NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

## Timing of Stoma Closure in Neonates (ToSCiN)

ToSCiN aims to answer the question, 'is it feasible to conduct a clinical trial comparing 'early' vs 'late' stoma closure in neonates?'

This survey aims to determine the viewpoints of UK clinicians and allied health professionals who regularly care for infants with stomas.

We would be very grateful if you could complete the survey: we will provide feedback of the results at the end of the ToSCiN study.

There are 50 questions in this survey.

### **Background Information**

### Your role \*

Please choose only one of the following:

Consultant Paediatric Surgeon

Consultant Neonatologist/Paediatrician (regularly cares for infants with stomas)

) Neonatal Surgical Specialist Nurse

) Dietician

) Other

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

#### Description of the type of unit you work in: \*

Only answer this question if the following conditions are met: Answer was 'Dietician' *or* 'Neonatal Surgical Specialist Nurse' *or* 'Consultant Neonatologist/Paediatrician (regularly cares for infants with stomas)' *or* 'Consultant Paediatric Surgeon' at question '1 [A01]' (Your role)

Please choose only one of the following:

Surgical centre with co-located Neonatal Intensive Care Unit

) Neonatal Intensive Care Unit with partner Neonatal Surgical Centre at separate site\*

) Neonatal Surgical Centre with partner Neonatal Intensive Care at separate site\*

Other

\* 'Separate site' defined as a requirement for external transfer of an infant from NICU to operating theatre for surgery

### Thank you for your interest but this survey is specifically seeking the viewpoints of those with the above roles

Only answer this question if the following conditions are met: Answer was 'Other' at question '1 [A01]' (Your role)

Thank you for your interest but this survey is specifically seeking the viewpoints of those working in the above types of units

Only answer this question if the following conditions are met: Answer was 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

#### Introduction

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NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

# Accepting there is no consensus/definition for 'early' or 'late', would you consider yourself a proponent of 'early' or 'later' stoma closure in infants who have had a stoma formed in the neonatal period? \*

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please choose only one of the following:

(	)	Earlv
	/	

) Later

🔵 Unsure

### Does your unit recycle stoma output through the mucous fistula?

Only answer this question if the following conditions are met:

Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please choose only one of the following:

() Routine
------------

) Sometimes

) Rarely

) Never

#### Scenarios

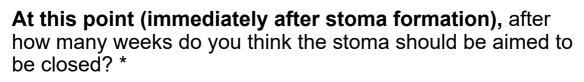
We will now describe 2 preterm and 2 term infant scenarios. Please indicate, in terms of your current practice, how you feel it would be best to manage each case.

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### Very preterm infant scenarios: Scenario 1

A premature infant born at 26 weeks gestation (birth weight 800g) deteriorates clinically on day 3 of life. An isolated perforation of the distal small bowel (ileum) is found at laparotomy and a stoma and mucous fistula are formed at this level.



Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please choose only one of the following:

Number of weeks (enter below)

Unsure

#### Please enter number of weeks: \*

Only answer this question if the following conditions are met:

Answer was 'Number of weeks (enter below)' at question '8 [Sc101]' (At this point (immediately after stoma formation), after how many weeks do you think the stoma should be aimed to be closed? )

• Only an integer value may be entered in this field. Please write your answer here:

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### Would you normally want the stoma closed before or after discharge home? \*

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please choose only one of the following:

) Before

) After

🔵 Unsure

### **In your experience**, what's the earliest you have seen stoma closure performed in a baby like this?

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please write your answer here:

weeks post formation

### **In your experience**, what's the latest you have seen stoma closure performed in a baby like this?

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please write your answer here:

weeks post formation

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

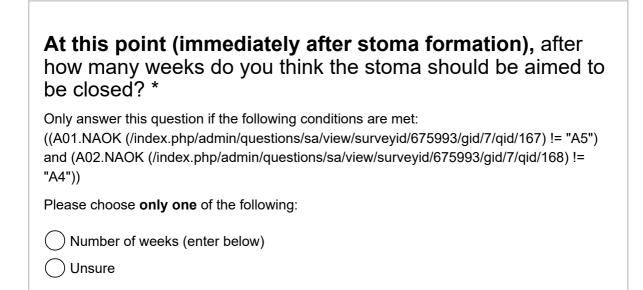
#### Any further comments:

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please write your answer here:

#### Very preterm infant scenarios: Scenario 2

A premature infant born at 26 weeks gestation (birth weight 800g) develops clinical signs of NEC at 4 weeks of age. A laparotomy confirms diffuse small bowel involvement and 50cm of bowel is resected. A stoma and mucous fistula are formed at the level of the mid-jejunum.



NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

#### Please enter number of weeks: \*

Only answer this question if the following conditions are met:

Answer was 'Number of weeks (enter below)' at question '14 [Sc201]' (At this point (immediately after stoma formation), after how many weeks do you think the stoma should be aimed to be closed? )

• Only an integer value may be entered in this field. Please write your answer here:

### Would you normally want the stoma closed before or after discharge home? \*

Only answer this question if the following conditions are met:

((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please choose only one of the following:

Before

🔿 After

) Unsure

### **In your experience**, what's the earliest you have seen stoma closure performed in a baby like this?

Only answer this question if the following conditions are met: ((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please write your answer here:

weeks post formation

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### **In your experience**, what's the latest you have seen stoma closure performed in a baby like this?

Only answer this question if the following conditions are met: ((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please write your answer here:

weeks post formation

#### Any further comments:

Only answer this question if the following conditions are met: ((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please write your answer here:

### Scenarios for term infants: Scenario 1

A term infant is born with signs of distal bowel obstruction and a failure to pass meconium. 'Simple' meconium ileus and a micro-colon are found at laparotomy. A stoma and mucous fistula are formed in the mid-ileum.

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

#### At this point (immediately after stoma formation), after how many weeks do you think the stoma should be aimed to be closed? \*

Only answer this question if the following conditions are met:

((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please choose only one of the following:

) Number of weeks (enter below)

DUnsure

#### Please enter number of weeks: \*

Only answer this question if the following conditions are met:

Answer was 'Number of weeks (enter below)' at question '20 [Sc301]' (At this point (immediately after stoma formation), after how many weeks do you think the stoma should be aimed to be closed? )

• Only an integer value may be entered in this field. Please write your answer here:

### Would you normally want the stoma closed before or after discharge home? \*

Only answer this question if the following conditions are met:

((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please choose only one of the following:

C	Before
С	) After
$\sim$	

() Unsure

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### **In your experience**, what's the earliest you have seen stoma closure performed in a baby like this?

Only answer this question if the following conditions are met: ((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please write your answer here:

weeks post formation

### **In your experience**, what's the latest you have seen stoma closure performed in a baby like this?

Only answer this question if the following conditions are met:

((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please write your answer here:

weeks post formation

#### Any further comments:

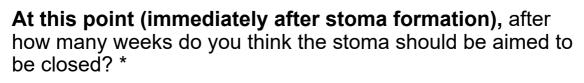
Only answer this question if the following conditions are met: ((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please write your answer here:

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### Scenarios for term infants: Scenario 2

A term infant is born with signs of proximal bowel obstruction and a failure to pass meconium. At laparotomy, a jejunal atresia is found. A stoma and mucous fistula are formed at the site of the atresia (mid-jejunum).



Only answer this question if the following conditions are met:

((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please choose only one of the following:

) Number of weeks (enter below)

) Unsure

#### Please enter number of weeks: \*

Only answer this question if the following conditions are met:

Answer was 'Number of weeks (enter below)' at question '26 [Sc401]' (At this point (immediately after stoma formation), after how many weeks do you think the stoma should be aimed to be closed? )

• Only an integer value may be entered in this field. Please write your answer here:

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### Would you normally want the stoma closed before or after discharge home? \*

Only answer this question if the following conditions are met:

((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please choose only one of the following:

) Before

After

Unsure

### **In your experience**, what's the earliest you have seen stoma closure performed in a baby like this?

Only answer this question if the following conditions are met:

((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please write your answer here:

weeks post formation

### **In your experience**, what's the latest you have seen stoma closure performed in a baby like this?

Only answer this question if the following conditions are met: ((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please write your answer here:

weeks post formation

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

#### Any further comments:

Only answer this question if the following conditions are met: ((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5")

and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

Please write your answer here:

#### **Current Practice**

### Which of these factors would make you delay a planned stoma closure?

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please choose the appropriate response for each item:

	Delay	Go ahead
Invasively ventilated (clinically stable and low/moderate support)	$\bigcirc$	0
Non-invasive respiratory support (clinically stable BIPAP, CPAP, high flow)	$\bigcirc$	0
Weight less than a specific threshold	$\bigcirc$	$\bigcirc$
Steroids within last week	$\bigcirc$	$\bigcirc$

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

#### Please specify weight threshold:

Only answer this question if the following conditions are met: Answer was 'Delay' at question '32 [C01]' (Which of these factors would make you delay a planned stoma closure? (Weight less than a specific threshold))

Please choose only one of the following:

500g
1,000g
1,500g
2,000g
2,500g
3,000g
3,500g
4,000g
4,500g
5,000g

Where 'delay' has been selected for 'weight less than a specific threshold' in the question above.

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### Which of these factors would make you expedite a planned stoma closure that was still some weeks away?

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please choose the appropriate response for each item:

	Expedite	Unchanged
Unable to recycle stoma distally effluent (down mucous fistula)	$\bigcirc$	$\bigcirc$
Concern about poor growth due to stoma	$\bigcirc$	$\bigcirc$
Parenteral nutrition issues e.g. liver disease or recurrent line sepsis	$\bigcirc$	$\bigcirc$
Inability to advance enteral feeds due to stoma outputs	$\bigcirc$	$\bigcirc$
Difficulties with managing the stoma e.g. leaking bags, prolapse, stricture, skin complications	0	$\bigcirc$

Are there any other factors you feel are important when deciding when to close the stoma of these infants or whether you would be willing to randomise to a trial?

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please write your answer here:

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### Perspectives on Clinical Trial Design

When answering the following questions, please consider how any future clinical trial would be most useful to you in terms of helping decision-making in your clinical practice.

#### Population

### 1. What groups of infants should be included in a trial?

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please choose the appropriate response for each item:

	Yes	No	Unsure
Premature infants with spontaneous intestinal perforation (SIP)	$\bigcirc$	$\bigcirc$	$\bigcirc$
Premature infants with NEC	$\bigcirc$	$\bigcirc$	$\bigcirc$
Term infants with emergency stoma formation for bowel obstruction (e.g. atresias, meconium ileus, complicated gastroschisis or malrotation/volvulus)	$\bigcirc$	$\bigcirc$	$\bigcirc$
Other (if yes, enter details below)	$\bigcirc$	$\bigcirc$	$\bigcirc$

We are not planning on including infants with anorectal malformations and Hirschsprung's disease, as stoma closures in these infants are usually part of a planned treatment pathway

#### If you have selected 'other' above, please describe here: \*

Only answer this question if the following conditions are met: Answer was 'Yes' at question '36 [E01]' (Population 1. What groups of infants should be included in a trial? (Other (if yes, enter details below)))

Please write your answer here:

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### 2. Are there any babies that you don't think should be included in a trial?

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please write your answer here:

#### Intervention

3. What do you think the 'early' time-point should be in a trial of early vs. late stoma closure in neonates? \*

Only answer this question if the following conditions are met:

Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

• If you choose 'Completed weeks after stoma formation:' please also specify your choice in the accompanying text field.

• Only numbers may be entered in 'Completed weeks after stoma formation:' accompanying text field.

Please choose only one of the following:

) Completed weeks after stoma formation (enter number of weeks below)

Unsure

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

#### Please enter number of weeks: \*

Only answer this question if the following conditions are met:

Answer was 'Completed weeks after stoma formation (enter number of weeks below)' at question '39 [E03]' (Intervention 3. What do you think the 'early' time-point should be in a trial of early vs. late stoma closure in neonates? )

Please write your answer here:

#### Comparison

4. What do you think the 'later' comparison should be in such a trial? \*

Only answer this question if the following conditions are met:

Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

• If you choose 'Completed weeks after stoma formation:' please also specify your choice in the accompanying text field.

• Only numbers may be entered in 'Completed weeks after stoma formation:' accompanying text field.

Please choose only one of the following:

) Completed weeks after stoma formation (enter number of weeks below)

) Unsure

#### Please enter number of weeks: \*

Only answer this question if the following conditions are met:

Answer was 'Completed weeks after stoma formation (enter number of weeks below)' at question '41 [E04]' (Comparison 4. What do you think the 'later' comparison should be in such a trial? )

Please write your answer here:

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

#### Outcomes

5. A core outcome set for neonatology has been identified to help standardise outcome selection in clinical trials and ensure these are relevant to those most affected by neonatal care (https://fn.bmj.com/content/105/4/425) (https://fn.bmj.com/content/105/4/425)). We would envisage these outcomes would be included in any trial of stoma closure.

In addition, there are likely to be study-specific outcomes that it are important to include. Please score how important you feel these potential trial outcome measures are.

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Not Little Very Extremely importantimportandemportantimportantimportant Length of hospital stay ()Duration of parenteral nutrition (PN)  $\bigcirc$ Time to full enteral feeds ()()()()Growth ()Complications of surgery e.g.  $\bigcirc$ ()()anastomotic leak or stricture Days of invasive ventilation postoperatively **Parental experience** ()Please indicate any others you  $\bigcirc$ think are important (describe below)

Please choose the appropriate response for each item:

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### For 'any others' selected above, please describe these outcomes here: \*

Only answer this question if the following conditions are met:

Answer was NOT at question '43 [E06]' (Outcomes 5. A core outcome set for neonatology has been identified to help standardise outcome selection in clinical trials and ensure these are relevant to those most affected by neonatal care (https://fn.bmj.com/content/105/4/425). We would envisage these outcomes would be included in any trial of stoma closure. In addition, there are likely to be study-specific outcomes that it are important to include. Please score how important you feel these potential trial outcome measures are. (Please indicate any others you think are important (describe below)))

Please write your answer here:

11/12/2020
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NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### 6. What should be the primary outcome of any trial of early vs. late stoma closure?

Only answer this question if the following conditions are met:

((A01.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/167) != "A5") and (A02.NAOK (/index.php/admin/questions/sa/view/surveyid/675993/gid/7/qid/168) != "A4"))

• Choose one of the following answers Please choose **only one** of the following:

The disc choose only one of the following.				
C Length of hospital stay				
O Duration of parenteral nutrition (PN)				
◯ Time to full enteral feeds				
Growth				
Complications of surgery e.g. anastomotic leak or stricture				
O Days of invasive ventilation post-operatively				
O Parental experience				
Survival				
Sepsis				
O Necrotising enterocolitis				
Brain injury on imaging				
Retinopathy of prematurity (preterm only)				
◯ General gross motor ability				
General cognitive ability				
Quality of life				
O Adverse events				
◯ Visual impairment or blindness				
O Hearing impairment or deafness				
Chronic lung disease/bronchopulmonary dysplasia (preterm only)				
Other				
* list from Core outcomes in neonatology and above list				

### Potential Organisational Barriers to a Clinical Trial

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

#### If we were to design a trial that compared prescribed timings of stoma closure, how would you foresee the following factors influencing this in your centre?

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please choose the appropriate response for each item:

	No issue	May be a problem	Likely to be a significant problem
Ability to access neonatal operating list at short notice	$\bigcirc$	$\bigcirc$	$\bigcirc$
Access to a ventilated neonatal bed post-operatively	$\bigcirc$	$\bigcirc$	$\bigcirc$
Surgeon availability e.g. flexibility within job plan	$\bigcirc$	$\bigcirc$	$\bigcirc$
Willingness of anaesthetists to facilitate the trial	$\bigcirc$	$\bigcirc$	0
Transfer of infant to the surgical centre for the closure	$\bigcirc$	$\bigcirc$	0
Willingness of you and your colleagues to facilitate the trial e.g. sharing cases	$\bigcirc$	$\bigcirc$	$\bigcirc$

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### Please indicate if there are other likely barriers to running the trial at your unit.

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please write your answer here:

#### In your unit, from when a decision to close a stoma is made, how long on average does it take to do this, taking into acount factors such as waiting for theatre space?

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please write your answer here:

weeks

### Would you be interested in attending a final consensus meeting at the end of the ToSCiN study?

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Please choose only one of the following:

$\bigcirc$	Yes
------------	-----

) No

NPEU Surveys - Timing of Stoma Closure in Neonates (ToSCiN)

### If you would like to receive feedback about the results of ToSCiN, please provide your details below:

Only answer this question if the following conditions are met: Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at question '2 [A02]' (Description of the type of unit you work in:)

Thank you for completing this survey.

We will provide feedback of the results at the end of the ToSCiN study.

29/09/2020 - 17:30

Submit your survey. Thank you for completing this survey.