Institut fur Ausbildungsforschung

Institute for Research in Professional Education
Hufnagelstr. 1, 80686 Munchen; Tel.: 089 5476-3020, Fax: -3021
Dr. med. Hannes Kapuste

Sir Liam Donaldson Chief Medical Officer Department of Health Richmond House 79 Whitehall London SW1A 2NL England

Ref. Expert Group to Investigate Cot Death Theories: Toxic Gas Hypothesis: Final Report, May 1998. Comments by Barry A Richardson who developed the hypothesis, June 1998

28. June 2004

Sir,

I am reviewing the literature on SIDS in connection with the Toxic Gas Theory of Richardson, in particular the Final Report of the Limerick Committee, defined above and published by HMSO (but now out of print), and studying in parallel the Comments to the Final Report by BA Richardson, a copy of which I enclose today.

Much of the alleged credibility of the Final Report is based on the allegation that is stated throughout, - and in particular pages 49ff - that the Expert Group replicated Richardson's original experiments, and moreover that this "work... was conducted with his cooperation and his presence at key stages ..," that e.g. "Richardson agreed that the experiments ... in Bristol, followed his procedures"... and that "By replicating and extending Richardson's work, it was demonstrated that his Interpretation of his findings was incorrect."

In his Comments of June 1998, however, Richardson states in detail with regard to most of these statements that they are not true and he explains the manner in which many of the procedures followed by the Expert Group would result in non-detection of the true causes of SIDS, i.e. toxic gases in particular.

Meanwhile, the medical establishment has accepted the conclusion of the Limerick Report that there was no evidence to show that toxic gases are the cause of SIDS. There is, however, no other cause or causes of SIDS available which could explain, as the Toxic Gas Theory does, all the epidemiology and so called "risk factors" related to it. In particular, it explains the most important prediction that babies will not die from SIDS if they are protected from toxic gases either by sleeping on mattresses wrapped in a gas-impermeable diaphragm (e.g. polythene) or mattresses free from phosphorus, arsenic and antimony.

This same prediction, meanwhile, has been tested in New Zealand, where Dr T.J. Sprott commenced a nation-wide public information campaign in late 1994. The results have been dramatic. Not one death has been reported amongst more than 120,000 or more babies who slept in cots in accordance with the protocol advised by Sprott (www.cotlife2000.com). And in New Zealand (where every case of SIDS is examined) the "nil reported death" statistic effectively means that there has not been a death where Sprott's advice has been followed. By contrast, during the 9 years of his mattress-wrapping campaign, some parents have not followed his advice. And to date, those parents have lost about 650 babies to SIDS. The statistical significance of Dr. Sprott's campaign is overwhelming, the "p" factor for the mattress-wrapping intervention being p = 8.6 x 10^{-27} (8.6E-27).

It is very surprising to me that I cannot find any mention of Richardson's Comments in the medical literature.

I have communicated with Lady Limerick, the Chairwoman of the Group, and with one of the Expert Group's members, Professor Fleming, enclosing for both a copy of Richardson's Comments but could not get an answer to my question whether there had been a paper by a member of the Expert Group discussing them. Richardson's Comments have not been mentioned to me in their replies, nor was there an acknowledgement of the copy of the Comments which was attached to my email. So it is now my impression that there might be tendencies to suppress these Comments. Now I would like to ask you definitely:

- 1. Have the Comments by Barry A Richardson (which he sent to the Secretariat of the Committee at the Department of Health) been distributed to the members of the Expert Group to Investigate Cot Death Theories: Toxic Gas Hypothesis?
- 2. Is there an adequate reply to his Comments available?

I read your interview on your homepage wherein you state: "My golden rules are no jargon and be as honest as possible, although there are sometimes legal restraints on what I can say" and "I think the best thing about the job, and this may sound idealistic, but the best thing is that I have the potential to save lives, prolong lives and give people healthier, better lives. I hope that doesn't come across as too idealistic because ultimately it's one of the things that drives me and makes me get up in the morning".

I look forward to your reply.

Before you answer, I could also send you the draft of one of the papers I have prepared for publication: "Sudden Infant Death: High Time for Changing the Paradigm." Please let me know if you would be interested by mailto:hannes.kapuste@t-online.de.

Best regards

Enclosure:

Barry A Richardson. Comments to the Final Report of the Expert Group to Investigate Cot Death Theories: Toxic Gas Hypothesis. Penarth Research International Limited. June 1998



Fax: 020 7972 5156/5167 E-mail address: robert.maynard@doh.gsi.gov.uk Skipton House 80 London Road London SE1 6LH Tel: 020 7972 2000

Direct Line: 020 79 72 5118

Dr Hannes Kapuste Institute for Research in Professional Education Hufnagelstr.1 80686 Munchen Germany

Dear Doctor Kapuste

3 September 2004

EXPERT GROUP TO INVESTIGATE COT DEATH THEORIES; TOXIC GAS HYPOTHESIS. BARRY RICHARDSON'S COMMENTS ON FINAL REPORT

Thank you for your letter of 28th June to Sir Liam Donaldson regarding the above. He has asked me to reply to you.

I should first explain that the Expert Group was an ad hoc Committee established in 1994 by Sir Kenneth Calman,the CMO at that time. It was charged with producing a report on the toxic gas hypothesis. A very comprehensive final report was produced in May 1998 which was, in general, well received by the scientific community and those involved with cot death. The Committee then ceased to exist. We thus did not circulate Mr Richardson's comments of June 1998 to the Expert Group.

What is clear is that Mr Richardson was involved at all stages in the design and execution of the studies to replicate his experiments. At the time of the initial studies he agreed that the experiments followed his procedures. Mr Richardson did express some concerns when the initial results of these studies were known and published in 1995. He made various suggestions as to why the experiments could not be repeated and these were all followed up by the Expert Group [this is discussed in the section of the report under the sub heading Richardson's response to the replication of the experimental work 5.27 –5.38]

It is pertinent that Mr Richardson's results were based on a very crude, non-quantitative analytical measure based in colour change in the test paper. The Expert Group felt that these experiments should be extended to more sensitive, quantitative analytical measurement. These failed to provide any evidence for the generation of the toxic gases.

I would also take issue with your claim that 'much of the alleged credibility of the Final Report is based on these replication experiments. This is simply not the case. Examination of Fig 12.1 (Key steps in our investigation of the Toxic Gas Hypothesis) clearly shows that it is only one, relatively small, stage in the overall pattern of data from which the Expert Group were able to draw their very clear conclusions.

I hope that this clarifies the position regarding Barry Richardson's comments,

Yours sincerely

Klhagrad.

R L MAYNARD CBE FRCP FRCPath Senior Medical Officer

Copy:

Dr R Fielder Professor Peter Fleming Mr L McGill

Institut fur Ausbildungsforschung

Institute for Research in Professional Education

Hufnagelstr. 1, 80686 Munchen; Tel.: 089 5476-3020, Fax: -3021 Dr. med. Hannes Kapuste

Dr. Hannes Kapuste, Institut fur Ausbildungsforschung Hufnagelstr. 1, 80686 Munchen Telefon: 089 5476 3020

R L Maynard CBE FRCP FRCPath Department of Health Skipton House 80 London Road London SE1 6HL England

Expert Group to Investigate Cot Death Theories: Toxic Gas Hypothesis; Barry Richardson's Comments on Final Report

10 September 2004

Dear Doctor Maynard,

Thank your for your reply of 3 September to my letter to the CMO Sir Liam Donaldson of 28th June informing me that Mr Richardson's comments of June 1998 to the final report produced by the Expert Group in May 1998 was not circulated by the Department of Health. Your reasons were, that the ad hoc Committee had ceased to exist and the final report, in general, was well received by the scientific community and those involved with cot death.

It is quite true that the most prominent members of the scientific community involved with cot death have chosen to accept the conclusions of the Expert Group without any independent evaluation, as e.g. Byard in Australia and Krous in the USA [1], Kurz, Kenner and Kerbl in Austria [2], and Poets and Jorch in Germany [3]. My interpretation of this, however, is that this did not relieve your department of its responsibility to circulate Mr Richardson's comments to scientists who would be qualified to evaluate the controversy between BA Richardson and the the Expert Group. Indeed, it added to that responsibility.

I am not qualified to evaluate in detail whether the discussion in part 5.27 - 5.38 of the report which you mention validates the conclusion presented in in Fig 12..1 (p 234) of the Final Report that all of the five key components of Richardson's hypothesis were incorrect, while the reasons for the verdict given by the Expert Group were all entirely correct. But I consider myself to be qualified to decide that the conclusion presented throughout the Final Report [4] (now out of print) and its Executive Summary [5] that there was no evidence for toxic gases in infant's beds is not true, because the experimental evidence presented in the scientific literature is definitely controversial [6].

Not controversial however, is the prediction by BA Richardson that the mattress precautions suggested by him will prevent sudden infant deaths effectively. So I wonder why you have not responded to the information I presented in my letter to the CMO:

This same prediction, meanwhile, has been tested in New Zealand, where Dr T.J. Sprott commenced a nation-wide public information campaign in late 1994. The results have been dramatic. Not one death has been reported amongst more than 120,000 or more babies who slept in cots in accordance with the protocol advised by Sprott (www.cotlife2000.com) And in New Zealand (where every case of SIDS is examined) the "nil reported death" statistic effectively means that there has not been a death where Sprott's advice has been followed. By contrast, during the 9 years of his mattress-wrapping campaign, some parents have not followed his advice; and to date, those parents have lost about 650 babies to SIDS. The statistical significance of Dr. Sprott's campaign is overwhelming, the "p" factor for the mattress-wrapping intervention being p = 8.6×10^{-27} (8.6E-27).

I had thought that this information, and my reminding the CMO of how he presents himself in the internet:

"My golden rules are no jargon and be as honest as possible, although there are sometimes legal restraints an what I can say" and "I think the best thing about the job, and this may sound idealistic, but the best thing is that I have the potential to save lives, prolong lives and give people healthier, better lives. I hope that doesn't come across as too idealistic because ultimately it's one of the things that drives me and makes me get up in the morning".

should have prompted him to accept the responsibility of the British Department of Health now to admit, that:

- 1 it was a serious mistake "not to circulate Mr. Richardson's comments of June 1998 to the Expert Group";
- 2 the evidence with regard to toxic gases is controversial;
- 3 parents have the right to be informed of the efficacy of mattress wrapping.

After evaluating your publications referenced in PubMed I should think that your qualifications in adverse effects of environmental exposure to air pollutants (nitrogen dioxide, ozone, etc) seasons, temperature, air pollution/legislation & jurisprudence, air pollution/statistics & numerical data, linear models, reference standards, reproducibility of results and risk assessment would enable you to be of great assistance to the CMO when he considered this suggestion.

I would like you to know that this would be extremely helpful to bring about the immediate succes of a new Child Survival Movement which the Journal of Nutritional & Environmental Medicine (JNEM) is about to launch. The Editorial of BA Richardson and the report of TJ Sprott have already been accepted, and I have submitted my review article (in which I quote from my letter to the CMO). There is no doubt that the amount of criticism directed towards the British Government for its devastating influence an the incidence of sudden infant deaths in the world which my review might initiate, would be substantially reduced if your department might decide to support our intervention.

Since our papers are about to go to press, I informed the Editor of the JNEM, Dr. Damien Downing of your letter and suggested that he communicate with you directly. I hope you will consider a basic change in your department's policy towards an optimal strategy to reduce the incidence of cot death in the world. As it would be much more effective to cooperate with the British Department of Health in the immediate future than to criticize its decisions in the past, I would be very glad to edit my review accordingly.

Best regards

References

- 1 Byard RW, Krous HF, eds. Sudden Infant Death Syndrome: Problems, Progress and Possibilities. London, Arnold Press, 2001:240-1.
- 2 Kurz R. Andere Krankheiten, pp 184-5. Kenner T, Kerbl T. Moegliche Ursachen fuer den ploetzlichen Saeuglingstod. Historische und theoretische Ueberlegungen. pp 133-43. In Kurz R, Kenner T, Poets C (Hrsg.). Der ploetzliche Saeuglingstod. Ein Ratgeber fuer Aerzte und Betroffene. Wien, New York, Springer, 2000.
- 3 Poets CF, Jorch G. Stellungnahme zum Thema "vermeidbare Risikofaktoren für den ploetzlichen Saeuglingstod." Monatsschrift Kinderheilkunde, 2000 11:1065-6.
- 4 Expert Group to Investigate Cot Death Theories: Toxic Gas Hypothesis (Chairman: Lady Limerick). Final Report May 1998 (ISBN 1851839 874 6, out of print)
- 5 Expert Group to Investigate Cot Death Theories: Toxic Gas Hypothesis (Chairman: Lady Limerick). Chairman's Foreword, Executive Summary, Abstracts, Conclusions and Recommendations, Terms of Reference and Members of the Group, May 1998. http://sidsnetwork.org/experts/expert groupto investigate cot .htm
- 6 Kapuste H. PubMed-References to SIDS AND toxic gases etc. Manuscript. mailto:hannes.kapuste@t-online.de