McCloud Consulting Group
International Biostatistics & Data Management Specialists

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13th October 2015

Emily Heffernan
Senior Associate
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Dear Emily,

I refer to your letter dated the 6th of October 2015 in which you requested I provide comments and observations on the enclosed expert material. I also refer to your subsequent emails dated the 8th, 9th, 10th, and 13th of October 2015.

In sundry fields of application such medical science, clinical trials, public health, and time series of death statistics the task of understanding causality is clouded because of random variation. It is well understood that unexpected peaks or troughs in time series of data are often the result of random variation.

In a number of the expert reports provided (Materials 1-12 below) the authors have noted an increase in the number of deaths during the period of the mine fire in 2014 compared to the same period for previous years, such as 2009-2013. The analyses have been based on the death statistics of 4 or more postcodes that were in the vicinity of the mine fire. The increase in the number of deaths has been shown to be of borderline statistical significance from both the frequentist and Bayesian perspective. However such an increase in the number of deaths during the period of the mine fire in 2014 compared to previous years does not prove that the pollution from the mine fire was the cause of the increase. The increase may result from changing demographic characteristics of the region, such as an aging or growing population, or it may simply be the result random variation.

I would like to make the following points.

Point 1

The absence of direct evidence such as deaths certificates that report death was caused by smoke, carbon monoxide, or other pollutants emanating from the mine fire weakens any claim that the mine fire caused an increase in deaths. I would like to offer 2 examples where such direct evidence is utilised.

1. In clinical trials that compare the safety of a new treatment to a standard treatment investigators will collect details of the adverse events that occur during the study. If a statistical analysis demonstrates an excess of adverse events in the new treatment compared to the standard treatment then the investigators or health authorities can

examine the specific reported adverse events in detail in order to assess if the increase was related to the new treatment.

2. During the influenza season an increase in the number of deaths during epidemics is often noted. However these raw numbers are supported by the death certificates reporting that the patient has died from complications arising from influenza.

It is this detailed medical assessment of the deaths during the period of the mine fire that is lacking from the current analysis. In my opinion the numbers alone are not adequate to justify a conclusion that the pollution from the mine fire caused the increase in deaths compared to previous years. A necessary additional step should be a medical assessment that attributes specific deaths to have been caused by the pollution of the mine fire.

Point 2

One of the strong indicators of cause and effect is the presence of a dose-response relationship, namely that as the dose of a stimuli is increased the response should increase. In the case of the mine fire a dose-response relationship would be in evidence if the increase in deaths during the period of the mine fire in 2014 compared to previous years was greatest in those regions that experienced the greatest impact from mine fire pollution.

The 4 postcodes included in nearly all analyses contained the towns of Morwell, Churchill, Moe, and Traralgon. Because of its relatively close proximity to the mine, Morwell would have been expected to have experienced the greatest impact from mine fire pollution. Therefore the presence of a dose-response relationship would be established if the greatest increase in deaths occurred in Morwell. In fact the opposite occurred.

Emeritus Professor Bruce Armstrong calculated that the rate ratio of deaths in 2009-13 compared to 2014 was 0.80 (95% CI: 0.51, 1.26, P = 0.34) for Morwell, and 1.36 (95% CI: 1.07, 1.71, P = 0.01) for Churchill, Moe, and Traralgon (Page 5, Table 1).

Emeritus Professor Bruce Armstrong commented (page 5, last paragraph),

"These results suggest that mortality rate ratios in Morwell in 2014 were different from those in Churchill, Moe and Traralgon. For each period, the ratio of the rate ratios (Morwell compared with Churchill, Moe and Traralgon) can be estimated, giving 0.59 (=0.80/1.36) *(95% CI 0.35-0.98) for the February-March comparisons and 0.86* (=1.05/1.22) *(95% CI 0.63-1.17) for the February-June comparisons5. That the upper bound of the 95% CI of the February-March comparison is very close to 1 and that the 95% CI of the February-June comparison includes 1 indicates that statistical evidence for this difference is quite weak."* Note the correction of 0.80 to 0.59.

The estimated ratio of rate ratios for the February-March period of 0.59 with a 95% CI: 0.35, 0.98 is significantly less than 1.0, because the 95% CI does not contain 1.0. Therefore the decrease in the rate of deaths in Morwell in 2014 compared to 2009-2013 was significantly less than the increase in the rate of deaths in Churchill, Moe, and Traralgon for the same period. In fact, for February-March, the most intense period of the mine fire, the estimated rate ratio of 0.80 in Morwell was 41% less than the estimated rate ratio of 1.36 for Churchill, Moe, and Traralgon. This result is diametrically opposed to the required dose-response relationship if mine fire pollution caused the increase in deaths. The greatest impact of mine fire pollution was probably in Morwell rather than Churchill, Moe, and Traralgon, therefore, we would have expected the rate ratio in Morwell to be greater than the rate ratio of Churchill, Morwell, and Traralgon not less. The failure to demonstrate a dose – response relationship is a weakness in the claim that the increase in deaths during the period of the mine fire in 2014 compared to previous years was caused by the mine fire pollution.

Point 3

The Final Rapid Health Assessment Report of Professor Michael Abramson et al modelled the relationship between the exposure of residents to the air pollution during the time of the mine fire, and the expected increase in deaths. The report of Professor Abramson goes beyond the simple assessment of the observed number of deaths to consider the expected number of deaths given the exposure. The expected number of deaths was estimated with an epidemiological model.

Prof Abramson at el (pg 5, 2014) wrote,

"Based on these findings about the types of health outcomes related to air pollutants, epidemiological modelling undertaken as part of this review found that for combined $PM_{2.5}$ exposures around 250 µg/m^3 in Morwell South and for exposures around the National Environment Protection Measure {NEPM) in the rest of Morwell, no additional deaths would be expected even if the exposure continues for 6 weeks. However, if this level of exposure had persisted for 3 months this level of $PM_{2.5}$ might be expected to result in some additional deaths from IHD {0.5 additional deaths), Stroke {0.2), COPD {0.1), Lung Cancer {0.1) and Acute Lower Respiratory Infection {ALRI) {0.2)."

Professor Abramson et al have estimated no additional deaths if the exposure from the mine fire continued for 6 weeks, and 1.1 additional deaths if the mine fire continued for 3 months; both of these figures are much less than the 23 increased deaths estimated from the latest analysis of Associate Professor Barnett (dated 25 September 2015).

Point 4

Associate Professor Barnett has described a new analysis based on the number of *"daily deaths from 1 January 2009 to 31 December 2014, which is 2191 days. The deaths were split by four postcodes (3840-Morwell, 3842-Churchill, 3825-Moe, 3844-Traralgon) according to usual place of residence. There were 3,414 deaths in total."*

In designing scientific studies one method to control for systematic bias is the selection of the control group. In earlier analyses of the Hazelwood mine fire the analysts generally used the period of the mine fire (February-March) from previous years 2009-2013 as the control group. In my opinion restricting the control group to the period of the mine fire may well provide a better control group than using all days of the year.

The control group restricted to the period of the mine fire excludes those days of the year not in the period of the mine fire, and therefore excludes many potential confounders associated with the autumn, winter, and spring months of the year. It can be difficult to model satisfactorily all such potential confounders with a statistical model. In the report dated 25th September 2015 Associate Professor Barnett commented that, *"This latest analyses gives a 99% probability of an increase in deaths during the 45 days of the fire, with an estimated 23 additional deaths."*

However, the 23 additional deaths is compared to the expected number of deaths based on the statistical model of deaths across the over 2,100 days in the control group. If the statistical model does not adequately account for all the potential confounders then the estimate of 23 additional deaths may be called into question.

In correspondence between Emeritus Professor Bruce Armstrong and Justine Stansen, Emeritus Professor Bruce Armstrong made a similar point when he commented,

"Barnett now describes how the numbers of additional deaths due to the fire in each postcode were calculated. This explanation, however, is not clear to me. There are two variables in the expression that Barnett offers on page 2, 4th line up from the bottom of the page:

1. *The mean number of deaths per day for each postcode. The period over which this average has been calculated is not stated; It should be. As I see it, the period should (a) be relatively recent so that it can provide a reasonably unbiased estimate of the expected number of deaths in the four postcode areas over the period of the fire, (b) not include the observed deaths during the period of the mine fire and (c) be based on a period long enough to remove most of the effect of day to day variation in daily numbers on the calculated mean numbers. All these may be true, but it is not clear that they are.*

2. *Exp (α_{20}), the relative risk of death during the fire. As far as I can tell this is the relative risk across all four postcodes. If this is true, postcode specific relative risks have not been used when estimating the excess deaths and, therefore, previously apparent variation between postcodes in relative risk of death during the period of the mine fire is not taken into account when calculating the numbers of excess deaths. If this is correct, a deficit of deaths in Morwell during the period of the mine fire would be obscured in this analysis."*

In my opinion the better control group for estimating the increased number of deaths in 2014 compared earlier years is that restricted to the period of the mine fire rather than using all days of the year.

Point 5

In correspondence on the 10th of October Emily Heffernan provided a summary of the deaths recorded by Births Deaths & Marriages for the period 9 February – 25 March for the years 2014, and 2015 for the postcodes most impacted by the mine including postcodes 3840, 3842, 3825, and 3844 which have been included in nearly all analyses. The numbers are summarised below. The data show that for the 4 most analysed postcodes the number of deaths for the period of the mine fire for 2015 (77 deaths) was similar to the number of deaths for 2014 (83 deaths), which is a difference of only 6 deaths. Therefore for the period of the mine fire the number of deaths in 2015 would also be high relative to the years 2009-2013. However, the increase in deaths in 2015 relative to the years of 2009-2013 cannot be explained by the impact of pollution from a mine fire. Therefore the increase in the number of deaths in 2015 relative to the years of 2009-2013 must be the result of demographic changes in the region such as an aging or growing population, or the result of random variation. Both the demographic changes in the region, and random variation are likely explanations for the increase in deaths in 2014 relative to the previous years of 2009-2013.

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Summary of deaths recorded by Births Deaths & Marriages in the period 9 February – 25 March (Postcode of Usual Place of Residence)

	Year	
Postcode	**2014**	**2015**
3840	18	22
3842	6	6
3825	32	29
3844	27	20
4 postcode total	83	77
3869	0	3
3870	0	1
6 postcode total	83	81
3854	1	0
3856	2	0
8 postcode total	86	81

Point 6

Associate Professor Adrian Barnett reported an analysis of the number of deaths during the mine fire compared to other months and previous years in September 2014. I would like to make the following observations. All the parameters included in the statistical model are appropriate, and on face value may play a role in predicting the number of deaths in each year, month, and postcode. However the credible intervals of all risk ratios except Intercept, and Postcode include one (Tables 1 and 2). Therefore we do not have strong evidence that the parameters: Trend, Season cos, Season sin, and Fire have a strong impact on the predicted number of deaths. In particular, the estimate of the Fire risk ratio was 1.14 with a credible interval of (0.92, 1.41) (Table 1), which includes the possibility that the effect of the Fire was “negative” so that less people died during the period of the fire than the average. In the analysis that included Temperature (Table 2), the estimate of the Fire risk ratio was 1.11 with a credibility interval of (0.87, 1.37), which again includes the possibility that the effect of the Fire was “negative” so that less people died during the period of the fire than the average. The common scientific thinking is that a parameter is important or significant if the credible interval or confidence interval does not contain one or zero depending on the key statistic. The relevance of the model is called into question because most of the parameter estimates are not significant.

I hope that the discussion above will be of assistance.

Yours sincerely,

Philip McCloud, PhD, AStat

Statistical reports before the Board for the purposes of the hearings on Term of Reference 6 conducted on 1, 2, 3 and 9 September 2015

1. Final Report – Rapid Health Risk Assessment dated 12 March 2014. Authors: Professor Michael Abramson, Dr. Martine Dennekamp, Professor Malcolm Sim, Associate Professor Manoj Gambhir, Professor Brian Priestly, Dr. Fay Johnston, Dr. Lisa Demos, and Professor John McNeil.
2. Report of Associate Professor Barnett dated September 2014 entitled Analysis of death data during the Morwell mine fire.
3. Report of Associate Professor Barnett dated December 2014 entitled An updated analysis of death data during the Morwell mine fire.
4. Report of Emeritus Professor Bruce Armstrong dated August 2015 entitled *Expert Assessment and Advice Regarding Mortality information as it relates to the Hazelwood Mine Fire lnquiry Terms of Reference - Final Report.*
5. Report of Professor lan Gordon dated 11 August 2015 entitled *Commentary on the Hazelwood Mine Fire and Possible Contribution to Deaths*.
6. Report of Dr Louisa Flander and others dated 28 April 2015 entitled Review of "*Analysis of death data during the Morwell mine fire*," A. Barnett, working paper, unpublished (2014, Queensland University of Technology) and "*An updated analysis of death data during the Morwell mine fire*," A. Barnett, working paper, unpublished (2015, Queensland University of Technology)"
7. Report of Dr Louisa Flander and others dated 4 June 2015 entitled Age-Standardised Mortality and Cause of Death in the Latrobe Valley at the Time of (and Five Years Prior to) the Hazelwood Coal Mine Fire in Morwell, Victoria.
8. Joint Report of Emeritus Professor Bruce Armstrong, Associate Professor Adrian Barnett, Professor lan Gordon and Dr Louisa Flander dated 31 August 2015, entitled "*Consultations relating to Term of Reference 6: Whether the Hazelwood Mine Coal Mine Fire contributed to an increase in deaths, heaving regard to any relevant evidence for the period 2009 to 2014*."
9. Report of Associate Professor Barnett dated 25 September 2015 entitled *Analysis of daily death data during the Hazelwood mine fire.*
10. Email of Emeritus Professor Bruce Armstrong dated 18 September 2015.
11. Report of Associate Professor Barnett dated 25 September 2015 entitled *Analysis of daily death data during the Hazelwood mine fire*.
12. Report of Associate Professor Barnett dated 7 October 2015 entitled *Analysis of daily death data during the Hazelwood mine fire*.

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14th October 2015

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Dear Emily,

I refer to my letter dated the 13th of October, in which I made comments regarding the control group for comparison to the mine fire period (Point 4), and comments regarding the September 2014 analysis of Associate Professor Adrian Barnett (point 6). I would like to provide the following additional comments regarding the recent analysis of Associate Professor Barnett dated the 25th of September 2015, and dated the 7th of October 2015.

Associate Professor Barnett has described a new analysis based on the number of *"daily deaths from 1 January 2009 to 31 December 2014, which is 2,191 days. The deaths were split by four postcodes (3840-Morwell, 3842-Churchill, 3825-Moe, 3844-Traralgon) according to usual place of residence. There were 3,414 deaths in total." (Report dated 25 September 2015).*

Associate Professor Barnett commented that,

"Table 1 shows a higher mean number of daily deaths in all four postcodes during the period of the fire compared with all other times. These crude figures do not adjust for the seasonal pattern in deaths or changes over time in population size, and the regression model below should give a truer picture of any increase in death rates."

The final comment that the regression model should *"give a truer picture of any increase in death rates"* depends on whether the statistical model for the number of daily deaths spread over 2,191 days adequately captures all sources of systematic variation. If the statistical model fails in this regard then the estimate of 23 additional observed deaths compared to the expected number of deaths based on the statistical model maybe unreliable.

The statistical model contained terms for the following:

- trend over time
- season using sinusoidal functions cosine and sine
- day of the week
- maximum temperature modelled with a spline, and
- the fire period

The parameter estimates and 95% credible intervals (Table 1, Barnett Report dated 7 October 2015) show that:

- Only 1 of 2 trend effects was significantly different from zero
- The postcode effects were significantly different from zero, which reflects the different number of deaths between the postcodes
- The seasonal effects of cosine and sine were not significantly different from zero
- The effects for days of the week were not significantly different from zero, and
- 7 of the 9 parameters associated with the splines for maximum temperature were not significantly different from zero.

Therefore very few of the parameters in the statistical model demonstrate a significant effect with the number of daily deaths, and most could be removed from the statistical model without impacting the expected number of deaths per day. Therefore there is either no association between the time or temperature variables included in the statistical model or the analysis lacks power. One reason for this lack of power may be the result of dividing the 3,414 deaths across the 8,764 days of observation, which equates to 2,191 days of observations multiplied by 4 for the postcodes. This equates to an average of 0.39 deaths per day of observation, so that many days within the postcodes will record either: 0, or 1 death. The absence of a significant effect for the parameters in the statistical model and the number of daily deaths may result from these many small frequencies.

In particular the non-significant parameter estimates for the seasonal components, cosine and sine, may mean that any increase in deaths associated with the summer months is being under estimated by the statistical model. For example, the number of deaths from the period of the mine fire (February-March) for the years 2009-2013 will have relatively little impact on the statistical model compared to the other roughly 1,600 days over this 5 year period. Therefore if the number of deaths from the February-March period is relatively high compared to the remainder of the year the new statistical model may under estimate the number of deaths for the February-March period. The nett effect would be to over-estimate the true difference between the number of observed deaths and the number of expected deaths based on the statistical model.

Associate Professor Adrian Barnett commented that,

"The mean estimated number of extra deaths during the fire over the four postcodes is 23 (95% credible interval: 2 to 46)." (Page 6, report dated 25 September 2015)

I would just make the observation that the 95% credible interval is relatively wide. The upper limit of 46 deaths is double the point estimate of 23, and the lower limit is close to zero. The wide 95% credible interval means that there is considerable uncertainty about the point estimate of 23 observed deaths.

In Point 6 of my letter dated 13 October 2015, I noted that the parameter *"estimate of the Fire risk ratio was 1.14 with a credible interval of (0.92, 1.41) (Table 1), which includes the possibility that the effect of the Fire was "negative" so that less people died during the period of the fire than the average."* In the analysis of Associate Professor Barnett dated 25 September 2015 of daily death data the estimate of the Fire risk ratio was 1.324 with a 95% credible interval of (1.034, 1.656), which does not include 1.0. However, the credible interval is relatively wide, so that considerable uncertainty remains about the point estimate for the risk ratio.

I hope that the discussion above will be of assistance.

Yours sincerely,

Philip McCloud

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