What was unethical about snoopers measuring particulates at a vape convention?

written by Clive Bates | 22 February 2016



I recently posted on *Public health snoopers detect vapour aerosol at vape conference and fake a particulates scare*. I mentioned that I thought the subterfuge involved was unethical and contemptuous, but didn't really explain why. My main point in that post was to focus on why this was bad science and why there was no basis to justify a policy recommendation to ban vaping wherever smoking is banned. Also, I mostly had a hostile *instinctive* reaction about it, rather than a fully worked through perspective worth sharing.

I've now had an opportunity to reflect on it more carefully. This is partly because I was contacted by a senior figure at the university (someone I respect) pointing out that the study been assessed against a flowchart encoding USDHHS definitions and regulations, and that they had concluded there was *no human subjects aspect of this study*. Without a human subject dimension, there is no requirement to seek an approval from an Institutional Review Board (IRB), a

committee that governs the ethical acceptability of research.

So I gathered my thoughts and responded:

> *Dear_____*
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> *Thank you for taking the trouble to respond and engage. I very much appreciate that.*
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> *Firstly, I did not focus my comments on the ethical aspects of this. My main concerns are threefold:*
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> 1. *That measurement of PM in itself provides little of value without meaningful comparators and some reason to believe that the PM measured are actually harmful – these particulates are very different physically and chemically from those thought to cause harm.*
> 2. *The attempt to retrofit a basis for health concern by mentioning toxins that were not measured in Soule et al but are found at extremely low levels in credible experiments undertaken elsewhere – at least when these use realistic vaping conditions.*
> 3. *The inclusion of a policy recommendation that was not, and never could be, supported by these measurements for the multiple reasons given in my post.*
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> *On the ethics, I did what I think we should all do and asked myself: does this feel right? It didn't and doesn't feel right to me. I don't doubt that by selective interpretation it is possible to navigate the HHS human subject flow charts. But here are the issues that trouble me and I think if you'd faced more robust challenge these would have meant you not securing approval. Carl V. Phillips has written about this here, and I won't repeat his excellent analysis. Rather I will just give you my own unvarnished reactions:*
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> 1. *A vaping event is a human construction, comprising human participants and involving measurements of a byproduct of human behaviour in which the participants have a great deal of interest, and which is subject to considerable controversy. Many will feel quite victimised by research of this nature, especially given the three major concerns I list above, and that the research was to be used in a way that would adversely affect their perceived interests (see point 3 above). Many*

participants would rightly view this as a hostile act against them and their wellbeing. There is a human element to this that is quite different to examining cells in a petri dish or passing gases through a mass-spectrometer. It would be wise to acknowledge rather than dismiss that.

2. *If no humans were involved, why were concealment and subterfuge necessary parts of the experimental design? The experimental design shows a deliberate effort to avoid the objections of participants by concealing the monitoring equipment – the human subjects, and avoiding their engagement, are thus integral to the design. A particular approach has been taken to addressing their objections: not explaining the value of the research, but concealing it.*
3. *There was always the opportunity to ask the organisers for permission and a further option to inform the participants if the organisers agreed. Perhaps you could pose the rhetorical question: why did the team choose not do this? – and see where it leads. It would certainly have been preferable, may have allowed for better science, and more strands of study etc. It would have avoided the criticisms you are now facing. So I suggest you examine carefully the reasons they didn't ask. If it is because they thought the organisers would say no, then there are two additional issues to consider: what reasons would the organisers have for saying no, and why the team think their objections are irrelevant (i.e. that it is okay simply not to ask them)?*
4. *This research created at least two breaches of the implicit contract offered by the organisers (or 'breaches of trust' if a less legalistic term is preferred). I assume the investigators signed up to attend the event, which I assume was a private function that required payment. The right to attend was sold with the implicit contract that it granted permission to attend the event as a participant – not to conduct contentious research there. A second breach of contract was also created between the organisers and participants, who attended in good faith expecting to be part of a vaping event, not part of an experiment detrimental to their interests. Misleading people in this way is unethical in my view. How do you know that you haven't harmed the organiser by doing this? How do you know you haven't added to the already large stock of distrust in this field?*
5. *I come back to my original concern – I think the approach of the*

investigators betrays a contemptuous attitude to people who are, for the most part, successfully dealing with the health risks of smoking and finding their lives rejuvenated and wish to see others do the same. They are the 'public' in 'public health' and it would help if everyone professionally engaged in this field treated them with more empathy and respect, and approached their work with more humility.

6. *If they were confident that their interpretation of the rules was correct (i.e. there were no human subject aspects to the study) then why not take that conclusion to an IRB and defend it? Surely it is obvious that this interpretation could be disputed (as I have above), so why not have it challenged and validated or rejected? The trouble is that the team has incentives to avoid ethical scrutiny: to save time; to avoid restrictions or costs; and to avoid the risk of having the work stopped altogether. So I would expect biases in the way the team approached the DHHS flowchart – and, therefore, a need for a some counter-balancing challenge. The team should have gone for an IRB review precisely because issues of human subject involvement is, at best, ambiguous (nb. this point added in a follow up email).*

Best regards

Clive Bates

I hope they respond to these observations, or, at least, reflect on their professional approach. (I won't publish any response to this without their permission).

Further reading: Serious ethical concerns about public health research conduct; the case of vape convention air quality measurement – Carl V. Phillips