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African Journal of Reproductive Health

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ABOUT AJRH

African Journal of Reproductive Health (AJRH) is published by the Women's Health and Action Research Centre (WHARC). It is a multidisciplinary and international journal that publishes original research, comprehensive review articles, short reports and commentaries on reproductive health in Africa. The journal strives to provide a forum for African authors, as well as others working in Africa, to share findings on all aspects of reproductive health, and to disseminate innovative, relevant and useful information on reproductive health throughout the continent.

AJRH is indexed and included in Index Medicus/MEDLINE. The abstracts and tables of contents are published online by INASP at <http://www.ajol.info/ajol/> while full text is published at <http://www.ajrh.info> and by Bioline International at <http://www.bioline.org.br/>. It is also abstracted in *Ulrich's Periodical, Feminist Periodicals African Books Publishing Records*.

Women's Health and Action Research Centre

Km 11, Benin-Lagos Express Way

Igue-Itheya

P.O. Box 10231, Ugbowo

Benin City, Edo State, Nigeria

Email: wharc@hyperia.com or africanjournalofreproductiveH@gmail.com

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The Women's Health and Action Research Centre (WHARC) is a registered non-profit organization, committed to the promotion of women's reproductive health in sub-Saharan Africa. Founded in 1995, the centre's primary mission is to conduct multidisciplinary and collaborative research, advocacy and training on issues relating to the reproductive health of women. The centre pursues its work principally through multidisciplinary groups of national and international medical and social science researchers and advocates in reproductive health.

WHARC receives core funding and support from the Ford Foundation and technical cooperation and mentorship from International Perspectives on Sexual and Reproductive Health and Studies in Family Planning. Principal funding for the journal comes from the Consortium on Unsafe Abortion in Africa. The goal of the centre is to improve the knowledge of women's reproductive health in Nigeria and other parts of Africa through collaborative research, advocacy, workshops and seminars and through its series of publications – the *African journal of Reproductive Health*, the *Women's Health Forum* and occasional working papers.

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APROPOS AJRH

La Revue Africaine de santé de la Reproduction (RASR) est publiée par le Women's Health and Action Research Centre (WHARC). C'est une revue à la fois pluridisciplinaire et internationale qui publie des articles de recherche originaux, des articles de revue détaillés, de brefs rapports et des commentaires sur la santé de la reproduction en Afrique. La Revue s'efforce de fournir un forum aussi bien à des auteurs africains qu'à des professionnels qui travaillent en Afrique, afin qu'ils puissent partager leurs découvertes dans tous les aspects de la santé de reproduction et diffuser à travers le continent, des informations innovatrices, pertinentes et utiles dans ce domaine de santé de la reproduction.

La RASR est indexée et figure sur l'Index Medicus/MEDLINE. Les résumés et les tables des matières sont publiés en ligne par INASP sur le site web <http://www.ajol.info/ajol> tandis que le texte est publié à <http://www.ajrh.info> par Bioline International sur le site web <http://www.bioline.org.br/>. Il est également résumé dans *Ulrich Periodical*, *feminist Periodical* et *African Books Publishing Records*

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Le WHARC est une organisation non gouvernementale à but non-lucratif s'engageé dans la promotion de santé de la reproduction chez la femme en Afrique sub-saharienne. Fondé en 1995, le Centre a pour objectif principal de mener des recherches pluridisciplinaires et en collaboration, de promouvoir et de former des cadres en matières relatives à la santé de la reproduction chez la femme. Le Centre travaille surtout à travers des groupes multidisciplinaires de chercheurs aussi bien nationaux qu'internationaux en sciences médicales et en sciences économiques dans le domaine de santé de la reproduction.

Le WHARC recoit une aide financière principale de la Fondation Ford et bénéficie de la coopération technique de l'*International Perspectives on Sexual and Reproductive Health* et de *Studies in Family Planning*. Le financencement principale pour la revue vient de la part du Consortium on Unsafe Abortion in Africa. L'objectif du Centre est d'améliorer la connaissance en matière de santé de la reproduction chez la femme au Nigeria et dans d'autres régions d'Afrique à travers la recherche en collaboration, le paidoyer, des ateliers et des séminaires à travers des séries de publication - *La Revue africaine de santé de la reproduction*, *Le Women's Health Forum* et des rapports des recherches de circonstance.

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EDITORIAL

Putting Women and the Girl Child at the Centre of Africa's Development

¹Rosemary Ogu and Friday Okonofua^{2*}

¹Senior Lecturer, Department of Obstetrics and Gynaecology, University of Port Harcourt, Port Harcourt, Rivers State. Nigeria;

²Editor, *African Journal of Reproductive Health*

Recent United Nations reports^{1,2} indicate that progress has been made globally in key components of the MDGs since 2000. These include significant reductions in levels of extreme poverty, enrolment of children in schools, improvements in HIV/AIDS prevention and treatment, expanded access to clean water and increased access to information and communication technology. However, progress made has been highly uneven between and within countries. Sub-Saharan Africa has had the slowest rate of growth in these indicators, with marginalised groups and populations in countries within the continent experiencing the slowest rate of improvement in these indicators.

Although many African countries have witnessed high economic growth rates during the past ten years fuelled largely by foreign direct investment, open markets and development assistance, only a small proportion of the population has been able to take advantage of this growth. A large proportion of the gains of economic growth remain concentrated in few urban centres, with benefits accruing only to a few high profile individuals. By contrast, in many parts of the continent, very limited efforts have been made to spread the gains of economic growth and to engage grassroots in participatory development. Throughout Africa, evidence now abound indicating that women and girls have witnessed the most severe forms of denial of opportunities related to the implementation of the MDGs³. For example, while the indicators of maternal and child health in the MDGs have remained largely unmet in the continent, women and girls continue to suffer various forms of inequities including lower level of literacy and education, higher rates of physical and psychological violence, lower levels of social and

political representation and highest levels of poverty as compared to men.

It is within this context that we see it as salutary the current framing of the post-2015 development agenda around tackling inequality that exists in many parts of the world⁴. Inequality is an important developmental challenge in sub-Saharan Africa that has tended to limit the overall attainment of the MDGs in the continent. For Africa, an important form of inequality is that between countries, with evidence indicating that workers in African countries have lower incomes as compared to those in other parts of the world. This has tended to promote cross-border transfer of skilled workers from Africa to the global north. And with increased globalization and the use of technology leading to a decline in the number of available jobs in the western countries, the overall effects of international migration on Africa's development has tended to be negative rather than positive.

When assessed at national levels, African countries are some of the most unequal societies in the world. Apart from differences in income levels, the structural differences that exist between women and men are the most glaring forms of inequality that exists in most parts of Africa. Gender inequality is clearly the most profound form of inequality in Africa buoyed largely by Africa's patriarchal, cultural and religious experiences and tendencies³. To date, women remain under-represented in economic, social and political spheres in many African countries, as compared to their male folks. As a corollary, the girl child continues to suffer collateral damage, with the same negative cultural and societal attitudes being visited on the girl-child, while there continues to be preference for the male child throughout the continent.

With the post-2015 developmental agenda focusing on addressing inequality, an important concern is how this would work for the African continent. Efforts to address gender equality and build agency for the girl child in the ICPD and MDG frameworks, have had limited success in the continent due largely to systemic factors. Some of the international agreements reached over the past two decades aimed at promoting gender equality and removing discrimination against women were never fully implemented in many African countries. For example, since the 1990s, a country like Nigeria has failed to domesticate CEDAW, an international instrument for systematically eliminating discrimination against women through appropriate legislation⁵. Also, the Prohibition of Violence against Persons bill (VAPP bill) has not been passed by the Nigerian National Assembly over the past several years due to lack of official interest.

There is a growing acceptance of the notion that the current MDGs do not properly address inequality, and that the post 2015 development agenda must be poised to tackle inequality differently --- for economic, political, ethical and even security reasons. Within the perspectives of African countries, it is evident that any strategies designed to deal with inequality that does not include the promotion of gender equality will be a wasted effort. However, there are ongoing debates as to how to reflect inequality in the post-2015 development framework. This could be either be as a stand-alone goal or by mainstreaming pertinent indicators across different goals. Arguments in favour of mainstreaming have been built around its ease of implementation and possibly greater political acceptability. By contrast, there are political issues to contend with when it is positioned as a stand-alone goal as it might be perceived as threatening to establishments and entrenched elites. There is also continuing debate as to how inequality might be measured and reported in a standalone goal. Regardless of what is finally decided, it is important to ensure that mainstreaming it will not make it disappear from the post-2015 agenda. Adequate preparatory plans and identification of key indicators for measuring progress as well as financing must be included to track the

performance of African countries on women and girl child inclusion policies and programs during the period.

Putting women and the girl child at the centre of Africa's development after 2015 is not only an ethical and moral issue; it is also the right choice. Africa's development will not be achieved unless women and girls are mainstreamed into all aspects of development. The extent to which African countries promote equality of access to resources between women and men, will determine the extent to which they promote inclusive growth needed to accelerate their pace of development. Appropriate principles and policies on gender equality and gender equity must be integrated into all development milestones, and African governments should be made aware about the rationale and methods for doing so. It must not be "business as usual". Being that previous efforts to promote gender equality have been more rhetorical than pragmatic, detailed implementation plans for engendering development in Africa must be prepared and disseminated throughout the African continent in the coming years. Strong political will and ownership at international, regional and national levels will be essential to promote the needed social change for women and girl child emancipation and social development. And high level advocacy and partnership building must be part of efforts to ensure that this happens. The long years of denial of the human rights of women and the girl child in Africa remains a "black box" and a developmental quandary. The time for real change is now.

Conflict of Interest

None

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Mettre les femmes et les jeunes filles au centre du développement de l'Afrique

¹Rosemary Ogu and Friday Okonofua^{2*}

¹Maitre de conférences, Département d'obstétrique et de gynécologie de l'Université de Port Harcourt, Port Harcourt, Etat de Rivers, Nigeria; ²Rédacteur, Revue africaine de santé de la reproduction

Un rapport récent des Nations Unies^{1,2} indique que des progrès ont été accomplis au niveau mondial dans les composants clés des OMD depuis 2000. Il s'agit notamment des réductions significatives dans les niveaux de la pauvreté extrême, l'inscription des enfants dans les écoles, l'amélioration de la prévention et du traitement du VIH / SIDA, l'accès élargi à l'eau potable et l'accès accru à la technologie de l'information et de la technologie. Toutefois, les progrès réalisés ont été très inégaux entre les pays et au sein des pays. L'Afrique sub-saharienne a eu le plus faible taux de croissance de ces indices, avec des groupes et des populations marginalisés dans les pays au sein du continent qui connaissent le taux le plus lent de l'amélioration de ces indices.

Bien que de nombreux pays africains aient connu des taux de croissance économique élevés au cours des dix dernières années alimentés en grande partie par l'investissement direct étranger, des marchés ouverts et l'aide au développement, seule une petite proportion de la population a été en mesure de profiter de cette croissance. Une grande partie des gains de la croissance économique est encore concentrées dans quelques centres urbains, avec des avantages revenant seulement à quelques individus de haut niveau. Par contraste, dans de nombreuses parties du continent, des efforts très limités ont été faits pour répartir les fruits de la croissance économique et à s'engager dans le développement local participatif. Partout en Afrique, les preuves abondent aujourd'hui indiquant que les femmes et les filles ont connu des formes les plus graves de refus d'opportunités liées à la mise en œuvre des OMD. Par exemple, tandis que les indices de la santé maternelle et infantile dans les OMD sont restés largement non satisfaits dans le continent, les femmes et les jeunes filles continuent à subir de diverses formes d'inégalités dont le niveau

inférieur de l'alphabétisation et de l'éducation, des taux plus élevés de violence physique et psychologique, le faible taux de représentation sociale et politique et les plus hauts niveaux de la pauvreté par rapport aux hommes.

C'est dans ce contexte que nous considérons comme salubre le cadrage actuel de l'agenda de développement post-2015 dans la lutte contre l'inégalité qui existe dans de nombreuses parties du monde². L'inégalité est un défi de développement important dans l'Afrique subsaharienne et elle a tendance à limiter la réalisation globale des OMD sur le continent. Pour l'Afrique, une forme importante de l'inégalité est celle entre les pays, avec des preuves qui indiquent que les travailleurs dans les pays africains ont des revenus inférieurs par rapport à ceux des autres parties du monde. Cela a tendance à favoriser le transfert transfrontalier de travailleurs qualifiés de l'Afrique vers le nord mondial. Et avec la mondialisation et l'utilisation des technologies conduisant à une baisse du nombre d'emplois disponibles dans les pays occidentaux, les effets globaux de la migration internationale sur le développement de l'Afrique ont eu tendance à être négatifs plutôt que positifs.

Lorsqu'on fait une évaluation sur les plans nationaux, les pays africains font parties des sociétés les plus inégalitaires du monde. Outre les différences de niveaux de revenu, les différences structurelles qui existent entre les femmes et les hommes sont les formes les plus flagrantes de l'inégalité qui existe dans la plupart des régions d'Afrique. L'inégalité des sexes est clairement la forme la plus profonde de l'inégalité en Afrique soutenue en grande partie par les expériences et tendance patriarcales, culturelles et religieuses³ de l'Afrique. À ce jour, les femmes restent sous-représentées dans les sphères économiques, sociales et politiques dans de nombreux pays

africains, par rapport à leurs homologues de sexe masculin. En corollaire, la jeune fille continue à souffrir des dommages collatéraux, avec les mêmes attitudes culturelles et sociétales négatives infligées à la petite fille, alors que la préférence pour l'enfant de sexe masculin subsiste toujours à travers le continent.

Etant donné que le programme de développement post-2015 met l'accent sur le traitement des inégalités, une préoccupation importante est de savoir comment cela fonctionnera pour le continent africain. Les efforts visant à lutter contre l'égalité des sexes et renforcer l'agence pour les filles dans les cadres de la CIPD et les OMD, ont eu un succès limité dans le continent en raison principalement du manque d'habilitation institutionnelle⁴. Certains des accords internationaux conclus au cours des deux dernières décennies visant à promouvoir l'égalité des sexes et l'élimination de la discrimination contre les femmes n'ont jamais été pleinement mis en œuvre dans de nombreux pays africains. Par exemple, depuis les années 1990, un pays comme le Nigeria n'a pas réussi à domestiquer CEDCF, un instrument international pour éliminer systématiquement la discrimination contre les femmes par une législation appropriée. En outre, l'interdiction de la violence contre le projet de loi sur les personnes (Projet de loi VAPP) n'a pas été adoptée par l'Assemblée nationale du Nigeria au cours des dernières années en raison du manque d'intérêt officiel.

Il y a une acceptation croissante de la notion que les OMD actuels ne traitent pas correctement les inégalités, et que l'ordre du jour du développement post 2015 doit être prêt à s'attaquer aux inégalités --- différemment pour des raisons économiques, politiques, éthiques et même de la sécurité. Dans les perspectives des pays africains, il est évident que les stratégies de la conception pour faire face aux inégalités qui n'inclut pas la promotion de l'égalité des sexes constitueront un gaspillage d'efforts. Cependant, il y a des débats en cours concernant la façon de refléter l'inégalité dans le cadre de développement post-2015. Cela pourrait être soit comme un objectif autonome ou en intégrant des indices pertinents pour des objectifs différents. Les arguments en faveur de l'intégration ont été

construits autour de sa facilité de mise en œuvre et peut-être une plus grande acceptabilité politique. Par contraste, il y a des questions politiques à combattre dans un objectif autonome car il pourrait être perçu comme une menace pour les établissements et les élites retranchées. Il y a aussi la poursuite du débat sur la façon dont l'inégalité peut être mesurée et rapportée dans un objectif autonome. Indépendamment de ce qui est finalement décidé, il est important de s'assurer que son intégration ne le fera pas disparaître de l'agenda post-2015. Il faut inclure les plans préparatoires adéquates et l'identification d'indices clés pour mesurer les progrès ainsi que le financement afin de suivre la performance des pays africains à l'égard des politiques et des programmes d'inclusion de la femme et de la jeune fille au cours de la période.

Mettre les femmes et les filles au centre du développement de l'Afrique après 2015 n'est pas seulement une question d'éthique et de morale; c'est aussi le bon choix. Le développement de l'Afrique ne sera pas accompli sauf si les femmes et les jeunes filles sont intégrées dans tous les aspects du développement. La mesure dans laquelle les pays africains favorisent l'égalité d'accès aux ressources entre les femmes et les hommes, permettra de déterminer la mesure dans laquelle ils favorisent la croissance inclusive nécessaire pour accélérer leur rythme de développement. Les principes et les politiques appropriées sur l'égalité des sexes et l'équité entre les sexes doivent être intégrées dans toutes les étapes de développement, et les gouvernements africains doivent être sensibilisés pour qu'ils comprennent les raisons et les méthodes pour ce faire. Il ne doit pas être «les affaires continuent». Étant donné que les efforts précédents visant à promouvoir l'égalité des sexes ont été plus rhétoriques que pragmatique, les plans de mises en œuvre détaillées pour engendrer un développement en Afrique doivent être préparés et diffusés à travers tout le continent africain dans les années qui viennent. Une forte volonté politique et l'appropriation aux niveaux international, régional et national seront essentielles pour promouvoir le changement social nécessaire pour les femmes et pour l'émancipation et le développement social. En plus, le plaidoyer de haut niveau et le

renforcement de partenariat doivent faire partie des efforts pour s'assurer que cela se produit. Les longues années de déni des droits fondamentaux des femmes et des jeunes filles en Afrique demeurent une «boîte noire» et un dilemme développemental. Le temps pour un vrai changement est maintenant.

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COMMENTARY

Reducing Barriers to the use of the Intrauterine Contraceptive Device as a Long Acting Reversible Contraceptive

Norman D. Goldstuck

Department of Obstetrics and Gynaecology, Faculty of Medicine and Health sciences, Stellenbosch University and Tygerberg Hospital, Cape Town, Western Cape 7505, South Africa.

*For Correspondence: Email: nahumzh@yahoo.com; Phone: +27823418200

Abstract

The intrauterine device (IUD) is the oldest long acting reversible contraceptive (LARC) method. There remain widespread barriers to its general acceptance, although some have been overcome, others remain. These stem from a lack of understanding of uterine anatomy and physiology. Uterine measuring techniques did not become popular, probably because of the extra effort required prior to IUD insertion. Unfortunately the information they provided regarding IUD design was also not heeded. In some countries varying sizes of other IUDs (second generation) are now available. The third generation hormonal carrying IUDs have also reduced barriers by lowering side effects and producing added health benefits. Fourth generation IUDs will provide added health benefits in addition to contraception and should further reduce barriers to IUD use. Most remaining IUD barriers are due to provider perceptions. Most are based on psychological, moral and religious prejudices. These should not be allowed to interfere with the provision of LARC methods of contraception. There are also acceptor barriers which can be modified by providing education about the method. The use of the IUD as a LARC method is increasing in many developed and developing countries. New technology should help propel the IUD into a more mainstream contraceptive. (*Afr J Reprod Health 2014; 18[4]: 15-25*).

Keywords: IUD, LARC, barriers, improvements

Résumé

Le dispositif intra-utérin (DIU) est la plus ancienne méthode contraceptive réversible à longue durée d'action (CRLDA). Il reste encore des obstacles généralisés à son acceptation globale ; bien que certains aient été surmontés, d'autres restent toujours. Ceux-ci découlent d'un manque de compréhension de l'anatomie et de la physiologie de l'utérus. Les techniques pour mesurer les utérins ne sont pas devenues populaires, probablement en raison de l'effort supplémentaire nécessaire avant l'insertion d'un DIU. Malheureusement, l'information qu'ils ont fournie quant à la conception de DIU n'a pas également été entendue. Dans certains pays, des tailles différentes d'autres DIU (deuxième génération) sont maintenant disponibles. L'hormonal de la troisième génération qui portent les DIUs a également réduit les obstacles en diminuant les effets secondaires et la production de bienfaits pour la santé. Les DIUs de la quatrième génération offriront des avantages supplémentaires pour la santé, en plus de la contraception et devraient encore réduire les obstacles à l'utilisation d'un DIU. La plupart des obstacles de DIU qui subsistent sont dus à des perceptions des fournisseurs. La plupart sont basées sur des préjugés psychologiques, moraux et religieux. Ils ne devraient pas être autorisés à interférer avec la fourniture de méthodes de la conception à la CRLDA. Il y a aussi des obstacles des accepteurs qui peuvent être modifiés par une éducation sur la méthode. L'utilisation du stérilet comme méthode de la CRLDA est en augmentation dans de nombreux pays développés et en développement. Maintenant, la technologie devrait aider à propulser le DIU en un contraceptif plus populaire. (*Afr J Reprod Health 2014; 18[4]: 15-25*).

Mots clés: DIU, CRLA, barrières, améliorations

Introduction

Our planet has over 7 billion people. Quality of life is deteriorating and directly or indirectly we are wiping out many other species that also inhabit our planet. Human fertility control is a priority. We know that long acting reversible contraceptive (LARC) methods are the most effective reversible methods for preventing pregnancy in the long term

and are the most cost effective methods¹. The cost of a copper IUD varies between \$5 - \$550 depending where it is sold. Several have a lifespan of 10 years plus and newer versions are becoming available with a life span of 25 years. The latter can be used in principle as an ultra long LARC and effectively can behave as a type of reversible sterilisation as well as a LARC. Additionally as well as benefitting the community as a whole,

IUDs are capable of providing individuals with their individual reproductive rights to control their fertility as they deem fit.

The final decision to use an IUD (or any LARC method) should always be that of the individual who should have free-will to choose the method & should not be coerced, especially with perverse incentives.

This review examines the history of the development of the intrauterine device/system IUD(S) and its difficulty in becoming accepted as a mainstream contraceptive method. This has been due to the many scares and doubts throughout its long history. While it has gained a strong foothold in some countries its penetration globally, especially in some of the major OECD countries and in Africa has been relatively poor. There is now evidence that the newer devices and some ideas that are in development will finally propel the IUD as the mainstream?

This review examines past problems & current improvements to the IUD. Contraceptives of the future will hopefully act not only as contraceptives but also act in a way to promote rather than detract from health. This is not a systematic review and reflects the biases of 40 years of practice and research and writing about IUDs.

The first paper published on IUDs was by Richard Richter in Germany in 1909². The concept of intrauterine contraception had been introduced to the western world. The journey from the introduction of the first IUD until the present will be outlined..

Early history of the IUD

Richter's IUD was two wound strands of silkworm gut. The free ends were copper combined with celluloid to prevent damaging the endometrium and united by a thin bronze filament to aid retrieval and to aid X-ray visualization. In the mid 1920's Karl Pust³ developed and used a silkworm thread with a stiff cervical extension to cover the cervix. Ernst Gräfenberg⁴ also began working on IUDs in the early 1920's. He was not apparently aware of the earlier work and also started using silkworm gut. Gräfenberg published his results. The silkworm gut IUDs were expelled so he designed a ring made of silver and copper filaments, the famous Gräfenberg ring. Many were

used and remained in use for up to 50 years. The author removed one of the last ones in 1976. Grafenberg was not specifically aware of the anti-fertility effects of copper. The copper in his ring was an alloy and it is uncertain if it provided any anti-fertility effect *per se*, other than helping the whole ring produce an anti-inflammatory effect. Shortly after this introduction the first reports of pelvic inflammatory disease with the IUD appeared, the first general barrier to use of the IUD had been erected.

Gräfenberg came to the United States in the mid 1930's. He was cautioned not to use the IUD in the U.S. because it was considered too risky. This was the first of many barriers to be thrown up against the IUD in the U.S. The Gräfenberg ring was used by Gräfenberg and a few others surreptitiously in the U.S. but widely used in England and many commonwealth countries like Canada and Australia. In the U.S. Halton, Dickinson and Tietze continued using silk IUDs with some success⁵. In Japan Tenrei Ota also developed a metallic silver or gold ring IUD. The second barrier to IUD use arose at this time. It was the suspicion that the IUD could cause uterine (endometrial) cancer.

Oppenheimer⁶ in Israel and Isihara⁷ in Japan published landmark papers in 1959 showing how successful the method was in 20,000 patients and effectively brought down the endometrial cancer barrier by refuting this notion. Christopher Tietze provided the first detailed analysis of IUD benefits and potential problems, and proposed methods for analysis of IUD performance⁸.

Plastics and the modern (first generation) IUD era

The post-war thermoplastics industry changed the nature of the IUD completely^{9,10}. Polyethylene in particular, a malleable and seemingly inert substance largely solved the problem of IUD insertion and removal. Polyethylene type devices could be straightened for insertion into a tube and then inserted and had a 'memory' and could therefore re-assume their original shape. Their flexibility also made them relatively easy to remove. Soon the first generation of IUDs became available. Examples of IUDs from this and later generations may be found in Table 1. The first

generation thermoplastic IUDs act by causing accelerated transport of ova through the Fallopian tube and by causing an endometrial inflammatory reaction¹¹. In order to do this the plastic devices require a significant surface area and bulk. This is responsible for some of the side effects of these devices. The best known of the plastic devices was the Lippes Loop. The most notorious was the Dalkon Shield which was alleged to have caused

infections due to its multifilament tail. There is some doubt as to whether this was indeed the case as significant infections were not found outside the United States¹². A few years later (early 80's) the plastic only devices were no longer being manufactured. The Dalkon Shield episode was a precursor to the departure of the first generation IUDs.

Table 1: Classification of modern IUDs

First generation (thermoplastic)	Second generation (copper bearing)	Third generation (progestin releasing)	Fourth generation (contraceptive+ additional pharmacological action)
Lippes loop A-D Margules spiral(Gynecoil)	Copper 7(Gravigard) Copper T (TCu200,220C,380A)	Progestasert Mirena	?IUD+ antibiotic(s)
Saf-T-Coil (22SX,32S,33XS)	Multiloal Copper (MLCu250[S],375[S])	Skylla(Jaydess)	Copper IUDs as reversible office sterilisation
Antigon(I-IV, F) Dalkon shield(standard and small)	Copper Omega Gyne-Fix 200,330 Flexi-T300(300+, 380)	Fibroplant Femilis	

*Generation refers to concept rather than time of introduction

The second generation IUDs all carry copper. In 1968 Zipper discovered that copper inhibits blastocyst development in rats and rabbits and suspected that the same may be true in humans¹³. Since copper is toxic to the blastocyst and inhibits implantation and is possibly toxic to sperm it allows the plastic frame to become a 'carrier'. This meant that the IUD frame could be chosen without reference to a minimum effective size because the plastic was no longer the contraceptive *per se*. It was hoped that the large size of the plastic IUDs would not be needed and this would lead to a reduction in the side effects, mainly pain and bleeding which the users were experiencing¹⁴. Unbeknown to Gräfenberg the success of his ring may have been due in part because it contained copper in the alloy.

Second generation copper IUDs

The aim of the designers of the second generation of IUDs was to design a frame which would most closely match the dynamic shape of the uterine cavity and then add copper for contraceptive effect. The frame would now simply act as a carrier for the copper. There were at least 50 different carrier frames for copper IUDs, evidence

that the dynamic (changing) size of the uterine cavity is poorly understood. More surprising is the fact that the original shapes and sizes of the earlier copper IUDs (with a few exceptions) have not been changed by recent knowledge of uterine anatomy and physiology¹⁵. High resolution 3-D ultrasound in particular has added to our knowledge and understanding of the inner uterus. After an initial attempt to make IUDs in a series of sizes, we are now firmly back to the "one size fits all" type of IUD (although a smaller levonorgestrel (LNG) device is now available) and remain astonished when it (or they) often performs poorly. Poor IUD performance represents both a physician and acceptor potential barrier to this LARC method. The most prominent copper IUDs are listed in Table 1. The first and most prominent (outside of China) is the 'T'- shaped device. Currently available in only one size and format in the USA as the TCu380A. Most other countries have some or all of the copper IUDs listed in Table 1.

Shortly after the copper IUDs became available a serious attempt was made to determine which types were the best. There were two ways in which this was attempted. The first method consisted of very large scale studies using the

available IUDs in large scale studies largely sponsored by the World Health Organisation (WHO) and other non-governmental agencies. Using these methods the TCU380A emerged as best when compared to existing devices¹⁶. However all the IUDs which were tested in the large scale studies have a very basic design flaw. That flaw is that their design was not based on the correct knowledge of the anatomy of the uterine cavity. In addition, all WHO studies were conducted in parous women. The first generation Lippes Loops were designed on the basis of the anatomical findings of Robert Dickinson, who published a textbook on human sexual anatomy¹⁷. Tatum, who observed women wearing a Lippes Loop who came to the clinic with uterine cramps and excessive bleeding, based the design for the frame of the copper T on casts of endometrial cavities despite evidence that it is too large for the uterine cavity in nulliparous and even in many multiparous women¹⁸. The size of the T-shaped IUD (e.g., TCU380A) remains unchanged and in some countries (including the USA) there are no smaller sized alternatives.

Uterine metrology in IUD development

Uterine metrology devices began to appear in the 1970's. The hope was that by choosing an IUD which matched the uterine cavity, a better fit would be achieved and problems should be reduced. This did not materialise. With hindsight it is easy to see why. One of the provider and (to a limited extent) the acceptor barriers to choosing an IUD is the insertional operation procedure itself because it is so much easier to dispense or prescribe pills or administer an injection. This is especially true for situations where swab tests and Pap smears are not routinely taken because of cost, as is common in most poorer countries. In these situations inserting an IUD becomes a big undertaking and having to make accurate uterine measurements beforehand just adds to the complexity. Even in countries where testing for infections and cancer is conducted on a wide scale like the United States, this barrier is forever present. A good example is the provision of emergency contraception where the IUD is very often not even mentioned let alone provided

despite the fact that it is of far superior efficacy in this situation¹⁹. In the Battelle study 70% of the subjects had uterine transverse diameters of less than 30 mm²⁰. This is too small for both the TCU380A and Mirena IUDs (but not Skyla if the transverse diameter is not less than 28 mm which is often the case). The uterus obviously has some ability to adapt to devices that are too large as many women tolerate them exceedingly well despite their being too large. In the absence of routine metrology we must logically assume that a fair number are being inserted where the uterine cavity is too small. However we cannot predict those who will and those who will not adapt. Some of the mal-adapters may experience pain and/or bleeding, expulsion and then subsequent unwanted pregnancy. A summary of the results of the major studies which evaluated the uterine cavity is given in Table 2. Imaging has replaced mechanical techniques in this regard, but is still a potential barrier if needed for routine use.

The first attempts to measure the uterine cavity were made by Hasson with Wing Sound I which measured the length from the fundus to the internal os and thus the size of the endometrial cavity. He showed that IUDs which were 12.5 to 17.5 mm shorter than the endometrial cavity worked best²¹. His Wing Sound II makes two uterine cavity measurements but complicated geometrical tables were needed to determine the outlines of the cavity²². The uterine measuring device produced by the Battelle Corporation of Ohio was used in Mexico by Aznar and colleagues who showed that 70 % of Mexican women had uterine cavity fundal widths less than 30 mm²⁰. It was not widely used. The Wang device was used in China for measuring uterine cavities before deciding on the size of the ring IUD which was to be used²³. Without doubt the most thoroughly tested and used uterine measuring device was the Cavimeter, designed by Karl Kurz in Düsseldorf, Germany¹⁸. A number of large studies were conducted using the Cavimeter. Although he planned to make the Cavimeter available commercially, Kurz realised that its use would be a barrier to, rather than an aid to encouraging more wide spread use of the IUD. These plans were abandoned and he decided to develop the Flexi-T range of IUDs. Initially this IUD was called the

Copper-Safe 300. It is still today the only device that was designed on the basis of uterine cavity measurements. The most recent of the second generation IUDs, the GyneFix 200 is frameless as it is held in place by attachment to the uterine fundus. The GyneFix will fit virtually any sized uterine cavity and it has been used in a cavity width of only 7 mm. For this reason the frameless

IUD was referred to 'precision intrauterine contraception'²⁴. A summary of the values of uterine cavity dimensions using various measuring techniques is given in Table 2. The dimensions of the most commonly used IUDs (outside of China) are listed in Table 3 for comparison. The integration of uterine cavity measurement data with IUD design is still not complete^{25,26}.

Table 2: Determination of uterine cavity measurements(mm)^o

Reference(s)	Method	Uterine cavity length [†] (range)		Uterine cavity width [*] (range)		Comments
		multiparous	Nulliparous	multiparous	nulliparous	
21, 22	Wing sound I and II	36 (18-69)	31	44 (26-65)		not made commercially available
20	Battelle caliper	35 (28.7-46.7)		30 (17.8-32.2)		not made commercially available
23	Wang caliper	37.5 [¶] (10-60)	30.8±3.4 [¶] (10-45)			? availability in China
18	Cavimeter	36.8 (32.1-40.3)	31.8 (31.4-32.1)	29.8 (23.4-34)	23.1 (22.8-32.6)	not made commercially available
25	Calculation			18-25	15-18	uterine dimensions determined by examining dimensions of IUD which gave least problems
26, 15	Ultrasound	38.4±0.3 (22-65) ^a	37±0.3 (22-65) ^a	31.13±6.49		

†-fundus to internal os, mean and range from combined studies

*-maximum transfundal width, mean and range from combined studies

^o-values are the combined mean values of the listed studies

[¶]-nulliparous and multiparous values

a-range includes both nulliparous and multiparous values

Third generation IUDs

The Progestasert[®], the first of the third generation IUDs was released in 1976. It had a difficult insertion technique, was expensive and only lasted one year. There was a curious notion that it would cause ectopic pregnancies, but this was not proven. It contained 38 mg of progesterone which was released at the rate of 65 mg/day. From 1986 - 1988 it was the only IUD available in the United States²⁷. The importance of the third generation IUDs or Intrauterine systems (IUS) as they are often called is that they are an attempt to go beyond simply providing contraception. The initial aim was of course to attempt to control the

excessive bleeding and pain produced by the first and second generation IUDs and to produce added health benefits. There is no health benefit to regular menstrual bleeding. To the contrary, the production of a quiescent endometrium is the aim of injectable and continuous use oral contraceptives as well as third generation IUD/Ss. The most successful third generation IUD or IUS is the Mirena developed by Tapani Luukkainen and colleagues at the steroid research laboratories in Helsinki, Finland²⁸. This IUD certainly overcame the bleeding barrier to IUD use, for both acceptors and providers. Its growing list of medical benefits in controlling menorrhagia, endometriosis, fibroids and other disorders has

ensured that it is well accepted by physicians and other providers. However beneficial third generation IUDs are they have erected another barrier to their use and that is cost. Currently their lifetime is only 3 to 5 years and the cost relative to that of some second generation copper IUDs which last 10 years or more is truly prohibitive. They are out of reach for many women in the more affluent countries of the world and totally out of reach for millions of women in Third World and other countries who could benefit from them the most. Hopefully much cheaper generic versions will soon become available.

Efforts to produce a generic Mirena are already underway. The Femilis[®] IUD is a LNG IUD which has a simple insertion technique and depending upon price may make this form of IUD more affordable. A frameless version of the LNG IUD is also being developed called Fibroplant[®], whose design is similar to the GyneFix 200 but in place of copper sleeves it has a LNG releasing fiber. Preliminary studies are favourable²⁹. Hopefully the cost and acceptability and efficacy will reduce some of the barriers for both acceptors and providers of IUDs, but other barriers to IUD use will still remain.

Fourth generation IUDs

Fourth generation IUDs are those which are truly novel. The distinction between the various IUD generations is somewhat blurred. The addition of sufficient copper to frameless and framed IUDs to give lifetimes of more than 25 years is currently being studied (Dr D Wildermeersch-Personal communication). The advantage is simplicity of the insertion technique and its reversibility. It will compete with office sterilization procedures like Essure[®] to produce what is effectively "reversible office sterilisation". Other modifications to make IUDs more suitable to use post-partum or immediately after caesarean section are also being developed. These cannot truly be considered fourth generation. The fourth generation of IUDs will be defined by their ability to provide an added health benefit to an intrauterine system, not just an improvement in tolerability of the intrauterine device and some tangential benefits in helping reduce uterine problems like the third generation

IUDs do. Fourth generation 'multipurpose' IUDs will actively target other areas of health problems. Primarily directed towards diseases of the female genital tract but perhaps using the uterus as a reservoir to target therapy to other physiological systems.

Currently under development are fourth generation IUDs which will be able to clear the upper genital tract and even the lower genital tract from infectious organisms. More ambitious is a project to design an IUS which releases anti-retroviral agents, or containing metallic nano- or microparticles, so as to help prevent the transmission of HIV/AIDS to both men and women. An IUS which would release folate in preparation for pregnancy and other vitamins and minerals e.g. calcium which would help prepare for pregnancy and also as a source of calcium to help women from getting osteoporosis are possibilities. Although these developments sound fanciful at present they will become more and more of a reality as nanotechnological techniques become available which will be capable of producing the kind of carriers which will make these products feasible. These technologies will help providers and acceptors reduce barriers to LARC methods as they begin to provide not only contraceptive but other health benefits.

Efficacy and cost effectiveness of IUDs

IUD and LARC methods in general are acknowledged to be very effective methods of contraception and the degree of utility and cost effectiveness will not be discussed further except to state that they have also been the subject of many cost efficiency studies and it is easy to figure out that a copper IUD which can be produced in some countries for as little as \$5 and lasts for 10 or more years is very cost effective³⁰. Some newer copper devices will last 25 years and can be viewed effectively as reversible office sterilisation. Even the newer fourth generation IUDs which will be expensive initially will be found to be cost effective in light of what they will be able to deliver. It is to be hoped that these benefits will help overcome many of the remaining barriers to IUD use and make them a more highly used option.

Barriers to more widespread use of IUDS

The historical background of IUD development and some of the technical aspects of IUD use enables an understanding of the barriers to IUD use. Some of the barriers to women getting an IUD have fallen, some have come down, partially if not completely. Others remain and new barriers to IUD use seem to be erected very easily. This section examines some of the common ones and demonstrates how they have been overcome, fully or only partially. Provider and acceptor barriers are largely interlinked but for the sake of clarity they are artificially separated.

Provider barriers

Initial provider barriers are due mainly to the perception, correctly or incorrectly, that IUDs are responsible for disease or immorality of some kind. If these barriers are overcome then the next line of defence for those who provide barriers are physiological and anatomical or methodological barriers. These include the problem of when to insert the IUD and technical problems in providing the insertion.

IUDs and disease

Pelvic inflammatory disease was falsely associated with the earliest IUDs. This loose association remains to this day in that women with an IUD *in situ* are often diagnosed with pelvic inflammatory disease simply because they have an IUD in position. Some landmark studies have shown that it is not the IUD which causes infection, but the factors which are known to cause pelvic infections in women in general³¹. Women who lead a life which predisposes them to getting pelvic infections will do so with or without an IUD.

Endometrial cancer was suspected to be a possible result of IUD use but was excluded in published studies in the 1950's and more recently³². Progestin releasing IUDs have a preventive (protective) effect on the development of endometrial cancer. Cervical cancer appears also to be reduced in IUD users³³.

Ectopic pregnancy was thought to be related to IUD use, especially the Progestasert and low-dose LNG-IUS, as it does not block ovulation. While users of IUDs may have a pregnancy which is

ectopic, the same is true of other methods of birth control (including oral contraceptives). Both copper and progestin IUDs can affect sperm physiology as a means of contraceptive action, which would not favour ectopic pregnancy, but not definitely exclude it³⁴.

IUDs do not cause intra-abdominal and bladder injuries unless the inserter mistakenly places them there, or abnormal uterine action forces them there. None of the foregoing is valid reasons to create a barrier against IUD use.

IUDs and abortions

This is a difficult barrier to overcome because the definition of abortion is not universally fixed and is mixed with philosophical and religious viewpoints. The copper IUD is a highly effective form of emergency contraception and undoubtedly can interfere with a fertilised ovum, possibly even if it is implanted in the endometrium¹⁹. Some providers in some countries use this as a barrier to providing IUDs. Curiously those who are generally most anti-science have a great interest in chromosomal amalgamation if it strengthens their convictions. This should not be used as a barrier to providing women IUDs.

Physiological barriers

The main physiological barrier to providing an IUD is the notion that a woman can only receive an IUD during a certain time of the menstrual cycle (during or shortly after menstruation). This leads some providers to insert IUDs only during or shortly after menstruation. This is to ensure the acceptor is not pregnant but even in those situations where it is certain that there is no pregnancy, some acceptors are turned away and required to return at this time of the cycle. There is evidence that insertions performed later on in the cycle give better results³⁵. It is also more physiologically appropriate to perform insertions around mid-cycle as the uterine fundal muscle is quiescent at this time and the uterine cavity is larger and more receptive to the IUD. It is also not necessary to wait for the results of cytological and bacteriological tests before inserting an IUD provided there is no clinical evidence of infection. Lactation and previous cesarean section are also

not grounds for delaying IUD insertion although insertions at this time should be performed with adequate caution because the chance of perforation is greater. Potential acceptors should receive their IUD at the time of presentation wherever possible and not be asked to return for fitting.

Anatomical barriers

While there are rare instances where true anatomical causes e.g. uterine abnormalities such

as a bi-cornuate uterus preclude fitting of an IUD, nulliparity is not one of them. The nulliparous uterus has more contractile myometrium and a smaller uterine cavity (Fig 1). Use of a small framed IUD e.g. Skyla and the frameless GyneFix where possible will ensure better results in this group. Ideally all IUDs should fit snugly in the endometrial cavity (Fig.2). The width of the IUD is determinative; if too small standard IUDs will cause side effects (e.g., cramping pain and abnormal bleeding) and result in displacement, expulsion or secondary perforation.

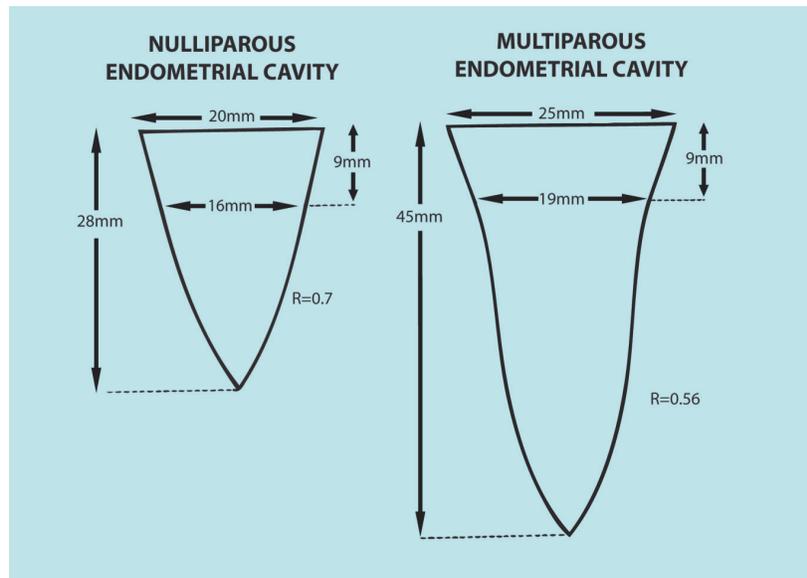


Fig 1: Size of the endometrial cavity in nulliparous and multiparous women. The dimensions are based on performance of various sized devices. R is the ratio of the horizontal to the vertical axis.

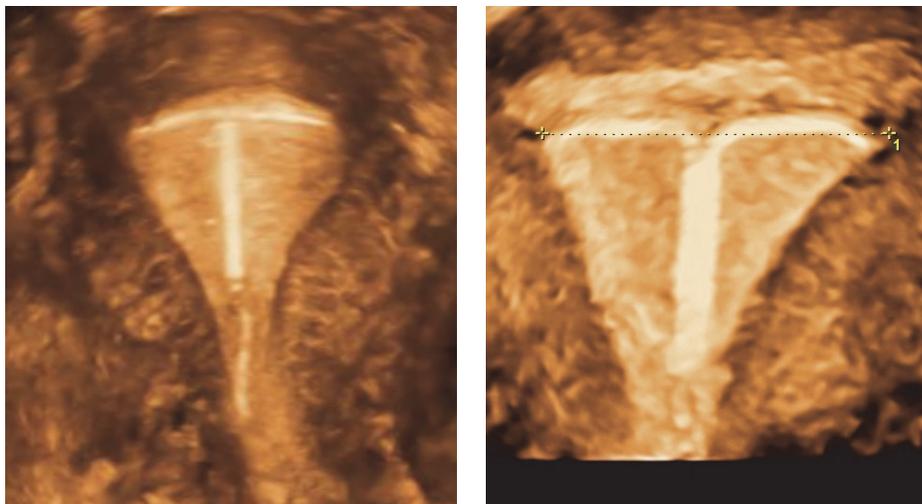


Fig 2: IUD in proper position in the endometrial cavity. Paragard (left) (courtesy of Dr Benacerraf), Mirena (right) (courtesy of Dr Pett and Jandi).

Table 3: Dimensions of commonly used IUDs(mm)

IUD	horizontal arm	vertical arm	main geographical area of use		Comments
TCu380A ^a	32	36	worldwide		inserter presenting diameter 6mm
Mirena [†]	32	32	worldwide		inserter presenting diameter 4.75mm
Skylla(Jaydess) [*]	28	30	Europe, North America		inserter presenting diameter 3.8mm
Flexi-T300 ^a	23	28	Europe, Canada		
Flex-T+300 ^a	28	32	Europe, Canada		
Flex-T+380 ^a	28	32	Europe, Canada		
GyneFix200 ^a	2.2	20	Europe		inserter presenting diameter 4 mm
GyneFix330 ^a	2.2	30	Europe		inserter presenting diameter 4 mm
Nova-T380 ^a	32	32	Europe, Canada, Australasia	Africa,	inserter presenting diameter 3.6 mm

†-contains 52mg LNG released at 20µg/day, declining to 10µg /day at 5 years

*-- contains 13.5mg LNG released at 14µg/day declining to 5µg/day at 3 years

a—surface area of copper (mm²)

Methodological barriers

Some providers still have technical problems inserting IUDs. The Bioceptive corporation in New Orleans, Louisiana, USA is currently developing a device which will hold the IUD. It will make one handed insertion possible as the device will attach to the cervix by section. The operator will squeeze a trigger which will advance the device into the uterus but will ensure that the force used will not be enough to cause damage(B. Capiello, CEO –personal communication). We do not as yet have IUDs which can be self-inserted. Women can take their own pills, insert their own contraceptive diaphragms and vaginal ring contraceptives. They can even inject their own injectable contraceptives. They are accustomed to insert tampons and some take their own cytological tests. There is as yet no method which allows them to insert their own IUDs. On the other hand, self-removal happens regularly and occurs mainly due to side effects (e.g., cramping pain). There is research underway to make the IUD much easier (and safe) using specific device inserters, requiring only a speculum and the use of one hand by the provider. There may well come a time when women will be able to insert their own IUDs, so reducing this barrier.

Acceptor barriers

Some of the provider barriers will also be barriers for potential acceptors e.g. if they think IUDs work by causing abortions. Depending on their level of knowledge they may also be worried about infections especially if they have not had children.

The main barrier to most acceptors is the prospect of whether they will experience insertional and subsequent pain, bleeding and /or discomfort with their IUD. There have been many studies and reviews on IUD pain and its preventions. Most mechanisms to prevent pain add to the methodological problems for providers and so while reducing barriers for the potential acceptors they increase them for the providers by adding the complexity of the insertion procedure³⁶. In women of low parity the most significant cause of pain is the diameter of the IUD inserter tube or its presenting surface area. As the IUD diameter increases so does the presenting surface area. This causes stretching of the cervical canal which is more pronounced with greater diameter.

The much maligned Copper 7 IUD had an inserter tube of 3 mm and caused the least pain on insertion. This problem for acceptors deserves

more attention. The main focus of all major IUD studies had been on performance and the role of tolerability is usually mentioned only in passing. The newer LNG releasing IUDs have smaller dimensions and a much narrower inserter tube (Table 3). For this they sacrifice lifespan, but if chosen correctly this trade off will be well worth it in most instances.

Discussion

This review has chronicled the developmental history of IUDs. It then focused on the kind of changes and developments that are being made to improve the concept to make it more appealing to potential LARC users. The overriding factor to successful use of the method seems to lie with the providers, rather than the acceptors at present. Whether and when providers promote or do not promote the method have been widely studied. In order to provide the method providers need to know two things 1) the technical aspects of the device as it relates to uterine anatomy and physiology and 2) have experience with the technique based on models and above all subjects. Both of these can be acquired fairly easily with some application. Too often they are missing and then in those instances the providers are not confident and will often recommend other non-LARC methods. Additionally the uterus is viewed as a 'black-box' into which the device must be made to disappear without thinking ahead as to what is likely to do once it is placed in the uterus cavity. The ability to be able to see beyond the 'black-box' is what separates the pure technicians who will not have the knowledge base to solve problems related to the IUD, either at insertion or later stage problems from the professionals who will be able to do this.

Conclusions

IUDs are a LARC method whose use is rising in North America and elsewhere. Increased uptake of the method will depend most vitally on improved technologies and on ensuring that providers have a thorough understanding of the method and do not erect unnecessary self-imposed barriers to the use of the method. As technology enhances and

especially when the insertion procedure becomes more tolerable, and the method is shown to provide additional health benefits the number of acceptors and potential acceptors, and willing providers will increase. Facilitating specialized service delivery by attending special training sessions for providers and holding information sessions for patients are equally of great importance. Both are extremely effective in moving the prevalence of IUD use forward. After all, what women want is safe, effective, well-tolerated, and long-acting contraception. IUDs and IUSs have this potential.

Competing Interests

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