CPAC - Canadian Partnership Against Cancer

CPG - Clinical practice guideline

CWG - Clinical Working Group

KTA - Knowledge to action

SOR – Strength of recommendation

SQUID - Summary QUality InDex

Abstract

Background: The Building on Existing Tools to Improve Chronic Disease Prevention and Screening (CDPS) in Primary Care Practice (BETTER) trial is a pragmatic randomized controlled trial that translates evidence to practice across multiple diseases: diabetes; cardiovascular disease; cancer (cervical, breast, colorectal); and associated lifestyle factors (nutrition, exercise, smoking, alcohol). We describe a new systematic process for establishing an integrated evidence platform, and new clinical tools to summarize Clinical Practice Guidelines (CPGs). **Methods**: Using the AGREE methodology, three to five high quality CPGs were identified for each disease. Recommendations for CDPS were extracted. A literature review was done for CDPS in patients with depression. A structured search of the grey literature was done for CDPS tools. **Results**: High-grade recommendations for CDPS were identified for the target diseases. Limitations included: conflicting recommendations, vague wording, and different taxonomies for strength of recommendation (SOR). No high quality evidence was found for maneuvers to improve CDPS in patients with depression. The tool search yielded 180 CDPS tools of interest. The BETTER Guideline Synthesis Framework and integrated clinical algorithms were developed. **Conclusion**: The BETTER intervention was built upon existing CPGs and tools, with the novel approach of engaging end-users in tailoring

the content and design of the implementation. To promote clinical utility, CPGs should be harmonized to deliver consistent clinical messages, and to use a single taxonomy for SOR. The clinical impact of shared decision making tools would be increased if they were indexed and validated for utility.

Key Words

Primary Care, Primary Prevention, Screening, Diabetes, Cardiovascular Disease, Breast Cancer, Cervical Cancer, Lung Cancer, Colon Cancer, Clinical Practice Guidelines

Word Count: 2354

Introduction

Family practice is the setting where most healthcare activities for improving chronic disease prevention and screening (CDPS) are applied.[1-6] There are a number of effective, evidence-based, maneuvers for CDPS which remain underutilized. This is particularly true for patients with mental illness. [7-9] There is a need for a CDPS strategy that concurrently addresses multiple conditions. Promoting practice organization that delivers integrated CDPS in a time-efficient manner is a priority. Provider time required to deliver all recommended CDPS maneuvers is estimated to be 7.4 hours daily with current practice structures.[10-17]

The Building on Existing Tools to Improve Chronic Disease Prevention and

Screening in Primary Care Practice (BETTER) trial is a clustered randomized controlled trial involving eight Primary Care Team practices across two Canadian Provinces. The objective is improving CDPS through practice and patient-level interventions while concurrently implementing evidence for multiple conditions into practice.

CDPS maneuvers are summarized in clinical practice guidelines (CPGs). In theory, CPGs are systematically developed summaries of the best evidence available on a single topic, but their effectiveness as tools to facilitate translation of evidence into practice has been inconsistent.[18,19] Multiple CPGs on the same topic cause confusion with conflicting recommendations. Han and colleagues have highlighted this multiplicity as being a significant problem in clinical decision making, particularly with breast and cervical cancer screening guidelines.[20]

This paper describes the process used to determine the evidence-base for the BETTER trial interventions for CDPS across multiple target conditions. In addition, we assessed the evidence for CDPS interventions in patients with depression, as in the study design moderate mental illness was our pre-specified subgroup. An adaption of the Knowledge to Action (KTA) Framework extended this model to situations requiring the integration of clinical practice guidelines across multiple medical conditions.[21] We present the findings of our tool search and suggestions for future work in the area of organization and validation of clinical tools.

Methods

The Knowledge to Action Cycle was the starting framework for the derivation of the evidence-base to inform the BETTER trial. The framework evolved to accommodate the inclusion of concurrent interventions for primary prevention and screening across diabetes, cardiovascular disease, and cancer (cervical, breast and colorectal), and associated lifestyle risk factors. (Figure 1) Rather than "knowledge creation" as the core of the KTA cycle, BETTER is based on using existing tools, in this case CPGs. It was important that we had a clear process with iterative stakeholder engagement to select high quality CPGs and then decide which recommendations to implement. To this end, we assembled a Clinical Working Group (CWG) composed of clinicians (Primary Care Physicians, a nurse practitioner, registered nurses, a licensed practical nurse and a dietician), a health services librarian, and members of the Centre for Effective Practice who are experts in guideline implementation and represent non-clinical participants.

High-quality CPGs were identified through a focused four-step process (Table 1).

This was based on the search strategy for CPGs developed by the Guidelines

Advisory Committee at the Centre for Effective Practice, published in the Canadian

Medical Association Handbook on Clinical Practice Guidelines. [22] The inclusion

criteria were: diabetes, cardiovascular disease, breast cancer, colorectal cancer,

cervical cancer, skin cancer, and lung cancer. The search was limited to guidelines

published in English between 2004 and 2009. Guidelines were excluded if they did

not include any recommendations related to screening or primary prevention of the areas of interest, or were not applicable to primary care. A search for effective CDPS in patients with depression was conducted (Table 1). The BETTER search and appraisal strategy for existing tools to promote CDPS is included in Tables 2 and 3.

Guidelines found for each clinical topic were retrieved in full text and were evaluated using the domains from the AGREE instrument (23) with particular focus on the domains of Rigour of Development and Editorial Independence. This ensured that a systematic search was conducted, all evidence was considered, recommendations in the guidelines were linked directly to the levels of evidence, and that the guideline was developed with minimal bias. In an effort to build on existing work in CPG evaluation, the Canadian Partnership Against Cancer (CPAC) was asked to provide the full AGREE scores for all breast, cervical, colorectal, lung and skin cancer guidelines published between 2005 and 2008. Additional guidelines in these areas published between 2008 and 2009 were identified and evaluated. Both sets of guidelines were then compared to determine the highest quality CPGs. By applying these criteria, the top three to five CPGs in each clinical area were identified. Where available, Canadian CPGs, and CPGs published most recently were used if they satisfied the quality criteria.

In the initial evidence review phase, smaller disease theme groups were developed from the members of the CWG for diabetes, cardiovascular disease, and cancer.

Horizontal theme groups were established for lifestyle modification (smoking,

alcohol, exercise, nutrition), family history, and mental health. Each of the disease theme groups reviewed the recommendations specific to their clinical area, while the horizontal groups considered all of the guideline recommendations as they related to their topic. At least two members of each group independently reviewed each recommendation and clinical tool, and where disagreement existed between the guidelines or reviewers, decisions were reached through discussion with the group. All recommendations were presented to the entire CWG for final review. A literature review was done by the mental health subgroup to find strategies to increase uptake of CDPS maneuvers in patients with depression.

It was the responsibility of the CWG to identify guidelines or recommendations considered clinically controversial, or additional relevant literature that may have postdated the publication of the guidelines. In these situations, primary literature was searched and/or updated guidelines were retrieved and included in the CWG review. To ensure that recommendations were appropriate within the specific provincial contexts, local guidelines and policies from provincial bodies were identified. These were compared to the selected recommendations to ensure consistency and applicability. These recommendations were tailored to patients' personal risk factors and family history.

Results

The selected guidelines can be found in Appendix A. Strong evidence was identified for maneuvers for CDPS for breast, colorectal and cervical cancer, diabetes, cardiovascular disease, and for the prevention of lung cancer. Given the absence of evidence for the general population screening in skin, lung, and colorectal and breast cancer ages 40-49, the CWG recommended these not be included in the project scope. Breast cancer screening and colorectal cancer screening were recommended in the 40-49 year range for those patients with family history indicating higher risk. The CWG requested additional searching for prostate cancer, and following the review concluded insufficient evidence to recommend population screening. The literature review for effective strategies to increase CDPS in patients with depression was done. The CWG concluded that there were no high quality studies demonstrating specific interventions for this patient population.

The harmonization of the guideline recommendations was critical to their effective implementation. For a recommendation to be clinically useful it not only had to have a high-grade level of evidence, it had to be formulated in a way that was actionable. Table 4 summarizes one example of this, showing the recommendations from four different guidelines about the timing of screening patients for diabetes. Each of the guidelines had a different taxonomy for indicating strength of recommendation and SOR. Recommendation number II is the only one that is specific, comprehensive and actionable.

Clinical algorithms simultaneously relay the principal results of the guideline review of the strongest available recommendations for CDPS across all of the maneuvers. They provided a clear and consistent approach specifically tailored to the intervention. Figure 2 is the algorithm for primary prevention and screening for cardiovascular disease and diabetes, Figure 3 depicts primary prevention and screening for cardiovascular disease in patients with existing type 2 diabetes, and Figure 4 depicts primary prevention and screening for breast, cervical, and colorectal cancer, and for the primary prevention of lung cancer.

Using a structured search of the grey literature (Table 2), 180 CDPS clinical tools, from over 1000 considered, were identified for review for inclusion in the BETTER tool kit. A selection of tools was chosen for the assessment of alcohol, depression, smoking, diet, exercise, and family history. A key finding of the study was the lack of a systematic organization of tools for implementing recommendations. These recommendations are not frequently published or indexed, nor was there a reliable filter for the quality and clinical utility in the repositories. To avoid redundancy, we proposed a ranking and indexing scheme to help facilitate the cataloguing and retrieving of high quality tools (Table 3).

Interpretation

The determination of the evidence base for the BETTER trial was an exercise in disassembling high quality clinical practice guideline recommendations into core

components, and re-assembling them to result in integrated, implementable, and measurable recommendations. The recommendations for CDPS maneuvers across multiple diseases then went into an algorithm to facilitate clinical decision-making. This evidence framework was combined with elements of shared-decision making, and the principles of motivational interviewing to form the basis for the BETTER interventions. Explicit in this framework are opportunities for patients to opt out of discussing any area they wish. This approach facilitates the patient-provider partnership in primary care, by supporting patients' autonomy, and recognizes the importance of patient's values, preferences, and readiness for change to the care relationships in primary care/ family practice.

No robust primary studies demonstrating solid outcomes for CDPS uptake interventions were identified for primary care patients suffering from depression. The lack of high-level evidence for such interventions suggests that further research into this area is needed.

The BETTER evidence review shed some light on why guidelines have been poorly implemented. Our iterative review of guideline recommendations, with an eye to clinical applicability, showed that the imprecise language of recommendations resulted in a discussion about what we should actually "do" – what was the spirit of the recommendation? We realized that for use across multiple diseases we needed to focus on the recommendations that have the greatest effect and best evidence. The variation in taxonomy regarding the strength of recommendations challenged

the proper interpretation of the strength of evidence for each guideline. We believe this is a major limitation to the applicability of guidelines. We propose that all guideline developers settle on the use a single taxonomy for strength of evidence, which is clear and easy for clinicians to understand.

We developed an algorithm format for displaying the clinical recommendations. This also provided a structure for adding "goal sets" to the electronic medical records that can be created for individual patients. We developed an iterative consensus among providers which responded to local practice patterns, and accepted variations in places where there was insufficient evidence to recommend a different approach. For example, there are different cervical cancer and colorectal cancer screening protocols in Ontario and Alberta, with insufficient evidence to support one over the other. Without the clear engagement of clinicians during the design of the intervention we believe that there is a risk of reduced uptake due to clinicians not being in agreement with all of the recommendations, or omitting recommendations due to error. For example, the American Diabetes Guidelines recommending the possible use of pioglitazone in the prevention of progression from pre-diabetes to diabetes was considered out of scope of this project by the CWG. The CWG's reasons included safety concerns, and a lack of evidence that it is superior to physical exercise in the prevention of diabetes. Given the superiority of exercise over metformin in this instance, exercise was recommended as the primary method for preventing the progression of impaired fasting glucose to diabetes, with

referral to the physician to discuss metformin as a secondary method for this study.[26]

Implementing CPGs in clinical care needs both high-grade recommendations and clear statements about clinically meaningful targets. However, measuring primary care by adherence to a rationalist view of attainment of clinical metrics has the risk of not focusing on the processes of care with strong evidence to support quality.

[27]

The BETTER trial was conceived to build upon existing tools. We tried to identify and review a large number of tools. This process was impeded by most of the tools in the grey literature having weak indexing or classification. The lack of structure in terms of clinical utility and robustness of the tools made the process difficult. We endeavored to index and classify the relevant tools we identified. Given the importance of effective patient communication in facilitating true evidence-based shared decision making, we recommend that future effort be directed towards categorizing and validating tools, making the investment of time and effort in their creation more profitable.

Conclusion

Both a solid evidence-base and including target end users in the identification and development of the knowledge products are required for initiatives to improve

clinical care processes for CDPS. It is impractical for individual projects to reproduce systematic reviews of the primary literature to establish the base. The use of high quality clinical practice guidelines is a more practical approach to handling this problem. A novel aspect of this work was the iterative approach employed to ensure that the evidence and knowledge products were reflective of the needs of the users. We found the conceptual framework of the modified BETTER- guideline synthesis cycle worked well. This produced a common frame of reference for inclusion and exclusion in the study scope helped to standardize the intervention, and helped in developing integrated recommendations and tools for CDPS. It also promoted a deliberative, iterative process to yield clinical recommendations that were explicit and measurable.

The emphasis in the BETTER intervention development was to build on what exists to develop effective tool kits and strategies for implementation. In order to make CPGs useful, focus on the implementation strategy of suites of recommendations is more congruent with practice. To promote clinical utility, CPGs should be harmonized to deliver consistent clinical messages, and use a single taxonomy for strength of recommendations. The BETTER care algorithms were an effective way to summarize the integrated recommendations. Clinical practice guidelines are useful syntheses of information regarding single diseases. Improved uptake in practice may be achieved by re-formatting them for multiple diseases as we have illustrated with these algorithms.

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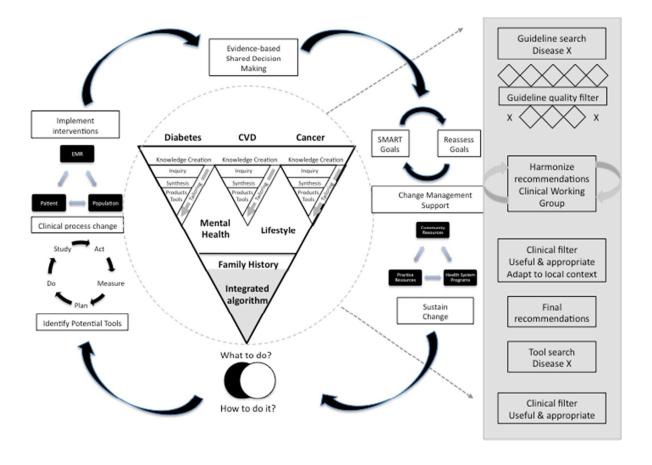
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- dissemination and implementation strategies 1966-1998. J Gen Intern Med. 2006:21(Suppl 2):S14-S20. doi: 10.1111/j.1525-1497.2006.00357.x. PMID: 16637955
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Figure 1: The BETTER – Guideline Synthesis framework for the derivation of the evidence platform and interventions for the BETTER Trial. The triangle in the centre of the diagram is an extension of the "knowledge creation funnel" in the knowledge to action (KTA) cycle. [21] In our model there is knowledge synthesis with each funnel representing existing literature captured in high quality clinical practice guidelines. This is then contextually integrated for each patient's family history and modifiable risk factors. The side bar shows the structured evidence review process of the clinical working group (CWG). The boxes around the circumference of the cycle refer to the steps for implementing the recommendations and tools in both the practice and patient level interventions of the BETTER trial.



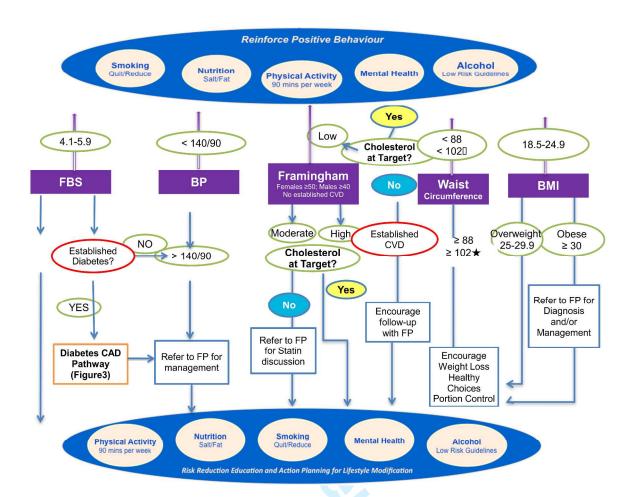


Figure 2: The BETTER Map for primary prevention and screening for type 2 diabetes and coronary artery disease summarizes all of the relevant recommendations from the CPGs. Starting at the rectangular boxes in the middle of the diagram, each parameter is evaluated for the patient. If the patient is on target, follow the arrows up and reinforce positive lifestyle behavior. If the patient is not on target, follow the arrow down, consider appropriate interventions, and intervene on lifestyle behaviors. The risk calculator is used for shared-decision making to illustrate the impact of behaviors like smoking on cardiovascular health.

Figure 3: The BETTER Map for primary prevention and screening for coronary artery disease in patients with pre-existing type 2 diabetes. This map summarizes the recommendations of the CPGs.

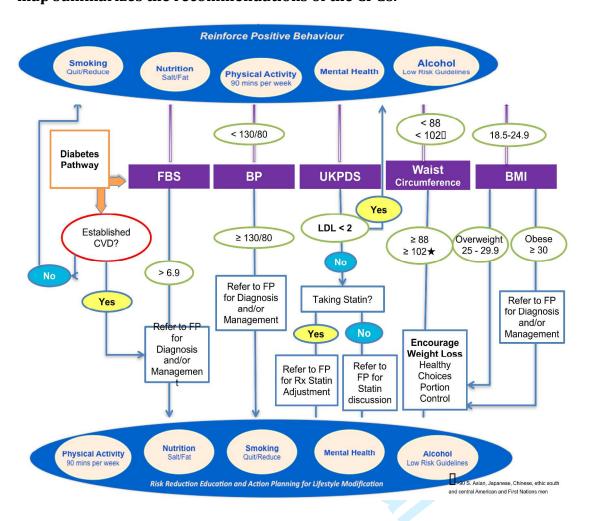


Figure 4: The BETTER Map for primary prevention and screening for common cancers in primary care. This algorithm incorporates tools, which take family history into account to assess where routine population screening measures should be modified for higher risk patients. It incorporates some regional differences in screening protocols between jurisdictions, all of which were deemed reasonable by the CWG.

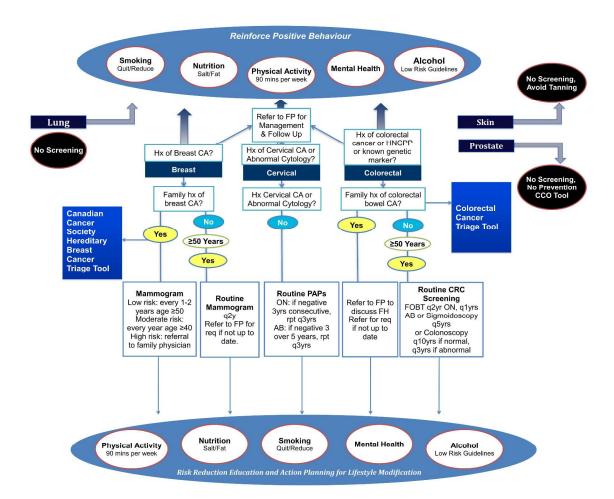


Table 1: Four Step Search Process for High-Quality Clinical Practice Guidelines

1) Guideline Repositories:

- CMA InfoBase Clinical Practice Guidelines: http://mdm.ca/cpgsnew/cpgs/index.asp
- National Guideline Clearinghouse: http://www.guidelines.gov

2) Renowned Developers:

- National Institute for Clinical Excellence: http://www.nice.org.uk/
- New Zealand Guidelines Group: http://www.nzgg.org.nz
- Scottish Intercollegiate Guidelines Network: http://www.sign.ac.uk/guidelines/index.html
- University of Michigan: http://cme.med.umich.edu/iCME/default.asp
- US Preventative Services Task Force: http://www.ahrq.gov/clinic/prevnew.htm
- 3) Websites of National and International Specialty Societies (e.g. for diabetes: the Canadian Diabetes Association,

American Diabetes Association, etc.)

4) General Internet Search:

Google: [Topic] AND [Guideline(s)]. First 3 pages of results examined

For the mental health CDPS uptake literature review

Medline and PsychINFO search using relevant mental health, primary care, and prevention MeSH search terms
yielded 239 abstracts. A clinical filter was applied, with a clinician reviewing these abstracts and identifying 17 articles
of interest. These articles were then reviewed by three other investigators for relevance; debate was resolved with
consensus. Of these, three were considered of sufficient quality and applicability for subsequent review with the larger
CWG of investigators for consideration of clinical applicability and acceptance in primary care.

Table 2: Search Process for High-Quality Clinical Tools

1) Criteria for Consideration:

- o Published in English
- o Address screening and primary prevention of topic area recommendations

2) Search Strategy:

- Public Health Agency of Canada's Canadian Best Practices Portal
- Agency for Healthcare Research and Quality (AHRQ)
 - o Preventive, Chronic and Primary Care
- Internet search using Google:
 - [Topic] AND [Tools] AND [Prevention/Screening] AND [Canada] AND [Patients] AND [Providers]
 - o [Country] AND [Topic]. First 3 pages of results examined
- Websites of national and provincial specialty societies

3) Criteria for inclusion:

- Screening and Prevention tools
- More weight given to the most up to date tools, and those from Canadian and American organizations

4) Extracting tools into table:

- o Includes name, description of tool, focus, source and organization
- Reviewer Instructions (type/usefulness and quality/applicability)
- CWG overall review for inclusion in tool kit

Table 3: Appraising and Cataloguing High Quality Tools for Guideline Recommendation and Implementation

1) Extraction of Tools:

Unique name, description of tool, focus, source, organization

2) Review Process:

- Two independent reviewers, process for resolving differences
- Clear process for criteria to evaluate tools:
 - Type of tool/ Clinical usefulness
 - Quality of the tool/ Applicability
 - Validation of the tool in multiple settings

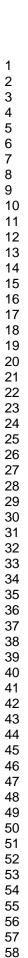
3) Placing tools into tables:

- o Includes name, description of tool, focus, source and organization
- Reviewer of Instructions (type/usefulness and quality/applicability)
- CWG overall review for inclusion in the tool kit

Example: Figure 5.

4) Need a method to index, search and retrieve tools in the literature:

 Dedicated repositories exist, but they are not well indexed and the tools are not preappraised



59 60



Table 4: Example of Harmonizing Guideline Recommendations by the CWG: Decisions Regarding Timing and Methods of Diabetes Screening in BETTER

Every source guideline had its own taxonomy for strength of evidence of the guideline recommendations. The CWG process aimed to establish an actionable goal consistent with the combination of the different guideline recommendations.

Guideline Recommendation	Verbatim Guidelines/ Varied Taxonomy for Strength of Recommendation from Different Developers	References	CWG Discussion
I	All individuals should be evaluated annually for type 2 diabetes risk on the basis of demographic and clinical criteria [Grade D, Consensus].	24	Non-specific recommendation, captured better in II
II	Screening for diabetes using an FPG should be performed every 3 years in individuals >=40 years of age [Grade D, Consensus]. More frequent and/or earlier testing with either an FPG or a 2hPG in a 75-g OGTT should be considered in people with additional risk factors for diabetes [Grade D, Consensus]. These risk factors include: First-degree relative with type 2 diabetes for members of a highrisk population (e.g. people of Aboriginal, Hispanic, Asian, South Asian or African descent) * • History of IGT or IFG * • Presence of complications associated with diabetes * • Vascular disease (coronary, cerebrovascular or peripheral) • History of gestational diabetes mellitus * • History of delivery of a macrosomic infant • Hypertension * • Dyslipidemia • Overweight • Abdominal obesity * • Polycystic ovary syndrome * • Acanthosis nigricans * • Schizophrenia	24	Chosen recommendation by CWG Those with * could feasibly be included in the project.
III	Testing to detect pre-diabetes and type 2 diabetes in asymptomatic people should be considered in adults of any age who are overweight or obese	25	Content included in II

IV	(BMI ≥25 kg/m2) and who have one or more additional risk factors for diabetes. In those without these risk factors, testing should begin at 45 years of age. (B) If tests are normal, repeat testing should be conducted, at least, at 3-year intervals. (E)	25	Content included in II
V	Monitoring for the development of diabetes in those with prediabetes should be performed every year. (E)	25	Chosen recommendation by CWG
VI	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg. Grade: B Recommendation.	26	Content included in II
VII	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for type 2 diabetes in asymptomatic adults with blood pressure of 135/80 mm Hg or lower. Grade: I Statement.	26	Rejected in favor of II. The decisions to screen are not based on high quality evidence.

Appendix A: High Quality Clinical Practice Guidelines (CPGs) Identified by Topic

Diabetes

- Canadian Diabetes Association Clinical Practice Guidelines Expert
 Committee. (2008, September). Canadian Diabetes Association 2008 clinical
 practice guidelines for the prevention and management of diabetes in
 Canada. Canadian Journal of Diabetes, 32(Supp1), S1-S201. Available from:
 www.diabetes.ca/for-professionals/resources/2008-cpg/
- American Diabetes Association. (2010). American Diabetes Association clinical practice recommendations 2009. Diabetes Care 32(Supp 1), S1-S96. Available from: http://care.diabetesjournals.org/content/33/Supplement 1
- U.S. Preventive Services Task Force. (2008, June). Screening for type 2 diabetes mellitus in adults. Agency for Healthcare Research and Quality. Available from: http://www.ahrq.gov/Clinic/uspstf08/type2/type2rs.htm

Cardiovascular

- Scottish Intercollegiate Guidelines Network (SIGN). (2007). Risk estimation and the prevention of cardiovascular disease: A national clinical guideline. Available from: http://www.sign.ac.uk/guidelines/fulltext/97/index.html
- Canadian Cardiovascular Society (CCS). (2009). 2009 Canadian Cardiovascular Society/Canadian guidelines for the diagnosis and treatment of dyslipidemia and prevention of cardiovascular disease in the adult: 2009 recommendations. Canadian Journal of Cardiology, 25(10), 567-579. Available from:
 - http://www.ccs.ca/download/consensus_conference/consensus_conference archives/2009 Dyslipidemia-Guidelines.pdf

Cancer - Breast, Colorectal, Cervical, Skin, and Lung

- U.S. Preventive Services Task Force. (2009, November 17). Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. Annals of Internal Medicine 151(10), 716-726. Available from: http://www.annals.org/content/151/10/716.full
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- Site Group of Cancer Care Ontario. (2005, May 20). Cervical screening: Practice guidelines report. Program in Evidence-Based Care, A Cancer Care Ontario Program. Available from: http://www.cancercare.on.ca/pdf/pebc_cervical_screen_s.pdf
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- American College of Chest Physicians. (2007). Diagnosis and management of lung cancer: ACCP guidelines, 2nd ed. Available from: http://chestjournal.chestpubs.org/content/132/3_suppl
- U.S. Preventive Services Task Force. (2009, February 3) Screening for skin cancer: U.S. Preventive Services Task Force recommendation statement. Annals of Internal Medicine 150(3), 188-193. Available from: http://www.annals.org/content/150/3/188.full.pdf+html
- New Zealand Guidelines Group. (2008). Clinical practice guidelines in Australia and New Zealand for the management of melanoma. Available from: http://www.nzgg.org.nz/guidelines/0141/Melanoma_Full_GL.pdf

Lifestyle

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 http://www.ahrq.gov/clinic/pocketgd09/pocketgd09.pdf

 Guidelines selected for Cancer, Cardiovascular Disease, and Diabetes with recommendations on lifestyle:
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Guidelines selected for Cancer, Cardiovascular Disease, Diabetes and Lifestyle with recommendations on family history:

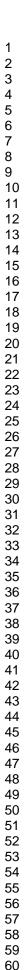
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- Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. (2008, September). Canadian Diabetes Association 2008 clinical practice guidelines for the prevention and management of diabetes in Canada. Canadian Journal of Diabetes, 32(Supp1), S1-S201. Available from: www.diabetes.ca/for-professionals/resources/2008-cpg/
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