Electronic monitoring of vaccine cold chain in a metropolitan area

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Successful immunisation strategies depend on the provision of immunogenic vaccines and the correct manufacture and storage of those vaccines. Studies in developed and developing countries have shown that vaccines are stored inadequately and that the vaccine cold chain can be disrupted.^{1,2} We measured the temperature of vaccines stored long term in a metropolitan area of a developed country using electronic data loggers to determine how long vaccines had been exposed to temperatures $<0^{\circ}\text{C}$.

Methods and results

In Adelaide childhood vaccines are distributed from a single centre to local council sites and general practices (providers). We randomly selected 20 of the 21 local councils and 20 of the 650 general practices.

Electronic temperature loggers (Hobo-Temp, Onset Computer, Pocasset, MA, USA) for recording temperatures of -5°C to 37°C (SD 0.2°C) were preset to record temperature every 24 minutes. A labelled logger was dispatched in the first vaccine order from each provider. Vaccines were supplied when requested and transported in an insulated cooled container. Each logger was stored with the bulk of the vaccine order. The centres were visited every 30 days and the data retrieved. Recordings finished on completion of an order or after 90 days.

Data were imported into Excel 4.0 and temperature distributions and frequencies determined. Each temperature reading was taken as representing 24 minutes at that temperature, allowing cumulative temperature times to be calculated. Two or more consecutive

readings $<-1^{\circ}\text{C}$, representing at least 24 minutes at that temperature, were selected as unacceptable exposure to cold. Unacceptable exposure to heat was defined as more than 10% of recordings $>8^{\circ}\text{C}$.

Forty sites were monitored for a median 1983 (range 449-2108) hours. Vaccines were exposed to unacceptable cold in 21 sites, being exposed to temperatures $<-1^{\circ}\text{C}$ for a median cumulative time of 39 hours (2-1212) (table 1). In nine sites vaccines were exposed to temperatures $<-4^{\circ}\text{C}$ for a median of 15 hours (0.4-651). In four sites vaccines were exposed to unacceptable heat ($>8^{\circ}\text{C}$) for a median time of 341 (317-529) hours. In three sites the temperature exceeded 22°C for a median 0.4 (0.4-0.8) hours.

Comment

Because vaccine damage depends on the ambient temperature and the duration of exposure to adverse temperatures, any assessment of the vaccine cold chain should document both variables. Unlike heat sensitive monitoring cards, cold sensitive cards cannot provide an accurate indication of the cumulative time of exposure of a vaccine to cold. We used electronic monitoring to measure temperature and time, and, to our knowledge, ours is the first study to document temperatures below 0°C and include data on time of exposure below this temperature in the assessment of the cold chain.

Adsorbed vaccines are freeze sensitive. Freezing of hepatitis B vaccine or diphtheria, pertussis, and tetanus vaccine results in reduced immunogenicity of the vaccine.^{3,4} The freezing point depression of the triple vaccine in use in Australia is $\Delta 0.59^{\circ}\text{C}$ so this vaccine is at risk of freezing if stored below -1.0°C (Commonwealth Serum Laboratories (vaccine manufacturer), Melbourne, Australia, personal communication). Vaccines were exposed to unacceptable cold in all but four of the 25 sites where vaccines were exposed to adverse temperatures.

Although most frozen adsorbed vaccines can be distinguished with the shake test it does not always discriminate frozen from unfrozen vaccines.⁴ Until freeze resistant vaccines are developed the only option is implementing cold chain guidelines and temperature monitoring.

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Table 1 Cumulative time (hours) of exposure to adverse cold at 21 sites with at least two consecutive recordings below -1°C

Site No	Total time $<-1^{\circ}\text{C}$	-1 to -2°C	-2 to -3°C	-3 to -4°C	$<-4^{\circ}\text{C}$
1	1.6	NE	NE	0.4	1.2
2	2.4	2.4	NE	NE	NE
3	7.2	7.2	NE	NE	NE
4	11.6	2.4	7.6	1.2	0.4
5	13.6	10.4	3.2	NE	NE
6	21.6	10.4	7.6	3.6	NE
7	24.0	13.2	5.2	5.6	NE
8	25.2	25.2	NE	NE	NE
9	30.0	30.0	NE	NE	NE
10	36.8	36.8	NE	NE	NE
11	39.2	20.4	13.2	5.6	NE
12	84.0	84.0	NE	NE	NE
13	127.2	123.6	3.6	NE	NE
14	219.2	36.4	88.0	1.2	93.6
15	318.4	179.6	100.0	30.8	8.0
16	332.4	201.6	94.8	20.8	15.2
17	424.0	394.4	29.6	NE	NE
18	908.0	422.0	326.8	152.4	6.8
19	996.4	33.2	37.2	275.2	650.8
20	1036.4	579.6	361.6	79.6	15.6
21	1212.4	328.4	194.4	68.8	620.8

NE=not exposed, indicating that vaccine was not exposed to temperatures between the given ranges.

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