



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Early Warning Systems

To detect New and Emerging
Risks of Chemicals, a.o.
Carcinogens

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Early warning systems – what’s the novelty?

Prevent negative impact by *early identification and control* of NERCCs
Important development for policymakers: *proactive action possible*

New and emerging risk:

- (Un)known hazard
- New exposure/use
- Increased risk
- New risk



Methods:

Proactive (“exposure first”)

- Forward looking
- Used in CAD/CMD (risk assessment)
- Deduction

Reactive (“disease first”)

- Signals from the field
- cases, clusters, trends
- Induction



Identification and Evaluation of NERC(C)s

Evidence for causality

- **Signal detection:**
 - Text mining (Literature)
 - Data mining (Databases)
 - Reports (Clinical Watch systems)
 - Active detection (Health Surveillance)
- **Signal strengthening**
- **Confirmation of a Signal**
- **From signal to action:**
 - Risk communication
 - Research
 - Measures



Identification



Evaluation



Measures



Challenges regarding Carcinogens

Identification:

- Physician (curative) may not be aware of occupational exposure
- Latency between exposure and cancer: 30 – 40 years
➡ early signaling even more important
- Retirement: no notification in occupational disease registries
- No report of occupational activities in most/all national cancer registries
- Moving of workers to other countries

Evaluation:

- Group level: epidemiological research – lack exposure data
- Individual level: translation epidemiological research to individuals
 - Difficulties in establishing a causal relationship exposure - effect
 - Historical exposure difficult to assess (latency)
 - Job history: many jobs/exposures that could lead to cancer
 - Mixed exposure
 - Cancer in general or specific type?



Challenges regarding Carcinogens

Possible measures:

- Informing inspection
- Informing professional societies on occupational health+safety
- Check NERC(C) (being) regulated in REACH/CLP?
 - Yes, inform ECHA/evaluating Member State on the NERCC
 - No, start a Risk Management Options Analysis (RMOA)
 - › Derivation OEL
 - › Identification of SVHC and authorization in REACH
 - › Proposal for (change in) harmonized classification/labeling (CLP)
 - › Need for additional information: Substance Evaluation (SEv)
 - › Other legislation (medicine, cosmetics, biocides, etc...)



Early warning systems; identification NERC(C)s

Types of early warning systems:



Clinical watch system:

Collection spontaneous reported cases:

- Health effect
- Exposure



Database on exposure and health effect:

- Hypothesis generation
- Epidemiological research



Biological (effect) monitoring:

Higher incidence of Health effects among Exposed workers?

- Exposure is leading
- Causal effect easier to prove



Availability in Europe of Early Warning Systems

[Palmen, NGM: Early warning systems to detect new and emerging risks in Europe, RIVM letter report 2016-0022](#)

Method: questionnaire sent to 51 European Countries

- Members of MODERNET¹ network
- Research institutions/ occupational health centers

Response:

- Overall: 45%
- EU member states: 64%
- Candidate member states: 60%



¹ MODERNET: Monitoring trends in Occupational Diseases and tracing new and Emerging Risks in a NETWORK



Clinical watch systems

3 types of clinical watch systems to detect NERC(C)s:

- **Designed for the purpose:**

- England and Ireland (THOR)
- France (RNV3P, GAST, OccWatch)
- The Netherlands and Belgium (SIGNAAL)
- Italy (MALPROF)
- Spain (regional initiatives)

- **Can be used:**

- Mainly occupational disease registers in 10 countries

- **In preparation:**

- Czech Republic





Clinical watch systems

Organizations collecting and evaluating possible NERC(C)s:

- Research organizations (n=6)
 - ➔ systems designed to detect NERCs
- Labour inspectorate (n=6)
- Insurance funds (n=5)

EXPERT GROUPS PLAY A KEY ROLE IN THE EVALUATION

Who can notify:

- Occupational physicians, medical specialists and GPs can report in most systems
- Industrial hygienists (4 systems)
- Employers and trade unions (2 systems)
- Self-reporting of workers (4 systems)



Databases

Types of databases:

- Based upon clinical watch system
- Occupational disease registries
- Cancer registries



Owners of databases:

- Occupational health provider
- Institute of occupational health
- Labour inspectorate
- Insurance funds

Epidemiological research often takes place

Expert Groups are available to discuss possible NERC(C)s



Biomarkers to detect carcinogens or mutagens

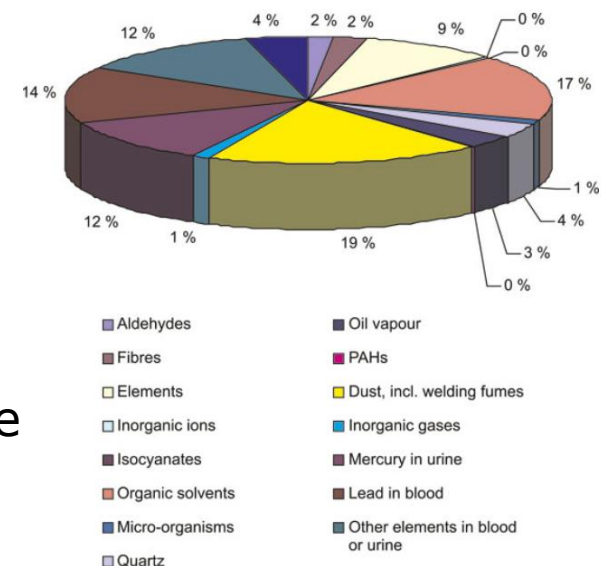
Are biomarkers used?

- Not on a regular basis in most countries
 - Unlike Czech Republic : markers of inflammation and oxidative stress
 - Unlike Romania: sputum cytology, micronuclei test, chromosomal aberrations
- If so, than specific in research projects

Who takes the initiative?

- Research institutions
- Occupational health services

Norway: data are collected in the EXPO database
5000 enterprises (n> 120.000)





Summary:

- National early warning systems are available
- NATIONAL expert groups evaluate possible NERC(C)s
- NERCCs: difficult to identify
- European cooperation is essential
 - Identification
 - Evaluation
 - Control





**What do we need to
Identify,
Evaluate and
Control
possible NERC(C)s ASAP!**



Questions to the participants (\pm 100)



Identification NERCCs:

What steps can we take to work together in putting and keeping early warning systems for carcinogens in place?

Evaluation and Control NERCCs:

What steps can we take to better and more rapidly assess the causal relationship between exposure to a potential carcinogen and cancer?



Answers

Awareness raising:

- Physicians → increase cancer registries
- Politicians and policymakers → access occupational health clinics

Data and risk assessment methods:

- More/better data on exposure (ambient and internal)
- More data on type of cancer, the mode of action and potency
- Toxicological effects after inhalation and dermal exposure
- Combined exposure in risk assessment

Interdisciplinary expert groups

- National expert groups
- Institutionalized expert group at EU level

Viewpoint paper was made and will be published



Thank you for your attention