DynaMed Plus™ Evidence-based Methodology
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Step 1: Identifying the Evidence

Systematic Literature Surveillance
To ensure that DynaMed Plus (and DynaMed) provides the best available evidence, an extensive set of current literature is monitored daily. Systematic Literature Surveillance is conducted using many journals, journal review services, systematic review collections, guideline collections and other sources considered relevant to a point-of-care clinical reference. For a comprehensive list of sources, see DynaMed Content Sources. These sources are derived from systematic evaluation of which sources and search strategies provide the greatest yield for identifying the most valid, relevant evidence (meeting criteria for “Selecting the Best Available Evidence”) included in DynaMed Plus.

New Topic Creation
As new topics are created, MEDLINE searches are conducted to identify recent guidelines and reviews of broad clinical scope. From these searches, general references are selected to guide the basic construct of the topic and support general statements where evidence is lacking or unnecessary. Original evidence is analyzed as needed for clarity and critical appraisal. Supplemental MEDLINE searches are conducted as needed to address specific clinical concepts.

Example of Importance of Identifying the Evidence
In traditional medical publishing, authors are expected to use their expertise to provide reviews that are current and thorough. Authors may search the literature for information to supplement what they know, but searches may be limited to the information they deem important to consider. New evidence could be clinically important but widely unknown and unconsidered, especially if not marketed to raise awareness. Below is an example of useful information when caring for patients with cold symptoms would not be an expected consideration if it were not for Systematic Literature Surveillance:

- *Andrographis paniculata* may reduce common cold symptoms in adults (level 2 [mid-level] evidence)
  - based on randomized trial with uncertainty if statistical analysis adjusted for multiple outcomes
  - 223 adults with uncomplicated upper respiratory tract infection randomized to *Andrographis paniculata* (KalmCold) 100 mg vs. placebo orally twice daily for 5 days
  - outcome measured by patient report of symptom scores on 9 symptoms - cough, expectoration, nasal discharge, headache, fever, sore throat, earache, malaise/fatigue, sleep disturbance
  - statistical analysis not reported to adjust for multiple outcomes
  - mean total symptom scores decreased significantly in both groups from day 1 to day 3, but then further decreased only in KalmCold group
  - comparing KalmCold vs. placebo
    - mean total symptom score on day 1 was 222 vs. 216
    - mean total symptom score on day 3 was 135 vs. 144 (not significant)
    - mean total symptom score on day 5 was 67 vs. 143 (p ≤ 0.05)
• symptoms improved in 97.2% vs. 84.3% (p ≤ 0.05, NNT 8)
  ○ Reference - Phytomedicine 2010 Mar;17(3-4):178

• Andrographis paniculata as Kan Jang tablets may reduce common cold symptoms (level 2 [mid-level] evidence)
  ○ based on systematic review without assessment of allocation concealment or intention-to-treat analysis
  ○ systematic review of 4 randomized trials comparing A. paniculata in form of Kan Jang tablet vs. placebo
  ○ severity of symptoms reduced in meta-analysis of 2 trials with 225 patients evaluating combination of A. paniculata with Andrographis senticosus
  ○ symptom scores reduced vs. placebo in 1 trial with 208 patients
  ○ clinical significance of these score reductions is not clear
  ○ Reference - J Clin Pharm Ther 2004 Feb;29(1):37

Step 2: Selecting the Best Available Evidence

Each article is assessed for clinical relevance and each relevant article is further assessed for validity relative to existing DynaMed Plus content. The most valid articles are summarized, the summaries are integrated with DynaMed Plus content, and overview statements and outline structure are updated based on the overall evidence synthesis. Article selection is completed by editors with clinical expertise and training in scientific analysis.

Determining Relevance

Determining clinical relevance is the first consideration in systematically selecting the best available evidence from that identified. The relevance of medical information is different for every user. DynaMed Plus is used in clinical care by varied types of practitioners with a wide range of global experience and interests, and is also used in medical education. When adding information to DynaMed Plus, the following considerations are used for determining relevance:

1. Does this information have a direct bearing on patient-oriented outcomes?

   Patient-oriented outcomes are outcomes that affect quality of life without extrapolation. Examples include mortality, incidence of myocardial infarction, and presence and severity of pain. These are also called clinical outcomes. Disease-oriented outcomes are used as surrogate markers for monitoring the effects of interventions ultimately intended to affect patient-oriented outcomes. Examples include cholesterol concentration, blood pressure and bone mineral density. Patients are only interested in these outcomes as a means for affecting clinically significant outcomes such as mortality or fracture incidence.

   Because DynaMed Plus is primarily a clinical tool for use during patient care, patient-oriented outcomes information is considered relevant and included. Patient-oriented evidence is given priority over disease-oriented evidence, with disease-oriented evidence entered only if it adds substantially new information.

2. In the absence of patient-oriented evidence, might this information be useful in clinical decision-making?

   Much of medical knowledge is still lacking in terms of patient-oriented outcomes research. Clinical decisions based on extrapolated disease-oriented evidence are not proven to be appropriate. However, clinicians still need to make decisions in situations where patient-oriented evidence is not yet available.

   Disease-oriented evidence is considered relevant for DynaMed Plus in situations where patient-oriented evidence is lacking. Individual clinicians will have to determine if this information is considered relevant within their practice.

3. Is this information that is of unique interest due to popularity or clinical controversy?

   Some medical information is not clinically relevant but widely publicized or part of a clinical controversy. Summarization of this type of information (often with commentary) is relevant to DynaMed Plus users if it is likely that clinicians will be asked about it during clinical encounters. It is important for physician and patient education to point out where this type of information is not clinically applicable.

Determining Validity

Clinically relevant articles must be assessed to determine the scientific validity of conclusions and facts presented before
consideration for use. Conducting critical appraisal for all articles would be wasteful if these articles would not make a change to the existing DynaMed Plus knowledge base.

Easily identifiable study features (e.g., study method, sample size) are compared with existing studies in DynaMed Plus to determine if new articles potentially represent the best available evidence. Articles that do not provide relevant information with validity that meets or exceeds the existing DynaMed Plus content are excluded at this stage.

The evidence hierarchy depends on the type of conclusion.

For conclusions about causation (i.e., the effect of interventions or exposures on outcomes), the evidence hierarchy from highest to lowest validity includes:

1. Randomized trials
2. Quasi-randomized trials
3. Cohort studies (observational comparisons of exposed and unexposed persons)
4. Case-control studies (observational comparisons of persons with and without the outcome of interest)
5. Case series (uncontrolled trials)
6. Expert opinion

For conclusions about diagnostic accuracy, the evidence hierarchy from highest to lowest validity includes:

1. Diagnostic cohort studies (with representative sample of patients with diagnostic uncertainty)
2. Diagnostic case-control studies (with non-representative samples of patients with known diagnosis and controls)
3. Diagnostic case series (including only patients with diagnosis to evaluate sensitivity only, or only patients without diagnosis to evaluate specificity only)
4. Expert opinion

For conclusions about prognosis, the evidence hierarchy includes:

1. Inception cohort studies
2. Retrospective cohort studies
3. Case series
4. Expert opinion

Within each stratum of the evidence hierarchy, systematic reviews are considered more valid than individual studies of similar quality.

**Determining which Guidelines to Summarize**

All relevant guidelines are listed but only a minority of guidelines are summarized. DynaMed editors select which guidelines to summarize with selections based on:

1. Scope of guideline (whole-topic view preferred over focused concept-specific guidelines)
2. Currency of guideline
3. Authority behind the guideline (national or international > local, professional association > non-affiliated expert consensus, etc.)
4. Quality of guideline (use of evidence-based process)
5. Relevancy of guideline
6. Ease of use (are the recommendations easy to interpret—clear and unambiguous?)
7. “Need” for additional guideline summarization to cover “missing information” in the topic

**Example of Importance of Selecting the Best Available Evidence**

Consider the question, “Is surgery effective for a painful rotator cuff tear in elderly patients?”

The first randomized trial to answer this question was published and summarized in DynaMed in 2014. Up until that
point, the best available evidence was based on case series and was available in DynaMed as early as 2005. This evidence was summarized in DynaMed Plus as:

- surgery reported to improve symptoms in patients > 60 years old with rotator cuff tears (level 3 [lacking direct] evidence)
  - based on 3 case series
  - 69 patients with mean age 75 years (range 70-90) treated with surgical repair of massive rotator cuff tears were followed for at least 2 years (mean 3 years)
    - bone-tendon repair considered good in 80%, fair in 7%, poor in 12%, and absent in 1 patient
    - 78% of patients achieved satisfactory results defined as University of California Los Angeles (UCLA) score ≥ 28
    - mean presurgical score 9.4 vs. postsurgical score at final follow-up 30.9 (p = 0.0001)
  - 105 consecutive patients > 62 years old with repair of rotator cuff tear evaluated
    - 92 patients with 97 rotator cuff tears were re-examined after ≥ 2 years
    - 5% had failure of repair, 6% had complications, including 1 infection and 1 brachial plexus stretch injury
    - 87% patients had good or excellent results
    - mean presurgical UCLA score 12.9 vs. postsurgical score 32.4 (p < 0.05)
  - 64 patients > 60 years old had arthroscopic rotation cuff repair and were evaluated by UCLA score
    - mean follow-up 27 months
    - mean baseline UCLA score 10.4 vs. postoperative UCLA score 30.5 (p < 0.0001)
    - 69% of patients reported excellent or good results with surgery
    - Reference - Arthroscopy 2005 Jan;21(1):48

This is considered more useful than simply stating an expert opinion. These articles were relevant and represented the best available evidence when this clinical question occurred in practice, yet would not be found in most evidence-based systems (which limit their focus to randomized trials) or textbooks (which rely primarily on expert opinion).

**Step 3: Critical Appraisal**

Abstracts in research publications often do not accurately reflect the methodologic quality and results found in full-text articles.

For DynaMed, full-text evaluation of articles is required for:

1. Any article rated as Level 1 [likely reliable] evidence or Grade A recommendation [consistent high-quality evidence]
2. Any article potentially ratable as Level 1 or Grade A based on abstract-only information; full-text evaluation is necessary to provide lower levels or grades
3. Any article for which definition of absolute magnitude of effect and/or detailed description of interventions or exposures are necessary, regardless of level of evidence
4. Any article which represents the most important guidance for a DynaMed Plus topic, regardless of level of evidence

Reports used for updating DynaMed Plus represent the best available evidence for the specific content under consideration. Evidence may be labeled in one of three levels as outlined under Levels of Evidence.

Articles that potentially warrant the highest evidence ratings undergo complete critical appraisal.

If serious methodological shortcomings are discovered (sufficient to affect clinically relevant results), then the evidence is labeled as mid-level evidence and the shortcomings are described.
Critical appraisal is completed by editors trained in critical appraisal.

**Example of Importance of Critical Appraisal**

Conclusions of randomized trials need to be put in perspective of biases that may influence the evidence. Critical appraisal includes evaluation of methodology and distinguishing clinical outcomes from surrogate outcomes.

In 2008 the ADVANCE trial was reported with a conclusion that “A strategy of intensive glucose control, involving gliclazide (modified release) and other drugs as required, that lowered the glycated hemoglobin value to 6.5% yielded a 10% relative reduction in the combined outcome of major macrovascular and microvascular events, primarily as a consequence of a 21% relative reduction in nephropathy.”

Here is the *DynaMed Plus* summary of the ADVANCE trial:

- **target HbA1c < 6.5% using gliclazide as initial therapy may increase hospitalization (level 2 [mid-level] evidence) with “benefit” possibly limited to reduction in development in macroalbuminuria (level 3 [lacking direct] evidence)**
- based on randomized trial with only statistically significant difference in clinical outcomes limited to 1 secondary outcome
- 11,140 patients ≥ 55 years old with type 2 diabetes with history of or additional risk factor for vascular disease were randomized to intensive glucose lowering vs. standard guidelines-based glucose lowering
- 6-week run-in period included usual methods of glucose control and fixed combination of perindopril and indapamide (blood pressure lowering arm)
- randomization after run-in period
  - intensive blood glucose control (target HbA1c ≤ 6.5%) with modified release gliclazide 30-120 mg daily
  - standard glucose control with target HbA1c levels defined on basis of local guidelines
- median follow-up 5 years
- comparing intensive blood glucose control vs. standard glucose control
  - mean HbA1c 6.5% vs. 7.3%
  - composite outcome of major macrovascular and microvascular events reached in 18.1% vs. 20% (p = 0.01, NNT 53)
    - macrovascular events in 10% vs. 10.6% (not significant)
      - nonfatal myocardial infarction in 2.7% vs. 2.8% (not significant)
      - nonfatal stroke in 3.8% vs. 3.8% (not significant)
      - death from cardiovascular causes in 4.5% vs. 5.2% (not significant)
    - microvascular events in 9.4% vs. 10.9% (p = 0.01, NNT 67)
      - new or worsening nephropathy in 4.1% vs. 5.2% (p = 0.006, NNT 91)
        - macroalbuminuria developed in 2.9% vs. 4.1% (p < 0.001, NNT 84)
        - need for renal-replacement therapy or death from renal disease in 0.4% vs. 0.6% (p = 0.09)
        - doubling of serum creatinine level to ≥ 200 mcmol/L (2.26 mg/dL) in 1.2% vs. 1.1% (not significant)
      - new or worsening retinopathy in 6% vs. 6.3% (not significant)
    - new-onset microalbuminuria in 23.7 % vs. 25.7% (p = 0.02, NNT 50)
  - adverse events
    - death from any cause in 8.9% vs. 9.6% (not significant)
    - hospitalization for any cause in 44.9% vs. 42.8% (p = 0.03, NNH 47)
    - hospitalization due to severe hypoglycemia in 1.1% vs. 0.7% (p = 0.04, NNH 250)
    - severe hypoglycemia in 2.7% vs. 1.5% (p < 0.001, NNH 83)
Step 4: Objectively Reporting the Evidence

When reporting the evidence, DynaMed Editors consider all of the following questions:

1. Were all relevant outcomes reported in the original article?
2. What are the most relevant outcomes to report in the DynaMed Plus topic?
3. For relevant outcomes, what is the magnitude of effect? This may be represented by absolute rates and number needed to treat (NNT) or harm (NNH) abbreviations, or by absolute differences in continuous variables (e.g., mean decrease in 1.3 points on 0-10 visual analog pain scale).
4. Were the findings clinically significant?
5. In the case of no statistically significant differences, were the findings robust enough to rule out clinically significant difference?
6. Are there any methodologic limitations sufficient to alter reliability of clinical conclusions?

DynaMed editors check the data against original study reports, and clinical editors review all summaries for validity and relevance at the point-of-care. Level of evidence labeling is done by protocol with explicit reasons stated for downgrading levels of evidence.

DynaMed editors check phrasing for possible ambiguity. Phrases which can be interpreted in more than one way are revised. Shortest unambiguous phrasing is used.

For individual studies, if results are available in both relative risk and absolute risk formats, the absolute risk data is used and NNT/NNH are calculated and presented (rounded up for NNT, rounded down for NNH) in the result lines for dichotomous outcomes. For systematic reviews, an NNT range is reported in results lines based on the odds ratio or risk ratio presented, the 95% confidence interval, and the control event rate.

Example of Importance of Objectively Reporting the Evidence

Consider the use of statins for reducing the risk of coronary disease in elderly patients. Consider a 75-year-old woman with total cholesterol 190 mg/dL, blood pressure 150/90 mmHg, and no history of heart disease, smoking or diabetes. Should she be given a statin?

In 2002 there was one randomized trial reporting clinical outcomes in this population. The original abstract states, “Mortality from coronary disease fell by 24% (p=0.043) in the pravastatin group,” and concludes “Pravastatin given for 3 years reduced the risk of coronary disease in elderly individuals.”

The DynaMed Plus summary reads:

• in patients aged 70-82 years with history of or risk factors for cardiovascular disease, pravastatin may reduce coronary mortality but may increase cancer mortality so no difference in overall mortality (level 2 [mid-level] evidence)
• based on randomized trial with results of borderline statistical significance
• 5,804 patients aged 70-82 years with history of or risk factors for vascular disease were randomized to pravastatin 40 mg/day vs. placebo for mean 3.2 years, baseline cholesterol levels 4-9 mmol/L (154.3-347.6 mg/dL)
• comparing pravastatin vs. placebo
  • no significant differences in overall mortality (10.3% vs. 10.5%)
  • 3.25% vs. 4.19% death from coronary heart disease (p = 0.043, NNT 107)
  • 3.98% vs. 3.12% death from cancer (p = 0.082, NNH 116)
  • 14.1% vs. 16.2% combined outcome of coronary heart disease death, myocardial infarction or stroke (p = 0.014, NNT 48)
• new cancer diagnoses reported in 8.5% pravastatin patients vs. 6.8% placebo patients (NNH 59); no significant difference in new cancer diagnoses in meta-analyses incorporating other trials, but these other trials were based on younger patients
no significant differences in women or in primary prevention in subgroup analyses


- DynaMed commentary – though reduction in coronary mortality is statistically significant at p < 0.05 (95% chance that mortality reduction is less than zero), the findings do not demonstrate clinically relevant mortality reductions throughout the 95% confidence interval which ranges from NNT 57 to NNT 2,387

Attention to absolute risks instead of relative risks, attention to multiple outcomes (not just the "statistically significant" outcome) and attention to subgroup analyses make this critical trial summary much different when comparing objective reporting with the original abstract.

**Step 5: Synthesizing Multiple Evidence Reports**

Evidence-based summarization of articles is necessary, but insufficient for a point-of-care reference. Understanding the best current evidence requires synthesizing multiple evidence reports.

Addition, deletion, and organization of information within DynaMed Plus is done with consideration of levels of evidence. When multiple articles are present on the same topic, preference for inclusion and organization is based on the quality of methodology (e.g., preference given to data derived from randomized controlled trials over data from prospective observational studies, which is given preference over retrospective studies, which is given preference over anecdotal reports—see the evidence hierarchy discussion above in “Selecting the Best Available Evidence” for more details). When data of lesser quality does not add any substantially new or different information, this data is then deleted from DynaMed Plus.

Evidence is also synthesized with guidelines, and areas of inconsistency are presented.

The outline format of DynaMed Plus, with conclusions first, allows for rapid navigation and interpretation without the need to skim though large blocks of text.

Clinical editors review all synthesis results for validity and relevance at the point-of-care.

**Example of Importance of Synthesizing Multiple Evidence Reports**

Reading the result of a single study can be misleading if the clinician is unaware of related studies. Yet during clinical practice there is not enough time to read many separate study summaries.

Coenzyme Q10 has been promoted for use in diabetes, and the synthesis in DynaMed Plus’ “Diabetes alternative treatments (biologic therapies)” topic provides a quick summary of five randomized trials:

**Coenzyme Q10**

- coenzyme Q10 has inconsistent results on blood pressure and glycemic control in 5 randomized trials
- coenzyme Q10 100 mg twice daily may improve blood pressure and glycemic control (level 3 [lacking direct evidence])
  - based on 2 randomized trials without clinical outcomes
  - coenzyme Q 100 mg twice daily reduced blood pressure by 6.1/2.9 mm Hg and HbA1c by 0.37% in 12-week randomized placebo-controlled trial in 74 patients with diabetes (Eur J Clin Nutr 2002 Nov;56(11):1137)
  - coenzyme Q 100 mg twice daily reduced systolic blood pressure and HbA1c in 12-week randomized placebo-controlled trial in 80 patients with type 2 diabetes and dyslipidemia (Atherosclerosis 2003 May;168(1):169)
- coenzyme Q10 100 mg twice daily may NOT affect glycemic control, blood pressure or lipid levels (level 3 [lacking direct evidence])
  - based on 3 randomized trials without clinical outcomes
  - no significant differences in glycemic control, blood pressure or lipid levels in 6-month randomized placebo-controlled trial in 23 patients with type 2 diabetes (Biofactors 1999;9(2-4):315)
○ no significant differences in glucose, lipid levels or blood pressure in 12-week randomized placebo-controlled trial in 40 patients with type 2 diabetes; coenzyme Q10 reported to improve resting blood flow and endothelial function in brachial artery (Diabetologia 2002 Mar;45(3):420)

○ coenzyme Q10 100 mg twice daily did NOT significantly affect insulin dose, glycemic control, cholesterol levels or general well-being in 12-week randomized placebo-controlled trial of 34 patients with type 1 diabetes (Mol Aspects Med 1997;18 Suppl:S307, Diabet Med 1999 Apr;16(4):312 in Alternative Medicine Alert 2004 Jun;7(6):61)

• review of coenzyme Q10 can be found in Am Fam Physician 2005 Sep 15;72(6):1065 full-text

Step 6: Basing Conclusions on the Evidence

Deriving overall conclusions and recommendations from the evidence synthesis is required for a comprehensive point-of-care reference. In DynaMed Plus, multiple evidence reports of similar quality are organized such that the overall conclusions quickly provide a synthesis of the best available evidence.

Treatment Overviews are based upon all of the available evidence and guidance in the treatment section. Key concepts in Treatment Overviews are explicitly linked directly to the supporting evidence synthesis.

Editors confirm that overviews are clinically useful and accurately match supporting data.

Example of Importance of Basing Conclusions on the Evidence

There are conflicting opinions regarding whether or not to use antibiotics for acute sinusitis, and which antibiotics to use. The clinician needs to be aware of this controversy, including the best available evidence, recommendations from authoritative sources and sufficient guidance for clinical decision-making (such as drug doses), yet without being told how to practice (cookbook medicine) or being misled by a single author’s opinion (“Here’s what I do”).

This is the “antibiotics” portion of the Treatment Overview for Acute sinusitis in Adults:

• antibiotics for acute bacterial sinusitis
  ○ most cases resolve without antibiotic treatment
  ○ only consider treatment with antibiotics if patient meets criteria for acute bacterial sinusitis
  ○ recommendations for antibiotics in adults vary
    • American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) recommends
      ○ consider watchful waiting without antibiotics in patients with uncomplicated mild illness (mild pain and temperature < 101 degrees F [38.3 degrees C]) with assurance of follow-up (AAO-HNSF Option)
      ○ if decision made to treat with antibiotics, amoxicillin is first-line therapy for most patients (AAO-HNSF Recommendation)
    • AAO-HNSF does not recommend specific doses but FDA approved dosing of amoxicillin is
      ○ 500 mg every 12 hours or 250 mg every 8 hours for mild-to-moderate illness
      ○ 875 mg every 12 hours or 500 mg every 8 hours for severe illness
    ○ no evidence to suggest difference in clinical outcomes associated with different dose or duration schedules
  • Infectious Diseases Society of America (IDSA) recommends
    ○ start antibiotics as soon as clinical diagnosis of acute bacterial sinusitis is made (IDSA Strong recommendation, Moderate-quality evidence)
    ○ use amoxicillin-clavulanate 500 mg/125 mg orally 3 times daily or 875 mg/125 mg orally twice daily as long as there are no risk factors for resistance
    ○ use of amoxicillin-clavulanate rather than amoxicillin alone (IDSA Weak recommendation, Low-quality evidence) based on prevalence data of beta-lactamase producing Haemophilus influenzae and in vitro susceptibility data in the United States
    ○ treat for 5-7 days if uncomplicated bacterial rhinosinusitis (IDSA Weak recommendation, Low-moderate-quality evidence)
• evidence for use of antibiotics
  • antibiotics slightly increase cure rate at 7-14 days in adults with clinically diagnosed acute rhinosinusitis (level 1 [likely reliable] evidence)
  • antibiotics improve symptoms at 7-15 days in adults with acute maxillary sinusitis but high rate of clinical improvement without antibiotics (level 1 [likely reliable] evidence)
  • no antibiotic is clearly superior for treatment of acute maxillary sinusitis in adults with ≥ 7 days of symptoms (level 2 [mid-level] evidence)
  • appropriate duration of antibiotics unclear
    • trimethoprim/sulfamethoxazole 160/800 mg twice daily for 3 days may be equally effective as 10 days (level 2 [mid-level] evidence)
    • amoxicillin/clavulanate for 5 days may be as effective as amoxicillin/clavulanate for 10 days (level 2 [mid-level] evidence)

**Step 7: Updating Daily**

Updating daily in *DynaMed*s evidence-based methodology is changing conclusions when new evidence alters the best available evidence. This is crucial because new evidence is published every day. Having new evidence summaries handled separately from reviewed content in a manner requiring the clinician to search in two locations to synthesize the entire story would make finding the best available evidence more difficult.

As soon as new evidence is evaluated using the prior steps governing systematic processing, it is added to the appropriate *DynaMed* topic(s) in context. This process allows immediate and comprehensive access to the best available evidence as it occurs.

This process occurs every day in *DynaMed*.

To see recent examples of practice-changing evidence, please visit the *DynaMed* EBM Focus Update Archive.