

HSE investigation of leukaemia and other cancers in the children of male workers at Sellafield : review of results published in October 1993.

Contributors

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INTRODUCTION

1. The report of the HSE investigation was published on 20 October 1993 after 3½ years of work. Until the final few weeks when the report had been sent for printing, and during which the Sellafield workforce were briefed on the results, contact with BNFL and AEA was kept to the minimum. In accordance with the protocol, all of the data were obtained in a manner which ensured that the identities of the study subjects were kept secret from all but the few people within the HSE team who needed to know them.

2. Since publication, BNFL has had the opportunity to examine the report, and has queried two of its conclusions which were each heavily influenced by the estimated dose received by particular individuals. These conclusions were:

- (i) the association with cumulative pre-conception external radiation dose when treated as a continuous variable for those resident outside Seascale at the time of the child's birth; and
- (ii) the weak association with 12-week pre-conception external radiation dose for those resident in Seascale at the time of the child's birth.

The report attaches a caveat to each of these conclusions (see Main Report, paragraph 114 and Appendix 3 paragraph 103 respectively).

3. Through previous work on the radiation exposures of employees, BNFL considered that it could identify the two study subjects concerned, and questioned how the data supplied had been translated into the doses used in the HSE study. HSE, in accordance with the protocol, indicated that it was not prepared to discuss particular individuals, but only the general methodology which had been used. This is described in Appendix 2 of the report.

4. The team translating the original dose data into modern-day units were faced with many problems, the two which were relevant to the BNFL queries being:

- (i) how to handle apparent "gaps" in the dose records, and
- (ii) what to do about doses recorded on "special badges", ie. badges worn in addition to routine badges whilst undertaking special tasks where high doses might be expected.

It should perhaps be pointed out that in the course of its normal regulatory activities, when HSE investigates dose records and is able to reveal the identity of the person concerned, such questions can almost always be resolved. In this study however, because of the undertakings given in the protocol that the identities of study subjects should not be revealed, it was not possible to make the usual inquiries. Appendix 2 of the report therefore explains how such situations were handled. BNFL argued that, particularly for the two cases which they considered they could identify, the procedures described in the report were not appropriate.

5. In the light of the case put forward, HSE agreed to review the treatment of "gaps" and "special badges", publishing any alteration to the report's findings if these were changed. In the course of this review, we have re-examined the records of all of the 10 study subjects (shown ringed in Figures 2 and 3 in Appendix 2 of the original report) whose doses were adjusted significantly as a result of the treatment used for handling both "gaps" and "special badges". Of the instances where dose had been significantly adjusted, 4 were because of apparent "gaps" in the dose records, and 6 were because of "special badges" being worn. This note summarises the outcome of that review.

Review of the treatment of "gaps" in the dose records

6. In the original study, "gaps" in the dose records were treated in one of two ways. For "short unexplained gaps", ie. those less than 30 days, the dose used in the main part of the statistical analysis was taken as zero. For "long unexplained gaps", the dose used in the study was determined by examining the individual's record. There were 123 such long gaps in the records, and for all but 20 of these, after examination, no adjustment was made, ie. the dose was taken to be zero. For 18 of the 20 remaining gaps, the imputation rules set out on page 93 of the original report were applied, resulting in a positive dose being ascribed for the gap concerned. For the final 2, for which the imputation rules were not considered to be appropriate, a special case procedure was used (see the penultimate paragraph on page 93).

7. More detailed examination of the records for these two individuals produced further useful evidence for Subject D in Figure 2 and Subject D in Figure 3. Taking this into account, coupled with some additional information from BNFL, it has been decided that for Subject D in Figure 2 the cumulative pre-conception dose (including the imputed element) should be reduced from 180.4mSv to 149.6mSv, and for Subject D in Figure 3 the imputed 12-week pre-conception dose should be reduced from 6mSv to 0mSv.

8. The consequence of the latter change is to further weaken the evidence of an association with the 12-week pre-conception external radiation dose for the Seascale subjects. Where there was statistically quite a strong association ($p=0.005$), heavily reliant on imputed data (and hence considered in the original report to be weak), we now have a statistically weak association ($p=0.08$) based on data we now believe to be less uncertain. This change is essentially caused by the reduction of the 12-week pre-conception dose for Subject D* on Figure 3 from 6mSv to 0mSv. It should be noted that there was

no clear evidence in the personnel records and job descriptions to which the HSE study team had access as to whether or not the individual was working in a radiation environment during the period concerned. However, on the basis of the additional information from BNFL, we have accepted that although the individual was working in a building where radioactivity was present in some areas, his duties during this period probably did not involve work with radioactive materials.

* Note that the effect of removing this subject from the analysis was wrongly described in the original report [Appendix 3, p132, paragraph 103: the sentence "Without this case the 4-group trend for Seascale subjects is not significant ($p=0.31$)...." should have read "Without this case the 4-group trend is less significant ($p=0.033$)...."].

Review of the treatment of "special badges"

9. In addition to the routine film badge, it was evident from the records that a further badge, termed a "special body badge" was sometimes issued to workers engaged on particular tasks. Such badges were, as with the routine badge, intended to be worn on the chest, the practice being prevalent in the 1950's. Inspection of the data showed unexpected differences between the routine and special badge entries, and the study team had to decide on an appropriate method of interpretation. Throughout this review and in the original report, only special body badges were taken into account, and not for example, extremity badges worn on the ankle, hand or head, which show the dose to individual organs rather than the whole body.

10. In the discussion following the publication of the report, BNFL argued that no account should be taken of the "special body badges", despite the fact that they often showed higher doses than the routine badges. BNFL offered two explanations for such higher readings:

- (i) the storage of the special body badges in areas of appreciable background radiation, ie. where

they were exposed to significant amounts of radiation whilst not being worn, and

- (ii) the lower sensitivity of the different film emulsion used in the special body badges giving poor resolution at the low dose levels to which they were generally exposed.

11. Lower sensitivity emulsion was originally used for the special badges so that in the event of an unusually high exposure, the film could still be interpreted to give an estimate of the dose to the wearer. In such an event, the film in the routine badge, being of higher sensitivity, would be likely to have been completely blackened, making interpretation impossible. As greater experience was gained, it was found that doses typically incurred were well within the measurement range capability of the higher sensitivity emulsion. The issuing of special body badges was discontinued early in the 1960's, when the Kodak "double emulsion" film became available.

12. In the original study, HSE took the doses recorded on special body badges into account using an algorithm to calculate an adjusted dose, termed A. This is described in Appendix 2 of the report, the algorithm being shown in Figure 1 on page 96, and the use of the adjusted dose, A, being shown in Table 2 on page 92. BNFL considered that the addition of the dose shown on the routine and special body badges was not justified, since it could be taken to imply that routine badges were "set aside" and not worn during special tasks. However, we have found a few instances in which special body badges were issued and show measurable dose whilst there was an "unexplained gap" for the routine badge.

13. In the light of this, we cannot rule out the possibility that special badges may have been issued to cover periods during which the routine badge was not worn.

14. Having reconsidered the matter, the present review has come to the conclusion that the application of the original algorithm

may have been unduly pessimistic. The only occasion when the special body badge readings should be taken into account is when there would otherwise be an "unexplained gap" in the routine badge record for the period concerned.

15. The adoption of this revised approach has the effect of lowering the imputed dose for Subject A in Figure 2 of Appendix 2 of the original report from 517mSv to 382mSv. Another 48 subjects had their doses reduced as a result of this change in the treatment of special badges: only 18 of these changes exceeded 5mSv.

16. The impact of this change depends on which group of the study population is being considered. Taking the population as a whole, the impact is relatively small: the statistical significance of the positive association (when radiation dose is treated as a continuous variable) is reduced from 0.006 to 0.017 for lymphatic leukaemia and NHL (LLNH) and from 0.01 to 0.021 for all leukaemias and NHL (LNHL).

17. However, since this individual is the single non-Seascale subject that generates the overall association (see original report p29, paragraph 76), the impact of the dose revision on the non-Seascale subjects alone is much greater. The continuous variable analysis of external dose on non-Seascale subjects with the revised data yields a clearly non-significant result* ($p=0.32$ for LLNH, $p>0.5$ for LNHL).

* Note that the p-value implied in the original report (see page 129, paragraph 88) by the sentence "(if external radiation is analysed as a continuous variable, a single non-Seascale father with an XG value over 500mSv generates a *just significant positive association*") was incorrect: even on the basis of the originally assessed dose of 517mSv for this individual, the association was non-significant ($p=0.13$).

18. The original HSE report described the evidence for an association between leukaemia and NHL and the father's radiation dose for non-Seascale subjects as "weak at best and arguably non-existent". The only evidence for such an association rested on the above individual, and this is

effectively eliminated by the downward revision of his estimated dose.

Conclusions

19. As a result of discussions with BNFL following the publication of the HSE report last October, HSE agreed to review procedures used for the treatment of "gaps" in the dose records and of "special badges". As a consequence of this review, which has resulted in a reduction of the adjusted dose for three of the study subjects, two of the statistical results reported must now be revised. These results were:

- (i) the association with cumulative pre-conception external radiation dose when treated as a continuous variable for those resident outside Seascale at the time of the child's birth, and
- (ii) the weak association with 12-week pre-conception external radiation dose for those resident in Seascale at the time of the child's birth.

20. We now consider that the following results should be substituted in their place:

- (i) for the non-Seascale subjects, there is no indication of any association of childhood leukaemia or NHL with the father's pre-conception external radiation dose, and
- (ii) for those resident in Seascale at the time of the child's birth, the weak association with 12-week pre-conception external radiation dose now becomes non-significant ($p=0.08$).

21. The report's other main findings all remain unchanged as a result of this review, namely:

- (i) the clear distinction between the incidence of childhood leukaemia and non-Hodgkin's lymphoma in Seascale and elsewhere in West Cumbria,

- (ii) the incidence in Seascale of these diseases in the children of Sellafield fathers being some 14 times the national average,
- (iii) the strong association for the children of Seascale families between the father's cumulative pre-conception external radiation dose and the incidence of these diseases,
- (iv) the concentration of the increased risk solely in the children of fathers who started work at Sellafield before 1965,
- (v) the absence for the non-Seascale subjects of an association with the father's 12-week preconception external radiation dose,
- (vi) the absence of any positive association for cancers other than leukaemia and NHL,
- (vii) the absence of any association with internal radiation dose, and
- (viii) the observation that the raised incidence in the children of Seascale fathers may, in some way, be associated with Seascale's unusually high proportion of in-comers, ie. non-Cumbrian born fathers.



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