Analysis of Safety Adverse Reporting Events of Essure Medical Device

The End Road of Essure

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Essure Medical Device

- Non-hormonal permanent implantable medical device (produced by Bayer)[1]
- >30,000 worldwide side effects reports[2]: bleeding, pelvic pain, and allergic reaction
- Introduced in 2002 and withdrawn in December 2018[3]

Objectives

- To analyze post-marketing Essure safety event reports
- To assess the surveillance policies of pharmaceutical company and the FDA

Data Source

- **MAUDE** (FDA Manufacturer and User Facility Device Experience) database
- All Essure reports to FDA MAUDE from January 2018 to October 2018

Methods

- Use the **NVivo®** software to review and category Essure safety reports
- Thematic analysis of random samples of 10% of all reports in further detail.
- Review of clinical studies and policies concerning Essure

Results

Symptom	Weighted Percentage	Symptom	Weighted Percentage
Hemorrhage	0.91%	Dyspareunia	0.39%
Surgery	0.51%	Dysmenorrhea	0.31%
Pain	0.50%	Menorrhagia	0.27%
Migraine	0.44%	Perforation	0.25%
Infection	0.43%	Anxiety	0.25%

Table 1 Top 20 adverse events of all 4982 reports

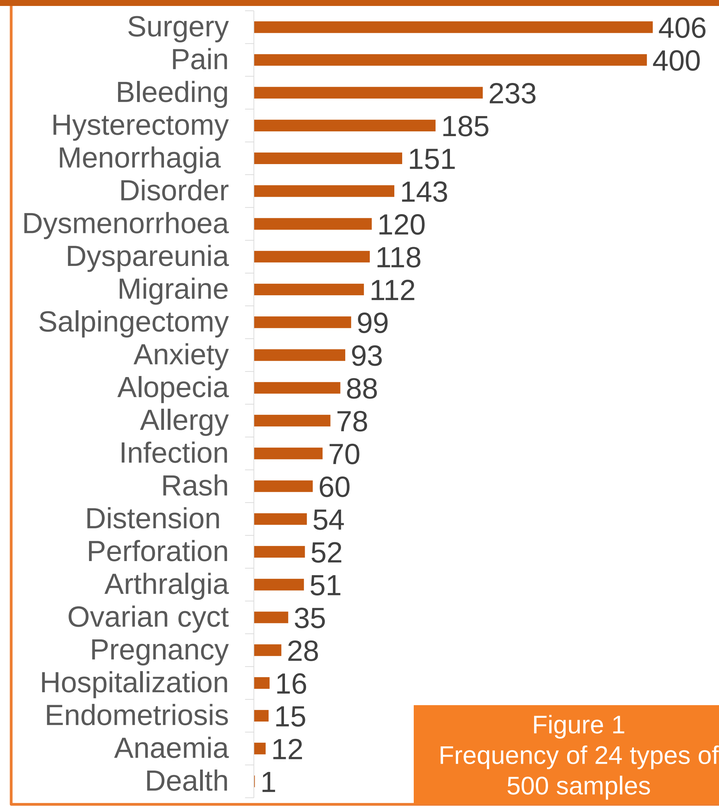

Figure 1
Frequency of 24 types of 500 samples

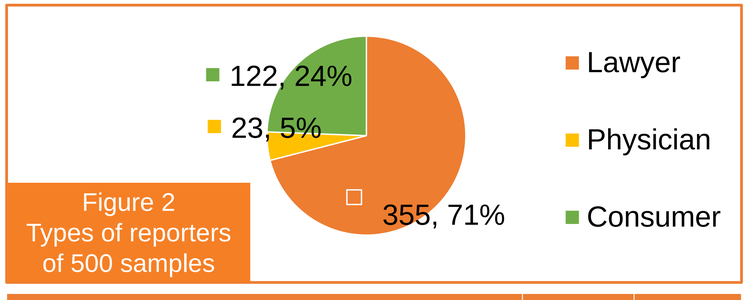

Figure 2
Types of reporters of 500 samples

Characteristic (N=23)		Number	Percent
Status	Not yet recruiting	1	4.35%
	Recruiting	2	8.70%
	Enrolling by invitation	1	4.35%
	Active, not recruiting	4	17.39%
	Terminated	1	4.35%
	Completed	12	52.17%
	Withdrawn	1	4.35%
Study Results	**With Results**	**2**	**8.70%**
	Without Results	21	91.30%

Table 2 Review of 23 clinical studies

Victim	Reporter	Cause of Death	Note
A woman	Consumer	Not mentioned	Using Facebook
A woman	Lawyer	Intra abdominal bleeding	Hysterectomy
A woman	Lawyer	Uterine perforation	Died During Essure insertion procedure
A woman	Health professional	Severe intestinal perforation	Died during the second removal surgery
A woman	Lawyer	Embolism	Hysterectomy
A newborn	Lawyer	Infection	
A fetus	Consumer	Not mentioned	

Table 3 Thematic analysis of seven Death Reports

February 2016 →	**October 2016**
Bayer was asked to conduct a phase 4 study	Warning box and decision checklist
April 2018 →	**December 2018**
Restrictions on Essure sales and distribution	Extend Essure's mandatory follow-up

Table 4 Policy implication

Limitation

- Represent only the 'tip of the iceberg'
- Limited narrative content
- MAUDE database conceals some safety information

Conclusion

- Essure device has significant safety problems
- Issue an alert of the device at an earlier stage
- Safety adverse reports of medical devices need to be further improved for public understanding and scientific research

[1] Horwell DH. End of the road for Essure? ®. J Fam Plann Reprod Health Care. 2017 Jul;43(3):240-241.
[2] Klimczak AM, Snyder RR, Borahay MA, Phelps JY. Medicolegal Review: Essure Lawsuits and Legal Strategies Adverse to Gynecologists. J Minim Invasive Gynecol. 2017 Jul - Aug;24(5):727-730.
[3] Dyer O. FDA places "unique" restrictions on contraceptive implant Essure. BMJ. 2018 Apr12;361.