Seminar CL2
Medical device vigilance

THE ITALIAN MODEL

and the experience of the Regione Veneto

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Conflict of interest:

nothing to disclose

Q & A

A: Do USERS have a central role in reporting incidents within le Medical Device Vigilance System?

B: Is Italy provided with a National database collecting Medical Device Incidents reports?

C: Do Hospital Pharmacists have a central role in the Regione Veneto for the governance of Medical Device Vigilance?

IT IS ESSENTIAL TO VIGILANCE ON MDs AFTER THE CE MARK

The risk assessment performed in the premarketing phase in order to obtain the CE mark for MDs

does not necessarily exclude the occurrence of safety problems <u>after the</u> MD is on the market

- ✓ lack of clinical studies showing the clinical efficacy and safety of MDs, despite the changes introduced by Directive 2007/47/ EC
- ✓ studies involving a limited number of patients, highly selected
- ✓ follow-up often too short and not comparable with the lifetime of the implants in patients.

MEDICAL DEVICES: VIGILANCE SYSTEM

The MD Vigilance System applies to all incidents which might lead, or have led a patient or a user to death or to a serious deterioration in their state of health.

Reasons:

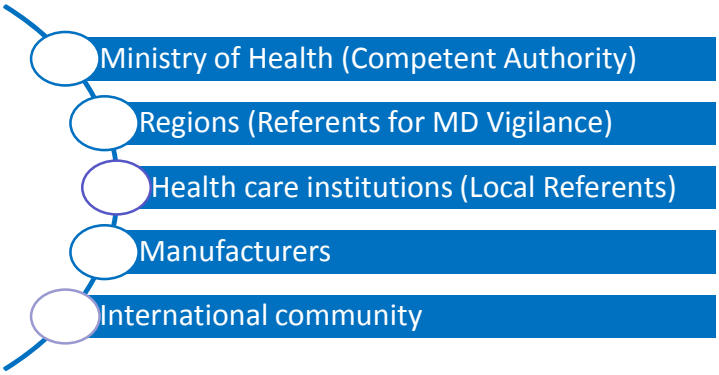
- any malfunction or deterioration in the characteristics or performance of a MD;
- any inadequacy in the labelling or the instructions for use;
- any technical or medical reason in relation to the characteristics or performance of a device which leads the manufacturer to systematically recall all devices of the same type.

OBJECTIVES OF THE VIGILANCE SYSTEM

The primary objective of the vigilance system is to improve patients and users safety through:

- Rapid identification of each new problem in order to identify corrective actions
- Information sharing between Competent Authorities and manufacturers to permit the timely implementation of corrective actions
- Monitoring of the effective implementation of corrective actions
- Prevention of the recurrence of similar incidents thanks to the implementation of appropriate corrective measures and the publication of warnings

NATIONAL LEVEL: ACTORS INVOLVED



In Italy, the Ministry of Health is identified as the Competent Authority for the medical devices vigilance

VIGILANCE SYSTEM: REGULATORY FRAMEWORK

EU Directives	Italian transposition in D.Lgs
- 90/385/CE (AIMD) - 93/42/CE (MD) - 98/79/CE (IVD) - 2007/47/CE	- D.Lgs 507/92 (AIMD) - 46/97 (MD) - 332/2000 (IVD) - 37/2010

Additional Regulations

Circ. Ministero Salute 27.7.2004 – "Vigilanza sugli incidenti con dispositivi medici"

Circ. Ministero Salute 28.7.2004 – "Segnalazioni di incidenti e mancati incidenti con dispositivi medici. Progetto di una rete di vigilanza"

D.M. 15.11.2005 – "Approvazione dei modelli di schede di segnalazioni di incidenti o mancati incidenti, che coinvolgono dispositivi medici e dispositivi medico-diagnostici in vitro"

Linee Guida MedDev 2.12-1 rev. 8 -January 2013, in vigore da luglio 2013 – Guidelines on a Medical Devices Vigilance System

Circ. Ministero salute 18.2.2014– Nuova modalità di segnalazione di incidente da parte di operatori sanitari-Modulo on line

The italian transposition of the EU Directive 2007/47 EC has also defined sanctions: "Manufacturers or their authorized representatives, health professionals, lawyers representatives of health facilities or, if appointed, the vigilance referents, that do not perform incidents reports, shall be punished with imprisonment up to six months and to pay a fine from 7,200 to 43,200 euros."

THE CENTRAL ROLE OF USER

The italian transposition of the European Directive has imposed:

MD users must notify immediately incidents report to the Ministry of Health (National Competent Authority)
The notification must be made directly by the users or through health facilities where the incident has occured in respect to regional provisions that provide Referents for MD Vigilance
The notification must also be sent to the manufacturer
The users are required to notify to the manufacturer any other inconvience that may permit corrective actions to ensure patients and users safety

NATIONAL INCIDENT REPORTING SYSTEM

Currently the information system supports health professionals which contribute to feed the national database by filling in the online form for incident reporting.

Compilation of the online of incident report form «USER»

Print the incident report form (.pdf)

(Regional)

Send the incident report form, signed by the local Referent for Vigilance, with certified e-mail to:

1. *NATIONAL AUTHORITY*
2. *MANUFACTURER*
3. *FEEDS THE REGIONAL DATABASE*

Ministry of Health, responsible for the management of the information received as "incident reports"

DISPOVIGILANCE: the national database

Regional referents: → Need of regional and hospital user profiles for vigilance referents to permit to interrogate the database and download its data

The system permits to link different incidents reports and aggregate data with the use of specific filters

From march 2015 these referent profiles will be activated

Regions referents

- Download regional data
- Query the database by selecting the hospital rather than the period and the outcome of the incident report
- Ability to download data related to all forms submitted by operators

Hospitals and local referents

- Visibility of the data of its own hospital
- Possibility of data download

INCIDENT REPORTING FORM (1)

Data related to the place where the incident occurred

- Data concerning the institution and the service
- Data concerning the user that detected the incident
- Contact information
- Data concerning the referent for vigilance

Data related to the medical device

- Manufacturer and distributor
- Commercial MD name
- MD code assigned by the manufacturer and by the national database
- Description and type of MD involved

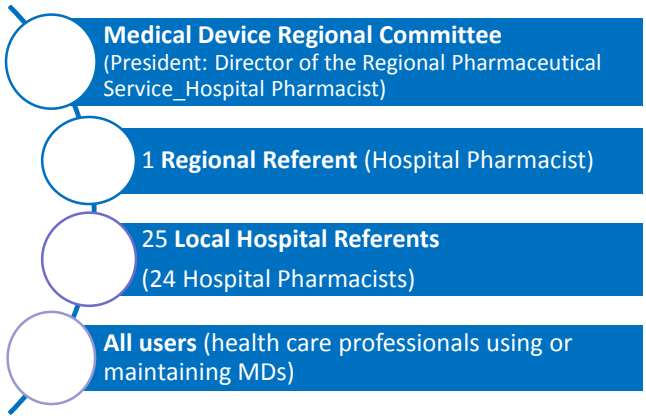
INCIDENT REPORTING FORM (2)

Data related to the incident

- Patient or user involved in the incident (age and name initials)
- Reason for use and MD procedure
- Incident description
- Incident consequence_____death
  _____surgery
  _____specific medical intervention
  _____hospitalization
- Availability and place in which the MD involved is preserved
- Information transmitted to____the manufacturer
  ____the hospital administrator
  ____the MD vigilance referent
- Date

Data related to the author of the incident report

THE REGIONAL VIGILANCE SYSTEM FOR MDs



REGIONAL OUTPUTS

1. "Regional guidance for the vigilance on medical devices" **(**Regional Commitee for MDs , 2011)

The guidance addresses to public and private health institutions.

Purpose: to clearly define, facilitate and uniform the application and implementation of the Medical Device Vigilance System in Veneto Region, regard to:
- *Incidents*
- *Reclaims*
- *Field Safety Notice*

2. Computer Program for the regional MD vigilance system *(from 2012)*

Data analysis and annual report

From the analysis of the information obtained through this program annual summary reports are produced

3. Monitoring

of patients implanted with hip prosthesis

The Region transmits twice a year to the Ministry of Health monitoring reports concerning follow-up of patients implanted in the regional healthcare institutions

Output 1. Regional guidance

ROLE OF THE REGIONAL REFERENT FOR MD VIGILANCE

1. Coordinates the network of local hospital referents for MD vigilance; it represents the regional reference for the national competent authority (Ministry of Health)

2. Promotes periodic training of local hospital referents

3. Collects and analyzes incident reports transmitted by local hospital referents

REGIONAL REFERENT OF VIGILANCE (PHARMACIST)

4. Receives by local hospital referents copy the monitoring performed on patients with implantable medical devices, if they are involved in corrective actions

5. Prepares periodic reports on regional incident reporting

ROLE OF THE LOCAL REFERENT FOR MD VIGILANCE

1. Defines an operative pathway for MD Vigilance in collaboration with services

2. Supports health care providers in the compilation of the reporting forms

3. Receives the reporting forms from Services, checks their completeness and their correct compilation and forwards them to the Ministry of Health, manufacturer and feeds the regional database

4. Guarantees the transmission of Field Safety Notice / withdrawals coming from manufacturers and / or distributors to Local Services

Output 1. Regional guidance

THE PROCESS FOR INCIDENT REPORTING

1. Receives the reporting forms by the user, checks the completeness and adequacy of the data and, if necessary, contacts the reporter\reporting source

2. Transmits the incident reporting forms (within 10 days) to the Ministry of Health, to the distributor and records it in the regional database

3. Checks for other MDs, belonging to the same lot, present in other Services and, if appropriate, orders its temporary suspension of use, waiting for proper investigations

4. Coordinates the delivery to the manufacturer of the involved MD for proper investigations

5. Records and archives reporting forms

Output 1. Regional guidance

THE PROCESS
IMPLANTED MEDICAL DEVICES

Incidents – Market withdraw- Field Safety Notice

Local-Hospital Referent for MD Vigilance

Hospital Administration

Chief of the department must produce a report:

- number of patient implanted with the MD
- investigation and clinical evaluations in progress or planned
- any additional surgical procedures necessary as a result of the alert

Regional Referent of MD Vigilace

Output 1. Regional guidance

INFORMATION REQUIRED TO HOSPITALS

IMPLANT (information about the implanted MD)

- MD model
- MD code
- MD National identification number
- Serial number of implantable MD
- Lot number
- Expiry date

SOFTWARES

EXPLANT (information with explant motivations)

- MD/prosthesis rupture
- End of life of the MD/prosthesis
- Infection
- Early battery depletion
- Dislocation
- Rejection

THE PROCESS Field Safety Notice - FSN

1. Receives FSN coming from manufacturers /Ministry of Health, verifies the presence/absence of the product/batch reported in the hospital.

LOCAL REFERENT OF VIGILANCE (PHARMACIST)

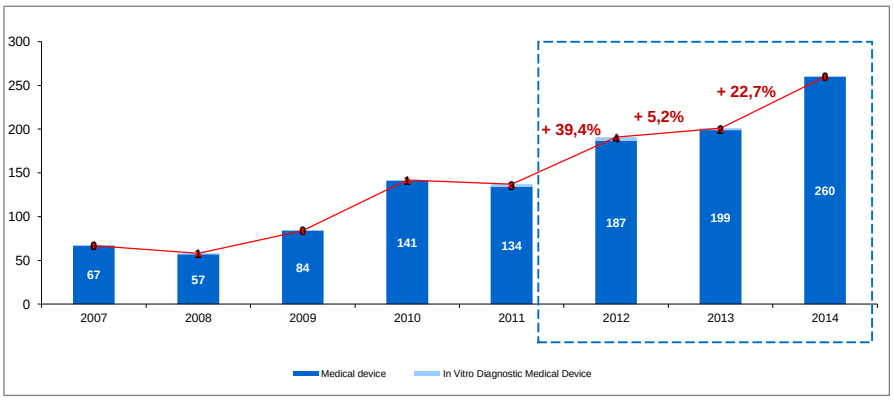
2. Forwards (by fax or e-mail) to users FSN

3. In case of a recall, coordinates with users and manufacturers the withdrawn and the replacement of MDs objective of the FSN or coordinates monitoring activities

5. Records and archives Field Safety Notice

FSN IN ITALY (2009-2013)= 2.329

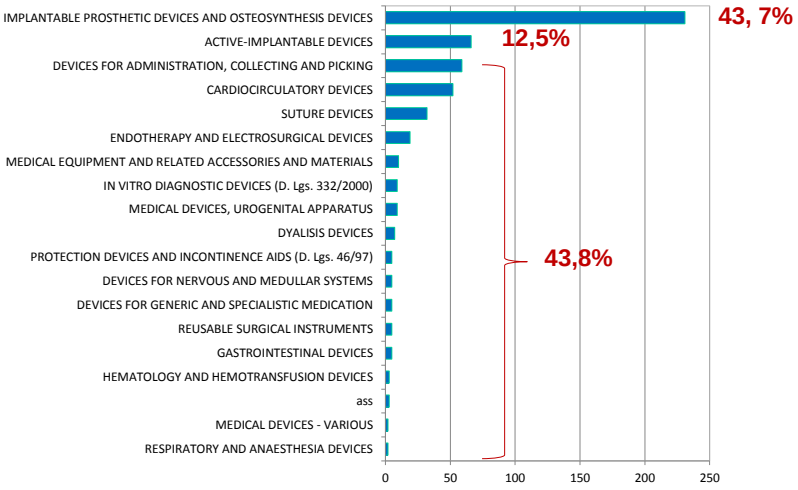
INCIDENT REPORTING IN THE REGIONE DEL VENETO



Regional Population: 4.926.818 (Istat)

- 4th region in Italy for number of incident reported
- Annual reporting rate 2014: 52,8 incident reports for million inhabitants and 5,3 incident reports per 100.000 patient hospital stay

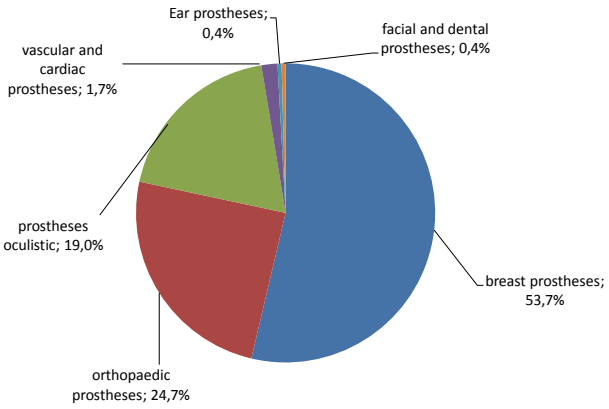
MD subject to reporting



Years 2011_2013

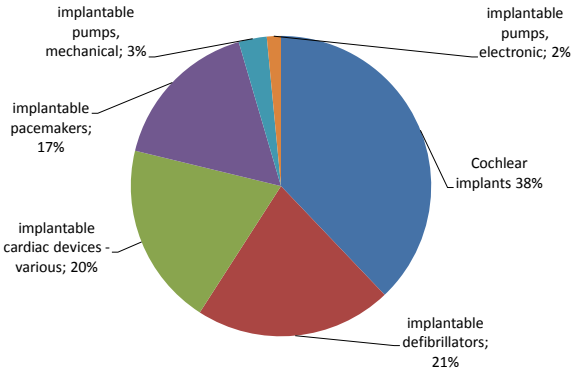
Output n.2 Regional database

IMPLANTABLE PROSTHETIC DEVICES AND OSTEOSYNTHESIS DEVICES



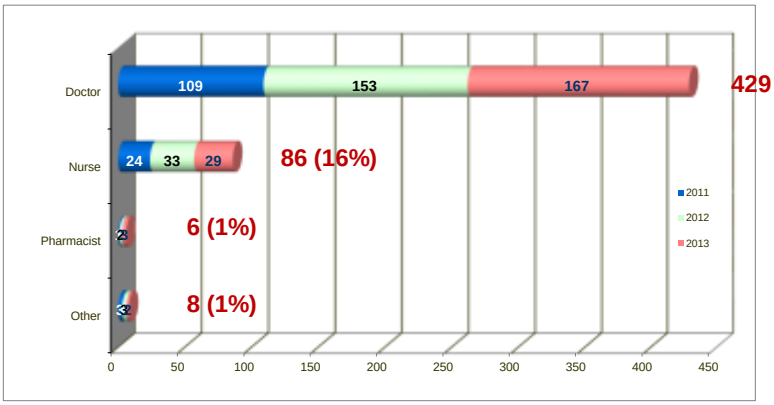
Years 2011_2013

ACTIVE-IMPLANTABLE DEVICES



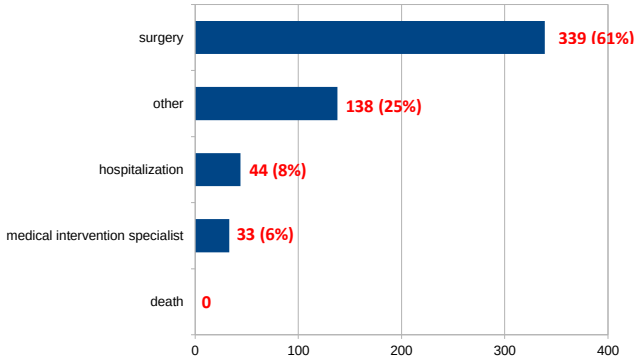
Years 2011_2013

SOURCES- AUTHORS OF MDs REPORTINGS



Years 2011_2013

INCIDENT CONSEQUENCES



The majority of reported incidents have determined conditions for which it was necessary surgery

Years 2011_2013

Hip replacement device

MANUFACTURER (november 2011)
Voluntary recall due to a high rate of repeat surgeries during the first 5 years from the implant

RECOMMENDATIONS OF THE ITALIAN COMPETENT AUTHORITY (January 2012):

- healthcare professionals to invite patients to undergo follow-up program;
- heathcare institutions must inform monthly the manufacturer and their Region:
  - confirm begin of patients follow up;
  - number of repeated surgeries executed;
  - reasons for repeated surgeries.

ADDITIONAL REGIONAL REQUEST TO LOCAL HOSPITALS AND THEIR VIGILANCE REFERENTS (February 2012)

- N. of patients implanted with these devices
- N. of devices implanted
- N. of patients that have not started follow up
- Reasons for missed follow up

SOFTWARES

Hip replacement device

RESULTS
2013

N. of implanted devices	486
N. of patients with these devices	457
N. of patients still in follow up	367
N. of patients that missed follow up	45
Number of repeated surgeries executed	75

Monitoring is still ongoing

Q & A

A: Do USERS have a central role in reporting incidents within le Medical Device Vigilance System?

YES

Q & A

B: Is Italy provided with a National database collecting Medical Device Incidents reports?

YES

Q & A

C: Do Hospital Pharmacists have a central role in the Regione Veneto for the governance of Medical Device Vigilance?

YES

Thank you!