Maintaining the cold chain when providing off site vaccination clinics

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This flu season will bring a new challenge to practices in providing increased numbers of flu immunisation in an environment where we need to be cognisant of the infection control measures and in particular the social distancing requirements brought about by the Coronavirus pandemic.

In addition to this advice practices need to be aware of the essential requirement to maintain the vaccine cold chain. To enable this practices/PCNs may wish to consider purchasing medical cool boxes/bags and medical cool packs. Practices should ensure that the temperature in the cool box/bag is closely monitored and may prefer to purchase a cool box with a built-in thermometer rather than utilising an external one. If using a cool box/bag ensure that it is packed according to the manufacturer's recommendations, general points include:

1. Vaccines should be transported in their original packaging.
2. The cool box/bag should only be filled immediately prior to transit:
3. Cool blocks/packs must not come into direct contact with the vaccine.
4. Place the cool blocks/packs on the bottom of the cool bag/box
5. Cover the cool blocks/packs with the insulating material (foil covered polystyrene sheets/bubble wrap etc)
6. Place the vaccine (original packs) on top of the insulating layer
7. If using an external thermometer, place the thermometer/thermometer probe in the centre of the bag/box at this level
8. Cover the vaccine stock with the insulating material
9. Place the cool blocks/packs on the top of the insulating material layer
10. Use insulating material (i.e. bubble wrap) to fill any spaces within the cool bag/ box
11. The maximum/minimum temperature should be monitored and recorded at regular intervals.
12. The time between removing vaccines from cool storage and use must be kept to a minimum.
13. The frequency of opening the cool box should be kept to a minimum.

When the cool bag/box is in use and the temperature rises above 8ºC but below 25 ºC, most vaccines will still be viable and the stock may be used at that vaccination session.

If the storage criteria have not been met during the immunisation session, vaccine stock should be marked (date/time removed/returned) and returned to the appropriate cold chain conditions separating (quarantining) this stock from other vaccines. Advice should be obtained from the vaccine manufacturer if the stock is suitable for use.

Once returned vaccines have been assured for re-use, they should be placed at the front of the fridge to ensure they are used first on subsequent immunisation sessions. Vaccines must only be placed back into the refrigerator once for potential reuse. If this stock is taken out again and not reused, then the vaccine should be discarded in accordance with waste regulations.

NHS England advice on cold chain policy

The NHS England website states:

> "We are aware that the following policy has now expired, however we are awaiting new national guidance and don't intend to review or amend this policy until that guidance is available. Please continue to use this policy until otherwise advised but also to refer to the current national guidance (including the Green Book chapter 3) which should always be the prime source of information for vaccine storage."

The guidance referred to is the NHS England Midlands and East policy on maintaining the vaccine cold chain and the Green Book, the relevant sections are copied below.

NHS England Midlands and East: Policy and Procedure for Maintaining the Vaccine Cold Chain (Nov 15), transporting vaccines

> "Suitable rigid containers will be used at all times to reduce damage to vaccines during transit and maintain temperature. Domestic cool bags should not be used to store, distribute or transport vaccines. Validated cool boxes (with maximum-minimum thermometers) and cool packs from a recognised medical supply company should be used. Individual manufacturers' instructions should be strictly adhered to (check with Electronic Medicines Compendium (EMC) for Summary of Product Characteristics3.
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> "Vaccine to be kept in original packaging, (or similar insulation material) and placed into a cool box with cool packs wrapped in bubble wrap or as recommended by the manufacturers' instructions. This will prevent direct contact between the vaccine and cool packs and will protect the vaccine from damage, such as being frozen.
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> "Cool packs should be used whenever possible. These must be insulated to prevent direct contact with the vaccine. They should be placed in the bag in accordance with manufacturers recommendations. They must not come into direct contact with the vaccine. Space within the container must be loosely filled to minimise circulating air.
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> "Cool boxes and packing material should be stored at the lowest temperature possible prior to packing with the vaccine load and vaccine should be loaded as late as possible before departure to minimise exposure time out of the fridge.
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> "On arrival at the vaccination session, vaccines should be transferred to a refrigerator if available. Otherwise they must be left in the closed cool box until they are required. Where vaccines are to be stored overnight, a dedicated vaccine fridge or an electric portable storage unit that maintains the correct temperature can be used. The unit is to be kept in a secure location and the vaccine to be used first the following day."

Green Book Chapter 3: Storage, distribution and disposal of vaccines, validated cool boxes (carriers) and transporting vaccines

"Domestic cool boxes should not be used to store, distribute or transport vaccines. Validated cool boxes and cool packs from a recognised medical supply company should be used in conjunction with validated maximum– minimum thermometers. Cool packs should be stored in accordance with the manufacturer's instructions, usually at +2˚C to +8˚C (not a freezer compartment) to ensure they maintain the cold chain at the right temperature. In general, ice packs and frozen cool packs should not be used as there is a danger of these freezing some vaccine doses during transit. The exception to this is when the cool box manufacturer's instructions specifically state that ice packs should be used. Individual manufacturer's instructions should be strictly adhered to.

"A validated cool box provides ongoing assurance that the vaccines will be maintained within the cold chain temperature range during transport. With time and use, cool boxes may no longer be able to maintain this temperature range for extended periods, so monitoring is always required. The cool box manufacturer should also provide sufficient evidence for assurance that a stable temperature within the range of the cold chain can be maintained for several hours.

"Vaccines must be kept in the original packaging, wrapped in bubble wrap (or similar insulation material) and placed into a cool box with cool packs as per the manufacturer's instructions. This will prevent direct contact between the vaccine and the cool packs and will protect the vaccine from any damage.

"When transporting vaccines, the named individuals are responsible for ensuring that only the amounts of vaccines necessary for each session are removed from the vaccine refrigerator. These should be placed quickly into the validated cool boxes and opening must be kept to a minimum. If there are any unused vaccines left over at the end of a vaccination session, providing there is evidence from the temperature monitoring that the cold chain has been maintained, the vaccines can be returned to the vaccine refrigerator. Returned vaccines should be used at the earliest opportunity. If the cold chain cannot be guaranteed, a risk assessment should be done, as described in the previous section."