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Reported Serious Adverse Drug Events: a knowledge source for Pharmaceutical Decision Support Systems learning

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Background and importance

Serious adverse drug events (SADE) leads to 10,000 deaths/year (France)
SADE are: death, permanent incapacity or life-threatening situation
SADE reporting to the Haute Autorité de Santé (HAS) is mandatory.
Healthcare professional's are encouraged to report **SADE** to their professional insurance (MACSF)

The modelization of risk situations from SADEs in a Pharmaceutical decision support system (PDSS) contributes to detect them.
It's an innovative way to patient safety

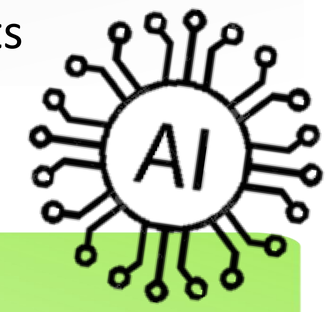
Aim and objectives

Potential of using
SADE databases
to modelize
pharmaceutical algorithms (PAs)
amenable to PDSS

Materials and methods

Three clinical pharmacists analyzed abstracts of reported prescription errors either issued from:
- the national SADE database of HAS
- or the national SADE database of MACSF

Selection of SADE which can be modeled into Pharmaceutical algorithms (PAs) according to 3 criteria:
- existence of a drug-related problem (DRP) with possible solutions
- explicit, encodable, and queryable nature of the assessment elements
- availability of patients' health and care context data in the PDSS regarding assessment elements



Results

The pharmacists selected a sample of 125 SADEs:
→ 57 events (46%) were identified as potentially detectable and preventable (53) or mitigatable (4)
→ **34 PAs** were therefore created
- Most of them involved cardiology drugs (8 PAs, 24%), followed by endocrinology (5) and analgesics (6)

- Modeled PAs would detect these main DRPs:
  - **contraindications** based on patient history (9 PAs, 27%): allergies or organ deficiencies
  - **untreated indications** (5 PAs) (e.g., absence of anticoagulants, antiplatelet agents)
  - **overdoses** (5 PAs) (including anticoagulants and acetaminophen);
  - **inadequate monitoring** (liver enzymes, electrolyte panels)

Conclusion and relevance

SADE reporting system seems a valuable source of PAs for spreading detection of these situations causing patient harm

Artificial intelligence through PDSS use is an innovative way to help professionals in detecting and reporting more SADE related to prescription, monitoring, or side effects.

Nevertheless, administration process is not under scope of PDSS for patient safety

Auger C et al. Serious adverse events in France: a reporting and learning system. International Forum on Quality & Safety in Healthcare. Copenhagen 2020

MACSF GHEMM Groupe Hospitalier de l'Est de la Meurthe-et-Moselle CPN HAS Haute Autorité de Santé