Statement from the FSRH Clinical Standards Committee, the Clinical Effectiveness Committee and the Associate Members' Working Group on the prescription, administration or supply of Contraceptive Medicines for use outside the terms of their licences

There are many generally accepted off licence ("off-label") usages of contraception.

The General Medical Council guidance document "Good Practice in Prescribing Medicines" (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 above committees have agreed that Clinical Effectiveness Unit 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 clinicians 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 Clinical Effectiveness Unit. Similarly, current guidance from the RCOG and NICE should be regarded as common practice.

Current guidance to nurse/midwife prescribers is different. The Nursing and Midwifery Council (NMC) advises that nurse or midwife independent prescribers may prescribe off-label if they are satisfied that this better serves the patient/client's needs, if they are satisfied that there is sufficient evidence-base and that they have explained to the patient/client the reasons why medicines are not licensed for their proposed use, and document accordingly.

The NMC also states it is acceptable for medicines used outside the terms of the licence to be included in Patient Group Directions (PGDs) when such use is justified by current best clinical practice and the direction clearly describes the status of the product.

References

1. General Medical Council. Good Practice in Prescribing Medicines (2008) http://www.gmc-uk.org/guidance/current/library/prescriptions_faqs.asp#p19
2. Faculty of Sexual & Reproductive Healthcare. Service Standards on Record Keeping 2009
3. Faculty of Sexual & reproductive Healthcare. Service Standards on Medicines Management 2009
4. Nursing and Midwifery Council. Standards of Proficiency for Nurse and Midwife Prescribers. 2006. Practice Standard 18; page 38.

   http://www.nmc-uk.org/aDisplayDocument.aspx?documentID=6942
5. Nursing and Midwifery Council. Standards for Medicines Management 2008. Standard 22; page 45 http://www.nmc-uk.org/aDisplayDocument.aspx?DocumentID=6978