Interventions to Promote Breastfeeding:
Updated Recommendations from the Canadian Task Force
on Preventive Health Care

October 2003
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Updated Recommendations from the Canadian Task Force on Preventive Health Care

Valerie A. Palda, MD, MSc, FRCPC
Assistant Professor, General Internal Medicine
Victoria 4-151, St. Michael’s Hospital
30 Bond Street
Toronto, Ontario M5B 1W8

Jeanne-Marie Guise, MD, MPH
Departments of Obstetrics and Gynecology
& Medical Informatics and Outcomes Research
Oregon Health & Science University
3181 SW Sam Jackson Park Road,
Portland, Oregon 97201-3908

C. Nadine Wathen, MA
Coordinator, Canadian Task Force on Preventive Health Care
117-100 Collip Circle
London, Ontario N6G 4X8
Tel: 519-858-5181 x22084 Fax: 519-858-5112
ctf@ctfphc.org
(address for correspondence)

with

The Canadian Task Force on Preventive Health Care

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Running Head: Palda et al. with CTF – Breastfeeding Update
In 1994, the Canadian Task for Preventive Health Care (CTFPHC) found good evidence to recommend that 1) women be counselled to breastfeed to increase rates and prolong duration of breastfeeding and 2) peripartum interventions promoting breastfeeding (early, frequent mother-infant contact, rooming in, banning provision of free formula samples) should be implemented (both A-level recommendations). Level II (cohort study) evidence of improved outcomes for infants who breastfed was also cited.¹

In 2000, the CTFPHC undertook updating counselling recommendations as a joint review with the United States Preventive Services Task Force (USPSTF), using revised methodology and addressing new evidence, restricted to developed countries, where breastfeeding rates and effectiveness of interventions to promote breastfeeding can differ from conditions in developing countries. This document presents the current status of breastfeeding in Canada, a summary of the collaborative systematic review, and updated CTFPHC recommendations.

**Benefits and Harms of Breastfeeding**

International consensus promotes breastfeeding as the favoured and optimal method of infant nutrition. Trials randomizing infants to breastfeeding versus no-breastfeeding are neither feasible nor ethical given the overwhelming and consistent non-randomized, controlled evidence to date. Recent randomized studies of interventions to promote breastfeeding that also look at clinical outcomes in addition to breastfeeding rates, and large, non-randomized, controlled systematic reviews of both maternal and infant outcomes provide the best quality evidence available of the benefit of breastfeeding.

**Infant outcomes**

A large RCT addressing the length and exclusivity of breastfeeding in the republic of Belarus found that breastfeeding significantly reduces risk of gastrointestinal tract infections (9.1% vs 13.2%; adjusted odds ratio (OR), 0.60; 95% CI, 0.40-0.91) and atopic eczema (3.3% vs 6.3%; adjusted OR, 0.54; 95% confidence interval (CI), 0.31-0.95), but does not reduce respiratory tract infections (intervention group, 39.2%; control group, 39.4%; adjusted OR, 0.87; 95% CI, 0.59-1.28).² A more recent meta-analysis of 7 cohort studies in developed countries indicates a dramatic reduction in respiratory disease requiring hospitalization, with a summary relative risk of 0.28 (95%CI 0.14-0.54) among infants breastfed exclusively for 4 months versus those who were not.³
This is consistent with earlier well-conducted cohort studies showing reduced rates of gastrointestinal, respiratory and overall illness\(^4\) and otitis media.\(^5\)

Exclusive breastfeeding during the first months of life is associated with lower incidence of atopic dermatitis during childhood in children with a family history of atopy (summary OR 0.68, 95% CI, 0.52-0.88);\(^6\) and lower asthma rates during childhood (summary OR 0.70, 95% CI 0.60 to 0.81).\(^7\)

Three systematic reviews have looked at the relationship of breastfeeding and neurologic development, and in general studies have shown consistent benefit from breastfeeding, although studies more likely to account for confounders are less conclusive.\(^8\)\(^-\)\(^10\)

The most widely cited potential harm for infants is the transmission of virus from HIV positive mothers.\(^11\) Postnatal exposure to PCBs through breastfeeding was not clearly related to any effect on neurological development.\(^12\)

\textit{Maternal Outcomes}

Cited maternal benefits of breastfeeding include more rapid post-partum return of uterine tone and weight loss, delay of ovulation, and decreased risk of breast, ovarian, and endometrial cancers. Potential harms include temporary outcomes such as sore nipples and mastitis.

A large re-analysis of 47 studies including 50,302 women with breast cancer and 96,973 women without, determined that the relative risk of breast cancer decreased by 4.3% (95% CI 2.9-5.8, \(p<0.0001\)) for every 12 months of breastfeeding, accounting for a number of confounding factors, including number of births, developed country, age, and menopausal status.\(^13\) These findings were replicated to a less dramatic extent in another, earlier meta-analysis.\(^14\)

Breastfeeding may have a modest effect on ovarian cancer rates, with a review of earlier case-control studies showing a 20% risk reduction (OR=0.8; 95% CI, 0.7-1.0) in women who breastfed compared to those who did not,\(^15\) and more recent case-control studies demonstrating either a significant (adjusted OR 0.31 [95% CI 0.18-0.53])\(^16\) or non-significant protective effect of breastfeeding on ovarian cancer.\(^17\)

\textit{Canadian context}

The prevalence of breastfeeding in Canada has risen in recent years. In the 1980s, approximately two-thirds of women breastfed their babies;\(^18\) in 1996/97, 78% of women aged 15-49 years reported breastfeeding (any duration), which was up from 73% in 1994/95. Breastfeeding is
correlated with age and education. In Canada, those 25 and older are more likely to breastfeed than younger mothers, and women with less than a high school education breastfeed less than women with a university education (~60% vs. ~95%).

Recent Canadian data indicate that 22% of women breastfeed for <3 months, and 32% for at least 3 months. These rates fall far short of the minimum 6-12 months duration recommended by most groups; studies have found that this premature discontinuation is more a result of difficulty with breastfeeding, including lack of information and support, than of women’s choice. In fact, the number of Canadian hospitals that would qualify as “Baby-Friendly” according to the WHO/UNICEF criteria was five out of the 523 hospitals responding in a 1993 survey with, according to UNICEF, only a sole hospital actually having that designation in 2002.

The Effectiveness of Primary Care Based Interventions to Promote Breastfeeding: Summary of the Systematic Evidence Review (SER) and Meta-analysis

In 1999, the USPSTF and CTFPHC jointly initiated a systematic review of the effectiveness of various methods to improve the initiation and/or duration of breastfeeding. This recently completed review is summarized below, and forms the evidence-basis for the CTFPHC’s updated recommendations.

Methods of the SER

RCTs of any counseling, behavioral or environmental interventions to improve breastfeeding initiation, duration, or both were chosen, where possible. If no RCTs were available, a system of “best available evidence” was used, whereby non-randomized concurrently controlled trials were included. Other inclusion criteria were: 1) English-language articles, 2) originated from a clinician's practice but could be implemented by any provider in any setting, 3) study took place in a developed country. Community-based or peer-originated interventions were not included.

MEDLINE (1966-2000), HealthSTAR, the Cochrane Database of Systematic Reviews, the National Health Service Centre for Reviews and Dissemination Databases, and bibliographies of identified trials and review articles were searched. Two reviewers independently reviewed all abstracts and titles for inclusion, and independently abstracted, from each study, assessment of pre-specified quality criteria and data to evidence tables. The quality criteria provide general guidelines for categorizing studies, including systematic reviews, into one of three internal validity categories: “good,” “fair,” and “poor” (Appendix 1). For systematic reviews and meta-analyses, the individual
key studies included in the analysis were also reviewed. Disagreements between the two reviewers were resolved by consensus.

In addition to the qualitative review of studies, three meta-analyses of RCTs were performed to examine the influence of specific components of counseling interventions on rates of 1) initiation; 2) duration of 1 to 3 months; and 3) duration of 4 to 6 months. Included were trials that offered education, interventions using in-person or telephone support, or both. Within these categories, the effect of using written materials as a co-intervention was examined. For details of the meta-analysis, please see original citation.\(^\text{24}\)

**Results of the SER**

Interventions were categorized as: breastfeeding education, support, written education materials, peer support, rooming-in, early maternal-infant contact, use of commercial discharge packets, and advice by primary obstetric or pediatric provider.

*Breastfeeding Education* was defined as individual instruction sessions or group classes that contained structured content including anatomy, physiology, and/or nutritional issues. These often included practical skills training (positioning, latch-on techniques, pump equipment use), and questions and answers to address common fears, problems and myths. Eleven RCTs studied the impact of individual or group education interventions on breastfeeding initiation and/or duration.\(^\text{26-36}\) Lactation specialists or nurses usually conducted these programs during antepartum sessions. Programs that had these educational components increased initiation (risk difference (RD) 0.23; 95% CI, 0.12-0.34) and short-term continuation up to 3 months (RD 0.39; 95% CI, 0.27-0.50). Education did not have a significant impact on long-term duration up to 6 months (RD 0.04; 95% CI, –0.06-0.16) (Table 1).

*Breastfeeding Support.* Eight RCTs\(^\text{27,30-32,37-40}\) studied the impact of in-person or telephone support on breastfeeding initiation and/or duration. Support programs involved telephone and/or in-person clinic, hospital, or home visits by lactation consultants, nurse or peer counselors,\(^\text{31}\) and combined prearranged appointments and unscheduled visits or calls for problems. Intervention content was often personalized to the individual’s needs. Overall, support alone significantly increased short- and long-term breastfeeding duration with RDs of 0.11 (95% CI, 0.03-0.19) and 0.08 (95% CI, 0.02-0.16) respectively, but did not have a significant effect on initiation (RD 0.06; 95% CI, –0.02-0.15) (Table 1).
Four RCTs combined breastfeeding support with educational programs, and used in-person contact through either clinics or home visits. Breastfeeding support enhanced the positive effect of education for initiation (RD 0.28; 95% CI, 0.17-0.40), short-term duration (RD 0.47; 95% CI, 0.34-0.58), and long-term duration (RD 0.13; 95% CI, 0.01-0.26) (Table 1).

**Written Materials.** Eight RCTs examined the effect of written materials, either alone or in combination with other interventions, on breastfeeding initiation and/or duration. No study of written materials alone proved effective at increasing breastfeeding rates. When the effect of written materials combined with education was examined in the meta-analysis, there was minimal additional benefit for initiation (RD 0.25; 95% CI, 0.13-0.37), no benefit for long-term duration (RD 0.01; 95% CI, −0.09-0.12), and suggestion of reversal of a strong positive effect of education for short-term duration (from RD 0.39; 95% CI, 0.27-0.50 to RD 0.10; 95% CI, −0.01-0.21) (Table 1).

**Peer Counseling.** One RCT of peer counseling was reviewed in the original SER. The poor quality RCT by Sciaccà evaluated support from peer counsellors combined with educational programs for low-income women. Thirty-four women were randomized to receive the counseling plus education intervention, and 34 were usual care controls. Women in the intervention group had higher rates of initiation (100% vs. 83%), and short-term duration (81% vs. 31%) than controls. The problems associated with this study included separating the effect of support from that of education and the unknown effect of financial incentives offered to enrolled patients.

Four non-RCTs of peer counsellors were also reviewed in the USPSTF SER. All were judged to be of “poor” quality due to assembly of dissimilar groups, important loss-to-follow-up, and/or lack of adjustment for important confounders. One of the non-randomized trials found significant benefit for breastfeeding initiation and two found significant benefit for short-term breastfeeding. There was a non-significant trend toward improved initiation in the remainder.

The CTFPHC additionally considered a large randomized trial conducted by Dennis et al., published after completion of the USPSTF SER, and therefore not included in their review. In this Canadian study, full-term, primiparous mothers who had elected to breastfeed were randomized to either the peer counseling intervention group (n = 132), or to the usual care control group (n = 126). A trained, volunteer peer counselor provided a mean of 5 post-partum contacts (mean length of contact 16 min ± 12 min) (initiated by either the peer or the mother) over the course of the 12-week intervention period. The primary outcome measure was breastfeeding rates at 4, 8 and 12 weeks. Initiation rates were not considered as an outcome.
The study was given a quality rating of fair due to the non-significant but potentially clinically important differences in both Caesarean-section rates, and timing of the decision to breastfeed between groups at baseline.

More women in the intervention group were breastfeeding at all follow-up times (at 12 weeks: 81% vs. 67%; RR 1.21, 95% CI 1.04-1.41, p = 0.01). Peer support significantly predicted duration at all follow-up times (at 12 weeks: OR 2.5, CI 1.33-4.78, p < 0.001). Furthermore, at 12 weeks, significantly more mothers in the peer support group were exclusively breastfeeding (57% vs 40%, p = 0.01) and significantly more control mothers were bottle-feeding (33% vs 19%, p = 0.01). Over 80% of women in the intervention group were satisfied with the peer intervention.

In summary, this fair quality RCT provides evidence, in the Canadian context, that a simple peer-based intervention can significantly improve breastfeeding rates, and maintain these for up to three months. Generalizability may be an issue, as the sample in this study was generally over age 25, married, well-educated, and fairly affluent across groups.

**Rooming-In.** Only one study\(^5^0\) conducted in a developed country included rooming-in as an intervention. This study contained multiple other interventions, thus the effect of rooming-in alone could not be ascertained.

**Early Maternal Contact** is defined as a period of time, typically 10 to 45 minutes of skin-to-skin contact between mother and infant soon after birth. The meta-analysis of four studies\(^5^1-5^4\) of early maternal contact conducted in developed countries found no significant benefit (OR 1.23; 95% CI, 0.65-2.05).\(^2^4\) The lack of significant benefit in these studies may not reflect a true lack of benefit, but rather in societies in which rooming-in is routinely practiced, it is difficult to show a significant benefit of initial contact within 30 minutes.

**Commercial Discharge Packages.** One good-quality Cochrane review of 9 randomized trials found that giving mothers commercial discharge packs often containing samples and coupons for formula reduced exclusive breastfeeding.\(^5^5\) Women with uncertain goals for breastfeeding were significantly less likely to breastfeed or to breastfeed exclusively if given commercial packs.

**Advice by Primary Obstetric or Pediatric Provider.** No trials were found examining the effect of the primary care physician or obstetrician’s advice on initiation or duration of breastfeeding.
Box: Summary of Key Evidence for Interventions to Promote Breastfeeding

- Individual or group educational sessions lasting 30-90 minutes may increase breastfeeding initiation and short-term duration rates by 20-30% (level I, fair (6 studies) poor (5 studies)).
- In-person or telephone support by itself may increase short- and long-term breastfeeding rates (level I, fair (6), poor (2)).
- In-person or telephone support strengthens the effect of education by an additional 5-10% increase in breastfeeding initiation and short-term duration (level I, fair (4)).
- Written materials are not effective either alone or in combination with other methods (level I, good(1), fair(3), poor(4)).
- Peer counselling increases initiation and duration of breastfeeding (level I, fair (1), poor (1), level II-1, poor (4)).
- There is insufficient evidence regarding rooming-in (no adequate studies), early maternal contact (level I, meta-analysis indicating no effect) and primary provider counseling (no adequate studies).
- Commercial discharge packages appear to decrease the rates of exclusive breastfeeding (level I, good, Cochrane review of 9 RCTs).

CTF Recommendations (see also Recommendation Table)

To develop recommendations, the evidence from the full USPSTF SER, as well as key evidence published after its completion, was presented by one of the authors (VAP) at two meetings of the Canadian Task Force (October 2002 and February 2003), for review and deliberation. At the end of this process, the specific clinical recommendations, outlined below and in the Recommendation Table, were finalized using the criteria defined by the Task Force (Appendix 1).

The CTFPHC concludes that there is:

- good evidence to recommend providing structured antepartum educational programs and postpartum support to promote breastfeeding initiation and duration (A recommendation).
- fair evidence to recommend peer counseling to promote initiation and maintenance of breastfeeding. (B recommendation)
- good evidence to recommend against providing written materials alone to promote breastfeeding. (D recommendation)
- insufficient evidence to make a recommendation regarding advice by primary caregivers to promote breastfeeding. (I Recommendation)
- good evidence to recommend against providing commercial discharge packages to new mothers. (E recommendation)
- no new evidence of compelling quality to overturn the earlier published A level recommendation in favour of rooming in and early maternal contact.
Clinical Implications

Interventions consisting of antepartum, structured breastfeeding education are effective at improving both initiation and continuation of breastfeeding during the first 2 months post-partum, compared to usual care. These interventions were shown effective when provided in the clinical setting by lactation specialists or nurses, and consisting of individual or group instruction about breastfeeding knowledge, practical skills and problem-solving techniques. Post-partum telephone or in-person support by lactation specialists, nurses or peer counsellors enhances the effectiveness of these interventions. In addition, the use of peer counsellors improves breastfeeding rates and duration, and these types of programs may offer a cost-effective alternative to professionally-delivered services, especially in places where professional services are scarce or not available.

The lack of effectiveness of written materials alone even in the absence of specific harm, and the proven decreases in breastfeeding rates in those given commercial discharge packages recommends against this approaches.

Advice from primary care providers has not been sufficiently evaluated, and remains a research gap.

Recommendations of Others

The USPSTF recommends structured education and counseling programs to promote breastfeeding (B recommendation); but found insufficient evidence to recommend for or against primary care provider counseling; peer counseling used alone and initiated from the clinical setting; or written materials, used alone or in combination with other interventions (I recommendations).56

In Canada, the Canadian Paediatrics Society (CPS), in joint statements produced with the Dietitians of Canada, Health Canada57 and the Society of Obstetricians and Gynaecologists of Canada (SOGC)58 recommend exclusive breastfeeding for at least the first 4 months of life, and breastfeeding for up to 2 years and beyond.57 All of these groups further recommend interventions to promote initiation and maintenance of breastfeeding, including: active public health, hospital, community and workplace support of breastfeeding; antenatal and postnatal counselling; encouraging frequent feeds during the early postnatal period; community-based programs supporting breastfeeding families, especially as post-natal hospital stays get shorter; and support for flexible work schedules, part-time nursing and the use of expressed breast milk.57 The SOGC-CPS statement on early discharge and length of stay further recommends ensuring adequate support and mother-infant contact in the case of re-admission of the infant.58
The College of Family Physicians of Canada (CFPC), in the Evidence-Based Well Baby Maintenance Guide\textsuperscript{59} co-endorsed by the CFPC and the CPS, indicate that the best evidence supports recommending breastfeeding for the first year, and exclusive breastfeeding to 4 months. Breastfeeding support interventions including early and frequent mother-infant contact, rooming in, and banning handouts of free infant formula are indicated to increase breastfeeding rates.

A number of international groups provide similar recommendations regarding counseling to support breastfeeding.\textsuperscript{60-64} The World Health Organization recommends exclusive breastfeeding for 6 months,\textsuperscript{60} and provides a number of steps to promote and support breastfeeding.\textsuperscript{21} The American Academy of Pediatrics provides a number of ways that pediatricians can be advocates for breastfeeding.\textsuperscript{63}

**Acknowledgements:**

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References


### Table 1. Results of Meta-analysis of Different Strategies to Promote Breastfeeding

<table>
<thead>
<tr>
<th></th>
<th>Education</th>
<th>Support</th>
<th>Education + Support</th>
<th>Education + Written Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initiation</strong></td>
<td>23% (12 to 34)</td>
<td>6% (-2 to 15)</td>
<td>28% (17 to 40)</td>
<td>25% (13 to 37)</td>
</tr>
<tr>
<td><strong>Short-term</strong></td>
<td>39% (27 to 50)</td>
<td>11% (3 to 19)</td>
<td>47% (34 to 58)</td>
<td>10% (-1 to 21)</td>
</tr>
<tr>
<td><strong>Long-term</strong></td>
<td>4% (-6 to 16)</td>
<td>8% (2 to 16)</td>
<td>13% (1 to 26)</td>
<td>1% (-9 to 12)</td>
</tr>
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</table>

*2 to 4 months; ** > 4 months
### Recommendation Table: Interventions to Promote Breastfeeding

<table>
<thead>
<tr>
<th>Manoeuvre</th>
<th>Effectiveness</th>
<th>Levels of evidence*</th>
<th>Recommendation*</th>
</tr>
</thead>
</table>
| Education programs and postpartum support to promote breastfeeding.** | Structured antepartum breastfeeding education improves both initiation and continuation of short term breastfeeding rates post-partum, compared to usual care.** In-person or telephone support strengthens the effect of education by an additional 5-10% increase in breastfeeding initiation and short-term duration. In-person or telephone support by itself may increase both short- and long-term breastfeeding rates. | Education:  
Level I – Fair\textsuperscript{26-30,32}  
Level I – Poor\textsuperscript{31,33-36}  
Education + Support:  
Level I – Fair\textsuperscript{27,30,32,37-39}  
Level I – Poor\textsuperscript{31,40} | There is good evidence to recommend providing structured antepartum educational programs and postpartum support\textsuperscript{1} to promote breastfeeding initiation and duration. \textbf{A recommendation} |
| Peer counseling to promote breastfeeding. | Significant effect from peer counsellors on breastfeeding rates and duration. | Level I – Fair\textsuperscript{49}  
Level I – Poor\textsuperscript{31}  
Level II-I – Poor\textsuperscript{45-48} | There is fair evidence to recommend peer counselling to promote initiation and maintenance of breastfeeding. \textbf{B recommendation} |
| Provision of written materials to new mothers to promote breastfeeding. | There is no benefit when written materials are used alone. | Level I – Good\textsuperscript{41}  
Level I – Fair\textsuperscript{28,32,38}  
Level I – Poor\textsuperscript{34,42-44} | There is good evidence to recommend against providing written materials alone to promote breastfeeding. \textbf{D recommendation} |
| Primary caregiver advice to expectant or new mothers to promote breastfeeding. | Unknown. | No studies found. | There is insufficient evidence to make a recommendation regarding advice by primary caregivers to promote breastfeeding. \textbf{I recommendation} |
| Provision of commercial discharge packages to new mothers. | Women receiving commercial discharge packages had decreased breastfeeding rates compared to patients not receiving packages. | Level I (Systematic review) – Good\textsuperscript{55} | There is good evidence to recommend against providing commercial discharge packages to new mothers. \textbf{E recommendation} |
| Rooming-in and early maternal contact to promote breastfeeding. | The sole new study of rooming-in included multiple interventions and does not allow drawing conclusions. Insufficient new data regarding early maternal contact. | Level I – Fair/Poor\textsuperscript{50}  
Level I (individual studies and meta-analysis) – Fair/Poor\textsuperscript{51-54} | There is no new evidence of compelling quality to overturn the earlier published \textbf{A recommendations} regarding rooming in or maternal contact to promote breastfeeding. |

*See Appendix 1 for definitions of the levels of evidence and grades of recommendations.

**In the studies reviewed, these interventions were usually provided in the clinical setting by lactation specialists or nurses, and consisted of individual or group instruction about breastfeeding knowledge, practical skills and problem-solving techniques..
### Appendix 1: Methodology of the Canadian Task Force on Preventive Health Care

#### Critical appraisal

The Task Force reviewed 1) the initial analytic framework and key questions for the proposed review; 2) the subsequent draft(s) of the complete manuscript providing critical appraisal of the evidence prepared by the lead author(s), including identification and critical appraisal of key studies, and ratings of the quality of this evidence using the task force's established methodological hierarchy (sidebar); and 3) a summary of the evidence and proposed recommendations.

#### Consensus development

Evidence for this topic was presented by the lead author(s) and deliberated upon during task force meetings in October 2002 and February 2003. Expert panelists addressed critical issues, clarified ambiguous concepts and analyzed the synthesis of the evidence. At the end of this process, the specific clinical recommendations proposed by the lead author were discussed, as were issues related to clarification of the recommendations for clinical application and any gaps in evidence. The results of this process are reflected in the description of the decision criteria presented with the specific recommendations. The group and lead author(s) arrived at final decisions on recommendations unanimously.

Subsequent to the meetings, the lead author revised the manuscript accordingly. After final revision, the manuscript was sent by the Task Force to 2 experts in the field (identified by Task Force members at the meeting). Feedback from these experts was incorporated into a subsequent draft of the manuscript.

Procedures to achieve adequate documentation, consistency, comprehensiveness, objectivity and adherence to the task force methodology were maintained at all stages during review development, the consensus process and beyond to ensure uniformity and impartiality throughout.

#### Levels of evidence

<table>
<thead>
<tr>
<th>Research design rating:</th>
<th>Evidence from randomized controlled trial(s)</th>
</tr>
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<tbody>
<tr>
<td>II-1</td>
<td>Evidence from controlled trial(s) without randomization</td>
</tr>
<tr>
<td>II-2</td>
<td>Evidence from cohort or case–control analytic studies, preferably from more than one centre or research group</td>
</tr>
<tr>
<td>II-3</td>
<td>Evidence from comparisons between times or places with or without the intervention; dramatic results from uncontrolled studies could be included here</td>
</tr>
<tr>
<td>III</td>
<td>Opinions of respected authorities, based on clinical experience; descriptive studies or reports of expert committees</td>
</tr>
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#### B. Quality (internal validity) rating (see Harris et al., 2001)²³:

- **Good**: A study that meets all design-specific criteria* well.
- **Fair**: A study that does not meet (or it is not clear that it meets) at least one design-specific criterion* but has no known “fatal flaw”.
- **Poor**: A study that has at least one design-specific* “fatal flaw”, or an accumulation of lesser flaws to the extent that the results of the study are not deemed able to inform recommendations.

*General design specific criteria are outlined in Harris et al., 2001. Inclusion/exclusion criteria are detailed in the Methods section.

#### Recommendations Grades for Specific Clinical Preventive Actions

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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<tbody>
<tr>
<td>A</td>
<td>The CTF concludes that there is <strong>good</strong> evidence to recommend the clinical preventive action.</td>
</tr>
<tr>
<td>B</td>
<td>The CTF concludes that there is <strong>fair</strong> evidence to recommend the clinical preventive action.</td>
</tr>
<tr>
<td>C</td>
<td>The CTF concludes that the existing evidence is <strong>conflicting</strong> and does not allow making a recommendation for or against use of the clinical preventive action, however other factors may influence decision-making.</td>
</tr>
<tr>
<td>D</td>
<td>The CTF concludes that there is <strong>fair</strong> evidence to recommend against the clinical preventive action.</td>
</tr>
<tr>
<td>E</td>
<td>The CTF concludes that there is <strong>good</strong> evidence to recommend against the clinical preventive action.</td>
</tr>
<tr>
<td>I</td>
<td>The CTF concludes that there is <strong>insufficient</strong> evidence (in quantity and/or quality) to make a recommendation, however other factors may influence decision-making.</td>
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The CTF recognizes that in many cases patient specific factors need to be considered and discussed, such as the value the patient places on the clinical preventive action; its possible positive and negative outcomes; and the context and/or personal circumstances of the patient (medical and other). In certain circumstances where the evidence is complex, conflicting or insufficient, a more detailed discussion may be required.