Ann Bullock, MD
Director
Division of Diabetes Treatment and Prevention
Indian Health Service

Lipid and Hypertension Management in Diabetes

Diabetes guidelines have changed a lot in the last few years

2007	2016
A1C <7%	A1C target should be individualized (e.g. <7%, <8%)
BP <130/80	BP <140/90
LDL <100mg/dL	Lipid Management: Moderate- and High-Intensity Statin Therapy
Aspirin in pts >40 yrs old	Antiplatelet agents Yes in CVD For rest, depends on CVD risk

Key Recommendations

- **Use a patient-centered communication style that incorporates patient preferences, assesses literacy and numeracy, and addresses cultural barriers to care. B**
- **Treatment decisions should be timely and based on evidence-based guidelines that are tailored to patient preferences, prognoses, and comorbidities. B**

Health Disparities

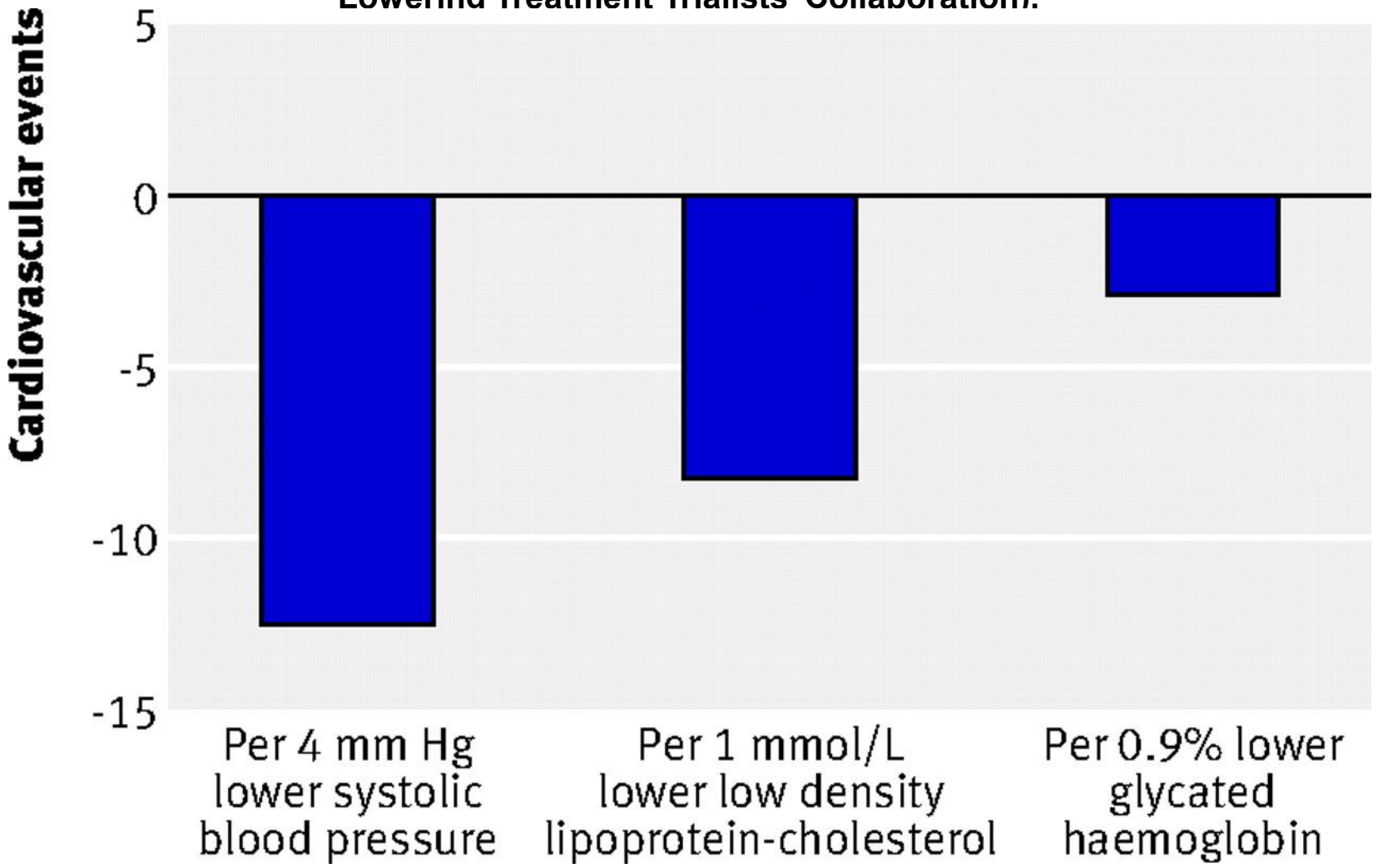
- **Lack of health insurance**
- **Food insecurity (FI)**
  - **Carefully evaluate hyperglycemia and hypoglycemia and propose solutions A**
  - **Recognize that homelessness, poor literacy, and poor numeracy often occur with food insecurity; appropriate resources should be made available for patients with diabetes. A**

American Diabetes Association

American Diabetes Association Standards of Medical Care in Diabetes. Strategies for improving diabetes care. *Diabetes Care* 2016; 39 (Suppl. 1): S6-S12

Blood Pressure

Absolute number of events prevented by different interventions per 1000 patient years of treatment (data taken from Cholesterol Treatment Trialists' Collaboration and Blood Pressure Lowering Treatment Trialists' Collaboration).



Preiss D , Ray K K BMJ 2011;343:bmj.d4243

Blood Pressure: JNC 8 Panel

- 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults
  - Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8) *JAMA* 2014;311(5):507-520
- Very rigorous guideline development process
- Target for people with diabetes +/- CKD:

  <140/90
- Recommended medications:
  - Thiazide diuretic, ACEI/ARB, Calcium Channel Blocker
  - If CKD: start with ACEI or ARB
  - Big change: Beta blockers no longer recommended for first-line treatment of hypertension (different issue from CVD)

Recommendations: Hypertension/ Blood Pressure Control (2)

Systolic Targets:

- People with diabetes and hypertension should be treated to a systolic blood pressure goal of <140 mmHg. **A**
- Lower systolic targets, such as <130 mmHg, may be appropriate for certain individuals, such as younger patients, if it can be achieved without undue treatment burden. **C**

American Diabetes Association Standards of Medical Care in Diabetes. Cardiovascular disease and risk management. *Diabetes Care* 2016; 39 (Suppl. 1): S60-S71

Recommendations: Hypertension/ Blood Pressure Control (3)

Diastolic Targets:

- Patients with diabetes should be treated to a diastolic blood pressure <90 mmHg. **A**
- Lower diastolic targets, such as <80 mmHg, may be appropriate for certain individuals, such as younger patients, if it can be achieved without undue treatment burden. **B**

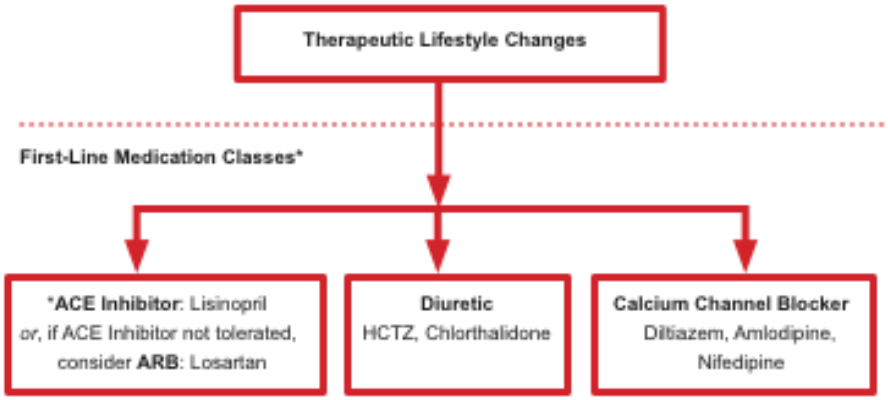
American Diabetes Association

American Diabetes Association Standards of Medical Care in Diabetes. Cardiovascular disease and risk management. *Diabetes Care* 2016; 39 (Suppl. 1): S60-S71

BP Targets

- **<140/90:** target for (most) diabetes patients
  - Good BP control definitely reduces CVD, CKD risks
  - Balance need for good BP control with risk of problems
    - Hypotension, fatigue, polypharmacy issues are common
    - Use caution in patients who have symptoms at <140/90 and/or with meds needed to achieve it
      - Higher risk: Older, comorbidities, longer duration of DM, on lots of meds, autonomic neuropathy
      - Antihypertensive meds associated with falls/injuries in elderly *JAMA Intern Med* 2014;doi:10.1001/jamainternmed.2013.14764

Hypertension Management



**consider ACE Inhibitor or ARB as intial medication for patients with Chronic Kidney Disease*
Do not use an ACE Inhibitor and ARB together in the same patient.

If BP not at goal in one month, consider titrating dose up and/or adding medication from a different class above. Utilize these 3 classes before considering addtional medication classes.

Consider Additional Medication Classes

If BP not at goal or unable to tolerate the first-line medication classes above, consider adding medications from additional drug classes. Base selection on individual patient indications.

Beta Blocker	Alpha Blocker
Metoprolol, Atenolol	Prazosin, Doxazosin

Treat BP to targets as tolerated:

Systolic BP target < 140**

Diastolic BP target < 90

** Individualize BP targets and medication therapy. Patients who are older and/or have significant comorbid conditions and cannot tolerate BP < 140/90, may require higher BP targets to prevent adverse effects (e.g. hypotension, fatigue, diziness). For example, consider systolic BP target < 150 in patients ≥ 60 years.

ACE Inhibitors (ACEI)/Angiotensin Receptor Blocker (ARBs) First line medication choice for patients with Chronic Kidney Disease Can cause ↑ K^+, ↑ creatinine; cough (with ACEI), rarely angioedema. Do not use an ACEI and an ARB at the same time.	
Lisinopril (Prinivil®, Zestril®)	Start 2.5-5mg daily; usually 20-40mg daily; max 80mg daily
Losartan (Cozaar®)	Start 25-50mg daily; max 100mg daily. Consider if unable to tolerate ACEI
Diuretics	
HCTZ	Start 12.5mg daily; usually 25-50mg daily; Can ↓ K^+ Higher doses may be used for other indications (e.g. edema)
Chlorthalidone	Start 12.5mg daily; usually 25-50mg daily; Can ↓ K^+ Higher doses may be used for other indications (e.g. edema)
Calcium Channel Blockers	
Amlodipine (Norvasc®)	Start 2.5-5mg daily; usually 5-10mg daily. Consider in patients with angina or CHF
Diltiazem (Cardizem®)	*Note*: multiple formulations exist: Immediate Release (TID-QID), SR/Sustained Release (BID), CD/Controlled Delivery (daily), and LA/Long Acting (daily) Consult your local formulary to assure appropriate selection and dosing For diltiazem CD start 180-240mg daily; usually 240-360mg daily; max 480mg daily
Nifedipine XL (Adalat®/ Procardia®)	Start 30mg daily; usually 30-90mg daily; max dose120mg daily Caution edema, CHF, and MI
Beta Blockers Don't use if bradycardia or 2nd/3rd degree block. Caution in severe CHF, asthma, or renal dysfunction.	
Atenolol (Tenormin®)	Start 25-50mg daily in 1-2 divided doses; usually 50-100mg/day Eliminated renally (caution Renal Failure)
Metoprolol (Lopressor®)	Start 50-100mg daily in 1-2 divided doses; usually 100-200mg/day. Max 450mg daily *XR formulation dosed once daily.* Eliminated hepatically (caution in Liver Failure)
Propranolol (Inderal®)	Start Long Acting 80mg daily or Immediate release 40mg BID; usually 120-240mg daily; max 640mg daily
Carvedilol (Coreg®) (Immediate Release Dosing)	Start 6.25mg BID; usually12.5-25mg BID. *CR formulation dosed once daily.* Also indicated for heart failure (start at 3.125mg BID)
Alpha Blockers	
Doxazosin (Cardura®)	Start 1mg immediate release at bedtime; Max dose 16mg daily Titrate up slowly; Can cause dizziness, drowsiness, and weakness
Prazosin (Minipress®)	Start 1mg PO BID-TID (first dose at bedtime); Max dose 15mg daily Titrate up slowly; Can cause dizziness, drowsiness, and weakness
Central Acting	
Clonidine (Catapres®)	Start 0.1mg BID (first dose at bedtime); usually 0.1-0.3mg BID; max 1.2mg BID Titrate up slowly; Can cause sedation/dizziness/weakness; Do not stop abruptly

Drugs in *italics* are **not** on the IHS National Core Formulary

Note: This is not a complete prescribing reference. This algorithm is not intended for treatment selection in children or in women who are or could become pregnant; some antihypertensive medications can cause fetal damage.

Ref: JNC 8 Panel; http://jama.jamanetwork.com/article.aspx?articleid=1791497.

ADA 2015 Clinical Practice Recommendations; http://care.diabetesjournals.org/content/38/Supplement_1.

Blood Pressure Measurement

So easy to do (incorrectly)!

BP Measurement

- Measure BP at all routine visits
- Measuring BP in clinic:
  - Patient has rested for 5 minutes, is seated with feet on floor, arm supported at heart level
  - Cuff size should be appropriate for upper arm
  - Confirm elevated values on a different day

ADA 2015 Clinical Practice Recommendations

- Differences in BP Devices
  - Mercury, aneroid, electronic

Common Sources of BP

Measurement Errors

- Incorrect cuff size
  - Use correct size for mid upper arm
  - Have all sizes of adult cuffs available where BPs measured
    - Small adult, Adult, Large adult, Adult thigh (for very large upper arms)
- Terminal digit bias
  - Significant tendency toward recording zeros
- Inadequate staff training and equipment maintenance
- Talking or listening to patient/colleague while taking BP
- BP cuff placed over clothing
- Smoking or caffeinated beverages within 30 min of BP
- Patient's back and/or arm unsupported
- Feet crossed or dangling

Lipid Management

GPRA

What used to be "Diabetes: LDL Assessed" is now:

"Statin Therapy to Reduce Cardiovascular Disease Risk in Patients with Diabetes"

2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults

J Am Coll Cardiol

E-pub: November 12, 2013

ACC/AHA Cholesterol Guidelines

- ATP IV panel's work in conjunction with ACC/AHA
- Guideline highlights (it's all about statins!)
  - No longer recommended to treat to LDL targets
  - Treat with moderate or high-intensity statin therapy:
    - Clinical CVD: high-intensity if <75 y/o, moderate if older
    - LDL ≥190mg/dL: high-intensity
    - DM pts 40-75 y/o with LDL 70-189 mg/dL but no known CVD: moderate—high-intensity if 10-yr CVD risk ≥7.5%
    - Other pts with 10-yr CVD risk ≥7.5%: moderate or high

Statin Therapy

- Statin dosing:
  - High-intensity: atorvastatin 40-80 mg, rosuvastatin 20-40 mg
  - Moderate-intensity: e.g. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg
- What do we do with the patients who can't tolerate statins: at high/moderate dose, low dose, or at all?
  - Try statin again—in clinical trials, *many* patients who thought they were statin intolerant were able to tolerate statin
  - Try different statin (esp. if symptoms with simvastatin), start at low dose/titrate up slowly
  - New: In certain high risk patients, can add ezetimibe to statin
  - It is not known if non-statin alone will reduce CVD risk

ADA 2016 Recommendations for Statin Treatment in People with Diabetes

Age	Risk factors	Recommended statin dose*
<40 years	None	None
	ASCVD risk factor(s)**	Moderate or high
	ASCVD***	High
40–75 years	None	Moderate
	ASCVD risk factors	High
	ASCVD	High
	Acute Coronary Syndrome and LDL >50mg/dL in patients who cannot tolerate high intensity statin	Moderate plus ezetimibe
>75 years	None	Moderate
	ASCVD risk factors	Moderate or high
	ASCVD	High
	Acute Coronary Syndrome and LDL >50mg/dL in patients who cannot tolerate high intensity statin	Moderate plus ezetimibe

* In addition to lifestyle therapy.

** ASCVD risk factors include LDL cholesterol ≥100 mg/dL (2.6 mmol/L), high blood pressure, smoking, and overweight and obesity, and family history of premature ASCVD.

*** Overt CVD includes those with previous cardiovascular events or acute coronary syndromes.

ADA. 8. Cardiovascular Disease and Risk Management. Diabetes Care 2016;39(suppl 1):S64, Table 8.1

ADA 2016 Recommendations: Combination Therapy

- Statin plus:
  - **Ezetimibe**: The addition of ezetimibe to moderate-intensity statin therapy has been shown to provide additional CV benefit compared with moderate-intensity statin therapy alone and may be considered for patients with a recent acute coronary syndrome with LDL cholesterol ≥50 mg/dL or for those patients who cannot tolerate high- intensity statin therapy.
  - **Fibrate**: statin/fibrate has not been shown to improve ASCVD outcomes and is generally ***not*** recommended.
    - However, therapy with statin and fenofibrate may be considered for men with both triglyceride level ≥204 mg/dL and HDL cholesterol level ≤34 mg/dL.
  - **Niacin**: statin/niacin has not been shown to provide additional cardiovascular benefit above statin therapy alone and may increase the risk of stroke and is ***not*** generally recommended.

GPRA Statin Therapy Measure

- Denominator:
  - **Clinical population of people with diabetes**
    - ages 40 through 75
    - age 21 and older with documented CVD
    - age 21 and older with LDL greater than or equal to ≥190 mg/dL “ever”.
  - Excludes: Patients with contraindications, documented allergy, intolerance, or other adverse effect to statin medication; pregnancy, breastfeeding; cirrhosis; acute alcoholic hepatitis; palliative care; ESRD; LDL <70 and not on a statin and who have never had an LDL result ≥ 190
- Numerator:
  - Patients prescribed a statin during the report period

GPRA Target

- Target for the GPRA 2016 year (July 1, 2015 – June 30, 2016) is to **baseline** the measure
  - Determine the percentage of people with diabetes who are eligible for statin therapy
  - Determine the percentage of people with diabetes who are prescribed statin therapy
  - The baseline will help to determine the target for the 2017 GPRA reporting period

Key Points

- Clinical research informs clinical guidelines, which then inform performance measures like GPRA
  - Hence, this change to the GPRA diabetes lipid measure
- Recent and upcoming clinical studies are already pointing toward further evolution in lipid guidelines
  - When will this again affect this GPRA measure?
- CVD is a common and impactful complication of diabetes
  - We all want to do what we can to reduce the risk of CVD in our patients with diabetes
    - It's clear that statins are an important tool for doing this
      - Medication adherence issues
    - This GPRA measure will help us see how well we're taking advantage of this evidence-based medication class

Type 2 Diabetes - Lipid & Aspirin Therapy

Lipid Panel Screening

Order a lipid panel:

- at diagnosis of diabetes
- if < 40 years old and not on a statin, consider annual lipid panel
- at age 40 if not yet on a statin to establish treatment baseline
- as needed every 1-2 years (e.g. to evaluate adherence to lipid therapy)

For all patients with diabetes, initiate lifestyle therapy, then:

Age	CVD Risk Factors*	Statin Therapy
<40 years	None	None
	1 or more	Moderate or High Intensity
	Overt CVD**	High Intensity
40-75 years	None	Moderate Intensity
	1 or more	High Intensity
	Overt CVD**	High Intensity
>75 years	None	Moderate Intensity
	1 or more	Moderate or High Intensity
	Overt CVD**	High Intensity

* CVD Risk Factors include: LDL ≥ 100mg/dL, High Blood Pressure, Smoking, or Overweight/Obesity
** Overt CVD includes previous cardiovascular events or acute coronary syndrome

Statin intolerance: Consider trying a different statin. May consider non-statin medication if no statin is tolerated; however, there is little evidence of CVD benefit from non-statin lipid medications.

Combination therapy (statin plus non-statin lipid medication): There is no evidence of CVD benefit in patients without advanced CVD. There is limited evidence for patients with advanced CVD.

Elevated Triglycerides: If Triglycerides elevated (≥ 500 mg/dL) identify secondary causes and consider triglyceride lowering therapy; if severely elevated (≥ 1000 mg/dL) begin triglyceride lowering medication to reduce the risk of pancreatitis.

Statin Medications

Statin	Moderate Intensity Dose	High Intensity Dose
Atorvastatin (Lipitor®)***	10-20 mg	40-80 mg
Rosuvastatin (Crestor®)	5-10 mg	20-40 mg
Simvastatin (Zocor®)	20-40 mg	NA
Pravastatin (Pravachol®)	40 mg	NA
Lovastatin (Mevacor®)	40-80 mg	NA
Fluvastatin (Lescol®)	80 mg	NA

Contraindications: acute liver disease, pregnancy, nursing mothers

Numerous drug interactions: consult package insert prior to prescribing; *Simvastatin and Lovastatin* - Caution or contraindication with strong CYP3A4 inhibitors (e.g., azole antifungals, erythromycins, HIV protease inhibitors, nefazodone); *All statins* - Caution or contraindication with gemfibrozil, cyclosporine, or danazole. *Decrease dose of simvastatin* with niacin, amiodarone, verapamil, diltiazem, amlodipine, and grapefruit.

Check ALT before initiating therapy; Routine monitoring not necessary

Non-Statin Lipid Medication	Usual Dose	LDL	HDL	Trig
Gemfibrozil (Lopid®)****	600 mg BID	-	↑	↓↓
Fenofibrate (Tricor®)****	145 mg Daily	↓	↑	↓↓
Niacin (Niaspan®)	500 mg HS to 2-3 g HS	↓	↑	↓↓
Fish Oil (Omacor®)	2-4 g Daily	↑	↑	↓↓
Ezetimibe (Zetia®)	10 mg Daily	↓	-	-
Colesevalem (Welchol®)	3-6 tab Daily	↓	-	-/↑

Note: Medications in green are not on the IHS National Core Formulary
*** *Note: Only atorvastatin 40-80mg is on the IHS National Core Formulary*
**** *Determine which fibric acid derivative is on your local formulary*

Aspirin Therapy

Consider aspirin 75 to162 mg/day for patients with:

- Known CVD
- Increased risk of CVD (10-year risk > 10%)
  - *Includes most men > 50 yrs & women > 60 yrs with ≥ 1 major CVD risk factors*
- Use clinical judgment if 10-year risk 5-10%

If allergic to aspirin, consider clopidogrel 75 mg daily

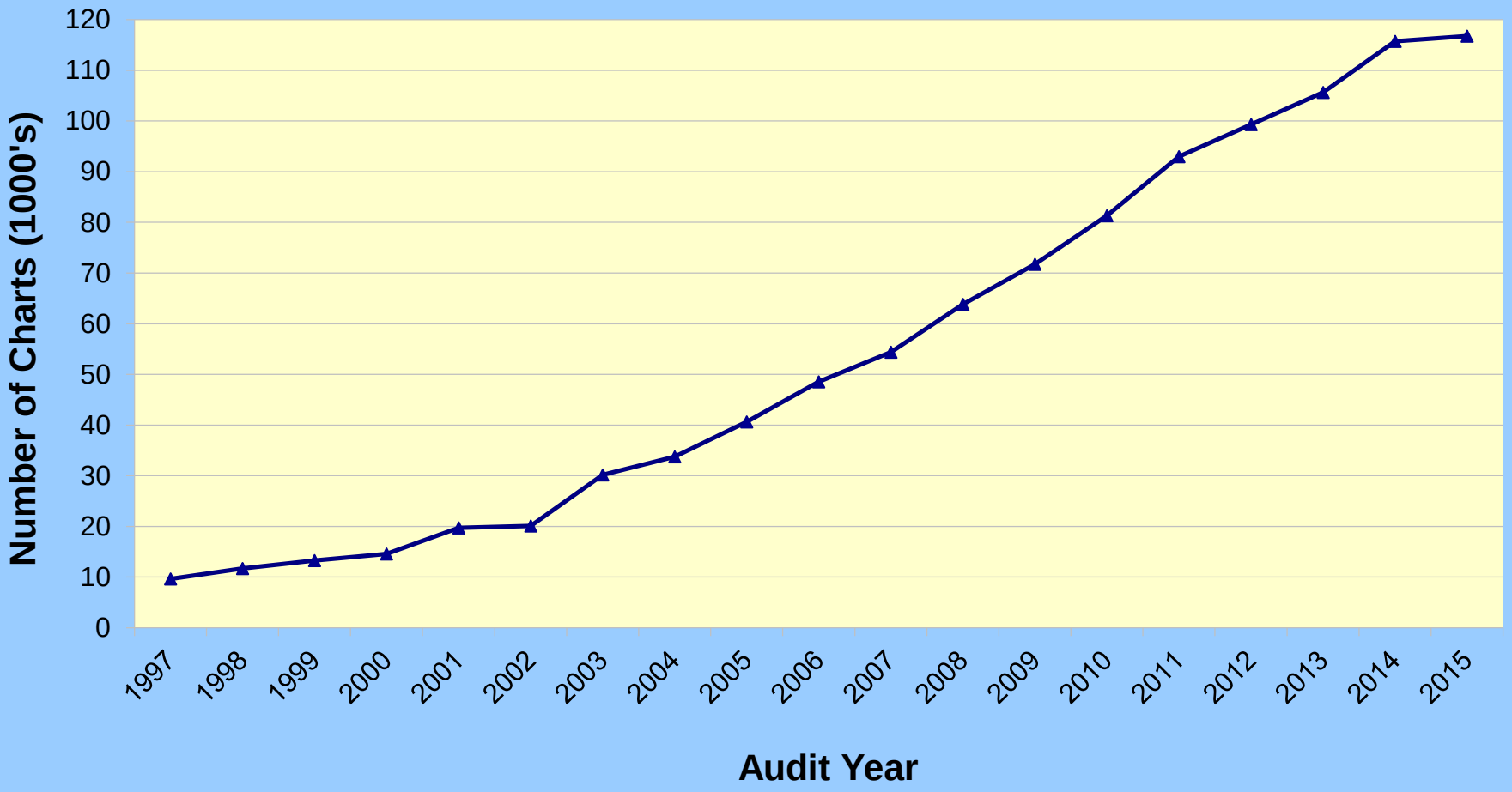
Ref: ADA Clinical Practice Recommendations 2015, DIABETES CARE, VOLUME 38, SUPPLEMENT 1, JANUARY 2015
ACC/AHA Cholesterol Guideline, 2013, https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a

Diabetes Care and Outcomes Audit 2015

333 I/T/U Facilities

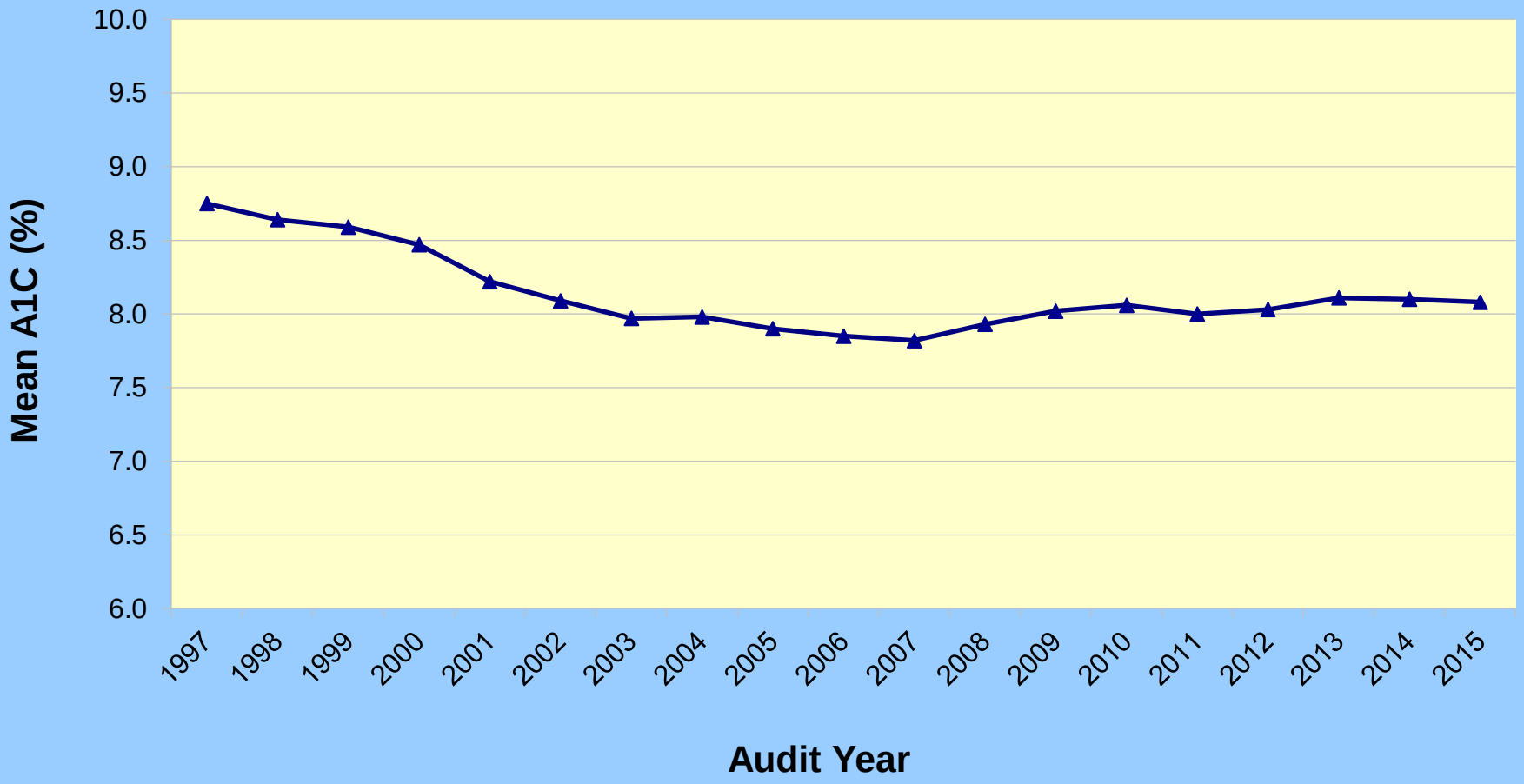
116,743 Charts

Number of Charts Audited
1997-2015



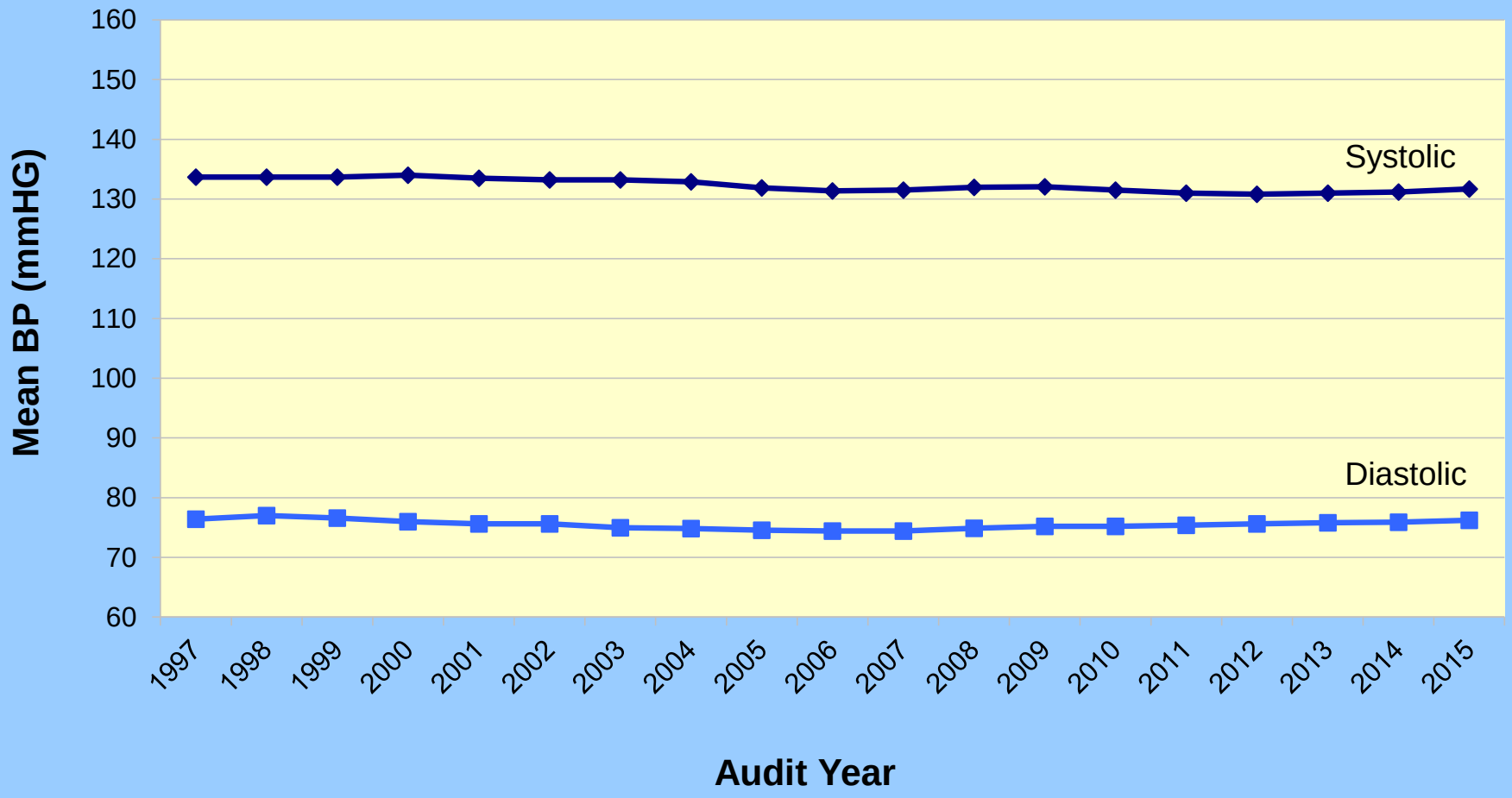
Source: IHS Diabetes Care and Outcomes Audit

Mean A1C
1997-2015



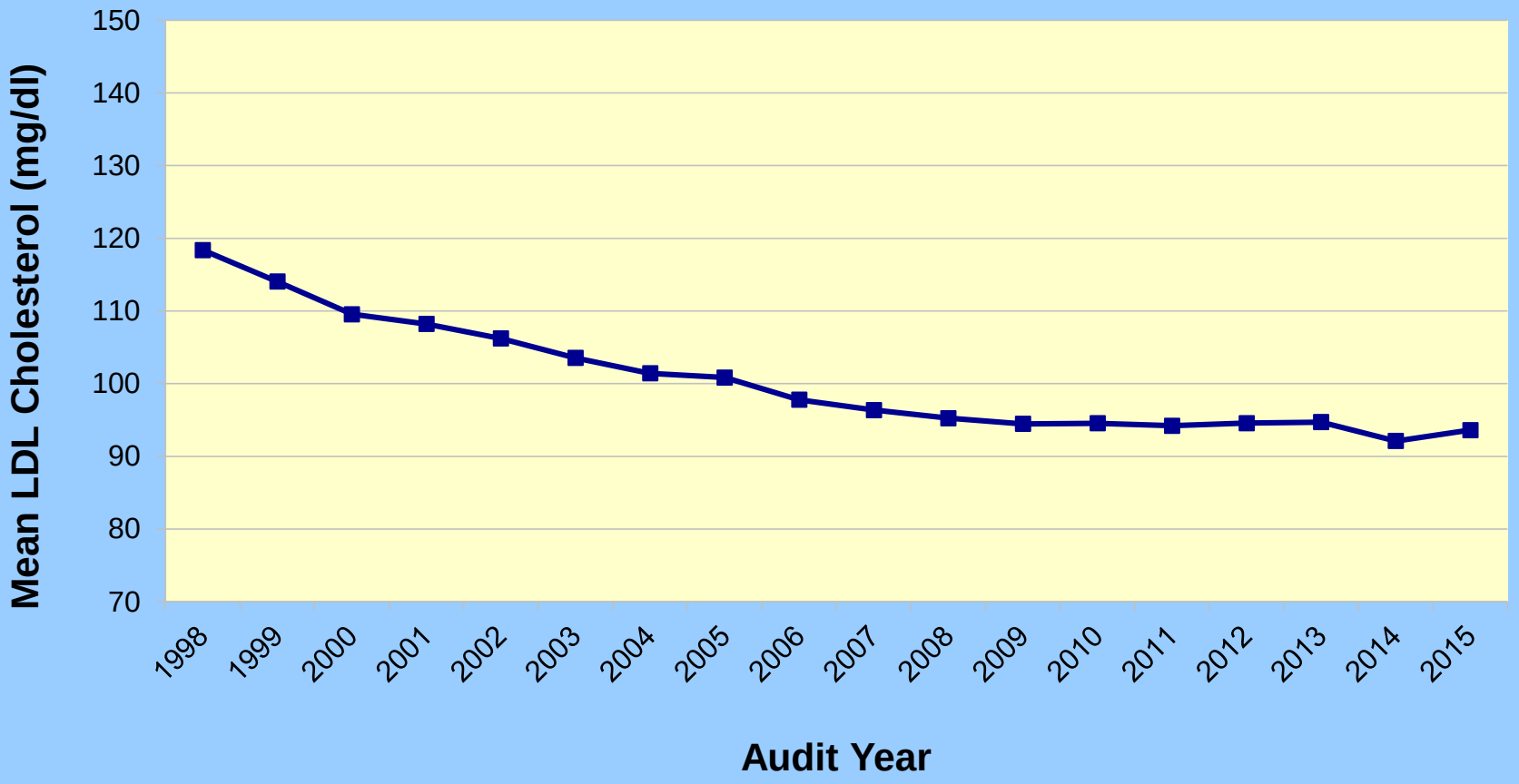
Source: IHS Diabetes Care and Outcomes Audit

Mean Blood Pressure
1997-2015



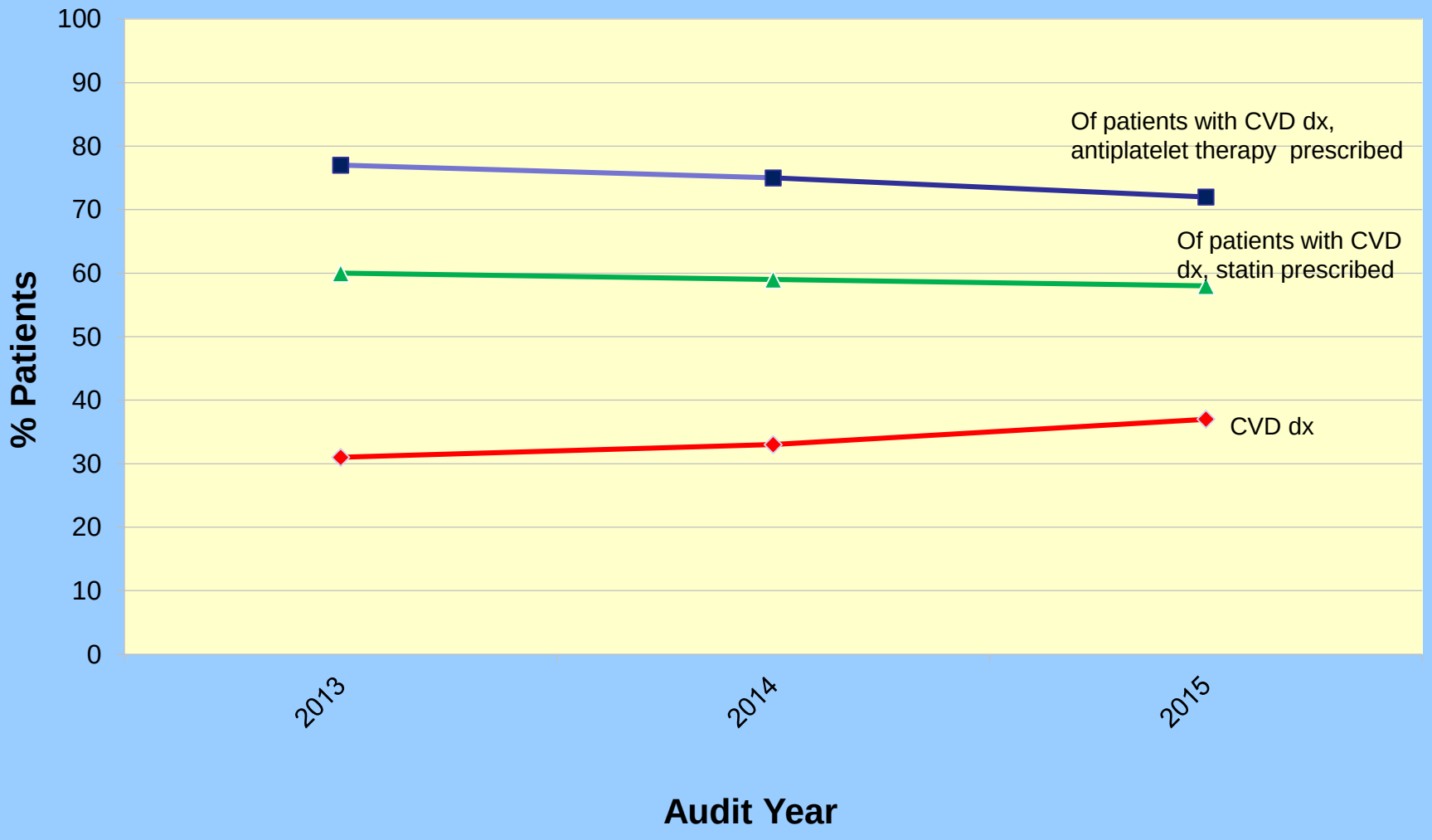
Source: IHS Diabetes Care and Outcomes Audit

Mean LDL Cholesterol
1998-2015



Source: IHS Diabetes Care and Outcomes Audit

Diagnosed CVD
2013-2015



Source: IHS Diabetes Care and Outcomes Audit

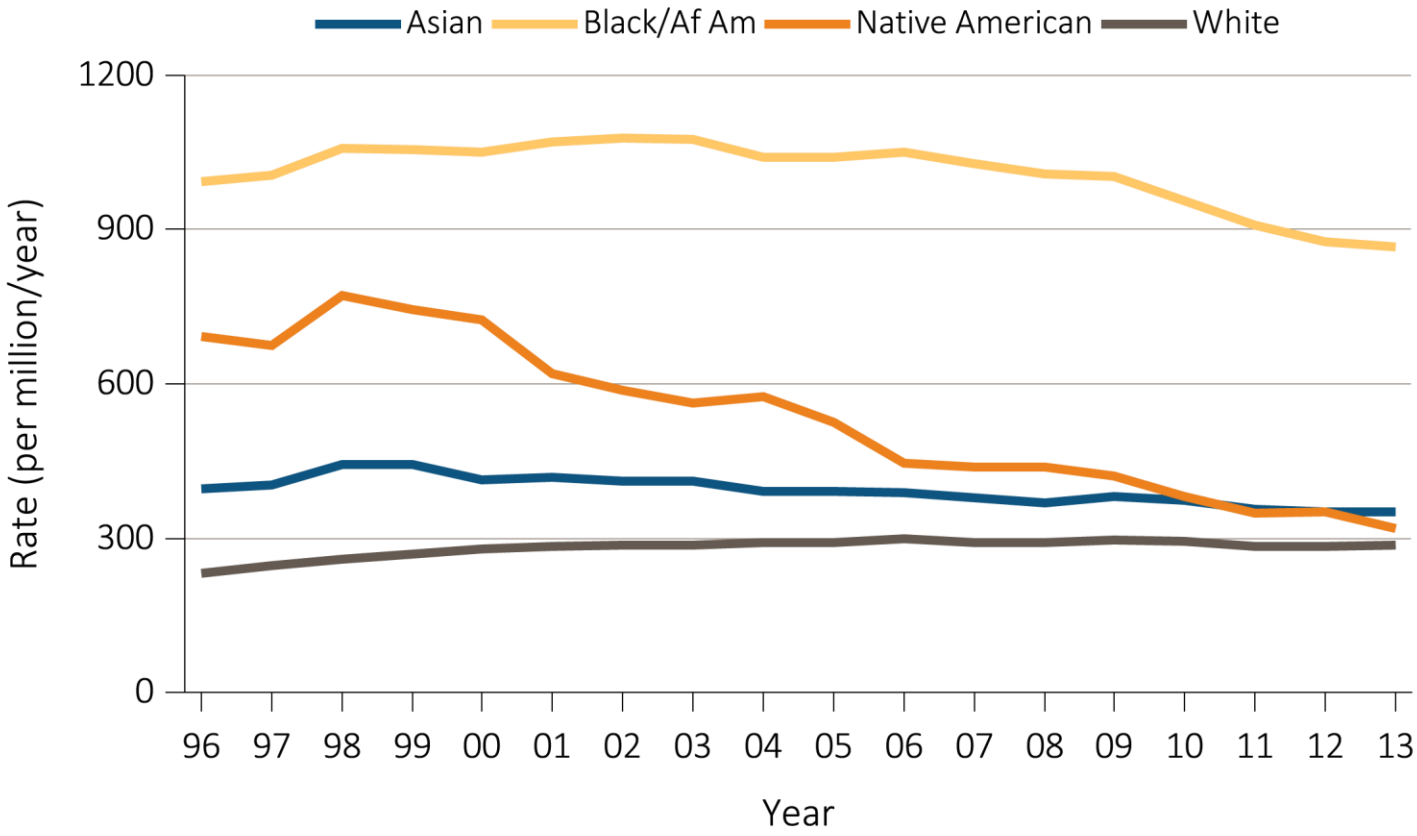
USRDS

UNITED STATES RENAL DATA SYSTEM

2015 ANNUAL DATA REPORT
VOLUME 2: END-STAGE RENAL DISEASE

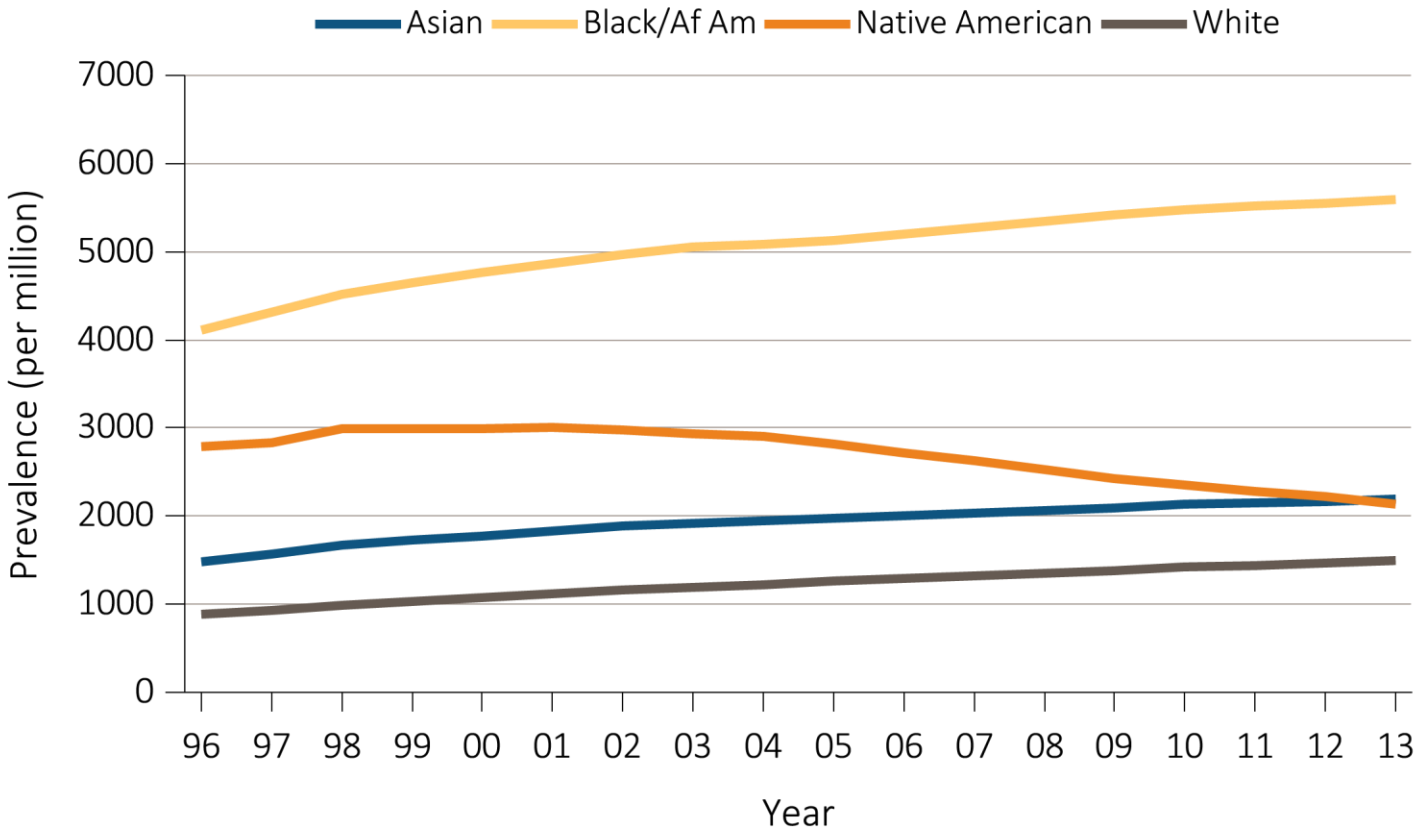
Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities

Figure 1.5(b) Trends in adjusted* ESRD incidence rate (per million/year), by race, in the U.S. population, 1996-2013



*Data Source: Special analyses, USRDS ESRD Database. *Adjusted for age and sex. The standard population was the U.S. population in 2011. Abbreviations: Af Am, African American; ESRD, end-stage renal disease.*

Figure 1.14(b) Trends in the adjusted* prevalence (per million) of ESRD, by race, in the U.S. population, 1996-2013



*Data Source: Special analyses, USRDS ESRD Database. *Point prevalence on December 31 of each year. Adjusted for age and sex. The standard population was the U.S. population in 2011. Abbreviations: Af Am, African American; ESRD, end-stage renal disease.*

USRDS

- "The ESRD incidence rates for Blacks, Native Americans, and Asians have declined over the nearly 20-year period shown in Figure 1.5.b. **The decline has been greatest (over 2-fold) among Native Americans**. …the ratio of incidence rates for Native Americans versus Whites decreased from 2.6 to 1.1."

  (USRDS 2015 ADR, ESRD, ch. 1, Highlights, emphasis added)

- "…the remarkable decline in incidence rates among Native Americans has resulted in a 29% decline in the prevalence of ESRD in this population since 2000. **This represents the only instance, since the beginning of ESRD care in 1973, of a decline in adjusted prevalence for a major racial group.**"

  (USRDS 2015 ADR, ESRD, ch.1 Highlights, emphasis added)

Resources From the IHS Division of Diabetes

www.diabetes.ihs.gov

DDTP Website: www.diabetes.ihs.gov

At no cost to I/T/U sites/clinicians:

- Diabetes Treatment Algorithms
- Standards of Care
- Online Catalog
  - Diabetes educational materials
- CME/CE Training
  - Live: “Advancements in Diabetes” monthly webinars
  - Online: Recorded trainings, new one added monthly

www.diabetes.ihs.gov – Home Page

Division of Diabetes Treatment and Prevention
Leading the effort to treat and prevent diabetes in American Indians and Alaska Natives

Thursday, April 12, 2012

HOME
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PROGRAMS
- SDPI
- Model Diabetes Programs
- IDEP

PEOPLE
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- ADCs
- TLDC

LEARN Hubs
- CKD
- Foot Care
- Glucose Management
- Physical Activity

TRAINING
- Web-Based
- AADE Partnership
- External Trainings
- Conferences

RESOURCES
- Audit
- Fact Sheets
- Instant Downloads
- Mobile Video Podcasts
- Online Catalog
- Patient Education Materials
- Podcasts
- Provider Resources

TOOLS
- Best Practices
- Clinical Guidelines
- Curricula
- DM Treatment Algorithms
- Quick Guide Cards

SITE MAP

Tools – Clinical Guidelines Update

Standards of Care: Type 2 Diabetes – Revised edition has new and enhanced sections about diabetes in youth, women of childbearing age and caring for patients with multiple comorbid conditions. Expanded tools and provider resources, plus better navigation.

1 2 3 4 5 6

Go To Guidelines

Provider Resources

Clinical Tools
- Diabetes Treatment Algorithms
- Quick Guide 'How To' Cards
- Diabetes LEARN

Clinical Guidelines
- Standards of Care and Clinical Practice Recommendations [PDF - 540KB]
  - Summary Table of Recommendations [PDF - 145KB]
  - Additional Tools and Resources [PDF - 260KB]
  - Bibliography [PDF - 245KB]

All CME Trainings
- Diabetes Foot Care
- Preventing Amputations in Diabetes
- Obstructive Sleep Apnea and Diabetes
- Diabetes Standards of Care and Treatment Targets
- Managing CKD
- Screening and Monitoring CKD
- CKD Nutrition

SDPI Spotlight

Community-Directed Programs
Application Information – Information and resources for **FY 2012** Continuation Application.

Reporting Requirements
FY 2011 Annual Progress Report - Templates and Resources.

FY 2012 Mid-Year Progress Report – Information and resources.

Open period for reporting for Cycle 2 begins May 1st!

Training Opportunities – Online seminars specific to grant requirements.

Mark your calendars now for upcoming SDPI Required Trainings:
July 11, 2012 @ 1 PM MDT
October 10, 2012 @ 1 PM MDT

Optional SDPI Training Series
Tipping the Motivational Balance for Change! Darryl Tonemah, PhD

Diabetes Prevention & Healthy Heart Initiatives
Information.

What's New

Advancements in Diabetes Seminars
Session information – CME/CE Series

Upcoming Sessions:

May 23, 2012 @ 1 PM MDT
Individualizing Diabetes Targets: One Size Does Not Fit All
Ann Bullock, MD

The IHS Diabetes Care and Outcomes Audit 2012
The WebAudit is now open and the RPMS/DMS patch is available.

2011 Best Practice Addendum
[PDF - 232KB] – Provides the most current information on the Required Key Measures along with examples of ways to obtain the measures.

Diabetes Foot Care Hub – April is Foot Care Awareness Month, great time to update your knowledge and skills for diabetes foot care treatment and prevention.

Division of Diabetes Treatment and Prevention | Phone: (505) 248-4182 | Fax: (505) 248-4188 | diabetesprogram@ihs.gov

IHS Diabetes Listserv

- Intended for I/T/U clinicians
  - Different from DDTP's SDPI grantee and Audit email lists
- Sign up on the DDTP homepage: www.diabetes.ihs.gov
- You'll receive email announcements on:
  - Upcoming trainings
    - Advancements in Diabetes and other CME/CE webinars
    - NDEP, VA, and other trainings
  - New diabetes materials/trainings on DDTP website
  - NIH Library list of new diabetes and AI/AN literature
  - Summaries of hot clinical topics related to diabetes/CVD

Thank You!

Questions?