Contraception 100 (2019) 42–47

Contents lists available at ScienceDirect

Contraception

journal homepage: www.elsevier.com/locate/con

Original research article

Impact of the contraceptive implant on maternal and neonatal morbidity and mortality in rural Papua New Guinea: a retrospective observational cohort study

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ARTICLE INFO

Article history:
Received 23 June 2018
Received in revised form 7 March 2019
Accepted 7 March 2019

Keywords:
Contraceptive implant
Maternal morbidity and mortality
Rural
Papua New Guinea
Reproductive health
Contraception

ABSTRACT

Objectives: Using routinely collected birth data, this study sought to measure changes in maternal and neonatal morbidity and mortality after introduction of the levonorgestrel contraceptive implant into a large, rural island population in Papua New Guinea (PNG).
Study design: We conducted a retrospective observational study of birth records from 4251 births that occurred between January 2010 and December 2016 on Karkar Island, PNG. The primary outcome was the change in crude birth rate (CBR) before (2010–2012) and after (2014–2016) introduction of the implant. Secondary outcomes were the change in rates (per year/1000 births) of severe postpartum hemorrhage, postpartum infection, hospital readmission, prematurity (<37 weeks), low birth weight (<2500 g) and maternal and neonatal mortality. We also studied changes in the number of pregnancies affected by grand multiparity (≥4) and short interpregnancy interval (<12 months) for the same time periods. Data were analyzed using interrupted time series and Poisson regression.
Results: CBR was stable until 2012 and then declined from 2014 (p<.0001). Following introduction of the implant, the annual rate/1000 births of selected adverse birth outcomes decreased between 56% and 74% (p<.0001). The number of women with parity ≥4 who gave birth decreased by 59% (p<.0001), and the number with interpregnancy interval <12 months decreased by 64% (p<.0001).
Conclusions: Introduction of the contraceptive implant was associated with reductions in CBR, maternal and neonatal morbidity, and the number of women with high-risk pregnancies giving birth.
Implications: These results encourage efforts to increase knowledge and availability of the contraceptive implant in low- and middle-income countries such as PNG. In cases where it reduces the CBR and the number of women with high-risk pregnancies birthing, the implant may have a beneficial impact on maternal and neonatal morbidity.

1. Introduction

Effective contraception can significantly lower maternal and childhood morbidity and mortality by limiting exposure to pregnancy and its complications [1–3]. Expanding access to contraception is also one of the most cost-effective interventions, and for each US dollar spent on contraception, it is estimated that $USD 120 of social benefit could be achieved [4]. Long-acting reversible contraceptives (LARC) are considered to be the safest, best tolerated and most cost-effective methods available [1–5]. Currently, the majority of LARC efficacy data focus on intrauterine methods, with no studies specifically evaluating the impact of contraceptive implants on maternal and child health [6,7].

Papua New Guinea (PNG) is the largest low- to middle-income country (LMIC) in the Western Pacific Region with a high unmet need for contraception and a contraceptive prevalence rate of only 20%–24% (rural–urban) [8–10]. It also has one of the highest maternal mortality ratios in the world, estimated to be between 300/100,000 in urban settings and 900/100,000 in rural settings [10–12]. Of the 20% of rural women using contraception between 2006 and 2012, most reported using Depo Provera (35.9%), female sterilization (33.8%), hormonal pills (15.6%) and male condoms (8.3%), with only 0.4% using an intrauterine device or implant [10,13,14].

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https://doi.org/10.1016/j.contraception.2019.03.042
0010-7824/© 2019 Published by Elsevier Inc.

Contraceptive implants are relatively new to PNG, and use of the method is lowest in rural regions [10,13,14]. However, since 2012, there has been a concerted effort to increase access to contraceptive implants through outreach programs led by *Rotary Australia International* and *Marie Stopes International.* A total of 88,000 levonorgestrel (150 mg) subdermal contraceptive implants have been inserted across 12 provinces in PNG [15]. Twelve-month follow-up data from two rural provinces (Madang and Milne Bay) confirmed high continuation rates, high patient satisfaction and low failure rates [15], but the impact of the method on maternal and neonatal health within PNG has not been previously reported.

In March 2013, implants were introduced to Karkar Island, a large rural community in the Momase region of PNG, via intensive programs which were led by local and foreign health professionals [15]. All women 15 years and over were approached in schools, villages and health centers and educated about the implant before consenting to use it [15]. Two thousand seven hundred implants were inserted in 2013, and by 2016, 26% of reproductive-aged women were using the implant (3527 inserted) [14,15]. The contraceptive prevalence rate on Karkar Island increased from 20.8% in 2006 to 33% in 2016, and the unmet need for contraception fell from 44.1% to 32.4% over the same period [5,14,17–19]. The sustainability of the implant program in PNG rests on the department of health taking over the responsibility for its delivery. Providing further information on the potential positive impact it may have on maternal and neonatal health may increase understanding of the method among health professionals and women and may secure this support [5,16]. In this study, we sought to evaluate how the introduction and uptake of the implant on Karkar Island influenced the crude birth rate and selected maternal and neonatal morbidity and mortality indicators.

2. Methods

2.1. Population context

In 2016, the estimated population on Karkar Island was 60,000 with 31,200 females (52%), of whom 51% were in the reproductive age range of 15–49 years [14]. Relative isolation from the mainland minimizes the effect of shifting populations on the location's health profile. In 2006, compared to national data, more women on Karkar Island were using Depo Provera (48% vs. 36%), but fewer women had undergone female sterilization (11% vs. 19%) or were using the oral contraceptive pill (10% vs. 34%) [13–15]. In 2016, the implant was the most commonly used modern contraceptive on Karkar Island (40%) [14]. The use of Depo Provera and the oral contraceptive pill fell slightly to 42% and 9%, respectively [14,19]. The unsupervised village birth rate is lower than the national average (33% vs. 60%), resulting in 67% of births occurring at a health facility [14].

2.2. Study design

We used a retrospective observational cohort study to assess the impact of the contraceptive implant on the crude birth rate and on the incidence of selected birth outcomes. We studied health facility recorded births and compared the number of births/year as well as the incidence and rate (per year/1000 births) of each birth outcome in the preimplant period (January 1st, 2010–December 31st, 2012) with the postimplant period (January 1st, 2014–December 31st, 2016).

2.3. Outcomes

The primary outcome was the change in the crude birth rate (number of live births/estimated population at midyear × 1000) [20] between the two time periods. Secondary outcomes were the change in rates (per year/1000 births) of maternal and neonatal morbidity and mortality. We also studied changes in the age-specific fertility rate (ASFR; number of live births per 5-year age interval/number of women in the same age interval), in the total fertility rate (sum of ASFR × 5) and in the number of pregnancies affected by grand multiparity (≥4) and short interpregnancy interval (<12 months) between the same time periods [1,20,21].

Maternal morbidity included the number of births affected by severe postpartum hemorrhage, postpartum infection (sepsis) and hospital readmission; neonatal morbidity included the number of births affected by prematurity (gestation <37 weeks) and low birth weight (<2500 g). Maternal mortality and neonatal mortality were measured as the number of women and neonates listed as “dead” at the time of maternal discharge (discharge range 0–13 days postpartum).

We defined severe postpartum hemorrhage as blood loss at birth of ≥1000 mL *and/or* necessitating hysterectomy *and/or* ≥5 U packed cell transfusion [22]. “Hospital readmission” within 1 week of birth was a proxy measure for morbidity because most women with uncomplicated births are discharged within 24 h. “Postpartum infection” was defined as having intravenous antibiotics during or up to 1 week after birth for any reason. Interpregnancy interval was defined as the period (in whole months) between delivery of the previous infant and conception of the index pregnancy [21].

2.4. Data collection

All birth data recorded between 2010 and 2016 were collected from the standardized National Birth Register (NBR) at Gaubin Hospital and Miak and Mapor Health Centers where all facility births on the island occur. Only births >20 weeks are included in the registry.

We generated an electronic template using the *Commcare* platform to collect information on date of delivery, maternal age, gravida, parity, interpregnancy interval, gestation at delivery, labor duration, mode of delivery, birth supervision, birth venue, blood loss, cause of hemorrhage, need for further management (hysterectomy, ≥5 U packed cell transfusion), use of intravenous antibiotics, hospital readmission, birth weight, neonatal status at discharge (alive or dead) and maternal status at discharge (alive or dead). Births occurring before arrival to a health facility were unsupervised and were recorded as “village” births. Previous birth history was captured from individual patient files, and conception of the index pregnancy was indicated by the last menstrual period. On Karkar Island, only deaths occurring during admission to a health facility are recorded.

2.5. Statistical analysis

To calculate the crude birth rate and fertility rates, we used the midpoint of each period to estimate the midyear population (i.e., 2011 for the preimplant period; 2015 for the postimplant period). Population figures for 2015 were interpolated from census and regional data [14,19,23]. The total birth count for each period was estimated by summing the number of facility births (including missing data) and the assumed number of unsupervised births (33%) [14,20]. The proportion of reproductive-aged women remained stable between the two time periods [10,14,17,19].

Interrupted time series analysis was conducted to assess whether the trends in birth outcomes on Karkar Island changed after introduction of the contraceptive implant in 2013. Birth data for the year the implant was introduced (2013) were excluded. It was proposed that if there was an effect, there would be a slope change in the rate (per year/1000 births) of these outcomes. This was modeled using segmented regression, assuming that the yearly counts of each outcome followed a Poisson distribution, and used the total number of births as an offset variable [24]. Adjusted Poisson regressions were used to study the association between birth outcomes and selected pregnancy characteristics: parity ≥4, and interpregnancy interval 0–5 months and 6–11 months. Due to the small number of documented maternal deaths in our sample, the exact binomial test was used to assess the potential

Table 1
Population estimates and fertility measures for Karkar Island from 2010 to 2016 using data from the National Birth Registers, population census and regional survey.

	Preimplant	Postimplant	p value
	(2010–2012)	(2014–2016)	
Total population at midyear (*n*)	43,344	55,346	
Number of females (*n*)	21,243	28,340	
Proportion of females Aged 15–49 years (%)	49	51	
Number of implants inserted (*n*)	3527		
Documented removals (*n*)	289		
Recorded births (*n*)	2366	1885	
Unsupervised births (*n*)	1465	1160	
Total births estimate (*n*)	4413	3516	.003
Crude birth rate		<0.0001	
Karkar Island	33.90	21.10	
National PNG	29.50	26.70	
ASFR			
15–19 yrs	0·15	0·05	
20–24 yrs	0·20	0·14	
25–29 yrs	0·18	0·11	
30–34 yrs	0·16	0·08	
35–39 yrs	0·12	0·04	
40–44 yrs	0·07	0·02	
45–49 yrs	0·009	0·002	
Total fertility rate	4·40	2·10	.003

Crude birth rate = (number live births/estimated population at midyear) × 1000, expressed per 1000 population; ASFR = number of live births to women in specified age group/number of women in same age group × 1000; total fertility rate = sum of ASFR × 5, expressed per woman [20]. Census and regional survey data [10,14,17,19,23].

change in maternal death probability between the pre- and postimplant periods. Statistical significance was assessed using Wald tests at the 5% significance level.

Statistical programs "R" and SPSS were used for all analyses. Ethics approval was sought from the Papua New Guinea National Department of Health's Medical Research Advisory Committee (MRAC number 17.08) and the Papua New Guinea Institute of Medical Research's Institutional Review Board (IMR IRB number 1703).

3. Results

From 1 January 2010 to 31 December 2016, a total of 4251 births (excluding the 1327 births in 2013) were recorded between the three facilities: Gaubin (*n*=2182), Miak (*n*=1477) and Mapor (*n*=592). Birth data in the NBRs from each facility were complete for all entries. Approximately 20% of facility-based deliveries were not captured in the NBR and represent missing data. Individual patient files were available for 90% of cases recorded in the NBR (*n*=3826), and previous pregnancy information was available for 76% of multiparous presentations (*n*=2902).

Postintroduction of the implant, the total number of births fell by 20.3% (p=.003) and the crude birth rate decreased by 37.8% (p<.0001) (Table 1, Fig. 1). The total fertility rate decreased by 52% (p=.003). Among birthing women, the mean parity fell from 4.12 to 2.36 (47% decrease, p=.03) and the proportion of women with parity ≥4 fell from 57% to 23.4% (p<.0001) (Table 2). Mean inter-pregnancy interval increased by 3.67 months (p<.0001) and mean gestation was prolonged from 36·51 to 37·12 weeks.

weeks (p<.0001). The proportion of unsupervised and/or village births decreased from 9.43% to 4.59% (p<.0001), and the proportion of births supervised by a midwife or doctor increased from 32.17% to 43.6% (p<.0001). There was no significant change in the mean maternal age at birth, mode of delivery or antenatal booking status.

In the postimplant period, there was strong evidence of a decrease in the annual rate/1000 births of all adverse birth outcomes (56%–74% decrease) (Table 3) and in the number of high-risk women giving birth (59%–70% decrease). Preimplant, the annual rates/1000 births of severe hemorrhage and readmission were increasing by a factor of 1·40 and 1·12 per year, respectively, and post-implant these rates fell by a factor of 0·26 and 0·56 per year, respectively (p<.0001). The yearly rates/1000 births complicated by postpartum infection, low birth weight, gestation <37 weeks, parity ≥4 and interpregnancy interval 0–5 and 6–11 months were already falling preimplant, but the rate of decline was more rapid after the implant was introduced (p<.0001). Between the pre- and postimplant periods, the number of neonatal deaths fell from 84 to 40 (54% decrease) and maternal deaths fell from 14 to 5 (64% decrease), but these were not statistically significant (p=.131 and p=.416 respectively).

Table 4 demonstrates that, independent of the implant, the incidence of adverse birth outcomes was associated with high-order parity and interpregnancy interval. Women with parity ≥4 and interpregnancy interval <12 months were 1.44 to 2.67 times more likely to sustain severe hemorrhage, have a low-birth-weight newborn or have a preterm birth compared to women with parity <4 and interpregnancy interval >12 months. The greatest increase in the likelihood of adverse birth outcomes was observed with interpregnancy interval <6 months.

4. Discussion

Our study demonstrates that introduction of the contraceptive implant on Karkar Island was associated with a 37.8% decrease in the crude birth rate and subsequent decreases in maternal and neonatal morbidity, as well as a fall in the number of women with high-risk pregnancy characteristics giving birth. These changes were observed when

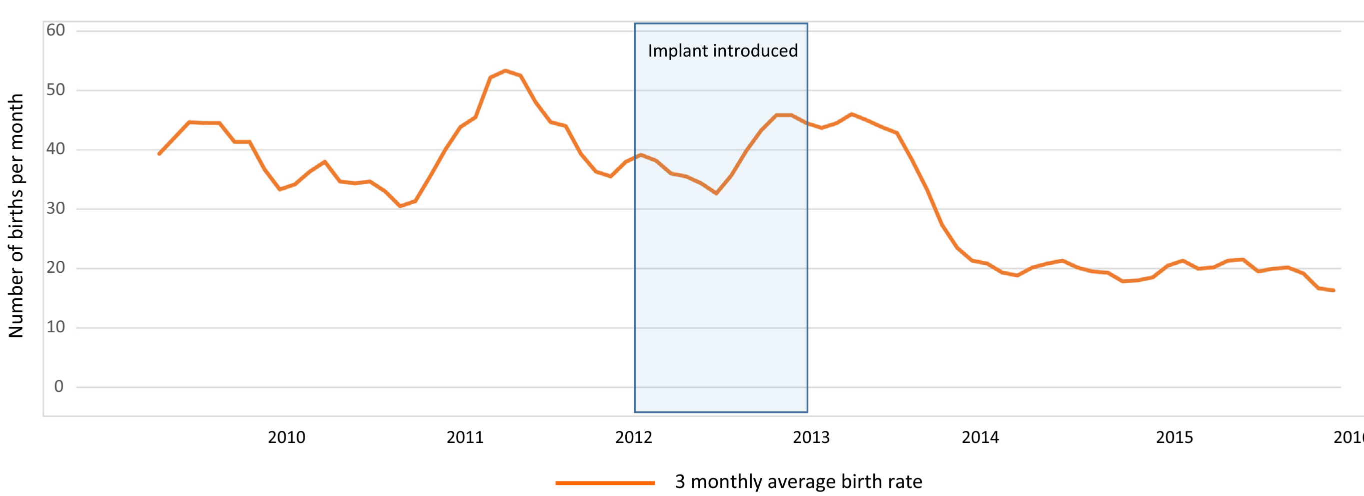

Fig. 1. Birth rates for Karkar Island from January 1, 2010, to December 31, 2016.

Table 2
Demographic data from the National Birth Registers at Gaubin Hospital and Miak and Mapor Health Centers describing all recorded births on Karkar Island from 2010–2016.

	Pre implant (2010–2012) (n=2366 births)	Post implant (2014–2016) (n=1885 births)	p value
Mean age in years (maternal)	25·34	25·37	.88
Proportion of birthing women with Parity ≥4 (%)	57	23.4	<.0001
Mean gestation at birth (weeks)	36·51	37·12	<.0001
Mean interpregnancy interval (months) for parity ≥1	10·35	14·02	<.0001
Antenatal booking status (%)			.19
Booked	50·10	51·30	
Unbooked	49·90	49·70	
Mode of delivery (%)			.28
Vaginal	88·50	89·50	
Instrumental	6·80	6·90	
Cesarean	4·60	3·50	
Primary birth venue (%)			<.0001
Village	9.43	4.59	
Health center	54·20	55·40	
Hospital	36·37	40·01	
Birth attendant (%)			<.0001
Unsupervised	9.43	4·59	
Skilled birth attendant	58·40	51·80	
Midwife	25·50	32·50	
Doctor	6·67	11·11	

the implant was being used by 26% of reproductive-aged women within the community.

The fall in crude birth rate observed on Karkar Island, which was three times greater than the fall in national crude birth rate for the same period, is probably due to the sudden expansion in contraceptive coverage [10,14,17,19]. The contraceptive prevalence rate on Karkar Island increased by 12% from 2006 to 2016, which was almost three times greater than the increase in the national contraceptive prevalence rate (4.5% increase) [5,14,17–19]. Targeted introduction of the implant would account for the sharp increase in contraceptive prevalence because no other methods were introduced to Karkar Island nor was there increased use of existing methods [14,19]. Health care workers observed a change in attitudes toward family size following a volcanic eruption on Karkar Island in 2012 which destroyed large amounts of farming and residential land [19]. The influence of natural disasters in motivating families to delay births and limit family size has been well documented in other populations [25]. The environmental stress of the volcanic eruption may have encouraged widespread uptake of contraception on Karkar Island at the time implants were made available [19].

Decreases in crude birth rate are expected to lead to proportional reductions in pregnancy morbidity by limiting pregnancy exposure. However, following introduction of the implant in our cohort, decreases in the annual rate/1000 births of all adverse outcomes were of a greater magnitude than the decrease in crude birth rate. We believe this is not only because the implant program decreased the number of unintended pregnancies but because it specifically lowered the number of women with high-risk pregnancies giving birth. Before the implant was introduced, two thirds of women had an interpregnancy interval <2 months, almost one quarter had an interpregnancy interval <6 months, and over half were parity ≥4. After the implant was introduced, the proportion of women giving birth with these characteristics decreased by more than half. International data confirm that morbidity and mortality are raised at parity 4–5 and are highest at parity greater than 6 [6,7,26]. On Karkar Island, pregnancies among high-parity women were more likely to be affected by severe hemorrhage, hospital readmission, prematurity and low birth weight. Similarly, interpregnancy interval <12 months has been associated with higher risks of preeclampsia, neonatal mortality, preterm birth and postpartum hemorrhage, with

Table 3
Interrupted time series analysis using segmented regression to describe the changing patterns of incidence and rate (per year per 1000 births) of adverse outcomes and high-risk pregnancy characteristics between the preimplant (2010–2012) and postimplant periods (2014–2016)

	Period 1 (2010–2012) Avg rate reduction 95% CI (LL–UL)	Trend/yr (Exp 12 × log-rate) 95% CI (LL–UL)	Period 2 (2014–2016) Avg rate/yr (n) 95% CI (LL–UL)	Trend/yr (Exp 12 × log-rate) 95% CI (LL–UL)	Avg rate reduction from P1 to P2 (1–P2/P1) × 100%	Change in trend/yr from P1 to P2 Exp (Δlog-rate P1–P2)	95% CI (LL–UL)
Adverse birth outcomes							
Severe Hemorrhage[a]	52·40 (51·80–53·01)	1·40 (1·38–1·42)	16·10 (15·83–16·21)	0·26 (0·24–0·28)	69	0·19	0·15–0·21
Postpartum Infection[a]	95·20 (94·63–96·02)	0·81 (0·78–0·84)	42·20 (41·54–52·78)	0·50 (0·45–0·55)	56	0·60	0·40–0·71
Readmission[a]	132·20 (131·54–133·01)	1·12 (1·01–1·20)	35·40 (29·72–41·26)	0·56 (0·53–0·59)	74	0·32	0·22–0·47
Low birth weight (<2500 g)[b]	261·90 (259·55–263·41)	0·79 (0·75–0·82)	110·50 (108·12–116·01)	0·43 (0·40–0·49)	57	0·58	0·48–0·64
Gestation <37 weeks[b]	365·80 (364·51–366·78)	0·92 (0·85–0·99)	150·70 (144·89–156·10)	0·52 (0·47–0·62)	59	0·56	0·47–0·63
High-risk pregnancy characteristics							
Parity ≥4[c]	89·00 (88·15–89·75)	0·81 (0·75–0·86)	36·60 (36·0–37·13)	0·46 (0·32–0·55)	59	0·56	0·50–0·61
IP 0–5 m[c]	119·10 (118·73–120·10)	0·86 (0·80–0·93)	43·20 (42·86–43·70)	0·42 (0·35–0·47)	64	0·54	0·48–0·61
IP 6–11 m[c]	140·00 (139·06–141·31)	0·82 (0·77–0·86)	42·60 (41·75–43·05)	0·35 (0·31–0·41)	70	0·42	0·38–0·45

IP 0–5 m = interpregnancy interval 0–5 months; IP 6–11 = interpregnancy interval 6–11 months. Avg rate/yr = average rate per year per 1000 births; Trend/yr = trend per year. Trend/yr <1 implies decreasing or negative slope; Trend/yr >1 implies increasing or positive slope.

[a] Adjusted for age, mode of delivery, birth venue, parity ≥4, interpregnancy interval.
[b] Adjusted for age, interpregnancy interval, parity ≥4.
[c] Adjusted for age.

Table 4
The relative risk of high-order parity and interpregnancy interval and adverse birth outcomes independent of the introduction of the implant for births recorded in the National Birth Register on Karkar Island

	Parity ≥ 4	Interpregnancy interval 0–5 months	Interpregnancy interval 6–11 months
	Relative risk (95% CI LL–UL	Relative risk (95% CI LL–UL)	Relative risk (95% CI LL–UL)
Severe postpartum hemorrhage	2·67 (2·58–2·74)	2·91 (2·73–3·04)	02 (1·98–2·12)
Postpartum infection	0·96 (0·89–1·08	0·94 (0·88–1·04)	0·97 (0·90–1·05)
Readmission	0·92 (0·88–0·96)	0·94 (0·89–1·03)	0·98 (0·86–1·04)
Low birth weight (<2500 g)	2·98 (2·94–3·01)	3·53 (3·47–3·57)	2·09 (1·98–2·13)
Gestation <37 wk	1·62 (1·58–1·67)	1·67 (1·62–1·74)	1·44 (1·40–1·51)

Adjusted for age, mode of delivery and birth venue. Gestation <37 weeks = gestation less than 37 weeks; 95% CI (LL–UL) = 95% confidence interval, lower and upper limits. For parity ≥ the comparison group was parity 1–3. For interpregnancy interval 0–5 months, the comparison group was interpregnancy group 12–60 months. For interpregnancy interval 6–11 months, the comparison groups were interpregnancy interval 12–60 months [1–3].

an even stronger association demonstrated for interpregnancy interval <6 months [7,27–31]. Our findings support the trend of increasing morbidity from hemorrhage, low birth weight and prematurity with decreasing interpregnancy intervals. Therefore, it is plausible that the introduction of the implant initially lowered morbidity by limiting the total number of pregnancies, while further decreases in morbidity could be due to reductions in the number of women with high-risk pregnancies giving birth.

Decreases in the annual rates/1000 births of severe hemorrhage and hospital readmission cannot exclusively be explained by changes in crude birth rate and in the risk profile of birthing women. An increase in the proportion of births supervised by midwives and doctors after the implant was introduced would probably have had the greatest influence on hemorrhage and sepsis rates because women received more timely and skilled care [31–33]. Increased use of uterotonics in the peripheral health centers (Miak and Mapor) from 2013 would also potentially lower hemorrhage rates [14,15,19]. Lastly, vehicle provision from local councils in 2015, which resulted in a dedicated transport service to and from health facilities, would have encouraged women to attend hospital earlier and minimize morbidity associated with delayed presentation [1,7,19].

The major limitation of this study is the retrospective cohort design which prevents us from establishing causality between introduction of the implant and the observed reductions in morbidity. Longer-term population data are unavailable, so we cannot comment on crude birth rate prior to 2010. Crude birth rate and fertility rate calculations are further compromised because we cannot account for births occurring outside of the three studied facilities. Our inability to account for all deaths on the island prevents us from commenting on the association between total mortality and introduction of the implant. Birth registers did not include information on important sociodemographic indicators, such as education and marital status, which may have affected health-seeking behaviors and subsequently some birth outcomes. Finally, estimation of gestational age of pregnancies relied on women recollecting their last menstrual period rather than dating ultrasound which was not available.

Access to reliable long-acting contraception is a relatively simple and cost-effective alternative to constructing more health facilities and upskilling workforces in order to minimize maternal and neonatal morbidity. Implants are the easiest LARC to distribute because they require the least amount of health worker training, minimal insertional equipment and no need for routine follow up [5]. They also have few insertion complications, a mild side effect profile and the advantage of reversibility over sterilization [5]. Our findings highlight an important association between increased use of the contraceptive implant and decreasing morbidity which may encourage governments to expand access to it throughout PNG and other LMICs.

Acknowledgments

We would like to acknowledge the medical and midwifery staff at Gaubin Hospital, Miak Health Centre and Mapor Health Centre on Karkar Island for their assistance with data collection.

Disclosure of interests

Associate Professor Kirsten Black was a member of the Bayer Healthcare advisory board for immediate postpartum contraception.

Funding

The Royal Australian and New Zealand College of Obstetricians and Gynecologists provided funding to assist with data collection on Karkar Island.

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