

16 August 2005

AMENDED PROTOCOL FOR LONG TERM MONITORING OF THE HEALTH OF LOCAL RESIDENTS FOLLOWING A CHEMICAL EXPOSURE IN OCTOBER 2000

SHORT TITLE:

THE SANDHURST CHEMICAL INCIDENT (OCTOBER 2000) LONG TERM FOLLOW-UP STUDY

(ONS ref: MR743; THE GLOUCESTERSHIRE CHEMICAL INCIDENT FOLLOW-UP STUDY)

1.0 AIMS:

- 1.1 To provide health information for local residents and inform West Gloucestershire PCT of any special health needs arising from the incident.

2.0 OBJECTIVES:

- 2.1 To look for evidence of excess cancer registration rates and mortality rates in the study population associated with an acute chemical exposure in 2000
- 2.2 To increase knowledge of the health impact of such events and disseminate it to a wider audience.

3.0 BACKGROUND

- 3.1 The Cleansing Services Group (CSG) site at Sandhurst was a licensed chemical waste transfer station and treatment facility jointly regulated by the Environment Agency (EA) and the Health and Safety Executive (HSE). A fire occurred at the facility at 02.00 on Monday 30th October 2000 during severe weather conditions.
- 3.2 Over 177 tonnes of organic solvents were ignited. Other chemicals involved in the incident included chlorinated solvents, pesticides, waste laboratory chemicals, mercury, zinc and cyanide. A small amount of low-level radioactive material and BSE contaminated waste was later found to have been stored on the site.
- 3.3 A plume of smoke from the explosions and fire was driven by the high prevailing wind in a predominantly north north-easterly direction over the village of Sandhurst, later veering to the east over Twigworth. Residents living close to the site were evacuated during the acute incident but allowed to return on the evening of Monday 30th October 2000. Residents were evacuated again when extensive flooding prevented access to the site by emergency services.
- 3.4 The major potential vector of pollution is considered to have been the airborne plume during the acute incident. However the potential for waterborne exposure to possible backflow of chemically contaminated floodwater, to airborne exposure from post fire gassing or further leaks of chemicals at the site and to slow evaporation of deposited solvents from the soil have also been considered. Immediately after the incident environmental monitoring was not possible. However, there were many anecdotal accounts from local residents of pollution occurring as a result of both the fire and subsequent flooding. Nevertheless, from its subsequent environmental monitoring the Environment Agency could find no evidence of significant contamination in floodwater, vegetation or soil. Health

studies have therefore concentrated on populations living under the modelled path of the plume where the majority of health effects would be expected to be concentrated and if present in great enough numbers, to be detectable by current statistical methods.

- 3.5 Complaints of illness were first received on Tuesday 31st October 2000. A Health Surveillance survey carried out in November/December 2000 and followed up in June 2001 concluded that a physical and/or psychological health effect following the fire could be demonstrated for some local residents. Some local people reported continuing symptoms seven months after the incident. Blood and urine samples from some emergency services staff were screened for a range of chemicals with no positive findings. Expert medical opinion has suggested that in the case of one individual a causal relationship between the onset of illness and exposure during the incident is probable.
- 3.6 The site changed ownership in 2003 and no longer operates as a Waste Transfer Station.

4.0 STUDY RATIONALE

- 4.1 The PCT seeks to identify sections of the community that are experiencing particularly poor health and subsequently to give the highest priority to effectively addressing their special circumstances and needs.
- 4.2 Due to the strength of community concern following the incident, Gloucestershire Health Authority undertook to set up a long term follow up study of the health of local people. It was clear that the statistical power of such a study would be low due to the small numbers of residents involved and the lack of information about exposure. Lack of statistical power is a common occurrence in small studies of exposure incidents and reduces the ability of researchers to draw robust conclusions.
- 4.3 An initial proposal to use an established research method to analyse mortality and cancer registration rates from ONS tagged records over 20 years using Kaplan Meier Survival Analysis was developed and received local ethical (LREC) approval in 2002. There have been a number of delays in setting up the study relating to changes in legislation affecting data collection and the requirements of Section 60 of the Health and Social Care Act which were beyond the control of the local researchers. However the data flow has now been established.
- 4.4 This study seeks to address some of the local concerns over the long-term impact of exposure to the acute incident. Funding has been set aside but the study must still meet criteria of being an effective investment of health resources.
- 4.5 In June 2004 experts in exposure assessment were consulted by the PCT to assess the quality of the data available to the study and to advise on what impact this might have on the analysis of the study. The key recommendation of the assessment was to redefine the 'exposed' population based on further plume modelling studies carried out at the University of Birmingham by Professor Sir Roy Harrison and his team.

5.0 METHODOLOGY:

- 5.1 A literature review of key studies will be undertaken to underpin the methodology and set findings into the context of current knowledge. The review will be updated regularly during the lifetime of the study.

- 5.2 The proposed study uses a well established research method to look for differences in the community health experience. Mortality and cancer registration rates for the exposed population will be obtained and analysed by using an identifier on individual medical records ('tagging') and compared with a non exposed group. Tagging is a fee-based service offered by the Office for National Statistics (ONS).
- 5.3 The original study population was composed of all residents in the parishes of Sandhurst, Twigworth, Longford, Down Hatherley, Walworth, Maisemore, Ashleworth, Norton and Priors Norton on 30th October 2000. Plume dispersion modelling was used to estimate exposure to the effects of the incident. Subsequently additional plume dispersion modelling using the ADMS 3 model carried out by Professor Roy Harrison at the University of Birmingham has supported the community view of a wider geographical area of potential exposure. Members of the 'new' potentially exposed population defined by this model are captured within the original study population of exposed and non exposed populations.
- 5.4 Sample size selection methodology. The study offers an over 90% chance of detecting a difference in death rates of 10% or more over 20 years. However it is unlikely that the very high level of exposure needed to produce such a change will have been achieved across the whole of the original study area. The smallest difference (odds ratio) that this study would have 80% power to detect is 6%. However expert opinion suggests that with such a short exposure (hours rather than weeks or months) it is unlikely that a difference as large as 6% this will be seen i.e. it is likely that the study will be unable to detect any anticipated differences. Increasing the size of the control group to 20 000 would change the smallest detectable difference to 5% but this would be unjustifiable in terms of any potential gain. In addition a difference of 20-50% would need to be seen before robust claims on attributing risk to exposure could be considered.
- 5.5 Redefinition of the potentially exposed population necessitates the selection of a 'new' control population. It is proposed that the principal comparison group will now be a selected 'basket' of parishes in Gloucestershire with similar death rates (prior to the incident), deprivation and other indices, but well away from the path of the plume.
- 5.6 The study will aim to compare health experience in terms of death rates and cancer registrations of the redefined exposed population (i.e. the entire original population) and the new control 'basket' of parishes. The exposed population will be divided into higher and lower exposure cohorts as defined by the plume model to look for a 'dilution' effect. Other comparisons between sub groups of the study population will be considered where appropriate.
- 5.7 Selection of the new control parishes is critical to the outcome of the study, and the project team wish to have external expert advice on this aspect. Therefore, a methodology for selecting new control groups in Gloucestershire will be developed with advice from the Small Area Health Statistics Unit (SAHSU), Imperial College, London. The new control parishes will be selected from parishes in Gloucestershire that are known to be well outside the path of the plume. The chosen parishes must also match the original parishes on a number of agreed characteristics, including death rates prior to 2000, age and gender profile, and socio-economic characteristics derived from the 2001 census. It would also be wise to avoid areas where anxieties over other environmental hazards are present. Details have yet to be agreed with SAHSU.

- 5.8 Experience in the original parishes shows that it will not be practicable to obtain individual consent for access to death and cancer registration records. The response rate to the original health questionnaire, two weeks after the incident in the immediate area, was only 60%. Therefore an application under Section 60 of the Health and Social Care Act 2001, to access these records without individual consent, will be made when the detailed methodology has been established, but before the control area is selected.
- 5.9 The period of comparison will need to be amended, as data are not available on the 'new' control population earlier than October 2002, i.e. 2 years after the incident. Name and address data for Gloucestershire at this date have been saved under the custody of the head of the Family Health Services registration team, pending Section 60 approval for this study and selection of the control parishes. Data for people who moved away from the control area before October 2002 cannot now be retrieved. It is therefore proposed that no comparison of health experience is made between the original and new areas for this period, but that the overall length of the comparison remains unchanged at 20 years by extending the study period for the potentially exposed group to 22 years, i.e. finishing data collection in October 2022.

6.0 ETHICAL CONSIDERATIONS

- 6.1 It is a requirement of studies conducted under Section 60 that the affected communities must be consulted on a proposal to access health records without individual consent. Public representatives in the new control group areas will be informed and consulted on a range of options for delivering information about the study to their community including written information, a telephone information line and media coverage.
- 6.2 The project team is mindful of the potential for causing concern in the (yet to be selected) control parishes. In consulting the communities in the selected parishes, it will be important to clarify the reasons for including their areas when there has been no local exposure to chemicals, and the rationale for undertaking a study with a relatively small chance of a definitive outcome.
- 6.3 The research team are aware of the disadvantages of the low statistical power of this study but have given weight to the argument from the community representatives that, in their view, a difference of greater than 6% cannot be excluded and therefore the study should go ahead. It was the community representatives' view that, in the event that no significant difference is found, the study may provide a degree of public reassurance. On balance, the PCT felt that this was a reasonable course of action.

7.0 PROJECT MANAGEMENT AND GOVERNANCE

- 7.1 Long term health monitoring of this population has been the responsibility of West Gloucestershire PCT since April 2002. The Principal Investigator for the PCT and chair of the Project Steering Group (PIAG) and Project Team is Dr Hugh Annett, Director of Public Health for West Gloucestershire PCT.
- 7.2 The Project Steering Group (terms of reference attached) has been set up to oversee the work of the Project Team. Membership of the Project Steering Group is drawn from the involved agencies and the local community to ensure that the concerns of the study population, the public and the stakeholder agencies are addressed. At the first meeting on 13th July 2004 the group agreed to implement

the recommendations of an Exposure Assessment Study carried out in June 2004.

- 7.3 Gloucestershire Research and Development Support Unit (RDSU) will undertake data processing and analysis and the Health Protection Agency will provide expert advice on interpretation. The Project Team will report to the Project Steering Group.

8.0 DISSEMINATION OF FINDINGS:

- 8.1 From 2005, a progress report on the study will be presented in the Annual Health Report of the Director of Public Health which is widely available. The report can be freely reproduced in local publications.
- 8.2 It is important that the recipients of the results of the study (the PCT and local people) are made aware of the limited ability of this study to demonstrate, monitor or predict health outcomes as a result of this exposure incident. Health risks will be expressed in terms that are readily understood and presented in ways which do not give rise to unnecessary fear in the community.
- 8.3 The results of the study will be made available to agencies or others wishing to undertake training on the public health issues which have been exemplified during this incident.

9.0 COSTS (2003 PRICES):

- 9.1 West Gloucestershire PCT has agreed to meet the costs of this study, including the staff time of the RDSU and the fees payable to the Office for National Statistics.

**PROJECT STEERING GROUP FOR
THE SANDHURST CHEMICAL INCIDENT (OCTOBER 2000) LONG TERM FOLLOW-
UP STUDY**

TERMS OF REFERENCE SEPTEMBER 2004

Purpose

To advise the project team on all aspects relating to the implementation of the study, and to ensure the manner in which the study is conducted and reported conforms with best practice and meets all reasonable expectations of the various stakeholders, especially the residents in the study area.

Terms of Reference

1. To oversee the implementation and reporting of the Sandhurst Chemical Incident (October 2000) Long Term Follow-up Study ("the study") (ONS ref: MR743; The Gloucestershire Chemical Incident Follow-Up Study).
2. To provide expert advice, or assistance in identifying sources of such advice, to the project team on all technical aspects of the study, including the strategy for analysing the cancer registration and mortality data.
3. To keep under review, given the long-term nature of the study, the continued relevance of the study objectives and analysis strategy, and to agree any changes that may be justified in light of new scientific knowledge.
4. To ensure the study team conduct and report the study in an open and transparent manner, respect confidentiality and remain sensitive to the concerns of the study population, the public and the other stakeholders including, Tewkesbury Borough Council, other concerned local authorities the Environment Agency, the Primary Care Trust and the wider health community.
5. To ensure the project team prepare and put in the public domain an annual report on the progress of the study.
6. To identify and bring to public attention any evidence that the study uncovers of any adverse health impact on the study population.

Accountability

The Steering Group is accountable to the Board of the West Gloucestershire Primary Care Trust primarily and will also inform the CSG Community Response Group, The Major Incident Co-ordinating Group and the Local Research Ethics Committee.

Membership

Director of Public Health, West Gloucestershire Primary Care Trust (Chair and Principal Investigator)

R&D Coordinator, Gloucestershire Research and Development Unit (study team member)

Medical Statistician, Gloucestershire Research and Development Unit (study team member)

Consultant in Communicable Disease Control, Health Protection Agency, Gloucestershire
(study team member)

Representatives/Members of the study population (two)

Environmental Epidemiologist, Chemical Hazards and Poisons Division, Health Protection
Agency

Representative, Tewkesbury Borough Council

Representative, Environment Agency

Integrated Pollution Prevention and Control Co-ordinator

Co-opted members as necessary to be agreed by the Group

Quorum

At least one representative from the community and one member of the Project Team must be present for a meeting to be quorate

Frequency of meetings

The Steering Group will meet annually to agree the Annual Report and more frequently when necessary at the request of members.