Long-term homoeoprophylaxis study in children in the United States. Part One: Factors contributing to the successful completion of sequential dosing of disease nosodes.

Free and Healthy Children International HP Research Study-2009-2018.

Kate Birch RSHom (NA) CCH, Su Sandon RPh RSHom (NA) CCH HMC, Sarah Damlo C.Hom, Kim Lane MD.

Abstract:

Introduction: Currently the largest movements to curb and prevent infectious contagious disease in children are sanitary public healthcare measures and/or antibiotics and vaccines that carry inherent risks (1-3). Individual adherence to public health programs is variable, based on education, economic standing, and confidence in those administering the program. Homoeoprophylaxis (HP) offers a low-risk infectious contagious disease prevention method to those parents looking for alternatives (1,2).

Method: The purpose of this study is to understand how best to implement, and who are likely candidates for, a self-administered 44-month long HP program. This is a long-term study using real-world participants who may have multiple diagnoses and needs. Part One reviews socio-economic factors that contributed to registration and successful study completion; it involved 682 healthy unvaccinated or partially vaccinated children between the ages of one month and 10 years old. Five per cent of the children were over 10 years of age.

Results: This program appealed to two parent families with above average income and undergraduate or graduate education. Of the children registered, 69% were unvaccinated, while others opted for HP even after they had received a few vaccines or had completed several years of vaccines. 34% of the registrants were under the age of one year. The majority of children will or did attend public or private school, watch TV every day, and were omnivores.

Of the 682 children initially registered, 50% we had No Contact with due to a poor document tracking system. Of the 37% Completed, 49% Completed in 50 months. 21% Started and Stopped, and 10% Withdrew. Degree of completion of the program was consistent with all ages. Children whose parents had undergraduate degrees, with incomes between \$30,000-\$50,000 (USD), and never watched TV were more likely to complete the program. Time management issues and lack of understanding were the two main limitations to completion.

These results led to several program enhancements to promote greater success in program completion. Changes include not only the diseases covered and order of nosodes[®] in the program, but supplemental parent education and enhanced practitioner support. Collection of a more thorough initial inquiry into immune system readiness for HP from prenatal, birth, and previous vaccine histories will demonstrate if there is a need for homoeopathic treatment prior to commencing the program.

Conclusions: We have found that when middle class families of unvaccinated and partially vaccinated children understand what they are doing and are supported by competent practitioners they are able to successfully complete this self-administrated HP program.

Keywords:

Children's Health, Developing Immune Systems, Homoeoprophylaxis (HP), Infectious Disease, Nosodes, Public Health Program, Unvaccinated, Vaccines.

Introduction

Parent and HP Supervisor education was directed towards understanding the following principles: HP is not vaccination, nor a substitute for vaccination, but rather a form of immunisation that – through the immune system responses generated – offers the possibility of gaining the benefits of natural acquisition of the disease by stimulating a mild, short lived, disease-specific response that activates the immune system towards immunity and enhances childhood development ^(1,2).

The homoeopathic nosodes/remedies used in the HP Program include whooping cough, mumps, measles, polio, pneumonia, meningococcal disease, tetanus, and Haemophilus influenza type B. Apart from polio, homoeopathic nosodes were used for each disease. For polio, Lathyrus sativus, a plant remedy with historical

success in the prevention was used ⁽¹⁾. Parents were informed that there could be immune responses generated from the doses given, and that these responses were intended to help develop the child's immune system ⁽¹⁾.

Research Question

Part One: Are parents capable of completing a self-administered homoeoprophylaxis program within a set time frame for the purpose of preparing their child's immune system towards infectious disease processes?

Method

All children were registered between April 1, 2009 and December 31, 2014 under the supervision of a homoeopathic practitioner

trained in HP (HP Supervisor). Once enrolled, they were to undertake a 44-month self-administered HP program, within 50 months, according to a previously set schedule for eight different diseases (see Prophylaxis Record following). At registration, an Initial Health Profile and indication of the number of and type of vaccines previously given, if any, outlined the initial health of the child. Study design was based in part on the research by Dr. Isaac Golden (1).

Each family was equipped with:

- 1. A HP Program Booklet which included the Prophylaxis Record and HP Supervisor contact information.
- 2. A written comprehensive overview of the program.
- 3. Written instructions on how to complete the program.
- A remedy dose/response journal.
- 5. Three questionnaires to be submitted at three different stages of the program.
- 6. A HP remedy kit. All nosodes/remedies in the kit were procured from the same registered homoeopathic pharmacy. Sources of nosodes serologically verified: all nosodes used were procured from active diseases in children collected from 2008-2011 by San Diego Pathologists (1).

Parameters of Research:

- Recruitment: passive registration through word of mouth, website searches¹ and public lectures.
- 2. Inclusion/Exclusion Criteria: inclusion and exclusion of participants was based on the following questionnaire: inclusion was denoted by one or more Yes responses in first section and one or more No responses in second section. Exclusion would include a negative to any one inclusion criteria. As there was interest in undertaking the program from overseas, we included them as well.

inciu: Yes	Tor	clusion Criteria
162	No	1. Questions
		As a parent do you have the desire to use an alternative infectious disease prevention method to vaccination?
		Do you reside in United States or Canada?
		Is your child under the age of eleven years old age for the proposed commencement date?
		Will you partake in the informed consent process?
		Will you be able to comply with follow up questionnaires?
		Do you have access to conventional or alternative medical care?
		Does your child display evidence of healthy immune function?
		2. Does or has your child need(ed) medication or treatment of any of the below conditions?
		Severe Allergies
		Severe Skin conditions
		Repeated illness (more than once a month)
		Developmental delay
		Behavioral difficulties
		Atypical Neurological Development

3. **Consent:** an extensive Informed Consent process was completed for each participant. All Personal Health Information (PHI) was ethically collected and protected. All parents of subjects had the opportunity to review and sign consent forms prior to meeting with their HP Supervisors.

These forms included the following points:

- Identification of sponsor: Free and Healthy Children International (FHCi)
- 2. Identification of procedure
- 3. Identification of risks and benefits

- 4. Fees and compensation
- 5. Withdrawal mechanism
- 6. Confidentiality and release of Personal Health Information (PHI) notice
- 7. Informed consent, parents sign
- 8. Minors consent for children over the age of 6
- 9. Minnesota (MN) HP Supervisor exemption waiver
- 10. State or Provincial HP Supervisor waiver
- 4. **Data protection:** all registration and follow-up documents were submitted by mail to the Document Collection Person (DCP). Only the DCP, Principle Investigators (PI), and Data Analysis Team (DAT) had access to this information. Personal Health Information (PHI) will not be used or disclosed to a third party, except as required by law or permitted by authorised signature by the research subject: parent or guardian. All personal identifiers were held separate from data entries for research parameters. All hard copies of the data were kept secure, and electronic versions password protected.

Publication of the data removes all personal identification of subjects except for the following:

- 1. Age
- 2. Geographical subdivisions such as state, province, or country
- 3. Health outcomes and nosode/remedy responses
- 5. Control and Ethical Considerations: in the study of infectious disease, it is unethical to deliberately expose study participants to infectious agents. Therefore, the control group used is infectious disease incidence in vaccinated and unvaccinated populations in the general public.
- **6. Blinding:** there was no blinding method built into the study. All participants received the actual nosodes (or in the case of polio, Lathyrus sativus).
- 7. Standardisation of Treatment: all subjects adhered to the HP program as delineated in Chart 1. Prophylaxis Record, with dosing dates to be the first Sunday of the month. Adjustment of the program was possible if other needs of the child arose, such as, but not limited to the following:
 - If there was an outbreak of a disease covered later in the program, that nosode/remedy could be administered earlier in the program.
 - 2. Supplemental nosodes could be added to the program in case of travel or disease outbreak. Responses to these remedies were not included in this data.
 - 3. If the child was sick at the time when a dose was to be taken, the dosing was postponed until one week after the sickness resolved. The following dose was to be given on time. If the parent forgot to give a dose, they were to give it as soon as they remembered and then continue with the program as scheduled on the first Sunday of the month. They were to wait at least two weeks from last HP dose before the next disease was introduced.
 - 4. If the parent gave one or two doses of the triple dose and forgot to give the second or third dose, they were instructed to give the entire triple doses series as soon as they remembered.

- **8. Data collection:** all data generated was procured directly from the parents via passive submission of follow-up questionnaires. Call for submissions was announced through newsletters, email correspondence, and telephone contact. The questionnaires are as below.
 - 1. Initial Socio-economic Data to determine the following points:
 - a) Family type (married, single, other)
 - b) Yearly income
 - c) Highest education of parents
 - d) Medical insurance coverage
 - e) Education choices for the child
 - f) Dietary choices
 - g) TV use
 - 2. Initial Health Profile parameters include:
 - 1. Gender and age of child at registration
 - 2. Previous vaccination
 - 3. Previous infectious disease exposure and acquisition
 - 4. Initial and ongoing health profiles
 - a) Ear infections
 - b) Colds/sore throats/coughs
 - c) Seasonal allergies
 - d) Food allergies
 - e) Asthma
 - f) Eczema
 - g) Behavioural conditions
 - i. Violence
 - ii. Mood swings
 - iii. Fears
 - h) Learning disorders
 - i. Speech delay
 - ii. Disturbance in cognitive function
 - iii. Disturbance in social function
 - iv. Neurological conditions
 - Nosode/Remedy Dosing and Documentation: all nosode/remedy responses were logged in the Remedy Journal provided.
 - 4. **Cohorts:** total registered and number of boys and girls in the following levels of completion of the program. The following cohorts were compared in tables reporting on:
 - a. Age of entry into the program
 - b. Prior vaccinations received
 - c. Socio-economic standing of the family
 - d. Reasons for incompletion of the program
 - e. Accessibility to HP supervision and regional differences in completion of the program.

Cohorts identified in the following tables (numbers and definitions) (200C and 10M denote homoeopathic potency):

1. Total registered: registered with an HP Supervisor by submitting informed consent form, initial health

- profile, and socio-economic data.
- **2.** *No contact*: no follow-up paperwork was received, or the paperwork was sent and lost in the mail.
- **3.** *Withdrew*: submission of written notice of withdrawal from the program. Some may have given one to three doses before withdrawing.
- **4. Started and Stopped**: a few doses in the first series were given and for a variety of reasons they stopped. They did not formally withdraw from the program but provided verbal or written notice of cessation of the program.
- **5. 200C Series:** completion of the first 16 months of the program as documented by submission of the first questionnaire and/or Prophylaxis Record.
- **6. 200C and first 10M series**: completion of the first 16 months and second 8 months of the program as documented by submission of the first and second questionnaires and/or Prophylaxis Record.
- 7. *Completed*: completion of all stages of the program as documented by submission of the first, second, and third questionnaires and/or Prophylaxis Record.
- **8.** Completed in 50 months: completion of the 44-month program within 50 months by comparison of start dates and completion dates documented on questionnaires and/or Prophylaxis Record.
- 9. Adverse Events: an Adverse Event reporting procedure was developed to track any life-threatening or permanently disabling events. Remedy responses that mimic the normal symptoms of the disease are not considered adverse events but rather the desired immunological response. Responses that lasted more than 12-24 hours were reviewed and supported with additional dosing or if needed treated homoeopathically based on symptom presentation.
- 10. Exit strategy: parents could opt out of the program at any time and if they wanted to pursue the use of vaccines they could at any time.

Chart 1. Homoeoprophylaxis program (Prophylaxis Record)

Monthly Doses	Remedy	Potency	Label	Date	Initials	Check for response
1 month	Pertussin	200C	A1	Company State		
2 months	Pertussin	200C, 200C, 200C	A1			
3 months	Pneumococcinum	200C	B1			
4 months	Pneumococcinum ,	200C, 200C, 200C	B1			
5 months	Lathyrus sativus	200C	C1			
6 months	Lathyrus sativus	200C, 200C, 200C	C1			
7 months	Haemophilus (Hib)	200C	D1			
8 months	Haemophilus (Hib)	200C, 200C, 200C	D1			
9 months	Meningococcinum	200C	E1			
10 months	Meningococcinum	200C, 200C, 200C	E1			
11months	Tetanus Toxin	200C	F1			
12 months	Tetanus Toxin	200C, 200C, 200C	F1			
13 months	Parotidinum	200C	H1			
14 months	Parotidinum	200C, 200C, 200C	H1			
15 months	Morbillinum	200C	l1			
16 months	Morbillinum	200C, 200C, 200C	I1			
17 months	Rest or Supplement	al Program				

Monthly	Remedy	Potency	Label	Date	Initials	Response
18 months	Pertussin	10M, 10M, 10M	A3			
19 months	Pneumococcinum	10M, 10M, 10M	В3			
20 months	Lathyrus sativus	10M, 10M, 10M	C3			
21 months	1 months Haemophilus (Hib) 10M, 10N		D3			
22 months	Meningococcinum	10M, 10M, 10M	E3			
23 months	Tetanus Toxin	10M, 10M, 10M	F3			
24 months	Parotidinum	10M, 10M, 10M	НЗ			
25 months	Morbillinum	10M, 10M, 10M	13			
26 months	Rest or Supplement	al Program				
Submit seco	ond questionnaire					
Monthly	Remedy	Potency	Label	Date	Initials	Response
28 months	Pertussin	10M,10M, 10M	A3			
30 months	Pneumococcinum	10M, 10M, 10M	В3			
32 months	Lathyrus sativus	10M, 10M, 10M	C3			
34 months	Haemophilus (Hib)	10M, 10M, 10M	D3			
36 months	Meningococcinum	10M, 10M, 10M	E3			
38 months	Tetanus Toxin	10M, 10M, 10M	F3			
40 months	Parotidinum	10M, 10M, 10M	НЗ			
42 months	Morbillinum	10M, 10M, 10M	13			
44 months	Rest or Supplement	al Program				

Date of administration to be noted for each dose and check marks for responses which are to be noted in separate journal pages. One (1) month is either the age of child at onset of the program or first month of doses given.

Relationship between nosode and specific disease: *Pertussin* – Whooping Cough; *Pneumococcinum* – Pneumococcus; *Lathyrus sativus* – Polio:

Haemophilus – Haemophilus Influenzae Type B/Hib; *Meningococcinum* – Meningococcus;

Tetanus Toxin – Tetanus; *Parotidinum* – Mumps; *Morbillinum* – Measles.

Results:

The tables below illustrate the number of children in various groupings and levels of completion in the program: review of gender, age, prior vaccination, socio-economic variables and access to HP Supervisors determine possible factors contributing to successful completion of the HP program.

Table 1.1 shows the total numbers and genders of children registered and at various completion levels of the program. Unspecified means that at registration the child was not yet born, or gender was never identified. The table indicates of the 34 that Withdrew, 15 were girls and 19 were boys, representing 44% and 56% respectively of the total Withdrew.

Table 1.1 Total number of registrants and levels of completion: comparing girls and boys

	Girls	Boys	Unspec	Totals
1 Total registered	330	341	11	682
Percentage of total	48	50	2	100
2. No contact	155	180	8	343
Percentage of total	45	52	2	100
Total respondants	175	161	3	339
Percentage of total repondants	52	47	1	100
3. Withdrew	15	19		34
Percentage of repondants	44	56		100
Started and Stopped	33	35	3	71
Percentage of repondants	46	49		100
5. 200C series	33	36		69
Percentage of repondants	48	52		100
6. 200C and 10M	29	10		39
Percentage of repondants	74	26		100
7. Completed	65	61		126
Percentage of repondants	52	48		100
8 Completed in 50 months	31	31		62
Percentage of completed	50	50		100

Table 1.2 identifies the number of children in different age groups compared to various levels of completion in the program. Percentages are relative to number of respondents. For example, 24 % (82) of all the respondents were 0-6 months of age and 8% (27) of the total respondents *Completed* the program and were 0-6 months of age.

Table 1.2 Age groups of registrants

Age groups	1	2	3	4	5	6	7	8	Totals
Age in months	0-<6	6 - <12	12 - <24	24 - <36	36 - <60	60 - < 84	84 - < 120	120 +	
Age in Years	< .5	.5 < 1	1<2	2 < 3	3 < 5	5 < 7	7- <10	10 +	
Total registered	148	81	109	92	94	69	58	31	682
Percentage of total	22	12	16	13	14	10	9	5	100
2. No contact	66	47	52	51	43	41	29	14	343
Percentage of total	19	14	15	15	13	12	8	4	100
Total Respondents	82	34	57	41	51	28	29	17	339
Percentage of respondents	24	10	17	12	15	8	9	5	100
3. Withdrew	5	1	10	4	5	6	2	1	34
Percentage of respondents	1.5	0.3	2.9	1.2	1.5	1.8	0.6	0.3	10.0
4. Started and Stopped	18	6	13	8	14	7	5	0	71
Percentage of respondents	5.3	1.8	3.8	2.4	. 4.1	2.1	1.5	0.0	20.9
5. 200C series	20	7	10	9	9	7	3	4	69
Percentage of respondents	5.9	2.1	2.9	2.7	2.7	2.1	0.9	1.2	20.4
6. 200C and 10M	12	7	3	3	5	1	5	3	39
Percentage of respondents	3.5	2.1	0.9	0.9	1.5	0.3	1.5	0.9	11.5
7. Completed	27	13	21	17	18	7	14	9	126
Percentage of respondents	8.0	3.8	6.2	5.0	5.3	2.1	4.1	2.7	37.2
3. Completed in 50 months	11	11	6	10	9	3	6	6	62
Percentage of respondents	3.2	3.2	1.8	2.9	2.7	0.9	1.8	1.8	18.3

Table 1.3 shows number of vaccine-disease doses of each disease recommended by the CDC. For example, in the first six months of life three doses of DTaP, are recommended. DTaP has three diseases resulting in nine total vaccine-disease doses.

Table 1.3 CDC early childhood immunisation schedule

Each score represents one vaccine-disease dose	Birth to 6 months	12-24 months	At kinder- garten	7th grade	Total vaccine- disease doses
Hepatitis B	2	1	1		4
Diphtheria, Tetanus, Pertussis (DTaP)	9	3			12
Haemophislis influenza type b (Hib)	3	1			4
Pneumonia (PCV)	3	1			4
Rotavirus	2	1			3
Influenza	1	1	1	1	4
Polio (IPV)	3	1	1		5
Measles, Mumps, Rubella (MMR)		1	1		2
Chickenpox (Varicella)		1	1		2
Hepatitis A		2			2
Tetanus, Diphtheria, Pertussis (TDaP)				3	3
Meningococcal (MCV4)				1	1
Total doses per age group	23	13	5	5	46

Table 1.4 shows us the absolute number of, and ranges of, the total number of previous vaccine-disease doses at each level of completion through the program. E.g., one DTaP vaccine contains three vaccine-disease doses. For example, we can see that 13 of the children who Completed the program had 24-41 vaccine-disease doses. Note: completed in 50 months is a subset of Completed. When compared to Table 1.3, we can estimate the ages of the children in each range. Such as, of the 126 who Completed the program, 13 children had between 24-41 vaccine-disease doses, thus upon registration they at least were over six months old, had either stopped vaccinating after 24 months of age, or were not older than Kindergarten (max number of vaccine-disease doses for first six months is 23, at kindergarten is no more than 41). Two of the 126 had over 42 vaccine-disease doses which places them at 7th grade or older at time of registration. Ages of children at registration are tabulated in table 1.2.

Table 1.4. Total number of previous vaccine-disease doses per child at registration and at various stages of the program

Ranges of number of vaccine disease doses	Total # of children	0	1-4	5-9	10 - 14	15 - 23	24 - 41	42+	Total # vaccine -diseas e doses
Total number of vaccine-disease doses per child	682	469	62	29	17	31	56	18	3433
Percentage of 1	100 0	68.8	91	43	2.5	4.5	82	26	
2 No contact	343	243	29	17	9	19	20	6	1506
Percentage of 2	100 0	70.8	8.5	5.0	26	5.5	5.8	17	
Total respondants	339	226	33	12	8	12	36	12	1927
Percentage of respondents	100.0	66 7	97	3.5	24	3.5	106	3.5	
3 Withdrew	34	21	4	2	0	1	4	2	271
Percentage of 3	100.0	618	11.8	5.9	0.0	2.9	11.8	5.9	-
4 Started and Stopped	71	49	12	1	2	1	3	3	283
Percentage of 4	100 0	69 0	16.9	1.4	28	1.4	4.2	4.2	
5 200C series	69	42	5	4	2	2	13	1	447
Percentage of 5	100 0	60 9	72	58	29	29	18.8	14	
6 200C and 10M	39	23	4	3	0	2	3	4	314
Percentage of 6.	100 0	59.0	103	77	0.0	51	77	10.3	
7 Completed	126	91	8	2	4	6	13	2	612
Percentage of 7	100 0	72.2	63	1.6	3.2	48	103	16	-
B Completed in 50 months	60	47	2	1	3	2	4	1	255
Percentage of 8	100 0	78.3	3.3	17	5.0	3.3	6.7	17	Marine St.

Table 1.4 shows number of doses of each disease recommended by the CDC. For example, in the first six months of life three doses of DTaP, are recommended. DTaP has three diseases resulting in nine total vaccine-disease doses. When compared to Table 1.3, we can estimate the ages of the children in each group. Such as, of the 126 who *Completed* the program, as 13 children had between 24-41 doses of vaccine-disease doses, upon registration they were over six months old, had either stopped vaccinating after 24 months of age, or were not older than kindergarten age (maximum number of vaccine-disease doses for first six months is 23, at kindergarten is no more than 41). Two of the 126 had over 42 vaccine-disease doses which places them at 7th grade or older at time of registration. Ages of children at registration are tabulated in table 1.2.

Tables 1.5.a-1.5.g identify the socio-economic demographics of families who would choose HP. These variables are compared at each level of completion of the program. Income currency is in USD.

Tables 1.5 a -1.5 g: socio-economic data of registrants in values and percentages

a) Family type	Unspec.	Single parent	Married	Stepparent	GLBTQ	Other	Totals
1 Totals	34	26	596	4	2	20	682
Percentage	5	4	87	1	0	3	100.0
2 No Contact	17	11	299	3	0	13	343
Percentage of 2	5.0	32	87 2	0.9	0.0	3.8	100 0
3 Withdrew	1	0	32	0	0	1	34
Percentage of 3	3	0	94	0	0	3	100.0
4 Started and Stopped	2	7	58	0	1	3	71
Percentage of 4	3	10	82	0	1	4	100 0
5 200C series	8	0	60	0	0	1	69
Percentage of 5	12	0	87	0	0	1	100 0
6 200C, 10M	2	1	36	0	0	0	39
Percentage of 6	5	3	92	0	0	0	100 0
7 Completed	4	7	111	1	1	2	126
Percentage of 7	3	6	88	1	1	2	100 0
8. Completed in 50 Months	3	3	54	0	0	2	62
Percentage 8	5	5	87	0	0	3	100.0

b) Yearly Income	Unspec	\$0-\$14,999	\$5,000- \$29,999	\$30,000- \$49,999	\$50,000- \$99,999	Over \$100,000	Totals
1 Totals	57	12	71	112	256	174	682
Percentage	8	2	10	16	38	26	100 0
2 No Contact	27	10	38	59	111	98	343
Percentage of 2	8	3	11	17	32	29	100 0
3 Withdrew	3	0	3	3	9	16	34
Percentage of 3	9	0	9	9	26	47	100 0
4 Started and Stopped	7	0	9	15	26	14	71
Percentage of 4	10	0	13	21	37	20	100 0
5 200C series	8	0	5	7	37	12	69
Percentage of 5	12	0	7	10	54	17	100 0
6 200C, 10M	4	1	3	3	20	8	39
Percentage of 6	10	3	8	8	51	21	100 0
7. Completed	8	1	13	25	53	26	126
Percentage of 7	6	1	10	20	42	21	100 0
8 Completed in 50 Months	5	0	7	15	19	16	62
Percentage 8	8	0	11	24	31	26	100 0

c) Highest education of parents	Unspec	*High School	Undergrad	Grad	Tech School	Specialty	Totals
1 Totals	48	45	228	273	45	43	682
Percentage	7	7	33	40	7	6	100.0
2 No Contact	19	25	89	173	19	18	343
Percentage of 2	6	7	26	50	6	5	100.0
3 Withdrew	5	4	17	4	1	3	34
Percentage of 3	15	12	50	12	3	9	100 0
4 Started and Stopped	5	6	27	25	2	6	71
Percentage of 4	7	8	38	35	3	8	100 0
5 200C series	10	1	35	18	3	2	69
Percentage of 5	14	1	51	26	4	3	100 0
6 200C, 10M	4	2	12	10	7	4	-39
Percentage of 6.	10	5	31	26	18	10	100.0
7. Completed	5	7	48	43	13	10	126
Percentage of 7	4	6	38	34	10	8	100.0
8. Completed in 50 Months	3	3	26	21	3	6	62
Percentage 8	5	5	42	34	5	10	100 0

d) Medical insurance coverage	Unspec	Don't have	Public assist	Private pay	Employee	Totals
1 Totals	56	61	81	153	331	682
Percentage	8	9	12	22	49	100 0
2 No Contact	30	34	44	87	148	343
Percentage of 2	9	10	13	25	43	100 0
3 Withdrew	1	2	5	7	19	34
Percentage of 3	3	6	15	21	56	100.0
4 Started and Stopped	7	5	9	15	35	71
Percentage of 4	10	7	13	21	49	100 0
5 200C series	10	8	0	12	39	69
Percentage of 5	14	12	0	17	57	100 0
6 200C and 10M	3	4	4	12	16	39
Percentage of 6	8	10	10	31	41	100 0
7. Completed	5	8	19	20	74	126
Percentage of 7	4	6	15	16	59	100 0
8 Completed in 50 Months	4	3	11	12	32	62
Percentage 8	6	5	18	19	52	100.0

e) Education choice for the child	Unspec	Day care 1-12 months	Day care 1-3 years	Home School	Private School	Public School	Totals
1 Totals	83	31	73	164	192	139	682
Percentage	12	5	11	24	28	20	100 0
2 No Contact	38	14	33	99	92	67	343
Percentage of 2	11	4	10	29	27	20	100.0
3 Withdrew	2	1	4	6	12	9	34
Percentage of 3.	6	3	12	18	35	26	100.0
4 Started and Stopped	10	3	8	15	21	14	71
Percentage of 4	14	4	11	21	30	20	100.0
5 200C series	13	6	6	13	26	5	69
Percentage of 5	19	9	9	19	38	7	100.0
6 200C and 10M	8	2	5	3	11	10	39
Percentage of 6.	21	5	13	8	28	26	100 0
7. Completed	12	5	17	28	30	34	126
Percentage of 7	10	4	13	22	24	27	100 0
8. Completed in 50 Months	6	3	7	13	17	16	62
Percentage 8	10	5	11	21	27	26	100.0

f) Dietary choice	Unspec	Vegan	Veg/ Eggs/ Dairy	Fish/ Chicken	Omnivore	Totals
1 Totals	70	12	32	84	484	682
Percentage	10	2	5	12	71	100 0
2 No Contact	34	0	12	25	272	343
Percentage of 2	10	0	3	7	79	100.0
3 Withdrew	2	2	0	1	29	34
Percentage of 3.	6	6	0	3	85	100 0
4 Started and Stopped	12	1	1	1	56	71
Percentage of 4	17	1	1	1	79	100 0
5 200C series	9	3	3	10	44	69
Percentage of 5	13	4	4	14	64	100 0
6 200C and 10M	3	3	2	6	25	39
Percentage of 6	8	8	5	15	64	100 0
7. Completed	10	3	14	41	58	126
Percentage of 7.	8	2	11	33	46	100.0
8. Completed in 50 Months	5	2	5	19	31	62
Percentage 8	8	3	8	31	50	100 0

g) TV use	Unspec	Never	1-2 times a week	Every day	More than 3 hours/ day	Totals
1 Totals	51	159	192	273	7	682
Percentage	7	23	28	40	1	100 0
2. No Contact	24	75	100	144	0	343
Percentage of 2	7	22	29	42	0	100 0
3 Withdrew	2	6	6	19	1	34
Percentage of 3	6	18	18	56	3	100.0
4 Started and Stopped	8	15	19	29	0	71
Percentage of 4	11	21	27	41	0	100 0
5 200C series	7	15	23	22	2	69
Percentage of 5.	10	22	33	32	3	100 0
6 200C and 10M	3	10	11	14	1	39
Percentage of 6	8	26	28	36	3	100.0
7. Completed	7	38	33	45	3	126
Percentage of 7	6	30	26	36	2	100.0
8. Completed in 50 Months	5	16	21	17	3	62

Table 1.6 Identifies limitations families had in completing the program. Data is from passive submission and confirmed by an additional survey and verbal confirmation. *Withdrawal* was notified in writing after 1-3 doses were administered. *Started and Stopped* included those who did several doses of various remedies but did not continue.

Table 1.6. Reasons for Withdrew or Starting and Stopping

Any and all reasons per child/family included	
Total number who Withdrew (34) or Started and Stopped (71)	110
Time management issues unable complete the program	27
2. Did not identify the reason	20
3. Lost program	13
4. There were too many responses to HP doses	13
5. Never started	10
6. Did not have enough societal support. Feelings of isolation	9
7. Did not understand the program	6
8. Decided to vaccinate	5
9. Did not have the supervision needed to complete the program	4
10. Saving kit to see if there is an outbreak	1
11. Occupied by homeopathic constitutional care for ongoing health issues	1
12. Too many colds so couldn't do the doses	3
13. There were no titers produced when I tested so I stopped	3
14. No longer interested in doing the program	2
15. Developed eczema and allergies	1
16. Developed autism	1

Tables 1.7.1 and 1.7.2 identify the number and location (State, Province or Country) of HP Supervisors and children upon registration and at document tracking time. When cross-referenced they compare regional location completion of the program relative to number of active HP Supervisors.

Tables 1.7.1 and 1.7.2 Comparison of regional distribution of HP Supervisors and children at registration and upon completion of document tracking

Number of HP Supervisors per state or province at registration				1-3	4.7	18	Total
Total	0			19	19	18	56
Percentage	0.00%			33.93%	33.93%	32 14%	
Where				CO (1), FL (2), ID (2), IL (1), MA (1), ME (1), MI (2), NC (1), PA (1), TN (1), WA (2), WI (2), Japan (1), Portugal (1)	BC (7), CA (8), TX (4)	MN (18)	
Number of children per state or province at registration	0	14	5-14	15-29	30-73	301	
Total	0	57	106	59	159	301	682
Percentage	0.00%	8.36%	16%	8.65%	23.31%	44 13%	
Where		(4), HI (2), IA (4), IN (2),	(5), MI (9), NY (5), ONT (6), VA (5), WA (9), WI (14), WY (7),	AZ (14) FL (29). PA (16)	BC (73), CA (56), TX (30)	MN (301)	

2 Number of HP Supervisors per state or province at data collection	0		1-3			11	
Total	0		14			11	31
Percentage	19.35%		45.16%		785	35.48%	
Where	AZ, BC, IL, NC, PA, Japan		CA (3), CO (1), FL (1), ID (1), MA (1), ME (1), MI (2), TN (1), TX (2), WA (1), WI (1), Portugal (1)			MN (11)	
2 Number of children per state or province at data collection	0	1-4	5-14	15-29	30-73	117	
Totals	15	35	45	44	0	117	257
Percentage	5.84%	13.62%	17 90%	17 12%		45 53%	201
Where	CO, GA, HI, ID, MS, NJ, NM, ONT, OR, SD, India, Japan, Mexico, Portugal, United Kingdom	AI (1), CT (1), DE (1), FL (3), IA (4), KS (1), LA (1), MA (1), ME (2), MO (1), NC (1), ND (3), NY (3), PA (2), QUE (1), TN (1), UT (1), VA (3), WA (1), Netherlands (3)	AZ (7), ID (6), IL (6) MI (5), TX (8), WI (5), WY (5)	BC (22), CA(22)		MN (117)	

Discussion

In 2009 this HP program was introduced to the public in the United States. At that time, parents of children of all ages and previous vaccination histories wanted to utilise it. Education of HP Supervisors in the management of HP was necessary to establish a mechanism of access to the program. At that time, access to HP was only through registration in this research. The research was set up to rely upon passive submission of the data. In 2014 the main office for the receipt of data was moved. After one year the postal system ceased to forward the mail. Throughout 2018 we actively pursued the collection of questionnaires. A number of those early registrants contacted said that they submitted the only copy of their questionnaires in the mail, however, we did not receive them. Many had said they would send data, but they never did. Despite verbal communication with many of those categorised as No Contact, and even with verbal confirmation of progress and completion, without submitted paperwork we were not able to tabulate their results. Due to this poor tracking system 50% of registrants did not submit any data. The numbers confirmed in these tables are from the received submissions. We expect that, those from whom we did not receive data share similar results to those whose data we did receive. The principal investigator registered 185 children, not only in the state of MN but around the country and internationally. Oversight of registered families and the other HP Supervisors in their management of the program reflect the results discussed below.

Gender of registrants: the program appealed equally to parents of both genders. Sex of the child does not appear to play a role in whether the parents were more likely to complete the program. There was a greater number of boys in the groups *No Contact* or *Withdrew*. However, due to the small sample size we cannot draw any conclusions about compliance to the program with regards to gender.

Age of registrant: those who started the program when the child was an infant or under the age of 12 months (Table 1.2, groups 1 and 2, 8% and 3.8% of total respondents, respectively) were more likely *Completed* and more likely *Completed in 50 months* (under 6 months - 3.2% and under one year - 3.2%). Group 3, children aged 12-24 months, were the next highest group in *Completed*. This trend was the same at all levels of progress in the program. In group 4 (ages 3-5) there are higher percentages of children who *Started and Stopped* or *Withdrew*.

Previous vaccination: table 1.3 reviews the number of prior vaccine-disease doses. 69% of registrants had not received any vaccines indicating that HP was their preferred choice for disease

prevention. As registrants were from all age groups this indicates that, once awareness of HP was available, parents wanted to participate in a public health care/disease prevention program regardless of the age of their child. For those who were introduced to HP with newborns or infants HP was their first choice, and others converted to HP from vaccination once they discovered this option. Of the registrants, 31% had received prior vaccination: 9% of the total had 1-4 vaccine-disease doses, 8% had between 24-41 vaccine-disease doses, and 3% had more than 42.

One important variable was if the number of previous vaccines influenced motivation for completion of the program; 72.2% of the unvaccinated children *Completed* regardless of age. The next highest percentage of *Completed* was in children who had between 24-41 vaccine-disease doses. Causes identified for *Withdrew* or *Stopped and Started* were time management issues and irregular or prolonged immune system responses due to previous susceptibilities and the age of child. There were no adverse events reported. Additionally, successful completion of the program was dependent on support from HP Supervisors.

Conversion to HP: conversations with registrants revealed that people turn away from vaccination for several reasons:

- 1. Adverse effects of vaccination.
- 2. They don't believe they work.
- 3. They don't like them.
- 4. They found HP a safer, more economical option.
- They had started to vaccinate but then changed their minds, either due to how their child responded to the vaccines or because of being introduced to HP.

Many families who *Completed* the HP Program had also completed the recommended vaccine schedule. Reasons for turning to HP include:

- 1. Wanting to introduce a more "natural" immunisation.
- 2. Doing HP might fix some of the effects on the child's health from the vaccines.
- 3. They didn't have faith that vaccination actually did what is was purported to do.

Parents of unvaccinated children were more committed to the process of HP; 72.2% of those who *Completed* had no prior vaccines and 77.4% of those who *Completed in 50 months* had no prior vaccines. Additionally, as 10.3% of the total *Completed* had received 24-41 vaccine-disease doses, this indicates that despite previous vaccination their commitment to HP was equally high. We can also see that 18.8% of those who had only made it through the *200C Series* had between 24-41 vaccine-disease doses. One of the explanations for the delay in the program was the number of sicknesses the child experienced, which either limited progression through the program or resulted in too many responses being generated, thus signifying that previous vaccine-disease doses increases susceptibility to acute disease or HP remedy responses.

Socio-economic influences: these tables show that at registration most parents were in the following categories:

- a) Married.
- b) The average annual income was between \$50,000 and \$99,000 (USD).

- c) The highest level of education was university graduate.
- d) They had employee paid health insurance (registration in the HP program was paid cash out of pocket).
- e) They chose private school.
- f) They were omnivores.
- g) They watched TV every day.

Those *Completed* fit this profile:

- a) Married.
- b) Income \$30,000-\$50,000 (USD).
- c) College undergraduate education.
- d) Employee paid medical insurance.
- e) Children went to public school.
- f) They were omnivores.
- g) Watched TV 1-2 times a week.

Household income of all levels of completion was \$50,000-\$99,999 (USD), except for 47% of the *Withdrew* who earned over \$100,000 (USD). Considering 42% of the children *Completed in 50 months* were from parents with undergraduate education, it may be that the families with younger children were still in the process of their own education. TV usage is high in the *200 Series* and *200 and first 10M Series* and may be the lifestyle factor that limits time management and the successful completion of the program. 17% of day care usage in *Completed* demonstrates the number of children in that age group of registrants and the family's commitment to HP during these years of the child's development. Parents with younger children and the economic benefit of a middleclass lifestyle are more likely to complete the program.

Obstacles to completion: time-management issues and confusion about responses to the nosodes were the biggest obstacles to completion of the program. Parents either did not communicate with their HP Supervisor or did not fully understand what the remedies were doing and so were hesitant to give the next dose and more likely to discontinue the program.

Program supervision: tables 1.7.1 and 1.7.2 inform us that those more likely to *Complete* lived in states/provinces where more HP Supervisors were offering HP and maintained membership with FHCi for the duration of the research. MN, BC (Canada), CA, and TX had the highest number of HP Supervisors and the highest number of registrants. These tables verify that response submission rates and completion of the program was more successful from families whose HP Supervisors were still with FHCi at the conclusion of the program. During these ten years, not all the same HP Supervisors remained with FHCi; four that we know of passed away, three retired, and others changed the focus of their practice or realised they did not fully understand the process of HP to 3. continue. Regional differences of registrants had to do with public awareness, acceptance of HP, and the ability to talk about it with their family and doctors. Since this program was established in Minnesota in 2009 public awareness has increased with regards to HP. Now some MN based medical doctors are happy to hear when families are doing HP if they are hesitant about vaccines. The net effect is a deeper commitment to the program. Conversely, the isolated registrants—those in states or provinces where there was only one HP Supervisor— undertook the program with little or no

community support. Often, parents of the same family were not in agreement and, if there was a divorce, court orders more often sided with the parent who wanted to vaccinate. Subsequently, they dropped out of the program.

Next steps: in order to increase compliance and completion of the program, an extensive review of those who discontinued was done. We cannot control individual participants, time management issues, nor family dynamics and the navigation through cultural beliefs and acceptance of HP. However, we can build community, and influence public education and the expertise of our HP Supervisors. To build community, we established a monthly-dosing-reminder newsletter and provided more ongoing information on what remedy responses mean. When we looked at the number, intensity, and duration of remedy responses in the Withdrew and Started and Stopped cohorts, we opted to take more initial health information at registration, to understand potential susceptibilities. Such health information includes: pregnancy issues, natural verses medical birth, and history of antibiotics and/or vaccines in both mother and child. With this information, the goal is to provide more homoeopathic support prior to HP to prepare these children's immune system for homoeoprophylaxis.

Conclusions

Families want to participate in public health care programs. They want to invest in a low-risk disease prevention program that strengthens their children's immune systems. Growing distrust and increased risks of vaccinations are driving parents to look for alternatives. Completion of this program is possible for the typical middle-class family with average income and lifestyle choices. The largest obstacle to completing the program was the amount of time spent watching TV, perhaps contributing to time management issues. We have determined that when an HP family is well supported, lives in a community that is accepting of HP, and can comprehend the process of immune system education with HP, then they are more able to complete a self-administered HP program.

Economic disclosure

Sponsored by Free and Healthy Children International (FHCi). 612-338-1668 FHCint@gmail.com, https://freeandhealthychildren.org/.

- Primary Investigator: Kate Birch, RSHom, CCH, 612-701-0629, katebhom@hotmail.com
- 2. Document Collection Person: Su Sandon, RPh, RSHom (NA), CCH, HMC, 612-889-2683 suhomeopathy@ earthlink.net
- 3. Medical Advisor: Kim Lane, MD 651-347-1952, wellnesslane@comcast.net

Who	Total paid from 2009- 2019 (USD)		
Kate Birch	\$3,290.00		
Su Sandon	\$6,865.77		
Sarah Damlo	\$3,685.00		
Katie Bromme	\$1,466 25		
Max Sagert	\$1,011.5		
Tana Harahan	\$670 0		
Kim Lane	N/A		
Total paid	\$16,988 52		

- Data Entry:
- 4. Sarah Damlo 952-212-3372, FHCigrants@gmail.com.
- 5. Tana Harahan, 651-272-0932, FHCint@gmail.com.
- Katie Bromme, 612-327-3855, FHCiresearch@gmail.com.
- 7. Max Sagert, 651-587-4047, FHCiresearch@gmail.com.

Free and Healthy Children International (FHCi) is a 501(c)3 nonprofit membership organisation dedicated to research, education, and access to homoeoprophylaxis. It is registered for business in the state of MN, USA. From April 2009-Dec 2014 682 children were registered in research. From January 2015 to July 16, 2019 we did not have a tracking system in place. Since July 17, 2017, 1044 additional children have registered with FHCi. We are independently funded by individual contributions and membership dues. All fees paid for organising and tabulating the research were paid on either a quarterly stipend or hourly basis. There are no 8. Adams, D (2018). Rudolf Steiner on traditional childhood illnesses personal direct economic benefits derived from the results of this study. FHCi is not economically associated with any pharmacy that would benefit from the sale of the homoeopathic remedies utilised in this research. All research staff are homoeopaths and live in the state of MN. We did this research because we are invested in the health of children. Homoeoprophylaxis is for free and healthy children.

References

- 1. Free and Healthy Children International. (Est 2011). https:// freeandhealthychildren.org/
- 2. CDC Immunization Schedule (2014). https://www.cdc.gov/vaccines/ schedules/index.html
- 3. World Health Organization (2018). Antimicrobial resistance. https:// www.who.int/en/news-room/fact-sheets/detail/antimicrobialresistance (Last viewed 26 September 2019).
- 4. Good, P (2018). Evidence the U.S. autism epidemic initiated by acetaminophen (Tylenol) is aggravated by oral antibiotic amoxicillin/ clavulanate (Augmentin) and now exponentially by herbicide glyphosate (Roundup). Clinical Nutrition ESPEN. 2018 Feb; 23:171-183. https://www.ncbi.nlm.nih.gov/pubmed/29460795 viewed 26 September 2019).
- 5. Taylor, G (2018). 157 Research papers supporting vaccine/ causation. http://mainevaxchoice.org/wp-content/ uploads/2018/10/VaccineAutismStudies.pdf (Last viewed 26 September 2019).
- 6. Golden, I (2004). The potential value of homoeoprophylaxis in the long-term prevention of infectious diseases, and the

- maintenance of general health in recipients. Graduate School of Integrative Medicine Swinburne University of Technology. https:// immunizationalternatives.com/wp-content/uploads/2015/04/ HP_Isaac_Golden_thesis_homeoprophylaxis1.pdf (Last viewed 26 September 2019).
- Carmen (2012). Natural vaccine alternatives for you and your kids. Off the Grid News. https://www.offthegridnews.com/alternativehealth/natural-vaccination-alternatives-for-you-and-your-kids/ (Last viewed 26 September 2019).
- and vaccines. Our Spirit Reflections. https://neoanthroposophy. com/2018/03/01/rudolf-steiner-on-traditional-childhood-illnessesand-vaccines/ (Last viewed 26 September 2019).
- 9. Sheffield F (2019). Tutorial 6 Provings. Can provings damage heath? Homeopathy Plus. https://homeopathyplus.com/tutorial-6provings/
- 10. Clever, H (2015). Epidemiological studies in homeopathy. https:// cleverhthemag.com/2015/12/01/epidemiological-studies-inhomeopathy/
- 11. Adams, D (2018). Rudolf Steiner on traditional childhood illnesses and vaccines. Our Spirit Reflections. https://neoanthroposophy. com/2018/03/01/rudolf-steiner-on-traditional-childhood-illnessesand-vaccines/
- 12. Golden, I (2004). The potential value of homoeoprophylaxis in the long-term prevention of infectious diseases, and the maintenance of general health in recipients. Graduate School of Integrative Medicine Swinburne University of Technology. https:// immunizationalternatives.com/wp-content/uploads/2015/04/HP_ Isaac_Golden_thesis_homeoprophylaxis1.pdf
- 13. San Diego Pathologists (2009). Certificate of analysis. https:// freeandhealthychildren.org/certification-in-homeoprophylaxis/ hpdocuments/remedy-sources/
- 14. Free and Healthy Children International. (Est 2011). https:// freeandhealthychildren.org/
- 15. CDC Immunization Schedule (2014). https://www.cdc.gov/vaccines/ schedules/index.html

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