Poisons centres’ case records can increase consumer safety

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Introduction, based on

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ROUND TABLE: ROLE OF POISONS CENTRES IN THE EYES OF THE EUROPEAN PARTNERS

TO INFLUENCE PUBLIC

HEALTH-RELATED DECISIONS

BASED ON WELL DOCUMENTED RISK ASSESSMENT

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... detection of rapidly emerging chemical threats to health (ASHT Project, ECHEMNET)
Daily Service of Poisons Centres

- Traditionally, focus on medical management for individual poisoned patient
  - to treat poisonings in the best way.

- Recently, another role of PC on public health issues has developed
  - to prevent poisonings by toxicosurveillance
Research in Poisons Centres

• ... has been traditionally mainly focussed to

  curative medicine
  – linked to hospitals treating poisonings
  – improving medical treatment of poisonings

• and is additionally focussed on

  preventive medicine
  – improving prevention of poisonings

now and in the future
(local, national, European, international level).
General role of preventive medicine

• Each year, millions of people die of preventable deaths. A 2004 study showed that about half of all deaths in the United States in 2000 were due to preventable behaviors and exposures (Mokdad et al. 2004)

• Exposures (chronic and acute) to chemicals play an important role

… that might be reduced by safer products.
Important aspect of PC research:

Case Documentation
Case Documentation for Curative Medical Purposes...

.. is related to medical scientific needs

• detailed description of severe case or cases with unusual poisons

• with limited need for completeness of cases without or with minor symptoms.
Case Documentation for Preventive Medical Purposes

... is more laborous and time-consuming:

• detailed description of all steps of consultation for all cases

• with strong need for standardisation and completeness

• even for cases without or with minor symptoms
  – those cases may be more important than severe cases
Important aspect of case documentation:

Follow up of cases
Follow up of cases

- Is needed for a complete case dataset for most research issues
- In curative as well as in preventive medicine.

Reasons

- To assign the correct Poisoning Severity Score \( \text{(Persson et al. 1998)} \) and outcome
- Very important to differentiate between exposures without or of minor toxicological concern and intoxications
Follow up of cases in Poisons Centres (PC)

Problems

• Follow up is time consuming
• Is mostly be performed for a subset of cases only
  • that have to be selected
    • by interest of the PC staff (scientific focus)
  • increasingly by external requests
    - authorities
    - industry
Example 1: Request from authorities

• The LiquiCaps Project
Single Dose Liquid Laundry Detergents Capsules (Liquid Caps)

- Child attractive containers
- Concentrated constituents (released in water)
- Lead to many exposures with poisoning concern reported to poisons centres (PC) since 2013
- Lead to conspicuous percentage of more than minor poisonings \((\text{ToxIndex})\) of 15 %,
  - Mainly caused by prolonged vomiting
  - In Europe and in the USA.

- Activities to improve product safety
  - Of industry and of European Commission
EU Regulation No 1297/2014: New Legal Safety Measures

- Bittering agent in covering film material
- capsule more stable against physical pressure
- delayed solution of capsule in water
- outer packaging nontransparent (opaque) ...
- Warning: 'keep away from children'
- into force in June 2015 (Jan 2016)
- Do these measures reduce poisonings?
EU Study on hazardous detergents mixtures contained in soluble packaging for single use (Tender no 406/PP/ENT/IMA/14/119429, short title: „LiquiCaps“)

1. Market analysis liquid capsules (what other products are developed?)
2. Analysis scientific literature on health effects
3. Prospective Case Data Collection in European PCs
4. Evaluation of existing and possible safety measures, with special respect to attractiveness for children
LiquiCasps Prospective Case Data Collection in European PCs

- **8 European PCs** (Bratislava, Dublin, Göttingen, Lisbon, Milan, Prague, Utrecht and the French PC Network) are involved
- performing interviews to investigate circumstances of exposure in order to evaluate and understand to the effectiveness of new safety measures
  - in addition to clinical follow-up
- PC provide project-tailored case datasets to answer the questions asked by the European Commission
  - no other data sources available
Example 2: Request from industry

Challenge: to find the best fitting classification and labelling of products ('mixtures') according to CLP (EU Regulation No 1272/2008)

E.g. for local effects on eye:

- using the official 'calculation method' (CLP Annex 1, chap 3.3.3) might often lead to 'overlabelling':
  - more than 3 % of ingredient classified as irreversibly damaging results in the same classification of the mixture
- no/limited data from animal testing for mixtures

Irreversible effects?

Would PC be of help? -> 2 cleaning product industry association (A.I.S.E., IKW) have sponsored a PC data collection study.
Example 2: Request from industry

- MAGAM II Study: Poisonings caused by eye exposures to household cleaning products
- 2 prospective study branches
- MAGAM II DEAT: 9 PC collected 586 cases, 90% were included in detailed analysis
- MAGAM II DISC (Denmark, Italy, Slovakia and Czech Republic): 4 European PC collected 657 cases, 90% with complete follow-up were included in detailed analysis

➢ Very few exposures lead to more than minor symptoms or irreversible effects (data presented on posters)
Example 2: How to use human case data?

Weight of Evidence Approach in REACH Legislation (on substances):

, ... Weight of evidence is the process of considering the strength and weaknesses of various pieces of information in reaching and supporting a conclusion concerning the property of the substance.

... Expierence of human exposure, such as accidental poisoning or occupational exposure, clinical studies or case reports may be useful to include in a weight of evidence approach. Adequate and reliable documentation shall be provided ...

Conclusion 1

Poisons centres’ case dataset, that were traditionally used mainly
• for curative medical scientific purposes
• for product safety evaluation
In Regulatory Toxicology.
Extra work on documentation of cases and follow up is needed to fullfil the requirements described (adequacy, reliability).
Conclusion 2

Poisons centres‘ have to decide whether extra work on documentation and reporting can be provided

• within externally sponsored projects or
• as part of their regular service.
Conclusion – ... for the future

- As many PC suffer from financial problems
- Extra workload to provide high quality documentation has to be reimbursed sufficiently.
- If reimbursement could be provided on a continuous long-term basis PC would get an important additional role in societies increasing their visibility and meaning.
Thank you for attention

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Case documentation in Poisons Centres (PC)

- Case records are traditionally documented on paper
- Total or part of information is stored in database, for
  - easy retrieval of cases
  - automated report generation
Methods for classification and labeling

Weight of evidence approach to assess substances and mixtures

• Physico-chemical features
• results of in vitro studies
• results of animal studies
• experiences from human exposures
  • today, mainly based on published case reports
    - arbitrary selection with publication bias
  • potential to systematically use poisons centres‘ data
    - unique datasets that cannot be created by anyone else except PCs
Traditional Role of Poisons Centres (PC)

- PC are an important part of emergency medical system in Europe and elsewhere
  - Performing clinical toxicological risk assessment and giving medical advice in individual exposure cases reported is their main duty
  - Case records are documented
  - Cases are followed up
  - all steps need working capacity - continuously
How can follow up of cases be improved

• Better basic funding of PC
  • by competent authorities
  • or additionally by third parties (e.g. Switzerland)
    could lead to a general improvement of documentation with respect to preventive medicine needs

• Performing prospective studies directed to specific problems sponsored by authorities or industry
  • easier to achieve
  • examples are presented
  • a long(er)-term agreements are needed to facilitate PC development
Case documentation in Poisons Centres (PC)

Reasons

• National legal requirements for medical treatments

• Legal reporting requirements
  • e.g. biocide poisoning reports according to European Biocides Regulation (EC No 528/2012)

• Scientific evaluation of cases
  • Traditionally, for scientific documentation of cases or case series
    - to be published and presented
  • for other purposes to be discussed here
Follow up of cases in Poisons Centres (PC)

Reasons

• To assign the correct Poisoning Severity Score (Persson et al 1998) and outcome
• very important to differentiate between exposures of minor toxicological concern and intoxications
Follow up of cases in Poisons Centres (PC)

Reasons

• no legal requirements
• limited unharmonised reporting requirements
  - reason for different percentages of follow up in European PC

• scientific evaluation of cases
  • for scientific documentation of cases or case series be published and presented