General

Guideline Title
Management of newly diagnosed type 2 diabetes mellitus (T2DM) in children and adolescents.

Bibliographic Source(s)

Guideline Status
This is the current release of the guideline.

All clinical reports and policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

Regulatory Alert

FDA Warning/Regulatory Alert
Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- April 8, 2016 – Metformin-containing Drugs: The U.S. Food and Drug Administration (FDA) is requiring labeling changes regarding the recommendations for metformin-containing medicines for diabetes to expand metformin’s use in certain patients with reduced kidney function. The current labeling strongly recommends against use of metformin in some patients whose kidneys do not work normally. FDA concluded, from the review of studies published in the medical literature, that metformin can be used safely in patients with mild impairment in kidney function and in some patients with moderate impairment in kidney function.

Recommendations

Major Recommendations
Definitions for the quality of the evidence (A-D, X) and the strength of the recommendation (strong recommendation, recommendation, option) are provided at the end of the "Major Recommendations" field.
Clinicians must ensure that insulin therapy is initiated for children and adolescents with type 2 diabetes mellitus (T2DM) who are ketotic or in diabetic ketoacidosis (DKA) and in whom the distinction between type 1 diabetes mellitus (T1DM) and T2DM is unclear; and, in usual cases, should initiate insulin therapy for patients:

a. Who have random venous or plasma blood glucose (BG) concentrations ≥250 mg/dL; or
b. Whose hemoglobin A1c (HbA1c) is >9%.

(Strong Recommendation: evidence quality X, validating studies cannot be performed, and C, observational studies and expert opinion; preponderance of benefit over harm.)

Action Statement Profile-Key Action Statement 1

- Aggregate evidence quality: X (validating studies cannot be performed)
- Benefits: Avoidance of progression of DKA and worsening metabolic acidosis; resolution of acidosis and hyperglycemia; avoidance of coma and/or death. Quicker restoration of glycemic control, potentially allowing islet β cells to "rest and recover," increasing long-term adherence to treatment; avoiding progression to DKA if T1DM. Avoiding hospitalization. Avoidance of potential risks associated with the use of other agents (e.g., abdominal discomfort, bloating, loose stools with metformin; possible cardiovascular risks with sulfonylureas).
- Harms/risks/cost: Potential for hypoglycemia, insulin-induced weight gain, cost, patient discomfort from injection, necessity for BG testing, more time required by the health care team for patient training.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Extensive clinical experience of the expert panel was relied on in making this recommendation.
- Role of patient preferences: Minimal.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Strong recommendation.

Key Action Statement 2

In all other instances, clinicians should initiate a lifestyle modification program, including nutrition and physical activity, and start metformin as first-line therapy for children and adolescents at the time of diagnosis of T2DM. (Strong recommendation: evidence quality B; 1 randomized control trial (RCT) showing improved outcomes with metformin versus lifestyle; preponderance of benefits over harms.)

Action Statement Profile-Key Action Statement 2

- Aggregate evidence quality: B (1 randomized controlled trial showing improved outcomes with metformin versus lifestyle combined with expert opinion)
- Benefit: Lower HbA1c, target HbA1c sustained longer, less early deterioration of BG, less chance of weight gain, improved insulin sensitivity, improved lipid profile.
- Harm (of using metformin): Gastrointestinal adverse effects or potential for lactic acidosis and vitamin B12 deficiency, cost of medications, cost to administer, need for additional instruction about medication, self-monitoring blood glucose (SMBG), perceived difficulty of insulin use, possible metabolic deterioration if T1DM is misdiagnosed and treated as T2DM, potential risk of lactic acidosis in the setting of ketosis or significant dehydration. It should be noted that there have been no cases reported of vitamin B12 deficiency or lactic acidosis with the use of metformin in children.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Committee members valued faster achievement of BG control over not medicating children.
- Role of patient preferences: Moderate; precise implementation recommendations likely will be dictated by patient preferences regarding healthy nutrition, potential medication adverse reaction, exercise, and physical activity.
- Exclusions: Although the recommendation to start metformin applies to all, certain children and adolescents with T2DM will not be able to tolerate metformin. In addition, certain older or more debilitated patients with T2DM may be restricted in the amount of moderate-to-vigorous exercise they can perform safely. Nevertheless, this recommendation applies to the vast majority of children and adolescents with T2DM.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

Key Action Statement 3
The committee suggests that clinicians monitor HbA1c concentrations every 3 months and intensify treatment if treatment goals for BG and HbA1c concentrations are not being met. (Option: evidence quality D; expert opinion and studies in children with T1DM and in adults with T2DM; preponderance of benefits over harms.)

**Action Statement Profile-Key Action Statement 3**

- Aggregate evidence quality: D (expert opinion and studies in children with T1DM and in adults with T2DM; no studies have been performed in children and adolescents with T2DM)
- Benefit: Diminishing the risk of progression of disease and deterioration resulting in hospitalization; prevention of microvascular complications of T2DM.
- Harm: Potential for hypoglycemia from overintensifying treatment to reach HbA1c target goals; cost of frequent testing and medical consultation; possible patient discomfort.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Recommendation dictated by widely accepted standards of diabetic care.
- Role of patient preferences: Minimal; recommendation dictated by widely accepted standards of diabetic care.
- Exclusions: None.
- Intentional vagueness: Intentional vagueness in the recommendation as far as setting goals and intensifying treatment attributable to limited evidence.
- Policy level: Option.

**Key Action Statement 4**

The committee suggests that clinicians advise patients to monitor finger-stick BG concentrations in those who:

a. Are taking insulin or other medications with a risk of hypoglycemia; or
b. Are initiating or changing their diabetes treatment regimen; or
c. Have not met treatment goals; or
d. Have intercurrent illnesses

(Option: evidence quality D; expert consensus. Preponderance of benefits over harms.)

**Action Statement Profile-Key Action Statement 4**

- Aggregate evidence quality: D (expert consensus)
- Benefit: Potential for improved metabolic control, improved potential for prevention of hypoglycemia, decreased long-term complications.
- Harm: Patient discomfort, cost of materials.
- Benefits-harms assessment: Benefit over harm.
- Value judgments: Despite lack of evidence, there were general committee perceptions that patient safety concerns related to insulin use or clinical status outweighed any risks from monitoring.
- Role of patient preferences: Moderate to low; recommendation driven primarily by safety concerns.
- Exclusions: None.
- Intentional vagueness: Intentional vagueness in the recommendation about specific approaches attributable to lack of evidence and the need to individualize treatment.
- Policy level: Option.

**Key Action Statement 5**

The committee suggests that clinicians incorporate the Academy of Nutrition and Dietetics' *Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines* in the nutrition counseling of patients with T2DM both at the time of diagnosis and as part of ongoing management. (Option; evidence quality D; expert opinion; preponderance of benefits over harms. Role of patient preference is dominant.)

**Action Statement Profile-Key Action Statement 5**

- Aggregate evidence quality: D (expert consensus)
- Benefit: Promotes weight loss; improves insulin sensitivity; contributes to glycemic control; prevents worsening of disease; facilitates a sense of well-being; and improves cardiovascular health.
- Harm: Costs of nutrition counseling; inadequate reimbursement of clinicians' time; lost opportunity costs vis-a-vis time and resources spent in other counseling activities.
Key Action Statement 6

The committee suggests that clinicians encourage children and adolescents with T2DM to engage in moderate-to-vigorous exercise for at least 60 minutes daily and to limit nonacademic screen time to less than 2 hours per day. (Option: evidence quality D, expert opinion and evidence from studies of metabolic syndrome and obesity; preponderance of benefits over harms. Role of patient preference is dominant.)

Action Statement Profile-Key Action Statement 6

- Aggregate evidence quality: D (expert opinion and evidence from studies of metabolic syndrome and obesity).
- Benefit: Promotes weight loss; contributes to glycemic control; prevents worsening of disease; facilitates the ability to perform exercise; improves the person's sense of well-being; and fosters cardiovascular health.
- Harm: Cost for patient of counseling, food, and time; costs for clinician in taking away time that could be spent on other activities; inadequate reimbursement for clinician's time.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Broad consensus.
- Role of patient preferences: Dominant. Patients may seek various forms of exercise. Patient preference should play a significant role in creating an exercise plan.
- Exclusions: Although certain older or more debilitated patients with T2DM may be restricted in the amount of moderate-to-vigorous exercise they can perform safely, this recommendation applies to the vast majority of children and adolescents with T2DM.
- Intentional vagueness: Intentional vagueness on the sequence of follow-up contact attributable to the lack of evidence and the need to individualize care.
- Policy level: Option.

Definitions:

Evidence Quality

<table>
<thead>
<tr>
<th>Evidence Quality</th>
<th>Preponderance of Benefit or Harm</th>
<th>Balance of Benefit and Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Well-designed randomized controlled trials (RCTs) or diagnostic studies on relevant population</td>
<td>Strong recommendation</td>
<td>Option</td>
</tr>
<tr>
<td>B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies</td>
<td>Recommendation/Strong Recommendation</td>
<td></td>
</tr>
<tr>
<td>C. Observational studies (case-control and cohort design)</td>
<td>Recommendation</td>
<td></td>
</tr>
<tr>
<td>D. Expert opinion, case reports, reasoning from first principles</td>
<td>Option</td>
<td>No Recommendation</td>
</tr>
<tr>
<td>X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm</td>
<td>Recommendation/Strong Recommendation</td>
<td></td>
</tr>
</tbody>
</table>

Note: Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is carried out leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation.

Definitions and Recommendation Implications

<table>
<thead>
<tr>
<th>Statement</th>
<th>Definition</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>A strong recommendation in favor of a particular action is made when the anticipated benefits exceed the anticipated harms.</td>
<td>Clinicians should follow</td>
</tr>
<tr>
<td>Statement</td>
<td>Definition</td>
<td>Implication</td>
</tr>
<tr>
<td>-----------</td>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td>recommendation</td>
<td>of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.</td>
<td>a strong recommendation unless a clear and compelling rationale for an alternative approach is present.</td>
</tr>
<tr>
<td>Recommendation</td>
<td>A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.</td>
<td>Clinicians would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.</td>
</tr>
<tr>
<td>Option</td>
<td>Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.</td>
<td>Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.</td>
</tr>
<tr>
<td>No recommendation</td>
<td>No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.</td>
<td>Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.</td>
</tr>
</tbody>
</table>

Note: It should be noted that because childhood T2DM is a relatively recent medical phenomenon, there is a paucity of evidence for many or most of the recommendations provided. In some cases, supporting references for a specific recommendation are provided that do not deal specifically with childhood T2DM, such as T1DM, childhood obesity, or childhood "prediabetes," or that were not included in the original comprehensive search. Committee members have made every effort to identify those references that did not affect or alter the level of evidence for specific recommendations.

Clinical Algorithm(s)
None provided

Scope

Disease/Condition(s)
Type 2 Diabetes Mellitus (T2DM)

Note: This document and its recommendations do not pertain to patients with impaired fasting plasma glucose (100–125 mg/dL) or impaired glucose tolerance (2- hour oral glucose tolerance test plasma glucose: 140–200 mg/dL) or isolated insulin resistance.

Guideline Category
Counseling
Management
Prevention
Treatment

Clinical Specialty
Endocrinology
Intended Users
Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

Guideline Objective(s)

To provide evidence-based recommendations and assist clinicians in decision-making on managing 10- to 18-year-old patients in whom type 2 diabetes mellitus (T2DM) has been diagnosed

Target Population

Patients 10 years to less than 18 years of age with type 2 diabetes mellitus (T2DM)

Interventions and Practices Considered

1. Insulin therapy for patients with:
   - Blood glucose (BG) concentrations ≥250 mg/dL or
   - Hemoglobin A1c (HbA1c) is >9%
2. Lifestyle modification program (including nutrition and physical activity) and metformin
3. Monitor HbA1c concentrations every 3 months
4. Monitor finger-stick BG concentrations in those who
   - Are taking insulin or other medications with risk of hypoglycemia
   - Changing diabetes treatment regimen
   - Have not met treatment goals
   - Have incurrent illnesses
5. Nutrition counseling
6. Encourage patients to engage in moderate-to-vigorous exercise for 60 minutes/day
7. Limit nonacademic screen time to less than 2 hours/day

Major Outcomes Considered

- Hemoglobin A1c (HbA1c)
- Blood glucose (BG)
- Weight loss/gain
- Lipid profile
- Insulin sensitivity
Adverse effects of medication
Cardiovascular health
Microvascular complications
Progression of disease and deterioration
Coma
Death

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

A literature search was performed in Medline, the Cochrane Collaboration, and Embase. Medical Subject Headings (MESH) terms used in various combinations in the search included diabetes, mellitus, type 2, type 1, treatment, prevention, diet, pediatric, T2DM, T1DM, NIDDM, metformin, lifestyle, RCT, meta-analysis, child, adolescent, therapeutics, control, adult, obese, gestational, polycystic ovary syndrome, metabolic syndrome, cardiovascular, dyslipidemia, men, and women. In addition, the Boolean operators NOT, AND, OR were included in various combinations. Articles addressing treatment of diabetes mellitus were prospectively limited to those that were published in English between January 1990 and June 2008, included abstracts, and addressed children between the ages of 120 and 215 months with an established diagnosis of T2DM. Studies in adults were considered for inclusion if >10% of the study population was 45 years of age or younger. The Medline search limits included the following: clinical trial; meta-analysis; randomized controlled trial; review; child: 6–12 years; and adolescent: 13–18 years. Additional articles were identified by review of reference lists of relevant articles and ongoing studies recommended by a technical expert advisory group. All articles were reviewed for compliance with the search limitations and appropriateness for inclusion in this document.

An additional literature search of Medline and the Cochrane Database of Systematic Reviews was performed in July 2009 for articles discussing recommendations for screening and treatment of 5 recognized comorbidities of T2DM: cardiovascular disease, dyslipidemia, retinopathy, nephropathy, and peripheral vascular disease. Search criteria were the same as for the search on treatment of T2DM, with the inclusion of the term 'type 1 diabetes mellitus.' Search terms included, in various combinations, the following: diabetes, mellitus, type 2, type 1, pediatric, T2DM, T1DM, NIDDM, hyperlipidemia, retinopathy, microalbuminuria, comorbidities, screening, RCT, meta-analysis, child, and adolescent. Boolean operators and search limits mirrored those of the primary search.

Number of Source Documents

Initially, 199 abstracts were identified for possible inclusion, of which 52 were retained for systematic review. An additional 336 abstracts were identified for possible inclusion, of which 26 were retained for systematic review.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

<table>
<thead>
<tr>
<th>Evidence Quality</th>
<th>Preponderance of Benefit or Harm</th>
<th>Balance of Benefit and Harm</th>
</tr>
</thead>
</table>

Evidence Quality
A. Well-designed randomized controlled trials (RCTs) or diagnostic studies on relevant population

<table>
<thead>
<tr>
<th>Evidence Quality</th>
<th>Preponderance of Benefit or Harm</th>
<th>Balance of Benefit and Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong recommendation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

C. Observational studies (case-control and cohort design)

D. Expert opinion, case reports, reasoning from first principles

X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm

<table>
<thead>
<tr>
<th>Evidence Quality</th>
<th>Preponderance of Benefit or Harm</th>
<th>Balance of Benefit and Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation/Strong Recommendation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evidence Quality</th>
<th>Preponderance of Benefit or Harm</th>
<th>Balance of Benefit and Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evidence Quality</th>
<th>Preponderance of Benefit or Harm</th>
<th>Balance of Benefit and Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evidence Quality</th>
<th>Preponderance of Benefit or Harm</th>
<th>Balance of Benefit and Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Recommendation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is carried out leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

An epidemiologist appraised the methodologic quality of the research before it was considered by the committee members.

The evidence-based approach to guideline development requires that the evidence in support of each key action statement be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is anticipated when the recommendation is followed. The AAP policy statement, "Classifying Recommendations for Clinical Practice Guidelines," was followed in designating levels of recommendation (see the "Rating Scheme for the Strength of the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The American Academy of Pediatrics (AAP) convened the Subcommittee on Management of Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents with the support of the American Diabetes Association, the Pediatric Endocrine Society (PES), the American Academy of Family Physicians (AAFP), and the Academy of Nutrition and Dietetics (formerly the American Dietetic Association). The subcommittee was co-chaired by 2 pediatric endocrinologists preeminent in their field and included experts in general pediatrics, family medicine, nutrition, Native American health, epidemiology, and medical informatics/guideline methodology.

Evidence was incorporated systematically into 6 key action statements about appropriate management facilitated by BRIDGE-Wiz software (Building Recommendations in a Developer's Guideline Editor; Yale Center for Medical Informatics).

Rating Scheme for the Strength of the Recommendations

Definitions and Recommendation Implications

<table>
<thead>
<tr>
<th>Statement</th>
<th>Definition</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong recommendation</td>
<td>A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.</td>
<td>Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is...</td>
</tr>
<tr>
<td>Statement</td>
<td>Recommendation</td>
<td>Definition</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------</td>
<td>------------</td>
</tr>
<tr>
<td><strong>Recommendation</strong></td>
<td>A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.</td>
<td>prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.</td>
</tr>
<tr>
<td><strong>Option</strong></td>
<td>Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.</td>
<td>Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.</td>
</tr>
<tr>
<td><strong>No recommendation</strong></td>
<td>No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.</td>
<td>Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.</td>
</tr>
</tbody>
</table>

Note: It should be noted that because childhood T2DM is a relatively recent medical phenomenon, there is a paucity of evidence for many or most of the recommendations provided. In some cases, supporting references for a specific recommendation are provided that do not deal specifically with childhood T2DM, such as T1DM, childhood obesity, or childhood "prediabetes," or that were not included in the original comprehensive search. Committee members have made every effort to identify those references that did not affect or alter the level of evidence for specific recommendations.

**Cost Analysis**

A formal cost analysis was not performed and published cost analyses were not reviewed.

**Method of Guideline Validation**

External Peer Review

Internal Peer Review

**Description of Method of Guideline Validation**

A draft version of this clinical practice guideline underwent extensive peer review by 8 groups within the American Academy of Pediatrics (AAP), the American Diabetes Association (ADA), Pediatric Endocrine Society (PES), American Academy of Family Physicians (AAFP), and the Academy of Nutrition and Dietetics. Members of the subcommittee were invited to distribute the draft to other representatives and committees within their specialty organizations. The resulting comments were reviewed by the subcommittee and incorporated into the guideline, as appropriate.

The Guidelines Review Group at Yale Center for Medical Informatics provided feedback on a late draft of these recommendations, using the GuideLine Implementability Appraisal.

**Evidence Supporting the Recommendations**

**Type of Evidence Supporting the Recommendations**

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

**Benefits/Harms of Implementing the Guideline Recommendations**
Potential Benefits

Appropriate management and treatment of children and adolescents with newly diagnosed type 2 diabetes mellitus (T2DM)

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

Insulin Therapy

- Potential for hypoglycemia
- Insulin-induced weight gain
- Cost
- Patient discomfort from injection
- Necessity for blood glucose (BG) testing
- More time required by the health care team for patient training

Metformin Therapy

- Gastrointestinal adverse effects or potential for lactic acidosis and vitamin B₁₂ deficiency
- Cost of medications
- Cost to administer
- Need for additional instruction about medication
- Self-monitoring blood glucose (SMBG)
- Perceived difficulty of insulin use
- Possible metabolic deterioration if type 1 diabetes mellitus (T1DM) is misdiagnosed and treated as type 2 diabetes mellitus (T2DM)
- Potential risk of lactic acidosis in the setting of ketosis or significant dehydration

Note: It should be noted that there are been no cases reported of vitamin B₁₂ deficiency or lactic acidosis with the use of metformin in children.

Monitoring Hemoglobin A1c (HbA1c) Concentrations

- Potential for hypoglycemia from overintensifying treatment to reach HbA1c target goals
- Cost of frequent testing and medical consultation
- Possible patient discomfort

Monitoring Finger-Stick BG Concentrations

- Patient discomfort
- Cost of materials

Nutrition Counseling

- Costs of nutrition counseling
- Inadequate reimbursement of clinicians' time
- Lost opportunity costs vis-à-vis time and resources spent in other counseling activities

Exercise and Limiting Screen Time

- Cost for patient of counseling, food, and time
- Costs for clinician in taking away time that could be spent on other activities
- Inadequate reimbursement for clinician's time

Note: Certain older or more debilitated patients with T2DM may be restricted in the amount of moderate-to-vigorous exercise they can perform safely.

Qualifying Statements
Qualifying Statements

- The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.
- This clinical practice guideline is not intended to replace clinical judgment or establish a protocol for the care of all children with type 2 diabetes mellitus (T2DM), and its recommendations may not provide the only appropriate approach to the management of children with T2DM. Providers should consult experts trained in the care of children and adolescents with T2DM when treatment goals are not met or when therapy with insulin is initiated.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)


Adaptation

Not applicable: The guideline was not adapted from another source.
Date Released
2013 Feb

Guideline Developer(s)
American Academy of Pediatrics - Medical Specialty Society

Source(s) of Funding
The American Academy of Pediatrics has neither solicited nor accepted any commercial involvement in the development of the content of this publication.

Guideline Committee
Subcommittee on Management of Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents

Composition of Group That Authored the Guideline

Committee Members: Kenneth Claud Copeland, MD, FAAP (Co-chair); Janet Silverstein, MD, FAAP (Co-chair); Kelly Roberta Moore, MD, FAAP; Greg Edward Prazar, MD, FAAP; Terry Raymer, MD, CDE; Richard N. Shiffman, MD, FAAP; Shelley C. Springer, MD, MBA, FAAP; Meaghan Anderson, MS, RD, LD, CDE; Stephen J. Spann, MD, FAAFP, MBA; Vidhu V. Thaker, MD, FAAP

Consultant: Susan K. Flinn, MA

Staff: Caryn Davidson, MA

Financial Disclosures/Conflicts of Interest
All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the Board of Directors.

- Janet Silverstein, MD, Co-chair — Endocrinology and American Diabetes Association Liaison (small grants with Pfizer, Novo Nordisk, and Lilly; grant review committee for Genentech; was on an advisory committee for Sanofi Aventis, and Abbott Laboratories for a 1-time meeting); published research related to type 2 diabetes.
- Kelly Roberta Moore, MD, General Pediatrics, Indian Health, AAP Committee on Native American Child Health Liaison (board member of the Merck Company Foundation Alliance to Reduce Disparities in Diabetes. Their national program office is the University of Michigan's Center for Managing Chronic Disease.)
- Greg Edward Prazar, MD, General Pediatrics (no conflicts)
- Terry Raymer, MD, CDE, Family Medicine, Indian Health Service (no conflicts)
- Richard N. Shiffman, MD, Partnership for Policy Implementation Informatician, General Pediatrics (no conflicts)
- Shelley C. Springer, MD, MBA, Epidemiologist (no conflicts)
- Meaghan Anderson, MS, RD, LD, CDE, Academy of Nutrition and Dietetics Liaison (formerly a Certified Pump Trainer for Animas)
- Stephen J. Spann, MD, MBA, American Academy of Family Physicians Liaison (no conflicts)
- Vidhu V. Thaker, MD QuIIN Liaison, General Pediatrics (no conflicts)
- Susan K. Flinn, MA, Medical Writer (no conflicts)

Guideline Status
This is the current release of the guideline.
All clinical reports and policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

Guideline Availability


Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

Availability of Companion Documents

The following are available:


Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on March 22, 2013. This summary was updated by ECRI Institute on April 15, 2016 following the U.S. Food and Drug Administration advisory on Metformin-containing Drugs.

Copyright Statement

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions. Please contact the Permissions Editor, American Academy of Pediatrics (AAP), 141 Northwest Point Blvd, Elk Grove Village, IL 60007.

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouse® (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.