What Is the Economic Cost of Unplanned Pregnancy Following Hysteroscopic Sterilization in the US? A New National Estimate Based on Essure® Procedure Prevalence, Failure Rates and Workforce Productivity

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Abstract

Objective: Although hysteroscopic sterilization (HS) (Essure®) has been available in the US since 2002, there is disagreement regarding its efficacy, and there has been no study of the economic impact of HS failure. Our investigation examined the economic consequences of contraceptive failure with Essure in the US. **Methods:** Contraceptive failure rates (CFR) of 5.7%, 7.7% and 9.6% were applied to the US cohort of HS patients (*n* = 600,000). Direct economic impact of productivity losses resulting from unplanned conceptions after HS was calculated by factoring Essure failure rate, the exposed population, US female labour force participation, unemployment rate, time away from work owing to vaginal delivery or pregnancy termination and weekly wages. **Results:** For the 9.6% CFR scenario, US workforce productivity loss from unplanned pregnancy and delivery was estimated at 771,065 days (2,112 years). Productivity loss secondary to conception and subsequent termination of pregnancy after Essure was approximately 23,725 days (65 years). Assuming CFR at 5.7%, livebirth delivery with total time missed from work at 65 days, this was associated with an aggregate economic impact of $49.2M in lost annual wages. Direct economic impact of unplanned pregnancy after Essure irrespective of outcome (terminations and deliveries) was estimated to result in US productivity losses valued at ~$130M. **Conclusion:** Although not all unplanned pregnancy costs are attributable to failed HS, estimates derived from earlier surveys have not considered this contraceptive method, and the economic consequences of unplanned pregnancy after Essure are not trivial. Quantifying the economic consequences of HS failure would be improved with specific ICD-10 coding for Essure-associated symptoms.

Introduction

Unintended pregnancies drive a major component of the US healthcare economy. As direct medical costs for this were already $5Bn by 2002 (Trussell 2007), current costs associated with unplanned pregnancy are certainly far larger now. The provision of female contraception is an important modulator of this equation, and the birth control method ultimately selected is influenced by how effectiveness and safety are understood by both the patient and the practitioner (Lopez et al. 2013). In the US alone, more than 300,000 women request permanent surgical sterilization each year (Jones et al. 2012). Although not all unplanned pregnancies result from failed female sterilization, earlier estimates of unplanned pregnancy costs were based on historic survey data and cannot register the impact of the latest contraceptive techniques (Green et al. 2002).

Against this background is the newest arrival on the birth control landscape, hysteroscopic sterilization (HS) with the Essure® device (Bayer HealthCare AG; Whippany, NJ). Approved by the US FDA in 2002, this novel non-incisional technique provides bilateral tubal occlusion via hysteroscopic placement of metal inserts at the utero-tubal junction. HS is thought to confer substantial advantages over conventional laparoscopic tubal ligation, including eliminating the need for abdominal access (Podolsky

et al. 2008; Yang et al. 2011), reducing overall cost (Kraemer et al. 2009) and minimizing anaesthesia requirements (Chapa and Venegas 2012). Although HS implants are latex-free, they contain acrylonitrile butadiene styrene, polytetrafluoroethylene, polyvinyl pyrrolidone, polyethylene terephthalate and nickel, among other components (Yu 2007). Market data supplied by the manufacturer indicate that approximately 750,000 of these contraceptive coil kits have been sold globally and some 600,000 are believed to have entered the US market (Rabin 2015; US FDA 2015a).

The current investigation addresses the recognized need for additional HS data. Using the 600,000 figure as a starting point, an estimate of economic consequences of unplanned pregnancy with HS in the US was developed. Population risk modelling based on US federal labour data and published Essure failure rates was used to project economic impact of pregnancy-associated workforce productivity losses when women using this contraceptive method faced either pregnancy termination or healthy term livebirth. To date, all published studies on Essure have addressed purely clinical aspects of this procedure; our study is believed to be the first to estimate an economic dimension of Essure birth control with an emphasis on unintended pregnancy.

Methods

Study cohort and computational approach

The study cohort included all women with at least one Essure device placed in the US. Although the exact number of US patients who have undergone HS is not known, the total number of contraceptive kits sold worldwide is 750,000 and, according to the manufacturer, 80% of this reached the US market (Chudnoff et al. 2015; US FDA 2015a). Thus, using 600,000 as our denominator, a range of pregnancy risk exposures for American women was developed as a function of two pregnancy rates calculated previously (Gariepy et al. 2015).

Contraceptive failure following HS was defined as any medically documented conception established at any time after having Essure, irrespective of whether HS was performed in a physician's office, hospital or outpatient ambulatory surgery setting. Because disagreement exists concerning the failure rate associated with HS over its lifetime of Essure use, we estimated frequency of unplanned pregnancy as follows:

1. 5.7% (Deardorff 2014; Gariepy et al. 2015);
2. 9.6% (Gariepy et al. 2015); and
3. the median of these values, or 7.7%.

These estimates were used to capture contraceptive failure after one year and after 10 years of HS, as patients have been exposed to the Essure device since 2002 and the treatment group continues to expand.

Calculation of productivity and lost wages

For our analysis, a mean annual gross income of $51,000 was imputed for women aged 25–34 years in the Essure exposure group, where average unemployment is 6.6% (<www.bls.gov/cps/cpsaat03.htm>). Although comprehensive demographic data have not been systematically collected for patients who undergo HS, information describing unplanned pregnancy after the Essure procedure has been published (Sills et al. 2015), where mean (±SD) age for HS failure was found to be 29.5 ± 4.6 years. Average weekly patient income for this group was thus calculated at $752 (<www.bls.gov/cps/cpsaat37.htm>), and US labour force participation rate was estimated at 88.2% (<http://www.bls.gov/web/empsit/cpseea08b.htm>). Using 2013 US Department of Labor statistics (the most recent available), we defined total national workforce study population (comprising 72.1 million women) as all civilian, non-institutionalized females of reproductive age in the US (US Department of Labor 2015).

When contraceptive failure with Essure occurred, for purposes of this analysis, all resulting conceptions were presumed to result either in an uncomplicated pregnancy and proceed to term vaginal delivery of a singleton livebirth, or a pregnancy that was electively terminated in first trimester without complication. This computational model assumed a 50:50 distribution of these two mutually exclusive reproductive outcomes. Time away from work owing to pregnancy-associated illness and maternity leave were computed separately, but because maternity leave and other pregnancy-associated benefits are provided unevenly across all employees in the US, days off and lost productivity costs were both estimated based on unpaid leave scenarios.

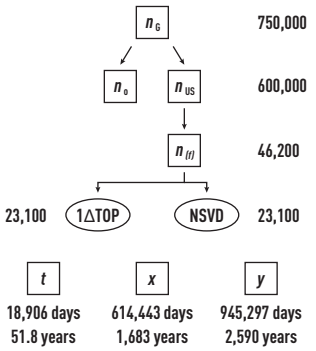
The downstream economic impact of pregnancy was estimated next, using projections for days of work lost. Variation among women working in the US makes estimates difficult because some employees stay on the job until near their due date, whereas others report missing as much as a month of work before delivery and then remain away from employment for another 35–70 days thereafter on maternity leave (Gao and Livingston 2015). Sensitivity analyses were developed to capture each possibility. Thus, our formula was based on a total exposed population of 600,000 US women multiplied by a range of contraceptive failure rates, adjusted by an 88.2% workforce participation, 93.4% employment and number of days lost divided by seven-day weeks, times $752 lost per week, as follows:

$$P = \frac{f(n)Q(1-r)}{2} \times h(w)$$

Where P = cumulative economic impact of unplanned pregnancy; f = contraceptive failure rate; n = exposed population; Q = labour force participation; r = unemployment rate; h = health absenteeism (time away from work owing to conditional pregnancy event; vaginal delivery versus elective first trimester termination); w = gross wages per week; and 50% of the population has no paid medical leave.

This analysis assumed a bimodal distribution of work days missed for the prenatal care and delivery sub-group, which consisted of two components, antenatal absences and maternity leave. For the former term, 30 days was used to account for all OB clinic visits and any pregnancy-related sickness. Time away from work after uncomplicated term vaginal delivery was set at either 35 or 70 days (yielding a total productivity loss secondary to pregnancy at 65 or 100 days, respectively). For the sub-group electing not to continue pregnancy, a total of two days away from work was allocated (Gao and Livingston 2015) (Figure 1).

Figure 1. Allocation of HS patients, unplanned pregnancy outcomes and estimated cumulative productivity impact in the US



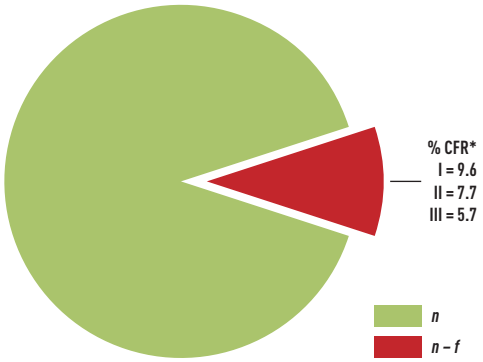
1ΔTOP = first trimester termination of pregnancy; HS = hysteroscopic sterilization; NSVD = normal spontaneous vaginal delivery. Distribution of women with Essure® worldwide (n_G) in the US (n_{US}) and elsewhere (n_o). Productivity loss estimates shown are based on HS contraceptive failure rate ($n_{(f)}$) of 7.7% (average of 1 year and 10 year failure rates). Calculations for missed work time for 1ΔTOP patients (t) are based on missed work time = 2 days only (no maternity leave). For NSVD patients, estimates are based on either (x) 65-day work absence or (y) 100-day work absence for pregnancy, delivery and maternity leave.

Results

In the exposed cohort of all Essure users in the US (n = 600,000), where contraceptive failure occurs with frequency of 5.7%, 7.7% or 9.6%, this represented an unplanned pregnancy event for sub-groups of sizes (a) 34,200, (b) 46,200 or (c) 57,600 women in the US, respectively. The two possible outcomes and associated costs were calculated for each of these three cohorts. If 65 days paid employment is lost by women should the device fail followed by pregnancy and delivery, this would result in a cumulative loss

of US workforce productivity of 457,820 days (1,254 years) for the entire cohort, assuming the lower Essure failure rate of 5.7% (Deardorff 2014; Gariepy et al. 2015). In the 9.6% contraceptive failure rate scenario, total workforce productivity loss secondary to unplanned pregnancy would be 771,066 days (2,112 years) for the national cohort (Figure 2).

Figure 2. Estimated economic impact of unplanned pregnancy after HS with the Essure® device, derived from three contraceptive failure rate scenarios in the US (2015)



	Term singleton NSVD§				First Δ TOP¶	
	d		$		*d*	$
	x	*y*	*x*	*y*	*d*	*t*
I	771,066	1,186,255	82,834,472	127,437,650	23,725	2,548,753
II	614,443	945,297	66,008,720	101,551,877	18,906	2,031,038
III	457,820	704,339	49,182,968	75,666,105	14,087	1,513,322

1ΔTOP = first trimester termination of pregnancy; *d* = days; HS = hysteroscopic sterilization; *n* – *f* = unplanned pregnancies among Essure® users in the US, where *n* = 600,000; NSVD = normal spontaneous vaginal delivery.
*Contraceptive failure rate. §Normal spontaneous vaginal delivery.
¶Termination of pregnancy (first trimester).
Calculations for missed work time (*d*) are based on either (*x*) 65-day work absence or (*y*) 100-day work absence for pregnancy, delivery and maternity leave. Calculations for TOP patients are based on missed work time = 2 days only (no maternity leave). Total estimated direct economic impact of unplanned conception after Essure® for each contraceptive failure rate scenario (I, II, or III) is the sum of either ([*x*] or [*y*]) + (*t*).

For patients who elected voluntary termination of unplanned pregnancy after Essure, we estimated aggregate time away from work to be 14,087 days (38.6 years), assuming the lower Essure failure rate of 5.7% (Deardorff 2014; Gariepy et al. 2015). As summarized in Figure 2, given the 9.6% contraceptive failure rate scenario, cumulative productivity loss secondary to conception and subsequent termination of pregnancy would be approximately 23,725 days (65 years).

Economic valuation of these productivity modifiers by factoring median income for Essure patients in the US revealed that unplanned conception and pregnancy termination after Essure, assuming a device failure rate of 5.7%, was associated with an economic impact of >$1.5M in lost wages. If the 10-year Essure failure rate of 9.6% were used, the economic impact of unplanned pregnancy would be >$2.5M in lost wages. Likewise, for women choosing to continue pregnancy after Essure failure with frequency at 5.7% (and total time missed from work = 65 days), this was associated with an economic impact of $49.2M in lost wages during the exposure interval. In the scenario where Essure fails at this same rate (5.7%) but the employee avails of more time off work after delivery (100 days), cumulative lost wages would exceed $75.7M. When all unintended pregnancies after HS failure in the US are considered irrespective of outcome (i.e., the sum of pregnancy terminations plus deliveries after Essure), this would result in ~$130M in lost productivity in aggregate, assuming the 10-year failure rate (9.6%) were applied with a 100-day absence for each pregnancy conceived and delivered in the US (Figure 2).

Discussion

Unintended pregnancy constitutes an important problem associated with substantial costs to health and social services, as well as severe emotional distress to women, their families and society at large. Provision of safe and effective contraception is a particularly cost-effective healthcare intervention because, in addition to preventing a significant number of unplanned pregnancies, it also results in substantial cost savings to society.

Vasectomy, female sterilization and long-acting reversible contraceptive methods constitute the most cost-effective contraceptive options (Mavranezouli 2009). Research on government health expenditure patterns suggests that implementing or expanding public policies to minimize unintended pregnancy has the potential to yield major savings in national health spending (Monea and Thomas 2011; Sonfield et al. 2011). In this context, the urgency of elective, permanent female sterilization was viewed as an appropriate application for FDA premarket approval, a process of scientific and regulatory review to evaluate the safety and effectiveness of medical devices that "support or sustain human life, are of substantial importance in preventing impairment of human health …" (US FDA 2015b).

The current analysis is the first to examine the economic impact of contraceptive failure after Essure, the newest method of permanent birth control available in the US. Here, we used population risk modelling and federal labour data to show that, depending on which outcome is tabulated and how much time the patient decides to take off from paid employment, the wage-related productivity lost owing to Essure failure can easily exceed $100 million. Although this economic burden is certainly not sequelae exclusive to HS, the Essure procedure is unique in how little is known about it, how many women actually use it or what can happen when it does not work as designed (US FDA 2015a). Recognizing these unknowns, the current study advances the understanding of HS by adding a new dimension to the Essure literature.

Despite more than a decade of clinical experience with Essure in the US, there is controversy regarding its effectiveness and safety. The device manufacturer claims that Essure is 99.83% effective at preventing pregnancy over five years, assuming the implant is used only for approved indications and according to "perfect use" guidelines (Deardorff 2014). However, the accuracy of this figure has been challenged (Gariepy et al. 2015), and an alternate assessment of this contraceptive method now exists. Using an evidence-based Markov model to estimate pregnancy rates after Essure placement over a 10-year interval, pregnancy probability at Year 1 and over 10 years was found to be substantially higher with Essure compared with standard laparoscopic sterilization (Gariepy et al. 2015). Because the device entered the US market in 2002, both 1-year and 10-year failure rates are relevant to current consumers and served as the basis for the current study.

Performing HS in a physician's office does make economic sense intuitively, and it can provide women with an important option in family planning. Also, HS can free space in hospital operating rooms, which may then be used for other procedures, thus improving access to care for more patients. In Canada, offering the Essure procedure in a non-hospital setting has been shown to result in statistically significant cost savings (Thiel and Carson 2008). Unfortunately, this advantage is lost if patients undergo HS in a hospital under general anaesthesia, as is sometimes done in the US. Because no US data are available to clarify how frequently Essure is performed in the doctor's office versus a formal hospital operating room, this represents an important missing piece in the Essure puzzle.

This research has important limitations that should be acknowledged. With increased clinical uptake of HS, there has emerged a better understanding of adverse events associated with Essure (Ricci et al. 2014). Unplanned pregnancy is only one such event, and our model was not designed to estimate the economic consequences of other more subjective problems like dysmenorrhoea, bleeding or dyspareunia secondary to uterine perforation or device malposition

(Al-Safi et al. 2013). According to data provided by the manufacturer, chronic pelvic pain occurs in approximately 4% of Essure patients (Otto 2015). But not all Essure complications are reported, and the true frequency of improper or abnormal device insertions is not known with precision. Even if subsequent surgery is not required to correct an injury due to the Essure procedure itself (Hodges and Swaim 2013), including a spontaneous pregnancy loss not requiring surgical intervention, impairment in function or reduced quality of life may still diminish productivity; these variables also escaped our estimate. Moreover, because no data exist on how many Essure patients undergo pregnancy termination versus continue to term and deliver when the device fails, our statistical assumption of a 50:50 mix perhaps oversimplified the downstream effects of unplanned pregnancy for this cohort. For Essure patients who continued their pregnancies to term, our methodology only attempted to estimate costs of vaginal births, not caesarean deliveries; child care expenses and support would form part of a broader fiscal impact estimate and were therefore not within the scope of our projection. Based on these factors, it is likely that our calculations underestimated the total economic effects of unplanned pregnancy with Essure in the US. Likewise, as more complete information becomes available concerning HS failures (particularly with regard to lost wages and/or impaired productivity), a more precise calculation of national economic impact will be possible. Systematic data collected from longitudinal studies on all Essure patients here should address many of these uncertainties.

In summary, Essure remains a somewhat enigmatic player on the contraceptive stage, and the state of published experience with the device remains surprisingly underdeveloped. The most recent post-marketing clinical trial was never registered, the study was discontinued early, no follow-up data were collected and its findings remain heavily redacted on the FDA website (Dhruva et al. 2015). Indeed, the worldwide scholarly output on Essure scarcely exceeds 200 papers despite 13 years of active clinical use. Counselling patients seeking advice on contraceptive options is thus frustrated by the paucity of literature addressing the overall epidemiology of Essure. These factors highlight the urgent need to increase awareness of the successes and failures of HS. Consideration should be given to the assignment of unique ICD-10 modifiers for pain associated with this device. This would offer an accurate, inexpensive data capture tool to enable proper monitoring of the Essure phenomenon. Further socioeconomic studies regarding HS are also needed as this contraceptive option becomes more widely accessed.

Authors' contributions

E.S.S. was principal investigator, conceived of the research and developed the manuscript; L.P.F. and C.A.J. contributed to the research design, assisted in the statistical analysis and assisted with editorial revisions. All authors read and approved the final version of this manuscript.

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