Human Data Initiative
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Is the best being made of human data for risk assessment purposes

- Continuing data gaps (HPV approx 70%)
- Demands to assure safety for all chemicals in commerce
- Animal welfare concerns - refine, reduce , replace
- Stretched toxicology testing facilities
- Scientific uncertainties in risk assessment
- New and emerging hazards – not yet fully understood
- Are we assessing the right things?

Opposite sides of the same coin

Risk Assessment/ Regulatory Toxicology ⟺ Clinical Toxicology Poisons Information

Why do we need to combine forces ?

- Poison Centres – preventive role as well as managing the effects of exposure
- Regulatory Toxicology – responsibility to show effectiveness
- Why hasn't it happened before ?
  - Different demands on time
  - Not aware of value of working together

Edinburgh Meeting – Sept 2001

Much to be gained from risk assessors and poison centre experts working together

Recommended that

- Effective dialogue needed
  - (also to include other specialized disciplines e.g. occupational toxicology and medicine, forensic toxicologists and molecular toxicology)
- Elaborate specific scientific and methodological issues – where human data might be useful
- Assess the feasibility of using poison centre information to identify case studies rich in human data

Possible uses -

- Implementation of Globally Harmonised System for Classification
- International Chemical Safety Cards
- Labels and MSDS
- Use in developing relevant classification criteria e.g aspiration

Possible Uses

- Prioritisation of risk assessments to meet actual needs
- More relevant information on circumstances of exposure

Why is timely for IPCS to initiate work in this area now ?

Priority for international policy

- Risk Assessments use all available information
  - A2 Cooperation of developing countries and countries with economies in transition ….. To ensure all relevant data used
  - Consider new priority for action on increasing public availability of information
- Capacity Building
  - D7 – by 2002 poisons centres established in 30 or more new countries ….strengthened in 70 that already exist
  - D7 by 2002 – extensive progress on national systems for collection of harmonised data – including poisoning cases

Feasibility Study - Chemicals

- Ethylene Glycol
- Methyl acetate
- Methylmethacrylate
- Cyclohexane
- 2-(2-methoxyethoxy)ethanol
- Hydrogen fluoride
- Hydrogen cyanide

Priority at regional and country level

- Changes in EU chemicals policy
- EU Initial Evaluation work showed 34/41 chemicals needed further work
- Relatively high proportion of consumer chemicals – missing information to identify chemicals of concern
- European Environment Bureau –
  - Late Lessons Learned from Early Warnings

Priority for Re-designed IPCS

- Cross-Cutting Issue
  - Global Poison Centre Networking
  - Risk Assessment of Specific Chemicals
  - Risk Assessment Methodology
  - Global Burden of Disease Estimates
  - Vulnerable Populations
  - INTOX

INTOX

- Data Management System
- CD ROM Database
- Global Network of Poisons Centres

INTOX Data Management System

- Harmonised Standardised Formats
  - Clinical cases
  - Product Composition
- Controlled Terminology (with definitions)
  - Definition of fields and terms used
  - Translation – e.g English, French, Spanish ….Chinese.
- Harmonised System
  - Chemical structures
  - Uses and Functions
  - Signs and Symptoms
- Poisoning Severity Grading

Feasibility Study

IPCS working with Poisons Centres and Regulatory Community

Feasibility Study - objectives

- Test availability of information
- Identify specific retrospective cases
- Identify chemicals rich in human case data
- Compare data routinely collected
- Explore how INTOX might be used to aggregate case data
- Usefulness of risk assessment reports

Feasibility Study – Poisons Centres

- Japan (Tokyo and Osaka)
- UK (London)
- Uruguay (Montevideo)
- France (Lille)
- Switzerland (Zurich)
- Australia (Perth)
- Germany – Multi centre Study 10centres/BGVV

Feasibility Study – Preliminary Results

- Reports being finalized by participating poisons centres
- Reports received from
  - France
  - Japan
  - Germany
  - Uruquay

Feasibility Study – Preliminary Results (Availability of Information)

	Ethylene Glycol	Methyl Acetate	Methyl Methacrylate	Cyclohexane	Methoxy Ethoxy Ethanol	Hydrogen Fluoride	Hydrogen Cyanide
Uruguay	5	-	-	3	-	-	2
France	206	206	27	-	-	105	17
Japan	18	-	-	-	-	101	3
Switzerland	61	160	-	3	-	160	87 (salts)
Australia	32	-	-	-	-	17	3
Germany	68	4	9	5	3	222	48

Feasibility Study – some initial comments

- Yes – poisons centres can retrieve information
- Specific chemicals not often linked to product names
- Mismatch between substances of concern to regulators and poisons centres ?
- Some centres have other relevant data – e.g. occupational

Feasibility Study – Follow-up work

- Input data as far as possible into INTOX-compare – refine INTOX reports for human data initiative
- Identification of prospective chemicals for case study – e.g. ethylene glycol
- How to link INTOX collected data with other data collection systems

Feasibility Study – Next Steps

- Reports being finalised
  - To include top 10 specific chemicals reported
  - Assessment of risk assessment proirities and call data
  - Brief evaluation of risk assessment reports