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19/01/2017

[redacted]

By email

[redacted]

Dear [redacted]

Request under the Freedom of Information Act 2000 (the "FOI Act")

I refer to your email of **19 December 2016** in which you requested information under the FOI Act from NHS Improvement. Since 1 April 2016, the Patient Safety functions under section 13R of the NHS Act 2006 have been exercised by the NHS Trust Development Authority, as part of the integrated organisation known as NHS Improvement.

Your request

You made the following request:

Please can I request the following information:

1. How many patient safety incidents have been reported to NHS Improvement on the use of the product Essure in hysteroscopic sterilisation in 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016? If possible, please break this down by year (either financial or calendar, however this information is held).*
2. Please can you provide further information of any reports without including any personal details of patients in breach of the Data Protection Act?

**By this, I mean any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care.*

Decision

NHS Improvement holds information relevant to your request.

The information we hold is from the National Reporting and Learning System (NRLS). By way of background, some information about the NRLS may be helpful. The primary purpose of the NRLS is to enable learning from patient safety incidents occurring in the NHS. The NRLS was established in late 2003 as a largely voluntary scheme for reporting patient safety

incidents, and therefore it does not provide the definitive number of patient safety incidents occurring in the NHS.

All NHS organisations in England and Wales have been able to report to the system since 2005. In April 2010, it became mandatory for NHS organisations to report all patient safety incidents which result in severe harm or death. All patient safety incident reports submitted to the NRLS categorised as resulting in severe harm or death are individually reviewed by clinicians to make sure that we learn as much as we can from these incidents, and, if appropriate, take action at a national level.

The NRLS is a dynamic reporting system, and the number of incidents reported as occurring at any point in time may increase as more incidents are reported. Experience in other industries has shown that as an organisation's reporting culture matures, staff become more likely to report incidents. Therefore, an increase in incident reporting should not be taken as an indication of worsening of patient safety, but rather as an increasing level of awareness of safety issues amongst healthcare professionals and a more open and transparent culture across the organisation.

We would also like to point out that all reports to the NRLS are anonymised on entering the system.

A recent search of the NRLS was carried out of all incidents reported as occurring between January 2009 and November 2016 if these had been uploaded to the NRLS by 20 December 2016 and where the freetext contained the term 'Essure' including misspellings. Whilst we have chosen key word searches in good faith as most likely to identify requested incidents we cannot guarantee that there are not additional relevant incidents that an alternative keyword search strategy might have found.

As a result of the above search 84 incidents were identified as containing these terms and these were clinically reviewed to see if they were relevant to your request as follows: "*How many patient safety incidents* (*By this, I mean any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care) have been reported to NHS Improvement on the use of the product Essure in hysteroscopic sterilisation in 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016?"* I can inform you that 59 of the incidents contained the key words. For the sake of completeness we have included any incidents where essure was not a misspelling, even when the mention of essure is incidental, for example an appointment to have essure fitted cancelled due to staff shortages, stock of essure run out, or a complaint there is no printer to put a record of essure placement in notes.

Table 1. Breakdown of the 59 reported patient safety incidents describing use of the product 'Essure' by calendar year in which the incident occurred

Calendar Year	**Degree of Harm as recorded by original reporter**			
	No Harm	**Low**	**Moderate**	**Total**
2009	0	0	1	**1**
2010	2	0	0	**2**

2011	3	0	1	**4**
2012	3	2	1	**6**
2013	4	1	1	**6**
2014	6	1	0	**7**
2015	15	2	3	**20**
2016	11	2	0	**13**
Total	**44**	**8**	**7**	**59**

In response to part 2 of your request, Annex 1 provides a summary of the 59 patient safety incidents reported as occurring between 2009 and 2016. The incident descriptions provided are verbatim and have been redacted where this was required to ensure that no information can potentially identify those involved with the incident. Redactions are indicated by square brackets.

We also have access to the Strategic Executive Information System (StEIS). StEIS is a database used for the notification of appropriate parties that Serious Incidents have occurred and to manage progress of investigations, as set out in the Serious Incident Framework 2015, please note it does not hold the full investigation report for Serious Incidents. The revised Serious Incident Framework published in March 2015 builds on previous guidance that introduced a systematic process for responding to serious incidents in NHS-funded care. It replaces, the National Patient Safety Agency (NPSA) National Framework for Reporting and Learning from Serious Incidents Requiring Investigation (2010) and NHS England's Serious Incident Framework (March 2013). The framework takes account of the changes within the NHS landscape and acknowledges the increasing importance of taking a whole-system approach, where cooperation, partnership working, thorough investigation and analytical thinking is applied to ensure organisations identify and learn what went wrong, how it went wrong and what can be done to minimise the risk of the incident happening again.

A search of StEIS was also carried out of all incidents reported as occurring during the period 2009 to 2016 if these had been reported to StEIS by 19 December 2016 and where the freetext contained the word: 'Essure' or 'Esure'. As a result of this key word search only one incident was identified as relevant to your request. This incident took place in 2013 and below is the verbatim incident description.

'There has been a problem with a technique called Essure. It is a hysteroscopic sterilisation rather than laparoscopic. There have been 3 failures (pregnancies) out of 86 procedures when the failure rate should be 1:1000.'

Review rights

If you consider that your request for information has not been properly handled or if you are otherwise dissatisfied with the outcome of your request, you can try to resolve this informally with the person who dealt with your request. If you remain dissatisfied, you may seek an internal review within NHS Improvement of the issue or the decision. A senior member of NHS Improvement's staff, who has not previously been involved with your request, will undertake that review.

If you are dissatisfied with the outcome of any internal review, you may complain to the Information Commissioner for a decision on whether your request for information has been dealt with in accordance with the FOI Act.

A request for an internal review should be submitted in writing to FOI Request Reviews, NHS Improvement, Wellington House, 133-155 Waterloo Road, London SE1 8UG or by email to nhsi.foi@nhs.net.

Publication

Please note that this letter and the attached information will shortly be published on our website. This is because information disclosed in accordance with the FOI Act is disclosed to the public at large. We will, of course, remove your personal information (e.g. your name and contact details) from the version of the letter published on our website to protect your personal information from general disclosure.

Yours sincerely,

NHS Improvement

Annex 1

This is a summary of 59 patient safety incidents reported by the original reporter, where the incident was reported to the NRLS between 2009 and 2016. The incident descriptions provided are verbatim and have been redacted to ensure that no information can potentially identify those involved with the incident. Please note any spelling errors or abbreviations are those used by the original reporter.

Incident Number	Incident Description
1	Pt for hysteroscopil essure sterilization . (GA) the instrument would not go down the working channel as it was blocked with debris . An alternative hysteroscope had to be got from main theatres to treat this pt delaying her operation & increasing her GA time .
2	During a routine scheduled ESSURE list : - 1 . Theatre staff unfamiliar with ESSURE was assigned to list . Delay in assistance . 2 . Wrong hysteroscope was set up (it was thought that the 3x loan hysteroscopes were used up in a previous day list) . ESSURE sheath traumatised - > trauma during cannulization - > tubal spasm ++ - > difficult cannulation - > additional AXR necessary and potentially complication and failure of procedure at 3 months assessment . 3 . Stack light not working , second system needed in theatre . Delay is surgery , clutter in theatre . 4 . Printer quality poor . Unable to document sterilisation with decent photo of ESSURE insert . .
3	Equipment for Essure not available , so patient who was booked for and brought in for Essure Hysteroscopic sterilsation had to have a laparoscopic steri on the day instead . Multiple issues with list - divisional manager doesn't respond to repeated e mails from consultant requesting kit be ordered , rep didn't arrive on day (shouldn't have to rely on rep to drive forward though) , kit not routinely stocked in central stores , therefore not available when requested on that day , theatre list not checked until morning of procedure therefore unable to get kit - even though submitted on [name] in plenty of time .
4	The Hysteroscope for Essure sterilisation was not with the correct attatchments . We had to open another pack and then found out that the equipment had been inappropriately assembled . The hysteroscope had very poor vision and I would request that the equipment be checked prior to be labelled fit for use .
5	[Name] theatre , superficial bowel injury before laparoscopic sterilisation , needed laparoscopic suturing and assure hemostasis . .
6	Instruments for performing Essure hysterscopic sterilisation not available when patient was under anaesthesia for procedure .
7	pregnant post essure sterilisation .
8	Gynae opd 30 Essure scope [number] not checked pre / post op . .
9	Essure sterilization . Hysteroscopy and novasure endometrial ablation . Perforation at time of opening novasure . Cavity check failed . Check hysteroscopy showed no evidence of perforation but low pressures when attemting thermachoice ablation . Check laparoscop showed small perforation not bleeding . .
10	essure hysteroscopic sterilisation 3rd of 65 current completed cases . Right side of fallopian tube scarred and more difficult to insert . HSG at 3 months reported as no dye beyond inserts both sides . 24 months later ,) I was called by patient as she had missed a period and had a positive pregnancy test . .
11	Patient admitted 5 days after Hysteroscopy , Essure and insertion of Mirena coil with severe abdominal pain and vaginal discharge . No evidence found to suggest that vaginal swabs were taken prior to procedure . .
12	pregnant post essure .
13	pregnancy post essure .

14	Whilst [Staff Name] the consultant gynaecological surgeon was performing a hysteroscopic sterilisation using the Essure device the device malfunctioned and broke off at the tip . .
15	Underwent Essure sterilisation on [date] . Attended on [date] with history of passing foreign body . Reviewed USS confirmed only one Essure coil in situ . .
16	Essure scopes too dark , unable to proceed with procedure . Second scope used resulting in [Patient name] being cancelled . .
17	Hysteroscope number [number] . Packed [date] checked . The above hysteroscope used for essure procedure , When the essure was pushed down the channel on the hysteroscope a lump of ' gunge' was pushed out with it (dried blood from previous patient) . First essure device bent beyond repair so second device had to be opened (cost implication) . .
18	Essure device bent on insertion down operating channel of hysteroscope , felt like there was an obstruction in the operating channel , Same happened to 2nd device , thus alternative hysteroscope used at which time view for procedure was not able to be obtained thus procedure abandoned . .
19	Clinican noticed ? fault on Essure device . Coil device not retracting properly . .
20	PATIENT UNDERWENT STRAIGHTFORWARD ESSURE STERILISATION PROCEDURE (WELL TOLERATED) . ESSURE DEVICE SEEMED TO RELEASE ON BOTH SIDES EASILY . ON CHECKING THE STEM AFTER THE PROCEDURE IT SEEMS PART OF THE DEVICE (THE INSIDE OF THE COIL) ON THE RIGHT SIDE STILL STUCK TO STEM . PICTURES TAKEN OF COIL IN UTERUS AFTER INSERTION SHOWING 4 LOOPS COIL ON RIGHT SIDE AND 3 LOOPS COIL ON LEFT SIDE (AS EXPECTED) . PATIENT TOLD OF FINDING . ADVICED TO CONTINUE CONTRACEPTION AS PER ROUTINE PRACTICE UNTIL CONFIRMATORY TEST BY HSG IN 3 MONTHS TIME . WARNED IN CASE OF FAILURE MAY NEED REPEAT PROCEDURE . STEM LEFT IN BOX AND COMPANY REP CONTACTED . INCIDENT NEEDS REPORTING TO MHRA .
21	Essure device deployed before it was activated at the introducer . Device passed from patient with hysteroscope . .
22	Failure of Essure device which was deployed from the introducer before it was triggered by surgeon . .
23	Attempted Essure hysteroscopic sterilisation via Versascope . Tip of device got bent in passing through operating channel of hysteroscope and could not be operated . .
24	Patient telephoned Outpatients advising she had had a recent Essure procedure and she had expelled the coil vaginally . Patient had had pain / bleeding over the weekend but had settled since . .
25	patient attended for Essure procedure . Procedure was not able to be performed as clinican unable to visualise tubal opening . .
26	Patient attended for Essure . Consultant reported device failed to release coil . .
27	ESSURE 4 / 7 post o . E / A on [date] for abdo pain . Following scan pt become unwell . S / b team and consultant . Transferred to [hospital] at A&E department . .
28	Essure device failure upon consultant inserting first guide wire . Device failed to release . .
29	[date] - NF , 32 , P2 , Hysteroscopic female strilisation (ESSUR) was carried out . Essure device inserted in the right tube without problem . But Essure could not be inserted through lfet ostium . ? tubal spasm . [date] - 2nd attempt , agian failled as ESSURE device could not be introduced in the left tube . Rt tubal insertion normal noted on hyeteroscopy . Post procedure no problem with patient . . Laparoscopic sterilisation carried out on [date] as ESSURE was not successful . At laparoscopy ESSURE device noted partially perforated through proximal tube on right . .
30	Patient contacted department to say that she had opted for Essure treatment . her original appiontment of [date] had been rearranged (? patient ? hospital changed) . she received a new letter for the [date] and had taken her pre treatment medication and was about to leave home when she realised that the appiontment was Weds

	[date] . pateint had taken a days holiday today and has no more entitlement untill April . .
31	pt attended for a review appointment today . last correspondence indicates that she has failed to attend her clinic appointment for Essure procedure in January . Appointment seems to have been made in error . .
32	Patient attended clinic for Essure Sterilisation procedure and had not been counselled prior to procedure being carried out by consultant . .
33	Pelvic collection / abscess post outpatient endometrial ablation and unilateral essure sterilisation and hysteroscopy .
34	Pt booked into wrong clinic . [clinic] (for ablation & essure on a Mon usually) . Unknown to clinic staff . Unprepared (need to obtain some supplies from theatre) . Only 1 RN . Staff shortage / sickness in dept also .
35	patient attended for Essure sterilisation . Easy insertion on right side . Device did not appear to release properly on right side with coil stretching in cavity before detaching . Suspected device failure (failure to release properly) on the left side . Patient informed and advised to continue using alternative contraception until HSG test in 12 weeks time
36	23 / 40 pregnant , heavy vaginal bleeding (APH) with EBL 4000ml . Had history of Novasure Endometrial Ablation and Essure sterilisation . Patient ventilated in ITU currently [date] [other medical condition].
37	Patient on theatre list booked on list as Laparoscopic sterilisation . However Clinic letter states that patient is for hysteroscopic sterilsation (essure) to be done by Dr [initial]. Incident form after request by Dr .
38	patient booked for essure procedure . began procedure , light source for camera (light bulb) stopped working . staff nurse changed light blub but machine still didnt work . we had borrowed a machine from day surgery that was outside the clinic room ready for the afternoon clinic . This machine was taken into the room to be used for this procedure . We connected all relevent cables which started up the machine . we then began procedure staff outside room knocking on door urgently stating that the machine could not be used as it was faulty and was being repaired . Machine turned off straight away and procedure abandoned . Patient was laid on the couch for around 30 minutes while staff tried to rectify the equipment . Procdure also abandoned due to lack of equipment for this procure which is regular occurance . .
39	Consultant Surgeon arrived for team brief & informed theatre team [consultant] had no assistant all day . There were 8 cases booked. 6 were laproscopic . Scrub nurse 1 and 2 both said that they could not assist the surgeon by holding the scope . Consultant repeated that there was no assistant available to assist all day & that consultant] would manage I said surely this is a patient safety issue & that I wanted to stop the line . Consultant went to find an assistant . During team brief it became obvious that the cases were not as stated on the printed list . Case 3 (Pt [number])Booked as Trans cervicleresection of fibroid - was also a diagnostic laparoscopy Case 4 which was listed as a laparoscopic sterilisation was in fact a bilateral salpingectomy Case 5 had the addtion of a dye test Case 7 listed as an Essure hysteroscopic sterilisation was in fact a laparoscopic sterilisation . Staff had to return to main theatres to collect additional equipment and instrumentation .
40	[[date time] the reporter] Patient underwent an Essure procedure in the [Name] clinic . Difficult procedure . Patient experienced pain post procedure . .
41	Patient attended for hysteroscopic sterilisation . Procedure cnacelled because we did not have appropriate hysteroscopes for Essure sterilsation . Verbal apology offered . Patient rebooked for [date] . .
42	patient pregnant 2 years after confirmation of successful essure sterilisation .
43	patient had an esure proceedure two weeks ago in the [place] . prior to the proceedure patient states she had a negative pregnancy test . patient did a home pregnancy due to her period been late and it was postive . seen in [place] and the scan showed a very early pregnancy of less than five weeks . on call consultant aware and patient is unsure whether to keep the pregnancy as it is unplanned .

	patient given [place] number for advice and been given the [place] number to self refer . .
44	Essure sterilisation carried out by specialist nurse in [date] . Subsequent hsg confirmed patent left tube and suspected incorrectly placed left essure . Laparoscopy today confirmed no evidence of tubal perforation or incorrect placement of essure . The tubes , ovaries and uterus looked normal . However , the left essure appears to have migrated and attached to the omentum (Seemingly through fimbrial end as tube looked normal with no evidence trauma or perforation) . The migrating essure device dissected off omentum and retrieved . Patient was consented for removal both tubes which was also carried out and the right essure device retrieved . Right essure appeared correctly placed at time removal . Incident needs to be reported to mhra and manufacturer please . In house essure audit ongoing . .
45	This patient and another patient were booked for hyst steri procedures . However no Essure devices available therefore patients had to be cancelled . One patient turned up to department as unable to contact by phone , apologies given . .
46	a patient was booked on the clinic list for 13:30 appt for an essure , this appt was a half hour slot when it should be an hour slot . the patient arrived but she was unaware of why she was here , last seen in [place] [date] . her letter stated she was only here for a review appt . She therefore had not taken any premed required for an essure procedure . I stated to the consultant that we could not provide a safe procedure in the time constraints and pressures of other patients booked on the clinic . [Consultant] was keen to go ahead with the procdeure but after talking to the patient [consultant] had decided to leave it till later .
47	Patient attending for routine gynaecology appointment but on the form with her appointment it says she will be having Essure Sterilisation at the time ! ! .
48	Essure steri kit opened and noted to be out of date as about to be used on the patient .
49	All day list with [initials] in theatre 1 , needed to borrow from onestop 3 versascopes , 3 mini touch and generator , 1 essure scope and kit . I was then informed after the WHO that a morcellator from one stop was needed for the first case , I sent an orderly down but the piece of equipment was in use , [initials] informed . THeatre 2 then informed me they needed a versascope as well which onestop kindly gave us . .
50	patient attended for an ambulatory essure procedure . the patient entered the procedure room where her consent form was checked by the attending consultant . The consultant explained to patient [consultant] was sorry she had to wait in the clinic , but [consultant] was unable to carry out the essure procedure . The consultant read the consent form which was not the correct consent form for the essure procedure . the risks had not been explained to the patient correctly . the consultant felt it would be best for the patient to read about the procedure and know all about the risks before she made a decision . the consultant will bring her back to clinic to disscuss her options and decision . I was unable to make her a follow up appointment as the consultant is on holiday . informed the patient i will contact her with an appointment . .
51	Essure Operative list and no extra nurse to look after these patients . I had Essure patients , TCI and emergencies on the go together . .
52	original gatu op list instructed to be closed back in December and an essure list to be set up in its place . email confirming gatu op list closed received from w / l and theatre in December . essures correctly booked on to the list but someone has somehow booked mysoure / novasures on to same list too . 2 full list (8 essure + 6-8 myosure / novasure) all turned up at same time for the ops . managed to do all myosure / novasure and 4 of the 8 essure but ran out of operating scopes so couldn't do the others . .
53	All Essure (Hysteroscopy clinic) patients from today clinic [date] attended with print out of last letter . All patient original notes missing and could not be found . No previous documentation / consent form / discussions regarding sterilizations .
54	[[date time] the reporter] Xray had benn requested to confirm location of ESSURE coil after failed hysteroscopic sterilisation performed in 2014 . This had been requested by to identify exactly where the coil was and for valuable reassurance for

	this lady who is extremely distressed . On arrival the procedure was refused by the Xray department . rational is unclear but the patient reported that as we were unlikely to want to remove it was not clinically required to identify actual position of the coil . .
55	Patient underwent essure sterilisation on [date] . Hsg was requested then to be carried out 3 months later . As patient did not receive appointment another request was placed on the system on [date] . Patient is still waiting for an appointment . A third request placed on the system today . .
56	Patients arrived for Essure list in the morning when they should have arrived in the afternoon . Consultant called from home (was on a / l in the morning) to do the list . This is second time now something like this has happened . Similar incident a month ago where the GATU op list was cancelled and Essure list put on in its place . That time both Essure and Myosures turned up . Today just essures turned up but in morning not afternoon .
57	Failed ESSURE Steilisation , pregnant and continuing .
58	patients procedure had to be cancelled due to no essure device in the department .
59	Printer broken from July 01 - present . We use this to take photographic evidence for procedures in the outpatient hysteroscopy clinic.i.e . ESSURE sterilisation , Endometrial Ablation , diagnostic and operative hysteroscopy procedures . We are still awaiting replacement . .