[64]. The use of video may also be effective: In a study of 38,635 patients, a brief theory based video shown in the waiting room of STI clinics reduced new STI infections across three clinics with a hazard ratio of 0.89 (95% CI 0.84-0.99)[65]. No randomisation of patients occurred but alternation of intervention with standard waiting room conditions happened every four weeks across a three-year period. Older studies have used video as part of behavioural interventions for selected groups of patients with significant reductions in incident STI, with greater effect size in those with multiple sexual partners[66]. Although the evidence suggests that the use of videos may be a low cost means of reducing STI rates in large numbers of individuals, the small overall effect size and confidence interval approaching 1.00 do not support a strong recommendation for routine adoption across all clinics. Video may be preferable to the routine use of leaflets in providing safer sex information to all clinic attendees.

Recommendations
Computer assisted interventions are comparable in effect and should be considered as an alternative or adjunct to human delivered interventions (Evidence level Ib, A).

Videos shown in waiting rooms should be considered as an additional aid to promoting behaviour change (Evidence level IIb, B).

Safer sex advice

The content of advice given to all those at continued risk of STI should be tailored to the individual's needs and understanding based on the sexual history. Advice on condom use should usually be included. Condom advice may not be relevant for all women who have sex exclusively with women (WSW), although advice on the use of condoms with sex toys may be appropriate. Advice should include verbal and written information on:

- condom efficacy and limitations
- condom types, sizes
- determinants of condom effectiveness
- motivation for condom use

Depending on HIV status, risk of future STI, sexual practices and partner gender, this may be supplemented in some individuals by skills building including condom demonstration and discussion on condom problems and condom sizing. Minimising individual risk may involve providing information on:

- oral sex and STI transmission
- other sexual practices
- hepatitis vaccination and the use of antiretroviral therapy for HIV

A combination approach recognising that the ideal of 100% condom use is not achievable for many individuals and supporting additional and alternative methods is appropriate. Identification and recognition of risk reduction techniques already in use may be important in providing tailored advice on improving the effectiveness of, or advising on the limitations of techniques including:

- partner reduction (or reduction in the number of unsafe sex partners, or unsafe behaviours)
- HIV seroadaptive behaviours including negotiated safety, serosorting and strategic positioning/ seropositioning.
- repeat testing for STI including HIV

Abstinence should not be promoted as the sole means of reducing sexual risk.

<u>Condom efficacy</u>

The per episode efficacy of condoms when used perfectly is near to 100% and reported failure rates per episode are 1-2.5%. Consistent use of the male latex condom is estimated to reduce the transmission of HIV in heterosexual couples by 80% (range 35-94%) compared to those who never use them[67]. It is likely that

self-report of consistent condom use is an over-estimate and correction of the resulting misclassification of the small number of HIV transmissions observed in any study (i.e. HIV transmissions occurring in couples reporting 100% condom use) is thought to lead to an estimate nearer to 99%. The pregnancy rate over 6 menstrual cycles of typical use of latex condoms was 7.0% and the consistent use rate was 1%[68]. It is therefore reasonable to suggest that the effectiveness of condoms against HIV *when used reliably and consistently* may be over 95%. There is little recent evidence for condom efficacy in MSM[69] although one retrospective study showed attempted consistent condom use reduced new HIV infections by 76%[70]. Of 14 studies included in the Cochrane review of condoms in heterosexual couples[67], 1 included anal intercourse and 6 did not explicitly define vaginal intercourse, so may have included anal intercourse. Older studies of condom use for heterosexual anal intercourse[71] and anal intercourse in MSM[72] suggest similar reductions in transmission rates as reported for heterosexual vaginal sex. In the absence of direct evidence it is believed therefore that the effectiveness of condoms in preventing HIV transmission in MSM is comparable to that in heterosexual couples.

With regard to other STIs, a systematic review of studies performed between 2000 and 2004, the majority from the USA, concluded that there was evidence of a reduction in the acquisition of chlamydia, gonorrhoea, syphilis and HSV-2 in both men and women and possibly trichomoniasis in women, associated with consistent condom use[73]. A further systematic review also concluded that there was evidence of effectiveness against syphilis[74]. Methodological limitations include variation in transmissibility of infections, the inclusion of unexposed individuals, duration of observation, variation in measures of consistency of condom use, the frequency of intercourse and confounders involving the inclusion of inconsistent users and non-users. These variables tend towards underestimating the effect of condoms on preventing bacterial STIs[75-76]. A systematic review of 56 studies showed condom use measurements are highly variable with no agreed 'gold standard', making it difficult to compare studies[77]. Condoms might be expected to be more effective against infections transmitted through penile and vaginal fluids (such as chlamydia, gonorrhoea, HIV, hepatitis B and trichomoniasis) than those involving contact with genital skin incompletely covered by condoms (herpes simplex, HPV, chancroid and syphilis). Transmission estimates per unprotected (heterosexual, anatomically undefined) contact with an infected partner are 0.001 for HIV, 0.2 to 0.5 for gonorrhoea, 0.45 for Chlamydia and 0.7 for chancroid[75]. Reductions in STI risk depend upon population, condom use consistency and infection type and range from 25% in sex workers to 50% in population based

samples[78] and 58% in STD clinic populations[76], but disease specific estimates vary.

The most convincing disease specific estimates for condom efficacy exist for chlamydia and gonorrhoea: Consistent condom use was associated with a 90% reduction in Chlamydia prevalence in heterosexual individuals with a known exposure: 13.3% of consistent condom users and 34.4% of inconsistent users with a known exposure were diagnosed with Chlamydia[79]. Condom use was also protective against rectal (OR 3.04 for never use vs always use) but not urethral chlamydial infection in MSM[80], although results were confounded by the inclusion of unexposed individuals. It is likely that the lack of protection against urethral infection was due to high rates of unprotected oral sex. A meta analysis suggests protection against HPV[81] and subsequently one small longitudinal study suggested a highly significant reduction in the acquisition of HPV[82] in young women using condoms reliably. There is some evidence of a statistically significant reduction in HSV-2 but not HSV-1 acquisition[83]. Self-reported recurrence of PID, pelvic pain and infertility in 684 women followed prospectively after an initial episode of pelvic inflammatory disease was reduced by 50%, 70% and 40% respectively in women who used condoms on 60% or more of occasions[84]

Recommendation
100% use of the male latex condom should be recommended to all those at risk of STIs including HIV (Evidence level III, B).

No studies of evidence of efficacy of latex versus non-latex condoms in terms of STI prevention were found. A Cochrane review of non-latex male condoms for prevention of pregnancy showed significantly higher rates of clinical breakage than latex counterparts[85] . Non-latex condoms may be suitable for those with sensitivity or allergy to latex condoms. No studies were identified that sought to assess the efficacy of non-latex condoms for anal sex. Non-latex condoms are preferred by some men with erectile dysfunction who report improved sensitivity and reduced erection loss compared with latex condoms. No studies were found comparing erectile loss with different condom types.

Non-latex condoms are an acceptable alternative to male latex condoms for vaginal sex but have higher rates of breakage (Evidence level Ia, A).

One large randomised controlled trial showed a non-significant reduction in four incident STIs in the group provided with female vs male condoms plus advice and counselling on their use (6.8 vs 8.5

STIs per 100 women-years, adjusted OR 0.79, 95%c.i. 0.59-1.06)[86]. Female condoms may have advantages in their tolerance of misuse of lubricant and additional skin coverage and are unlikely to be inferior to male condoms in the prevention of STIs. The provision of female condoms either as an alternative or in addition to male condoms may increase women's perception of entitlement to protection and change negotiation around condoms from 'use/ non use' to a discussion over the type of condom used[87]. A systematic review of research, including RCTs, of female controlled barrier methods in preventing STIs (including HIV) concluded that female condoms confer as much protection from STIs as male condoms[88]. Familiarising men with the appearance and use of female condoms may improve their acceptability if introduced by a female partner at a later date.

Female condoms are (at least) equivalent to male latex condoms in the prevention of STIs and should be offered as an alternative or supplement to male condoms to all women (Evidence level Ib, B).

Men should be made aware of the availability and use of female condoms (Evidence level IV, C).

Female condoms may also be used for anal sex by heterosexual couples or by MSM. A minority of MSM in USA studies were aware of the use of female condoms for anal sex[89] but over 50% of users preferred them to male condoms. A small crossover study in gay men found that pain and discomfort were more commonly reported with female than with male condoms[90], but in the minority (21%) of men who were willing to use them with serodiscordant partners in future, they were felt to be more comfortable and safer. Provisional advice on the use of female condoms[69] for anal sex suggests it is applied to the penis as an oversize male condom, although alternatively it can be inserted into the anus before sex.

Female condoms can be used as an alternative to male condoms for anal sex but are preferred to latex male condoms by a minority of MSM who have used them (Evidence level IIb, B).

<u>Determinants of condom effectiveness</u>
Understanding the individual factors known to affect condom use may be useful to clinicians providing condom advice. Condom effectiveness is affected by:

- consistency of condom use[91]
- condom use errors
- breakage
- slippage
- lubricant use

late application and early removal
condom-associated erectile loss

Behaviour change interventions that promote consistent condom use should provide the skills required. While information alone does not affect behavioural skills it does have a direct (negative) effect on condom use errors[92]. Condom use errors including breakage, slippage and incomplete use occur in up to 40% of encounters[91] There is a significant dose-response relationship between increased condom protection and the risk of gonorrhoea and chlamydia[91 93]. The risk of STI increased by 22% with each reported incidence of condom breakage in the past 90 days in a sample of 1412 adolescents[94]. Condom associated erectile loss was reported to have occurred at least once in the past 3 months by 37% of a young (average age 23.7 years) population of heterosexual STI clinic attendees and was strongly associated with inconsistent use of condoms[95]. Erectile loss was also associated with condom use in HIV positive MSM[96] and in studies of US college students[97-98]

Condom errors include:

failure to expel air from the condom
not holding condom during withdrawal
unrolling the condom before putting it on
starting to have sex before applying the condom
putting the condom on inside out before flipping it over

Nearly one third of a sample of young heterosexual men reported a recent condom breakage and breakage was more likely in men reporting problems with the fit and feel of condoms, or with failing to expel air from the condom[92]. Failure rates of 2.5/100 episodes of insertive anal sex and 1.9/100 episodes of receptive anal sex, or 16.6% in the last six months were reported in MSM[99-100]. Condom breakage is by a blunt penetration mechanism[101]. The likelihood of breakage but not slippage increased with penile circumference[102] and breakage was less likely (0.7% vs 1.4%) with a condom individually fitted to penis size (by self taken length and girth measurements matched to one of 55 condom sizes) than with standard condoms during vaginal or anal intercourse, especially in men with larger penile dimensions[103-104]. Although this is not currently possible in routine practice, providing a range of condom sizes is likely to be helpful. However, slippage was more likely after withdrawal with fitted condoms and men may need specific advice when larger condoms are provided[104]. There is evidence from one RCT that thicker condoms are no less likely than standard condoms to break or slip off when used by homosexual men for anal sex in established relationships. Risk of condom failure was significantly increased by the use of saliva, oil based lubricant or no lubricant rather than a water based lubricant, longer duration of intercourse

(especially in excess of 45 minutes). Breakage was less likely if lubricant was applied inside the anus, around the anus or all over the outside of the condom, but slippage was more likely if lubricant was applied inside the condom[105]. Lubricant use doubled the risk of condom slippage for vaginal sex but reduced the risk for anal sex[103] .No evidence was found of reduced risk of condom failure with lubricant use for vaginal sex[106], suggesting that the use of additional lubricant should not be a routine recommendation for vaginal sex and should be recommended only where dryness or discomfort is a problem. Choice of condoms improved acceptability but did not affect rates of STI acquisition[107].

Conference presentations have suggested that some lubricants may damage the rectal and vaginal mucosa[108] and that some or all may increase the risk of STI[109]. This suggests that those lubricants which are pH neutral and isotonic may be safer than others. However this evidence is not felt to be a sufficiently robust basis for a definitive recommendation on lubricant type.

Recommendations
Less than 100% condom use will offer some protection – advise that using condoms as much as possible is better than not at all (Evidence level IIb, B).

MSM should be advised that thicker condoms are no less likely than standard condoms to break or slip off than standard condoms during anal sex (Evidence level Ib, A).

Non-oil based lubricant should be applied all over the condom and inside the anus, but not inside the condom, before anal sex (Evidence level Ib, A).

There is no advantage, in terms of condom safety, in the routine use of lubricant use for vaginal sex (Evidence level IIb, B).

Providing a range of condom sizes is a quick and more practical alternative to formal condom sizing (Evidence level IV, C)

A large cross sectional study of young people in England showed that of 375 individuals who had used a condom on the last episode of intercourse, 6% had applied the condom after penetration and 6% had removed it early before (final) withdrawal[49]. Late application was reported at least occasionally by 31- 58% of young people and early removal by 9-15%[49 69 75] . Reported condom

failure for both male and female condoms falls dramatically with increasing experience in women[110]. Condom slippage and errors were strongly associated with lack of training on correct condom use in US college students[50] Women who apply condoms to their partners have more positive attitudes to sex but mistakes in condom application are common[98].

Recommendation
Both men and women should be instructed on the correct use of male condoms and the importance of applying a condom before penetration and avoiding early removal (Evidence level IIb, B).

Motivation for condom use

Only 5.1% of STI clinic attendees used condoms on every occasion of intercourse in the year following an STI clinic visit[111]. In a detailed qualitative diary study of 60 US college students, around a third used condoms consistently, a third shifted from consistent to inconsistent condom use and 13% maintained a pattern of inconsistent use. The commonest reason for condom use was for the avoidance of pregnancy, and this was even more pronounced in inconsistent condom users[112]. Australian studies also suggested that young people use condoms to prevent pregnancy: 25% reported not using condoms because they were using another method of contraception[113]. Adolescent women were more likely to protect themselves against pregnancy than infection[114]. Young adults were more likely to use condoms reliably than older adults, but condom use was consistently driven more by concerns about pregnancy than about STIs[115] . Condoms are rarely applied specifically for STI prevention. Late application (for ejaculation only) may be associated with use of condoms for pregnancy prevention rather than STI[115] and timing of application and removal differs between casual and regular encounters by the same individual.

Understanding the key themes that shape young people's sexual behaviour is helpful in giving advice. A systematic review identified factors affecting condom use: young people assessed partners as 'clean or 'unclean'. Condoms were seen as a sign of a lack of trust[116]. Reminder cues have been shown to improve rates of condom use, particularly under the effect of alcohol[117]

Recommendation:
Advice should be based on an exploration of reasons for condom use and recognise that for heterosexual couples, the avoidance of pregnancy rather than STI is a major motivator (Evidence level III, B).

Advice on Oral Sex

Around a quarter of young people in the UK were unaware that STIs could be transmitted through oral sex and less than 2% reported consistent condom use for fellatio[118]. In MSM only 8% reported condom use for insertive and 5% for receptive oral sex[119]. Only 4% of a mixed population of LGBT college students reported consistent condom use for oral sex and only 4% of women prisoners supplied with dental dams for oral sex reported ever using them for cunnilingus[120].

An accurate assessment of the risk of transmission of all STIs through oral sex is difficult because all epidemiological and research data is compromised by the confounding of oral sex and other sexual risk practices. Herpes simplex virus (HSV), Human papilloma virus (HPV), gonorrhoea, Chlamydia, syphilis, HIV and Hepatitis B are transmissible through oro-genital sex[121-123]. The possibility of Hepatitis C transmission through oral sex cannot be definitively excluded, but no evidence was found to support it. Non-STI organisms including *N. meningitides* and adenoviruses may also be transmitted through oral sex causing symptoms in the genital (insertive) partner.

For HIV and viral infections other than HSV, case reports and biological factors suggest that the risk to the oral partner is greater than that to the genital partner[124]. For most bacterial infections the risk of fellatio is thought to be higher than the risk of cunnilingus. Around 33% of MSM diagnosed with syphilis in the UK reported exclusively oral sexual contact[125] and the risk of infection has been associated with number of oral sexual partners but not with specific sexual acts[119]. HSV-1 acquisition was strongly associated with receptive oral sex without vaginal intercourse in women[126] and with insertive oral sex with casual partners in MSM[127]. Pharyngeal chlamydial infection is strongly associated with the frequency of receptive oral sex with ejaculation in MSM[128] but we found no evidence regarding the significance of ejaculation with respect to other infections. The largest and most robust epidemiological studies relate to HIV transmission, but the risk of HIV transmission through oral sex remains unclear[129]. Retrospective data suggest that up to 2.6% of HIV infections in UK MSM may be acquired through oral sex[130] and data from US and Australian cohorts attribute up to 8% of cases in MSM to this route[131]. However, several longitudinal studies have shown very few transmissions in serodiscordant couples reporting oral sex alone[124 132] and the per-contact risk of transmission is low. Risk is likely to be much higher during HIV seroconversion – therefore the risk of oral sex with multiple and/or casual partners is likely to be higher than the risk of

unprotected oro-genital sex in a long-term serodiscordant relationship. Transmission is also likely to be associated with oral ulceration, contact with semen or blood.
Oro-anal sex carries the risk of acquisition of Hepatitis A, Hepatitis B and enteric bacterial, protozoal and helminthic infections by the oral partner. Only one case of oro-anal transmission of HIV has been reported, involving gingivitis in the active partner and Hepatitis C seropositivity was not independently associated with oro-anal sexual practices[133] Overall, the risk of STI acquisition through oral sex is likely to be considerably lower than through unprotected vaginal or anal sex. Whilst routinely advocating condom use for oral sex is unrealistic, oral sex should not be promoted as risk free. Practitioners report an extremely low level of uptake and use of dental dams.

Recommendations
Safer sex advice should include information on the risks of oral sex, recognising that individuals must make an informed decision on the level of risk that is acceptable to them, and supporting pragmatic alternative risk reduction techniques. The risk of transmission of bacterial and viral STIs including HIV applies to both oral and genital partners but the risk to the genital partner is thought to be considerably lower. The risks of transmission associated with oral sex are (considerably) lower than for unprotected vaginal or anal sex except in the case of HSV-1. Techniques to further reduce risk include:

- *avoiding oral sex with ejaculation reduces the risk of HIV and possibly other infections (Evidence level IV, C)*
- *insertive fellatio is lower risk than receptive (Evidence IV, C)*
- *avoiding brushing teeth or flossing before having oral sex reduces the risk of HIV and possibly other infections (Evidence level III, B).*
- *avoiding oral sex if oral cuts or sores are present, or a sore throat. (Evidence level IV, C)*
- *using condoms for fellatio and dental dams for cunnilingus and oro-anal contact (Evidence level IV, C)*

<u>Other sexual practices</u>

A wide range of other sexual practices are reported, some of which are associated with particular groups. No sexual practice can be regarded as without risk of transmission of any STI. Antibodies to HPV are detectable in around 3% of children and 5% of adults who

have never had sex[134] and clinical manifestations of HSV infection suggest that non-penetrative skin to skin contact (body rubbing, (non penetrative) mutual masturbation and tribadism) carries the risk of transmission of HPV and HSV. Evidence relating to the non-sexual and accidental transmission of gonorrhoea[135], Chlamydia and syphilis[136] suggests that these infections may also rarely be transmitted in this way but there is no suggestion of HIV or BBV transmission by non-penetrative routes. Case reports of Hepatitis B transmission[137] and of syphilis transmission through the premastication of food[138] suggest that deep kissing might potentially transmit infection (in the case of syphilis through oral mucosal ulceration), but there is evidence that kissing is not a risk factor for pharyngeal chlamydial infection[128] and it is not thought to be route of transmission for HIV. In penetrative practices including digital stimulation, use of sex toys and fisting, transmission risk is related to the degree of trauma.

Women who have sex with women (WSW) may have a variety of risks for sexually transmitted disease transmission through penetrative practices involving fingers, hands and sex toys. Use of preventative measures such as gloves, or condoms for sex toys by WSW is low[139]. Risks may also include sex with men[140-141]. Use and knowledge of safer sex practices is low. Case reports suggest that the use of sex toys may be associated with the transmission of STIs including HIV[142] in WSW although there are few reports of transmission. There is an increased risk of bacterial vaginosis in WSW who give a history of sharing sex toys or whose partners have BV[143]. The use of dental dams for cunnilingus between women is also low when they are supplied to women prisoners and the risks associated with sharing sex toys, or manual sex may be higher[120] Fisting in MSM carries significant risk of Hepatitis C[144] and is implicated in the transmission of Lymphogranuloma venereum (LGV)[145-146]

Recommendations
No form of sexual contact is entirely without risk of STI transmission. Non penetrative contact carries the lowest risk. (Evidence level IV, C)

In penetrative sex (including fingering, using sex toys and fisting) the risk of transmission is related to the degree of trauma. The use of gloves should be recommended for traumatic digital penetrative sex. (Evidence level IV, C)

Abstinence

Programmes to promote abstinence from sexual intercourse, including delay in age of first intercourse, have been pursued in

some countries (notably USA and Uganda) as a way of preventing acquisition of STIs and HIV. A systematic review of abstinence only programmes to prevent HIV in high income countries[147] identified 13 trials involving US youth. Compared with various controls, no programme affected incidence of unprotected vaginal sex, number of partners, condom use, or sexual initiation. One trial observed adverse effects at short term follow-up (STIs, frequency of sex) and long term follow-up (STIs, pregnancy) compared with usual care, but findings were offset by trials with non-significant results. More relevant to the GUM setting, elective abstinence is chosen by a minority of people living with HIV[148] as a means of preventing onward transmission. African women living with HIV in the UK appear to be more likely than men to report abstinence[149] and partner status, CD4 count, antiretroviral therapy and perceived responsibility for transmission are also linked to abstinence choice.

Recommendations

Recommendation
The promotion of abstinence alone as a routine component of safer sex advice is not recommended. (Evidence level 1a, A)

Partner reduction
The spread of STIs depends on the rate of change of sexual partners, particularly concurrent partners. Reduction in the number of partners at population level has been implicated in the reduction in heterosexual HIV transmission in Thailand and Uganda[150] although a causal link has not been proven and the issue remains controversial[151]. There was also evidence of a significant (community initiated) reduction in partner number in MSM in the early 1980s[152]. The risk of HIV infection increased monotonically (i.e. stepwise) with increasing number of sexual partners in observational studies in Tanzania[153]. A phylogenetic study in Quebec suggested that 49% of onward transmission events were attributable to seroconversion and only 12% to those on treatment[154], supporting the idea that concurrent and frequently changing sexual partnerships carry a high risk of onward HIV transmission. The risk of chlamydial infection was greater in those with 2 or 3 previous partners than in those with one[155], although there did not appear to be a linear effect with increasing partner number. Syphilis infection was associated with the number of oral sex partners in MSM[119]. Modelling suggests that reduction in partner number may have a greater effect on the prevalence of infection than a similar proportionate increase in condom use, particularly for bacterial infections[156]. A comprehensive analysis of the effectiveness of interventions for the reduction of HIV transmission suggests that partner reduction is effective in individuals at medium

or high risk in peer-orientated or school-based interventions[157]. However a large trial of clinic based interventions did not show evidence of reductions in partner number[25] . Hence although behavioural interventions can be effective in reducing partner number there is no direct evidence for an effect of partner reduction interventions delivered to individuals in the clinical setting.

Recommendation
Safer sex advice should include discussion regarding reduction in number of partners or the number of unprotected sex partners, and in particular the risks associated with concurrent partnerships in those at increased risk of HIV infection. (Evidence level III, B)

Advice should include reduction in the number of partners with whom the individual has oral sex. (Evidence level IIb, B with respect to syphilis in MSM)

Repeat testing for STIs

Prior infection with Chlamydia is a risk factor for reinfection with Chlamydia, gonorrhoea and *Trichomonas vaginalis* (TV) in women[5] with peak reinfection rates of 19-20% at 8-10 months post infection[158]. Prior rectal Chlamydia, gonorrhoea or syphilis infection is associated with incident HIV infection in MSM[9]. Ulcerative and non-ulcerative STIs affecting either HIV positive or HIV negative sexual partners increase HIV transmission and acquisition [159-161]. Studies looking at treatment of STI to reduce HIV transmission in populations have been conducted in resource limited settings with a mixture of results. One study[162] showed a highly significant reduction in HIV transmission with five other controlled trials showing no effect[163-167]. Despite these findings it is likely that at an individual level the avoidance of STIs, and prompt diagnosis and treatment if acquired, will reduce the risk of HIV acquisition or transmission.

Although the role of HIV testing in HIV prevention is unclear there is good evidence that people who know their HIV status do, in the short term at least, have less unprotected sexual intercourse[168]. In addition, HIV risk reduction techniques including seroadaptive behaviours and the use of antiretroviral therapy (as early initiation of ART, PEPSE or PrEP) to reduce HIV transmission risk depend upon accurate knowledge of an individual's current HIV status. There is little evidence on the optimum frequency of screening for STIs. Frequent re-testing (as often as every three months) may be appropriate for those at the highest risk of HIV infection[169-171]. Detailed guidance on HIV testing is provided in recent guidelines[172].

Recommendations
Retesting for asymptomatic STIs should be recommended to all individuals with a prior STI diagnosis including HIV (Evidence level III, B).

Screening for asymptomatic STIs should be recommended at least annually (and in some cases as frequently as every three months) to all individuals at risk of acquisition or transmission of HIV (Evidence level IV, C).

HIV testing should be routinely recommended to all individuals attending GUM or sexual health services. Pre and post test discussions and counselling support should be available (Evidence level IV, C).

Hepatitis vaccination
Advice on Hepatitis vaccination should be given to those at risk. Detailed information on sexually acquired Hepatitis infection is contained in BASHH guidelines[173] from which the following is taken. Although rates of Hepatitis A (HAV) IgG antibodies are similar in heterosexual and homosexual men, outbreaks have been reported among MSM in large UK cities transmitted through oro-anal or digital- anal contact. BASHH Guidelines recommend that clinics in these areas offer Hepatitis A vaccination to MSM and advice should be based on local clinic policy. Sexual transmission of Hepatitis B (HBV) occurs in unvaccinated MSM through unprotected peno-anal, oro-anal or oral sex. Other groups at risk of Hepatitis B infection include intravenous drug users, sex workers and heterosexual partners of people from areas where Hepatitis B infection is endemic (i.e. outside Western Europe, N. America and Australasia). All those at risk should be advised to test for Hepatitis B and vaccination offered to all at continuing risk. Vaccination against HBV is also recommended in all non-immune HIV infected adults[174].

Recommendation:
Advice on the sexual transmission of Hepatitis A and Hepatitis B and the availability of vaccination should be given to all those at elevated risk of acquisition.

Advice specific to the prevention of sexual transmission of HIV infection.

The guidance presented in this document is applicable to those who are HIV negative, HIV positive and for those who as yet do not know their status. More detailed advice relating specifically to HIV transmission may be required by those who have serodiscordant partner(s) or who have or are likely to have partners from groups

with a high prevalence of HIV infection. For a minority of people living with HIV, psychological factors affecting treatment adherence and safer sex behaviours may overlap and increase the risk of HIV transmission[175]. Standards for the psychological support of adults living with HIV address these issues and describe a hierarchy of interventions that correlate with those described in this document[176]. It is important that any discussion around HIV transmission acknowledges the complex issues relating to disclosure for those who are HIV positive. Detailed advice on sexual and reproductive health for people living with HIV (PLHIV) is given in guidelines by BHIVA, BASHH and the Faculty of Sexual and Reproductive Health (FSRH)[177].

HIV infectivity on ART

The HIV viral load in plasma and genital secretions is the most important factor in the transmission of HIV[178-180]. Successful highly active HIV therapy reduces plasma viral load to below the level of detectability of most currently used laboratory assays (<50 copies/ml) and at these levels, HIV transmission is extremely rare[181]. Meta analysis of 11 cohorts showed no case of transmission within discordant heterosexual couples with an undetectable viral load below 400 copies/ml who were receiving HAART but occasional transmission in those below this level who were not receiving HAART[182]. In a study of 2993 HIV serodiscordant couples the infection rate was 3.4/100 in those not on HAART and 0.7/100 in those where the HIV positive partner was receiving HAART with a relative reduction in risk of 0.21 (95% CI 0.08 – 0.59)[183]. Estimated transmission risk in Ugandan couples on ART was reduced by 91%, from 47.3 to 4.2/1000 person-years over 3 years, despite high rates of unprotected sex and increased sexual activity following ART initiation[184].

The issue of HIV transmission at low plasma viral loads has been extensively discussed in the recent literature [177 181 185-186]. Although the likelihood of HIV transmission from an HIV positive individual to their negative partner can be hypothesised to approach zero, there remains concern about the validity and the public health implications of statements relating to transmission risk[187]. There is also the concern that a perceived reduction in infectiousness may lead to sexual disinhibition resulting in an overall increase in HIV incidence at population level, as was seen in one study from the Netherlands[188], as well as concerns about the applicability of study findings in heterosexual populations to MSM. Most commentary accepts that the likelihood of HIV sexual transmission through vaginal sex is extremely low if the plasma viral load is suppressed and a recent study shows that there is a high probability that HIV

remains suppressed in between plasma viral load measurements, with only 7% having a VL greater than 1000 over the 3 and a half year study period[189]. However, a negative plasma viral load cannot always be considered as a marker of an undetectable seminal viral load. Longitudinal studies on semen and blood HIV RNA post HAART have taken place. Of 33 HIV-positive men who had plasma viral loads of <50 copies/mL for a mean of 3.96 years and who had been screened for STIs, two (6%) had detectable HIV in their semen[190]. In a prospective cohort of 25 men free of STIs initiating HAART and achieving a plasma viral load of <50 copies/mL, HIV was detectable in semen samples of 48% of the men on more than one occasion. In 13 other HIV-infected men who had undetectable plasma viral load at every 3-monthly assessment for the past 7 years, HIV was detected in semen samples in 31%. No relationship between semen viral loads and the concentration of antiretroviral drugs in that compartment was found and HIV detected in semen samples was sensitive to the drugs taken by study participants[191]. These reports of semen/plasma viral load discordancy are consistent with reports of HIV transmission with undetectable plasma viral load[182]. One model suggests that there are a low but definite number of transmissions over a period of time. The risk is thought to be higher for homosexual couples compared to heterosexual couples engaging in vaginal intercourse[192-193].

Whether the concentration of antiretroviral agents in seminal and vaginal fluids or the anal mucosa is linked to transmission however, remains unknown. The risk of HIV transmission through peno-anal sex is likely to be higher in the absence of ART. A systematic review and meta-analysis of 43 publications including 25 different study populations attempted to quantify heterosexual transmission risks in the absence of antiretrovirals[194]. The pooled receptive anal intercourse estimate was much higher (1.7% per act [95% CI 0.3-8.9]) than the overall pooled transmission estimates in both high income (female-to-male (0.04% per act [95% CI 0.01-0.14]) and male-to-female (0.08% per act [95% CI 0.06-0.11]) and low-income countries (female-to-male (0.38% per act [95% CI 0.13-1.10]) and male-to-female (0.30% per act [95% CI 0.14-0.63])).

With respect to MSM there is more limited data available on transmission risk. Data were collected from a longitudinal cohort study of 1427 HIV-negative homosexual men in Sydney; participants were recruited from June 2001 to December 2004[195]. The estimated per-contact probability of HIV transmission for receptive UAI was 1.43% [95% confidence interval (CI) 0.48–2.85] if ejaculation occurred inside the rectum, and 0.65% (95% CI 0.15–1.53) if withdrawal occurred prior to ejaculation. Despite the fact

that a high proportion of HIV-infected men in the population in which the study was conducted were likely to be on antiretroviral treatment and have undetectable viral load, the per-contact probability of HIV transmission due to UAI was similar to estimates reported from developed country settings in the pre-HAART era.

A systematic review and meta-analysis of the literature on HIV-1 infectiousness through AI in both heterosexuals and MSM identified four publications reporting per-act and 12 reporting per-partner transmission estimates with no significant difference between per-act risks of URAI for heterosexuals and MSM[196]. Modeling demonstrated that it would require unreasonably low numbers of AI HIV exposures per partnership to reconcile the summary per-act and per-partner estimates, suggesting considerable variability in AI infectiousness between and within partnerships over time. The limited available evidence suggests that the residual transmission risk for anal sex in heterosexuals and MSM with undetectable plasma viral load is higher, more variable and possibly more sensitive to the effects of co-existing STIs than the risk for vaginal sex.

On an individual basis detailed discussion on HIV transmission for sero-discordant couples should include discussion of greatly reduced infectiousness on HAART and placed in the context of the residual risk when condoms are used reliably in untreated individuals; however several critical issues suggest caution should be taken in considering the public health message of any guidance on HIV transmission. These include the reported discordance between plasma and genital viral loads, the possibility of STIs increasing transmission risk, and the limited data for sexual transmission in anal sex both for heterosexual and MSM populations.

Recommendations
Advice to people living with HIV, their sexual partners and those from groups with higher incidence of HIV infection should include:

Taking effective antiretroviral therapy and having a quantitative plasma viral load below the limit of detection of currently available assays significantly reduces the risk of HIV transmission (Evidence level Ia, A)

Despite routine undetectable plasma viral load measurements a residual risk of transmission is likely to exist (Evidence level IIb, B)

This residual risk is likely to be higher for anal sex than for vaginal or oral sex (Evidence level III, B)

The risks are increased with reduced ART adherence or the presence of STIs in either partner. The risks can be reduced by using condoms and having regular STI screens (Evidence level IV, C).

Irrespective of HIV status, couples might consider discontinuing use of condoms for a number of reasons, in a long term monogamous relationship, in the planning of a pregnancy etc.

Recommendation
Serodiscordant or HIV+ve seroconcordant couples should receive detailed expert counselling and support on the transmission risks and other relevant issues (Evidence level IV,C).

In addition, the Expert Advisory Group on AIDS provides the following guidance regarding disclosure of HIV status[197]:

- Disclose HIV status before having sex with a new partner and always use a condom. Condoms are considered protective against HIV.

- If the condom slips or breaks, and HIV status has not yet been disclosed, disclose HIV status promptly to allow the exposed person to seek post-exposure prophylaxis. The exception to this would be if HIV viral load is undetectable, when the need to disclose HIV status is diminished as there is negligible risk of HIV transmission under these circumstances. However, disclosure might still be sensible so that a risk assessment can be made by a clinician.

- Within regular sero-discordant partnerships, both parties should be aware of the risks of HIV transmission from someone on highly active antiretroviral therapy with undetectable viral load. Thus, disclosure of status by the HIV-positive individual should still take place. With good adherence to therapy and no other STIs there is negligible risk of transmission through unprotected *vaginal* sex and the risk of HIV transmission under these circumstances is no greater than with consistent condom use.

Initiation of HAART to reduce transmission risk

A multi-national, randomised, controlled trial showed a 96% reduction in the risk of HIV transmission in heterosexual couples in which the infected partner was given immediate ART, compared to a deferred group[198] .Mathematical modelling has been used to estimate the population reduction of HIV transmission achieved by identifying and treating all individuals with HIV infection irrespective of the clinical criteria for treatment[199-200]. This approach would require widespread regular HIV testing of a population or a risk group and the immediate commencement of treatment, a policy coined 'test and treat'. There is currently no public health policy of treatment as prevention in the UK. Nonetheless the early initiation of antiretroviral therapy may be an option to be discussed with HIV positive individuals who are at high risk of onward transmission of HIV infection (e.g. because of difficulty maintaining safer sex behaviour)

Recommendation
Discussion regarding the early initiation of antiretroviral therapy to reduce the risk of HIV transmission may be appropriate as part of safer sex counselling for some people living with HIV (Evidence level Ib, A).

Seroadaptive behaviours including negotiated safety, serosorting and seropositioning

Seroadaptation includes serosorting (choosing partners with concordant HIV status), 'strategic positioning', also interchangeably termed 'seropositioning'[201] (choosing the position taken during sexual practices according to HIV status) and negotiated safety. Negotiated safety (NS) usually refers to the use or non-use of condoms according to a partner's HIV status but may include the open discussion of risk factors (such as HIV serostatus) prior to sex, the establishment of ground rules for sex both within and outside a regular sexual relationship, or agreement on indications for and frequency of repeat HIV testing. Such agreement may include for example, an HIV negative man only being ano-insertive with his male HIV positive partner, or a positive man not ejaculating inside a negative woman. There may also be rules about condom use; with a non-use agreement within a seroconcordant relationship but consistent use with all other partners. These alternative risk reduction strategies have been most extensively researched in MSM, in whom 14-44% report serosorting and 6-35% seropositioning[202]. Serosorting has also been described in heterosexual populations with higher HIV prevalence including intravenous drug users[203] and African populations in London[204] and

elsewhere. There is some evidence that these techniques may be more common and better adhered to than consistent condom use [205-206], reinforcing the idea that promotion of 100% condom use is not the best or only approach. Seropositioning appears to be significantly more common in HIV+ve partnerships than seronegative[205], but a UK study found a higher prevalence of UAI with partners of unknown status in HIV positive than in HIV negative or untested men[207]

It has been suggested that such techniques may partially explain the absence of a rise in HIV prevalence despite increases in bacterial STIs and reported unprotected intercourse[208]. Data from one RCT [209] as well as cohort and case control studies[210] is available to suggest that serosorting may be associated with a small decrease in the risk of seroconversion, but it remains a controversial harm reduction technique[211] and has been characterised as 'seroguessing' because around 30% of men have been found to assume rather than know the status of partners[212]. Other models suggest that serosorting could increase the rate of HIV transmissions depending on the proportion of untreated and recently infected individuals in the population disclosing as 'HIV negative'[213-214].

Overall, the use of seroadaptive risk reduction techniques is almost certainly safer than UAI with unselected partners but less safe than avoiding UAI altogether[215] There is also evidence that there may be an increase in other STIs when serosorting occurs[216]. Rectal infection with LGV is particularly associated with HIV infection in MSM[217], with between 67% and 100% of cases being HIV co-infected. Acute infection with Hepatitis C is associated with UAI and other unprotected sexual behaviours in HIV infected MSM[218]. Any protective effect of seroadaptation is highly dependent upon the reliability of understanding of HIV status (and therefore depends on a high frequency of testing). At a population level, the selection of seroconcordant partners by HIV positive individuals is likely to be an effective means of reducing onward transmission, although it carries the theoretical risk of superinfection with HIV. It appears that as long as at least one partner is taking effective antiretroviral therapy and has an undetectable viral load, the risk of such 'superinfection' is extremely low. Serosorting by those of HIV negative or unknown status is likely to be less effective as HIV status may change.

Negotiated safety has been criticised as 'negotiated danger' and agreements must be detailed and specific if negotiated safety is to be an effective harm-reduction tool[219]. A qualitative study of the practice of NS among HIV-negative men in seroconcordant relationships found that some men violated NS-defining rules, placing themselves and potentially their primary partners at risk of

HIV infection[220]. It concluded that prevention interventions involving NS should emphasize the importance of agreement adherence, disclosure of rule breaking, and routine STI testing. Additional support with communication skills, assertiveness and disclosure of status may be required.

NS and serosorting strategies may be affected by knowledge and perception of reduced HIV transmission risk on ARV therapy: a 2005 study from Sydney showed that although unprotected anal intercourse rates in serodiscordant relationships were low overall, the rate was increased if the positive partner had an undetectable viral load[221]. Serosorting depends on disclosure and responsibility for disclosure may be seen to lie with the HIV positive partner. It is important to emphasise the shared responsibility for prevention of HIV transmission. Individuals in the United Kingdom have been prosecuted and convicted for the reckless transmission of HIV and other sexually transmitted infections[222-224]. Those living with or at increased risk of HIV infection should be made aware of the potential legal implications of the transmission of infection. Recommendations for clinical services is given in the UK guideline for sexual and reproductive health for people living with HIV[177]. Further BASHH/BHIVA Guidelines on the Criminalisation of HIV infection are in preparation.

Discussion around NS and serosorting will differ according to the serostatus of the individual(s) involved, but may include:

- the importance of knowing (rather than assuming) HIV status and the need for repeat testing for HIV negative individuals following risk
- the importance of disclosure, communication skills and adherence to agreements.
- the elevated risk of onward HIV transmission during seroconversion and the suggestion that barrier protection is reintroduced following any risk.
- the risk of HIV superinfection[225] in those who are already HIV infected. The risks and implications of this are not yet known[226].
- the risk of acquiring STIs other than HIV, e.g. through unprotected oral sex, and the consequent increased risk of subsequent HIV transmission.
- the availability and use of PEPSE
- the possibility of early treatment initiation for HIV positive individuals to further reduce risk.
- The possible legal implications of HIV transmission

Recommendations

*Negotiated safety and serosorting should be discussed with those who are known or suspected to be unable or unwilling to maintain 100% condom use (*Evidence level *IV, C)*

MSM should be advised that serosorting is less effective than consistent condom use but more effective than non selective non-use in preventing HIV acquisition or transmission (Evidence level III, B).

HIV positive MSM should be advised of the risk of acquiring other STIs, in particular Lymphogranuloma venereum and Hepatitis C, through unprotected sex with other HIV positive men. (Evidence level III, B).

Post exposure prophylaxis following sexual intercourse and pre exposure prophylaxis

BASHH guidance on post exposure prophylaxis following HIV sexual exposure is available[227] and a revision will soon be published. BHIVA, BASHH and the FFP recommend that all units have explicit local policies on the implementation of PEPSE[177]. Useful regional and local policies also exist and a detailed guideline for use in emergency rooms is also available[228]. The guidance provides information on assessing the overall risk by considering the risk of the exposure route and risk that the source is HIV positive.
There is concern that low risk perception in MSM groups may limit the seeking of post exposure prophylaxis following high risk exposure[229-230]. A number of randomised controlled trials have shown a reduction in HIV acquisition in heterosexual men and women and in MSM with oral or topical PrEP (pre-exposure prophylaxis for HIV). A joint BHIVA/BASHH statement recommends that ad-hoc prescribing is avoided, and that currently PrEP should only prescribed in the context of a clinical research trial[231].

Recommendation
All individuals at increased risk of HIV acquisition (including those in serodiscordant relationships, MSM and those from, or with partners from, populations with high HIV seroprevalence) and those at risk of transmitting HIV should receive verbal and written advice on the indications for and availability of PEPSE (Evidence level IV,C).

Male circumcision
Three randomised controlled trials in Uganda, Kenya and South Africa have shown that male circumcision (MC) protects against the acquisition of HIV in men in the setting of a high prevalence

(generalised) HIV epidemic[232-128]. Meta analysis found little evidence of a direct effect on HIV incidence rates in female partners[233]. MC has also been shown to be protective against the acquisition of HSV and HPV but not the acquisition of syphilis or gonorrhoea[234-235]. Published trials examine heterosexual (presumed vaginal) intercourse. There is currently no randomised control trial (RCT) evidence on the role of MC in countries of low HIV prevalence or for anal sexual intercourse. Neither is there evidence as to whether MC protects against HIV transmission in MSM who engage in anal sex. The question about the effectiveness of MC as part of a HIV prevention strategy in situations outside Sub-Saharan Africa, has been explored[236] but there is little evidence to guide any recommendations at present. A Cochrane review of 21 observational studies concluded that there was evidence of a protective effect of circumcision in MSM practising insertive anal sex, but that this was insufficient to recommend circumcision as a prevention intervention[237]. In the UK there has been no survey on levels of male circumcision in heterosexual men. In a low prevalence setting such as the UK, it is not envisaged that MC will become part of a national strategy for HIV prevention. Even at an individual level there is little basis at present to offer MC as part of a risk reduction strategy for particular high risk individuals.

Recommendation
There is currently no public health evidence to recommend MC as a strategy for HIV transmission reduction in the UK, either at a population or individual level (Evidence level IV,C).

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Conflict of Interest
None

Rigour of development
The guideline was developed by review of Cochrane Library, Medline, Embase and Conference reports and existing guidelines from 2000-Week 40 2008. Following consultation main title searches and searches relating to seroadaptive behaviours and HIV transmission were repeated and updated to May 2011.. Main title searches included keywords 'Condoms' (1762 citations), 'Behavioural interventions' and 'Motivational interviewing'. Other keyword searches included 'Sexual intervention', 'Intervention meta-analysis STI' ,' Brief intervention sexual health', Safer sex behavioural intervention', 'CBT sexual health intervention', 'skill sexual', 'condom skill', STI prevention', 'combination prevention',

safer sex, 'condom error/s', 'condom breakage', 'condom' and 'erectile dysfunction', 'female condom' 'partner reduction', 'abstinence', 'contraception', 'negotiated safety', 'serosorting', seroadaptive, 'testing in relationships', 'frequency AND rescreening', 'seminal viral load' and others.

'Oral sex', 'anal sex', 'digital', 'non-sexual', 'accidental', 'non-sexual' and 'kissing' were combined individually without mapping with sexually transmitted infections, HIV, syphilis, herpes, HSV, Chlamydia, gonorrhoea, warts. STI risk combined with 'sex workers', sex work, 'prisoners', 'looked after, accommodated, adolescents'. 'Sexual behaviour' combined with 'compulsion'. Title searches were used by individual co-authors to identify articles of relevance. Articles published in English only were included. In the absence of directly applicable evidence, recommendations are based on expert opinion and practice.

The document was not subject to consultation but was updated according to feedback received on the guideline document.

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