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Presenting risk information in sexual and reproductive health care

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Abstract:	Objectives: Presenting risk information to patients is an important part of clinical encounters. Good risk communication improves patient satisfaction with care and their decisions. In sexual and reproductive health care, women frequently need to make decisions based on their perceived risk. Risk perception can be altered by how actual risk is presented to patients. Methods: Databases were searched using MeSH terms combined with a keyword search for articles relevant to sexual and reproductive health; the search was limited to English language. Results: Personalised risk communication where a risk score is provided, increases knowledge and slightly increases uptake of screening tests. Decision aids improve patient's knowledge of the options, create realistic expectations of their benefits and harms, reduce difficulty with decision-making and increase participation in the process. The most effective way to present risks uses a range of structured, tailored presentation styles; interactive formats are best. Framing the information improves patient understanding. Most people understand natural frequencies or event rates better than probability formats with varying denominators. Expressing changes in risk as an absolute risk reduction or relative risk reduction with baseline risk formats improves understanding. Descriptive terms such as 'low risk' or 'high risk' should be quantified as a frequency rather than a percentage. Using a consistent denominator to portray risk is recommended. Using the "number needed to treat" and visual aids puts benefits or risks into perspective. The duration of risk should be presented. Conclusions: Presenting risk information to patients can be optimised using a number of strategies.

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Presenting risk information in sexual and reproductive health care

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Keywords: ~~health education,~~ health education, counseling, ~~medico-legal, education and training,~~ sexual and reproductive health ~~family planning~~ service provision, ~~epidemiology~~communication of risk, clinical decision-making, decision support techniques, clinical decision support systems, informed consent, reproductive medicine,

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Abstract

Objectives: Presenting risk information to patients is an important part of clinical encounters. Good risk communication improves patient satisfaction with care and their decisions. In sexual and reproductive health care, women frequently need to make decisions based on their perceived risk. Risk perception can be altered by how actual risk is presented to patients.

Methods: Databases were searched using MeSH terms combined with a keyword search for articles relevant to sexual and reproductive health; the search was limited to English language. ~~We searched the literature to identify strategies to improve patient understanding of risks and decision-making with relevance to sexual and reproductive health.~~

Results: Personalised risk communication where a risk score is provided, increases knowledge and slightly increases uptake of screening tests. Decision aids improve patient's knowledge of the options, create realistic expectations of their benefits and harms, reduce difficulty with decision-making and increase participation in the process. The most effective way to present risks uses a range of structured, tailored presentation styles; interactive formats are best. Framing the information improves patient understanding. Most people understand natural frequencies or event rates better than probability formats with varying denominators. Expressing changes in risk as an absolute risk reduction or relative risk reduction with baseline risk formats improves understanding. Descriptive terms such as 'low risk' or 'high risk' should be quantified as a frequency rather than a percentage. Using a consistent denominator to portray risk is recommended. Using the "number needed to treat" and visual aids puts benefits or risks into perspective. The duration of risk should be presented.

Conclusions: Presenting risk information to patients can be optimised using a number of strategies.

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Key Message Points

- Presenting risk information to patients is an important part of clinical encounters and good risk communication improves patient satisfaction with care.

- Strategies to improve patient understanding of risks include providing personalised risks, using decision aids, presenting information in a variety of structured, tailored and/or interactive formats.

- To quantify risk, use numbers rather than words, event rates or natural frequencies,rather than probabilities or relative risk reduction, absolute risks rather than relative risks.

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Introduction

Healthcare professionals often need to discuss risks with patients in sexual and reproductive health care. One suggested approach involves first describing the frequency of the risk and then the possible associated harm (1). For instance, the risk of perforation during insertion of an intrauterine device (IUD) is 0-2.3 per 1000 insertions, which is rare to uncommon, but this must be qualified by the amount of associated harm such as bowel perforation and peritonitis. Both healthcare professionals and patients have difficulty understanding risk in terms of numerical odds and probabilities (2). The RCOG Clinical Governance Advice on Presenting Information on Risk provides general principles on how best to communicate risk in women's health (3). In this paper we discuss how best to define and present descriptions of risk in clinical decision-making with patients in sexual and reproductive health, using examples relevant to sexual and reproductive health care.

Methodology

We searched the Cochrane Library (Cochrane Central Register of Controlled Trials (CENTRAL), HTA and the National Research Register), Cochrane Database of Systematic Reviews, the Centre for Reviews and Dissemination, the Database of Abstracts of Reviews of Effects (DARE), MEDLINE (Ovid), Excerpta Medica dataBASE (EMBASE), Turning Research Into Practice (TRIP) database, National Electronic Library of Health and Medline for relevant studies and articles published between 1966 and August 2015. The databases were searched using the relevant MeSH terms including all sub-headings ('clinical decision-making', 'decision support techniques', 'decision support systems, clinical', 'decision-making, computer-assisted', 'decision trees', 'communication', 'informed consent', 'consent forms', 'reproductive medicine' and 'health education'. This was combined with a keyword search that included 'presentation of risk', 'public perception of risk', 'communication of risk', 'consent', 'decision-aid', 'counseling', and the search was limited to English language. The following websites were also searched using the above phrases: Bandolier, MHRA, Royal College of Physicians, Royal College of Anaesthetists, Royal College of Surgeons, Royal College of Obstetricians & Gynaecologists, Department of Health, Medical Defence Union, NICE, SIGN, National Screening Committee, World Health Organisation, The Risk Information Institute, Kings Fund, Royal Society, Research Findings Register, The National Health and Medical Research Council of Australia, the International Patient Decision Aid Standards Collaboration, The Institute of Risk Management. We included trials, qualitative studies, systematic reviews and reviews addressing decision-making, decision-aids,

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counselling, risk presentation, communicaton or its public perception and consent, in relation to sexual and reproductive health.

~~Databases were searched using the relevant MeSH terms, including all subheadings, combined with a keyword search. We used the following search words: 'presentation of risk', 'public perception of risk', 'communication of risk', 'consent', 'decision making'; the search was limited to English language.~~

What is risk?

A risk is the likelihood (or probability) that harm will occur from a particular hazard (4). Patients may be concerned with broader qualitative attributes, such as the origin of the risk (natural or technological), whether a risk is imposed or temporary and the power that they have to control the risk (5). Many times in reproductive healthcare there are hazards associated with a particular decision. For example, there are risks of pelvic inflammatory disease with an IUD,, a probability of up to 9 in 100 of pregnancy with typical use of combined oral contraception (6) or a consequence that well over half of progestogen implant users experience a change in menstrual bleeding pattern (7). Patients will generally take risks if they perceive that there is an advantage or benefit. Normally, the benefits should outweigh the risks by a significant margin. There is no such thing as a zero risk (8)(9) and patients should be made aware that there is no medicine or drug without a possible risk or side effect, including medicines used for contraception.

Risk perception is subjective (10). Patients tend to act on the basis of their perception of the risk rather than the on 'actual' risk presented to them (11). Their estimates of risk may differ from those of the healthcare professional who counsels them (12)(2)(13). Other factors may play a role. For example uptake of genetic testing in prenatal care was strongly predicted by women's general attitude to genetic testing, independent of risk perception (14). Risks may be perceived as far less tolerable if the treatment or intervention is voluntary, the technology is unfamiliar or has no benefit for the patient.

The importance of good risk communication

Good communication helps to build trusting relationships between patients and professionals, leads to greater satisfaction on both sides (4), with less fear of treatments (15), helps people to take more responsibility for their own health, reduces medical errors and mishaps and even malpractice claims (16)(10).

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Healthcare professionals tend to consider risk as the mathematical probability of something happening within a whole population group (for example, the chance of an ectopic pregnancy in women using an IUD), which is supported by statistical information (1). This way of assessing risk is important, but it is objective, impersonal and deals with populations rather than individuals. Patients on the other hand, use an everyday concept of risk that is bound up in the individual's concerns, anxieties and fears about the present and the future ("What is *my* risk of having an ectopic pregnancy while using an IUD?" for example). Understanding the uncertainty about a treatment is thought to be a critical element of an informed decision and should be communicated effectively to patients (17)(18). At the same time, healthcare professional should make an assessment of the patient's mental capacity to understand the information given, considering this in light of the Mental Capacity Act 2005. Healthcare professionals have traditionally communicated risk poorly (19), but developments such as patient decision aids can improve risk communication (20).

Legal aspects of risk pertaining to patient consent

The legal position on whether or not a doctor or other healthcare professional is negligent in failing to mention a risk to a surgical patient was decided in the UK in the case of Sidaway (21). The more recent Montgomery vs Lanarkshire judgment (22) highlights the importance of an individual approach to advising a patient about a risk. When discussing the benefits and risks of various treatment options with patients, the new ruling requires doctors to consider whether "a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it" (22). Rather than a radical change in medical practice, the judgement has been considered to bring the law in line with current ethical guidance for UK doctors, as stated in the GMC guidance on consent (23). It is therefore advisable to inform the patient of any 'material' or 'significant' risks of the proposed treatment, any alternatives to it and the risks incurred by doing nothing. A Court of Appeal judgment stated that it will normally be the responsibility of the doctor to inform a patient of 'a significant risk which would affect the judgment of a reasonable patient' (Pearce v United Bristol Healthcare NHS Trust (1998) 48 BMLR 118 (CA) (24). It is appropriate to warn of a relatively rare risk for an elective procedure, for example pregnancy following laparoscopic sterilization, since this has a huge impact on the patient if it occurs.

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How to communicate risks

Risks in sexual and reproductive healthcare are personal and rich in uncertainty and there are no clear best practices for presenting information about uncertainty (17). Risk communication can be improved however, by using certain strategies described below.

1.Firstly, personalised risk communication tailors information to an individual's risk status. For example, current evidence suggests a risk of weight gain with Depo Provera® injection use compared to the oral contraception or no hormonal contraceptive method, and more so if the user is already overweight. This risk can be personalised eg. by telling a woman with a body mass index (BMI) of 32 that the average increase in weight over 18 months after starting Depo Provera® is 9.4kg compared to 0.2kg if she took oral contraception and 3.1kg if she did not use hormonal contraception (25). Personalising risk communication enhances informed decision-making (26). A Cochrane Systematic Review found that for individuals undergoing screening procedures, interventions with a 'personalised risk communication element', enhance informed decision making (26). Overall 45.2% (592/1309) of participants who received personalised risk information made informed choices, compared to 20.2% (229/1135) of participants who received generic risk information (Odds ratios for random effects 3.65 (95% CI 2.13 to 6.23). Personalized risk communication does not significantly increase the uptake of such screening tests.

2. Using a range of presentation styles and risk communication tools is the most effective way to give information about risks to patients (27). An RCT of women's understanding of the effectiveness of contraceptive methods found that tables with categories such as "more" or "less effective" communicated relative effectiveness better than numeric tables. However, women grossly overestimated the risk of pregnancy unless they were shown tables with numbers, so a combination of both methods was best (28). Graphically presenting risk information in addition helped general practitioners to build a relationship with women, and allowed them to convey absolute and relative risks quickly without having to explain these concepts (29). A specifically designed tool, the Paling palette (Risk Communication Institute, http://www.riskcomm.com/paling_palettes.htm) can display most medical risks with a probability of higher than 1/1000. The chart shows 1000 people, with the number

experiencing a particular effect coloured in (Figure 1). An alternative system uses icon arrays (www.iconarray.com), a matrix of usually 100 to 1000 icons to represent an at-risk population, simultaneously displaying both the number of expected events and the number of expected non-events.

3. Framing health information as negative or positive can affect patient understanding of risk (30)(31). For example, the chances of combined oral contraception can be presented: in a good user failing (less than 1 in 100, negative framing) versus the chances of successful contraception (over 99 in 100, positive framing). People receiving information framed as a positive or a gain, are more confident of a treatment than those receiving information presented as a negative or loss. Since framing of information can have such a profound effect on patient perception of risk, framing information in a variety of ways is recommended to avoid misunderstanding (32). For example, a patient may be told that there is a 1 in 10 chance that she will have a pregnancy in the first year of using a diaphragm, so this is a 9 out of 10 chance that she will not conceive in the first year (typical risk of contraceptive failure with a diaphragm is 16%).

4. The duration of the risk should also be discussed with the patient at the same time as discussing the amount of risk (33). For example the risk of pelvic inflammatory disease after insertion of an IUD among 22,908 IUD insertions and during 51,399 woman-years of follow-up was 1.6 cases per 1000 woman-years of use on average, but after adjustment for confounding factors, PID risk was more than six times higher during the 20 days after insertion than during later times (unadjusted rates, 9.7 vs 1.4 per 1000 woman-years, respectively); the risk was low and constant for up to eight years of follow-up (34).

Aiding Decision-making

Decision aids such as pamphlets or videos prepare patients to participate in decisions by providing information about treatment or screening options and their associated outcomes. When compared with usual care, decision aids performed better in terms of greater knowledge, more realistic expectations, lower decisional conflict and an increased proportion of people participating in decision-making (20). More detailed decision aids such as booklets or computer based programs are better than simpler ones and significantly improve knowledge, create more realistic expectations and greater agreement between values and choice. A decision aid to

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choose pregnancy termination methods for example, improved knowledge and reduced risk-perception scores about both methods compared to usual counseling (35). In general, structured, tailored and/or interactive communication tools are more effective at increasing patient's understanding of evidence (36). For contraceptive methods, a recent systematic review found that a range of educational interventions can increase knowledge (37). Further research is needed however to determine what aspects of educational interventions are most effective, whether an educator is needed and how education may impact behaviours.

Presenting Numerical Risk Information for Patients

The format in which written and verbal information on probability is presented affects patient understanding of risk. Patients have a more accurate perception of risk if the information is presented as numbers rather than words (36). Presenting natural frequencies, which is a joint frequency of two events, such as the number of patients with a disease and who have a positive test result (38) may also be of benefit.

A change in risk is better understood if absolute risk reduction, or a relative risk reduction with the baseline risk format for the disease, is used (36). For example, there is up to a 30% (30 out of 100) chance of pregnancy when a woman has unprotected sex during her fertile period. Typical failure of condoms to prevent pregnancy is 10-15% (10-15 per 100 women). By using the IUD for emergency contraception this risk of pregnancy is reduced to less than 1% (less than 1 in 100 women will get pregnant). The absolute pregnancy risk reduction is 29% with IUD use, greater than with condom use. Further worked examples for calculating risk reduction are available (39). Descriptive terms such as 'very low risk' or 'high risk' may be used, but they should be qualified by giving a figure, such as a frequency since they can reflect the speaker's perspective and not the patient's view (40).

European Union (EU) guidelines recommend verbal descriptors of risk (9). From a regulatory perspective for patient information leaflets, the emphasis is to express risk as a statistical probability, for example a verbal descriptor such as 'very rare' corresponds to 'up to 0.01%' (less than 1/10 000). However, research into what individuals understand by terms such as 'very rare' or 'common' suggests that the current EU guidelines on verbal descriptors are not correctly matched with statistical probabilities (41)(42). The public equate the verbal descriptors (very rare, common, and so on) to risks that are substantially higher than those defined in regulatory documents. The current EU guidelines are provided in Table 1 (9).

Percentages are an abstract way of portraying risk (for example 5%), whereas the

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actual number of people who could be affected is more vivid to some patients (for example, five of every 100 people). When quantifying risks therefore, it is recommended to use frequencies rather than percentages to portray risk (41), and to help compare between risks, use a consistent denominator (42). Example 1 below uses a consistent denominator to compare venous thromboembolism risks. Another example using a constant denominator considers contraceptive efficacy, stating that in a year of use, 99 out of 100 women will not get pregnant with an IUD, whereas only 85 out of 100 women will not get pregnant with typical use of a male condom.

Using relative risks alone to compare different options can be misleading (41) as was demonstrated in the 1995 'pill scare'. Epidemiologists reported that use of third-generation oral contraceptives doubled the risk of thromboembolism compared with use of second generation oral contraceptives (43). The initial reports did not mention that the absolute risks were low: 1/3000 compared with 1/6000, that the background risk in non-users was 1/20 000 or that the increased risk of death was around 1/1 000 000. The risk was not put into context and media and public panic ensued (44). Evidence suggests that presenting the risk of thrombosis complications in terms of incidence rather than relative risk may improve communication of side effects during counselling for combined hormonal contraception initiation (Machado et al. 2015). Over the last decade there has however been little improvement in the reporting of absolute risks (45). For many observational studies and meta-analyses, absolute risks cannot be reported easily or meaningfully. Wherever possible absolute risks should be stated, since using absolute data allows the consumer to more easily compare different risks (41).

Examples of communicating risks in sexual and reproductive healthcare are listed below.

Example 1: A woman asks you what her risk is of having venous thromboembolism (VTE) while using the combined pill.

The risk of VTE (deep venous thrombosis and pulmonary embolism) in women who are not using the combined contraceptive pill is 2-5/10,000 woman-years (46). This means that in 10,000 women not using the pill over a one-year period up to 5 may have VTE (hence it is "rare"). This doubles to 5-12/10,000 woman years, which is still rare to uncommon, in women who are using combined hormonal contraception (47)(48). In pregnancy and the immediate postpartum, the risk of VTE is much higher: 29/10000 woman years and over 10 times higher postpartum - 300-

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400/10000 woman years. VTE is therefore rare in women who use the combined pill. Women are at a far greater risk of VTE postpartum or during pregnancy than while taking the combined pill as shown in Table 2.

Example 2: A woman is interested in having intrauterine contraception but has heard intrauterine devices (IUDs) are associated with pelvic infection. She asks what her risk is of having a pelvic infection if she chooses an IUD.

The risk of a pelvic infection while using intrauterine contraception is generally low (49), but is increased where there is a sexually transmitted infection (STI) and in the first 3 weeks after IUD insertion. The most comprehensive review to date of insertions and IUD use suggests a risk of up to 16/10,000 woman years (34). Hence pelvic infection after IUD insertion or with IUD use is uncommon. Also, pelvic infection has not been found to be higher in women using IUDs compared to women who are using other methods of contraception such as progestogen-only injectables (50) or no contraception (51). By preventing STIs, the risk of pelvic infection with IUD is further reduced. The patient should be offered an STI screen before her IUD insertion and should practise safer sex to reduce her risk of pelvic infection with the IUD (52).

Example 3: You offer a woman with post-coital bleeding (PCB) a chlamydia test but she declines. Her last STI screen, 6 months ago, was negative and she has not changed partner since. Her partner has never screened for STIs before, but she believes he has no infection as her own results have been negative. What will your advice be?

her own negative test results may suggest, but cannot guarantee, that her partner does not have an infection. Most currently used STI test kits have a sensitivity and specificity of over 97%, so the test will miss 3 in 100 (or 1 in 30) infections. The efficiency of a test depends on the test's ability to give a positive result when there is an infection (sensitivity) and its ability to give a negative result when there is no infection (specificity). Contaminants and hormonal factors may affect a test result; hence no test is 100% (53). It is therefore good practice to repeat some tests when indicated, even if the patient may have done the test previously. This patient has post-coital bleeding and a chlamydia test is clinically indicated. You would therefore recommend a repeat chlamydia test, and an STI screen for her partner.

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Conclusions

Presenting information about risk in a way that facilitates patient understanding improves decision-making and patient satisfaction with care. Presenting risk in a personalised way, using decision aids or interactive methods, presenting information in a variety of formats and framing the risk in both a negative and a positive way all improve risk communication. Patients have a more accurate perception of risk if information on probability is described in numbers rather than words. Most people understand natural frequencies or event rates better than probability formats with varying denominators.

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Table 1. Risk table (modified from (54)**)**

Verbal description[a]	Risk	Risk description[b]
Very common	1/1 to 1/10	A person in family
Common	1/10 to 1/100	A person in street
Uncommon	1/100 to 1/1000	A person in village
Rare	1/1000 to 1/10 000	A person in small town
Very rare	Less than 1/10 000	A person in large town

a EU-assigned frequency

b Unit in which one adverse event would be expected

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Table 2: Risk of venous thromboembolism (VTE) associated with non-use, combined hormonal contraception (CHC) use over the course of 1 year (55).

	Risk of VTE per 10,000 healthy women
Non contraceptive users and not pregnant	2
CHC containing ethinylestradiol plus levonorgestrel, norgestimate or norethisterone	5-7
CHC containing etonogestrel (ring) and norelgestromin (patch)	6-12
CHC containing ethinylestradiol plus gestodene, desogestrel, drospirenone	9-12
Pregnancy	29
Immediately post partum	300-400

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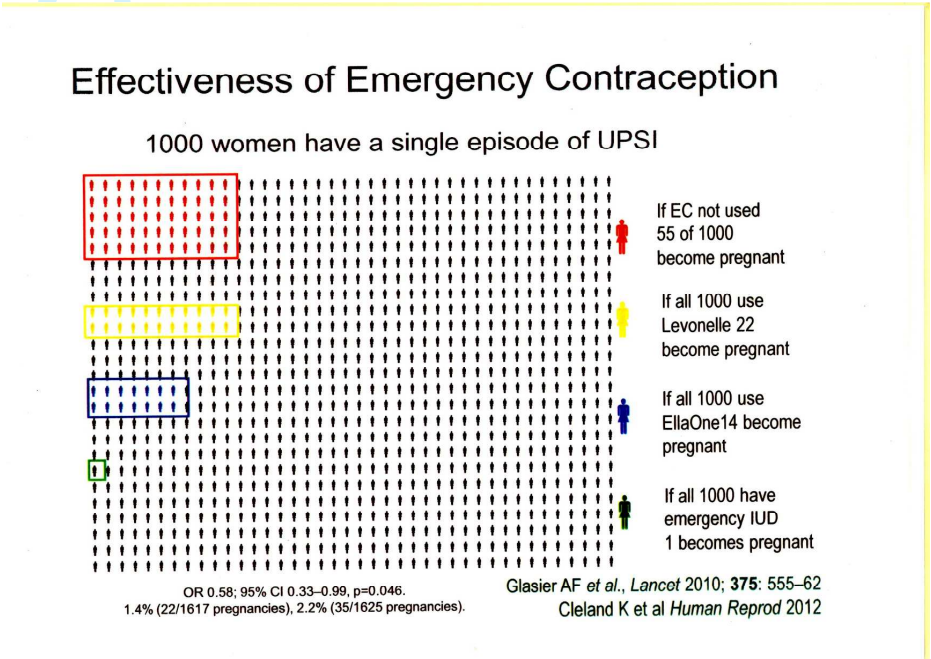
Figure 1: A graphic display to compare the effectiveness of different types of emergency contraception. Developed using data from (56)(57).



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