



INPHET Working Party 3: “Ethics and Confidentiality”

May 14th and 15th, City of Modena, Italy.

Working Party Report

FINAL V1.0 7/10/14

Chairs

The working party was chaired by Lisbeth Knudsen (LK), from the Department of Public Health, University of Copenhagen, Denmark, and Tony Fletcher (TF), Environmental Epidemiologist, from Public Health England and the London School of Hygiene and Tropical Health. The rapporteur was Helen Crabbe (HC), Environmental Public Health Scientist (Epidemiology and Surveillance), Public Health England.

Objective:

To consider what ethics/confidentiality concerns do we advise to pay particular attention to in upcoming INPHET projects? To review ethics and confidentiality in recent epidemiology and surveillance projects we have each been involved in.

Attendees

The following participants attended the workshop:

Edoardo Bai (EB), ISDE, Italy

Claudia Bellucci (CB) University of Modena, Italy

Luca Carra (LC), ZADIG, Italy

Susanna Conti (SC), National institute of Public Health, Italy

Tommaso Filippini (TF), University of Modena, Italy

Alfonso Gelormini (AG), Eni SpA, Italy

Paolo Lauriola (PL), ARPA Emilia-Romagna, Italy

Silvano Piffer (SP), Azienda Provinciale per i Servizi Sanitari, Italy

Francesco Venturelli (FV), University of Modena, Italy

Ben Wheeler (BW), European Centre for Environment and Health, UK

Tommaso Trenti (TT), Local health Authority, Modena Italy

Adriano Zavatti (AZ), Italy

Pre meeting information

Background documents were circulated to the attendees before the meeting for background reading; -‘Research ethics: How to Treat People who Participate in Research’ by the U.S. National Institutes of Health Clinical Center Department of Bioethics, by Ezekiel Emanuel, Emily Abdoler and



Leanne Stunkel.¹ And the UK Medical Research Council's ethics series: 'Good research practice: Principles and guidelines,' MRC, July 2012.²

Working party (WP) participants were asked to prepare by considering ethics principles in relation to environmental public health tracking examples, such as waste management, and public communications issues.

Each participant was invited to share experiences relevant to one of the issues above, e.g. a particular project and its confidentiality or ethical obligations, and/or some principles which would be useful for the INPHET network going forward. Delegates were invited to provide a brief overview of relevant case studies where ethics and confidentiality placed a key role in tracking projects.

A report from the FEHES project summarizing arrangements across Europe by Susanna Conti, was also circulated prior to the meeting (see section below).

Questions to consider

Delegates were asked to consider the following questions during the working party.

- 1 What are the key principles, legal obligations and concerns on ethics and confidentiality, relevant to EPHT?
- 2 What experiences (positive and negative) do have in implementing these principles in surveillance, research and tracking?
- 3 Each WP is asked to consider and propose topics for planned projects in INPHET.
- 4 For INPHET planned projects, what ethics/confidentiality concerns do we advise to pay particular attention to?

Presentations

Paolo Lauriola: Understanding of health effects on decision making concerning waste.

Paolo presented some thought provoking questions on the ethics of Science and decision making processes. Questions posed included 'Who must provide the evidence?' 'What quality of evidence is good enough?', and 'What type of evidence is acceptable?'

The traditional approach to public health protection is based on the approach of the association between exposure and risks and health outcomes. This is subject to many influences, e.g. first type errors- false positives and false negatives, which is probably more important in prevention. Therefore the level of evidence of knowledge on associations determines this. This is the basis of

¹ http://bioethics.nih.gov/education/FNIH_BioethicsBrochure_WEB.PDF

² <http://www.mrc.ac.uk/news-events/publications/good-research-practice-principles-and-guidelines/>

evidenced based medicine- determines what value or weight should be given to different studies of effect.

Without time series data, it would be impossible to prove the effects of air pollution on health. But what is the level of uncertainty and understanding? How much confidence should we put into the assumptions made?

The focus on less strong risk factors or associations may be more important than larger known effects and risks. The strength of evidence is of course important e.g. the Bradford Hill criteria. However, following the Precautionary Principle (PP)³, we should not wait for better evidence, before taking action.

The required standards of evidence depend upon the context; the determination of evidence (consistency) and evidence of effect. The PP does not mean blocking activities. A good example is the application to waste management and making decisions on waste management options.

Susanna Conti (SC)- National Institute of Public Health (ISS), Rome, Italy.

SC presented some work from the conclusions of the FEHES project – ‘Feasibility of a Health Examination Survey’⁴. A report of the findings of work package (WP) 7 – ‘Effects of Legislation’ titled “ The most relevant issues regarding ethical and legal aspects in surveys regarding health, conducted in Europe: experience from an European Project” was circulated to all participants before the meeting.

The work package report outlines (in application to ethics in medical research) the most important documents and also for safeguarding privacy, covering data protection and subject rights. E.g. EC Directive 95/46/EC-for the protection of personal information. SC outlined the definitions of commonly used terms, used to describe issues in sensitive data and data protection, as these vary in legislation.

The rights of access of personal data vary across Europe as each country implements and interprets its own version of the Directive in local laws. Commonly though, the transfer of personal data to other countries is restricted. This has significant impact when sharing data between different countries.

³ In 1992 the Declaration of Rio, as a result of the United Nations Conference on Environment and Development, the item 15 states: “In order to protect the environment, wide measures of precaution must be applied by all nations according to their ability. In the face of risk and serious or irreversible damage, the absence of scientific certainty should not be a pretense to put off the adoption of efficient measures directed at preventing the degradation of the environment”

More recently (November 17, 1998) the General Committee XXIV (General Committee “Consumer policies and Health Protection”) defined PP as “A risk management approach in a scientifically uncertain situation, which calls for **action** in the face of a proportionally serious risk without waiting for the conclusive findings of scientific research”

See also: EEA Report No 1/2013 (<http://www.eea.europa.eu/publications/late-lessons-2>)

⁴ www.thl.fi/fehes/



Written and informed consent:- issues include the future uses of data and the possibility to withdraw.

The results of the survey for each country on the controls on data protection, are summarised in the WP report circulated. The wide variation between countries was evident, e.g. in the requirement for approval from ethics committees and the controls imposed.

In January 2012- the EC proposed a reform of EU data protection rules, to make it fit for the 21st century. The 1995 directive needed updating with respect to internet use and the widespread use of mobile phones etc. The proposal was for a regulation from the European Parliament for the processing of personal data and on free movement of data. Protection for preventing criminal activities was included. The proposals are currently being discussed by two EU co-legislators; the European Parliament and Council of the EU propose a 'new data collection proposal for Europe'. The agreement on data protection reform is possible before the end of 2014.

There are benefits for citizens, as this will make it easier to have access to own data. There is a need to harmonise the conditions for health data processing across Europe. The right to opt out of registries is not however covered.

A discussion followed that discovered that institutions conducting cohorts studies, etc, could be restricted in accessing information if no specific consent for the actual study was present. In several countries, the new proposal limiting access to data is criticised, e.g. as it would stop follow-up studies in cancer registries. This would lead to a loss of important data streams as data is too protected. This has the potential to make data sharing too controlled and restricted. The issue of the right for public health to have access to data for the public good was recommended.

Luca Carra (LC)- ZADIG, Italy. Risk Communication.

LC is a science journalist from Milan. He reports on epidemiology studies and ARPA ER. He reports on the awareness of the importance of data. Data journalists are important reporters of the application of data in epidemiology and tracking studies.

LC reported on the variability of risk perception and the public reaction. Risk and the 'outrage factor' were important in the interpretation of hazard and risk. Outrage is the emotive part- on the perception of risk- other than the scientific and technical parts. Misjudging risks and tolerance were common issues. Risks are more worrying if they are perceived as being involuntary, unequally distributed and cannot be managed. Luca outlined the mechanisms of media coverage in application to health topics: and by hyping the problem the result may be stirring up fears. The US EPA rules on environmental health communication is a good model of practice.

An outline of how to manage risk communications, to control the outrage factor is suggested to include transparency and monitoring.

The importance of data monitoring, as applied to Environmental health, was stressed as a measure to increase the public's trust of control over the situation. The waste sites in Italy are good examples.



Public concerns highlight the lack of data, so to provide some test data is a good start. However, this strengthens the need for data understanding of scientific terms, e.g. probability, uncertainty etc.

The use of data for advocacy, political statements etc, highlights the need for the process of capacity building in data understanding, i.e. training for the public to help understand the implications of data and its limitations.

The role of social media was discussed. This has changed from monologue to dialogue with the media, as twitter, etc., allows a two way conversation, however with no evaluation of the credibility of the information passed. People rely less on original sources of information and more on secondary sources. Information is now obtained through intermediators, or other people, through tweets and statements, etc. And the media now provide interpretation. In this context, a question arose if INPHET/EPHT should have a twitter account? There is increasing use of twitter by organisations and institutions and its use in communication.

Applications of 'Citizen Science' and 'open data' was discussed. Citizen science includes the public participation in scientific research. e.g. 'Emitter' in Canada, listing the emitters of pollution, or 'find the pollution in your back yard' type examples. Personalising data outputs via websites, by entering your postcode or zip code etc, allows personal outputs and interpretation. A key message was efforts made in making the data intelligent, help people to understand the data.

Edoardo Bai (EB): ISDE, Italy

EB presented a case study in Italy where human health impacts were estimated from exposure to waste water in Lambro, a town with 25,000 inhabitants, with issues from a historic land use from a company manufacturing dyes and war gases. Public concerns of a well polluted by toluene and many other substances, with 950mg/l benzene measured in the water. Bladder cancer incidents were found to be high, with a relative risks for Females 2.2 – and 2.6 for men. Concerns of TCDD, PCDD and dioxins levels also present. Women polluted in 1966, had double the risk of bladder cancer.

Furthermore he introduced the case of the new construction of a highway, with the movement of contaminated soil. Risk of lung cancer in workers is very high. Remediation of the land is not complete. High levels of PCBs and asbestos, etc are present in up to 20m depth in the ground. There is a need for further research and funding to examine effects. However industrial funding and data protection confound the study; also the role of the mafia, potentially biasing the study. Although the study is authoritative for the local population, conflicts of interests are clear.

Adriano Zavatti (AZ): Arsenic in groundwaters in Italy.

AZ outlined the problem of arsenic in groundwaters in mostly Northern Italy, with levels high in both public and private wells, with a maximum concentration of 200 ug/l but this is variable. The issue is mostly near Milan, but also in south Italy. The Italian limit level is 10ug/l.

Problems arise as there is no standard monitoring of water quality in these risk areas. The public administration fear the media and public reaction in the communications of risk. This has limited the

level of publishing data and monitoring. Some public bodies have under evaluated the problem- so that the water doesn't look polluted. Arsenic is relatively easy to remediate, through water filters, but this is costly. This raises questions of how to inform people and how to assure decision makers? How do we increase interdisciplinary knowledge, to make it clear to both parties? We must use similar language and there is a real need to communicate.

HC and TF outlined a similar case of arsenic in private water supplies, in Cornwall, UK. 6% of wells sampled were over the prescribed concentration limit of 10ug/l. A programme of public awareness and stakeholder involvement has followed and the local authority now monitor arsenic as standard in their monitoring programme. Issues surrounding the publication of results and confidentiality in reporting results on a small scale followed.

Other case studies discussed included waste incineration, pesticides and pollution from steel mills. A common issue of where to site incinerators was also highlighted.

Discussion.

On the second day a second session of the working party followed with a discussion of the common themes arising. A list of questions was circulated by the coordinators, to stimulate discussion. The following themes were important for prospective INPHET projects.

a. Protecting personal data

BW, a health geographer from the European Centre for Environment and Health, UK, highlighted the example of using meteorological datasets and linking them to health datasets, and the governance issue of using personal data to find these links, creates restrictions on the environmental health research that is possible.

Other issues arising included:

- The misuse of data – selling data to other parties, e.g. insurance companies.
- TF highlighted one argument for EPHT is to save money- e.g. in application to the Italian contaminated land sites and the costs for remediation. The tracking role is to highlight and stimulate activities in areas that are not being considered, highlighting the need for the studies that need to be done. Tracking studies are not simply to re-study established relationships - e.g. air pollution and health links have been studied many times. Concerns related to arsenic in drinking water and contaminated land are potential areas for tracking.
- Concern about the over-regulation of data- that prevents enquiry is possible through the new legislation EU Directive.
- Contaminated land investigation and the use of routine clinical laboratory data to trace adverse health effects; In the USA, increased interest in the field of the use of big databases (Big Data) and exploitation⁵. Researchers, health systems, and other stakeholders are generating and exploring huge amounts of clustered information—so called big data—to

⁵ (<http://www.aacc.org/publications/cln/2014/march/Pages/Big-Data.aspx#>)

explain patterns that remained hidden under old data models. Big data has plenty of applications in this field. The initial focus should be to use data derived from laboratory electronic health record (EHR) systems, as clinically selected biomarkers, to improve the evaluation of human health due to exposure to toxic substances, incineration, pesticides, pollution, etc., if suitable data are already present by combining them. Nevertheless, such studies should not be jeopardised, because of issues of protecting personal data. Issues such as informed consent for the individual uses of biomonitoring and biomarkers data; the limits on feeding back the risk related to individual exposure and the clinical markers measured; the limitations in interpreting the role of biomarkers; need to be recognized and carefully evaluated. The need to protect personal identities and personal data was unanimously agreed, although care was needed to avoid data protection Acts that could jeopardise the conduction of epidemiological studies.

- The suggested use of clinical data in EPHT might be a topic for a WHO collaboration.

b. Role of informed consent

TF highlighted the issue of public confidence, on the use of data. In the UK, an initiative called 'care.data' has raised public concern over the use of health data and data linkages without informed consent. The scheme allows care and health data to be shared among health sector organisations (the NHS) without formal consent, to better plan services and ensure continuity of care. The default is allowance of data sharing, although individuals can opt out. Confidence in data security seems low in the general public, as concern about a 'big brother' approach has been reported in the press.

LK: The need for consent has to be made clear, with clear messages of what purposes the controller is using the data for, for what purposes. Can generic consent be given? Informed consent is needed on use of biomarkers. Care is needed on feeding back the risk of exposure or results from measurements of biomarkers with no risk assessment/management. It is suggested to explore the possibility of using data from clinical laboratory samples if data is linked and ethical permission is granted- there is no need for prior consent.

c. Preserving and using archived samples

Human biomonitoring is a tool that may be used to quantify exposure. Potential ethics and confidentiality issues for tracking projects could be limited by starting with less invasive techniques- monitoring the environment first, as a first line of investigation. Human biomonitoring may be then used to justify exposure and effect. For contaminated land, there is a need to identify pathways before biomarkers can be used- identify the chemicals and routes of exposures first. Bio-banks could be used as a gold standard? There is an argument to make use of existing data sources for investigation before setting up new studies.

Biomarkers are good at establishing some exposure routes. Biomonitoring may be part of screening/surveillance. For chemicals where we have good toxicological data, for validated biomarkers, then human biomonitoring can be used as screening method, for exposure/health effects. Biomarkers of effect- clinical data, related to hospital treatment etc, need to be used in the correct application. Can we use such data scientifically, and what do we tell the patients about the

investigation and use of data? Often biomarkers are unrelated to disease or effect. This was flagged as an upcoming issue that we need to discuss and explore.

d. Communicating data back to individuals

Communication of results; there are difficulties of reporting back findings and results and managing expectations- if the public think a solution is available. We need to understand what people think of interventions and solution and how acceptable they are. The concept of “if you are looking for something- you will find something”, e.g. cluster investigations. The good use of Cochrane reviews and the use of screening, e.g. WHO criteria for screening applications could be used and applied to tracking projects, if we can prevent or cure the illness.

e. Making the public health case for using population data

Questions over the use of pooling results of samples- so that anonymity is assured. e.g. individual blood samples pooled? This use is dependent upon the application, e.g. incinerator epidemiology study of the effect of exposures on pregnancy. There is a need to follow up cases to explore exposure to examine effects in the future. By removing personal data the level of detail is lost as ‘losses to follow up’ would be difficult to identify.

The issues of ethics when collecting data and removing personal details arose, where data is collected for a different purpose. This highlighted the role of informed consent. Study persons need to be told what exactly what they (or their data) are going to be used for.

The use of medical data was offered, as clinicians have a lot of data on pathology, exposures, and clinical symptoms. Clinicians would want to share the data in order to help diagnoses and interventions. However strict control by data protection laws prohibit this. Big data ideas and applications could help answer important environment/health linkage questions. Information on location- address, sex, age, occupation etc, can clarify potential exposures. There is a need to anonymize data in order for it to be used. One participant, being a medical doctor, reported that he had access to some 14 million records a year – being 50,000 test results since 2005. The use of this data, if it was possible to use, would be a biased sample, as it is subject to referral routes, reporting biases through hospital data, and the subjects are already selected as having ill health. The offer prompted interesting debates on the availability and restrictions of this type of data. A geographical confounding or bias could occur as there are uneven referral rates– as one hospital or clinician may favour one type of test. Individual clinicians make choices of which tests to use, so referral rates and sample numbers would be heavily biased and geographically biased. Nevertheless this type of data could be used for general trends.

Communication was a key issue to include in tracking activities. e.g the use of Google analytics and use of key words or hashtags, e.g. flu, or environmental hazard, etc, for ‘tracking’ popularity of web search terms and possible indication of the incidence or prevalence of disease or exposure in the

population. Or sentiments, e.g. vaccine- can try to analyse public sentiment on topics, or the 'outrage factor' related to environmental issues. This technique was used in the Triple S project⁶.

f. Addressing concerns related to partners' self interests (eg industry)

The general population has interest in knowledge about individual exposure and the relation to risk, risk management and prevention. This must be communicated in a sober and scientifically unbiased way with reference to validated monitoring data and confirmed associations to adverse health effects. Sober communication may be hampered by competing interests, e.g. from the polluting industry not allowing release of data revealing increased risk. The increasing use of social media for communication and information exchange raises the question of validation of information given e.g. by critical review.

Case study: 'Terra de fuochi' near Napoli, Italy.

'Terra dei fuochi' or 'Land of Fire' is an example where ethical and confidentiality issues arise in the reporting of health effects through pollution caused by the illegal dumping of contamination on land and in water. Screening of the general population to pick up potential exposures was proposed by the Italian Ministry of health. SC was asked to advise on the benefit of mass population screening. It was suggested to screen 1.3 million people. Advice highlighted the huge cost of this programme and the potential problem of false positives. Screening of the general population is often seen by media or public as the solution to an environmental problem. Hospitalisation rates could infer exposures and health effects, but issues of different admission criteria across hospitals confound this. The practical issues of screening over 1 million people include confounding by fish consumption and liver complications, and isolating any environmental exposure effect. In not doing screening, there is a public perception of suspicion and cover up. Thus there are potential problems of communicating environmental exposures and effects.

Data from the case study was to be produced at an aggregated level- e.g. local health authority level. So informed consent was not used, but normal ethics examination was used for the study. Pathology, oncology and cardiovascular health outcomes and examinations were outcomes used in the study.

55 towns were involved in the 'terra dei fuochi' – but the legal definition only includes 38 towns. These towns received central government funding for examination. Other towns did not, creating a political tension. 57 national Italian sites were classed as having contamination of the soil from measurements. But other areas were not included- but still just as contaminated. Some sites were downgraded as regional- not national contamination sites. Some sites are the subject of other pollution, but they are also very deprived areas. Outcomes have been standardised, i.e. adjusted by deprivation indices. Socio-economic deprivation index was used, based on census data, unemployment, number of people living in poverty etc. However the outcomes show not much difference between adjusted and non-adjusted results. Cancer registries data was used successfully.

⁶ <http://www.syndromicsurveillance.eu/>

The Region of Campania wanted a cancer registry system to manage health status and disease levels in the region.

Trust is an overarching theme for the public institutions. The reputation of the institutes involved is good but public trust is low- if they say that the land is not a hazard. But the general consensus is that the public are willing to participate in programme of investigation- for medical checks. This screening hasn't started yet. GPs will invite patients and they expect a high participation. The programme will cost 50 million euros for a 2 year investigation which is funded by the national government.

How can we relate this to EPHT? Is it a model to follow, although being an expensive model? The methodological study is not ideal, as there potential geographic variations in GP diagnostic practice and referrals. In Italy, GPs are gateways to the health system. Referral rates could bias the investigation. It was suggested to concentrate on regional centres to screen with standardised protocols and methods.

Is there a remediation strategy? Is surveillance activity needed? What is the role of tracking in this?

The contamination was thought to come from old industrial uses of the land; - steel plants, textile, petrol refineries, asbestos production sites and a pesticide factory were all present since the turn of the century. Contamination entered into ground water and soil. Known pollution and chemicals can be tested for. But there was also illegal waste sites, which are harder to measure and know what is there. Responsibility is the issue- who owns the land, who's responsible? It involves very large sites- e.g. 1 km in size. How do you prioritise clean up and sites? These are political decisions that come with ethical considerations.

How will the tracking programme help in the priority of action? Is it based on cost, or health conditions? The provision of urgency and cost is needed. Should determinants include public outrage and concern or be based on risk assessment? Tracking can help highlight the health burden issues- mortality and morbidity, e.g. hospital admissions etc. by surveillance. Excess of cases and proof of evidence and strength of evidence play a key role.

Similar queries over measuring the effect of EMF exposure and use of epidemiological data arose. The use of personal data and DNA or personal profiles was raised in such similar cases.

Summary:

Presentations were given in the working party that highlighted some common themes in the concepts of ethics and confidentiality in future INPHET/tracking projects;

- Evidence, science and uncertainty
- European variations in data protection rules/EU directives
- Risk perception and risk communication.

The following case studies and exposures were reviewed;

- Sentieri/Burning waste and contaminated land

- Arsenic in drinking water in the Po valley, Italy and Cornwall, UK
- Industrial pollution – to air and land.

Themes

Issues discussed:

- a. Protecting personal data
- b. Role of informed consent
- c. Preserving and using archived samples
- d. Communicating data back to individuals
- e. Making the public health case for using population data
- f. Addressing concerns related to partners' self interests (eg industry).

Conclusions from the working party

Some conclusions of our discussions;

1. Personal data: We need to protect access to personal data for assessing local environment-health associations. However care is needed to avoid implementation of EU data protection rules jeopardising the opportunity for public health use of such data.
2. Role of biomarkers: Potentially useful for EPHT studies, but need to prioritise the least invasive, and recognise limitations in interpreting biomarkers, eg short half-lives
3. Of course we need informed consent for the individual uses of biomonitoring data.
4. Need to be careful on feeding back the risk related to individual exposure markers or clinical markers, and may be impossible in some cases.
5. Should explore possibility of using accumulated lab samples if they can be geo-referenced and if ethical approval is given. Probably does not need prior informed consent.
6. Main emphasis is population (rather than individual) use of data to characterise risk, as individual data may be very difficult to interpret in terms of risk.
7. Communication – consider analysing public concern, e.g. in twitter or Google searches to identify perception of environmental problems as part of surveillance.

Report prepared by Helen Crabbe, Lisbeth Knudsen, Paolo Lauriola and Tony Fletcher
August 2014.