

MEDICAL DEVICES VIGILANCE NETWORK: EXPERIENCE IN AN ITALIAN LOCAL HOSPITAL

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WHAT WAS DONE?

In October 2022 the Ministry of Health developed
DISPOVIGILANCE
 a new tool that supports Health System's vigilance network

Any event or suspect event that occurs with a medical device (MD) is classified as "incident" and it has to be notified to Ministry of Health

We collected incident reports of MDs in our hospital from January 2023 to October 2024

WHY WAS IT DONE?

To analyse the MDs involved in incident in an italian local hospital, since the introduction of Dispovigilance

HOW WAS IT DONE?

Stratifying the incident reports by:

- risk classes (I, II, IIa, IIb, III, IA);
- CND (National Classification of Medical Devices);
- type of reporter.

Data were collected in an Excel database

WHAT WAS CONCLUDED?

- MDs reporting in our hospital is well stratified for both risk class and CND;

- Injection cannulas have been involved in 24% of all incidents



We substituted them, in order to protect patient and healthcare worker's safety;

- Nurses are the major reporters and there is underreporting between clinicians



We sensibilized them to importance of reporting incidents or suspect incidents occurring with medical devices;

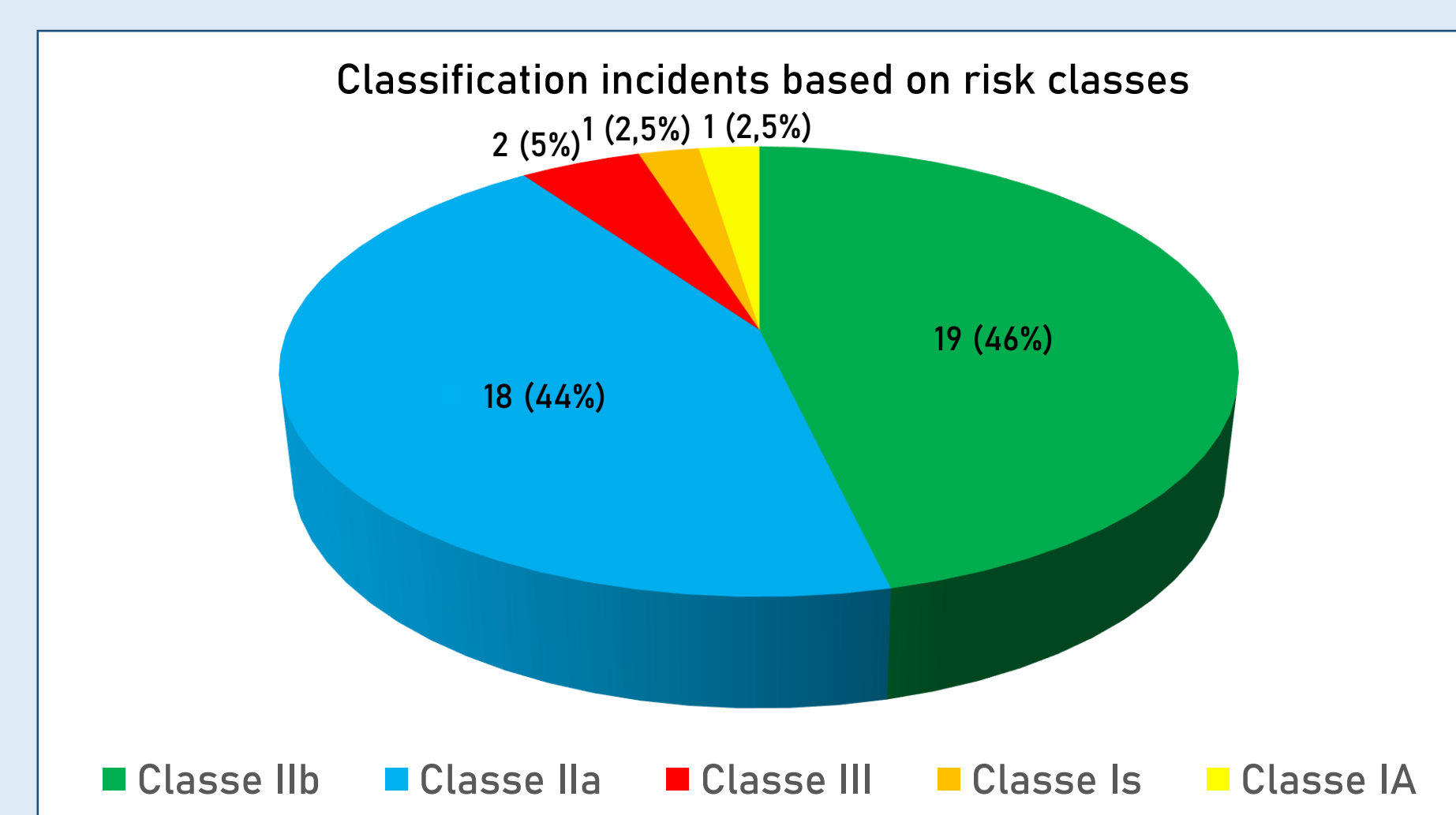
- From 2023 and 2024 reporting has been increased probably due to implementation of Dispovigilance.

WHAT HAS BEEN ACHIEVED?

Between January 2023-October 2024 we reported 41 incidents:

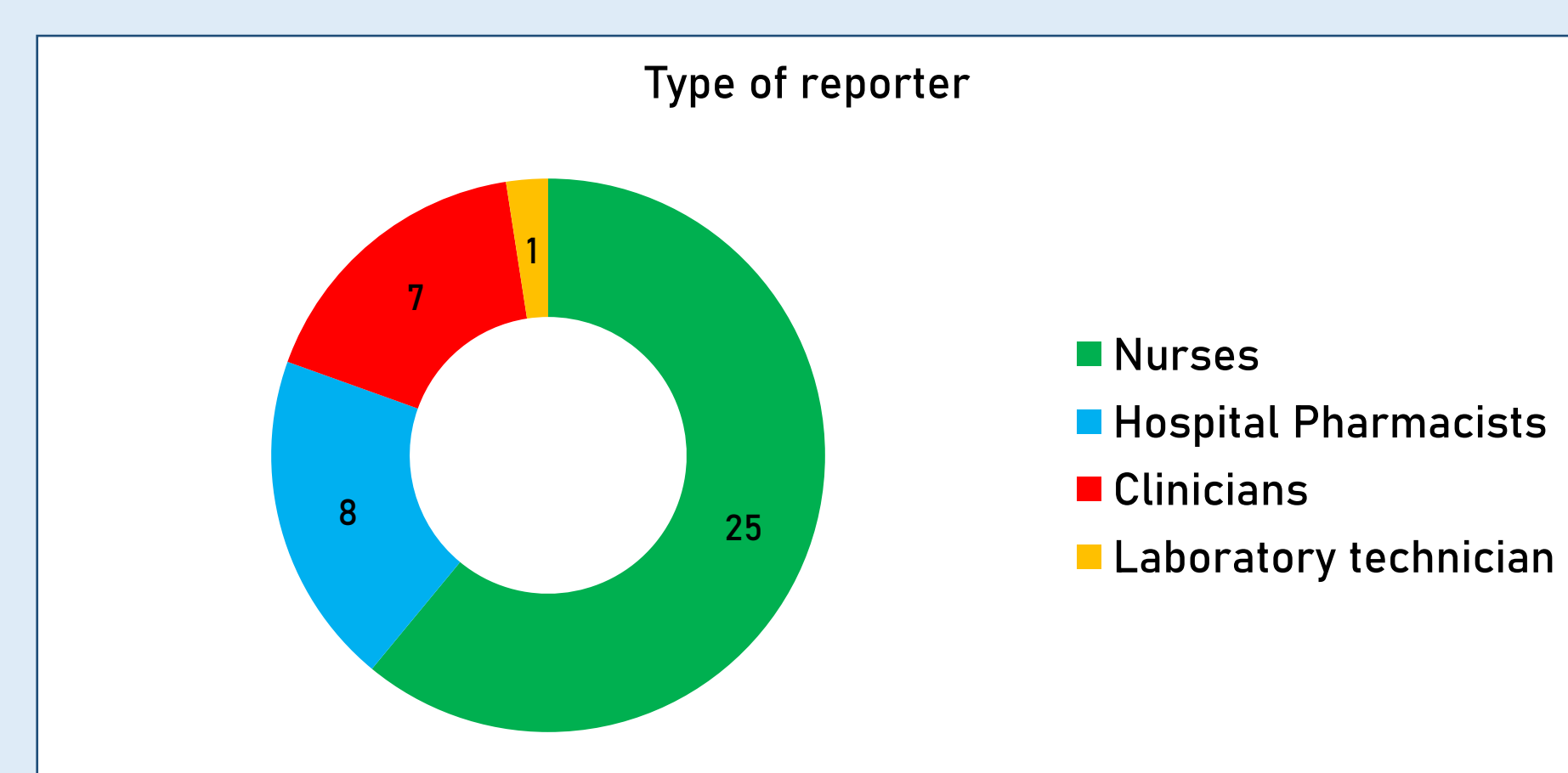
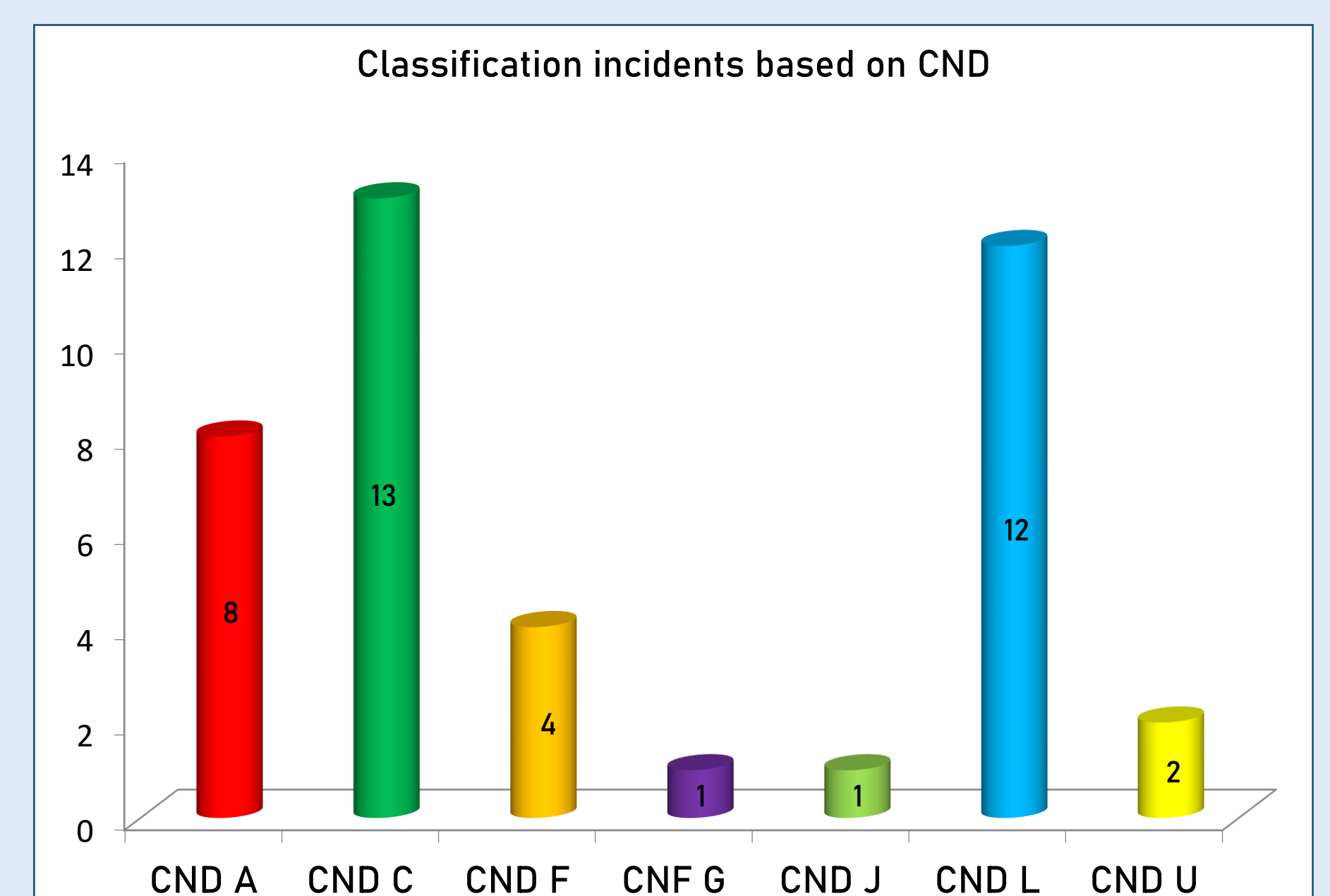
16 in 2023

25 in 2024



CND:

- **CND A:** devices for administration and collection;
- **CND C:** cardiocirculatory system devices;
- **CND F:** devices for hemodialysis;
- **CND G:** gastrointestinal system devices;
- **CND J:** active implantable devices;
- **CND L:** surgical instruments not disposable;
- **CND U:** urogenital system devices.



MORE INFORMATION

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