

# Parents' trust 'betrayed' as health body fails to publish vaccine test result

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By Henry Bodkin

THE failure of England's public health body to publish results of three major studies into vaccines for children makes it impossible for experts to establish whether the drugs could be harmful, scientists have claimed.

Hundreds of children took part in three potentially risky government drug trials, but Public Health England (PHE) breached the law by failing to add the findings to the official register set up to allow the scientific community to scrutinise the outcomes.

Experts have accused PHE of an "incomprehensible" violation of the trust of parents who gave consent for their children to take part in the tests. The largest trial involved 640 participants under the age of 16, whose parents gave consent for them to be selected at random to try a new meningococcal and whooping cough booster vaccine.

While dangerous side-effects in a trial at this stage are rare, a risk does exist. Participants also take a gamble by offering themselves for selection for a new drug that might not protect them as well as the standard therapy.

The trial concluded in 2016, but the results have not yet appeared on the EU Clinical Trials Register (EUCTR) - a breach of EU law, which requires registration within 12 months - nor published anywhere else. The failure to register means there is no way for the public to know how the children fared.

Last night, Dr Ben Goldacre, the Oxford academic whose analysis revealed

the PHE omission, told *The Sunday Telegraph*: "It is incomprehensible to me for Public Health England, of all the trials it could leave unreported, to have failed to comply with the legal requirements to report trials of vaccines, when patients participate and take a risk with their own health.

"We have to respect their contribution by publishing the results properly. If we don't, that is a betrayal of trust."

The EUCTR was set up partly to counter the tendency of many scientific journals, the traditional mode of

49.5pc

The proportion of clinical trials where results were reported, according to eu.trialstracker.net

publication, to polish results, downplaying the therapies that failed.

The transparency it affords is supposed to promote confidence in science at a time where the "anti-vax" movement - those who argue that vaccines are useless and actually cause disease - is buoyant.

Andrew Wakefield, the discredited British doctor whose fraudulent research prompted a scare that the MMR vaccine causes autism, is enjoying widespread support in the US and a boost from sympathetic comments by President Donald Trump.

"Withholding the results of a clinical

trial makes a mockery of all our efforts to promote trust in medicine, and I'm particularly sad to see vaccine trials going unreported," said Dr Goldacre.

A second PHE trial, which concluded in 2010, investigated the effectiveness of a meningitis C vaccine in a group of 130 one-year-olds, while a third, which concluded in 2011, involved 75 adults trialing a meningitis B vaccine.

PHE said the results of these studies had been published in academic journals, while results of the larger 640-patient trial are "still being analysed".

The omission by PHE forms part of a bigger picture of widespread disregard for the registration law.

Dr Goldacre's research via his website (eu.trialstracker.net) shows that, of the 7,274 trials where results have been due, only 49.5 per cent reported them. However, no organisation has ever been sanctioned for breaching the law.

The research showed that pharmaceutical companies tended to comply more than academic institutions, with 68 per cent of company-sponsored trials reporting their results, compared with 11 per cent from universities.

Fergus Sweeney, the head of inspections at the European Medicines Agency, said: "This study helps spread the word on how important it is to post trial results once a clinical trial is over."

"We at EMA are firm believers that transparency and public availability and scrutiny of clinical trial information and results are fundamental for the protection and promotion of public health."

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