Pharmacy MANAGEMENT NATIONAL FORUM
FORUM WORKSHOP

What does governance look like in homecare?

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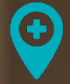
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Definitions

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Clinical governance is a systematic approach to maintaining and improving the quality of patient care within a health system

This definition is intended to embody three key attributes: recognisably high standards of care, transparent responsibility and accountability for those standards, and a constant dynamic of improvement

The concept has some parallels with the more widely known **corporate governance**, in that it addresses those structures, systems and processes that assure the quality, accountability and proper management of an organisation's operation and delivery of service.

Integrated governance has emerged to refer jointly to the corporate governance and clinical governance duties of healthcare organisations.

What should be measured in clinical homecare governance?

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If you can't
MEASURE it
you can't **MANAGE** it.

CQC governance regulation

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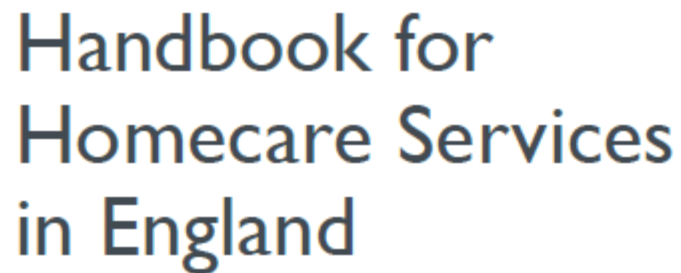
Care Quality Commission Regulation 17: Good governance
Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17

- Providers must have effective governance, including assurance and auditing systems or processes. These must assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service. The systems and processes must also assess, monitor and mitigate any risks relating the health, safety and welfare of people using services and others. Providers must continually evaluate and seek to improve their governance and auditing practice.
- In addition, providers must securely maintain accurate, complete and detailed records in respect of each person using the service and records relating the employment of staff and the overall management of the regulated activity.
- As part of their governance, providers must seek and act on feedback from people using the service, those acting on their behalf, staff and other stakeholders, so that they can continually evaluate the service and drive improvement.



Handbook for Homecare Services in England

May 2014

RPS Handbook for Homecare

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New RPS Handbook Appendix 2016
Further guidance on managing incidents and complaints

- The NHS Medicines Homecare Committee subgroup working on the national standard for Key Performance Indicators in 2014 resolved that the complexity and diversity of complaint, incident and non-conformance processes between organisations meant it was not possible at that time to agree national standard governance KPIs.
- **Furthermore differences in terminology between NHS Trusts and Homecare providers were causing confusion and undermining trust in the medicines and clinical homecare sector.**
- A stakeholder consultation on draft guidance on managing incidents and complaints and KPI's is underway and a new appendix to the RPS homecare handbook will be launched early in 2015

Overlapping definitions

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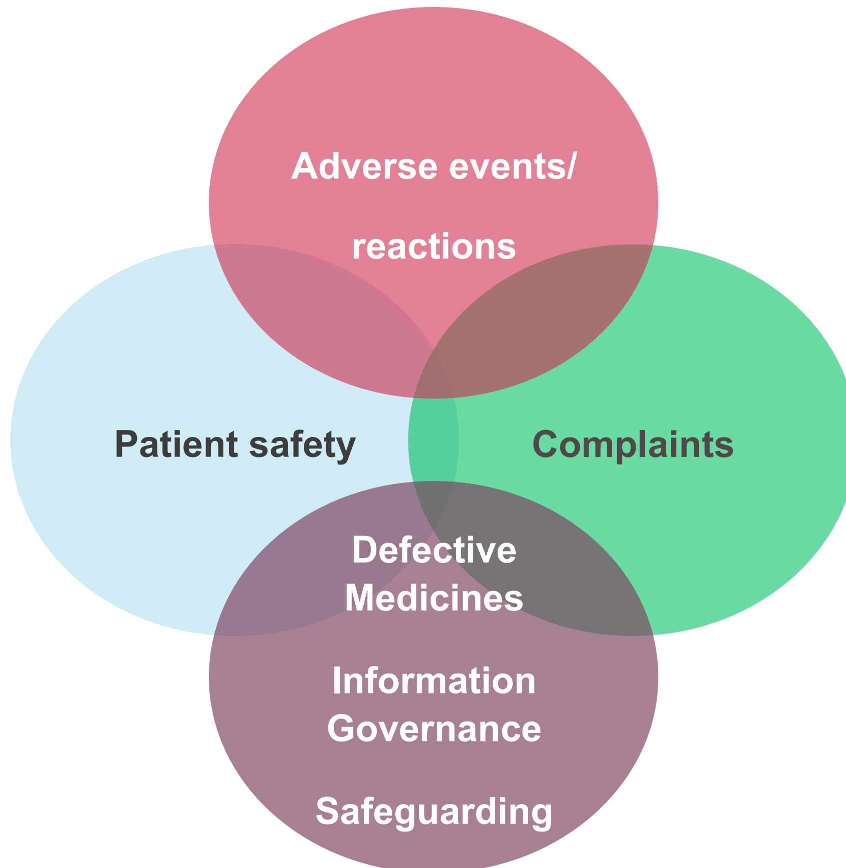

Regulators and stakeholders

Care Quality Commission

General Pharmaceutical Council

Nurses and Midwives Council

MHRA

Health and Safety Executive

NHS England, Scotland, Wales and Northern Ireland

Health and Social Care Information Centre

ISO 9001

Pharma Customers

NHS Customers

Independent Healthcare Customers

Example of a homecare incident / coding

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A vulnerable adult, that has difficulty self administering their injectable medicine and has very limited support from a carer, is sent their own medicines and medicine intended for another patient. The patient does not detect that the additional medicines are labelled with the other patients name, and self administers these medicine. As a result the patient experiences symptoms as a direct result of the additional medicines and has to be admitted to hospital

Incident codes/investigations to be associated with this incident:

- Adverse event
- Patient safety incident
- Safeguarding incident
- Information governance incident
- Formal complaint

ABPI Guidance on Patient Support Programmes

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Guidance notes

for Patient Safety and Pharmacovigilance in Patient Support Programmes

9 May 2011

a PSP is defined as a service for direct patient or patient carer interaction or engagement designed to help management of medication and/or disease outcomes.

Examples of services provided by healthcare professionals to support:

- medicine administration
- medicine adherence,
- awareness and education

Adverse Event Reporting

When the PSP involves direct interaction with patients, there is always the possibility that adverse events or product complaints relating to any of the MAH's products may be mentioned.

Adverse event report collection is a mandatory requirement when conducting PSPs due to the European wide legislation governing PV for pharmaceutical companies.

Careful consideration should be given to the **design** and collation of data to ensure compliance with relevant pharmacovigilance legislation and reporting requirements. Therefore, it is strongly recommended PSPs are designed in collaboration with pharmacovigilance, clinical and legal colleagues.

Adverse events – wide definition
No causality requirement and 100% reporting compliance required by Pharma

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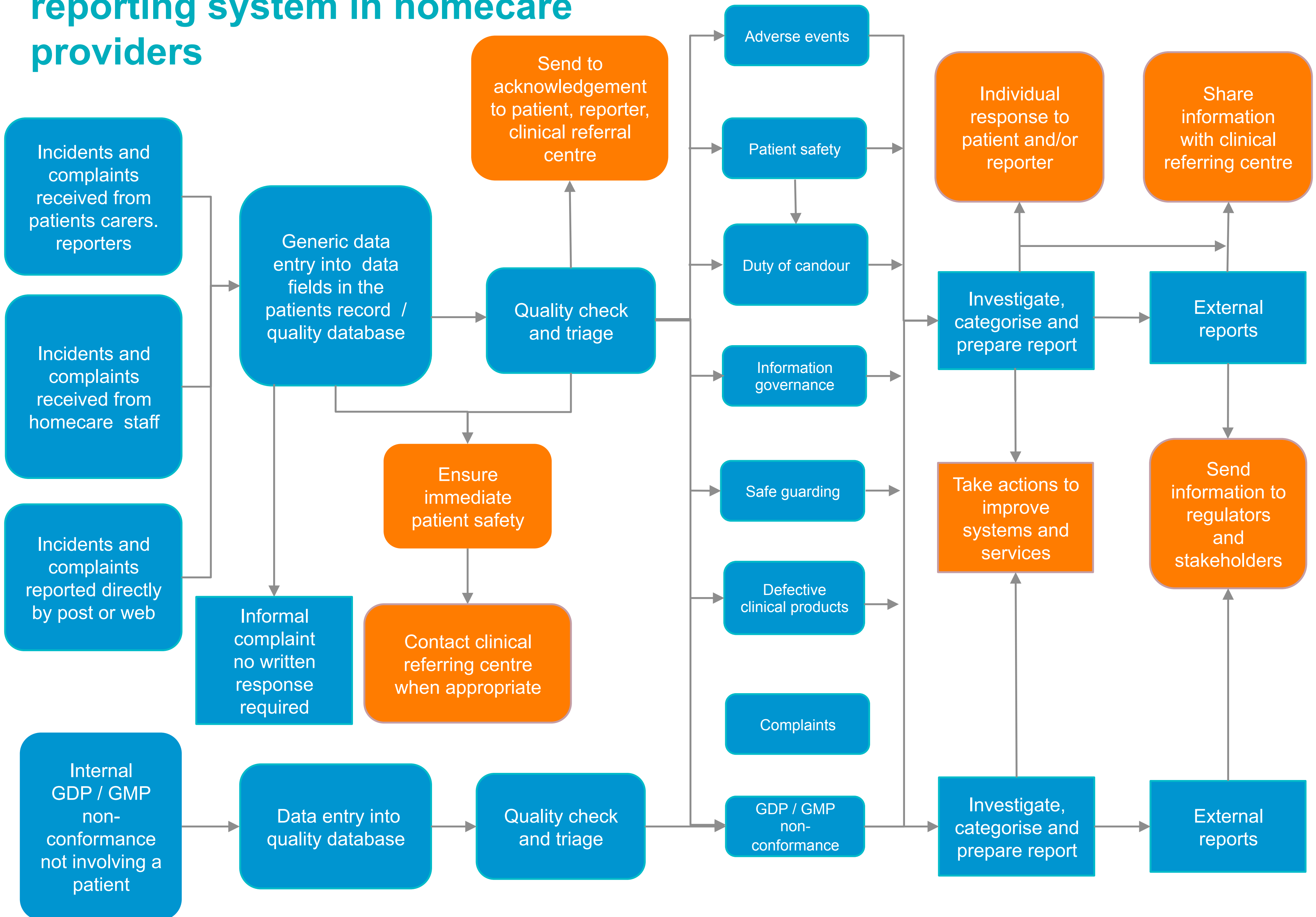
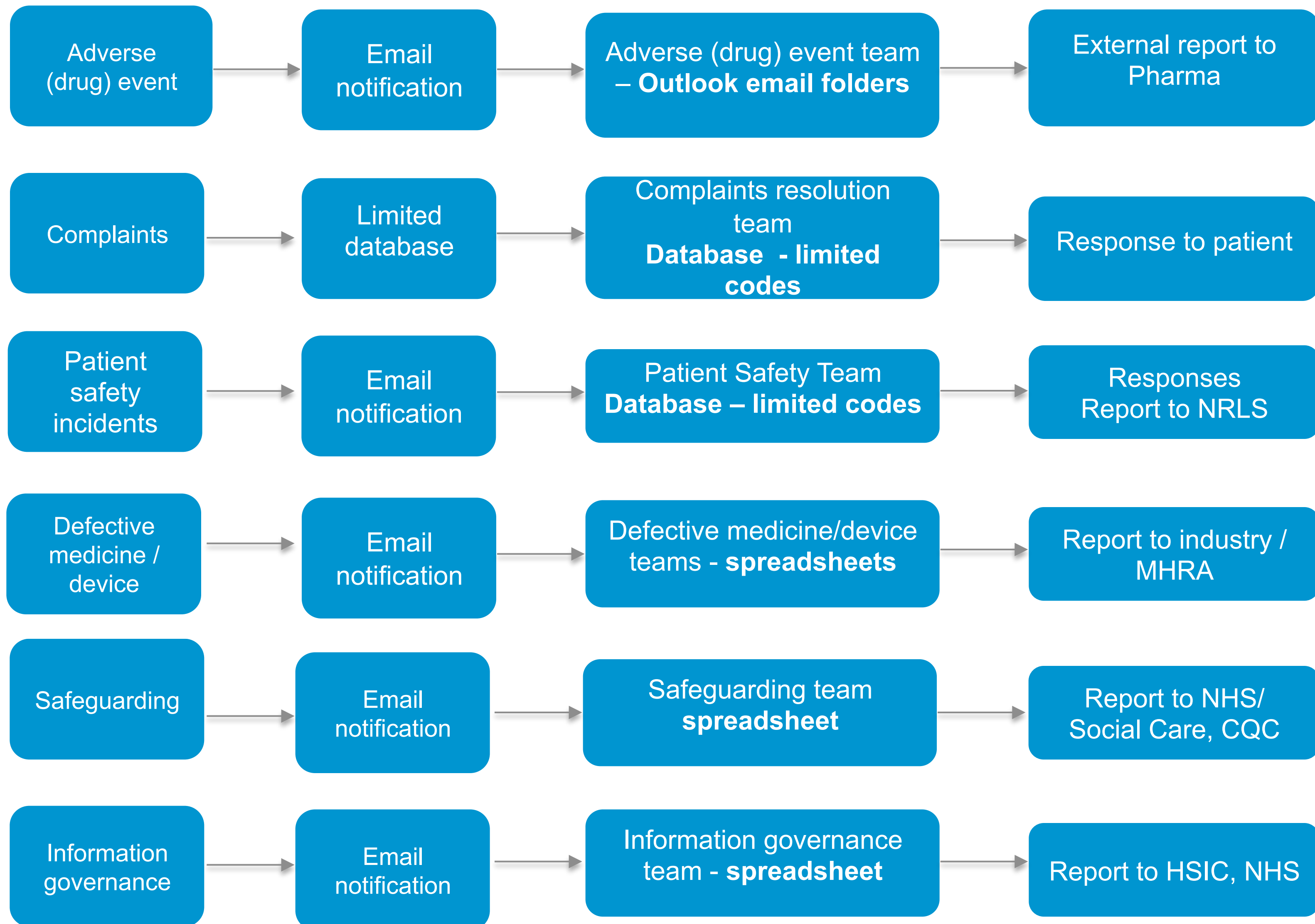
Any untoward (medical) occurrence temporally associated with the use of a medicinal product, but not necessarily causally related. This will include harm resulting from dose reductions and discontinuation of drug therapy

- Abnormal test findings
- Clinically significant signs and symptoms
- Changes in physical examination findings
- Drug abuse
- Drug dependency
- Exposure during pregnancy and breastfeeding
- Extravasation
- Hypersensitivity
- Lack of drug efficacy
- Medication errors
- Misuse
- Occupational exposure
- Off-label use
- Overdose
- Progression or worsening of the underlying disease
- Signs and symptoms resulting from drug withdrawal and drug interactions
- Unexpected beneficial therapeutic effects aside from the use which it has be given

New design for Incident and reporting system in homecare providers



Example of an existing
Incident and reporting system design clinical homecare providers



Demographic data fields

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1	Homecare Incident/complaint number
2	Homecare patient number
3	NHS number
4	Hospital number (Use of NHS Number preferred)
5	Patient surname
6	Patient forename
7	Carers name - for child or vulnerable adult
8	Date of birth
9	Gender
10	Ethnicity
11	Address
12	Location (home setting, work, school, care home, nursing home, hospital, other)
13	Country (England, Northern Ireland, Scotland, Wales)
14	Therapy/contract type
15	Medical history
16	Diagnosis
17	Referring centre
18	Clinical services team location - if applicable

Incident data fields

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19 Date that the complaint or incident occurred
20 Time that the complaint or incident occurred
21 Date reported
22 Time reported
23 Reporting route - which homecare department ?
24 Reporter type (Patient, carer, non-clinical, doctor, nurse, pharmacist, other)
25 Name of reporter (if not the patient)
26 Address
27 Telephone
28 Email
29 Was the patient actually harmed? Yes or No
30 Was this event preventable? Yes or No
31 Describe what happened (do not include any personal identifiable data)
32 What was the harm and to what part of the body (if applicable)
33 Personal identifiable information about the incident or complaint
34 Immediate corrective and preventative actions taken
35 For medical products - does the reporter agree to be contacted by the manufacturer to obtain more information? Yes or No
36 For complaints - does the patient/reporter require a written response? Yes or No
37 Attach documents, audio recording, photographs etc to describe the incident
38 Name of homecare staff completing the complaint/incident report
39 Contact details of homecare staff completing the report

Medicine and medical device data fields

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40 Approved medicine name or
41 Proprietary medicine name
Form (oral solid, oral liquid, injection, to be
42 applied to the skin, other)
43 Strength
44 Frequency
45 Route
46 Manufacturer
47 Batch number
48 Expiry date
49 Is the product available for inspection ?
50 If yes, specify location
In you opinion how likely is this event due
51 to the use of medicine
Details of other medicines being taken at
52 the same time

53 Name of medical device
54 Model
55 Catalogue number
56 Serial number
57 Manufacturer
58 Supplier
59 Batch number
60 Expiry date
61 Date of manufacture
Is the device available for inspection ?
63 Location

Proposed new KPI's for incidents and complaint reporting

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Overarching incident / complaint process	
1	Number of incidents / complaints requiring written response acknowledged within 3 working days as a % of number of incidents / complaints requiring written response received
2	Number of overdue incidents / complaints requiring written response as a % of number of incidents / complaints requiring written response received
3	Number of appeal requests received for any written response to an incident / complaint as a % of total number of incidents / complaints requiring written response received
4	Number of open incidents / complaints requiring written response as a % of number of incidents / complaints requiring written response received
5	Number of days longest open incident / complaint requiring written response has been open and remains open at point of report generation

Proposed new KPI's for incidents and complaint reporting

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Patient Safety Incidents	
6	Number of patient safety incidents(Moderate – death) as % of number of active patients
7	Number of patient safety incidents (low – no harm) as % of number of active patients
8	Number of patient safety Incidents (low – death) as % of number of patient safety incidents reported

Adverse events and adverse drug reactions	
9	Total number of reported adverse drug reaction incidents as a % of number of active patients
10	Number of adverse drug reaction incidents (Moderate – death) as % of number of active patients
11	Number of adverse drug reaction incidents (low – no harm) as % of number of active patients
12	Total number of reported adverse event incidents as a % of number of active patients
13	Number of Adverse event incidents (Moderate – death) as % of number of active patients

Proposed new KPI's for incidents and complaint reporting

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Faulty medicine and medical device products	
14	Total number of faulty medicine product incident reports
15	Total number of faulty medicine device incident reports

Safeguarding incidents	
16	Total number of safeguarding incidents
17	Number of safeguarding incidents relating to children
18	Number of safeguarding incidents relating to adults

Information governance incidents	
19	Number of level 0 information governance incidents as a % of active patients
20	Number of level 1 information governance incidents as a % of active patients
21	Number of level 2 information governance incidents as a % of active patients

Proposed new KPI's for incidents and complaint reporting

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Complaints	
22	Number of informal complaints received as a % of active patients
23	Number of formal complaints received as a % of active patients

An example of a important patient safety concern in homecare

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Late homecare prescriptions from the NHS accounts for over 50% of patient safety incidents reports in HAH

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Homecare prescription management process - repeat prescriptions

5 Weeks before planned delivery date – request repeat prescription

2 weeks before planned delivery date – planned call date to arrange delivery – send reminder

On day of planned delivery – send reminder

Each week after the planned delivery date – send reminder

Example incident

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Date reported: 15/06/2015
Therapy: Biopharmaceutical
Clinical Outcome: Moderate harm

Details of the incident report:
The patient contacted HAH on 11/06 to say that they had missed treatment.

Chronology of events:

31/03 - Prescription requested
30/04 – Prescription requested another 5 times
22/05 - Inbound call from patient - no prescription, advised 2 injections missed
27/05 - Inbound call – patient going to contact the hospital.
27/05 - Inbound call – Patient advised prescriber had sent the prescription to their pharmacy to have the purchase order number attached and then this will be sent to HAH
03/06 - Prescription requested
08/06 - Prescription received with no purchase order number - queried with hospital
08/06 - Outbound call to hospital to confirm purchase order number - no answer
09/06 -Outbound call to patient; HAH Pharmacist gave advice on missed dose, at this point the patient had **missed 11 injections**
10/06 - Inbound call - Prescription query no purchase order number
10/06 - Prescription query resolved - delivery can be arranged
10/06 - Delivery confirmed 12/06

Action to address late homecare prescriptions

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- Raise awareness – work with the NHS to minimise the risk
- Share prescription requests and late prescription reports with with hospital chief pharmacists/homecare staff and prescribers
- Introduce a more formal communication process to place a patient' account 'on hold'
- A new escalation process for late prescriptions. With the end stage that HAH places the patients account 'awaiting prescription' and formally communicating this to the NHS referral centre and patient
- Clarify use of faxed prescriptions only for emergencies according to GPHc guidance
- Clarify minimum standards for collection, delivery and acknowledgement of physical prescriptions
- Investigate the use of electronic prescribing/trading systems for homecare

Questions?

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