

# Service Standards for Sexual and Reproductive Healthcare

November 2011



*“Setting standards in contraception  
- improving sexual health for all”*

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Faculty of Sexual & Reproductive Healthcare  
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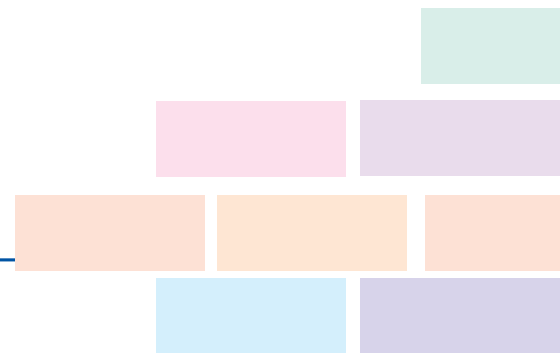
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## Introduction

These Service Standards have been developed by the Faculty of Sexual and Reproductive Healthcare (FSRH) to support both providers and commissioners in providing safe, high-quality sexual & reproductive health services and are based on current evidence of best practice. The Standards are recommended for use by all providers commissioned or contracted by the National Health Service (NHS) to provide contraception and sexual infection management and services providing pregnancy planning, pregnancy choices, abortion, community gynaecology, sexual wellbeing and health promotion. There are some areas where the standards indicate that they are for specific service types such as Specialist Community SRH services.

The Standards have been developed to be applicable to all countries in the UK. Key documents from England, Scotland, Wales and Northern Ireland have been used to inform their production and they have been subject to consultation in the four countries.

This core document outlines **eleven** general service standard statements. Standards have also been produced by the Clinical Standards Committee of the FSRH in relation to specific issues (e.g. medicines management, resuscitation). These more detailed Standards have been attached to this document in the form of Appendices. The Standards are auditable and have been developed by the committee by a process of review of all evidence of best practice. This process is repeated every 3 years with new evidence incorporated. After each Standard is reviewed it is placed onto the FSRH website for consultation. This is an ongoing process hence each document has a different review date.

There has been variation in the background of clinical leaders of community SRH services. All services should have appropriately trained leadership to ensure quality of service provision, development, training and clinical governance (**Standard Statement 1**). It is envisaged that all services should be consultant-led and Level 3 services should link with Level 1 and 2 services to provide support.

Services should provide comprehensive sexual and reproductive healthcare (**Standard Statement 2**). This should include access to all methods of contraception including emergency intrauterine device (IUD) insertion; early pregnancy and abortion assessment and counselling; screening for pertinent national screening programmes; sexually transmitted infection testing and treatment appropriate for community SRH services; community gynaecology and psychosexual assessment, and referral where in-house services are not available. Services should conform with the Service Standard in **Workload in Services (Appendix 1)**.

Services need to be patient focussed ensuring good communication, and provide clear patient information (**Standard Statement 3**). There should be clear patient pathways and services should adhere to Faculty Standards on **Consent (Appendix 2)** and **Confidentiality (Appendix 3)**.

Services should demonstrate that user and public involvement has been fundamental to service development, provision, monitoring and evaluation (**Standard Statement 4**). User engagement should be encouraged and evidence provided that it has been used in service planning.

Services should provide open access with a mixture of appointment and 'walk-in' timings (**Standard Statement 5**). There should be information available about the timing of services and there should be easy and non-discriminatory access for all.

All staff working in SRH services should be appropriately trained (**Standard Statement 6**). For doctors this should be the minimum standard of the Diploma of the Faculty of Sexual and Reproductive Healthcare (DFSRH). For those performing intrauterine and subdermal procedures, appropriate Letters of Competence should be held. All other health professionals working in all levels of SRH services should be trained to the competencies laid down by their educational bodies and administrative staff trained to deliver confidential and patient-focussed care.

SRH service provision should be evidence-based, which will include the use of national and local guidelines and policies (**Standard Statement 7**). The standards outline which standards should be used for different aspects of service provision. The Clinical Standards produced by the Clinical Standards Committee should be used to inform specific issues including **Resuscitation (Appendix 4)** and **Medicines Management (Appendix 5)**.

All clients seeking SRH services should be confident that their right to confidentiality will be respected (**Standard Statement 8**) and record keeping in all services should be of a high standard, to provide maximum benefit in patient management, to facilitate audit and record the process of obtaining valid consent (**Standard Statement 9**). Services should work to the Service Standards for **Record Keeping (Appendix 6)**.

Nurses often work in isolation in SRH services and their role should be supported and enhanced (**Standard Statement 10**). Finally, all services should continually monitor and evaluate themselves in order to maintain and improve performance (**Standard Statement 11**). A process of **Risk Management** should be evident to ensure that services provide a safe and high quality patient care (**Appendix 7**).

## Scope of the Document

These Standards are recommended for organisations providing contraceptive/sexual and reproductive health (SRH) services, including pregnancy planning, pregnancy choices, abortion, prevention and treatment of sexually transmitted infections (STIs), as well as sexual wellbeing and health promotion.

## Introduction<sup>1</sup>

Within UK countries there is considerable variation in how SRH services are provided. These vary from distinctly separate general practice and community-based contraceptive provision with hospital-based abortion and genitourinary medicine services, to fully integrated SRH services in the community.

The Faculty of Sexual and Reproductive Healthcare (FSRH) acknowledges the great differences that exist between services and this document provides a framework of standards, which can be applied to all SRH services to enable equitable service provision. These include services within general practice, hospital- and community-based clinics and pharmacies, as well as voluntary and independent-sector organisations.

This Faculty document incorporates elements from the following key documents (and is based on available evidence and best practice where evidence is lacking):

- The National Strategy for Sexual Health and HIV<sup>1</sup> for England
- The Scottish Strategy, *Respect and Responsibility*<sup>2</sup>
- The Medical Foundation for AIDS & Sexual Health (MedFASH) *Recommended Standards for Sexual Health Services*<sup>3</sup>
- NHS Quality Improvement *Scotland Sexual Health Services*<sup>4</sup>
- A Strategic Programme for Promotion of *Sexual Health in Wales*<sup>5</sup>
- Sexual Health Promotion (Northern Ireland Strategy)<sup>6</sup>
- BASHH Standards for the Management of STIs<sup>7</sup>

### I. Standard Statement on Leadership

All sexual and reproductive health services should have appropriately trained leadership to ensure quality of service provision, development, training and clinical governance.

Currently there is considerable variation in the background, training and experience of consultants/lead clinicians working in community-based SRH services. This is due to the absence of appropriately structured training programmes in the past. It is expected that all Level 3 services in future will become consultant-led. These consultants will have the postgraduate qualification and structured training approved by the FSRH/the Royal College of Obstetricians and Gynaecologists (RCOG) and the General Medical Council (GMC).

- 1.1 All SRH services at Level 3 as specified in the National Strategy for Sexual Health and HIV<sup>1</sup> for England and equivalent services in the rest of the UK, should be **consultant-led** and have one full-time consultant with current accreditation [including Membership of the Faculty of Sexual and Reproductive Healthcare (MFSRH)] per population of 125,000 to ensure adequate quality of service provision, training, clinical governance and risk management across all three levels of service provision.<sup>3,4</sup>
- 1.2 Consultant leads should not work in isolation and should be supported by consultant colleagues and a team of associate specialists/specialty doctors, specialty trainees and other specialists in contraception and sexual health.
- 1.3 Level 3 services should link with Level 1 and 2 services to support quality of clinical service provision and clinical governance.<sup>1</sup>

## 2. Standard Statement on Service Provision

Service provision should include a range of sexual and reproductive health services.

### 2.1 Contraception

- 2.1.1 RH services should provide unrestricted open access services with clear clinical pathways and supported as appropriate by clinical networks.<sup>3,7</sup>
- 2.1.2 Access to and availability of the full range of contraceptive methods should be available and include choice within products (e.g. a range of different combined oral contraceptives and IUDs) to maximise patient acceptability.<sup>8,9</sup>
- 2.1.3 Provision of counselling and direct referral for male and female sterilisation should be provided.<sup>6</sup>
- 2.1.4 Provision of emergency contraception, including timely access for postcoital IUD insertion, should be provided.<sup>3,8,10</sup>

### 2.2 Pregnancy and abortion

- 2.2.1 Services should provide basic counselling/information for pregnancy planning and preconception care.<sup>8</sup>
- 2.2.2 Services should offer access to pregnancy testing on site with results being available at the first visit.<sup>3,8</sup>
- 2.2.3 Services should offer access to empathetic unintended pregnancy information and decision support.<sup>3,8</sup>
- 2.2.4 Referral to abortion services should be available without delay – this should meet the standards set out in the current RCOG abortion guidelines.<sup>11</sup>
- 2.2.5 Abortion services should provide advice and concurrent provision (including insertion of IUDs and implants where clinically appropriate) of a full range of contraceptive methods. This may be provided by close liaison or integration with contraceptive services.<sup>12</sup>

### 2.3 Screening

- 2.3.1 Cervical cytology screening should be available in line with national<sup>13,14</sup> and local guidelines.
- 2.3.2 Services should offer screening for Chlamydia infection with protocols for treatment and partner notification, or appropriate onward referral, according to national guidelines.<sup>13</sup>
- 2.3.3 Services should participate in the English National Chlamydia Screening Programme for under-25s<sup>15</sup> or its equivalent in other UK countries.<sup>6</sup>



### 2.4 Sexually transmitted infection (STI) services

- 2.4.1 Services should offer advice and information on STIs, including HIV, with supporting leaflets.<sup>3,8</sup>
- 2.4.2 Appropriate testing, treatment and partner notification for STIs for both men and women should be available through all SRH services, with onward timely referral to more specialist services when appropriate.<sup>3,7,8</sup>

### 2.5 Psychosexual services

- 2.5.1 Services should offer access to psychosexual counselling or appropriate onward referral.<sup>1,8</sup>
- 2.5.2 Services should offer people with organic sexual dysfunction treatment or appropriate onward referral.<sup>1</sup>

### 2.6 Other reproductive health services

- 2.6.1 Services should offer advice and information on medical gynaecological issues such as menopause, premenstrual syndrome, and menstrual dysfunction with supporting leaflets, and onward timely referral to appropriate services. Ideally, these services should be available within a community-based service.

### 2.7 Services for patients with special needs

- 2.7.1 Appropriate arrangements should be in place to enable patients with special needs to access SRH services without undue delay, for example appropriate young people's services (including young people in care of the local authority), access to interpreters, clinic facilities for people with physical disabilities, learning disabilities, complainants of sexual assault, sex workers and substance misusers.<sup>2,3</sup>
- 2.7.2 Outreach services should be provided for patients unable to access mainstream services.<sup>8</sup>

### 2.8 Training and support in SRH

- 2.8.1 Specialist services (Levels 2 and 3) should have structures in place to provide easily accessible clinical advice and support to professionals working in other services.<sup>1</sup>
- 2.8.2 Specialist services should have structures in place to provide and support training in sexual health.<sup>1,3</sup>

### 2.9 Sexual Health Networks (or Referral pathways between services)

- 2.9.1 Specialist services should be involved in establishing local Sexual Health Networks<sup>3,7</sup> and there should be clear referral pathways between services.<sup>3</sup>

### 3. Standard Statement on Patient Focus

Services need to be patient-focussed ensuring good communication, clear patient information and working to Faculty standards on consent and confidentiality.

- 3.1 SRH service providers should ensure clear information is available to patients regarding all services provided, in the form of leaflets and posters. Services should be advertised through easily available media such as Yellow Pages/websites/general practice leaflets.<sup>3,8,16</sup>
- 3.2 If the provider does not offer certain services, clear information on alternative sources for service provision locally should be made available.<sup>3,8,16</sup>
- 3.3 Services should be organised so that there are clear patient pathways.<sup>3</sup>
- 3.4 Objective, evidence-guided written information such as Family Planning Association (FPA) leaflets should be readily available and accessible to assist patients in making informed choices about methods of contraception, sexual and reproductive health. There should be a choice of languages/formats appropriate to the patient groups served by the provider, including those with sensory impairment.<sup>3,8,16</sup>
- 3.5 Verbal counselling advice should be supported by appropriate written/pictorial/audiovisual information, which patients can take away.<sup>3,7,8</sup>
- 3.6 Consultations should be conducted with due regard to the privacy of patients regardless of age, gender and sexual orientation.<sup>3,8,16</sup>
- 3.7 Adequate time should be given for all consultations.<sup>17</sup> First visits, initial counselling and provision of all contraceptive methods, STI treatment and partner notification, counselling for sterilisation/vasectomy and referral, pregnancy information, decision support and referral for abortion, will require more time compared to uncomplicated repeat visits for supply of hormonal contraception.
- 3.8 Patients undergoing intimate examinations should be offered the presence of a chaperone, irrespective of the gender of the clinician<sup>18,19</sup> whether doctor or nurse. There should be prominent notices displayed in the waiting and clinical rooms informing patients of their right to request a chaperone if desired.
- 3.9 Services should be delivered to conform with the Department of Health *You're Welcome* criteria.<sup>16</sup>

### 4. Standard Statement on User and Public Involvement

Services should demonstrate that user and public involvement has been fundamental to service development, provision, monitoring and evaluation.<sup>20-22</sup>

- 4.1 An annual user and public involvement plan should be developed.
- 4.2 User engagement should be encouraged (e.g. with suggestion and comments boxes in clinics and regular user satisfaction surveys). An example of a validated patient satisfaction questionnaire is attached as Annex A.
- 4.3 The patients' compliments/comments/complaints procedure should be clearly displayed in the clinic/practice.<sup>23</sup>
- 4.4 Services should respond appropriately to user feedback.
- 4.5 Public consultation is essential when service redesign or development is planned. This would include involving 'hard to reach' groups, and collaboration and partnership working with the voluntary and community sectors.

## 5. Standard Statement on Access

**There should be easy and quick non-discriminatory access to sexual and reproductive health services for all.**

- 5.1 There should be effectively led local co-ordination of access to SRH services.<sup>1,2</sup>
- 5.2 Service providers should clearly advertise location, opening times, and services provided, and keep the FPA, NHS Direct and NHS 24 fully informed. They should have an answering machine outside opening hours to give information on opening times and services including emergency contraception. They should have mechanisms to monitor missed phone calls.<sup>4</sup>
- 5.3 There should be choice in terms of times and types of clinic/practice services for the population served (daytime/evening, walk-in/appointment).<sup>3,8</sup>
- 5.4 Clinics should be in easily accessible/convenient locations and clearly signposted.<sup>3,8</sup>
- 5.5 It should be possible for patients to access emergency contraceptive services (within the required timeframe). This should be provided on the same day on weekdays. In rural areas where specialist clinics may not be accessible locally throughout the week, development of appropriate alternative services should be addressed.<sup>3,8,10</sup>
- 5.6 Arrangements for appropriate provision of emergency contraception as well as contraceptive supplies over weekends and public holidays should be in place.<sup>8</sup>
- 5.7 Advance provision of emergency hormonal contraception and instructions on use should be offered to patients where appropriate.<sup>10</sup>
- 5.8 Provision for patients with special needs should be ensured (see 2.7.1.).<sup>3,7,8</sup>
- 5.9 Walk-in clinics should have staffing to provide safe medical practice and enable a maximum waiting time of 2 hours.<sup>7,8</sup>
- 5.10 Services that operate an appointment system instead of walk-in clinics should provide appointments within 2 working days for non-specialist, non-urgent consultations.<sup>3,7</sup>
- 5.11 Specialist services such as those providing sterilisation/vasectomy or psychosexual services should ensure that they conform with devolved NHS targets.<sup>24,25</sup>

### 6. Standard Statement on Training

All staff working in sexual and reproductive health services should receive appropriate training and must maintain their skills.

- 6.1 All doctors providing contraception within SRH services should hold a current Diploma in Sexual and Reproductive Healthcare (DFSRH) or be trained to equivalent competencies and show evidence of re-accreditation.<sup>26,27</sup>
- 6.2 All doctors providing contraception within SRH services, who obtained their DFSRH, or equivalent, prior to 2003, should undertake additional STI training and show evidence of maintaining appropriate skills.<sup>27</sup>
- 6.3 All doctors offering IUD, intrauterine system (IUS) and contraceptive implant insertion should hold the DFSRH and an up-to-date Letter of Competence in Intrauterine Techniques (LoC IUT)/Letter of Competence in Subdermal Contraceptive Implants (LoC SDI) of the FSRH or have achieved equivalent competencies and show evidence of re-certification/re-accreditation.<sup>25,28,29</sup>
- 6.4 All nurses, pharmacists and other health professionals working in all levels of SRH services should be trained to the competencies laid down by their educational body.<sup>30-32</sup>
- 6.5 All administrative staff involved in SRH services should receive appropriate training, including confidentiality, child protection and customer care.<sup>7,8</sup>
- 6.6 All doctors, nurses and other health professionals working in SRH services should be trained to the competencies and training programmes **jointly** agreed by all their educational bodies including the Royal College of General Practitioners (RCGP), RCOG, FSRH, British Association for Sexual Health and HIV (BASHH), Society of Sexual Health Advisors, Royal College of Nursing (RCN), Royal Pharmaceutical Society of Great Britain, Pharmaceutical Society of Northern Ireland and supported by user representatives such as the FPA.
- 6.7 Dedicated young people's services should be staffed by those who have an understanding of adolescent development and experience of working with young people.<sup>5,33,34</sup>
- 6.8 Staff working with vulnerable groups (e.g. young people or people with learning disabilities) should be appropriately trained.<sup>35</sup>

## 7. Standard Statement on Clinical Practice

**Sexual and reproductive health service provision should be evidence-based, which will include the use of national and local guidelines and policies.**

SRH services should have the following local policies in place:

- 7.1 Evidence-based policies based on nationally recognised guidelines, for example, FSRH Clinical Guidance, NHS guidelines, including National Institute for Health and Clinical Excellence (NICE) and World Health Organization (WHO) Recommendations (as amended for UK practice where relevant) for provision of all contraceptive methods.<sup>9,36</sup>
- 7.2 Policies governing STI service provision that follow the guidelines outlined in the National Sexual Health Strategy/Commissioning Toolkit for STI services/BASHH Standards for the management of STIs and are consistent with BASHH guidelines.<sup>7,8,37</sup>
- 7.3 Policies governing abortion that follow current RCOG abortion guidelines.<sup>11</sup>
- 7.4 Policies relating to child protection/safeguarding children<sup>33</sup> and vulnerable adults<sup>35</sup> that follow national guidelines.
- 7.5 Policies that address the recommendations in the National Strategy for Sexual Health and HIV for England, its implementation plan<sup>38</sup> and commissioning toolkit<sup>8</sup> and the sexual health promotion toolkit<sup>39</sup> or its equivalent in other UK countries.<sup>4-6</sup>
- 7.6 Policies that address MedFASH recommended standards for sexual health services.<sup>3</sup>
- 7.7 Locally applicable standards for administrative staff.
- 7.8 Appropriate IT services and provision for staff to access up-to-date guidance.
- 7.9 Services should aim to achieve standardisation of delivery of care (e.g. record keeping) as described in the Faculty standards.<sup>40</sup>
- 7.10 Services should work to Faculty standards on record keeping, medicines management, resuscitation and obtaining consent in sexual health services.<sup>40-43</sup>

### 8. Standard Statement on Confidentiality

**All users seeking sexual and reproductive health services should be made aware that their right to confidentiality will be respected and maintained in line with GMC, NMC and other professional bodies' recommendations.<sup>44-46</sup>**

- 8.1 Services should prominently display their confidentiality statement at their premises.<sup>16,47,48</sup>
- 8.2 Confidentiality training should be provided to all staff.<sup>16,47,49</sup>
- 8.3 Staff providing these services should be familiar with the Fraser Guidelines, best practice guidance<sup>28</sup> and appropriate guidance in other UK countries.<sup>47,49</sup>
- 8.4 Patients should have the assurance of confidentiality with regard to their consultations regardless of age, gender, sexual orientation, religion or ethnicity unless the clinician has concerns about wellbeing and/or safety of the patient or others.<sup>44</sup>
- 8.5 Staff working with young people and vulnerable adults should be familiar with both local and national guidelines.<sup>33,34,49</sup>
- 8.6 Specific permission from the patient should be sought prior to sharing any information with anyone outside the service except in issues relating to child protection when the patient should be informed that sharing will happen (though even in these cases ideally the consent of the young person to share information should be obtained).<sup>34</sup>
- 8.7 Services should work to the Faculty Confidentiality Standards.<sup>49</sup>

## 9. Standard Statement on Record Keeping

**Record keeping in all services should be of a high standard, to provide maximum benefit in patient management, to facilitate audit and record the process of obtaining valid consent.<sup>48</sup>**

- 9.1 All services should work to the Faculty Record Keeping Standards.<sup>40</sup>
- 9.2 Adequate notes regarding the consultation and management plan should be made to help other clinicians following up the management of patients.<sup>40</sup>
- 9.3 The offer of a chaperone during an intimate examination should be documented. If it is accepted or declined, this should also be clearly recorded in the notes including the name of the chaperone (see also 2.8.).<sup>18,19</sup>
- 9.4 Clinical records must be kept confidential at all times and stored in a secure place.<sup>40</sup>
- 9.5 All record systems, whether written or computerised, must have processes in place that follow the Caldicott Guidelines<sup>50</sup> and are compatible with the Data Protection and Freedom of Information Acts.<sup>51,52</sup>
- 9.6 In recognition of the work being developed by the Department of Health in England on a common Sexual and Reproductive Health Activity Dataset (SRHAD) and similar work in the other UK countries, all services should be working towards computerised systems.<sup>53</sup> Data should be submitted to commissioners and the appropriate body in a timely and appropriate manner.
- 9.7 Contemporaneous, legible and complete signed records of consultations must be maintained. Each entry in electronic records should include the name of the clinician (who will be logged on to the system as a registered user).<sup>40</sup>



### 10. Standard Statement on Nurse-Led Service Provision

**The role of nurses in sexual and reproductive health service provision should be enhanced.<sup>38</sup>**

- 10.1 Services should have mechanisms in place to support nurses to supply and administer, or prescribe all methods of contraception, either through adequately supported patient group directions and/or nurse prescribing initiatives.<sup>54</sup>
- 10.2 Experienced nurses working in contraception should, when appropriate, be supported to acquire competencies for intrauterine and subdermal implant techniques and other new technologies as they are developed.<sup>55, 56</sup> They should also be supported when appropriate to become Faculty-registered nurse trainers.<sup>57</sup>
- 10.3 Services should fully develop the scope of nurses in service delivery including adequately supported fully nurse-led clinics providing the full range of SRH services, including counselling for abortion, menopause and vasectomy.<sup>58</sup>
- 10.4 The role of healthcare assistants/clinical support workers should be developed.

## 11. Standard Statement on Monitoring and Evaluation

**All services should continually monitor and evaluate themselves in order to maintain and improve performance.**

- 11.1 All providers should have a programme to regularly audit clinical service provision<sup>3,59</sup> in terms of quality as well as access, process and outcome issues from a consumer viewpoint. The results of audits should be acted upon to ensure appropriate improvements in service provision.
- 11.2 Commissioners for sexual health together with Level 3 services for their population should establish structures and processes for monitoring and evaluation of initiatives introduced to improve local sexual healthcare provision.<sup>3</sup> User involvement is essential in this process.<sup>3,8</sup>
- 11.3 All services should provide quarterly reports (e.g. SRHAD) to the appropriate body in a timely manner.<sup>53</sup>
- 11.4 Services should work to Faculty standards for risk management.<sup>60</sup>

### Glossary

BASHH	British Association for Sexual Health and HIV
DFSRH	Diploma of the Faculty of Sexual and Reproductive Healthcare
FFSRH	Fellow of the Faculty of Sexual and Reproductive Healthcare
FPA	Family Planning Association
FSRH	Faculty of Sexual and Reproductive Healthcare of the RCOG, formerly the Faculty of Family Planning and Reproductive Health Care (FFPRHC)
GMC	General Medical Council
IUD	intrauterine (contraceptive) device
IUS	intrauterine (contraceptive) system
MedFASH	Medical Foundation for AIDS & Sexual Health
MFSRH	Member of the Faculty of Sexual and Reproductive Healthcare
NICE	National Institute for Health and Clinical Excellence
NMC	Nursing and Midwifery Council
Open access	services which users can self-refer, irrespective of their area of residence
RCOG	Royal College of Obstetricians and Gynaecologists
SRH	sexual and reproductive health(care)
SRHAD	Sexual and Reproductive Health Activity Dataset
STI	sexually transmitted infection
Walk-in	services which users can access without an appointment
WHO	World Health Organization

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## Annex A



**Patient Experience Survey  
Contraception and Sexual Health Service  
'We need your views to help improve our service'**

We are keen to learn from your experiences of our services. Please help us by taking the time to answer the following simple questions:

1. What is the first part of your postcode? (e.g. M40)
2. Are you the patient / carer / parent / guardian / friend *(Please circle)*?
3. Which clinic did you attend?  Walk-in  Appointment
4. On what day have you attended *(Please circle)*?  
Monday / Tuesday / Wednesday / Thursday / Friday / Saturday
5. How did you hear about the clinic *(Please circle)*?  
GP / Internet / Poster / Service Information Leaflet / Friend / School Nurse / Walk-in centre / Other
6. What did you think about the following? *(Please tick one box for each question)*

	Excellent	Good	Fair	Poor
Clinic opening times	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Time taken to book in at reception	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Level of privacy and dignity at reception	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Respect and courtesy shown by reception staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cleanliness of the waiting area	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



7. How long have you waited to see a doctor/nurse today?

Less than 30 minutes

30–60 minutes

Between 1 and 2 hours

Over 2 hours

8. Thinking about your consultation with the doctor / nurse today, how do you rate the following?  
(Please tick one box per question)

	Excellent	Good	Fair	Poor
The doctor / nurse introducing themselves to you	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Whether the 'confidentiality policy' was explained to you	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How well you were listened to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Your involvement in decisions about your care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Your questions being answered well enough	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How private and confidential your appointment felt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The respect and courtesy shown by the doctor / nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How safe you felt during your appointment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you received about the service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information you received about your treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How satisfied you were after your visit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If you are aged under 25 years, how friendly the environment felt from your point of view	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Service Standards for Sexual and Reproductive Healthcare

9. Have you any other comments about this service?  
Please let us know how you felt about your visit, both good or bad, in the box below.

<p>All information shared with us will be used anonymously, stored confidentially and not shared with any external third party. This survey can be produced in other languages on request. We can also provide the information in other formats such as Braille and audio CD.</p>

If you are interested in being part of a service user group to help us develop and improve our service further (e.g. input into service leaflets) please leave your name and contact details below. We will contact you with more information.

Name	
Address	
Phone	
<p>How would you prefer we contact you?</p> <p> <input type="checkbox"/> Phone             <input type="checkbox"/> Letter             <input type="checkbox"/> Email         </p>	
Email address	

If you would like help or advice for any general community health issues you can contact the Patient Advice and Liaison Service (PALS):

Telephone .....

email .....

Or write to the PALS team at:

.....

.....

.....

## Service Standards for Sexual and Reproductive Healthcare

There is evidence to suggest that some groups of people suffer worse experiences of health services than others. We are keen to ensure that our services are suitable for all our communities so we'd be grateful if you would help us by completing the following.

(Please tick the boxes that apply to you)

Please state your age group:			<input type="checkbox"/> 0-18	<input type="checkbox"/> 18-30	<input type="checkbox"/> 31-50	<input type="checkbox"/> 51-64	<input type="checkbox"/> 65+ years
			<input type="checkbox"/> I do not wish to disclose this				
Please select your gender:							
Gender:			<input type="checkbox"/> Male	<input type="checkbox"/> Female	<input type="checkbox"/> Transsexual		
			<input type="checkbox"/> I do not wish to disclose this				
Do you consider yourself to have a disability?			<input type="checkbox"/> Yes	<input type="checkbox"/> No (Please move to next question)			
			<input type="checkbox"/> I do not wish to disclose this				
If yes, please state the type of impairment which applies to you. People may experience more than one type of impairment, in which case you may indicate more than one. If none of the categories apply, please mark 'Other'.			<input type="checkbox"/> Physical impairment				
			<input type="checkbox"/> Sensory impairment				
			<input type="checkbox"/> Mental health condition				
			<input type="checkbox"/> Learning disability/difficulty				
			<input type="checkbox"/> Longstanding illness				
			<input type="checkbox"/> Other - Please state:				
Please indicate your religion or belief:							
<input type="checkbox"/> Christianity	<input type="checkbox"/> Sikhism				<input type="checkbox"/> Other		
<input type="checkbox"/> Islam	<input type="checkbox"/> Buddhism				<input type="checkbox"/> None		
<input type="checkbox"/> Hinduism	<input type="checkbox"/> Judaism				<input type="checkbox"/> I do not wish to disclose this		
I would describe my ethnic origin as:							
<b>White</b> <input type="checkbox"/> British <input type="checkbox"/> Irish <input type="checkbox"/> Any other White background			<b>Black or Black British</b> <input type="checkbox"/> African <input type="checkbox"/> Caribbean <input type="checkbox"/> Any other Black background			<b>Other Ethnic Group</b> <input type="checkbox"/> Chinese <input type="checkbox"/> Any other ethnic group - please state:  <input type="checkbox"/> I do not wish to disclose this	
<b>Asian or Asian British</b> <input type="checkbox"/> Bangladeshi <input type="checkbox"/> Indian <input type="checkbox"/> Pakistani <input type="checkbox"/> Any other Asian background			<b>Mixed</b> <input type="checkbox"/> White & Asian <input type="checkbox"/> White & Black African <input type="checkbox"/> White & Black Caribbean <input type="checkbox"/> Any other mixed background				
Please select the option which best describes your sexuality:							
<input type="checkbox"/> Heterosexual	<input type="checkbox"/> Lesbian	<input type="checkbox"/> Gay	<input type="checkbox"/> Bisexual	<input type="checkbox"/> I do not wish to disclose this			

## Appendix I

### SERVICE STANDARDS FOR WORKLOAD

Published: July 2005

Current Version: May 2009

Review date: May 2012

#### Introduction

Within the UK there is considerable variation in sexual health service delivery, ranging from primary care/community-based contraceptive services which are separate from abortion services and genitourinary medicine (GUM) services, to fully integrated sexual health services in the community.

The quality of a service can be difficult to quantify and one of the measures which can be used is the workload expected from staff. Adequate time should be given to clients, without compromising quality of advice and service.

These standards apply to dedicated Sexual and Reproductive Health (SRH) (family planning) clinics working at Levels 1, 2 and 3 for contraception and Levels 1 and 2 for sexually transmitted infection (STI) services as described by the National Strategy for Sexual Health and HIV for England.<sup>1</sup> These services may be located in the community, general practice or hospital. The concept of 'levels' may not be replicated in other parts of the UK, but these Faculty of Sexual and Reproductive Healthcare (FSRH) recommendations are valid for other healthcare systems.

Published work on setting standards that has been checked for compatibility include Improving Working Lives,<sup>2</sup> Guidelines on Working Patterns for Junior Doctors,<sup>3</sup> the recently updated European Working Time Directive,<sup>4</sup> the Medical Foundation for AIDS & Sexual Health (MedFASH) sexual health standards,<sup>5</sup> the Scottish Standards for Sexual Health Services<sup>6</sup> and the Service Standards for Sexual Health Services from the FSRH.<sup>7</sup>

The original standards document written in 2005 was informed by a pilot questionnaire to members of the Clinical Standards Committee and an audit of length of consultations from one of the largest sexual health services, Abacus in Liverpool. An audit of those standards was undertaken in 2007. Recommendations from the audit have been taken into account when preparing this document.<sup>8</sup>

The work of administrative and clerical staff, especially receptionists, in providing a quality service should never be underestimated, but standards for this group of staff are outside the remit of this document.

Workload includes the following components:

- Numbers of clients seen in clinics;
- Length and type of consultation, including specific procedures [e.g. intrauterine device (IUD) or implant];
- Allowances for trainees, medical students and additional activities (e.g. research, audit);
- Skill mix and the role of doctors, nurses, clinical support and clerical staff;
- Characteristics of the population served (e.g. minority ethnic groups, asylum seekers, those whose first language is not English, those with other special needs or disabilities).

All services using these standards should be able to audit themselves against them.<sup>9</sup>

### I. Standard Statement on Meeting Population Needs

Services should aim to meet the needs of the population which they serve.<sup>9</sup>

- 1.1 Services should provide a selection of walk-in and appointment-only clinics. They should define open access both in terms of clinic provision and access to information. They should involve the local population in assessing their needs in terms of clinic mix, in conjunction with other sexual health services (e.g. by using accurate local data and client surveys).<sup>10,11</sup> Information should be available by leaflet, Internet, local telephone directories and as recorded information on an answerphone. The definition of an open access service is one to which clients can self-refer from anywhere (i.e. they do not need referral by a general practitioner or other health professional). The term walk-in refers to sessions for which there are no appointments.
- 1.2 Clients should be able to access urgent provision the same working day.<sup>7</sup>
- 1.3 Clients should be able to access telephone advice on the same working day.
- 1.4 Clients should be able to access non-urgent information, advice or services within 2 working days.<sup>7</sup>
- 1.5 For walk-in clinics, the waiting time should be no longer than 2 hours.<sup>7</sup> Appointments for procedures for long-acting methods should (if clinically appropriate) be offered within 4 weeks of initial contact.
- 1.6 There should be a mechanism to monitor missed telephone calls (9.00am–5.00pm).<sup>6</sup>
- 1.7 Services should adhere to national targets with respect to waiting times (i.e. 48-hour access to GUM, 12 weeks to first appointment, 18 weeks referral to treatment for specialist services).
- 1.8 Services should address workload in a way that is sensitive to the religious and cultural needs of the population, including asylum seekers (e.g. female staff in certain clinics, availability of chaperones,<sup>12</sup> access to asylum seeker support).
- 1.9 Services should have systems in place to address the needs of those for whom English is not the first language (e.g. translated leaflets, access to interpreting services, audio tapes for visually impaired clients, signers for people with hearing impairment).
- 1.10 Commissioners and service leads should work together to ensure that an SRH needs assessment has been undertaken within the last 3 years to determine the pattern of service provision. This is likely to include that there should be an equivalent of at least 2 full days per week of integrated sexual health clinic provision within 30 minutes' travelling time per settlement of 10,000 population.<sup>6</sup>
- 1.11 There should be local co-ordination of access to different services (e.g. to hub-and-spoke clinics, pharmacy provision, school-based services, outreach and primary care).
- 1.12 Clients should be able to access services at various locations and at various times of the day to suit their individual needs.

## 2. Standard Statement on Length of Consultation

**Clinics should be staffed to allow adequate time for clinical consultation, contemporaneous record keeping and associated administrative tasks, in order to provide clients with a high standard of appropriate care.**

2.1 At least 20 minutes should be allocated to a practitioner or clinical team (e.g. nurse + doctor) for the following consultations:

- 2.1.1 A new consultation
- 2.1.2 The first prescription of hormonal contraception
- 2.1.3 An IUD/ IUS insertion
- 2.1.4 An implant insertion and/ or removal
- 2.1.5 Pregnancy counselling
- 2.1.6 Male or female sterilisation counselling
- 2.1.7 A new contraceptive method.

Additional time is needed when multiple issues such as cervical smear taking, sexual health screening or partner notification is also undertaken or when there is a need to address complex contraceptive problems.<sup>13,14</sup>

- 2.2 At least 10 minutes should be allocated to a practitioner or clinical team for a routine follow-up appointment.
- 2.3 Extra time should be allotted to clients with special needs (e.g. the very young) and those groups that have special needs as identified by individual services (e.g. those requiring an interpreter).
- 2.4 Time should be allotted within clinic sessions for contemporaneous documentation, either written or IT input.
- 2.5 Clinicians should work for no more than 6 hours in the clinic setting with clients without a break (of at least 20 minutes).<sup>4</sup>
- 2.6 Time should be allotted within clinic sessions for letter writing/e-mail correspondence and related administrative work including IT data inputting.

### 3. Standard Statement on Skill Mix

Services should ensure that an appropriate skill mix of clinical staff is employed to maximise each clinician's potential to provide a high standard of care for clients.

- 3.1 Services, but not necessarily individual clinics, should be staffed by doctors, nurses and healthcare assistants working as a cohesive clinical team, to provide a high standard of effective care for clients and well-organised clinic facilities.
- 3.2 Services should have appropriate senior staff input. When provided, independent nurse clinics should be appropriately supported<sup>7</sup> by the presence of a doctor or senior nurse in the building or accessible by telephone.
- 3.3 Services should have in place mechanisms to support all clinicians to continue appropriate development, through ongoing training and other initiatives, including appropriately supported patient group directions (PGDs)<sup>7</sup> and standardisation of delivery of care.
- 3.4 Time should be allocated within the working week for reflective practice, liaison with colleagues and personal development.

## 4. Standard Statement on Training

**Adequate provision should be made within clinic time for the appropriate supervision of trainees and others in a learning role.**

- 4.1 Clinicians supporting a trainee should have appropriate allocated time, both within and outside clinic time (e.g. 20% fewer clients in clinics where training is taking place, longer appointment times or additional staff members with appropriate skill mix).
- 4.2 There should be on going encouragement of regular appropriately trained staff to become mentors/trainers.



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## Appendix 2

### SERVICE STANDARDS ON OBTAINING VALID CONSENT

Published: June 2007

Current Version: September 2011

Review date: September 2014

#### Introduction

**Consent** is a person's agreement for a health professional to provide care.

"It is a general legal and ethical principle that health professionals must obtain valid consent before starting treatment or physical investigation, or providing personal care. This principle reflects a person's right to determine what happens to his or her own body, and is a fundamental part of good practice."<sup>1</sup> Patients have rights to dignity, privacy and confidentiality. Seeking consent is also a matter of common courtesy between health professionals and patients.

For consent to be valid, the person must:

- Be competent to make that decision
- Have enough information to take the decision
- Be free from duress.

'Valid consent' is obtained by the person being informed of the nature and purpose of any proposed treatment and the likely outcome(s), including any significant possible adverse outcomes, and the likely result of not proceeding with the proposed treatment, so that the person can make an informed decision. The term 'informed consent' should not be used as this legally means that the person has been informed of every conceivable outcome and risk, however remote.

While there is no English statute setting out the general principles of consent, case law ('common law') has established that touching a person without valid consent may constitute the civil or criminal offence of battery. Further, if doctors and other healthcare professionals fail to obtain valid consent and the person subsequently suffers harm as a result of treatment, this may be a factor in a claim of negligence against the professional involved. Poor handling of the consent process may also result in complaints from patients. Case law on consent has evolved significantly over recent years. Further legal developments may occur after this guidance has been issued, and health professionals must remember their duty to keep themselves informed of legal developments that may have a bearing on their practice. Legal advice should always be sought if there is doubt about the legal validity of a proposed intervention. While much of the case law refers specifically to doctors, the same principles will apply to other health professionals involved in examining or treating patients.

The Human Rights Act 1998<sup>2</sup> came into force in October 2000, giving further effect in the UK to the rights enshrined in the European Convention on Human Rights. In future, courts will be expected to take into account the case law of the European Court of Human Rights, as well as English case law.

### Capacity and Incapacity

In order to give valid consent a patient must have capacity. This is a legal concept and relates to the way in which the patient arrives at a decision, rather than the appropriateness of their decision.

The law in England and Wales, and in Northern Ireland,<sup>3</sup> presumes that adults (persons aged 18 years and over) have the capacity to make their own decisions unless there is reason to believe otherwise. The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position of adults, in particular, where treatment is being refused. Young people aged 16 or over, but under 18, can give independent consent to their own treatment (but this can be overruled by a court order). Young people under 16 can give their own consent to treatment provided that they are judged capable of understanding what is involved; each case being judged on its own merits. The law in Scotland presumes that people aged 16 and over have the capacity to make their own decisions. In Scotland,<sup>4</sup> a young person under 16 can consent to, or refuse, any treatment if the qualified medical practitioner attending them believes that they are capable of understanding the nature and possible consequences of the treatment.

The Mental Capacity Act 2005 (<http://www.justice.gov.uk/guidance/mental-capacity.htm>) covering England and Wales, enshrines in statute what common law suggests regarding the care of those who lack capacity to consent. It provides a statutory framework for people who may not be able to make their own decisions, for example, because of a learning disability, an illness such as dementia or mental health problems. It sets out who can take decisions, in which situations, and how they should go about this. It defines incapacity as an inability to make a decision for each intervention and states "A person is unable to make a decision if s/he cannot:

- Understand information relevant to the decision
- Retain that information for as long as necessary to make that decision
- Use or weigh that information, or
- Communicate the decision."

It goes on to state "**before deciding that a person is incapable, all practical steps should be taken to assist the person to make his/her decision**". This should include involving more specialist colleague(s). Guidance on how people should be helped to make their own decisions is given in Chapter 3 of the Mental Capacity Act (2005) Code of Practice.<sup>5</sup>

In Scotland, the framework for regulating interventions into the property, financial affairs and personal welfare of adults with impaired capacity is set out in The Adults with Incapacity (Scotland) Act 2000.<sup>6</sup> Guidance on this Act and how it affects health professionals is also available.<sup>7</sup>

## Note

This document has been produced to assist health professionals working in the field of contraception and reproductive health service provision. Consequently it has been assumed that colleagues working in these settings will not be involved in obtaining valid consent in the following situations:

- Removal of organs or tissue from patients who have been declared dead, whether for diagnostic, therapeutic or research purposes
- Specialised subfertility practice covered by the Human Fertilisation and Embryology Act 2008
- Organ transplantation
- Withdrawing and withholding life-prolonging treatment
- Permission to conduct a post-mortem examination.

To avoid multiple reference annotation, it should be noted that statement points not specifically referenced can be found in numerous documents already referenced.

### I. Standard Statement on Training in Seeking and Obtaining Valid Consent

**All staff should have training and ongoing support in seeking and obtaining valid consent.**

- 1.1 Clinical and non-clinical staff should receive appropriate training in obtaining valid consent.
- 1.2 All staff should receive training on national Child Protection procedures and be able to use local Child Protection/Safeguarding Children policies and protocols.
- 1.3 All staff working with young people should be familiar with the latest Department of Health Guidance on the care of under-16s.
- 1.4 All staff working with young people under 16 should be familiar with and use the Fraser Guidelines (or equivalent guidance) on competence.
- 1.5 All staff should be trained in the legal requirements of the Data Protection Act as they apply to health services.
- 1.6 All staff should receive Caldicott training.

## 2. Standard Statement on Process of Obtaining Valid Consent

All staff should be aware of the process of obtaining valid consent. This includes: purpose, process, assessment of capacity, provision of information and assessment of a patient's autonomy.

### 2.1 Purpose

- 2.1.1 All staff should be aware that people have a fundamental legal and ethical right to determine what happens to their own bodies.
- 2.1.2 Valid consent should be obtained before examining, starting treatment or physical investigation, or providing personal care for a patient.
- 2.1.3 The consent of a patient is required before any disclosure of information obtained in the course of their healthcare, except in exceptional circumstances where disclosure is to protect the individual from serious harm or is in the public interest (cf. *Standards on Confidentiality* published by the FSRH;<sup>8</sup> MedFASH Sexual Health Standards<sup>9</sup>).
- 2.1.4 Health professionals should be aware that if they do not respect this principle, they may be liable both to legal action by the patient and action by their professional body.
- 2.1.5 Employing bodies should be aware that they may be liable for the actions of their staff if this principle is not respected.

### 2.2 Process

- 2.2.1 For consent to be valid the patient must:
  - Be competent to take the particular decision **and**
  - Have received sufficient information to take the particular decision **and**
  - Not be acting under duress or undue influence from partners, family, friends, health professionals or other agencies.
- 2.2.2 Giving and obtaining consent is usually a process, rather than a one-off event. Patients can change their minds and withdraw their consent at any time.
- 2.2.3 A person may be competent to make some healthcare decisions, even if s/he is not competent to make others (i.e. consent is 'decision-specific').

### 2.3 Assessment of Capacity to Consent

- 2.3.1 The health professional seeking to obtain valid consent must be sure that the person giving consent can understand, retain and use/weigh the information relating to the decision.
- 2.3.2 Adults (persons aged 18 years and over) are assumed to be competent to give consent unless there is reason to believe otherwise (see Introduction regarding Capacity and Incapacity).
- 2.3.3 No-one can give consent to examination or treatment on behalf of an adult who is deemed unable to give consent for him/herself (see Standard 8).
- 2.3.4 Adults are presumed to have capacity to give or withhold consent to examination, investigation or treatment, but where any doubt exists the health professional should assess the capacity of the patient to take the decision in question.
- 2.3.5 The assessment of capacity and the conclusions drawn from it should be recorded in the patient's notes.
- 2.3.6 An adult's incapacity may be temporary or long-standing and in these circumstances the law permits interventions, which are necessary in the patient's best interests.
- 2.3.7 Where the adult has never been competent, relatives, carers and friends may be well placed to advise on the patient's needs and preferences. It is advisable to involve a consultant in learning disability psychiatry and the multidisciplinary team in the decision-making process, and to document their involvement (see also Standard 8).
- 2.3.8 Under Section 8 of the Family Law Reform Act 1969,<sup>10</sup> young people aged 16 and 17 years are entitled to consent to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic. As for adults, consent is valid only if it is given voluntarily by an appropriately informed patient capable of consenting to the particular intervention. However, unlike adults, the refusal of a competent person aged 16-17 years may in certain circumstances be overridden by either a person with parental responsibility or a court (see 9.11).
- 2.3.9 Young people aged under 16 who understand fully what is involved in the proposed procedure or treatment can give consent (although their parents, or someone with parental responsibility, should ideally be involved)<sup>3,4,11</sup> (see 9.1).
- 2.3.10 Where a young person is assessed as not competent to give consent, someone with parental responsibility must give consent on the young person's behalf (see 9.10).
- 2.3.11 If a competent young person consents to treatment, a parent cannot override that consent (see 9.1).
- 2.3.12 Health professionals should take all reasonable steps to facilitate communication with the patient, using interpreters or communication aids as appropriate.

### 2.4 Provision of Information Prior to Obtaining Valid Consent

2.4.1 Patients should receive evidence-led, objective information, supplied in a way that they can understand, before they give or withhold consent to the proposed examination, diagnostic procedure or treatment. Information should include:

- The nature of the intended intervention
- The purpose of the treatment
- The known risks, benefits and uncertainties of the treatment (including some quantification of risk, if known)
- The implications of not carrying out the procedure or treatment (including some quantification of risk, if known)
- The known risks, benefits and uncertainties of alternative interventions (including some quantification of risk, if known).

2.4.2 Information should be given regarding 'significant' risks (i.e. information to which any reasonable person in the same situation would attach significance).<sup>12,13</sup>

2.4.3 Information about anaesthesia should be given as well as information about the procedure.<sup>14</sup>

2.4.4 Patients need to know whether additional procedures are likely to be necessary as part of the procedure; consent should be sought for any treatment to deal with problems that may arise during the procedure.

2.4.5 GMC guidance<sup>15</sup> and MedFASH standards<sup>9</sup> state that clinicians should do their best to find out about patients' individual needs and priorities when providing information about treatment options and that if the patient asks specific questions about the procedure and associated risks these should be answered truthfully.

2.4.6 If the health professional believes that to follow the guidance in the above paragraphs in full would have a deleterious effect on the patient's health, the GMC guidance states that this view, and the reasons for not following the guidance, should be recorded in the patient's notes.

If information about the treatment that is being proposed is offered to a patient and declined, it is good practice to record this fact in the notes.

2.4.7 Patients should be treated with courtesy and respect and their dignity should be maintained at all times. Adequate privacy should be ensured for information giving. Patients should not be given important information or asked to make decisions whilst undergoing intimate examinations.

2.4.8 Staff should reinforce verbal information with information that is appropriate to the user, for example, printed (or written) information, pictorial or information in other media which the patient can retain.



### 2.5 Assessment of a Patient's Autonomy

- 2.5.1 To be valid, consent must be given voluntarily and freely, without pressure or undue influence being exerted on the patient either to accept or refuse treatment.
- 2.5.2 Health professionals must ensure that patients have reached their own decisions and understand that they can change their minds if they do not wish to continue with the procedure.
- 2.5.3 Health professionals should be alert to the possibility that pressure or undue influence can come from partners, family members or friends, as well as healthcare and social care professionals, and where appropriate should arrange to see the patient on their own to establish that the decision is truly that of the patient.
- 2.5.4 In environments where involuntary detention may be an issue (e.g. prison, mental health settings), staff should be careful to avoid the potential for treatments to be perceived coercively, since coercion invalidates consent.

### 3. Standard Statement on Who Should Seek Consent

The clinician providing the treatment or investigation is responsible for ensuring that the patient has given valid consent before treatment begins.

- 3.1 Where verbal, non-verbal or written consent is being sought for examination, investigation, treatment or care, the health professional carrying out the procedure should seek consent from the patient. If the task of seeking written consent is delegated to another health professional, that professional must be capable of performing the procedure in question, or have been suitably trained and qualified, have sufficient knowledge of the proposed investigation or treatment, and understands the risks involved, in order to be able to provide any information the patient may require.<sup>15</sup>
- 3.2 The clinician performing the procedure must ensure that valid consent has been obtained before treatment begins. If the clinician delegates, he/she is still responsible for making sure that the patient has been given enough time and information to make an informed decision, and has given their consent, before starting any investigation or treatment.<sup>15</sup>

### 4. Standard Statement on When to Obtain Consent

Staff should be aware that the process of seeking consent may take place at one time, or over a series of meetings and discussions. This should be documented appropriately.

All staff should be aware that:

- 4.1 A health professional can initiate a procedure immediately after discussing it with the patient, provided that the principles of obtaining valid consent (capacity, information and voluntariness) have been met.
- 4.2 For procedures where written consent is sought, health professionals must allow the patient sufficient time to absorb the information necessary for her/him to make her/his decision; it is good practice to seek the patient's consent to the proposed procedure well in advance and then check, before the procedure starts, that the patient still consents.
- 4.3 The timing of the process of seeking consent should be sufficiently close to the intervention for the patient to recall what they have been told about it; however, seeking consent when the patient may be feeling vulnerable is likely to be regarded as invalid.

### 5. Standard Statement on Method of Giving and Recording Consent

Valid consent may be given in a number of different ways but should be documented.

All staff should be aware that:

- 5.1 Legally, verbal and written consent are **equally** valid.
- 5.2 Consent may be implied (non-verbal) or expressed (verbal or written).
- 5.3 The form in which the patient expresses consent should be documented in the patient's record.<sup>16</sup>
- 5.4 Implied consent (non-verbal) or verbal consent is sufficient for procedures such as venepuncture, taking blood pressure, speculum examination, taking of swabs, cervical cytology, colposcopy, insertion or removal of intrauterine devices and subdermal implants.
- 5.5 It is good practice to obtain written consent for specific procedures such as:
  - A procedure that involves significant risks (e.g. abortion, sterilisation)
  - A procedure that involves general/regional anaesthesia or sedation
  - Pelvic examination by medical students of anaesthetised women
  - Participation in a research project or programme
  - A procedure or treatment being offered that is of an experimental nature<sup>17</sup>
  - Recording and use of multimedia images
  - Disclosure of records.<sup>16,18</sup>
- 5.6 For procedures involving significant risks, it is essential for health professionals to document clearly both a patient's agreement to the intervention and the discussions that led up to this agreement, including the provision of any patient information materials.
- 5.7 A signature on a consent form is not proof of valid consent but is evidence of the process of consent-giving and is not a binding contract; patients may, if they wish, withdraw their consent after they have signed a form.
- 5.8 If consent has been validly given and documented, the lack of a completed consent form is no bar to treatment.
- 5.9 Completion of a consent form is in most cases **not** a legal requirement (exceptions include certain requirements of the Mental Health Act 1983 and of the Human Fertilisation and Embryology Act 2008).

- 5.10 A patient who has capacity to consent, but is illiterate, may be able to make a mark on a consent form to indicate that the consent-giving process has taken place. It is good practice for this mark to be witnessed by an appropriate adult, and for that fact that the patient has chosen to make their mark in this way to be recorded in the patient's notes.
- 5.11 If a patient has capacity to consent, and wishes to give consent, but is physically unable to mark the form, this fact should be recorded in the notes.
- 5.12 Explicit consent must be sought for the presence of medical students and other clinicians in training during consultations, in operating theatres as observers and assistants, and for students performing clinical examinations; this may be given verbally and documented accordingly.

### 6. Standard Statement on the Duration of a Patient's Consent

Staff should be aware that valid consent to an intervention remains valid for an indefinite duration unless it is withdrawn by the patient or the patient loses capacity to consent in which case this should be clearly documented.

All staff should be aware that:

- 6.1 If consent has been obtained a significant time before undertaking the intervention, it is good practice to confirm that the person who has given consent retains capacity and that the person still wishes the intervention to proceed. This applies even if no new information needs to be provided or further questions answered. A health professional involved in their care on the day should document that the patient still wishes to go ahead and has had any further questions answered.
- 6.2 If new information becomes available regarding the proposed intervention (e.g. new evidence of risks or new treatment options) between the time when consent was sought and when the intervention is undertaken, a health professional should inform the patient and reconfirm their consent by repeating the process of seeking consent on the basis of this new information. Similarly, if the patient's condition has changed significantly in the intervening time it may be necessary to seek consent again, on the basis that the likely benefits and/or risks of the treatment may also have changed.
- 6.3 A patient with capacity is entitled to withdraw consent at any time, including during the performance of a procedure.

### 7. Standard Statement on Refusal of Treatment by Adults with Capacity

**If an adult with capacity makes a voluntary and appropriately informed decision to refuse treatment this decision must be respected, except in circumstances defined by the Mental Health Act 1983.**

All staff should be aware that:

- 7.1 The Mental Health Act 1983<sup>19</sup> [Mental Health (Care and Treatment) (Scotland) Act 2003]<sup>20</sup> sets out circumstances in which patients detained under the Act may be treated without consent for their mental disorder. It has **no** application to treatment for physical disorders unrelated to the mental disorder, which remains subject to the common law principles set out in Standards 2.
- 7.2 Patients may have an 'advance directive' specifying how they would like to be treated in the case of future incapacity. An advance refusal of treatment which is valid (made voluntarily by an appropriately informed person with capacity) and applicable to subsequent circumstances, in which the patient lacks capacity, is legally binding and must be respected. If there is doubt about the validity of an advance refusal a ruling should be sought from the court.
- 7.3 Decisions taken by a patient, which are unusual, unexpected or not what the health professional would have chosen for him/herself, do not mean that the patient lacks capacity; it may highlight the need for further information or a clearer explanation. People are entitled to make decisions based on their own religious belief or value system, even if it is perceived by others to be irrational, as long as the patient understands what is entailed in their decision. However, if the decision that appears irrational is based on a misperception of reality then the patient may not be able to comprehend and make use of the relevant information and hence may lack capacity to make the decision in question.

### 8. Standard Statement on Treatment of Adults Who Lack Capacity

The Mental Capacity Act 2005 should be referred to when caring for adults who lack the capacity to make their own decisions.<sup>5</sup>

- 8.1 Treatment can be given if it is believed by the health professional to be in the patient's 'best interests'. The process of reaching this decision can be recorded using Consent Form 4.<sup>21</sup> 'Best interests' are not confined to best **medical** interest but the most appropriate therapeutic response should also be considered where relevant.<sup>1</sup>
- 8.2 In considering the relevant circumstances, the Act rules that the healthcare professionals **must** take the following steps:
- Consider whether the person is likely to regain capacity and if so involve the person as fully as possible in the decision that is being made on their behalf.
- As far as possible, consider: the person's past and present wishes and feelings (in particular if they have been written down) any beliefs and values (e.g. religious, cultural or moral) that would be likely to influence the decision in question, and any other relevant factors, and the other factors that the person would be likely to consider if they were able to do so.
- 8.3 As far as possible, consult other people if it is appropriate to do so and take into account their views as to what would be in the best interests of the person lacking capacity, especially:<sup>22</sup> anyone previously named by the person lacking capacity as someone to be consulted anyone engaging in caring for or interested in the person's welfare any attorney appointed under a Lasting Power of Attorney any deputy appointed by the Court of Protection to make decisions for the person.
- 8.4 Independent Mental Capacity Advocates (IMCAs) are not decision-makers for the person who lacks capacity. They are there to support and represent that person and to ensure that decision-making for people who lack capacity is done appropriately and in accordance with the Mental Capacity Act 2005.<sup>23</sup>
- 8.5 Where there is doubt about an individual's capacity or best interests, a court ruling should be sought. It is good practice to seek a court ruling prior to undertaking certain interventions which arouse particular concern, namely sterilisation for contraceptive purposes, medical or surgical abortion.
- 8.6 The Mental Capacity Act 2005 Code of Practice<sup>5</sup> sets out a legal framework for involving people who lack the capacity to consent to taking part in research. The Act does not include clinical trials, which are covered by The Medicines for Human Use (Clinical Trials) Regulations 2004 (<http://www.legislation.gov.uk/ukSI/2004/1031/contents/made>).



### 9. Standard Statement on Consent to Treatment for Children and Young People

**The process of obtaining valid consent to treatment for children and young people must be in accordance with current legislation and follow guidance from professional and employing bodies.<sup>11,24,25</sup>**

- 9.1 The legal framework on consent, confidentiality and safeguarding (child protection) is covered by the General Medical Council publication, *0-18 Years: Guidance for All Doctors*.<sup>26</sup> This document includes more detailed information covering each of the UK nations. In law, any competent young person in the UK can consent to medical treatment including contraception. Young people over 16 years of age, including those with a disability/impairment, are presumed to be competent to give consent to medical treatment unless otherwise demonstrated. For young people under the age of 16 years, however, competence to consent has to be demonstrated. A young person must have sufficient understanding and maturity to understand fully what is proposed (England, Wales and Northern Ireland) or be capable of understanding the nature and possible consequences of the treatment (Scotland).<sup>6</sup>
- 9.2 In England, Wales and Northern Ireland, those under the age of 13 years are considered unable to legally consent to sexual activity.<sup>27,28</sup> In Northern Ireland, there is no statutory duty under criminal law to report to the police cases of sexual activity involving children under the age of 16 years unless the child is under 13 years or the other party is aged 18 years or over. In the Sexual Offences Scotland Act 2009,<sup>29</sup> sexual activity with a male or female aged under 13 years is “rape of a young child”.
- 9.3 The assessment of a young person’s capacity to make a decision about contraception or medical treatment is a matter of clinical judgement guided by professional practice and legal requirement.<sup>30</sup> Assumptions should not be made about an individual’s capacity to consent based on age alone or disability.<sup>6,30</sup>
- 9.4 Following the case of Gillick<sup>31</sup> in 1986, the courts have held that children and young people under 16 who have sufficient understanding and maturity to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent for treatment (Fraser competence).<sup>11,32</sup> In England, Wales and Northern Ireland, in order to provide contraception to young people under 16 years of age without parental consent, it is considered good practice to follow the Fraser Guidelines/criteria.<sup>26</sup> In Scotland, although the Fraser Guidelines are sometimes used by health professionals, they have no authority in Scottish law. The primary legislation when determining ‘competency’ is the Age of Legal Capacity (Scotland) Act 1991, whereby the only criterion is that the child understands the nature and consequence of the treatment.

Fraser Guidelines/criteria:<sup>4</sup>

1. The young person understands the professional’s advice.
2. The young person cannot be persuaded to inform their parents.
3. The young person is likely to begin, or to continue having, sexual intercourse with or without contraceptive treatment.
4. Unless the young person receives contraceptive treatment, their physical or mental health, or both, are likely to suffer.
5. The young person’s best interests require them to receive contraceptive advice or treatment with or without parental consent.

Health professionals may wish to use a checklist (e.g. Fraser Guidelines) to assess competency and risk when providing contraceptive advice or treatment to young person.

- 9.5 A clinician should assess a young person's competence to consent to treatment by their ability to understand information provided, to weigh up the risks and benefits, and to express their own wishes.
- 9.6 Competence to consent to treatment should be assessed and documented at each visit where relevant (e.g. for under-16-year-olds).<sup>32</sup>
- 9.7 In England, Wales and Northern Ireland, unlike adults, the refusal of treatment by a competent person aged 16–17 years may in certain circumstances be overridden by either a person with parental responsibility or a court. This is not the case in Scotland where young people aged 16 years and over are considered competent to consent to, and refuse treatment.<sup>3,30</sup>
- 9.8 As the understanding required for different interventions will vary considerably, a young person under 16 may have the capacity to consent to some interventions but not others (decision-specific consent).
- 9.9 Where a child or young person lacks capacity to consent, consent can be given on their behalf by anyone with parental responsibility or by the court. Those giving consent on behalf of young people must have the capacity to consent to the intervention in question, be acting voluntarily and be appropriately informed. The power to consent must be exercised according to the 'welfare principle'. Even where a child lacks capacity to consent on their own behalf, it is good practice to involve the child as much as possible in the decision-making process.
- 9.10 The Children Act 1989<sup>33</sup> sets out persons with parental responsibility. These include:
  - The child's parents if married to each other at the time of conception or birth;
  - The child's mother, but not the father if they were not so married unless the father has acquired parental responsibility via a court order or a parental responsibility agreement or the couple subsequently marry;
  - The child's legally appointed guardian;
  - A person in whose favour the court has made a residence order concerning the child;
  - A Local Authority designated in a care order in respect of the child;
  - A Local Authority or other authorised person who holds an emergency protection order in respect of the child.

Section 2(9) of the Children Act 1989 states that a person who has parental responsibility for a child "may arrange for some or all of it to be met by one or more persons acting on his behalf". Such a person might choose to do this, for example, if a childminder or the staff of a boarding school have regular care of their child. As only a person exercising parental responsibility can give valid consent, in the event of any doubt specific enquiry should be made. Foster parents do not automatically have parental responsibility.

- 9.11 The Adoption and Children Act 2002<sup>34</sup> amended The Children Act 1989<sup>33</sup> to provide that an unmarried father acquires parental responsibility where he and the child's mother register the birth of their child together; and introduced a new special guardianship order, intended to provide permanence for children for whom adoption is not appropriate.
- 9.12 The Civil Partnerships Act 2004<sup>35</sup> amended The Children Act 1989<sup>33</sup> under the section relating to "acquisition of parental responsibility by step-parent" to include civil partners as well as married partners.
- 9.13 Consent given by one person with parental responsibility is valid, even if another person with parental responsibility withholds consent.
- 9.14 Where the mother of a child is herself under 16, she will only be able to give valid consent for her child's treatment if she herself is 'Fraser competent'.<sup>11</sup>
- 9.15 Where a child or young person is a ward of court, no important step may be taken in the life of the ward without the prior consent of the court. This is likely to include more significant medical interventions.
- 9.16 Where a young person of 16 or 17, or a child under 16 who is deemed 'Fraser competent, consents to treatment, this cannot be overruled, but if they refuse treatment, such a refusal can be overruled (except in Scotland) either by a person with parental responsibility for the child or by the court. This power to overrule must be exercised on the basis that the welfare of the child/young person is paramount. As with the concept of 'best interests', 'welfare' does not just mean physical health. The psychological effect of having the decision overruled must also be considered. While no definitive guidance has been given as to when it is appropriate to overrule a competent young person's refusal, it has been suggested that this should be restricted to occasions where the child/young person is at risk of suffering "grave and irreversible mental or physical harm". It may include a young person with capacity refusing an abortion being overruled by a person with parental responsibility. It is recommended that health professionals seek a court ruling prior to undertaking the intervention, particularly as the parent(s) must be provided with information about their child's condition which the child/young person may not be willing for them to receive and this may involve a breach of confidence on the part of the clinician treating the young person (which may be justifiable where it is in the child's best interests).
- 9.17 If the young person seeks advice or treatment in relation to abortion and cannot be persuaded to inform her parent(s), every effort should be made to help them find another adult (such as another family member or a specialist youth worker) to provide support. The putative father of a fetus cannot influence whether or not his partner requests an abortion (cf. case law).

### 10. Standard Statement on Consent Policies

All services should have a written policy on seeking and obtaining valid consent.

- 10.1 Service consent policies generally should be informed by, and updated in line with, latest national guidance [e.g. from the Department of Health, Scottish Executive, The Welsh Office, the Department of Health, Social Services and Public Safety (Northern Ireland), GMC and other professional organisations].  
<http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?contentid=4006131&chk=DCfGrj>  
<http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=465&id=99091>  
[http://www.sehd.scot.nhs.uk/mels/HDL2006\\_34.pdf](http://www.sehd.scot.nhs.uk/mels/HDL2006_34.pdf)  
[http://www.dhsspsni.gov.uk/public\\_health\\_consent](http://www.dhsspsni.gov.uk/public_health_consent)  
[http://www.gmc-uk.org/guidance/ethical\\_guidance/consent\\_guidance\\_index.asp](http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp)
- 10.2 Service consent policies should be in line with and endorsed by local NHS Trusts.
- 10.3 All staff should work to the service's consent policy.

### Further Guidance

The Department of Health has issued a range of guidance documents on consent and these should be consulted for details of the law and good practice requirements on consent. Doctors and other health professionals must also be aware of any guidance on consent issued by their own regulatory bodies (e.g. GMC, NMC, RSPGB).

The following guidance documents are available from the Department of Health and can be accessed on the Internet at [www.dh.gov.uk/consent](http://www.dh.gov.uk/consent).

- ✓ Reference Guide to Consent for Examination or Treatment<sup>1</sup> provides a comprehensive summary of the current law on consent, and includes requirements of regulatory bodies such as the GMC where these are more stringent.
- ✓ 12 Key Points on Consent: The Law In England. This one-page document summarises those aspects of the law on consent which arise on a daily basis and is available at:  
[www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4006131&chk=DCfGrj](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4006131&chk=DCfGrj)
- ✓ Specific guidance, incorporating the law and good practice advice, is available for health professionals working with children, with people with learning disabilities and with older people.
- ✓ Model policy for consent to examination or treatment:  
[www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_1036431](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_1036431)
- ✓ Consent forms:
  - About the consent form<sup>36</sup>
  - Consent Form 1 – patient agreement to investigation or treatment<sup>37</sup>
  - Consent Form 2 – parental agreement to investigation or treatment for a child or young person<sup>38</sup>
  - Consent Form 3 – patient/parental agreement to investigation or treatment (procedures where consciousness not impaired)<sup>39</sup>
  - Consent Form 4 – form for adults who are unable to consent to investigation or treatment.<sup>40</sup>

These consent forms are in the process of being updated and guidance is given to assist in amending them locally in the light of the Department of Health guidance 2009.<sup>1</sup>

The Welsh Office has guidance available at:

<http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=465&id=99091>

The Scottish Executive issued a document in June 2006 [NHS HDL (2006) 34] to assist health professionals working in NHS Scotland entitled *A Good Practice Guide on Consent for Health Professionals in the NHS Scotland* and this is available at: [www.sehd.scot.nhs.uk/mels/HDL2006\\_34.pdf](http://www.sehd.scot.nhs.uk/mels/HDL2006_34.pdf)

The Department of Health, Social Services and Public Safety in Northern Ireland has published a *Reference Guide to Consent for Examination, Treatment of Care* and this may be accessed at:

[http://www.dhsspsni.gov.uk/public\\_health\\_consent](http://www.dhsspsni.gov.uk/public_health_consent)

Guidance on consent is also produced by the General Medical Council,<sup>15</sup> the Royal College of Obstetricians and Gynaecologists<sup>40</sup> and the British Medical Association.<sup>41</sup>

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## SERVICE STANDARDS ON CONFIDENTIALITY

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### Introduction

Patient information is generally held under legal and ethical obligations of confidentiality. Patients entrust the National Health Service (NHS) or allow it to gather sensitive information relating to their health and other matters as part of their seeking treatment. They do so in confidence and they have the legitimate expectation that staff will respect this trust. It is essential, if the legal requirements are to be met and the trust of patients is to be retained, that the NHS provides, and is seen to provide, a confidential service. This is of particular importance to matters relating to sexual and reproductive health (SRH).

SRH services have an excellent track record as far as confidentiality is concerned, but services need to keep up to date with current national policies and guidance. The core guidance document is the NHS Confidentiality Code of Practice<sup>1</sup> with which all staff should be familiar as it is a guide to required practice for all those working within or under contract to NHS organisations. This Code has been endorsed by the Information Commissioner, General Medical Council (GMC), British Medical Association (BMA) and the Medical Research Council (MRC). In addition, all staff should be aware of the NHS Code of Practice on Information Security Management 2007<sup>2</sup> and the document Joint Guidance on Use of IT Equipment and Access to Patient Data published by the Department of Health (DH), GMC and Information Commissioner.<sup>3</sup> The duty of confidence must be included within NHS employment contracts as a specific requirement linked to disciplinary procedures.

All healthcare professionals must maintain the standards of confidentiality laid down by their professional body, such as the GMC or Nursing and Midwifery Council (NMC), or risk complaint for professional misconduct. Breach of confidence, inappropriate use of health records or abuse of computer systems may result in a warning, restriction of practice, removal from the register, and possibly result in legal proceedings.

The term 'service' is used in this document to denote any provider of SRH services (i.e. it includes services in general practice, community clinics and hospital-based settings). The standards apply to all NHS organisations, including NHS Foundation Trusts, and private/independent and voluntary providers of NHS care. Throughout this document the term 'staff' is used to mean all personnel, whether paid or voluntary, who are involved in the delivery of the service. This includes volunteers and visitors to services as well as students and trainees.

The Faculty has already published a document on Service Standards for Sexual Health Services,<sup>4</sup> which includes a standard on confidentiality. This paper seeks to expand on the initial statement, to cover guidance from the DH<sup>1-3,5-8</sup> GMC<sup>9,10</sup> and other professional organisations.<sup>11-14</sup> The DH published *Standards for Better Health*<sup>5</sup> in 2004 and this states as Core Standard C13: Healthcare organisations must have systems in place to ensure that:

- Staff treat patients, their relatives and carers with dignity and respect;
- Appropriate consent is obtained when required for all contacts with patients and for the use of any patient confidential information;
- Staff treat patient information confidentially, except where authorised by legislation to the contrary.

Clients need to know that personal information is secure and that it is handled with care and respect by health professionals, but confidentiality does not mean that information cannot be shared. It is paramount that clients understand why and in what circumstances information needs to be passed on to others and whether it will be identifiable or anonymous.

Individuals already have the right to access their own personal information under the Data Protection Act 1998.<sup>15</sup> The Freedom of Information Act 2000<sup>16</sup> extends this to allow access to all types of public information. It is important that clients understand that the protection of their identifiable personal information always overrides this.

Fundamental to the whole of this document is the existence of a written confidentiality policy for every service. Guidance is given as to the content of the policy. In particular, SRH service providers need to be aware of the possibilities of inadvertent breaches of confidentiality (e.g. overhearing of conversations between staff, overhearing of telephone conversations between staff and clients, information seen on computer screens, fax machines, etc). It is essential that clerical and other non-clinical staff are as conversant with confidentiality issues as are clinical staff. A sample confidentiality policy, agreement and statement, together with staff training modules, are available in the Royal College of General Practitioners (RCGP)/Brook publication *Confidentiality and Young People Toolkit*.<sup>13</sup>

Confidentiality is a clinical governance issue – serious breach of confidentiality by NHS employees carries with it severe penalties. The Caldicott principles<sup>17,18</sup> should always be followed:

- Justify the purpose
- Don't use patient identifiable information unless it is absolutely necessary
- Use the minimum necessary patient identifiable information
- Access to patient identifiable information should be on a strict need-to-know basis
- Everyone should be aware of their responsibilities
- Understand and comply with the law.

There are three areas of law that are most relevant to the processing of patient information. These are:

## 1. The Human Rights Act 1998<sup>19</sup>

Article 8 of the Human Rights Act establishes a right to “respect for private and family life”. Anyone who processes patient information must do so for necessary and legitimate purposes or be in breach of the Act.

## 2. The Data Protection Act 1998<sup>15</sup>

The Data Protection Act regulates how data about identifiable individuals may be processed. It contains eight principles and a number of other relevant sections, the most significant of which in this context are:

- 2.1 The 1st Principle which requires data processing to be fair to the individual concerned and lawful in terms of wider UK law.
- 2.2 The 7th Principle which requires those responsible for personal data to protect it against unauthorised or unlawful processing and against accidental loss, destruction or damage. It also requires that security measures must be commensurate with the nature of the data and the harm that may be suffered from a breach of security. Steps must also be taken to ensure that staff with access to the data are reliable.
- 2.3 Section 55 which makes it a criminal offence to obtain or disclose personal data unlawfully.

### 3. The Common Law of Confidentiality

Although not codified in an Act of Parliament, common law is built up from case law where practice has been established by individual judgements. The key principle is that information confided for the purpose of receiving care and treatment should not be processed for other purposes except in circumstances where the law permits or requires it. The great majority of health professionals take their responsibility for safeguarding clinical patient information extremely seriously and appreciate the obligations of confidentiality that apply. However although non-clinical patient contact details are, in most cases, not held under legal obligations of confidentiality, this is not the case for all patients, so it is DH policy to treat demographic data held within the Personal Demographic Service as if it were.

The Information Commissioner is the independent authority responsible for overseeing and governing the Data Protection Act 1998 and the Freedom of Information Act 2000. He has a range of duties including promotion of good information handling and encouragement of codes of practice for data controllers (those who decide how and why personal data are processed). His website (<http://www.ico.gov.uk/>) provides guidance on general issues relating to data protection and freedom of information, but also provides a large amount of health-specific guidance.

#### The NHS Care Records Service

Under the National Programme for Information Technology (NPfIT), the NHS Care Records Service is being introduced over the next few years and this will hold electronic health records in both national and local systems. This is covered by the NHS Care Records Guarantee.<sup>7</sup> Services will include picture archiving and communication systems, electronic prescription systems, pathology messaging, etc. All systems and services delivered through NPfIT incorporate stringent security controls and safeguards to prevent unrestricted or uncontrolled access to personal information. An audit trail will be kept of every time a patient NHS Care Record is viewed and edited. Staff should only access patient information when strictly necessary (i.e. when they, or their immediate team, are directly involved in the care of that patient). Organisations will run regular comparisons of audit trails with the patients who have attended appointments and Caldicott Guardians will receive automated alerts of irregular activity. Patients will be able to request a copy of their audit trail. Further information is available from NHS Connecting for Health ([www.connectingforhealth.nhs.uk](http://www.connectingforhealth.nhs.uk)) and reference 20.

#### Information Governance in IT Systems:<sup>21</sup>

- NHS Connecting for Health has developed an Information Governance (IG) toolkit,<sup>22</sup> which provides information on standards in information governance, guidance, awareness and educational materials, performance measurement tools and support for implementing the standards. Key areas include confidentiality and consent, Data Protection Act, Caldicott standards, information management and technology, security, records management and data accreditation.

- The international standard for information security management is BS ISO/IEC 27002:2005.<sup>22,23</sup> All information security requirements in the NHS Information Governance Toolkit are based on the standard.
- NHS Connecting for Health has produced an Information Governance Training Tool which contains a range of e-learning modules, trainer materials and a resource library. Further information is available from <http://www.igte-learning.connectingforhealth.nhs.uk/igte/index.cfm>
- NHS Connecting for Health and the BMA have issued a useful document *Joint Guidance on Protecting Electronic Patient Information* which covers personal and organisational responsibilities, including guidance on use of NHSmail for exchanging confidential information, guidance on use of laptops and other mobile devices, use of smartcards, passcodes encryption, etc. It emphasises that there should be no transfers of unencrypted person identifiable data held in electronic format across the NHS.

The document can be downloaded by BMA members from  
[http://www.bma.org.uk/ap.nsf/AttachmentsByTitle/PDFprotectinginfo/\\$FILE/protectingpatient\\_info.pdf](http://www.bma.org.uk/ap.nsf/AttachmentsByTitle/PDFprotectinginfo/$FILE/protectingpatient_info.pdf)

The GMC is due to publish further guidance on confidentiality in 2009. This will cover:

- Reporting concerns about patients to the Driver and Vehicle Licensing Agency (DVLA)
- Disclosing records for financial and administrative purposes
- Reporting gunshot and knife wounds
- Disclosing information about serious communicable diseases
- Disclosing information for insurance, employment, benefit claims and similar purposes
- Disclosing information for educational and training purposes
- Responding to criticism in the press.

### I. Standard Statement on Confidentiality Policies

All services should have a written confidentiality policy.

- I.1 Service confidentiality policies should be informed by, and updated in line with, latest national guidance (e.g. from the DH,<sup>1-3,5</sup> GMC<sup>6,7</sup> and other professional organisations.<sup>8,9</sup>
- I.2 Service confidentiality policies should be in line with and endorsed by local NHS Trusts.
- I.3 All staff should sign up to the service's confidentiality policy.
- I.4 Policies should include guidance on:
  - I.4.1 Handling written, electronic and verbal information<sup>1,24</sup>
  - I.4.2 Legal frameworks\* for information sharing as dictated by current guidance<sup>1,25,30</sup>
  - I.4.3 Sharing information with other NHS services, and non-NHS organisations and agencies in line with current guidance<sup>23-25</sup>
  - I.4.4 Under-16s<sup>7,26</sup>
  - I.4.5 Those unable to give consent<sup>27</sup>
  - I.4.6 Avoidance of inadvertent breach of confidentiality<sup>1,13,14</sup>
  - I.4.7 Disposal of confidential information<sup>17</sup>
  - I.4.8 Secure storage of paper and electronic records,<sup>17</sup> visual and audio recordings, use of email, faxes, SMS, etc<sup>14,24,31-35</sup>
  - I.4.9 Client access to paper and electronic records<sup>20</sup>
  - I.4.10 Copying letters to clients<sup>29</sup>
  - I.4.11 Safeguarding children/child protection<sup>7,36</sup>
  - I.4.12 Safe transporting and storage of client records (both paper-based and electronic) when it is necessary to take them in cars or keep at home (e.g. for domiciliary visits<sup>32</sup>)
  - I.4.13 Procedure for reporting incidents involving breaches of security or confidentiality<sup>1</sup>

- 1.4.14 Procedures for use of CCTV and recording of telephone calls, publication in print, radio, TV, video and internet media<sup>14</sup>
  - 1.4.15 Disclosure required by statute, disclosure to police, social services and partner organisations, disclosure to solicitors, courts, tribunals and regulatory bodies, disclosure for insurance and occupational health purposes and financial audit, and statutory restrictions on disclosure<sup>14</sup>
  - 1.4.16 Procedures for secondary uses of information<sup>14</sup> such as research, epidemiology, public health surveillance, health service planning and education
  - 1.4.17 Procedures for handling patient information for teaching, and training, including logbooks and training portfolios
  - 1.4.18 Procedures for seeking advice in circumstances when staff are uncertain whether a disclosure without consent is justified.
- 1.5 Service users should be involved in the production and implementation of the service's confidentiality policy.<sup>37</sup>

\*Particular note should be taken of guidance regarding information on sexually transmitted infections (STIs),<sup>25</sup> using information from screening programmes,<sup>26</sup> the Data Protection Act<sup>27</sup> rights of access to personal health records,<sup>27-29</sup> Abortion Regulations 1991 and reporting of notifiable diseases.

### 2. Standard Statement on Confidentiality Training

Services should provide all staff with a programme of training on confidentiality.

- 2.1 Clinical and non-clinical personnel should receive accessible and appropriate training in confidentiality and handling enquiries about sensitive information.<sup>13</sup>
- 2.2 All staff should receive training on national safeguarding children procedures,<sup>38</sup> and be able to use local safeguarding children policies.
- 2.3 All staff should be trained in the legal requirements of the Data Protection Act<sup>15,27,28</sup> as they apply to health services.
- 2.4 All staff should receive Caldicott training.<sup>26</sup>
- 2.5 All staff should receive training on the secure use of personally identifiable information in computer systems, fax machines, electronic mail, and all forms of portable computing media such as laptops, handhelds, solid state memory cards, USB memory sticks, pen drives, DVDs, CD-ROMs, etc.<sup>2,39</sup>
- 2.6 All staff should receive training in confidentiality on taking up employment within the NHS or under contract to an NHS organisation and this training should be regularly updated in line with local Trust policies.

### 3. Standard Statement on Clients' Rights to Confidentiality

**All clients have the right to expect that information about them will be held in confidence.**

- 3.1 All services should prominently display their confidentiality statement, which should acknowledge that information will be shared with colleagues within the service in order to provide quality and continuity of care, except in certain well-defined circumstances.
- 3.2 Client literature/service leaflets should contain a statement concerning rights to confidentiality.
- 3.3 Specific permission should be sought from the client regarding the communication to them of test results and any other information<sup>29</sup> (i.e. whether writing, telephoning, texting or any other means is acceptable to them).
- 3.4 There should be a mechanism for returning undelivered client letters without opening them (e.g. PO box number).
- 3.5 Specific permission should be sought from the client to sharing any information with anyone outside the service, other than those directly involved in client care (e.g. laboratory staff, except as below).<sup>\*</sup> Information disclosed for secondary uses such as audit, service planning, medical research, and so on should be anonymised or pseudonymised, but if this is not practicable, the client's express consent should be sought.
- 3.6 With issues relating to safeguarding children/child protection, the client should be informed that sharing will occur<sup>\*</sup> and the reasons for the disclosure should be given.
- 3.7 All staff should be familiar with guidance about the use of photographs and video recordings.<sup>14,40</sup>
- 3.8 All client records, paper and electronic, should be securely stored and only be accessed on a 'need-to-know/see' basis.
- 3.9 The transfer of written clinical information to other professionals by letter, email or fax should be secure, and clearly marked 'In Confidence'.
- 3.10 The transfer of clinical information or other personally identifiable information to other professionals by email should be by NHS Mail, which uses the secure N3 network and all accounts end in @nhs.net other email accounts that are not encrypted should not be used for this purpose (<https://www.nhs.net/AcceptableUse.do>).
- 3.11 The Caldicott principles<sup>17</sup> should be applied to all information sharing concerning clients.
- 3.12 No personally identifiable or sensitive information held in electronic format should be transferred across the NHS or to another organisation unless encrypted.

<sup>\*</sup>There may be an exception to this when telling a victim of abuse that information will be shared may alert the abuser who could move elsewhere and cause harm to others.



### 4. Standard Statement on Sharing Non-identifiable Information

Services should ensure that clients are informed that anonymised information may be used for service improvement, audit and clinical governance purposes.

- 4.1 Information used for clinical governance, audit, teaching or other quality improvement purposes should always be anonymised or pseudonymised.<sup>14</sup>
- 4.2 Service leaflets should contain a statement concerning the use of anonymised information, including explanation about information from screening programmes,<sup>1,26</sup> cancer, genetic and disease registers.

### 5. Standard Statement on Working with Young People

Services should ensure that their staff are aware that all people, irrespective of age, are entitled to the same duty of confidentiality, provided they understand the implications of the advice and treatment offered.

- 5.1 All staff should be familiar with the latest DH Guidance on the care of under-16s<sup>6,41</sup> and guidance from the GMC.<sup>10</sup>
- 5.2 All staff working with young people under 16 should be familiar with and use the Fraser Guidelines<sup>10,13,41-43</sup> (or appropriate equivalent guidance<sup>36,39</sup>) on competence.
- 5.3 All staff working with young people under 18 should be familiar with local and national safe guarding children/child protection guidance and procedures and their impact on confidentiality.<sup>6,38</sup>

### 6. Standard Statement on Disposal of Confidential Information

All services should have mechanisms for disposal of confidential information.

- 6.1 Services should have clear guidelines for archiving and disposal of old notes.<sup>24</sup>
- 6.2 All staff should have easy access to shredding for all paper carrying identifiable information (including notes on message pads).
- 6.3 Identifiable audio or electronic information that is no longer required should be permanently deleted.

## 7. Standard Statement on Disclosure without Consent

Services should inform clients that personal information should only be disclosed if it is in the public interest, or to protect the individual.

### Essential (minimum):

- 7.1 All staff and clients should understand that there are exceptional circumstances when confidentiality may not be upheld.<sup>1,9,14,38</sup> Disclosure may be justified to protect the individual or others to risk of death or serious harm, or be required by law (see Annex A).
- 7.2 All staff should be made aware that if they are in any doubt about whether to share information they should seek advice from an experienced colleague, a named or designated doctor for child protection, a Caldicott Guardian, from a professional body, defence organisation or the GMC.

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### Annex A (from BMA Confidentiality Toolkit 2008<sup>41</sup>)

#### Serious Harm and Serious Crime

Disclosure of information without consent may be justified in the public interest if failure to disclose would expose the client or others to risk of death or serious harm. The NHS Code of Confidentiality suggests that serious harm could be child abuse or neglect, assault, a traffic accident or the spread of a serious communicable disease – which the GMC regards as HIV, tuberculosis, hepatitis B and C. Disclosure without consent may also be justified when disclosure would assist in the prevention, detection or prosecution of serious crime. There is no agreed definition of serious crime but the NHS Code of Confidentiality lists examples as murder, manslaughter, rape, treason, kidnapping, child abuse or neglect and also includes serious harm to the security of the State or public order. The wishes of a competent person to decline consent for disclosure should usually be respected but if their decision exposes others to a risk so serious that it outweighs the client's and the public interest in maintaining confidentiality, information should be disclosed to an appropriate person or authority and the client should be informed of the reasons for the disclosure. Health professionals are expected to participate in procedures set up to protect the public from violent and sex offenders.

#### Disclosure Required by Statute

Examples include:

- Notification of diseases under the Public Health (Control of Disease) Act 1984 and Public Health (Infectious Disease) Regulations 1988 – note that the list of notifiable diseases varies within the countries of the UK
- Abortion Regulations 1991
- Road Traffic Act 1988
- Terrorism Act 2000
- The Information Sharing Index (England) Regulations 2007

#### Disclosure Permitted by Statute

Examples include:

- Data Protection Act 1998
- Crime and Disorder Act 1998
- Children Act 1989

#### Disclosure to Solicitors

Health records required for legal proceedings are obtained via the Data Protection Act or Access to Health Records Act 1990. Health professionals should ensure that they have written consent to disclosure and confirm that the client understands the nature and extent of the information disclosed.

#### Disclosure to Courts, Tribunals and Regulatory Bodies

Courts, some tribunals and bodies such as the GMC have legal powers to require disclosure, without the client's consent, of information that may be relevant to matters within their jurisdiction (e.g. fitness to practice inquiries). Clients can make representations to the court if they object to disclosure. Healthcare professionals can apply to the court if they know that the court order requests the release of records that contain information about third parties unconnected with the proceedings.

## Statutory Restrictions on Disclosure

Health professionals are required by law to restrict disclosure of some specific information for example:

- Gender Recognition Act 2004
- NHS (Venereal Diseases) Regulations 1974 and the NHS Trusts and PCTs (Sexually Transmitted Diseases) Directions 2000
- Human Fertilisation and Embryology Act 1990

### SERVICE STANDARDS FOR RESUSCITATION

Published: July 2006

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Review date: October 2013

#### Introduction

This document addresses standards for resuscitation in the context of sexual and reproductive health (SRH) service provision.

Resuscitation may be required in a number of situations:

- Collapse during or following any clinical procedure (e.g. hyperventilation syndrome, vasovagal episodes, bradycardia, epileptic seizures)
- Anaphylactic response to administered medication or as a result of contact with another provoking agent (e.g. latex gloves)
- Spontaneous collapse unrelated to sexual and reproductive procedure but related to underlying medical condition (e.g. diabetes, epilepsy, cardiac or pulmonary problems).

This document should be used in conjunction with national guidelines from other relevant professional bodies and locally agreed policies and procedures. It is important that each service identifies the level of equipment and training needed to deal with common emergencies on the basis of local risk assessment.<sup>1</sup>

## I. Standard Statement on Training in Resuscitation

Training and regular updating in resuscitation is essential for all staff dealing with emergencies arising during the provision of sexual health services.

- I.1 All staff providing sexual health services should receive appropriate training in Basic Life Support (BLS).<sup>2</sup>
- I.2 All new members of staff should have resuscitation training as part of their induction programme.<sup>2</sup>
- I.3 All clinical staff should be updated annually in BLS.<sup>2</sup>
- I.4 All staff should know how to summon emergency assistance.<sup>3</sup>
- I.5 All clinical staff should be trained to recognise and treat an anaphylactic reaction.<sup>4</sup>
- I.6 Clinical staff should be trained to manage other medical emergencies that may arise (e.g. vasovagal episode, epileptic fit, bradycardia).

### 2. Standard Statement on Emergency Drugs

**Essential drugs required for resuscitation must be available, accessible, clearly labelled, adequately maintained and their location known to all staff.**

2.1 Recommended drugs required for resuscitation are:

- Epinephrine (adrenaline) 0.5 mg intramuscular (IM) (0.5 ml of 1:1000 injection) for the management of anaphylaxis<sup>4</sup>
- Atropine 500 µg, intravenous use, for the management of bradycardia<sup>5</sup>
- Oxygen
- Rectal diazepam.

2.2. Emergency drugs should be labeled with the recommended dosage regimes.

2.3 Epinephrine (adrenaline) 1:1000 injection must be available or carried whenever drugs are administered by injection or other routes with rapid absorption, even when the recipient is not considered to be at risk.

2.4 Weekly checks of emergency drugs should be undertaken to ensure that emergency drugs have not passed their expiry date.<sup>3</sup>

2.5 All clinical staff must know the precise location of emergency drugs.

2.6 Emergency drugs should be stored in tamperproof containers, which once opened should be replaced.

### 3. Standard Statement on Emergency Equipment

**Essential resuscitation equipment should be available, accessible, well-maintained and its location known to all staff.**

- 3.1 Services should ensure that equipment required for resuscitation or other medical emergencies is available and accessible for use as quickly as possible.<sup>1</sup>
- 3.2 All clinical staff must know the precise location of emergency equipment.
- 3.3 Basic resuscitation equipment for managing the airway and administering drugs should be available and accessible in clinics.<sup>6</sup>
- 3.4 Essential emergency equipment<sup>6</sup>

In addition to standard equipment (i.e. sphygmomanometer, sharps box, non-latex gloves, scissors and tape) the following should be available and accessible:

- Appropriate selection of needles and syringes
- Pocket mask with one-way valve
- Adjustable couch with ease of access in case of an emergency situation.

- 3.5 Emergency equipment should be single-use and latex-free.<sup>3</sup>

### 4. Standard Statement on Co-ordination

**One named individual should be responsible for the overall co-ordination of resuscitation services.<sup>2</sup>**

- 4.1 A named individual should be responsible for maintaining all emergency equipment and drugs.
- 4.2 A named individual should be responsible for co-ordinating training in resuscitation.
- 4.3 The resuscitation training of all staff should be recorded in a central database.
- 4.4 Local protocols for the management and referral of medical emergencies should be clearly displayed in all clinical areas.
- 4.5 All staff should know how to access emergency services.
- 4.6 Emergency telephone numbers should be clearly displayed.
- 4.7 A local protocol for the use of drugs by nurses for the purpose of saving life in an emergency should be in place.

### 5. Standard Statement on Risk Management

Locally agreed risk management policies for the treatment of emergencies should be in place and take into account national recommendations.<sup>7</sup>

- 5.1 A risk assessment should be performed in all clinical situations, including where staff are working in isolation.
- 5.2 All significant adverse clinical events should be recorded and reported according to local policies.
- 5.3 Significant events should be discussed with the individual(s) involved and there should be a process for the whole team to learn from them.<sup>8</sup>
- 5.4 An appropriately trained assistant should be present during cervical instrumentation procedures. This person may be required to call for additional assistance, monitor the condition of the patient or perform BLS.<sup>9</sup>
- 5.5 Significant bradycardia may result from IUD/IUS insertions so whenever this procedure is performed, a clinician competent in intravenous injections should be available in case intravenous atropine is required.<sup>10</sup>



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## Appendix 5

### SERVICE STANDARDS FOR MEDICINES MANAGEMENT

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#### Introduction

Medicines management is the clinical, cost-effective and safe use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimising potential harm (Medicines and Healthcare products Regulatory Agency, 2004). *The Safe and Secure Handling of Medicines, A Team Approach*<sup>1</sup> published in March 2005, gives definitive guidance on detailed medicines management within all National Health Service (NHS) organisations in the UK. Reference to this resource, where more detailed information can be found, is made throughout this document. Although its scope does not include general practice or community pharmacy, we would commend the basic principles in these settings.

These standards relate to contraceptive drugs and devices and other medicines used within sexual and reproductive healthcare (SRH), wherever this is provided. Wherever the term 'medicine' is stated in this document, this should be interpreted to cover all the areas listed here. This standard applies equally to medicines and devices used in research trials.

The term 'medicines management' has been interpreted to cover the processes and systems for providing medicines to users within these areas. In this context it does not include reference to evidence-based prescribing, for which readers should refer to the relevant Clinical Effectiveness Unit and National Institute for Health and Clinical Excellence (NICE) guidance where relevant.

These standards should be read in conjunction with Service Standards for Risk Management<sup>2</sup> and Service Standards for Record Keeping.<sup>3</sup>

### I. General Standard Statement on the Process of Medicines Management

**Good medicines management should ensure a process for giving appropriate and safe therapies to clients in the most effective way.**

- 1.1 There must be a medicines policy for each employing organisation, which is accessible to staff.
- 1.2 There should be an agreed process for deciding on medicines to be held in stock in clinical settings, and systems for the provision of medicines that are not held as stock.
- 1.3 Every service should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use. This is to ensure the safety and security of medicines stored and used in it. Appropriate pharmaceutical advice must be taken in the development of systems for the safe and secure handling of medicines. Guidelines for developing and implementing standard operating procedures can be found on the Royal Pharmaceutical Society of Great Britain (RPSGB) website.<sup>4</sup>
- 1.4 Staff should understand the principles of safe and secure handling of medicines, including storage, handling, issuing and prescribing of drugs.
- 1.5 There is an audit trail for each client's medicines.

## 2. Standard Statement on Access to Treatment

All clinicians should be able to directly provide medication or a prescription to service users to meet their contraceptive and sexual and reproductive health needs.

- 2.1 All clients choosing to access contraception, sexual and reproductive health services should receive prompt medication as treatment for their contraceptive, sexual and reproductive health needs without the need to go to another prescribing clinician.
- 2.2 Services should ensure that clients are able to directly access medication or a prescription that is appropriate to their contraceptive, sexual and reproductive health needs. This represents efficient treatment and endorses patient choice of provider and underpins and enhances access to appropriate and timely services.

### 3. Standard Statement on the Process of Safe and Secure Handling of Medicines

**The process of ordering, logging receipt, labelling, storage, transport, stock rotation and disposal of medicines should be in accordance with national and local guidance.**

- 3.1 The SOPs for the management of medicines within the service must include reference to medicines that are heat- and light-sensitive, medicines for clinical emergencies, any medicines liable to misuse, and disposal of medicines no longer required.
- 3.2 All staff, whether clinical or non-clinical, should be trained in the parts of these procedures relevant to their duties.
- 3.3 A designated person should be responsible for ordering medicines from the pharmacy to maintain agreed stocks.
- 3.4 Medicines coming into the clinic should be checked against the requisition by a designated person who should record that he/she has so checked. In the clinic, the responsibility for the safekeeping of the medicines lies with that designated person.
- 3.5 Where premises are shared, each service should be responsible for its own stock of medicines, which should be stored separately.
- 3.6 When an outreach worker takes medicines out of the clinic setting, that outreach worker is responsible for the safe and secure transport and storage of medicines.<sup>5</sup>
- 3.7 All medicinal products dispensed by the practitioner should be labeled correctly. Standard labeling requirements for all dispensed items includes: the name of the person to whom the medicine is to be administered, the name and address of the service, the date of dispensing and the words 'keep out of reach of children'.
- 3.8 All medicinal products should be stored in accordance with the patient information leaflet (PIL), summary of product characteristics document found in dispensed UK-licensed medication and in accordance with any instruction on the label. Lockable cupboards that comply with the relevant regulations should be used for the storage of medicines in the clinic or practice setting. The current British Standard is BS2881 (1989) – NHS Estates Building Note No. 29.
- 3.9 If heat-sensitive products are kept (e.g. vaccines), a suitable dedicated fridge should be available. There should be monitoring of the temperature of the refrigerator on each working day, which is recorded and signed by the person monitoring the temperature.
- 3.10 Medicines for clinical emergencies should be held in packs clearly marked 'for emergency use'.

- 3.11 It should be the duty of a pharmacist to ensure that systems are in place to ensure that medicines are only supplied on the instruction of an authorised clinician. The pharmacist should carry out inspections of the stock in the clinic, with reconciliation where necessary.
- 3.12 There should be local process of stock rotation of medicines to ensure that medicines approaching their expiry date are used in preference to those with a longer shelf life.
- 3.13 There should a policy agreed with the local pharmacy team for the safe disposal of medicines.

### 4. Standard Statement on Process for Security of Prescription Pads

**Prescription pads and other controlled stationery  
must be kept securely.**

- 4.1 There should be an agreed process for ordering and signed receipt of prescription pads and other controlled stationery (e.g. internal order forms).
- 4.2 Prescription pads should only be held by qualified practitioners who have been issued with them and who should be responsible for their security. This includes security of any pads used outside of the clinic or practice setting (e.g. home visits).
- 4.3 Prescription pads and other controlled stationery should be kept in locked cupboards.
- 4.4 Records of serial numbers of prescription pads received and issued should be retained for at least 3 years.<sup>6</sup>
- 4.5 There should be an audit trail for numbered prescriptions.

## 5. Standard Statement on Process for Prescribing

All prescribers should follow legal and professional frameworks.

5.1 Medicines should only be prescribed in the following ways:

- 5.1.1 Patient-specific direction (i.e. entry on clinic record card)
- 5.1.2 FP10 prescription
- 5.1.3 Outpatient prescription form for dispensing in a hospital pharmacy.

For ease of reference, the term 'prescription' is used in this document for all three situations.

- 5.2 All prescribers should follow the guidance on writing prescriptions given in the *British National Formulary*.
- 5.3 Non-medical prescribers must undertake a programme of training approved by their professional body, and this must be recorded in the relevant professional register. For nurses, the Nursing and Midwifery Council (NMC) fulfils this function<sup>7</sup> and for pharmacists it is the RPSGB.<sup>4</sup>
- 5.4 Nurse and pharmacist prescribers working within this setting must ensure that they prescribe only in accordance with current NHS guidance on independent and supplementary prescribing.<sup>8-11</sup>
- 5.5 Non-medical prescribers are permitted to prescribe black triangle\* drugs as long as it is accepted practice to do so, for instance where such products are included in local formularies.

\*A black triangle will be assigned to a product if the drug is a new active substance. However, a product containing previously licensed active substances may also be monitored if it meets one or more of the following criteria:

- A new combination of active substances;
- Administration via a novel route or drug delivery system;
- A significant new indication which may alter the established risk/benefit profile of that drug.

The black triangle drugs are monitored closely for a minimum of 2 years and the black triangle symbol is not removed until the safety of the drug is well established.



### 6. Standard Statement on Process for Supply or Administration on a Patient Group Direction (PGD)

Clinicians who are not doctors who have specific training may be authorised to supply or administer medicines on a PGD to people who, following an assessment, meet the inclusion criteria of that document.<sup>12</sup>

- 6.1 Any Patient Group Directions (PGDs) in use must have been agreed through the authorising process within the relevant NHS organisation(s).
- 6.2 PGDs should only be used by registered healthcare professionals who have been assessed as competent and whose name is identified within each document. Anyone involved in the delivery of care within a PGD should be aware of the legal requirement.<sup>5</sup>
- 6.3 If a PGD cannot be used (e.g. where one has not yet been approved, or an individual falls outside the inclusion criteria), medication can only be provided through a valid prescription.
- 6.4 Training, updating and audit of those working to PGDs should be provided.
- 6.5 PGDs should be reviewed and re-authorised according to local guidelines, especially in the event of any changes in clinical practice.
- 6.6 Black triangle drugs (see under 5.5), and medicines used outside the terms of the summary of product characteristics (off-label), may be included in PGDs provided such use is exceptional, justified by current best clinical practice and that a direction clearly describes the status of the product.
- 6.7 When supplying under PGD, this should be from the manufacturers' original packs or over-labelled pre-packs so that the patient details, date and additional instructions can be on the label at the time of supply. Practitioners must not split prepared pre-packs.<sup>5</sup>

### 7. Standard Statement on Supply and Administration of Medicines to Patients

**Medicines are supplied or administered to service users by clinicians accurately and safely.**

- 7.1 The authorisation of a suitably qualified practitioner (i.e. doctor or nurse/pharmacist prescriber) should be obtained before medicines can be supplied or administered to service users. This authority is given in one of three ways:
- 7.1.1 An instruction written by a doctor or a qualified nurse or pharmacist prescriber on an official medicine record chart or in the electronic prescribing system (i.e. a patient-specific direction)
  - 7.1.2 In accordance with locally agreed clinical procedures (e.g. for off-prescription medicines)
  - 7.1.3 In accordance with PGDs.
- 7.2 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product.
- 7.3 A record of administration should be made, and the administering nurse/doctor/practitioner identified (e.g. an entry in the medicines record or electronic health record).
- Medication that is not given due to refusal, wastage or lack of availability should be recorded.
- 7.4 If a second clinician checks the administration of a medicine (e.g. lidocaine) the identity of the checking clinician should also be recorded; however, the ultimate responsibility remains with the administering nurse/doctor.

### 8. Standard Statement on Process for Issue of Medicines to Service Users

**Only a trained member of healthcare staff can administer medicines that have been prescribed for an individual patient. Medicines should be dispensed in accordance with legislation.**

- 8.1 Prescription-only medicines may only be issued by a suitably trained member of healthcare staff.
- 8.2 When administering or supplying a medicine, the supplier has a duty to check the client's identity, that the client is not allergic to the product, consents to take the medication and that the product is appropriately labelled. Only one clinician needs to perform this task. Nurse prescribers may supply a medication that they have prescribed but the NMC state that this should be only in exceptional circumstances and covered by a locally agreed SOP<sup>13</sup>. Community SRH clinics are exceptional circumstances as medication is both prescribed and issued on the same site. Nurse prescribers who are both prescribing and issuing in community clinics should be competent and familiar with all the medication they prescribe.
- 8.3 When administering medicine, the expiry date must be checked, contraindications excluded and a clear and immediate record of administered medicine should be made.<sup>5</sup>
- 8.4 Dispensing is classed as "to label stock and supply a clinically appropriate medicine, for self-administration or administration by another professional and to advise on safe and effective use". This can only be undertaken by a qualified professional (e.g. registered nurse, doctor, pharmacist) and should be outlined in a local SOP.<sup>5</sup>
- 8.5 Wherever 'take-home', pre-packed medication is issued from the healthcare setting, the senior pharmacist is responsible for ensuring that there is a legal system to ensure that all medicines handed out to service users are recorded and properly labelled.
- 8.6 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

### 9. Standard Statement on Process for Prescribing Unlicensed Medicines, and for the Use of Medicines Outside the Manufacturer's Licence (Off-label Prescribing)

The use of unlicensed medicines, and licensed medicines outside the manufacturer's licence, should be explicit and follow national and professional guidance.<sup>8-11,14</sup>

- 9.1 The purpose of using a medication outside its licence should be justifiable and in line with a recognised body of opinion.
- 9.2 Practitioners should be satisfied that they have sufficient information to administer an unlicensed or 'off label' drug safely
- 9.3 The recipient should be made aware of this off-licence supply and documentation of the discussion about use kept.\*
- 9.4 Any medication provided in this way as a 'named patient prescription' should have an audit trail.
- 9.5 Where instruction for the off-licence use varies from the PIL, this should be brought to the attention of the user, backed up with tailored written information.
- 9.6 Adverse reactions occurring during use of a medicine outside its licence should be reported on a Yellow Card to the MHRA.<sup>15</sup>

#### \*ADDENDUM November 2009

The General Medical Council produced the guidance document *Good Practice in Prescribing Medicines* in September 2008. This document states that where current practice supports the use of a medicine in an unlicensed way, it may not be necessary to draw a client's attention to the licence when seeking consent to use that medicine.<sup>16</sup> When a contraceptive preparation is used within current guidance from the FSRH's Clinical Effectiveness Committee (CEC), it is accepted best practice and it is therefore not necessary to counsel the client that the medicine is being used 'off-licence'. The situation for non-medical prescribers is different and is dictated by their professional organisations and a Joint Statement by the Clinical Standards Committee and the CEC has been produced.<sup>17</sup>

### 10. Standard Statement on Process for Reducing and Reporting Drug Adverse Effects and Errors in Prescribing or Issuing Medication

**Systems should be in place to identify and learn from incidents and adverse events related to medication.**

- 10.1 Details of the person using the medicine should be checked before issue or administration.
- 10.2 The name of the medicine should be checked with the user prior to administration or supply, and attention drawn to the PIL.
- 10.3 Clinical history, including anaphylaxis and past side effects, and concurrent medication should be checked and updated at each visit.
- 10.4 Dosage, instructions and expiry date should be checked on the label and contents and recorded in the notes.<sup>3</sup>
- 10.5 Warnings to identify contraindications to medicines should be clearly identifiable in the records.
- 10.6 Where packaging is similar for different medicines, these supplies should not be kept adjacent to each other. Systems should be employed to minimise this source of risk.
- 10.7 Adverse effects to a medicine should be reported to the MHRA on a Yellow Card, according to their guidelines.<sup>8</sup>
- 10.8 Any incident (including errors, adverse effects, and theft of supplies or prescriptions) should be reported on local incident forms to aid the process of remedial action, and learning from experiences to reduce future risk.
- 10.9 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to service users and staff.

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Medicines Management – Safe and Secure Handling. Crown copyright 2003 CNST

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## Appendix 6

### SERVICE STANDARDS FOR RECORD KEEPING

Published: May 2005

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#### Introduction

All individuals who work for a National Health Service (NHS) organisation are responsible for any records which they create or use in the performance of their duties. Furthermore, any record that an individual creates is a public record and may be subject to both legal and professional obligations.

This guidance relates to documentation in patient health records of consultations in sexual and reproductive healthcare (SRH). The Appendices should be used in conjunction with the Faculty's Clinical Effectiveness Unit (CEU) method-specific guidance and the UK Medical Eligibility Criteria for Contraceptive Use (UKMEC), as this record keeping document is about what to record, not how to choose or use a contraceptive method.

Information should be recorded in a manner that accurately reflects the consultation and shared decision-making between client and clinician. Guidance applies to paper and electronic records.

Services may wish to develop local protocols for record keeping to address all standards referred to in this document in ways that will facilitate its implementation.

Guidance about record keeping for various methods of contraception is included as appendices to this document. This list is not exhaustive.

#### The Prescription of Contraceptive Medicines for Use Outside the Terms of Their Licence - 'Off-licence Use' or 'Off-label Use'<sup>1</sup>

There are many generally accepted off-licence usages of contraception. The General Medical Council guidance document *Good Practice in Prescribing Medicines*<sup>2</sup> (2008) states that "when prescribing a medicine for use outside the terms of its licence, you must be satisfied that there is sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy, and make a clear, accurate, legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing the medicine. Some medicines are routinely used outside the scope of their licence... Where current practice supports the use of a medicine in this way it may not be necessary to draw attention to the licence when seeking consent....".

The Clinical Standards Committee of the FSRH and the Clinical Effectiveness Committee have agreed that CEU Guidance on use of contraceptives is guidance on 'common practice' and 'current practice' in the use of these medicines and devices. Therefore it is recommended that it may not be necessary for doctors to document every occasion when a contraceptive preparation is prescribed outside the product licence if such use falls within current guidance issued by the Faculty's CEU. Similarly, current guidance from the Royal College of Obstetricians and Gynaecologists (RCOG) and the National Institute for Health and Clinical Excellence (NICE) should be regarded as common practice.



### Records Management

NHS organisations need robust records management procedures to meet the requirements set out under the Public Records Act 1958, the Data Protection Act 1998 and the Freedom of Information Act 2000. Storage, retrieval, disclosure, transfer, archiving and disposal of health records must comply with Records Management: NHS Code of Practice.<sup>2</sup> Part 1 was published in April 2006 and Part 2 was published in January 2009. Guidance on retention of health records is summarised in Appendix 7 of this document.

The Department of Health Records Management Roadmap contains a range of practical tools and guidance designed to support organisations in the implementation of an effective records management system in line with the principles contained in the Records Management: NHS Code of Practice.<sup>2</sup> The Roadmap contains a model Records Management Policy and a model Records Management Strategy, together with guidance on records management audit. The Roadmap complements guidance in the Information Governance Toolkit. The Roadmap can be accessed at: <http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/records>.

Guidance on maintaining the confidentiality of health records is available from the NHS Confidentiality Code of Practice,<sup>2</sup> FSRH Service Standards for Sexual Health Services<sup>3</sup> and FSRH Standards on Confidentiality.<sup>4</sup>

## I. Standard Statement on Purpose

Clear record keeping is important for clinical governance and serves the needs of clients.

Good record keeping<sup>2-5</sup> ensures that:

- I.1 Clinicians and other staff can work with maximum efficiency without having to waste time searching for information.
- I.2 There is an 'audit trail' that enables any record entry to be traced to a named individual at a given date/time with the secure knowledge that all alterations can be similarly traced.
- I.3 Those making a subsequent entry can determine the reason for, and results of, the consultation and the outcome.
- I.4 Any decisions made can be justified or reconsidered at a later date.
- I.5 Complaints, untoward incidents and medico-legal cases can be handled efficiently.

### 2. Standard Statement on Process

**The process of making clinical records should be accurate and show evidence of clinical reasoning.**

- 2.1 Records should include up-to-date personal data (name, date of birth, address, postcode and telephone number) with an indication of the preferred mode of contact and any restrictions on mode of contact as requested by the client.
- 2.2 Records should contain the client's unique identification number and/or NHS number in accordance with local Trust policies.
- 2.3 Records should be well organised with all sections in date order. It is essential that paper and electronic records are managed consistently to ensure that a complete health record is available at the point of need.
- 2.4 Entries in paper records should be written legibly and indelibly in black or blue ink.<sup>5</sup>
- 2.5 Records should indicate the client's name and either date of birth or unique identification number on each page/screen.
- 2.6 Each entry should have the date noted (and time of day if relevant).
- 2.7 Records should be contemporaneous; contemporaneous corrections and later additions should be dated and signed, or on electronic records amended clearly showing the user's name.
- 2.8 Each entry in paper records should be signed, with name of clinician and role/job title printed; each entry in electronic records should include the name of the clinician (who will be logged on to the system as a registered user) together with the name of any trainees involved in provision of each episode of client care.
- 2.9 Clinical alert details (e.g. hypersensitivities, significant contraindications, etc) should be recorded in a timely manner and clearly displayed/documentated.
- 2.10 Appropriate mechanisms should be in place for action on the results of investigations and recording of those actions.<sup>5</sup>
- 2.11 Abbreviations that are generally (or locally) agreed may be used, but these must be listed and retained for staff reference.
- 2.12 Medico-legal, complaints documents or incident forms should not be filed within the case note folder or personal electronic record, but stored/filed separately.

- 2.13 Text should make clear:
  - 2.13.1 The reason for attendance
  - 2.13.2 Where the consultation took place
  - 2.13.3 All persons present and relationship to client (e.g. partner, relative, friend, chaperone, trainee)
  - 2.13.4 Use of interpreter, with name and language used (and language line number as appropriate)
  - 2.13.5 Outcome, future plan and review date
  - 2.13.6 Investigations.
- 2.14 Communications should be recorded, namely:
  - 2.14.1 Copies of letters sent
  - 2.14.2 Whether a copy was offered/sent to the client
  - 2.14.3 If a standard letter was sent it should be identified
  - 2.14.4 Telephone conversations and SMS messages
  - 2.14.5 Faxes/emails sent and security measures taken to ensure security of transfer and confidentiality (e.g. use of NHS mail).<sup>4</sup>
- 2.15 Record consent where appropriate.<sup>5-8</sup>
- 2.16 Record if chaperone offered and accepted or declined, name and role of chaperone if present.
- 2.17 Record client participation in decision making where appropriate.
- 2.18 Health professionals may wish to use checklists (e.g. Fraser guidelines) to assess competence and risk when providing contraceptive advice or treatment to young people.
- 2.19 Record any advice sought/actions taken/disclosures made in accordance with Safeguarding Children or Safeguarding Vulnerable Adults policies.
- 2.20 Record written/website information or audio/video cassettes/CD-ROM/DVD given, identifying source and date of publication (e.g. FPA leaflets).
- 2.21 Records management policies should be regularly reviewed and updated in accordance with the NHS Code of Practice<sup>2</sup> and compliance with record keeping standards should be audited regularly.

### 3. Standard Statement on Prescribing and Issuing

**All drugs and devices prescribed, issued or provided should be clearly documented and the identity of the prescriber should be recorded.**

- 3.1 Record, date and sign all prescriptions. Where drugs or devices are supplied, record batch numbers, expiry date and manufacturer's product patient information leaflet (PIL) given.<sup>9</sup>
- 3.2 When prescribing a medicine for use outside the terms of its product licence ('off-licence' or 'off-label') the prescriber must make a clear and accurate record of the reasons for prescribing the medicine and the steps taken to obtain valid consent from the client when this use falls outside common practice; however, the use of contraceptive medicines as recommended in current guidance from the FSRH CEU is regarded as common practice.<sup>1,6,7,9</sup>
- 3.3 Adverse reactions – where a 'suspected adverse drug reaction' report (including any reactions with 'black triangle' drugs) is sent to the Medicines and Healthcare products Regulatory Authority (MHRA) as a Yellow Card or via the MHRA website,<sup>10</sup> this should be recorded.
- 3.4 Protocols for patient group directions (PGDs) should include the standards in this record keeping guidance.<sup>11</sup>
- 3.5 Those issuing drugs under PGDs must ensure record keeping is in line with agreed protocols.<sup>12</sup>

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8. Faculty of Sexual and Reproductive Healthcare (FSRH). Service Standards on Obtaining Valid Consent in Sexual Health Services. June 2007
9. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use
10. Faculty of Sexual and Reproductive Healthcare (FSRH). Standards for Medicines Management. 2009
11. Medicines and Healthcare products Regulatory Agency (formerly Medicines Control Agency and Medical Devices Agency). [www.mhra.gov.uk](http://www.mhra.gov.uk)
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### Other Information Sources

- Royal College of Obstetricians and Gynaecologists (RCOG) (e.g. Patient Record Standard for Tubal Occlusion Procedures in Women)
- British Association for Sexual Health and HIV (BASHH) [e.g. UK National Guidelines on Undertaking Consultations Requiring Sexual History Taking (2006); UK National Guideline on the Management of STIs and Related Conditions in Children and Young People (2009)]
- General Medical Council (GMC) Good Medical Practice
- Nursing and Midwifery Council
- Data Protection Act 1998
- Freedom of Information Act 2000
- NHS Connecting for Health
- The Healthcare Commission
- Local Trust record-keeping policy

## ANNEXES

### Standard Statement

**Recording of up-to-date history and clinical assessment should include information provision, prescription and follow-up advice.**

- This guidance is about what to record once a particular method has been chosen and should comply with the current *UK Medical Eligibility Criteria for Contraceptive Use*. It is not prescriptive about how information is recorded, nor about the format of clinical case notes.
- Local services may wish to develop record-keeping tools which can record a holistic history.
- If previous records are not available, women who are already taking a particular contraceptive should have details recorded according to the recommendations below.

Annex A	Estrogen-containing Contraception (combined oral contraceptive, combined contraceptive patch, combined contraceptive vaginal ring)
Annex B	Progestogen-only Pill (POP)
Annex C	Progestogen-only Implants
Annex D	Progestogen-only Injectable Contraception
Annex E	Intrauterine Contraception (IUD and IUS)
Annex F	Emergency Contraception
Annex G	Retention of Health Records

Annexes A–G form part of the generic document on record keeping and should be read in conjunction with it.



### Service Standards for Record Keeping for Estrogen-containing Contraception

#### I. Medical history and clinical assessment

- 1.1 Personal and lifestyle history
  - 1.1.1 Age
  - 1.1.2 Current smoking, number per day
  - 1.1.3 Ex-smoker, number per day and date of cessation
  - 1.1.4 Alcohol and substance misuse
  - 1.1.5 Current/recent immobility
- 1.2 Contraception
  - 1.2.1 Current method
  - 1.2.2 Previous contraception used and any problems encountered
  - 1.2.3 Awareness and use of emergency contraception
- 1.3 Gynaecological history
  - 1.3.1 Menstrual history including start date of last menstrual period
  - 1.3.2 Coital history
- 1.4 Obstetric history
  - 1.4.1 Postpartum <21 days
  - 1.4.2 Current breastfeeding
- 1.5 Medical history
  - 1.5.1 Ischaemic heart disease
  - 1.5.2 Hypertension
  - 1.5.3 Known hyperlipidaemia
  - 1.5.4 Other vascular disease
  - 1.5.5 Complicated valvular and congenital heart disease
  - 1.5.6 Stroke
  - 1.5.7 Venous thromboembolism
  - 1.5.8 Known thrombogenic mutations
  - 1.5.9 Raynaud's disease with lupus anticoagulant
  - 1.5.10 Diabetes, duration of diabetes, presence/absence of nephropathy/retinopathy/neuropathy
  - 1.5.11 Systemic lupus erythematosus
  - 1.5.12 Headaches
  - 1.5.13 Migraines with/without aura
  - 1.5.14 Symptomatic gallbladder disease
  - 1.5.15 Cholestasis related to past combined oral contraception use
  - 1.5.16 Active viral hepatitis
  - 1.5.17 Cirrhosis, liver tumours
  - 1.5.18 Current or recent breast cancer
  - 1.5.19 Any other serious medical condition
- 1.6 Surgical history
  - 1.6.1 Recent major surgery with immobilisation

- 1.7 Medication
  - 1.7.1 Prescribed, particularly drugs which affect liver enzymes and broad-spectrum antibiotics
  - 1.7.2 Non-prescribed/complementary
- 1.8 Allergies
- 1.9 Family history
  - 1.9.1 Carrier of gene mutation known to be associated with breast cancer
  - 1.9.2 Venous thromboembolism (VTE) in first-degree relative <age 45
  - 1.9.3 Stroke/myocardial infarction (MI) in first-degree relative <age 45
- 2. Examination**
  - 2.1 Blood pressure (BP)
  - 2.2 Weight and body mass index (BMI)
  - 2.3 Any other examination/tests
- 3. Information, advice and counselling**
  - 3.1 Contraceptive choices discussed/preparation chosen
  - 3.2 Risks/benefits/uncertainties discussed
  - 3.3 How it works/efficacy
  - 3.4 Side effects
  - 3.5 Teaching about use of method, including when to access emergency contraception
  - 3.6 Information given on symptoms which should prompt urgent medical advice
  - 3.7 Leaflets given – including manufacturer’s PIL
  - 3.8 Advice on practising safer sex
  - 3.9 Follow-up arrangements
- 4. Prescribing and issuing**
  - 4.1 Record prescription and quantity issued, batch number and expiry date
  - 4.2 Special instructions if any (e.g. additional contraception for 7 days)
- 5. Subsequent attendance**
  - 5.1 Any change in personal or family history, medication or examination findings since the last attendance should be recorded.

## Information Sources

- 1. Faculty of Family Planning and Reproductive Healthcare. Clinical Effectiveness Unit Guidance. First Prescription of Combined Oral Contraception. 2006 (updated 2007). <http://www.fsrh.org/admin/uploads/FirstPrescCombOralContJan06.pdf>
- 2. Faculty of Family Planning and Reproductive Healthcare. Clinical Effectiveness Unit Guidance. UK Medical Eligibility Criteria for Contraceptive Use. 2009. [www.fsrh.org](http://www.fsrh.org)
- 3. Faculty of Sexual and Reproductive Healthcare. New Product Review on Evra. 2003. New Product Review on Nuvaring. 2009. [www.fsrh.org](http://www.fsrh.org)
- 4. Faculty of Sexual and Reproductive Healthcare. Statement on Qlaira. 2009. [www.fsrh.org](http://www.fsrh.org)

#### Service Standards for Record Keeping for Progestogen-only Pill (POP)

##### 1. Medical history and clinical assessment

###### 1.1 Personal and lifestyle history

###### 1.1.1 Age

###### 1.2 Contraception

###### 1.2.1 Current method

###### 1.2.2 Previous contraception used and any problems encountered

###### 1.2.3 Awareness and use of emergency contraception

###### 1.3 Gynaecological history

###### 1.3.1 Menstrual history including start date of last menstrual period

###### 1.3.2 Coital history

###### 1.3.3 Ovarian cysts

###### 1.4 Obstetric history

###### 1.4.1 Ectopic pregnancy

###### 1.5 Medical history

###### 1.5.1 Ischaemic heart disease

###### 1.5.2 Stroke

###### 1.5.3 Venous thromboembolism

###### 1.5.4 Headaches

###### 1.5.5 Migraines with aura

###### 1.5.6 Active viral hepatitis

###### 1.5.7 Severe cirrhosis, liver tumours

###### 1.5.8 Current or recent breast cancer

###### 1.5.9 Any other serious medical condition

###### 1.6 Medication

###### 1.6.1 Prescribed, particularly drugs which affect liver enzymes

###### 1.6.2 Non-prescribed/complementary

###### 1.7 Allergies

##### 2. Examination

###### 2.1 Blood pressure (BP)

###### 2.2 Weight and body mass index (BMI)

###### 2.3 Any other examination/tests

##### 3. Information, advice and counselling

###### 3.1 Contraceptive choices discussed/preparation chosen

###### 3.2 Risks/benefits/uncertainties discussed

###### 3.3 How it works/efficacy

###### 3.4 Side effects

###### 3.5 Teaching about use of method, including when to access emergency contraception

- 3.6 Information given on symptoms which should prompt urgent medical advice
- 3.7 Leaflets given – including manufacturer's PIL
- 3.8 Advice on practising safer sex
- 3.9 Follow-up arrangements
  
- 4. Prescribing and issuing**
  - 4.1 Record prescription and quantity issued, batch number and expiry date
  - 4.2 Special instructions if any (e.g. additional contraception)
  
- 5. Subsequent attendance**
  - 5.1 Any change in personal history, examination findings or medication since the last attendance should be recorded.

### Information Source

- 1. Faculty of Sexual and Reproductive Healthcare. Clinical Effectiveness Unit Guidance. Progestogen-only Pills. 2009

#### Service Standards for Record Keeping for Progesterone-only Implants

- 1. Medical history and clinical assessment**
  - 1.1 Personal and lifestyle history
    - 1.1.1 Age
  - 1.2 Contraception
    - 1.2.1 Current method
    - 1.2.2 Previous contraception used and any problems encountered
    - 1.2.3 Awareness and use of emergency contraception
  - 1.3 Gynaecological history
    - 1.3.1 Menstrual history including start date of last menstrual period
    - 1.3.2 Coital history
    - 1.3.3 Unexplained vaginal bleeding before evaluation
  - 1.4 Medical history
    - 1.4.1 Ischaemic heart disease
    - 1.4.2 Stroke
    - 1.4.3 Current venous thromboembolism on anticoagulants
    - 1.4.4 Headaches
    - 1.4.5 Migraines with aura
    - 1.4.6 Active viral hepatitis
    - 1.4.7 Severe cirrhosis, liver tumours
    - 1.4.8 Current or recent breast cancer
    - 1.4.9 Any other serious medical condition
  - 1.5 Medication
    - 1.5.1 Prescribed, particularly drugs that affect liver enzymes
    - 1.5.2 Non-prescribed/complementary
  - 1.6 Allergies
- 2. Examination**
  - 2.1 Weight and body mass index (BMI)
- 3. Information advice and counselling**
  - 3.1 Contraceptive choices discussed
  - 3.2 Risks/benefits/uncertainties discussed
  - 3.3 Mode of action and efficacy of implant
  - 3.4 Duration of use
  - 3.5 Effects on bleeding pattern
  - 3.6 Effects at insertion site
  - 3.7 Explanation of insertion and removal procedure
  - 3.8 Consent obtained
  - 3.9 Leaflets given – including manufacturer's PIL
  - 3.10 Advice given on practising safer sex

## 4. Details of insertion procedure

- 4.1 Name of operator and assistant if present
- 4.2 Local anaesthesia used, batch number and expiry date
- 4.3 Site of insertion (i.e. which arm and where)
- 4.4 Type of implant inserted, batch number and expiry date
- 4.5 Implant palpable after insertion
- 4.6 Problems encountered, if any, and actions taken

## 5. Post-insertion follow-up advice

- 5.1 After-care instructions for insertion site
- 5.2 Special instructions if any (e.g. additional contraception for 7 days)
- 5.3 Follow-up date if arranged; "see if any problems" acceptable

## 6. Follow-up

- 6.1 Problems encountered, if any, and actions taken
- 6.2 Implant palpable in subdermal position
- 6.3 If removal is planned, alternative contraception discussed and/or other issues discussed

## 7. Details of removal procedure

- 7.1 Reason for removal
- 7.2 Duration of use
- 7.3 Alternative contraception method advised/provided if any
- 7.4 Name of operator and assistant if present
- 7.5 Local anaesthesia and any instruments used with batch numbers and expiry dates
- 7.6 Technique of removal used
- 7.7 Problems encountered, if any, and actions taken
- 7.8 After-care instructions

## Information Source

- 1. Faculty of Sexual and Reproductive Healthcare. Clinical Effectiveness Unit Guidance. Progestogen-only Implants. April 2008

#### Service Standards for Record Keeping for Progestogen-only Injectable Contraception

##### I. Medical history and clinical assessment

- I.1 Personal and lifestyle history
  - I.1.1 Age
  - I.1.2 Current smoking, number per day
  - I.1.3 Ex-smoker, number per day and date of cessation
  - I.1.4 Alcohol use
- I.2 Contraception
  - I.2.1 Current method
  - I.2.2 Previous contraception used and any problems encountered
  - I.2.3 Duration of use of the injectable progestogen-only contraception to date
  - I.2.4 Awareness and use of emergency contraception
- I.3 Gynaecological history
  - I.3.1 Menstrual history including start date of last menstrual period
  - I.3.2 Coital history
  - I.3.3 Unexplained vaginal bleeding before evaluation
- I.4 Medical history
  - I.4.1 Ischaemic heart disease
  - I.4.2 Hypertension
  - I.4.3 Known hyperlipidaemia
  - I.4.4 Other vascular disease
  - I.4.5 Stroke
  - I.4.6 Current venous thromboembolism on anticoagulants
  - I.4.7 Diabetes, duration of diabetes, presence/absence of nephropathy/retinopathy/neuropathy
  - I.4.8 Headaches
  - I.4.9 Migraines with aura
  - I.4.10 Active viral hepatitis
  - I.4.11 Severe cirrhosis, liver tumours
  - I.4.12 Current or recent breast cancer
  - I.4.13 Eating disorder (e.g. anorexia nervosa)
  - I.4.14 Any other serious medical condition
- I.5 Medication
  - I.5.1 Prescribed, particularly anticoagulants, corticosteroids
  - I.5.2 Non-prescribed/complementary
- I.6 Allergies
- I.7 Family history
  - I.7.1 Stroke/myocardial infarction (MI) in first-degree relative <age 45
  - I.7.2 Osteoporosis

## 2. Examination

- 2.1 Blood pressure (BP)
- 2.2 Weight and body mass index (BMI)
- 2.3 Any other examination/tests

## 3. Information, advice and counselling

- 3.1 Contraceptive choices discussed
- 3.2 Risks/benefits/uncertainties discussed
- 3.3 How it works/efficacy
- 3.4 Side effects
- 3.5 Explanation of injection procedure
- 3.6 Leaflets given – including manufacturer's PIL
- 3.7 Advice given on practising safer sex
- 3.8 Follow-up arrangements

## 4. Prescribing and administering

- 4.1 Record prescription with batch number and expiry date
- 4.2 Site of injection
- 4.3 Special instructions if any (e.g. additional contraception for 7 days)

## 5. Subsequent attendance

- 5.1 Any change in history or medication since last attendance should be recorded
- 5.2 Date of last injection or number of weeks since last injection
- 5.3 Contraceptive choices discussed

## Information Source

- 1. Faculty of Sexual and Reproductive Healthcare. Clinical Effectiveness Unit Guidance. Progestogen-only Injectable Contraception. 2009



#### Service Standards for Record Keeping for Intrauterine Contraception (IUD and IUS)

##### 1. Medical history and clinical assessment

##### 1.1 Personal and lifestyle history

##### 1.1.1 Age

##### 1.2 Contraception

##### 1.2.1 Current method

##### 1.2.2 Previous contraception used and any problems encountered, including difficulty in IUD/IUS insertion

##### 1.2.3 Awareness and use of emergency contraception

##### 1.3 Gynaecological and sexual history

##### 1.3.1 Menstrual history including start date of last menstrual period

##### 1.3.2 Coital history and sexual history to identify risk of sexually transmitted infection (STI)

##### 1.3.3 Unexplained vaginal bleeding

##### 1.3.4 Cervical surgery, including treatment to cervix

##### 1.3.5 Current cervical, endometrial or ovarian cancer

##### 1.3.6 History of STIs and pelvic inflammatory disease (PID)

##### 1.3.7 Immediate post-septic abortion

##### 1.3.8 Uterine fibroids with distortion of uterine cavity

##### 1.3.9 Uterine anatomical abnormality including cervical stenosis

##### 1.3.10 Recent gestational trophoblastic neoplasia with abnormal HCG

##### 1.4 Obstetric history

##### 1.4.1 Caesarean section(s)

##### 1.4.2 Ectopic pregnancy

##### 1.4.3 Postpartum 48 hours to <4 weeks

##### 1.4.4 Puerperal sepsis

##### 1.4.5 Current breastfeeding

##### 1.5 Medical history

##### 1.5.1 Current venous thromboembolism

##### 1.5.2 Migraines with aura

##### 1.5.3 Active viral hepatitis

##### 1.5.4 Severe cirrhosis, liver tumours

##### 1.5.5 Current or recent breast cancer

##### 1.5.6 Pelvic tuberculosis

##### 1.5.7 Any other serious medical condition

##### 1.6 Medication

##### 1.6.1 Prescribed

##### 1.6.2 Non-prescribed/complementary

##### 1.7. Allergies

## 2. Information, advice and counselling

- 2.1 Contraceptive choices discussed
- 2.2 Risks/benefits/uncertainties discussed
- 2.3 Mode of action and efficacy of IUDs
- 2.4 Choice of devices and duration of use
- 2.5 Effects on bleeding pattern
- 2.6 Risk of spontaneous expulsion and perforation and advisability of thread check and teaching
- 2.7 Risk of post-insertion pelvic infection and record of any swabs taken if applicable
- 2.8 Explanation of insertion procedure
- 2.9 Consent obtained
- 2.10 Leaflets given – including manufacturer's PIL
- 2.11 Advice given on practising safer sex

## 3. Details of insertion procedure

- 3.1 Name of operator and assistant
- 3.2 Any tests undertaken
- 3.3 Bimanual examination and speculum findings
- 3.4 Analgesia/local anaesthesia if used
- 3.5 Tenaculum/Allis forceps application
- 3.6 Uterine sounding/uterocervical length
- 3.7 Type of device, batch number, expiry date
- 3.8 Use of no-touch technique
- 3.9 Problems encountered, if any, and actions taken

## 4. Post-insertion follow-up advice

- 4.1 Other treatment if any (e.g. antibiotics)
- 4.2 Special instructions if any (e.g. post-coital IUD)
- 4.3 Follow-up if any problems or cannot feel thread

## 5. Details of removal

- 5.1 Reason for removal
- 5.2 Coital history (since last menstrual period) to identify risk of pregnancy
- 5.3 Alternative contraception method advised/provided if any
- 5.4 Technique of removal used
- 5.5 Problems encountered, if any, and actions taken

## Information Source

- 1. Faculty of Sexual and Reproductive Healthcare. Clinical Effectiveness Unit Guidance. Intrauterine Contraception. 2007

#### Service Standards for Record Keeping for Emergency Contraception

##### 1. Medical history and clinical assessment

- 1.1 Reason for request for emergency contraception (EC)
  - 1.1.1 Unprotected sexual intercourse (UPSI)
  - 1.1.2 Contraceptive method problem
  - 1.1.3 Advance provision
- 1.2 Unprotected sexual intercourse (UPSI)
  - 1.2.1 Number of hours since most recent UPSI
  - 1.2.2 Day of cycle when this occurred
  - 1.2.3 Consensual or non-consensual
  - 1.2.4 First episode of UPSI in cycle
  - 1.2.5 Previous use of EC in cycle
  - 1.2.6 Date(s) when this was used
  - 1.2.7 Method problem (e.g. missed pills, late Depo-Provera)
- 1.3 Bleeding/menstrual/obstetric history
  - 1.3.1 Last normal menstrual period
  - 1.3.2 Shortest/usual cycle length
  - 1.3.3 In case of recent pregnancy – date of delivery, abortion or miscarriage
- 1.4 Drug interaction
  - 1.4.1 Use of interacting medication (e.g. enzyme inducers or products that increase gastric pH)

##### 2. Sexually transmitted infection (STI) risk

- 2.1 STI risk assessment
- 2.2 Information re timing and access to STI screening
- 2.3 Ongoing safer sex information

##### 3. Counselling, information and advice

- 3.1 Counselling hormonal emergency contraception
  - 3.1.1 Which products discussed and product selected for use
  - 3.1.2 IUD discussed and fitting offered if appropriate
  - 3.1.3 Mode of action
  - 3.1.4 Risk of failure particularly in view of the time of the cycle when UPSI occurred and time since UPSI
  - 3.1.5 How to take product
  - 3.1.6 Action to take if patient vomits within 2 or 3 hours
  - 3.1.7 Possibility of irregular bleeding and timing of next menses
  - 3.1.8 Indications for pregnancy test and follow-up
  - 3.1.9 Product gives no ongoing contraception
  - 3.1.10 Method leaflet given
  - 3.1.11 Off-licence use

- 3.2 Counselling re copper intrauterine device (see also Appendix 5)
  - 3.2.1 Mode of action
  - 3.2.2 Efficacy
  - 3.2.3 Risks/benefits/side effects
  - 3.2.4 Ongoing contraception offered by method
  - 3.2.5 Infection risk discussed and antibiotic cover offered if indicated
  - 3.2.6 Method leaflet given
  
- 3.3 Counselling re future contraception
  - 3.3.1 Client's chosen method issued after appropriate assessment or clear pathway to accessibility, counselling and teaching of the method
  - 3.3.2 Advice about action where client continuing with current method
  - 3.3.3 Advice on practising safer sex
  
- 4. Prescribing and issuing**
  - 4.1 Levonorgestrel or ulipristal acetate emergency contraception
    - 4.1.1 Record prescription with batch number and expiry date
    - 4.1.2 Special instructions if any (e.g. off-licence use)
    - 4.1.3 Copper intrauterine device fitted – refer to Intrauterine Contraception Record Keeping Standard

### Information Sources

1. Faculty of Sexual and Reproductive Healthcare. Clinical Effectiveness Unit Guidance. Emergency Contraception. 2006. [www.fsrh.org](http://www.fsrh.org)
2. Faculty of Sexual and Reproductive Healthcare. Clinical Effectiveness Unit. New Product Review: Ulipristal Acetate. October 2009. [www.fsrh.org](http://www.fsrh.org)

### Retention of Health Records

Table extracted from Records Management: NHS Code of Practice Part 2 Annex D1 – this table should be read in conjunction with Annex D. For guidance on retention of business and corporate (non-health) records and retention of electronic records/audit trails please refer to Annex D 2 and Annex D3.

Download from:

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4131747](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4131747)

Health Record	Minimum Retention Period
Abortion – Certificate A (Form HSA1) and Certificate B (Emergency Abortion)	3 years
Audit trails (Electronic Health Records)	NHS organisations are advised to retain all audit trails until further notice
Cervical screening slides	10 years
Children and young people (all types of records relating to children and young people)	Retain until the patient's 25th birthday or 26th if young person was 17 at conclusion of treatment, or 8 years after death. If the illness or death could have potential relevance to adult conditions or have genetic implications, the advice of clinicians should be sought as to whether to retain the records for a longer period
Clinical audit records	5 years
Clinical protocol (GP, in house)	25 years
Clinical psychology	20 years
Counselling records	20 years or 8 years after the patient's death if patient died while in the care of the organisation  Guidance for best practice: The Employment of Counsellors and Psychotherapists in the NHS, British Association for Counselling and Psychotherapy (BACP) (2004)  NB "Those (counsellors) working within the NHS may be obliged to make counselling entries onto the patient's medical records or in a case file..." These records are subject to the retention periods in this schedule

<p>DNA (health records for patients who did not attend for appointments as outpatients)</p>	<p>Where there is a letter or correspondence informing the healthcare professional/organisation that has referred the client/patient/service user that the patient did not attend and that no further appointment has been given, so this information is also held elsewhere. Retain for 2 years after the decision is made. Where there is no letter or correspondence informing the healthcare professional/organisation that has referred the client/patient/service user that the patient did not attend and that no further appointment has been given. Retain for the period of time appropriate to the patient/specialty, for example, children's records should be retained as per the retention period for the records of children and young people; mentally disordered persons (within the meaning of the Mental Health Act 1983) 20 years after the last entry in the record or 8 years after the patient's death if patient died while in the care of the organisation</p>
<p>Contraception and sexual health records (including where a scan is undertaken prior to termination of pregnancy but the patient goes elsewhere for the procedure)</p>	<p>8 years (in adults) or until 25th birthday in a child (age 26 if entry made when young person was 17), or 8 years after death. See also Guidance on the Retention and Disposal of Hospital Notes, British Association for Sexual Health and HIV (BASHH) <a href="http://www.bashh.org/committees/cgc/servicespecific/guidance_retention_disposal_notes_0606.pdf">http://www.bashh.org/committees/cgc/servicespecific/guidance_retention_disposal_notes_0606.pdf</a>.</p>
<p>Genitourinary medicine (GUM) (including sexual health records)</p>	<p>For records of adults: retain for 10 years after last entry. For clients under 18: retain until 25th birthday or for 10 years after last entry, whichever is the longer [i.e. records for clients aged 16–17 should be retained for 10 years and records for clients under 16 should be retained until age 25 (i.e. still retained for at least 10 years)]. Records of deceased persons should be retained for 8 years after death. See also Guidance on the Retention and Disposal of Hospital Notes, British Association for Sexual Health and HIV (BASHH) <a href="http://www.bashh.org/committees/cgc/servicespecific/guidance_retention_disposal_notes_0606.pdf">http://www.bashh.org/committees/cgc/servicespecific/guidance_retention_disposal_notes_0606.pdf</a></p>
<p>Immunisation and vaccination records</p>	<p>For children and young people: retain until the patient's 25th birthday or 26th if the young person was 17 at conclusion of treatment. All others retain for 10 years after conclusion of treatment</p>
<p>Learning difficulties and learning disabilities</p>	<p>Retain for the period of time appropriate to the patient/specialty [e.g. children's records should be retained as per the retention period for the records of children and young people; mentally disordered persons (within the meaning of the Mental Health Act 1983) 20 years after the last entry in the record or 8 years after the patient's death if patient died whilst in the care of the organisation]</p>

Operating theatre lists (paper)	4 years (for those lists that only exist in paper format and are the sole record); 48 hours (for prints taken from computer records)
Operating theatre registers	8 years after the year to which they relate
Outpatient lists (where they exist in paper format)	2 years after the year to which they relate
Referral letters (for patients who are treated by the organisation to which they were referred)	Referral letters should be filed in the patient/client service user's health record, which contains the record of treatment and/or care received for the condition for which the referral was made. This will ensure that the patient record is a complete record. These records should then be retained for the period of time appropriate to the patient/specialty [e.g. children's records should be retained as per the retention period for the records of children and young people; mentally disordered persons (within the meaning of the Mental Health Act 1983) 20 years after the last entry in the record or 8 years after the patient's death if patient died while in the care of the organisation]
Referral letters for clients referred to health or care services but not accepted	Where there is a letter or correspondence detailing the reasons for non-acceptance that goes to the organisation that has referred the client, so the information is also held elsewhere: retain for 2 years after the decision is made. Where there is no letter or correspondence detailing the reasons for non-acceptance that goes to the organisation that has referred the client: retain for the period of time appropriate to the patient/specialty [e.g. children's records should be retained as per the retention period for the records of children and young people; mentally disordered persons (within the meaning of the Mental Health Act 1983) 20 years after the last entry in the record or 8 years after the patient's death if patient died while in the care of the organisation]
Ultrasound records (e.g. vascular, obstetric)	Retain for the period of time appropriate to the patient/specialty [e.g. children's records should be retained as per the retention period for the records of children and young people; mentally disordered persons (within the meaning of the Mental Health Act 1983) 20 years after the last entry in the record or 8 years after the patient's death if patient died while in the care of the organisation]
Standard Operating Procedures (current and old)	30 years

## Service Standards for Sexual and Reproductive Healthcare



<p>Referral letters [to PCT clinical service (e.g. ECG) where the results are sent back to GPs]</p>	<p>2 years</p>
<p>Referral letters – where the appointment was cancelled by the patient before the referral letter was included in the patient record (i.e. before the clinic preparation process)</p>	<p>Where a letter is sent to the referring clinician detailing the reason(s) why the patient/client cancelled the appointment: retain for 2 years after the date the appointment was cancelled. Where there is no letter or correspondence detailing the reasons for the patient not attending for their appointment that goes to the clinician that referred the patient/client: retain for the period of time appropriate to the patient/specialty [e.g. children's records should be retained as per the retention period for the records of children and young people; mentally disordered persons (within the meaning of the Mental Health Act 1983) 20 years after the last entry in the record or 8 years after the patient's death if patient died while in the care of the organisation]</p>
<p>Scanned records relating to patient care</p>	<p>Retain for the period of time appropriate to the patient/specialty [e.g. children's records should be retained as per the retention period for the records of children and young people; mentally disordered persons (within the meaning of the Mental Health Act 1983) 20 years after the last entry in the record or 8 years after the patient's death if patient died while in the care of the organisation]. NB. Providing the scanning process and procedures are compliant with BSI's BIP:0008 – Code of Practice for Legal Admissibility and Evidential Weight of Information Stored Electronically, once the case notes have been scanned the paper records can be destroyed under confidential conditions</p>



## SERVICE STANDARDS FOR RISK MANAGEMENT

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### Introduction

Risk management is an approach to improving the quality and safety of healthcare by identifying circumstances that put patients and staff at risk and acting to prevent or control those risks.

Definitions of risk management may vary, but the most commonly accepted comprehensive definition is provided by the joint Australia/New Zealand standard 4360:1999<sup>1</sup>:

“... a logical and systematic method of establishing the context, identifying, analysing, evaluating, treating, monitoring and the communication of risks associated with any activity, function or process in a way that will enable organisations to minimise losses and maximise opportunities. Risk Management is as much about identifying opportunities as avoiding or mitigating losses.”

These processes have now been integrated into the Standards for Better Health (2004).<sup>2</sup> The standards are the main driver for continuous improvement in quality. They provide the framework for the provision and assessment of healthcare in terms of safety, clinical and cost effectiveness, governance, patient focus, accessible and responsive care, environment and amenities and public health.

Good risk management is central to clinical governance. Every NHS Trust should have an ongoing risk management process of identifying, assessing and prioritising risks with the objective of preventing avoidable risks and managing and controlling those risks that remain.

Clinical risk is interdependent on other types of risk (i.e. operational and financial and should not be viewed in isolation). There may be resource implications to minimising or eliminating risk.

Risk management strategy should be read in conjunction with all other Trust key documents, policies and procedures, having relevance to the management of risk, that have been set in place to support the Trust in the management and control of risk such as:

- Health and Safety Policy
- Fire Policy
- Infection Control Policies
- Incident Reporting Policy
- Complaints Procedure
- Claims and Legal Advice Policy
- Manual Handling Policy
- Information Governance Policy
- Record Keeping Policy
- Lone Working Policy.

The management of clinical risk is the responsibility of all staff and should be part of a quality improvement programme. All staff must accept the management of risk as one of their fundamental duties. Individual roles and responsibilities should be clearly understood. Risk should not be ignored. Ongoing training in quality improvement and risk management is important for all professionals working in sexual and reproductive health (SRH) services.

Risk will always be a factor present in the provision of healthcare. The key to successful risk management is to strike a balance between overprotection that inhibits progress and innovation, and insufficient protection which can lead to unnecessary injury, loss or damage.

The NHS Litigation Authority has produced Risk Management Standards.<sup>3</sup> Trusts are scored on the standards of:

1. Governance
2. Competent and Capable Workforce
3. Safe Environment
4. Clinical Care
5. Learning from Experience.

The progression of organisations through the standards is logical and follows the development, implementation, monitoring and review of policies and procedures.

## Level 1 – Documenting (Policy)

This demonstrates that the process for managing risks has been described and documented.

## Level 2 – Implementing (Practice)

This demonstrates that the process for managing risks, as described in the approved documentation, is in use. Evidence should be provided for a number of departments and/or staff groups and/or patient types, etc. The evidence may include risk assessments, records (e.g. training, medical device inventories, incident reports, completed proformas, evaluations, etc).

## Level 3 – Monitoring (Performance)

This demonstrates whether or not the process for managing risk, as described in the approved documentation, is working across the entire organisation. Where failings have been identified, action plans must have been drawn up and changes made to reduce the risks. Monitoring is normally proactive - designed to highlight issues before an incident occurs - and should consider both positive and negative aspects of a process.

Awareness of these Trust requirements will allow services to respond to Trusts appropriately (see Annex).

This document outlines the basic principles of risk management and the process for implementing risk management in the context of contraceptive and SRH services.

### I. Standard Statement on Risk Management Strategy

**Sexual and reproductive healthcare services should have a Risk Management Strategy which is linked with the NHS Trust's own Risk Management Strategy.**

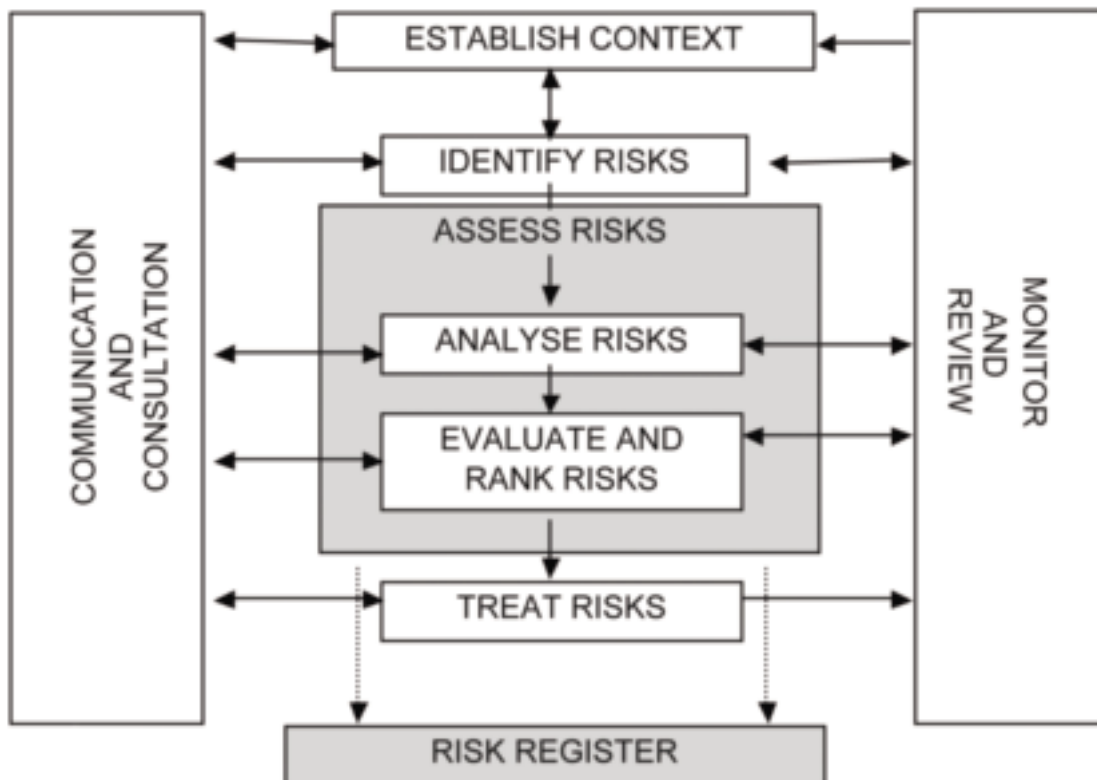
- 1.1 Clinical risk management should follow a structured approach within a clinical governance framework, to meet the needs of the client, clinician and organisation.
- 1.2 Strategic direction should be provided by a risk management group with a senior clinician as the designated lead.
- 1.3 Membership of this group should be multi-disciplinary (e.g. nurses, administrative staff and link person from the Trust's clinical governance team). Consultation and involvement of staff and service users is essential.
- 1.4 A risk register, which includes clinical and non-clinical risks, should be established. There should be an action plan relating to the risks contained in the register.
- 1.5 Systems should be in place to communicate effectively with all staff. Staff involvement will increase awareness of potential risks and make it easier to implement changes in practice. It should be the responsibility of every member of staff to recognise, respond to, report, record, be accountable and reduce risks whilst they are undertaking work for the Trust.
- 1.6 Training and updating programme for risk management should be available to all staff.

## 2. Standard Statement on Risk Management Process

**The Risk Management Process should identify, assess and treat risk. A risk register should be established with a process for monitoring and review of risk.**

An effective Risk Management System is the systematic application of management policies, procedures and practices to the tasks of establishing the context of, identifying, analysing, evaluating, treating, monitoring and communicating risk.

### A Typical Risk Management Process<sup>1</sup>



### 3. Standard Statement on Risk Identification

**Sexual and reproductive healthcare services should have a system that enables a comprehensive approach to risk identification and should include both prospective and retrospective indicators.**

- 3.1 All areas where services are provided should have formal processes for identifying anything which may interfere with the delivery of a safe, good quality service. This includes outreach settings.
- 3.2 All staff should be able to complete an incident report.
- 3.3 Local tools used to identify risk include:
- Incident and near-miss reporting systems (a suggested trigger list for incident reporting in SRH services are contained in the Annex)
  - Complaints and claims
  - Freedom of Information (FOI) request
  - Client satisfaction surveys
  - Staff consultation – surveys, workshops, interviews
  - Clinical audit
  - Structured assessment when reviewing service or planning changes in service
  - New or changing legislation
  - Performance monitoring
  - Following an inspection by infection prevention, fire or safety experts, etc.
- 3.4 National data useful in identifying risk:
- National Patient Safety Agency (NPSA) Alerts
  - Healthcare Commission reports
  - Medical Defence Society's data
  - Training, accreditation and competencies (e.g. DFRH and LoC)
  - MHRA reports
  - NICE Guidance
  - National Service Frameworks
  - NHSLA
  - SIGN.
- 3.5 Although avoidance of complaints/litigation is important, the care and safety of users, carers and staff should be the primary concern.

## 4. Standard Statement on Risk Assessment and Evaluation

**Risk assessment should be carried out to establish the level of risk associated with a particular incident.**

- 4.1 Risk is regarded as being composed of two factors: the likelihood of an event occurring and the consequences that take place as a result.
- 4.2 Likelihood and consequences are combined to produce a level of risk. A risk might have a low likelihood of occurring, but if it did, would have severe consequences for the user, staff and/or the organisation. Alternatively, a risk may occur every day, but have little or no consequence.
- 4.3 Every NHS organisation has its own Risk Assessment Matrix, where a severity ranking is applied to give an indication of how serious an event would be.
- 4.4 Relevant staff should be familiar with their local Risk Assessment Matrix.

### 5. Standard Statement on Treatment of Risk (Action Plan)

The cause of any incident should be managed by identifying the range of options for dealing with the risk associated, assessing the options, preparing a risk reduction action plan and implementing the plan.

5.1 Risk Treatment Options: one of the following options should be considered:

Risk Avoidance:	Do not proceed with activity or enter that situation
Risk Reduction:	Put in place measures to minimise the consequences
Risk Acceptance:	Risk will never be completely eliminated
Risk Transfer:	Arrange for another party to share some part of the risk through joint ventures, contracts or partnerships, etc.

5.2 Risk treatment will be influenced by the risk rating.

5.3 An action plan should be developed by the risk management group to define the strategies to be implemented to reduce the risk of similar events occurring again.

5.4 There should be identification of significant resource implications required to reduce risk and where a change in the culture of the service is needed.

5.5 The action plan should address responsibility for implementation of each action item identified including a timeframe.

5.6 The action plan should also have strategies for measuring the effectiveness of the action items.

### 6. Standard Statement on Monitoring, Review and Feedback

**Risk should be monitored by establishing and maintaining a risk register.**

- 6.1 All identified risks, action plans and consequent outcomes should be entered into a risk register.
- 6.2 The risk management group should meet regularly to monitor and review incidents within the service.
- 6.3 This group should liaise with the protocol group to inform changes in protocols and patient referral pathways.
- 6.4 Feedback within the service should be provided via newsletter, meetings or email where available. Feedback should:
- Acknowledge the contribution of staff
  - Include the issues identified
  - Demonstrate learning using the data
  - Identify the actions taken or seek assistance to address these.
- 6.5 Feedback should also be given to individual staff; the objective of this is to:
- Reassure them that they make a valuable contribution to the enhancement of safety
  - Develop trust in the system
  - Make them understand the importance of risk management and the value of reporting.
- 6.6 Communication to external sources as relevant (e.g. NPSA, NHSLA, MHRA) should take place through the Trust's risk management team.



### GLOSSARY OF TERMS which may be used with regard to risk

**Controls** - those documents, systems, processes, devices and equipment intended to mitigate the likelihood and/or severity of a risk

**Event** - a hazard which materialises

**Hazard** - an event or situation that has the potential to cause injury, loss, damage or harm to:

- people (staff, patients, contractors, public);
- the organisation (finance, operations, objectives, reputation); or
- the environment (pollution, inefficient use of resources).

**Incident** - any event which results, or might have resulted, in injury or abuse to any staff, patients, visitors, external contractors, students, volunteers or other person or loss of or damage to property or equipment

**Near Miss** - a hazard which fails to turn into an event by chance or by timely intervention, for example, medicines discovered to be out of date and removed. If the medicine were administered but the patient suffered no ill effects, that would be a 'no harm' incident

**Risk** - the likelihood of occurrence and severity of consequence of an event occurring. Other words, such as probability, or impact are sometimes used instead

**Risk Assessment** - the systematic process for prioritising risks on the basis of a combination of the severity of consequence and likelihood of occurrence

**Risk Management** - the systematic process for identifying, assessing, mitigating and reviewing risk

NHSLA	NHS Litigation Authority
MHRA	Medicines and Healthcare products Regulatory Authority
NPSA	National Patient Safety Agency
DFSRH	Diploma of the Faculty of Sexual and Reproductive Healthcare
LoC	Letters of Competence of the Faculty of Sexual and Reproductive Healthcare
IUD	Intrauterine Device
PGD	Patient Group Direction

## Annex to Standard Statement 3 on Risk Identification

These are areas of potential risk in SRH settings. Please note that the lists below are not exhaustive. They are a guide and should be added to as and when further information becomes available.

### I. Procedures

#### I.1 Invasive procedures:

- Intrauterine instrumentation (e.g. IUD insertion, surgical abortion)
- Cervical screening
- Genital swabs
- Implanon insertion and removal
- Vasectomy
- Venepuncture
- Immunisation.

#### I.2 Intramuscular injection (e.g. Depo-Provera).

#### I.3 Improper handling of sharps and clinical waste.

#### I.4 Use of latex.

#### I.5 Resuscitation: training, equipment and drugs.

### **2. Organisation and/or Environmental Hazards**

- 2.1 Lack of communication to staff regarding change in organisation of clinics/services.
- 2.2 Poor standards of cleanliness.
- 2.3 Poor physical environment.
- 2.4 Lack of prompt access to appropriate healthcare for staff exposed to blood-bourne viruses.
- 2.5 Interruptions causing distraction and potential mistakes.
- 2.6 Non availability or poor quality of equipment necessary for the procedure (e.g. non-adjustable couch could cause a back injury to clinician).
- 2.7 Lack of security for staff.
- 2.8 Aggression of clients.
- 2.9 Lack of team working.
- 2.10 Lone working.
- 2.11 Inadequacy of relevant information sharing between agencies.

### **3. Capacity versus Workload (see also Faculty website for Workload Standards<sup>4</sup>)**

- 3.1 Too many patients for capacity.
- 3.2 Too few doctors/nurses in individual settings.
- 3.3 General staff shortages and difficulty covering sickness and annual leave leading to process not meeting needs of patients (e.g. in walk-in clinics).
- 3.4 Shortage of time to counsel patients properly.
- 3.5 Excessive number of trainee/junior staff needing time.
- 3.6 Clinics running over time.
- 3.7 Staff doing too many clinics in one day (tiredness of staff).
- 3.8 Poor communication resulting from working under pressure of time.
- 3.9 Vulnerable clients needing staff time and expertise (e.g. under-16s).

### **4. Staff Management (see also Faculty website for Sexual Health Services,<sup>5</sup> Record Keeping<sup>6</sup> and Workload Standards<sup>4</sup>)**

- 4.1 Lack of training, competencies and accreditation.
- 4.2 Lack of clinical supervision and regular appraisals.
- 4.3 Poor morale, communication skills and team working.
- 4.4 Inadequate/no time for continuing professional development.
- 4.5 Limited or no access to up to date departmental and national guidelines, in paper and electronic format.
- 4.6 Lack of clarity about individual roles and responsibilities.
- 4.7 Lack of awareness of risk and importance of risk management.
- 4.8 Inadequate knowledge of particular service (new staff/locums).
- 4.9 Patchy record keeping.
- 4.10 User identification not clearly established.
- 4.11 Patient consent not obtained.
- 4.12 Inadequate labelling of diagnostic samples.
- 4.13 Lack of adequate chaperone provision.
- 4.14 Lack of support around communication (e.g. interpreters).

### **5. Medicines Management (see also Faculty website for Record Keeping<sup>6</sup> and Medicines Management Standards<sup>7</sup>)**

- 5.1 Labelling is not clear and does not meet legal requirements.
- 5.2 Inappropriate storage, handling and administration of medication.
- 5.3 No patient information leaflets provided with supply of medicine.
- 5.4 Inadequate medical history, hence inability to prevent drug interaction and anaphylaxis.
- 5.5 Lack of security to prevent theft of drugs and prescription pads.
- 5.6 Usage of similar containers for different drugs.
- 5.7 Lack of processes in place for checking expiry date and stock rotation.
- 5.8 Lack of clear prescribing.
- 5.9 Provision of treatment outside clinician's competence (e.g. issuing beyond PGD parameters).
- 5.10 Inadequate knowledge and use of reporting systems for errors or adverse reactions both organisational internal incident reporting procedure and externally to MHRA (Yellow Card).
- 5.11 Lack of system where appropriate, for explanation to user and recording of supply/administration off-licence.

### **6. Confidentiality (see also Faculty website for Confidentiality<sup>8</sup> and Record Keeping Standards<sup>6</sup>)**

- 6.1 Absence of confidentiality statements in all clinics.
- 6.2 Lack of staff training in confidentiality.
- 6.3 Lack of awareness/avoidance of conversations (including those on the telephone) being overheard.
- 6.4 Communication status not discussed with patients and documented before any contact from the clinic.
- 6.5 Records/forms left where other clients can read them.
- 6.6 Lack of sound-proofing of rooms.
- 6.7 Lack of access to confidential electronic network (e.g. nhs.net).

### **7. User Involvement (see also Faculty website for Sexual Health Service Standards<sup>5</sup>)**

- 7.1 Lack of user involvement in service design.
- 7.2 User's needs not catered for in service design.



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