# **Public Health BMJ**

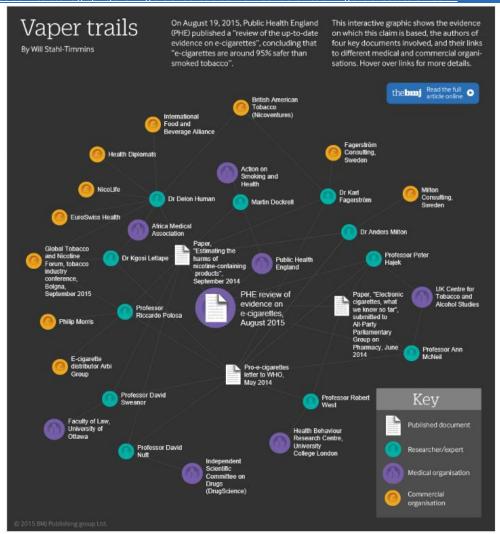
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### England's troubled trail

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### **Vaper Trails**

Click here to see our interactive graphic, showing the evidence that informed Public Health England's "95% safer" claim.



http://www.bmj.com/content/351/bmj.h5826/infographic

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The handling of evidence for its controversial report on e-cigarettes adds to questions about the credibility of the organisation's advice, finds **Jonathan Gornall** 

The connection between Trélex, an unremarkable Swiss village about 15 miles north of Geneva, and the endorsement of electronic cigarettes by Public Health England might not be immediately apparent. But the small village is home to half a dozen Swiss registered companies whose sole owner's business activities are central to rising concerns about the credibility of Public Health England (PHE).

PHE was created as an "operationally autonomous executive agency" of the Department of Health on 1 April 2013, when responsibility for public health passed to local authorities. Its function is to "protect and improve the nation's health and wellbeing, and reduce health inequalities" by providing government, local government, the NHS, public health professionals, and the public with "evidence-based professional, scientific and delivery expertise and advice." 1 2

In the two and a half years since then, PHE has been embroiled in a series of controversies about the quality and credibility of advice it has issued on topics including fracking, NHS health checks, and the NHS Diabetes Prevention Programme, raising concerns about both its competence and its supposed independence (box). It has recently been in the firing line again, accused of bowing to political pressure by initially agreeing not to publish its review of measures to reduce sugar consumption.3

## Fracking and other criticisms

To the astonishment of MPs and environmental groups alike, Public Health England's priority on its formation was not to tackle one of the big bêtes noires of public health but to weigh-in on the debate over the government's plans to encourage large scale extraction, or fracking, of shale oil and gas in the UK.

In October 2013, PHE's Centre for Radiation, Chemical and Environmental Hazards released a draft literature review of the impact of fracking, which concluded that the risks to public health were "low if operations are properly run and regulated." 33 The conclusion remained unchanged in the final report, published in June 2014. 34

An editorial in *The BMJ* warned that while the review had been "rigorous in its presentation of the evidence" there were "problems with its conclusions ... Unfortunately, the conclusion that shale gas operations present a low risk to public health is not substantiated by the literature." 35

The conclusion that Public Health England should have drawn was that "the public health impacts remain undetermined and that more environmental and public health studies are needed." 35

To members of the House of Commons Health Committee, which took PHE's leadership to task the following month, the decision to prioritise fracking over many more pressing public health issues seemed perverse.

One of the committee members suggested that PHE, nominally independent, appeared to be serving the policy agenda of a government promoting the potential of fracking "to provide the UK with greater energy security, growth and jobs." 36

Duncan Selbie, PHE's chief executive, formerly head of Brighton and Sussex University Hospitals and the first director general of commissioning for the NHS, was given a rough ride when he gave evidence to the committee on 19 November 2013.

It had been "hopelessly naive" for PHE to tackle fracking as and when it had, Barbara Keeley, the MP for Worsley and Eccles South, told him. There were "real concerns that there is not enough monitoring, in any sense, to tie in with what you have said [and] I found your report naive in the extreme."

There was, Selbie insisted, "thought given to this, and it was very carefully examined."

For Rosie Cooper, MP for West Lancashire, the issue placed a question mark over PHE's "credibility. You are saying that you dealt with fracking as opposed to smoking, alcohol or a million other really important public health issues. Out of the blue, without your board deciding it, but because somebody somewhere whom you have not named decided to do it, you picked that one issue."

Perhaps, she added, PHE was "being helpful to the government's agenda."

Paul Cosford, PHE's medical director and director for health protection, said the work on fracking was already under way under the auspices of the Health Protection Agency when PHE took over its role. It was not, he said, an accurate reflection of PHE's priorities "to say that this was our highest priority, over and above smoking, alcohol, obesity and all the other public health harms. We are absolutely passionate about addressing those."

There was a further awkward moment during the committee's questioning of Selbie that appeared to reinforce concerns that the organisation was not as autonomous as it ought to be.

Asked to outline "any specific [government] policies that you believe are widening health inequalities," Selbie declined, agreeing with a suggestion that to do so would be too controversial. 37 In its subsequent report, the committee expressed concern "that the chief executive of PHE should regard any public health issue as 'too controversial' to allow him to comment directly and believes that PHE should be able to address such matters without constraint."

On fracking, the committee concluded it had been "unwise for PHE to follow through the work on shale gas extraction which had been initiated by [the Health Protection Agency] without first taking care to satisfy itself that this work reflected both the public health priorities of PHE and the research quality criteria embraced by the new organisation."38

Friends of the Earth, one of many organisations critical of fracking, said that PHE's conclusions had been drawn "from what it admits is limited evidence" 39 and, as Physicians, Scientists and Engineers for Healthy Energy had pointed out, "lack of data is not an indication of an absence of harm." 40

Elsewhere, public bodies had not been so quick to give fracking a clean bill of health. In November 2013, one month after PHE published its draft conclusions, the German government banned fracking until it was "clear that there are no health implications." 41

In the US, where the use of fracking is much more advanced than in Europe, scientists have warned that there is a "paucity of scientific evidence looking at the public health impact ... among those living in close proximity to shale gas drilling."

Society, concluded the authors of a paper published in the *American Journal of Public Health* in July 2013, had a responsibility "to study the potential for harm and to mandate policies and strengthen regulations to ensure that adverse effects to the public's health are not an unfortunate consequence of an industry's eagerness to capitalise on this new energy boom." 42

Furthermore, PHE's reassurance in its evidence review that "in the UK strict regulatory requirements governing onshore oil and gas exploration already exist and shale gas extraction will be regulated within this framework" appeared complacent in the light of the European Commission's cautionary observation that "Existing legislation in Europe is not fully equipped to tackle the resulting environmental impacts and risks" of a technology of which there was "very limited experience ... in the EU." 43

#### **Diabetes**

This September PHE was under fire again, for its role in the NHS Diabetes Prevention Programme, a joint project between PHE, NHS England, and Diabetes UK that will be rolled out nationally from 2016.44 Writing in *The BMJ*, diabetes and primary care experts expressed "serious concerns that the programme consists entirely of a top down, highly standardised behavioural intervention offered to a fraction of the population" that was "divorced from the multilevel, community-wide, and politically engaged prevention plans recommended by the World Health Organization."

Furthermore, "astonishingly, given that this lifestyle intervention will become national policy," the PHE report gave "no formal estimate of the programme's cost or cost effectiveness," beyond an "assumption that it will save money ... based on speculation." 45

Jim O'Brien, national director of the Diabetes Prevention Programme, responded to say PHE recognised that the programme alone "will not provide an answer to the growing incidence of diabetes, but it can be expected to make an important contribution." He defended the programme as "a pivotal moment in public health" that, as the first national behaviour change programme in England, "could lead to broader investment in prevention in the longer term." 46

Trisha Greenhalgh, a professor at the Nuffield Department of Primary Care Health Sciences at the University of Oxford and lead author of the critical editorial in *The BMJ*, was unavailable for comment.

#### Not an academic institution

Walter Holland, former president of the Faculty of Public Health, told *The BMJ* he believed "the basic problem" with PHE was that, as it was currently structured, it was "not an academic institution and has not really been able to establish a proper linkage to academe and to expert advice." Compounding this, it was also "not listening to advice."

Holland says PHE resisted his advice over its implementation of the NHS health check programme, introduced as a collaboration between PHE, the Department of Health and others. He went to see Selbie and his number two to suggest ways to "assess whether they were doing any good or not, rather than just going ahead blindly." His advice—that local pilot programmes should be introduced and assessed before national rollout—was not taken on board. Subsequently the programme has been criticised as ineffective and not evidence based. 47 48

One study in 2014 concluded that the change in the reported prevalence of diabetes, hypertension, coronary heart disease, chronic kidney disease, and atrial fibrillation did not differ between practices which did and did not provide health checks.

But it is the furore generated by its pronouncement in August that e-cigarettes "are around 95% safer than smoked tobacco" that crystallises these concerns into a single question: is PHE fit for purpose?

### Questionable evidence

On 19 August 2015, PHE published an "evidence update" on e-cigarettes, commissioned from Ann McNeill of the National Addiction Centre, King's College London, and Peter Hajek of the Wolfson Institute of Preventive Medicine. "In a nutshell," wrote PHE chief executive Duncan Selbie in the foreword, "best estimates show e-cigarettes are 95% less harmful to your health than normal cigarettes." 4

After the figure was reported widely, some of the concerns of the public health community were voiced in an editorial in the *Lancet.* PHE had relied on the findings of a research paper "that the authors themselves accept is methodologically weak." This, and "the declared conflicts of interest surrounding [the work's] funding," raised

"serious questions not only about the conclusions of the PHE report, but also about the quality of the agency's peer review process." 5

An article in *The BMJ* on 15 September pointed out that although some UK health organisations had endorsed the PHE's report, and the media had accepted the evidence as "unequivocal," many other organisations, including the BMA, the Faculty of Public Health, the US Centers for Disease Control and Prevention, and the World Health Organization, "have come to the opposite opinion." 6

A director of public health in north west England, who spoke to *The BMJ* on condition of anonymity, said he and his colleagues in the region have found PHE's stance on e-cigarettes "problematic on a number of levels," not least of which was the lack of consultation with public health professionals on the ground.

One of the key issues, he said, was that e-cigarette fluids "have a wide variety of formulations, many of which are untested and not formulated to any specific safety regulations. We're not talking about a unitary product, so to claim safety for something as diverse and as unregulated as e-cigarette fluid is just not operationally or scientifically credible."

Furthermore, "in looking only at the risk and benefits of e-cigarette use to smokers, and failing to consult the field, PHE has overlooked predictable though unintended consequences which raise risks of enabling emerging new routes to nicotine addiction in young people through normalisation."

The PHE guidance also threatened to undermine the work by public health officials who "have spent the past 18 months persuading public venues, council buildings, and others to agree to ban e-cigarette use in enclosed public spaces," he said.

The crucial debate about the potential roles of e-cigarettes in renormalisation of smoking or as a possible gateway to smoking remains unresolved. However, although the latest figures from the Health and Social Care Information Centre show that in 2014 the proportion of 11-15 year olds who had ever used cigarettes (18%) was at its lowest level since the survey began in 1982, more than a fifth (22%) had used e-cigarettes at least once. 7

This cohort, said the director, "may now be treating PHE guidance as a 'green light.' Yet for them there is no 'safer'; there is only a new risk and increased ongoing risk of a new addiction." The PHE advice "seems to risk being an iatrogenic public health intervention for this younger population."

Concerns about PHE's stance go to the heart of the schism in public health over e-cigarettes, dividing supporters of the potential benefits to people who wish to give up smoking from those wary of the as yet unknown population level consequences. 8

Many working in tobacco control have also noted that the e-cigarettes market is being increasingly dominated by the big four tobacco companies and are suspicious of their motives. 9

On 27 August, PHE responded to growing concern about its report by publishing an "authors' note." McNeill and Hajek said they had looked at "studies that have recently been widely reported as raising new alarming concerns on the risks of e-cigarettes" and concluded that they did "not in fact demonstrate substantial new risks and that the previous estimate by an international expert panel (Nutt et al, 2014) endorsed in an expert review (West et al, 2014) that e-cigarette use is around 95% safer than smoking, remains valid as the current best estimate based on the peer-reviewed literature." 10

The West review, which McNeill and Hajek coauthored, was a summary of the evidence on e-cigarettes submitted to the All-Party Parliamentary Group on Pharmacy in June 2014.11 It did not endorse the Nutt paper but simply

cited its findings, saying: "The precise extent of harm from long-term use is not known but has been estimated at around 1/20th that of smoking tobacco cigarettes."

#### Harm reduction champions

The panel of 12 that generated the "95% safer" figure was assembled by the Independent Scientific Committee on Drugs (since renamed DrugScience) for a two day workshop in London in July 2013. DrugScience is an "independent, science-led drugs charity" founded by David Nutt in 2010 after his dismissal by the home secretary as chair of the Advisory Council on the Misuse of Drugs. 12 13 Nutt is now director of the Neuropsychopharmacology Unit at Imperial College London.

The panel's conclusions were subsequently published in *European Addiction Research* in September 2014,<u>14</u> where the authors described themselves as "experts [selected] from several different countries to ensure a diversity of expertise and perspective."<u>14</u> But at least six of the authors, including Nutt, were already established champions of e-cigarettes as part of the "harm reduction" strategy embraced enthusiastically by the tobacco industry.

In May 2014, Nutt, Karl Fagerström, Kgosi Letlape, Anders Milton, Riccardo Polosa, and David Sweanor were among 56 "specialists in nicotine science and public health policy" who wrote to Margaret Chan, director general of WHO, to complain that harm reduction had been "overlooked or even purposefully marginalised" in preparation for the sixth conference of the parties to WHO's Framework Convention on Tobacco Control.

McNeill and Hajek, authors of the PHE's review of evidence on e-cigarettes, were also signatories of that letter. 15

Alarmed by the letter, 129 public health experts responded with a letter of their own to Chan. It was, they said, "fundamental" that WHO and other public health bodies did not "buy into the tobacco industry's well-documented strategy of presenting itself as a partner." 16

As *The BMJ* reported in June 2015, Gerry Stimson, one of the organisers of the first letter, had previously accepted hospitality and funding from Nicoventures, British American Tobacco's flagship harm reduction company. Nutt's coauthor Fagerström, a Swedish clinical psychologist, had also accepted consultancy fees from Nicoventures, partly for lobbying members of the Australian parliament about the benefits of e-cigarettes.

The Nutt paper discloses that Fagerström "has served as a consultant for most companies with an interest in tobacco dependence treatments" but makes no mention of BAT or Nicoventures. It also records that Polosa, whose organisation Lega Italiana Anti Fumo is thanked "for supporting this research," has served as a consultant for Arbi Group, a distributor of e-cigarettes. It does not record that in 2004 Polosa and LIAF received \$315 000 from Philip Morris for a study on nicotine addiction. <u>17</u>

Another of Nutt's coauthors was Martin Dockrell. At the time the panel sat, he was director of research and policy for Action on Smoking and Health (ASH), which has consistently supported the role of e-cigarettes. 9 18 In March 2014, six months before the panel's paper was published, Dockrell joined Public Health England as lead of its tobacco control programme.

### **Swiss connections**

It is the identity and connections of the Nutt panel's sponsor that leads to the small Swiss village of Trélex and poses serious questions about transparency and conflicts of interest that PHE has failed to address.

The Nutt paper thanked "Euroswiss Health (Switzerland) for funding." Registration documents lodged with the commercial register of the Canton de Vaud say that the company's aims are the creation and management of

networks of private hospitals, doctors' offices, and drug distribution services throughout Europe and "all investment activities in the general area of health and medical research." 19

The company was registered in 2003 at 8 Place de le Tour, Trélex, by Delon Human, a South African doctor resident in Switzerland. He used the same address to register several other companies, including Health Diplomats. This appears to be a lobbying organisation whose clients include, or have included, the drug industry and food and drink companies. 20 EuroSwiss Health has no website and searches for the company default to the Health Diplomats website.

The LinkedIn page of Curt Tyler, who claims to have been the Health Diplomat's chief executive for four years until 2014, reveals more about the activities of the company. He describes his role there as "managing the day-to-day functions of the International Food and Beverage Alliance"—an association of 11 global companies including Coca-Cola, Nestlé, Mars, and McDonald's—and pursuing "public health advocacy with the World Health Organisation and the United Nations." 21 Tyler did not respond to attempts to contact him. Human's LinkedIn page shows that he was secretary general of the International Food and Beverage Alliance. 22 A spokesperson for the alliance confirmed Human had stepped down from the role in January 2014.

A third company registered by Human is NicoLife. In Human's biography as a speaker at the Global Forum on Nicotine in Warsaw in 2014, NicoLife was described as "a group specialising in tobacco harm reduction and the appropriate use and recognition of nicotine." 23

It has also served as a conduit for funding from British American Tobacco (BAT). In 2010, BAT paid Human to produce a book called *Wise Nicotine—Uncovering Tobacco Harm Reduction, the Best Kept Secret in Public Health*. 24 On a dedicated website, the author describes the book as "a provocative commentary on the blind spots in modern tobacco control" and "a clarion call for … harm reduction." There is no mention of BAT. 20

But BAT's website notes that "in 2010, we funded NicoLife ... in its production of a book, *Wise Nicotine* ... We hope that the book will play an important role in raising awareness of tobacco harm reduction." 24

According to a report on harm reduction published by British American Tobacco in 2013, NicoLife also provided "consultancy services to BAT on our approach to harm reduction." The report quotes and includes a photograph of Human: "Whatever people think about 'big tobacco,' it can't be denied that they understand the needs of smokers and can deliver alternative products at a large scale. BAT and its subsidiaries … could become part of the solution to addressing the epidemic of tobacco-related disease." 25

Despite these connections, a blog posting on DirectScience's website in August 2015 states that there were "no links or contracts, current or historic, between EuroSwiss Health and any tobacco company." 26

Asked if he had approached EuroSwiss Health to fund his panel's assessment of the relative harms of nicotine containing products, or if he had been approached by the company, Nutt told *The BMJ*: "There was no pursuit of anyone, rather a shared interest that led to the MCDA [multicriteria decision analysis] project. We all thought that applying the MCDA principles to tobacco and nicotine would not only advance science but could help protect millions of lives from tobacco related disease and premature death."

The donation, he added, had been "in support of the groundbreaking work done in harm reduction, risk quantification, and risk communication by DrugScience as evidenced by the Nutt et al 2010 *Lancet* paper." 27

Nutt told *The BMJ* that while he was happy with the way PHE had represented and relied on his work in support of its "95% safer" claim, he felt the figure was "subject to misinterpretation ... percentages are not well understood by the public and the statement implies that both nicotine products are safe. Our paper made clear that both products are potentially harmful."

As "even those disputing the 95% figure agree that [a] twentyfold ratio of relative harms is the best estimate we have at present for cigarettes and ENDS [electronic nicotine delivery systems] currently ... it seems to me that the critique of the 95% figure is a roundabout attempt to get the conclusions of our MCDA study discredited," he said.

This, he added, was "not scientific and potentially very damaging to human health if it puts people and regulators off ENDS and back to cigarettes."

Nutt did not clarify whether he was, or had been, aware of Human's connections with the tobacco industry.

Contacted by *The BMJ*, Human declined to explain the nature of EuroSwiss Health's business. He also declined to discuss his history of engagement with the tobacco industry or whether he, or any of his companies, was currently in its pay. Nor would he discuss whether the idea for the panel was his or Nutt's.

He did, however, state that, having "consulted several colleagues on how we can stay focused in this e-cigarette debate on substantive science," his concern was that "answers to your questions might lead to further misrepresentation and distraction."

He added: "For the avoidance of doubt, I wish to confirm there was no tobacco company involvement in the funding or execution of the Nutt study."

However, Human has clearly maintained contact with the tobacco industry. In September, he attended the global tobacco and nicotine forum, a three day industry conference in Bologna, Italy, where he moderated a discussion on public health. Hosted by industry newspaper *Tobacco Reporter* and its offshoot *Vaper Voice* the conference was sponsored by the big four tobacco companies—BAT, Imperial Tobacco, Japan Tobacco International and Philip Morris International.

The forum was also attended by two members of Nutt's panel and his co-authors on the paper that generated the "95% safer" claim.

Kgosi Letlape took part in a discussion on ethics as part of a panel that included David O'Reilly, BAT's director of science and research and development. Letlape and Human are colleagues: Letlape is president of the Africa Medical Association and Human is its secretary general. 28

Another member of Nutt's panel, Polosa, professor of internal medicine at the University of Catania, gave a keynote address, "Nicotine reloaded," and took part in two panels. On one, "Consumer wants and needs," he was joined by Simon Clark, director of pro-smoking group FOREST. He also took part in a subsequent discussion about public health, moderated by Human, before the conference adjourned for a lunch sponsored by US tobacco firm Reynolds American.29

#### International alarm

Such connections have only added to the alarm caused by the PHE's report in Europe, says Pekka Puska, the Finnish president of the International Association of National Public Health Institutes. Pukka says he emailed PHE chief executive Duncan Selbie and Kevin Fenton, director of health and wellbeing at PHE, on 7 September to say that public health professionals and health ministry officials in Finland had been "surprised and concerned" by the organisation's endorsement of e-cigarettes as 95% safer than tobacco. There was "still much research needed" before PHE or anyone else could reach the conclusions it had. "It adds to our concern," he said, "that many of the experts/consultants that promote this kind of e-cigarette approach have various connections with the industry."

PHE told *The BMJ* its report had been "subject to significant misreporting and we have been in touch with international colleagues, including Professor Puska, to clarify our position. The PHE report responds to the realities

and patterns of e-cigarette use in England and builds upon a strong track record of national and local tobacco control activities."

However, Pukka told *The BMJ* that, having spoken to Fenton, he remained "firmly behind the arguments [against the report] as do many other international tobacco control experts. Many are very surprised and worried that this English report may do serious harm to tobacco control work that is currently progressing reasonably well in Finland, England, and so many Western countries."

#### PHE response

On 15 September, PHE, responding to the criticism in *The BMJ*, rounded up a dozen public health organisations, including ASH and Cancer Research UK, to sign a joint statement defending its position. The concerns raised by McKee and Capewell in *The BMJ*, it said, had been "fully responded to before." 30

But a letter from PHE published in the *Lancet* in response to that journal's criticisms of the e-cigarette evidence review did not even begin to address the various relationships and funding connections behind the Nutt paper. 31

A spokesperson for PHE said questions relating to the "methodology and composition" of the Nutt study were a matter for Nutt. But John Newton, PHE's chief knowledge officer, told *The BMJ* that its endorsement of ecigarettes as 95% safer than smoking "was not based on one paper but is rather an assessment of the conclusion of that paper in the light of all the other evidence considered in the review." It was, therefore, "independent of the methodology used by Nutt et al."

Nevertheless, PHE did "absolutely not" accept that the credibility of the Nutt paper, and hence the PHE's conclusion, was undermined either by its funding source or by the apparent conflicts of interest of at least half of the Nutt panel.

"Accusations against one study out of over 180 cited would not affect the overall findings of the PHE report and the accompanying implications for policy and practice," said Newton.

Yet PHE's endorsement of e-cigarettes appears to be at odds with that of the World Health Organization. It's 2014 report stated that when designing regulatory strategies for electronic nicotine delivery systems (ENDS), governments should "impede ENDS promotion to and uptake by non-smokers, pregnant women and youth" and "protect existing tobacco-control efforts from commercial and other vested interests of the tobacco industry."

WHO also pointed out that Article 5.2(b) of the Framework Convention on Tobacco Control, to which the UK is a signatory, committed parties "not only to preventing and reducing tobacco consumption ... but also to preventing and reducing nicotine addiction independently from its source. Therefore, while medicinal use of nicotine is a public health option under the treaty, recreational use is not." 32

Newton denied PHE's position on e-cigarettes was contrary to the cautious stance adopted by signatories to the framework convention. "We have always been clear that e-cigarettes are not 100% safe, that they should only be used by people trying to cut down or quit smoking and the evidence should be closely monitored," he said.

The WHO, a spokesperson told *The BMJ*, had "no comment at this time on the Public Health England's report on ecigarettes" but confirmed that its position on e-cigarettes remained that outlined in the 2014 report. WHO, the spokesperson added, "is currently in the process of evaluating further scientific basis and evidence in order to submit an updated report to the 7th meeting . . . in 2016," when signatories "may or may not opt to revise their previous decision."

### Notes

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### **Footnotes**

- Competing interests: I have read and understood BMJ policy on declaration of interests and have no relevant interests to declare.
- Provenance and peer review: Commissioned; not externally peer reviewed.

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