

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## INDICATOR DEVELOPMENT PROGRAMME

### Consultation report

**Indicator area:** Screening

**Consultation period:** 23 November – 21 December 2020

**Date of Indicator Advisory Committee meeting:** 22 June 2021

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**Summary of indicators included in the consultation:**

ID	Indicator	Evidence source
IND 2020- 93	The proportion of babies who have a negative screening test on newborn physical examination but have identified risk factors and undergo assessment by specialist hip ultrasound within 6 weeks of age.	<p>Newborn physical examination is supported by: <a href="#">NICE's guideline on Postnatal care up to 8 weeks after birth</a> recommendation 1.4.11</p> <p>Screening for DDH risk factors and ultrasound is recommended by: <a href="#">UK National Screening Committee (NSC) recommendation on Developmental dislocation of the hip screening in newborns</a> (2006)</p> <p>Screening is carried out in the first week of life and again at 6-8 weeks of age. The first screen is a question to identify high risk factors. Babies with risk factors should be referred for ultrasound examination.</p>
IND 2020- 94	The proportion of babies who have a not suspected result for all the conditions tested for by newborn blood spot testing and have a results letter sent to their parents directly from the child health information service (CHIS) within 6 weeks of birth.	<p>Newborn blood spot testing is supported by: <a href="#">NICE's guideline on Postnatal care up to 8 weeks after birth</a> recommendation 1.4.12</p> <p>And the recommendations of the <a href="#">UK National Screening Committee</a></p>
IND 2020- 95	The proportion of babies who have a not suspected result for all the conditions tested for by newborn blood spot testing and have a results letter sent to their parents directly from the CHIS within 6 weeks of notification of movement in.	<p>Newborn blood spot testing is supported by: <a href="#">NICE's guideline on Postnatal care up to 8 weeks after birth</a> recommendation 1.4.12</p> <p>And the recommendations of the <a href="#">UK National Screening Committee</a></p>
IND 2020- 96	The proportion of parents receiving newborn blood spot screen positive results within 28 days of age.	<p>Newborn sickle cell screening as part of newborn blood spot screening is supported by: <a href="#">NICE's guideline on Postnatal care up to 8 weeks after birth</a> recommendation 1.4.12</p> <p>Screening newborns for sickle cell disease is supported by the recommendations of the <a href="#">UK National Screening Committee</a>. Detection of thalassaemia is not part of the programme but it is expected that beta thalassaemia major would be detected as a by-product and the same standards for communicating results to parents and enrolment into care apply.</p>

ID	Indicator	Evidence source
IND 2020- 97	The proportion of eligible people with diabetes who have not attended for diabetic eye screening in the previous 3 years.	Repeat annual eye screening is supported by: <a href="#">NICE's guideline on type 1 diabetes in adults</a> recommendation 1.15.1 <a href="#">NICE's guideline on type 2 diabetes in adults</a> recommendation 1.7.1 <a href="#">NICE's guideline on diabetes (type 1 and 2) in children and young people</a> recommendation 1.3.52
IND 2020- 98	The proportion of eligible people with diabetes who are offered an appointment for diabetic eye screening.	Repeat annual eye screening is supported by: <a href="#">NICE's guideline on type 1 diabetes in adults</a> recommendation 1.15.1 <a href="#">NICE's guideline on type 2 diabetes in adults</a> recommendation 1.7.1 <a href="#">NICE's guideline on diabetes (type 1 and 2) in children and young people</a> recommendation 1.3.52
IND 2020- 99	The proportion of eligible people with diabetes who are suspended from diabetic eye screening due to previous screening results.	Repeat annual eye screening is supported by: <a href="#">NICE's guideline on type 1 diabetes in adults</a> recommendation 1.15.1 <a href="#">NICE's guideline on type 2 diabetes in adults</a> recommendation 1.7.1 <a href="#">NICE's guideline on diabetes (type 1 and 2) in children and young people</a> recommendation 1.3.52
IND 2020- 100	The proportion of eligible people with diabetes who are excluded from diabetic eye screening as they have opted out or are classed as medically unfit.	Repeat annual eye screening is supported by: <a href="#">NICE's guideline on type 1 diabetes in adults</a> recommendation 1.15.1 <a href="#">NICE's guideline on type 2 diabetes in adults</a> recommendation 1.7.1 <a href="#">NICE's guideline on diabetes (type 1 and 2) in children and young people</a> recommendation 1.3.52

## General comments

The following is a summary of general (non-indicator-specific) comments:

- Support for the indicators as a way of improving the quality of care and raising the profile of the importance of screening.
- The indicators are seen as a priority for reporting and monitoring at local level and with the local providers.
- Different outcomes that could be improved by the indicators were highlighted.
- The presentation of information in the report is not easy to follow.
- The newborn bloodspot indicators for sickle cell disease could have a differential impact on people of African or African Caribbean family origins, which could be addressed by reducing the length of time allowed to report on screen positive and negative results.

## **IND 2020-93: Timeliness of intervention for developmental dysplasia of the hip (DDH) risk factors**

*The proportion of babies who have a negative screening test on newborn physical examination but have identified risk factors and undergo assessment by specialist hip ultrasound within 6 weeks of age.*

Reporting period: 12 months.

Indicator type: Clinical Commissioning Group level indicator

### ***Rationale***

Approximately 1 or 2 in 1,000 babies have hip problems that require treatment. Developmental dislocation of the hip (DDH) is a condition where a baby is born with a hip joint that is not properly formed. Without treatment, DDH may lead to problems later in life, including developing a limp, hip pain and osteoarthritis. With early diagnosis and treatment, most children are able to develop normally and have a full range of movement in their hip.

### ***Specification***

Numerator: number of babies with an indication for specialist hip ultrasound based on risk factors only who attend for specialist hip ultrasound within 6 weeks of age.

Denominator: number of babies who have a negative screening test on newborn physical examination in the reporting period but have identified risk factors for DDH, excluding babies with a hip abnormality identified on newborn physical examination, such as babies found to have dislocated or dislocatable hips on physical examination with or without risk factors (screen positive).

### ***Summary of consultation comments***

Stakeholders made the following comments in relation to IND2020-93:

Stakeholders highlighted that selective ultrasound screening has increased estimates of the UK incidence of DDH.

### ***Considerations for the advisory committee***

The committee is asked to consider not progressing this indicator for inclusion on the NICE menu given the unknown but likely low numbers of patients in the denominator. NICE CCG level indicators are intended for use where there is an average of 50 patients or more per CCG. It was not possible to calculate average numbers of patients per CCG for this indicator as the number of babies in the denominator was unknown. However, we can estimate that there are between 5 and 10 babies per CCG with hip problems that require treatment. The [Office for National](#)

[Statistics](#) reports 640,370 live births in England in 2019:  $640,370/135$  equals 4,743 births per CCG. If 1 or 2 per 1,000 of those had hip problems, it would be between 5 and 10 babies per CCG.

## **IND 2020-94: Timeliness of results for newborn blood spot testing to parents for CCG responsibility at birth**

*The proportion of babies who have a not suspected result for all the conditions tested for by newborn blood spot testing and have a results letter sent to their parents directly from the child health information service (CHIS) within 6 weeks of birth.*

Reporting period: 12 months.

Indicator type: Clinical Commissioning Group level indicator

### ***Rationale***

The newborn blood spot (NBS) screening programme enables early identification, referral and treatment of babies with 9 rare but serious conditions. Rapid results from the NBS testing supports timely diagnosis for babies and the commencement of appropriate care and treatments. Conveying NBS screening results in a timely manner to parents will also minimise anxiety.

### ***Specification***

Numerator: number of babies who have a not suspected result for all the conditions tested for by newborn blood spot testing and have a results letter sent to their parents directly from the CHIS within 6 weeks of birth.

Denominator: number of babies who have a not suspected result for all the conditions tested for by newborn blood spot testing recorded on CHISS  $\leq$  6 weeks of birth.

Excluding babies who:

- have a condition suspected or carrier result for any of the conditions tested for.
- have a status code that denotes a declined condition, a repeat required or screening incomplete.
- are covered by a CHIS that does not send results letters directly to parents (for example the results are communicated by health visitors instead).

### ***Summary of consultation comments***

Stakeholders made the following comments in relation to IND2020-94:

- Stakeholders supported this indicator as a way of having robust timelines for notifications in place, reducing regional variation in performance and

measuring improvements, as well as improving quality and support regionally.

- Stakeholders stated that this indicator would enable a more collaborative approach between PHE, the Bloodspot Screening Programme, NHS England and NICE in quality improvement.
- The need to check that current NBS screening programme data remains fit for purpose and has no existing issues was raised.
- Stakeholders raised a concern around ensuring that more indicators do not present additional burdens on regional teams in terms of data collection.
- One stakeholder highlighted that they will be consulting with users on their views on the communication of carrier/affected results and timeliness of results.

### ***Considerations for the advisory committee***

The committee is asked to consider the burden of data collection to regional teams.



## **IND 2020-95: Timeliness of results for newborn blood spot testing to parents for movers in**

*The proportion of babies who have a not suspected result for all the conditions tested for by newborn blood spot testing and have a results letter sent to their parents directly from the CHIS within 6 weeks of notification of movement in.*

Reporting period: 12 months.

Indicator type: Clinical Commissioning Group level indicator

### ***Rationale***

The newborn blood spot (NBS) screening programme enables early identification, referral and treatment of babies with 9 rare but serious conditions. Rapid results from the NBS testing supports timely diagnosis for babies and the commencement of appropriate care and treatments. Conveying NBS screening results in a timely manner to parents after changing clinical commissioning group or moving from another area or country (“movement in”) will also minimise anxiety.

### ***Specification***

Numerator: number of babies who have a not suspected result for all the conditions tested for by newborn blood spot testing and have a results letter sent to their parents directly from the CHIS within 6 weeks of notification of movement in.

Denominator: number of babies who have a not suspected result for all the conditions tested for by newborn blood spot testing recorded on the CHISS within 6 weeks of notification of movement in.

Excluding babies who:

- have a condition suspected or carrier result for any of the conditions tested for.
- have a status code that denotes a declined condition, a repeat required or screening incomplete.
- are covered by a CHIS that does not send results letters directly to parents (for example the results are communicated by health visitors instead).

### ***Summary of consultation comments***

Stakeholders made the following comments in relation to IND2020-95:

- Stakeholders supported this indicator as a way of ensuring quality improvement and addressing regional variation in performance.

- Stakeholders queried whether differences in practice are due to people being missed in terms of receiving results.
- Stakeholders felt that the indicator should also include those with a positive suspected result, and were concerned that they would not be picked up by IND2020-96.
- The age of the baby (possibly 1 year of age) was raised as a standard exclusion criteria for newborn screening results for movers in.

### ***Considerations for the advisory committee***

The committee is asked to consider:

- The appropriateness of including an age exclusion for this indicator.
- Including babies who have a positive result in this indicator.

## **IND 2020-96: Reporting newborn blood spot screen positive results to parents**

*The proportion of parents receiving newborn blood spot screen positive results within 28 days of age.*

Reporting period: 12 months.

Indicator type: Clinical Commissioning Group level indicator

### ***Rationale***

Approximately 1 baby per CCG will test positive for sickle cell disease or thalassaemia in a 12 month period. Public Health England's [Antenatal screening standards: data report 1 April 2018 to 31 March 2019](#) reports 267 infants tested positive for sickle cell or thalassaemia: 267/195 equals 1.4 per CCG. Providing timely results to parents of screen positive infants for sickle cell disease or thalassaemia is important so that support can be given to parents and carers, the importance of early penicillin prophylaxis can be emphasised and prompt referral into treatment is ensured.

### ***Specification***

Numerator: number of newborn infants with newborn blood spot screen positive results for whom parents receive results within 28 days of age.

Denominator: number of newborn infants born within the reporting period with newborn blood spot screen positive results.

### ***Summary of consultation comments***

Stakeholders made the following comments in relation to IND2020-96:

- Stakeholders highlighted the importance of parents receiving results as early as possible to allow the appropriate clinical care for the child, to prevent any damage and improve the child's life chances and outlook.
- Stakeholders supported the role the indicator could play in improving performance for this standard.
- Comments from some stakeholders related to the 9 conditions screened for by newborn blood spot testing, rather than just sickle cell disease or thalassaemia, as they thought this indicator included all of the conditions.
- Stakeholders felt that the timeframe of up to 28 days to give results to parents was too long, as waiting causes anxiety and could detrimentally affect parental education and support.

### ***Specific question included at consultation***

Question: The number of patients for this indicator is very small and makes the indicator unsuitable for use. Data quality issues were identified in the data source, but do the numbers of patients identified reflect the numbers you are aware of?

Stakeholders referenced figures of patients diagnosed with cystic fibrosis through the newborn screening programme were provided.

### ***Considerations for the advisory committee***

The committee is asked to consider:

- Not progressing this indicator for inclusion on the NICE menu given the very low numbers of patients included in the denominator.
- If progressed, amending the indicator wording to specify that the results are for sickle cell disease or thalassaemia.

## **IND 2020-97: Repeat non-attendance for diabetic eye screening**

*The proportion of eligible people with diabetes who have not attended for diabetic eye screening in the previous 3 years.*

Reporting period: 12 months.

Indicator type: Clinical Commissioning Group level indicator

### ***Rationale***

This indicator examines the number of people with diabetes who do not regularly attend routine digital eye screening appointments. A range of eye problems can affect people with diabetes. One of these conditions is diabetic retinopathy, caused by high blood sugar levels damaging the back of the eye (retina). Diabetic retinopathy can cause blindness if it is left undiagnosed and untreated, however if problems are caught early, treatment can help prevent or reduce vision loss. This indicator will also enable providers to identify and implement interventions to increase participation in this cohort.

### ***Specification***

Numerator: number of people with diabetes on the diabetic eye screening pathway who have not attended screening within the previous 3 years and have been on the register for at least 3 years.

Denominator: number of people with diabetes on the diabetic eye screening pathway who have been on the register for at least 3 years.

### ***Summary of consultation comments***

Stakeholders made the following comments in relation to IND2020-97:

- Stakeholders supported this indicator as a way of making this data more accessible, and helping primary care to support people who are not attending to take up screening.
- Stakeholders highlighted that the screening provider holds the data relating to diabetic eye screening at CCG level, and non-attendance details are forwarded to primary care in paper format. They felt that data would need to be sent to primary care electronically to allow data extraction from primary care systems.
- Stakeholders stated that the indicator should make it easier to identify repeat non-attenders from all groups at all ages.
- Stakeholders highlighted that the indicator could have an adverse effect on the elderly or other individuals who are no longer eligible or have been

excluded from screening on clinical grounds, and whose records have not been updated.

- Stakeholders raised a concern that GPs might be penalised for patient non-attendance even if it is due to informed choice of the patient. They suggested dividing non-attendance into patients who have been contacted, those who it was not possible to contact and those who have declined despite being informed.

### ***Considerations for the advisory committee***

The committee is asked to consider:

- The feasibility of the indicator given potential issues with data sharing between the screening provider and primary care that could make it difficult to implement.
- The potential unintended consequence of GPs being penalised for non-attendance.
- How the results of this indicator should be used.

## **IND 2020-98: Offer of routine digital diabetic eye screening**

*The proportion of eligible people with diabetes who are offered an appointment for diabetic eye screening.* Note: All people with diabetes over the age of 12 are eligible except those with no perception of light in both eyes.

Reporting period: 12 months.

Indicator type: Clinical Commissioning Group level indicator

### ***Rationale***

To maximise the impact of the diabetic eye screening programme, all eligible people should be offered an annual appointment for routine digital screening (RDS), unless they are suspended or excluded.

A range of eye problems can affect people with diabetes. One of these conditions is diabetic retinopathy, caused by high blood sugar levels damaging the back of the eye (retina). Diabetic retinopathy can cause blindness if it is left undiagnosed and untreated, however if problems are caught early, treatment can help prevent or reduce vision loss.

### ***Specification***

Numerator: number of eligible people with diabetes, offered an appointment for diabetic eye screening during the reporting period (programme performance report).

Denominator: number of eligible people with diabetes, on the final day of the reporting period.

### ***Summary of consultation comments***

Stakeholders made the following comments in relation to IND2020-98:

- Stakeholders supported this indicator as a way of improving the variation in practice and increasing the number of offers.
- Stakeholders raised a concern that the specification for the indicator states that it will be counted as an offer if an eligible person attends a walk-in clinic, when they might not be attending for diabetes-related care or offered screening at the clinic.
- Stakeholders highlighted that screening for diabetic retinopathy in ophthalmology is often done as part of normal clinical investigations to detect eye disease.
- Stakeholders mentioned that the screening provider holds the data relating to diabetic eye screening at a CCG level but it is not included in the National Diabetes Audit results. They suggested that, as the CCG

does not receive this information directly, the data source would need to be identified and appropriate governance procedures followed in implementing the indicator.

- A differential impact raised was that the indicator might help to highlight different groups not obvious at a practice level and assist in reducing health inequalities.
- One stakeholder questioned the focus on annual screening (NHSEI are potentially extending the interval to 2 years: <https://phescreening.blog.gov.uk/2020/01/15/diabetic-eye-extended-screening-intervals-what-information-do-we-really-need/>).

### ***Considerations for the advisory committee***

The committee is asked to consider:

- The acceptability of counting attendance at a walk-in clinic as an offer of an appointment.
- The indicator is currently valid, but the frequency of screening may need to be amended if there are changes to the recommended interval.
- The feasibility of the indicator given potential issues with data sharing between the screening provider and CCGs that could make it difficult to implement.



## **IND 2020-99: Suspended from diabetic eye screening**

*The proportion of eligible people with diabetes who are suspended from diabetic eye screening due to previous screening results.*

Reporting period: 12 months.

Indicator type: Clinical Commissioning Group level indicator

### ***Rationale***

To maximise the impact of the diabetic eye screening programme, all eligible people should be offered an appointment for routine digital screening, unless they are suspended or excluded.

Monitoring the proportion of suspended and excluded people in the eligible population should help ensure that people are not being suspended or excluded unnecessarily.

### ***Specification***

Numerator: number of eligible people with diabetes who are suspended from diabetic eye screening due to previous screening results on the final day of the reporting period.

Denominator: number of eligible people with diabetes on the final day of the reporting period.

### ***Summary of consultation comments***

Stakeholders made the following comments in relation to IND2020-99:

- Stakeholders supported this indicator as a way of ensuring quality assurance and identifying variation between units and screening areas.
- Stakeholders highlighted that this information is not currently made publicly available.
- Stakeholders mentioned that appropriate recording of people as suspended could depend on the provider receiving relevant information from the treating eye unit/hospital ophthalmology department.
- Stakeholders raised the potential for this indicator to reduce the number of patients being invited for eye screening when they have been suspended whilst undergoing treatment and the screening provider has not been informed.
- Stakeholders felt that this indicator could reduce the number of appointments that individuals are asked to attend and improve patient flow for the service.

- Stakeholders stated that it was difficult to assess whether this indicator has the potential for differential impact on protected groups.
- A potential adverse impact was raised around the need for clear communication that an individual needs to re-join the screening programme when they have completed treatment, and that there might be an issue for groups where English is not their first language.

### ***Considerations for the advisory committee***

The committee is asked to consider:

- The feasibility of indicator given potential data sharing issues between services that could cause issues with implementing this indicator.
- How the results of this indicator should be used.

## **IND 2020-100: Excluded from diabetic eye screening**

*The proportion of eligible people with diabetes who are excluded from diabetic eye screening as they have opted out or are classed as medically unfit.*

Reporting period: 12 months.

Indicator type: Clinical Commissioning Group level indicator

### ***Rationale***

To maximise the impact of the diabetic eye screening programme, all eligible people should be offered an appointment for routine digital screening, unless they are suspended or excluded.

Monitoring the proportion of suspended and excluded people in the eligible population should help ensure that people are not being suspended or excluded unnecessarily.

### ***Specification***

Numerator: number of eligible people with diabetes who are excluded from diabetic eye screening as they have opted out or are classed as medically unfit on the final day of the reporting period.

Denominator: number of eligible people with diabetes on the final day of the reporting period.

### ***Summary of consultation comments***

Stakeholders made the following comments in relation to IND2020-100:

None received.

### ***Considerations for the advisory committee***

The committee is asked to consider:

- Should development of this indicator continue?
- How the results of this indicator should be used.

## Appendix A: Consultation comments

### General comments

ID	Stakeholder organisation	Comment	NICE Response
1	ArchAngel MLD Trust	<p>Please note that Indicators in respect of physical examination and dysplasia of the hip and diabetic eye screening are not within our field of expertise and therefore it is not appropriate for us to comment.</p> <p>Please also note that in the time available we have not had the opportunity to consult with colleagues in the patient organisations to check if identification of dysplasia of the hip is an early indication in the diagnosis of a rare disorder (i.e. where NBS is not available for that disease). If this was the case then we might wish to give further consideration to the impact of a proposed NICE CCG indicator.</p> <p>Consequently our comments are on the Newborn Bloodspot Testing Areas.</p>	Thank you for clarifying the focus of your comments.
2	British Society for Paediatric Endocrinology and Diabetes (BSPED)	No comment.	N/A
3	The College of Optometrists	We welcome the proposed new NICE indicators for Diabetic eye screening as they will help reflect the quality of care across the UK which can help identifying health inequalities.	Thank you for your support for the proposed indicators for diabetic eye screening.

ID	Stakeholder organisation	Comment	NICE Response
4	Cystic Fibrosis Trust	We welcome the proposed NICE indicators for newborn blood spot testing. We hope the indicators will act to support and improve the quality of care available to babies and their families, especially where a positive diagnosis for one of the nine conditions is suspected. Rapid results from the newborn blood spot test supports timely, early diagnosis for babies with cystic fibrosis and the commencement of appropriate care and treatments. Since the nationwide roll-out of newborn blood spot testing, the average age at diagnosis has fallen to below 30 days. The median age at diagnosis for patients aged under 16 in 2019 was 22 days (UK CF Registry Annual Report 2019, 2020).	Thank you for your support for the proposed indicators for newborn blood spot testing.
5	Royal College of Nursing	The Royal College of Nursing welcome these draft screening indicators and welcome the opportunity to comment on them.	Thank you for your support for the proposed screening indicators.
6	Royal College of Nursing	<p>These are all essential indicators and must be reported.</p> <p>With the changes to the clinical commissioning group (CCG) structures moving to wider integrated care system, these indicators are a priority for reporting and monitoring at local level and with the local providers.</p> <p>Not monitoring any of these properly at 100% is a potential huge risk to the system.</p>	Thank you for your comment. The June 2021 Indicator Advisory Committee agreed that these indicators are suitable for use at CCG level. NICE is currently developing plans to consider indicators that can be used at integrated care system (ICS) level.
7	The Royal College of Ophthalmologists	The Royal College of Ophthalmologists supports the indicators suggested by NICE in this consultation and welcomes the opportunity to raise the profile of the importance of diabetic eye screening.	Thank you for your support for the proposed indicators for diabetic eye screening.

ID	Stakeholder organisation	Comment	NICE Response
8	Royal College of Paediatrics and Child Health	These indicators are very important the from the viewpoint of families, patients and society. Implementing these indicators may prevent disability or prevent a serious outcome of many metabolic disorders or developmental deformities.	Thank you for your support for the proposed screening indicators.
9	Royal College of Paediatrics and Child Health	It was noted that the way NICE have presented the information is not easy to follow, the clearer the questions that are being asked and the less unnecessary words on the page the better. A distilled series of questions with links which allows those who want to delve more, would be most beneficial, otherwise NICE may put people off which misses the opportunity for greater feedback.	Thank you for your comment. NICE is currently working to improve the approach to consultation, and we have shared your feedback with the team working on this.
10	Royal College of Paediatrics and Child Health	The reviewer was happy with this guideline.	Thank you for your comment.

ID	Stakeholder organisation	Comment	NICE Response
11	Sickle Cell Society	<p>General comments including from the Sickle Cell Society:</p> <p>It is good to see newborn bloodspot screening standards for sickle cell being included as part of the draft NICE indicators. However, all three indicators have potential unintended consequences for newborn babies and their families. In particular, these indicators have potential for differential impact on people of African or African Caribbean family origins who are most affected by sickle cell disease and who are impacted by significant health inequalities. One way to address this would be to reduce the length of time allowed in reporting screen positive results and screen negative results. However, we realise that though each indicator is measured and has to have an ultimate time i.e. less than or equal to 28 days or less than or equal to 6 weeks, this doesn't mean that results take that long and that the choice of the indicator for timeliness is probably a pragmatic one and a time that is reasonable to achieve.</p>	<p>Thank you for your comment. The June 2021 Indicator Advisory Committee noted your suggestion to consider a reduction in the length of time for reporting results to people of African or African Caribbean family origin. Unfortunately, the population size would not support separate reporting for population sub-groups for these indicators at CCG level. The timescales are those used for the <a href="#">newborn blood spot screening data collection and performance analysis</a>.</p>

**Question 1: Do you think there are any barriers to implementing the care described by these indicators?**

ID	Stakeholder organisation	Comment	NICE Response
12	Cystic Fibrosis Trust	None	Thank you for your comment.

**Question 2: Do you think there are potential unintended consequences to implementing/ using any of these indicators?**

ID	Stakeholder organisation	Comment	NICE Response
13	Cystic Fibrosis Trust	None	Thank you for your comment.

**Question 3: Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.**

ID	Stakeholder organisation	Comment	NICE Response
14	Cystic Fibrosis Trust	None	Thank you for your comment.

**Question 4: If you think any of these indicators may have an adverse impact in different groups in the community, can you suggest how the indicator might be delivered differently to different groups to reduce health inequalities?**

ID	Stakeholder organisation	Comment	NICE Response
15	Cystic Fibrosis Trust	None	Thank you for your comment.



**Question 5: The number of patients for this indicator (IND2020-96) is very small and makes the indicator unsuitable for use. Data quality issues were identified in the data source, but do the numbers of patients identified reflect the numbers you are aware of?**

ID	Stakeholder organisation	Comment	NICE Response
16	Inherited Metabolic Disorders Newborn Screening Advisory Board and British Inherited Metabolic Disease Group	Please refer this question to the Sickle cell newborn Screening advisory board	Thank you for your comment. We did not receive a response to this question from the Sickle Cell Newborn Screening Advisory Board.

### **Indicator 2020-93**

ID	Stakeholder organisation	Comment	NICE Response
17	Royal College of Midwives	The incidence in the UK before ultrasound screening became available was quoted as 1 and 2 per 1000. Since the advent of selective ultrasound screening, which selectively scans the hips of babies who are thought to be at high risk of DDH, estimates of the UK incidence have increased and range from 5–30 per 1000 Developmental dysplasia of the hip. <i>Sewell MD, Rosendahl K, Eastwood DM BMJ. 2009 Nov 24; 339():b4454.</i>	Thank you for this information which was shared with the June 2021 Indicator Advisory Committee.

**Indicator 2020-94**

<b>ID</b>	<b>Stakeholder organisation</b>	<b>Comment</b>	<b>NICE Response</b>
18	ArchAngel MLD Trust	The time immediately after birth is challenging for many parents. We work on the assumption that guidelines are followed and that parents are fully informed by health workers of the purpose of newborn bloodspot screening during pregnancy to ensure consent. Any delay between the test taking place and the receipt of results is a stressful time. It is important that robust timelines for notification of results are in place. We were unaware of the regional variations in England outlined in reporting results to parents. We would concur that meeting the target is truly important. Introducing NICE indicators to ensure improvement in quality and support at a more regional CCG level would be of benefit.	Thank you for your comments and support for this indicator. The committee agreed it is important to ensure that robust timescales for notification of results of blood spot testing are in place.
19	ArchAngel MLD Trust	We agree that introducing a further indicator would enable a further tier of comparison of regional variations and enable specific improvement plans to be put in place and effective measurement of the improvements. It will enable a more collaborative approach between PHE, the Bloodspot Screening Programme and NHSE NICE in quality improvement.	Thank you for your comment and support for this indicator.
20	ArchAngel MLD Trust	Although it appears that the data collected by the newborn bloodspot screening programme is repeatable, looking at the possibility of further NICE indicators maybe does allow a further opportunity to look at that existing data to determine that it remains fit for purpose and there are no existing issues. We anticipate that you will do this, however it is not clear.	Thank you for your comment. The June 2021 Indicator Advisory Committee were satisfied that the NHS newborn blood spot screening programme operates under published standards and quality assurance frameworks.

ID	Stakeholder organisation	Comment	NICE Response
21	ArchAngel MLD Trust	In terms of consequences. we need to ensure that initiating further indicators does not present additional burdens on already challenged regional teams in terms of data collection. A need to avoid the risk of an adverse effect and less robust information being collected.	Thank you for your comment. The June 2021 Indicator Advisory Committee considered the burden of data collection on regional teams but on balance felt the indicator is important and has the potential to support joining up of data flows into primary care.
22	ArchAngel MLD Trust	We cannot foresee any barriers to implementing the care described, however anticipate that other stakeholders will have greater experience and perhaps more comments. We cannot identify any potential for differential impact.	Thank you for your comment.
23	Cystic Fibrosis Trust	We have no further comments on indicator "IND 2020-94: Timeliness of results for newborn blood spot testing to parents for CCG responsibility at birth" for those who are not suspected to have one of the nine conditions screened for as part of the newborn blood spot test.	Thank you for your comment.
24	Inherited Metabolic Disorders Newborn Screening Advisory Board and British Inherited Metabolic Disease Group	No comment.	Thank you for your comment.

ID	Stakeholder organisation	Comment	NICE Response
25	Sickle Cell Society	It is good to note that this standard excludes babies who might have sickle cell trait and that these results are expected to be given to parents in less than 6 weeks. The SCS will be embarking on a project on behalf of the Screening Programme to consult with users on their views on the communication of carrier /affected results and we hope to find out what they think of the timeliness too.	Thank you for your comment. Any changes to timelines for the newborn blood spot screening programme in the future can be reflected in future updates of this indicator.

### **Indicator 2020-95**

ID	Stakeholder organisation	Comment	NICE Response
26	ArchAngel MLD Trust	We have noted the performance on results being conveyed to parents who are movers in. There are significant gaps in performance as you point out and we note that the issues appear to be around problems at a regional and area level. When you indicate such a difference in practice it always prompts an alert to whether actually some people are actually being missed in terms of receiving results. We do not know if this has been an issue. However our thoughts are that a NICE CCG indicator is perhaps the best way of addressing such regional variations and ensuring quality improvement.	Thank you for your comment. The June 2021 Indicator Advisory Committee agreed this is an important indicator that will pick up 'movers in', or babies who have changed CCGs or moved from abroad.

ID	Stakeholder organisation	Comment	NICE Response
27	Cystic Fibrosis Trust	<p>Whilst we welcome the focus on “movers-in” within indicator IND 2020-95, we are disappointed that it only focuses on those who have a not suspected result for all the conditions tested for by newborn blood spot testing. It is vital that there is an equal focus and provision for movers in who also have a positive suspected result. This is not part of indicator IND 2020-96, which covers those with a positive suspected result and means that the speed at which “movers-in” receive notification of a suspected positive newborn blood spot screen is not monitored.</p>	<p>Thank you for your comment. As timescales for positive results are different to not suspected results it requires a separate indicator and cannot be included within IND 2020-95. Please note that the June 2021 Indicator Advisory Committee agreed not to progress IND 2020-96 on reporting for positive results due to small numbers not allowing comparison at CCG level.</p>
28	Inherited Metabolic Disorders Newborn Screening Advisory Board and British Inherited Metabolic Disease Group	<p>Standard exclusion criteria for newborn screening results for movers in: I believe there is an age cutoff for newborn screening that is done on movers in (I think this is 1 year, but please check). Children above this cut-off age should be excluded from this indicator.</p>	<p>Thank you for your comment. We have added information to the validity assessment for this indicator to confirm the age limit for screening.</p>

**Indicator 2020-96**

ID	Stakeholder organisation	Comment	NICE Response
29	ArchAngel MLD Trust	<p>We acknowledge that PPV stakeholders with detailed familiarity with Sickle Cell and thalassaemia will be in a better position to comment on this proposed indicator, including the question of a differential or adverse impact on groups in the community.</p> <p>Our more general comment is the criticality of parents receiving any positive screen tests at the earliest opportunity to allow the appropriate clinical care for their child and to alleviate suffering. The impact of this cannot be underestimated, especially in conditions where a 2<sup>nd</sup> tier confirmation requires recall of the child.</p>	<p>Thank you for your comment. Please note that the June 2021 Indicator Advisory Committee agreed that this is important but agreed not to progress IND 2020-96 on reporting for positive results due to small numbers not allowing comparison at CCG level.</p>
30	Cystic Fibrosis Trust	<p>The Cystic Fibrosis Trust welcome the proposed indicator on “IND 2020-96 Reporting newborn blood spot screen positive results to parents: The proportion of parents receiving newborn blood spot screen positive results within 28 days of age.” Diagnosis as early as possible is critical to support timely care and to prevent the onset of damage that is the cause of morbidity and mortality in cystic fibrosis. With the introduction of highly effective CFTR modulators at an earlier and earlier age (currently Kalydeco is available for babies with responsive mutations from the age of 4 months), diagnosis at the earliest possible point supports the outlook and life chances of a baby born with cystic fibrosis. We are concerned that the existing data from the Antenatal screening standards: data report 1 April 2017 to 31 March 2018 reports that the performance for this standard in England was only 65.9 percent and this indicates the scope for improvement and the role this indicator could play.</p>	<p>Thank you for your comment. Please note that the June 2021 Indicator Advisory Committee agreed that this is important but agreed not to progress IND 2020-96 on reporting for positive results due to small numbers not allowing comparison at CCG level.</p>

ID	Stakeholder organisation	Comment	NICE Response
31	Cystic Fibrosis Trust	<p>The national UK CF Registry collects outcomes data for the proposed indicator and could be utilised to populate the indicator for cystic fibrosis. All cystic fibrosis specialist centres enter data into the UK CF Registry. The UK Cystic Fibrosis Registry is a national, secure, centralised database sponsored and managed by the Cystic Fibrosis Trust, with UK National Health Service (NHS) research ethics approval and consent from each person for whom data are collected. Using data from the UK CF Registry data would be efficient and effective. Furthermore, using registry data would ensure the data is robust and avoid duplication and unnecessary resource outlay and address the concern set out in the “Question for consultation 5. The number of patients for this indicator is very small and makes the indicator unsuitable for use. Data quality issues were identified in the data source, but do the numbers of patients identified reflect the numbers you are aware of?” In answer to this question, based on UK CF Registry Data, the number of diagnosed patients through newborn screening was 164 in 2014, 168 in 2015, 216 in 2016, 192 in 2017, 167 in 2018 and 137 in 2019. Further data is available within the <a href="#">UK CF Registry annual data report</a> or through a data request approved in line with the <a href="#">UK CF Registry Data Sharing Policy</a>.</p>	<p>Thank you for providing this information. Please note that the June 2021 Indicator Advisory Committee agreed that this is important but agreed not to progress IND 2020-96 on reporting for positive results due to small numbers not allowing comparison at CCG level.</p>
32	Cystic Fibrosis Trust	<p>Under the title “importance” it is asserted that “Providing timely results to parents of screen positive infants is important so that support can be given to parents and carers, the importance of early penicillin prophylaxis can be emphasised and prompt referral into treatment is ensured.” Prophylactic penicillin treatment is for sickle cell only. We suggest this statement be widened to show the wide variety of treatments available for babies diagnosed with any of the nine screened for conditions and to ensure the indicator is future proofed. Prophylactic antibiotic use in cystic fibrosis is currently the subject of research to show whether it is indeed the most effective treatment for babies with cystic fibrosis. As detailed above, treatment improvements in cystic fibrosis mean that for many babies it is now the early initiation of CFTR modulators that will impact their health status most substantially.</p>	<p>Thank you for your comment. Please note that the June 2021 Indicator Advisory Committee agreed that this is important but agreed not to progress IND 2020-96 on reporting for positive results due to small numbers not allowing comparison at CCG level.</p>

ID	Stakeholder organisation	Comment	NICE Response
33	Cystic Fibrosis Trust	The specified conditions to be detected in newborn screening as detailed under “specifications” are listed as “HbSS, HbSC, HbS/beta thalassaemia (S/beta+, S/beta degree, HbS/delta beta, HbS/γ delta beta, S/Lepore), HbS/DPunjab, HbS/E, HbS/OArab, HbS/HPFH, Hb S with any other variant and no Hb A, and other clinically significant haemoglobinopathies likely to be detected as by-products of newborn screening including beta thalassaemia major, Hb E/beta thalassaemia, and beta thalassaemia intermedia. Carrier results need to be followed up but are excluded from this standard.” This does not include cystic fibrosis and other conditions and therefore does not reflect the breadth of conditions covered by newborn screening	Thank you for your comment. Please note that the June 2021 Indicator Advisory Committee agreed that this is important but agreed not to progress IND 2020-96 on reporting for positive results due to small numbers not allowing comparison at CCG level.
34	Cystic Fibrosis Trust	It is unclear in the indicator whether the indicator covers the entire diagnostic pathway from newborn blood screen to positive diagnosis for each of the nine conditions, or whether it only measures the communication of suspected results. Cystic fibrosis screening often results in equivocal results that may need further tests and result in a time delay. Furthermore, if the indicator only covers those with an eventual positive diagnosis for one of the nine conditions, those with a suspected positive blood spot test but who are eventually found not to have one of the nine conditions or are a carrier, are not covered by any of the proposed indicators.	Thank you for your comment. We confirm that the focus of the indicator was on providing timely results to parents. Please note that the June 2021 Indicator Advisory Committee agreed that this is important but agreed not to progress IND 2020-96 on reporting for positive results due to small numbers not allowing comparison at CCG level.



ID	Stakeholder organisation	Comment	NICE Response
35	Cystic Fibrosis Trust	<p>The current indicator does not cover which professionals are involved in the diagnosis of one of the nine conditions. For cystic fibrosis, if a suspected diagnosis is given to the family, it is imperative to have a CF specialist present from the onset to address any questions and concerns the family may have. It is often the case that a family is told of a suspected diagnosis and then receive an appointment days later for further testing. This results in the family doing their own research to better understand the condition and can cause increased anxiety and stress.</p>	<p>Thank you for your comment. We confirm that the focus of the indicator was on providing timely results to parents and not on support available to parents who receive a positive result. Please note that the June 2021 Indicator Advisory Committee agreed not to progress IND 2020-96 on reporting for positive results due to small numbers not allowing comparison at CCG level.</p>
36	Sickle Cell Society	<p>For the standard of reporting screen positive results to parents, 28 days is too long for parents to wait to know their baby is affected by sickle cell disease. Parents may well be aware of the risk to their baby if they have had antenatal screening for sickle cell disease and that their baby is at risk of a serious haemoglobinopathy. It is well known that parental education and support is vital in ensuring that babies and children with sickle cell disease stay well. This process could be seriously undermined if the results of the screening test are delayed until the baby is one month old. We have had feedback from the personal experiences of parents who have gone through the NHS Sickle Cell &amp; Thalassaemia Screening Programme that a long wait causes anxiety on the one hand and on the other can give false assurance that their babies are not affected. In one case the parent was wrongly told by a health professional that 'no news is good news' when in fact her baby ultimately had sickle cell disease.</p>	<p>Thank you for your comment. The timescales for this indicator are those used for the newborn blood spot screening data collection and performance analysis. Please note that the June 2021 Indicator Advisory Committee agreed not to progress IND 2020-96 on reporting for positive results due to small numbers not allowing comparison at CCG level.</p>

**Indicator 2020-97**

<b>ID</b>	<b>Stakeholder organisation</b>	<b>Comment</b>	<b>NICE Response</b>
37	Diabetes UK	We would welcome the inclusion of this indicator, as this data is not currently easily accessible although collected. We know that the risk of developing sight threatening retinopathy is raised in people who do not regularly attend screening. While a 2-year gap has been found to be relatively safe, after a three-year gap, the risk of sight threatening retinopathy being detected is increased. We believe that primary care could support people who are not attending to take up the national screening programme offer and highlighting this population could help primary care intervene more effectively, particularly considering the reasons for non-attendance highlighted by the Stutton study.	Thank you for your comment. The June 2021 Indicator Advisory Committee agreed this indicator is important and noted that it would help link the data flow into primary care.
38	NHS South Sefton CCG	<ol style="list-style-type: none"> <li>1) At the present time the screening provider holds the data relating to diabetic eye screening at CCG level, non-attendance details are forwarded to primary care but there can be a delay in recording this on the primary care system as the information is sent to primary care in a paper format. If the data is to be extracted from primary care systems, then it would be better if information was sent from the provider to primary care in a coded electronic format.</li> <li>2) If the data was to be sourced from primary care, then ideally information would need to be sent to primary care systems in a coded electronic format for the results to be robust.</li> <li>3) It should make it easier to identify repeat non-attenders from all groups at all ages.</li> <li>4) It may have an adverse effect on the elderly or other individuals who are no longer eligible or been excluded from diabetic eye screening on clinical grounds, and have been given full relevant information, and whose records have not been appropriately updated.</li> </ol>	Thank you for your comments. We confirm that data is currently collected as part of the NHS Diabetic Eye Screening programme. The June 2021 Indicator Advisory Committee agreed this indicator is important and noted that it would help link the data flow into primary care. Please note that proposed indicator IND 2020-99 includes people with diabetes who are suspended from eye screening due to previous screening results and IND 2020-100 includes people with diabetes who are excluded from diabetic eye screening.

ID	Stakeholder organisation	Comment	NICE Response
39	Primary Care Diabetes Society	<p>Important data to collect but needs to be broken down to assess reason and whether this can be changed. Concern that GPs may be penalised for patient's non-attendance despite mechanisms in place to contact and review reason behind non-attendance. This may be down to patients 'informed choice'.</p> <p>Suggest repeat non-attendance for eye screening divided into patients who have been contacted / those unable to contact and those who have declined despite informed.</p>	<p>Thank you for your comment. The June 2021 Indicator Advisory Committee agreed that this indicator is important and that it should progress to the NICE menu at CCG level. The Committee noted that it would help link the data flow into primary care and may prompt local improvement initiatives to understand the issue in more detail.</p>

### **Indicator 2020-98**

ID	Stakeholder organisation	Comment	NICE Response
40	The College of Optometrists	<p>We would suggest clarifying this statement: "If an eligible person attends a walk-in clinic or is screened for diabetic retinopathy while in care of ophthalmology for non-diabetic retinopathy it will be counted as an offer for that date".</p> <p>If an eligible person attends a walk-in clinic, it is not clear whether it is to receive any care related to diabetes. If not, this may overestimate the number of people offered screening. Simply attending a walk-in clinic does not infer an offer or mean they have been enrolled into the service. Further, screening for diabetic retinopathy in ophthalmology is often done as part of normal clinical investigations to detect eye disease.</p>	<p>Thank you for your comment. The June 2021 Indicator Advisory Committee noted that, significant changes have been made to the national eye screening programme and questioned whether this indicator is still needed. Further work will be carried out to clarify any indicators still required including the issue highlighted.</p>

ID	Stakeholder organisation	Comment	NICE Response
41	Diabetes UK	We would support this indicator because of the existing variation in practice across England. Although we accept that 100% of eligible people being offered eye screening may not be possible, we believe that more could be done in this area and sharing this data more widely may help drive up the number of appropriate offers.	Thank you for your support for this indicator. The June 2021 Indicator Advisory Committee noted that, significant changes have been made to the national eye screening programme and questioned whether this indicator is still needed. Further work will be carried out to clarify any indicators still required on diabetic eye screening.
42	NHS South Sefton CCG	<ol style="list-style-type: none"> <li>1) At present the screening provider holds the data relating to diabetic eye screening at a CCG level but it is not included in the National Diabetes Audit results. To the best of my knowledge the CCG does not receive this information directly and so the data source would need to be identified and appropriate governance procedures followed in implementing this indicator.</li> <li>2) It is difficult to assess as this work is already being carried out at practice level in primary care.</li> <li>3) It might help to highlight different groups not obvious at a practice level and assist in reducing health inequalities.</li> <li>4) None known.</li> </ol>	Thank you for your comment. The June 2021 Indicator Advisory Committee noted that, significant changes have been made to the national eye screening programme and questioned whether this indicator is still needed. Further work will be carried out to clarify any indicators still required including the issue highlighted.

ID	Stakeholder organisation	Comment	NICE Response
43	Primary Care Diabetes Society	This seems to still imply that annual screening is recommended.	Thank you for your comment. The June 2021 Indicator Advisory Committee noted that, significant changes have been made to the national eye screening programme and questioned whether this indicator is still needed. Further work will be carried out to clarify any indicators still required.

### ***Indicator 2020-99***

ID	Stakeholder organisation	Comment	NICE Response
44	Diabetes UK	We would support this indicator. This information is not currently available but could certainly help in ensuring quality assurance.	Thank you for your comment. The June 2021 Indicator Advisory Committee noted that, significant changes have been made to the national eye screening programme and questioned whether this indicator is still needed. Further work will be carried out to clarify any indicators still required.

ID	Stakeholder organisation	Comment	NICE Response
45	NHS South Sefton CCG	<ol style="list-style-type: none"> <li>1) The number recorded as being suspended appropriately from diabetic eye screening could depend on the provider receiving relevant information from the treating eye unit/hospital ophthalmology department, but it would help to identify variation between units and screening areas.</li> <li>2) If implemented correctly it might reduce the number of patients being invited for eye screening when in reality, they have been suspended whilst undergoing treatment and the screening provider has not been informed. This could reduce the number of appointments that individuals are asked to attend and improve patient flow for the service</li> <li>3) It is difficult to assess.</li> <li>4) The only potential adverse impact could arise once the treatment has been completed and the suspension completed, and the individual re-joins the screening programme. This again relies upon clear communication which may be problematic for different groups such as those who do not have English as their first language.</li> </ol>	<p>Thank you for your comment. The June 2021 Indicator Advisory Committee noted that, significant changes have been made to the national eye screening programme and questioned whether this indicator is still needed. Further work will be carried out to clarify any indicators still required.</p>

### ***Indicator 2020-100***

No comments.

## Appendix B: Equality impact assessment

### ***Protected characteristics***

- Age
- Disability
- Gender reassignment
- Pregnancy and maternity
- Race
- Religion or belief
- Sex
- Sexual orientation

### **Note:**

1) The characteristic of marriage and civil partnership is protected only from unlawful discrimination. There is no legal requirement to consider the need to advance equality and foster good relations.

2) The definition of direct discrimination includes less favourable treatment of someone associated with a person with a protected characteristic, such as the carer of a disabled person.

### ***Socioeconomic factors***

The relevance and nature of socioeconomic factors will vary according to the quality standard topic. They may include deprivation and disadvantage associated with particular geographical areas, or other geographical distinctions (for example, urban versus rural).

### ***Other definable characteristics***

Certain groups in the population experience poor health because of circumstances distinct from – though often affected by – sharing a protected characteristic or socioeconomic factors. The defining characteristics of groups of this sort will emerge from the evidence (although a quality standard topic will sometimes explicitly cover such a group). Examples of groups identified are:

- looked-after children
- people who are homeless
- prisoners and young offenders.

# Indicator Equality Impact Assessment

**Development stage: Consultation**

**Topic: Screening indicators**

**1. Have any potential equality issues been identified during consultation, and, if so, what are they?**

Stakeholders commented that the indicator on repeat non-attendance for diabetic eye screening could have an adverse effect on the elderly if they are no longer eligible or have been excluded from screening on clinical grounds, and their records have not been updated.

Stakeholders also commented that there could be an issue for indicator IND2020-99 for groups where English is not their first language as clear communication that an individual needs to re-join the screening programme when they have completed treatment is needed.

**2. Have any population groups, treatments or settings been excluded from coverage by the indicators at this stage in the process. Are these exclusions justified – that is, are the reasons legitimate and the exclusion proportionate?**

No population groups, treatments or settings have been excluded from coverage at this stage.

**3. Do any of the indicators make it more difficult in practice for a specific group to access services compared with another group? If so, what are the barriers to, or the difficulties with, access for the specific group?**

No – comments from consultation do not suggest that the indicator will make it impossible or unreasonably difficult in practice for a specific group to access a test or intervention.

**4. Is there potential for the indicators to have an adverse impact on people with disabilities because of something that is a consequence of the disability?**

No – comments from consultation do not suggest that the indicator will have an adverse impact on people with disabilities.

Completed by lead technical analyst: Stacy Wilkinson

Date: 26/04/21

Approved by NICE quality assurance lead: Craig Grime

Date: 10.06.21