

The Cold Chain and Vaccine storage

Cliona Kiersey
Chief Pharmacist
National Immunisation Office



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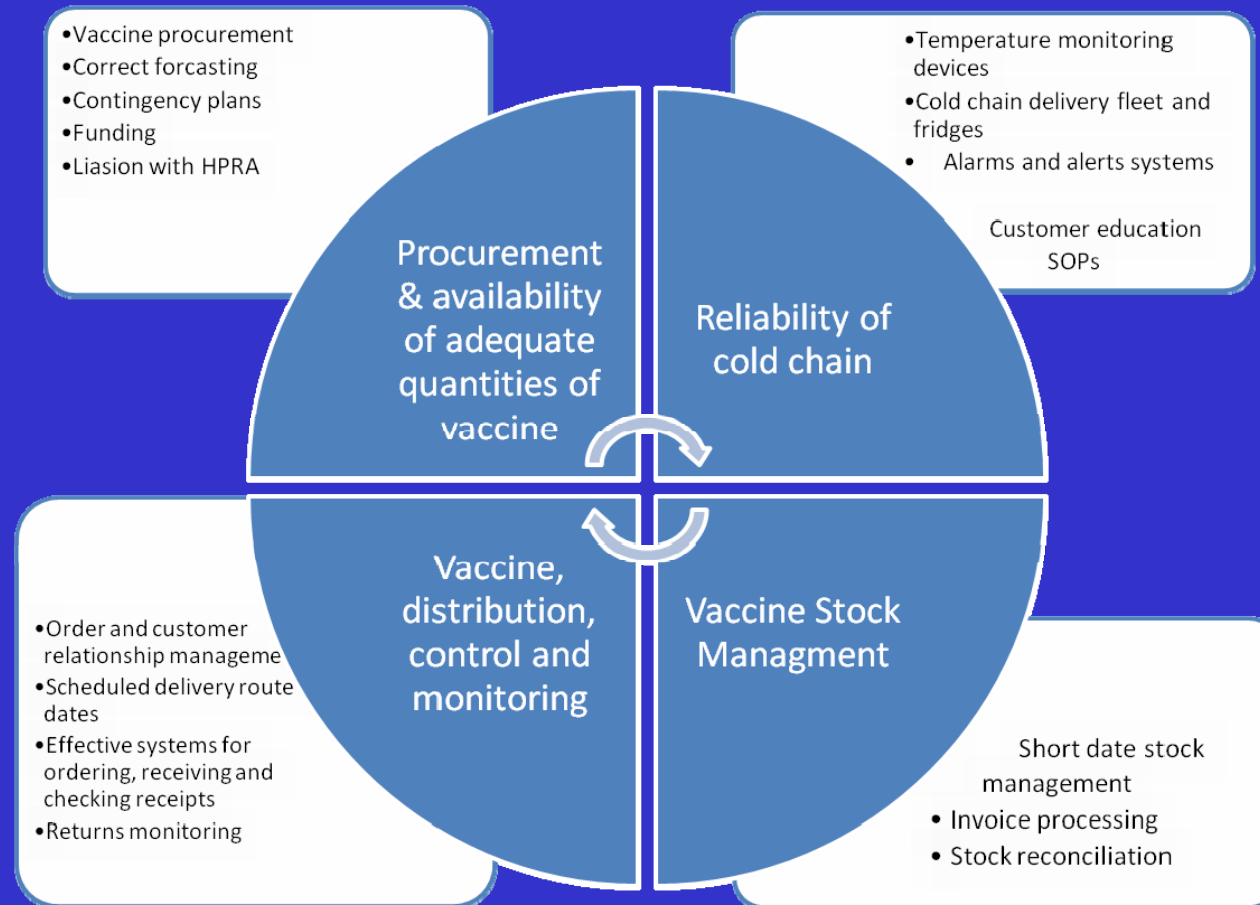
Objectives

- To explain the cold chain and vaccine delivery service including importance of using vaccine returns service
- To understand the importance of monitoring the cold chain within your own practice
- To understand the correct procedures for handling and storage of vaccines
- To recommend procedures following cold chain breach
- C&AG Requirement to do Annual Stock-take



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Factors affecting vaccine management performance



Relevant sections

- Use of temperature monitoring devices
- Cold chain delivery fleet and fridge
- Alarms and alerts systems
- Use of freeze or heat indicators during transport
- Customer education
- Standard Operating Procedures

Reliability
of cold chain

Vaccine
distribution, control
and monitoring

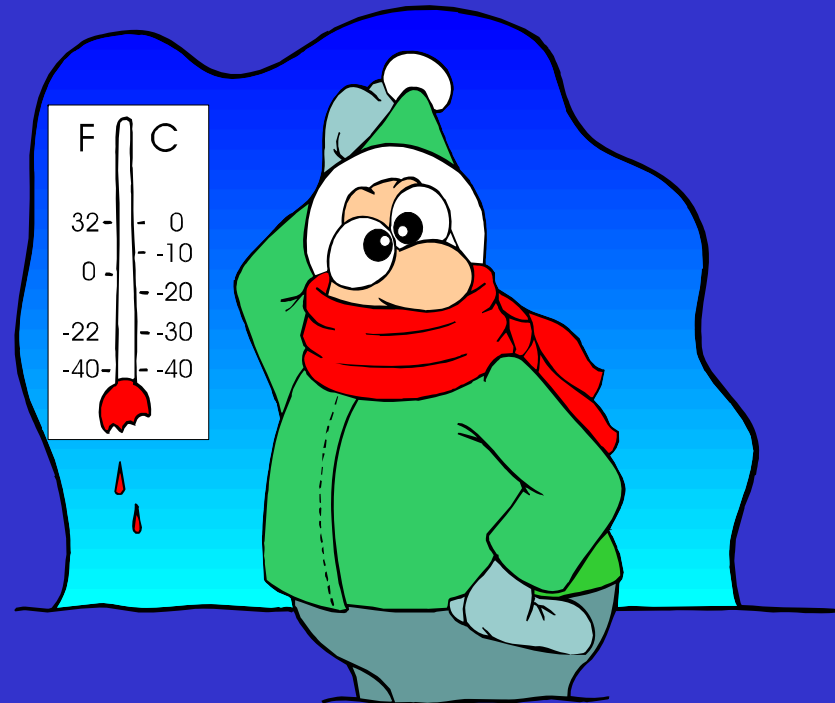
- Order and customer relationship management
- Scheduled delivery route & dates
- Effective systems for ordering, receiving & checking receipts
- Returns monitoring



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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)
- Every vaccine from time of manufacture up to point of delivery to surgery has a verified temperature record
- Assurance in product potency ensures maximum benefit from immunisation



Reliability of 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



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National Cold Chain Service (HSE NCCS)

- Commenced 1st January 2005, delivering to ~1650 sites annually now has increased to 2,635 sites receiving 2.1 million doses annually
- responsible for ~€35 million annually.
- United Drug Distributors based in Citywest with satellite sites in Limerick and Ballina



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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 probeAlarm 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.



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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

Fortnightly deliveries from mid-September to mid-November



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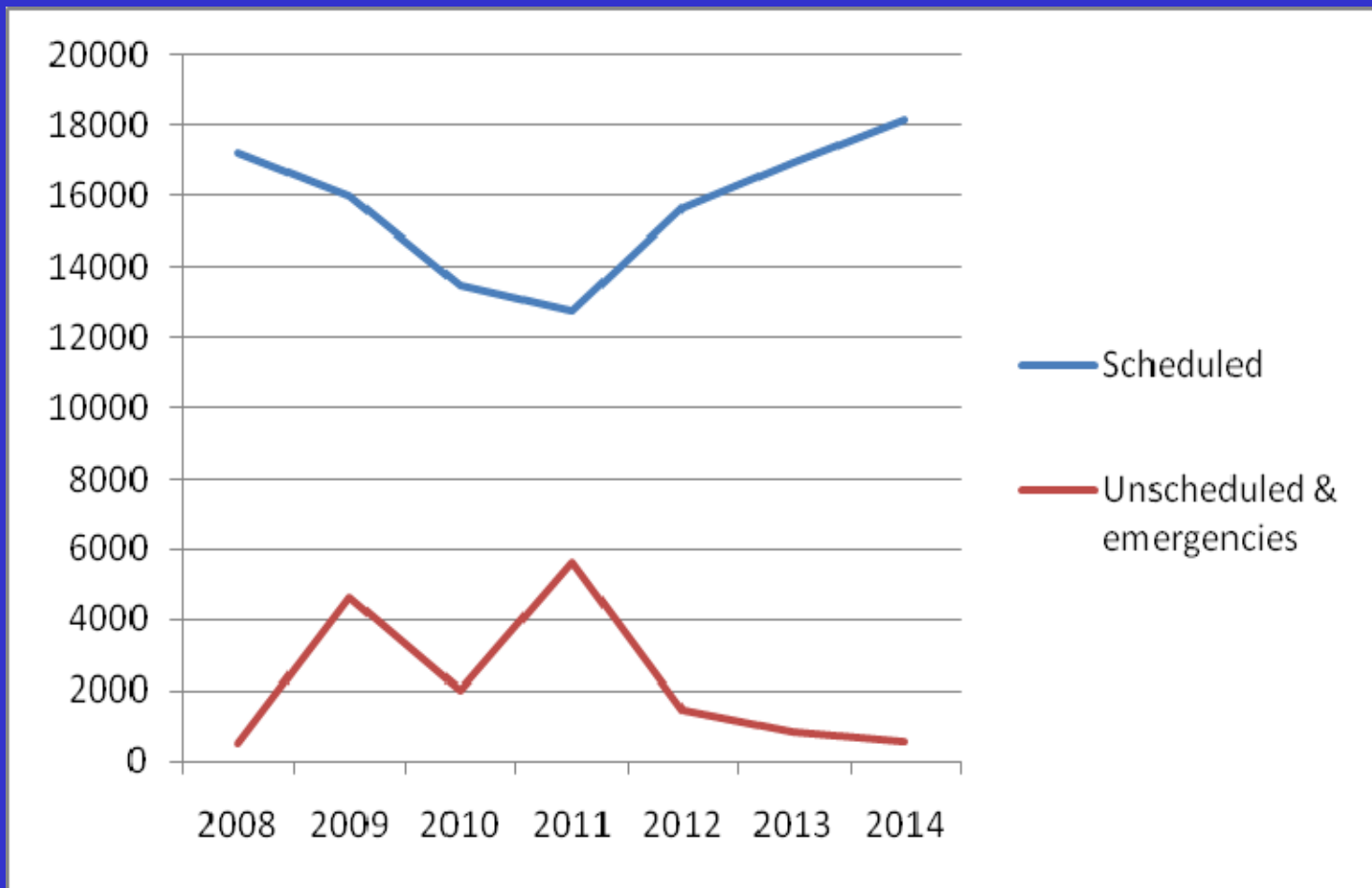
Vaccine Deliveries

- 1635 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 5 scheduled deliveries within two and a half months (2 weekly cycle).
- There are an extra ~1000 sites who get only flu / PPV deliveries in flu season.
- Unscheduled
- Emergency



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Number of Deliveries 2008- 2014



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Unscheduled / Emergency Deliveries

- Contract is for 14 scheduled deliveries to each site.
- Each non scheduled / emergency delivery is an extra charge.
- Disruption to routine deliveries



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Vaccine distribution, Control & Monitoring

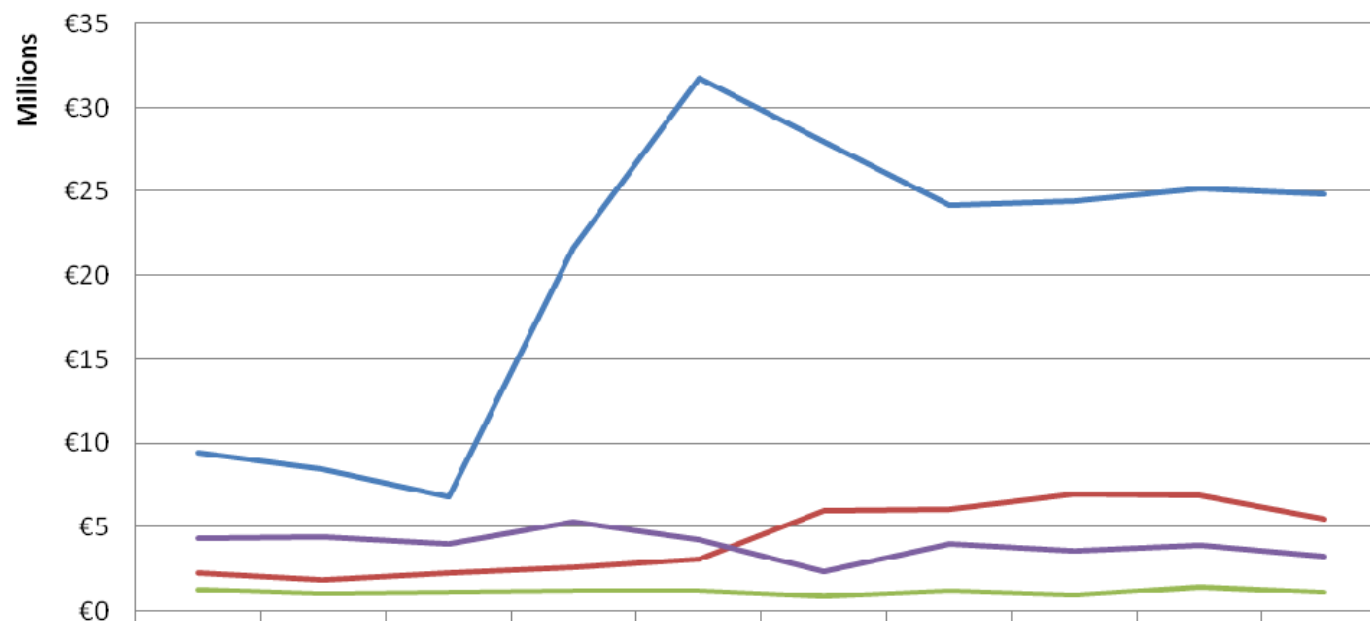
Vaccine distribution is monitored to ensure it is consistent with target cohort requirements as significant deviations may indicate over or under stocking.

Each site should order monthly to facilitate proper stock levels and reduce overstocking of vaccines in surgeries



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Cost of Vaccines Purchased



	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Primary Childhood	€9,431,9	€8,484,4	€6,818,0	€21,607,	€31,741,	€27,922,	€24,179,	€24,417,	€25,135,	€24,804,
Schools	€2,212,6	€1,813,1	€2,213,5	€2,520,3	€3,052,9	€6,001,0	€6,039,5	€6,961,1	€6,883,9	€5,505,0
Others	€1,233,9	€1,055,6	€1,069,0	€1,180,1	€1,190,1	€855,082	€1,179,9	€937,007	€1,432,8	€1,083,9
Flu and PPV	€4,315,0	€4,404,0	€4,003,6	€5,288,2	€4,272,1	€2,385,7	€4,034,3	€3,566,5	€3,950,2	€3,305,5

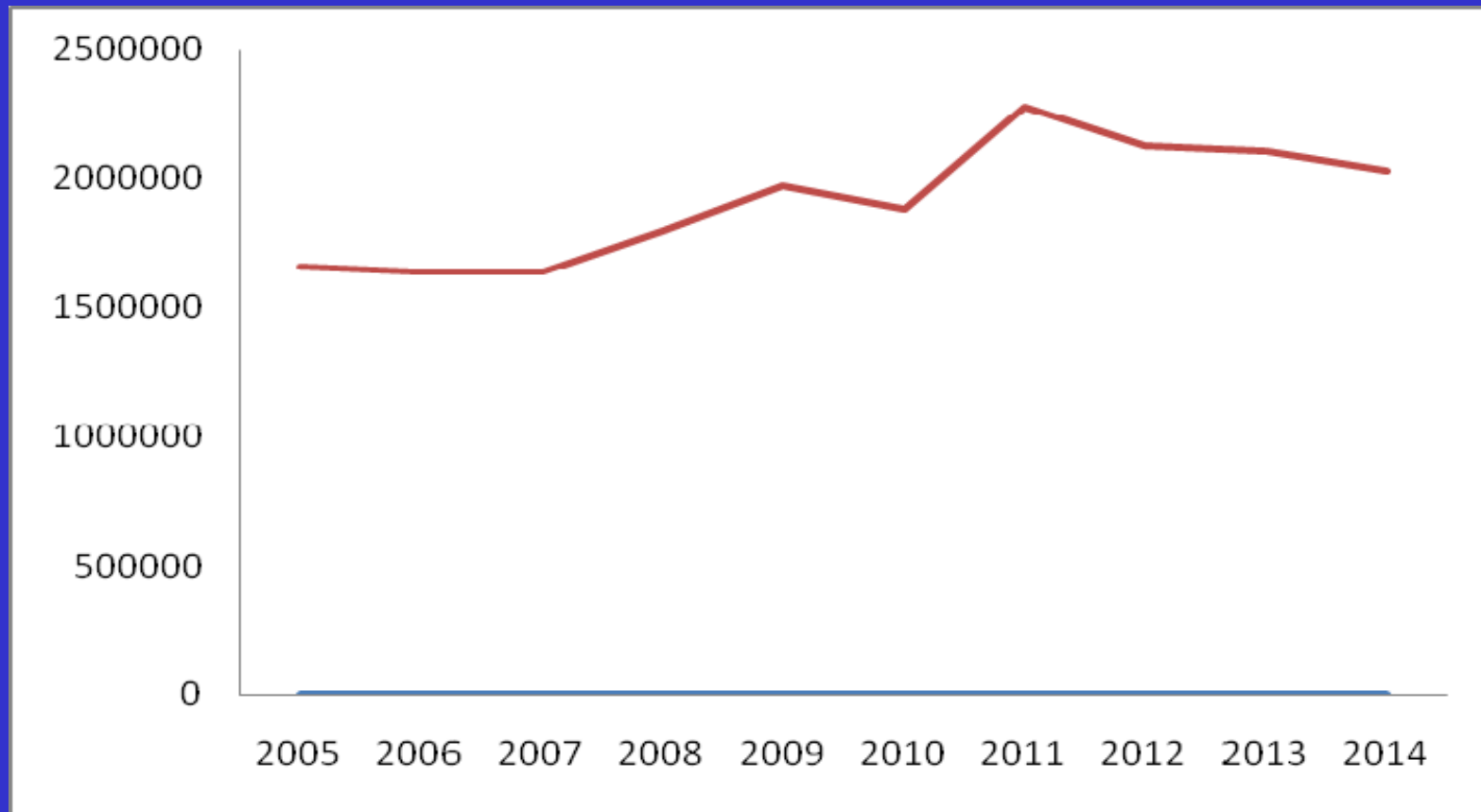


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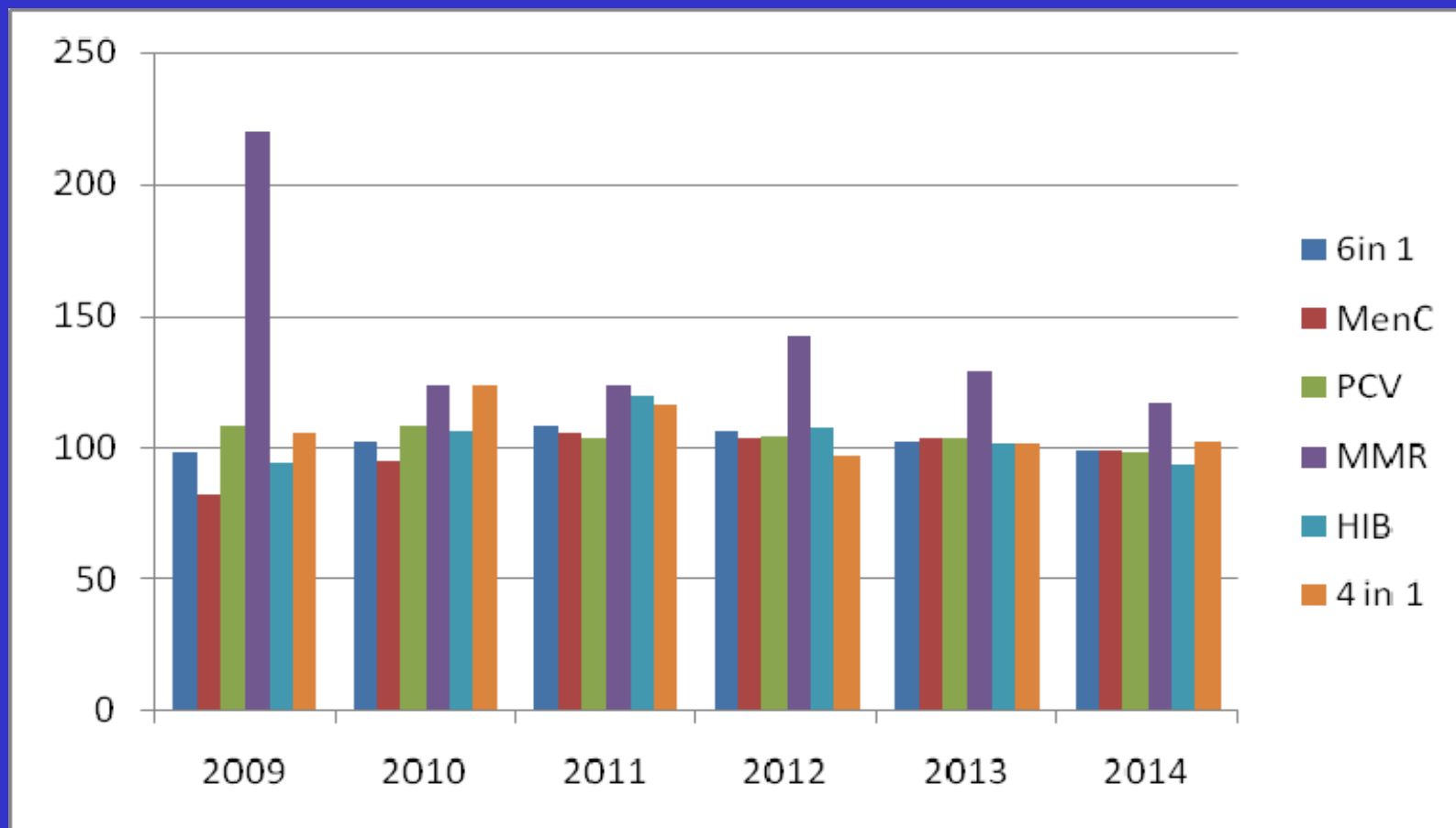
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Number of Doses Distributed



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Number of doses distributed as % of cohort requirements in 2009-2014



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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 directly to these sites.



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Vaccines supplied

	Vaccines
Primary Childhood vaccines	6 in 1, Men C, PCV, MMR, Hib
Adult vaccines	Td, Tdap Influenza, Pneumococcal polysaccharide vaccine
HSE vaccines	BCG, Tuberculin , 4 in 1, MMR, Tdap, HPV
Restricted vaccines	Hepatitis A, Hepatitis B, Hepatitis A +B Td/IPV, Tdap/IPV, MenACW ₁₃₅ Y, MenB

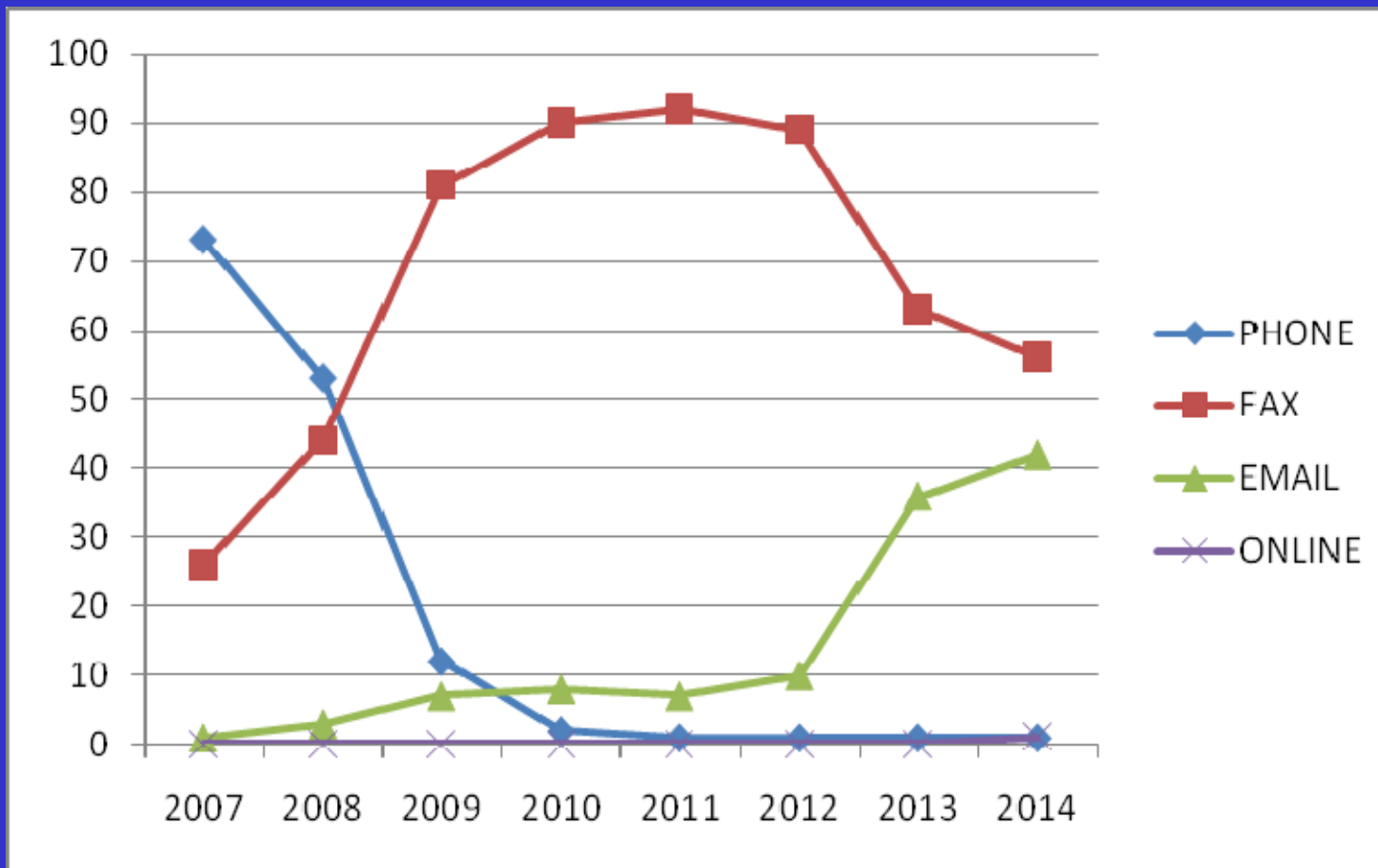
Current list of available vaccines

- from United drug
- in newsletter
- on immunisation website

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Order source (%)



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Online Ordering System

- Improve ordering process for both Clients and HSE NCCS staff
- Assist in stock management
- Improve communication methods to sites
- Provide a means of online stock-take on 31st December each year as required by C&AG



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Roll out of Online System

- Prior to implementation 21 early innovator sites were selected to use the system and give feedback on design and process
- In November 2014, all GP (1548) and HSE sites (109) received a newsletter, a system manual, temporary passwords and explanatory letter with details of the Go live date
- The online ordering system was made available to all sites in December 2014. Customer support was available to any site that had queries or complaints.



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www.ordervaccines.ie

- Limits were based on 2014 orders and adjusted to reflect changes in previous 6 months
- Monthly ordering required for orders > 10 doses of Infanrix Hexa
- Facility to order extra vaccines by emailing Vaccines@udd.ie
- Site specific monthly limits can be increased if required
- The value of the vaccines based on indicative pricing is visible



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National Cold Chain Service

Delivered by United Drug in partnership with the HSE

Login

Username/Email:

customer@ncc.com

Account ID:

30030

Password:

LOGIN

[Forgotten your Password?](#)

Vaccine Ordering

Welcome to www.ordervaccines.ie. 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



United Drug Supply Chain Services

We're committed to keeping our simple promise, every day. We work with principals, pharmacies and hospitals to shape our services around their requirements. And we get your products to the people who need them – your patients.

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Useful Links

[HSE Immunisation Website](#)

[United Drug Supply Chain Services](#)



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National Cold Chain Service

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NCC Web Ordering (30030)

Logout

VACCINE ORDER FORM

ORDER HISTORY

DELIVERY SCHEDULE

CHANGE PASSWORD

Welcome to your HSE National Cold Chain Dashboard

Messages

MESSAGE HEADLINE	DATE
STOCKTAKE REQUIRED	19 Nov 2014

[VIEW ALL MESSAGES](#)

Last Order - 19 November 2014

VACCINES	QTY
6 in 1	10
Dtae	5
Men C	10
PCV	10

[VIEW YOUR ORDER HISTORY](#)

Delivery Schedule - November

MON	TUE	WED	THU	FRI	SAT	SUN
27	28	29	30	31	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
1	2	3	4	5	6	7

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

GREEN on your Calendar is your delivery date.



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National Cold Chain Service

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DR SALEEM SHARIF (34595)
Logout

VACCINE ORDER FORM

ORDER HISTORY

DELIVERY SCHEDULE

CHANGE PASSWORD

Vaccine Order Form

VACCINE	PACK SIZE	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.

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

CONTINUE TO REVIEW ORDER PAGE

Requested Vaccines

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
TOTAL		2,258.27



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NORTH WEST DUBLIN LOCAL HEALTH OFFICE **
(39510)
[Logout](#)

[VACCINE ORDER FORM](#)

[ORDER HISTORY](#)

[DELIVERY SCHEDULE](#)

[CHANGE PASSWORD](#)

Vaccine Order Form

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 (ENGRIX 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	+ -
Pneumococcal	1	21.05	

Requested Vaccines

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

[CONTINUE TO REVIEW ORDER PAGE](#)

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Useful Links

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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**.

■ Green on your Calendar is your **delivery date**.

April 2015

MON	TUE	WED	THU	FRI	SAT	SUN
		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
				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	31

June 2015

MON	TUE	WED	THU	FRI	SAT	SUN
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					

July 2015

MON	TUE	WED	THU	FRI	SAT	SUN
		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	31		

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Useful Links

HSE Immunisation Website

United Drug Supply Chain Services



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Success or Not? Early days

- 90% of all sites on system are ordering online. 4% do not have email and 6% have not placed orders this year.
- It is estimated that the introduction of this system will result in an annual saving of €100,000 of vaccines lost due to expiry or cold chain breaches and savings should increase as stockholding in sites reduces.

Sites have commented that

- ordering time halved & order can be placed at anytime
- Useful to see previous history & to manage stock
- Too restrictive
- Vaccines very costly



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Recommended procedure for ordering and accepting vaccines

- Should have a named, trained and designated person and deputy
- Order one month's requirement on-line before closing date
- Remove expired vaccines from fridge and prepare for return
- Give vaccine returns to UD driver
- Check vaccine deliveries against the order for damage or discrepancies
- Place vaccines in the vaccine refrigerator immediately
- NEVER leave vaccine delivery at room temperature



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What Quantity to Order

Limits or restrictions are set, these can be altered if required.

No more than 6 weeks stock should be in the fridge at any time

If vaccines are required due to stock out or a fridge issue vaccines are taken from a neighbouring practice

These are not borrowed as they should not be returned

Please DO NOT return vaccines to a practice as vaccines should be ordered by them and delivered directly to them from HSE National Cold Chain Service. A neighbouring practice will receive vaccines on the same day.



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Vaccine Fridge

- **Vaccines must be stored in a fridge to comply with licence**
 - Store within the temperature range of 2-8⁰C
 - Store in original packaging
- Store on shelves, not touching the sides
- Record fridge temperature twice daily
- Set fridge to alarm at +3⁰C or +7⁰C to allow time to react before +2⁰C or +8⁰C is reached
- Wire fridge directly to the power supply without use of a plug.
- **Never unplug the fridge**
- **Never use out of date vaccines**



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Guidelines

HSE Guidelines for maintaining the vaccine cold-chain including maintenance of vaccine fridges and management of vaccines

www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sop.pdf

HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes

www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/SOPCoolBoxes.pdf



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Max/Min Thermometers

- Maximum / Minimum temperatures should be recorded daily.
- ENSURE the memory is erased daily, preferably before closing surgery.
- Recording only shows the highest temperature registered but not the duration.
- Usually the highest recorded temperature is while the door is open.



Data Loggers

- 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



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Data loggers



Recommended procedure following a 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
- *If this happens*
 - 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
 - Contact the Chief Pharmacist, National Immunisation Office for further advice. (087 9915452 or 01 8676108)



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

- Any vaccine not stored between 2⁰-8⁰C 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. This data is batch specific.
- Vaccines which cannot be used must be returned to the National Cold Chain Service for destruction
- The value of the vaccines must be claimed from your insurance and passed to HSE National Immunisation Office.



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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

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Some typical vaccine orders with Values

Qty	Vaccine
10	INFANRIX HEXA
10	PREVENAR
10	MEN C
4	MMR
4	HIB
5	DITE BOOSTER
Total	<u>€2,307.57</u>

Qty	Vaccine
30	INFANRIX HEXA
30	PREVENAR
30	MEN C
10	MMR
10	HIB
10	DITE BOOSTER
Total	<u>€6,772.26</u>

Qty	Vaccine
100	INFANRIX HEXA
100	PREVENAR
100	MEN C
40	MMR
40	HIB
20	DITE BOOSTER
Total	<u>€22,696.70</u>



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Insurance

- Are you vaccines covered by insurance?
- In the Guidelines for Immunisations in General Practice it states:

“In the event of a refrigerator breakdown ensure that an insurance claim is submitted for damaged vaccines and that this amount is passed on to the HSE National Immunisation Office”



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Insure for how much??

- As deliveries are every 4 weeks, stock in fridge should be at a maximum 6 weeks supply so insurance should cover as a minimum :
- Monthly order of
- 10 x Infanrix Hexa + = € 3,000
- 30 x Infanrix Hexa + = €10,000
- 60 x Infanrix Hexa + = €22,000
- 100x Infanrix Hexa + = €35,000



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Returns

- All unused or damaged vaccines must be returned to the HSE NCCS for destruction
- As part of their contract manufacturers must dispose of expired or damaged
- If there is a batch recall, all doses must be accounted for and returned/destroyed vaccines must be included
- Sharps bins are NOT for disposing of vaccines



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€6m worth of vaccines destroyed in six years



Priscilla Lynch

Topics: Brenda Corcoran World Health Organisation

Tue, Jan 28, 2014, 01:00

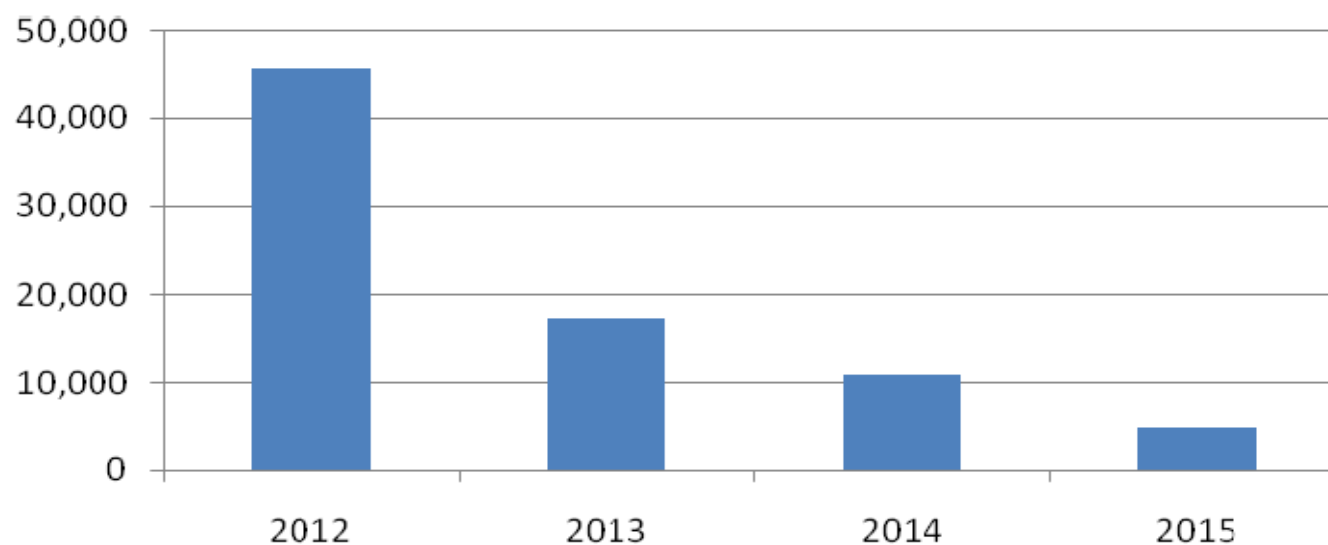
The HSE has destroyed €6.614 million worth of vaccines in the past six years, figures obtained by this newspaper reveal.



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Expired Stock Returned

**number of doses returned >6 months
expired**



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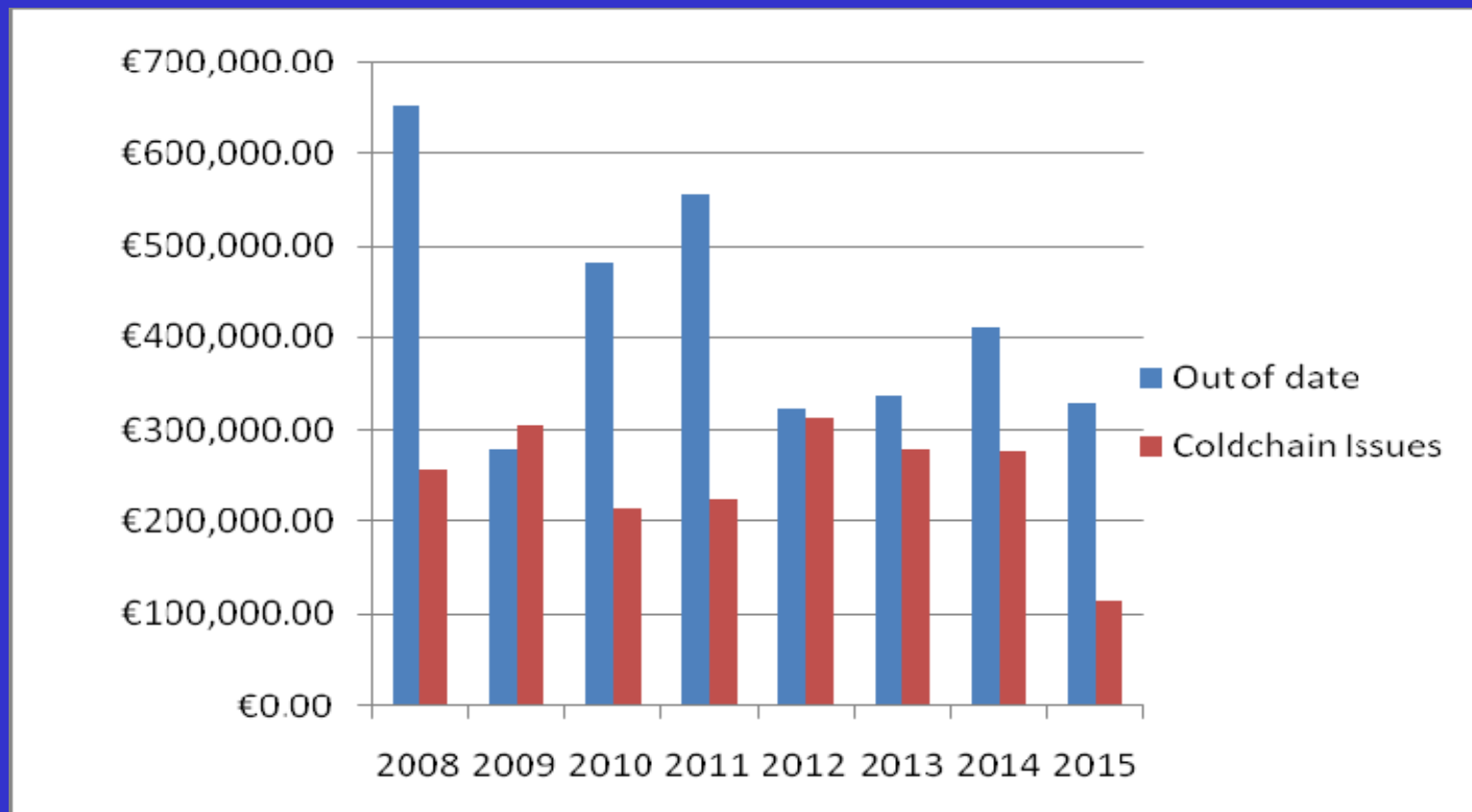
Returns service commenced in 2005

- In 2012, 2TU Mantoux test (expiry 05/2002) was 10 years and two months expired when returned.
- In 2013, Pneumovax (expiry 03/2007) was 6 years and three months expired when returned.
- In 2014, Pentavac (expiry 09 /2002) was 11 years and 6 months expired when returned. Removed from schedule in 2009.
- In 2015, Hiberix expired in 31/07/2010 was returned in August.



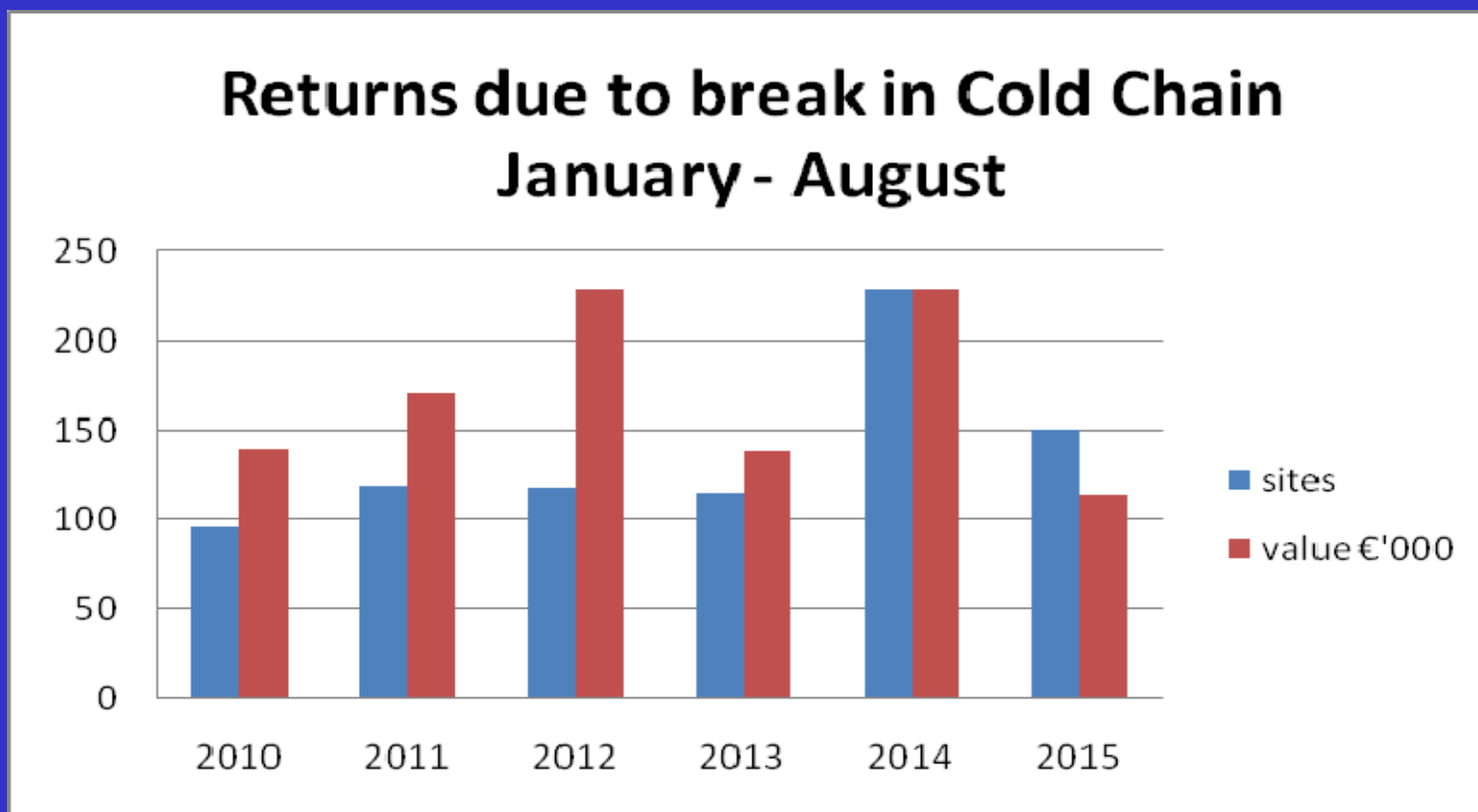
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Value of vaccines Expired compared to Coldchain issues (2015 = 8 months)



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Number of Sites and Values for Cold Chain Breaks comparing years- has online made an impact?



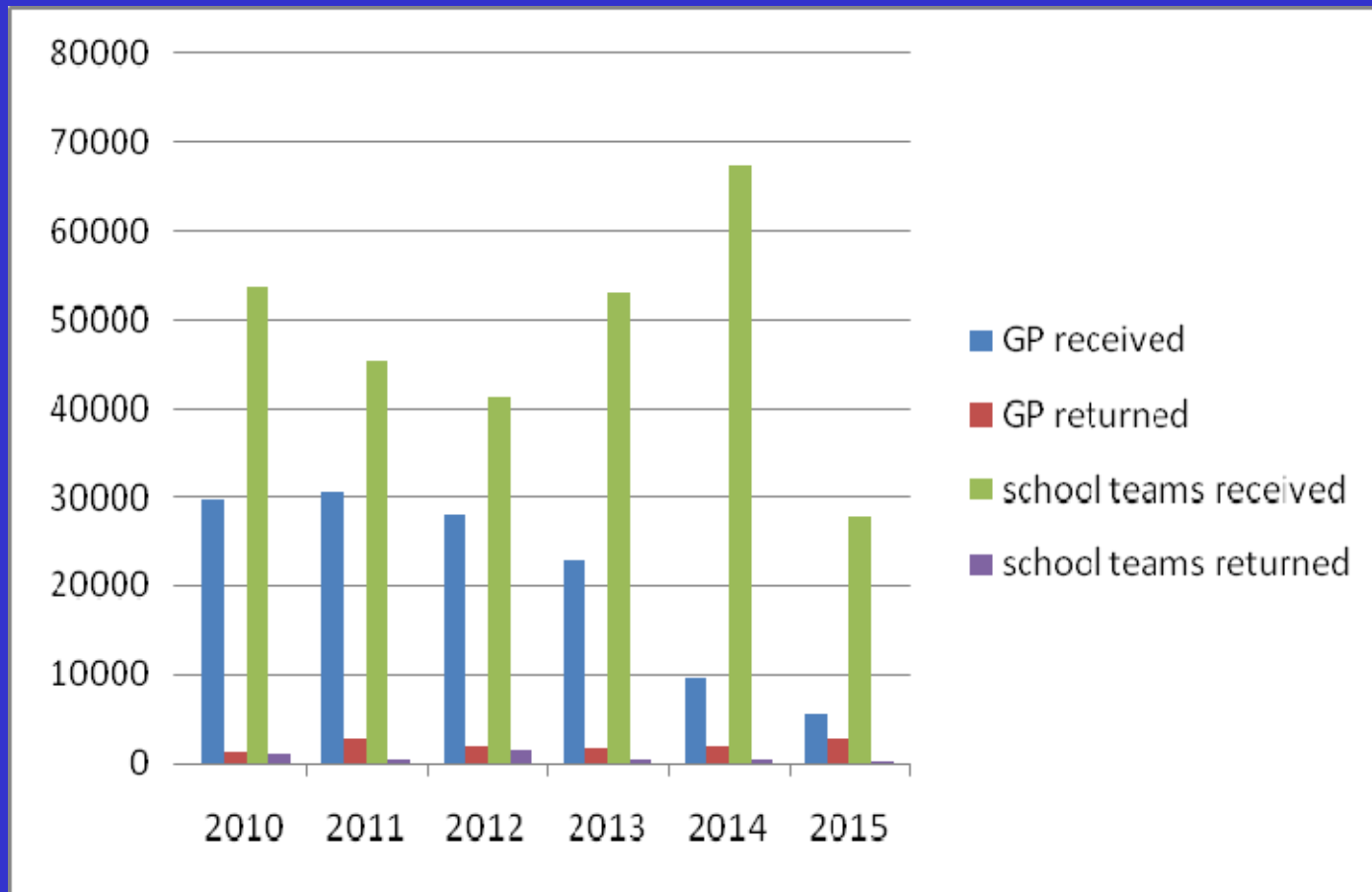
DTaP/IPV

- Due to pertussis shortage IPV-Infanrix is only distributed to School vaccination Teams
- Insufficient stock to allow doses to be held in surgeries
- Exceptions are Donegal and Sligo/ Leitrim



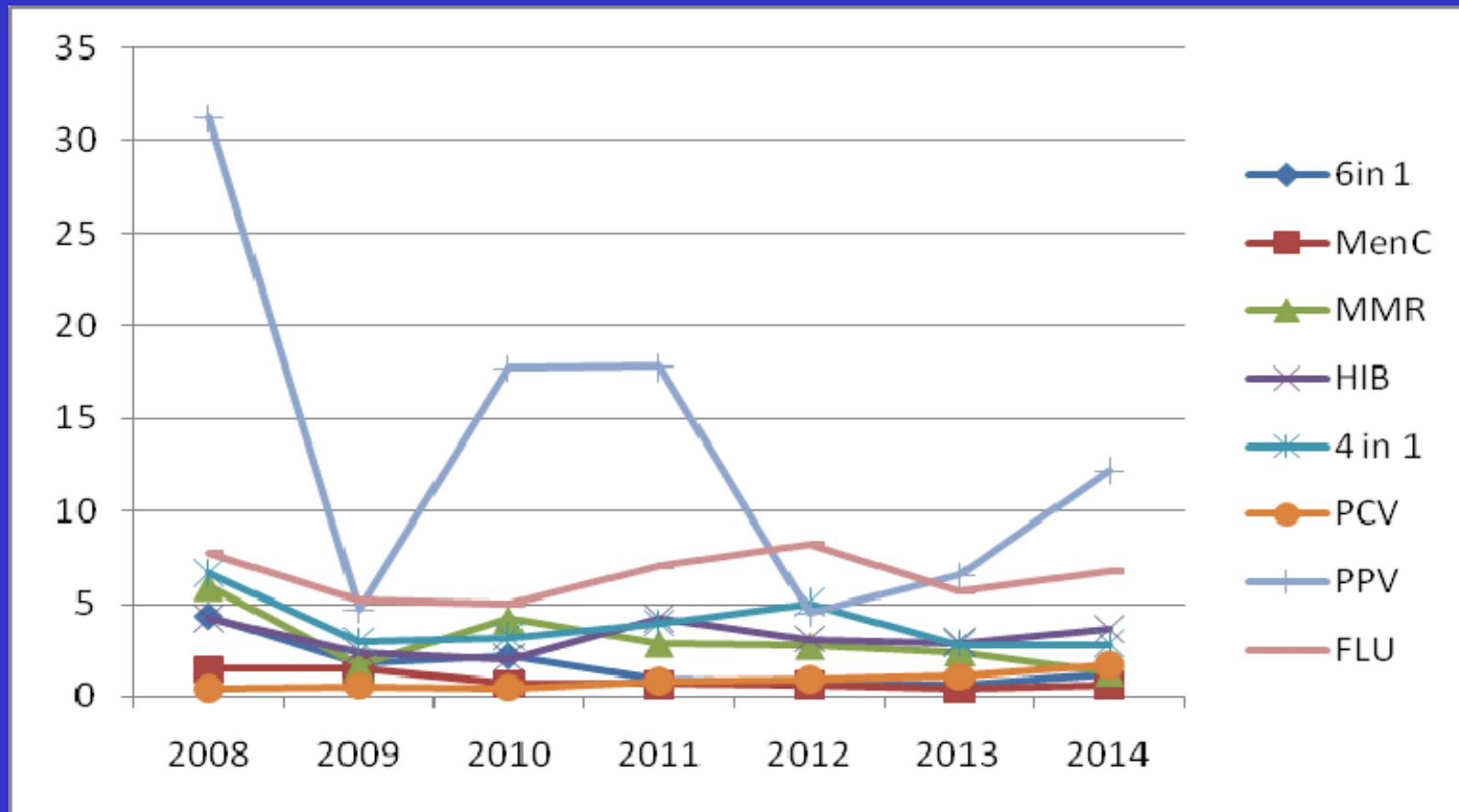
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Doses of DTaP/IPV delivered to and returned from GPs and School Teams



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% Vaccines Returned compared to Distributed



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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.



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- Report by the Comptroller and Auditor General in January 2015 highlighted as weakness in the system that there is no knowledge of the quantity of vaccines throughout the country.
- Every December a stock take must be done in every site that receives vaccines
- Online is the most efficient way to compile data
- Reduction of waste in the system must be demonstrated



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Conclusions

- Vaccines are expensive and must be insured
- Good housekeeping is essential for vaccine management
- Stock must be kept to a minimum
- Annual stock take must be completed



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Useful resources

- Australian Government Department of Health and Ageing National Vaccine Storage Guidelines, Strive for 5
<http://www.health.gov.au/internet/immunise/publishing.nsf/Content/IMM77-cnt>
- Department of Health UK. November 2006. Immunisation against infectious disease.
<http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook>
- Irish Pharmaceutical Healthcare Association Medical Compendium.
<http://www.medicines.ie>.
- Health Products Regulatory Authority. <https://www.hpra.ie/>.
- National Immunisation Office Ireland. Health Service Executive.
<http://www.immunisation.ie>.
- Royal College of Physicians of Ireland. Immunisation Guidelines for Ireland. Available at www.rcpi.ie or www.immunisation.ie or www.hpsc.ie



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