and flow diagram, as well as an additional paper explaining it. Last month the new CONSORT statement, with its revised recommendations, appeared simultaneously in the *Annals of Internal Medicine*,[2] *JAMA*,[3] and *Lancet*.[4] The explanatory document was published in the *Annals of Internal Medicine*.[5]

Some of the changes in CONSORT are minor, designed to improve ease of use. More substantial improvements are the more precise requirements for the diagram depicting the flow of patients in the trial, one of the most important elements in CONSORT. Authors are now asked to specify the number of patients in each of the four phases of a trial: enrolment, intervention allocation, follow up, and analysis.

The explanation and elaboration document is undoubtedly the lengthiest (14 000 words) and most impressive addition to CONSORT.[5] In understandable terms, it explains the items in the checklist and provides the rationale and helpful examples on how to use them. For example, the revised checklist has separated out "recruitment" from participant flow and asks for dates defining periods of recruitment and follow up. The explanatory paper argues that dates are helpful to place the study in a historical context. It also emphasises the need to include length of follow up and cites a study of oncology trials in which nearly 80% reported the start and end dates of accrual of patients but only 24% stated when follow up ended.[5]

The journals publishing the revised statement have waived copyright protection, making CONSORT easily available to all readers and trialists. The checklist, the explanatory document, and more can also be found on the internet (www.consort-statement.org).

JAMA has also published two related studies on the use of CONSORT. One is a study on the use of the 1996 flow diagram, of which the results seem to have been incorporated in the revised CONSORT flow diagram.[6] The second is a before and after evaluation of CONSORT: it examined 211 studies in three journals that adopted CONSORT, with the *New England Journal of Medicine* as a comparator journal, and showed improved reporting after the adoption of CONSORT.[7]

The amount of exposure for this new version of CONSORT is both unique and entirely fitting for the importance of this initiative. CONSORT is a logical next step in a continuing process towards efficiency and transparency in scientific communication, following on from the IMRAD structure (introduction, methods, results, and discussion) of a scientific article and the structured abstract. What makes CONSORT so special is that this is the product of a joint effort of editors, methodologists, and trialists, with a specific focus on the important aspects of internal and external validity of trials. This endeavour has been and will be followed by others, directed at other types of studies, such as QUOROM for meta-analyses of randomised trials[8] and STARD (standards for reporting on diagnostic accuracy), which is still being developed. All try to facilitate the critical appraisal and interpretation of studies through better reporting, relying on current methodological knowledge and evidence about the potential for bias and lack of applicability.

A 22 item checklist and a flow diagram are, however, no panacea for sound science. Depending on the application, we would like to see still more detail in the report of a randomised controlled trial in order to judge its validity and appraise the results. CONSORT deserves widespread dissemination and support from everyone who believes—or knows—that better decision making follows from better evidence, to be found in transparent reports of good quality trials.

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Do probiotics prevent childhood illnesses?

They show promise, but bigger studies are needed

Concerns about antibiotic resistance have lead to an increased interest in alternative approaches for controlling common childhood infections. Since prevention would obviate the need for treatment, the prophylactic use of probiotic bacteria to prevent these illnesses has been proposed, and a study in this week's issue examines the effect of a probiotic milk on diarrhoeal and respiratory infections in children attending day care centres in Finland (p 1327).[1]

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Probiotics are viable bacteria that colonise the intestine and modify the intestinal microflora and their metabolic activities, with a presumed beneficial effect for the host,[2 3] Many of these probiotics are lactic acid bacteria, such as lactobacillus or bifidobacterium, but

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not all probiotics have the same characteristics and, presumably, not the same efficacy.[3] To be effective a probiotic must be able to survive passage through the acidic environment of the stomach and grow in and colonise the intestine, even in the presence of antibiotics.[4–6] To be widely used a probiotic must also be safe.[7] Lactobacilli are generally regarded as non-pathogenic, as they occur naturally in the intestine. The ideal probiotic bacteria would lack virulence factors, such as the ability to degrade intestinal mucus or its glycoproteins or lead to aggregation of platelets—properties that are present in some lactobacillus strains. Probiotics are presumed to promote healing of the intestinal mucosa by reducing gut permeability and by enhancing local intestinal immune responses, particularly the IgA response,[3] as well as by reconstituting the intestinal flora. These are not universal properties among lactobacillus strains, and not all lactobacilli have shown the same beneficial effects.[4–6]

The study by Hatakka in this issue uses *Lactobacillus rhamnosus* strain GG, which has been extensively studied in the treatment of childhood infections. For example, it has been shown to enhance children's recovery from rotaviral diarrhoea and to potentiate their intestinal immune response. Lactobacillus GG has been used in several randomised placebo controlled trials for treating childhood diarrhoea and has been shown to reduce the duration of acute diarrhoea, particularly that caused by rotavirus.[8 9]

There are far fewer data, however, on the efficacy of specific probiotics, including lactobacillus GG, in *preventing* diarrhoeal or respiratory diseases. Studies suggest that the lactobcacillus GG is effective in preventing antibiotic-associated and travellers diarrhoea in adults.[10 11] Other prevention trials include a study that examined the ability of lactobacillus GG to prevent diarrhoea in undernourished Peruvian children (aged 6-24 months)[12] and this week's study.[1]

The Peruvian study showed fewer episodes of diarrhoea in children who received lactobacillus GG (5.21 episodes *v* 6.02 in the placebo group, P = 0.028). This benefit was particularly evident in non-breast fed children aged 18-29 months (4.69 *v* 5.86 episodes, P = 0.005). Hatakka et al's study suggests that, though there was no difference in the numbers of days spent with diarrhoeal or respiratory symptoms, the group treated with lactobacillus seemed to have less severe disease, as measured by reduced numbers of days absent from day care, frequency of complications such as otitis media, and numbers of antibiotic prescriptions.[1] The two studies are difficult to compare as definitions, study design, and outcome variables differed. The Peruvian study included only undernourished children, defined an episode of diarrhoea as one day with four or more loose stools, documented rates of diarrhoea with daily home visits, and directly administered lactobacillus as a gelatin capsule at home six days of the week.[12] The Finnish study included older children (up to 6 years); administered the probiotic in milk containers given three times a day, five days a week, with snacks; and asked parents to record a daily symptom diary for their children. The study in Peru lasted 15 months, that in Finland 7 months (in the winter, when the rates of respiratory illnesses might be highest). Both groups looked for evidence of colonisation with stool cultures (more children in the placebo group in Finland (4% at the beginning and 15% at the end of the study) were colonised with lactobacillus GG). Importantly, there were no adverse events in either study related to the use of the probiotic.

In short, both studies offer positive results, but not overwhelmingly so. Is this related to the study design, the populations studied, or the limits of the probiotic? The results of both studies are intriguing enough to encourage additional larger, carefully controlled studies, which should incorporate lessons learnt from these studies. Future studies should probably be done in younger children and those at highest risk of diarrhoeal or respiratory disease, with study personnel recording symptoms.

The observation made in the Peruvian study that the probiotic works best in children who are not breast fed, makes intuitive sense as it mirrors how we expect probiotics to work—that is, by maintaining normal gut flora and preserving intestinal mucosal integrity.[12] The Finnish study suggests that probiotics may be useful in preventing respiratory infections, a mucosal site not in direct contact with the site of colonisation by the probiotic. This finding requires a hypothesis to explain these systemic effects. Probiotics may somehow stimulate immune factors, such as secretory IgA, at all mucosal surfaces, but data to support this supposition are needed.

We do not yet have a final answer on whether probiotics (or a particular probiotic) are sufficiently effective in preventing common childhood diseases that they can be routinely recommended. But the accumulating data suggest that these organisms may help prevent both respiratory and diarrhoeal diseases in children at increased risk of such infections, such as those in day care facilities or living in developing countries.

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