Dáil Éireann Leinster House Kildare Street, Dublin 2

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Re: PQ 10966/25

To ask the Minister for Health the incidents reported to the State Claims Agency which related to the Health (Regulation of Termination of Pregnancy) Act 2018, per year from 2019 to 2024, in tabular form, specifically incidents causing harm (broken down by severity); other reported incidents (including near miss); the number of complaints by service users/patients; and if she will make a statement on the matter.

Dear Deputy Nolan

I refer to your parliamentary question which has been referred to HSE Quality and Patient Safety Incident Management for response. I can provide incident data recorded on the National Incident Management System (NIMS) but not complaints data. We engaged with colleagues from the HSE National Complaints Governance and Learning Team, they have provided their narrative and data summary below. The response is described in two parts therefore.

Part 1 - Incidents

Incident reporting is impacted by a number of factors. Incident reporting is not focused on nor optimized for statistical analysis but primarily aids as a system that helps incident management and learning from such events. Please be advised that there are data limitations and anomalies that include potential duplication of incidents, variance in reporting and limited data validation, etc. The data provided below pertains to HSE statutory hospitals only and excludes voluntary hospitals.

On the current National Incident Management System (NIMS) there is no one field describing 'termination of pregnancy'. Therefore multiple search terms were used to extract relevant data, followed by a validation exercise to determine whether incidents were directly related to termination procedures. In some cases, terminations were referenced in the incident but carried out as appropriate clinical management, in line with the Health (Regulation of Termination of Pregnancy) Act 2018 and not included here therefore. For example, in cases of risk to life or serious harm to the pregnant woman or the presence of a fatal fetal anomaly.

Incident Data Summary:

Total number of Incidents	50 with no incidents of severe harm reported.

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Severity		Negligible: 28% (n=14)					
		Minor: 17% (n=7)					
		Moderate: 58% (n=29)					
		Severe: 0% (n=0)					
2019	2020	2021	2022	2023	2024		
8 (<5	6	8 (7 moderate	<5 (<5	8	15 (7		
moderate	(<5moderate	harm,	moderate harm,	(<5moderate	moderate		
harm, <5	harm,	<5negligible)	<5 minor harm	harm,	harm,		
minor harm,	<5negligible)		and	<5minor and	<5minor		
<5negligible)			<5negligible)	<5negligible)	and 7		
					negligible)		

The most commonly reported incidents involved heavy or irregular bleeding post-procedure, with a small number of post-procedure infections also documented. It is important to emphasize that abortion procedures are generally very safe. While most women do not experience any complications however, like any medical procedure there is a risk of complications including: Infection, heavy bleeding, damage to the womb or retained pregnancy tissue. Internationally, the abortion-related complication rate is estimated to be approximately 2%.

With regard to the reporting of adverse events and the TOP related data capture, it is important to note the following:

NIMS is not an outcome measurement tool but serves to capture and analyse reported events for continuous service improvement.

Termination of Pregnancy service data is compiled separately by the Department of Health through a statutory notification process, as required under the Health (Regulation of Termination of Pregnancy) Act 2018. The Minister has a statutory obligation, to prepare an annual report by the 30th of June, each year, of the number of notifications received in the previous year.

The HSE is currently working to define quality measures and implement data collection mechanisms for Termination of Pregnancy nationally.

Part 2 - Complaints

The Complaints Management System (CMS) is the national database management system developed to support the HSE's complaints management process and to enable tracking of Stage 2 formal complaints as set out in the *Your Service Your Say: The Management of Service User Feedback for comments, compliments and complaints Policy 2017.* All statutory HSE services are mandated to use the CMS.

There is no one field describing 'termination of pregnancy' on the CMS. Therefore, multiple search terms were used to extract the relevant data, followed by a validation exercise to determine whether the complaints recorded were directly related to termination procedures.

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For the period of the 1st January 2019 to 31st December 2024, the below table outlines the number of recorded complaints relating to termination of pregnancies

Complaints Data Summary:

Year	2019	2020	2021	2022	2023	2024
No of Stage 2 formal complaints	<5	0	<5	<5	<5	0

I hope this provides you with assistance.

Yours sincerely

Lorraine Schwanberg Assistant National Director Quality and Patient Safety Incident Management

Christopher Rudland
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