**Commentary**

**Closing the Gap: Ensuring Access to and Quality of Contraceptive Implant Removal Services is Essential to Rights-based Contraceptive Care**

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**Abstract**

The use of the subdermal contraceptive implant is increasing globally, and particularly so in lower- and middle-income countries in sub-Saharan Africa. For initiation or discontinuation of the implant, users need to have access to services for insertion and removal by healthcare providers. Providing access to safe and effective contraceptive implant removal services presents both clinical and programmatic challenges. The most challenging implant removal cases, termed “difficult removals”, place additional demands upon removal services. In this commentary, we outline challenges for the provision of removal services. Based on our experience in this field, we make recommendations on how healthcare providers and health services can plan for these challenges. Through maximising the provision of comprehensive and accessible implant removal services, including those for difficult removals, implant users can be empowered to discontinue their use of this method of contraception if they choose, thus upholding the principles of rights-based contraceptive care.

**Keywords:** Contraception, contraceptive implant, implant removal, difficult implant removal

**Running title:** Access to Implant Removal Services

**Introduction**

Over the past decade, availability and use of the subdermal contraceptive implant has expanded globally, and particularly so throughout sub-Saharan Africa (SSA)1, where national family planning programmes have embraced the implant as an important option to help meet the unmet need for contraception. The implant has been actively promoted due to its status as a form of long-acting reversible contraception (LARC) with the key assets of increased effectiveness and continuation rates compared with shorter-acting or traditional contraceptive methods2,3. The implant also plays a critical role in expanding contraceptive choice, which contributes to increased contraceptive utilisation and user satisfaction4. This ongoing trend to increased implant use has created a corresponding and growing need for access to implant services, both for the initiation and for the discontinuation of this contraceptive method.

Contraceptive implants are a highly efficacious, cost-effective, convenient, long-acting and reversible method of contraception with few medical contraindications5. These highly desirable characteristics have led to their growing popularity worldwide. Uptake has been facilitated through access pricing in low- and middle-income countries (LMICs)6,7, as well as active demand creation and promotion. Marie Stopes International, one of the leading non-governmental organisation (NGO) implant providers, noted a nine-fold increase in their provision of implants in SSA between 2008 and 2012 and estimated that there remained an unmet demand for further provision8. This estimation has been borne out, with a recent study noting an increase in the prevalence of implant use across all sociodemographic groups in ten diverse SSA countries, with the highest implant contraceptive prevalence rate being among married Kenyan women - 18.1% in 2016, compared with 1.7% 13 years previously1.

The scale-up of this LARC has the potential to have a significant positive impact on the lives of women and girls around the world through the reduction of unintended pregnancies, maternal and infant deaths, unsafe abortions, adolescent fertility, and total fertility9. Addressing the unmet need for family planning through “universal access to sexual and reproductive health and reproductive rights” is also one component of Sustainable Development Goal five to “achieve gender equality and empower all women and girls”10. However, the recent large scale-up of contraceptive implants in many LMICs brings to the fore important considerations regarding the provision of rights-based family planning services because they cannot be initiated or discontinued independently by the user: specially trained healthcare providers are needed both to insert and also to remove implants.

An essential component of rights-based family planning is that users have a right to choose when to start, continue, or discontinue their chosen contraceptive method11. This is in accordance with the expected standards of human rights-based provision of contraceptive care and allows users of contraception to “decide freely…the number, spacing and timing of their children,” as called for at the 1994 International Conference on Population and Development12. Accepted principles to enable the provision of rights-based family planning include: universal access; removal of barriers to access; a continuous and wide-ranging supply of safe, effective and high-quality commodities; appropriately skilled health workers; good quality facilities; voluntary informed choice; and monitoring to ensure that human rights are respected13. Implant provision must be implemented fully in accordance with these principles.

Alongside the documented challenges of scaling up of implant availability - which include demand creation, ensuring real contraceptive choice, adequate pre-insertion counselling, management of side effects, and tackling misinformation14 - clients and healthcare providers alike are beginning to encounter challenges in relation to implant removals15. The implant is a safe and effective contraceptive method which should continue to be promoted and used globally, and nurse/midwife-led provision in primary healthcare settings is appropriate and important because it maximises accessibility to clients16. In order to sustain ongoing acceptability and increasing implant use, it is vital that prevailing challenges to removal services are addressed through the development of responsive health systems.

**Overview of Implant Removal Challenges**

With appropriate training and equipment, most implant procedures are straightforward17. However, clinical and programmatic challenges have arisen with respect to the provision of implant services. Clinical challenges encompass the performance of insertion or removal procedures on individual clients, whereas programmatic challenges include larger-scale logistical health systems issues. In general, implant insertion may require a lower level of technical clinical competence and logistical support than that required by implant removal.

***Clinical challenges***

The currently available subdermal contraceptive implants are: Implanon NXT®/Nexplanon® (etonogestrel (ENG), Merck), Jadelle® (levonorgestrel (LNG), Bayer), and Sino-implant®/Levoplant® (LNG, Shanghai Dahua Pharmaceutical Co Ltd). Historic implants are: Implanon® (ENG, akin to Implanon NXT® but non-radiopaque, Merck), and Norplant® (LNG, Wyeth-Ayerst Laboratories). With regards to technical difficulty, the Implanon NXT® applicator was redesigned to help healthcare providers consistently and easily achieve correct implant placement, reducing deep insertions and therefore reducing the incidence of subsequent difficult removals18. The Jadelle® and Levoplant® implants both retain a technically more demanding trocar-based insertion technique. In contrast, implant removal requires greater autonomy on the part of the healthcare provider, who must decide the location and length of an incision, when to use additional instruments, and when their personal limits of competence have been reached thus making abandonment of the procedure and referral to a more experienced colleague the best course of action.

Manufacturers have taken some steps to facilitate implant removal, for example: reducing the number of rods in newer implants compared with earlier models, making removal of the single-rod Implanon® significantly faster than removal of the six-rod Norplant® (2.6 minutes vs. 10.2 minutes) and significantly less likely to be associated with complications (0.2% vs. 4.8%)17; making the rod semi-rigid so that it is more amenable to removal by means of the “pop-up” technique19; making the rod radiopaque and therefore identifiable on X-ray18; and amending insertion advice for Implanon NXT®/Nexplanon® away from the sulcus between the biceps and triceps muscles and instead advising the inner side of the non-dominant upper arm overlying the triceps muscle20,21. However, despite these advances, removal may still present a wider spectrum of technical difficulty than insertion. Some removals will be achieved quickly and easily, others will take longer and require greater skill and different equipment. The most challenging removals are those generally described as “difficult removals”.

“Difficult removals”, which are rare in comparison to routine removals22, but nonetheless important, encompass removal procedures in which one or more of the following factors come into play:

1. Poor implant placement at insertion: for example, an implant that is not placed subdermally, resulting in a deep insertion into the subcutaneous fat or muscle, or an insertion into the sulcus between the biceps and triceps muscles with consequent proximity to neurovascular structures (brachial vessels, median and ulnar nerves) and risk of damage during the removal procedure. This was noted historically with Norplant®23 and has been associated with placement by private healthcare providers who might engage in less ongoing training compared with their public counterparts24.
2. Implant migration: for example, implants may rarely be placed in a blood vessel allowing for migration from the original insertion site25.
3. Implant structural failure: for example, a broken implant, removal of which may require more than one incision26,27, or a bent implant, removal of which may require a longer incision28.
4. Increased tissue fibrosis surrounding implant: due to a longer interval since implant insertion24.
5. Complications due to client weight changes since insertion: weight gain possibly resulting in increased dermal thickness and therefore deepening of implant position24; weight loss decreasing surrounding tissue and increasing the risk of implant migration29.
6. Failure of initial removal: the trauma of the first attempt may cause localised bruising and oedema which might make subsequent attempts more challenging and increase the risk of complications such as bleeding, infection or scarring30.
7. Requirement for additional personnel or referral to another healthcare provider: this includes colleagues within the same service who may act as an assistant19 or may have more experience of performing implant removals, but also includes referral to other specialties, particularly gynaecology, surgery and interventional radiology, for example, techniques used in other types of procedures have been also used to facilitate removal of deeply inserted implants located close to neurovascular structures31.
8. Requirement for additional or more specialised equipment: additional equipment such as skin retractors19 or modified vasectomy clamps32; ultrasound for implant location, ideally encompassing a high-frequency linear array transducer, which should be routinely used in difficult removals referral centres for location of difficult, non-palpable, non- (or only locally-) migrated implants33,34; other imaging modalities for implant location, such as X-ray29,35, computed tomography or magnetic resonance imaging36, or real-time ultrasound- or fluoroscopic-guidance37 during the removal procedure.
9. Requirement for additional investigations: for example, the capacity to test serum ENG levels to confirm the presence or absence of a non-palpable ENG implant38.
10. Requirement for additional facilities: for example, access to operating theatres in very rare cases30.

***Programmatic challenges***

The logistical challenge of providing implant removal services includes training healthcare providers in difficult removal techniques, establishing referral pathways, and either referring to or locally sourcing imaging equipment. There is also a geographical challenge of transporting clients to appropriate healthcare providers in regional removal centres, who may be much less accessible than the local clinic in which the implant was originally inserted. Regional teams for the management of difficult removals have been established in high-income countries, such as the United Kingdom20 and France30. Careful thought needs to be given to the adoption of the same regional referral model in LMICs.

Even when removals are straightforward and routine, the provision of removal services can be logistically more challenging than the provision of insertion services. For example, removal packs may need to be assembled by individual clinics, this involves sourcing of surgical instruments, may involve sterilisation procedures either on- or off-site, and ensuring access to disposable commodities such as scalpel blades and sterile gloves. In contrast, much of the equipment for implant insertion is disposable and is included within the implant packaging. Additionally, during the initial rollout of the implant healthcare provider training has often focused on insertion rather than removal, as there has been a limited demand from clients for removal during the early stages of implant introduction. This has led to fewer healthcare providers who are competent and confident to perform implant removal relative to the number providing implant insertion39. Post-insertion follow-up, including access to removal services, has also been lacking for clients who have had implants inserted during mobile clinics39.

***Difficult removal services***

Christofield *et al*.39 outlined the requirements for quality removal services. These include: availability of removal commodities; healthcare provider competence and confidence; systems being in place for managing difficult removals; provision of counselling, side effect management, resupply and switching; clients being informed of and being able to access the removal services at a convenient time and location; the service being affordable; and collection and monitoring of removal data.

To expand upon the third requirement, i.e. for a system being in place to manage difficult removals, we have outlined below what a quality difficult removal service should provide based on our experience. Given the challenges laid out above, these requirements can be summarised as: advanced training in difficult removals for a subgroup of removal providers; distribution of these advanced removal providers so that they are accessible to clients; referral pathways to access advanced removal providers and other specialist colleagues; access to imaging services on-site, particularly ultrasound for real-time guidance; and referral pathways to access imaging services and other additional investigations if not locally available34.

Of the 4.9-5.8 million implant removals which were predicted to be required in 2018, it is difficult to ascertain what proportion comprised difficult removals. The reported rate of complex Implanon® removals is 1 per 1000 insertions20, but this figure may be different for Jadelle® or Levoplant® removals and may be subject to underreporting. The rate of difficult removals could be higher in LMIC settings due to lower levels of ongoing healthcare provider support and quality monitoring following initial training, but this is unknown. The cost of providing a removal service, including that for difficult removals, should be considered alongside that of the initial rollout of insertions40. Failure to plan for universal access to removal, with an adequate supply of high-quality equipment, healthcare providers and facilities, would lead to violation of the priorities of accessibility and quality care in rights-based family planning. To inform implant rollout, the Implant Removal Task Force’s survey of removal availability, which was proposed to be undertaken in three SSA countries between 2016 and 2017, will help establish the current level of service provision, and predict what funding will be required to tackle current shortfalls41.

***Planning for anticipated challenges in the provision of implant removals***

In order to meet the anticipated demand for implant removal, both straightforward and difficult, it is important to plan a comprehensive implant removal service. National family planning programmes should not be caught unawares by a sharp increase in demand for implant removal three to five years after those same programmes have introduced and promoted the implant, and on an ongoing basis. Furthermore, programmes need to recognise that appreciable numbers of clients will require interval or “early” removal due to their decisions to discontinue implant use for reasons ranging from dissatisfaction with the method to desire for pregnancy, as has been noted across a variety of contexts14,42-44. In some settings, a comprehensive database of women who have had an implant insertion may aid in keeping abreast of when removal will be due. This is helpful to clients who can be contacted with information related to scheduling removals, to healthcare providers at a local level, and to programme managers at a national level for monitoring and evaluation purposes. One example of a comprehensive database of this nature is the Client Information Center (CLIC) maintained by Marie Stopes International8. In addition to insertion data, removal data also needs to be monitored to inform programme evaluation and improvement, but record-keeping on removal has been neglected in some national programmes45. Another example of an implant database, including removal information, is currently being implemented in Botswana, an initiative in which the authors of this article are actively involved. This database allows monitoring of implant insertions and removals following the introduction of implants in the public sector in 2016, and therefore the anticipated surge in demand for routine removals which will occur from 201946. Healthcare providers should be prepared to meet the demand for “early” removal of implants, allowing women to exercise their right to choose when to stop, replace or change their method of contraception.

**Recommendations**

Available, accessible, high-quality removal services should be as fundamental as insertion services in the upscaling of implant programmes. This can be encouraged by integrating removal information into national implant guidelines, including guidance about the management of difficult removals. Removal training can be integrated with insertion training, achieving three aims: firstly, that correct insertion of implants makes for more straightforward subsequent removal; secondly, that all healthcare providers who are trained to insert implants are also trained to remove implants as part of a standard training course, maximising the number of removal providers; thirdly, that healthcare providers feel adequately trained and confident to routinely counsel all women who request implant insertion about the removal procedure. A study of South African family planning nurses found that many felt inadequately trained to perform removals47. These sentiments may help to inform an increased focus on removal skills as part of routine implant training in other national family planning programmes. As contraceptive implants are provided by government health services, NGOs, and the private sector, efficient and comprehensive removal services, which are fundamental to upholding the principles of rights-based family planning, can only be achieved by collaboration between all three of these sectors.

**Conclusion**

The subdermal implant has many assets as a contraceptive method and it should be, and is increasingly being, made available to women globally. Ensuring timely access to removal services is as fundamental as the provision of insertion services in the delivery of this contraceptive method. Healthcare provider competence in insertions contributes to easier removals, and similarly, competence in removals contributes to maintaining client satisfaction and demand for insertions in new users and replacements in existing users. If women are not easily able to access safe and effective removals, the image of the implant could be tarnished and its uptake could diminish. This situation has recently been documented in South Africa15, where potential users have perceived a dearth of access to services for side effect management and removal14. In the 1990s, difficulty in accessing removal services led to a decline in the public image and consequent uptake of Norplant®, one of the earlier versions of the implant48. Family planning programmers must learn from the experience of their predecessors and international colleagues: by anticipating the need for comprehensive and accessible implant removal services, including for difficult removals, they can ensure that women are empowered to start using the implant but also to stop using the implant, thus upholding the principles of rights-based family planning.

It is imperative that the global rollout of the contraceptive implant is implemented in accordance with the principles of rights-based family planning, this is a moral and a legal obligation13 and is essential to quality care49. In order to sustain the expansion in implant use, international and national organisations, both governmental and non-governmental, will need to develop health systems which are capable of continuously providing adequate insertion and removal commodities and facilities, and initial and ongoing training of healthcare providers in both insertions and removals, including difficult removals. Accessible, rights-based, high-quality family planning services, within which the implant is a key tool, are essential for the improved health and empowerment of women and girls worldwide.

**Contribution of Authors**

CM, LM and RH conceived the initial idea for the manuscript. RH and AMG wrote the first draft of the manuscript under the supervision and guidance of CM and GP. TK, LM, SM, TM and MP provided substantive inputs into all drafts. All authors contributed to the revision of the manuscript and approved the final manuscript.

**Acknowledgements**

AMG’s time working on this publication was supported by the Fogarty International Center of the National Institutes of Health (NIH) under Award Number D43 TW010543 and the Afya Bora Fellowship Program. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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