National Institute for Health and Care Excellence

8-year surveillance (2016) – Irritable bowel syndrome (2008) NICE guideline CG61

Appendix B: stakeholder consultation comments table

Consultation dates: 11 to 24 November 2016

Do you agree with the proposal not to update the guideline?

Stakeholder	Overall response	Comments	NICE response
The a2 Milk Company Limited	No	No comments	Thank you for your comment.
British Dietetic Association	Yes	1.2.1.4 The bullet point regarding decreasing fibre and resistant starches needs to be clearer that it relates to IBS-D not IBS-C. 1.2.1.5 In IBS-C the advice might be to increase fibre along with fluid, not decrease. Need to distinguish between the 2 again.	Thank you for your comment. Recommendation 1.2.1.4 is a summary of general dietary advice. Recommendation 1.2.1.5, which addresses fibre in more detail was developed after a full review of the evidence on the effects of fibre in IBS: **Recommendation 1.2.1.5 –** Healthcare professionals should review the fibre intake of people with IBS, adjusting (usually reducing) it while monitoring the effect on symptoms. People with IBS should be discouraged from eating insoluble fibre (for example, bran). If an increase in dietary fibre is advised, it should be soluble fibre such as ispaghula powder or foods high in soluble fibre (for example, oats). This recommendation was developed based on a review of 20 studies (randomised controlled trials including crossover studies that had a washout period of at least 4 weeks). Most studies included a combination of IBS types. Four specified constipation-predominant IBS. In most analyses of the data (particularly for fibre compared with placebo) it was not possible to stratify the results into IBS subtypes. When developing the recommendations, the committee 'suggested that GPs should investigate the person's usual fibre intake with a view

			to modifying fibre levels to suit the symptom profile and they should monitor the person's response to dietary modification.' In surveillance, we did not identify sufficient new evidence to indicate that diarrhoea-predominant IBS may respond specifically to a reduction in fibre or that constipation-predominant IBS may respond specifically to an increase in fibre. Therefore, there is no reason to update this section of the guideline at this time. The wording of recommendation 1.2.1.5 acknowledges that fibre may be modified in either direction, depending on the person's symptoms, and that the effects of fibre modification should be monitored. This wording reflects the evidence base and also encourages person-centred care.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
The a2 Milk Company Limited	Yes	1. A1 beta-casein, a sub-fraction of casein derived from cows' milk of Bos Taurus origin, has been shown to impact the contractile physiology, mucus secretions and inflammatory status of bowel tissue. This may impact those with Irritable Bowel Syndrome whos symptoms are made worse by ingestion of cows' milk, independent of the lactose content of the milk. Links to supporting references regarding post-dairy discomfort in the absence of lactose intolerance: http://betacasein.org/index.php?p=post-dairy-discomfort Links to References - human clinical trials: http://www.nature.com/ejcn/journal/v68/n9/full/ejcn2014127a.html http://nutritionj.biomedcentral.com/articles/10.1186/s12937-016-0147-z 2. A1 Beta-casein, has been shown to reduce serum glutathione production in those with confirmed milk intolerance, whilst milk free from A1 beta-casein, doubles production. This may have implications for the preventing the development of further	Thank you for your comment. In developing the guideline, the concept of food intolerance was discussed: 'There are no objective tests available to identify food intolerance and few to confirm food allergy. Data from dietary elimination and food challenge studies are contradictory.' Milk intolerance was not specifically addressed by the guideline. Allergy to proteins in milk would usually mean that the diagnosis of IBS would no longer be appropriate for the person. In reviewing the references provided, most were laboratory studies that we would not be able to use to derive recommendations for clinical practice. In surveillance, we select studies for inclusion on the basis of information contained in the abstract. In reviewing the references to clinical trials provided: • Ho et al. (2014) did not provide sufficient information in the abstract about the population assessed. It was not clear whether

		inflammation-induced damage to the intestinal endothelium and prevention of other chronic diseases associated with a reduced glutathione status. Links to references: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5041571/ 3. Acknowledgement of the role of A1 and A2 Beta-casein variants in the management of IBS in the British Dietetic Association IBS Guidance Update. Pages 566-567. Links to references https://www.ncbi.nlm.nih.gov/pubmed/27265510	participants had IBS, or milk intolerance, or were healthy volunteers. • Jiangin et al (2016) included people with 'self-reported lactose intolerance'. Because this study did not recruit a population with IBS, we cannot include this study as a source of evidence in the current surveillance review. • The participants in Deth et al. (2015) were healthy volunteers rather than people with IBS, thus we cannot include this study as a source of evidence in the current surveillance review. We recognise the important role of specialty-specific guidelines produced by other organisations. However, we do not include guidelines as a source of evidence in surveillance reviews. Instead, we can check the sources used by other guidelines. When considering the role of A1 and A2 beta-casein in IBS, The British Dietetic Association systematic review and evidence based practice guidelines for the dietary management of irritable bowel syndrome in adults (2016 update) cited the studies by Ho et al. (2014) and Jiangin et al (2016) It concluded: 'further research is warranted to determine whether these findings can be repeated in patients with IBS. Therefore, evidence is insufficient at present to update the guideline to address the role of A1 and A2 beta-casein in IBS. The guideline recommends that a healthcare professional with expertise in dietary management should give advice on single-food avoidance and exclusion diets to people whose IBS symptoms persist while following general lifestyle and dietary advice. Clinicians with expertise in dietary management should be aware that milk is one of several foods that people may have difficulty digesting, and so could propose a milk-exclusion diet if it is suitable for their patient.
British Dietetic Association	No	No comments	Thank you for your comment.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
The a2 Milk Company Limited	No	No comments	Thank you for your comment.
British Dietetic Association	No	No comments	Thank you for your comment.

The Department of Health – I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.

The Royal College of Nursing – This is to inform you that the Royal College of Nursing have no comments to submit to inform on the above surveillance review.