

 KAISER PERMANENTE®

**PHASE**



PREVENTING HEART ATTACKS  
& STROKES EVERY DAY



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Community!**

May 29, 2019

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2. Lines are muted. You can **chat in questions** or **unmute your line** by pressing \*7 to ask a question (\*6 to re-mute).
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# Our Speakers Today



**Landis Coghlan, MD**

Clinical Lead- CV Risk Reduction,  
Statin, Aspirin  
The Permanente Medical Group



**Lisa Gilliam, MD, PhD**

Clinical Leader, Kaiser Northern California  
Diabetes Program  
The Permanente Medical Group



**Ronald Scott, MD**

CVD Co-Lead, Integrated Cardiovascular  
Health Lead  
Southern California Permanente Medical  
Group

# PHASE – highlights and key updates

**Landis Coghlan, MD**  
TPMG Clinical Lead- CV Risk  
Reduction, Statin, Aspirin

**Lisa K. Gilliam, MD, PhD**  
Clinical Leader, Kaiser Northern  
California Diabetes Program  
The Permanente Medical Group

May 30, 2019

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# Agenda

- **2018/ 2019 Changes to PHASE on a Page**
- **Elements of Success with PHASE**
- **Operational Workflows to get value from POAP**
- **What's next? New areas of focus for PHASE**

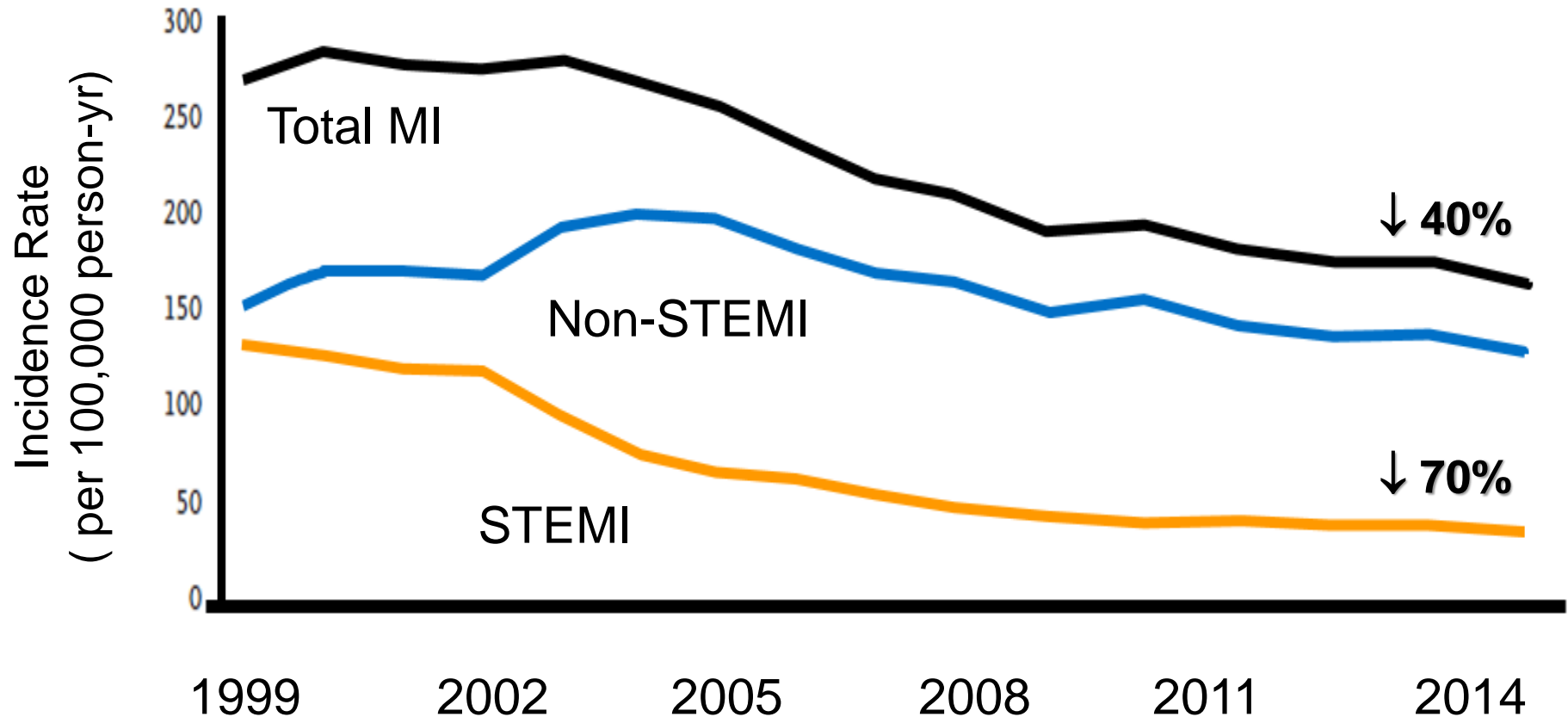


# **PHASE**

- **Preventing Heart Attacks and Strokes Everyday**
- **Identify at risk population**
- **Algorithm for lifestyle and medication management of cardiovascular risk factors – diabetes, hypertension, statin, aspirin, smoking, exercise, diet**
- **Clear accountability for this care**
- **Multiple touch points with patients**

# PHASE: Prevent Heart Attacks and Strokes Every day

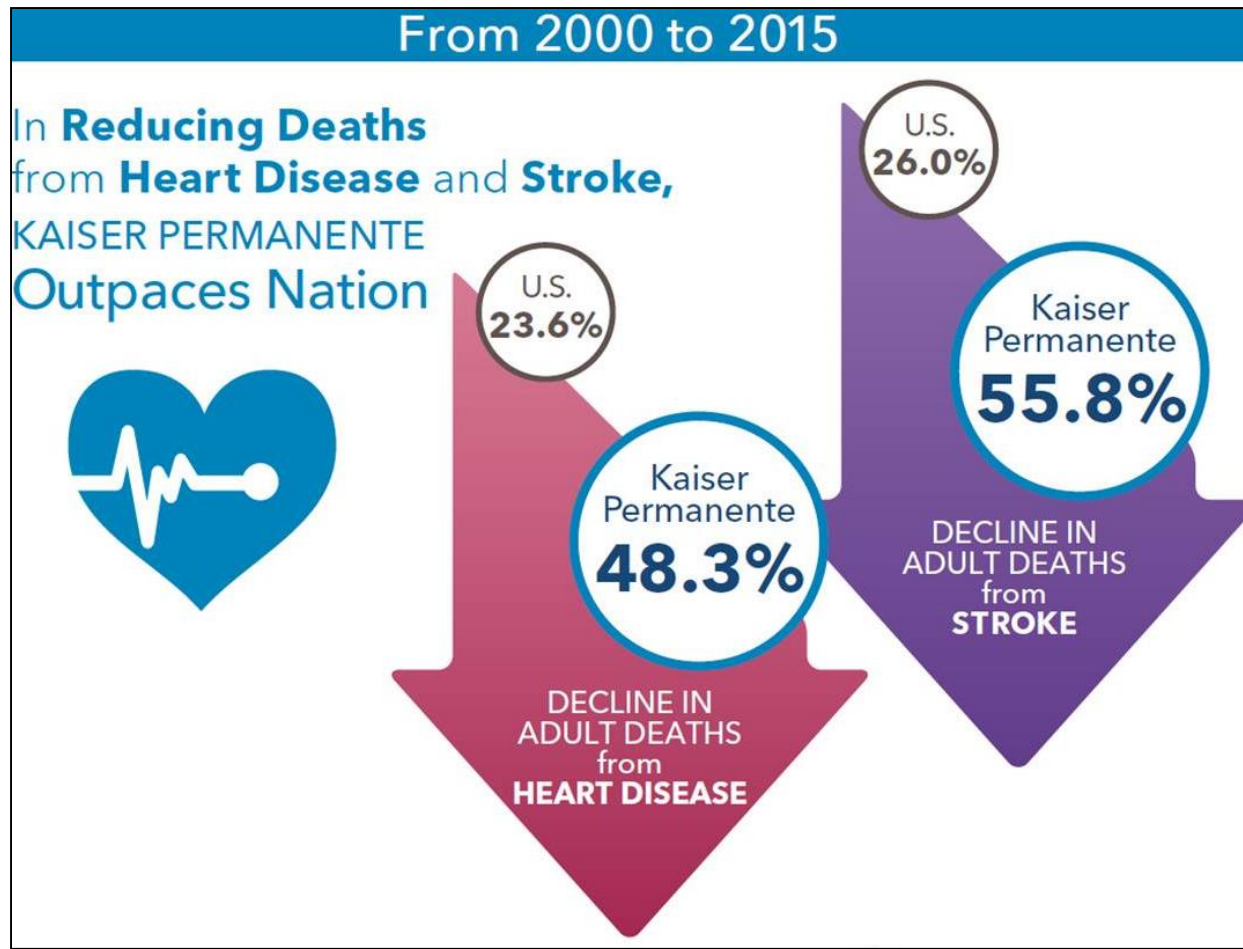
## BP Control, Statins, Aspirin, A1c Control + Optimize Lifestyle



Yeh RW. Engl J Med 2010;362:2155-165.

Solomon MD. J Am Coll Cardiol. 2016;68(6):666-668.

# Did Preventing ASCVD Events Save Lives? YES!





# PHASE

## Changes in 2018/ 2019

# PHASE Updates 2018/2019

## Blood pressure:

- Goal back to <140/ <90 for all
- Speed up escalation of meds in the algorithm
- Aim for point of care med changes (when patient comes in for BP check, and its high, intervention is made at that time)
- AOBP especially for white coat hypertension

# PHASE Updates 2018/2019

## Diabetes:

- Recognition/addition of SGLT2 and GLP1 medications
- Separate DM1/ DM2
- Attention to populations/disparities especially Latino

# Trial data supporting SGLT2/GLP-1 use in special populations

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes

Bernard Zinman, M.D., Christoph Wanner, M.D., John M. Lachin, Sc.D., David Fitchett, M.D., Erich Bluhmki, Ph.D., Stefan Hantel, Ph.D., Michaela Mattheus, Dipl. Biomath., Theresa Devins, Dr.P.H., Odd Erik Johansen, M.D., Ph.D., Hans J. Woerle, M.D., Uli C. Broedl, M.D., and Silvio E. Inzucchi, M.D., for the EMPA-REG OUTCOME Investigators

The NEW ENGLAND  
JOURNAL of MEDICINE

ESTABLISHED IN 1812

JULY 28, 2016

VOL. 375 NO. 4

## Liraglutide and Cardiovascular Outcomes in Type 2 Diabetes

Steven P. Marso, M.D., Gilbert H. Daniels, M.D., Kirstine Brown-Frandsen, M.D., Peter Kristensen, M.D., E.M.B.A., Johannes F.E. Mann, M.D., Michael A. Nauck, M.D., Steven E. Nissen, M.D., Stuart Pocock, Ph.D., Neil R. Poulter, F.Med.Sci., Lasse S. Ravn, M.D., Ph.D., William M. Steinberg, M.D., Mette Stockner, M.D., Bernard Zinman, M.D., Richard M. Bergenstal, M.D., and John B. Buse, M.D., Ph.D., for the LEADER Steering Committee on behalf of the LEADER Trial Investigators\*

ORIGINAL ARTICLE

## Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy

V. Perkovic, M.J. Jardine, B. Neal, S. Bompont, H.J.L. Heerspink, D.M. Charytan, R. Edwards, R. Agarwal, G. Bakris, S. Bull, C.P. Cannon, G. Capuano, P.-L. Chu, D. de Zeeuw, T. Greene, A. Levin, C. Pollock, D.C. Wheeler, Y. Yavin, H. Zhang, B. Zinman, G. Meininger, B.M. Brenner, and K.W. Mahaffey, for the CREDENCE Trial Investigators\*

# SGLT2 inhibitors

## Empagliflozin (Jardiance) NF\*,

Dapagliflozin (Farxiga)<sub>NF</sub>, Canagliflozin (Invokana)<sub>NF</sub>, Ertugliflozin (Steglatro)<sub>NF</sub>

**Blocks renal glucose reabsorption, promotes glucosuria**

**A1c: ↓ 0.7 - 1.1%**

### Advantages

- Oral
- Modest weight loss (~2-3 kg)
- Lowers blood pressure
- CV benefit in pts w/ CVD
- Renal and CHF benefit in pts w/ clinical CVD or CVD risk factors

### Disadvantages

- High copays / cost
- **GU infections (10%)**
- UTI / urosepsis, pyelonephritis
- DKA
- Polyuria / hypotension / dizziness
- Fracture risk
- Not effective in pts with renal impairment and **contraindicated for GFR<30**

If prescribing **Empagliflozin**, start with **½ tabs (½ of 25 mg tab = 12.5 mg)** to reduce cost from \$\$\$\$\$ to \$\$\$\$

\* **Non-formulary preferred agent**

# GLP-1 receptor agonists

## Liraglutide (Victoza) NF\*

Exenatide ER inj (Bydureon) NF\*, Dulaglutide inj (Trulicity) NF, Semaglutide (Ozempic) NF, Lixisenatide (Adlyxin) NF

**A1c:** ↓ 0.7 - 1.5

### Advantages

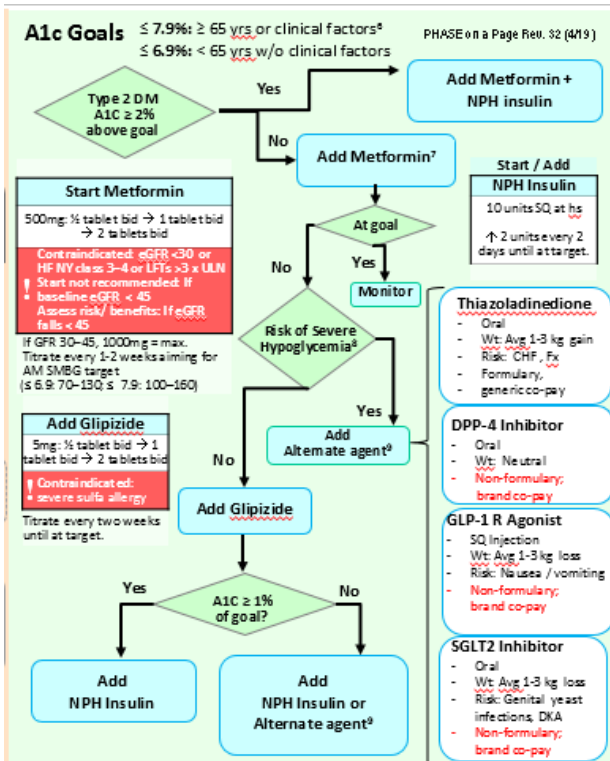
- Modest weight loss
- Once weekly dosing
- Less hypo risk
- CV benefit in pts w/ CVD (Liraglutide)

### Disadvantages

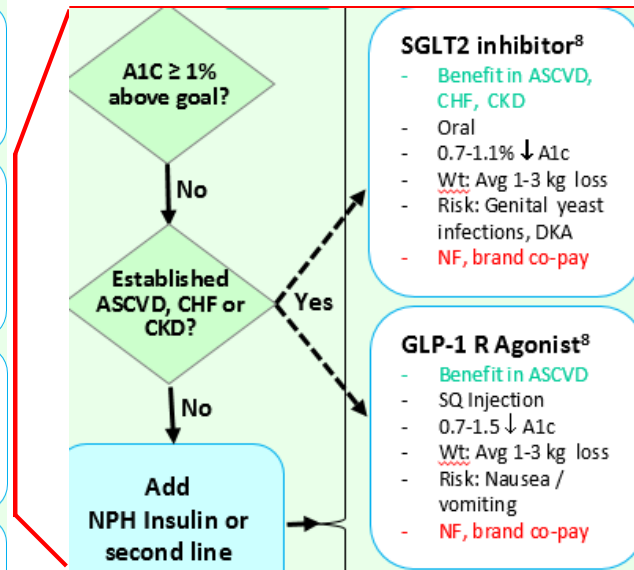
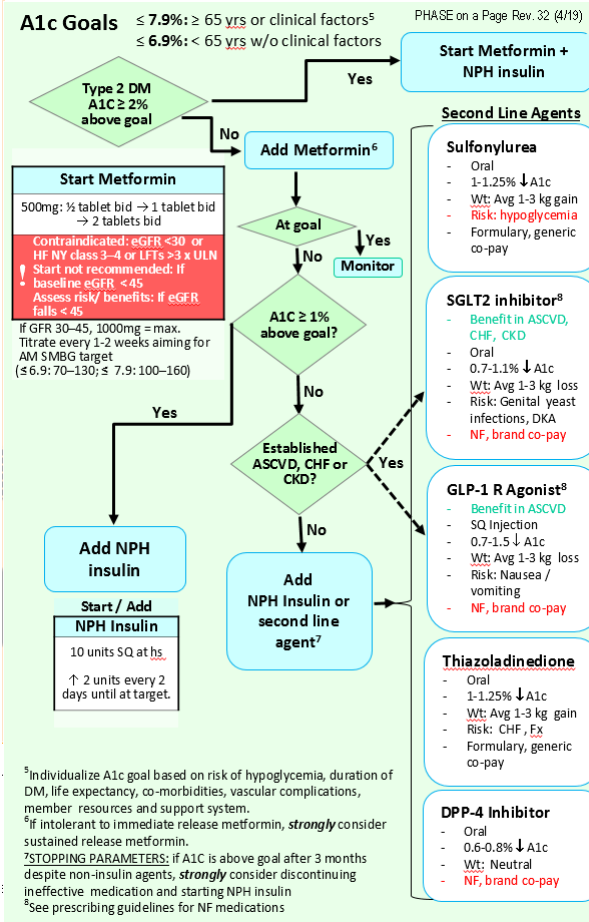
- Injected
- **GI SE's** (N/V, diarrhea in 20 - 40%)
- **VERY** costly
- **Contraindicated** if FHx of MTC or MEN2 (Boxed warning)
- Acute pancreatitis

# PHASE on a Page DM Updates

## CURRENT VERSION



## NEW VERSION



<sup>3</sup>Clinical Atherosclerotic Cardiovascular Disease (ASCVD), e.g. CAD, TIA/CVA, Symptomatic PAD.  
<sup>4</sup>Individualize A1c goal based on hypoglycemia risk, duration of DM, life expectancy, co-morbidities, vascular complications, member resources and support system.  
<sup>5</sup>If intolerant to immediate release metformin, **strongly** consider sustained release metformin.  
<sup>6</sup>Severe Hypoglycemia = Hypoglycemia resulting in / likely to result in seizure, loss of consciousness, or needing help from others. Mild to moderate hypoglycemia = Symptoms of neuroglycopenia such as hunger or sweating that the patient can effectively self-treat.  
<sup>7</sup>A1c above goal 3+ months despite non-insulin agents, **strongly** consider discontinuing ineffective medications and initiating insulin + metformin.

<sup>3</sup>Individualize A1c goal based on risk of hypoglycemia, duration of DM, life expectancy, co-morbidities, vascular complications, member resources and support system.  
<sup>4</sup>If intolerant to immediate release metformin, **strongly** consider sustained release metformin.  
<sup>5</sup>STOPPING PARAMETERS: if A1c is above goal after 3 months despite non-insulin agents, **strongly** consider discontinuing ineffective medication and starting NPH insulin  
<sup>6</sup>See prescribing guidelines for NF medications

# PHASE Updates 2018/2019

## Cholesterol/ Statins:

- Reframe as ‘to prevent heart attack and stroke’  
(not ‘for cholesterol’)
- NONFASTING lipid tests
- Separate ASCVD and DM populations

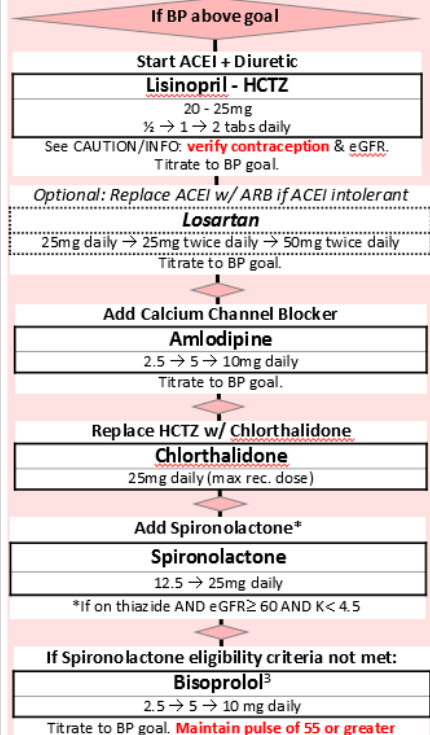


# PHASE Updates 2018/2019

## Aspirin:

- No change if ASCVD
- Primary prevention (including diabetics) - more caution overall about recommending
- Stop/don't start for patients >70yo

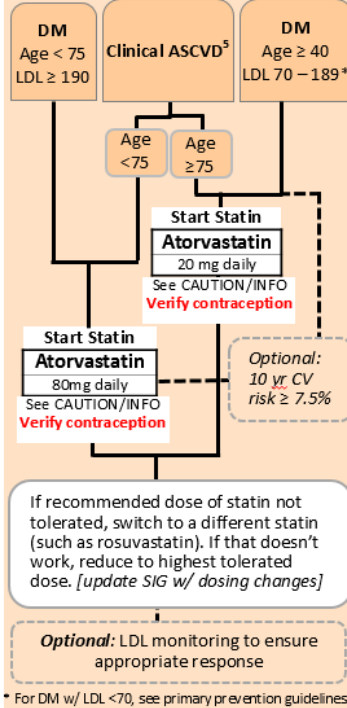
BP Goals <sup>1</sup> (in mm/ Hg)	Conventional Office	AOBP or Avg <sup>2</sup> Home Reading
All Adults Strong Rec.	≤ 139 / 89	≤ 134 / 84
If: ≥ 75 yrs, eGFR 20–59 mL/min, ASCVD or ≥10% 10-yr ASCVD risk	Consider ≤ 129/89	Consider ≤ 129 / 84



<sup>1</sup>BP algorithm applies if eGFR ≥ 20 and if LVEF ≥ 40%.  
<sup>2</sup>Automated Office BP (AOBP) avg. is the avg. of 3 readings measured with the patient unobserved using an AOBP device.

**Statin Goals**

- Atorvastatin 40-80 mg:**
- Clinical ASCVD<sup>5</sup> Age < 75 + any LDL
  - DM: Age < 75 + LDL ≥ 190
- Atorvastatin 10-20 mg:**
- Clinical ASCVD Age ≥ 75 + any LDL
  - DM: Age ≥ 40 + LDL 70-189\*



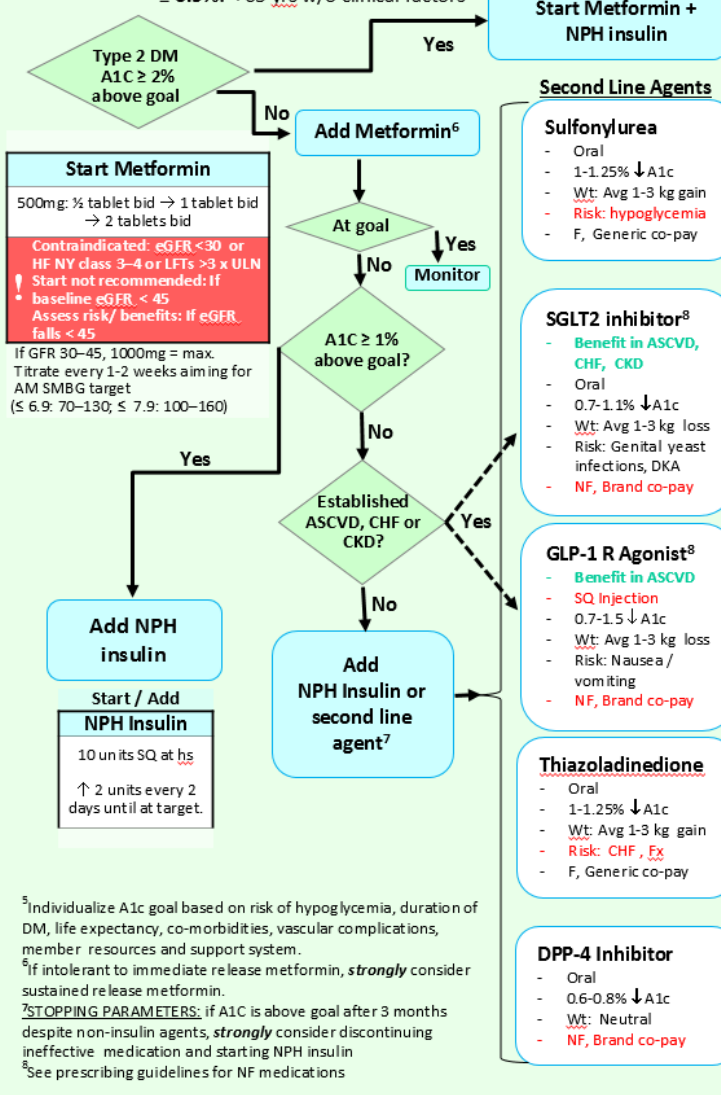
<sup>3</sup> Beta Blockers, independent of their mild anti-hypertensive effect, are sometimes indicated for secondary cardio-protection

Adapted from KP NC CPG for: CAD, DM, Cholesterol, HTN, HF and Stroke Complete guidelines, including updated guidelines on the Dx of HTN, can be found in the Clinical Library at <http://clkg.org>

Contact: Jonathan Lee, Sr Consulting Assoc., Regional Health & Design; Vince Rowell, Quality and Operations Support ©2019 Kaiser Permanente

**A1c Goals**

≤ 7.9%: ≥ 65 yrs or clinical factors<sup>5</sup>  
≤ 6.9%: < 65 yrs w/o clinical factors



<sup>5</sup> Individualize A1c goal based on risk of hypoglycemia, duration of DM, life expectancy, co-morbidities, vascular complications, member resources and support system.  
<sup>6</sup> If intolerant to immediate release metformin, **strongly** consider sustained release metformin.  
<sup>7</sup> STOPPING PARAMETERS: if A1C is above goal after 3 months despite non-insulin agents, **strongly** consider discontinuing ineffective medication and starting NPH insulin  
<sup>8</sup> See prescribing guidelines for NF medications



**Cardiovascular Risk Management Medications and Lab Chart Rev. 28 (05/19)**

**PHASE POPULATIONS**

**CAD** Symptomatic **PAD**

**CVA/TIA** Ischemic

**ASA:** If 10 y CV risk > 10%:

Ages 40-59: Consider ASA;

Ages 60-69: No rec. for/against ASA.

Age 70+ : Stop / do not start ASA.

**PHASE MEDICATIONS & CAUTIONS**

**Established ASCVD: ASA Recommended**

<b>ASA</b>	81mg daily
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**CAUTION/INFO** If ASA intolerant: Clopidogrel; CAD, Sx PAD

**ACEI**

<b>Lisinopril</b>	10mg daily
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**CAUTION/INFO** Verify effective contraception in women of childbearing potential: Use Chlorthalidone or HCTZ.

Use ACEI with caution: eGFR <30, K >5.5 ARB may be inappropriate : Hx of Angioedema, renal failure or hyperkalemia on ACEI.

**STATIN**

- Clinical ASCVD<sup>3</sup> Age < 75 + any LDL
- DM: Age < 75 + LDL ≥ 190

<b>Atorvastatin</b>	40-80mg daily
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- Clinical ASCVD Age ≥ 75 + any LDL
- DM: Age ≥ 40 + LDL 70-189\*\*

<b>Atorvastatin OR Rosuvastatin</b>	10-20mg daily
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**CAUTION/INFO** Verify effective contraception in women of childbearing potential.

**BETA BLOCKER – FOR CAD/Sx PAD**

<b>Bisoprolol</b>	25mg daily
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**CAUTION / INFO** Use with caution: HR <55, asthma, hypotension.

\*\* For DM w/ LDL <70, see primary prevention guidelines.

Drug info site: <http://pharmacy.kp.org>  
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<b>BP</b>	<b>Preferred Dosage Forms</b>	<b>Max. Rec. Dose</b>	<b>Optimal Titration Interval</b>	<b>Baseline Labs</b>	<b>Titration</b>
<b>ACE Inhibitor - Diuretic</b> Lisinopril - HCTZ ( <b>Prinzide®</b> ) F	Tab 20 / 25mg	40 / 50mg daily	2 weeks	K+ and <u>SCr</u> , < 6 months (Na+ optional)	K+ and <u>SCr</u> , 1 week after initiation or dosage change (Na+ optional)
<b>Thiazide Diuretics</b> HCTZ ( <b>Hydrodiuril®</b> , <b>Esidrix®</b> ) F	Tab 25mg	HCTZ 50mg daily	2 weeks	K+ and <u>SCr</u> , < 6 months (Na+ optional)	K+ and <u>SCr</u> , 1 week after initiation or dosage change (Na+ optional)
Chlorthalidone ( <b>Hygraton®</b> ) F	Tab 25mg	25mg daily	2 weeks	K+ and <u>SCr</u> , < 6 months (Na+ optional)	K+ <u>SCr</u> , 1 week after initiation or dosage change (Na+ optional)
<b>ACE Inhibitor</b> Lisinopril ( <b>Prinivil®</b> ) F	Tab 5, 10, 20mg	40mg daily	1 week	K+ and <u>SCr</u> , < 6 months	K+ and <u>SCr</u> , 1 week after initiation. K+ 2 weeks after dosage change
<b>ARB</b> Losartan ( <b>Cozaar®</b> ) F	Tab 25, 50mg	100mg daily or 50mg BID	1 week	K+ and <u>SCr</u> , < 6 months	K+ and <u>SCr</u> , 1 week after initiation. K+ 2 weeks after dosage change
<b>Calcium Channel Blocker</b> Amlodipine ( <b>Norvasc®</b> ) F	Tab 2.5, 5, 10mg	10mg daily	1 week	None	None
<b>Potassium Sparing Diuretic</b> Spironolactone ( <b>Aldactone®</b> ) F	Tab 25mg	25mg daily	1 week	K+, <u>SCr</u> , < 1 month	K+ and <u>SCr</u> , 1 week after initiation & 2 weeks after dosage change
<b>Beta 1 blocker</b> Bisoprolol ( <b>Zebeta®</b> ) F	Tab 5, 10mg	10mg daily	1 week	None	Maintain pulse ≥ 55

<b>DM 2 (non-insulin agents)</b>	<b>Preferred Dosage Forms</b>	<b>Max. Rec. Dose</b>	<b>Optimal Titration Interval</b>	<b>Baseline Labs</b>	<b>Cautions / Contraindications</b>
<b>Biguanide</b> Metformin ( <b>Glucophage®</b> ) F	Tab 500, 1000mg	1000mg BID	2 weeks	<u>SCr</u> , (CBC optional)	Contraindicated: eGFR <30 or HF NY class 3-4 or LFTs >3 x ULN; Not recommended: baseline eGFR < 45; Assess R/B: If eGFR falls < 45
<b>Sulfonylurea</b> Glipizide ( <b>Glucotrol®</b> ) F	Tab 2.5, 5, 10mg	20mg BID ac	2 weeks	None	Contraindicated: severe sulfa allergy
<b>Thiazolidinedione</b> Pioglitazone ( <b>Actos®</b> ) F	Tab 15,30,45 mg	45 mg daily	2 months	ALT, ( <u>AlkP</u> , <u>T bili</u> optional)	Contraindicated: CHF stage III or IV
<b>DPP-4 inhibitor</b> Linagliptin ( <b>Tradjenta®</b> ) NF	Tab 5 mg	5 mg daily	N/A	None	N/A
<b>SGLT2 inhibitor</b> Empagliflozin ( <b>Jardiance®</b> ) NF	Tab 10, 25 mg	25 mg daily	2 weeks	<u>SCr</u> .	Contraindicated: eGFR <45
<b>GLP-1 receptor agonists</b> Liraglutide ( <b>Victoza®</b> ) NF	SQ Inj 0.6, 1.2 mg	1.8 mg daily	1 week	<u>SCr</u> .	Contraindicated: personal or FH Medullary thyroid CA or MEN2
Exenatide ER inj ( <b>Bydureon®</b> ) NF	SQ Inj 2 mg	2 mg weekly	N/A	<u>SCr</u> .	Contraindicated: personal or FH Medullary thyroid CA or MEN2

<b>Statins</b>	<b>Preferred Dosage Forms</b>	<b>Max. Rec. Dose</b>	<b>Optimal Titration Interval</b>	<b>Baseline Labs*</b>	<b>Titration</b>
Atorvastatin ( <b>Lipitor®</b> ) F	Tab 40, 80mg	80mg daily <u>hs</u>	N/A	ALT, <u>SCr</u>	N/A
Rosuvastatin ( <b>Crestor®</b> ) F	Tab 10, 20mg	20mg daily <u>hs</u>	N/A	ALT, <u>SCr</u>	N/A

F: Formulary \*Do not routinely measure CK. Consider baseline CK if inc. risk for adverse muscle events (s.a. personal or family history of statin intolerance or muscle disease, clinical presentation, or concomitant drug therapy that might inc. the risk for myopathy).

# PHASE

**Most important aspects  
for clinical benefit**

# PHASE: key aspects for benefit

- Identify patients at point of care, limit back sweep work
- Identify and standardize goals and meds across providers (POAP)
- Easy med escalation, usually generics
- Evidence based
- Enables providers at several levels (MA, nurse, PharmD, doctors) to intervene on patient's behalf

# PHASE: Operational workflows

## Blood pressure:

- BP measurement excellence
- AOBP
- Same day med escalation
- Identify cohort, get high BPs back in for recheck
- Outreach plan, accountability
- Reports/tracking

# PHASE: Operational workflows

## Diabetes:

- Identify cohort and their specific needs (updated lab vs medication escalation)
- Someone accountable
- Offer diet, exercise, education to patients
- Clear medication escalation instructions
- Start insulin early, it is not a sign of failure

# PHASE: Operational workflows

## Cholesterol/ Statins:

- NONFASTING labs
- The doctor voice is powerful
- Reinforce medication adherence and give positive feedback at every encounter
- Myalgia – don't stop the statin, change to a different statin
- Emphasize lifestyle and diet changes, ongoing



# PHASE

## What is next area of focus?

# PHASE: Next focus areas

BP, Diabetes, Statins, Aspirin- Ongoing efforts:

- new modes of measurement
- keeping up with guideline changes

In addition:

- Disparities – HTN, DM. Identify and close the gap, Culturally inclusive messaging
- Medication adherence – reinforcement across the medical center
- Motivational interviewing – key at all levels



**Thank you**

# PHASE discussion

**Ronald Scott, MD**

Family Medicine, KP West LA

KPSC CVD Co-Lead

KP National Integrated Cardiovascular Health (ICVH) Clinical Lead

KP National Cholesterol and Cardiovascular Risk Clinical Lead

## Elements for Success

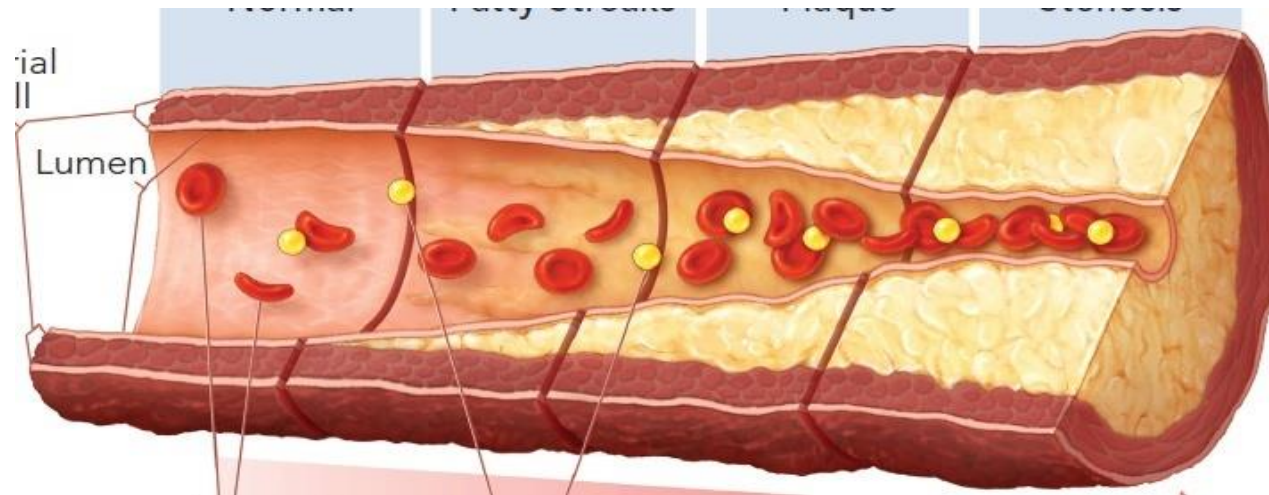
- Champion, network of champions.
- Know and try to align evidence, metrics, guideline and protocol.
- Simplified protocols. Minimize complexity and branchpoints.
- Data / feedback preferably unblinded. Sharing of best practices, performance improvement.

## Key Operational Workflows:

- Hypertension – KP national to <140/90 end of 2017 (with ICVH consensus statement). Point of Care med changes, AOBP.
- DM –similar to KP Nor Cal.

## Key Messages – align with Million Hearts

- Heart attacks and strokes are preventable, yet they remain leading causes of death and disability. Hits many middle age adults (age 50-64 years).
- “Screening, lifestyle, and medicines together can help you live a longer healthier life.”
- KPARE – Kaiser Permanente ASCVD Risk Estimator (ARisk) launch, Dec 2018.
- Statins – Agree with KPNC “to help prevent heart attack and stroke”, “to help keep arteries open” messages.



# Statin Impact, primary prevention

Randomized Clinical Trial	ARisk	RRR	NNT
MEGA Prava 10-20 mg, <b>LDL -17%</b>	<b>5.1%</b>	24%	<b>82</b>
AFCAPS Lova 20-40 mg, <b>LDL -27%</b>	<b>6.9%</b>	26%	<b>56</b>
JUPITER Rosuva 20 mg, <b>LDL -50%</b>	<b>7.6%</b>	44%	<b>25</b>
ACC Guideline “High Intensity” <b>LDL -50%</b>	<b>10%</b>	45%	<b>22</b>

# Preferred LDL lowering options

Medicine	% LDL lower	Medicine	% LDL lower
Rosuva 40 mg	63	Atorva 80 mg	53
Rosuva 20 mg	55	Atorva 40 mg	48
Rosuva 10 mg	47	Atorva 20 mg	41
Rosuva 5 mg 2x/week (Mon, Thurs) + ezetimibe			40

Rosuvastatin effective, inexpensive, great safety.  
(For GFR <45, use atorvastatin)



# 2019 Four Cholesterol Management Groups, KPSC

## Clinical ASCVD (age $\leq 75$ )

- ▲ Start rosuvastatin 20 mg daily (R20), aim for  $\geq 50\%$  reduction in LDL levels.
- ▲ If LDL remains  $\geq 70$  mg/dL, consider ezetimibe.

## LDL $\geq 190$ (age 20-75)

- ▲ Start R20, aim for  $\geq 50\%$  reduction in LDL levels.
- ▲ If achieve  $< 50\%$  reduction, and/or LDL  $\geq 100$  mg/dL, consider ezetimibe.

As age to  $\geq 76$  years, shift to consider statin. For GFR  $< 45$  use atorvastatin.

## DM (age 40-75)

- ▲ KPARE  $\geq 7.5\%$  and LDL  $\geq 70$ , R20.
- ▲ KPARE  $< 7.5\%$  or LDL  $< 70$ , R10.

## By Risk (age 40-75, LDL 70-189)

- ▲ KPARE  $\geq 10\%$ , R20
- ▲ 7.5-9.9%, consider R20.
- ▲ 5-7.4%, consider discussing R10.

Over 60% increase in high-intensity statin use 2009 – 2015. Reynolds et al, ACC, March 2017

## Learn / improve at multiple levels. Seek out member convenient synergy.

- Individual physician level, Module leader level, Regional level (13 medical centers KPSC), KP National Level – Learn from other KP Regions
- Working outside KP, researchers – share and learn, keep improving care.
- Seek synergy, example: 65+ yo male former smoker AAA screening → No AAA, but find aortic atherosclerosis → promote statin use and adherence.

Questions?



# See you at the In-Person PHASE Convening!

*Engaging Patients as  
Active Partners*

**Tuesday, June 11**

8:30 a.m. – 4 p.m.

Hilton Oakland Airport

Agenda & Materials available here:

[careinnovations.org/phase-jun-2019-convening/](https://careinnovations.org/phase-jun-2019-convening/)

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**PHASE**



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