

# Surveillance proposal consultation document

2018 surveillance of <u>diarrhoea and vomiting caused by</u>
gastroenteritis in under 5s: <u>diagnosis and management</u> (NICE
guideline CG84)

# Proposed surveillance decision

We propose to not update the NICE guideline on diarrhoea and vomiting caused by gastroenteritis in under 5s: diagnosis and management.

During surveillance editorial or factual corrections were identified, which will be addressed through editorial amendments.

## Reasons for the proposal

Evidence was found for antidiarrhoeal medication (racecadotril) in acute gastroenteritis however it was inconclusive in terms of benefits as a treatment. We found 1 ongoing trial relating to racecadotril which will be monitored and results considered when available. Evidence was also found for the use of anti-emetic medication (ondansetron) however this is not currently licensed in the UK for children with gastroenteritis and the evidence found suggested an increased risk of diarrhoea. Three ongoing trials on ondansetron in the guideline population have been identified and will be assessed for any impact on the guideline upon publication. One trial relating to the use of diluted fruit juice was highlighted however as it only covered one type and brand of fruit juice therefore this evidence was considered to be insufficient to have an impact on the guideline at this time.

#### Overview of 2018 surveillance methods

NICE's surveillance team checked whether recommendations in <u>Diarrhoea and vomiting</u> <u>caused by gastroenteritis in under 5s: diagnosis and management</u> (NICE guideline CG84) remain up to date.

The surveillance process for NICE guideline CG84 followed the static list review process. It consisted of:

- A search for new or updated Cochrane reviews
- Consideration of evidence from previous surveillance
- A search for ongoing research

- Examining related NICE guidance and quality standards and NIHR signals
- Feedback from topic experts via a questionnaire
- Consultation on the decision with stakeholders (this document).

After consultation on the decision we will consider the comments received and make any necessary changes to the decision. We will then publish the final surveillance report containing the decision, the summary of the evidence used to reach the decision, and responses to comments received in consultation.

For further details about the process and the possible update decisions that are available, see <u>ensuring that published guidelines are current and accurate</u> in developing NICE guidelines: the manual.

### Evidence considered in surveillance

#### Cochrane reviews

We searched for new Cochrane reviews related to the whole guideline. We found 2 relevant Cochrane reviews published between January 2008 and June 2018. However, none were considered to impact NICE guideline CG84 recommendations.

One Cochrane review (MacGillivray et al. 2013) found that non-lactose containing milk reduced the duration of diarrhoea in children with gastroenteritis by approximately 18 hours and reduced treatment failure with oral rehydration solution by around half compared to lactose containing milk. The full guideline reviewed evidence on reintroduction of full strength cow's milk and found no evidence of harm. The full guideline analysed 3 RCTs regarding the use of lactose-free milk products, and found no statistically significant benefit compared to lactose containing milk following dehydration. As there is conflicting evidence for the role of lactose-free milk, this should be considered again at the next review.

One Cochrane review (Lazzerini et al. 2016) assessed oral zinc for treating diarrhoea in children with both acute and persistent diarrhoea. The review found that in children aged over 6 months the duration of diarrhoea was reduced by approximately half a day with zinc supplementation, and the risk of vomiting was increased. A reduction in diarrhoea by 1 day was seen in those with malnutrition. The authors also state that the World Health Organization currently recommend zinc for the treatment of diarrhoea. However, the majority of trials included in the review were conducted in Asian countries with a high risk of zinc deficiency, so the results may not be applicable in the UK setting. One topic expert stated that although zinc use for diarrhoea treatment is popular it represents an additional cost burden to the NHS that is not currently justified in the UK. CG84 does not currently recommend zinc or other supplements for the treatment of diarrhoea and further evidence would be needed in this area before it would be included, particularly regarding the risk of increased vomiting.

#### Previous surveillance

Three-year surveillance was carried out in 2012. New evidence was found in the areas of antidiarrhoeal agents and probiotics however this was considered insufficient to update at the time. The guideline was added to the static list in 2014

#### Ongoing research

We checked for relevant ongoing research; of the ongoing studies identified, 5 studies were assessed as having the potential to change recommendations; therefore we plan to check the publication status regularly, and evaluate the impact of the results on current recommendations as quickly as possible. These studies are:

- Clinical study to evaluate the efficacy of probiotic product Bio-Kult Infantis as concomitant treatment of acute infectious diarrhoea in children
- Double blind clinical trial, controlled, randomized, phase IV, comparative of the effect of oral serum and racecadotril versus oral serum and placebo in children with acute diarrhoea.
- Oral ondansetron vs domperidone for symptomatic treatment of vomiting during acute gastroenteritis in children: multicentre randomized controlled trial
- The effect of oral ondansetron on referral rate in children aged 6 months to 6 years attending in primary care out of hours service with acute gastro-enteritis and vomiting.
- The added effect of oral ondansetron to care-as-usual on persisting vomiting in children aged 6 months to 6 years, presenting at primary care out of hours service with acute gastro-enteritis and concomitant vomiting.

### Related NICE guidance

Since the publication of NICE guideline CG84 in April 2009 there have been related NICE guidelines published which should be considered for cross-referencing to, these are detailed in the editorial amendments section

# Intelligence gathered during surveillance

### Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline. For this surveillance review, topic experts completed a questionnaire about developments in evidence, policy and services related to NICE guideline CG84.

Seven questionnaires were received from 13 sent to topic experts, 4 thought that the guideline should be updated and 3 did not. Topic experts either:

- participated in the guideline committee who developed the guideline
- were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty.

A systematic review (<u>Falszewska et al. 2018</u>) highlighted by a topic expert, assessed the diagnostic accuracy of 3 clinical dehydration assessment scales and found that only the clinical dehydration scale may help in diagnosis. CG84 uses a list of signs and symptoms for clinical assessment rather than a scale. Further evidence for this method of assessment would be required before an impact on the current recommendations would be anticipated.

One topic expert states that any reference to E.coli 0157 needs replacing with verotoxin producing E.coli (VTEC). A question has been included for the consultation as to whether this change should be made.

Two topic experts suggest that the use of ondansetron should be considered as no antiemetics are currently recommended in CG84. A health economic analysis for ondansetron was undertaken when the guideline was written. The guideline development group concluded that more evidence was required for ondansetron, particularly relating to diarrhoeal outcomes before its use in routine practice could be justified. As the new evidence found in this surveillance review continues to find an association between ondansetron and increased diarrhoea, further evidence in this area is required before an impact on the guideline can be determined.

One topic expert highlighted a systematic review (Gordon et al. 2016) regarding the effect of racecadotril on acute diarrhoea. No significant difference was seen when racecadotril was compared to loperamide or a placebo, however a significantly shorter duration of symptoms was seen when racecadotril was compared to a placebo. One topic expert highlighted a set of European guidelines (Guarino et al. 2014) that are broadly supportive of the recommendations made in CG84, however the European guidelines also include the use of racecadotril. One topic expert stated that although medication use for diarrhoea treatment is popular it represents an additional cost burden to the NHS that is not currently justified in the UK.

#### Other sources of information

We considered all other correspondence received since the guideline was published. We considered one issue placed on the topic issue log regarding the mention of fruit juice in the guideline recommendations. An RCT (<u>Freedman et al. 2016</u>) was identified which found that half strength apple juice was non-inferior to electrolyte maintenance solution in children aged 6 to 60 months with mild gastroenteritis and minimal dehydration. As this RCT only looked at one brand/type of fruit juice, further evidence would be required before the recommendations on fruit juice would be amended.

#### Views of stakeholders

Stakeholders are consulted on all surveillance decisions except if the whole guideline will be updated and replaced. Because this surveillance decision was to not update the guideline, we are consulting on the decision.

See <u>ensuring that published guidelines are current and accurate</u> in developing NICE guidelines: the manual for more details on our consultation processes.

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## **Equalities**

No equalities issues were identified during the surveillance process.

#### **Editorial amendments**

During surveillance of the guideline we identified the following points in the guideline that should be amended.

- The section on patient-centred care will be replaced by the 'informed decisions' text box which states: People have the right to be involved in discussions and make informed decisions about their care, as described in your care.
  - <u>Making decisions using NICE guidelines</u> explains how we use words to show the strength (or certainty) of our recommendations, and has information about professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.
- Recommendation 1.8.2.1 Footnote 6 the link to Health Protection Agency (2006) Guidance on Infection Control In Schools and other Child Care Settings will be removed and replaced with Public Health England Health protection in schools and other childcare facilities, as this guidance has been updated and the name has changed.

### Overall decision

After considering all evidence and other intelligence and the impact on current recommendations, we decided that no update is necessary.

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