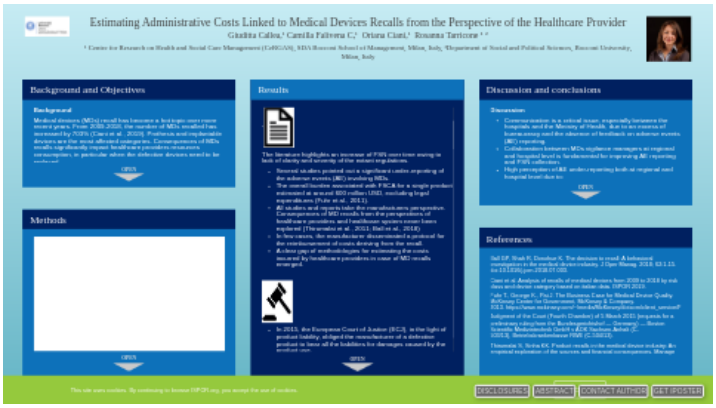
Estimating Administrative Costs Linked to Medical Devices Recalls from the Perspective of the Healthcare Provider



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PRESENTED AT:

BACKGROUND AND OBJECTIVES

Background

Medical devices (MDs) recall has become a hot topic over more recent years. From 2009-2018, the number of MDs recalled has increased by 703% (Ciani et al., 2019). Prothesis and implantable devices are the most affected categories. Consequences of MDs recalls significantly impact healthcare providers resources consumption, in particular when the defective devices need to be replaced.

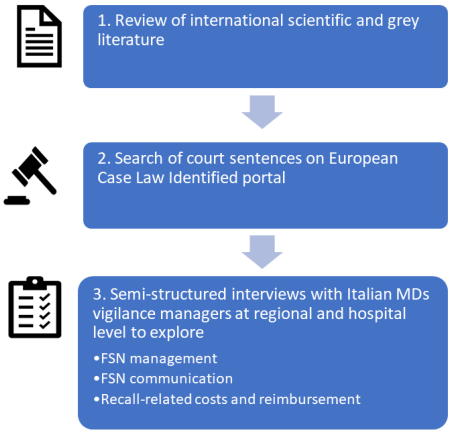
The new European Regulation of MDs (MDR) has strengthened the provisions regulating vigilance of MDs, increasing the number of actors appointed at issuing field safety corrective actions (FSCA) and the number of actions that can be taken for patient safety.

Despite these efforts, there is still a lack of evidence around the administrative and clinical costs borne by healthcare providers and healthcare systems in case of MD recalls.

Aims of the work

1. To understand how field safety notices (FSN) are managed in Italy at regional and hospital levels.
2. To identify methods currently used to estimate administrative and clinical costs related to MDs recalls.

METHODS



- **FSN management**: how FSN are managed and collected by public providers.
- **FSN communication**: how the various actors (i.e., competent authority, regions, healthcare providers, manufacturers) communicate and share information.
- **Recall-related costs and reimbursement:** whether and according to which methodologies expenses incurred by providers as a consequence of MDs recalls are estimated and refunded.

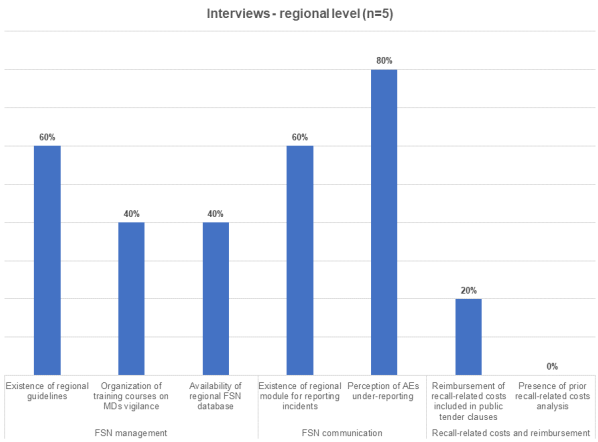
RESULTS

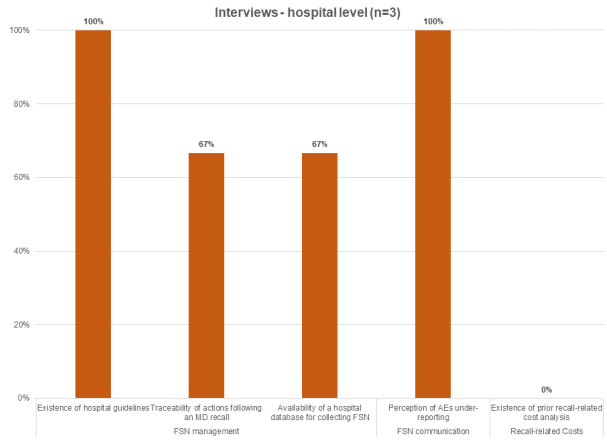
The literature highlights an increase of FSN over time owing to lack of clarity and severity of the extant regulations.

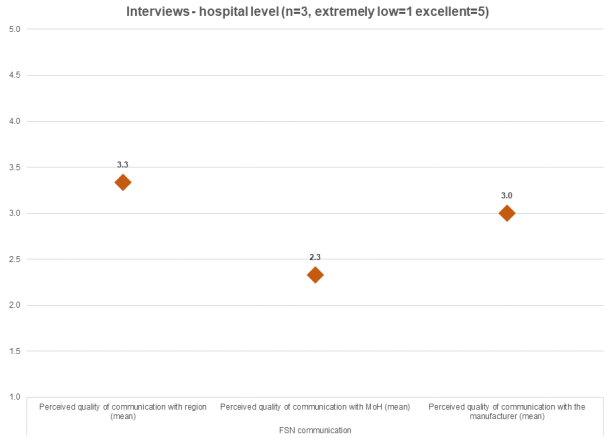
- Several studies pointed out a significant under-reporting of the adverse events (AE) involving MDs.
- The overall burden associated with FSCA for a single product estimated at around 600 million USD, excluding legal expenditures (Fuhr et al., 2011).
- All studies and reports take the manufacturers perspective. Consequences of MD recalls from the perspectives of healthcare providers and healthcare system never been explored (Thirumalai et al., 2011; Ball et al., 2018)
- In few cases, the manufacturer disseminated a protocol for the reimbursement of costs deriving from the recall.
- A clear gap of methodologies for estimating the costs incurred by healthcare providers in case of MD recalls emerged.

- In 2015, the European Court of Justice (ECJ), in the light of product liability, obliged the manufacturer of a defective product to bear all the liabilities for damages caused by the product use.
- According to the ECJ, products belonging to the same of group or series of a product resulted defected are considered defective without any need of a case-by-case assessment.
- Anyhow, the methodology to estimate the reimbursement is not made explicit.

Interviews with 5 regions and 3 hospitals.




Interviews - hospital level (n=3)
100%
80%
60%
40%
20%
0%
100%
67%
67%
100%
0%
Existence of hospital guidelines
Traceability of actions following an MD recall
Availability of a hospital database for collecting FSN
Perception of AEs under-reporting
Existence of prior recall-related cost analysis
FSN management
FSN communication
Recall-related Costs


Interviews - hospital level (n=3, extremely low=1 excellent=5)
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
3.3
2.3
3.0
Perceived quality of communication with region (mean)
Perceived quality of communication with MoH (mean)
Perceived quality of communication with the manufacturer (mean)
FSN communication

DISCUSSION AND CONCLUSIONS

Discussion

- Communication is a critical issue, especially between the hospitals and the Ministry of Health, due to an excess of bureaucracy and the absence of feedback on adverse events (AE) reporting.
- Collaboration between MDs vigilance managers at regional and hospital level is fundamental for improving AE reporting and FSN collection.
- High perception of AE under-reporting both at regional and hospital level due to:
    1. lack of culture on MDs vigilance and surveillance by hospital practitioners;
    2. overwork of physicians;
    3. weak digitalization of AE reporting procedure.
- Two regions (Veneto and Tuscany) regulate recall-related incurred clinical costs (e.g., visits, tests, hospitalizations) within public tenders for the purchase of MDs.
- No experience of recall-related cost analysis performed.

Conclusions

- The adoption of a structured, time-driven activity-based costing (TDABC) methodology for the estimation of recall-related costs is recommended:
    - To identify the processes and the relevant activities.
    - To estimate the resource consumption for each activity.

REFERENCES

Ball GP, Shah R, Donohue K. The decision to recall: A behavioral investigation in the medical device industry. J Oper Manag. 2018; 62:1-15. doi:10.1016/j.jom.2018.07.003.

Ciani et al. Analysis of recalls of medical devices from 2009 to 2018 by risk class and device category based on italian data. ISPOR 2019.

Fuhr T., George K., Pai J. The Business Case for Medical Device Quality. McKinsey Center for Government, McKinsey & Company.
2013. https://www.mckinsey.com/~/media/McKinsey/dotcom/client_service/Public%20Sector/Regulatory%20excellence/The_business_case_for_medi

Judgment of the Court (Fourth Chamber) of 5 March 2015 (requests for a preliminary ruling from the Bundesgerichtshof — Germany) — Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt (C-503/13), Betriebskrankenkasse RWE (C-504/13).

Thirumalai S, Sinha KK. Product recalls in the medical device industry: An empirical exploration of the sources and financial consequences. Manage Sci. 2011;57(2):376-392. doi:10.1287/mnsc.1100.1267.

DISCLOSURES

CONFLICTS OF INTEREST: The authors have no conflicts of interest to declare

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ABSTRACT

OBJECTIVES: Field safety corrective actions (FSCA), communicated through field safety notices (FSN), are actions taken by manufacturers to reduce risk of death or serious deterioration in the state of health associated with use of medical devices (MD) that are already placed on the market. These may include return of the MD to manufacturer or its representative. As the European Medical Device Regulation has tightened up requirements to effectively guarantee safety after marketing, there is a need to identify a methodology to estimate administrative and clinical costs borne by healthcare providers and healthcare systems in case of MDs recalls. The goal of this work was to identify standard methods to use for this purpose.
METHODS: We conducted a review of scientific literature and court sentences. We interviewed Italian regional and hospital MDs vigilance managers asking (i) how FSCA are managed and FSN are collected by public providers; (ii) how the various actors (competent authority, regions, healthcare providers, and manufacturers) communicate and share information; (iii) whether, and according to which methodologies, expenses incurred by providers, as a consequence of MDs recalls, are estimated and refunded. **RESULTS**: MDs post-marketing surveillance appeared as fragmented across the country, with Northern regions characterized by higher maturity and capacity of implementing best practices to manage FSN. All respondents, instead, underlined a weak attitude to report adverse events by physicians due to scarce culture of FSN. No standardized methods to deal with FSCA legal and economic implications have been identified in the literature or in the jurisprudence. Italian regions and hospitals have never quantified the amount of administrative costs related to MDs recalls nor developed a structured methodology to estimate them. **CONCLUSIONS**: A theoretical framework, based on time-driven activity-based costing, to estimate costs related to MDs recalls is under development. Empirical analyses, collaboration among stakeholders and training of healthcare professionals are warranted.