

Contraceptive sales in the setting of the Zika virus epidemic

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STUDY QUESTION: Has there been any influence of the Zika virus (ZIKV) outbreak on the sales of contraceptive methods in Brazil?

SUMMARY ANSWER: Contraceptive sales in the 24 months of evaluation showed little variation and no significant change has been observed since the ZIKV outbreak.

WHAT IS KNOWN ALREADY: Transmission of ZIKV is primarily by *Aedes aegypti* mosquitoes; however, sexual transmission has also been described. The association of several birth defects and the ZIKV infection during pregnancy has been established, and it was estimated in Bahia, Brazil that the infection rate could range from 10% to 80%. The World Health Organisation (WHO) declared the cluster of microcephaly cases and other neurological disorders a health emergency on 1 February 2016. The Brazilian government also made recommendations for women who were planning to become pregnant and who reside in ZIKV-affected areas to reconsider or postpone pregnancy.

STUDY DESIGN, SIZE, DURATION: The objective of this study was to assess the sales of contraceptive methods in Brazil, tracking it from before and through the ZIKV outbreak. We obtained information from all pharmaceutical companies based in Brazil and from the manufacturers of long-acting reversible contraceptives (LARCs), including the copper-intrauterine device (IUD), the levonorgestrel-releasing intrauterine system (LNG-IUS) and implants, about contraceptives sales in the public and private sectors between September 2014 and August 2016.

PARTICIPANTS/MATERIALS, SETTING, METHODS: We analyzed the data for: (i) oral contraceptives, i.e. combined oral contraceptives (COC) and progestin-only pills (POP), and vaginal and transdermal contraceptives, (ii) injectable contraceptives, i.e. once-a-month and depot-medroxyprogesterone acetate, (iii) LARCs and (iv) emergency contraceptive (EC) pills.

MAIN RESULTS AND THE ROLE OF CHANCE: Monthly sales of COC, POP, patches and vaginal rings represent the major sales segment of the market, i.e. 12.7–13.8 million cycles/units per month (90%). The second largest group of sales was injectables, representing 0.8–1.5 million ampoules per month (9.5%). Following this, are LARC methods with sales of 37 000–41 000 devices per month (0.5%). It is important to note that although the peak months of sales were different for each group of contraceptives, there were no significant differences overall between the months of observation. The EC pill sales were between 1.0 million and 1.3 million of pills per month.

LIMITATIONS, REASONS FOR CAUTION: Although the use of contraceptive methods was already high and no change was noted, the ZIKV outbreak may have changed the pregnancy intentions of Brazilian women. Consequently, the number of women planning pregnancy may be lower than that recorded. The contraceptive sales figures did not include condoms. Since condoms might not only prevent pregnancies, but also sexual transmission of ZIKV, this lack of information is a limitation.

WIDER IMPLICATIONS OF THE FINDINGS: The results from this assessment showed that the sales of contraceptives presented little variation during the ZIKV outbreak in Brazil. Furthermore, it is possible that access to LARC methods was limited. Although we did not investigate the reason for low LARC uptake, we suspect that it is due to lack of availability of LARC in the public sector, the high cost of the methods and the incomplete insurance coverage on contraception for women. Projections estimate millions of additional cases of ZIKV transmission. Thus, a coordinated response is needed to ensure access to a wide range of contraceptive methods for women during the ZIKV outbreak. In conclusion, this assessment of contraceptive sales in Brazil identifies challenges in contraceptive access, especially for

LARC methods, and represents an alternative source of data to help us understand the trends in demand for contraception in ZIKV-affected areas.

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Introduction

Zika virus (ZIKV) is a flavivirus and the transmission is primarily by *Aedes aegypti* mosquitoes; however, perinatal transmission, transfusion transmission and sexual transmission have also been described (Hayes, 2009; Besnard et al., 2014; Musso et al., 2015; Davidson et al., 2016). The association of birth defects and the ZIKV infection during pregnancy is clear, but the magnitude of the risk is not fully understood (Rasmussen et al., 2016). Some studies have also described association of ZIKV with fetal deaths, in-utero growth restriction with or without microcephaly, ventricular calcifications and other central nervous system (CNS) lesions (Musso et al., 2014; Brasil et al., 2016; Cauchemez et al., 2016; Mlakar et al., 2016). Sexual transmission of ZIKV has also been reported in some studies (Musso et al., 2015; Brooks et al., 2016; Davidson et al., 2016; D'Ortenzio et al., 2016; US-CDC, 2016a). Furthermore, up to 80% of ZIKV infections are asymptomatic, which poses difficulties for couples trying to become pregnant and avoid ZIKV (Brasil, MOH, 2016a).

World Health Organisation (WHO) declared the cluster of microcephaly cases and other neurological disorders a health emergency on 1 February 2016 (WHO, 2016a). Consequently, the Brazilian and other Latin American (LA) governments declared national emergencies and made recommendations for women who are planning to become pregnant and who reside in ZIKV-affected areas to reconsider or postpone pregnancy. Furthermore, the US Centers for Disease Control and Prevention (US-CDC, 2016b) also recommended that women and their partners should discuss pregnancy planning, even if they have no symptoms, with their healthcare provider. It also recommended that individuals with symptoms delay pregnancy for a certain period of time. However, the recommendation to postpone pregnancy has limitations and does not help those who are already in the initial weeks of pregnancy. The Brazilian Ministry of Health (MoH) also encouraged women, planning to postpone pregnancies, to seek contraceptive methods at Basic Health Units (Brasil, MOH, 2016b).

As of 15 September 2016, 72 countries and territories have reported evidence of mosquito-borne ZIKV transmission since 2007 (70 have reports from 2015), of which 55 countries are experiencing a first outbreak of ZIKV since 2015, with no previous evidence of circulation. The ongoing transmission is primarily by mosquitoes (WHO, 2016b), while there is evidence of sexual transmission of ZIKV (Armstrong et al., 2016). Since almost 74% of the Brazilian population depend entirely on government provided healthcare, we conducted an assessment to report the trends in sales of hormonal and non-hormonal

contraceptives in Brazil both in public and private sectors both before and throughout the ZIKV outbreak.

Materials and Methods

We obtained specific data from all pharmaceutical companies based in Brazil, regarding the sales of hormonal contraceptives in both the public and private sector. Data about the levonorgestrel-releasing intrauterine system (LNG-IUS, Mirena, Bayer Oy, Turku, Finland) were obtained from Bayer Oy; data regarding the subdermal implant (Implanon, Merck, Oss, The Netherlands) were from Merck and data regarding the copper-intrauterine device (TCu380A IUD, Optima) were from the Brazilian manufacturer (Injeflex, Sao Paulo, Brazil). Our data tracked sales from September 2014 through to August 2016. The individual sales of each company were aggregated up to monthly sales. We categorized sales of: (i) oral, vaginal and transdermal contraceptives, i.e. combined oral contraceptives (COC), progestin-only pill (POP), patches and vaginal rings, together in cycles/units of 1 month supply; (ii) injectable contraceptives, i.e. DMPA and once-a-month injectables, together in ampoules, although the latter are effective for only 1 month; (iii) long-acting reversible contraceptives (LARCs), i.e. IUD, the LNG-IUS and implants, in devices and (iv) emergency contraceptive (EC) pills, i.e. the LNG-pill (the only EC available in Brazil) in single pills. The data represent monthly sales. Furthermore, we calculated the average for the sales of each group of contraceptives before the declaration and the announcement of the first case of microcephaly and the warning to reconsider or postpone pregnancy by the Brazilian MoH, i.e. October/November 2015.

To estimate the unmet needs of contraception, we used the US method of estimation to calculate the number of Brazilian women who need and desire effective contraceptive methods (Daniels et al., 2015) and made the following assumptions. Unmet needs was defined according to the WHO (2016b) as 'those women who are fecund and sexually active but are not using any method of contraception, and report not wanting any more children or wanting to delay the next child'. Of the 208 million inhabitants, almost 52 million are women of reproductive age (15–49 years). From this number, we excluded pregnant and 4 weeks' postpartum women, infertile and sterilized women (22 million) and those who want to become pregnant, or are not sexually active (8 million). Based on these calculations, we assume that at least 22 million women will need contraception to avoid unintended pregnancy (Daniels et al., 2015).

Results

We estimated that our data cover more than 95% of the real sales of contraceptives at national level. The majority of sales comprise of

COCs, POPs, patches and vaginal rings, representing 12.7–13.8 million cycles/units per month (90%). The second largest sales were of injectables, representing ~0.8 to 1.5 million ampoules per month (9.5%). The LARC methods showed sales of 37–41 thousand devices per month (0.5%). The peak of sales was different for each group of contraceptives; however, no significant increase was observed for any method either after the outbreak of ZIKV in Brazil or in line with the advice from the Brazilian MoH to avoid or postpone pregnancy.

The EC pill sales were between 1.0 and 1.3 million of pills per month. We estimated that the figures presented here cover almost 18 million women. The bimonthly data are shown in Table I and monthly data are shown in Fig. 1. In addition, Table II shows that there were no significant changes in the average monthly sales among the three groups of contraceptives before and after the announcement of the first case of microcephaly and the Brazilian MoH warning to avoid pregnancy.

Discussion

Our assessment showed that despite the ZIKV outbreak, the number of sales of units of contraceptives did not show significant changes during the 24 months of observation, even though the study period included the peak of the ZIKV epidemic and the reported cases of microcephaly and other CNS disorders in newborns. In addition, the sales of LARC methods, which are the most effective contraceptive methods, were very low (Bahamondes et al., 2014; Secura et al., 2014). This indicates that most contraception users utilize methods, which have comparatively lower effectiveness with typical use, such as COCs, POPs and injectables.

The last Brazilian Demographic and Health Survey (DHS) was conducted almost 20 years ago (Brazil, DHS, 1996) but estimates from other sources (Daniels et al., 2015; Population Reference Bureau, 2015; UNFPA, 2016) have indicated that 75% of women aged 15–49 years old use hormonal and LARC methods and that there is an 8% unmet need for family planning. Among those women using contraception, COC and tubal ligation were the most prevalent among methods and LARC methods accounted for only 1.8% of the methods used (Brazil, DHS, 1996). We assume that at least 22 million women need contraception to avoid unintended pregnancy and we found that almost 18 million women are protected with actual sales of contraceptives. However among the users, 90% use contraceptives with low typical use effectiveness. Consequently, there are high rates of unplanned pregnancies in Brazil, which are estimated to account for ~55% of all pregnancies (Le et al., 2014) and are possibly associated with the high number of sales of EC pills (Rocha et al., 2010). The unmet need for contraception is likely to rise further if, in near future, fewer women decide to get pregnant in response to ZIKV epidemic. Their contraceptive demands will not be met with the observed current sales.

In Brazil, contraceptives such as COC, POP, patches, vaginal rings and EC pills are available over the counter, but the low sales figures for LARC indicate that fewer women are using them. The low utilization of LARC could be due to many barriers such as lack of supply of the LNG-IUS and implants in the public sector, a lack of training of health-care providers on LARC placement, incomplete insurance coverage or a lack of reimbursement for LARC, high up-front costs and a low number of contraceptive service sites. It is well described that the high cost of LARC methods is one important barrier to access these methods

Table I Two month sales of different contraceptives in Brazil, September 2014–August 2016.

Methods ^a	Sep/Oct 2014	Nov/Dec 2014	Jan/Feb 2015	Mar/Apr 2015	May/June 2015	Jul/Aug 2015	Sep/Oct 2015	Nov/Dec 2015	Jan/Feb 2016	Mar/Apr 2016	May/June 2016	Jul/Aug 2016
PPR (1 month supply)	2 629 583	2 658 869	2 649 616	2 741 043	2 544 765	2 683 311	2 716 475	2 748 355	2 406 028	2 749 536	2 612 543	2 624 362
Injectables (ampoules for 1 or 3 months supply)	2 699 527	2 659 398	2 513 794	2 802 138	2 832 114	2 977 429	3 049 179	2 921 591	1 606 866	2 819 374	2 689 332	2 756 770
LARC (devices)	75 807	74 155	73 873	77 543	76 407	77 404	78 653	76 433	77 645	80 481	82 055	80 060
EC (pills)	2 465 818	2 390 439	2 529 002	2 467 804	2 433 864	2 565 853	2 567 767	2 630 388	2 507 205	2 584 521	2 514 382	2 802 971

^aPPR: combined oral contraceptives; progestin-only pills; transdermal patch and vaginal ring; LARC: long-acting reversible contraceptives (copper-IUD, the LNG-IUS and implants); EC: emergency contraceptive pills.

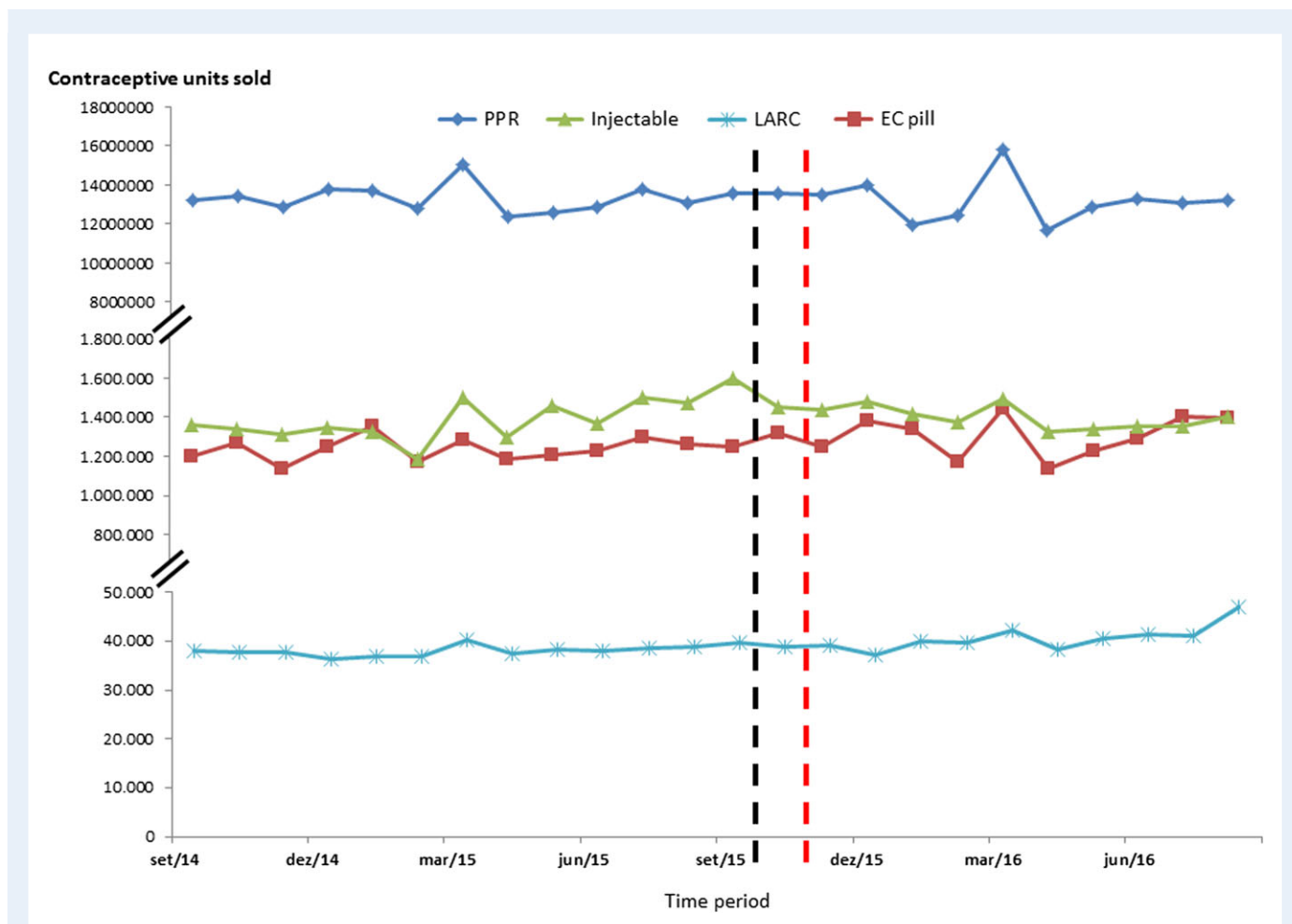


Figure 1 Monthly sales of different contraceptives in Brazil, September 2014–August 2016. PPR: COC + POP + transdermal patch + vaginal ring; LARC: long-acting reversible contraceptives, i.e. copper-IUD + the LNG-IUS + implants; EC: emergency contraceptive pills. The black line indicates the first Brazilian report of microcephaly associated with ZIKV and the red line indicates the alert to women to avoid pregnancy, from the Brazilian MoH. COC, combined oral contraceptives; POP, progestin-only pills.

Table II Average monthly sales of different contraceptives before and after the announcement of the first case of microcephaly and the warning to avoid pregnancy by the Brazilian MoH.

Methods ^a	Sep 2014/Sep 2015	Dec 2015/Aug 2016
PPR (1 month supply)	13 436 351	13 459 924
Injectables (ampoules for 1 or 3 months supply)	1 448 961	1 370 094
LARC (devices)	38 629	39 419

^aPPR: combined oral contraceptives; progestin-only pills; transdermal patch and vaginal ring; LARC: long-acting reversible contraceptives (copper-IUD, the LNG-IUS and implants).

(Peipert et al., 2012). In Brazil, the low availability of LNG-IUS and contraceptive implants in the public sector and the high cost in the private sector is a major barrier for many women. All of these variables impact the ability of women to prevent unintended pregnancies. It is important to take into account that the Brazilian National Health System (*Sistema Unificado de Saude*) provides free coverage, including contraceptive methods (except the LNG-IUS and implants, with rare exceptions) at no cost to women, to ~74% of the population through

the public health posts and hospitals. The remainder of the population depends on private insurance or out-of-pocket payments in the private sector.

In the context of the ZIKV outbreak, access to effective contraceptive methods in Brazil must be improved. There are barriers in the basic health network in obtaining consultations and LARCs are methods that only physicians are allowed to insert; sometimes they expire on the shelf at service delivery points. It is necessary to employ a new

model of family planning management to increase access and use of LARC methods to reduce unintended pregnancies through task sharing, where applicable.

Requests for mifepristone/misoprostol for medical termination were recently reported in 19 Latin American countries (Aiken et al., 2016). In Brazil, despite the autochthonous ZIKV infection, abortion is illegal in most circumstances and women were advised to avoid pregnancy due to risk of transmission. The authors reported 1210 requests for medical termination between November 2015 and March 2016, when the number of expected requests was 582, based on 5-year trends. The relative change between actual and expected requests was 108% ($P < 0.001$). These results may further indirectly indicate the lack of access to effective and acceptable contraception among Brazilian women, especially in the wake of advice to avoid pregnancy due to ZIKV.

Our assessment has several limitations. Although the use of contraceptive methods was already high and no change was noted during the study period, the ZIKV outbreak may have changed the pregnancy intentions of women in Brazil. Consequently, the number of women planning pregnancy may be lower than recorded. In addition, the contraceptive sales figures did not include the sales of condoms, which are an affordable approach, although their contraceptive effectiveness is less than that of the LARC methods (Trussell, 2011). This lack of information is a limitation, as the condoms might not only prevent pregnancies, but also ZIKV-related sexual transmission. In addition, although the data represent sales to public health posts, hospitals and private sector, this does not necessarily represent actual use by women. One of the strengths of this study was that the information on contraceptive sales was obtained from various reliable sources, including all sales of LARC methods, that allowed our study to fill an important gap in current assessments of women's reproductive needs including contraceptive use and method preference, primarily in the ZIKV-affected areas.

Projections estimate millions of additional cases of ZIKV infection. A coordinated response is needed from federal, state and municipal governments as well as academia, professional organizations, private insurance companies, policy makers and all stakeholders, to ensure access to a wide range of contraceptives for women during the ZIKV outbreak. This Brazilian assessment identifies challenges in contraceptive access, especially for LARC methods, and represents an alternative source of data to help us understand trends in demand for contraception in ZIKV-affected areas. In case of another outbreak in countries where there is substandard availability and accessibility of contraception, authorities and family planners might learn from these data in order to work together for adequate and rapid solutions.

Authors' roles

L.B., M.A., I.M. and A.F. contributed equally to the study idea, the development of the study, the writing of the manuscript and the review all the versions.

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Conflict of interest

None declared.

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