

## **NHMC** Homecare Update

Susan Gibert, MRPharmS, Chair NHMC



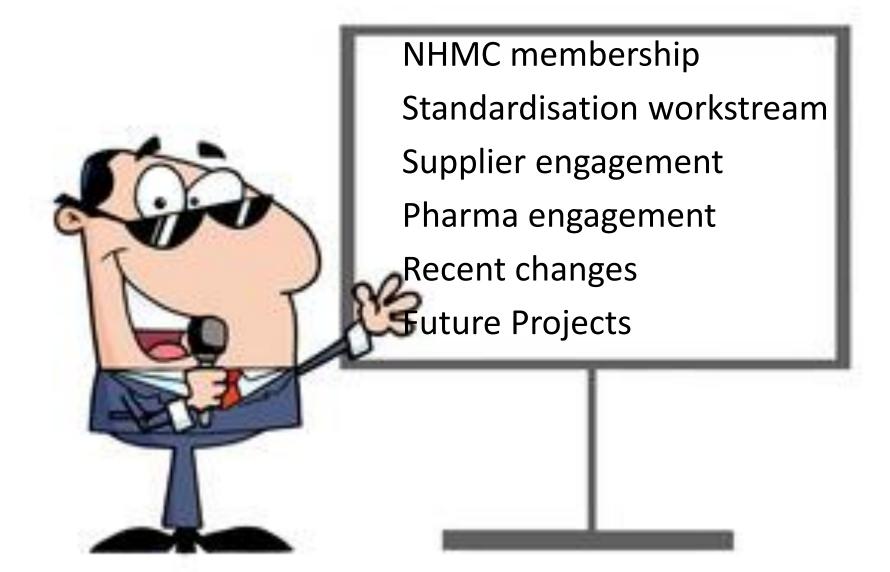
## NHMC Homecare Update

NHMC

September 2017

## Overview

#### **NHMC**



## National Homecare Medicines Committee Membership Review



England, Scotland, Wales, Northern Ireland

#### **NHS** members

**NHS E CMU** 

**NHS Regional Homecare Specialists** 

**PMSG** 

NHSE Spec Com Pharmacist

NHS CC CCG representative

**Chief Pharmacist** 

Nurse representative

MoD

NHS QA

#### **Non NHS members**

**NCHA** 

**ABPI** 

**RPS** 



## NHMC - Subgroup of PMSG



#### **National Pharmaceutical Supply Group (NPSG)**

The strategic organisation of medicines procurement is ratified by the National Pharmaceutical Supplies Group (NPSG).
 Membership of this group consists primarily of secondary care chief pharmacists representing their geographical area and representatives from the devolved administrations (Northern Ireland, Scotland and Wales).

#### Pharmaceutical Market Support Group (PMSG)

• The Pharmaceutical Market Support Group (PMSG) enacts the strategic requirements set by NPSG. Membership of PMSG consists of the Regional Pharmacy Procurement Specialists and leads from the Commercial Medicines Unit for branded and generic medicines along with the principal pharmacist lead. Representatives from the devolved administrations, Department of Health, NHS Pharmaceutical QA Committee and Medicines Information subgroups of SPS also attend. PMSG is chaired by a secondary care chief pharmacist who is a member of NPSG. PMSG has three subgroups – the Generic Medicines subgroup, the Branded and Biosimilar subgroup and the National Homecare Medicines Committee (NHMC).

#### **National Homecare Medicines Committee (NHMC)**

• The National Homecare Medicines Committee (NHMC) is a subgroup of PMSG and acts as the national focus for developing and improving administration and governance processes for medicine homecare services. Membership consists of Regional Homecare Specialists and Procurement leads, CMU Homecare team, NHS commissioners, National QA representative, Royal Pharmaceutical Society representative and clinical colleagues. The committee also has representatives from Association of British Pharmaceutical Industry (ABPI) and the National Clinical Homecare Association (NCHA). NHMC has three subgroups: Digital Strategy group, Supplier Engagement group and the Standardisation group. The Digital Strategy group is involved in various NHS IT development projects around homecare medicines services, the Supplier Engagement group meets regularly with all homecare providers to review performance and support innovation in the homecare market. The Standardisation group has a work plan approved by NHMC which aims to provide documents to support the NHS in the delivery of homecare services.

# Standardisation Workstream NHMC (Sept 2017)

- 24 projects
- 16 active
- 5 on hold
- 3 implementation phase

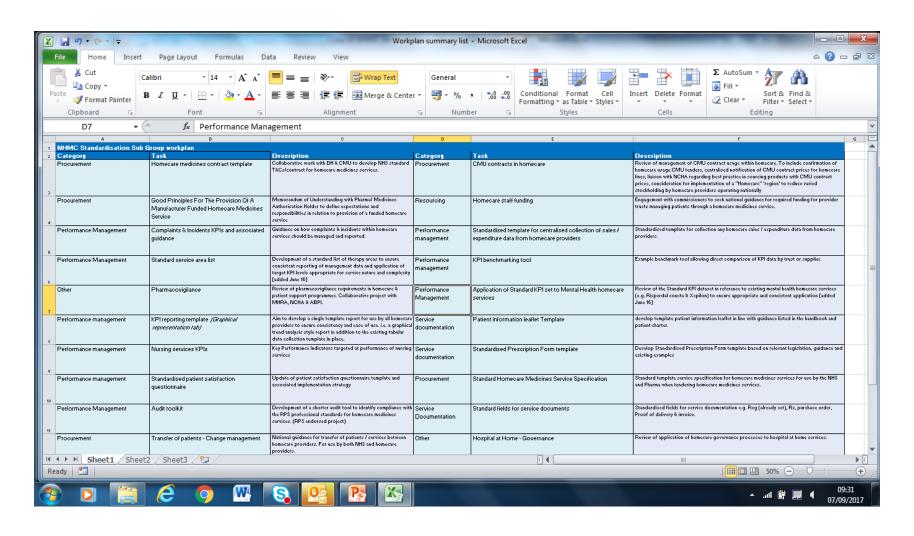




Focus on 6 4 affect NCHA members 2 affect NHS only

## NHMC Standardisation Workplan NHMC

(Sept 2017)



# Management of Complaints NHMC and Incidents

Appendix 19 RPS Handbook for Homecare Services

- NHMC/PharMan event 28<sup>th</sup> September
  - NHS train the trainer day
  - Strategy Stream for Senior Pharmacists

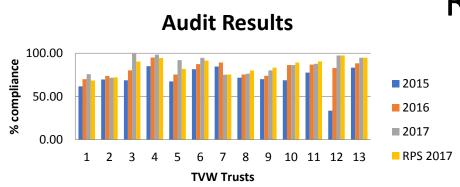
# Standardisation Workstream











#### RPS audit toolkit

Based on RPS Standards
Simplifies 195 dimensions to
50 statements
Regional and National
standard audit

Homecare Team Funding Model
Commissioner funded teams
Based on patient volumes
Presented to NHSE MO CRG
Discussed by NHSCC

Max Patient numbers	Staff numbers	Cost per patient	Total annual cost
200	1.05	£213	£42,652
350	1.42	£161	£56,264
500	1.88	£145	£72,372
650	2.2	£135	£87,702
1000	3.2	£114	£114,433
1200	3.7	£111	£133,788
1500	4.23	£109	£162,822
2000	5	£89	£177,455
2500	6.2	£85	£211,927
3000	7.4	£84	£252,390
3500	8.6	£83	£292,186
4000	9.9	£83	£332,664
5000	10.13	£83	£415,119
6000	15.1	£83	£495,745
7000	18	£82	£574,940
8000	20.6	£81	£649,291
10000	24	£79	£790,750

## Engagement

#### **NHMC**

#### Supplier

- Encourage NCHA membership
- Expand company engagement
  - New homecare companies
  - Nursing partners

#### Pharma

- NHMC/NHS/CMU consultation on new schemes
- 3 to 6 months prior to scheme launch



## Recent changes





Market stability
Company acquisitions and mergers
Specialisation

NHC/CMU encourage open dialogue Worst case scenarios Regular contact and updates NHS/CMU support HCPs

Impact on NHS
Underestimated?
Misunderstood?
Not heard?



## Future Projects

#### **NHMC**

- Pharmacovigilance
  - newly started
- KPI review
  - implementation
- Recovery at Home
  - Scope
  - Chief Pharmacist involvement
- Regional Leads
  - Impact/support feedback





# National Clinical Homecare Association

**Alison Davis** 

**Chair National Clinical Homecare Association** 



#### **National Clinical Homecare Association**

- Established in 2006
- Trusted source of homecare information
- Represent and promote the patient-led interests of member organisations whose primary activity is to provide medical supplies, support and clinical services to patients in the community
- Raise the awareness of the benefits of clinical homecare
- Ensure that high standards in the provision of clinical homecare are maintained
- 13 full members
- Elected Member Chair since 2015



### Who are the suppliers? **Clinical Homecare Providers (NCHA Members)**





























#### Stakeholder Engagement

- National Homecare Medicines Committee (NHMC)
- Association of the British Pharmaceutical Industry (ABPI)
- Medicines & Healthcare Products Regulatory Agency (MHRA)
- Royal Pharmaceutical Society (RPS) / Royal College of Nursing (RCN)
- Commercial Medicines Unit (CMU)
- General Pharmaceutical Council (GPhC)
- NHS England, Scotland and Wales / NHSE Specialised Commissioning



#### **NCHA Work Plan**

Strategy to work with other key stakeholders on 3 specific work streams;

**Market robustness & Finance** 

Operational measurement, reporting and service contract management

**Clinical Governance** 



#### What have we achieved?

Homecare now has national governance standards against which all Homecare Services can be measured.

- RPS Homecare Standard
- RPS Homecare Handbook
- Further Guidance on managing C&I in Homecare

Homecare now has standardised and robust contracting processes which allow likefor-like comparison of providers offer to patients

- Collaborative development of standard specification
- Operational KPI dataset

Homecare now has standardised operational processes which supports transition between homecare providers and ensures good governance standards are implemented in practice

- Standard Patient Registration Form
- Patient Change Request Form within NHS and Pharma funded Clinical Homecare Services.



#### What have we achieved?

NHS/DH CMU/Pharma have a greater understanding of the complexity of homecare delivery at scale

NCHA is continuing to reinforce the robustness of the homecare market building on the Hackett Report.

 Review of the cash flow position of members and subsequent submission of the NCHA position paper on the importance of cash flow in homecare services

We still need to

Improve strategic planning for homecare services to support investment in infrastructure

Collect and publish comparative outcomes data – patient love clinical homecare services, we need evidence to show that this results in improved outcomes as well.



#### **Current Focus**

NHS Digital project which builds on the outputs of the NCHA Homecare Systems Workshop

Implementation of the Governance KPIs

Benchmarking patient experience within homecare and between supply routes

Finalise the national standard pharmacovigilance training package for homecare staff & reduce overzealous ADE reporting

Collection of member data to establish market data to build business cases for change

- Number of active patients
- On time delivery performance
- Aged debt

Maintain our excellent working relationship with NHS and Pharma



#### The Future

Maintain and grow the influence of the NCHA in support of patient choice

Build on relationships with DH, NHS, Providers, Pharma and wider Healthcare Industry

Continue to deliver on our workstream agenda

**Continue to deliver on the NHS Homecare Agenda** 

- Delivering cost savings and efficiencies
- Care closer to home

Continue to be the authoritative source of trusted information on clinical homecare

Support the development of innovative models for care







## **Overview of Appendix 19**

Jane Kelly, Principal Pharmacist Commercial Medicines Unit, NHS England





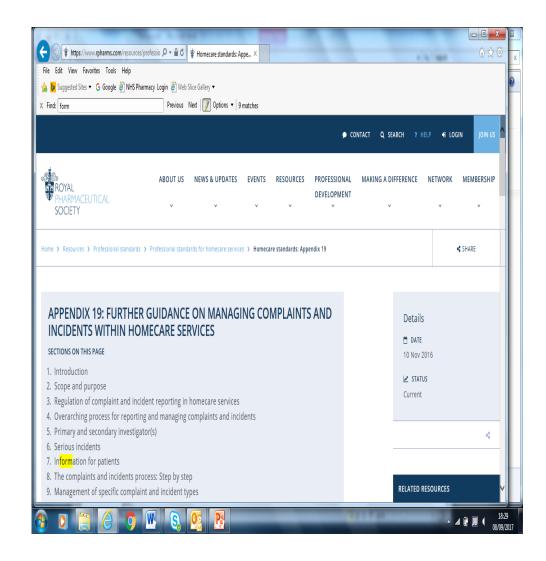
# Overview of Appendix 19

Jane Kelly
Principal Pharmacist
Commercial Medicines Unit
NHS England
September 2017

## Summary



- Context
- Background
- Overview of guidance and recommendations
- Implementation by NHS
- Implementation by Homecare Providers



#### **NHMC**

### Context

#### Why did we do this?

- Incidents have occurred in the homecare setting and learning was not captured
- Incidents were not shared between organisations
- Learning was not shared between organisations

#### Who's idea?

Former Chair NHMC Allan Karr

#### What difference will the guidance make to patients?

- Learning implemented
- Service improvements where necessary

## Historic Multiple Reporting Routes NHMC

Gaps and duplication

Separate reporting methods and records

Gaps in recording, coding, investigation

- Preventive actions missed
- Incomplete external reports

Multiple versions of same incident

- Lessons not shared
- Lessons not learned

One overarching process will reduce gaps and duplication and will improve learning

## Background

#### **NHMC**

- September 2014 development of Homecare Key Performance Indicators
- Service KPIs development highlighted the need for governance KPIs
- Management of Complaints and Incidents project group
  - 6 workstreams / c&i categories
  - NHS, CMU, NCHA collaboration
  - Guidance, coding and KPIs
- Service KPIs launched March 2015

## Background timeline

**NHMC** 

- First consultation December 2015 Jan 2016
- Responses from NHS, CMU, ABPI NCHA Guild of Healthcare Pharmacists
- Review of responses and changes (Feb-May 16)
- Appendices- Annexes KPIs finalised September 2016
- Final edit and submission to RPS October 2016
- Published November 2016

## Publication by RPS



- Royal Pharmaceutical Society (RPS) support this guidance
- Appendix to RPS Handbook for Homecare Services
- RPS Homecare Standards Advisory Group Review all documentation and guidance
- GPhC audit to RPS standards

https://www.rpharms.com/resources/professional--standards/professional-standards-for-homecareservices/appendix-19

## Overview Appendix 19

NHS some

sections

require

action

#### **NHMC**

Homecare Organisation:

any organisation providing homecare services (homecare companies and NHS)

Relevant to all Homecare organisations

Comprehensive guidance on management of both complaints and incidents

NHS needs awareness of whole document

NHS some sections essential reading







## Aims of the guidance



All clinically significant complaints and incidents should be reported to the relevant clinical referring centre

One method of reporting all types of complaints and incidents

**Triage and coding** of all complaints and incidents

records (where a patient has been involved) as well as in the local quality management system

Regular reviews of serious complaints and incidents reports and trends by the relevant Clinical Governance Group(s)

A national standard set of data fields

A system which enables data from non-personal identifiable fields to be shared as part of the quality audit processes

A training programme for homecare staff on how to correctly follow the complaints and incidents reporting and learning procedures

## Complaint/Incident reported

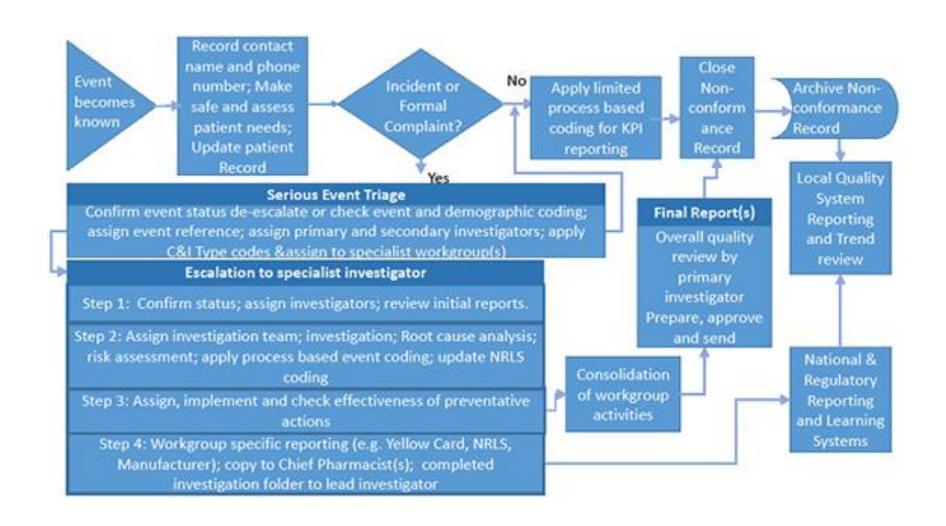


- Step by step process
- Detail in guidance
- Receiver must ensure patient safety
- Aim to avoid formal complaint process
- Use process to:
  - ensure information is collected only once at the beginning of the process
  - avoid duplication of effort
  - avoid repeated contact with patient



### NHMC

## Over-arching process



## Investigators



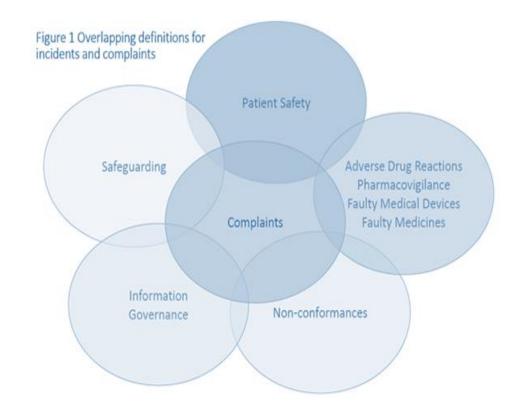


- Organisation receiving report is the default primary investigator
- If appropriate can be passed formally to another organisation
- Responsible for:
  - Investigation, identify other organisations
  - Written response and implementation of any agreed actions



# Often overlap – 'a single homecare service complaint or incident may need to be managed as one or more types'

Patient safety (Duty of Candour)
Adverse drug reactions
Faulty medicines/devices
Safeguarding
Information governance
Complaints
Non conformances



#### **Useful Information**



Timelines – comprehensive table

Regulation
Regulatory framework
Standards and codes
of practice
Registration, audit and
monitoring

Coding lists abbreviated and in full

Template letters for patients

Template report forms for NHS and patients

Links to suggested reading

## When to report?

#### **NHMC**

# Patient Safety

Immediate corrective and preventative actions take priority over recording

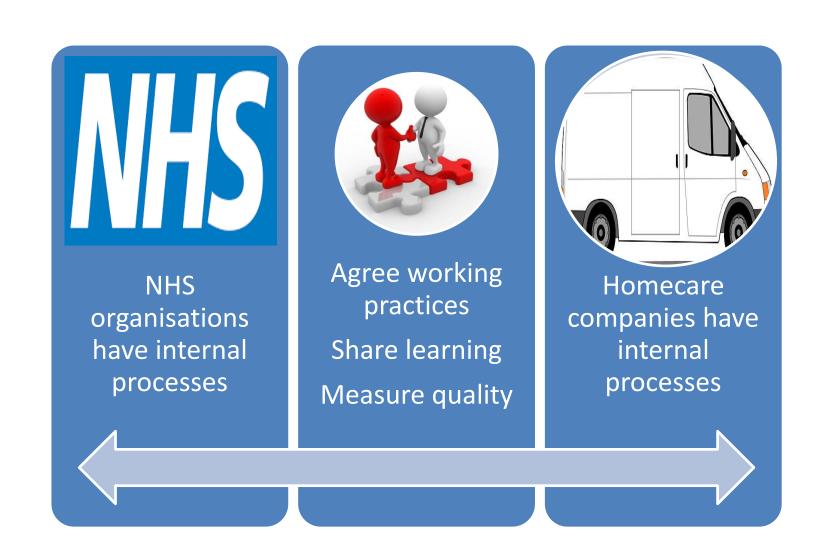
Patient Experience

All complaints and incidents should be reported on trust system

Consider necessity of adding to **risk** register

Report to **NRLS** – e.g.. all patient safety incidents

## Cross organisational Boundaries



### Implementation Action Required!

NHMC

Chief Pharmacist has strategic oversight



For Action

Level 2 pharmacy homecare staff
Homecare team members

Level 3 1(min) person in each organisation

Homecare manager/team leader





## Strategic Workstream

**Chief Pharmacist** 

- strategic oversight
- Requires understanding of homecare
- Requires knowledge of Appendix 19

Specialist Pharmacists –

- (IG, safeguarding, MSO, MDO leads)
- Requires in depth knowledge of specialist area (e.g. Safeguarding, IG, Medicines/Device Safety)





#### **Training Workstream**

# **Homecare Managers**

- Complete the workbook
- Complete the suggested additional training as listed in workbook

# Level 3

- Once trained need to implement guidance
- Once trained need to train others

# Implementation by Homecare Providers



- Guidance written collaboratively (NHMC, NCHA, homecare providers – prior knowledge)
- Implementation started before publication
- Expectation:
  - KPIs reporting expected January 2018
  - KPIs verified by July 2018
- If timelines slip NHMC informed







- Management of homecare complaints and incidents MUST be embedded in your organisations
- This document supports cross organisational boundary working
- Invest in training all staff to support implementation

Improved learning from complaints and incidents will lead to improved services and better patient experience



# Any questions?







#### **Appendix 19 - The Patient Perspective**

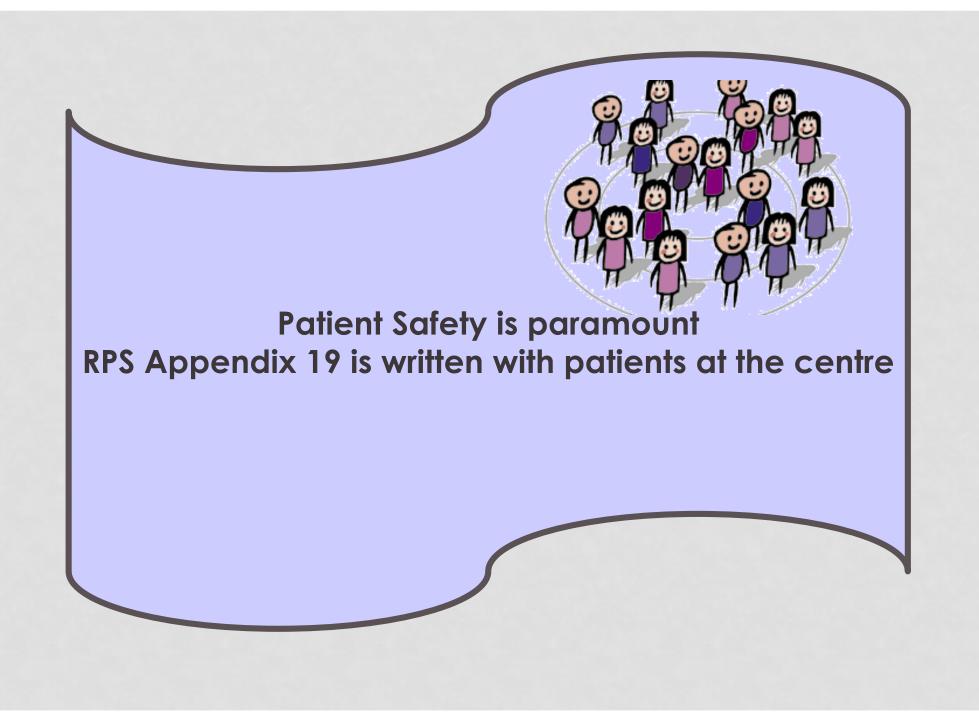
Jennifer Bestford - Regional Homecare Specialist Yorkshire & Humber Pharmaceutical Purchasing Consortium

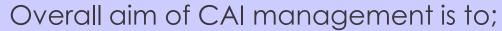
Richard Marshall – Pharmacy Homecare Services Manager Royal Berkshire NHS Foundation Trust



# RPS APPENDIX 19: THE PATIENT PERSPECTIVE

JENNIFER BESTFORD - REGIONAL HOMECARE SPECIALIST
YORKSHIRE & HUMBER PHARMACEUTICAL PURCHASING CONSORTIUM
RICHARD MARSHALL - PHARMACY HOMECARE SERVICES MANAGER
ROYAL BERKSHIRE NHS FOUNDATION TRUST

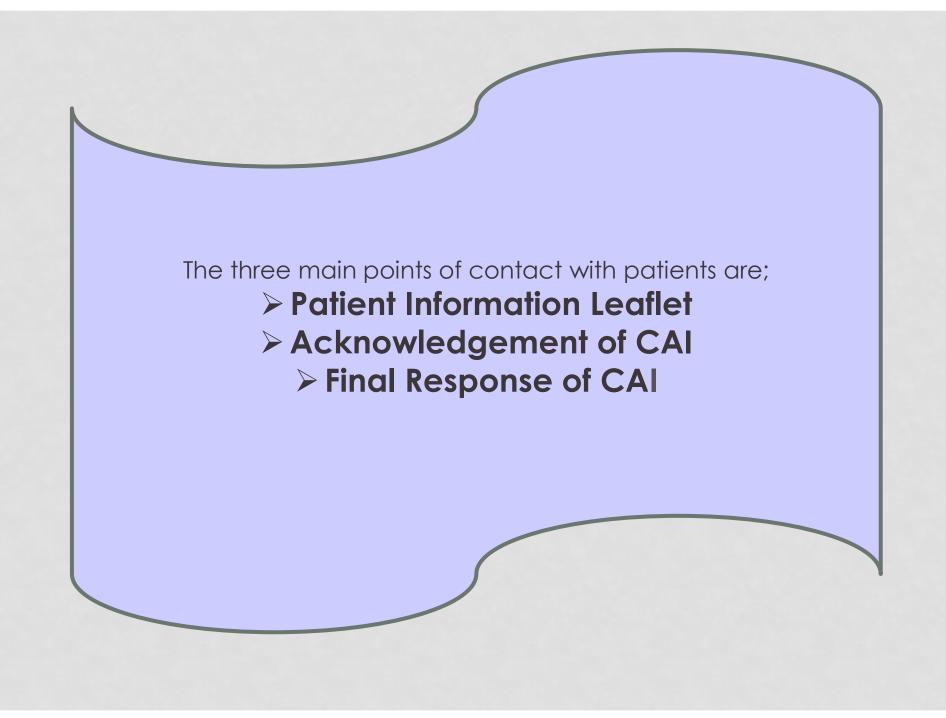




- > Improve patient safety
- > Improve patient experience
- > Improve clinical outcomes

#### RPS Appendix 19:

supports the guidance in the RPS Homecare Handbook standardises the Complaints and Incidents (CAIs) process encourages learning from CAIs to improve safety



#### PATIENT INFORMATION LEAFLET

# Patients should be given information describing the complaint and incident procedure

The clinical referring centre should provide this information

The homecare provider can supply additional company specific information

#### Information Provided Should Include;

How to report a complaint/incident, including;

- Which organisation to contact (Inc. alternative)
- Contact Details
- Examples of incidents that should be reported

How a complaint/incident will be handled, including;

- How confidentiality will be maintained
- Reassurance that treatment will not be affected by reporting a CAI
- When a response should be expected
- Advice on additional steps if they are unsatisfied with the formal response

Details of what constitutes a Duty of Candour patient safety incident

Patient support services available





Patient information directs CAI reporting via homecare providers.

Patients should also be able to report CAIs via their clinical referring centre.

RPS Appendix 19 includes templates for reporting CAIs;

#### Template Patient Complaint & Incident Form (Homecare Organisation)

Microsoft Word Document

#### Template Complaint & Incident Form (Patient Self-Reporting)

https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Professional%20standards%20for%20Homecare%20services/Appendicies/20b---template-c-i-report-forming and t-self-reporting.docx

Microsoft Word Document

#### PATIENT COMMUNICATIONS

Use patient centred terminology

Investigate all incident categories but reference their original 'complaint' in communication

#### PATIENT COMPLAINT

Where possible:

Respond to complaint / incident without the need of a formal written response

If significant harm:

Duty of Candour reporting applies

All patient safety incidents – above moderate harm:

Will be notifiable

Duty of Candour will apply

#### **ACKNOWLEDGMENT OF CAI**

When a written response is required acknowledgement of the complaint should be sent to:

- ➤ Complainant
- ➤ Clinical referring centre (if different) within 3 working days of the CAI report

If the investigation is completed within 3 days send the final response (no acknowledgement is needed)

#### CAI Acknowledgement Communications Should Include;

CAI reference number

Homecare provider patient number

NHS/clinical referring centre number

Patient and/or carer name and address

Clinical referring centre

Homecare service or therapy

Date of acknowledgement

Date of CAI and date CAI was reported

Summary of original CAI

Duty of Candour declaration

Apology statement

Confirmation that an investigation will take place including timescales for response. Including primary and secondary investigators where more than one organisations are involved

Signature and job title

Contact details if complainant wishes to clarify/discuss

Notification a copy of the response will go to clinical referring centre



#### CAI FINAL RESPONSE

Send to the complainant within 30 working days unless this has been agreed and extended.

The response should be a collaborative response between homecare provider and clinical referring centre.

Where there is more than one investigator the Secondary (additional) investigators should see the response at least 5 business days before the response is due for issue.

Secondary investigators should not delay the final response

#### Final Written Responses Should Include;

Homecare service patient number and homecare incident number

NHS or clinical referring centre number

Patient and/or carers name and address

Clinical referring centre

Homecare service or therapy

Date of written response

Date of CAI and date it was reported

Summary of original CAI

Apology

Details of investigation/chronology of reported CAI

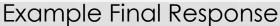
Contributing factors and root causes of the CAI

Actions that have been taken to minimise this re occurring

Final apology, signature and job title

Contact details if complainant would like to clarify/discuss any information

Confirmation that a copy of the response will be sent to clinical referring centre





# Right to Appeal

#### Complainants can appeal if;

- > Facts are incorrect/misrepresented
  - > Investigation is not thorough
- > Element of complaint not addressed
- > Corrective actions or Preventative actions not appropriate

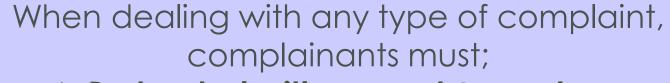
If complainants are still not satisfied direct to: Parliamentary & Health Service Ombudsman

#### **DUTY OF CANDOUR**

Patient Safety Incidents above moderate harm:

- >Tell the relevant person, in person, as soon as reasonably practicable
- >provide support
- >Advise the relevant person if further enquiries are appropriate
- ➤Offer an apology
- Follow up the apology by giving the same information in writing
- >Provide an update on the enquiries

Although a CAI is reported the complainant may have no dissatisfaction therefore a written repose may not be needed. On the flip side a complainant may report and request a written response for an issue not classified as a CAI (e.g. multiple delivery's outside time window, rude and inappropriate behaviour, long call wait time)



- > Be treated with respect & courtesy
- > Assisted to understanding the procedure and advise where additional information can be found
  - > Receive timely and appropriate responses

# Examples

#### **GOVERNANCE**

- ➤ Broadly split into 4 categories
  - > Information
  - > Clinical
  - ➤ Operational
  - > Financial

>A complaint arises from a failure in one of these areas

#### INFORMATION GOVERNANCE

- > Delivery to wrong address
- > Acknowledgement
- ➤Transparency
- ➤ Apology
- >Re-training

#### CLINICAL GOVERNANCE

- >Trusts still retain clinical responsibility for the patient
- Example patient attempts to decline delivery as stopped therapy, but homecare provider insists as prescription is still valid
- ➤ Example missed doses

#### OPERATIONAL GOVERNANCE

- >Most patient complaints fall in this category
- ➤ Failed delivery
- > Lack of communication
- >Process breakdown

#### FINANCIAL GOVERNANCE

- >Doesn't affect patient directly
- >Invoice accuracy
  - > Price
  - ➤ Contract
  - > Patient
- >Timely dispute resolution
- Commissioner 12 week rule

#### PATIENT EXPECTATIONS

To receive a service which is equal or greater than they would receive in a hospital environment

➤ Continuity

**≻**Reliability

#### **PERSPECTIVE**

>The majority of homecare patients experience a good service

>When things do go wrong, it can have a profound impact on that individual

#### MANAGEMENT OF THE SERVICE

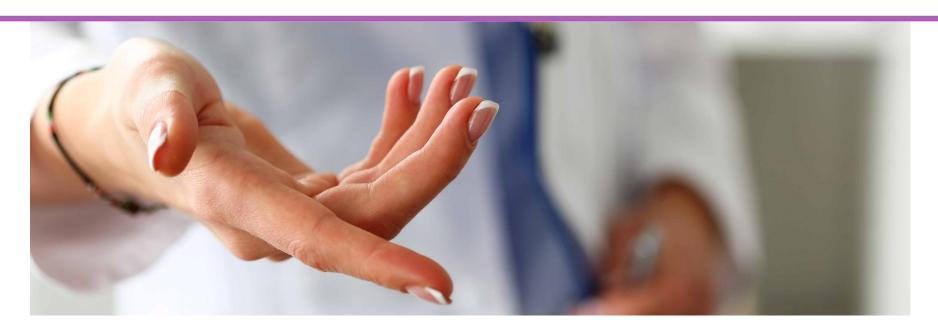
- > Communication
- ➤ Relationships
- ➤ Escalations
  - ➤ Regional/National Leads
  - > Senior management
- ➤ Suggestions
- >KPI data
  - > Facts behind the data
- > Service review meetings

# Any Questions?



# Managing Complaints and Incidents across organisational boundaries

Dr Carol McCall FRPharms, FFRPS
Senior Governance Advisor
National Clinical Homecare Association



# Managing Complaints and Incidents across Organisational Boundaries

Dr Carol McCall FRPharms, FFRPS
Senior Governance Advisor
National Clinical Homecare Association
Member of the NHMC C&I workgroup

Editor RPS Homecare Services Handbook



# Why are homecare C&I "special"?

- Covers many types of C&I managed by the same team within the NHS organisation
- Often involves multiple organisations and outsourced services
- Often complex services requiring a high level of co-operation between the parties
- Patients want one comprehensive response
- Duplicate or no reports
- We must collate and share learning to improve patient safety

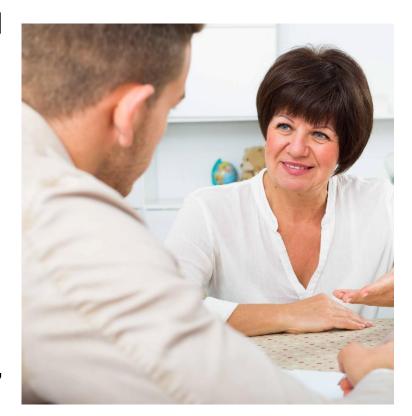


Homecare C&I reports provide evidence of quality



## How does Appendix 19 address this?

- Defines the C&I process to be followed
- Defines the responsibilities of each party
- Sets training standards for homecare staff for C&I
- One set of standard KPI data showing the quality of the overall service irrespective of homecare organisation
- This means no "throwing hot potatoes" over organisational boundaries or blaming the other parties involved



We must all work together



## Prerequisites for collaboration

- Follow the RPS Professional Standard for Homecare Services
- Use the tools provided in the RPS Homecare Services Handbook
- Document & share clinical pathways including homecare decision points
- Document agreed service specifications
- Robust "account management" of your own organisation and outsourced partners (KPIs etc)



# What is a primary investigator?

The homecare organisation which receives the initial complaint or identifies the incident

Or

The homecare organisation most suited to lead the overall investigatio of the incident identified on a case by case basis



What happens if the two are not the same?

BY AGGREMENT status can be transferred



# **Examples**

When would an organisations status change?



How will agreement to change primary investigator be reached and documented?



What actions must be taken if primary investigator changes?



# Responsibilities of the Primary Investigator

- The primary investigator must identify other organisations that have, or may have, regulatory or reporting responsibilities relating to the incident
- Co-ordinate the investigation across all organisations involved and documenting the overall incident report
- Drafting the responses to patients/complainants
- Ensures responses involving other organisations are reviewed by all those organisations before sending



# Responsibilities of secondary investigators

- Remain responsible for reporting the results of their internal investigation to the Primary Investigator
- Remain responsible for their own reporting of the incident to regulators (use references so the regulators can identify duplicate reports)
- For complaints and incidents requiring a written response there is a duty for all parties to co-operate toward provision of a single co-ordinated response to the complainant by the primary investigator



# Joint Responsibilities

- Determine which organisation is the most appropriate primary investigator and agree transfer of that responsibility if necessary
- Co-operate in the investigation, root cause analysis and risk analysis across organisational boundaries
- Share learning from all C&I
- Implement changes that cross organisational boundaries to minimise recurrence and/or reduce risk



#### Individual responsibilities of all parties

- Undertake internal investigations and root cause analysis
- Update their own organisations risk register as needed
- Ensure Appendix 19 guidance is implemented in their organisational procedures
- Continuous improvement

Your Trust will have existing complaints and incidents policies and processes.

How can you ensure investigations include other service partners and responses are timely and reviewed by service partners?



# Any questions?





#### Thank you for your attention

carol.mccall@clinicalhomecare.co.uk

www.clinicalhomecare.co.uk



## **FAQ**

# The guidance only applies to 3<sup>rd</sup> party homecare providers, doesn't it?

 No – the RPS standards, RPS Homecare Handbook and Appendix 19 apply to the entirety of all homecare services irrespective of which organisation provides which elements of the homecare service.

#### Do we perform a full investigation on all incidents?

 No – "minor" incidents where there is no patient harm are coded sufficiently to allow KPI reporting. These types of minor incidents may be subject to a full investigation if adverse trends are recognised.





# NHS Reporting Systems - Considerations and Configuration

Liz Chapman

Head of Patient Experience and Engagement

Berkshire Healthcare Foundation Trust

# NHS Reporting Systems - Considerations and Configuration

Liz Chapman

Head of Patient Experience and Engagement
Berkshire Healthcare Foundation Trust

# When to report?



NHS staff have a duty to report all incidents on the clinical referring centre's incident reporting systems; this includes homecare complaints and incidents.

#### Report

- All formal complaints (see Section 9.7 complaints definitions)
- All informal complaints that are resolved but highlight occurrence of an incident (see Section 9.7)
- All incidents

# When not to report?

Section 4.3

.... resolve the incident or complaint without the formality of a written response

Avoid formal complaint if possible

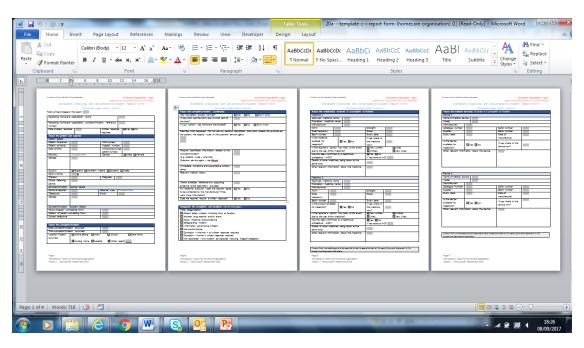
#### **Options**

Local resolution module
Can report all informal complaints

but not mandatory



# How to report?



• Section 9.1

A chronology of events should be compiled to describe the details of the patient safety incident.

# Reporting Guidance

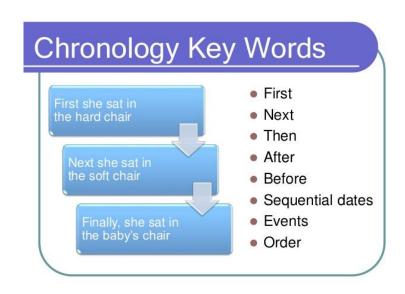
Section 4.1

..... able to **distinguish between reports** relating to events occurring as part of the homecare service and those relating to complaints and incidents that have occurred elsewhere within the clinical referring centre.

Section 9.1 Patient Safety Incidents

It is important that **all NRLS reports relating to homecare** are identifiable. Until there is a specific NRLS location code for homecare, all NRLS reports of homecare incidents must contain the **keyword homecare** in their description.

# Reporting Guidance



- Chronological report
- Use word 'homecare' in the report
- Configure 'homecare' as a clinical area?
- Module options available
- No names within the body of text

All patient safety incidents should be escalated to NRLS

**Seven Steps to Patient Safety** 

#### NRLS Escalation

#### Section 9.1

Homecare providers should share patient safety incidents arising from homecare services to patients in England and Wales with the NRLS.

There are two ways to report incidents to the NRLS:

- Individual reports via the NRLS website
   Each report has to be keyed in separately
- Batch reporting via the NRLS data portal

Reporting team

Access
NRLS Reporting
here

# **NHS** Reporting Systems

- 2 main providers
- NHMC contacted Datix and Ulysses





- Systems have optional modules
  - Local resolution
  - Formal complaint
  - Incidents
- Systems are modifiable for homecare
- Systems can be configured 'in house'

# **NHS** Reporting Systems

Configure using the standard data sets

Standard data set in Appendix 22 (link in App

19)

Abbreviated lists in Appendix 19

#### Action for Homecare Managers:

Share the data set with organisation reporting teams

Encourage adaptation of NHS system for homecare

Contact regional specialist for further support



# Coding – Reporting System Leads

- Organisations must use the top level codes
- Sub codes are optional
- If using sub codes make sure they are correct
- In each sub code section there is an unclassified if not using the sub code – then all reports will be coded as unclassified

			Sub Name +			
Group + Ref	Heading + Ref	Name + ref	ref	Final Code & Ref	Code Description / Comments	Data Properties
1 - Demographic codes				1 - Demographic codes		Header
1 - Demographic codes	1.1 - Patient details			1.1 - Patient details		Header
1 - Demographic codes	1.1 - Patient details	1.1.1 - Homecare provider patient number		1.1.1 - Homecare provider patient number		Number
1 - Demographic codes	1.1 - Patient details	1.1.2 - NHS number		1.1.2 - NHS number		Number
1 - Demographic codes	1.1 - Patient details	1.1.3 - Hospital number		1.1.3 - Hospital number	(Use of NHS Number preferred)	Number
1 - Demographic codes	1.1 - Patient details	1.1.4 - Surname		1.1.4 - Surname		text
1 - Demographic codes	1.1 - Patient details	1.1.5 - Forename		1.1.5 - Forename		text
1 - Demographic codes	1.1 - Patient details	1.1.6 - Carer or guardian name		1.1.6 - Carer or guardian name	mandatory for child or vulnerable adult	text
1 - Demographic codes	1.1 - Patient details	1.1.7 - Date of birth		1.1.7 - Date of birth		Date /Time
1 - Demographic codes	1.1 - Patient details	1.1.8 - Gender		1.1.8 - Gender		Header



# Faulty Medicines and Devices Reporting in Homecare

Sharon Jackson
QA Specialist, North West Regional QA





## **Faulty Products**

Sharon Jackson
QA Specialist
North West Regional QA

The first stop for professional medicines advice







#### **OBJECTIVES**

To define "faulty products"

To outline reporting and trending mechanisms





#### What is a faulty product?

#### **Medicines & Medical Devices (CE Marked)**

Faulty manufacture, product deterioration, non-compliance with a medicine's marketing authorisation or product specification file, or any other serious quality problems, including detection of falsification or counterfeit.

#### e.g.

- Contamination with microorganisms
- Leaking containers
- Presence of foreign bodies
- Degradation of active ingredient
- Missing labels or batch numbers

- Pre-filled syringes do not activate when plunger depressed
- Half tablets inside blister packs
- Spelling errors on labels counterfeit?





#### What is a faulty product?

#### **Medicines & Medical Devices (CE Marked)**

Faulty manufacture, product deterioration, non-compliance with a medicine's marketing authorisation or product specification file, or any other serious quality problems, including detection of falsification or counterfeit.

Remember counterfeit products and

e.g.

- Contamination with microorganisms
- Leaking containers
- Presence of foreign bodies
- Degradation of active ingredient
- Missing labels or batch numbers

- invalid supply chains
   Pre-filled syringes do not activate when plunger depressed
- Half tablets inside blister packs
- Spelling errors on labels counterfeit?





#### What is a faulty product?

#### **Medicines & Medical Devices (CE Marked)**

Faulty manufacture, product deterioration, non-compliance with a medicine's marketing authorisation or product specification file, or any other serious quality problems, auding detection of falsification or counterfeit.

e.g.

- Contamination with microorganisms
- Leaking containers
- Presence of foreign bodies
- Degradation of active ingredient
- Missing labels or batch numbers

This training is not about what is and is not faulty. If in doubt ask your Medication Safety Officer or Medical Device Safety Officer for further training.

02/07/2018





#### Other product complaints and near-misses

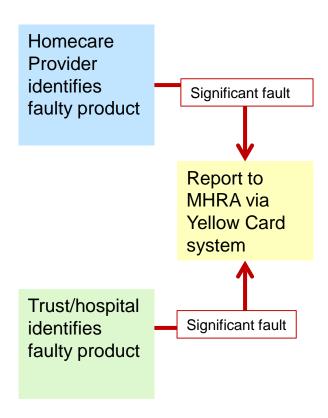
- Poor labelling or design
  - Mix-ups between look-alike medicines
  - Dose confusion
  - Difficult to use
    - > Report
- Other products
  - Fridges and pumps
    - > Report
- Adverse reaction/side effects?
  - > Separate reporting mechanism

Remember: if in doubt, report it anyway!





#### How to report faulty products

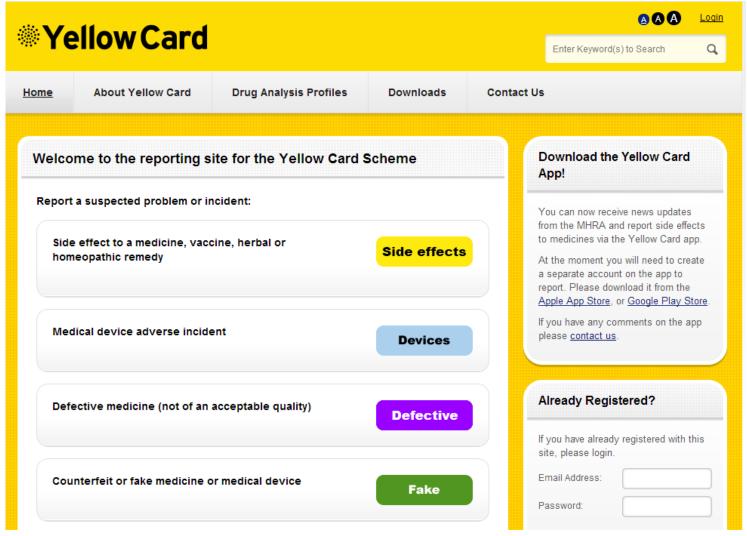


https://yellowcard.mhra.gov.uk/

www.sps.nhs.uk 02/07/2018 108





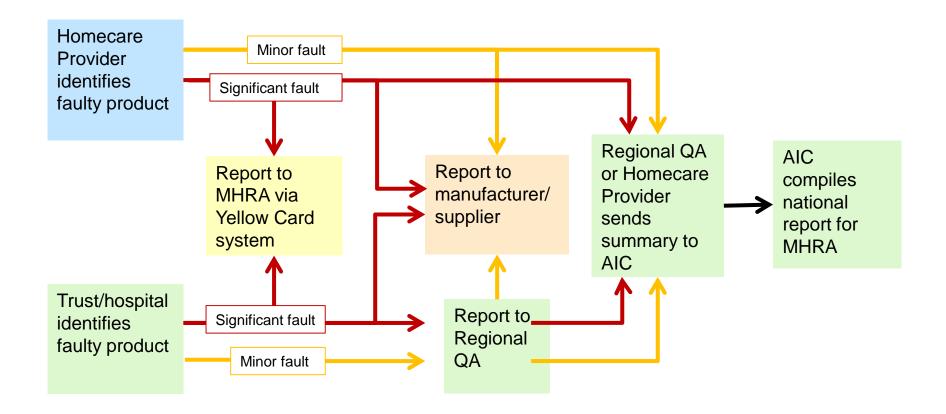


www.sps.nhs.uk 02/07/2018 109





#### How to report faulty products



www.sps.nhs.uk 02/07/2018 110





#### **Analytical Information Centre reporting (AIC)**

#### **Homecare Providers:**

 Please summarise your local reports using the AIC report template -Appendix 21 of RPS Homecare Handbook

https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Professional%20standards%20for%20Homecare%20services/Appendicies/21---aic-reporting-template-sept2016-final%20%281%29.xlsx

Submit monthly to AIC

#### **Trusts:**

- Send your faulty product (defective medicines and devices) reports to your Regional Pharmaceutical QA specialists
- Regional QA will summarise and submit to AIC





#### **Analytical Information Centre reporting (AIC)**

#### **Homecare Providers:**

 Please summarise y Appendix 21 of RPS Homecare.

https://www.rpharms.com/Portals/ ndards/Professional%20standards template-sept2016-final%20%281

This reporting process is for all faulty products identified in the NHS – not just

How good is your Trust's current Submit monthly to A reporting process?

#### **Trusts:**

- Send your faulty product (defective medicines and devices) reports to your Regional Pharmaceutical QA specialists
- Regional QA will summarise and submit to AIC





#### What happens next?

- Supplier will investigate the faulty product complaint and report findings and remedial actions back to the reporter
- MHRA may initiate a Drug Alert or a Medical Device Alert
- AIC collates national reports and
  - sends back to Regional QA
  - sends to MHRA
- AIC identifes trends, and may raise with the MHRA or suppliers directly





## Thank you!

## Any Questions?

sharon.jackson@rlbuht.nhs.uk



## Pharmacovigilance in Homecare

Stephen Cook
Director of Pharmacy & Quality





#### **Definitions**

**Pharmacovigilance** (PV or PhV), also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products

Adverse Drug Reaction (ADR) is defined in DIR 2010/84/EU as a response to a medicinal product that is noxious and unintended (side effect) which results not only from the authorised use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorisation, including the misuse and abuse of the medicinal product and occupational exposure

Adverse Drug Event (ADE) is defined as any untoward medical occurrence in a [homecare] patient administered a medicinal product which *does not necessarily have a causal relationship* with the medicinal product ....

#### **Definitions**

#### Reports can be spontaneous or solicited

- **Spontaneous** reports arrive from HCP's, consumers, competent authorities (and others) and tend to imply a reasonable suspicion of causality
- Solicited reports of suspected adverse reactions are those derived from
  manufacturer's organised data collection systems, which include clinical trials, noninterventional studies, registries, post-approval named patient use programmes,
  other patient support and disease management programmes, surveys of patients
  or healthcare providers, compassionate use or name patient use, or information
  gathering on efficacy or patient compliance

What is different about Adverse Drug Reaction reporting by NHS Homecare Organisations?

## Nothing

(unless you are directly subcontracted by a manufacturer and paid to provide a homecare service)

## Report via NRLS or using the Yellow Card Scheme

(as per your NHS organisations policy)

#### Reporting Responsibilities

#### Pharma (MAH)

- All serious ADR's must be reported to the Regulator (MHRA) as Individual Case Safety Reports (ICSR's) within 15 days of awareness
- All non-serious ADR's must be reported within 90 days of awareness
- Assess reported ADE's and report validated solicited reports as a 'study report'
  within timescales above
- All solicited reports that are not validated as ADR's, may require reporting amongst others within the Periodic Benefit-risk Evaluation Report (PBRER)

#### Reporting Responsibilities

#### **NHS** centres

- Use internal reporting systems to report ADR's & Patient Safety Incidents
- Investigate suspected ADR's often as primary investigator
- Support Pharma to provide information about suspected ADR's
- Report Patient Safety Incidents to NRLS
- No requirement to report via Yellow Card Scheme if already reported to Manufacturer (this will have happened via Homecare provider if PSP) or through NRLS

#### Reporting Responsibilities

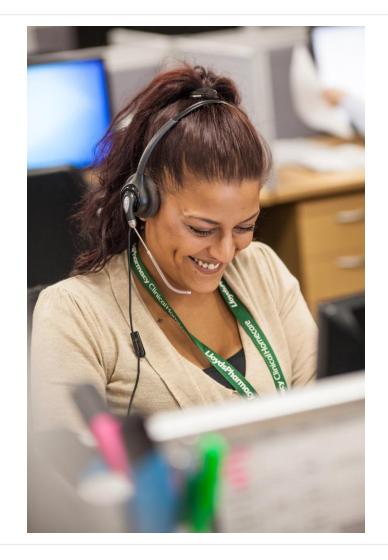
#### **Homecare PSP schemes**

- Report ADR's to NHS (as ADR & Patient Safety incident)
- Report anonymised ADR's to Pharma according to contract
- Report anonymised ADE's to Pharma
- Consider need to report non-PSP's ADR's to Pharma

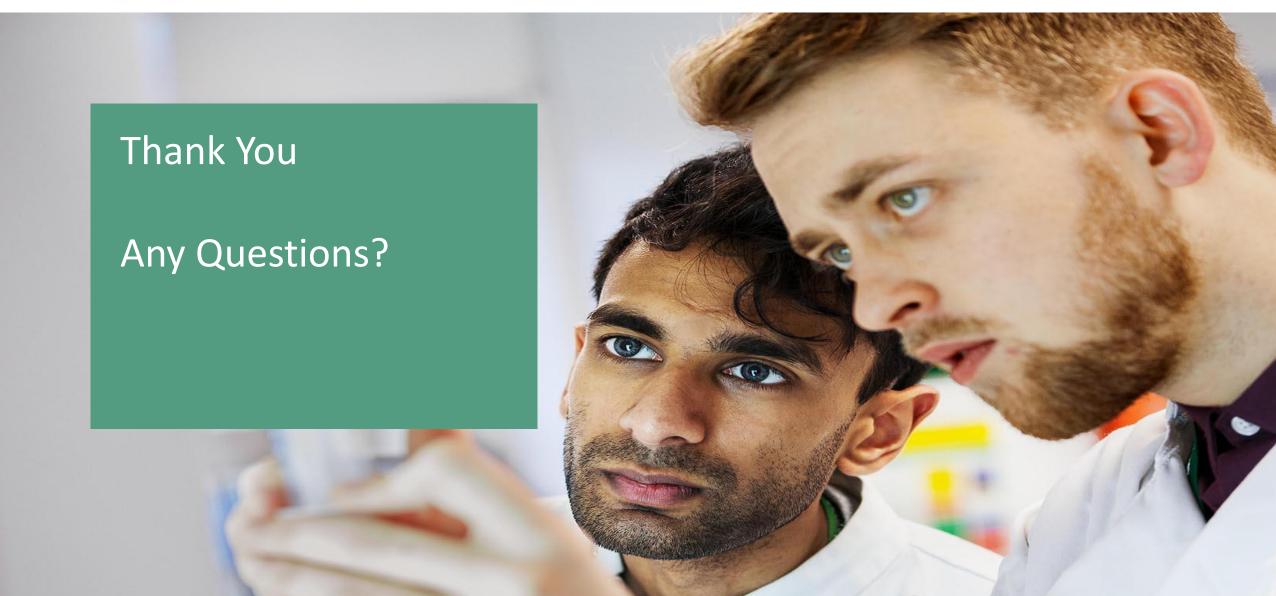
Do not report ADE's to NHS unless it is a Patient Safety Incident (LPCH currently reports circa 2,500 AE's per month to Pharma)

#### Pharmacovigilance Training

- Homecare staff should undertake a generic training programme on the general principles of adverse drug reaction and adverse drug event reporting.
  - A training module for this has been created by the NCHA and is going through approval with ABPI & MHRA
- Duplication of this general training with individual manufacturer branded training programmes is not recommended, and may introduce new risks where staff are not dedicated to delivering specific manufacturer's service(s).









## Implementation of Appendix 19 Key Performance Indicators

Tracie Dawson
Procurement Category Manager/Regional Lead,
South West
Peninsula Purchasing and Supply Alliance



#### **National Homecare Medicines Committee**

# Implementation of Appendix 19 Key Performance Indicators

#### **Tracie Dawson**

Procurement Category Manager/Regional Lead, South West

Peninsula Purchasing and Supply Alliance



#### **National Homecare Medicines Committee**

## New Governance KPIs

Reference	KPI Requirement
K21	Formal C/Is opened as a % of the total number of active patients
K22	Formal C/Is responses sent where response to complainant/reporter has not been provided within 30 business days in the reporting period as a % of number of Formal C/Is opened
K23	Open Formal C/Is as a % of number of Formal C/Is opened
K24	Patient safety incidents as a % of active patients
K25	Total number of reported adverse drug reaction incidents as % of active patients
K26	Adverse drug event incidents as % of active patients
K27	Faulty medicinal product and device incident reports as % of active patients
K28	Safeguarding incidents as % of active patients
K29	Information governance incidents as % of active patients

## Implementation

- Complaints and Incidents KPIs available from Homecare providers January 2018
- For the early part of 2018 data may need to be validated
- Each Trust should ensure they receive KPI reports for each homecare service in place
  - Regional Leads/Specialist Support available for a number of regions
  - Direct to Trust and/or via regional template
- No thresholds set



## Managing KPIs – Potential data errors

- A template benchmarking report is already in use in some regions
- KPIs are indicators and exceptions should be initially investigated for data accuracy
  - Where to flag suspected data errors to?
- Interpretation/definitions are provided in the KPIs

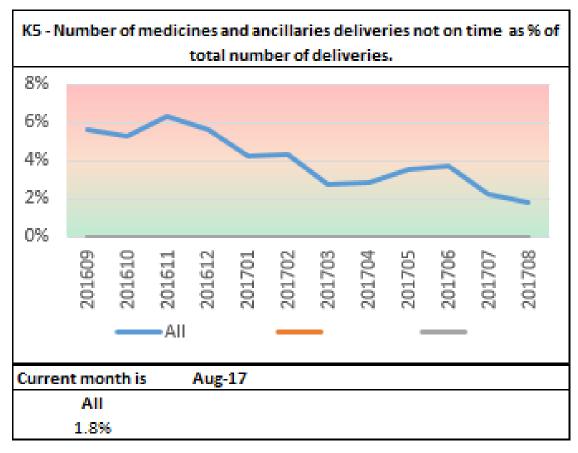


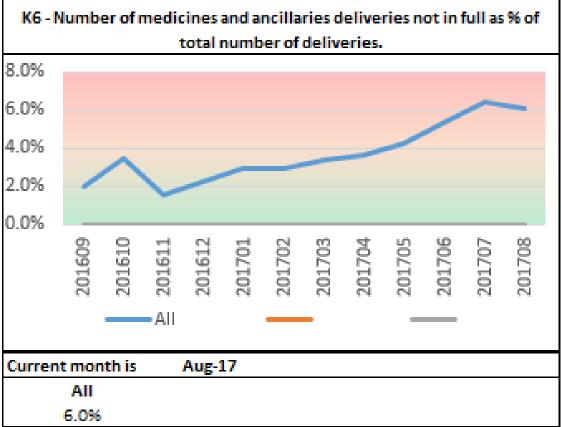




## Recognising trends

## **National Homecare Medicines Committee**





## Process for dealing with declining trends

- Negative/upward trend raise with Key Account Manager (KAM)
  - Investigate and explore reason
  - Corrective / preventative actions required?
  - Agree timelines
  - Agreed timelines missed next steps?
- Learning from operational KPIs





## **KPIs from NHS Trusts**

- Trusts as the primary investigator Trust systems?
- System development required?





#### **How To Apply What You Have Learned**

**Susan Gibert Chair, NHMC** 



#### **National Homecare Medicines Committee**

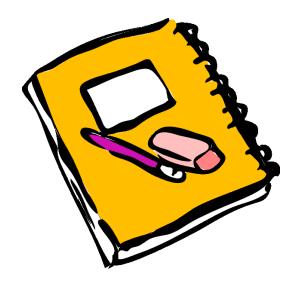
## How to apply what you have learned

Susan Gibert

Chair, NHMC

## NHS Implementation





- Training day attendance
- Workbook
  - Completion of tasks
  - Completion of practice example
- Additional training

Train others

Trainer for pharmacy homecare team members Trainer for clinical teams



#### Workbook

**NHMC** 

- Downloadable from PharMan website
- Refers to Appendix 19 (continuously)
- Workbook becomes a 'manual'
- Contain useful 'NHS Organisation' information for all staff members
- 1 master list of useful people
- Documents current services
- Serves as a reference document
- Work through in 'chunks' of time or sections
- Complete all of the tasks



#### Workbook





#### Completion of tasks

- Throughout the workbook
- Multiple elements to each task
- Review current Trust/Health Board documentation
- Supports a review current practice
- Encourages updates to documents and practice
- Consider actual activity
- Supports learning from Complaints and Incidents

## Workbook

**NHMC** 

- Completion of practice example
- Completely fictitious
  - One scenario which progresses through
  - Covers all essential elements of process
  - Attempt all questions
  - Encourages reflection
  - Sample answers given



## **Additional Training**



- List of suggested additional training in workbook
- Attend Trust/Health Board training
- Consider appropriate training (gap analysis)



- therapy specific
- specialist specific (e.g., safeguarding, IG)
- reporting systems
- Record CPD

#### **Train Others**

**NHMC** 

- Trainer for pharmacy homecare team members
- Trainer for clinical teams

- Guidance describes levels of training
- Workbook encourages needs analysis
- Support from Senior Pharmacists
- Consider how to 'roll out' in NHS organisation
- Support from regional homecare specialist

## Questions

#### **NHMC**





## **Learning from Complaints and Incidents**

Patrick Doyle MRPharmS
Risk and Governance Lead
Frimley Health NHS Foundation Trust

## **Learning from Complaints and Incidents**

Patrick Doyle MRPharmS
Risk and Governance Lead
Frimley Health NHS Foundation Trust

## RPS Appendix 19 vs Current Practice



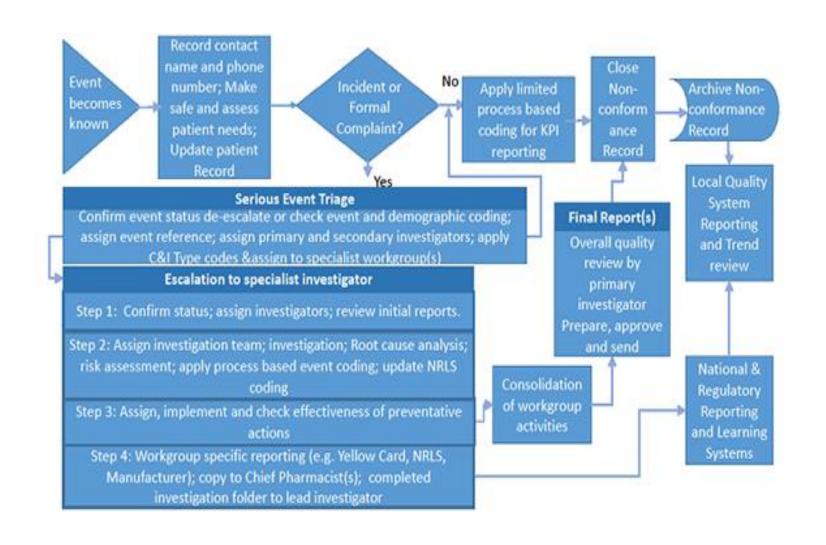
- Appendix 19 contains:
  - Over-arching process flow
  - Process flow for each incident category

#### NHS organisations:

- Need to review current practice
- Identify gaps
- Implement necessary changes to ensure compliance



## RPS Appendix 19: Over-arching Process



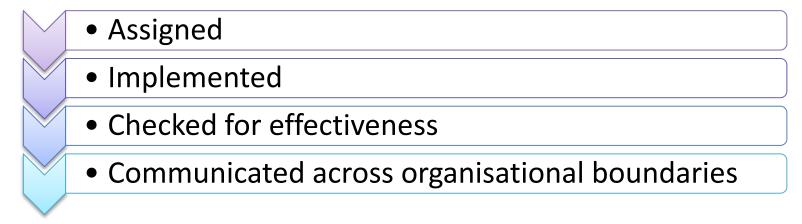
## Step 2 in detail

 Assign investigation team who review the report and then complete:

- Investigation
- Root cause analysis (RCA)
- Risk assessment
- Apply process based event coding
- Update NRLS coding
- Ensure robust liaison with secondary investigators
- Close the report on reporting system

## Step 3 in detail

Preventative Actions must be:



- After closing the incident; review the risk assessment and amend if necessary
- Amend organisation's Risk Register if necessary

## Investigations



- NHS organisation
  - will not always be the primary investigator
  - should record on NHS reporting system as 'homecare'
  - should assign an internal investigator/ handler
  - should review all homecare patient safety incidents by Pharmacy Clinical Governance Group (or equivalent)

## NHS Investigator/Handler

Ensures that the investigation is complete including:

- Risk Register review and update if necessary
- Mitigating action assessment
- CAPA (corrective and preventive actions) effectiveness review

Satisfactory response gained from primary investigator

Response goes to patient (if required)

Local NHS policy is followed

Incident is 'closed' on reporting system

## NHS Experts- Specialist Investigators



Medicines
Safety Officer
MSO



Safeguarding Lead



Device Safety Office DSO



Information Governance Lead Specialist investigators may be required for some complaint/incident types

#### Risk Assessment

★Lessons learned						<u>^</u>	
*Consequence of Incident	<u>~</u>						
★ Risk grading	Consequence						
	Likelihood	Negligible	Minor	Moderate	Major	Extreme	
	Almost Certain - Occurs on a daily basis - persistent issue	•	•	•	•	•	
	Likely - Expected to occur at least weekly	•	•	•	•	•	
	Possible - Expected to occur at least monthly	•	•	•	•	•	
	Unlikely to occur more than once a year	•	•	•	•	•	
	Rare - Not expected to occur	•	•	•	•	•	
			Grade:				
Closed date (dd/MM/yyyy)    Ellipsed date (dd/MM/yyyy)							

NOTE: Use standard – risk assessment prior to starting new services. When an incident occurs - is this revalidated?

### New Service Risk Assessment

- NHMC document
- Approved 2016
- Implementation is slow
- Regional support available from regional homecare specialists

Overall Risk Rating Key						
Very Low Risk	Score 1-3					
Low Risk	Score 4-6 Score 8-12					
Moderate Risk						
High Risk	Score 15-25					

Cost Analysis - Medicines excluded from the Tariff							
		Cost Category	Current Cost to Commissioners (NHSE/CCG)	Cost of Proposed Homecare Service			
Α	Medicines Acquisitition Cost	Medicine pack price ex VAT £  Number of packs used per patient per course or year  VAT rate %  Level 1 oncost %  Medicine cost inc VAT and Level 1 oncost  Level 2 oncost %  Level 3 oncost £	£0.00	£0.00			
		Medicine acquisition cost per patient per course or year A	£0.00	£0.00			
В	Activity Tariff Income	Tariff charge per drug administration  Number of drug administrations per patient per course or year					
		Tariff for activity per patient per course or year <b>B</b>	£0.00	£0.00			
O Homecare Service Fee	Homecare delivery fee (per delivery) Number of delveries per course or year	N/A N/A					
	ecare Se	Homecare nurse fee (per visit)  Number of nurse visits per course or year	N/A N/A				
	Hom	Total cost of equipment and ancillaries per course or year	N/A				
		Total homecare service fees per patient per course or year <b>C</b>	N/A	£0.00			
D		Cost per patient per course or year <b>D</b>	A + B = £0.00	A + B + C = £0.00			
E		Number of patients per year E					
		Total cost per patient cohort per year	D x E = £0.00	D x E = £0.00			

## Risk Register



#### **RPS Appendix 19: Section 4.3**

 Once contributory factors and root causes have been identified, the organisation risk registers should be reviewed to check if the factors and root causes are recorded as a known risk, with associated corrective/preventative/miti gating actions.

## **Assess Mitigating Actions**

 Further decisions are required on whether any existing mitigating actions have been effective or whether additional investigation and actions are required, including additional entries in the organisations' risk registers



'Mitigation' is assigned to a risk 'Preventative actions' are defined following an incident

#### Assess CAPA effectiveness



Final investigation reports should describe root causes and recommended preventative actions

Each organisation should have processes in place to assess the effectiveness of corrective and preventative actions (CAPAs) that have been implemented arising from complaints and incidents



## Frimley Reporting Process

Datix email notification

Review Incident form content and quality check information

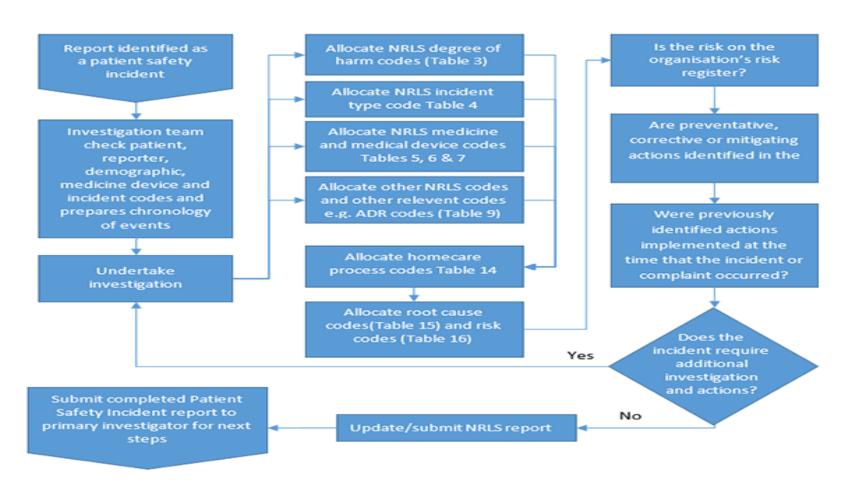
Undertaken Incident investigation; complete actions and implement lessons learnt



All Incidents are required to be reviewed and investigated within 14 working days of being reported

Incident Handler Risk Grades incident Incident Handlers feedback the outcome of investigation and share any lessons learnt with Incident Reporter

## Patient Safety Incident Process Flow



NOTE: Duty of Candour incidents require communication with patient/representative in addition to above process flow

## RPS Appendix 19 says:

- Share patient safety incidents with NRLS
- Patient safety incidents coded with the NRLS codes as moderate or severe or death will usually meet the notifiable safety incidents criteria under Duty of Candour regulations
- If patient safety incident results from an ADR/faulty medicine/device but has already been reported via NRLS there is no need to report via Yellow card system





## **Root Cause Analysis**

- National drive to improve quality of RCA
- National drive to improve lesson learned

 NHS organisations will have a specialists trained in RCA who are available for support



## Review and Trend Analysis

- All records kept and reviewed for trends including complaints
- Clinical governance groups should review all patient safety incidents



## The Frimley Approach

Datix Web

- Incident reported on Datix® Web
- If recorded as Drug/Medication Incident

Medication Category Choices

- Only 8 headings to choose from
- Administration, ADR, Dispensing, Prescription, Drug unavailable, Labelling, Storage, TTOs

Handler/Inves tigator

- Once incident opened needs to be registered as as "being reviewed" and handler/investigator re-grades the incident (if necessary)(see figure below).
- Medication R/V Group meets before MSG monthly to R/V incidents and look for 'harm'/'no harm'.

MSG

• MSG meets monthly. All moderate incidents and above reviewed in depth. Time allowing all other minor incidents are also reviewed. Representation from ward/directorate areas encouraged to attend to answer queries pertaining to the incidents raised.

Reporting

• 5 key messages prepared and disseminated on Intranet based on the incidents reported that month. Themes examined. As with every Trust in the country administration and prescription occupy top spots.

# Process Based Event Coding Master Code List

#### Why introduce coding?

 So that NHS and Homecare organisational reporting systems can link up with NRLS

Datix

Homecare Providers and NHS will start talking the same language

High level codes must be used, use lower codes if possible

## Key Messages



- Homecare complaints and incidents:
  - Are important
  - Should be integrated in NHS organisation's systems and processes
  - Should be communicated and handled across organisational boundaries
- Ensure incidents are reviewed and learning is put into practice



