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Pertussin 30—preventive for whooping cough?
A pilot study

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Abstract
The primary purpose of this study was to be a pilot for a further, larger study to determine whether the homœopathic preparation *Pertussin* 30c was effective in preventing whooping cough. It was recognized that neither the numbers involved, nor the method followed would of themselves be sufficient to prove efficacy, but it was hoped that a positive result would permit the conclusion to be drawn that a further study would be in the public interest.

694 valid replies from 1100 questionnaires sent to the parents of children who had had *Pertussin* 30 were compared with Hillingdon District's notified figures. Hillingdon FPC provided evidence of a wide degree of variability in the notification rates of pertussis. When these were taken into account the result suggested a degree of activity for *Pertussin* in excess of 50%. Although the assumptions are reasonable in themselves, no claim can be made to have demonstrated the effect of *Pertussin* in a statistically valid way. It is reasonable, however, to conclude that there is a good technical case for further investigation to be undertaken, although with rising immunization rates it may not be justified in terms of reward for its cost. The trial has helped to define a possible method for doing this, which is described.

Introduction
The theoretical principle underlying homœopathy was a generalization made from observation by its founder, Samuel Hahnemann, who also recalled it in Hippocrates' writings.[1] For example, scarlet fever resembles belladonna poisoning, so a suitable dose of the latter should cure the former, which it did, according to Hahnemann. The ideal dose was found by trial and error to be reached by serial dilution and succussion, and to be exceedingly small.

In the present case the drug is made from the sputum of a whooping cough victim. Drugs made from any such pathological sources are called nosodes, and their use in the same disease, rather than a similar one, is isopathy. Using an isopathic nosode preventively is clearly quite different from prescribing for an ill patient a similar remedy chosen on the basis of his symptoms, so this trial is not homœopathy as such, and should be recognized for what it is: a limited isopathic pilot study in a specific situation.

Pertussin 30c is a preparation diluted 1 in 100 thirty times. Each dilution is followed by the vigorous jolting shake known as succussion, which has been found to be essential in the production of any active potentized drug. (Drugs so produced are called potencies.) Its choice is based on experience. The 30c is a commonly effective potency, chosen for this study empirically on this basis. There is no question as to its safety. No evidence exists which purports to suggest any significant side-effect. The duration of action of such a potency is unknown, but on the basis of its use clinically, and that of other nosodes, it is not likely to be long. It is not, therefore, in serious competition with orthodox vaccination where this is indicated. As new-born babies are held to respond well to homœopathic treatment it is reasonable to suppose that they would also respond as well to *Pertussin* 30c as anyone else.

Patients and methods
The empirically chosen regime was to give babies *Pertussin* 30c every three months during the first year of life, an eighteen month dose, and further doses on each birthday until the age of 6. An extra dose was to be given in case of contact with pertussis, unless a routine dose had recently

been given. In practice few extra doses were requested. Instructions were given in the proper care and administration of remedies so as to maximize their chance of success.

The patients were those whose parents had requested homœopathic protection. Many had been advised that the orthodox vaccine was contra-indicated. Others had rejected it out of choice. Many came privately, mostly from a short distance, and some National Health Service patients agreed to participate after explanation of the aims of the project. In all cases the case for orthodox vaccination and the uncertainty surrounding *Pertussin* were explained, either by interview or (occasionally) by letter.

Details of the child's birth history, subsequent history, family and social histories including parental occupation were taken, with specific reference to standard contra-indications to vaccination. It was hoped that this might enable comparison to be made with matched controls, but this proved beyond our resources.

Social classes 2–4 predominate in Hillingdon, and the *Pertussin* patients tended to be 2–3—not that this is considered important as a factor in the incidence of whooping-cough.[2]

The time period 1980–82 was chosen as Hillingdon District were able to provide details of notified whooping cough broken down into vaccinated, partially vaccinated and unvaccinated fractions. This enabled a comparison to be made with unvaccinated children as well as with standard vaccination. Children of 0–5 years of age who contracted pertussis in this period were included. These years also covered a peak incidence year.

Hillingdon Family Practitioner Committee provided anonymous data on differences in notification between practices, and the percentage population each category served. The percentage of the total population born in each year and thus in the age group in question was also provided.

Questionnaires were sent to the parents of the 1,100 children who had taken *Pertussin* 30c regularly. These asked whether the child had contracted whooping cough, and if so the grounds for the diagnosis. All doctors' diagnoses were included. In order to establish the diagnosis more securely questions were included on the clinical features of whooping cough: the prodromal snuffles, coughing spasms, whoop and vomit, and the duration of each of these. It revealed that no cases were bacteriologically confirmed. The clinical features are analysed elsewhere.[3]

Results

The sample

851 (77%) of the 1,100 questionnaires were returned. 157 were excluded, mostly on the child's age being outside the chosen limits. A few were excluded due to inadequately completed questionnaires, subsequent orthodox vaccination, or the child having developed whooping cough almost immediately after the first dose of *Pertussin* 30c. It was assumed that these did not bias the residue. Of the remainder, ninety claimed that whooping cough had developed, sixty-seven (9.65%) diagnosed by the general practitioner and twenty-three by the parents alone. When parental diagnoses were assessed by analysis of the questionnaire, only five of the twenty-three were thought likely to have had whooping cough. Thirteen of the doctors' diagnoses also seemed doubtful due to lack of symptoms or the brevity of the illness. Nonetheless, the doctors' figures were used as these best correlate with the controls.

The controls

Hillingdon District Health Authority figures (Table 1) show that notified whooping cough occurred in 5.1% of children. Only 8.8% of cases occurred in vaccinated children, a figure compatible with nationally accepted data.[4,5,6] Five per cent of the population were under the care of doctors who notified 9–10 cases per thousand total population (Hillingdon Family Practitioner Committee Table 2) there is neither geographical nor social bias in the uneven notification. This figure is assumed to be more nearly accurate than the others. It parallels notification rates of other illnesses and correlates better with the data obtained by the Royal College of General Practitioners.[7] Dr Crombie (personal communication) agreed that this assumption was reasonable. The FPC also report that 6% of the population fell in the 0–5 year age group at the time of the study. That is 60, or 15%, of the 405 unvaccinated children who had notified pertussis. Given an immunization rate of 50% and that from DHA figures about 10% of cases occur in vaccinated children, as many as 27% of unvaccinated children contracted whooping cough, and it is this figure which compares with the 9.65% in the *Pertussin* sample.

TABLE 1 *Whooping cough notification 1980–82 in Hillingdon District (Hillingdon District Health Authority figures)*

	0–5 figures vaccination	total pop. partial	in age group none	17658 total
1980	6	9	45	67
1981	6	13	74	104
1982	32	27	286	384
Total	44	49	286	384
%	0.24	0.28	3.15	3.74
1980-82 cases	29	25	288	342
Total pop. (b. 1.10.79 onw.) 9 147				
%	0.32	0.27	3.15	3.74

Conclusion

If the arguments made to establish comparable controls, each of which is innately reasonable in itself, are accepted, a reduction in whooping cough by a factor of approximately two in three has been demonstrated. Clearly the assumptions made reduce the reliability of this figure. The only conclusion which can be drawn, therefore, is that whilst this study was not capable of demonstrating efficacy of *Pertussin* 30c as a preventive for whooping cough, there is a prima facie case for a further trial of *Pertussin* 30c.

TABLE 2 *Pertussis notifications to Hillingdon FPC at 1982*

Notification per 1000 patients	Population* represented at this rate
0– 2	82.5
3– 7	12.5
8–10	5.0

*JME's excluded

TABLE 3 *Effectiveness of Pertussin as a prophylactic*

	Pertussis diagnosed	No pertussis	Total
Unimmunized plus Pertussin 30c	67	627	694
Unimmunized	936	7 064	8 000
Total	1 003	7 691	8 694

Chi-square = 2.42, p>0.1

Assumptions made

—High notifiers give an accurate rate which is 9 per 1000 patients or 11.7% of children.

—8 000 of the 17 658 children were unimmunized. 11.7% (=936) of the 8 000 children developed whooping cough.

Discussion

The problem of diagnosis

This bedevils any pertussis study. While the typical case is easily recognized, milder cases are inevitable. Where do you draw the line? Are high notifiers over-notifiers? Or are they the accurate ones, as Crombie suggests; which makes a nonsense of the notification system as a means of assessing morbidity. Classical descriptions suggest a much more serious disease than the one I encountered, but I have been unable to find any recent analyses of symptoms to compare with my own.

The criticism is sometimes raised that there should have been bacteriological evidence to support the diagnosis. Not only is this logistically difficult and expensive, but given the high rate of negative cultures in clinically obvious cases there are grounds for doubting that bacteriology adds significantly to the accuracy of such diagnoses.

The problem of study design

Given the efficacy of the orthodox vaccine, a study which denied it to eligible babies would now be unethical. In the climate of public opinion which obtained when this study was started this was not the case. Future studies would therefore have to embrace orthodox vaccination in their design and measure the incidence of pertussis in babies up to the age of 9 months, by which time vaccination could be presumed effective. Those with specified contra-indications to orthodox vaccination constitute another potential study group.

This pilot study has shown what should have

been obvious to start with: that notification and other indirect data are inadequate and unacceptable as a control. Any further study should be methodologically unimpeachable. A statistically significant double-blind, single-tail trial of babies from birth to nine months would require 4,000 subjects, a massive undertaking which would have to be conducted on a national scale.

Freshly prepared standard *Pertussin* should be used culled from bacteriologically positive cases. In view of the recently recognized problem of changing incidence of agglutinin serotypes[8] the material used should be demonstrated to contain all three agglutinins. Whether a conventional nosode should be used, or a potency made directly from the agglutinins is debatable. A frequent dosage regime should be used, assuming a short duration of action. The choice would remain empirical, but from the experience of this pilot study I would now recommend more frequent doses during an epidemic and for potential contacts, as I think it might be more effective. Although it was not shown in the analysis, most of the cases that were positive had not had *Pertussin* within three months.

Recommendations for further research

When considering a potential research project one has to weigh the benefits to patients which might accrue from a positive outcome against its chances of success and its cost. It would also have to be compared with any alternative bid for the same funding.

It is unfortunately not possible on the basis of this pilot study to forecast a positive result with any conviction, although such is not ruled out. (A strong clinical impression still exists amongst homœopaths that *Pertussin* would be effective in a properly controlled trial.)

Is a trial necessary or even desirable? The groups most at risk in an epidemic are the ones in which vaccination is not fully effective, the babies under 6–9 months, when most deaths occur,[5,9,10,11] and those children who have valid contraindications for conventional vaccination. The very arguments which are used to advise against pertussis vaccination would tend to make the disease more dangerous if it were contracted. There are still an average of seven deaths a year[5] which ought to be prevented, so any potentially useful method ought to be considered to prevent the deaths, morbidity and hardship caused by the disease.

The answer to this question really hinges on one's estimate of the chances of eradicating whooping cough by orthodox vaccination. It is normally considered necessary to achieve 75–80% immunization rates to achieve 'herd immunity'. Rates fell from 77% in 1974 to 31% in 1978, while notifications rose from 46,525 in 1974–77 to 137,299 for the next four years, with a peak of 65,957 in 1978. Interestingly, deaths fell in the same four years from 35 to 30. Since 1978 immunization rates have risen by 5% per annum to 65% in 1984.[5] The public is more inclined to accept now that the damage done by vaccines is less great than was feared in the mid-seventies, although there is still some dispute over the actual incidence of vaccine damage. Recent evidence[13,14] suggests that only 7% of children have a medical contraindication to full orthodox pertussis immunization. There are therefore grounds for optimism that the necessary figure of 80% fully vaccinated children will be achieved.

The prospect of newer, safer vaccines after trials shortly to take place would also have to be taken into consideration when planning a further *Pertussin* study.[12] Whilst increased confidence in their safety might lead to a higher uptake, there is the acknowledged risk that they might be even less effective than the vaccine in current use.

There is the thought, more common amongst those of homœopathic persuasion, that immunization procedures may yet be found to be factors promoting the increased incidence of (for example) allergies and immune disorders. This is a possibility we should not dismiss entirely. Too many iatrogenic complaints have taken a long time to emerge as such, and the contention could not be other than difficult to prove. However, at present it remains nebulous and largely theoretical, and should not detract from the main conclusion.

The cost of a trial of *Pertussin* on the scale required would be very great, and far beyond limited homœopathic resources. It could only be carried out and funded nationally. The only way in which that might be possible would be as a part of the forthcoming trial on new vaccines.

Bearing these factors in mind, it is concluded that such a trial is probably not worth pursuing, unless expert opinion is sufficiently pessimistic about the future prospects for successful conventional vaccination.

Summary

A methodologically unsound trial of *Pertussin* 30c failed, possibly for that reason, to demonstrate its usefulness in preventing whooping

cough. Further research on these lines is discussed but not recommended.

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