Review of scientific published literature on infant feeding and
development of atopic and autoimmune disease:

Review C – Maternal and infant diet

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Introduction

This is one of 3 systematic reviews being undertaken as part of a review of the scientific literature on infant feeding and development of atopic and autoimmune diseases commissioned by the UK Food Standards Agency. Atopic conditions such as asthma, eczema, rhinoconjunctivitis and food allergy appear to have increased in prevalence in recent decades in many countries, and are now the leading causes of chronic illness during childhood in the UK. The apparently rapid changes in disease prevalence, combined with data from migration studies, suggest that early life environmental factors may be important modulators of atopic disease risk. Similar findings apply to the autoimmune diseases type I diabetes mellitus and Crohn’s disease, which also appear to have increased in prevalence in some countries. Significant attention has focussed on dietary exposures in relation to these immune-mediated atopic and autoimmune diseases for 2 reasons – first the temporal association between rises in atopic/autoimmune conditions and changing dietary exposures in the relevant populations; second the gut associated lymphoid tissue is our largest collection of immune tissue, and our most mature immune organ at the time of birth. Hence early enteral exposures are likely to be especially potent modulators of immune development and risk of immune-mediated disease. Although there are a large number of observational studies, some intervention trials and several systematic reviews in this area, they tend to focus on one specific area of diet and a limited number of immune outcomes. The purpose of these 3 systematic reviews is to comprehensively assess the existing literature regarding the relationship between maternal and infant dietary exposures and a child’s risk of any of the common atopic and autoimmune disease, in order to inform UK Department of Health feeding guidance for mothers and their infants. These protocols have been developed by the authors, but have been modified after independent expert peer review and reviews and
meetings with members of the UK Food Standards Agency and the UK Scientific Advisory Committee on Nutrition. The specific outcomes of interest for these reviews, chosen due to their high prevalence in the UK population, and described in more detail below, are: Food allergy, Eczema, Asthma, Allergic rhinitis, Allergic conjunctivitis, Allergic sensitisation, Type 1 diabetes mellitus, Coeliac disease, Inflammatory bowel disease, Autoimmune thyroid disease, Juvenile rheumatoid arthritis, Vitiligo, Psoriasis.

**Key words**

Infant; diet; maternal; pregnancy; lactation; supplement; nutrient; allergy; atopy; asthma; eczema; food allergy; sensitisation; rhinitis; conjunctivitis; autoimmune; diabetes; crohn; inflammatory bowel disease; coeliac; thyroiditis; juvenile arthritis; vitiligo; psoriasis; systematic review
Review question(s)

C1. Does exposure to specific dietary patterns, food groups or nutrients during the first year of life, influence children’s future risk of atopic disease, allergic sensitisation or autoimmune disease.

C2. Does maternal exposure to specific dietary patterns, food groups or nutrients during pregnancy or lactation, influence children’s future risk of atopic disease, allergic sensitisation or autoimmune disease.

Inclusion criteria:

Types of studies to be included

We will include randomised controlled trials (RCT), quasi RCT, and where necessary prospective cohort or longitudinal studies, retrospective cohort studies, nested case-control studies or other case control studies. We will take a hierarchical approach to study design, such that where data are absent or limited from certain types of studies, we will include lower level study designs. So where high quality intervention studies are lacking, we will include prospective cohort studies; where high quality prospective cohort studies are lacking we will include retrospective cohort studies; where high quality retrospective cohort studies are lacking we will include data from nested case-control studies, and where these are lacking we will use other types of case control studies. We will not include non-comparative studies, or non-human studies.

Participants/population

Infants between the age of 0 and the end of the 12th postpartum month (question C1) and their mothers during pregnancy and lactation up to the end of the 24th month postnatally (question C6).
C2). If infants are characterised as high or standard risk for allergic disease based on family
history, this information will be recorded so that subgroup analysis can be made.

**Context**

Our primary analyses will exclude studies in which participants were defined by a disease
state - eg pregnant women with specific nutritional deficiencies, infants born prematurely
(<31 weeks gestation) or other groups clearly representing <5% of the UK population, since
the results of this review should apply to the general UK population. We will include studies
of specific ethnic groups. Studies where subject eligibility is defined on the basis of a family
history of allergy will be included, since this applies to a majority of infants in the UK.

Studies restricted to populations at specific genetic risk of autoimmune disease (eg by HLA
type) will also be included, since it is difficult to undertake studies of autoimmune disease
prevention in the general population due to low prevalence.

**Interventions/exposures**

*Review question #C1*: Exposure of infants in the first 12 months, to specific dietary patterns,
dietary components (as groups eg vegetables, fruits, nuts; and individually) or nutrients/food
supplements (eg. antioxidants, vitamin D, omega-3 and omega-6 fatty acids, vitamin B3,
probiotics). For probiotics, we will include studies where they are given as supplements, or in
infant formula. Where possible, the exposures will be measured as a continuous variable
rather than categorically. Because of the variety in diet, we will in principle, attempt to
classify foods according to their nutritional properties and similarities. We will classify the
foods following the European Food Consumption Survey Method, recently used by VGL in a
large epidemiological survey of dietary risk factors for allergic diseases across Europe\(^6\). We
will also consider the UK Department of Health proposed classification for fruits and
vegetables ([www.nhs.uk/5aday](http://www.nhs.uk/5aday)) in our interpretation of the data, and the UK Reference

C7
Nutrient Intake. Whenever possible, foods will be classified as indicated in the list below.

This method allows for more ambiguous classifications to be included.

- Hard fruits - apple, pear, peach
- Oily fruits - olive, avocado
- Berries (any)
- Nectarines - nectarine, apricot
- Citrus - orange, kiwi, lemon, mandarin, grapefruit
- Dried fruits - raisin, prune, dates
- Fresh fruit juice
- Tropical fruits - mango, pineapple, banana
- Tinned fruits
- Melon/watermelon
- Other fruits - plum, cherries, grapes, fig, rhubarb
- ‘Any fruits’ (to include studies which only included a general question on fruit intake)
- Other classifications of fruits: ‘flavanoid-rich fruits’ – these will be included as a separate group if the publication has grouped fruits as such without separating individual intake (e.g. apples, grapes, berries)
- Leafy vegetables - lettuce, spinach, chard, fenugreek, herb, wild greens
- Fruity vegetables - artichokes, tomato, cucumber, okra, aubergine, capers
- Root vegetables - carrot, parsnips, turnip, ginger, radish, taro, beetroot
- Cabbage - cauliflower, coleslaw, brussel sprouts, broccoli, cabbage
- Stalk - celery, asparagus
- Allium vegetables - leek, onion, garlic, shallots,
- Pickled vegetable
For studies of overall dietary pattern, such as Mediterranean or organic diet, we will look in detail at the definition and only consider meta-analysis where at least 50% of the definition is shared across studies.

- inclusion criteria - studies where infant dietary exposure is characterised during the first 12 months of life, in such a way that it can be classified for determining the exposure(s) of interest as above; or an intervention study. We will classify the exposures according to how they were measured, i.e. what type of dietary questionnaire or assessment. In general, we will not include studies of blood/plasma/serum/urine levels of circulating nutrients without an assessment of dietary intake, since the purpose of this review is to inform dietary advice for pregnant and lactating mothers and their infants. The single exception is vitamin D, since the primary source of vitamin D is sunlight exposure, so that estimation of vitamin D status based on dietary assessment alone is unreliable. We will include studies of vitamin D status in blood, measured as 25-hydroxy vitamin D in nmol/L or ng/ml, where 2.5nmol/L = 1 ng/ml.
Review question #C2: Exposure of mothers during pregnancy and/or lactation, to specific dietary patterns, dietary components (as groups eg vegetables, fruits, nuts; and individually) or nutrients/food supplements (eg. antioxidants, vitamin D, omega-3 and omega-6 fatty acids, vitamin B3, probiotics). Where possible, the exposures will be measured as a continuous variable rather than categorically. We will follow the same classification proposed above to classify the dietary exposure during pregnancy and lactation up to 24 months.

Inclusion criteria - studies where maternal dietary exposure is characterised during pregnancy and/or lactation, in such a way that it can be classified for determining the exposure(s) of interest as above; or an intervention study. We will classify the exposures according to how they were measured, i.e. what type of dietary questionnaire or assessment.

In general, we will not include studies of blood/plasma/serum/urine levels of circulating nutrients without an assessment of dietary intake, since the purpose of this review is to inform dietary advice for pregnant and lactating mothers and their infants. The single exception is vitamin D, since the primary source of vitamin D is sunlight exposure, so that estimation of vitamin D status based on dietary assessment can be unreliable. We will include studies of vitamin D status in blood, measured as 25-hydroxy vitamin D in nmol/L or ng/ml, where 2.5nmol/L = 1 ng/ml.

Comparator(s)/control

All comparators will be included, including studies which compare different doses or forms of an exposure eg different doses/levels of vitamin D, or different probiotic interventions. In the case of studies that only document food intake as reported frequency, we will aim to categorise groups for binary comparisons e.g. ‘at least weekly intake’ vs. ‘never’; ‘at least daily intake’ vs. ‘weekly or less frequently’.

C10
Search strategy

We will search for eligible studies in MEDLINE, EMBASE, Cochrane, Web of Science and LILACS with no specified start date. We will include peer reviewed publications, and also include proceedings and abstracts presented in scientific conferences in the last 3 years, if they have not subsequently been published as a peer reviewed publication. We will search for studies in progress, or completed but unpublished studies using http://apps.who.int/trialsearch/, and will contact international experts in the field of nutritional exposures in relation to allergy and autoimmune disorders, including where appropriate pharmaceutical or food industry representatives, to identify important unpublished work. We will review the bibliography of eligible studies for possible additional publications, and will include all eligible publications, regardless of the language. Where necessary, and where feasible within the limited timescale of this project, the authors of eligible or potentially eligible studies will be contacted by the research team to obtain any data that might not be available in the abstract/publication. Potentially eligible studies are studies which have clearly recorded both an exposure and an outcome of interest, but have not reported an analysis of the relationship between these.

The MEDLINE search strategy is at the end of this document, as an Appendix.

We will separately search for existing systematic reviews which cover any of the same exposure(s)/outcome(s) as these, and were published since 1\textsuperscript{st} January 2011. We will quality assess such existing systematic reviews using the revised AMSTAR criteria \textsuperscript{5}. We will not duplicate any existing systematic reviews with revised AMSTAR score $\geq 32$, but will instead summarise the findings of such reviews and include the summary in our final report. As far as possible, these data will be presented using Cochrane Summary of Findings tables, generated using GradePro. For these pre-existing, high quality systematic reviews, we will also
summarise any eligible publications identified in the searches, which were published subsequent to the relevant systematic review, in our final report.

**Study Outcomes [identical to Review A]**

We have selected atopic and autoimmune outcomes on the basis of their population prevalence in children and young adults in the UK or other affluent nations. We have included diseases with a prevalence of at least 1 in 1000, in children/adolescents or young adults (aged <40 years), but have not included rarer diseases \(^6\). We have not included pernicious anaemia or adult-onset rheumatoid arthritis despite a high prevalence in middle aged or elderly people, because their prevalence in young people is lower than 1 in 1000, and prospective studies of infant feeding in relation to diseases of older adults are unlikely to have been undertaken. For all outcome measures, age at assessment will be grouped as 1-4 years, 5-14 years, 15-24 years, 25-44 years, 45-64 years and \(\geq 65\) years. Where studies report the same outcome at different timepoints within one of these frames, we will use the timepoint which has the most complete dataset ie lowest percentage of missing data as the primary assessment point. For each outcome measure in this review, there is more than one possible method of assessment. We have therefore included our preferred method of assessment for each outcome, which is the *a priori* ‘primary outcome measure’, assessed at the optimal age as defined above. We will however document all relevant outcomes measured using different assessment tools, in each included study. This will allow for meta-analysis of different studies where they have used similar outcome measures.

**Atopic outcomes:**

1. *Asthma* - defined as either ‘asthma’, ‘infantile wheeze’ or similar, using parent/self report, doctor diagnosis, a validated questionnaire, scoring system or objective measure such as...
bronchial hyper-reactivity, forced vital capacity, peak expiratory flow rate or reversible
airways obstruction using forced expiratory volume in 1 second.

Primary assessment: parent or self-report using a validated questionnaire such as the
International Study of Asthma and Allergies in Childhood questionnaire 7, at 5-14 years.
Where multiple measures are used, cumulative incidence of wheezing will be used
preferentially.

2. Eczema – defined using parent/self report, doctor diagnosis, a validated questionnaire,
scoring system or objective measure.
Primary assessment: parent or self-report using a validated questionnaire such as the UK
adaptation of Hanifin and Rajka criteria 8 at 1-4 years. Where multiple measures are used,
cumulative incidence of eczema will be analysed preferentially, but point prevalence will also
be reported.

3. Allergic Rhinitis – defined using parent/self report, doctor diagnosis, a validated
questionnaire, scoring system or objective measure.
Primary assessment: parent or self-report using a validated questionnaire such as the
International Study of Asthma and Allergies in Childhood questionnaire 7, at 5-14 years.
Where multiple measures are used, cumulative incidence will be analysed preferentially.

4. Allergic Conjunctivitis - defined using parent/self report, doctor diagnosis, a validated
questionnaire, scoring system or objective measure.
Primary assessment: parent or self-report using a validated questionnaire, at 5-14 years.
Where multiple measures are used, cumulative incidence will be analysed preferentially.

5. Food allergy - defined by double blind placebo controlled food challenge, by open food
challenge, by medical diagnosis or by self/parent report.
Primary assessment: challenge-proven food allergy, assessed at 1-4 years. Where multiple measures are used, cumulative incidence will be analysed preferentially.

6. Allergic sensitisation – to an inhalant, an ingestant, or both – defined as positive skin prick test and/or specific IgE test to the relevant allergen using recognised methodologies and scoring criteria.

Primary assessment: sensitisation to at least one inhalant or ingestant, assessed at 5-14 years or older. Where multiple measures are used, point prevalence will be analysed preferentially.

7. Total IgE – measured using a recognised technology such as ImmunoCAP (ThermoFisher, Massachusetts).

Autoimmune outcomes:

1. Type 1 diabetes mellitus – defined as a medical diagnosis, or a surrogate marker such as autoantibodies against insulin, GAD65, IA-2 or the ZnT8 transporter in the first 3 years of life.

Primary assessment: medical diagnosis of type 1 diabetes mellitus using the 1999 WHO recommendations for diagnosis and classification of diabetes mellitus or similar. Where multiple measures are used, cumulative incidence will be analysed preferentially.

2. Coeliac disease – defined by characteristic histological features (intraepithelial lymphocytes, crypt hyperplasia and villous atrophy) with improvement in symptoms and histology after institution of a gluten free diet, a medical diagnosis, or a surrogate marker such as IgA tissue transglutaminase or IgA endomysial antibodies.

Primary assessment: medical diagnosis of coeliac disease using a histological diagnosis. Where multiple measures are used, cumulative incidence will be analysed preferentially.

3. Inflammatory bowel disease (Crohn's disease or Ulcerative colitis) – defined as a medical diagnosis.
Primary assessment: medical diagnosis using a histological diagnosis. Where multiple measures are used, cumulative incidence will be analysed preferentially.

4. Autoimmune thyroid disease (Graves' disease or Hashimoto's thyroiditis) - defined as a medical diagnosis.

Primary assessment: medical diagnosis using serology and thyroid function testing. Where multiple measures are used, cumulative incidence will be analysed preferentially.

5. Juvenile rheumatoid arthritis – defined as a medical diagnosis.

Primary assessment: medical diagnosis using the 2001 revised International League of Associations for Rheumatology (ILAR) classification criteria. Where different time-points are reported, then the cumulative incidence to the latest reported time-point will be used preferentially. Where multiple measures are used, cumulative incidence will be analysed preferentially.

6. Vitiligo - defined as a medical diagnosis.

Primary assessment: medical diagnosis using the Vitiligo European Task Force 2007 criteria or similar. Where multiple measures are used, cumulative incidence will be analysed preferentially.

7. Psoriasis - defined as a medical diagnosis.

Primary assessment: medical diagnosis. Where multiple measures are used, cumulative incidence will be analysed preferentially.

Study selection and Data Extraction

Study selection

Two members of the research team (RB and VGL) will independently review titles and abstracts of identified studies. The full text of the paper will also be independently assessed
by RB and VGL, and will be assessed for eligibility against the inclusion criteria. Any
discrepancies will be resolved through discussions with the research team and, as appropriate,
the study sponsor (UK Food Standards Agency, FSA). Electronic records will be kept
regarding included and excluded studies for audit purposes, specifying reasons for any
exclusion, and these details will be included in the final report. Full text articles will be
reviewed in duplicate (by two research team members - RB and VGL), and studies for
inclusion will be selected – any discrepancies will be resolved through discussions with the
research team and the FSA, as appropriate. The reasons for the exclusion of any relevant
studies will be recorded, however ineligible studies will not be analysed further.

Data extraction

A pilot of the data extraction form will be undertaken using a minimum of 5 papers, after
which the extraction form will be amended/updated as necessary. The data extraction form
will be used to extract the relevant data fields from each included study independently (by
two research team members - RB and VGL), and where appropriate data will be entered into
Stata IC 12 statistical software for meta-analysis.

Risk of bias (quality) assessment

Review level bias

Publication bias will be assessed using funnel plots and Egger's test. Where asymmetry is
evident on the funnel plot, a trim and fill analysis will be used. Possible causes for asymmetry
other than publication bias (eg between study heterogeneity) will also be considered. Where
significant population based cohorts or randomised controlled trials have assessed mode of
infant feeding but not reported relevant atopic or autoimmune outcomes, we will consider
contacting authors for original datasets if atopic or autoimmune outcome assessments appear to have been made.

**Study level bias**

The risk of bias in included RCTs will be assessed using the Cochrane Collaboration Risk of bias tool, which includes sequence generation, allocation concealment, blinding, incomplete outcome data, and selective outcome reporting, and other bias. RCTs will be considered at low risk of bias where the risk of bias is judged to be low for all key domains of the Cochrane Risk of bias tool. The risk of bias in included cohort and case control studies will be assessed using the National Institute for Clinical Excellence methodological checklist for cohort and case-control studies respectively, which includes considerations of subject selection, assessment of exposure and outcome, and measures to assess confounding. Studies will be considered at low risk of bias where most of the criteria in the checklist are addressed, and those that are not addressed or not reported are judged unlikely to change the study findings.

For both RCTs and cohort studies, a level of <20% loss to follow up for atopic/autoimmune outcomes will generally be accepted as representing low risk of bias from incomplete outcome data, if there are no other features to suggest increased risk of bias. For all studies, a summary Table of Study Characteristics will be presented for each relevant exposure and outcome, which will include a summary of each study's risk of bias, in addition to the population characteristics, methods used for assessing exposure and for outcome assessment.

**Strategy for data synthesis**

Where appropriate, meta-analysis will be undertaken. If meta-analysis is deemed inappropriate, individual study results will be summarised and a balanced conclusion made. Separate analyses will be undertaken for each disease outcome, for each group of similar outcome assessment methods for any given disease, and for each intervention/exposure.
Results for randomised or quasi-randomised controlled trials, prospective cohort or longitudinal studies, or where appropriate retrospective cohort studies, nested case-control studies or other case-control studies will be reported separately for each comparison.

Data extraction

Data will be extracted either using raw values, crude estimates of effect (including odds ratios, risk ratios, incidence rate ratios, hazard ratios, mean differences) or as adjusted estimates of effect. Adjusted estimates of effect will be used in preference, where available.

Random effect meta-analyses will be performed to allow for the anticipated heterogeneity between the studies.

Heterogeneity

Heterogeneity will be quantified using $I^2$. We will explore reasons for heterogeneity using subgroup analyses based on study level factors. Where extreme levels of heterogeneity are detected ($I^2 > 75\%$), we will perform sensitivity analyses to assess the effect of excluding outliers, and re-consider whether quantitative data synthesis is appropriate. Where possible, meta-regression and subgroup analysis will be used to explore sources of heterogeneity arising from study characteristics - ordered forest plots and graphical methods will be used to further investigate potential effects of continuous confounders on study effects. Individual patient data analysis will not be undertaken.

Data analysis

Data from individual studies will be pooled using the generic inverse variance method.

Pooled results for binary outcomes will be presented as relative risks with 95% confidence intervals and 2-sided p values, and also expressed as risk differences where possible. Pooled results for continuous outcomes measured using similar scales will be presented as mean differences with 95% confidence intervals and 2-sided p values. However, where different
scales are pooled across studies, we will report results using standardised mean differences. P<0.05 will be considered statistically significant. Relevant results will be presented in Summary of Findings tables similar to those used by the Cochrane Collaboration. All analyses will be performed using STATA IC 12.

**Planned subgroup analyses**

1. **High study quality** - high quality RCT or cohort studies as defined above will be separately analysed.

2. **Increased disease risk** - studies of populations at increased risk for atopic or autoimmune disease will be separately analysed - for example infants with a family history of atopic or autoimmune disease.

3. **Type of data** - unadjusted versus adjusted data. Factors that we expect to be adjusted for within studies: siblings (parity or birth order or family size); gender; age at outcome assessment; disease risk based on family history; maternal or household smoking (asthma outcomes); maternal age; maternal education or socioeconomic status; duration of breastfeeding or exclusive breastfeeding.

4. **Quality of dietary assessment** - use of a validated food frequency/nutritional exposure assessment tool, or in the case of intervention studies, documented compliance with the study intervention for over 80% of intended doses. Studies which meet these criteria will be analysed separately.

5. **Quality of dietary exposure** - studies of nutrient intake/supplementation in the natural form of the nutrient, as opposed to specific supplementation, will be analysed separately. Some studies have shown stronger effects for foods in their natural form than when given as specific nutritional supplements.

**Graphical exploration of heterogeneity**

C19
1. Study year (average year of assessment/birth for study population)

2. Average age of study population at examination/assessment

**Review registration**

This systematic review will be registered with the International Prospective Register of Systematic Reviews (www.crd.york.ac.uk/Prospero), prior to selecting any studies from the search results. This review protocol has been revised following peer review by the UK Food Standards Agency, the UK Scientific Advisory Committee on Nutrition, independent experts Professor Graham Devereux and Dr Carina Venter, and the Lancet.

**Dissemination of findings**

The findings of this review will inform the Food Standards Agency review of infant feeding which will in turn inform the revised Department of Health guidance on infant feeding in the UK. The reviews will be submitted for publication as peer reviewed manuscripts in academic journals, and presented at national and international conferences. A summary of the findings will be sent to relevant stakeholders such as charities, health and educational institutions involved in advising on or supporting infant feeding in the UK.
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