National Institute for Health and Clinical Excellence

Constipation in children
Guideline Consultation Comments Table
1 October – 25 November 2009

SH = Registered Stakeholders. These comments and responses will be posted on the NICE website when the guideline is published.
PR = Peer Reviewers or Experts. These comments and responses will be posted on the NICE website when the guideline is published.

number	Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
1.	PR	NETSCC-HTA (1)	10.01	Full	general	general	**Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)** I am not aware of any.	Thank you
2.	PR	NETSCC-HTA (1)	10.02	Full	general	general	**Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).** The work appears competent and thorough.	Thank you
3.	PR	NETSCC-HTA (1)	10.03	Full	general	general	The GDG should be commended on their thorough literature search and review of articles considered. Inevitably in such a large document a few typos/transcription errors are present but these do not impact on the findings.	Thank you, we have gone through the document to correct as many typos as possible.
4.	PR	NETSCC-HTA (1)	10.04	Full	4	38-70	In assessing the diagnostic value of tests for idiopathic constipation the GDG have appropriately reported levels of Sensitivity	Thank you for your comment, we agree. In writing recommendations the GDG not only considered the trade-off between sensitivity and

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							and Specificity, and where available evaluated inter and intra observer reliability. The trade-off between Sensitivity and Specificity means that the value of any test depends upon whether it is considered a screening tool or whether confirmation/elimination of a condition is required.	specificity, but also and where appropriate other features of the test e.g. how invasive/distressing they are for the child. Constipation can be diagnosed by history taking and physical examination in the vast majority of children and additional tests are only required in a very small group who either does not respond to treatment or present with very specific signs and symptoms which flag serious but infrequent organic disorders.
5.	PR	NETSCC-HTA (1)	10.05	Full	4.3	42	Line 29 The prevalence of hydrothyroidism and celiac disease in children with chronic constipation are conditional (posterior) probabilities, which cannot be estimated from the studies presented without additional information.	Thank you for your comment. We agree and we stated in the "Overview of available evidence" that none of these studies investigated the prevalence of coeliac disease in children with idiopathic constipation but rather looked at the associations between coeliac disease and symptoms of constipation in a variety of populations of children. No studies were identified for inclusion that considered the prevalence of hypothyroidism in children with idiopathic constipation. Therefore we concluded that there is no published evidence on the prevalence of hypothyroidism and coeliac disease in children with idiopathic constipation, hence the recommendation of not testing as a routine but only in the ongoing management of intractable constipation and when requested by specialist services
6.	PR	NETSCC-HTA (1)	10.06	Full	4.4	44	A very minor point. In diagnostic testing it is common for a positive result to indicate disease and for the first row of tables to indicate these. Thus perhaps absence (-) of RAIR in table 4.1 should be labelled as	Thank you for your comment. We have amended this as suggested

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							a positive result?	
7.	PR	NETSCC-HTA (1)	10.07	Full	4.5	48-49	A minor point. Accuracy, Positive and Negative Predictive Values (PPV, NPV) depend upon disease prevalence and reference to these is not helpful in case-control studies and may lead to confusion.	Thank you for your comment. We agree and that is why we have given a low grade to the evidence to reflect this bias. We have made this more explicit in the narrative.
8.	PR	NETSCC-HTA (1)	10.08	Full	5	71-150	When assessing the effect of interventions reliance is placed upon appropriate use of statistical methods and inevitably there is an element of trust placed on reported p-values. The evidence tables (appendix J) are very useful in this respect but these are not numbered and not always listed in sequence (Eg Mousa et al (129) follows Curry et al (132). Some papers appear to report significant differences from incorrect analyses (e.g. papers 90, 108, 129, 130) and others report significant findings that are inconsistent with results (e.g paper 122 reports p = 0.18 as significant),.Lack of clarity is often indicated in the evidence tables but is not always transparent in the narrative summaries.	Thank you for your comment. We are pleased that you found the evidence tables useful. We have now ordered the papers in the evidence tables to match the narrative summaries. The evidence tables include all findings relevant to outcomes of interest as reported in the papers. This is summarised in the narratives but not all details are included here. Paper 122 reports the p value as 0.018 which is significant as stated. The previous figure of p=0.18 was a typographical error.
9.	PR	NETSCC-HTA (1)	10.09	Full	general	general	Caution must also be exercised when multiple tests have been carried out since these lead to an increase in risk of type one errors.	Thank you for your comment, we agree and have limited our reviewing to pre-specified outcomes as documented in the PICO tables.
10.	PR	NETSCC-HTA (1)	10.10	Full	5.2, 5.4	general	Lack of evidence is not evidence of equivalence (particularly if there is	Thank you for your comment.

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					& 5.5		considerable loss to follow-up & small samples). To conclude that two treatments are equally effective on the grounds of a non-significant result could be misleading, particularly where confidence intervals for differences are not presented. On numerous occasions treatments are said to be "as effective" or "equally effective" and this may not always be supported by the data.	We have amended the evidence statements accordingly so that this is made clear as you suggest.
11.	PR	NETSCC-HTA (1)	10.11	Full	6	159	The evidence statement (line 1) incorrectly concludes that nurse led clinics significantly reduce time to cure.	Thank you for your comment. We agree and have amended accordingly.
12.	PR	NETSCC-HTA (1)	10.12	Full	4	38-70	Sample sizes are often too small to provide reliable estimates of indices used to discriminate between tests and inter and intra observer reliability is often neglected. The findings in this section are consistent with the statistical evidence	Thank you for your comment
13.	PR	NETSCC-HTA (1)	10.13	Full	5	general	In the general the statistical results do not contradict the findings of the GDG nor the research recommendations.	Thank you
14.	PR	NETSCC-HTA (1)	10.14	Full	general	general	As stated previously, it appears that interventions are reported "as effective" or "equally effective" on the grounds of no significant difference being found. This may not be fully justified.	Thank you for your comment, we agree and have amended the wording in the evidence statements to make clear the fact that no significant differences found between intervention does not mean that they are equally effective
15.	PR	NETSCC-HTA (1)	10.15	Full	6	159	The evidence statement (line 1) incorrectly concludes that nurse led clinics significantly reduce time to cure. On page	Thank you for your comment. We agree and have amended accordingly.

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							161 line 30 the two interventions are considered "as effective" which appears contradictory. The statistical interpretation is that the difference in cure times could be due to chance.	
16.	PR	NETSCC-HTA (1)	10.16	Full	5	71-150	**Are any important limitations of the evidence clearly described and discussed?** Reference to small sample size and inadequate information is mentioned. Consideration of the appropriateness of the statistical analysis is not obvious.	Thank you for your comment. Inappropriate statistical analysis would be commented on but we do not comment specifically if the statistical analysis is deemed appropriate.
17.	PR	NETSCC-HTA (1)	10.17	Full	general	general	Generally narrative reviews followed by evidence statements seem a good idea. However, there is a considerable amount of detail to consider and in some cases matching up the evidence statement to the narrative summary is not obvious.	Thank you for your comment. We agree, it is sometimes difficult where there is a lot of detail in the narrative summary. In order to help this we have presented the studies in the same order in the evidence statement as in the narrative summary and given a brief descriptive term for each study and its evidence level to help with cross-referencing.
18.	PR	NETSCC-HTA (1)	10.18	Full	general	general	It would help if papers were numbered in the evidence tables (appendix J).	Thank you for your comment. We are sorry but it is not possible with our software to generate reference numbers in the evidence tables at the same time as the full reference. Each evidence table has the title of the corresponding review narrative and papers follow the same order in both.
19.	PR	NETSCC-HTA (1)	10.19	Full	general	general	Whilst conclusions and research recommendations are not contradicted by the statistical evidence, interpretation of	Thank you for your comment. We have now added more detail to the GDG interpretations in order to improve clarity.

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							the findings of the GDG is often phrased in general terms that it is not clear precisely what motivated the recommendations.	
20.	PR	NETSCC-HTA (1)	10.20	Full	general	general	**Please comment on whether the research recommendations, if included, are clear and justified.** I would say they are clear and "supported".	Thank you
21.	PR	NETSCC-HTA (2)	11.01	Full	General	general	**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)** No – the work appears to fulfil the key intentions	Thank you
22.	PR	NETSCC-HTA (2)	11.02	Full	General	general	**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).** Search strategies for published evidence appear sound	Thank you
23.	PR	NETSCC-HTA (2)	11.03	Full	5.1	82	(& Appendix E: 184) **Cost analysis for disimpaction**: Comparative clinical efficacy data for rival drug treatments/doses were lacking such that the efficacy inputs (low dose, high dose, combination, manual evacuation) used in the modeling process were based on expert opinion – not a good starting point for health economic analysis. The methodology used for producing opinion-	Thank you for your comment. We agree with this observation. No clinical efficacy data were available on which to base any of these parameter estimates in the model which would have been an optimal starting point. The following sentence has been added to clarify that the derivation of the estimates was an informal consensus based discussion with the GDG: "The decision to take this approach was made by GDG consensus given the absence of data on the

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							based estimates isn't described but may have been an informal consensus or discussion rather than the more formal consensus methodology used in evaluation of clinical recommendations.	comparative effectiveness of these treatments, and given that these treatments are currently used interchangeably in the NHS."
24.	PR	NETSCC-HTA (2)	11.04	Full	5.1	82	(& Appendix E: 184) A simplifying assumption was made that all drug treatments had similar efficacy (cost-minimization) but sensitivity analysis explored the effect of 'low', 'medium' and 'high' success rates for drug treatment over a three month time horizon. Similarly, real data for deriving estimates of direct medical costs associated with treating IC were not available and again the model inputs were based on an estimate of cost based on opinion and standard drug and hospitalization costs. Hence, there is considerable uncertainty to the inputs and probabilities used for the baseline scenario.	Thank you for your comment, we agree with this observation. We have described the uncertainty in the inputs and parameters in this model and will highlight these uncertainties further in the discussion and conclusion, and in the health economic summaries in the main body of the guideline.
25.	PR	NETSCC-HTA (2)	11.05	Full	5.1	82	(& Appendix E: 184) Nevertheless, the model appears sufficient to illustrate some of the likely drivers of cost-effectiveness. Assuming equal efficacy of all drugs (a big assumption), the model suggests that for the range of drug treatments available, variation in acquisition cost for the different drugs has a limited impact on overall cost-effectiveness. It is the success rate of initial treatment that dominates the picture since down-stream	Noted, thank you.

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							costs associated with treatment failure are high (ie. hospitalization costs for a minority of cases). This seems plausible.	
26.	PR	NETSCC-HTA (2)	11.06	Full	5.1	82	(& Appendix E: 184) Whilst the authors cite a lack of quality evidence (eg. comparative RCTs) to serve as a source for model inputs it seems unlikely that there are no reports of lesser quality (eg. observational studies; open label, uncontrolled studies; large audits or grey literature) that might have provided some calibration / credibility to the modeling inputs. No published or unpublished information is cited to support the key modeling assumptions. The summary states that 'the economic analysis used the clinical effectiveness evidence that was available' but cites only the 'GDG' as the source for effectiveness data.	Thank you, we agree. The systematic review of the evidence did not identify any additional information that could have been used to increase the credibility of the model. What data that we did identify was used, such as the dose effectiveness of Movicol. We are fully aware of the limitations of this model and the fact that it was developed in a largely evidence-free clinical area. Your comment poses larger questions that we often face as to the value of economic modelling under these circumstances, especially the benefit of modelling to support GDG decision transparency in making its recommendations versus its cost in terms of time and effort.
27.	PR	NETSCC-HTA (2)	11.07	Full	5.1	82	(& Appendix E: 184) There are similar issues with the maintenance modeling.	Thank you, we agree. The systematic review of the evidence did not identify any additional information that could have been used to increase the credibility of the model. What data that we did identify was used, such as the dose effectiveness of Movicol. We are fully aware of the limitations of this model and the fact that it was developed in a largely evidence-free clinical area. Your comment poses larger questions that we often face as to the value of economic modelling under these circumstances, especially the benefit of modelling to support GDG decision transparency in making its recommendations versus its cost in terms of time

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								and effort.
28.	PR	NETSCC-HTA (2)	11.08	Full	2.7	27-28	**Evidence to recommendations:** The evidence-based for many of the recommendations is relatively weak owing to a lack of high quality research evidence. The resulting guideline is based in many areas on a consensus opinion of the group although feedback from stakeholders formed part of the process. It is therefore difficult to comment on whether the individual guideline recommendations are 'justified' since pragmatic group opinion has filled the knowledge gap. The authors have emphasized this aspect.	Thank you for your comment.
29.	PR	NETSCC-HTA (2)	11.09	Full	general	general	**3.2 Are any important limitations of the evidence clearly described and discussed?** Yes	Thank you
30.	PR	NETSCC-HTA (2)	11.10	Full	1.1	3	In Table I, the interpretation of 'very loose' and 'very smelly' may present difficulties – how are these subjective descriptors defined?	Thank you for your comment. We have now defined the terms as follows: Very loose = no form Very smelly = smells more unpleasant than normal poo Please see glossary for definitions of overflow soiling and diarrhoea
31.	PR	NETSCC-HTA (2)	11.11	Full	1.1	4-5	The green/amber/red labeling system in Table II & III is useful but these are cumbersome and lengthy tables for use in clinical practice. A table which brings together all 'red-flag' items might be	Thank you for your comment. We have amended the tables to improve readability. We have kept the table entry for 'green' (although we are not using colours anymore in response to

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							helpful. A summary of 'alarm' or 'red flag' features alone would be consistent with other guidelines where the emphasis is to assist GPs in identifying signals for possible serious organic disease. For a number of features, the table entry for 'green' (eg. 'reflexes present and of normal amplitude') is simply the opposite of 'red' (eg. 'abnormal reflexes') – this seems repetitive and makes the tables less readable. This comment applies to Tables B and C in the algorithm - readability might be improved by bringing together 'red flag' symptoms in one list .	other stakeholder comments) as the idea is to emphasise that a positive diagnosis of idiopathic constipation is possible. A table of 'red flag' features alone does not help to diagnose idiopathic constipation This guideline is not about signalling for serious organic disease, it is about making a positive diagnosis of idiopathic constipation and managing accordingly. 'Amber flags' have now been added to the bottom of the table.
32.	PR	NETSCC-HTA (2)	11.12	Full	1.2	8	Table I – replace 'history' (lower left box) with 'Past history'	Thank you for your comment This section comprises findings both from the past and the present history, hence the use of the general term "History" to include both
33.	PR	NETSCC-HTA (2)	11.13	Full	1.3	15-17	Given the relative lack of evidence for a number of recommendations there could have been a long list of research recommendations. Those selected by the group appear important and justified.	Thank you for your comment.
34.	SH	Airedale Acute Trust	9.01	full	1.1	3	Line 7: Over flow soiling here is said to be very smelly – some find it so but is it really?	Thank you for your comment. All of the GDG agreed that it was appropriate to describe overflow soiling as "very smelly"
35.	SH	Airedale Acute Trust	9.02	full	1.2	7	Line 3: This very comforting advice does not fit with other parts of the document e.g. page 59 line 54 where it talks about encopresis alone. From my observations	Thank you for your comment. We recognise that there will occasionally be treatment failures, but anticipate that offering children and their families a point of contact with a specialist health professional

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							if the parents do not agree with you on the meaning of the term constipation all other comments are lost. I do find talking about faecal overloading covers all bases. Also papers indicate treatment failures e.g.p89 line 34	who can give support will go some way to addressing this.
36.	SH	Airedale Acute Trust	9.03	full	1.2	10	Line 25: Heading is hypothyroidism and celiac disease but nothing is said about hypothyroidism	Thank you for your comment, the recommendation has now been amended to refer to hypothyroidism as well
37.	SH	Airedale Acute Trust	9.04	full	1.2	12	Line 2: Implies only use phosphate enema if a number of citrate enemas have failed. Does it not mean try using a number of oral medications first then if that fails try a citrate enema then if that fails a phosphate enema can be used	Thank you for your comment Recommendations follow on from each other, therefore we are recommending using all oral medications first then if that fails try a citrate enema then if that fails a phosphate enema can be used, but only under specialist supervision and in hospital
38.	SH	Airedale Acute Trust	9.05	full	1.2	14	Line 32: Perhaps I have missed the point I thought this section was a summary for the non specialist (see 2.4), if that is the case then should it not be non specialist to specialist to surgeon. Not non specialist to surgeon	Thank you for your comment We have amended this recommendation to make this clearer. It now reads as follows: "Refer children and young people with idiopathic constipation who still have unresolved symptoms on optimum management to a –paediatric surgical centre to assess their suitability for an antegrade colonic enema (ACE) procedure."
39.	SH	Airedale Acute Trust	9.06	Full	1.3	15	Line 30: Rectal treatments especially in hospital, are more common than oral treatments at home. Seems unlikely to me should the "oral" be rectal.	Thank you for your comment. We have re-written the sentence to say: "Rectal treatments are used more commonly in hospital than at home"
40.	SH	Airedale Acute Trust	9.07	Full	2.3	21	Line 27 (Table): Anal stenosis says constipation results. If you then read what	Thank you for your comment

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							constipation means I am not sure of this. Constipation to parents usually means to them passing of large stools, this you cannot do that through a stenosis. Do all regions of the country use constipation to mean the same thing e.g regional variation in the term croup?	Glossary definitions are correct but we understand that sometimes it might be confusing for parents. Constipation does not always mean large stools. Will try to address this misunderstanding during the implementation phase
41.	SH	Airedale Acute Trust	9.08	Full	2.3 2	21	Abbreviations – not clear if this is meant to be a full list e.g.Page 36 line 48 DRE, page 60 line 50 also PSTC NDTC same page PC P62 uses terms P and C p 63 TGITT BET p64 IBS p65 GC p65 plus FFR and FC p65 US p69 also SSS and DRE same page RCT p 72 BNFC p79 MOM p84 PEG p 88RCT p103 GDG and likely others further on. I am NOT saying these are not detailed in the text but sometimes not when first used	Thank you for your comment. We have gone through the document and tried to ensure that the acronyms are defined at their first use. We have also included those abbreviations in the list at the beginning where appropriate
42.	SH	Airedale Acute Trust	9.09	Full	2.6	24	Line 23 (General): Declaring no conflict of interest at the start is not the same as saying it at the end of the work you have done.	Thank you for your comment. NICE aims to be accurate and transparent regarding potential conflicts of interest. The GDG's declarations of interest have been sought throughout the guideline development, including the post consultation phase and updated throughout. We acknowledge that one GDG member has declared a personal pecuniary interest associated with Norgine, and three GDG members have declared non-pecuniary interests. Ten GDG members have no interests in Norgine. Throughout the development of the guideline the GDG chair, supported by the technical team, has striven to ensure the recommendations are based on the evidence and supported by interpretations based

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								on GDG expertise. We acknowledge that one declaration was made too late to take the appropriate action (i.e. declare the interest and withdraw from discussions) during development and in particular in the discussions relating to PEG 3350 + electrolytes. In addition, when voting on the key recommendations for implementation, the expert advisor was given the opportunity to vote when he should not have been. The GDG votes were subsequently recounted to exclude the votes of the expert advisor and the GDG member who had declared a personal pecuniary interest. Excluding the votes from these two people did not alter the decision about the key priorities for implementation. In addition, independent reviews of the clinical and cost effectiveness evidence were conducted by NICE technical teams and members of the Guidelines Review Panel. Subsequent changes have been made to the recommendations for disimpaction and maintenance (the generic terms for laxatives have been used rather than product names and the recommendations now say to "offer" PEG 3350 + electrolytes as a first line treatment, rather than to "use" it). The GDG interpretations of the evidence for these sections have also been expanded to make clearer the GDG's justification for their recommendations.

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43.	SH	Airedale Acute Trust	9.10	full	2.7	25	Line 11 (General): In many places there is the comment that none of the searches are limited by date of publication. Would it not be more honest to say date of publication not restricted other than by the coverage of the data base under consideration?	Thank you for your comment. Section 2.7 provides the dates of publications that the different databases cover. It is usual to use this term when referring to search strategies given the understanding that the databases themselves are limited by date. Limitation by date refers to additional limitations being written in to the search strategies and this was not the case.
44.	SH	Airedale Acute Trust	9.11	Full	3.1	33	In the table it talks of back arching, an arch can be concave or convex would back extension be a better term?	Thank you for your comment The GDG felt that back arching was clear and well understood and that in this instance no amendment was necessary.
45.	SH	Airedale Acute Trust	9.12	Full	3.2	37	Line 34: Should there be a "of child" between preferences and about. Otherwise what if the examiner was a naturist?	Thank you for your comment, the recommendation now says "the child's individual preferences…"
46.	SH	Airedale Acute Trust	9.13	Full	4.2	38	Line 22: This as elsewhere reads as if the papers had to include neonates and infants and children. I think it needs a few ors	Thank you for your comment. We have changed the "and" to "or" to make this clearer
47.	SH	Airedale Acute Trust	9.14	Full	4.5	50	Recommendations – since doing transit studies requires no more radiation and does not necessarily need more clinic or hospital attendances should this not be used in those capable of swallowing the markers?	Thank you for your comment The guideline does not recommend using either abdominal radiography or transit studies to make a diagnosis of idiopathic constipation, but only when required by specialist services because of intractable constipation Radiation burden for transit studies equivalent to 1or 2 abdominal radiographies in the majority of circumstances, however transit studies provide different data from abdominal radiography. If this

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								kind of data is required then transit studies should be performed but it is out of the remit of the guideline to provide specific recommendations for care in specialist services.
48.	SH	Airedale Acute Trust	9.15	Full	4.6	56	Line 8: Should the any be replaced by one – just makes it clearer – I think.	Thank you for your comment, we feel that "any" is clear and avoids questions of whether we mean exactly one, or one or more features.
49.	SH	Airedale Acute Trust	9.16	Full	4.7	60	A definition of PSTC would have helped me.	Thank you for your comment. PSTC stands for paediatric slow transit constipation. There is no agreed definition for this term and it is defined variously in different papers.
50.	SH	Airedale Acute Trust	9.17	Full	4.7	60	Line 32: Reads as if night time soiling was more common than a rectal palpable mass. I find soiling when asleep is rare is there an error here or is the error in me?	Thank you for your comment These are the outcomes of the multivariate analysis. We have checked these figures and they appear as reported in the paper.
51.	SH	Airedale Acute Trust	9.18	Full	4.7	61	Line 3: To me / means per would "in" be better?	Thank you for your comment. We agree and have changed the "/" to "in"
52.	SH	Airedale Acute Trust	9.19	Full	4.7	62	Line 44: I found this difficult to follow I wonder if the use of abbreviation C +4, C-4 and C +E mixed in with a lot of statistics is a problem to others?	Thank you for your comment. We agree that sometimes the use of abbreviations using symbols can be difficult but feel in this instance it is preferable to writing full descriptions which can also become unwieldy and difficult to follow.
53.	SH	Airedale Acute Trust	9.20	Full	4.7	63	Line 54: TGITT defined line 64 first used line 40	Thank you for your comment – TGITT has now been clarified at its first use
54.	SH	Airedale Acute Trust	9.21	Full	4.7	65	Line 35: Refers to SCT should this be STC again not in summary of abbreviations if this summary is only for short version surely the long version merits one	Thank you for your comment. SCT has been changed to STC and it has been included in the abbreviations list

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55.	SH	Airedale Acute Trust	9.22	full	4.7	65	Line 44: 25% of defecation time does it really mean that or does it mean 25% of defecation events – very difficult to measure defecation time.	Thank you for your comment. We agree that this phrase is difficult to interpret, however that is how it is reported in the paper and it is not possible to ascertain precisely what is meant. For the sake of accuracy we feel it better to report what the paper states rather than apply an interpretation.
56.	SH	Airedale Acute Trust	9.23	full	4.7	66	Line 2: Defecations / hours should be defecations per hour or defecations in hours	Thank you for your comment. The "/" has been changed to "in"
57.	SH	Airedale Acute Trust	9.24	Full	4.7	66	Line 22: No bran damage. ? means no brain damage	Thank you, this has been amended
58.	SH	Airedale Acute Trust	9.25	Full	4.7	66	Would a low transit time indicate hyper-peristaltic soiling? This could be a value of the study but not mentioned	Thank you for your comment. We agree that a low transit time would indicate hyper-peristaltic soiling The GDG concluded that transit studies may be of value to inform clinical and surgical decision making in a small number of children with intractable constipation following referral to specialist services. It is the GDG's view that transit studies can also help in demystifying constipation as a "psychological" problem and facilitate communication with the parents.
59.	SH	Airedale Acute Trust	9.26	Full	4.8	70	Line 22-23: Given that "symptoms of chronic constipation are notoriously subjective" – (GDG statement) how does this tie in with page 5 line 3? If its subjective for the doctor its is likely to be so for the patient there may be a conflict	Thank you for your comment. We recognise that the phrase you quote could potentially be misleading and have deleted it

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							of views which I feel is best avoided as previously commented	
60.	SH	Airedale Acute Trust	9.27	Full	5.1	71	Line 4-6: No page number on this page. As written means cannot have faecal impaction without soiling. That may be true but is it what the statement is meant to mean.	Thank you for your comment. The page number is in the mid-bottom of the page The definition is meant to imply that faecal impaction can be a large faecal mass, overflow soiling, or both. We believe this is capture by saying "and/or"
61.	SH	Airedale Acute Trust	9.28	full	5.1	74	Line 43: Less children implies not whole numbers of children one can have less cake but only fewer cakes.	Thank you, "less" has been changed to "fewer"
62.	SH	Airedale Acute Trust	9.29	full	5.1	76	Line 48: If the GDG interpretation of the evidence is that parents "should be informed" is this also included in the summary version?	Thank you for your comment. We have now included this as a recommendation. Families should be informed that disimpaction treatment can increase symptoms of soiling and abdominal pain initially
63.	SH	Airedale Acute Trust	9.30	Full	5.1	77	Line 51-53: Difficult to read, perhaps leave out "that are saved" or put "saving of" in at some point.	Thank you for your comment. This has been amended to say: "The analysis by dose of PEG 3350 plus electrolytes showed that highly effective strategies will lead to cost savings. This is due to avoiding the high cost of invasive treatment requiring hospitalisation.
64.	SH	Airedale Acute Trust	9.31	Full	5.1	78	Line 10: "To increase be 2.6% more" should the "be" "by" or is it 2.6 times more effective or have I just lost it?	Thank you, this is an editing error. The sentence has now been amended to say: "The threshold analysis showed that the effectiveness of PEG 3350 plus electrolytes would have to be 2.6% higher than the next best alternative (in this case Senna) in order for it to

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								be….."etc
65.	SH	Airedale Acute Trust	9.32	Full	5.1	80	Line 14-15: Rectal treatments …more common than oral treatments. It does not make it clear (to me) what the oral treatment is and for what it is given. does this need to be qualified by a with what?	Thank you for your comment. We have amended this now to say: "rectal treatments are used more commonly in hospital than at home"
66.	SH	Airedale Acute Trust	9.33	Full	5.2	85	Line 56: Should "varied" be replaced by "determined"	Thank you, "varied according to…" has been replaced with "determined by…" as you suggest.
67.	SH	Airedale Acute Trust	9.34	full	5.2	89	Line 1: Do you need both "proportion of children" and (% children) in the same sentence?	Thank you for your comment. We have amended this to say "percentage of children" and have deleted (% children)
68.	SH	Airedale Acute Trust	9.35	full	5.2	89	Line 40-41: 2 non cases of non-compliance.	Thank you, the first "non" has been deleted.
69.	SH	Airedale Acute Trust	9.36	full	5.2	90	Line 31-34: I count 10(and 9) but may have this wrong, not an easy read with so many (and)	Thank you for your comment, the number of parentheses now match
70.	SH	Airedale Acute Trust	9.37	full	5.2	91	Line 19: Last word is form should this be from?	Thank you, "form" has been changed to "from"
71.	SH	Airedale Acute Trust	9.38	full	5.2	94	Line 3-4: "increasing both the number of defections does this mean defecations or was taste a problem?	Thank you, "defections" has been changed to "defecations"
72.	SH	Airedale Acute Trust	9.39	full	5.2	94	Line 48-49: Two Were weres	Thank you, the extra "were" has been deleted
73.	SH	Airedale Acute Trust	9.40	full	5.3	98	Line 1-2: A number of references in this section to say height and weight unaffected or no change. Should the word centiles be included?	Thank you for your comment. There were no references to centiles in the paper. Height and weight were reported as median (range) for the whole population
74.	SH	Airedale Acute Trust	9.41	Full	5.3	100	Line 25: Thre should be three	Thank you, this has been amended
75.	S	Airedale	9.42	full	5.3	100	Line 43: This line would read esier if the	Thank you, we have included the word

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	H	Acute Trust					word investigation was included.	"investigation" as you suggest
76.	SH	Airedale Acute Trust	9.43	Full	5.3	102	Line 43: (30cc/10kg of paraffin oil) Everywhere else talks in mls. Could read as 30 cc or 10 kg is the dose. 30 mls per 10Kg body weight would be clear or if you like 30ccs/10kg body weight.	Thank you for your comment. We have amended this to say 30 mls per 10Kg body weight
77.	SH	Airedale Acute Trust	9.44	full	5.3	103	Line 8: Talks of lactulose or liquid paraffin being given as a suspension at 1ml/Kg. Lactulose would give a solution and liquid paraffin an emulsion (if shaken very well) The fault may be in the original article.	Thank you for your comment. We agree with the comment but have reported as per original article
78.	SH	Airedale Acute Trust	9.45	full	5.3	104	Line 7: Mean weight see comment 40	Thank you for your comment. There were no references to centiles in the paper.
79.	SH	Airedale Acute Trust	9.46	Full	5.3	105	Line 18: to refuse to refuse	Thank you, the extra "to refuse" has been removed
80.	SH	Airedale Acute Trust	9.47	Full	5.3	105-106	Table 5.1: Lactulose v peg height and weight unaffected see comment 1	Thank you for your comment. We assume the comment refers to not using the word centiles. There were no references to centiles in the paper. Height and weight were reported as median (range) for the whole population
81.	SH	Airedale Acute Trust	9.48	Full	5.3	106-107	Table 5.2: Miralax section 5th box down take out and.	Thank you, the "and" has been removed
82.	SH	Airedale Acute Trust	9.49	full	5.3	106-107	Table 5.2: Peg 3350. I think 2 papers talked of 1 child being allergic to PEG 3350. I think this needs including especially as it may be an unexpected effect.	Thank you for your comment. One paper talked of 1 child being allergic to PEG 3350. We have now included this in table 5.2
83.	SH	Airedale Acute Trust	9.50	full	5.4	109	The very bottom section between the blue lines doesn't read correctly	Thank you, the footnote has been reworded to say: "Movicol Paediatric Plain is the only unflavoured macrogol licensed for children under 12 years"
84.	SH	Airedale Acute Trust	9.51	full	5.4	112	Line 8, 10: By age selection these were infants the report switches between infants and children this confuses me	Thank you for your comment. We have amended this to say infants

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							unless there were 2 groups one of infants and one of children.	
85.	SH	Airedale Acute Trust	9.52	Full	5.4	113	Line 16: Crying: 2) seems out of style also the previous line should no difficulties be followed by a 0?	Thank you for your comment. Crying was the measure used in the paper. The "0" has been added
86.	SH	Airedale Acute Trust	9.53	Full	5.4	114	Line 8: (10g/125ml;fibre mixture (per 100ml); does fibre mixture (100ml) need leaving out?	Thank you for your comment. 10g/125 ml is the amount of mixture in the total volume of the drink, whereas fibre mixture (100ml) details the amount of different solutes in 100 ml of solution. We have amended this to make it clearer
87.	SH	Airedale Acute Trust	9.54	full	5.4	114	Line 27: The word but implies a value judgement, buts OK in interpretation but not otherwise.	Thank you for your comment. The word "but" is here used to contrast the results at 3 weeks with the results at 8 and 12 weeks (as they were different) and is not meant to imply a value judgement
88.	SH	Airedale Acute Trust	9.55	full	5.4	114	Line 42: I don't understand the phrase general disimpaction. Surely it was just GIT disimpaction.	Thank you for your comment. We have deleted the word "general".
89.	SH	Airedale Acute Trust	9.56	full	5.4	114	Line 53: Better to put or than :.	Thank you for your comment. We feel that the sentence is clear as it is
90.	SH	Airedale Acute Trust	9.57	full	5.4	115	Line 26: Leave out only or ;ut it somewhere else	Thank you, the word "only" has been moved earlier in the sentence to make this clearer
91.	SH	Airedale Acute Trust	9.58	full	5.4	116	Line 18: Suggest put "duration" after 12 months	Thank you, we have now included the word "duration"
92.	SH	Airedale Acute Trust	9.59	full	5.4	118	Line 10: Change form to from.	Thank you, this has been amended
93.	SH	Airedale Acute Trust	9.60	Full	5.4	118	Line 51: 4 x 109 needs to change to 10 to power of 9	Thank you, this has been amended
94.	SH	Airedale Acute Trust	9.61	full	5.4	120	Line 12: Prorated is this a true word?	Thank you for your comment. It was reported as such in original paper and from the context we understand the authors meant "extrapolated "
95.	S	Airedale	9.62	full	5.4	125	Line 43: Change no to not.	Thank you, this has been amended

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	H	Acute Trust						
96.	SH	Airedale Acute Trust	9.63	full	5.4	127	Line 33, 36: The GDG found little evidence does little mean no? Osmotic laxatives are not effective without sufficient fluid intake. Likely true but in a well child would they not ensure that they had enough fluid?	Thank you for your comment. The GDG interpretation refers to the only study found on increasing fluid intake as an intervention to treat constipation. We agree that osmotic laxatives will not be effective without sufficient fluid intake and this further adds justification for the recommendation
97.	SH	Airedale Acute Trust	9.64	full	5.5	131	Line 17: Change defections to defecations unless the children did really run away.	Thank you, "defections" has been changed to "defecations"
98.	SH	Airedale Acute Trust	9.65	full	5.5	131	Line 31: Change 14-yeor to 14 year	Thank you, this has been amended
99.	SH	Airedale Acute Trust	9.66	full	5.5	132	Line 52: Change defection to defecation	Thank you, "defection" has been changed to "defecation"
100.	SH	Airedale Acute Trust	9.67	Full	5.5	133	Line 26: Change sample to no also p 138 line 13	Thank you, "sample" has been replaced by "number"
101.	SH	Airedale Acute Trust	9.68	full	5.5	138	Line 27: Twice daily the dose of lactulose ??	Thank you for your comment. This sentence has been reworded to say: "…child was offered a dose of lactulose twice daily (amount not reported)"
102.	SH	Airedale Acute Trust	9.69	full	5.7	144	Line 37: Delete other before surgical	Thank you, "other" has been deleted
103.	SH	Airedale Acute Trust	9.70	Full	general	general	It is likely that I am just proof reading so I will stop and not irritate you any more. I don't know if the document gives an answer to the following questions. What is the indication for external anal sphincter botox? Should all children who soil have disability living allowance or similar? I find this a difficult question as no independent evaluation of problem. I think it only	Thank you for your comment Botox is not specifically mentioned in the scope in any of the categories of interventions. The scope has been finalised and it was agreed that these issues were outside the scope of this guidance. At the time the scope was written this was a research question

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							makes maters worse to pay to soil even if it is tragic.	It is outside of the NICE's remit to comment on the provision of disability living allowance
104.	SH	Airedale Acute Trust	9.71	Full	6	151	Switch from parents line 7 to parent line 14	Thank you for your comment. In this context, we feel it stylistically appropriate to refer to "the parent" in that sentence
105.	SH	Airedale Acute Trust	9.72	Full	6	151	Line 19-20: Should this advice be part of line 2-5 page 10?	Thank you for your comment. We understand how important it is to actively involve the child and the family in the treatment. We already have recommendations addressing this issue in the section on information and support.
106.	SH	Airedale Acute Trust	9.73	Full	6	154	Line 17-18: There were no significant differences between NLC and PGC …re inter-visit contacts but page 153 line 77 78 says inter-visit contacts for NLC was 6 PGC 0	Thank you for your comment. As stated there were no significant differences between NLC and PGC regarding inter-visit contacts. The values cited in the comment are reported as median and range in the paper. The median number of inter-visit contacts to the NLC was 6.0 (range 2 to 16) as compared to the PGC: 0.0 (range 0.0 to 29).
107.	SH	Airedale Acute Trust	9.74	Full	6	159	Line 5: No should be not.	Thank you, "no" has been changed to "not"
108.	SH	Airedale Acute Trust	9.75	Full	6	160	Line 24: Suggest parents change to suggest to parents	Thank you, this has been amended as you suggest
109.	SH	Airedale Acute Trust	9.76	Full	6	160	Line 32-36: This section does not ask where the bowel actions are occurring certainly for the child who is of an age where continence would be expected the place is to my mind of more important to the family than many other factors	Thank you for your comment. We understand that the comment refers to encopresis, which is outside the scope of this guideline. Encopresis is defined in the guideline as "Deliberate defecation in an inappropriate place. This is not to be confused with soiling".
110.	SH	Airedale Acute Trust	9.77	Full	6	161	Line 45 (General): Implies that there has been no research on social impact of constipation – possibly true but is it balanced to leave out soiling at this stage.	Thank you for your comment. When referring to constipation this also includes constipation with soiling. The research recommendation has been amended to make it clear that it is the social impact

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							Is the intention to say there has been no research on social impact of different models of service?	of constipation that is being referred to and the effectiveness of different models of care in improving social outcomes as well as clinical outcomes.
111.	SH	Airedale Acute Trust	9.78	Full	Appendix A	162	Line 6-7 (General): Advice for constipation is not the same as that for soiling, by not being about soiling managent the guidance lacks clarity. If a child is constipated then the goal is to reduce stooling difficulty. If the problem is soiling then the goal is continence or at least predictable incontinence. The family and child are mostly concerned re incontinence at school or nursery or mosque. Stimulant laxatives with a predictable time of action and as such hold specific value in this situation, this is not shared with movicol. Movicol has specific roles in disimpaction and stool softening but the papers quoted success in terms of continence in the early stages is sometimes limited. A treatment appropriate to the school holidays is not necessarily appropriate at treatment initiation.	Thank you for your comment Soiling as defined in the guideline is entirely related to constipation, thus the GDG believes that advice/treatment for constipation will also resolve the soiling. Management of faecal incontinence due to other causes is outside the scope of the guideline. The GDG believes that soiling is the result of faecal impaction hence the guideline recommends to asses all children with constipation for faecal impaction and to provide treatment for disimpaction if indicated. The guideline also recommends providing tailored follow-up to children and their parents or carers according to a child's response to treatment and giving verbal information supported by (but not replaced by) written or website information in several formats about how to take their medication, what to expect when taking laxatives. This should include the child's individual circumstances like attending school or religious activities or taking holidays The GDG recognises the unpredictability of stooling while using Movicol as part of disimpaction process and has added a new recommendation on

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								informing the parents about this.
112.	SH	Airedale Acute Trust	9.79	Full	Appendix B	General	Most people had no declaration of interest but almost all who did had an interest in Movicol or Norgine including one of the Peer Reviewers. Norgine at least by virtue of one of its representatives may have specifically encouraged professionals sympathetic to the use of movicol to engage in the development of this guideline. I think that would be within the rules but not within the spirit of balance.	Thank you for your comment. NICE aims to be accurate and transparent regarding potential conflicts of interest. The GDG's declarations of interest have been sought throughout the guideline development, including the post consultation phase and updated throughout. We acknowledge that one GDG member has declared a personal pecuniary interest associated with Norgine, and three GDG members have declared non-pecuniary interests. Ten GDG members have no interests in Norgine. Throughout the development of the guideline the GDG chair, supported by the technical team, has striven to ensure the recommendations are based on the evidence and supported by interpretations based on GDG expertise. We acknowledge that one declaration was made too late to take the appropriate action (i.e. declare the interest and withdraw from discussions) during development and in particular in the discussions relating to PEG 3350 + electrolytes. In addition, when voting on the key recommendations for implementation, the expert advisor was given the opportunity to vote when he should not have been. The GDG votes were subsequently recounted to exclude the votes of the expert advisor and the GDG member who had declared a personal pecuniary interest. Excluding the votes from these two people did not alter the decision about the key priorities for implementation.

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								In addition, independent reviews of the clinical and cost effectiveness evidence were conducted by NICE technical teams and members of the Guidelines Review Panel. Subsequent changes have been made to the recommendations for disimpaction and maintenance (the generic terms for laxatives have been used rather than product names and the recommendations now say to "offer" PEG 3350 + electrolytes as a first line treatment, rather than to "use" it). The GDG interpretations of the evidence for these sections have also been expanded to make clearer the GDG's justification for their recommendations.
113.	SH	Alder Hey Children's NHS Foundation Trust	14.01	Full	1.3	16	Comments as follows Should be explicit in full document that there is no reason for digital rectal examination in primary care and inspection of the perineum should be sufficient	Thank you for your comment We have reworded and reordered the recommendations in the DRE section to make it clearer who should/should not perform a DRE.
114.	SH	Alder Hey Children's NHS Foundation Trust	14.02	NICE	1.2.3	23	As above – in NICE guideline this section should be first under 1.2 to ensure that it is clear that digital rectal examination should only be performed by those who can interpret the findings and who are using it to plan further investigations or interventions. Same could be said for the investigations listed where again it should be clear that these are only indicated in a very small number and in specific circumstances	Thank you for your comment. We have reworded and reordered the recommendations in the DRE section to make it clearer who should/should not perform a DRE. We are already recommending first "Do not perform…" for most of the investigations listed and/or providing a recommendation on the specific circumstances in which they may be considered useful.

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115.	SH	Alder Hey Children's NHS Foundation Trust	14.03	All	General	General	There was a meeting regarding constipation yesterday between the surgeons and the gastroenterology teams. We looked at the constipation guidelines and both teams seemed fairly happy with the document although we all felt that dietary advice should be the first line in treatment. There was also some concern that 'movicol' is being promoted as the main treatment option when lactulose and senna are still being widely used in this hospital to very good effect.	Thank you for your comment. The GDG found no evidence to suggest that dietary advice alone as a first line treatment is effective in treating constipation. Available clinical evidence, economic modelling and clinical experience support the use of oral PEG (movicol) as first line treatment for both disimpaction and maintenance: PEG is cost-effective as monotherapy, works quickly, is easy to titrate and is well tolerated. For these reasons it is recommended. No evidence was found for the effectiveness of either lactulose or senna for disimpaction; however, from clinical experience the GDG concluded that they can be useful as a second/third-line intervention. In the light of this, the GDG collated the information into a table so that clinicians can select the most appropriate second-line doses of each laxative (or combination of laxatives) for their patients. Regarding maintenance, a metanalysis showed that PEG is more effective than lactulose, whereas the evidence found for senna had very low quality from a methodological point of view. Again, despite this the GDG recognises that other medications, used singly or in combination, are available, effective and commonly used and in the light of this, the GDG collated the information into a table so that clinicians can select the most appropriate second-

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								line doses of each laxative (or combination of laxatives) for their patients. We have now made a research recommendation for head to head trials of PEG vs. stimulant laxatives.
116.	SH	Alder Hey Children's NHS Foundation Trust	14.04	All	General	General	I think there are areas that lack clarity. 1. What are we suggesting for the children less than 1 month age? 2. Term for encopresis – 3. Calls colonic wash outs ACE – BUT rectal irrigation can be used in children from age 3 years and irrigation should be offered as a treatment BEFORE surgery. 4. What training will go with this? Especially if first line treatment is going to be community based 5. What is a specialist service they you refer to? –did I miss that somewhere?	Thank you for your comment. 1. For children less than 1 month of age the same recommendations as for all ages apply, except when stated otherwise in the specific recommendations made for children under 1 year of age 2. Encopresis has been defined in the glossary as: "Deliberate defecation in an inappropriate place. This is not to be confused with soiling" 3. No evidence was found on rectal irrigation as a treatment for constipation. It is the GDG's view that there are better ways of clearing the bowel. Rectal irrigation is not suitable as a daily treatment as it involves a risk of perforation. The GDG considers it would be inappropriate for the majority of children in guideline because it will be poorly tolerated. It is more often tolerated by children with loss of sensation (organic causes of constipation) but they are out of the scope of the guideline. After referral to specialist service, part of assessment of suitability for ACE may include the tolerance of and efficacy of rectal washouts. However providing recommendation for care in specialist services is out of the scope of the

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								guideline 4. We recognise the need for training but recommendations on training issues are outside of the remit of this guideline. We anticipate that training issues will be addressed as part of the implementation strategy 5.We have defined specialist service in the guideline glossary and provided greater clarity when this term is used in the text.
117.	SH	Association of Child Psychotherapists	25.01	FULL	5.5	129	Lines 15-17: We would like to agree with this paragraph that clinicians should introduce interventions in a 'child-friendly' way and that parents should also be offered support and understanding.	Thank you
118.	SH	Association of Child Psychotherapists	25.02	FULL	5.5	129	General: We agree that the medical management of constipation is of great importance so that the child's experience of passing stools is reasonably comfortable and non-anxiety provoking. However, a close working relationship with colleagues in the Psychological team is of great importance as it will enable a smooth transmission to such services or for some joint work with medical and psychological staff with the child and family.	Thank you for your comment. We agree. We do not say it is always secondary, we say it is likely to be for majority of children. Agree that it can be valuable to have joint management in certain circumstances. The GDG felt however, that it was not appropriate to involve the psychological team in all cases.
119.	SH	Association of Child Psychotherapists	25.03	FULL	5.5	129	Lines 3-6: We would not agree that the psychological component of children's constipation is always secondary, although the medical situation needs to be clearly assessed before assuming	Thank you for your comment. There is no evidence to support that all children who have constipation should be seen by a mental health professional.

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							psychological aspects. Many young children withhold their faeces for extended periods for a variety of psychological reasons. For some, the humiliation of accidental leakage or the anxiety of waiting to pass a stool will absorb much of their thinking, distracting them from the learning that could be taking place. We would like to suggest that management be joint wherever possible. With toddlers a brief intervention with parents often helps the family get over the obstacle posed by the child's domination of family life based around bowel function. Sometimes an extraordinarily powerful control is exerted by the infant which the parents can find hard to resist.	We are not saying that the psychological component is always secondary but that that there is a very high proportion of children where the psychological component is secondary and any physical problem needs to be addressed first before psychological strategies are implemented or a psychological problem is felt to be primary. Also that withholding of faeces causes physical problems which need to be managed appropriately. The GDG felt that good management was by those who had expertise and use behavioural advice appropriately but do not need to be mental health professionals necessarily.
120.	SH	Breastfeeding Network	26.01	NICE	General	General	We welcome an opportunity to comment on this guideline. It is a shame that during the consultation and development of the scope of this guideline, that newborns and infants were not found to warrant a separate guideline, regardless of whether the constipation is idiopathic or known cause. The differences between a 17 year old and a 3 day old are huge. The 17 year old can adequately describe symptoms, whilst the 3 day old is still relying on his parents who are still learning to read the baby's 'cues'. In addition to this a school	Thank you for your comment. The scope of the guideline has now been finalised and so it is not possible to consider neonates and babies under six months as a separate group for consideration in this guideline. Where appropriate, reference has been made to specific aspects of the history taking and physical examination that are relevant to children under 1 year of age. In addition, the dosing table for laxatives (table 4) provides recommended doses for younger children where these are appropriate. Where appropriate, we have included notes in parentheses to indicate where exclusively breastfed babies are excluded.

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							age + child has some if not all the control over their diet, whereas the parent is solely responsible for the dietary needs of the baby. It is a particularly vulnerable time for the parents of a newborn and a particularly vulnerable time for a young baby. We would therefore strongly suggest babies (and particularly those under 6 months and who solely milk fed) should be covered separately, in this guidance, if they are to be included in the scope. This could be done in separate tables. Since there are big differences in stool patterns of breast and infant formula fed babies it would be also be good to develop guidelines according to what is normal for each of them and at the different ages of development.	
121.	SH	Breastfeeding Network	26.02	Full	1.1	3	Good to see that under 1s and over 1s are separated in the table. It would be useful for this to be developed further.	Thank you for your comment. Within the tables we have separated under 1s and over 1s where possible, and noted where a particular finding does not apply to an exclusively breastfed child. In addition the guideline also provides specific recommendations for under 1s and over 1s. Please see recommendations on rectal examination
122.	SH	Breastfeeding Network	26.03	NICE	KPIs	8	Table 1 (Middle Column): There is a widespread misunderstanding of the	Thank you for your comment.

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							normal stool pattern of breastfed babies who are exclusively breastfed in the first 6 months. The stool pattern of a breastfed baby is very different to the stool pattern of a formula fed baby. It can be common and normal for a breastfed baby to not pass a stool in 7 days or longer, after the first few weeks. Such babies are often prescribed Lactulose by their GP. There is a widespread expectation among professionals and parents that breastfed babies should have the same stool pattern as formula fed babies. Lactulose is prescribed to exclusively breastfed babies when the only symptom is that a stool has not been passed for several days.	Recognised that the stool pattern of exclusively breastfed babies may be less regular than bottle-fed babies. We have now made it clear in the table where a specific sign does not apply to exclusively breastfed babies.
123.	SH	Breastfeeding Network	26.04	NICE	General	General	It is common practice for professionals to recommend diluted orange juice/prune juice for breastfed and formula fed babies of any age (including under 6 months) if the parents feel their baby is 'constipated'. This includes breastfed babies who have not passed a stool for several days. This could be a sign of inadequate milk transfer in a very young baby or it could be perfectly normal in an older breastfed baby. Another recommended treatment is for the (breastfeeding) mother to eat natural liquorice. If the supporting evidence is not explored the practice will continue	Thank you for your comment. If the parents feel their baby is constipated and they take the baby to be seen by HCPs they should be able to diagnose whether the baby is constipated or not if they follow the guideline recommendations. Any intervention to treat constipation should be justified only if a correct diagnosis has been made and other causes have been excluded (e.g. inadequate milk transfer in very young baby, normal findings in an older breastfed baby). The scope has been finalised and no new interventions can be added at this stage. Our searches included fresh fruit, fruit juices and vegetables and we did not find any evidence to

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							unchallenged. It would be useful to explore the evidence within these NICE guidelines so that traditional practice can be challenged, if appropriate, using an evidence base.	support their effectiveness or otherwise therefore we made a general recommendation of offering children a balanced diet including adequate fibre and fluid intake in line with guidance from the DH. The guideline recommends giving parents/carers verbal information supported by (but not replaced by) written or website information in several formats about how the bowels work at different ages, what is "normal" and what is not
124.	SH	Breastfeeding Network	26.05	Full	1.1	3	Line 7: In the Stool Patterns section the Bristol Stool Form Scale may not be a useful tool to use with an exclusively breastfed baby who's stool would normally be a Type 7 (ie - Watery, no solid pieces. Entirely liquid) which could imply "overflow soiling". This could lead to misdiagnosis and mistreatment. This is very worrying and could serve to not only to undermine breastfeeding but more importantly it could have long lasting effects on the gut flora of a perfectly normal infant, by giving oral medications which could interfere with the lining of the gut flora. It would be useful to see an alternate tool being used to assess exclusively breastfed babies. Such as an Infant Stool Form Scale.	Thank you for your comment Within the tables we have noted where a particular finding does not apply to an exclusively breastfed child. It should also be noted that the Bristol stool form scale is not for normal population – but is intended for specific use in constipation management. It would be inappropriate to use it to measure normal breastfed babies' stools.

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							The National Childbirth Trust have a resource called "what's in a nappy?" and can be found here:- http://www.nct.org.uk/info-centre/information/view-44	
125.	SH	Breastfeeding Network	26.06	NICE	KPIs	8	Table 1: Middle column "Symptoms associated with defaecation" "Distress on stooling" and "straining" are symptoms that are reported by parents of babies who are not constipated (as well as babies who are constipated). If a baby is crying, appears distressed, the cause of the crying is often interpreted as 'tummy ache' and 'needs to do a poo but can't' even if the baby then passes a soft stool.	Thank you for your comment. The guideline says there needs to be a combination of two or more symptoms, rather than a single one for constipation to be diagnosed
126.	SH	Breastfeeding Network	26.07	Full	1.1	3	Line 7: In the Symptoms section – we would suggest there needs to be further discussion in the symptoms in a less than one year old. Signs of hunger may be interpreted as signs of constipation if the baby whilst crying happened to pass a watery poo. The appropriate treatment for that would be referral to a breastfeeding specialist for a full assessment of feeding.	Thank you for your comment. We have now added that the finding of less than 3 completed stools per week does not apply to an exclusively breastfed infant. In addition the recommendation states that a diagnosis of constipation should be the result of a combination of two or more symptoms.
127.	SH	Breastfeeding Network	26.08	Full	1.1	4	Table 2: Timing of Onset Good to see in Table 2 that constipation reported from birth or within the first few weeks is flagged red. It would also be good to see mentioned that an urgent referral would be needed to a breastfeeding specialist if the baby is	Thank you for your comment -Failure to thrive is covered under faltering growth and this is included in the table. Referral will be to most appropriate HCP which may include a breastfeeding specialist.

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							breastfed, since the risk of failure to thrive would be significant. Passage of meconium In our experience it can be normal for meconium to be passed in the first 2-3 days – certainly more than 24 hours. It can also be a useful way of assessing breastfeeding. Jack Newman, a Canadian Paediatrician and breastfeeding expert suggests several days for passing meconium, is within the normal range. It may be useful to look at extending this period beyond 24 hours otherwise a baby could be unnecessarily referred on, when it's still within the normal range.	-Passage of meconium has been changed to be considered not necessarily normal if delayed for over 48 hours
128.	SH	Breastfeeding Network	26.09	Full	1.2	9	Table 2: In diet and fluid intake we would suggest changing the wording to *Infant* Formula. In addition to this it would be useful to mention the negative impact and significance of introducing infant formula to a breastfed infant and not necessarily just changing from infant formula brand to brand.	Thank you for your comment. We agree and have amended the wording to say "Infant formula". Whilst we acknowledge your concern, possible triggers/causes for idiopathic constipation falls outside the scope of this guideline.
129.	SH	Breastfeeding Network	26.10	NICE	KPIs	10	Table 2: As above. In diet and fluid intake we would suggest changing the wording to *Infant* Formula.	Thank you for your comment. We have now changed the wording to say infant

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							In addition to this it would be useful to mention the negative impact and significance of introducing infant formula to a breastfed infant and not necessarily just changing from infant formula brand to brand.	formula as you suggest. The GDG did not feel it was appropriate to highlight the possible negative impact of changing from breast to artificial feeding in this guideline which is targeted at children and young people who already have idiopathic constipation.
130.	SH	Breastfeeding Network	26.11	NICE	KPIs	15	The first section "Do not use dietary interventions alone as first-line treatment for childhood constipation". A rationale of why this is not appropriate would be useful. In our work we support parents who have found infant formula to cause constipation in their baby and who come to us for support and help in returning to full breastfeeding. Use of dietary interventions in this instance would resolve the constipation and would therefore be an appropriate first line intervention, without any need for medication.	Thank you for your comment. We did not find any evidence on dietary interventions alone as an effective first-line treatment for childhood constipation. We recognise that breastfeeding is the optimal nutrition for an infant but there is no evidence for returning to breastfeeding as being an effective treatment for constipation.
131.	SH	Breastfeeding Network	26.12	Full	1.1	3	Line 11,12,13 We welcome inclusion of the following:- If a child has any "red flags" symptoms do not treat for constipation. Instead, refer them urgently to a health care	Thank you for your comment.

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							professional experienced in child health.	
132.	SH	Breastfeeding Network	26.13	NICE	Patient-centred care	6	We welcome a patient centred care approach	Thank you
133.	SH	Breastfeeding Network	26.14	NICE	1.1.2	20	Table 2: Good to see flagged red in the middle column:- Reported from birth or first few weeks of life	Thank you
134.	SH	Breastfeeding Network	26.15	NICE	1.1.2	20	Table 2: Growth and wellbeing Suggest "faltering growth" alongside parent's reporting constipation be flagged red as it could imply inadequate milk transfer and therefore baby would be at risk of failure to thrive.	Thank you for your comment -Failure to thrive is covered under faltering growth and this is included in the table. Referral will be to most appropriate HCP which may include a breastfeeding specialist.
135.	SH	Breastfeeding Network	26.16	NICE	1.5.4	29	Parental advice – we would suggest expanding on the "Where appropriate" part of this statement as it could undermine safe infant feeding practices if parents are unclear about what age they should introduce the following:- Adequate fibre. Recommend including foods with a high fibre content (such as fruit, vegetables, baked beans and wholegrain breakfast cereals). Do not recommend unprocessed bran, which can cause bloating and flatulence and reduce the absorption of micronutrients. Adequate fluid intake (see table 5).	Thank you for your comment. We have now added that this recommendation on fibre intake does not apply to exclusively breastfed babies. Table 5 now makes it clear that adequate fluid intake is assumed for breastfed babies.
136.	SH	Breastfeeding Network	26.17	NICE	1.5.4	29	Table 5: The Fluid requirements are not appropriate where a mother is exclusively	Thank you for your comment. The table now makes it clear that adequate fluid intake is assumed for

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							breastfeeding her infant. Having to measure fluid intake would seriously undermine breastfeeding.	breastfed babies.
137.	SH	Breastfeeding Network	26.18	NICE	KPIs	12	Suggest the term "Digital Rectal Examination" either be avoided or more clarity given about what this actually means. The "digital" part may imply (technology) such as probe, scan or xray will be used and not the examiner's finger. This could cause additional anxiety and distress to parents.	Thank you for your comment. We agree that in some cases this may lead to confusion but we have followed the wording in the guideline scope. We will ensure that the term digital is fully explained in the Understanding Nice Guidance which is the version of the guideline targeted at parents and children, and we have added the term to the glossary.
138.	SH	Breastfeeding Network	26.19	NICE	1.8.3	31	For all the reasons already given above a very young baby would need follow up sooner than 3 months.	Thank you for your comment. Young babies should be assessed within a week of starting treatment for disimpaction (in case they are impacted) and at least 1 month after starting any treatment in general (DRE recommendations)
139.	SH	Breastfeeding Network	26.20	NICE	General	General	At various points in the document the NICE Guidance on "When to suspect maltreatment in children" is mentioned. It would be useful to see other relevant NICE Guidelines which should also be highlighted, such as the Maternal and Child Nutrition Guidance.	Thank you for your comment. We have now cited the Maternal and Child Nutrition NICE public health guidance as a related document to be referred to in line with this guideline.
140.	SH	British Dietetic Association	24.01	NICE	General	General	Thank you for giving The British Dietetic Association the opportunity to comment on the draft guidance.	Thank you
141.	SH	British Dietetic Association	24.02	NICE	1.5.3	29	The section on dietary modification should include the requirement to obtain an accurate dietary history/assessment.	Thank you for your comment. This is already included in history taking section

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142.	SH	British Dietetic Association	24.03	NICE	1.5.4	29	The section on adequate fibre should include high fibre bread.	Thank you for your comment. We have now added this.
143.	SH	British Dietetic Association	24.04	NICE	4.3	33	The section on Specialist services should include the requirement for a Dietitian to provide dietary advice based on the dietary history.	Thank you for your comment. The specialist services referred to in this research recommendation does not refer to dietetic services.
144.	SH	British Dietetic Association	24.05	Full	5.5	134	The table should be referenced.	Thank you for your comment. The GDG decided to use a different table and this is referenced
145.	SH	British Dietetic Association	24.06	Full	5.5	134	Commenting on the accuracy of Table 5: The Dietary Reference Values for Food Energy and Nutrients for the United Kingdom 1991 do not give fluid requirements for children by age group. Recommended water intakes are given by: EFSA (European Food Safety Authority) (2008) Draft Dietary reference values for water: Scientific opinion of the Panel on dietetic products, nutrition and allergies. *The EFSA Journal* 1-49. IoM (Institute of Medicine) (2005). Dietary reference intakes for water, potassium, sodium chloride and sulfate. Washington DC: The National Academies Press.	Thank you for your comment. We are now using the table of the IoM (Institute of Medicine) (2005).
146.	SH	British Dietetic Association	24.07	Full	5.5	134	The fluid requirements should be made clear so that the table states whether the requirements are for the total fluid in food	Thank you for your comment. We are now using the table of the IoM (Institute of

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							and drinks or just the fluid a child is expected to drink each day in addition to their fluid intake from food.	Medicine) (2005).
147.	SH	British National Formulary	13.01	NICE	1.4.2	26-27	Table 4: BNFC 2009 (section 1.6, p.77) says in a box: <For children with chronic constipation, it may be necessary to exceed the licensed doses of some laxatives. Parents and careers of children should be advised to adjust the dose of laxative in order to establish a regular pattern of bowel movements in which stools are soft, well-formed, and passed without discomfort>. Please keep this in mind when deviating from doses in BNFC.	Thank you very much. The GDG were very much aware of these issues and did bear them in mind when making recommendations.
148.	SH	Department of Health	27.01	NICE	General	General	We are concerned about the use of the term 'overflow soiling' in the table - Potential Findings - on page 8. This term is not used universally for children with constipation and soiling, and we feel that this could mislead practitioners if soiling is not very loose. We are also concerned by the comment in table 3 advising against the routine examination of leg (ankle) reflexes, as children with missed sacral lesions can have normal lumbar spine function. Could you please clarify the level of evidence on which that statement is based.	Thank you for your comment. We have amended the wording slightly in order to provide more detail as to what constitutes overflow soiling. We hope the guideline will help to standardise terminology in this field This was based on GDG consensus (which included two GP members) that GPs did not have enough time during the first appointment to examine routinely for lower limb reflexes**.** We now refer to Senna syrup and have removed the word Senokot.

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							On a general note, we realise the difficulties with preparations (and their constituents) available, but there is considerable use of the trade names of medicines. Could you please note that 'Senokot' appears to be mis-spelt in table 4.	
149.	SH	Education and Resources for Improving Childhood Continence	17.01	Full	1.1	5	Under the heading disimpactions; bullet point 2 states 'add a stimulate laxative if movicol does not lead to disimpaction after 2 weeks' however in table 4-headed 'Movicol', it states for a child of 5 to 12 years should 'treat until impaction resolves or for a maximum of 7 days. The information is inconsistent.	Thank you for your comment. We have amended this accordingly and removed reference to maximum of 7 days, providing a note in parentheses that is outside the BNF-C dosing schedule.
150.	SH	Education and Resources for Improving Childhood Continence	17.02	Full	1.2	12	Please could we put a warning note at the foot re potential danger of using phosphate enema's	Thank you for your comment The guideline recommends to not administer phosphate enemas for disimpaction unless under specialist supervision in hospital, and only if all oral medications and sodium citrate enemas have failed. The GDG believes that if these recommendations are followed properly no major incidents should occur with phosphate enemas, however if they occur children would have been placed under the best circumstances for these to be adequately treated.
151.	SH	Education and Resources for Improving Childhood	17.03	Full	1.2	12	Frequently asked questions by parents are; How do I know when impaction is complete? And how do I know when I should stop the disimpaction regime and go onto the maintainence regime?	Thank you for your comment We have now added a recommendation on how to diagnose impaction

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		Continence						The guideline also recommends that HCPs should assess children undergoing a disimpaction regime within a week therefore parents will know if the regime needs to stop and then go to maintenance
152.	SH	Education and Resources for Improving Childhood Continence	17.04	Full	1	general	Re-assess a child 'frequently' what is meant by 'frequently'?	Thank you for your helpful comment. We have added the following sentence to this recommendation to clarify what is meant by frequently: "The frequency should be tailored to the individual needs of the child and their families (and could range from daily contact to contact every few weeks)"
153.	SH	Education and Resources for Improving Childhood Continence	17.05	Full	1.2	14	60 minutes exercise is important for healthy living not specific to constipation or are you saying children with idiopathic constipation need to take more exercise? It's not clear in the text.	Thank you for your comment. Despite the fact that there is no good quality evidence for the effectiveness of increasing physical activity to improve constipation, it is the opinion of the GDG that exercise should be encouraged. It is a common clinical observation that a lack of physical activity can be a contributing factor to constipation. Whilst recognising that physical activity is not in itself a treatment for constipation, the GDG felt that it was important to encourage children to be physically active, as it may decrease the likelihood that they will develop constipation again once an episode has been medically treated. It has been recommended by The Department of Health that children should do at least 60 minutes of moderate intensity physical activity per day as part of a healthy lifestyle. (*Department of Health (2004) At least five a week: evidence on the impact of physical activity and its*

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								relationship to health. London: Department of Health) and reiterated in the NICE public health guidance "Promoting physical activity for children and young people" (PH17) We have now reworded this recommendation to say: "Advise daily physical activity that is tailored to the child's stage of development and individual ability as part of ongoing maintenance in children and young people with idiopathic constipation" For clarity we also reordered that section and moved this recommendation to the end and grouped all diet recommendations at the beginning.
154.	SH	Education and Resources for Improving Childhood Continence	17.06	Full	1.3	15	What is 'adequate'?	Thank you for your comment We have checked this page and section and are assuming you are referring to the research recommendation on disimpaction where we use the word "optimum". "Optimum management" which means the right drug(s) at the right dose(s) for the right time and all interventions as recommended in the guideline. Apologies if this is not what you are referring to but we cannot find the word "adequate" in this section.
155.	SH	Education and Resources for Improving Childhood	17.07	Full	1.3	15	Under the third bullet point a line should be added 'do not stop taking the laxatives until advised to do so by your health care specialist'.	Thank you very much for your comment. This has now been added to the recommendation as you suggest.

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		Continence						
156.	SH	Education and Resources for Improving Childhood Continence	17.08	Full	5.4	109	What is the definition 'of acute simple constipation where the effective treatment recommended is high fibre and fluid .this appears to be a contradiction to what follows in the next paragraph where it says 'there was no evidence to say that increasing fibre was effective in treating constipation' . Is it necessary to include the statement about 'acute simple constipation' as this is not what the guideline is about. -Either rephrase 'high fibre diet' in the introduction to healthy balanced diet which would include high fibre or refer to: Fibre Rich Foods- page 126-'Food for the Growing Years'; to avoid any confusion. Heading . Diet and Lifestyle. The second paragraph carries an important message 'there is some times the belief that a childs chronic constipation has been caused by a lack of fibre or fluids in the diet ' ,This assumption has lead to parents being blamed for poor parenting'. with the evitable consequences for some parents of being referred to social services. I do not feel this paragraph will have the impact necessary to influence a change in practice	Thank you for your comment. This has now been amended as we don't make reference to acute constipation

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157.	SH	Education and Resources for Improving Childhood Continence	17.09	Full	5.4	127-128	Heading 'Recommendations' . Should the positive statement appear first 'treat constipation with laxatives and a combination of:' followed by diet and 60 minutes of exercise'.	Thank you for your comment. The GDG wanted to stress that current practice (dietary modification) is not appropriate, therefore it felt that starting with the negative statement would help to change this practice
158.	SH	Manchester Community Health	21.01	NICE	introduction	5	Children with autism also are prone to constipation due to their dietary restrictions as they are often 'faddy'	Thank you for your comment, we agree and have included children with autism within the scope of this guideline. We have now made this more explicit in the introduction.
159.	SH	Manchester Community Health	21.02	NICE	KPIs	11	Inspection of perianal area- is this a must for all ages if examination is to be done by G.P. or advanced practitioner rather than a consultant paediatrician	Thank you for your comment. Inspection of perianal area can be done by anyone with appropriate skills, and should be done for all ages
160.	SH	Manchester Community Health	21.03	NICE	KPIs	13	Table 4: Disimpaction says treat for maximum of 7 days, but clinical management says add in stimulant laxative after 2 weeks if disimpaction not worked so what do we do between 1 and 2 weeks if disimpaction not worked	Thank you for this comment. Table 4 has now been amended and the 7 days removed.
161.	SH	Manchester Community Health	21.04	NICE	definitions	17	Would be better at the beginning or the end of document	Thank you for the comment. The definitions have now been moved to the start of the document.
162.	SH	Manchester Community Health	21.05	NICE	1.1.1	18	Repeated from key priorities section ,makes it confusing	Thank you for your comment. The key priorities are chosen from the full list of recommendations in the guideline. These are produced at the start of the document followed by a complete list of all of the recommendations in the guideline.
163.	SH	Manchester Community Health	21.06	NICE	1.1.2	20	Table 2: Traffic lighting is excellent, makes it easier to make clinical judgements. Very helpful	Thank you. We are really sorry but we received a number of other stakeholder comments who found the colour

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								coding difficult e.g. for printing out. We have retained the terminology and have added further detail to make it clear what to do in the case of amber flags. We hope you still find the tables useful.
164.	SH	Manchester Community Health	21.07	NICE	1.2.1	23	Referral to healthcare professional competent to do this examination may take some time. Should treatments be continued whilst awaiting for the child to be seen	Thank you for your comment. Children should be referred urgently. We have amended recommendation 1.2.1 to say instead "Refer urgently to a healthcare professional competent to interpret features of anatomical abnormalities or Hirschsprung's disease all children younger than 1 year with a diagnosis of idiopathic constipation that does not respond to adequate treatment within 4 weeks". If a clinician is unable to get an appointment for the child urgently then a telephone discussion with an appropriate specialist could be considered in order to decide what is the appropriate course of action whilst waiting.
165.	SH	Manchester Community Health	21.08	NICE	1.7.1	30	How long should children with constipation symptoms on specialist management plans wait before this referral should be made	Thank you for your comment. Children need to be assessed individually
166.	SH	Medicines and Healthcare products Regulatory Agency	28.01	All	General	General	I just wanted to confirm that we do not have any comments on this guideline. Also the proposed footnotes are acceptable to us as they are fully in line with the licensing position.	Thank you for confirming that the footnotes match the licensing position

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		(MHRA)						
167.	SH	National Autistic Society	16.01	Full	3	29 -	In children 1 year and above 1. Recognition that constipation may be common in children with autism but different modes of pain response 2. This to be carefully noted and considered- referral to knowledgeable professional and fully investigated 3. Whenever behavioural problems are present in a child with autism constipation should be investigated as one possible explanation 4. Constipation occurs in some children with autism right up to and through adolescence. They may not recognise or spontaneously report this. 5. Local referral service should be alert to this and have someone with an interest 6. Special (exclusion) diets, supplements and medications only under medical supervision	Thank you for your comment We understand that children with autism have a high prevalence of constipation. While we acknowledge that it might be difficult to recognise symptoms of constipation in this group of children (as it would probably be the case with symptoms of other conditions), we are not aware of any special provisions that should be made to diagnose and treat constipation in children with autism, therefore all recommendations in the guideline also apply to them. If the comment is related to the need of "screening" for constipation in these groups of children then we believe that advice in this respect should be sought from the NICE guideline addressing Autism. The scope of the Constipation guideline states that the principles of assessment and management covered in the scope will apply to children with other conditions who may also have constipation but the guideline will not address any additional management that these children might require.

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							7. Please note the recommendation contained in the National Autism Plan for Children (2003)* :4.2.4.3/9 page 38 '*Although routine investigation of the gastro-intestinal tract is not recommended, an adequate clinical history of bowel function based on standard best paediatric clinical practice with knowledge of normality and abnormality at appropriate ages is recommended. More detailed investigations are recommended in situations of failure to thrive and other clinical indicators of inflammatory bowel disorder (for example, evidence of blood in the stools, ulceration of oral mucous membrane, fever and chronic ill health). Constipation with overflow may need to be specifically enquired for and if present investigated by abdominal examination and/or plain abdominal X-ray.'* * Published by The National Autistic Society for NIASA in collaboration with The Royal College of Psychiatrists (RCPsych), The Royal College of Paediatrics and Child Health (RCPCH)	

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							and the All Party Parliamentary Group on Autism (APPGA)	
168.	SH	NHS Direct	20.01	Full	General	General	NHS Direct welcome the guideline and its content.	Thank you
169.	SH	NHS Forth Valley	8.01	Full	General	General	The length is likely to lead to many of the target readers being put off, the Quick reference Guide will no doubt be helpful but some differentiation inot clinical, service planning, economics and research would be helpful	Thank you for your comment. The full guideline is designed to give a complete description of all of the clinical and economic evidence considered, along with the GDG's interpretation of the evidence, and the recommendations. In order to assist clinicians, we have included a list of the recommendations and research recommendations at the beginning of the document and sub-headings throughout. A complete description of the health economics has also been included as an appendix. We anticipate that the Quick Reference Guide will be of particular benefit to clinicians
170.	SH	NHS Forth Valley	8.02	Full	2.4	23	Target users: I suggest that health promotion departments and staff especially physical activity coordinators should be included Community pharmacists are now offering minor ailment services and advising parents on this topic and shouel be targeted for more than simply use of drugs in treatment	Thank you for your comment. For NICE clinical guidance the intended target audience is health care professionals and the guideline is written with this in mind. We will, however, be able to take your comment to inform the implementation of the guideline.
171.	SH	NHS Forth Valley	8.03	Full	5.2	80	There should be a much stronger emphasis on the role of education establishments in influencing the progress of children with constipation – both in Nurseries and schools in relation to fluid intake as water, healthy eating behaviours and especially adequate toilets and personal care	Thank you for your comment. NICE clinical guidelines are aimed at a target audience comprising health care professionals, thus educational establishments are not covered by this guidance. However, school nurses are included within the target audience and have now been explicitly mentioned where appropriate. In addition, we will be looking to involve schools in the

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								implementation of guideline
172.	SH	NHS Forth Valley	8.04	Full	5.2	80-95	Management section on 5.2: It is not adequate to state that progress should be reviewed frequently – this is one of the commonest reasons for failure and the time spent in revewing children with constipation is not generally resourced adequately – need to specify whose job this should be and how it should be supported. I think there are many options that work but few are implemented. A nurse led clinic can be done by a children's nurse, a Health Visitor , a School Nurse or a doctor but someone has to be identified and the frequency specified with criteria for reducing this	Thank you, we agree. We have now amended the recommendation to provide more specific information as follows: "Reassess children frequently during maintenance treatment to ensure they do not become reimpacted and assess issues in maintaining treatment such as taking medicine and toileting. The frequency of assessment should be tailored to the individual needs of the child and their families (and could range from daily contact to contact every few weeks). Where possible, reassessment should be provided by the same person/team".
173.	SH	NHS Forth Valley	8.05	Full	General	General	Media role and potential for adverse influence by advertising etc might be included	Thank you for your comment. Consideration of the role of the media and the impact and influence of advertising was outside the scope of this guideline
174.	SH	NHS Forth Valley	8.06	Full	general	referral	Emphasise that specialist referral should rarely be needed if adequate early recognition and treatment is ensured and that ongoing review if relapse should be offered in primary Care as part of the information given to parents – with criteria to recognise risk situations for relapse	Thank you for your comment The guideline provides recommendations for early recognition of constipation and its management in primary and secondary care. We believe that if these recommendations are put into practice then specialist referral should rarely be needed. The information and support section provides guidance regarding ongoing support and advice, and we have now added to this talking to children and parents about possible triggers for constipation

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175.	SH	NHS Forth Valley	8.07	Full	General	General	Target users: Hospital wards with children and adolescents with chronic diseases of other kinds should be aware of the risk for CC developing during hospitalisation and introduce appropriate measures to minimise the risk – with physical activity hour for inpatients who can do this, water coolers in every ward accessible to children, fruit and healthy snacks etc	Thank you for your comment. These seem very good ideas however it is outside the scope of this guideline to make recommendations on service delivery.
176.	SH	NHS Forth Valley	8.08	Full	General	General	Thank you for at last brining this important topic to a wider health professional audience's attention	Thank you for your comment.
177.	SH	NHS Forth Valley	8.09	full	Appendix A	168	Include risk of UTI or asymptomatic bacteriuria specifically in this text, not just as reference as readers may not seek out additional guideline and bacteriuria may not be full UTI but still contribute to symptoms	Thank you for your comment. Appendix A comprises the scope for this guideline. This section of the scope sets out the currently published NICE guidance that relates to constipation. It was not appropriate to provide detail about the associated risks of UTI or asymptomatic bacteriuria here. Cross-reference to these associated documents will be provided in the full version and the NICE version of the published guideline.
178.	SH	Norgine Pharmaceuticals	12.01	All	General	General	Throughout the documents references to macrogol/polyethylene glycol are suffixed by '3350'. The molecule is generally referred to as macrogol/polyethylene glycol 3350 without the need for apostrophes.	Thank you for your comment. We have removed the quotation marks.
179.	SH	Norgine Pharmaceuticals	12.02	Full	2.3	22	Definition of terms: Macrogols. The current wording defines macrogols as: "A form of osmotic laxative. PEG 3350 and PEG 4000 are examples of macrogols." We would suggest that this wording be	Thank you for your comment. We have amended the definition as you suggest

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							changed to read: Osmotic laxatives. Macrogols with the mean molecular weight of 3350 and 4000 are used as laxatives.	
180.	SH	Norgine Pharmaceuticals	12.03	NICE	definitions	17	Definition of terms. Comments as above.	Thank you for your comment, we have amended the definition as you suggested
181.	SH	Norgine Pharmaceuticals	12.04	NICE	1.4	25	**Section 1.4 Clinical management** This section currently consists of recommended treatment for disimpaction and maintenance therapy but there is no guidance how to manage a child who presents with constipation and who is not faecally impacted. One of the main reasons that children become faecally impacted is that often GPs do not treat constipation adequately when the child presents in primary care in the first place. Low doses of ineffective laxatives are often prescribed which may make symptoms worse and may not relieve the constipation. The logical way to rearrange the clinical management section would be to cover 1. Constipation 2. Faecal impaction and 3. Maintenance therapy after disimpaction. It is worth noting that Norgine conducted 3 clinical studies in support of the paediatric indication for Movicol, and 2 of those	Thank you for your comment. We have added a recommendation (after 1.4.1) stating "start maintenance therapy if the child is not faecally impacted" We acknowledge that one of the main reasons that children become faecally impacted is low doses of ineffective laxatives prescribed by HCPs but children might also present to HCPs for the first time with impaction without having being previously treated at all by HCPs or after having been given OCT medications by parents/carers. Because GDG's experience suggests that currently HCPs rarely assess children for faecal impaction and that this is a cause of treatment failure the guideline stresses the importance of assessing for impaction and treating for disimpaction by putting this first in the management section.

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							studies (Thomson et. al. and Hardikar et. al.) recruited children with constipation and who were not faecally impacted. In section 1.4.10 reference is made to "ongoing treatment or maintenance therapy" so the wording of this existing section could be used for the constipation treatment recommendations, eg: • Use macrogol 3350 + electrolytes (Movicol Paediatric Plain) as first line treatment. • Adjust the dose of macrogol 3350 + electrolytes (Movicol Paediatric Plain) according to symptoms and response. • Add a stimulant laxative if macrogol 3350 + electrolytes (Movicol Paediatric Plain) does not work. • Substitute a stimulant laxative if macrogol 3350 + electrolytes (Movicol Paediatric Plain) is not tolerated by the child. Add another laxative such as lactulose or docusate (see table 4) if stools are hard. • Continue medication for several weeks after regular bowel habit is established. Laxative therapy should not be suddenly discontinued but the dose gradually reduced.	
182.	SH	Norgine Pharmaceuticals	12.05	Full	1	5-7	(5: Line 15 – 7: Line 20): Same comments apply as above	Thank you for your comment We have added an additional recommendation

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								(after 1.4.1) stating "start maintenance therapy if the child is not faecally impacted" We acknowledge that one of the main reasons that children become faecally impacted is low doses of ineffective laxatives prescribed by health care professionals (HCPs) but also children might present to HCPs for the first time with impaction without having being previously treated at all by HCPs or after being given over-the-counter medication by parents/carers. It is the GDGs experience that currently HCPs tend not to assess children for faecal impaction and that this is a cause of treatment failure the guideline stresses the importance of assessing for impaction and treating for disimpaction by putting this first in the management section.
183.	SH	Norgine Pharmaceuticals	12.06	NICE	1.4.2	25	Our SmPC for Movicol Paediatric plain refers to it being made up in water not 'a cold drink'. Nevertheless, we are aware that parents often make up the solution with numerous different cold (and hot) drinks.	Thank you for your comment. The GDG deliberately recommended use of a cold drink as their experience is that for many this children this makes the medication more palatable.
184.	SH	Norgine Pharmaceuticals	12.07	Full	5.1	72	Line 44: The product used in this study was Colyte which contains electrolytes.	Thank you for your comment. The information reported in the guideline reflects that reported in the published paper. For consistency of reporting we feel it is better not to add additional information at this stage to some studies whilst this is not possible for all.
185.	S	Norgine	12.08	Full	5.1	75	Line 10: The product used in this study	Thank you for your comment.

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	H	Pharmaceuticals					was Miralax which does not contain electrolytes	The information reported in the guideline reflects that reported in the published paper. For consistency of reporting we feel it is better not to add additional information at this stage to some studies whilst this is not possible for all.
186.	SH	Norgine Pharmaceuticals	12.09	Full	5.1	75	Line 16: The product was PEG3350 + electrolytes	Thank you for your comment. The information reported in the guideline reflects that reported in the published paper. For consistency of reporting we feel it is better not to add additional information at this stage to some studies whilst this is not possible for all.
187.	SH	Norgine Pharmaceuticals	12.10	Full	Appendix H	215	The study: Vincent R, Candy DCA. Movicol for the treatment of faecal impaction in children. Gastroenterology Today 2001;11(2):50-52. Is not included in the references, was this an oversight or was it deliberately excluded?	Thank you for your comment Thank you for highlighting this paper. It has now been considered and excluded as it did not meet the inclusion criteria
188.	SH	Norgine Pharmaceuticals	12.11	NICE	Table 4	13 & 26	The scope of the guideline is to cover children and young people up to the age of 18. There is no dosage recommendation given for macrogol + electrolytes for young people age 12 – 18, although for the other laxatives listed dose recommendation is given up to age 18.	Thank you for your comment. We have now amended the table to include this age group

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							Our product Movicol (macrogol + electrolytes 13.8g sachets) is licensed for the treatment of constipation and faecal impaction in the 12 – 18 age group. The dose for constipation is 1 – 3 sachets daily. For faecal impaction the dose is 8 sachets daily dissolved in 1 litre of water taken daily for up to 3 days.	
189.	SH	Norgine Pharmaceuticals	12.12	Full	5.1	79	Table 4: Comments as above. No mention of the dose of macrogol + electrolytes required for 12 to 18 year olds.	Thank you for your comment. We have amended the table to add this information.
190.	SH	North East Wales NHS Trust	19.01	NICE	KPIs	11	Abdominal examination – Green area does not specifically mention presence of a faecal mass.	Thank you for your comment. The GDG felt presence of a faecal mass should not be included here because its presence does not discriminate between idiopathic constipation and red flag, and neither does its absence
191.	SH	North East Wales NHS Trust	19.02	NICE	KPIs	12	Section DRE: Is it worth adding something like " and you are able to interpret results" otherwise inappropriate people may use this as a carte blanche to perform DRE when they don't know what to do with their findings. I still feel that this suggest that GPs will do more DREs than before. I know the word consider is out of favour but I feel that a GP or even paediatrician will give a sub therapeutic dose of medication and when the child doesn't improve will then feel that its OK to do a DRE.	Thank you for your comment The guideline already recommends that a DRE should be undertaken only by healthcare professionals competent to interpret the results. We have moved this recommendation to be the first one in that section to make this clearer
192.	SH	North East Wales NHS	19.03	NICE	1.1.5	22	Table 3: Abdominal examination – Green area does not specifically mention	Thank you for your comment. The GDG felt that presence of a faecal mass should not be included

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		Trust					presence of a faecal mass.	here because its presence does not discriminate between idiopathic constipation and red flag, and neither does its absence
193.	SH	North East Wales NHS Trust	19.04	NICE	1.2.1	23	Do we need to quantify what not responding to adequate treatment means?	Thank you for your comment. By adequate response we mean that there is some improvement of symptoms to the degree that the clinician feels is appropriate for the amount of treatment given. If this is not the case a change in treatment should be considered. Due to the highly variable nature of this it was not felt appropriate to include a more specific definition in the guideline.
194.	SH	North East Wales NHS Trust	19.05	NICE	1.2.2	23	Right answer should be in Block capitals and in bold	Thank you for your comment, it is not NICE style to emphasise recommendations with bold font or capitalisation
195.	SH	North East Wales NHS Trust	19.06	NICE	1.4.2	25	Is it worth giving an example of a cold drink i.e. Water, milk or fruit juice? It might just prompt our colleagues?	Thank you for your comment. This was not felt to be necessary.
196.	SH	North East Wales NHS Trust	19.07	NICE	1.7.1	30	It is worth giving some idea of a time scale for this otherwise you could get the situation where a health care professional gives 5 mls of lactulose for a week and then send to surgeons. Do we need to explain what optimum specialist management is?	Thank you for your comment. We have given some idea of timescales where this was thought to be appropriate, see for example the table 4 describing maintenance therapy. Optimum management refers to management as described in the guideline. This term has now been added to the glossary to make this clearer.
197.	SH	Royal College of General Practitioners	7.01	FULL	1.1	3	I am surprised that the definition needs such a time frame as a month. In primary care, most if not all will be have been in a week and I would be concerned if such a problem was left so long.	Thank you for your comment. We have taken out "with symptoms lasting >1 month" - all children should be treated early as you suggest.
198.	S	Royal	7.02	FULL	1.1	5	It mentions assessment of impaction but	Thank you for your comment.

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	H	College of General Practitioners					no guidelines on how to do this.	We have now included a recommendation on how to asses for impaction "Faecal impaction is diagnosed by a combination of history taking and physical examination – looking for overflow soiling and/or faecal mass palpable abdominally and/or rectally if indicated"
199.	SH	Royal College of General Practitioners	7.03	FULL	1.2	10	The section on not doing rectal exams on children unless the doctor is confident of diagnosing anatomical changes should be stressed	Thank you, we have now moved this recommendation so that it comes first in order to underline its importance.
200.	SH	Royal College of Nursing	23.01	NICE	General	General	The RCN welcomes this guideline. It is comprehensive and easy to read.	Thank you
201.	SH	Royal College of Nursing	23.02	NICE	1.2.3	23	Digital Rectal examination: - by Health care professionals competent to interpret – It would be helpful to clarify 'who this is' – the professional will require more guidance / training.	Thank you for your comment. The guideline cannot be specific about who should do this. Professional competencies are the remit of the royal colleges, rather than NICE.
202.	SH	Royal College of Nursing	23.03	NICE	1.5.2	28	**60** minutes physical activity **per day** – is this a realistic target?	Thank you for your comment. Despite the fact that there is no good quality evidence for the effectiveness of increasing physical activity to improve constipation, it is the opinion of the GDG that exercise should be encouraged. It is a common clinical observation that a lack of physical activity can be a contributing factor to constipation. Whilst recognising that physical activity is not in itself a treatment for constipation, the GDG felt that it was important to encourage children to be physically active, as it may decrease the likelihood that they will develop constipation again once an episode has been medically treated. It has been

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								recommended by The Department of Health that children should do at least 60 minutes of moderate intensity physical activity per day as part of a healthy lifestyle. (*Department of Health (2004) At least five a week: evidence on the impact of physical activity and its relationship to health. London: Department of Health*) and reiterated in the NICE public health guidance "Promoting physical activity for children and young people" (PH17) We have now reworded this recommendation to say: "Advise daily physical activity that is tailored to the child's stage of development and individual ability as part of ongoing maintenance in children and young people with idiopathic constipation" For clarity we also reordered that section and moved this recommendation to the end and grouped all diet recommendations at the beginning.
203.	SH	Royal College of Nursing	23.04	NICE	1.5.4	29	Table 5: Fluid Requirements: it would be helpful to know where this is referenced from in this version. In our view, obese children would require more fluid intake.	Thank you for your comment. We agree and have included a footnote taking this into account. We are now using the IoM (Institute of Medicine) table in this recommendation
204.	SH	Royal College of Nursing	23.05	NICE	4.2	33	Taking any medication = suggest that this be changed to: taking *'all prescribed medication'* - none compliance is the reason for most failed treatment.	Thank you for your comment, the recommendations have been amended as suggested.
205.	SH	Royal College of Nursing	23.06	NICE	5.1	35	Constipation link – day & night-time wetting: There is no mention in the NICE version	Thank you for your comment. Urinary symptoms caused by constipation to be

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							of the effects of constipation on the bladder - constipated children frequently also have daytime wetting and nocturnal enuresis.	dealt with by relevant guidelines (Urinary tract infection in children. NICE clinical guideline 54 (2007). Available from www.nice.org.uk/CG54, Nocturnal enuresis- NICE clinical guideline. Publication expected October 2010 It is likely that we will do some joint implementation work with the nocturnal enuresis guideline
206.	SH	Royal College of Nursing	23.07	All	General	General	We recognise that childhood constipation is still a taboo for many people, particularly children. The RCN will welcome proposals by NICE to publicise this guideline to help implementation. Nurses working in various settings, for example school nurses, practice nurses, children community nursing teams are well placed to do this and should be supported to get this important issue on the agenda.	Thank you for your comment. NICE produces a series of implementation tools following the publication of the guideline to assist in the implementation of the guidance. NICE would welcome the input of the RCN in developing these tools to ensure that they are effective
207.	SH	Royal College of Paediatrics and Child Health	29.01	Full	General	General	The College notes this is a much needed guideline. It is straightforward, clear, sensible, will change the lives of many children and families, and will mean less children need to be referred to secondary services. It is also an easy guideline to cut and paste into local protocol folders without many amendments.	Thank you for your comment.
208.	SH	Royal College of Paediatrics	29.02	All	General	General	The College believes that this document is excellent, a significant aid for the management of constipation which will aid	Thank you

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		and Child Health					practitioners and aid further research into this area given that the evidence base for any therapy is poor.	
209.	SH	Royal College of Paediatrics and Child Health	29.03	Full	General	General	The guideline is well written and evidence is very good.	Thank you for your comment.
210.	SH	Royal College of Paediatrics and Child Health	29.04	All	General	General	The College notes that the guideline makes formal recommendations for practices which many within the speciality have adopted.	Thank you for your comment.
211.	SH	Royal College of Paediatrics and Child Health	29.05	Full	General	General	The frequent reference to specialist services is unhelpful. The College believes that this guideline would benefit from clarification on whether this is intended for a community-based constipation clinic or a paediatric gastroenterology unit clinic. The College would recommend the terminology be changed to the appropriate person "in a constipation service."	Thank you for your comment. The guideline is intended for primary and secondary care and not intended to provide specific advice on care received at specialist services. We have provided the following definitions: -Specialist: Healthcare professional with either interest, experience and/or training in the diagnosis and treatment of constipation in children and young people Examples: specialist continence nurse, community paediatrician with an interest -Specialist services: services for children and young people which include constipation management Some recommendations containing the words "specialist (s)"/"specialist services" have been

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								amended to make them clearer in this respect, but it is outside the remit of guideline to be specific about which specific service to use
212.	SH	Royal College of Paediatrics and Child Health	29.06	Full	General	General	There are some issues relating to *severe constipation,* which have not been fully explored. A child with a megacolon with long standing soiling is unlikely to respond to changing the quality of the diet until the bowel is more responsive. This approach may simply impose more misery on the child and guilt on the parent. It also fuels delay at the primary care level. We note that diet has an important role once symptoms of chronic megacolon have resolved. Children with severe megacolon and strong tendencies to anxiety withholding are unlikely to respond to Macragols alone and the elective use of a combination of Macrogols/ stimulant may be needed to establish rhythm and mandate stooling. Clearer advice on weaning off should be provided. The College thinks that clarification on the risks of a reduction from 5 mls of a stimulant given daily to 2.5 mls, and a review within a month, once the first dosage produces a single normal quality stool without diarrhoea or pain should be included.	Thank you for your comment We have not recommended dietary changes alone as a first line treatment for children with constipation, whether they have megacolon or not. We agree that this approach may impose more misery on the child and guilt on the parent and fuel delay at the primary care level. Regarding weaning, there is no evidence and therefore we cannot be specific about time-frames, doses etc. this should be left to the professional judgment of clinicians. We have now specified in the recommendation what is meant by "frequent" reassessment.

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							There is anecdotal evidence to support giving exactly the same dose on 5 to 6 days of the week and giving the child one or two spaced days off to see if they can stool without treatment. This may be a safer approach and can be started quite early in the whole course (leaving a "window" in every week). This may be preferable to discovering after a month that the child stooled for a week or two (because of established rhythm) but was all the time collecting a plug and that months or years of treatment has been undone, with a painful impaction event. We recommend the weaning process be either omitted from the guideline or further options be described. Anecdotal evidence suggests that many serious cases have been originally treated correctly and then carelessly "weaned" with inadequate tight supervision. These cases are also often more reluctant to continue long term treatment.	
213.	SH	Royal College of Paediatrics and Child Health	29.07	NICE	Introduction	4	The College believes that the term "irregular bowel actions" may be unclear, and would rather suggest the use of "infrequent". We also note this the list of symptoms is presented in a confusing way, and that it may be more logical to cover bowel/abdominal symptoms first, and then	Thank you for your comments. We agree with both of them and have made amendments accordingly.

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							the general ones such as loss of appetite, mood, etc.	
214.	SH	Royal College of Paediatrics and Child Health	29.08	NICE	Introduction	4	The College notes that stool holding is often seen in toddlers and can be less obvious in older children, though they still tend to hold on – often when playing, distracted, in school, etc.	Thank you for your comment. We agree.
215.	SH	Royal College of Paediatrics and Child Health	29.09	NICE	Introduction	4	We think that medicines should be noted as one cause of constipation.	Thank you for your comment. We agree and have now included this.
216.	SH	Royal College of Paediatrics and Child Health	29.10	Full	1.1	5	The evidence base for Movicol as first line is not as strong as the guidance implies and,whilst a reasonable first line choice, it is not the only choice.. Anecdotal evidence suggests that many paediatricians use Senna first in many cases. The guideline should list other medications as options, such as sodium picosulphate, picolax for disimpaction, rather than focusing on Movicol. Pijpers MA,Tabbers MM, Benninga MA, Berger MY. Currently recommended treatments of childhood constipation are not evidence based: a systematic literature review on the effect of laxative treatment and dietary measures. Arch. Dis. Child. 2009;94;117-131	Thank you for your comment Available evidence, economic modelling and clinical experience support the use of oral PEG as first line treatment for both disimpaction and maintenance: PEG is cost-effective as monotherapy, works quickly, is easy to titrate and is well tolerated. No evidence was found for the effectiveness of either lactulose or senna for disimpaction; however, from clinical experience the GDG concluded that they can be useful as a second/third-line intervention. In the light of this, the GDG collated the information into a table (table 4) so that clinicians can select the most appropriate second-line doses of each laxative (or combination of laxatives) for their patients. We recognise the need for more evidence in this area and have now made a research recommendation for head to head trials of PGE vs.

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								stimulant laxatives.
217.	SH	Royal College of Paediatrics and Child Health	29.11	Full	1.1	5	We note that in New South Wales, Australia, Movicol is also very much first line management. Many paediatric surgeons like hydrolysed guar gum (benefibre) as an alternative second line treatment to lactulose.	Thank you for your comment The GDG considered hydrolysed guar gum (benefibre) as a dietary intervention; therefore it is not considered as an alternative to lactulose which is included as a laxative.
218.	SH	Royal College of Paediatrics and Child Health	29.12	Full	2.1	19	The College recommends that children with communication disorders and ADHD, who have a high prevalence of constipation, be specifically covered in the guideline.	Thank you for your comment We understand that children with communication disorders and ADHD have a high prevalence of constipation. While we acknowledge that it might be difficult to recognise symptoms of constipation in these groups of children (as it would probably be the case with symptoms of other conditions), we are not aware of any special provisions that should be made to diagnose and treat constipation in these groups of children, therefore all recommendations in the guideline also apply to them. If the comment is related to the need of screening for constipation in these groups of children we believe that advice in this respect should be sought from the guidelines addressing those specific conditions. The scope of the constipation guideline states that the principles of assessment and management covered in the scope will apply to children with other conditions who may also have constipation but the guideline will not address any additional management that these children might require and we have made all recommendations with this in mind..
219.	S	Royal	29.13	Full	2.2	20	This states that the care received in	Thank you for your comment

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	H	College of Paediatrics and Child Health					specialist services after referral is excluded, but that surgery, e.g. ACE, and anal manometry, is included. This requires clarification..	As stated in the scope the guideline covers indications for referral to specialist services and mentions procedures provided in those services children may be referred for, but it does not provide any specific recommendations on how to perform these procedures (e.g. ACE, manometry) because that is out of the scope of the guideline
220.	SH	Royal College of Paediatrics and Child Health	29.14	NICE	Patient-centred care	6	We note there is no mention of the role of the multidisciplinary team to provide holistic care, liaison with school, etc. We believe that this should be included in the guideline.	Thank you for your comment. We have now added a recommendation to this effect: "Health care professionals should liaise with school nurses to provide information and support and to help school nurses raise awareness of the issues surrounding constipation with children and school staff".
221.	SH	Royal College of Paediatrics and Child Health	29.15	All	Tables	General	In general, the College believes that these tables are clearly presented. However, the comment in the key to the red cells in each of the tables to "exclude idiopathic constipation" is unclear. It sounds like clinicians should exclude idiopathic constipation before considering other diagnoses. The College would recommend removing these words or replace them with "idiopathic constipation only as a diagnosis of exclusion".	Thank you for your comment. We have changed the phrase "exclude idiopathic constipation" to say "not idiopathic constipation"
222.	SH	Royal College of Paediatrics and Child Health	29.16	Full	Table 1		The College would like to see information included on what clinicians should be aiming for with treatment. The College believes that 'no pain' and 'no overflow' are key aims, but the guideline should provide clarification on frequency and	Thank you for your comment. The main aim of the guideline is to provide clinicians with evidence based recommendations for practice. Assessment of when a child is fit for discharge from care should be a judgement based on the clinician's knowledge of normal physiology,

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							consistency, i.e. once a day, Bristol type 3 or 4? We would like to know when paediatricians can be confident that the child is dischargeable from their care, and when the GP can be confident that the problem is sorted. This should include information on what alarm bells the parent should know about to prevent a relapse. Although the College understands that these may be subjective, patient-dependent and without evidence, it would be beneficial if the GDG could provide recommendations on this as we think that many clinicians would find it helpful.	the individual child' s history and response to treatment, and the child's circumstances. This will be based upon the need for on-going support as well as frequency and type of bowel movement and needs to be judged on an individual basis.
223.	SH	Royal College of Paediatrics and Child Health	29.17	All	Table 1	General	In the Stool Patterns row, the guideline states that that overflow soiling is very loose. We note that it may also be thick, sticky stool or dry flaky stool.	Thank you. We will clarify that overflow soiling is commonly loose but that it can also be thick and sticky or dry and flaky
224.	SH	Royal College of Paediatrics and Child Health	29.18	NICE	Table 1	General	Recurrent abdominal pain should be included as a symptom association with defacecation, especially if worse after meals.	Thank you for your comment. Abdominal pain is already included as a symptom associated with defaecation in table 1 for over 1s.
225.	SH	Royal College of Paediatrics and Child Health	29.19	NICE	Table 2	General	Urinary symptoms, such as dribbling urinary incontinence, should alert to the possibility of a neurological problem. Also allergic tendency, worsening of symptoms with specific foods would alert to possible food intolerance such as cows milk protein intolerance.	Thank you for your comment. After extensive discussion the GDG decided not to include urinary problems as a red flag. The GDG believes that motor signs/symptoms already included would be sufficient to alert to the possibility of a neurological problem

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								Urinary symptoms caused by constipation to be dealt with by relevant guidelines (Urinary tract infection in children. NICE clinical guideline 54 (2007). Available from www.nice.org.uk/CG54, Nocturnal enuresis- NICE clinical guideline. Publication expected October 2010. We are likely to do some joint implementation work with the nocturnal enuresis guideline. There was insufficient evidence to include food intolerance as a cause of constipation.
226.	SH	Royal College of Paediatrics and Child Health	29.20	All	Table 2	General	The College believes that the guideline should amend the red flag "Passage of meconium" to "failure to pass/delay of more than 48 hours [rather than 24 hours] - after birth."	Thank you for your comment. We have amended this appropriately.
227.	SH	Royal College of Paediatrics and Child Health	29.21	NICE	Table 2	General	The College believes that medicines should be included as one key component of history taking to diagnose idiopathic constipation.	Thank you for your comment. We have now added a reference to medicines in table 1 (timing of onset box) as a precipitating factor
228.	SH	Royal College of Paediatrics and Child Health	29.22	NICE	Table 2	General	The College recommends that dietary history, particularly fibre intake, be included.	Thank you for your comment. Dietary history has already been included in the history taking table. No specific evidence about the effect of fibre intake was found.
229.	SH	Royal College of Paediatrics and Child Health	29.23	NICE	Table 3	General	We think that distension as a finding is difficult because most constipated children have a degree of distension. We note that distension may be due to faecal loading and may not therefore indicate	Thank you for your comment. We are saying that "gross abdominal distension" not only "distension" is a red flag.

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							organic disease. The College recommends that it is used as a red flag sign in conjunction with others.	
230.	SH	Royal College of Paediatrics and Child Health	29.24	NICE	KPIs – clinical mgmt	12	The combination of sodium picosulphate with senna (as used in bowel preparation for colonoscopy) for disimpaction has not been mentioned and this should be included.	Thank you for your comment. The GDG found no evidence for using these laxatives in combination We have now drafted a research recommendation for head to head trials of PGE vs. stimulant laxatives.
231.	SH	Royal College of Paediatrics and Child Health	29.25	All	Table 4	General	There is no information on dosage of Movicol for children aged 12 -18 years of age. Further information on this age group should be provided.	Thank you for your comment. We have now provided this information
232.	SH	Royal College of Paediatrics and Child Health	29.26	All	Table 4	General	We note that there is no minimum age suggested for Movicol paediatric plain for disimpaction/maintenance therapy. If the recommendation is that the product can be used at this dose from birth upwards, this should be explicitly stated as this is not in line with current British National Formulary for Children (BNF-C).	Thank you for your comment. The GDG felt that it was not appropriate to stipulate a minimum age. There may be instances where it would be appropriate to use Movicol in a baby and these should be judged individually by the clinician.
233.	SH	Royal College of Paediatrics and Child Health	29.27	Full	Table 4	General	The guideline includes a recommendation to obtain informed consent to prescribe Movicol paediatric plain in those age groups where its use is outside the terms of the product licence. However, the same recommendation is not made for the unlicensed prescribing of sodium picosulphate/senna. The College believes	Thank you for your comment. We have now included a footnote for all recommended medications and doses that are off-licence which states that informed consent should be obtained. The GDG felt that it would be appropriate to seek informed consent for all episodes of off-label prescribing.

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							that advice should be consistent. The College is concerned that it may not be reasonable to expect informed consent to be obtained for every episode of off-label prescribing and requests that NICE produce a generic leaflet for this purpose.	It is outside the scope of this guideline to consider producing a leaflet for the purpose of obtaining informed consent
234.	SH	Royal College of Paediatrics and Child Health	29.28	NICE	Table 4	General	The use of Movicol should be cautioned as its use may result in frequent, small stools instead of normal bowel motions.	Thank you for your comment. Published evidence and GDG experience is that is related to dose. Once the dose is titrated appropriately to patient response, a normal bowel motion should be established. Frequent small stools can be a side-effect of many laxatives
235.	SH	Royal College of Paediatrics and Child Health	29.29	NICE	Table 4	General	The use of lactulose should be avoided in children with soiling but without palpable faecal loading per abdomen. Candy DC, Edwards D, Geraint M. Treatment of faecal impaction with polyethelene glycol plus electrolytes (PGE + E) followed by a double-blind comparison of PEG + E versus lactulose as maintenance therapy. J Pediatr Gastroenterol Nutr. 2006 Jul;43(1):65-70.	Thank you for your comment. Children with soiling are by definition constipated and need treatment with laxatives whether or not there is palpable faecal loading per abdomen. This is because faeces may be impalpable in children taking laxatives and also transit studies may identify children with soiling and faecal loading of the rectum only which would not be palpable per abdomen. The paper cited demonstrated that a macrogol-based laxative could be used for oral disimpaction and that the macrogol-based was better than lactulose as a maintenance laxative. Faecal continence was an outcome measure but, for those children on lactulose who completed the trial without re-impacting (23% re-impacted on lactulose in spite of adding senna vs. 0% on macrogol) there

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								was no significant difference in outcome between those treated with macrogol or lactulose.
236.	SH	Royal College of Paediatrics and Child Health	29.30	NICE	Table 4	General	The use of lactulose should be cautioned as its use may lead to flatulence and caries (as it is very sweet).	Thank you for your comment. The GDG is unaware of the evidence for caries, and this was not reported as an adverse effect in any of the reviewed evidence. The guideline only recommends lactulose after other treatments have been tried and failed and only if the stools are hard.
237.	SH	Royal College of Paediatrics and Child Health	29.31	NICE	Table 4	General	We note that idrolax macrogol 4000 (Ipsen) is a very good substitute for movicol if the taste of movicol is not tolerated. The College recommends that this should be included.	Thank you for your comment. The GDG understands that Idrolax macrogol 4000 (Ipsen) has ceased manufacture
238.	SH	Royal College of Paediatrics and Child Health	29.32	All	Table 4	General	The College believes that reference to senna liquid should include an equivalent dose of senna tablets as many patients younger than 6 years old will take the tablets in preference to the liquid due to the taste. This should be applied to all points at which senna appears in the guideline.	Thank you for your comment- we have added a dose for senna tables for children aged between 2 and 6 years. We believe it is not appropriate to recommend tablets for children under 2 years.
239.	SH	Royal College of Paediatrics and Child Health	29.33	NICE	Table 4	General	Anecdotal evidence in secondary care suggests that the threshold for using stimulant laxatives alongside osmotic diuretics is in practice much lower than these guidelines would indicate. We assume there is consensus that Movicol is the best medicine to trial alone in all situations?	Thank you for your comment. Available evidence, economic modelling and clinical experience support the use of oral PEG 3350 with added electrolytes as first line treatment for both disimpaction and maintenance: PEG is cost-effective as monotherapy, works quickly, is easy to titrate and is well tolerated. Little/low quality/no evidence was found for the effectiveness of other laxatives; however, from

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								clinical experience the GDG concluded that they can be useful as a second/third-line intervention. In the light of this, the GDG collated the information into a table so that clinicians can select the most appropriate second-line doses of each laxative (or combination of laxatives) for their patients. We have now drafted a research recommendation for head to head trials of PGE vs. stimulant laxatives.
240.	SH	Royal College of Paediatrics and Child Health	29.34	NICE	Table 4	General	The guideline does not included liquid paraffin and would like to know whether the GDG has a view on the use of this.	Thank you for your comment. The GDG believes the evidence on liquid paraffin is poor. Taking it involves a risk for children whose swallowing is impaired: due to the small risk of aspiration. Titration of liquid paraffin is difficult and it cannot be used with Docusate. We have now added this to the GDG interpretation of the evidence
241.	SH	Royal College of Paediatrics and Child Health	29.35	NICE	Table 4	General	We would like clarification that the British National Formulary for Children, which is distributed by the Department of Health, has been fully engaged and supports the new dosages included.	The BNF-C is a registered stakeholder for the guideline. The BNF-C recognises that doses of laxatives may need to exceed those stated in the BNF-C and where this is the case in this guideline we have made this explicit.
242.	SH	Royal College of Paediatrics and Child Health	29.36	All	Table 4 And elsewhere	General	The College notes that this draft guideline is remarkable in its unusual recommendation for using a specific product from a specific manufacturer (Movicol, Norgine) as the first line treatment for both disimpaction and for maintenance treatment. This is of particular importance given the	Thank you for your comment. The recommendations have now been amended and use the generic term PEG 3350 + electrolytes rather than Movicol. Available evidence, economic modelling and clinical experience support the use of oral PEG 3350 with added electrolytes as first line treatment for both

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							way that the guideline is likely to be used within NHS institutions and serious consideration needs to be given to the overt support that is given to Norgine in the guideline. To its credit the guideline does list the interests of the guideline development group members and co-opted members. The involvement of these members in Norgine's trials and support given to GDG members does raise the possibility of witting or unwitting bias towards the use of Movicol. The recommendation to use Movicol does extend outside of the agent's licensed uses. The evidence in favour of such uses must be explicitly stated if these aspects of the guideline are to have intellectual integrity.	disimpaction and maintenance: PEG is cost-effective as monotherapy, works quickly, is easy to titrate and is well tolerated. The little evidence that was found for the effectiveness of other laxatives was often of low quality; however, from clinical experience the GDG concluded that they can be useful as a second/third-line intervention. In the light of this, the GDG collated the information into a table (table 4) so that clinicians can select the most appropriate second-line doses of each laxative (or combination of laxatives) for their patients. We recognise the need for more evidence in this area and have now made a research recommendation for head to head trials of PGE vs. stimulant laxatives. Despite the previous, we acknowledge that there is a publication bias and that most of the published evidence focuses on PEG 3350. Some of this research has not been funded by Norgine, but by North American companies. NICE aims to be accurate and transparent regarding potential conflicts of interest. The GDG's declarations of interest have been sought throughout the guideline development, including the post consultation phase and updated throughout. We acknowledge that one GDG member has declared a personal pecuniary interest associated

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								with Norgine, and three GDG members have declared non-pecuniary interests. Ten GDG members have no interests in Norgine. Throughout the development of the guideline the GDG chair, supported by the technical team, has striven to ensure the recommendations are based on the evidence and supported by interpretations based on GDG expertise. We acknowledge that one declaration was made too late to take the appropriate action (i.e. declare the interest and withdraw from discussions) during development and in particular in the discussions relating to PEG 3350 + electrolytes. In addition, when voting on the key recommendations for implementation, the expert advisor was given the opportunity to vote when he should not have been. The GDG votes were subsequently recounted to exclude the votes of the expert advisor and the GDG member who had declared a personal pecuniary interest. Excluding the votes from these two people did not alter the decision about the key priorities for implementation. In addition, independent reviews of the clinical and cost effectiveness evidence were conducted by NICE technical teams and members of the Guidelines Review Panel. Subsequent changes have been made to the recommendations for disimpaction and maintenance (the generic terms for laxatives have

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								been used rather than product names and the recommendations now say to "offer" PEG 3350 + electrolytes as a first line treatment, rather than to "use" it). The GDG interpretations of the evidence for these sections have also been expanded to make clearer the GDG's justification for their recommendations.
243.	SH	Royal College of Paediatrics and Child Health	29.37	NICE	KPIs – maintenance therapy	14	Large doses are required for maintenance therapy, and the addition of a stimulant laxative may decrease the dose required. We note that it may also be difficult to wean off Movicol without adding a stimulant laxative.	Thank you for your comment. As they currently stand the recommendations allow for a variety of regimes including use of stimulant laxative We have now drafted a research recommendation for head to head trials of PGE vs. stimulant laxatives.
244.	SH	Royal College of Paediatrics and Child Health	29.38	NICE	KPIs – maintenance therapy	14	The final paragraph on this page recommends continuing maintenance therapy for several weeks. Anecdotal experience suggests that this is too short, especially in children with a long duration of constipation or those who are soiling. If weaned too quickly relapse is very likely. The College would recommend the need to maintain regular bowel actions for at least three months before weaning be considered.	Thank you for your comment. We have now changed the recommendation to read: "continue medication at maintenance dose after regular bowel habit is established. This may take several months. Do not stop medication abruptly. Some children may require laxative therapy for several years. A minority may require ongoing laxative therapy."
245.	SH	Royal College of Paediatrics and Child Health	29.39	NICE	KPIs – diet and lifestyle	15	The College notes that there is no mention of toilet training. A child who is constipated is unlikely to successfully toilet train. We recommend that toddlers remain on laxatives until they are successfully toilet trained then start weaning doses.	Thank you for your comment. We agree that and have amended the recommendation as suggested.

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246.	SH	Royal College of Paediatrics and Child Health	29.40	NICE	General Introduction Patient-centred care Key priorities: Diet	General 4 (para 4) 5 6 15	There are anomalies in focus and emphasis between different parts of the guideline with regard to the psychological impact of constipation and soiling, and the very brief and negative 'psychological and behavioural interventions' section. For example: 1) It is stated that 'families may delay seeking help for fear of a negative response from health care professionals (HCPs)' and that "some health care professionals underestimate the impact of constipation on the child and family." It is stated that failing to do this may contribute to poor outcomes. This should include advice to HCPs on how to engage a family and how to develop a therapeutic working relationship that is collaborative and non-blaming. 2) The guideline acknowledges that 'many children experience social, psychological and educational consequences that require prolonged support' but psychological advice available to those who will manage the child and family is so minimal as to be of little value. 3) The guideline states the importance of appropriate care and support for families but should also include advice to allow HCPs to provide appropriate	Thank you for your comment. Engaging with patients in positive and non-blaming way is not specific to constipation and is an important component of good practice. The importance of psychological support was recognised by the GDG who wished to emphasise this by incorporating it under the heading of information and support in order that it would be seen as a component of good usual care and not the remit of specialist psychological team. We recognise this had the effect of leaving just a few more negative recommendations under the specific heading and so we have now removed this and incorporated all the recommendations under the more general heading. It is outwith the scope of this guideline to provide recommendations on specific training and education programmes – this is rather the remit of the professional bodies. We would very much welcome input from the royal colleges in order to support the implementation of this guideline.

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					and lifestyle		psychological care. 4) The second bullet point gives examples of behavioural and psychological interventions that should not be hidden away under this heading. They are important components of treatment and require separation as per sections 1.5 and 1.6. It appears to be assumed that all HCPs know what is meant by 'scheduled toileting' and 'reward systems' and how to teach families about them. The College believes that this is not necessarily the case as these are specific skills that need to be learnt. The guideline should include further information on how to use a star chart The commonest cause of failure of a star chart is that the healthcare professional did not explain it properly. The College believes that this should be addressed in section 1.6 (page 30) and more detail should be included on how to use a reward system such as a star/sticker chart to maximise its effectiveness.	
247.	SH	Royal College of Paediatrics and Child Health	29.41	NICE	1.6	30	The College believes that this section requires further clarification as at present this is too brief and gives only negative advice. This section should provide practical advice and guidance to the	Thank you for your comment. Engaging with patients in positive and non-blaming way is not specific to constipation and is an important component of good practice. The importance of psychological support was recognised by the GDG

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							majority of healthcare professionals who manage constipation who are not necessarily trained in behavioural and psychological methods. The College agrees that it would be inappropriate to refer every child with constipation to CAMHS. However there should be a low threshold for the discussion of children who have not responded promptly to treatment with child mental health professionals as part of the established paediatric liaison service or as a consultation with the local CAMH service. This should ensure that subtle psychological problems in the child or family are detected and managed.	who wished to emphasise this by incorporating it under the heading of information and support in order that it would be seen as a component of good usual care and not the remit of specialist psychological team. We recognise this had the effect of leaving just a few more negative recommendations under the specific heading and so we have now removed this and incorporated all the recommendations under the more general heading. Appropriate training for health care professionals regarding what constitutes behavioural advice and psychological support could be considered by the royal colleges.
248.	SH	Royal College of Paediatrics and Child Health	29.42	NICE	1.6.1	30	Paediatricians and paediatric nurses should be able to undertake the sort of simple behavioural measures that will support the management of idiopathic constipation, with or without soiling. Components of the behavioural aspects of paediatric management could include the following. • Sitting on the toilet two or three times per day after meals for five minutes, whether or not stool is produced. A parent should be nearby. • Making this environment	Thank you for your comment. We agree and we think this information would be good for an information sheet/implementation support.

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							comfortable and pleasant by attention to one or more of: the decor, lighting and warmth of the room; a stool for the child's feet; music to listen to; and books or comics to read. • A reward programme for sitting that may involve verbal or non-verbal praise, sticker or star charts, and material or enjoyable activity rewards. Reinforcement of some sort should be given for just sitting, but extra praise or rewards may be given if a stool is produced. • A non-judgemental and matter-of-fact approach to any soiling episodes that occur. Soiled garments should be washed with the minimum of fuss, and there should be no punishment. • If soiling occurs, it should be spoken about in a child-friendly way that externalises the problem, such as using a metaphor like 'sneaky-poos' (depending on the age of the child): making it seem that the soiling is something that sneaks up on the child and catches her unawares, and is not her fault.	

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249.	SH	Royal College of Paediatrics and Child Health	29.43	Full	5.5	141-2	The College agrees that it is important for laxatives to be used appropriately to enable any psychological input to work and that many of the psychological problems associated with faecal soiling are a result of inadequate laxative treatment, rather than causing the constipation, as used to be thought. The College believes that the GDG should acknowledge the importance of behavioural interventions in routine paediatric practice and then include recommendations on these interventions. A recommendation could be added to the effect that, despite the lack of RCTs showing the effectiveness of behavioural measures in combination with laxatives, clinical practice would suggest that paediatric services should offer behavioural advice (*see previous comment*) in addition to tailoring laxatives to the child's bowel habit. It is important that this sort of advice is offered in paediatric services, as CAMHS may be less likely to take a holistic approach and acknowledge the importance of adequate laxative use, and may thereby inadvertently exacerbate the psychological consequences of the constipation (as implied by the GDG). Joint paediatric/CAMHS clinics can	Thank you for your comment. There are recommendations included in diet and lifestyle section which stress importance of medical, psychological and dietary interventions. In order to make this clearer we have removed "behavioural interventions" from the heading. The recommendations have now been amended to address the points you raise. Service provision is outside the scope of this clinical guideline.

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							overcome this problem: there could also helpfully be a recommendation to this effect.	
250.	SH	Royal College of Paediatrics and Child Health	29.44	Full	1.1	3-4	The document states to "refer them urgently to a health care professional experienced in child health." We recommend this be reworded to "refer or manage", as the child is likely to be seen by an HCP experienced in child health. For example, peri-anal strep may not need referral, rather treatment; whereas, Coeliac disease will likely to need referral for diagnosis, etc.	Thank you for your comment we have now amended this recommendation to say: "If a child has any "red flag" symptoms do not treat them for constipation. Instead refer them urgently to a health care professional with experience in the specific aspect of child health which is causing concern." With perianal strep, we have now added a recommendation to say: "If the physical exam shows evidence of perianal streptococcus treat for constipation and also treat the infection".
251.	SH	Royal College of Paediatrics and Child Health	29.45	Full	1.1	6	The dosage for sodium picosulphate is here expressed in mg; but we note it is usually seen in ml, and this should be referred in document.	Thank you for your comment The dose for sodium picosulphate is expressed in mg in the BNFC when indicated for constipation and we have replicated this in the guideline. When indicated as bowel cleansing solution in the form of powder this is expressed in number of sachets according to age group
252.	SH	Royal College of Paediatrics and Child Health	29.46	Full	1.1	6	We recommend that the mg dose of standard senna tablets be stated as the 'double strength' as 15mg dosing is widely available.	Thank you for your comment. We have amended this accordingly and have provided the BNF-C doses based on one tablet=7.5mg.

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253.	SH	Royal College of Paediatrics and Child Health	29.47	NICE	1.1.3	21	We recommend that food allergy be included as a differential diagnosis.	Thank you for your comment. This was considered by the GDG who felt there was insufficient evidence to include food allergy as a primary cause for constipation.
254.	SH	Royal College of Paediatrics and Child Health	29.48	Full	1.2	10	We think that the recommendation on testing for Coeliac disease and hypothyroidism is unclear as both can present with constipation and it is unclear what the "specialist services" referred to are. We recommend that those children with chronic constipation, particularly those who do not respond to a simple laxative regimen or have suspicious features, have a basic blood test. A blood test would include a full blood count, urea and electrolytes, iron status, inflammatory markers, with thyroid function testing if there were other suggestive features.	Thank you for your comment. We have included testing for hypothyroidism in the recommendation "Test for coeliac disease and hypothyroidism in the ongoing management of intractable constipation in children if requested by specialist services" We have included a definition of "specialist services" in the guideline glossary .
255.	SH	Royal College of Paediatrics and Child Health	29.49	Full	1.2	14	We recommend that children be referred for paediatric gastroenterology/multidisciplinary assessment prior to referral for antegrade colonic enema (ACE). It seems over stated to refer for consideration. We note that the real issue is to refer on children who fail with this simple regimen and need consideration of other approaches.	Thank you for your comment. The referral for assessment for suitability for an ACE only comes after optimum management which includes referral to other members of the multidisciplinary team prior to this where appropriate as covered by the following recommendation: "Refer children and young people with idiopathic constipation who do not respond to initial treatment within 3 months to a practitioner with expertise in the problem**."**

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256.	SH	Royal College of Paediatrics and Child Health	29.50	Full	1.3	15	The College believes that research recommendations should include other drug therapies for disimpaction and maintenance, and the practicalities of using them. We also think this should sit above the research recommendation on ACE.	Thank you for your comment We agree and have included a new research recommendation on assessing the effectiveness of PEG 3350 as compared to older products (senna, bysacodil and sodium picosulphate) Research recommendations are not ranked in priority order (other than key recommendations)
257.	SH	Royal College of Paediatrics and Child Health	29.51	NICE	1.4	25	There is no mention of Kleenprep bowel washout for disimpaction. This is extremely useful in those who fail to tolerate or to respond to oral movicol disimpaction. While it should only be used within specialist centres and it may require in -patient admission and NG tube, this should be considered.	Thank you for your comment. The GDG discussed the use of Klean-Prep bowel washout for disimpaction as they were aware that some clinicians use it in children who fail to tolerate or to respond to oral disimpaction. The GDG noted that Klean-Prep should only be used within specialist centres and it may require in-patient admission and insertion of a nasogastric tube. The GDG also noted that the BNFC says that bowel cleansing solutions (including Klean-Prep) are used before colonic surgery, colonoscopy, or radiological examination to ensure the bowel is free of solid contents, but they are not treatments for constipation. For these reasons, they agreed that they should not recommend its use.
258.	SH	Royal College of Paediatrics and Child Health	29.52	NICE	1.4.10	28	What is the rationale and evidence for recommending Movicol PP as first line in maintenance? Senna as a stimulant laxative would seem an appropriate first line single agent maintenance therapy as well.	Available evidence, economic modelling and clinical experience support the use of oral PEG 3350 with added electrolytes as first line treatment for both disimpaction and maintenance: PEG is cost-effective as monotherapy, works quickly, is easy to titrate and is well tolerated. Little/low quality/no evidence was found for the

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								effectiveness of other laxatives; however, from clinical experience the GDG concluded that they can be useful as a second/third-line intervention. In the light of this, the GDG collated the information into a table so that clinicians can select the most appropriate second-line doses of each laxative (or combination of laxatives) for their patients. We have now made a research recommendation for head to head trials of PGE vs. stimulant laxatives.
259.	SH	Royal College of Paediatrics and Child Health	29.53	Full	2.3	21	The word characteristic is misspelled.	Thank you, this has been amended
260.	SH	Royal College of Paediatrics and Child Health	29.54	Full	2.3	22	Megarectum: We think this description is misleading. It implies that children have loss of sensation even after disimpacation. Many children describe that, whilst they have loss of sensation to more stool accumulating when they have an impacted rectum, sensation improves dramatically once they have been disimpacated even if megarectum remains.	Thank you for your comment We have amended this definition to say "A large rectum as a result of chronic faecal loading"
261.	SH	Royal College of Paediatrics and Child Health	29.55	Full	3.2	27	The College believes that the information about how to diagnose impaction is very important. We note that many clinicians are worried about giving disimpaction doses of Movicol if they haven't done a rectal examination in case the child was not impacted and they are risking	Thank you for your helpful comment We have added a recommendation on how to diagnose impaction

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							overdosing them. The College believes that this information should be more prominent and included in the NICE version.	
262.	SH	Royal College of Paediatrics and Child Health	29.56	NICE	3.2	35	The guideline recommends to "not perform digital rectal examination in a child older than 1 year unless there are positive red flag signs". The College does not believe that the two papers the GDG have selected for evidence are very appropriate as they use plain abdominal X-ray to assess faecal loading in the rectum and compare it with digital rectal examination findings. We note that the guideline's Clinical investigations section (4) also does not recommend the abdominal radiograph. We believe this poses a conflict. Presence of faecal mass in the rectum is one of the diagnostic criteria in the Rome III process (Rasquin A, Di Lorenzo C, Forber D, Guiraldes E, Hyams JS, Saiano AM,et al. Childhood functional gastrointestinal disorders: child/adolescent. *Gastroenterology* 2006;130:51527-37). It is important that clinicians who want to positively use Rome III criteria in the management and research would not be able to use this important physical sign in practice.	Thank you for your comment As stated the two papers included used plain abdominal X-ray to assess faecal loading in the rectum and compared it with digital rectal examination findings also regarding faecal loading (but not anatomical abnormalities which is what the red flags refer to). According to the results the evidence neither supports the routine use abdominal radiograph nor the routine use of DRE of to diagnose faecal loading (constipation). However the guideline recommends that DRE can be used in certain instances. The GDG believes that it is possible to diagnose faecal impaction without performing a DRE (by finding faecal mass in abdomen and/or overflow soiling elicited from the history) The Gold paper was excluded from the review as it is a discussion paper, not primary research.

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							It is important in the management of functional constipation to consider disimpaction. It is not possible to assess faecal impaction without doing a digital rectal examination and therefore not doing this simple physical examination may have serious drawbacks in the management. Digital rectal examination is an important part in the physical examination when assessing a child with constipation. Gold et al (Gold DM, Levine J, Weinstein TA, Kessler BH, Pettei MJ. Frequency of digital rectal examination in children with chronic constipation. *Arch Pediatr Adolesc Med* 1999;153:377-79) have shown that digital rectal examination rates were unacceptably low in children with chronic constipation. By recommending not doing digital rectal examination in older children with constipation in the guideline as a result of lack of evidence it will not do the justice to patients. The College would recommend at least one digital rectal examination at the initial consultation rather than omitting it completely.	
263.	SH	Royal College of Paediatrics and Child	29.57	Full	5.1	78	We note that Kleenprep in disimpaction is widely used when these other disimpaction regimens fail and very effective, and think this should be	Thank you for your comment. The GDG discussed the use of Klean-Prep bowel washout for disimpaction as they were aware that

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		Health					included in the guideline.	some clinicians use it in children who fail to tolerate or to respond to oral disimpaction. The GDG noted that Klean-Prep should only be used within specialist centres and it may require in-patient admission and insertion of a nasogastric tube. The GDG also noted that the BNFC says that bowel cleansing solutions (including Klean-Prep) are used before colonic surgery, colonoscopy, or radiological examination to ensure the bowel is free of solid contents, but they are not treatments for constipation. For these reasons, they agreed that they should not recommend its use.
264.	SH	Royal College of Paediatrics and Child Health	29.58	Full	Appendix F	200	The College believes that it is a good idea to involve children in guideline development and believes that this adds integrity to the guideline.	Thank you
265.	SH	Royal Pharmaceutical Society of Great Britain	18.01	Full	General	General	The RPSGB welcomes these draft guidelines and endorses the comments of the NPPG.	Thank you
266.	SH	Royal Pharmaceutical Society of Great Britain	18.02	NICE	Introduction	4	Should there not be a mention of 'MEDICINES' as a cause of constipation?	Thank you for your comment. We agree and have now included this.
267.	SH	Royal Pharmaceutical Society of Great Britain	18.03	NICE	KPIs	10	As above	Sorry, we are not able to work out what this comment refers to.
268.	SH	Royal Pharmaceuti	18.04	NICE	KPIs	13	Whilst I have no problems with the doses that are suggested I hope that the BNF-C	Thank you for your comment. The BNF-C is a registered stakeholder for the guideline.

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		cal Society of Great Britain					has been fully engaged and that they support the new dosage. The BNF-C is distributed by the DH and it would seem strange to have 2 different dose guidelines.	We have stated each time where the doses recommended in this guideline are outside of what the BNFC recommends
269.	SH	Royal Pharmaceutical Society of Great Britain	18.05	NICE	General		In practice in secondary care the threshold for utilising stimulant laxatives alongside osmotic diuretics seems much lower than these guidelines would indicate. I assume there is consensus that Movicol is the best medicine to trial alone in all situations?	Thank you for your comment. Available evidence, economic modelling and clinical experience support the use of oral PEG 3350 with added electrolytes as first line treatment for both disimpaction and maintenance: PEG is cost-effective as monotherapy, works quickly, is easy to titrate and is well tolerated. Little/low quality/no evidence was found for the effectiveness of other laxatives; however, from clinical experience the GDG concluded that they can be useful as a second/third-line intervention. In the light of this, the GDG collated the information into a table (table 4) so that clinicians can select the most appropriate second-line doses of each laxative (or combination of laxatives) for their patients.
270.	SH	Royal Pharmaceutical Society of Great Britain	18.06	Full	General	General	Community Pharmacists, as part of their public health role in the community pharmacy contractual framework, are contracted to provide information and advice, treatment (where appropriate) and signpost/refer patients to other healthcare agencies such as GP surgeries. This is particularly relevant to common ailments such as constipation in children.	Thank you for your comment. We recognise the valuable role played by community pharmacists in relation to constipation.
271.	SH	Telford & Wrekin PCT	15.01	Full	6	160	Line 46-47: In the recommendations, you say to refer children if they do not respond	Thank you for your comment. The recommendation specifically talks about "responding" to treatment,

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							to initial treatment within 3 months to a practitioner with expertise. This is a short length of time and may result in unrealistic expectations of outcome in 12 weeks. We feel that a more realistic time scale would be 6 months after the initial treatment, as this would facilitate effective implementation of treatment and concordance. If it remains at 3 months there will be a deluge of children referred to the 'practitioner with expertise' and not the capacity or resources to deal with the consequence of this.	rather than resolution. We agree that many children will not be cured within 3 months. However, we feel that if after three months there has been no improvement in the child's symptoms (i.e. no *response* to treatment at all), it is appropriate to refer to a practitioner with expertise.
272.	SH	Telford & Wrekin PCT	15.02	Full	General	General	It is a very well written and comprehensive document that will prove invaluable to all practitioners to maintain best practice.	Thank you for your encouraging comment.
273.	SH	Welsh Assembly Government	22.01	NICE	Patient-centred care	6	The text in the second sentence of the second paragraph reads: *"If children do not have the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines – 'Reference guide to consent for examination or treatment' (2001) (available from www.dh.gov.uk).* Could the following text be added to reflect that similar guidance has been issued in Wales:	Thank you for your comment, we have added the text that you suggested

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							"In Wales, healthcare professionals should follow the guidance issued by the Welsh Assembly Government in 2008 – 'Reference Guide for Consent to Examination and Treatment' (available from www.wales.nhs.uk/consent)"	