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TIMING OF NEONATAL STOMA CLOSURE: A SURVEY OF HEALTH PROFESSIONAL PERSPECTIVES AND CURRENT PRACTICE

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3 **TIMING OF NEONATAL STOMA CLOSURE: A SURVEY OF HEALTH PROFESSIONAL PERSPECTIVES**
4 **AND CURRENT PRACTICE**
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58 **Word count 1271**
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ABSTRACT

Optimal timing for neonatal stoma closure remains unclear. In this study we aimed to establish current practice and illustrate multidisciplinary perspectives on timing of stoma closure using an online survey sent to all 27 UK neonatal surgical units, as part of a research programme to determine feasibility of a clinical trial comparing 'early' and 'late' stoma closure. 166 responses from all 27 units demonstrated concordance of opinion in target time for closure (6 weeks most commonly stated across scenarios), although there was high variability in practice. A sizeable proportion (41%) of respondents use weight, rather than time, to determine when to close a neonatal stoma. Thematic analysis of free-text responses identified 9 key themes influencing decision making; most related to nutrition, growth and stoma complications. These data provide an overview of current practice that is critical to informing an acceptable trial design.

Word count: 142

INTRODUCTION

Neonates undergoing emergency abdominal surgery frequently require stoma formation. Reversing (closing) stomas with a second operation is an essential part of the infant's recovery, but evidence to inform the optimum timing of stoma closure is limited and conflicting [1-4]. The Timing of Stoma Closure in Neonates (ToSCiN) study will use mixed methods to determine the feasibility of a clinical trial comparing 'early' and 'late' stoma closure in neonates. In this part, we undertook a survey of neonatal surgical professionals in the United Kingdom (UK), to establish current practice for stoma closure in neonates and explore their perspectives to inform future trial design.

METHODS

An online survey was developed which focused on three domains (Appendix 1):

- (1) The clinical role of the respondent and structure of their neonatal surgical institution
- (2) Current practice for timing of stoma closure and clinical considerations for expediting or delaying surgery
- (3) Focused questions on preferred practice across four clinical scenarios: preterm and term infants with congenital or acquired gut pathologies

The survey was distributed using LimeSurvey© to consultant neonatologists, consultant paediatric surgeons, neonatal dieticians and specialist neonatal surgical nurses in all 27 UK units caring for surgical neonates. We also disseminated the survey via national organisations (British Association of Paediatric Surgeons and British Association of Perinatal Medicine) and personal contacts of the study team. Our target response was ≥ 2 surgeons and ≥ 2 neonatologists from each centre, whilst ensuring sampling variance (e.g. geographical area and healthcare professional type). Finally, we used snowball sampling whereby invitees were encouraged to cascade the survey to help maximise responses. Reminder emails were sent to potential participants to encourage completion and the survey was open for 3 months.

Survey data were described using counts and percentages for categorical variables and median [interquartile range] or mode for continuous variables. Qualitative free-text responses were indexed and analysed thematically [5].

RESULTS

A total of 166 professionals across all 27 UK neonatal surgical centres completed the survey, with 87 (52%) responses from surgeons, 66 (40%) neonatologists, 8 (5%) specialist nurses and 5 (3%) dieticians. All UK neonatal surgical centres responded: ≥ 2 surgeons responded from 24/27 centres and ≥ 2 neonatologists from 24/27.

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3 Without defining 'early' or 'later', 78/166 (47%) respondents generally considered themselves proponents of
4 'early' stoma closure, 47/166 (28%) proponents of 'later' stoma closure and 41/166 (25%) unsure.
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7 **Achieving a pre-defined time interval prior to stoma closure**

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9 Attitudes towards timing of stoma closure were sought for each of four clinical scenarios (table 1). The target
10 time to closure was most commonly 6 weeks, although there was variability between scenarios; more
11 respondents favoured a longer time interval between stoma formation and closure for premature infants.
12 Common free-text explanations for a longer interval suggested that greater morbidity and instability would
13 be expected in premature or very-low-birth-weight infants. Inflammatory pathologies (i.e. bowel
14 perforation, peritonitis and necrotising enterocolitis) were often considered to be justifications to extend the
15 interval between procedures to allow evolution of gut sequelae and abdominal quiescence, along with
16 resolution of the catabolic phase of recovery (table 2). While 70-76% of respondents preferred stoma
17 closure prior to discharge in preterm infants and a term infant with a jejunostomy, only 46% would prefer
18 this approach in the term infant with an ileostomy. In all scenarios, a sizeable proportion (29-37%) of
19 respondents indicated they were unsure when would be best to close the stoma.
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Table 1

	Scenario 1	Scenario 2	Scenario 3	Scenario 4
	<i>"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."</i>	<i>"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."</i>	<i>"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."</i>	<i>"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)."</i>
Target stoma closure time	n=118/166 (71%) weeks specified: median [IQR] = 8 [6, 12], mode = 6 n=48/166 (29%) unsure	n=110/166 (66%) weeks specified: median [IQR] = 8 [6, 10], mode = 6 n=56/166 (34%) unsure	n=105/166 (63%) weeks specified: median [IQR] = 4 [6, 8], mode = 6 n=61/166 (37%) unsure	n=104/166 (63%) weeks specified: median [IQR] = 6 [4, 6], mode = 6 n=62/166 (37%) unsure
Preference for closure in relation to discharge	Before: 117 (70%) After: 25 (15%) Unsure: 24 (14%)	Before: 126 (76%) After: 15 (9%) Unsure: 25 (15%)	Before: 77 (46%) After: 53 (32%) Unsure: 36 (22%)	Before: 120 (72%) After: 26 (16%) Unsure: 20 (12%)
Earliest experience of closure in comparable scenario	n=153/166 (92%) weeks specified: median [IQR] = 6 [4, 6], mode = 6	n=153/166 (92%) weeks specified: median [IQR] = 6 [4, 8], mode = 6	n=135/166 (81%) weeks specified: median [IQR] = 4 [4, 6], mode = 4	n=125/166 (75%) weeks specified: median [IQR] = 4 [3, 6], mode = 4
Latest experience of closure in comparable scenario	n=154/166 (93%) weeks specified: median [IQR] = 20 [12, 30], mode = 12	n=143/166 (86%) weeks specified: median [IQR] = 20 [12, 26], mode = 12	n=126/166 (76%) weeks specified: median [IQR] = 16 [12, 24], mode = 12	n=115/166 (69%) weeks specified: median [IQR] = 12 [8, 16], mode = 12

Table 2

Theme	Sub-theme [number of respondents who mentioned this theme]	Example free-text responses [respondent role]
Factors supporting expediting stoma closure	Growth failure and PN dependence (including liver disease) [127]	<i>"If there are growth issues, PN [parenteral nutrition] requirement or stoma complications, I would aim for an early closure."</i> [Respondent 146, Paediatric Surgeon]
	High output (or proximal) stoma [112]	<i>"If a baby is failing to thrive, high output stoma losses and TPN [total parenteral nutrition] dependent then we would close sooner rather than later and certainly before discharge".</i> [Respondent 150, Neonatologist]
	Peristomal issues (e.g. skin breakdown, prolapse, granulation) [26]	<i>"Usually, with high-output stomas, early closure is required to avoid growth failure. However, a stably growing infant with successful pro-cycling of stoma outputs can have delayed closure."</i> [Respondent 11, Neonatologist]
	Social issues [18]	<i>"...if the baby had difficult social situation and the risk of a stoma at home and picking up issues high [risk] then would advocate for early closure."</i> [Respondent 154, Neonatal Surgical Specialist Nurse]
Factors supporting delaying planned stoma closure	Vascular access [7]	<i>"Timing of stoma closure is multifactorial - depends on stoma care, stoma complications, level of stoma, success of recycling, distance family are from home, social circumstances, tolerance of feed, IV [intravenous] access, parent's wishes, other pathology, and many other factors i.e. it is individualised to each child and family."</i> [Respondent 22, Paediatric Surgeon]
	Thriving with stoma and enterally autonomous (including successful recycling) [109]	<i>"I am not sure if the timing of stoma closure is my main concern as a neonatologist. My main concern is time to full feeds, and growth rate. Stoma closure is secondary, and I am happy to consider discharge home with a stoma. In fact, I would prefer to discharge this baby home with a stoma than prolong hospital stay to achieve closure before discharge home."</i> [Respondent 165, Neonatologist]
	Comorbidities (not optimised for surgery and/or anaesthetic) [56]	<i>"Ideally if patient is well with good stoma management and recycling and gaining weight then I would wait until a few months of age."</i> [Respondent 59, Paediatric Surgeon]
	Underlying gut pathology/surgical technical concerns [35]	<i>"This baby is more likely to have co-morbidities which will influence surgical and anaesthetic risk, especially CLD [chronic lung disease]...Some of these babies get closed many months post-discharge if they are complicated".</i> [Respondent 28, Neonatologist]
	Difficulty accessing theatre lists (including Covid-19 limitations) [14]	<i>"Ideally, I would wait for 6 weeks after NEC [necrotising enterocolitis], to allow for maturation and identification of post-NEC strictures, which may have bearing on success of closure ...I would move to close sooner if MDT [multidisciplinary team] discussion agreed best for baby; again, other comorbidities have a bearing on timing of closure."</i> [Respondent 34, Paediatric Surgeon]
		<i>"One of our main confounding issues at the present time is timely access to theatre lists. Our capacity was diminished pre COVID and worse now. The 1 year wait for stoma closure was certainly not through choice but reflects this problem."</i> [Respondent 144, Paediatric Surgeon]

Reasons for delaying stoma closure

40% (60/150) of respondents reported they would delay stoma closure due to 'Invasive ventilation (clinically stable and low/moderate support)', 29% (44/150) due to 'non-invasive respiratory support (clinically stable, BIPAP, CPAP, high flow oxygen)', and 58% (80/138) due to 'Steroids within the last week'.

Achieving a defined weight threshold prior to stoma closure

Weight was a recurrent theme in both free-text responses and closed questions on preferred timing of stoma closure. Just under half (54/132, 41%) of respondents would delay stoma closure until an infant had reached a pre-defined weight, although the weight threshold varied: median [IQR] 2000g [1625 - 2500g]; mode 2500g.

Reasons for expediting stoma closure

The large majority of respondents indicated they would bring stoma closure forward if there were problems with an infant's growth, nutrition and stoma. 96% (158/164) reported they would expedite closure due to 'Concern about poor growth due to stoma', 97% (157/162) due to 'Parenteral nutrition (PN) issues (e.g. liver disease or recurrent line sepsis)', 93% (152/163) due to 'Inability to advance enteral feeds due to stoma outputs', and 95% (154/162) due to 'Difficulties with managing the stoma (e.g. leaking bags, prolapse).' Recycling of stoma effluent was a variable practice amongst respondents: 'Routine' = 41/164 (25%), 'Sometimes' = 68/164 (41%), 'Rarely' = 42/164 (26%), and 'Never' = 13/164 (8%). 52% (73/140) reported they would expedite stoma closure due to 'Inability to recycle stoma effluent distally.'

Qualitative analysis of free-text responses

For each clinical scenario respondents were asked for further comments and considerations on timing of stoma closure. Through thematic analysis of 355 free text responses, 9 key themes were identified as factors influencing decision making. Those supporting expediting stoma closure included: growth failure and PN dependence, high output stoma, peristomal problems and vascular access. Factors supporting delaying stoma closure included: thriving with stoma, comorbidities (not optimised for surgery), underlying gut pathology/surgical technical concerns and difficulty accessing theatre lists (table 2).

DISCUSSION

This large study of practice and practitioner views illustrates the sometimes conflicting clinical variables that impact timing of stoma closure. Whilst there appears to be some concordance of opinion about an initial target time for closure (6 week interval most common for all scenarios), there remains a high degree of variability, with intervals of 12 weeks or more frequently advocated. This study also demonstrates that a sizeable proportion (41%) of respondents use weight, rather than time, to determine when to close a

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3 neonatal stoma. Furthermore, 1 in 3 respondents expressed uncertainty about timing of stoma closure,
4 perhaps highlighting the lack of a clear evidence-base in this area but also the difficulty in committing to a
5 time when faced with sometimes conflicting and changing clinical parameters in an already heterogenous
6 population.
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10 Whilst often lifesaving, neonatal stomas can lead to significant challenges, with morbidity from fluid and
11 electrolyte imbalances, peristomal complications, consequences of PN, and the need for central vascular
12 access [1-2]. Our survey reflects these concerns and highlights 9 key factors that affect timing of closure,
13 with the majority relating to nutrition and growth. Perhaps unsurprisingly we found that a respondent's
14 clinical role altered their responses (e.g. surgeons more often quoted technical factors and neonatologists
15 medical factors as reasons for delaying or expediting surgery). However, the above-mentioned key factors
16 were common to responses from all professions.
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23 A key strength of our survey is its wide coverage with multidisciplinary responses from all UK neonatal
24 surgical units. As with most surveys of practice, a limitation is that respondents reported what they believe
25 their practice to be, rather than providing data on actual clinical cases. We attempted to mitigate against this
26 through provision of real-world clinical scenarios and will capture observational data about practice in future
27 work within the ToSCiN study.
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32 A clinical trial comparing 'early' vs. 'late' stoma closure would provide high-quality evidence on which to
33 base decision-making. This work provides an overview of current practice that will be critical to informing
34 acceptable trial design.
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38 Future work will further determine trial feasibility based around real-world cases using quantitative and
39 qualitative methods. This will include assessing eligibility in a group of infants with a range of clinical
40 characteristics (and how this may change over time) and whether a trial of early vs. late closure would be
41 acceptable to parents and clinicians caring for these infants.
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51 **COMPETING INTERESTS**

52 The authors have no competing interests.
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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

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:)

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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:

- Early
- Later
- Unsure

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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

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Scenarios

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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:)

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.

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:

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:

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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:)

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Please choose **only one** of the following:

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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

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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

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.

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)
- Unsure

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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:

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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:

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- Before
- After
- Unsure

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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:

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weeks post formation

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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.

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

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Only answer this question if the following conditions are met:

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((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"))

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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 '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:

- Before
- After
- Unsure

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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:

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).

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)
- 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:

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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

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)	<input type="radio"/>	<input type="radio"/>
Non-invasive respiratory support (clinically stable BIPAP, CPAP, high flow)	<input type="radio"/>	<input type="radio"/>
Weight less than a specific threshold	<input type="radio"/>	<input type="radio"/>
Steroids within last week	<input type="radio"/>	<input type="radio"/>

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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.

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)	<input type="radio"/>	<input type="radio"/>
Concern about poor growth due to stoma	<input type="radio"/>	<input type="radio"/>
Parenteral nutrition issues e.g. liver disease or recurrent line sepsis	<input type="radio"/>	<input type="radio"/>
Inability to advance enteral feeds due to stoma outputs	<input type="radio"/>	<input type="radio"/>
Difficulties with managing the stoma e.g. leaking bags, prolapse, stricture, skin complications	<input type="radio"/>	<input type="radio"/>

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:

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)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Premature infants with NEC	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Term infants with emergency stoma formation for bowel obstruction (e.g. atresias, meconium ileus, complicated gastroschisis or malrotation/volvulus)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (if yes, enter details below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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:

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

6 Only answer this question if the following conditions are met:

7 Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at
8 question '2 [A02]' (Description of the type of unit you work in:)
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10 Please write your answer here:
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Intervention

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

32 Only answer this question if the following conditions are met:

33 Answer was NOT 'Other' at question '1 [A01]' (Your role) *and* Answer was NOT 'Other' at
34 question '2 [A02]' (Description of the type of unit you work in:)
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36 **!** If you choose 'Completed weeks after stoma formation:' please also specify your choice
37 in the accompanying text field.

38 **!** Only numbers may be entered in 'Completed weeks after stoma formation:'
39 accompanying text field.
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41 Please choose **only one** of the following:
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- 43
44 Completed weeks after stoma formation (enter number of weeks below)
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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:

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:)

Please choose the appropriate response for each item:

	Not important	Little importance	Some important	Very important	Extremely important
Length of hospital stay	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Duration of parenteral nutrition (PN)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Time to full enteral feeds	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Growth	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Complications of surgery e.g. anastomotic leak or stricture	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Days of invasive ventilation post-operatively	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Parental experience	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Please indicate any others you think are important (describe below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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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:

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:

- Length of hospital stay
- Duration of parenteral nutrition (PN)
- Time to full enteral feeds
- Growth
- Complications of surgery e.g. anastomotic leak or stricture
- Days of invasive ventilation post-operatively
- Parental experience
- Survival
- Sepsis
- Necrotising enterocolitis
- Brain injury on imaging
- Retinopathy of prematurity (preterm only)
- General gross motor ability
- General cognitive ability
- Quality of life
- Adverse events
- Visual impairment or blindness
- 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

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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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to a ventilated neonatal bed post-operatively	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Surgeon availability e.g. flexibility within job plan	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Willingness of anaesthetists to facilitate the trial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Transfer of infant to the surgical centre for the closure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Willingness of you and your colleagues to facilitate the trial e.g. sharing cases	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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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 account 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:

Yes

No

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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:)

12 Thank you for completing this survey.
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16 We will provide feedback of the results at the end of the ToSCiN study.
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21 29/09/2020 – 17:30
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24 Submit your survey.

25 Thank you for completing this survey.
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