

SETTING UP POST-PARTUM INTRAUTERINE DEVICE (PPIUD) SERVICES IN A LOW- RESOURCE SETTING: LESSONS IN A DEVOLVED HEALTH SYSTEM, KENYA

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ABSTRACT

Family planning (FP) is an important pillar in Safe Motherhood and has been demonstrated to avert up to 30% of maternal and 10% of newborn deaths. Postpartum family planning [PPFP] focuses on unintended and closely-spaced pregnancies throughout the first year of birth. Postpartum intrauterine device (PPIUD) is the only FP method which is highly effective, reliable, inexpensive, non-hormonal, immediately reversible, and long-acting contraceptive that can be initiated during the immediate postpartum period and has no negative effect on lactation. However, its uptake remains unacceptably low. In this paper, we describe the process of how we setting up PPIUD services with the aim of institutionalizing the routine provision of immediate PPIUD as a method of FP in resource limited setting.

BACKGROUND

Family planning (FP) is an important pillar of Safe Motherhood. It permits mothers to avert complications arising from pregnancy and childbirth by providing for planned birth spacing to have the intended number, spacing and timing. Evidence shows FP can reduce up to 30% of maternal and 10% of new born deaths(1). The postpartum period is recognized as a timeframe that has high unmet need for contraception, with limited choices available to women. Postpartum intrauterine device (PPIUD) is the only FP method which is highly effective, reliable, inexpensive, non-hormonal, immediately reversible, and long-acting contraceptive that can be initiated during the immediate postpartum period and it has no a negative effect on lactation(1–3). Postpartum family planning accords an opportunity to reduce missed opportunities as clients are already in contact with the health providers; promotes the contraceptive uptake and reduces the unmet need for FP while providing mothers with an opportunity to nurture their newborns and gainfully contribute to her family

and community(2–5).

The Kenyan government is promoting facility-based delivery by making maternity care free for women through the implementation of a free maternity policy from June 2014 and Linda Mama; a national health insurance package. This resulted in an increase in utilization of maternal and newborn health services with many health facilities in Kenya registering an increased rate of institutional deliveries. While this provides a unique opportunity for providing FP services, the proportion of postnatal women leaving the facilities without a contraceptive method remains high. There is notably low uptake of immediate postpartum long acting reversible contraceptives and sterilization. The revised National Reproductive Health Strategy 2009-2014 aimed to reduce the unmet need for FP, reduce unplanned births, and narrow the socioeconomic disparities in the Contraceptive Prevalence Rate (CPR)(1–3). Intra-uterine device placement in the postpartum and post-abortion period became policy in Kenya in the year 2009 but its uptake is still less than 1%. Implementation of

PPIUD services should be provided within facilities that follow appropriate infection prevention practices, offer counseling for informed choice and consent, and have access to skilled providers within a robust health system supportive of this intervention(3) .

Health system strengthening particularly in low resource setting needs to sustain efforts to have structures, processes and outcomes that will impact towards reducing morbidity and mortality. PPIUD programs are aimed at addressing leadership and governance, infrastructure, finances, human resource, medical products and technologies, service delivery, health management information system to enhance access and coverage; quality and safety culminating in healthier outcomes that are more responsive to clients; reduced financial risk and provided with improved efficiency(6). As part of this broad program of work, the Kenya PPIUD project aimed to institutionalize and routinely provide immediate PPIUD as a method of FP we sought to: i) Improve counselling services for PPIUD clients attending antenatal and delivery services; ii) Strengthen capacity in terms of knowledge and skills of health professionals in PPIUD service delivery; iii) Strengthen the health system in institutionalization of PPIUD services; and iv) Evaluate the uptake and trends of utilization of PPIUD services.

SETTING UP THE PPIUD PROGRAM

This programme of work was considered an implementation research project and as such ethical approval was required. Ethical approval was sought and granted by the Kenyatta National Hospital/ University of Nairobi and Moi Teaching and Referral Hospital Ethics Review Committees commencement of the project. To achieve this, a formal research proposal was developed in collaboration with the International Federation of Gynecology and Obstetrics (FIGO), as this was part of a multi-country project and standardization was key to allow comparison across countries. However, for practical and logistical reason, contextualization to in-country situation was done based on the following considerations: teaching and referral health facilities with the potential to scale up capacity building in the pre- service cadres offering services in the maternity units were selected; work-load/ workforce ratio; willingness of the county and individual facilities

to participate in the initiative; and availability of a supportive working environment.

STAKEHOLDER ENGAGEMENT

To promote institutionalization of the PPIUD program, we engaged the Ministry of Health as it is responsible for policy formulation and oversight through the National Reproductive Maternal Health Service Unit (RMHSU), the counties since they are responsible for coordination of service delivery and proposed health facilities for implementation as they were to be responsible for the PPIUD service delivery.

INTRODUCTION OF THE INITIATIVE TO THE NATIONAL REPRODUCTIVE MATERNAL HEALTH SERVICE UNIT (RMHSU)

During the proposal development stage and implementation of the PPIUD program, there was continued engagement to promote buy-in and integration of the PPIUD services into the unit's plan of activities. After ethical approval was granted, an induction meeting was held at the RMHSU with a broader set of stakeholders to outline the project activities, deliverables and roles of the different partners. The stakeholders included: Ministry of Health officials, training institutions, representatives from counties and participating hospitals. This was followed by training of officers, development of information education communication (IEC) materials. After roll-out of the project facilitative supervisory visits at the selected project sites and feedback reports was done every 6 months.

INTRODUCTION TO COUNTIES

Following the promulgation of the new constitution in August 2010 in Kenya, a new governance framework was adopted with a national government and 47 counties. This resulted to a highly decentralized system of governance with services being devolved to 47 County governments. Each county is subdivided into smaller administrative regions called sub-counties. In a similar manner, under this new framework, health services delivery was assigned to counties while policy, national referral hospitals, and capacity building are the national government's responsibility(7). Therefore, successful implementation necessitated that we conduct

induction meetings between the national team and County officers prior to onset of the project in the selected sites to outline the roles of each. The officers were namely: The Chief Executive Commissioner Health, Health management team, Reproductive Health Coordinators, Facility board members and administrators, Project Facility Coordinators, community strategist and Health information system in-charges. During the duration of the project, training of the leadership at the health facility facilitated their understanding of the processes and for service delivery and regular quarterly feedback interrogating site performance through monitoring and evaluation meetings was conducted.

SELECTION OF STUDY SITES

The project sought to strengthen the capacity of health professionals in the provision of PPIUD services, provide continuous learning and assure scalability of services in the pre- service and on- job training. As such, we were interested in teaching hospitals serving an average population of more than 1,000,000-4,000,000 people and providing comprehensive obstetric care with an average delivery of 3000 per year in each of the facilities. Teaching hospitals, which also served as county teaching and referral hospitals were considered as ideal as they had infrastructure and personnel to support continuous learning for doctors, interns, nurses and clinical officers. The institution's workload also provides a better pool to evaluate trends of utilization and uptake of PPIUD services, with lessons learnt used to inform government policy, that sought to support postpartum FP to include PPIUD as a cost effective long term reversible family planning option. After consultations with stakeholders, the following health facilities were selected while taking into account geographical variation and willingness to participate: Moi Teaching and Referral Hospital, Eldoret Uasin Gishu County, ii) Coast General Hospital, Mombasa County, iii) Meru Level 5 Hospital, Meru County, iv) Thika Level 5 hospital, Kiambu County, v) Kisumu District Hospital, Kisumu County, and vi) Rift Valley General Hospital, Nakuru County.

These teaching and referral health facilities work closely with lower level facilities in the catchment area with Nurses/midwives providing services in

these lower level facilities being trained and supported to provide PPIUD services. A robust hierarchy of clinical personnel and referral mechanisms were put in place to handle complications if the need arose.

Based on the KDHS (2014)(8), over 50,000 deliveries took place at these six selected facilities over a period of one year. FP practices indicated approximately 0.3% of the clients received permanent methods and 9% received hormonal methods. Studies have shown through analysis of demographic health surveys that 95% of women want to avoid pregnancy post-partum in the next 24 months, however 70% of them are not using contraception. The selected facilities are teaching hospitals serving an average population of more than one and up to four million people and providing comprehensive obstetric care with an average delivery of 3,000 per year in each of the facilities.

PROCEDURES

The PPIUD is a clinical procedure of insertion of the intra-uterine device Copper 380A Intrauterine device. It is a safe and effective contraceptive with a low failure rate of less than 1%. Its long-acting, easily reversible, return to fertility is immediate and with fewer medical eligibility contraindications and complications. It can be used amongst breastfeeding mothers, providing an attractive option in the postpartum period with higher rates of satisfaction and motivation for continuance (9,10).

The procedure of PPIUD insertion had minimal risk to the participant as the Reproductive and Maternal Health Services Unit (RMHSU) of the Ministry of Health in the FP guidelines had already adopted it as a recognized intervention for those consented and met the Medical eligibility criterion for FP services.

The risks and benefits of the procedure and service were communicated to each participant in a language they understood. The clients were provided an opportunity to ask questions and received clarification on all aspects pertaining to the project. Informed consent was sought explicitly explaining the nature and the voluntariness of participating in the study. Anyone wishing to withdraw from the project was free to do so at any point without victimization and provided with standard of care. Confidentiality was

maintained with the data collected being handled only by the research team. In the report, codes instead of names were used to identify participants and the procedures were conducted in private. In the event of protocol deviation or violation in the course of carrying out this initiative, this was to be reported to the ethical review board within 5 days of the time the PI becomes aware of the event. During the project regular feedback reports and annual renewal of the ethical approvals were undertaken.

PUTTING UP RESILIENT HEALTH SYSTEM FOR IMPLEMENTATION OF PPIUD SERVICES

To ensure sustainability and scalability of the PPIUD program, a multifaceted approach was adopted spanning the health systems building blocks and aspects of implementation research to allow routine monitoring and evaluation. The aim was to allow knowledge and skills transfer coupled with integration of PPIUD services in the continuum care and as a consequence enabling institutionalization of PPIUD services. In the following section we outline how different health system building blocks were applied to the PPIUD program and expound how this prompted integration of these services to routine care.

Leadership and clinical governance: Clinical governance is seen as a systematic, multi-faceted, integrated approach to ensuring safe and quality healthcare. This was delivered through a combination of strategies that include: ensuring clinical competence, clinical audits, patient involvement, education and training, risk management, data for decision making and enhanced staff management utilizing a wide range of resources and guidelines. Due to the devolved nature of health care in Kenya it was required that governance be implemented at the various levels at national, county, health institutions, amongst implementers of services and in liaison with the national team providing oversight to the immediate PPIUD Project.

Infrastructure: As part of the project set-up, the PPIUD program provided resources to ensure an enabling environment for implementation. This involved provision of delivery suites, gynecological couch, adequate lighting, expendable supplies, infection prevention commodities -protective gear and solid waste management, delivery kit and

immediate postpartum placement insertion and removal kits comprised of Kidney dish gulle pot, ring artery forceps, tenaculum, Sims speculum, Kelly forceps and IUD thread retrievers.

Capacity of Human resource: A two-day master training was done at the national level generating the facility champions. The personnel trained constituted twinning of facility coordinators who are Obstetricians and gynecologist and deputy facility coordinators who were nursing officer in-charges of the labor ward. They in turn were expected to train service providers at the respective service delivery points on processes for PPIUD namely the ANC, Maternity and at the Post –natal ward. The training content comprised of pedagogy, competence training using the humanistic model - Mama-U with standardized checklists; actual insertions performed on patients who consented and met the medical eligibility criteria for the procedure. Training at the respective health facilities engaged in the project was provided through a 3 day workshop with Didactic and practical sessions on Mama U(10,11).

A standard PPIUD skills checklist based on JHPIEGO guidelines (12) was used to evaluate competencies in the service provisions among health professionals during the training; periodically at work and during the continuous professional development assessment. During the training certification was provided after 10 correct insertions made on Mama U. Proficiency certification was given after 10 insertions on clients and certification as a master trainer after 30 client insertions. These post training certifications were sent via email automatically upon attaining the respective milestone. There was a mentorship program for those undergoing on- job training conducted by master trainers. A short message reminder from the national data center office helped improve motivation towards certification for proficiency and as master trainers.

The Facility Coordinators and the deputy facility coordinators also provided support through continuous professional development by conducting simulation trainings in their institutions on PPIUD service provision using the Mama- U models and cascading this to health professionals in the peripheral institutions to ensure the project has sustainability and scalability.

Training of community health volunteers: The community strategy in Kenya commenced in 2006 but yet to be appreciated and scaled up for family planning services(13). The community health strategy was embraced in August 2017 in the PPIUD project with the aim of providing health education and improving demand generation for postpartum family planning services. This strategy further enhanced reducing the unmet need, missed opportunities and increased the contraceptive prevalence rate at the County and National level. A two-day training package for community health extension workers and volunteers was provided through didactic sessions, role play for counseling and use of job aids to facilitate knowledge and skills translation for PPIUD. An integrated approach for transfer of health education in postpartum family planning, addressing socio- cultural barriers, myths and taboos; mothers autonomy in decision making; counseling; consent, referral with linkage to the health facilities and follow up done during household visits. This was integrated along other MNH activities such as antenatal care, individual birth planning, emergency preparedness, maternal danger signs, breastfeeding, neonatal cord care, neonatal danger signs, identifying the sick neonate besides other public health messaging.

During the household visits the community health volunteers targeted pregnant mothers, their partners and provided health education on postpartum family planning, counseling was conducted either to the mother or through couple counseling for PPIUD. If consent was provided the mother was referred to the nearest facility where she could obtain PPIUD services. The mother- baby booklet was stamped adjacent to the antenatal profile indicating the number of counseling sessions, informed voluntary consent, PPIUD insertion and follow up visits – the last two were filled after insertion of the IUD. The CHV also provided a documented referral note to the health facility for PPIUD services. At the health facility, the client was linked into care via the antenatal or labor ward as her entry point. A client who had selected PPIUD as her method of choice was further provided with information and the consent reaffirmed. If the client's delivery was uneventful and the mother met the medical eligibility criteria, PPIUD services were given between 10mins (immediately post-placenta removal) and 48 hours. Upon return in the community

the CHV followed up the client at the household for up to six weeks providing a further opportunity for postpartum tracking of mothers and neonates. A standardized tool for documentation of these processes was filled by the CHV, submitted to the community health extension worker (CHEW) who cascaded the information to the data clerk facilitator on a weekly basis. Compilation of the monthly return was done for the County community strategist and the national data center manager. This data was reviewed by the community officers at their quarterly monitoring and evaluation meetings giving an opportunity for feedback from themselves and clients and addressing process gaps. In the community the CHEW organized monthly feedback meeting with CHV through community dialogue days to further promote the PPIUD program.

Information, Education and Communication (IEC) Material: In collaboration with the Ministry of Health - Department of Reproductive Health and Maternal Service unit, IEC materials were developed in the form of algorithms for health care providers, information leaflets and audio – visuals for the clients and the community. The audio- visual televisions were strategically placed at the points of care in the antenatal clinic and postnatal ward.

Financing: The national policy for Free maternity and the existence of “Linda mama” a National health insurance facilitated mothers not making any payment associated with delivery and family planning services provided in the immediate postpartum period. Finances that supported infrastructure, equipping, human resource and non- pharmaceutical and contraceptive methods need to be in place and followed through at the facility and county level and were provided by the PPIUD program. The role of the Reproductive Health Coordinator was crucial in ensuring there were no stock outs and in identifying collaborative partners.

Medical products and technologies: The Copper 380 A intrauterine device is provided through the National Family planning service distribution program. However, in areas where the demand increased outstripping the supply, logistics that facilitated pooling of commodities from other health facilities in the County or purchase by the relevant health facility were put in place.

Service delivery: This was provided in the continuum of patient care from the community, antenatal care, intra-partum, delivery, post-partum and follow up to six weeks. The services were modeled in an integrated manner to offer a one-stop-shop with other reproductive health and neonatal health services. Within the community additional health education on various public health issues outlined in the community health curriculum such as de-worming, disease surveillance, oral rehydration, WASH, personal hygiene and care of the environment were also provided.

Health management information system: To allow for routine monitoring and evaluation of the project, mechanisms for routine data collection and use were put in place. Baseline data on prenatal, delivery and PPIUD services was collected for one month before commencement of the project at the study sites. Primary data collection utilized a standard questionnaire as provided by the PPIUD project, to collect information on the capacity of health professionals with a pre- and post-course knowledge assessment administered before and after the trainings.

The collection of data for PPIUD service was made across the service delivery points in the continuum of care: the community, antenatal, intra-partum, post-partum and during the follow up period. There was one person at the headquarters responsible for all the data streaming and collating and review from all the study sites. Data abstraction is made from the mother – baby booklets; relevant registers in the antenatal, delivery and postpartum and family planning and through exit interviews of individual clients. Data was entered in the respective tools by trained local data collection officers and the mid- wives. This manual data base was then uploaded onto smart phones and further relayed through a web platform (Comm-Care- Dimagi) to the national data collecting center. Here the data was de-identified and stored in excel sheets. Oversight of these processes and address to missing variables or concerns were handled by the facility coordinators, facility data in- charge, national data clerk and the principal investigators locally and internationally. Data were checked regularly on a daily, weekly and monthly basis. Issues arising were raised with the respective site via email, Short text

messages or telephone communication.

Quality assurance: The pedagogy was collaboratively developed with the FIGO program investigators and participating countries. The training of facility coordinators and data clerks by the national team provided a standardized approach to knowledge and skills transfer and they assumed a master trainer status after 5 days of training. The skills transfer used the high-fidelity simulation approach on Mama U. In the respective health facilities, the facility coordinators and deputies provided daily facilitative supervision and management of issues arising in the PPIUD program. The initial trainings at the project sites were conducted by the master trainers supervised by the technical officers from the MOH Reproductive and Maternal Health Unit in collaboration with KOGS to ensure that they complied with the laid down guidelines and protocols. The health personnel had access to the didactic training manuals and Mama U for initial and repetitive revision. This was further backed by the mentorship program in the maternity unit and the quarterly monitoring and evaluation of services.

Clinical quality assurance required that ethical, respectful and patient rights were observed in the continuum of patient care. Informed voluntary consent and individualized clinical evaluation were conducted with pre-procedure confirmation of consent and clinical re-evaluation after delivery against the medical eligibility Criterion (14) applied before the PPIUD procedure was conducted. PPIUD insertion followed the standardized checklist in JHPIEGO Guidelines(12) and post-procedure triage with immediate attention to complications if any attended being done. Information on danger signs, sixth week review date and discharge summary were provided to the stable client. Follow up was conducted in the community but the client was provided with an emergency hotline and advised to return to the facility in case of any problem or at her sixth post-delivery week. During the follow up visit, in-person patient evaluation was conducted. If follow up was conducted using a telephone review, standardized questions were asked by the interviewer who was either the clinician or a data clerk. In all these clinical processes documentation was made.

Analysis	Implementation issue	Consequence (Lessons learnt)
Strengths	Counseling on PPF and IEC Contact visits with the health facility: <ul style="list-style-type: none"> • Community to health facility • Number of health facility contact with skilled providers Postpartum follow up contact visits and communication Capacity of health personnel More personnel with skills (scale up through OJT and mentorship) Services for free immediately after delivery Improved clinical care documentation and data for evidence Service delivery expanding in- facility and to adjacent health facilities Demand from private sector for PPIUD community to health facility linkage	Awareness and BCC Demand generation Responsive Skilled quality care from community, antenatal, delivery and family planning given Opportunity to reduce maternal and neonatal morbidity and mortality Competent professionals in communities and health facilities Financial risk reduction Quality of care, safety Operational research Demand, Sustainability and scalability
Weakness	Myths and taboos Patriarchal socio- cultural system Social determinants affecting health care Weak/ lack of mother's decision making Weak health system Poor commodity supply Not all health facilities have access to PPIUD	Not accessing services Need for mothers Autonomy in decision making Male engagement Gender empowerment Access and coverage; needs to be scaled up Robust response to client's needs for PPF
Opportunity	PPF strengthening: reduction of unmet need, missed opportunities, avert pregnancy and childbirth complications due to birth spacing Mother nurturing herself, newborn and family Follow up added value in integration of other reproductive health services PPF choices accessible	Informed voluntary choice for PPF Improved postpartum care Reduced maternal and neonatal morbidity and mortality Mothers more productive contributing to household, community and national development Value added: cervical cancer, maternal immunization and prophylaxis from helminthes, malaria and anemia; case management of medical and Obstetric complications, neonatal immunization, support for breastfeeding, child bonding, growth monitoring, IMCI Increase in cost – effective, high impact intervention FP armamentarium in the postpartum period
Threats	Poor supportive Politics for FP Incentivized programs Project driven programs	Politicians understanding the value of family planning to SDG, healthier communities, reduction of maternal and neonatal morbidity/ mortality Two national elections and Industrial strikes that affected the program for the better part of 2016 Ownership important for institutionalization, routine and sustainability Understanding FP as a right Gender empowerment a crucial aspect for FP uptake Health indicators for maternal, neonatal and contraceptive uptake adversely affected

Programmatic quality assurance was ensured through the facility coordinators who supervised the implementation of project services, conducted clinical audits and reported back to the national team on a quarterly basis to determine and address gaps in the project. During the implementation determination of patterns of utilization and compliance by the health professionals in integrating PPIUD services routinely was assessed across the continuum of care. The gaps identified were used to inform PPIUD programming as a post-partum family planning option. Facilitative supervision by the national team through quarterly facility site visits includes checking on data quality and service quality analysis was also undertaken.

DISCUSSION

PPIUD as a postpartum family planning option has progressively increased in uptake at all selected sites since inception of the Initiative in 2015. The community strategy; address of women in the continuum of care from pregnancy up to their postpartum period with a robust health system that provides ownership of the processes and rigorous implementation research has resulted in embracing, sustaining and scale up of PPIUD, healthier outcomes for the mothers and babies with a possibility to gainfully participate in nation building.

Universal health coverage is a cornerstone towards achieving SDG's. It includes five pillars namely: finances and human resources for health, leadership and governance, medical products and medical technologies and embracing data technology(15). The PPIUD program in the six counties has provided opportunities for task sharing / shifting to nurse midwives as the frontline providers; utilization of the free maternity platform reducing unmet need and out of pocket expenditure in accessing family planning services; provided for leadership and governance through capacity building, mentorship, facilitative supervision, conducting clinical audits, having a resilient public and health system in place; engaged public – private collaboration; equipping to undertake PPIUD services; addressed supply logistics for intrauterine device and online streaming of data. This has resulted in insights on what successful programs need to adopt towards health packages for Universal health coverage. Exceptional to these processes is the engagement of communities

and institutionalization at health facilities providing for ownership, an equilibrium in the programmatic supply and demand, enhanced quality of care and patients empowered to make choices with favorable experience.

CONCLUSIONS

PPIUD as a postpartum family planning option has increased the contraceptive prevalence rate since inception of the Initiative in 2015. Ownership of the processes and rigorous implementation research has resulted in embracing, sustaining and scale up of PPIUD offered quality of care for mothers in pregnancy, childbirth and the postpartum period.

AUTHOR CONTRIBUTIONS

The listed authors participated in design, planning and manuscript writing. AK and BE drafted the initial draft of the manuscript and all authors reviewed and approved the final version.

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CONFLICT OF INTEREST

Though the authors work in the FIGO PPIUD project, FIGO had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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