Clinical Harm in DESP

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With great thanks to Sarah Meredith …

Introduction

- What is clinical harm?
- Harm in screening
- Harm in Diabetic Eye Screening
- What is a clinical harm review?
- Communication inc Duty of Candour

Quality assurance (QA)

the process of checking that national standards are met (ensuring that screening programmes are safe and effective) and encouraging continuous improvement

eg maximising benefit and minimising harm

What is Clinical Harm?

Categories of Clinical Harm

Definitions of Harm 18 week RTT pathway

- **Severe**

  Irreversible progression of disease

  Death on the waiting list from index condition
- **Moderate**

  Increase in symptoms

  Increase in medication or treatment
- **Low**

  Prolongation of symptoms

Definitions of Harm

Serious incident framework | NHS Improvement

severe harm

permanent lessening of bodily, sensory, motor, physiological or intellectual functions

moderate harm

harm that is significant so that it requires a moderate increase in treatment and harm that is significant but not necessarily permanent

prolonged psychological harm

a minimum of 28 continuous days

Clinical harm is caused by the incident rather than the disease/condition

What incidents cause harm in screening?

safety incidents

serious incidents

Outcomes of Screening incidents

any unintended or unexpected incident(s)

- acts of commission
- acts of omission that occur in the delivery of an NHS screening programme

that could have or did lead to harm to

- one or more persons participating in the screening programme
- to staff working in the screening programme
- or because one or more persons eligible for screening are not offered screening

What makes harm caused by screening different?

- apparently minor local incidents can have a major service impact due to the large number of people screened
- if the problem is widespread in other local screening services there can be an impact on the population and screening can do more harm than good
- incidents often affect the whole screening service not just the local department or provider organisation in which the problem occurs
- incidents may involve several organisations across geographical boundaries
- local incidents can affect public confidence in screening services in other areas

Due to the public interest in screening, the likelihood of adverse media coverage with resulting public concern is potentially high even if no harm occurs.

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Breast cancer

The computer glitch that led to 450,000 cancelled breast screenings

Health secretary says women in England will have died as a result, but some experts say it is wrong to call it a disaster

Have you been affected?

Sarah Boseley *Health editor*

Wed 2 May 2018 19.18 BST

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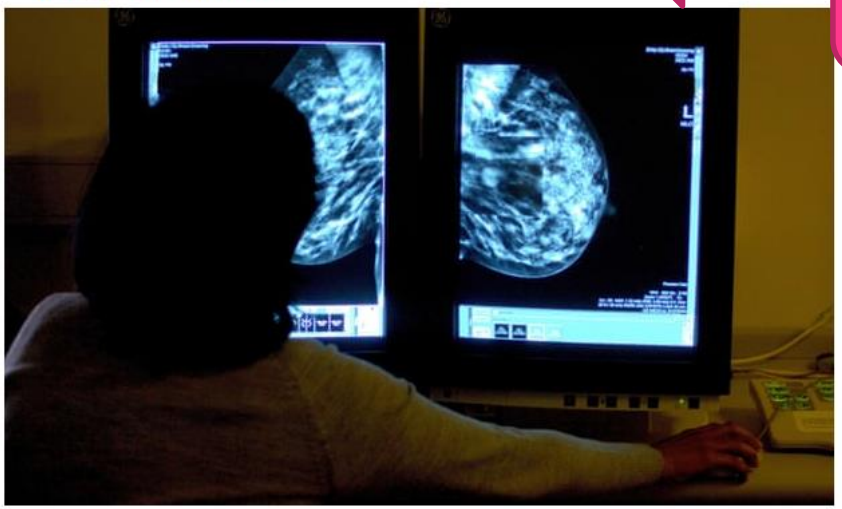

▲ The AgeX trial was set up to test whether cancers could be usefully picked up, without undue harm, in those aged 47 to 49 and those aged 71 to 73. Photograph: Rui Vieira/PA

Up to 450,000 women in England were not called for their last mammogram before they turned 70 because of a computer failure that goes back to 2009,

Big numbers

High visibility

So, can we begin to define harm in DESP?

But remember where we started….

harm must be caused by the incident rather than the disease/condition

Difficulties diagnosing harm in DESP

- How much loss of vision represents a loss of function?
- Is this loss due to delayed treatment?
- Would loss have happened anyway?
- Risks of treatment for asymptomatic disease eg PRP laser can cause field loss
- Significantly more treatment?
- Harm due to screening incident or poor diabetic care?
- Quantifying reputational losses

What helps us to define harm in DESP?

- Facts of the incident
- Data eg uptake decreasing
- Factual measurements eg visual Loss
- Clinical Opinion – was more treatment needed?
- Clinical Opinion eg – what would have happened if….?

"Historically, in diseases of the macula, because of disease progression, efficacy outcomes primarily analysed the "*avoidance of VA loss*" *as the* proportion (%) of subjects with "loss of <15 letters";

no loss (i.e. ± 5 letters) was relevant and of clinical benefit to the patient."

Definition of a serious incident in DESP that could cause harm

- An unintended occurrence that could have, or did, lead to an adverse outcome that seems to have been caused by the incident rather than diabetic retinopathy
- And the adverse outcome was a loss of function or significantly more treatment that wasn't likely to have been needed by the retinopathy otherwise
- Or an event that could be adversely affecting a lot of people
- Or a minor event that could be present in a different programme and have worse outcomes there

Clinical Harm Reviews

You've declared a 'serious incident'
You think that there may have been 'harm' .....

What about a clinical harm review?

When may a clinical harm review be useful?

- We have an area of concern
- The area of concern has been reported as a serious incident potentially causing harm
- We need to assure ourselves, patients, patient groups, commissioners, the public as to whether anybody has been harmed

Purpose of a clinical harm review

- Can harm be avoided by identifying those at risk?
- Has anyone already come to harm?
- What needs to be actioned?
- What can be learnt?

The bit before the review starts is really important

- Secure really senior sponsorship
- Engage stakeholders early when the serious incident is first identified
- Find a suitable chairperson
- Who are going to be the members of the advisory group –consider inviting an external expert
- Write the terms of reference

First meeting

- Identify project support resource
- Clarify if this is to be incorporated into existing quality review mechanisms or a standalone process
- Have a communications strategy
- Stress a focus for the group discussions is quality rather than performance
- Agree a completion point if possible

Action plan

- Define the cohort of people at risk of harm (case definition)
- Identify the individuals at risk (prioritisation)
- Set up a secure database
- Decide on the action to take for the individuals identified as affected –for example in screening that may be a decision about who is recalled for screening
- SQAS regional team member is a resource to provide impartial advice at all stages

After the review

- Write up your reflections
- Write up lessons learned
- Share learning

Don't forget to communicate!

- No such thing as overcommunication
- Communication is key in a harm review
- A communications lead with experience of handling incidents and dealing with national and local media should be part of the incident team from the start and have a strategy
- Public Health England will provide expert advice for the specific screening programme to support the communications plan
- Staff working in the programme and GPs must be kept informed and supported so they can answer questions from the patients

Duty of Candour

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and in the NHS standard contract

Health care providers have a duty of candour.

Providers should inform and apologise to the service users harmed

The duty criminalises NHS bodies that fail to notify and apologise to their patients for incidents that have caused them harm

Health care providers should encourage their staff to report quality concerns so that action is taken to reduce risks and improve the service

Duty of Candour

- For all those with moderate, severe, and prolonged psychological harm
- Best face to face
- AND has to be in writing as well
- Engaging the patients GP has been highlighted as very helpful by external review panels

Duty of candour

- For the duty to apply the investigation has to have reached the point when the individuals affected are known
- Providers should be able to show they have undertaken due diligence in assessing how the duty of candour applies to each serious incident
- Seek legal advice where necessary
- Individuals affected should be told
  - the facts
  - the further enquires that are being carried out
  - receive an apology in person that is confirmed in writing

More help…..

External Clinical Harm Review Handbook

Version number: 5

First published: 14 March 2016

Dr Henrietta Hughes

Public Health England. Managing safety incidents in NHS Screening Programmes. 2015

www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes NHS England.

National serious incident framework March 2015

Serious incident framework | NHS Improvement

Public Health England. NHS Screening Programmes guidance on applying duty of candour and disclosing audit results. September 2016

NHS screening programmes: duty of candour - GOV.UK

Thankyou

Thankyou