NHS Improvement

Medical Device Safety: What does “the future” really mean?

Sarah Jennings: Patient Safety Clinical Lead for Medical Devices at NHS Improvement

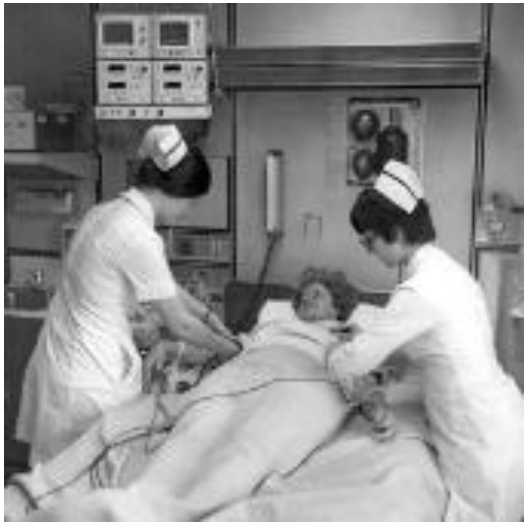
NAMDET Conference 2018

Progressively wider definitions of safety….

*"The simplest definition of patient safety is **the prevention of errors and adverse effects** to patients associated with health care."* WHO website

"…avoiding injuries to patients from the care that is intended to help them"
Institute of Medicine

Safety is a moving target



"Patient safety ….is concerned with errors of commission (doing the wrong thing) and ***errors of omission (failure to do the right thing)*** *and is* ***inextricably linked with the other aspects of quality****"*

Clinical effectiveness = the right thing to do

Patient safety = doing the thing right

QI = continual efforts to ensure we always do the right thing the right way?

Paradigm Shift

Pictures courtesy of Imaginarium Productions

Can it go wrong?

"Despite the best selection, training, experience, competence and intentions, all users of poorly designed medical devices, equipment and technologies will at least operate inefficiently and, at worst, make errors that can contribute to harm or death". *U.S. Food and Drug Administration 2015*

IF THERE'S MORE THAN ONE WAY TO USE A DEVICE, AND ONE OF THOSE WAYS CAN RESULT IN PATIENT HARM, THEN SOMEONE WILL DO IT THAT WAY

WHAT CAN'T GO WRONG WON'T GO WRONG

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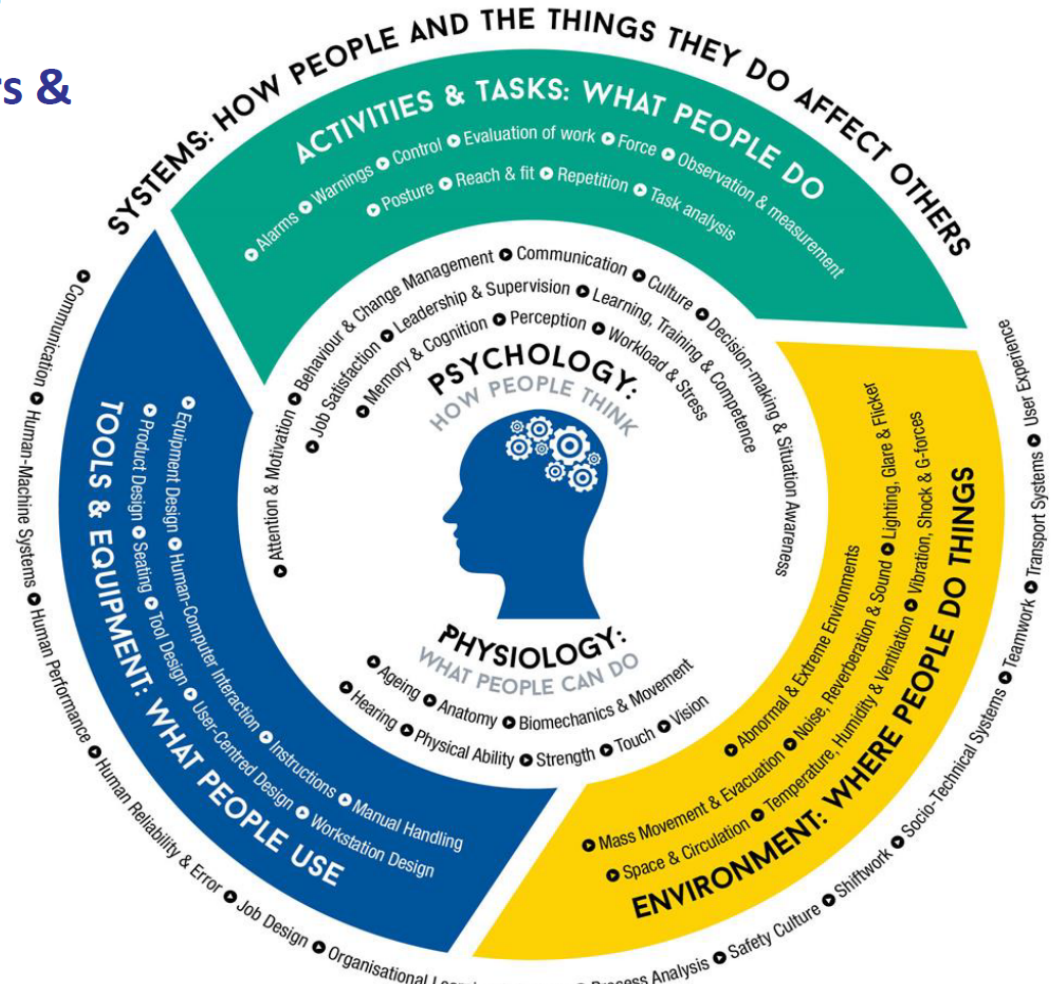
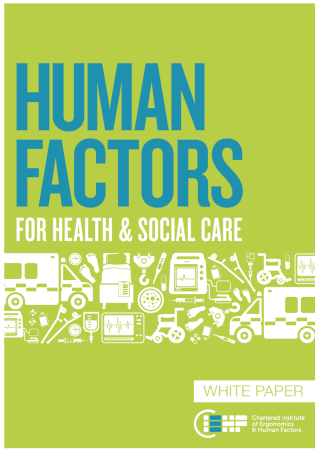
Using a broad definition of Human factors & ergonomics





Royal College of Art
THE HELEN HAMLYN CENTRE FOR DESIGN

chfg

Key changes - increased traceability of devices

NHS Improvement

Eudamed will be expanded – collating information on multiple pre- and post-market aspects

Increased focus on identification and traceability through a mandatory unique device identifier (UDI) that will be placed on all device labels

SCAN4SAFETY
Patient. Product. Place. Process.

For devices other than class III implantable devices, health institutions will need to store and keep the UDI of the devices with which they have been supplied

Patients with implantable devices will receive implant cards linking the device with their identity

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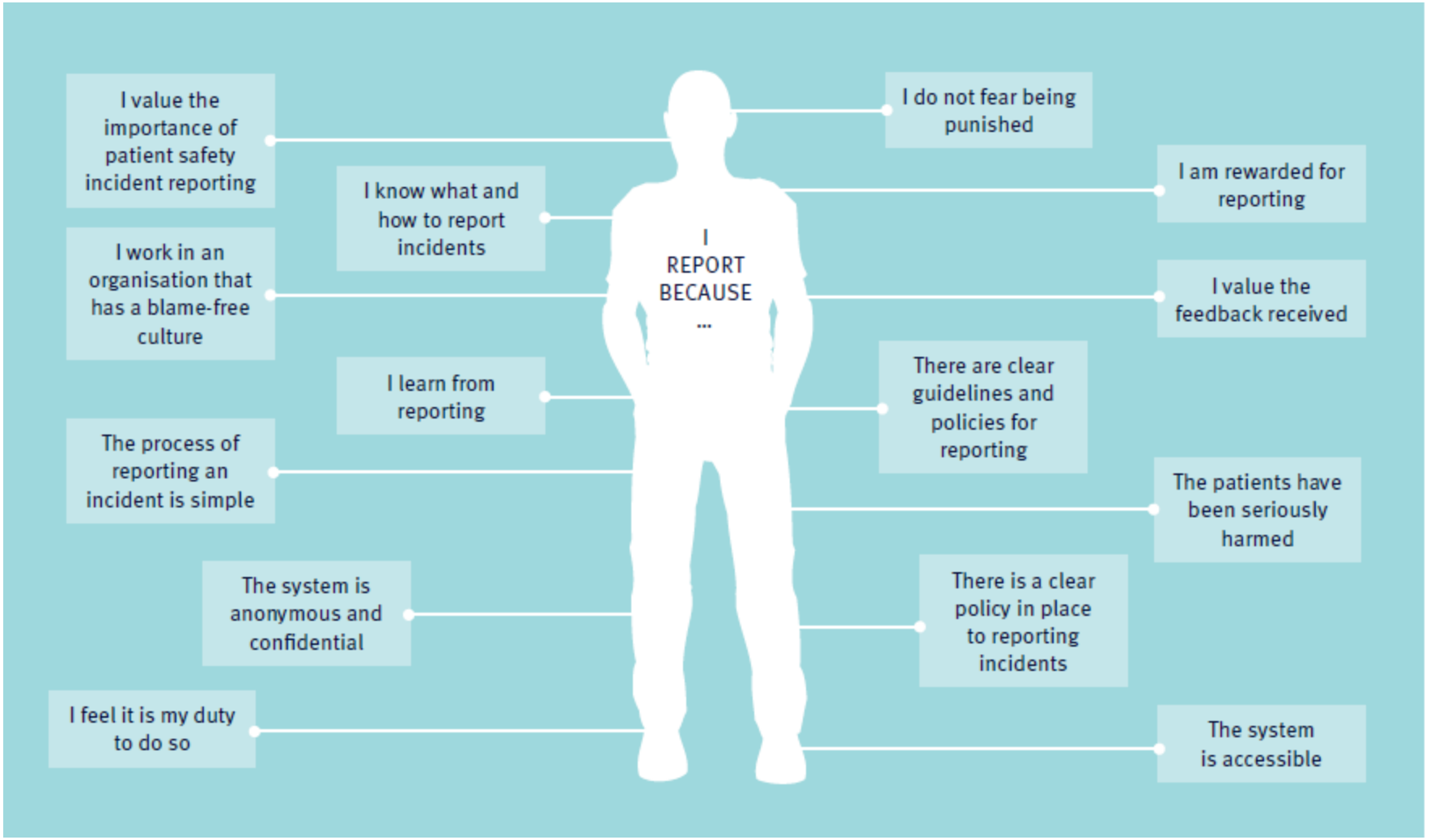
We want to support the NHS to become a system devoted to continuous learning and improvement of patient safety.

Increasing our understanding of what goes wrong in healthcare

Enhancing the capability and capacity of the NHS to improve safety

By tackling the major underlying barriers to widespread safety improvement


I value the importance of patient safety incident reporting
I know what and how to report incidents
I work in an organisation that has a blame-free culture
I learn from reporting
The process of reporting an incident is simple
The system is anonymous and confidential
I feel it is my duty to do so
I REPORT BECAUSE ...
I do not fear being punished
I am rewarded for reporting
I value the feedback received
There are clear guidelines and policies for reporting
The patients have been seriously harmed
There is a clear policy in place to reporting incidents
The system is accessible


I DO NOT REPORT BECAUSE ...
Cause of incident is already clear
Reporting process is too complicated
Fear of negative response by co-workers
Unaware of whose responsibility it is to report
Additional administrative task
Lack of anonymity and confidentiality
No major patient consequences
Incident has already happened before and has already been reported
Too time-consuming
Workload
Incident was not preventable
Not a priority
Fear of viewed as incompetent by colleagues
Lack of belief that reporting system will lead to a change
Interrupts work process
Incident unlikely to happen again
Fear of punishment
Lack of clear definition of what to report
Fear of disciplinary action
Lack of feedback

Development of the Patient Safety Incident Management System

"a single port of call for recording, accessing, sharing and learning from patient safety incidents, in order to support improvement in the safety of NHS-funded services at all levels of the health system".

Introducing DPSIMS

The DPSIMS project offers an opportunity to use modern technology to improve the health service for patients and carers, healthcare staff, NHS organisations and decision-makers, so that time and energy can be invested in the right things: **working to reduce harm**.

DPSIMS's overarching vision statement:

"a single port of call for recording, accessing, sharing and learning from patient safety incidents, in order to support improvement in the safety of NHS-funded services at all levels of the health system".

Rationalise NRLS & STEIS

Direct and via LRMS

Review and update

Both with national team, and with peers

Data analytics, free text analysis, collaborative insight building

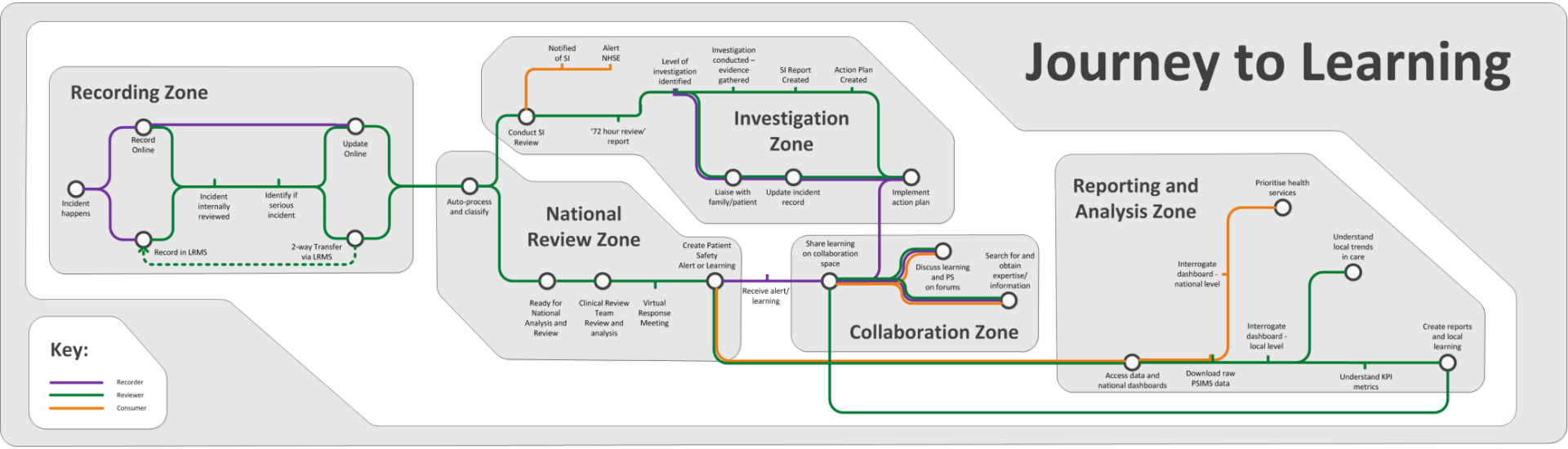
More and better resources and feedback

Less Acute-centric: works in GP, dentistry care homes, community, LA care etc

But not excluding private providers

'True incidents', plus unexpected poor outcomes, and risks

What will PSIMS offer?



5 main "zones" of functions to support NHS Improvement's statutory patient safety duties:

- *To collect and analyse information about what goes wrong in the NHS*
- *To provide advice and guidance on reducing the risks to patients...*
- *To help providers better understand what goes wrong in care*
- *To support increased transparency around patient safety data*

(NHSI 2017-19 Business Plan)

High level plan

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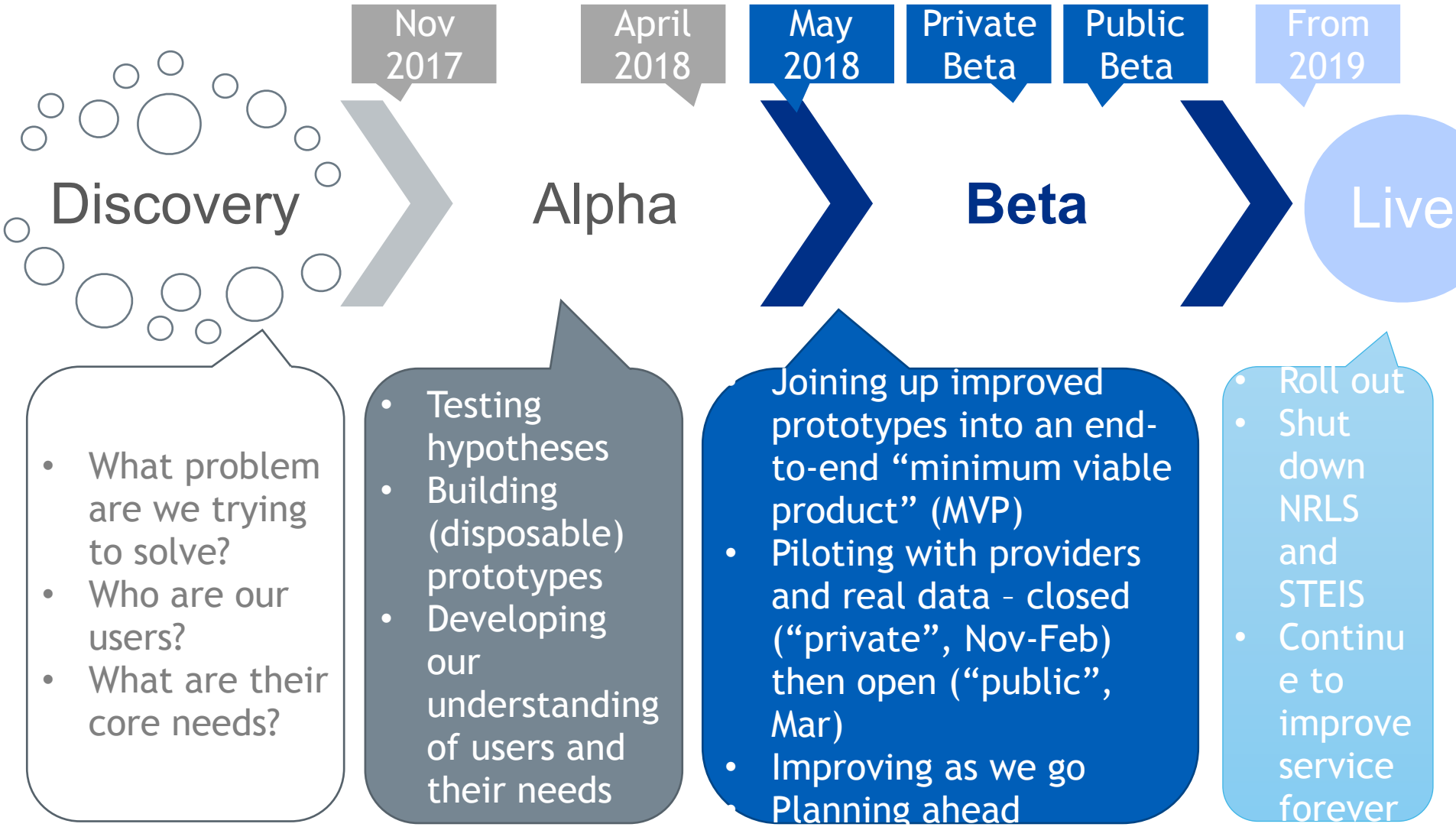

A single system for all National Patient Safety Alerts



NHS Improvement

MHRA summit for UK partners January 2018

"Many national bodies in England, Scotland, Wales, Northern Ireland, or those with a UK-wide remit, issue communications to the healthcare service asking for action to be taken to protect patient safety. These may be called alerts, bulletins, messages, notices or go by other names, and may be issued via the Central Alerting System or alternative systems, including in the devolved nations"

Many different styles

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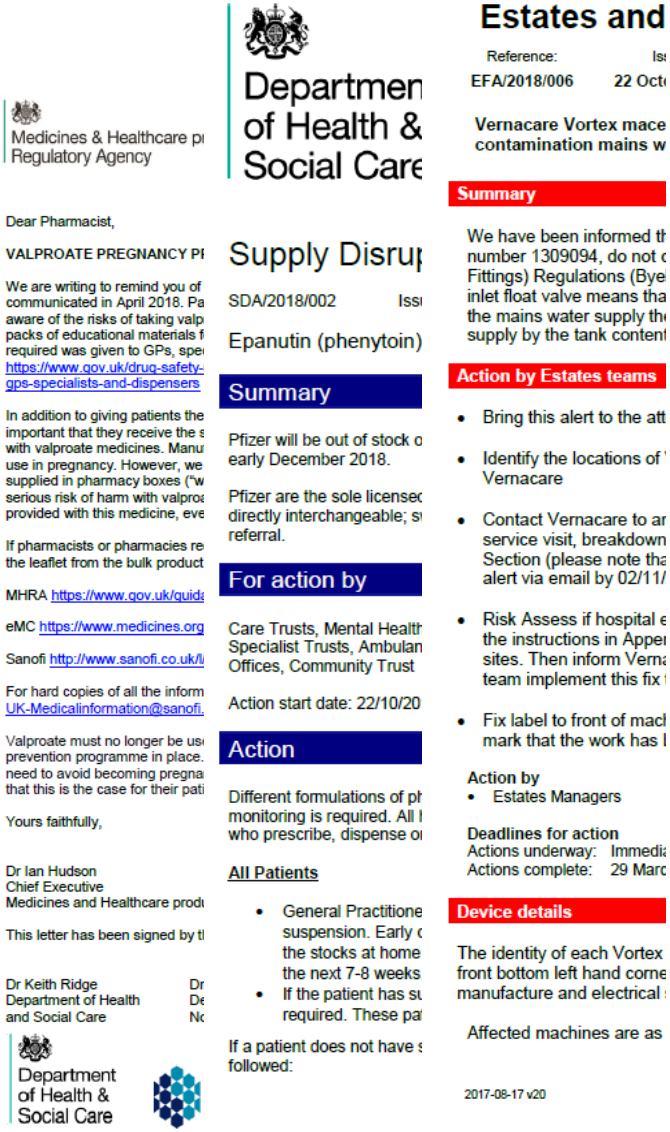


Medicines & Healthcare pr
Regulatory Agency

Dear Pharmacist,

VALPROATE PREGNANCY PI

We are writing to remind you of
communicated in April 2018. Pa
aware of the risks of taking valp
packs of educational materials f
required was given to GPs, spe
https://www.gov.uk/drug-safety-
gps-specialists-and-dispensers

In addition to giving patients the
important that they receive the s
with valproate medicines. Manu
use in pregnancy. However, we
supplied in pharmacy boxes ("w
serious risk of harm with valproa
provided with this medicine, eve

If pharmacists or pharmacies re
the leaflet from the bulk product

MHRA https://www.gov.uk/guida

eMC https://www.medicines.org

Sanofi http://www.sanofi.co.uk/l

For hard copies of all the inform
UK-Medicalinformation@sanofi.

Valproate must no longer be us
prevention programme in place.
need to avoid becoming pregna
that this is the case for their pati

Yours faithfully,

Dr Ian Hudson
Chief Executive
Medicines and Healthcare produ

This letter has been signed by tl

Dr Keith Ridge
Department of Health
and Social Care

Dr
De
Nc

Department
of Health &
Social Care

Departmen
of Health &
Social Care

Supply Disrup

SDA/2018/002 Issu

Epanutin (phenytoin)

Summary

Pfizer will be out of stock o
early December 2018.

Pfizer are the sole licensec
directly interchangeable; s
referral.

For action by

Care Trusts, Mental Health
Specialist Trusts, Ambulan
Offices, Community Trust

Action start date: 22/10/20

Action

Different formulations of ph
monitoring is required. All
who prescribe, dispense o

All Patients

- General Practitione
  suspension. Early
  the stocks at home
  the next 7-8 weeks
- If the patient has su
  required. These pa

If a patient does not have s
followed:

Estates and

Reference: Is
EFA/2018/006 22 Oct

Vernacare Vortex mace
contamination mains w

Summary

We have been informed th
number 1309094, do not
Fittings) Regulations (Bye
inlet float valve means tha
the mains water supply th
supply by the tank content

Action by Estates teams

- Bring this alert to the att
- Identify the locations of
  Vernacare
- Contact Vernacare to ar
  service visit, breakdown
  Section (please note tha
  alert via email by 02/11/
- Risk Assess if hospital e
  the instructions in Appe
  sites. Then inform Verna
  team implement this fix
- Fix label to front of macl
  mark that the work has

Action by
- Estates Managers

Deadlines for action
Actions underway: Immedia
Actions complete: 29 Marc

Device details

The identity of each Vortex
front bottom left hand corne
manufacture and electrical

Affected machines are as

2017-08-17 v20

Medicines & Healthcar
Regulatory Agency

Date: 05 October 2018

Dear Healthcare Professional,

Allergan Pharmaceutic

Ozurdex 700 microgram
applicator

(Dexamethasone)

Batch Number	
E76937	
E77093	
E77113	
E77331	
E77512	
E78167	
E78897	
E79233	
E79272	
E79467	
E79891	
E80684	
E80824	
E81080	
E81350	
E82127	
E82509	

- Allergan Pharmaceutica
  single loose silicone pa
  from the needle sleeve
  along with the implant.
- Additional testing has sl
  defective units but defec
- Batches on the market
  available. However defe
  once sufficient defect fre
- A Dear Healthcare Profe
  see attached.

EL (18)A/16

Classification: Official

NHS Improvement

Patient Safety Alert

Resources to support safe and timely management of hyperkalaemia (high level of potassium in the blood)

8 August 2018

Alert reference number: NHS/PSA/RE/2018/006

Resource Alert

Potassium is essential for the body's normal function, including maintenance of normal heart rhythm. The way the body responds to hyperkalaemia – a higher than normal level of potassium in the blood – is unpredictable; arrhythmias and cardiac arrest can occur without warning. Hyperkalaemia can affect patients in hospital and being cared for at home.

Hyperkalaemia is a potentially life-threatening emergency which can be corrected with treatment.[1]

Over a recent three-year period, the National Reporting and Learning System (NRLS) received 35 reports of patients suffering cardiac arrest while hyperkalaemic. These suggest that some healthcare professionals may not appreciate that clinical assessment, treatment and ongoing monitoring of hyperkalaemia is time critical.

Typical extracts from incident reports read:

"the patient had a raised potassium which required treatment and [a member of staff] apparently stated that the day team could deal with it."

"[Treatment for hyperkalaemia] was prescribed and administered at approx 16:30; however, no further review of the patient was undertaken and no repeat treatment or bloods were done until the patient arrested at 09:26."

Review of local guidance to manage hyperkalaemia found some examples that were not evidence-based, and/or were not written in a way that was easy to follow during an emergency.

This alert signposts to resources on the NHS Improvement website that can help organisations ensure their clinical staff have easily accessible information to guide prompt investigation, treatment and monitoring options. The resources include an example of how hospitals could make this easier for their staff by pre-preparing sets of the equipment, guidance and medication they would need in an emergency.

The resource webpage also includes short videos organisations can use to help frontline staff recognise that hyperkalaemia is a medical emergency and encourage them to familiarise themselves with local guidance and equipment.

Sharing resources and examples of work

If there are any resources or examples of work developed in relation to this alert you think would be useful to others, please share them with us by emailing patientsafety.enquiries@nhs.net

Actions

Who: All organisations providing NHS funded-care for adults or children where blood test results may be received and reviewed, including GP services*

When: To begin as soon as possible and be completed by 8 May 2019

1. Identify a senior clinician in the organisation to lead the response to this alert
2. Review or produce local guidance (including key steps or easy reference guides) for the management of hyperkalaemia that aligns with the evidence-based sources highlighted in the linked resources
3. Ensure that local guidance can be easily accessed by all staff including bank and agency staff
4. Ensure relevant guidance and resources are embedded in clinical practice by revising local training and audit
5. Use local communication strategies (such as the videos, newsletters, local awareness campaigns, etc) to make all staff aware that hyperkalaemia is a potentially life-threatening emergency and that its timely identification, treatment and monitoring during and beyond initial treatment is essential

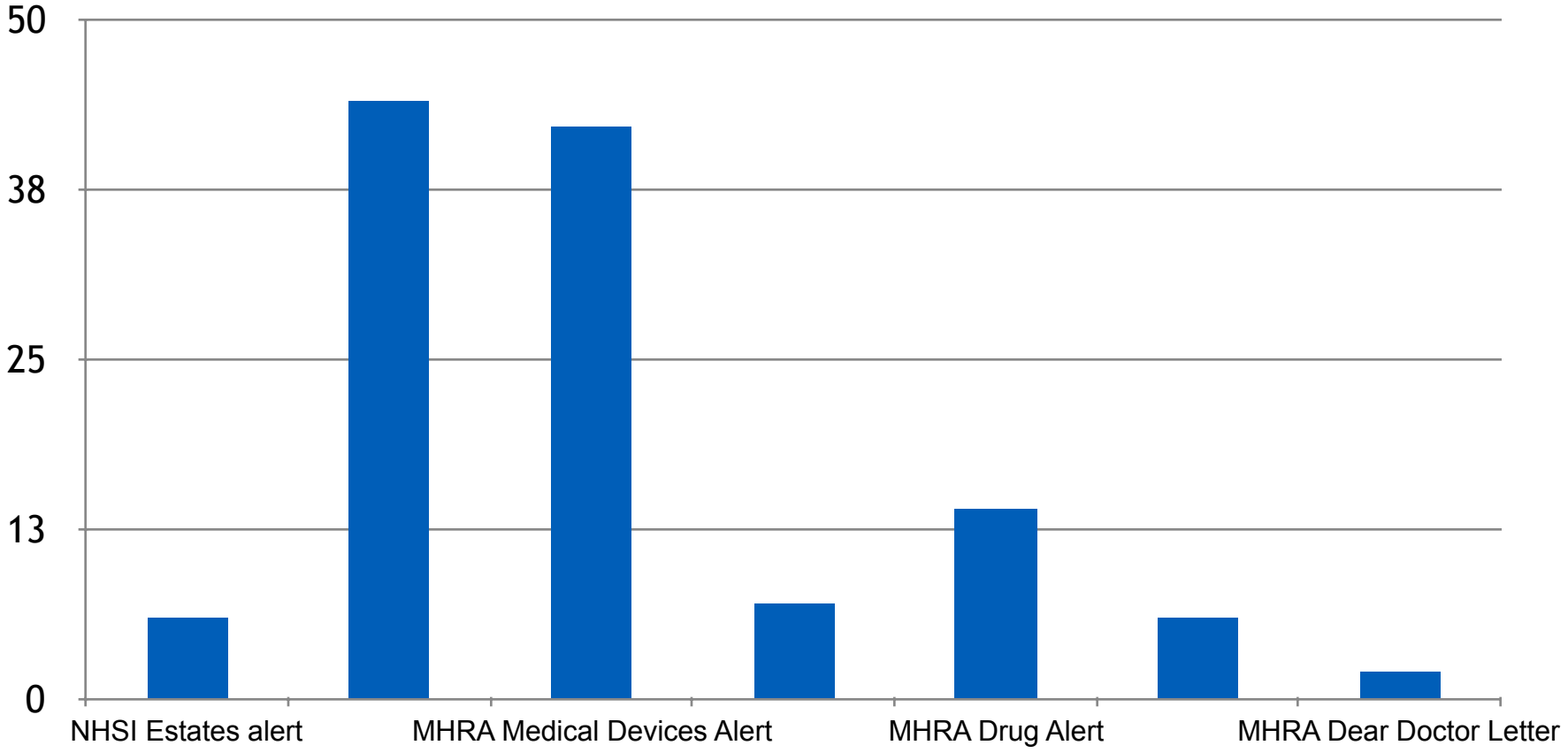
*While general practices will not need hyperkalaemia treatment protocols or equipment, they will need to ensure they implement all actions that will support the right response to any blood test results they receive indicating hyperkalaemia.

Patient Safety
improvement.nhs.uk/resources/patient-safety-alerts

See page 2 for resources, references and advice on who this alert should be directed to.

NHS Improvement (August 2018) Contact us: patientsafety.enquiries@nhs.net Publication code: IT 10/18

Types/numbers of some safety communications sent via CAS



NHS Improvement

Issues:

- Feeling overwhelmed by communications (many local/regional)
- Tradition/custom and practice (from some decades past)
- Assumption alerts intended to warn individuals to try harder not to make mistakes leading to 'circulate and sign' approach
- Delegation to multiple units to act rather than coordinated efforts
- Not always on executive/senior/clinical leadership radar
- Alerts signed off as action completed without actions completed

What people wanted:

- Create a clear distinction between **requirements for organisational action by a specific date (NHSI leading)** and **messages conveying information for individuals to read and remember (MHRA leading)**
- Consistency of presentation of key content including clear actions
- Highlight those that need board/leadership involvement
- Issue fewer of them, to increase focus on those that matter (but also noting issues they felt should have been alerts not letters/

National Patient Safety Alert Committee

- The Committee will establish criteria to help NHS safety bodies give appropriate ‘national alert’ status to risks of death, disability or other serious harm. In turn this will make it easier for trusts, GPs and other NHS providers to understand when they need to coordinate urgent action to protect patients.

- The new National Patient Safety Alert Committee will agree common standards for those that require an immediate or co-ordinated response by providers.

- In future, an alert that requires complex action and organisational leadership will stand out.

Minister of State for Care Caroline Dinenage said:

"All NHS staff want to keep their patients safe and we will do our utmost to support them. The establishment of a National Patient Safety Alert Committee is another important intervention to ensure the NHS is supported to recognise, understand and implement the key steps that will reduce the risk of future tragedies - continuing our drive to making the NHS the safest healthcare system in the world."

The Committee will be chaired by National Director of Patient Safety Aidan Fowler with Chief Inspector of Hospitals Ted Baker as deputy chair.

The Care Quality Commission will also monitor compliance with specific National Patient Safety Alerts as appropriate during their inspections with plans to roll out the current pilot approach to Trusts in the Autumn.

We've all been working on it

National Patient Safety Alert Committee

- All Alert issuers represented at highest levels + CQC
- Draws from past experience of accreditation for clinical guidelines (e.g. NICE and Royal College guidance) – *multiple issuing bodies, but users can trust 'kite marked' clinical guidance*
- Common standards, thresholds and formats to be mutually agreed (we're getting there) confirmed and maintained - *including an inherent need to set thresholds at a level that reduces overall numbers*
- 'Credentialing' is authorisation for the issuing body/team to designate a specific publication as a **National Patient Safety Alert** when these common standards are met - *not an extra committee approval stage for individual alerts*
- We've got consensus on principles, aiming to establish by late 2018

MEDICAL DEVICE SAFETY

MHRA
Regulating Medicines and Medical Devices

chfg

NAMDET

NHS Improvement

Yellow Card

bsi.

Sign up to SAFETY

NHS Collaborative Procurement Partnership

avma
action against medical accidents

ISO

PATIENT SAFETY FIRST

HSIB
HEALTHCARE SAFETY INVESTIGATION BRANCH

abhi

Department of Health & Social Care

NHS Improvement
National Reporting and Learning System

MHRA

NHS England

Patient Safety Alert

Stage Three: Directive
Improving medical device incident reporting and learning
20 March 2014

Alert reference number: NHS/PSA/D/2014/006 Alert stage: Three - Directive

Care Quality Commission

The AHSN Network

NHS England

NHS Innovation Accelerator

or design it, or at the very least, **influence** it!