

IPPF Medical Bulletin

Contents

- IMAP Statement on comprehensive sexuality education 1
Termination of pregnancy in the first trimester with misoprostol alone
Oi Shan Tang, Marcel Vekemans, Helena von Hertzen, Pak Chung Ho 3

IMAP statement on comprehensive sexuality education

This Statement was prepared by the International Medical Advisory Panel (IMAP) in October 2007

IPPF recognizes the need for increased access to high quality, rights-based, gender-sensitive, comprehensive sexuality education for all young people.¹ Therefore, one of the objectives of its strategic framework for adolescents/young people is “to increase access to comprehensive sexuality education”.

Currently, there are numerous approaches to sexuality education used in schools, colleges, educational settings, and many other contexts around the world. The development and implementation of these different approaches are shaped by the values of the cultural context in which such education is provided. Depending on the context, sexuality education may be controversial.

Comprehensive sexuality education is defined as “a lifelong process of acquiring information and forming attitudes, beliefs and values about identity, relationships and intimacy. It encompasses sexual development, reproductive health, interpersonal relationships, affection, intimacy, body image and gender roles. Comprehensive Sexuality Education addresses the biological, socio-cultural, psychological and spiritual dimensions of sexuality from a cognitive, affective and behavioural domain, including skills to communicate effectively and make responsible decisions”. Approaches that do not include all of these features are considered less complete or less effective than comprehensive sexuality education.

This statement provides a response to the growing need for guidance and consensus on the topic among Member Associations. As IPPF’s Global Indicators show that almost all Member Associations are providing sexuality education in some way, this statement is also designed to ensure that the organization continues to improve the quality and effectiveness of such programmes.

Rationale for comprehensive sexuality education

The right of young people to information and education, including sexuality education, is embodied in several international treaties and conventions, including the Convention on the Rights of the Child (CRC), the International Covenant on Economic, Social and Cultural Rights (ICESCR), and the International Conference on Population and Development (ICPD) Programme of Action. The right to sexuality education is underpinned by a working definition from international experts on sexual rights, which declares it, “the right of all persons, free of coercion, discrimination and violence, to: the highest attainable standard of sexual health, including access to sexual and reproductive health care services; seek, receive and impart information related to sexuality; sexuality education; respect for bodily integrity; choose their partner; decide to be sexually active or not; consensual sexual relations; consensual marriage; decide whether or not, and when, to have children; and to pursue a satisfying, safe and pleasurable sexual life”. While young people have a right to effective sexuality education, it is also essential to help them prepare for healthy and fulfilling lives. High-quality information and comprehensive sexuality education can

equip them with the knowledge, skills and attitudes they need to make informed choices, now and in the future. It will enhance their independence and self-esteem; and help them to experience their sexuality and relationships in positive and pleasurable ways.

Since they become sexually aware or active at an early age, comprehensive sexuality education, which is age-appropriate and age-sensitive, needs to be targeted at young people before they become sexually active. The age at first sexual intercourse is decreasing in many parts of the world. Comprehensive sexuality education is needed to address concerns and queries relating to the prevention of STI and HIV/AIDS transmission, and also to provide guidance to counter the fear and potential risk of unwanted pregnancy.

Young people frequently receive conflicting messages on sex and sexuality: these are often negative and associated with guilt, fear and disease, yet the media and young people’s peers generally portray them as positive and desirable. The effect that these messages have on young people depends on their level of awareness of their rights and responsibilities, on gender expectations and also on their level of cognitive and emotional maturity. Comprehensive sexuality education can give them the necessary skills to dispel myths associated with sexuality, which can in turn help to reduce discrimination, stigma and violence, including abuse by intimate partner or family.

It is important to understand that comprehensive sexuality education presents for young people the full range of possibilities for safe sex and includes abstinence. Contrary to what is often argued, comprehensive sexual and reproductive health education does not attempt to replace traditional family values: it helps young people to identify their own values, and increase their awareness of all the available choices suitable to their needs

Evidence

There is conclusive evidence that comprehensive sexuality education can effectively delay the initiation of sexual activity, reduce the frequency of sexual activity and unprotected intercourse, decrease the number of sexual partners and also increase the use of modern methods of contraception. Contrary to the concern that providing comprehensive information on safe sex may encourage young people to become sexually active and display irresponsible sexual behaviour, research has increasingly shown that involving young people in making free, informed choices about contraception does not lead to increases in risky sexual behaviour, nor to initiating adolescent sexual activity. There is a growing body of scientific literature demonstrating that comprehensive sexuality education not only increases knowledge about sex and sexuality, but also directly affects the sexual behaviour of young people. In particular, comprehensive sexuality education has been demonstrated to lead to a delay in sexual intercourse, a reduction in the frequency of sex and numbers of sexual partners, and an increase in the use of condoms and other contraceptives.

In developing and developed countries alike, reviews of curriculum- and group-based sexuality and HIV education programmes have also found that programmes are far more likely to have a positive than a negative impact on sexual behaviour, and that the more comprehensive the approach, the more effective it is in changing behaviour. This is reinforced by increasing evidence from various countries that health outcomes can benefit from an approach to comprehensive sexuality education which addresses gender norms and power disparities, and takes a more positive approach to sexual experience. Several studies have demonstrated that greater openness and acceptance of adolescent sexuality can increase young people’s ability to negotiate their sexual and contraceptive decision-making.

Characteristics of effective sexuality education

By enabling young people to live healthier lives, comprehensive sexuality education programmes can lead them to a higher quality of life. Recent reviews of effective sexuality education programmes have found common characteristics that are beneficial to young people's sexual health. These include:

- A strong focus on reducing specific risky behaviours
- A clear understanding of what influences people's sexual choices and behaviour
- Clear, and continually reinforced, age-appropriate messages about sexual behaviour and risk reduction, including knowledge, skills, values, attitudes, norms and communication
- Accurate information about the risks associated with sexual activity, about contraception and birth control, and different ways of avoiding or deferring intercourse
- Advice about peer, and other social, pressures on young people; and providing opportunities to practice communication, negotiation and assertion skills
- A variety of approaches to teaching and learning, that engage young people and help them to personalize the information
- Approaches to teaching and learning which are appropriate to young people's age, experience and cultural background
- Good linkages with contraceptive and STI/HIV/AIDS services

The World Health Organization (WHO) has issued a publication entitled "Preventing HIV/AIDS in young people: a systematic review of the evidence from developing countries", which reviewed evidence for policies and programmes on young people and HIV/AIDS prevention in developing countries and showed similar outcomes. It has also highlighted the important links between school-based sexuality education, a reduction in injecting drug use, and increased referrals to health services. It also found that promoting community interventions which model skills was effective in reducing unprotected sex (including gender-based violence).

Research has increasingly demonstrated the low efficacy of abstinence-only sexuality education programmes in protecting young people from HIV/AIDS, STIs and unwanted pregnancy. A focus on abstinence-only can lead to the adoption of safer sexual behaviours in certain groups (such as very young people with strong religious and traditional values and backgrounds). However, there is insufficient evidence that abstinence-only programmes have a positive impact on delaying the age of first intercourse or reducing teen pregnancy. Indeed, such programmes are often counterproductive, causing a negative impact on health and the quality of life: younger people who make abstinence-only virginity pledges are one third less likely to use contraception and seek treatment for sexually transmitted infections when they do become sexually active. There is also a common belief among young people that abstinence applies only to vaginal intercourse, leaving them unaware of the risks of other types of sexual activity, such as anal intercourse. Moreover, presenting heterosexual marriage as the only acceptable setting for sexual relations can alienate some young people who do not fit into this norm.

IPPF's implementation of comprehensive sexuality education

In view of the aforementioned evidence, IPPF promotes a comprehensive approach to sexuality education that focuses on specific attitudes and behaviours related to human rights, gender equity, integrating HIV/AIDS prevention, promoting sexual well-being and reaching the most vulnerable and underserved groups.

Sexual and reproductive rights

Comprehensive sexuality education should embrace a rights-based approach, which is founded on human rights principles and laws that guarantee human dignity and equal treatment for all. Using a rights-based approach, comprehensive sexuality education should also emphasize the critical thinking skills that foster responsible behaviour, effective citizenship and an understanding of how institutions and laws function in society.

Gender equity

Comprehensive sexuality education should work towards goals of reducing gender inequalities and eliminating stereotypes, and should be made accessible as early as possible.

Integration of HIV/AIDS

Sexuality education is often seen as separate from HIV/AIDS prevention programmes, focusing primarily on preventing unwanted pregnancies and sexually transmitted infections. However, they are closely interlinked. HIV/AIDS information and prevention is an integral part of comprehensive sexuality education. For young people, this information serves as the best means for preventing the spread of HIV, through its impact at various levels: by providing young people with a complete picture of HIV/AIDS; by teaching the skills, including correct and consistent use of condoms, that enable young people to make positive decisions regarding their health; and by addressing social norms and gender inequalities that may render some groups of the population (women, for example) more vulnerable to coercion and less able to negotiate safe practices.

Sexual well-being

Another dimension that needs to be addressed is the dichotomy between the way the media and popular discourse tend to portray sex as positive and pleasurable, whereas sexuality education and health services often focus only on the negative, harm-related side of sexuality. In order to bridge this gap, the role of pleasure and acceptance of positive sexuality should also feature more prominently in sexuality education. There is, therefore, a need for a model of sexuality education that takes a positive, respectful approach to sexual relationships, and equips young people, both the sexually active and abstinent, with the information and skills to make informed decisions and enjoy a healthy, pleasurable sexual life, free from unwanted pregnancy, STIs and HIV/AIDS.

Reaching vulnerable groups

A broad approach to comprehensive sexuality education can lead to improved health outcomes for a greater proportion of young people than are usually reached. It can target those who are most at risk, vulnerable or marginalized, and who are often excluded from conventional sex education programmes, such as out-of-school youth, injecting drug users, men having sex with men, and women having sex with women. In addition, comprehensive sexuality education recognizes that all individuals, including the mentally and physically disabled, should be able to enjoy sexual and reproductive health and rights.

The process of providing sexuality education can often be as important as the outcomes. People involved in planning sexual education should adopt an appropriate methodology that promotes participation and supports the acquisition of new knowledge, attitudes and skills. This approach should be part of a continuing process of learning and behavioural change, and should be firmly linked to youth-friendly sexual and reproductive health services.

IPPF's framework for comprehensive sexuality education

IPPF has developed a framework for comprehensive sexuality education, which provides an overview of what is believed to be the most effective model of sexuality education for improving the sexual health and well-being of young people. In the framework, IPPF takes a rights-based and gender-sensitive approach to comprehensive sexuality education: it seeks to equip young people with the knowledge, skills, attitudes and values they need to determine and enjoy their sexuality – physically and emotionally, individually and in relationships. It views 'sexuality' holistically, and within the context of emotional and social development. IPPF recognizes that information alone is not enough, and that young people need to be given the opportunity to acquire essential life skills and develop positive attitudes and values.

What can Member Associations do?

IPPF Member Associations can work at several levels to provide and promote comprehensive sexuality education.

Within their own programmes and services:

- Create and implement sexuality education programmes or update existing (peer) education programmes, to ensure that they cover all areas of the IPPF framework for comprehensive sexuality education, and sexuality education guidelines
- Develop high quality information, education and communication (IEC) materials with messages that are rights-based, non-

judgmental, address a range of issues (not just reproductive health) and utilize innovative methods to convey the messages concerning comprehensive sexuality education. They include the promotion of condoms, and safe sex

- Train service providers, including health professionals and peer educators, in rights-based, comprehensive sexuality education, including a range of participatory methodologies²
- Ensure linkages between their sexuality education programme activities and youth friendly health services.
- Pursue the involvement of young people in the design, implementation and evaluation of comprehensive sexuality education programmes
- Provide training for parents and discussion groups on how to talk openly about sexuality with their children, and stimulate good communication between parents and teachers on the issue

Within the school system:

- Train and support teachers to raise professional standards for delivering comprehensive sexuality education in schools
- Ensure that comprehensive sexuality education is a mandatory subject both for primary and secondary schools, with clearly set minimum standards and teaching objectives, and that the necessary resources and materials, appropriate for young people, are provided. The implementation of sexuality education should be monitored and evaluated
- Monitor how sexuality education curricula, inside and outside the school setting, are implemented at local, regional and national levels.

Reaching vulnerable groups

Make special efforts to provide information and education, both through outreach and facility-based programmes, to vulnerable and marginalized groups, such as those who drop out of school, street children, young people living with HIV, men who have sex with men, women who have sex with women, young people who are at risk of being trafficked, those subjected to female genital mutilation, and young people with disabilities. Flexible, creative approaches, which are carefully planned and monitored, should be used to reach these groups.

Influence at national and policy level

- Build partnerships with parents and communities working to promote comprehensive sexuality education. This includes establishing strong networks of committed advocates among governmental/non-governmental and international partners, to ensure positive developments
- Create sustainable advocacy networks to promote comprehensive sexuality education and undertake national advocacy/campaigning activities
- Lobby the media and the advertising sector, to ensure that the messages they disseminate, regarding sexuality education, are comprehensive, accurate and unbiased
- Support the development of further research on the efficacy of comprehensive sexuality education, particularly education that takes a broad approach to rights, sexuality and gender issues. Member Associations should document effectively and share the results of research
- Acknowledge and address local stereotypes and perceptions regarding sexuality education in the community, and strive to overcome them with credible, informed and evidence-based messages

A list of resources and additional information on comprehensive sexuality education can be found in the IPPF Framework for Comprehensive Sexuality Education.³

IPPF reserves the right to amend this statement in the light of further developments in this field.

1. The term 'young people' refers to the composite age group 10-24 years, also recognized by the World Health Organization

2. Participatory methodologies actively involve and empower the participants, and ensure that they are fully informed about, and partake in, the decisions that affect their lives. These methodologies can include group discussions, value clarification exercises to clarify and explore personal attitudes and values, and self-exploratory exercises to develop critical thinking skills

3. See: <http://www.ippf.org/en/Resources/Guides-toolkits/Framework+for+Comprehensive+Sexuality+Education.htm>

Termination of pregnancy in the first trimester with misoprostol alone

Oi Shan Tang, Marcel Vekemans, Helena von Hertzen, Pak Chung Ho

Vacuum aspiration is currently the standard management for termination of pregnancies up to 12 completed weeks. It is an effective method, with a rate of continuing pregnancy of under 1 per cent.¹ However, it is an invasive procedure that is associated with major complications in up to 1 per cent of women and minor problems in 10 per cent,² even when carried out by trained providers in hygienic conditions. The situation is much worse in many developing countries without safe abortion services, where the complications of unsafe abortion, including incomplete abortion, sepsis, haemorrhage and intra-abdominal injury, can cause up to 50 per cent of maternal deaths.³ Many of the complications of surgical abortion can be avoided if pregnancy is terminated pharmacologically, by medical abortion. This is especially important in settings where surgical evacuation is unsafe.⁴ Medical abortion can also be a good way of introducing abortion services in developing countries where resources for operating theatres are limited, as vacuum aspiration is needed in only 5 to 10 per cent of cases.

Standard regimen for medical abortion in the first trimester

The discovery of the antiprogesterone mifepristone, in 1980, made it possible to develop an effective non-surgical method for the termination of pregnancy. Mifepristone acts by blocking progesterone receptors so that the influence of progesterone is inhibited. This leads to the softening and dilation of the uterine cervix and increased sensitivity of the uterus to prostaglandins. Thus, pretreatment with mifepristone reduces the amount of prostaglandin required for medical abortion. When prostaglandin is administered 24 to 48 hours after mifepristone, uterine contractions expel the products of conception.

During the last decade, an E1 prostaglandin analogue, misoprostol, has replaced PGE2 and PGF2 α as the prostaglandin of choice, as it is effective, cheap, widely available and stable at room temperature. It also has a very favourable side effect and safety profile. The sequential regimen of mifepristone and misoprostol has been approved by the World Health Organization for early termination of pregnancy up to 9 weeks. This regimen is used in 36 countries, and there is evidence that the regimen also works between 9 and 13 weeks of gestation, although repeated doses of the prostaglandin analogue are often required.

Need for a misoprostol-alone regimen due to unavailability of mifepristone

The widespread use of this sequential regimen is limited, because mifepristone is not available in many countries due to political or other reasons. Also, the cost of mifepristone may prohibit its use. Misoprostol, on the other hand, is widely available as it is registered worldwide for the management of peptic ulcer. In order to make medical abortion available to women in countries where mifepristone is not available, researchers have tried to develop a regimen using misoprostol alone.

Evidence-based regimens for medical abortion with misoprostol alone

A series of reports has been published in the past decade on the use of misoprostol-alone regimens for medical abortion in the first trimester.⁵⁻²¹ However, it is not possible to compare the results of these reports due to the lack of uniformity in many of the variables. Most of the studies were not randomized, and some of them involve small sample sizes and a wide range of gestational ages. Intervals between doses vary from three to 48 hours and the time points for assessing the outcome differ from a few days to several weeks, so that it is difficult to recommend the best regimen for the use of misoprostol alone for medical abortion in the first trimester.

It is well recognized that for misoprostol-alone regimens, repeated doses of misoprostol are often required, even in early pregnancy. Therefore, to evaluate the regimens, we have to consider the dosage

of misoprostol, the dosing interval, the route of administration and the total number of doses required to achieve a high efficacy. While the rate of continuing pregnancies is less than 1 per cent after the sequential regimen of mifepristone and misoprostol, misoprostol-alone regimens fail to terminate from 4 to 9 per cent of pregnancies. In addition to the regimen, the success rate seems to be associated with the length of gestation, so that the efficacy is higher in earlier pregnancies.

The rate of complete abortion is higher with the sequential regimen and with vacuum aspiration than with misoprostol alone. While complete abortion rates with medical abortion seem to be associated with the experience of the provider,²² achieving abortion (terminating the pregnancy) is more dependent on the regimen, the gestational age and factors related to the woman.

Dosage of misoprostol

Most publications report vaginal administration of multiple doses of 800 µg of misoprostol.¹⁵⁻¹⁹ Regimens using lower doses of 200-600 µg reported lower abortion rates that could not be compensated for by shorter administration intervals.^{5,19-20} A dose as high as 1000 µg has also been used, but the complete abortion rate was not superior to that in studies using 800 µg misoprostol doses.⁸ Therefore, 800 µg misoprostol is probably the optimal dose, and it is the most frequently used dose for misoprostol-alone regimens.

Route of administration

The effects of misoprostol on the uterine cervix and contractility are crucial for successful abortion. About three hours after misoprostol administration the cervix has softened and dilated, and this effect occurs whichever route of administration is used. However, regular contractions fail to develop after oral administration of misoprostol and abortion rates are very low,¹⁸ so the oral route is not the route of choice. When misoprostol is administered vaginally, misoprostol levels are sustained for more than six hours after one single dose²³ and uterine contractility continues to increase for at least for four hours.²⁴ Sublingual administration induces strong contractions, which start diminishing about two or three hours after administration.²⁵

Dosing interval and number of doses

The data on the pharmacokinetics of misoprostol²⁶ indicate that the route of administration is important for the efficacy of the regimen, and also for choosing the optimal interval after which the dose is repeated. Therefore, less frequent doses are needed for vaginal administration when compared to the sublingual route.

A recent randomized trial compared sublingual and vaginal administration of three doses of 800 µg misoprostol when administered either at three-hour or 12-hour intervals for abortions up to nine weeks of gestation. A three-hour interval was chosen as this regimen was considered to be more convenient, since the three-dose course of misoprostol can be administered within one day. The results showed that vaginal misoprostol is probably the route of choice for the misoprostol-alone regimen. When misoprostol was given vaginally, abortion was induced in 96 per cent of the women in the three-hour interval group and in 95 per cent of women in the 12-hour interval group. This difference was not significant, and the rates of complete abortion were similar (85 per cent and 83 per cent, respectively). It seems, therefore, that vaginal administration is not very sensitive to the time interval between doses, and the most convenient interval can be chosen between three and 12 hours. According to pharmacokinetic studies, the optimal interval could be six hours. However, if misoprostol is administered sublingually, the efficacy is significantly higher if the drug is administered at three-hour intervals compared to the 12-hour interval: pregnancy continued in 9 per cent of the women in 12-hour group and 6 per cent of those in the three-hour group, and complete abortion rates were 78 per cent and 84 per cent, respectively. The advantage of giving misoprostol at a shorter interval is that the induction-to-abortion interval is shorter, although the incidence of some side-effects may be higher.¹⁹

In most studies that used 800 µg of misoprostol, the women were given up to three doses. The number of doses needed may depend on the length of gestation, and in early first trimester very few additional complete abortions occurred after the third dose.

There is much less evidence on the efficacy for gestations beyond 63 days, but the available evidence suggests that failure rates are higher and complete abortion rates lower than in earlier pregnancies.⁵⁻⁷

Problems with misoprostol-alone regimens

As misoprostol-alone regimens have a lower efficacy than the sequential regimen, more women will require surgical evacuation to complete the treatment. Since it is not possible to predict which women will fail to respond, it is vital to monitor every woman undergoing medical abortion, to identify the failures. Women who continue to have symptoms of pregnancy and those who have only spotting, but no real bleeding, are likely to be still pregnant. In many cases, confirmation of the passage of the products of conception may be difficult clinically, and ultrasound examination is useful in dubious cases, so the follow-up of women after treatment is very important.

The total amount of drug used in misoprostol-alone regimens is high, therefore it is expected that the women will experience more side-effects than after the sequential regimen. At the normal dosage, the misoprostol-alone regimen is safe: no serious complications have been reported. Until now, the misoprostol-alone regimen has been approved for abortion only in Brazil.

Exposure to misoprostol in early pregnancy has been associated with congenital malformations, which is a concern when the pregnancy continues despite treatment. Vasoconstriction during strong uterine contractions causes temporary disruptions in the placental perfusion, leading to ischaemia, hypoperfusion and hypoxia in the developing fetus. Central nervous system and limb defects are the most commonly reported anomalies. Mobius' syndrome, which is characterized by congenital facial paralysis, with or without limb defects, has been associated with misoprostol exposure.²⁷ Other abnormalities like transverse limb defects, ring-shaped constrictions of the extremities, arthrogryposis, hydrocephaly, holoprosencephaly and exostrophy of the bladder have been reported.²⁸ Malformations are more often associated with the use of misoprostol alone for abortion, as compared to the mifepristone-misoprostol sequential regimen. Therefore, the woman must be counselled that the pregnancy has to be terminated once she has been exposed to misoprostol. It is very important to follow up, and terminate the pregnancy surgically in cases of failure.

It appears from the reported series that the complete abortion rates decrease with increases in gestational age. The women must receive counselling and information concerning the higher failure rate with increased gestation, so that they can choose for themselves the appropriate method of abortion.

Conclusion

For induced abortion, misoprostol alone, although not as effective as the mifepristone-misoprostol sequential regimen, remains an alternative for women who do not accept surgical evacuation, and for women in areas where surgical evacuation is associated with high morbidity. However, it should not be regarded as a method that can replace surgical evacuation in areas where the latter is not accessible, because surgical evacuation is always required as a back-up for the failures. Nevertheless, in some areas the use of misoprostol alone can still be safer than some other, very unsafe techniques.

References

The full list of references can be found in the online Medical Bulletin, March 2008. <http://www.ippf.org/en/Resources/Medical/>