Failsafe
NHS Diabetic Eye Screening Programme

Version 1.1   19 September 2013

About the NHS Diabetic Eye Screening Programme

The NHS Diabetic Eye Screening Programme aims to reduce the risk of sight loss among people with diabetes through the early detection and treatment, if needed, of diabetic retinopathy. Screening using digital photography is offered every year to all eligible people with diabetes in England aged 12 and over.

The UK National Screening Committee and NHS Screening Programmes are part of Public Health England (PHE), an executive agency of the Department of Health. PHE was established on 1 April 2013 to bring together public health specialists from more than 70 organisations into a single public health service.

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About this publication

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	26/6/13	Review by Pathway Group for compliance w s/w	
	26/6/13	DESP Management Team	Agreed proposed dissemination process
V0.7	27/6/13	Updated by LL	following actions from 26/6
	27/6	Sent to DT cc SC, AS	To incorporate remaining QA queries.
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V0.8	06/08/2013	Final copy needs PHE compliant template.	Review Generic failsafe text
V0.9	12/08/2013	Template change	Updated by MH and LL

| V1.0 | 22/08/2012 | Changes to generic text from ED | Updated to align with other programme failsafe guidance |
| V1.1 | 19/09/2013 | Formatting corrections | |

Review / approval

Version	Date	Requirement	Signed
1.0	22/08/2013	Final approval	S Cohen, L Lacey
1.1	19/09/13	Formatting corrections	M Harris

Contents

Failsafe

The NHS Diabetic Eye Screening Programme (NDESP) has developed failsafe processes as a back-up mechanism in addition to usual care.

These ensure that if something goes wrong in the screening pathway, processes are in place to identify:

- what is going wrong
- what action follows to ensure a safe outcome

This document describes the failsafe processes that sit alongside NDESP's Map of Medicine care pathway and an additional document produced in conjunction with the Royal College of Ophthalmologists relating to failsafe in Hospital Eye Services (HES).

Failsafe - Diabetic Eye Screening Programme

Introduction

The UK National Screening Committee (UK NSC) is developing quality assurance (QA) processes across the national screening programmes in the English NHS.

The aim of QA is to provide information to the public and professionals about the quality of screening programmes. Quality assurance and performance management are an integral part of all national screening programmes to ensure that all programmes achieve the highest possible standards. Part of this work involves the development of failsafe processes and Map of Medicine care pathways.

Further details of cross-programme QA, including the work on failsafe, can be found at http://www.screening.nhs.uk/quality-assurance

What is Failsafe?

Screening should be offered to the eligible population in a timely manner; and those who are screened should receive their results (whether positive or negative) in a timely manner with sufficient information to understand them, and have them acted on appropriately. 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 right action is not taken to follow up those with abnormal test results.

Failsafe is a back-up mechanism, in addition to usual care, to ensure that if something goes wrong in the screening pathway, processes are in place to (i) identify what is going wrong and (ii) what action follows to ensure a safe outcome.

Most risks and errors in a screening pathway can be predicted. They often arise from a systems failure along the screening pathway, as opposed to individual error. A failsafe is a mechanism to 'design out' or reduce these risks. It is a back-up mechanism, in addition to usual care, to ensure that any errors in the screening pathway are identified and corrected before harm occurs.

The Failsafe Process

Failsafe should be a 'closed loop' process. The effective monitoring of failsafe requires the point at which a required activity is commenced and the point at which it is concluded to be noted (usually through a systematic process and/or an IT system), and a system to ensure that all opened loops have been closed within an appropriate timescale.

- **Opening the loop** – a point where a process requiring a failsafe control has started; for example, the event of being diagnosed with diabetes and a subsequent referral to the diabetic eye screening programme triggers the offer of a screening test.

- **Closing the loop** – a point where a process is completed; for example, the dispatch of a letter to inform the patient that the screening test was normal.
  There may be different events that can result in a particular loop being closed; for example, a loop which is opened by something other than a negative result might be closed by a referral

- **Ensuring the loop has been closed** – a group check, to identify any individual for whom a failsafe loop has been opened but not closed within a defined timescale; for example, a systematic check that all patients on a remote clinic list have an outcome recorded on the central system after an information transfer

Implementation of Failsafe in national screening programmes

This failsafe strategy requires action at national, regional and local level. The main roles and responsibilities for each stakeholder are outlined below.

- **National**: National screening programmes have assessed the screening pathway and identified areas of high risk that require failsafe measures. Assessments have considered the probability of an error occurring and the severity of the consequence, drawing on the learning from serious incidents. Each national programme has developed a diagram superimposed on their Map of Medicine pathway(s) showing the key risks along the screening pathway.

- **Regional: R**egional teams will provide expert advice to providers and commissioners about reducing risks in local programmes. They will assess the robustness of local arrangements through audit as part of peer review, and in the investigation of any incidents that may occur. They will act as a conduit for information and dialogue between national, regional and local levels.

- **Commissioners:** Commissioners are expected to provide a service in line with the national service specification and incorporate national guidance to reduce risk and to oversee service implementation and functioning. They are responsible for ensuring
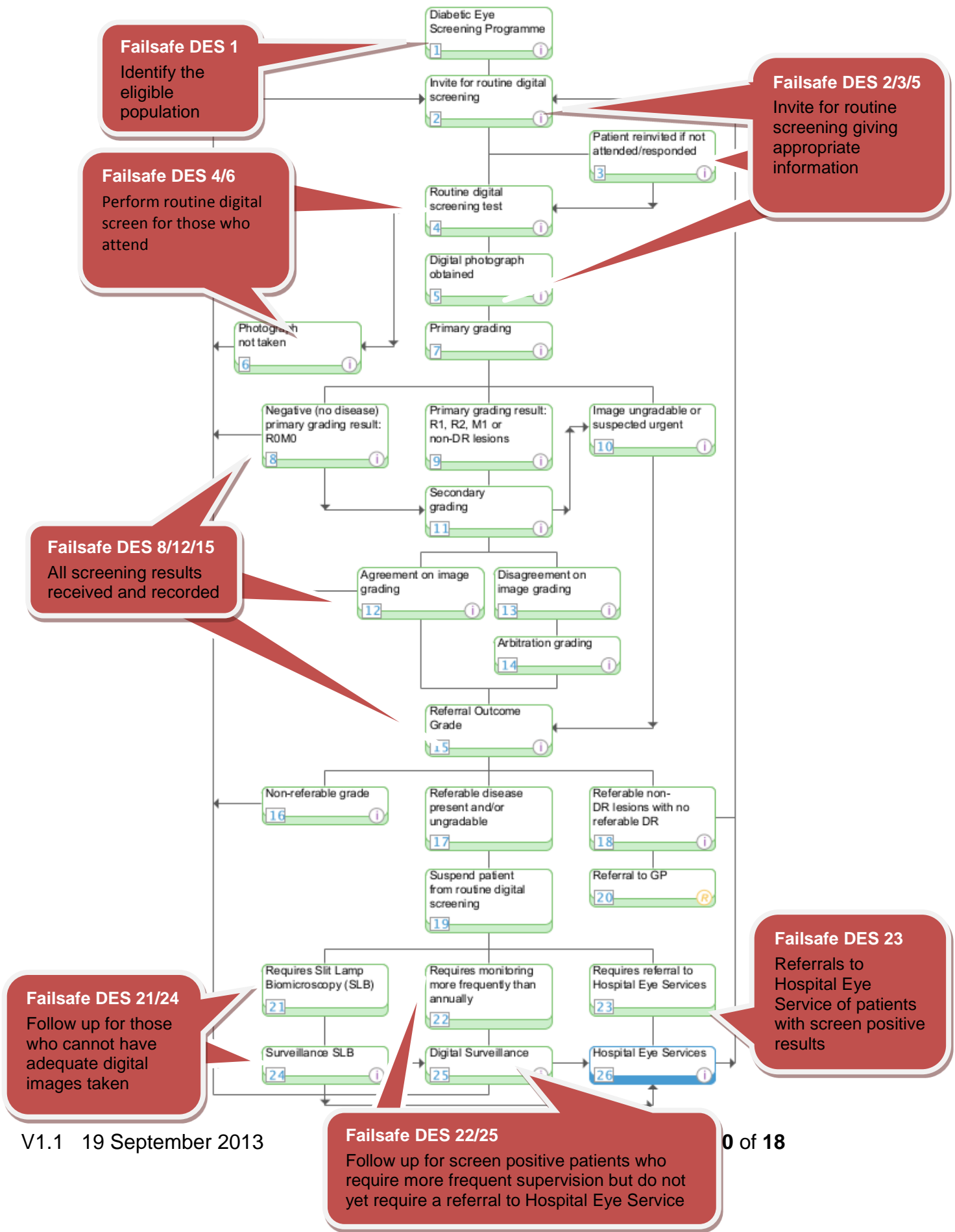
that the whole pathway is commissioned and that the elements communicate properly to ensure all failsafe processes are functioning correctly. This will require clarity about roles and responsibilities of different providers, particularly at the interfaces

- **Providers:** All providers are expected to risk-assess local pathways and work with commissioners to develop, implement and maintain appropriate risk reduction measures in line with national guidance. This should involve mechanisms to audit implementation and report incidents. Effective implementation requires routine staff training and development and may need changes to local roles and responsibilities. Provider organisations are also expected to ensure that appropriate links are made with internal governance arrangements, such as risk registers.

The Map of Medicine

Map of Medicine is a visual representation of evidence-based, practice-informed care pathways for common and important conditions. Pathways are freely available for health professionals through NHS Evidence and for the public on NHS Choices. They are also signposted from each screening programme's website and from the UK Screening Portal. They have been developed to provide accurate information on screening for health professionals and to promote safe, high quality screening services throughout the NHS.

Failsafe overview

Failsafe DES 1

Identify the eligible population

Failsafe DES 2/3/5

Invite for routine screening giving appropriate information

Failsafe DES 4/6

Perform routine digital screen for those who attend

Failsafe DES 8/12/15

All screening results received and recorded

Failsafe DES 21/24

Follow up for those who cannot have adequate digital images taken

Failsafe DES 23

Referrals to Hospital Eye Service of patients with screen positive results

Diabetic Eye Screening Programme
1

Invite for routine digital screening
2

Patient reinvited if not attended/responded
3

Routine digital screening test
4

Digital photograph obtained
5

Primary grading
7

Photograph not taken
6

Negative (no disease) primary grading result: R0M0
8

Primary grading result: R1, R2, M1 or non-DR lesions
9

Image ungradable or suspected urgent
10

Secondary grading
11

Agreement on image grading
12

Disagreement on image grading
13

Arbitration grading
14

Referral Outcome Grade
15

Non-referable grade
16

Referable disease present and/or ungradable
17

Referable non-DR lesions with no referable DR
18

Suspend patient from routine digital screening
19

Referral to GP
20

Requires Slit Lamp Biomicroscopy (SLB)
21

Requires monitoring more frequently than annually
22

Requires referral to Hospital Eye Services
23

Surveillance SLB
24

Digital Surveillance
25

Hospital Eye Services
26

Failsafe DES 22/25

Follow up for screen positive patients who require more frequent supervision but do not yet require a referral to Hospital Eye Service

Number (Node)	Failsafe Process	Owner	Activity (opening the loop- Trigger)	Process (Closing the loop – conclusion)	Failsafe - – additional checks	Reporting/ Measure
1	Identify the eligible population	GP DESP	GP practices are responsible for providing screening programme with an accurate list of patients diagnosed with diabetes. This should include timely updates in relation to newly diagnosed patients. Screening Programme identifies institutions, such as prisons, which then provide screening programme with a list of non-registered patients diagnosed with diabetes.	Programme is responsible for updating the single collated list (SCL) through actions such as adding new patients and removing deceased patients and those who have moved out of the area. The updating of patient addresses and contact details could be achieved using software mechanisms. Programme regularly updates list of non-registered patients from institutional contacts.	Programme should compare lists from GP practices with DESP database. Programmes should work with/escalate to GPs/commissioners where there is a discrepancy. Programmes should check patients are only excluded or suspended in line with national policy. Programmes should check Post Office returns, summary care record, acute trust records, Open Exeter for deceased patients and those who have moved out of the area. Follow database cleansing standard operating procedure (SOP).	QAS 1 Programme should produce a quarterly report listing differences between GP lists and DESP database to Programme Board. Programme should undertake regular audits of patients presenting with disease to symptomatic services in line with NDESP standards and guidelines.

Number (Node)	Failsafe Process	Owner	Activity (opening the loop- Trigger)	Process (Closing the loop – conclusion)	Failsafe - – additional checks	Reporting/ Measure
2/3/5	Invite for routine digital screening, giving appropriate information.	DESP	Produce a report that identifies patients due and overdue for routine digital screening. Issue invitation.	Generate invitation letter and assemble required information to be sent to patient.	Check invitation/ appointment letters match lists and number of envelopes to be posted. Check correct information leaflet is sent with invitation Have robust system to identify non responders and non-attendees, send second invitation and execute any additional local protocols.	QAS 2,17 Audit Post Office returns. Audit repeat non attendance. Audit any existing register of patients aged under 12 years to ensure they are added to the cohort of eligible patients when they reach the age of 12. Report all detected failures to invite to programme board at appropriate intervals. Where using an external provider the programme board should receive reports on these checks.

Number (Node)	Failsafe Process	Owner	Activity (opening the loop-Trigger)	Process (Closing the loop – conclusion)	Failsafe - – additional checks	Reporting/ Measure
4/6	Perform routine digital screen for those who attend.	DESP	Screener obtains verbal consent/decline and records in DESP software.	Screener ensures that standard set of retinal images are taken with informed consent and that they are attached to the correct patient record.	Ask patient to state their full name, address and DOB to check that the details match the patient record. Check database at the end of clinic to make sure that an outcome is recorded (DNA or screening test result) for the total number of listed appointments. Where images cannot be taken maintain a record/list of patients, check that the patient is returned to the administration system for repeat invitation. Refer to pathway document 'Inadequate/Adequate Images and where images cannot be taken'	QAS 3 KPI DE1 Internal QA – review reports. Ongoing performance reports. Produce a report for any appointments in the past with no outcome. Audit grading queues versus clinic appointment lists. Report all detected failures to screen to programme board.

Number (Node)	Failsafe Process	Owner	Activity (opening the loop-Trigger)	Process (Closing the loop – conclusion)	Failsafe - – additional checks	Reporting/ Measure
			Remote screening service transfers records to central system.	Ensure remote and central systems remain properly synchronised. Ensure software upgrades are applied to all computers.	Where the standard image set (two per eye) cannot be obtained, the number of images captured and an explanation should be noted in patient record. Check the number of episodes and images transferred matches the number of episodes and images on the remote system for the patients that attended.	
8/12/15	Make sure that the results are properly recorded and received by those who need them.	DESP	Images graded and final outcome grade recorded on software.	Result letter sent to patient and GP.	Check that the number of results printed and then issued to patients and GPs matches the number expected. Produce a report that identifies any appointments in the past without any outcomes.	QAS 6 KPI DE2 Report all detected failures to programme board.

Number (Node)	Failsafe Process	Owner	Activity (opening the loop- Trigger)	Process (Closing the loop – conclusion)	Failsafe - – additional checks	Reporting/ Measure
					Check all referral results letters against a timeline tracking system. Regular check of results letters to make sure they have the correct information based on the final grade. Check all grading queues daily to make sure there are no images stuck in the grading queue.	
21/24	Follow up for those who cannot have adequate digital images taken. Refer for slit lamp biomicroscopy (SLB) surveillance	DESP	Adequate retinal examination cannot be obtained using digital imaging. Refer to use different screening method.	Suspend patient from annual screening pathway and invite for SLB examination. Repeat annually whilst condition persists. Reset due dates for screening when discharged from SLB.	Produce reports to check that patients who have attended have an outcome. I.e. return to annual digital screening or remain in SLB surveillance. Check that number of encounters for SLB surveillance match the number of outcomes for each clinic and	QAS 4, 10 Internal QA – Review and report monthly capacity and queue size to programme board to ensure backlogs do not develop. Report all detected failures to programme board.

Number (Node)	Failsafe Process	Owner	Activity (opening the loop-Trigger)	Process (Closing the loop – conclusion)	Failsafe - – additional checks	Reporting/ Measure
		DESP GP			number of referrals. Produce reports to check for any patients that are overdue for SLB examination and send invitation/appointment. Follow up DNAs and DNRs and make GP aware. Unless patient opted out or excluded as medically unfit, re-invite DNAs attenders to SLB surveillance clinic at appropriate interval	
22/25	Follow up for screen positive patients who require more frequent supervision but do not yet require a referral to Hospital Eye Service. Refer for digital surveillance.	DESP	Screen positive patient requires monitoring more frequently than once a year. Refer to digital surveillance.	Suspend patient from annual screening pathway and record due date in surveillance as determined by referral outcome grader (ROG).	Produce reports to check for any patients overdue the intended appointment date. Check that all encounters for digital surveillance match the number of outcomes for each clinic and numbers referred.	Internal QA – review software reports. Report monthly capacity and queue size to programme board to ensure backlogs do not develop.

Number (Node)	Failsafe Process	Owner	Activity (opening the loop- Trigger)	Process (Closing the loop – conclusion)	Failsafe - – additional checks	Reporting/ Measure
		DESP/ GP		Record referral and offer an appointment date.	Track movement of patients in and out of surveillance, screening and HES. Follow up DNAs/DNRs and make GP aware. Unless patient opted out or excluded as medically unfit, re-invite DNAs to surveillance clinic at appropriate interval.	Report all detected failures to programme board.
23	Referrals to HES of patients with screen positive results.	DESP	Referral letter sent to HES or programme makes appointments directly.	Record acknowledgment of receipt of referral from HES. Record appointment date.	Check to make sure HES has accepted clinical responsibility of referred patient. Check that referral received date is recorded. If referral sent by fax obtain a received fax confirmation.	QAS 7,8,9 Escalate through clinical governance any patients where clinical responsibility for patient has not been received and follow up these patients with HES. Follow guidance for DESP on failsafe required for screen positive referrals into HES.

Number (Node)	Failsafe Process	Owner	Activity (opening the loop- Trigger)	Process (Closing the loop – conclusion)	Failsafe - – additional checks	Reporting/ Measure
		HES	HES acknowledge referral received.	HES receive referral and offer an appointment date for the patient.	Check that patient offered an appointment (urgent/routine) as per national guidance.	Investigate and report any breaches to PB.
		DESP			Investigate all cases where the patient has not had an appointment offer within national timeframes.	Ongoing review of performance and report to Programme Board.
					DNAs/DNRs detected by programme.	Feedback from HES.
					DNAs/DNRs to discuss with GP.	Make GP aware.
		GP			DNAs/DNRs notified to or detected by GP.	GP to re-refer to HES as appropriate and inform DESP of the outcome.