The Evolution of Care Recommendations for Older and Complex Patients with Diabetes: Implications for Measuring Quality and Attaining Value

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CHSOR Seminar
Johns Hopkins University
February 9, 2017
Outline

• Background: Diabetes and Aging
• Translational Research and Health Policy
• Recent clinical trials and observational studies
• Evolution of care recommendations
• Implications for efforts to improve diabetes care by CMS programs
Background: Diabetes and Aging
Prevalence of Diagnosed & Undiagnosed Diabetes by Age, NHANES, 1999–2002

Projected Direct Medicare Spending on Diabetes and Its Complications for Different Cohorts, 2009-2034

Diabetes Increases Risk of Adverse Health Outcomes


• Cardiovascular events  \((Lancet 1997;350(Suppl 1):S14-S19)\)

• Microvascular events  \((Am J Med 1986;81:837-42)\)

• Geriatric conditions
  – Dementia  \((Diabet Med 1999;16:93-112)\)
  – Depression  \((Diabetes Care 2001 June;24:1069-78)\)

• Functional decline  \((Diabetes Care 2002; Jan; 25(1); 61-7)\)
Translational Research and Health Policy
Traditional Translational Research Model

T1
From Gene Discovery to Health Application

T2
From Health Application to Evidence-Based Guideline

T3
From Guideline to Health Practice

T4
From Health Practice to Impact

Health Policy Has Strong Influence on Practice

- **T1**: From Gene Discovery to Health Application
- **T2**: From Health Application to Evidence-Based Guideline
- **T3**: From Guideline to Health Practice
- **T4**: From Health Practice to Impact

For Older Patients, Policy Decisions Preceded Research

• In U.S., we have guaranteed coverage of diabetes care for the oldest and sickest

• Historical events
  – Medicare (1966)
  – ESRD covered by Medicare (1972)
  – Self-monitoring blood glucose (1997)

• Diabetes: poster child of chronic diseases
  – Best practices assumed to be fixed
General Population Goals Seared into Minds of MDs, Policymakers

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Recommended Target</th>
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<tbody>
<tr>
<td>Glucose control (A1C)</td>
<td>&lt;7.0%</td>
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<tr>
<td>Blood pressure</td>
<td>&lt;130/80 mm Hg</td>
</tr>
<tr>
<td>Cholesterol (LDL cholesterol)</td>
<td>&lt;100 mg/dl</td>
</tr>
</tbody>
</table>

Standards of Medical Care. Diabetes Care 2011
Historical Goals Follow General Framework for Glycemic Control Decision

A1C < 8%

Course of Diabetes with A1C < 8%

Health Outcomes

A1C < 7%

Course of Diabetes with A1C < 7%

Health Outcomes
Evidence from Past Decade* – Need to Individualize

Subgroup 1 (e.g., younger)

- A1C < 8%
  - Course of Diabetes with A1C < 8%
  - Health Outcomes

- A1C < 7%
  - Course of Diabetes with A1C < 7%
  - Health Outcomes

Subgroup 2 (e.g., older)

- A1C < 8%
  - Course of Diabetes with A1C < 8%
  - Health Outcomes

- A1C < 7%
  - Course of Diabetes with A1C < 7%
  - Health Outcomes

Glycemic Control in Clinical Trials
Trials of Glucose Lowering Have Excluded Older, Sicker Patients

- United Kingdom Prospective Diabetes Study
  - Newly diagnosed diabetes
  - 26-65 years of age at baseline
  - Excluded with prior cardiovascular event, high creatinine, heart failure

- Applying UKPDS exclusions, 49% of patients with new onset diabetes would be excluded

- Among 7 major trials of glucose lowering, 39% of type 2 population would be excluded

UKPDS – Time to Benefit and Legacy Effect

Intervention Trial
Median follow-up 10.0 years

- RR = 0.88 (0.79-0.99)
- P = 0.029

Intervention Trial + Post-trial monitoring
Median follow-up 16.8 years

- RR = 0.91 (0.83-0.99)
- P = 0.040

## Recent Diabetes Trials (2008)

<table>
<thead>
<tr>
<th></th>
<th>ACCORD</th>
<th>ADVANCE</th>
<th>VADT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, mean</strong></td>
<td>62.2</td>
<td>66</td>
<td>60.4</td>
</tr>
<tr>
<td><strong>Duration of DM</strong></td>
<td>10 yrs (median)</td>
<td>8 yrs (mean)</td>
<td>11.5 yrs (mean)</td>
</tr>
<tr>
<td><strong>Achieved A1C</strong></td>
<td>7.5% vs. 6.4%</td>
<td>7.3% vs. 6.5%</td>
<td>8.4% vs. 6.9%</td>
</tr>
<tr>
<td><strong>Achieved A1C</strong></td>
<td>(I vs. S)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Follow-up time</strong></td>
<td>3.5 years</td>
<td>5 years</td>
<td>5 years</td>
</tr>
<tr>
<td><strong>Selected Mortality Results</strong></td>
<td>257 deaths/5128 (intensive)</td>
<td>No excessive deaths</td>
<td>More sudden deaths in intensive arm (11/4) but not significant</td>
</tr>
</tbody>
</table>

Impact of intensive glucose-lowering therapy by coronary calcification (VADT)

Summary of Clinical Trials

- Trials have typically excluded older, sicker pts
- Intensive glucose control reduces risk of microvascular events
- Intensive glucose control reduces risk of cardiovascular events but only in patients with new onset diabetes and long life expectancy (Legacy Effect)
- Trials results hint at subgroup differences
  - Duration of diabetes (0-10 years, >10 years)
  - Cardiovascular disease (yes, no)
Glycemic Control and Patient Subgroups Outside of Clinical Trials
# Characteristics of geriatric diabetes population, U.S. 2009-2010

<table>
<thead>
<tr>
<th>Age Group</th>
<th>60-69</th>
<th>70-79</th>
<th>≥80</th>
<th>≥65</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>1440</td>
<td>1030</td>
<td>549</td>
<td>2254</td>
</tr>
<tr>
<td>Duration of Diabetes, mean (SE)</td>
<td>11.6 (0.36)</td>
<td>14.8 (0.43)</td>
<td>17.0 (0.87)</td>
<td>14.7 (0.32)</td>
</tr>
<tr>
<td>&lt;5 years, % (SE)</td>
<td>29.1 (1.43)</td>
<td>21.3 (1.44)</td>
<td>21.6 (2.25)</td>
<td>23.0 (1.05)</td>
</tr>
<tr>
<td>5- &lt;10 years</td>
<td>23.5 (1.06)</td>
<td>21.4 (1.60)</td>
<td>17.9 (2.22)</td>
<td>20.4 (1.13)</td>
</tr>
<tr>
<td>≥10 years</td>
<td>47.4 (1.59)</td>
<td>57.3 (1.68)</td>
<td>60.5 (2.51)</td>
<td>56.6 (1.25)</td>
</tr>
</tbody>
</table>

*Source: National Health Interview Survey*
Figure Legend:
Rates of Estimated Hospital Admissions for Hyperglycemia and Hypoglycemia Among Medicare Beneficiaries With Diabetes Mellitus, 1999 to 2010. The circles and diamonds indicate observed values; the lines represent the smoothed trend over time.
## Glycemic Control and Mortality Risk in the Elderly (Diabetes and Aging Study)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Baseline Glycosylated Hemoglobin</th>
<th>HR</th>
<th>95% CI</th>
<th>HR</th>
<th>95% CI</th>
<th>HR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;6.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60-69</td>
<td></td>
<td>1</td>
<td>0.79-1.07</td>
<td>0.83</td>
<td>0.70-0.99</td>
<td>0.91</td>
<td>0.74-1.11</td>
</tr>
<tr>
<td>70-79</td>
<td></td>
<td>1</td>
<td>0.75-0.92</td>
<td>0.83</td>
<td>0.75-0.96</td>
<td>0.86</td>
<td>0.73-1.01</td>
</tr>
<tr>
<td>80+</td>
<td></td>
<td>1</td>
<td>0.74-0.93</td>
<td>0.83</td>
<td>0.72-0.95</td>
<td>1.05</td>
<td>0.86-1.27</td>
</tr>
</tbody>
</table>

A1C-Mortality Relationship in UK Diabetes Population

Metformin+Sulfonylurea

Insulin

Implications of Being Sicker – Expected Benefits of Glucose Control Decline

A. New-onset diabetes

Reduction in Cardiovascular Risk Associated with A1C ≤6.5% by TIBI Subgroup

<table>
<thead>
<tr>
<th>TIBI Score</th>
<th>Unadjusted Hazard Ratio (95% CI)</th>
<th>Adjusted Hazard Ratio (95% CI)</th>
<th>P for interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;12</td>
<td>0.58 (0.41, 0.82)</td>
<td>0.60 (0.42, 0.85)</td>
<td>0.036</td>
</tr>
<tr>
<td>≥12</td>
<td>0.93 (0.68, 1.26)</td>
<td>0.92 (0.68, 1.25)</td>
<td></td>
</tr>
</tbody>
</table>

TIBI = Total Illness Burden Index
Models adjusted for age and sex

Classifying Older Adults with Diabetes by Comorbid Conditions (NSHAP)

Laiteerapong N, Iveniuk J, John P, Das A, Laumann EO, Huang ES.
Prev Chronic Dis. 2012 May;9:E100.
# Clinical Complexity Groups (HRS)

<table>
<thead>
<tr>
<th>Health Status Groups</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Relatively Healthy Group</td>
<td>No comorbidities, or comorbidities constrained to osteoarthritis and hypertension, and with no impairments.</td>
</tr>
<tr>
<td>Difficulties with Diabetes Self-Management</td>
<td>Multiple comorbidities and/or any one of the following: mild cognitive impairment, poor vision, and 2 or more IADL impairments.</td>
</tr>
<tr>
<td>A Limited Benefit Group</td>
<td>Poorest health status, with one or more of the following: moderate to severe cognitive impairment, 2 or more ADL dependencies, and/or residence in a long-term nursing facility.</td>
</tr>
</tbody>
</table>

Summary of Patient Subgroups (Part I)

- A1C-outcome relationships are similar by age groups (60s, 70s, 80+)
- A1C-mortality curve has U-shaped relationship in clinical practice populations
Summary of Patient Subgroups (Part II)

• Comorbid illness and functional impairment may help identify subgroups unlikely to benefit from intensive glucose control
  – Competing mortality risk

• Multiple schemes for identifying subgroups
  – Comorbidity alone (TIBI, NSHAP)
  – Comorbidity and functional status (Chicago)
  – Comorbidity, functional status, self-care (HRS)
Evolution of Diabetes Care Guidelines for Older Patients
## General Population Diabetes Care Goals

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<th>Recommended Target</th>
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Standards of Medical Care. Diabetes Care 2011
# California Healthcare Foundation/AGS - 2003

<table>
<thead>
<tr>
<th>Preventive care</th>
<th>Target goals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-Frail</td>
</tr>
<tr>
<td>Glucose</td>
<td>A1C&lt;7%</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>SBP&lt;130 mm Hg</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Goals unchanged</td>
</tr>
<tr>
<td>Aspirin prophylaxis</td>
<td>Goal unchanged</td>
</tr>
</tbody>
</table>

## ADA Consensus Panel Framework

<table>
<thead>
<tr>
<th>HEALTH STATUS</th>
<th>RATIONALE</th>
<th>REASONABLE A1C GOAL</th>
<th>FASTING OR PREPRANDIAL GLUCOSE (mg/dl)</th>
<th>BEDTIME GLUCOSE (mg/dl)</th>
<th>BLOOD PRESSURE (mmhg)</th>
<th>LIPIDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>Longer life expectancy</td>
<td>&lt;7.5%</td>
<td>90 – 130</td>
<td>90 – 150</td>
<td>&lt;140/80</td>
<td>Statin (unless contraindicated or not tolerated)</td>
</tr>
<tr>
<td>Complex Intermediate</td>
<td>Intermediate life expectancy; high treatment burden; hypoglycemia vulnerability; fall risk</td>
<td>&lt;8.0%</td>
<td>90 – 150</td>
<td>100 – 180</td>
<td>&lt;140/80</td>
<td>Statin (unless contraindicated or not tolerated)</td>
</tr>
<tr>
<td>Very Complex Poor Health</td>
<td>Limited life expectancy; treatment benefit uncertain</td>
<td>&lt;8.5%</td>
<td>100 – 180</td>
<td>110 – 200</td>
<td>&lt;150/90</td>
<td>Consider benefit with statin; (secondary prevention &gt; primary)</td>
</tr>
</tbody>
</table>

## Comparison of Guidelines

<table>
<thead>
<tr>
<th>Description of patient stratum</th>
<th>A1C goal</th>
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<th>A1C goal</th>
<th>Description of patient stratum</th>
<th>A1C goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>7.0-7.5%</td>
<td>None or very mild microvascular complications; life expectancy of 10-15 years</td>
<td>&lt;7.0%</td>
<td>Healthy (few co-existing chronic illnesses; intact cognitive and functional status)</td>
<td>&lt;7.5%</td>
<td>Without major comorbidities</td>
<td>7.0-7.5%</td>
</tr>
<tr>
<td>Moderate comorbidities</td>
<td>7.5-8.0%</td>
<td>Long duration of diabetes (&gt;10 years); requires combination drug regimen including insulin</td>
<td>&lt;8.0%</td>
<td>Complex/intermediate (examples: multiple co-existing chronic illnesses*, ≥2 instrumental ADL impairments, or mild-moderate cognitive impairment)</td>
<td>&lt;8.0%</td>
<td>Frail patients (dependent; multi-system disease; care home residency, including those with dementia)</td>
<td>7.6-8.5%</td>
</tr>
<tr>
<td>Multiple comorbidities</td>
<td>8.0-9.0%</td>
<td>Advanced microvascular complications and/or major comorbid illness; life expectancy &lt;5 years</td>
<td>8.0-9.0%</td>
<td>Very complex/poor health (examples: long term care, end stage chronic illnesses†, moderate-severe cognitive impairment, or ≥2 ADL dependencies)</td>
<td>&lt;8.5% ‡</td>
<td></td>
<td></td>
</tr>
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</table>
Choosing Wisely (AGS) - 2013

<table>
<thead>
<tr>
<th>Health Status</th>
<th>A1C Goal</th>
<th>Medication Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>7.0-7.5%</td>
<td>Avoid using medications to achieve A1C&lt;7.5%</td>
</tr>
<tr>
<td>Moderate comorbidity</td>
<td>7.5-8.0%</td>
<td></td>
</tr>
<tr>
<td>Multiple morbidities</td>
<td>8.0-9.0%</td>
<td></td>
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</table>
From: Potential Overtreatment of Diabetes Mellitus in Older Adults With Tight Glycemic Control

From: Potential Overtreatment of Diabetes Mellitus in Older Adults With Tight Glycemic Control

Efforts to Improve Diabetes Care by CMS Programs
Evidence-Based Medicine  Health Policy
Medicare’s Projects on Disease Management

- Six major demonstrations in past decade
  - Medicare Coordinated Care
  - Peikes, JAMA 2009; 301 (6): 603-618

- Interventions: Pt education, Monitoring, Communication, MDs

- 34 programs found, on average
  - No effect on hospital admissions
  - No effect on regular Medicare expenditures
Medicare’s Projects on Disease Management

• Concept – deliver chronic disease care better and complications will happen less

• Were the expectations for reductions in utilization and costs reasonable?
  – Timeframe reasonable? 3-4 years
  – Disconnected from natural history of chronic diseases like diabetes?
  – Where are cost savings going to be produced by ACOs, CMMI demos?
Physician Quality Reporting System (PQRS)

- 2006 Tax Relief and Health Care Act
- Physicians report on quality of care
- Incentive payment equal to 1.0% of the group practice’s total estimated Medicare Part B PFS
- PQRS = pay for reporting
- PQRS moving to pay for performance
Payment Policies and Programs

• Payment is going to be increasingly linked to quality of care
  – Repeal of the Sustainable Growth Rate, Reform of Physician Payments (MACRA)
  – Medicare ACOs/Pioneer ACOs
  – CMMI – Health Care Innovation Awards

• None of the policies/programs currently incorporate geriatric care guidelines
CMS Uses Diabetes Performance Measures Intended for General Populations

- Diabetes Performance Measures (e.g., Medicare ACOs)
  - Limited to 18-75 years of age
  - A1C>9.0%, measure of “poor” control
  - Composite measure
    - A1C<8.0%
    - BP<140/90
    - LDL<100
    - Non-smoking
    - Aspirin prophylaxis (when appropriate)
Problems with Current Measures

• Patients >75 left out (>50% of >65 pop)
• Can still lead to overly aggressive diabetes care because no lower limits
• Does not reward individualization
• Does not address multiple chronic conditions, prioritization
Other Problems - Perpetuation of Old Recommendations

• Performance measures change through a long consensus process

• Different players are involved in measuring, ensuring quality – have to reach all players
  – Quality Improvement Organizations
  – Chronic Disease Management
  – Insurance plans
  – Nurses, Diabetes Educators

• Care is segregated and performance measures differ across settings
Recommendation 1

• Stratify goals of care by health status
• Two or three strata based on comorbidity in claims
  – Healthy, complex, very complex
  – Use ADA Consensus Panel A1C and Blood Pressure Upper Thresholds
Recommendation 2

- Measure adverse effects of diabetes care
- Add measures for
  - Hypoglycemia – inpatient admission, ER visit
  - Overtreatment measure
    - A1C<6.0% with multiple glucose lowering medications
    - A1C<7.0% in patients at high risk for hypoglycemia
    - Archives IM; 2012;172(19):1510-1512
- Existing geriatric condition measures (e.g., falls) may help reduce overtreatment
- QIOs now starting hypoglycemia initiative
Recommendation 3

• Track inappropriate use of medications
  – Glyburide in elderly patients
  – Beers criteria medications
  – Polypharmacy
Recommendation 4

- Any evaluation of a Medicare program’s impact on diabetes should acknowledge new individualized care guidelines
  - CDC evaluated quality of diabetes care using both general population thresholds and individualized thresholds
Summary

- Older diabetes population growth is exponential
- Clinical trial evidence to guide diabetes care has been historically lacking
- Recent evidence has led to rec’s to individualize targets and treatments
- Without reform of quality measurement, we are on path to more collisions between evidence-based medicine and health policy
“Thank you for your article in this week’s JAMA. In my 79th year, I still try to keep up with medicine and was shocked to find myself included in the very old age group. Having T2D, very mild without complications, I am pleased to note that my physician said she will allow my A1C to go as high as 7.0% without further ado. Evidence based medicine is a wonderful thing! Thanks for your article from a very old physician.”
Funders

• NIDDK K24 DK105340
• NIDDK R01 DK081796
• NIA R01 AG030481
• Centers for Disease Control and Prevention U36 CCU319276
• American Diabetes Association (1-08-CR-25)
• The Retirement Research Foundation (2007-250)
• NIA K23 AG021963
• NIDDK P30 DK092949
• NIDDK P60 DK20595
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ACCESS
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Shared Decision Making Resources
- Nananda Col
Thank You

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