

The Cold Chain and Vaccine storage

Cliona Kiersey
Chief Pharmacist
National Immunisation Office



www.immunisation.ie

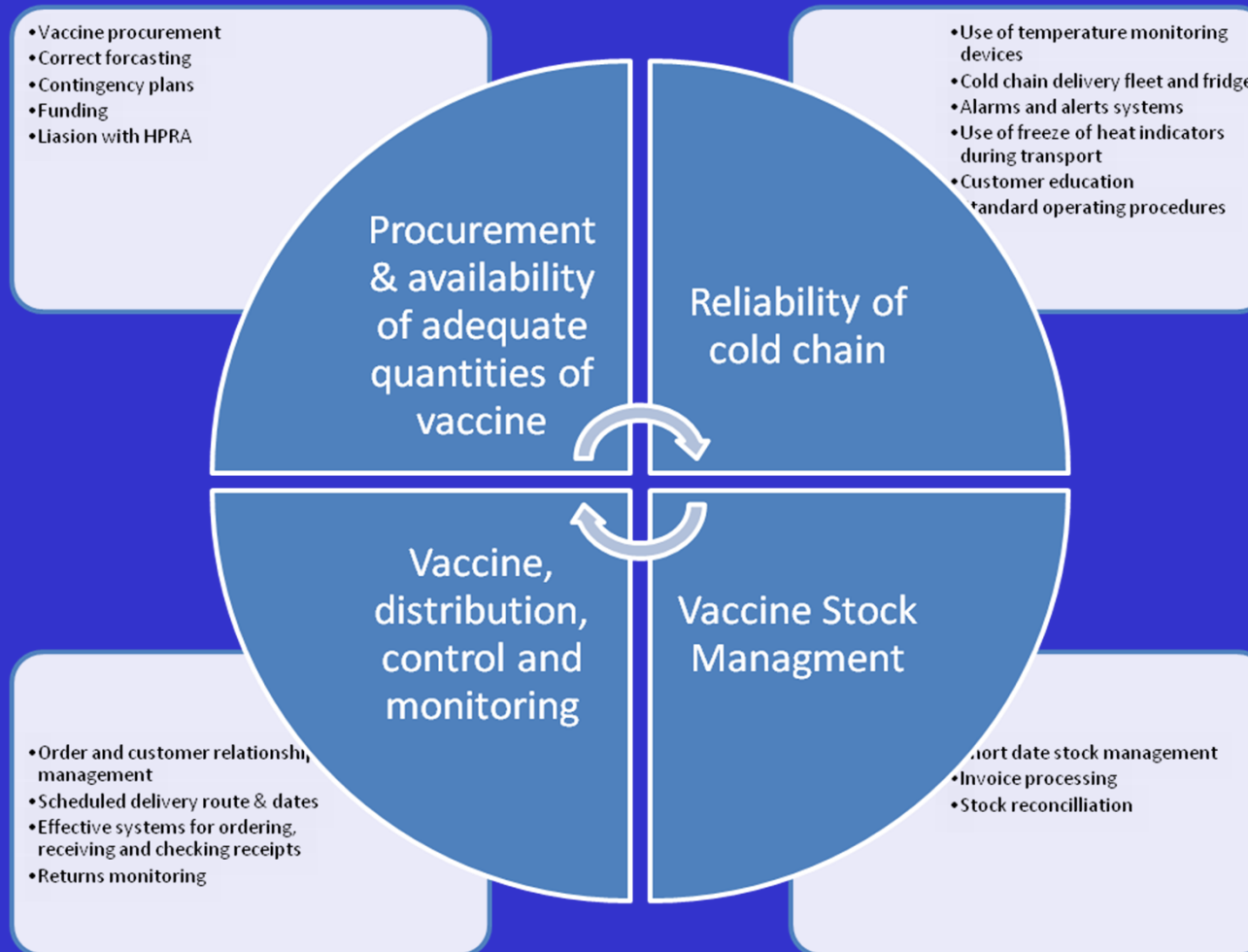
Objectives

- To outline the complexity of vaccine management, the importance of cold chain
- To understand the importance of ordering appropriately and the delivery service
- To explain 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



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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

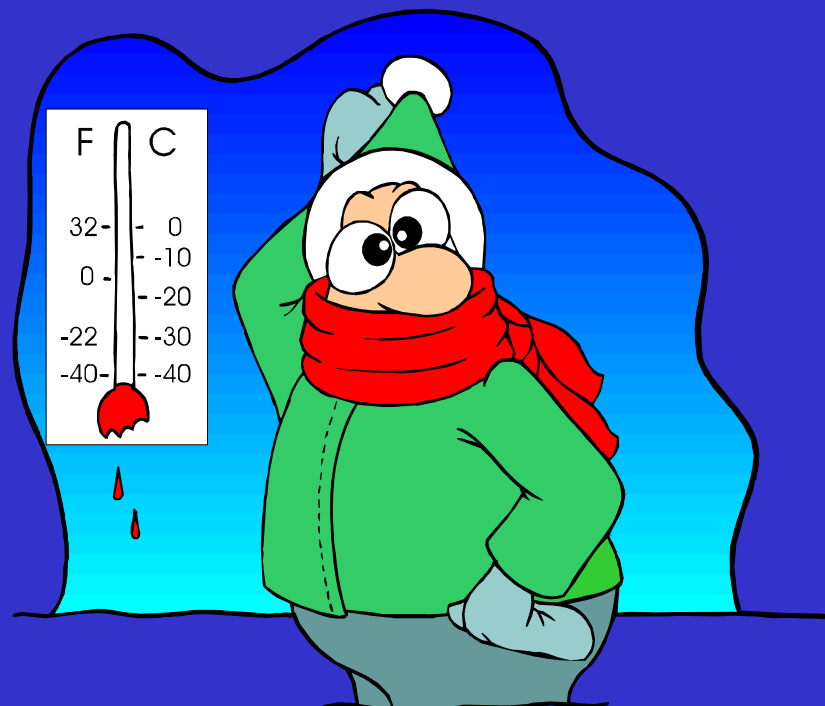
- Order and customer relationship management
- Scheduled delivery route & dates
- Effective systems for ordering, receiving & checking receipts
- Returns monitoring



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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 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 3 main elements
in each of the 3 areas

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



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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



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National Cold Chain Delivery Service (2nd Link)

- Commenced 1st January 2005, delivering to ~1650 sites annually now has increased to 2,707 sites receiving 2.5 million doses annually
- United Drug Distributors based in Citywest with satellite sites in Limerick and Ballina
- Storage fridge has 4 individual refrigerating units and backed up by an independent generator. Alarms/alert systems are monitored 24/7
- Fridges in Dublin, Limerick and Ballina are also mapped and inspected by HPRA



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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.



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 September to December



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Annual Vaccine Deliveries

- 1700 sites are entitled to 12 scheduled (monthly) plus 3 extra deliveries during the “flu season”. An additional ~1000 sites who get only flu / PPV deliveries in flu season, therefore 2707 sites receive fortnightly deliveries .
- The 12 deliveries are based on 4 weekly cycles (and there are 4 “down” weeks). During the flu season deliveries are fortnightly .
- 2018 Flu deliveries will commence Sept 17th and every site will have received flu vaccines if they have placed an order as per schedule.
- All sites will have a delivery in the New Year by 18th of January 2019.
- Please check your calendar and place your order on time. No unscheduled deliveries can be accommodated during this period.



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Unscheduled / Emergency Deliveries

- Contract is for 15 scheduled deliveries to each site, including fortnightly deliveries from beginning of September to December (15 scheduled deliveries to each site)
- Each emergency delivery is an extra charge(costly) and cause a disruption to routine deliveries
- **Unscheduled deliveries cannot be accommodated between September and January.**



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Importance of Ordering Appropriately

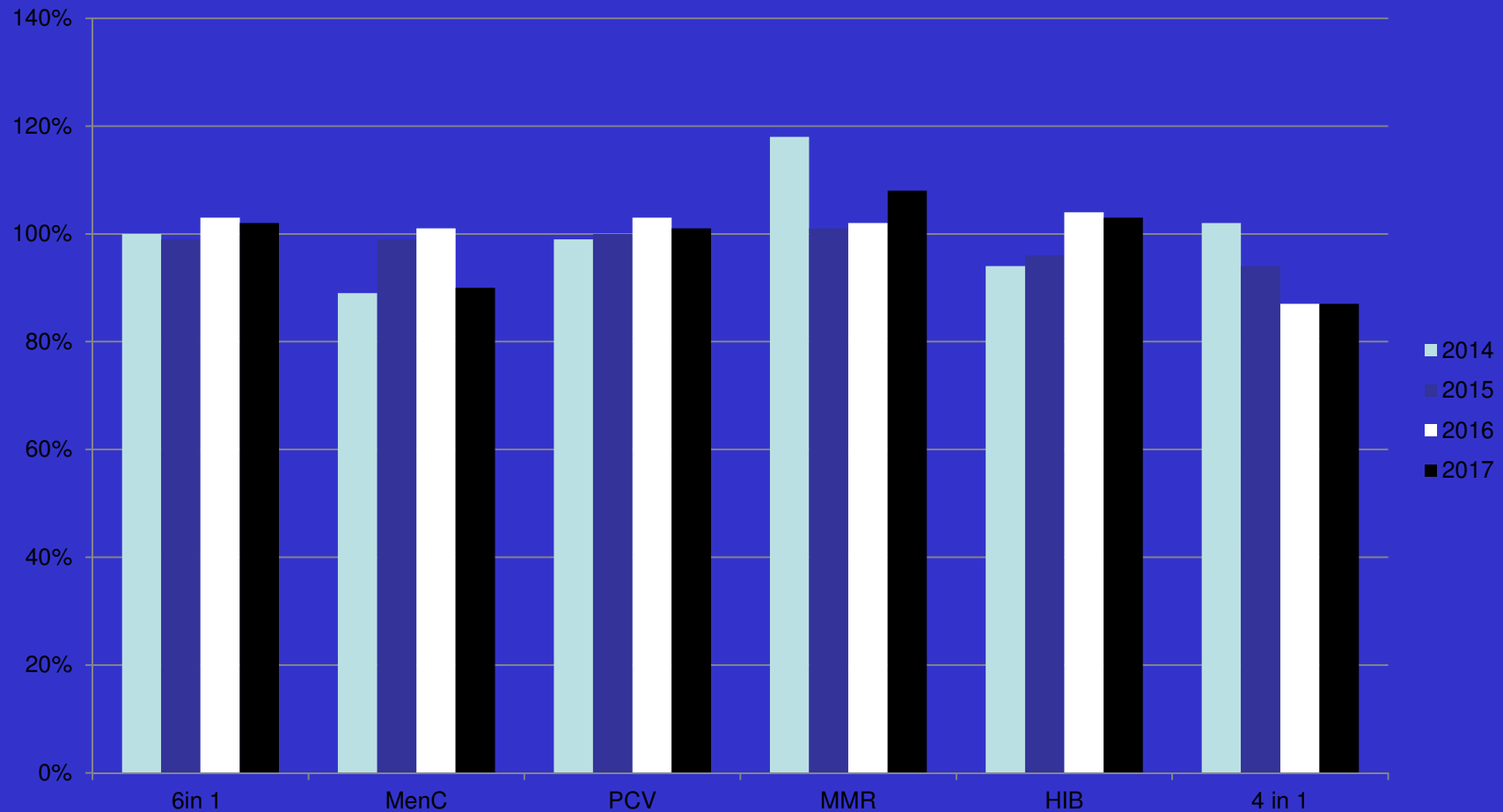
Vaccine orders are monitored to ensure consistency with target cohort requirements. Significant deviations may indicate over or under stocking, leading to vaccine wastage or missed opportunity to vaccinate.

Each site should order monthly to ensure proper stock levels.



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Doses Distributed as % of Cohort

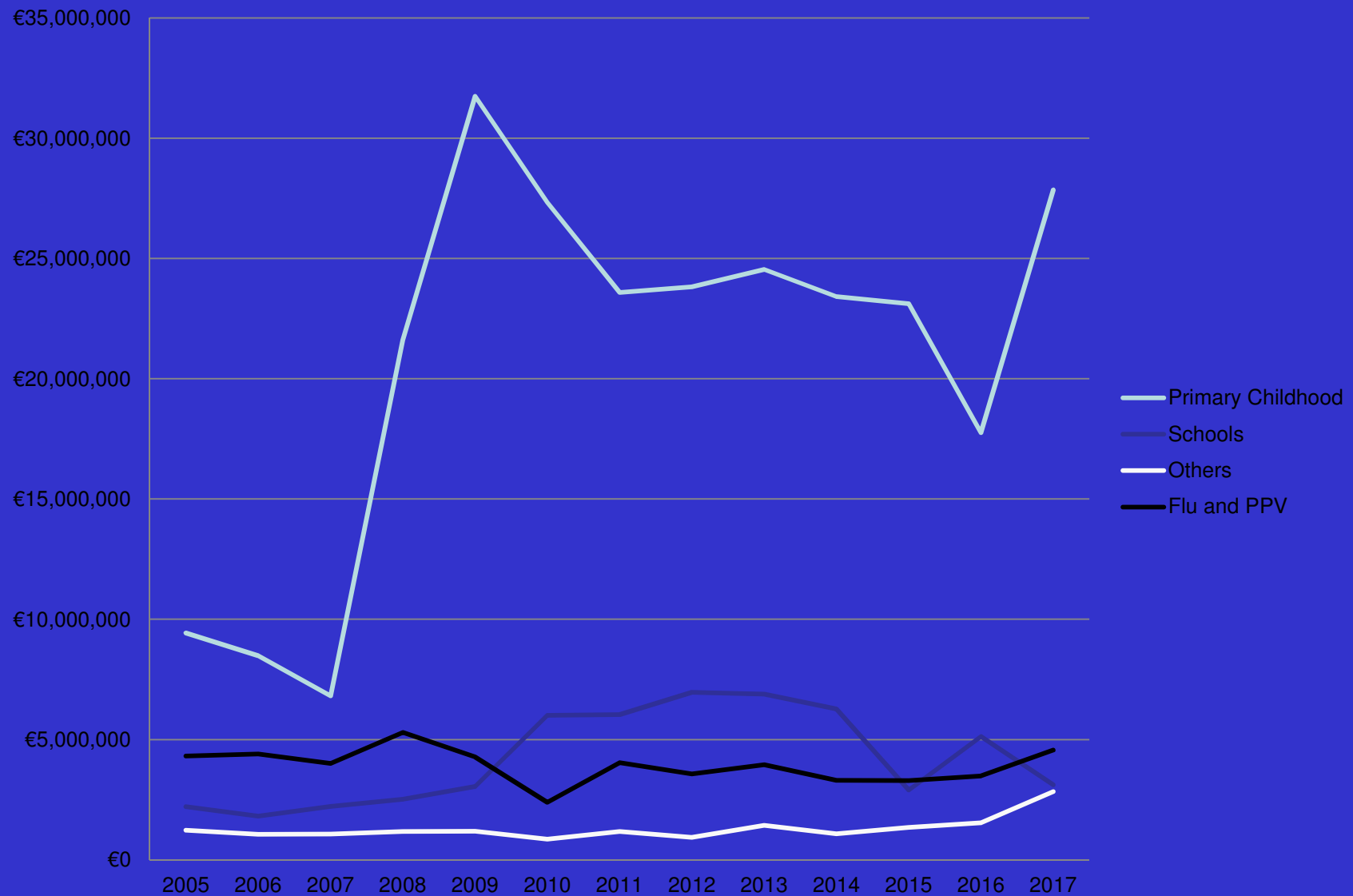


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Value of Vaccines Purchased



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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 direct to these sites.



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Vaccines supplied

| | |
|---------------------------------|--|
| Primary Childhood vaccines | 6 in 1, Men C, PCV, MMR, Hib/MenC, 4in1, Men B, Rotavirus |
| Adult vaccines | Td, Tdap Influenza, Pneumococcal polysaccharide vaccine |
| HSE / school programme vaccines | Tdap/IPV, MMR, Tdap, HPV, Men C (BCG), Tuberculin |
| Restricted vaccines | Hepatitis A, Hepatitis B, Hepatitis A +B Td/IPV, Tdap/IPV, MenACW ₁₃₅ Y, |

Current list of available vaccines

- from United drug
- in newsletter
- on immunisation website



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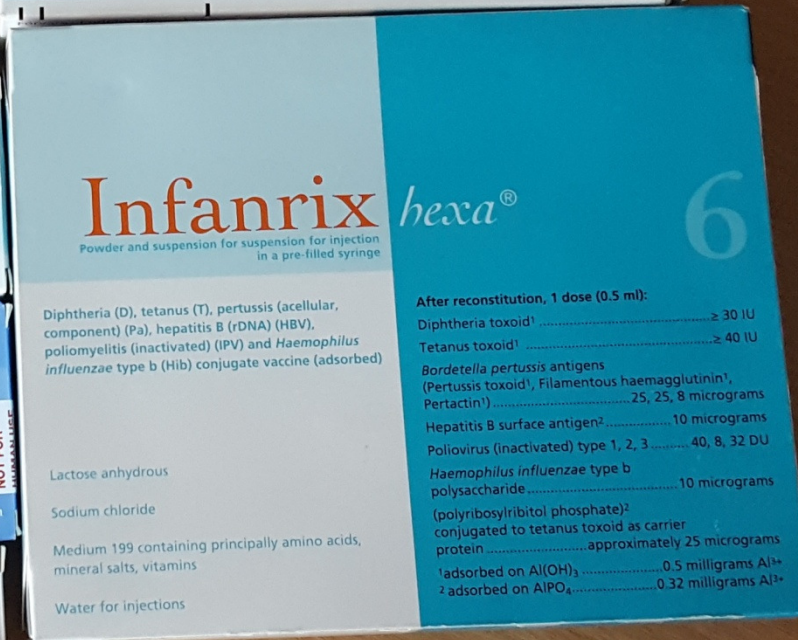
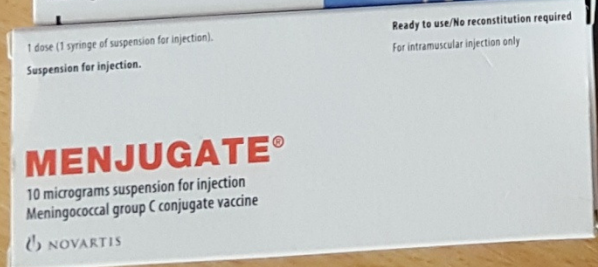
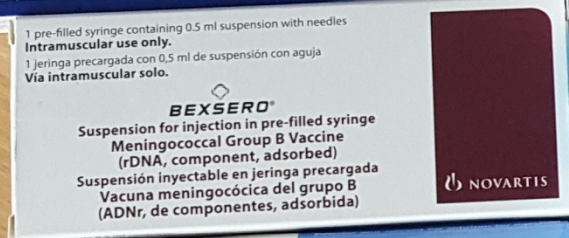
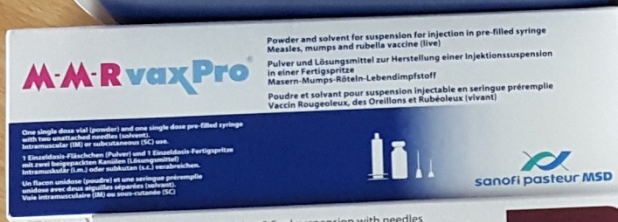
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Value of Vaccines per Child

- 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**



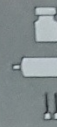
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Priorix®

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



10 vials with powder
10 pre-filled syringes with solvent
20 needles
10 x 1 dose (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 $10^{3.6}$ CCID₅₀³
Live attenuated mumps virus¹ (RIT 4385 strain, derived from Jeryl Lynn strain) not less than $10^{3.7}$ CCID₅₀³
Live attenuated rubella virus² (Wistar RA 27/3 strain) not less than $10^{3.5}$ CCID₅₀³

¹ produced in chick embryo cells
² produced in human diploid (MRC-5) cells
³ Cell Culture Infective Dose 50%

EXCIPIENTS

Vaccine:

Amino acids
Lactose (anhydrous)
Mannitol
Neomycin sulphate
Sorbitol
Phenol red

Sodium chloride
Potassium chloride
Magnesium sulphate
Calcium chloride
Potassium di-hydrogen phosphate
Di-sodium hydrogen phosphate

Solvent:

Water for injections.




GlaxoSmithKline

Priorix®



10 vials with powder
10 pre-filled syringes with solvent
20 needles
10 x 1 dose (0.5 ml)

10 x 1 dose (0.5 ml) 
10 pre-filled syringes + 10 needles
Suspension for injection
Intramuscular use

Shake well before use

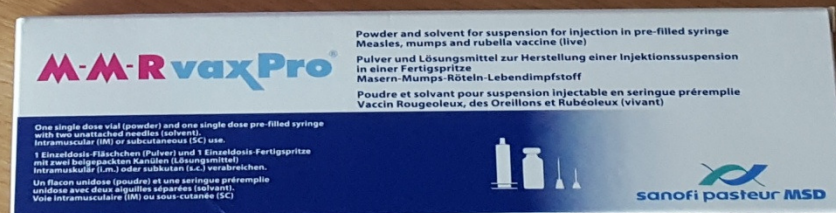
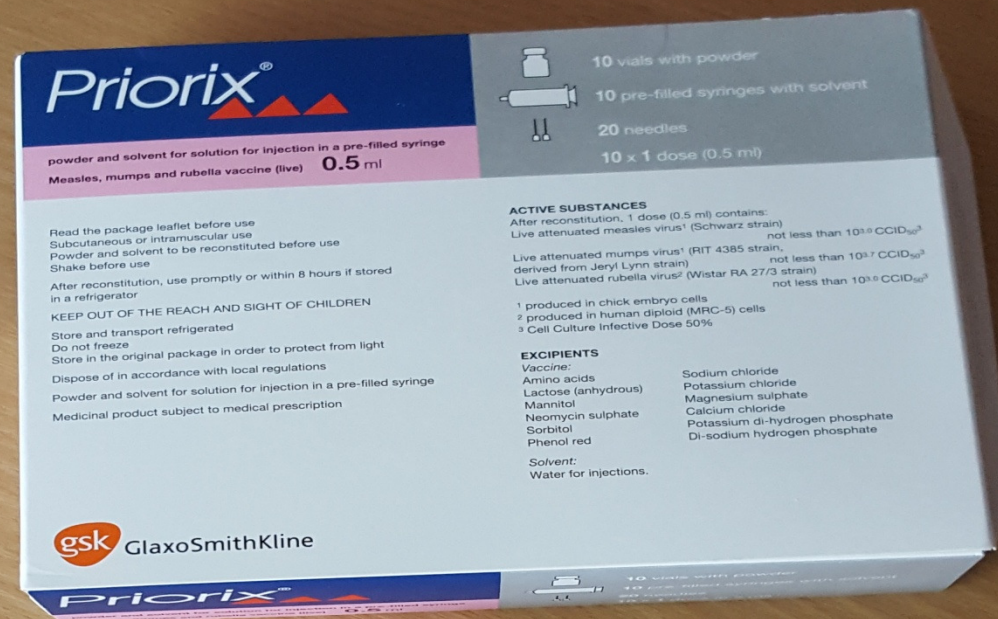
IPV-Boostrix®
suspension for injection in pre-filled syringe

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



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MMR Products



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School Immunisation Programme Second Level.



New presentation of PPV23 vaccine

PPV23 vaccine comes as a prefilled syringe with two needles, 23G x 25mm (blue) and 25G x 16mm (orange).

Attach the 23G x 25mm (blue) needle to the prefilled syringe to administer.

This vaccine does not need to be reconstituted.

Doses in old presentation were last distributed in September 2017 and will expire at the latest on 31st August 2018.



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Flu season 2018

- There will be deliveries every fortnight from September 2018 to January 2019 (15 scheduled deliveries to each site)
- Flu vaccine deliveries will commence September 17th and every site will have received vaccine by September 28th



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Season 2018/2019 Flu vaccine



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Influvac 2018 /2019



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Needle included with vaccines

- Bexsero 23G 25mm + 25G 16mm
- Boostrix 23G 25mm
- Gardasil 23G 25mm + 25G 16mm
- 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
- Pneumovax 23 23G 25mm + 25G 16mm



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Nimenrix will be available instead of Menveo. Two needles included, 23G and 25G – 25 mm.



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Cost of typical Deliveries

| 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> |

| 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> |

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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
- **Remove expired vaccines from fridge** 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**



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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



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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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Online

Online is now used by 95% of sites

Value of vaccine distributed decreased by 2%

Number of doses distributed decreased by 2%

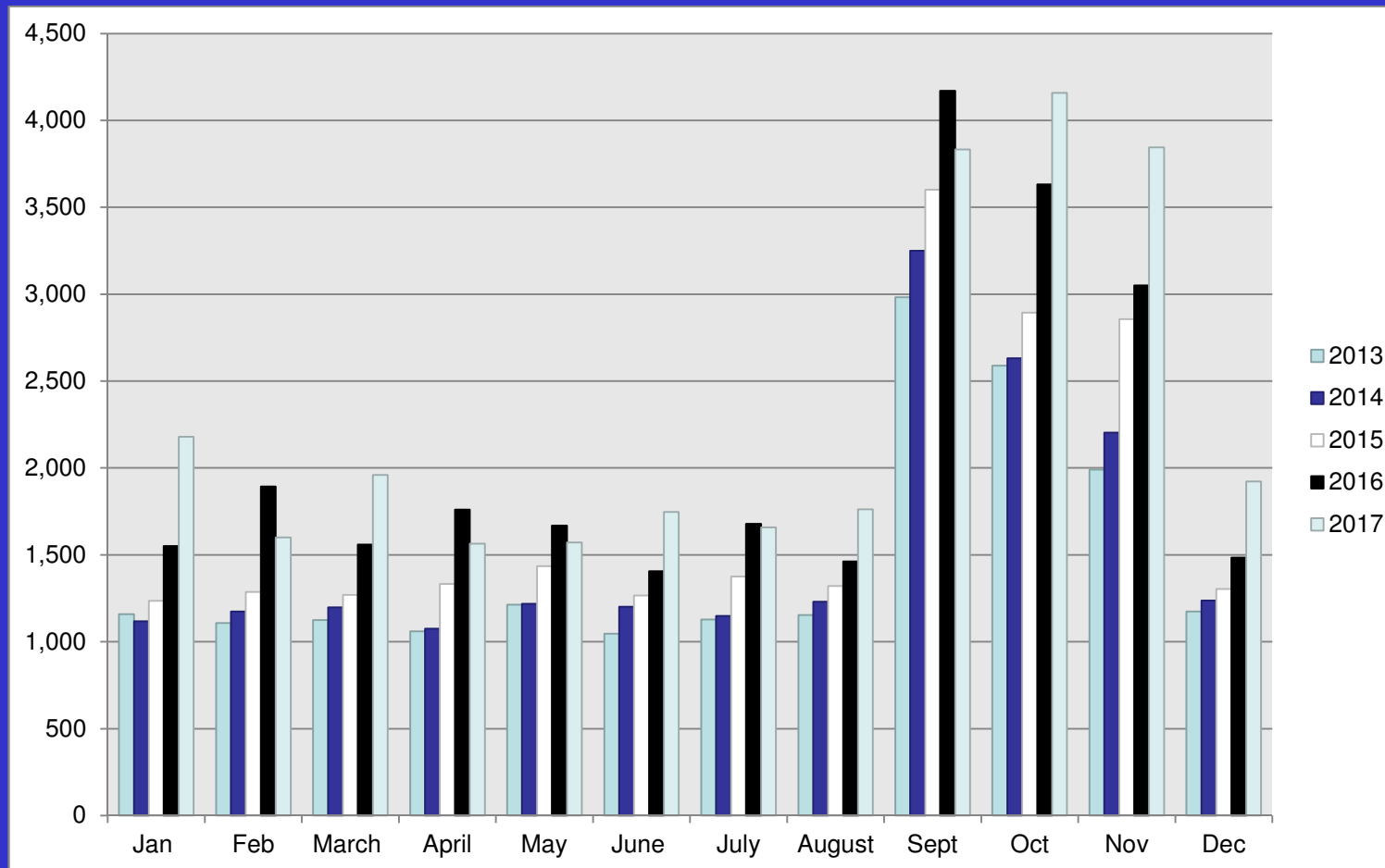
Number of doses returned for destruction decreased by 2%

Value of vaccines returned for destruction decreased by 19%



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Number of orders per month



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Storage of Vaccines & Monitoring of Vaccine Fridge temperature

- Vaccines must be stored in a Pharmaceutical 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



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Max/Min Temperature Readings

- 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.




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
- They do not replace recording Max/ Min readings twice daily.




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New Datalogger on the Market




feel safe



Agent (Ireland)
TCCS Limited
T: +353 1 8276266
W: www.tccs.ie

Fridge-tag® 2L



Temperature recording upgraded from 60 days to **112 days**

Audio-ALARM signal

available now

SWISS Quality

www.berlinger.com/fridge-tag2L

This device will record temperatures over 24 hours and record the Min and Max temperature.

30 days display on screen.

PDF file can be downloaded at any time.

Can Monitor Fridges, Freezers and a variety of Controlled Ambient areas

Key Features

- Temperature measurement intervals = Every Minute for table
- Logging interval of 5, 10 or 15 min for graph view
- Accuracy 0.5
- Displays daily Min / Max temperature
- Displays 30 days on screen
- PDF download with possibility to have 28, 56, 84 or 112 days
- PDF with Min/ Max table & Weekly graph view
- 2 individual programmable alarms
- Audible alarm
- Operating temperature -25°C to +55°C
- Every device is calibrated (NIST standard) / Certificate for 3 years
- Operating life time = 3 years
- External sensor optional (recommended for freezers)

Head Office: Berlinger & Co. AG, Mitteldorfstrasse 2, CH-9608 Ganterschwil, Switzerland (www.berlinger.ch)
Agents (Ireland): Translogic Cool Chain Solutions Ltd, Building 4, Manor Street Business Park, Dublin 7, Ireland (www.tccs.ie)

Note: Information quoted is for reference only and subject to change without notice



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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

Do not remove them from a working fridge unless instructed to do so by the Chief Pharmacist or Medical officer in NIO



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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)



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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.
- 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 must not put into a sharps bin.



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Details Required after Cold Chain Issue

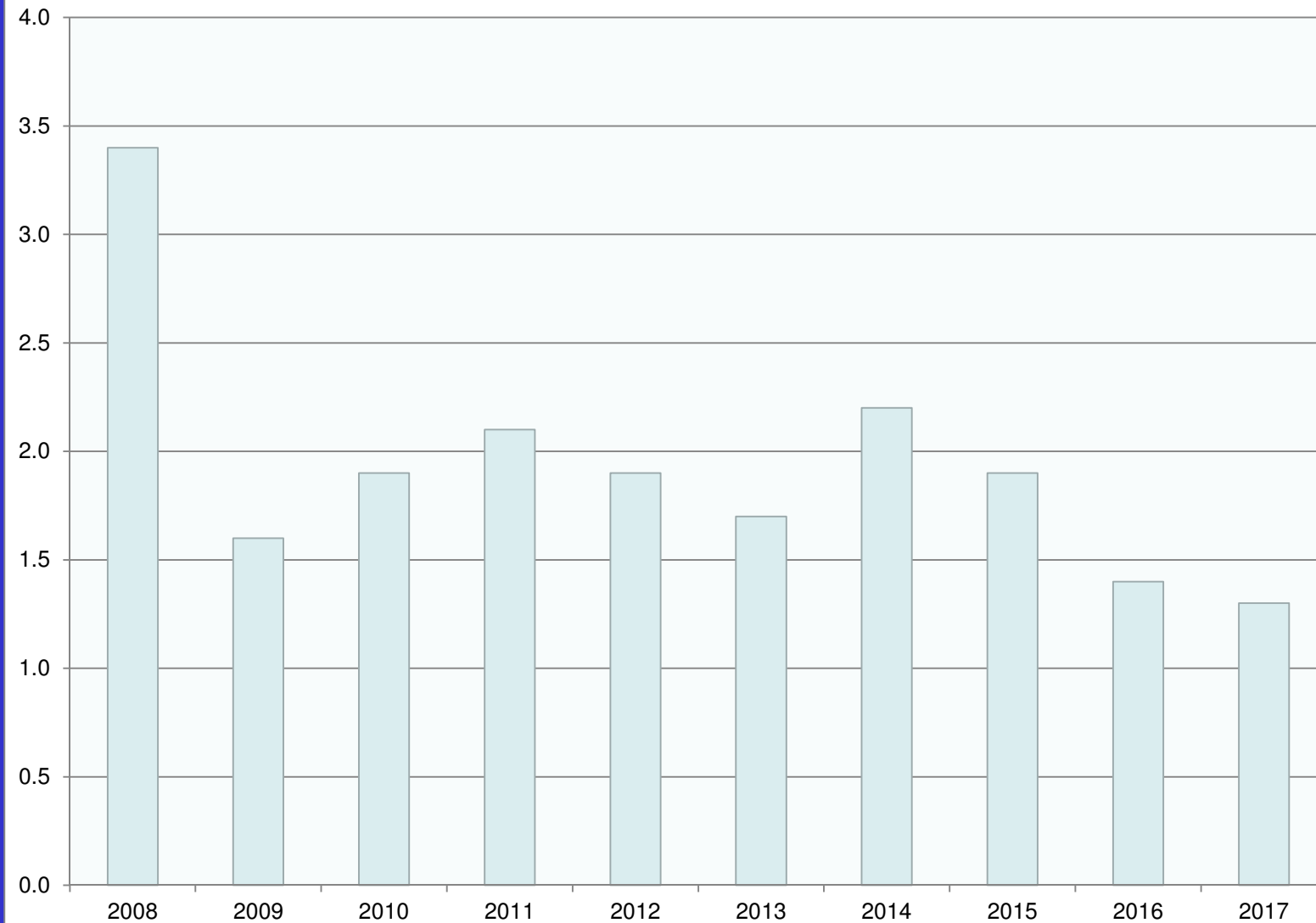
- Name of practice
- Account number
- Current fridge temperature
- Duration of temperature breach
- Maximum temperature reached
- Name, quantity and batch numbers of vaccines in the fridge.

Send to Cliona.Kiersey@hse.ie



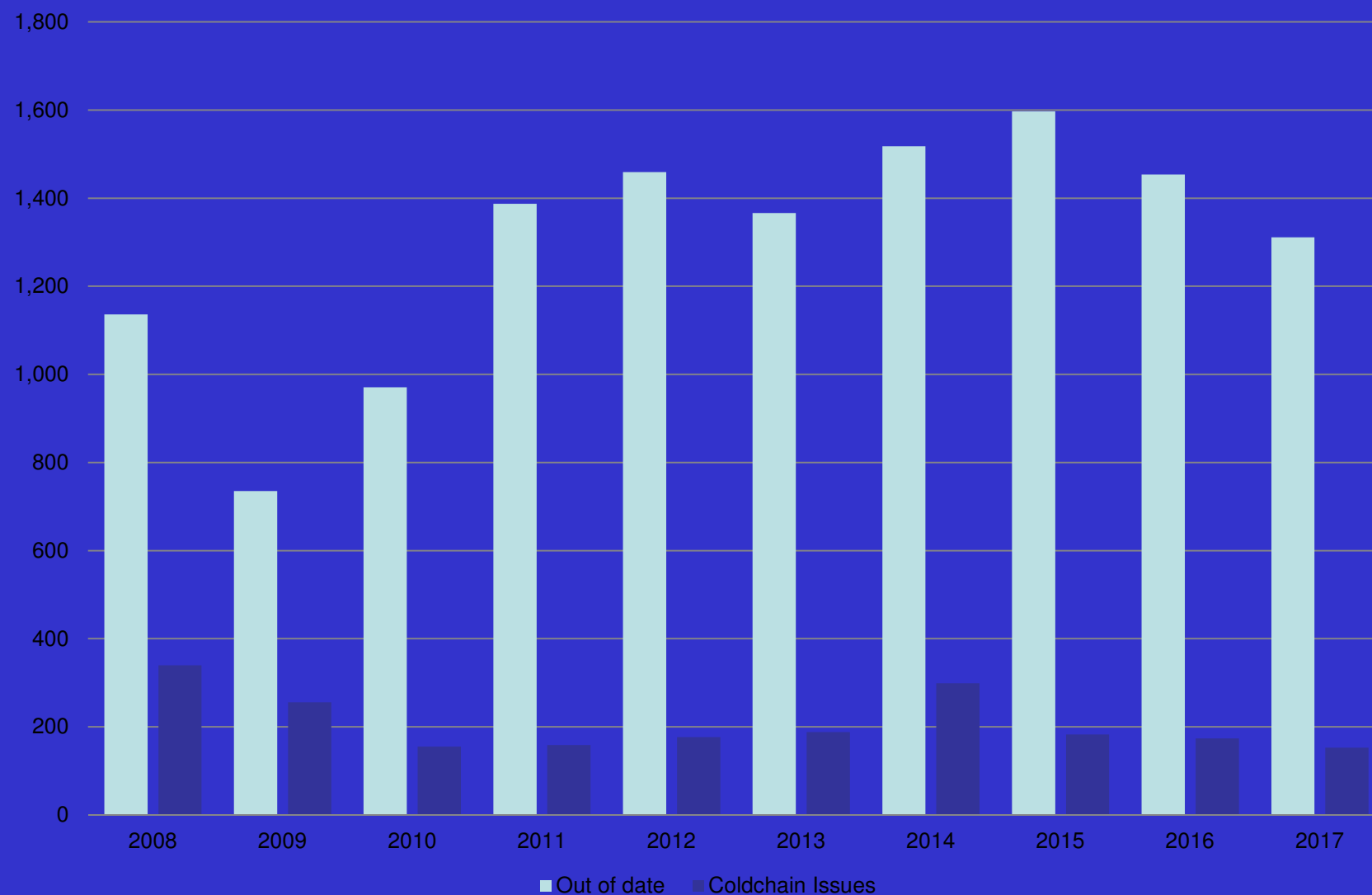
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% Returned vs Distributed (based on cost)



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Number of Sites using Returns Service

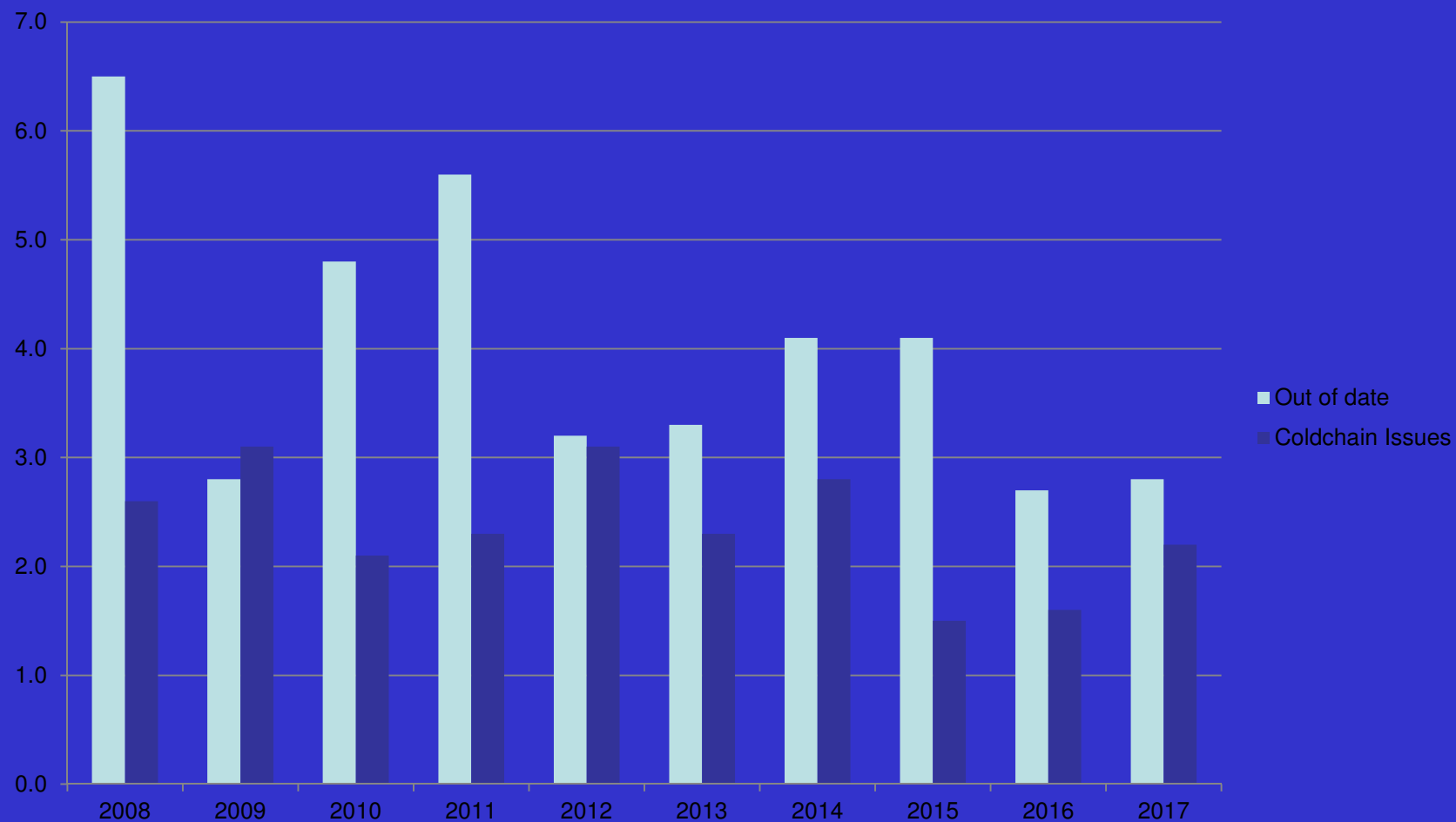


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Vaccines for Destruction (Value)



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Vaccines returned with expiry date greater than 6 months.

- 2012- 44,184 doses - 2TU Mantoux test (expiry 05/2002) was 10 years and two months expired when returned.
- 2013 - 16,753 doses - Pneumovax (expiry 03/2007) was 6 years and three months expired when returned.
- 2014 -10,737 doses - Pentavac (expiry 09 /2002) was 11 years and 6 months expired when returned. Removed from schedule in 2009.
- 2015 - 9,168 doses- MMR (expiry 03/2004) was 11 years and 6 months expired & Pentavac also returned.
- 2016- 4,830 doses –Hep A was 6years and 3 months expired
- 2017 –3,137 doses -Infanrix Hexa was 5 yrs 2 months expired
- 2018 - to date 1988 doses -Hiberix was 4 yrs 4 months expired.

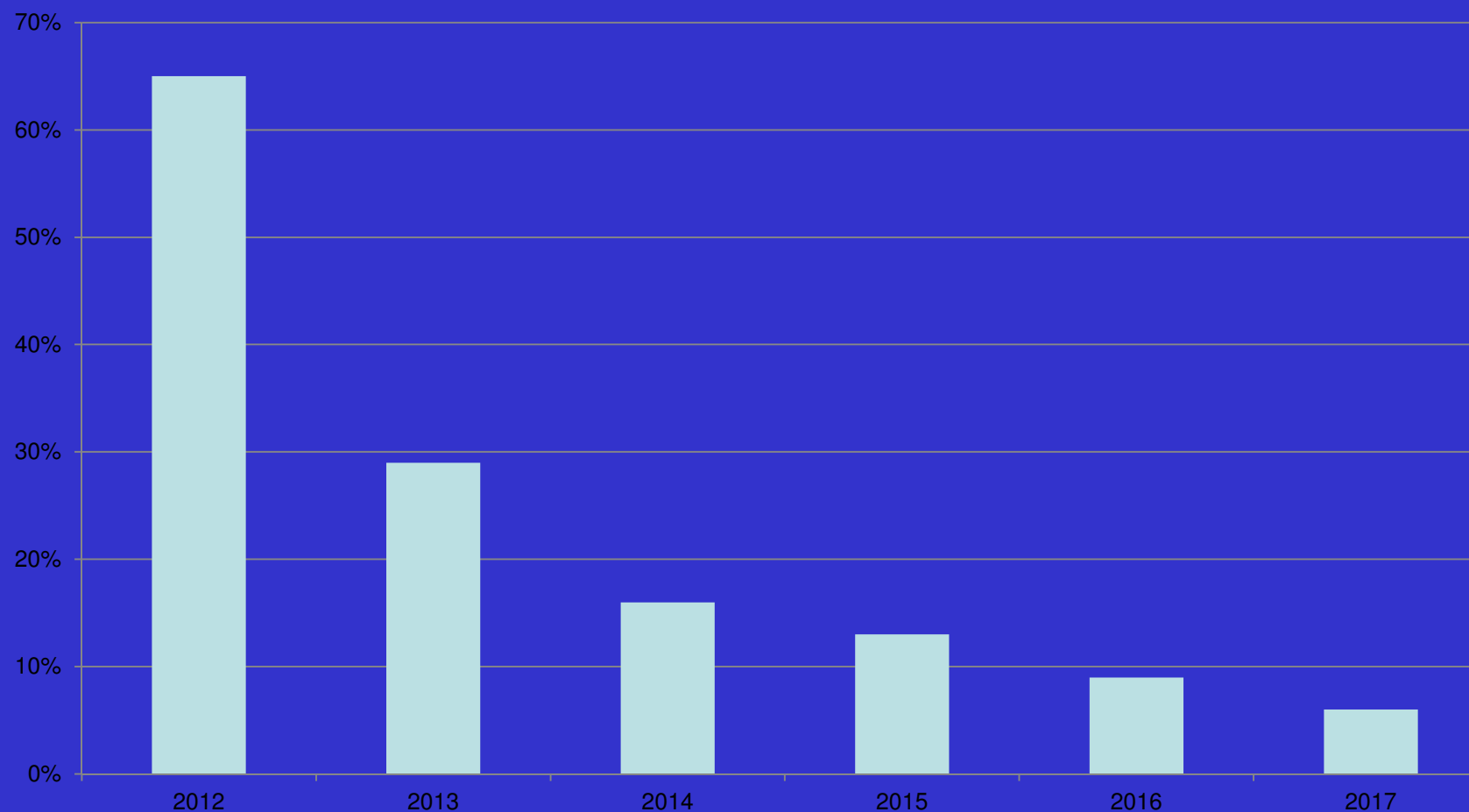


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% of Expired Vaccines Returned that expired more than 6 months



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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**



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

***Recommendations for a
planned power outage***



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“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.



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Conclusions

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



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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/provider-store>
- Department of Health UK. November. Immunisation against infectious disease.
http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254
- Irish Pharmaceutical Healthcare Association Medical Compendium.
<http://www.medicines.ie>.
- Irish Medicines Board. <http://www.imb.ie>.
- National Immunisation Office Ireland. Health Service Executive.
<http://www.immunisation.ie>.
- Public Health Agency Canada. National Vaccine Storage and Handling Guidelines for immunisation providers. <http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php>.
- 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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