The Cold Chain and Vaccine storage

Cliona Kiersey Chief Pharmacist National Immunisation Office





Objectives

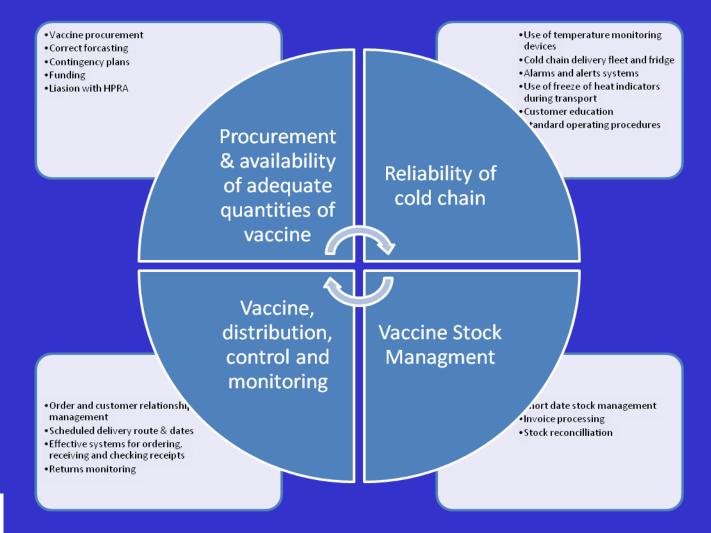
- To outline the complexity of vaccine management, the importance of cold chain and the delivery service
- To understand the importance of ordering appropriately and the roll out of the new vaccines
- To understand the importance of monitoring the cold chain within your own practice, the correct procedures for handling and storage of vaccines including procedure following cold chain breach and returns service







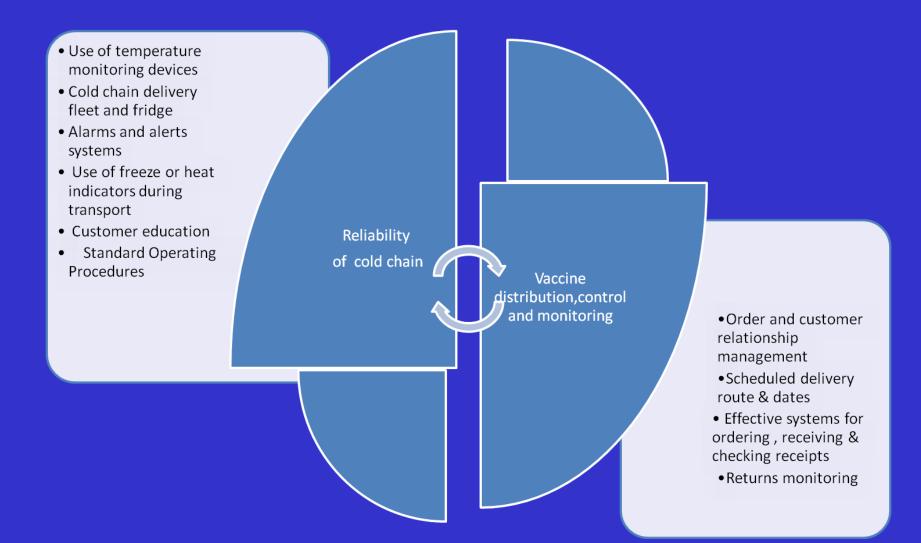
Factors affecting Vaccine Management Performance







Relevant sections



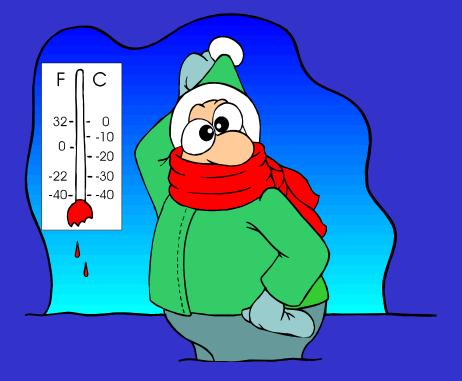






Why is the cold chain important?

- Vaccines must be stored within a specific temperature range between +2 and +8°C to ensure their potency and to comply with regulations (PA/EU licence)
- Vaccines are sensitive biological products that may become less effective or even destroyed when exposed to less than +2 and greater than +8°C and/or exposed to direct sunlight or fluorescent light
- Assurance in product potency ensures maximum benefit from immunisation







Reliability of Cold Chain

Cold Chain relies on <u>3 main elements</u>

in each of the 3 areas

- manufacturing site
- distribution site
- Provider facility
- Well trained personnel
- Reliable storage equipment & transportation
- Efficient management procedures







Who's Responsible for Cold Chain

Temperature records are available for every vaccine from point of manufacturing to delivery at GP surgery. Storage fridges and transport vehicles are all equipped with heat / cooling devices and alarms/alert systems which are monitored 24/7

The lower 3 links refer to when the vaccines are your responsibility and they should be covered by the practice insurance











National Cold Chain Delivery Service (2nd Link)

- Commenced 1st January 2005, delivering to ~1650 sites annually now has increased to 2,594 sites receiving 2.1 million doses annually
- responsible for ~€37 million annually.
- United Drug Distributors based in Citywest with satellite sites in Limerick and Ballina







11 Delivery Vans

- Van fridges are equipped with alarms (auditory in cab& text message sent to driver & UD staff) and heating/cooling systems, navigation & location tracking systems.
- Each van has been mapped and 4 temperature probes positioned to record appropriate temperatures
 - Product probe
 - Right side probe
 - Left side probe
 - Air return probe

Alarm activated once temperature of +3°C or +7°C registered

- Robust contingency plans in case of power failure or breakdowns. 2 fridge units (1 Backup fridge unit) and battery as back up.
- Standard operating procedures govern all processes.







100 Routes

- Dublin (72% of orders)
 - 60 Routes
 - 3 Vans & 3 drivers
- Limerick (17% of orders)
 - 20 Routes
 - 1 Van & 1 driver
- Ballina (11% of orders)
 - 20 Routes
 - 1 Van & 1 driver

Double deliveries from mid September to mid November





Annual Vaccine Deliveries

- 2594 sites are entitled to 12 scheduled (monthly) plus 2 extra deliveries during the "flu season".
- The 12 deliveries are based on 4 weekly cycles (and there are 4 "down" weeks). Between September – November ("flu season") there are fortnightly deliveries.
- There are an extra ~1000 sites who get only flu / PPV deliveries in flu season.
- Unscheduled
- Emergency







Vaccine Deliveries in 2016

- Contract is for 14 scheduled deliveries to each site, however in 2016 there will be extra deliveries from beginning of September to December (16 scheduled deliveries to each site)
- Flu vaccine will be available from September 2016 which should be administered by November creating space in the fridge for new vaccines.
- New vaccines will be available from November for administration from December 1st 2016. There will be 2 deliveries in November facilitating smaller order sizes.





Unscheduled / Emergency Deliveries

- Contract is for 14 scheduled deliveries to each site, however in 2016 there will be extra deliveries from beginning of September to December (16 scheduled deliveries to each site)
- Each non scheduled / emergency delivery is an extra charge and cause a disruption to routine deliveries

immunisation.ie





Importance of Ordering Appropriately

Vaccine orders are monitored to ensure consistency with target cohort requirements. Significant deviations may indicate over or under stocking, leading to vaccine wastage or missed opportunity to vaccinate.

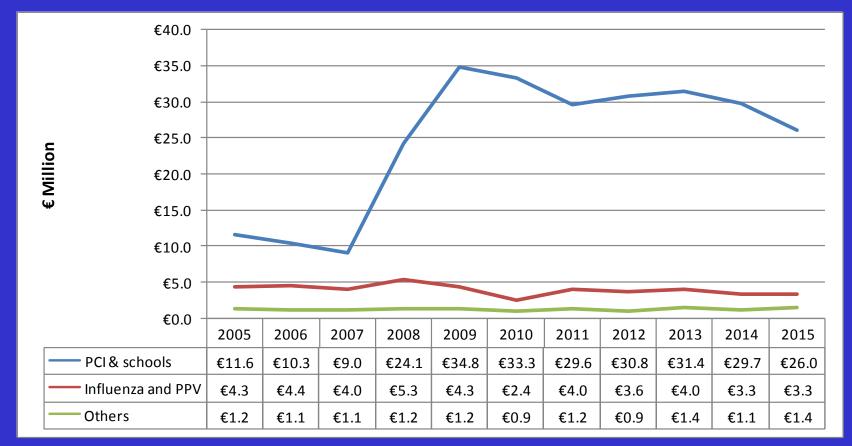
Each site should order monthly to ensure proper stock levels.







Cost of Vaccines Purchased

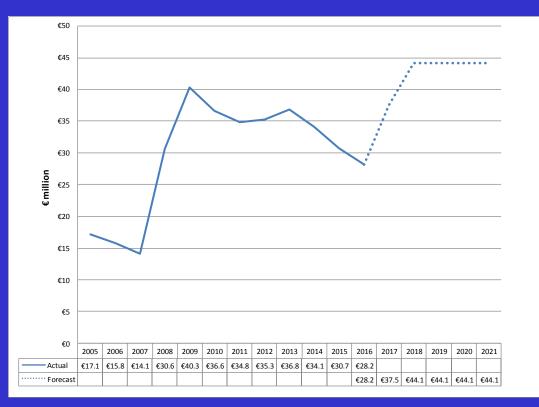








Actual and forecasted vaccine expenditure 2005 - 2021







Who can order vaccines?

- GPs who hold an immunisation contract
- Community Health Doctors who run the school immunisation service, BCG clinics
- Hospitals who require vaccines
- Authorised Flu Sites (Retail Pharmacies and Nursing homes)
- Vaccines are delivered monthly direct to these sites.





Vaccines supplied

	Vaccines	
Primary Childhood vaccines	6 in 1, Men C, PCV, MMR, Hib, 4 in 1	
Adult vaccines	Td, Tdap Influenza, Pneumococcal polysaccharide vaccine	
HSE vaccines	BCG, Tuberculin , 4 in 1, MMR, Tdar HPV, Men C	
Current list of available va Restricted vaccines •from United drug •in newsletter	^{ccines} Hepatitis A, Hepatitis B, Hepatitis A + Td/IPV, Tdap/IPV, MenACW ₁₃₅ Y, Mer	
•on immunisation website	ww.immunisation.ie	Reidhmeannacht na Seirbhíse Sláin Health Service Bxecutive

a ?

Current Schedule Value of Vaccines per Child PCI: 6in1, Men C, PCV, MMR, Hib

Junior School: 4in1 and MMR

Secondary School Tdap, MenC and HPV

Indicative price €1,030







New Schedule Value of Vaccines per Child

- PCI: 6in1,MenB, Rotarix, Men C, PCV, MMR, Hib/MenC
- Junior School: 4in1 and MMR
- Secondary School Tdap, MenC and HPV

Indicative price €1,350





Current PCI Schedule













MENJUGATE°

10 micrograms suspension for injection Meningococcal group C conjugate vaccine

() NOVARTIS



Bexsero – Men B

Bexsero suspension for injection in pre-filled syringe 2 needles- 23G x 25mm & 25G x 16mm Meningococcal group B Vaccine (rDNA, component, adsorbed)



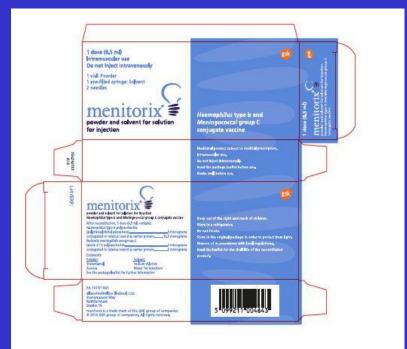






Menitorix (Hib-MenC)

Powder and solvent for solution for injection White powder and a clear colourless solvent 2 Needles 23G x 25mm & 21G x 40mm









Forwaras i originalforpackningen, tjuskansligt – Forwaras i kytskap – Får et frysa Sallytä alkuperälepakkauksessa, tierkka valoite – Sallyta jaaraapissa – Ei saa jääryä Oppbevares i originalpakningen for å beskytte mot tys – Oppbevares i kyteleskap – Må ikke fryses

Färdig att användas/ Ingen beredning krävs Käyttövalmis/ Sekoittamista ei tärvita Klar til bruk/ Rekonstituering er ikke nødvendig

gsk GlaxoSmithKline

10 x 1 dos/annosta/dose (1,5 ml) 10 förfyllda **orala** applikatorer 10 esitäytettyä **oraalista** annostelulaitetta 10 ferdigfylte **orale** applikatorer



Oral suspension i förfylld oral applikator Oraalisuspensio esitäytetyssä oraalisessa annostelulaitteessa Mikstur, suspension i ferdigfylt oral applikator Rotavirusvaccin, levande Rotavirusrokote, elävä Vaksine mot rotavirus, levende

Oral användning/ Får ej injiceras! Suun kautta/ Ei saa antaa injektiona! Oral bruk/ Må ikke injiseres!



Current Schools Immunisation Programme (Junior)





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Priorix

powder and solvent for solution for injection in a pre-filled syringe Measles, mumps and rubella vaccine (live) 0.5 ml

Read the package leaflet before use Subcutaneous or intramuscular use Powder and solvent to be reconstituted before use Shake before use

After reconstitution, use promptly or within 8 hours if stored in a refrigerator

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Store and transport refrigerated

Do not freeze Store in the original package in order to protect from light

Dispose of in accordance with local regulations

Powder and solvent for solution for injection in a pre-filled syringe

Medicinal product subject to medical prescription

ACTIVE SUBSTANCES

After reconstitution, 1 dose (0.5 ml) contains: Live attenuated measles virus1 (Schwarz strain) not less than 1010 CCIDse Live attenuated mumps virus1 (RIT 4385 strain, not less than 1017 CCID derived from Jeryl Lynn strain) Live attenuated rubella virus? (Wistar RA 27/3 strain) not less than 1010 COIDan 1 produced in chick embryo cells 2 produced in human diploid (MRC-5) cells

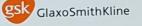
³ Cell Culture Infective Dose 50%

EXCIPIENTS

ccine:	
nino acids	Sodium
ctose (anhydrous)	Potassi
annitol	Magne
eomycin sulphate	Calcium
orbitol	Potass
henol red	Di-sod

chloride um chloride sium sulphate n chloride lum di-hydrogen phosphate lium hydrogen phosphate

Solvent: Water for injections.



Priorix

10 x 1 dose (0.5 ml) Suspension for injection Intramuscular use

Shake well before use

IPV-Boostrix® suspension for injection in pre-filled syringe

Diphtheria, tetanus, pertussis (acellular component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)

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IPV-Boostrix

- Suspension for injection in pre-filled syringe.
- IPV-Boostrix is a turbid white suspension.
- 10 needles 25G x 25mm









MMR Products



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School Immunisation Programme Second Level.





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Needle included with vaccines

- Bexsero 23G 25mm + 25g 16mm
- Boostrix 23G 25mm
- Gardasil 23G 25mm + 25g 16mm
- Hiberix 2 x 25G 25mm
- Infanrix Hexa: (10 pack) 20 x 25G 25mm
- IPV-Infanrix 23G 25mm + 25g 16mm
- IPV Boostrix (10 pack) 20 x 25G 25mm
- Menjugate 23G 25mm + 25g 16mm
- Menitorix 23G 25mm + 21g 40mm
- MMRvaxPro 23G 25mm + 25g 16mm
- Prevenar 13 (10 pack) 10 x 25G 25mm
- Priorix (10 pack) 20 x 25G 25mm





Some typical vaccine orders with Costs

Qt	Vaccine	Qty	Vaccine	Qty	Vaccine	
У		30	INFANRIX HEXA	60	INFANRIX HEXA	
10	INFANRIX HEXA	30	PREVENAR			
10	PREVENAR			60	PREVENAR	
		10	IPV-Infanrix	20	IPV-Infanrix	
7	MEN C	5	Boostrix	20	Boostrix	
4	MMR	20	MEN C	40	MEN C	
4	HIB	20	MMR	40	MMR	
		20		20	HIB	
5	DITE BOOSTER	10	HIB	10	DITE BOOSTER	
		5	DITE BOOSTER	- -		
	<u>€1,067.80</u>			Total	<u>€6,830.93</u>	
PROPAGATION AND AND AND AND AND AND AND AND AND AN	SPIT ST	Total	<u>€3,353.72</u> www.immunisati	on.ie		Reidhmeannacht na Seirbhíse Sláinte Health Service Executive

New schedule costs

Qty	Vaccine
10	INFANRIX HEXA
10	PREVENAR
10	MenB
10	Rotavirus
4	MEN C
8	MMR
4	MENITORIX
4	IPV BOOSTRIX
5	DITE BOOSTER
3	BOOSTRIX
Total	<u>€1,786.28</u>
	www.immur

Qty	Vaccine
60	INFANRIX HEXA
60	PREVENAR
60	MenB
40	Rotavirus
20	MEN C
40	MMR
20	MENITORIX
20	IPV BOOSTRIX
10	DITE BOOSTER
20	BOOSTRIX
Total	<u>€10, 082.25</u> .Ie



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Recommended procedure for ordering and accepting vaccines

- Should have a named, trained and designated person and deputy
- Order on-line before closing date
- <u>Remove expired vaccines from fridge</u> and prepare for return to NCCS driver
- Check vaccine deliveries against the order for damage or discrepancies
- Place vaccines in the vaccine fridge immediately, ensuring the shortest dated vaccine is at the front
- NEVER leave vaccine delivery at room temperature
- Confirm vaccines are covered by practice insurance





How much vaccine should be ordered?

- Vaccine stocks should be kept to a minimum by regularly ordering only the quantity of vaccine required until the next delivery. The designated person should know how much vaccine stock they require at any one time, according to the size of the target population.
 - Restrictions placed by online system
 - Maximum of 6 weeks supply should be in the fridge at time of delivery
 - During 'flu season this can be reduced to 3 weeks supply as deliveries will be fortnightly





Restrictions on New Vaccines

- Bexsero Schedule Months 2 & 4 & 12
 - Quantity of Bexsero restricted to 1/3 of monthly requirements of Infanrix Hexa for first 2 months, then increase to 2/3 until Sept 2017 when equal quantites of both delivered.
- Rotarix Schedule Months 2 & 4

Quantity of Rotarix restricted to 2/3 of monthly requirements of Infanrix Hexa

Menitorix Schedule Month 13

- Available October 2017





Delivered by United Drug in partnership with the HSE

Login

Username/Email:

Account ID:

30030

Password:

.....

LOGIN

Forgotten your Password?

customer@ncc.com

Vaccine Ordering

Welcome to www.ordervaccines.le. This is the online vaccine ordering page from the National Cold Chain Delivery Service. We provide vaccines for publicly funded immunisation programmes to healthcare settings in Ireland.

If you have an account for ordering vaccines but you have not registered for online vaccine ordering please click "Forgotten your Password?" on the left to begin the registration process. If you would prefer to contact customer services we will set you up with an online username and password.

Once you have your username, account number and password please login using the panel on the left. If you need any help? - Please contact United Drug customer service on 01 463 7770 or vaccines@udd.ie





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Useful Links

HSE Immunisation Website

United Drug Supply Chain Services





www.immunisation.ie

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VACCINE ORDER FORM ORDER HISTORY

NCC Web Ordering (30030) Logout

DELIVERY SCHEDULE CHANGE PASSWORD

Welcome to your HSE National Cold Chain Dashboard



VACONES	QTY
6 is t	10
Dite	. 5
Men C	30
PCV	10

Delivery Schedule - November

MON	TUE	WED	THU	FRE	SAT	SUN
मर.	.78	39	30	34	1	2
3	.4	- 5	6	1		
10	31	- 32:	33	(14)	15	18
3.7	18	19	20	- 25	22.	.23
24	25	- 26	22	28	29	-30
1	2	- 3	-4	1.5	6	20

RLD on your Calendar is your last date to place order. Green on your Calendar is your delivery date.



Useful Links

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www.immunisation.ie





Last Order - 19 November 2014

DR SALEEM SHARIF (34595) Logout

felivered by United Drug in partnership with the H

VACCINE ORDER FORM

ORDER HISTORY DELIVERY SCHEDULE

CHANGE PASSWORD

TOTAL

Vaccine Order Form

VACCINE	PACK	INDICATIVE PRICE	QTY
6 in 1	10	90.13	10
Men C	1	43.05	10
PCV	10	73.80	10

These vaccines must be ordered together in defined ratios. If you only need quantities of individual vaccines please contact customer service.

VACCINE	QTY	PRICE
6 in 1	10	901.30
4 in 1	3	73.80
Boosterix (Tdap)	2	51.52
Dite	5	63.15
Men C	10	430.50
PCV	10	738.00

2,258.27

Requested Vaccines

4 in 1	1	24.60	3
Boosterix (Tdap)	1	25.76	2
Dite	5	12.63	5 00
Hep B (ENGERIX PAED)	1	15.40	
Hep B (HBVAXPRO5)	1	15.40	
HepB (ENGERIX ADULT)	1	20.81	
HepB (HBVAXPRO10)	(1 .)	20.81	
Hib	1	30.69	
Influenza	10	7.38	
MMR	1	20.17	
Pneumoccoal	1	21.05	

CONTINUE TO REVIEW ORDER PAGE





NORTH WEST DUBLIN LOCAL HEALTH OFFICE ** (39510)Logout

VACCINE ORDER FORM ORDER HISTORY DELIVERY SCHEDULE CHANGE PASSWORD

Vaccine Order Form

Requested Vaccines

You have requested no vaccines, please enter your desired quantities in doses using the vaccine order form on the left.

VACCINE	PACK SIZE	INDICATIVE PRICE	QTY
2TU	10	23.70	
4 in 1	1	24.60	
BCG	5	17.45	
Boostrix (Tdap)	1	25.76	
HepB (ENGERIX ADULT)	1	20.81	
HepB (HBVAXPRO10)	1	20.81	
HPV	1	141.45	
Influenza	10	7.38	
Men C	1	43.05	
MMR	10	20.17	
Pneumoccoal	1	21.05	

CONTINUE TO REVIEW ORDER PAGE

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Useful Links

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United Drug Supply Chain Services





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DR SALEEM SHARIF (34595) Logout

VACCINE ORDER FORM ORDER HISTORY DELIVERY SCHEDULE CHANGE PASSWORD

Delivery Schedule

RED on your Calendar is your last date to place order.

April 2015

		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

May 2015

MON	TUE	WED	THU	FRI	SAT	SUN
				11	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Green on your Calendar is your delivery date.

June 2015

MON	TUE	WED	тни	FRI	SAT	SUN
13	2	3	-40	5	б	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

July 2015

MON	TUE	WED	THU	FRI	SAT	SUN
		1	2	3	4	5
б	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

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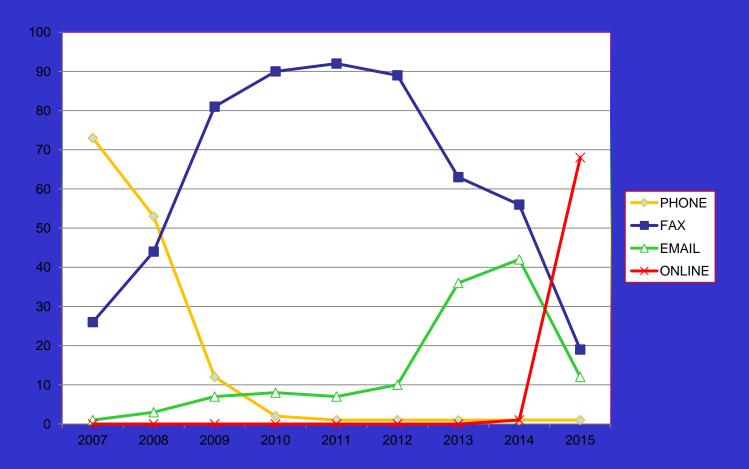
Useful Links

HSE Immunisation Website

United Drug Supply Chain Services

Feidhmeannacht na Seirbhíse Sláinte Health Service Executive

Order Source %







Storage of Vaccines & Monitoring of Vaccine Fridge temperature

- Vaccines must be stored in a <u>Pharmaceutical</u> fridge
- To comply with product licence, they must be
 - Stored within the temperature range of 2-8°C
 - Stored in original packaging to protect from light & box contains batch details
- Store on shelves, not touching the sides
- Record fridge temperature twice daily
- Set fridge to alarm at +3°C or +7°C to allow time to react before +2°C or +8°C is reached
- Wire fridge directly to power without use of a plug and have a dedicated circuit. Never unplug the fridge



Never store out of date vaccines in the fridge



Max/Min Thermometers

- Maximum / Minimum temperatures should be recorded twice daily.
- ENSURE the memory is erased twice daily, in the morning and just before closing surgery, i.e. the maximum, minimum and current temperatures should be checked again and if the thermometer has been correctly reset these three readings should all show the same temperature (i.e. current temperature)
- Recording only shows the highest temperature registered but not the duration.
- Usually the highest recorded temperature is while the door is open.









- USB temperature data logger for use with pharmacy fridges independent of fridge power supply
- Measurement range from -35°C to +80°C
- Can store up to a year's worth of data (16,382 readings)
- Flashing LED status indicators mean user can see the status of the logger without having to download data
- They do not replace recording Max/ Min readings twice daily.





Break in the Cold Chain

• Can occur due to a problem with the vaccine fridge. E.g.

- Electricity power cut
- Switch turned off
- Fridge door left open.
- Fridge malfunctions

Vaccines should be transferred immediately to a working fridge or power restored.
Never leave vaccines at room temperature
<u>Do not</u> remove them from a working fridge unless instructed to do so by the Chief Pharmacist or Medical officer in NIO





Recommended procedure following a break in the Cold Chain (1)

Make sure that the fridge is now working properly or transfer to a working fridge.

 Check the temperature and find out how long the fridge breakdown has been

- Send the following to Cliona.Kiersey@hse.ie

- Name of practice
- Account number
- Current fridge temperature
- Duration of temperature breach
- Maximum temperature reached
- Name, quantity and batch numbers of vaccines in the fridge.

Ring for further advice. (087 9915452 or 01 8676108)





Recommended procedure following a break in the Cold Chain (2)

- Any vaccine not stored between 2⁰-8^oC is no longer a licensed product
- Company data show that vaccines can be used if exposed to short deviations. Each temperature deviation must be judged on a case by case scenario. Each vaccine has specific criteria and will remain stable for different lengths of time.
- Expired and damaged unopened vaccines must not be used and should be removed from the fridge and returned to the NCCS deliveryman with a completed vaccine return form. Vaccine return forms are available to download from http://www.immunisation.ie/en/VaccineOrderingandStorage/.
- Expired and damaged unopened vaccines <u>must not</u> put into a sharps bin.





Details Required after Cold Chain Issue

- Name of practice
- Account number
- Current fridge temperature
- Duration of temperature breach
- Maximum temperature reached
- Name, quantity and batch numbers of vaccines in the fridge.

Send to Cliona.Kiersey@hse.ie





REMEMBER THE 4Rs

- **Read:** Twice daily readings of the fridge thermometer's maximum, minimum and current temperatures at the same time morning and evening daily during the working week.
- **Record:** record fridge temperatures in a standard fashion and on a standard form stating date and time of reading and sign/initial (Appendix 1) and down load data logger regularly.
- **Reset:** reset the max/min thermometer (i.e. clear the thermometer memory) after each reading and after a period of high activity once temperatures have stabilised and also at the end of every day.
- **React:** the person making the recordings should take action if the temperature falls outside +2°C to +8°C and document this action (Appendix





Planned power outage

- Keep the room as cold as possible
- Fill your fridge. Place containers of very cold salty water days before the outage in spaces. Double wrap ice blocks with bubble wrap and place on bottom of fridge
- Lock the fridge
- Record the temperature
- Use a Datalogger





WWW.immunisation.ie

HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock

Recommendations for a planned power outage





"Borrowed Vaccines"

If vaccines are required due to stock out or a fridge issue you can get vaccines from another practice.

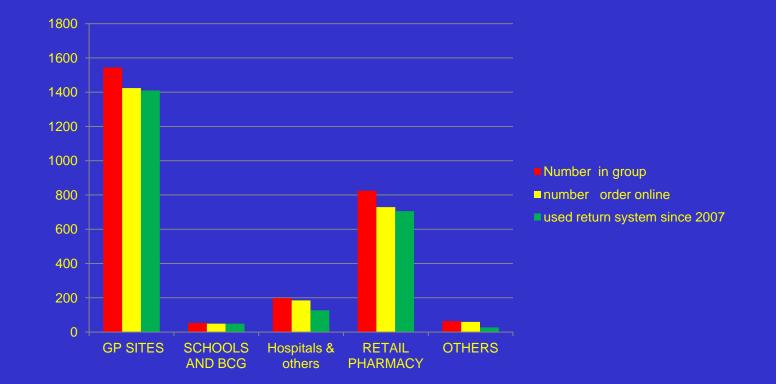
Please do not return vaccines to this practice as vaccines should be ordered by them and delivered directly to them from HSE National Cold Chain Service.







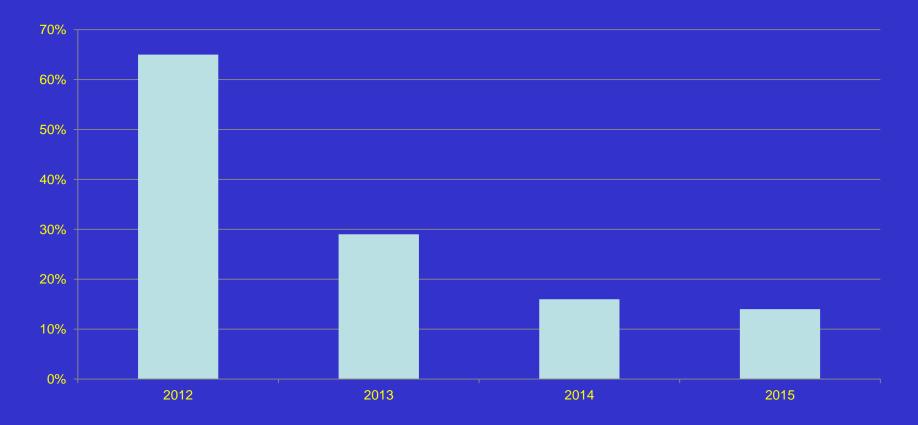
Sites using online & the returns service







% Expired Stock Returned with greater than 6 months expiry









Vaccine expired more than 6 months

• <u>2012</u>

44,184 doses - 2TU Mantoux test (expiry 05/2002) was 10 years and two months expired when returned.

• <u>2013</u>

16,753 doses - Pneumovax (expiry 03/2007) was 6 years and three months expired when returned.

• <u>2014</u>

10,737 doses - Pentavac (expiry 09 /2002) was 11 years and 6 months expired when returned. Removed from schedule in 2009.

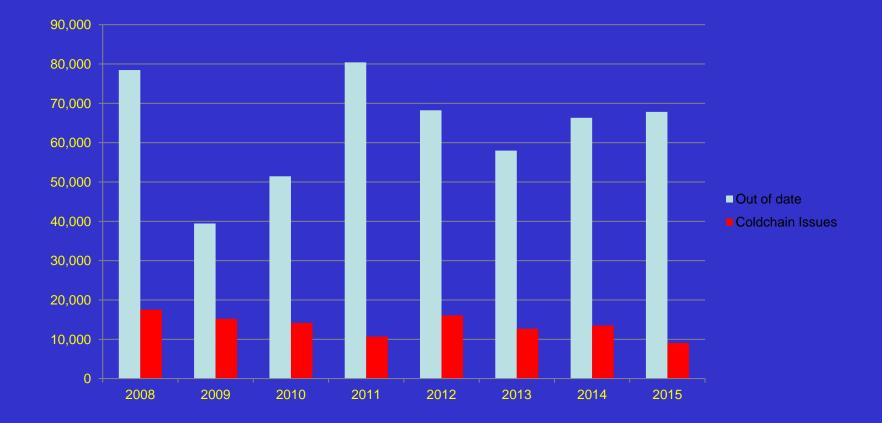
• <u>2015</u>

9168 doses- MMR (expiry 03/2004) was 11 years and 6 months expired & Pentavac also returned.





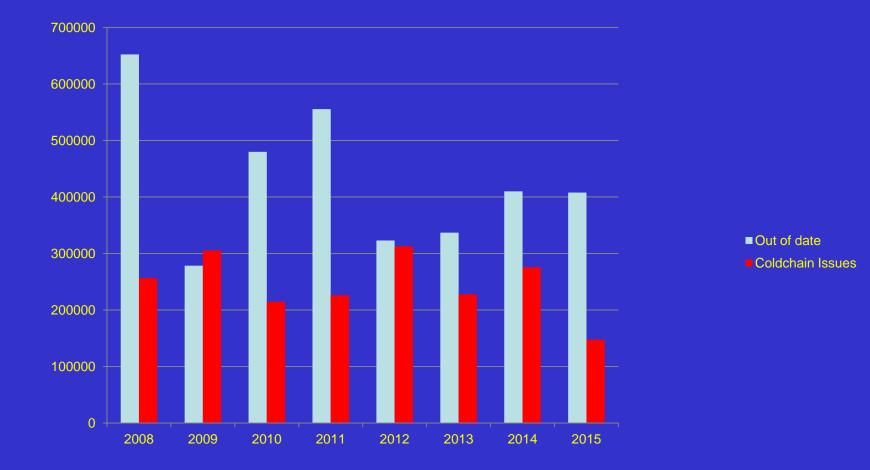
Number of Doses of returned vaccines Expired compared to Coldchain issues







Value of vaccines Expired compared to Coldchain issues







Batch Numbers

- The valid batch number is the number on the box and is the only number to record.
- Please use peel off sticker where available.
- Combination vaccines or vaccines which require reconstitution will have a different batch numbers on each constituent, the number on the box refers to the reconstituted vaccine.
- Only the appropriate batch number can be accepted on the child's record, any other batch number will register as invalid.







Conclusions

- Vaccines are expensive
- Good housekeeping is essential for vaccine management





Useful resources

- Australian Government Department of Health and Ageing National Vaccine Storage Guidelines 2005, Strive for 5 <u>http://www.health.gov.au/internet/immunise/publishing.nsf/Content/provider-store</u>
- Department of Health UK. November 2006. Immunisation against infectious disease. <u>http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH</u> 4097254
- Irish Pharmaceutical Healthcare Association Medical Compendium. http://www.medicines.ie.
- Irish Medicines Board. <u>http://www.imb.ie</u>.
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