



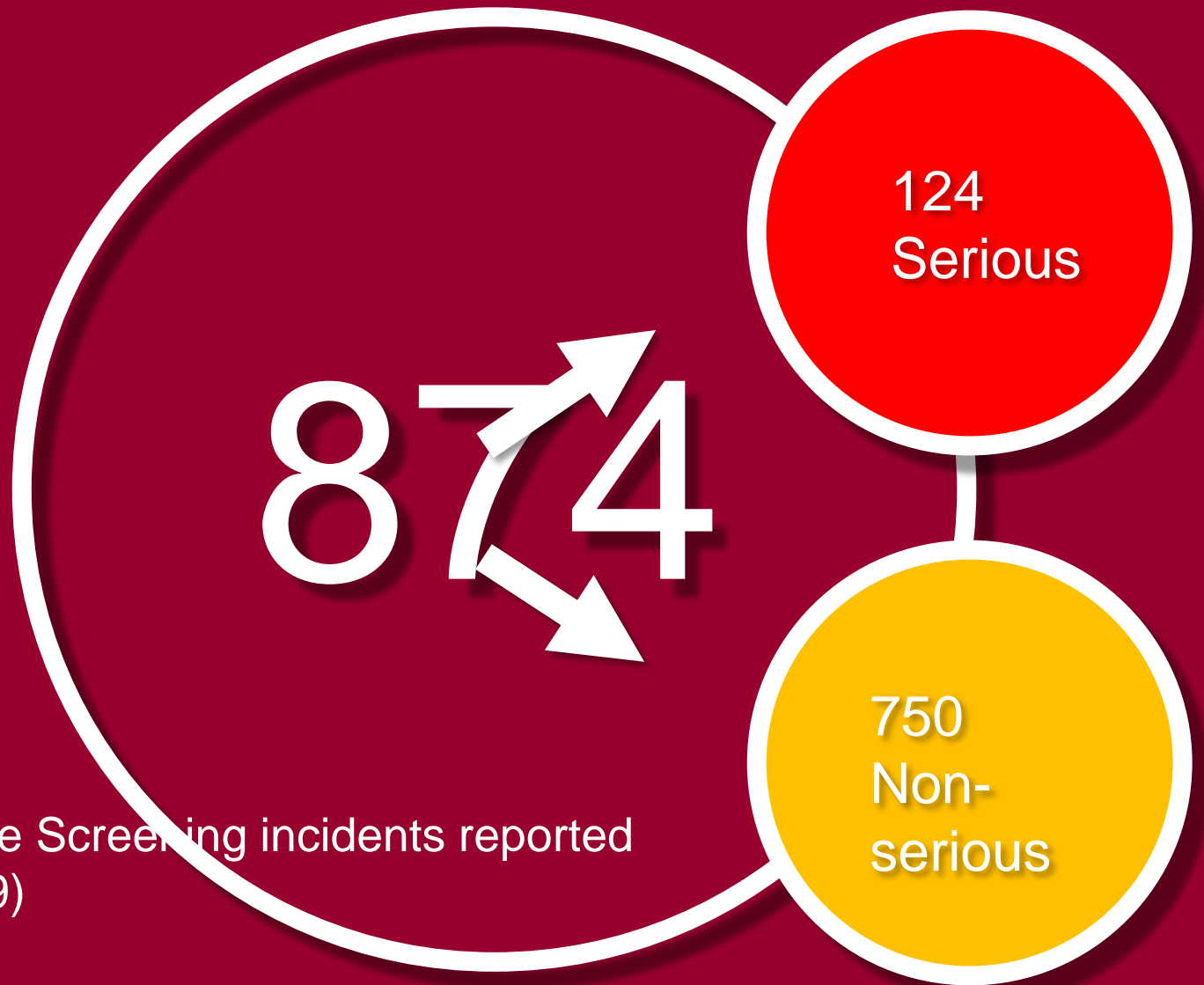
Public Health
England



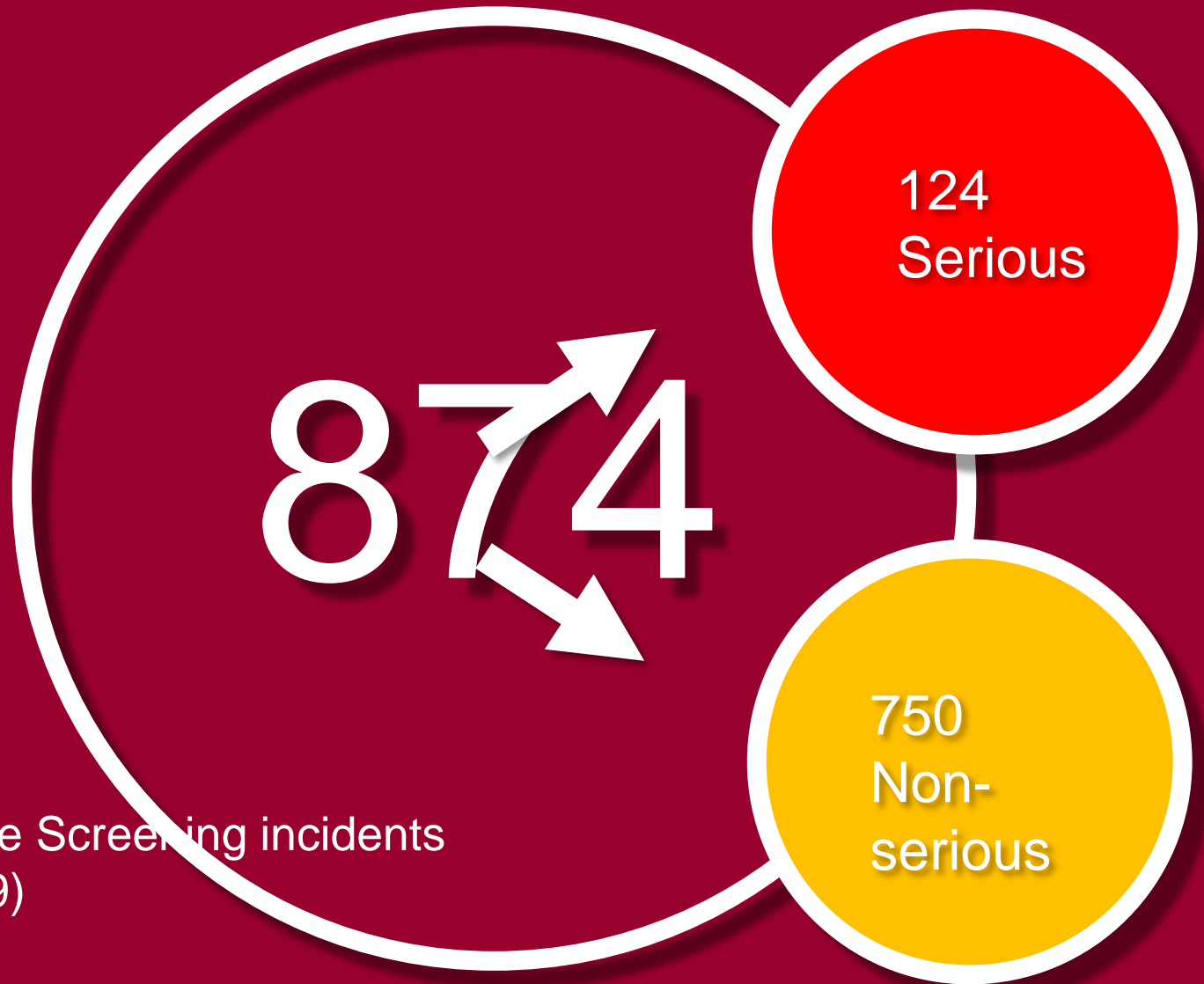
Failsafe

A quality assurance (QA) perspective

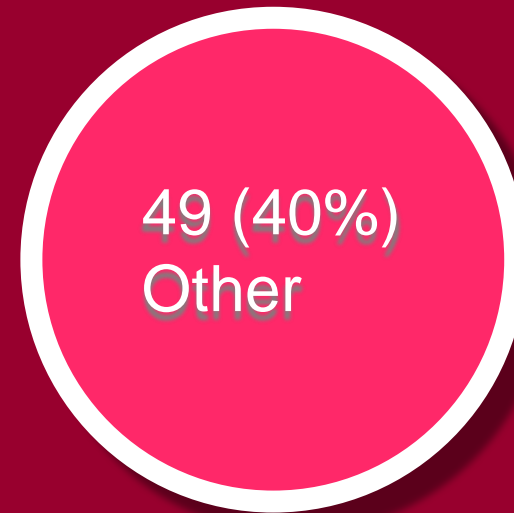
Public Health England leads the NHS Screening Programmes



Diabetic Eye Screening incidents reported
(Since 2009)



Diabetic Eye Screening incidents
(Since 2009)





75 (60%)
Failsafe

Issue	No	%
Single Collated List (SCL)	28	37.4%
Other pathway issues	27	36.0%
HES Feedback	18	24.0%
Re-procurement	2	2.6%



...at least 20% of all
incidents relate
to failsafe



Why is failsafe important?

“The value of a screening programme will be diminished if appropriate action is not always taken to ensure that the right people are invited for screening or if the necessary action is not taken on follow-up people with abnormal test results.”



Failsafe: NHS Diabetic Eye Screening Programme guidance

What is failsafe?





“...a system or plan that comes into operation in the event of something going wrong or that is in place to prevent such an occurrence”



Many DES providers

Why is failsafe so difficult?



Different software systems
and lack of IT connection



Fragmented
communication of
patients



Complicated HES &
GP Interface



Guidance not clear



Letter generation

HES Interface

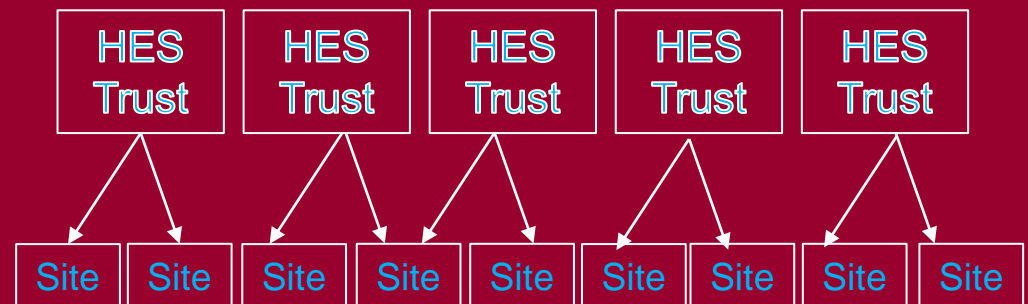
DESP



x1 HES Trust

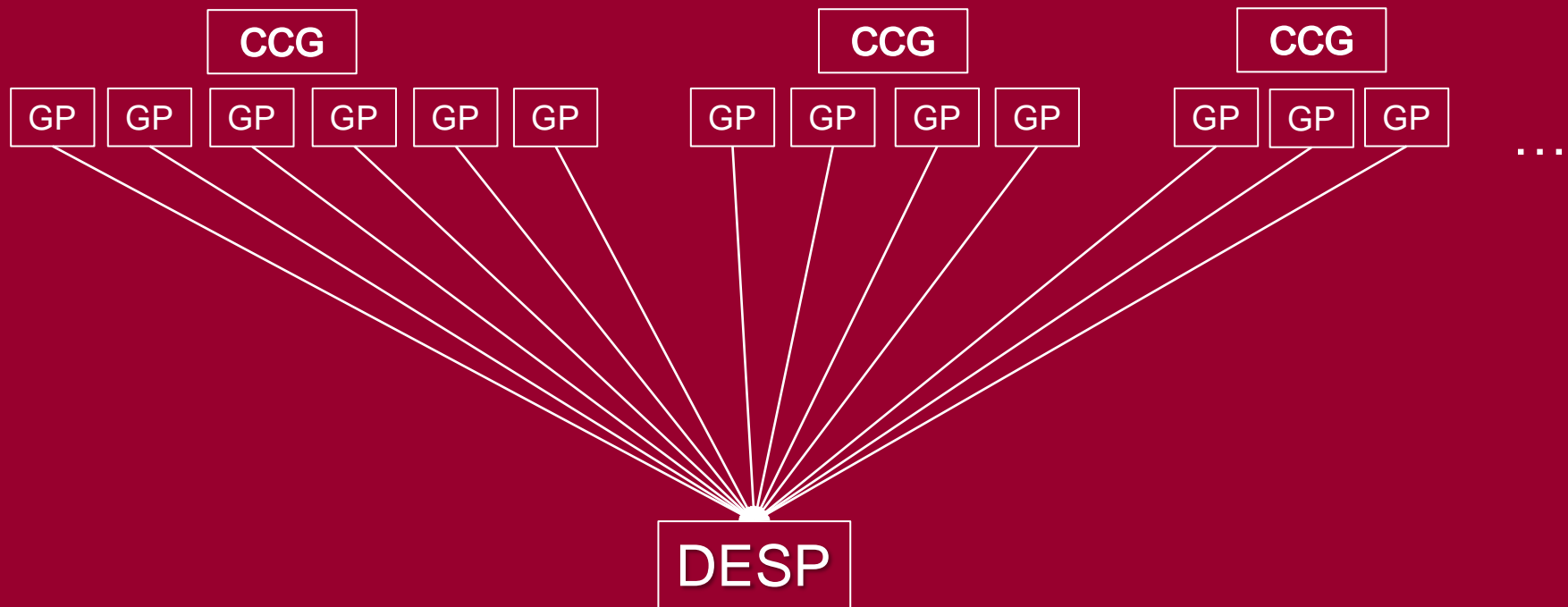
Even better if the
DESP & HES are the
same Trust (in theory)

DESP



...some prefer fax, others email, others letters etc.

GP Interface



Different extraction process for different providers (e.g. manual, electronic, fully automated)

GP Interface

...and for different GPs:

- 'Please give us a list of your diabetic patients'
- MIQUEST (some run by GPs, other by centralised commissioning IT systems)
- Electronic systems such as GP2DRS, Spectra etc.

Commissioning

NHS England –
Regional
Commissioners

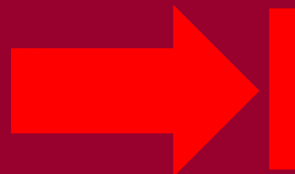


DESP

Clinical
Commissioning
Groups



HES & GPs



...QA visit reports cannot make
recommendations to address quality
issues within HES

Quality issues in associated services

Issues with primary care (GPs) & secondary care (HES) will be addressed by CCGs

Issues are escalated via local Screening and Immunisation teams (SITs)

SITs will support the development of improved interfaces between DESP & these services

- Failsafe will vary in complexity between DESP providers

- Accountability & responsibility will vary between DESP providers

What does this mean for QA?

- Levels of assurance that failsafe processes are in place will also vary between DESP providers



As a QA team, it is our job to seek assurance that there are no gaps in process.

- ...and we do this by questioning in detail every step taken

Group work #1

Become a QA advisor



Scenario #1

“A patient is screened, graded and identified as referral. The referral letter is printed and either put in the post or faxed to HES, depending on the treatment centre. The HES is contacted two weeks later to check if the patient attended.”

- What additional questions would you ask?
- What are the immediate concerns with each statement?
- What are the risks/gaps in process?
- How could they mitigate the risks?

Scenario #2

“A DESP provider refers into a single treatment centre which is within the same Trust and building as their own service. When a ROG grader sign off a referral, the results letter is printed and the batch of referrals from each ROG grading session is taken, by hand, to the HES consultant’s secretary for an appointment to be booked. Several consultants receive these referrals”

- What additional questions would you ask?
- What are the immediate concerns with each statement?
- What are the risks/gaps in process?
- How could they mitigate the risks?

Key aspects of failsafe

- It is a backup mechanism to ensure that any errors in the screening pathway are identified and corrected before harm occurs
- Often arise from a systems/process failure, anywhere along the screening pathway, as opposed to individual error
- Requires clear lines of accountability, responsibility and oversight
- Good quality standard operating procedures (SOPs)

- Breaches in performance standards are well understood, described and action plans in place

How to assure stakeholders

- QA will always be looking for a good suite of SOPs in each programme



- To show (we hope) that the service has thought through each step of each task and has thoroughly documented each step to ensure all tasks are performed consistently
- So what is an SOP?



“A standard operating procedure, or SOP, is a set of step-by-step instructions compiled by an organisation to help workers carry out complex routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations”

*failure to comply with industry regulations,”
performance, while reducing miscommunication and*

- Stored at location where procedure performed

- Reviewed regularly to ensure procedures are in-line with

expected practice

What makes a good quality SOP?



staff who are
the delivery of the

detail ensure each task is performed



accurately

- Have been tested to ensure the steps are not misinterpreted or that steps are missing
- That measures are in place to ensure all staff have read the SOPs necessary for their role

Group work #2



Bakewell Slice

Ingredients provided:

Self-raising flour

Plain flour

Baking powder

Caster sugar

Granulated sugar

Icing sugar

Lemon juice

Ground almonds

Raspberries

Cherries

Glace cherries

6 eggs

Flaked almonds

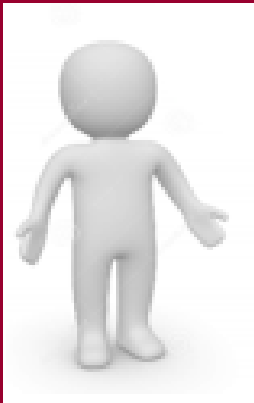
Almond flavouring

500g butter

- Preheat the oven
- Mix together the 225g flour and 110g butter until it resembles breadcrumbs. Add cold water until the mix forms a dough. Gently knead the dough and roll out to the thickness of a £1 coin.
- Grease the tin and bake the pastry blind until just golden
- Make the jam
- Once the pastry has cooled spread the jam on the pastry base
- Whisk together the 3 egg whites and set aside
- To make the frangipane mix together 110g butter and 110g sugar, add the egg yolks, fold in 50g ground almonds. Add 1tsp almond essence and 1 tsp lemon juice. Using a metal spoon mix in the egg whites a little at a time to ensure the air is not knocked out.
- Carefully spoon the frangipane on top of the jam and bake until risen and golden
- Remove from the oven and leave to cool
- Decorate the top with icing, flaked almonds and cherries.

HES Feedback

If a patient is under HES, do we have to have an RxMx grade?



Short answer....No!

So what's all the fuss about RxMx grades?

Previously used to compare retinopathy outcomes between the screening programme and ophthalmology as part of grading quality

The introduction of the ROG grader has eliminated inappropriate referrals/gatekeeping

So what's all the fuss about RxMx grades?

Each DESP must have a 'handshake' protocol to transfer duty of care patients from DESP to HES

The programme subsequently requires assurance on an annual basis as to whether the patient is continuing to be managed in HES or discharged to DESP

HES should actively provide information on this status

So what's the problem?

Many programmes are reporting issues with HES feedback, including:

- No feedback whatsoever
- No RxMx grade notation
- Partial RxMx grade notation
- Delays in clinic letters being generated (months) by HES

Possible improvements

To eliminate the need for an RxMx grade for failsafe purposes
(RxMx grades can continue to be used for grading quality)

Identify 'clinical responsibility' instead

Annual HES feedback to comprise of 'Yes/No' response:

- Yes = Remains in HES – Failsafe trigger reset to 12 months
- No = Return to screening

Incidental findings (non-DR)

Incidental findings are not within the screening programmes remit

Incidental findings should be referred to HES via the patient's GP

These cases may be managed/commissioned according to an agreed local protocol (direct referral):

- Failsafe arrangements will in consequence need to match this protocol
- Incidents occurring within this pathway are unlikely to be deemed a screening incident

Incidental findings (non-DR)

Patients remain within screening and will continue to receive annual appointments

During a Non-DR HES appointment:

- If referable DR is detected the patient is suspended from screening and post-referral failsafe applied.
- If screening occurs (criteria specific) an RxMx grade will be required by the programme and results returned for entry into the DESP database

Incidental findings (non-DR)

Non-DR pathway:

- We are aware that some DESP software systems operate a Non-DR pathway
- There was evidence that some Non-DR pathways maybe overriding DR referrals
- If both a DR referral and Non-DR referral occurs simultaneously, we would expect two referrals to be generated.
- Programmes should ensure that this is occurring

Questions & Answers



