Comparison of Total Annual Direct Costs Among Swedish Residents with Poorly Controlled Type 1 Diabetes: Standard Care versus Real-Time Continuous Glucose Monitoring

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Background

- Poorly controlled T1DM ➡ increased risk for complications[1]
- Intensive diabetes therapy ➡ reduced risk[2,3]
- Many with T1DM do not maintain good glucose control[4,5]
- Self-monitoring of blood glucose (SMBG) provides only a “snapshot”
  - No information on rate or direction of change[6]
- Real-time continuous glucose monitoring (CGM) measures glucose levels continuously in real time and indicates rate and direction of change
  - Is more likely to detect excursions[6]
  - Aides treatment decision making[6]
  - Demonstrates significant improvements in A1c[7,8]
    - ► As early as 3 months from initiation
    - ► Without increasing hypoglycemia

1. International Diabetes Federation. *Diabetes Atlas, Third Edition*. Belgium: International Diabetes Federation; 2008.
2. DCCT Research Group. *N Engl J Med*. 1993;329:977-86.
3. Reichard P, et al. *N Engl J Med*. 1993;329:304-9.
4. Eeg-Olofsson K, et al. *Diabetes Care*. 2007;30:496-502.
5. Vincze G, et al. *Diabetes Educ.* 2004;30:112-25.
6. Burge MR, et al. *Diabetes Spectrum*. 2008;21:112-9.
7. Bergenstal RM, et al. *N Engl J Med* 2010;363:311-20.
8. JDRF CGM Study Group. *N Engl J Med* 2008;359:1464-76.

Sweden Health and Medical Service Act

Efficiency and Equity are Central to Sweden's Health Policy

Goals of Health and Medical Services

"Health and medical services are aimed at assuring the entire population of good health and of care on equal terms."

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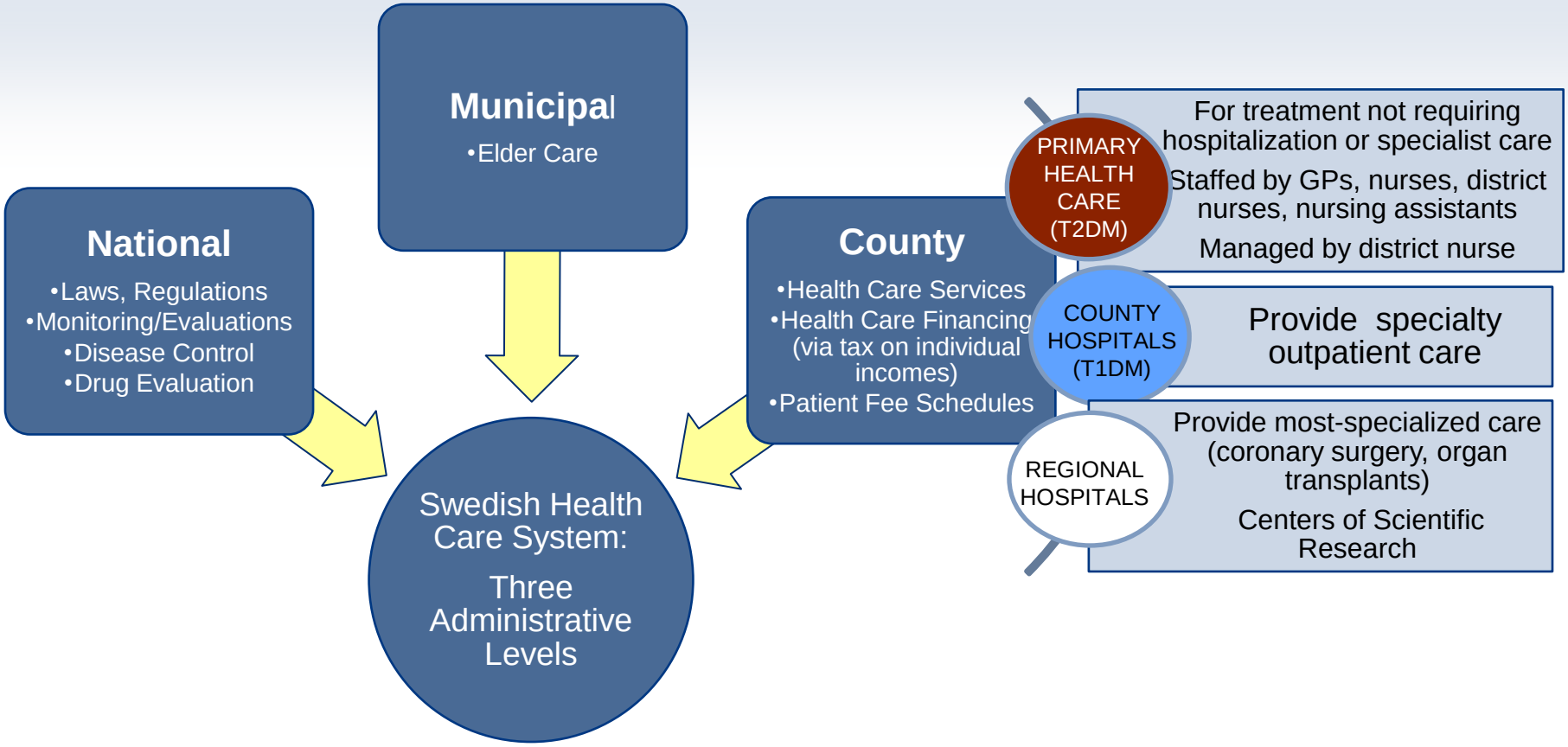
The Swedish Health Care System



In general, patient fees are:

- Outpatient County Visit: 150-200 SEK/Visit ($21-$27)
- Inpatient Stay: 80 SEK/Day ($11)
- Specialist Visit: 250-300 SEK/Visit ($34-$41)

Objective

Using decision-tree analysis, we sought to compare anticipated rates and costs of diabetes-related complications among a hypothetical group of Swedish residents with poorly controlled T1DM (A1c ≥9%) who receive CGM with intensive standard care versus intensive standard care alone

Model Assumptions and Data Sources

MODEL ASSUMPTIONS

- Country of analysis: Sweden
- Target population: Community residents with T1DM
- Venue of care: Outpatient setting
- Time horizon: 1 year
- Model approach: Decision-tree analysis
- Perspective: Swedish health care system
- All costs reflect direct health costs (no indirect)

DATA SOURCES

- **Clinical Parameters**
  - T1DM prevalence: Sweden National Board of Health and Welfare[1]
  - A1c breakdown: Swedish National Diabetes Registry[2]
  - Rates of A1c improvement by CGM versus standard care (SC): Randomized controlled trial[3]
  - Rates of microvascular complications: Stockholm Diabetes Intervention Study[4] and the Diabetes Complications and Control Trial[5]
  - Incidence of hypoglycemia requiring medical assistance: Observational study[6] and an extension of a randomized, controlled trial of CGM[7]
- **Economic Parameters**
  - Annual direct costs of diabetic complications: Published literature (see next slide)
  - Costs converted to USD and inflated to 2009 USD values (using Consumer Price Index – Medical Services Component)[8]

1. Socialstyrels. Diabetes. http://www.socialstyrelsen.se/medicinskvard/sjukdomar/endokrinasjukdomar/diabetes. Accessed September 29, 2009.
2. Eeg-Olofsson K, et al. *Diabetes Care*. 2007;30:496-502.
3. Deiss D, et al. *Diabetes Care*. 2006;29:2730-2.
4. Reichard P, et al. *N Engl J Med*. 1993;329:304-9.
5. The DCCT Research Group. *N Engl J Med*. 1993;329:977-86.
6. Bragd J, et al. *Diabet Med*. 2003;20:216-9.
7. JDRF Continuous Glucose Monitoring Study Group. *Diabetes Care*. 2009;32:2047-9.
8. Bureau of Labor Statistics. Consumer Price Index for 2009. http://data.bls.gov/cgi-bin/surveymost?cu . Accessed 11/20/09.

Sources: Annual Direct Costs of Diabetic Complications

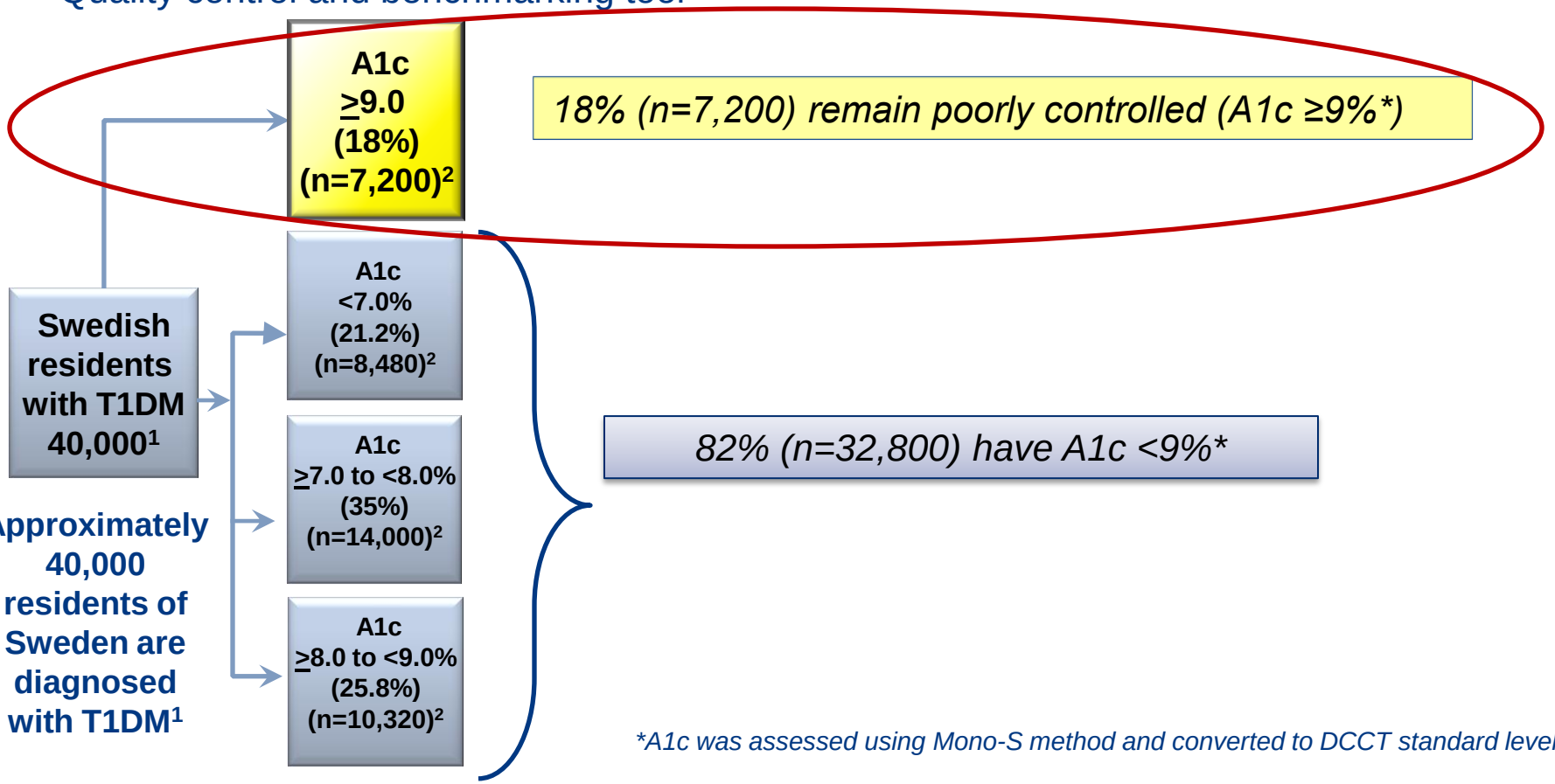
- **Serious Retinopathy**
  - Mean annual direct cost of blindness in Switzerland: CHF 13,098/patient in 1998[1] (2009 USD $31,142)
- **Nephropathy**
  - Population-based Norwegian study: 2% of persons with nephropathy have end-stage renal disease (ESRD) and are treated with hemodialysis[2]
    - ► Mean annual direct cost of hemodialysis in Sweden: SEK 517,092/patient in 2001[3] (2009 USD $71,945)
  - Patients with diabetic nephropathy were assumed to require additional treatment: mean annual direct cost $6,000/patient USD in 2009
- **Peripheral Neuropathy**
  - Incidence of lower-extremity amputation (LEA) in Sweden: 0.1% per patient per year[4]
  - Patients with poorly controlled T1DM have a 3- to 5-fold greater risk for amputation[5]
    - ► Incidence of amputation: 0.1% for those with A1c <9% and 0.3% for those with A1c ≥9%
  - Mean direct medical cost of LEA among diabetics in Sweden: $52,000/patient in 1996 USD[6] (2009 USD $89,617)
- **Hypoglycemia**
  - Mean annual direct cost of hypoglycemia (requiring medical assistance) in Sweden: €335/patient in 2005[7] (2009 USD $320)

1. Meads C, Hyde C. *Br J Ophthalmol* 2003;87:1201–1204
2. Hallan SI. *J Am Soc Nephrol*. 2006;17:2275-84.
3. Jonsson L, et al. *J Med Econ*. 2005;8:131-8.
4. Jonasson JM, et al. *Diabetes Care*. 2008;31:1536-40.
5. Moss SE, et al. *Diabetes Care.* 1999;22:951-9.
6. Eneroth M, et al. *Acta Orthop Scand.* 1996;67:459-65.
7. Jonsson L, et al. *Value Health*. 2006;9:193-8.

Estimated Rates of Poorly Controlled T1DM in Sweden

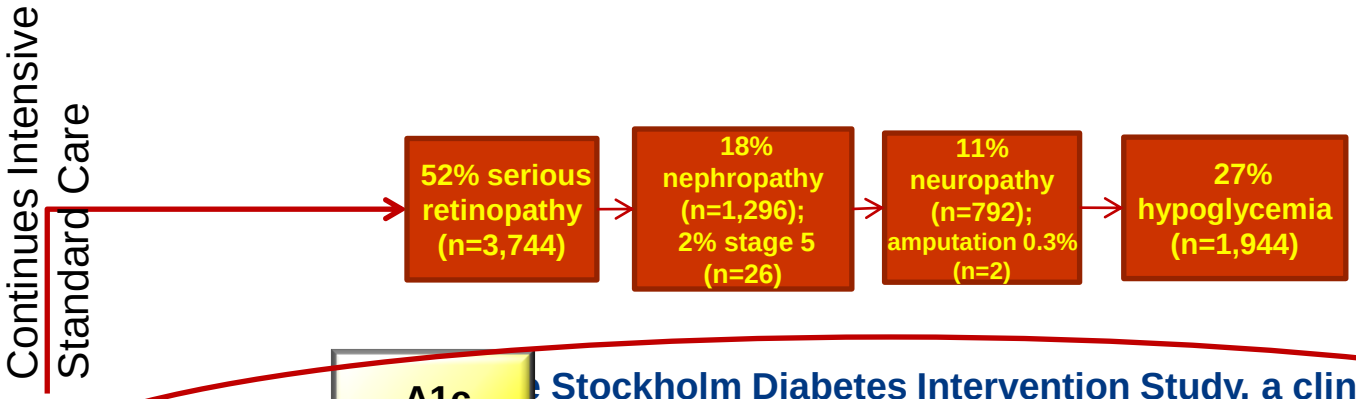
Data from the Swedish National Diabetes Register (NDR)[1]

- Among the largest national diabetes registers in the world
- Initiated in 1996 by Swedish Society for Diabetology
- Quality control and benchmarking tool



*A1c was assessed using Mono-S method and converted to DCCT standard levels

1. www.socialstyrelsen.se/publicerat. Accessed September 4, 2010.
2. Eeg-Olofsson K, et al. *Diabetes Care*. 2007;30:496-502.



A1c ≥9.0 (18%) (n=7,200)

e Stockholm Diabetes Intervention Study, a clinical trial of lish patients with T1DM, after 7.5 years, among those ving standard care:[1]

- 52% developed serious retinopathy[1]
- 18% developed nephropathy[1]
  - Dialysis rate among patients with kidney disease in Norway is 2%[2]
- 11% developed peripheral neuropathy[1]
  - In the Swedish NDR, 0.3% of patients with T1DM and A1c ≥9% undergo lower limb amputations annually[3]
- Hypoglycemia
  - 27% per year among T1DM in Sweden responding to clinic questionnaire[4]
    - "Episode for which help from another person was required"

1. Reichard P. *N Engl J Med.* 1993;329:304-9.
2. Hallan SI, et al. *J Am Soc Nephrol.* 2006;17:2275-84.
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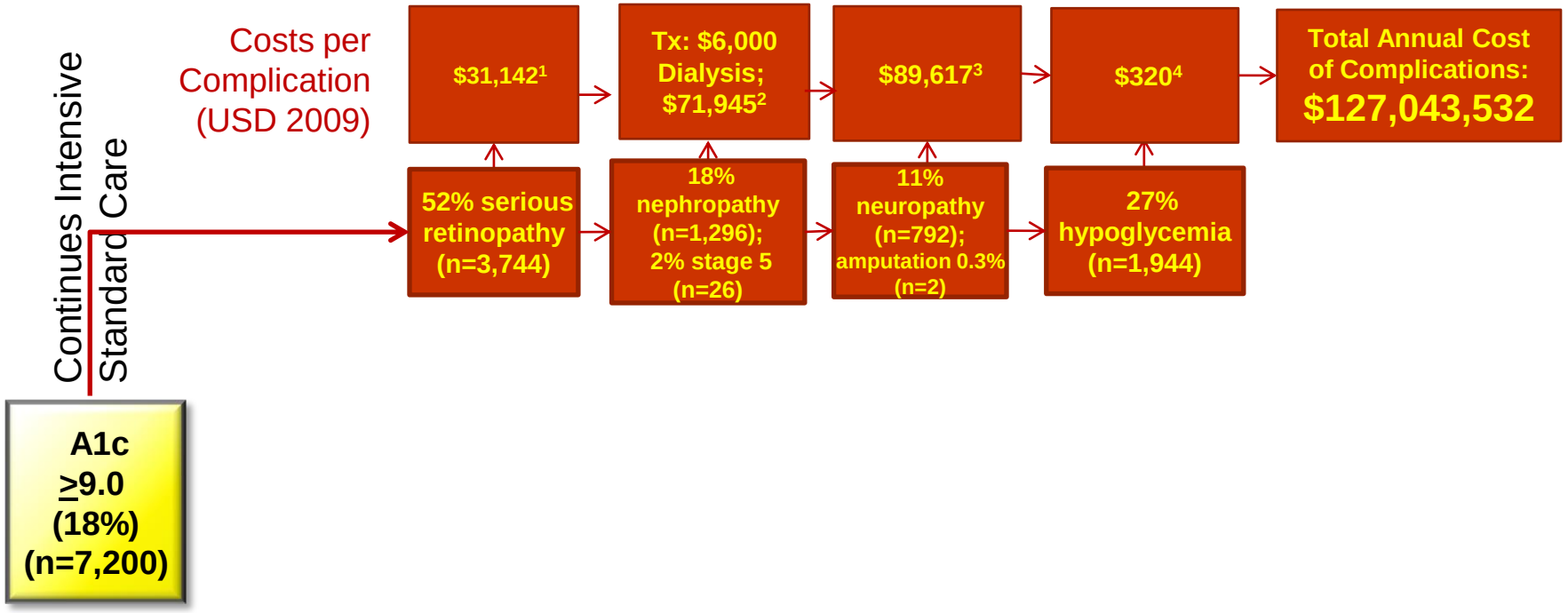

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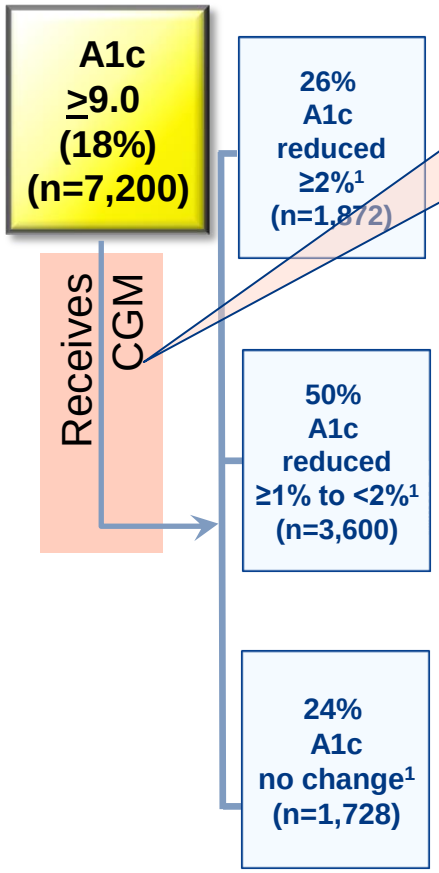
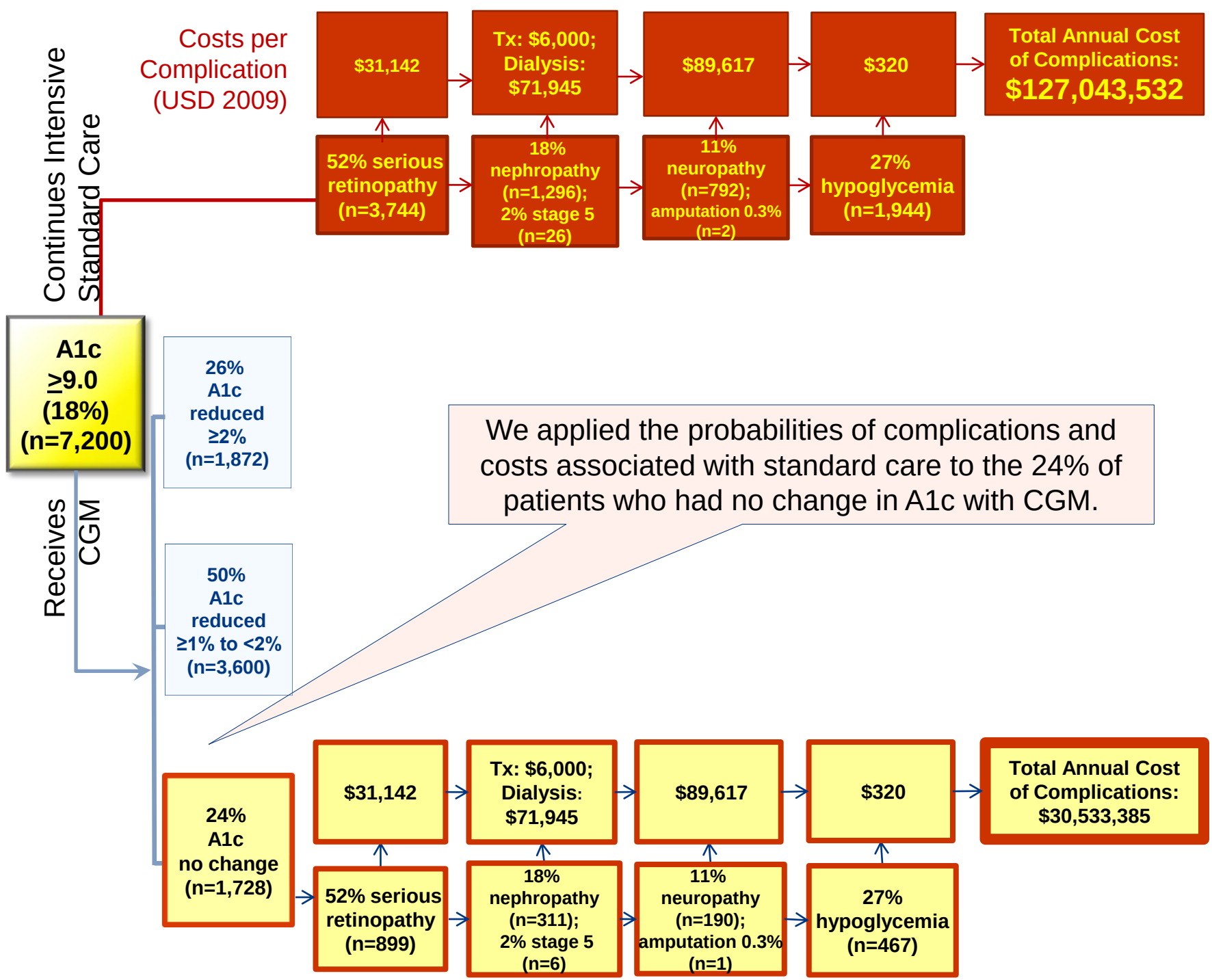
Next, we modeled the rates of complications and their costs for poorly controlled patients who received CGM.

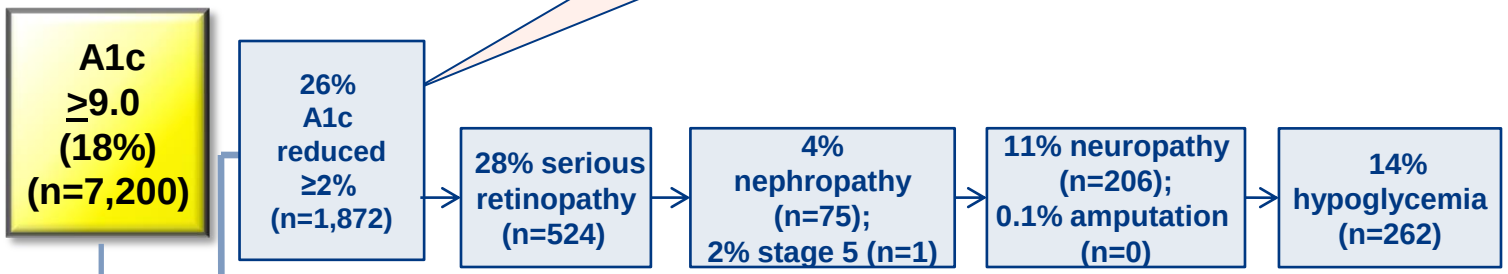


- **Deiss et al. randomly assigned subjects with stable T1DM to real-time continuous glucose monitoring (CGM) or standard care alone[1]**
- **At baseline, patients had A1c levels ≥8.1% despite intensive treatment**
- **3 months after study initiation, among patients receiving CGM:**
  - **26% achieved A1c reduction of ≥2%**
  - **50% achieved A1C reduction of ≥1% to <2%**
  - **24% had no change in A1c**
- **We applied these findings to the 7,200 Swedish residents with A1c ≥9.0**

1. Deiss D, et al. *Diabetes Care.* 2006;29:2730-2.


Costs per Complication (USD 2009)
$31,142
Tx: $6,000; Dialysis: $71,945
$89,617
$320
Total Annual Cost of Complications: $127,043,532
52% serious retinopathy (n=3,744)
18% nephropathy (n=1,296); 2% stage 5 (n=26)
11% neuropathy (n=792); amputation 0.3% (n=2)
27% hypoglycemia (n=1,944)
Continues Intensive Standard Care
A1c ≥9.0 (18%) (n=7,200)
Receives CGM
26% A1c reduced ≥2% (n=1,872)
50% A1c reduced ≥1% to <2% (n=3,600)
24% A1c no change (n=1,728)
We applied the probabilities of complications and costs associated with standard care to the 24% of patients who had no change in A1c with CGM.
$31,142
Tx: $6,000; Dialysis: $71,945
$89,617
$320
Total Annual Cost of Complications: $30,533,385
52% serious retinopathy (n=899)
18% nephropathy (n=311); 2% stage 5 (n=6)
11% neuropathy (n=190); amputation 0.3% (n=1)
27% hypoglycemia (n=467)

We examined rates of complications and costs for patients who achieved ≥2% A1c improvement.



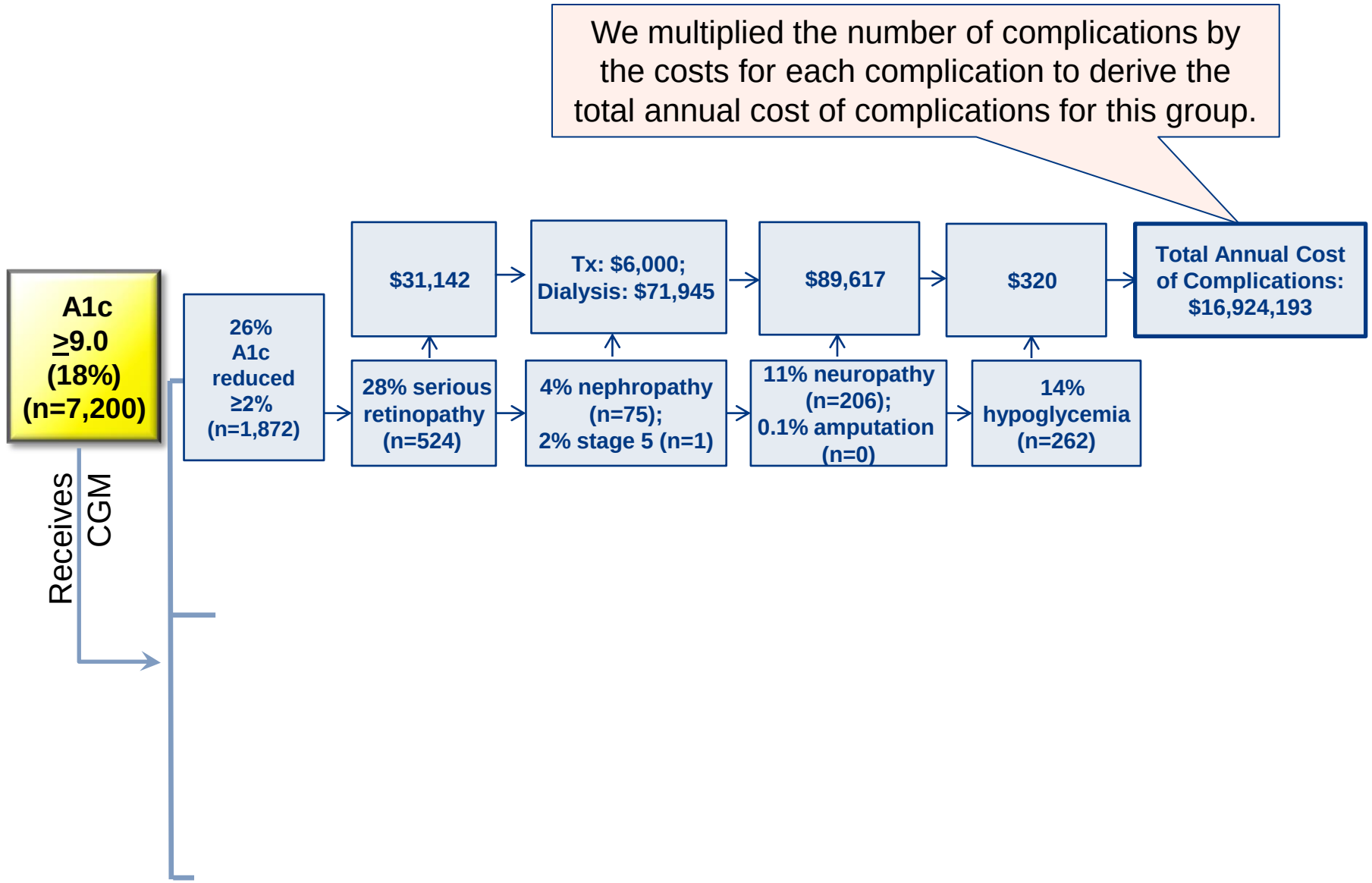
Receives CGM

In the Stockholm Diabetes Intervention Study,[1] a clinical trial of Swedish patients with T1DM, after 7.5 years, among those receiving intensive treatment whose A1c was reduced by ≥2%:

- **28% developed serious retinopathy[1]**
- **4% developed nephropathy[1]**
  - **Dialysis rate among patients with kidney disease in Norway is 2%[2]**
- **11% developed neuropathy[1]**
  - **In the Swedish NDR, 0.1% of patients with T1DM and A1c <9% undergo lower limb amputations annually[3]**

In an extension study of 83 adults with T1DM who received CGM for 6 months following a 6-month RCT of CGM, a hypoglycemic event (an event that required medical assistance) was experienced by 14% of patients over a period of 12 months[4]

1. Reichard P. *N Engl J Med*. 1993;329:304-9.
2. Hallan SI, et al. *J Am Soc Nephrol.* 2006;17:2275-84.
3. Jonasson JM, et al. *Diabetes Care.* 2008; 31:1536-40.
4. JDRF CGM Study Group, et al. *Diabetes Care*. 2009;32:2047-9.



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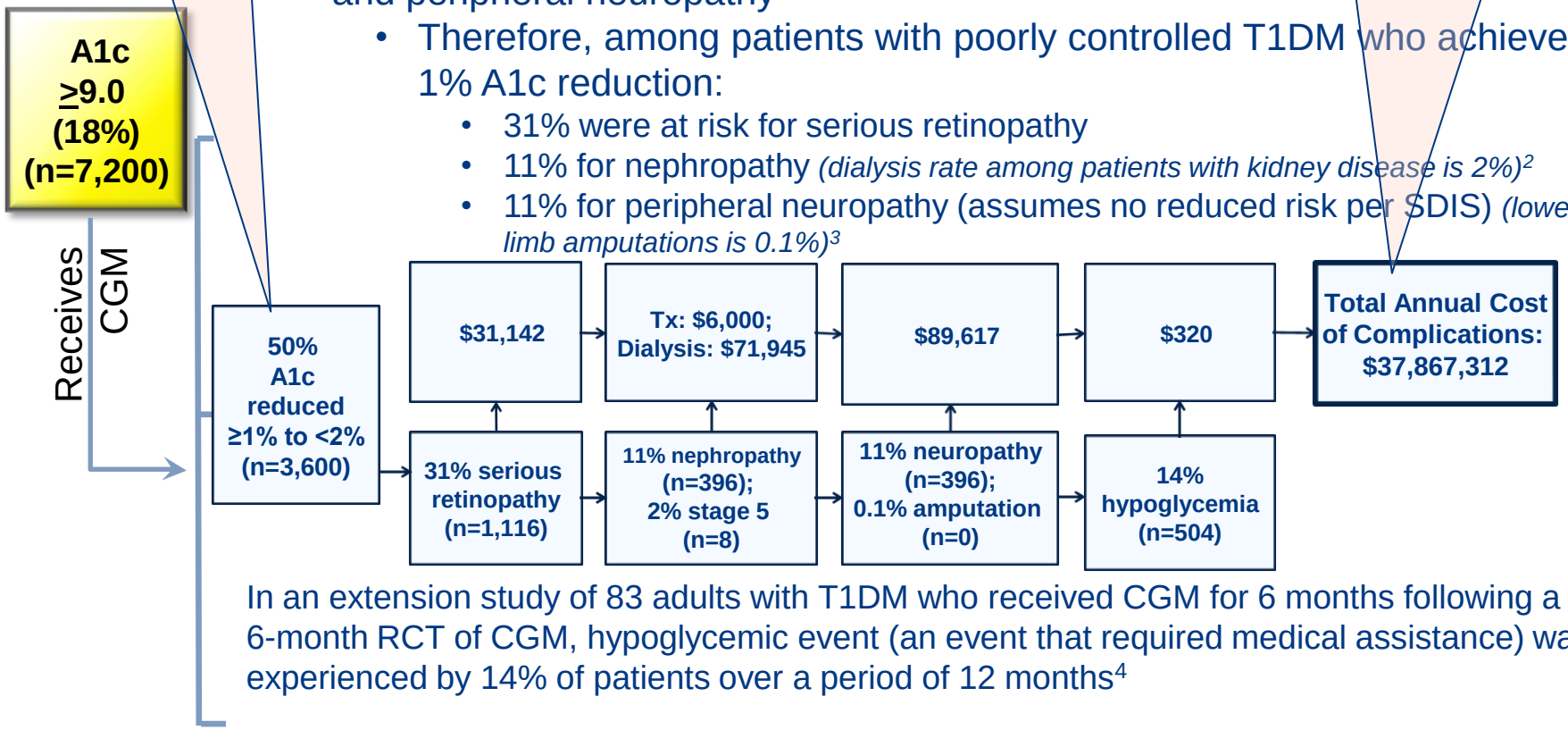
We then conducted the analysis for patients who achieved 1% A1c improvement.

We multiplied the number of complications by the costs for each complication to derive the total annual cost of complications for this group.

- The DCCT demonstrated that each 1% reduction in A1c was associated with a 40% decrease in the risk of serious retinopathy, nephropathy, and peripheral neuropathy[1]
  - Therefore, among patients with poorly controlled T1DM who achieve a 1% A1c reduction:
    - 31% were at risk for serious retinopathy
    - 11% for nephropathy *(dialysis rate among patients with kidney disease is 2%)*[2]
    - 11% for peripheral neuropathy (assumes no reduced risk per SDIS) *(lower limb amputations is 0.1%)*[3]



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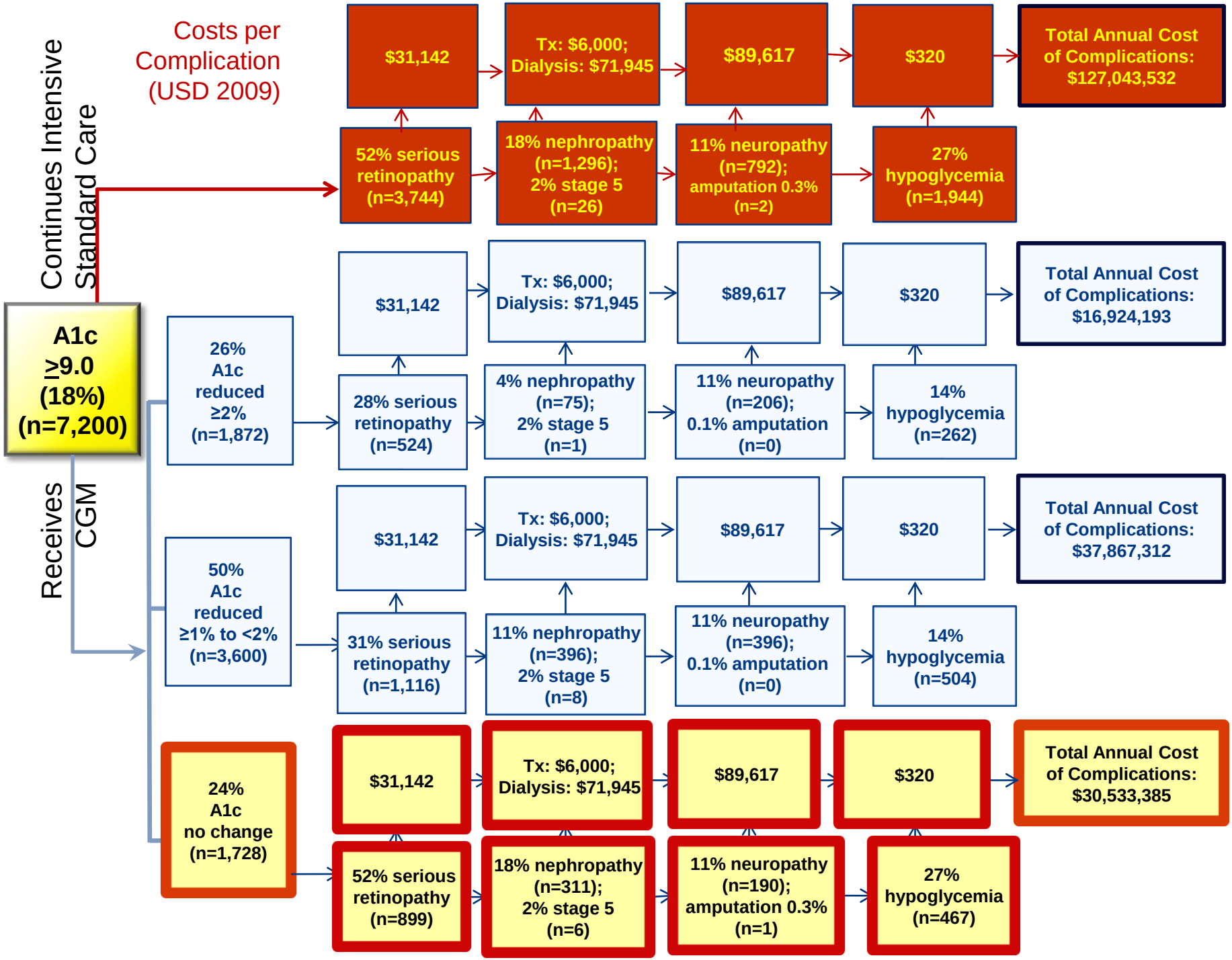
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24% A1c no change (n=1,728)
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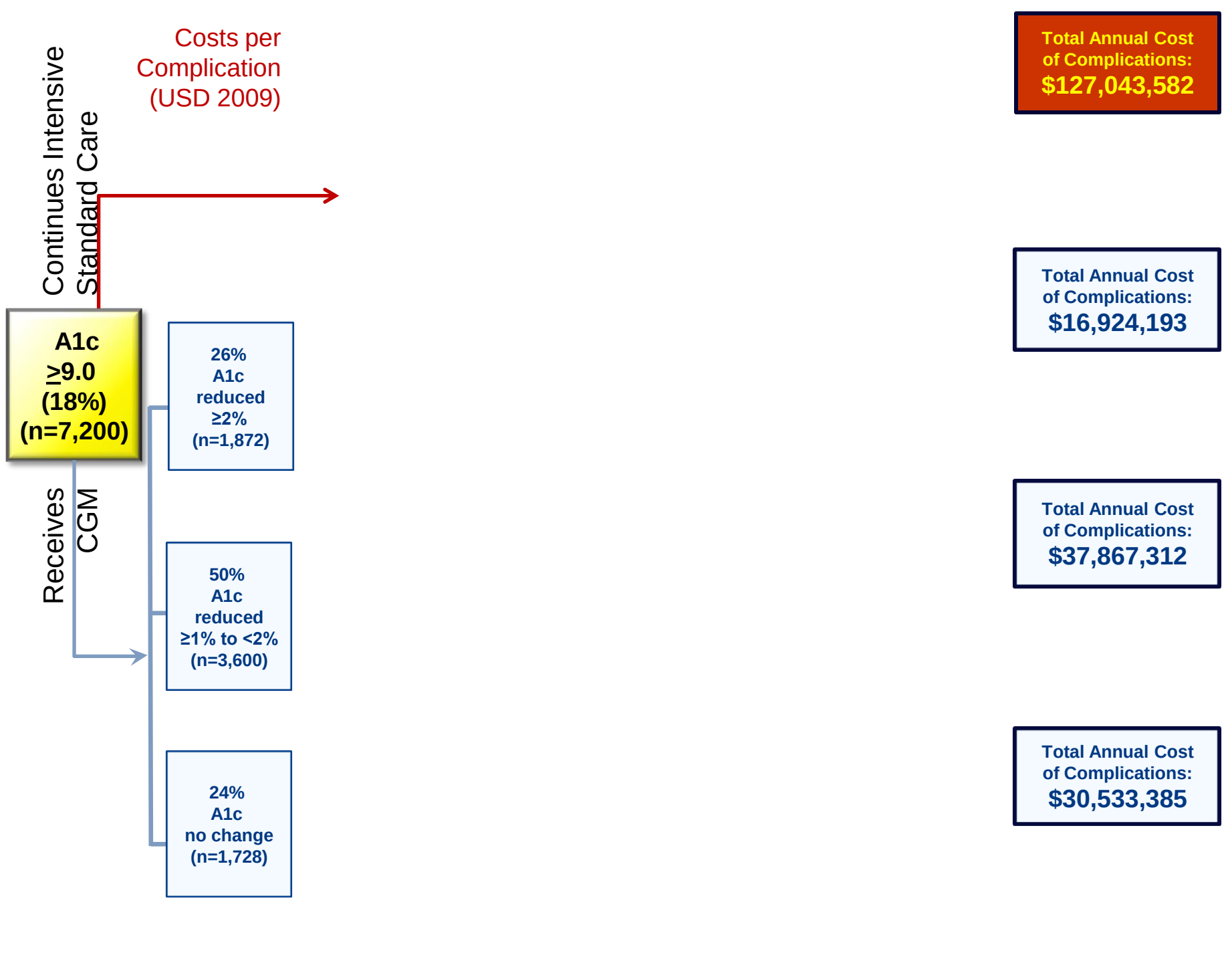
11% neuropathy (n=792); amputation 0.3% (n=2)
27% hypoglycemia (n=1,944)
$31,142
Tx: $6,000; Dialysis: $71,945
$89,617
$320
Total Annual Cost of Complications: $127,043,532
28% serious retinopathy (n=524)
4% nephropathy (n=75); 2% stage 5 (n=1)
11% neuropathy (n=206); 0.1% amputation (n=0)
14% hypoglycemia (n=262)
Total Annual Cost of Complications: $16,924,193
31% serious retinopathy (n=1,116)
11% nephropathy (n=396); 2% stage 5 (n=8)
11% neuropathy (n=396); 0.1% amputation (n=0)
14% hypoglycemia (n=504)
Total Annual Cost of Complications: $37,867,312
52% serious retinopathy (n=899)
18% nephropathy (n=311); 2% stage 5 (n=6)
11% neuropathy (n=190); amputation 0.3% (n=1)
27% hypoglycemia (n=467)
Total Annual Cost of Complications: $30,533,385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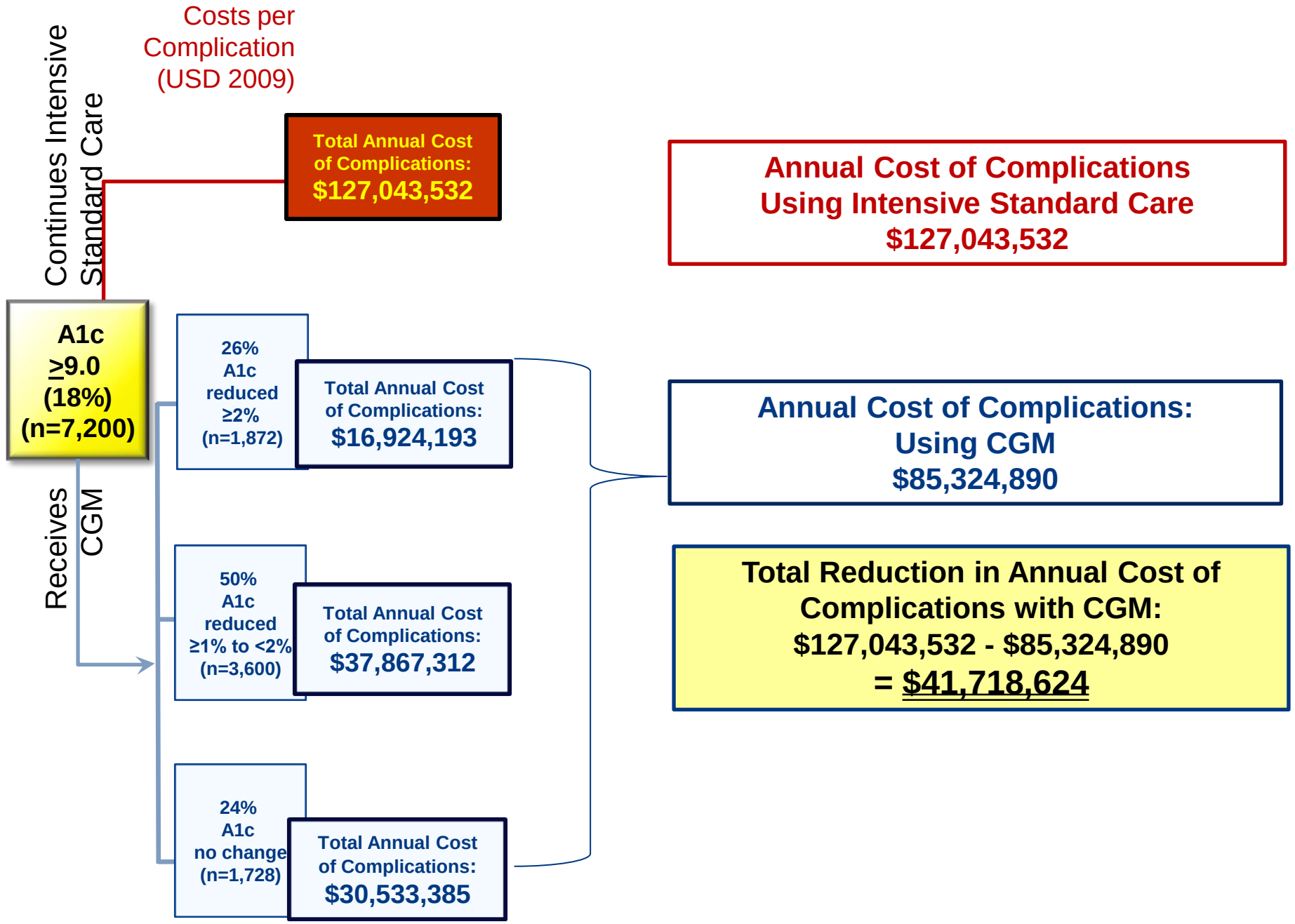
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Total Annual Cost of Complications: $37,867,312
24% A1c no change (n=1,728)
Total Annual Cost of Complications: $30,533,385
Annual Cost of Complications Using Intensive Standard Care $127,043,532
Annual Cost of Complications: Using CGM $85,324,890
Total Reduction in Annual Cost of Complications with CGM: $127,043,532 - $85,324,890 = $41,718,624

Total Reduction in Annual Cost of Complications with CGM in Poorly Controlled T1DM

Annual Cost of Complications Using Intensive Standard Care
$127,043,532

−

Annual Cost of Complications: Using CGM
$85,324,890

=

Total Reduction in Annual Cost of Complications with CGM:
$127,043,532 - $85,324,890
= $41,718,624

Annual Per-Patient Reduction in Cost of Complications Conferred by CGM
$5,794

Limitations

- Decision-tree analysis provides one method for analyzing allocations.
  - Other methods include
    - Markov modeling
    - Cost-utility analysis (QALY)
    - Budget impact modeling.
- Assumptions are limited by available data.
  - Older data should be updated when more current information becomes available.
  - Data used in our analysis may not be representative of
    - Current treatment modalities and standards of care
    - Swedish health care system
    - Swedish patients, or
    - Individuals with T1DM.

Conclusions

- In this decision-tree model, use of CGM by 7,200 Swedish residents with poorly controlled T1DM resulted in fewer diabetic complications per year compared with intensive standard care, at an estimated reduction in direct costs of ~$42 million.
- CGM conferred an estimated annual per-patient reduction in costs of complications of $5,794 ($41,718,624 / 7200) among poorly T1DM.
- Because not all direct costs for diabetes-related complications (e.g., diabetic ulcers, background retinopathy, microalbuminuria, macrovascular events) were included in the model, CGM may be associated with even greater cost savings relative to intensive standard care.
- The model demonstrates that CGM is a cost-savings approach to reducing diabetes-related complications among Swedish residents with poorly controlled T1DM.
  - Model assumes that those with poorly controlled T1DM may currently receive insulin via MDI or pump.
  - Model suggests that earlier use of CGM may be clinically and economically appropriate for poorly controlled T1DM in individuals using MDI.
- Improved access to this technology could result in significantly decreased national health care spending for complications related to T1DM.

CGM Is Consistent with Goals of Sweden's Health Policy

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