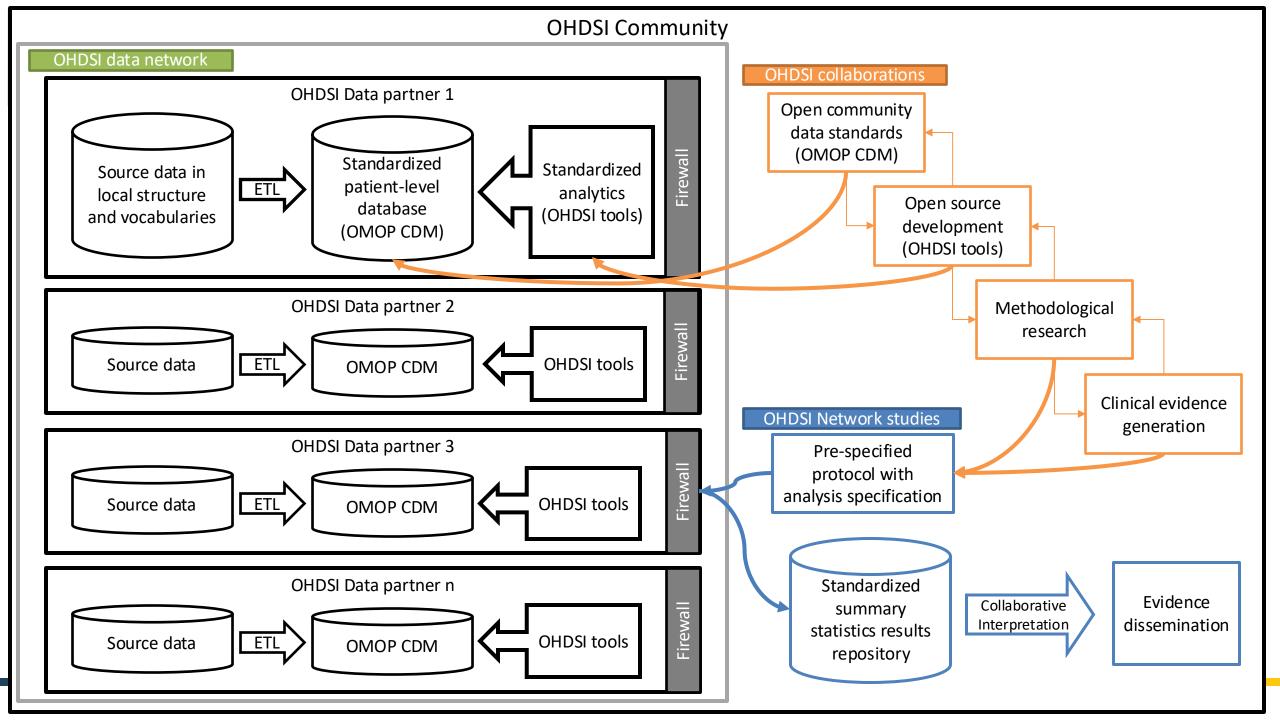


# OHDSI in 2025: Where can we go together?



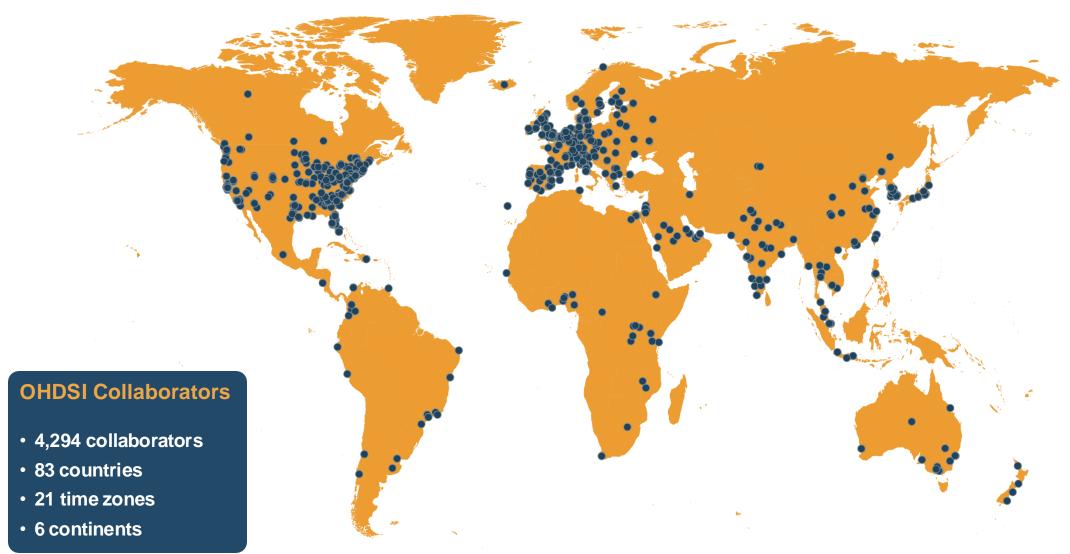
## OHDSI's mission

To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care





# OHDSI collaborators



Join the Journey at <a href="https://ohdsi.org/">https://ohdsi.org/</a>



## What do you want OHDSI to accomplish together in 2025?

Nobody has responded yet.

Hang tight! Responses are coming in.



# Calendar of events of potential interest to OHDSI community

January	,							April							July							Octob	er					
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Conference	Submission Deadline	Event	Location
AMIA Informatics Summit	closed	Mar10-13	Pittsburgh, PA, USA
American College of Cardiology (ACC) Scientific Session	closed	Mar29-31	Chicago IL USA
American Academy of Neurology	closed	April5-9	San Diego, CA, USA
Digestive Disease Week (DDW) 2025	closed	May 3-6	San Diego, CA, USA
ISPOR	closed	May13-16	Montreal, Quebec, CA
American Psychiatric Association (APA) Annual Meeting		May 17-21	Los Angeles CA USA
American Society of Clinical Oncology (ASCO) Annual Meeting	28-Jan	May30-Jun3	Chicago IL USA
European Alliance of Associations for Rheumatology (EULAR) Congress	15-Jan	June11-14	Barcelona, Spain
DIA	closed	Jun15-19	Washington DC USA
OHDSI Europe	tba	July5-7	Hasselt, Belgium
ICPE	15-Feb	Aug22-26	Washington DC USA
European Society of Cardiology (ESC) Congress	1-Mar	Aug29-Sept1	Madrid Spain
JSM	3-Feb	Aug2-7	Nashville, TN, USA
MedInfo	10-Jan	Aug9-13	Taipei, Taiwan
American Academy of Pediatrics (AAP) National Conference	4-Apr	Sept26-30	Denver CO USA
DIA Real World Conference		Oct 16-17	San Diego, CA, USA
European Society for Medical Oncology (ESMO) Congress	7-May	Oct17-21	Berlin Germany
American Academy of Ophthalmology		Oct17-20	Orlando FL USA
ISOP		Oct 24-27	Cairo Egypt
American College of Rheumatology (ACR) Convergence		Oct 24-29	Chicago IL USA
AMIA Annual Symposium		Nov15-19	Atlanta, GA, USA
OHDSI APAC	tba	Dec6-7	Shanghai, CN
OHDSI Global			







# OHDSI Global Symposium 2018



### What's in a guideline?

### **Clinical Practice Guideline: Executive Summary**

2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines



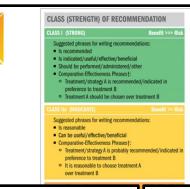




Table 18. Oral Antihypertensive Drugs

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### 8.1.6. Choice of Initial Medication

### **Recommendation for Choice of Initial Medication**

References that support the recommendation are summarized in Online Data Supplement 27 and Systematic Review Report.

COR	LOE	Recommendation
ı	A <sup>SR</sup>	<ol> <li>For initiation of antihypertensive drug therapy, first-line agents include thiazide diuretics, CCBs, and ACE inhibitors or ARBs. S8.1.6-1,S8.1.6-2</li> </ol>

SR indicates systematic review.



Class	Drug	Usual Dose, Range (mg/d)*	Daily Frequency	Comments
Primary agents				
Thiazide or	Chlorthalidone	12.5-25	1	Chlorthalidone is preferred on the basis of
thiazide-type	Hydrochlorothiazide	25-50	1	prolonged half-life and proven trial reduction of
diuretics	Indapamide	1.25-2.5	1	CVD.
4	Metolazone	2.5-10	1	Monitor for hyponatremia and hypokalemia, uric acid and calcium levels.  Use with caution in patients with history of acute gout unless patient is on uric acid—lowering therapy.
ACE inhibitors	Benazepril	10-40	1 or 2	Do not use in combination with ARBs or direct renin
	Captopril	12.5-150	2 or 3	inhibitor.
	Enalapril	5-40	1 or 2	There is an increased risk of hyperkalemia, especially
	Fosinopril	10-40	1	in patients with CKD or in those on K+ supplements
10	Lisinopril	10-40	1	or K+-sparing drugs.
10	Moexipril	7.5-30	1 or 2	There is a risk of acute renal failure in patients with
	Perindopril			severe bilateral renal artery stenosis.
	Quinapril	10-80	1 or 2	Do not use if patient has history of angioedema with
	Ramipril	2.5-10	1 or 2	ACE inhibitors.
	Trandolapril	1-4	1	Avoid in pregnancy.     Only 29 different
ARBs	Azilsartan	40-80	1	Do not use in combination with ACE inh
	Candesartan	8-32	1	direct renin inhibitor. drugs in 5
	Eprosartan	600-800	1 or 2	There is an increased risk of hyperidical different classes
	Irbesartan	150-300	1	in those on K+ supplements or K+
(8)	Losartan	50-100	1 or 2	There is a risk of acute renal failure in patien to choose from!
	Olmesartan	20-40	1	severe bilateral renal artery stenosis.
	Telmisartan	20-80	1	Do not use if patient has history of angioedem
TI	Valsartan	80-320		with ARBs. Patients with a history of angioedema with an ACE inhibitor can receive an ARB beginning 6 weeks after ACE inhibitor is discontinued
CCB-	Amlodipine	2.5-10	1	Avoid in pregnancy.     Avoid use in patients with HF/EF;     Distinguished from 28
dihydropyridin	Felodipine	5-10	1	felodipine may be used if required
es	Isradipine	5-10	2	They are associated with dose-religious in 12 other classes
	Nicardipine SR	5-20	1	They are associated with dose-religible which is more common in women drugs in 12 other classe.
(5)	Nifedipine LA	60-120	1	that are classified as
	Nisoldipine	30-90	1	
CCB-	Diltiazem SR	180-360	2	Avoid routine use with beta block potential secondary agent
nondihydropyri	Diltiazem ER	120-480	1	increased risk of bradycardia and h. (including Beta Blockers)
dines	Verapamil IR	40-80	3	Do not use in patients with HFrEF.
	Verapamii SR	120-480	1 or 2	There are drug interactions with diltiazem and
	Verapamil-delayed	100-480	1 (in the	versasmil /CVP2A4 major substrate and moderate
$\overline{\mathcal{L}}$	onset ER (various forms)	100 430	evening)	whelton et al., Hypertension 201

Whelton et al., Hypertension 2018



## THE LANCET



# Comprehensive comparative effectiveness and safety of first-line antihypertensive drug classes: a systematic, multinational, large-scale analysis



Marc A Suchard, Martijn J Schuemie, Harlan M Krumholz, Seng Chan You, Ruijun Chen, Nicole Pratt, Christian G Reich, Jon Duke, David Madigan, George Hripcsak, Patrick B Ryan

#### Summary

Background Uncertainty remains about the optimal monotherapy for hypertension, with current guidelines recommending any primary agent among the first-line drug classes thiazide or thiazide-like diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, dihydropyridine calcium channel blockers, and non-dihydropyridine calcium channel blockers, in the absence of comorbid indications. Randomised trials have not further refined this choice.

Methods We developed a comprehensive framework for real-world evidence that enables comparative effectiveness and safety evaluation across many drugs and outcomes from observational data encompassing millions of patients, while minimising inherent bias. Using this framework, we did a systematic, large-scale study under a new-user cohort design to estimate the relative risks of three primary (acute myocardial infarction, hospitalisation for heart failure, and stroke) and six secondary effectiveness and 46 safety outcomes comparing all first-line classes across a global network of six administrative claims and three electronic health record databases. The framework addressed residual confounding, publication bias, and p-hacking using large-scale propensity adjustment, a large set of control outcomes, and full disclosure of hypotheses tested.

Findings Using 4.9 million patients, we generated 22 000 calibrated, propensity-score-adjusted hazard ratios (HRs) comparing all classes and outcomes across databases. Most estimates revealed no effectiveness differences between classes; however, thiazide or thiazide-like diuretics showed better primary effectiveness than angiotensin-converting enzyme inhibitors: acute myocardial infarction (HR 0.84, 95% CI 0.75–0.95), hospitalisation for heart failure (0.83, 0.74–0.95), and stroke (0.83, 0.74–0.95) risk while on initial treatment. Safety profiles also favoured thiazide or thiazide-like diuretics over angiotensin-converting enzyme inhibitors. The non-dihydropyridine calcium channel blockers were significantly inferior to the other four classes.

Interpretation This comprehensive framework introduces a new way of doing observational health-care science at scale. The approach supports equivalence between drug classes for initiating monotherapy for hypertension—in keeping with current guidelines, with the exception of thiazide or thiazide-like diuretics superiority to angiotensin-converting enzyme inhibitors and the inferiority of non-dihydropyridine calcium channel blockers.

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See Online/Comment https://doi.org/10.1016/ S0140-6736(19)32461-4

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2023 ESH Guidelines for the management of arterial hypertension

The Task Force for the management of arterial hypertension of the European Society of Hypertension

Endorsed by the International Society of Hypertension (ISH) and the European Renal Association (ERA)

Authors/Task Force Members: Giuseppe Mancia (Chairperson)<sup>a,\*</sup>, Reinhold Kreutz (Co-Chair)<sup>b,\*</sup>, Mattias Brunström<sup>c</sup>, Michel Burnier<sup>d</sup>, Guido Grassi<sup>e</sup>, Andrzej Januszewicz<sup>f</sup>, Maria Lorenza Muiesan<sup>g</sup>, Konstantinos Tsioufis<sup>h</sup>, Enrico Agabiti-Rosei<sup>l</sup>, Engi Abd Elhady Algharably<sup>b</sup>, Michel Azizi<sup>j,k</sup>, Athanase Benetos<sup>l</sup>, Claudio Borghi<sup>m</sup>, Jana Brguljan Hitij<sup>n</sup>, Renata Cifkova<sup>o,p</sup>, Antonio Coca<sup>q</sup>, Veronique Cornelissen<sup>r</sup>, J. Kennedy Cruickshank<sup>s</sup>, Pedro G. Cunha<sup>t,u</sup>, A.H. Jan Danser<sup>v</sup>, Rosa Maria de Pinho<sup>w</sup>, Christian Delles<sup>x</sup>, Anna F. Dominiczak<sup>y</sup>, Maria Dorobantu<sup>z</sup>, Michalis Doumas<sup>aa</sup>, María S. Fernández-Alfonso<sup>bb,cc</sup>, Jean-Michel Halimi<sup>dd,ee,ff</sup>, Zoltán Járai<sup>gg</sup>, Bojan Jelakovic<sup>hh</sup>, Jens Jordan<sup>ii,jj</sup>, Tatiana Kuznetsova<sup>kk</sup>, Stephane Laurent<sup>II</sup>, Dragan Lovic<sup>mm</sup>, Empar Lurbe<sup>nn,oo,pp</sup>, Felix Mahfoud<sup>qq,rr</sup>, Athanasios Manolis<sup>ss</sup>, Marius Miglinas<sup>tt,uu</sup>, Krzystof Narkiewicz<sup>vv</sup>, Teemu Niiranen<sup>ww,xx</sup>, Paolo Palatini<sup>yy</sup>, Gianfranco Parati<sup>zz,aaa</sup>, Atul Pathak<sup>bbb</sup>, Alexandre Persu<sup>ccc</sup>, Jorge Polonia<sup>ddd</sup>, Josep Redon<sup>oo,eee,fff</sup>, Pantelis Sarafidis<sup>ggg</sup>, Roland Schmieder<sup>hhh</sup>, Bart Spronck<sup>iii</sup>, Stella Stabouli<sup>jij</sup>, George Stergiou<sup>kkk</sup>, Stefano Taddei<sup>III</sup>, Costas Thomopoulos<sup>mmm</sup>, Maciej Tomaszewski<sup>nnn,ooo</sup>, Philippe Van de Borne<sup>ppp</sup>, Christoph Wanner<sup>qqq</sup>, Thomas Weber<sup>rrr</sup>, Bryan Williams<sup>sss</sup>, Zhen-Yu Zhang<sup>ttt</sup>, and Sverre E. Kjeldsen<sup>uuu</sup>



2023 ESH Guidelines for the management of arterial hypertension

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### 11.3 Diuretics

### 11.3.1 Thiazide/Thiazide-like

The effectiveness of Thiazide/Thiazide-like diuretics in preventing CV morbidity and mortality has been shown in RCTs and meta-analyses [539-541,565], with an effect similar to the effect of other major antihypertensive agents. In meta-analyses of RCTs, Thiazide/Thiazide-like appear to be more effective than other major drug classes in preventing HF, but this finding may be influenced by the results of the ALLHAT study [566], in which patients largely under a background diuretic treatment were rolled over to comparison drugs, with a possible emergence of HF symptoms previously under diuretic-based symptomatic control. The thiazide-like diuretics, chlorthalidone and indapamide, are more potent and have a longer duration of action compared with hydrochlorothiazide, but a greater incidence of side effects has been reported for chlortalidone in some studies [567]. A meta-analysis of placebo-controlled studies based on thiazides, chlorthalidone, and indapamide found similar effects for the three types of diuretics on CV outcomes [539]. A greater risk of CV events and HF has been reported with Thiazide diuretics in another meta-analysis [568]. Yet, no major difference between hydrochlorothiazide and chlorthalidone has been observed in a large observational cohort study [LEGEND] using a database spanning from January 2001 to December 2018 [569]. Furthermore, similar results have been obtained by a recent open-label study, DCP, on hypertensive US Veterans older than 65 years [570]. In this study, patients who were already on hydrochlorothiazide were randomized to either chlorthalidone (n = 6756) or hydrochlorothiazide continuation (n = 6767). Patients on treatment with hydrochlorothiazide 25 or 50 mg were converted to 12.5 or 25 mg chlorthalidone, respectively. No difference in CV outcomes between the two drugs was found, except for patients with a prior stroke in whom there was a greater benefit with chlorthalidone. Despite some limitations (in the last study, very few patients were on hydrochlorothiazide monotherapy at baseline, which means that the results could have been affected by concomitant medications and adherence to their use), the above-mentioned recent observations justify the recommendation of the present guidelines to still consider Thiazide/Thiazide-like diuretics both as suitable antihypertensive agents and as similarly effective in CV prevention. Both Thiazide/Thiazide-like can lower serum potassium and have a sideeffect profile that is less favorable than RAS blockers. This may account for their higher rate of treatment discontinuation. Depending on the dose, they may also increase insulin resistance and, hence, the risk of new-onset diabetes. Potassium plays an important role in the metabolic effects of Thiazide/Thiazide-like, and evidence is available that these effects are reduced by the combination of Thiazide/Thiazide-like with a potassium-sparing diuretic [571,572] or with an RAS blocker. A recent placebo controlled study [573] has demonstrated that shlorthalidane affectively lowers PD and albuminuria in nationts with

569. Hripcsak G, Suchard MA, Shea S, Chen R, You SC, Pratt N, et al. Comparison of Cardiovascular and Safety Outcomes of Chlorthalidone vs Hydrochlorothiazide to Treat Hypertension. JAMA Intern Med 2020; 180:542–551.



2023 ESH Guidelines for the management of arterial hypertension

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### 11.5 Beta-blockers

RCTs and meta-analyses have demonstrated that when compared with placebo, first-generation and second-generation BBs like propranolol, atenolol and metoprolol significantly reduce the risk of stroke, HF and major CV events in hypertensive patients. When compared with other BP-lowering drugs, BBs were almost equivalent in preventing major CV events, except for a less effective prevention of stroke [539–541,583,584]. It is possible that this difference on stroke data between BBs and other antihypertensive drug classes originates from small differences in achieved BP, including central SBP, to which cerebrovascular events may be especially sensitive. BBs are also associated with increased risk of new-onset diabetes in predisposed individuals (mostly those with the metabolic syndrome). They also exhibit a less favorable side-effect profile than that of RAS blockers, with a higher rate of treatment discontinuation when assessed in real-life conditions [514]. In previous guidelines [4,32,488], BBs were included among the five major antihypertensive drug classes. However, in the general treatment algorithm, they were recommended only when there is a specific indication, e.g. in patients with HF, angina, post-MI, AF or in younger hypertensive women of child-bearing potential or planning pregnancy. BBs do not constitute an homogeneous class but show several pharmacological differences, among which beta1-selectivity and an additional direct vasodilating property are of special interest. Third-generation BBs, such as nebivolol or carvedilol, exhibit direct vasodilating properties. Studies not only with nebivolol but also with bisoprolol, i.e. BBs with higher beta-1 selectivity and limited to nebivolol an added vasodilatation via increased release of nitric oxide, reported a more favorable side effect profile than other BBs, including fewer adverse effects on sexual function [585,586]. RCTs with carvedilol, bisoprolol, metoprolol and nebivolol showed improved outcomes in patients with HFrEF [587]. However, there are no outcome trials with vasodilating BBs in hypertensive patients, and the same applies to bisoprolol. There are also some recent large realworld studies with vasodilator BBs conducted in the USA, with inconsistent results. In one study, there was no statistically significant difference in CV outcomes between 118 133 patients receiving either nebivolol or carvedilol and 267 891 patients receiving atenolol [588]. In other studies, use of nebivolol led to greater CV protection compared with use of atenolol or

588. Chan You S, Krumholz HM, Suchard MA, Schuemie MJ, Hripcsak G, Chen R, et al. Comprehensive comparative effectiveness and safety of first-line beta-blocker monotherapy in hypertensive patients: a large-scale multicenter observational study. Hypertension (Dallas, Tex: 1979) 2021; 77:1528–1538.



Table 1: Similarities and Differences Between ACC/AHA and ESH Guidelines on Hypertension

Guideline Similarities	2017 ACC/AHA	2023 ESH				
Accurate Blood Pressure Measurement	Office-based BP measurements and home/ambulatory BP monitoring are recon	use of validated, cuffed devices and nmended prior to diagnosing hypertension.				
Cardiovascular Risk Calculator for Treatment Thresholds	Pooled Cohort Equation and SCORE2/SCORE2-OP provide estimates for 10-year risk fatal and non-fatal cardiovascular events and should be used to guide treatment decision					
Initial Pharmacotherapy Recommendations	Initial therapeutic choices include ACE inhibitors, angiotensin-receptor blockers, thiazide or thiazide-like diuretics, and calcium channel blockers.  Single pill combination therapy is a first-line strategy for many patients.					
<b>Guideline Differences</b>	2017 ACC/AHA	2023 ESH				
Hypertension Definition	≥ 130/80	≥ 140/90				
Normal BP Ranges (mmHg)	Normal: < 120/80 Elevated: 120-129/<80	Optimal: < 120/80 Normal: 120-129/80-84 High-Normal: 130-139/85-89				
Hypertensive BP Ranges (mmHg)	Hypertension Stage 1: 130-139/80-89 Hypertension Stage 2: ≥ 140/90	Hypertension Grade 1: 140-159/90-99 Hypertension Grade 2: 160-179/100-109 Hypertension Grade 3: ≥ 180/110				
BP Targets for Treatment						
18 – 64 years (mmHg)	< 130/80	< 130/80				
65-79 years (mmHg)	< 130/80	< 140/80*				
≥ 80 years (mmHg)	< 130/80	140-150/<80				
Pharmacotherapy	Initial therapy with beta-blockers reserved for specific conditions including ischemic heart disease or heart failure	Beta blockers included as first-line therapy for hypertension.				

<sup>\*</sup> Target < 130/80 if tolerated



8.1.6.1. Choice of Initial Monotherapy Versus Initial Combination Drug Therapy

# Recommendations for Choice of Initial Monotherapy Versus Initial Combination Drug Therapy\*

COR	LOE	Recommendations
_	C-EO	Initiation of antihypertensive drug therapy with 2 first-line agents of different classes, either as separate agents or in a fixed-dose combination, is recommended in adults with stage 2 hypertension and an average BP more than 20/10 mm Hg above their BP target.
lla	C-EO	Initiation of antihypertensive drug therapy with a single antihypertensive drug is reasonable in adults with stage 1 hypertension and BP goal <130/80 mm Hg with dosage titration and sequential addition of other agents to achieve the BP target.

<sup>\*</sup>Fixed-dose combination antihypertensive medications are listed in Onlin Data Supplement D.

## **Synopsis**

Systematic review of the evidence comparing the initiation of antihypertensive treatment with monotherapy and sequential (stepped-care) titration of additional agents versus initiation of treatment with combination therapy (including fixed-dose combinations) did not identify any RCTs meeting the systematic review questions posed in the PICOTS format (P=population, I=intervention, C=comparator, O=outcome, T=timing, S=setting). However, in both ACCORD and SPRINT, 2-drug therapy was recommended for most participants in the intensive- but not standard-therapy groups.





## Introduction and Methodology: Standards of Care in Diabetes—2025

Diabetes Care 2025;48(Suppl. 1):S1-S5 | https://doi.org/10.2337/dc25-SINT

Diabetes is a complex, chronic condition requiring continuous medical care with comprehensive risk-reduction strategies beyond glycemic management. Ongoing diabetes self-management education and support are critical to empowering people, preventing acute complications, and reducing the risk of long-term complications. Significant evidence exists that supports a range of interventions to improve diabetes outcomes.

The American Diabetes Association (ADA) "Standards of Care in Diabetes," referred to here as the Standards of Care, serves as a comprehensive resource to clinicians, researchers, policy makers, and other stakeholders. It outlines key elements of diabetes care, sets treatment goals, and provides tools

DiabetesPro at professional.diabetes.org/ standards-of-care/living-standards-update. The Standards of Care supersedes all previously published ADA statements—and the recommendations therein—on clinical topics within the purview of the Standards of Care; while still containing valuable analysis, ADA statements should not be considered the current position of the ADA. The Standards of Care receives annual review and approval by the ADA Board of Directors and is reviewed by the ADA scientific team and clinical leadership. The Standards of Care also undergoes external peer review annually.

### SCOPE OF THE GUIDELINES

The recommendations in the Standards

American Diabetes Association Professional Practice Committee\*

Table 1-	-ADA evidence-grading system for "Standards of Care in Diabetes"
Level of evidence	Description
A	Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including:  • Evidence from a well-conducted multicenter trial  • Evidence from a meta-analysis that incorporated quality ratings in the analysis  Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:  • Evidence from a well-conducted trial at one or more institutions  • Evidence from a meta-analysis that incorporated quality ratings in the analysis
В	Supportive evidence from well-conducted cohort studies, including:  • Evidence from a well-conducted prospective cohort study or registry  • Evidence from a well-conducted meta-analysis of cohort studies  Supportive evidence from a well-conducted case-control study
С	Supportive evidence from poorly controlled or uncontrolled studies, including:  • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results  • Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)  • Evidence from case series or case reports  Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience



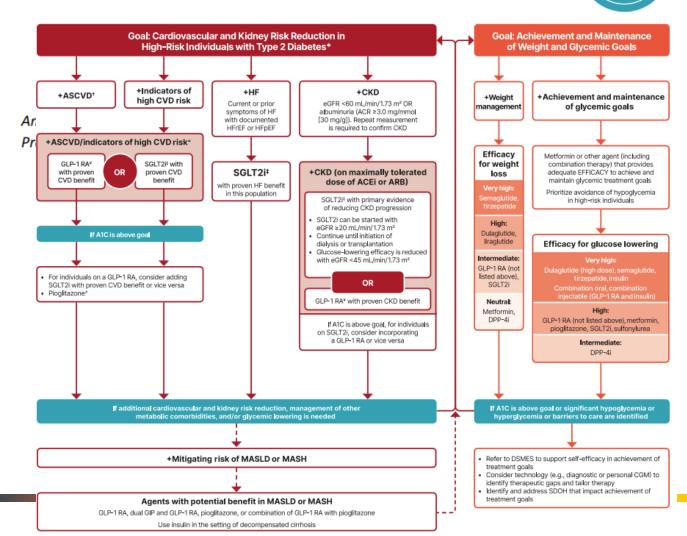
Diabetes Care Volume 48, Supplement 1, January 2025

# 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2025

Diabetes Care 2025;48(Suppl. 1):S181-S206 | https://doi.org/10.2337/dc25-S009

## HEALTHY LIFESTYLE BEHAVIORS; DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT; SOCIAL DETERMINANTS OF HEALTH

To avoid therapeutic inertia, reassess and modify treatment regularly (3–6 months)





Diabetes Care Volume 48, Supplement 1, January 2025

# 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2025

Diabetes Care 2025;48(Suppl. 1):S181-S206 | https://doi.org/10.2337/dc25-S009

be included in the glucose-lowering management of type 2 diabetes. A 9.8 A person-centered shared decision-making approach should guide the choice of glucose-lowering medications for adults with type 2 diabetes. Use medications that provide sufficient effectiveness to achieve and maintain intended treatment goals with consideration of the effects on cardiovascular, kidney, weight, and other relevant comorbidities; hypoglycemia risk; cost and access; risk for adverse reactions and tolerability; and individual preferences (Fig. 9.3 and Table 9.2). E

**9.9** Combination therapy can be considered in adults with type 2 diabetes at treatment initiation to shorten time to attainment of individualized treatment goals. **A** 

**9.10** In adults with type 2 diabetes and established or high risk of atherosclerotic cardiovascular disease, the treatment plan should include medications with demonstrated benefits to reduce cardiovascular events (e.g., glucagon-like peptide 1 receptor agonist [GLP-1 RA] and/or sodium—glucose cotransporter 2 [SGLT2] inhibitor) for

glycemic management and comprehensive cardiovascular risk reduction (irrespective of A1C) (Fig. 9.3 and Table 9.2). A

**9.11** In adults with type 2 diabetes who have heart failure (HF) (with either reduced or preserved ejection fraction), an SGLT2 inhibitor is recommended for both glycemic management and prevention of HF hospitalizations (irrespective of A1C) (**Fig. 9.3**). **A** 

**9.12** In adults with type 2 diabetes and symptomatic heart failure with preserved ejection fraction (HFpEF) and obesity, a GLP-1 RA with demonstrated benefits for both glycemic management and reduction of HF-related symptoms (irrespective of A1C) is recommended. **A** 

**9.13** In adults with type 2 diabetes who have CKD (with confirmed estimated glomerular filtration rate [eGFR] 20–60 mL/min/1.73 m<sup>2</sup> and/or albuminuria), an SGLT2 inhibitor or GLP-1 RA with demonstrated benefit in this population should be used for both glycemic management (irrespective of A1C) and for slowing progression of CKD and reduction in cardiovascular

events (Fig. 9.3). The glycemic benefits of SGLT2 inhibitors are reduced at eGFR <45 mL/min/1.73 m<sup>2</sup>. A

**9.14** In adults with type 2 diabetes and advanced CKD (eGFR <30 mL/min/ 1.73 m<sup>2</sup>), a GLP-1 RA is preferred for glycemic management due to lower risk of hypoglycemia and for cardiovascular event reduction. **B** 

9.15 In adults with type 2 diabetes, metabolic dysfunction—associated steatotic liver disease (MASLD), and overweight or obesity, consider using a GLP-1 RA or a dual glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 RA with potential benefits in metabolic dysfunction—associated steatohepatitis (MASH) for glycemic management and as an adjunctive to healthy interventions for weight loss. B

9.16a In adults with type 2 diabetes and biopsy-proven MASH or those at high risk for liver fibrosis (based on noninvasive tests), pioglitazone, a GLP-1 RA, or a dual GIP and GLP-1 RA is preferred for glycemic management due to potential beneficial effects on MASH. B



and worsening of cardiometabolic abnormalities that often result from sudden discontinuation of weight management pharmacotherapy.

Recommendation 8.25 was revised to emphasize use of a CGM device to improve safety in individuals with postmetabolic surgery hypoglycemia.

Updated Tables 8.1 and 8.2 provide detailed information on the efficacy, common side effects, safety considerations, and costs of approved weight management pharmacotherapy options.

Discussion of medication cost and access barriers was added to the text, including suggestions to members of the interprofessional diabetes care team on mitigating financial barriers.

#### Section 9. Pharmacologic Approaches to Glycemic Treatment (https://doi.org/10.2337/dc25-S009)

This section was reorganized and expanded with two new subsections: 1) a subsection titled "Additional Recommendations for All Individuals With Diabetes" that includes new recommendations as well as recommendations previously listed with those for individuals with type 1 or type 2 diabetes if pertinent to individuals regardless of their type of diabetes, and 2) a subsection titled "Special Circumstances and Populations."

Figure 9.1 was revised for clarity, and a general statement was added to Table 9.1 on dose adjustments when using AID systems.

The subsection on insulin administration technique was expanded to address inhaled insulin and use of insulin bolus patches.

Recommendation 9.8 was revised to emphasize the importance of selecting glucose-lowering medications that provide sufficient effectiveness and achieve and maintain multiple treatment goals simultaneously, including improving cardiovascular, kidney, weight, and other relevant outcomes, reducing hypoglycemia risk, and considering cost, access, risk for adverse reactions, and individual preferences.

Recommendations were revised to explicitly advise on choice of pharmacotherapy for individuals with type 2 diabetes and established or high risk of atherosclerotic cardiovascular disease (ASCVD) (Recommendation 9.10), heart failure (Recommendation 9.11), and chronic kidney disease

health outcomes for individuals with these conditions irrespective of A1C.

Recommendation 9.12 was added to recommend use of GLP-1 RA with demonstrated benefits in individuals with type 2 diabetes, symptomatic heart failure with preserved ejection fraction, and obesity.

Recommendation 9.13 was revised to recommend use of either SGLT2 inhibitor or GLP-1 RA with demonstrated benefits in individuals with type 2 diabetes

Recommendations 9.15 and 9.16 were added to recommend treatment of individuals with type 2 diabetes and MASLD or MASH with GLP-1 RA, dual GIP and GLP-1 RA, pioglitazone, or a combination of GLP-1 RA and pioglitazone based on the staging of liver disease risk and need for weight management.

Figure 9.3 and the text discussing choice of glucose-lowering therapy in adults with type 2 diabetes were extensively revised to facilitate evidence-based selection of glucose-lowering therapies based on individualized treatment goals. Considerations of glucose-lowering medication effects on MASLD and MASH were added to Fig. 9.3.

Table 9.2 was simplified and revised to better highlight important considerations when choosing medications for lowering glucose in type 2 diabetes.

Recommendation 9.20 was clarified to recommend reassessing the need for and/or dose of medications with higher hypoglycemia risk (i.e., sulfonvlureas, meglitinides, and insulin) when initiating a new glucoselowering medication to minimize the risk of hypoglycemia and treatment burden.

Recommendation 9.21 was added to advise against concurrent use of a dipeptidyl peptidase 4 inhibitor with a GLP-1 RA due to lack of additional glucose lowering beyond that of a GLP-1 RA alone.

Recommendation 9.24 was clarified by specifying that a GLP-1 RA or a dual GIP and GLP-1 RA is preferred to insulin in adults with type 2 diabetes only in the absence of evidence of insulin deficiency.

Text in the "Basal Insulin" section was revised to provide guidance on switching between different basal insulin formulations.

Figure 9.4 was revised for clarity, and the list of options for prandial insulin was

Recommendation 9.27 was revised to remove consideration of basal insulin doses exceeding 0.5 units/kg/day as evi-(CKD) (Recommendation 9.12) to improve dence of overbasalization. Instead, signs

of overbasalization including significant bedtime-to-morning or postprandial-topreprandial glucose differential, occurrences of hypoglycemia (aware or unaware), and high glycemic variability should be used.

Tables 9.3 and 9.4 were updated with glucose-lowering medication and insulin costs as of 1 July 2024, and an expanded discussion on medication costs and affordability was added to the text.

In the new subsection "Special Circumstances and Populations," Recommendations 9.31a, 9.31b, and 9.31c were added to advise on actions to take when medications are not available (such as medication shortages); Recommendations 9.32a and 9.32b were added to address care considerations for individuals of childbearing potential; and Recommendation 9.33 was added to provide guidance on mitigating risk of ketoacidosis when individuals at risk for ketoacidosis or who follow a ketogenic eating pattern are treated with SGLT inhibition. Additional text in this subsection discusses considerations for glucoselowering pharmacotherapy for individuals with diabetes secondary to chemotherapy and with other types of diabetes (i.e., pancreatogenic diabetes, cystic fibrosisrelated diabetes, posttransplant diabetes, maturity-onset diabetes of the young, and neonatal diabetes).

#### Section 10. Cardiovascular Disease and Risk Management

(https://doi.org/10.2337/dc25-S010) Recommendation 10.1 was updated with details on the frequency of recommended blood pressure monitoring.

Figure 10.2 was updated to provide clarity on medication classes for the treatment of confirmed hypertension in nonpregnant people with diabetes.

Recommendation 10.12 was modified to specify appropriate monitoring for increased serum creatinine levels, serum potassium levels, and hypokalemia when ACE inhibitors, angiotensin receptor blockers (ARBs), or mineralocorticoid receptor antagonists are used.

Recommendation 10.13 was added to specify hypertension treatment options that should be avoided during pregnancy and in sexually active individuals of childbearing potential not using reliable contraception.

Recommendation 10.26 was added to recommend that in most cases lipidlowering agents should be discontinued prior to conception and avoided in sexually

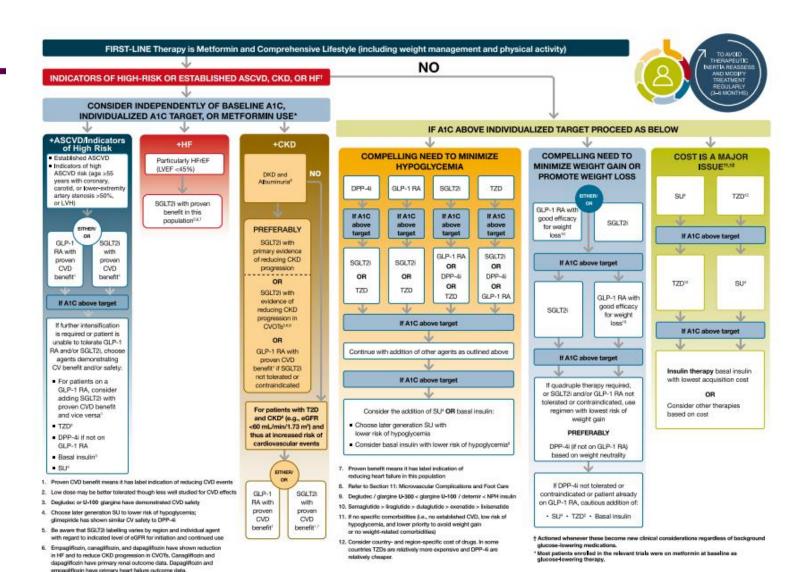


Diabetes Care Volume 44, Supplement 1, January 2021

# 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2021

Diabetes Care 2021;44(Suppl. 1):S111-S124 | https://doi.org/10.2337/dc21-S009

Guidelines are rapidly evolving, but is real-world practice keeping pace?









# Therapy for Stage IV Non-Small Cell Lung Cancer With Driver Alterations: ASCO Living Guideline, Version 2024.2

Lyudmila Bazhenova, MD¹ (a); Nofisat Ismaila, MD² (b); Fawzi Abu Rous, MD³ (b); Krishna Alluri, MD⁴ (b); Janet Freeman-Daily, MS, Engr⁵ (b); Balazs Halmos, MD⁶ (b); Narinder Malhotra, MD³; Kristen A. Marrone, MD®; Sonam Puri, MD⁰ (b); Angel Qin, MD¹¹ (c); and Natasha B. Leighl, MD¹¹ (c)

DOI https://doi.org/10.1200/JCO-24-02133

#### **ABSTRACT**

Living guidelines are developed for selected topic areas with rapidly evolving evidence that drives frequent change in recommended clinical practice. Living guidelines are updated on a regular schedule by a standing expert panel that systematically reviews the health literature on a continuous basis, as described in the ASCO Guidelines Methodology Manual. ASCO Living Guidelines follow the ASCO Conflict of Interest Policy Implementation for Clinical Practice Guidelines. Living Guidelines and updates are not intended to substitute for independent professional judgment of the treating clinician and do not account for individual variation among patients. See the Appendix for disclaimers and other important information (Appendix 1 and Appendix 2, online only). Updates are published regularly and can be found at https://ascopubs.org/nsclc-da-living-guideline.

#### ACCOMPANYING CONTENT

- Disten to the podcast by Dr Bazhenova at https://ascopubs.org/ do/therapy-stageiv-nsclc-driveralterations-ascoliving-guidelineupdate-2024-2
- Articles, April 10, 2024 issue on p. e1 and July 10, 2024 issue on p. e44
- Appendix
- Data Supplement

Accepted October 4, 2024 Published November 12, 2024

Evidence-Based Medicine Committee approval: September 17, 2024

J Clin Oncol 42:e72-e86
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#### TABLE A2. All Recommendations

	Driver Alteration	Recommendation	Evidence Quality	Strength of Recommendation
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NOTE:

For recommendations with multiple treatment options of the same evidence quality and strength of recommendation, the decision of which agent to offer should be tailored to each patient incorporating both efficacy and toxicity.

All biomarkers should be available at the time of decision making.

The following recommendations (strong or weak/conditional) and terminology (Data Supplement, online only) represent reasonable options for patients depending on clinical circumstances and in the context of individual patient preferences. Recommended care should be accessible to patients whenever possible

Clinical Question 1: What are the most effective first-line treatment options for patients' status based on the driver alterations:

EGFR	Exon 19 deletion, exon 21 L858R substitution									
	1.1. Clinicians should offer osimertinib	Moderate	Strong							
	<ol> <li>1.1.1. Clinicians may offer osimertinib with platinum doublet chemother- apy or amivantamab plus lazertinib</li> </ol>	Moderate	Weak							
	Qualifying Statement: Although Recommendation 1.1 addresses many patients in the target population, the guideline manuscript presents additional options that may be reasonable, based on the evidence reviewed. In addition, use of osimertinib in patients previously treated with adjuvant TKIs is not reflected in this guideline									
	Others									
	<ol> <li>1.2. For other activating EGFR alterations, (G719X, L861Q, S768I), clinicians may offer afatinib</li> </ol>	Low	Strong							
	1.2.1. or osimertinib	Low	Weak							
	1.2.2. or standard treatment following the nondriver alteration guideline	Low	Weak							
	Qualifying Statement: Recommendations 1.2, 1.2.1, and 1.2.2 exclude exon 20 insertion alterations, T790M									
	1.3. For any activating EGFR alteration, regardless of PD-L1 expression levels (including exon 20 insertions), single-agent immune checkpoint inhibitors should not be offered as first-line therapy	Moderate	Strong							
	Exon 20 insertions									
	1.4. Clinicians may offer chemotherapy and amivantamab	Moderate	Strong							
	1.5. If amivantamab is not available, clinicians should offer standard treatment following the nondriver alteration guideline	Moderate	Strong							
ALK	1.6. Clinicians should offer alectinib or brigatinib or lorlatinib	High	Strong							
	<ol> <li>1.7. If alectinib, brigatinib, or Iorlatinib are not available, clinicians should offer ceritinib or crizotinib</li> </ol>	High	Strong							
ROS1	1.8. Clinicians may offer crizotinib, entrectinib, or repotrectinib	Moderate	Strong							
	<ol> <li>1.9. If crizotinib, entrectinib, or repotrectinib are not available or not tolerated, clinicians may offer ceritinib or lorlatinib</li> </ol>	Low	Weak							
BRAF <sup>V600E</sup>	<ol> <li>Clinicians may offer dabrafenib and trametinib, or encorafenib and binimetinib</li> </ol>	Low	Strong							
	1.11. If dabrafenib and trametinib, or encorafenib and binimetinib are not available, clinicians may offer standard first-line therapy following the nondriver alteration guideline	Low	Strong							
MET exon 14 skipping mutation	1.12. Clinicians may offer capmatinib or tepotinib	Low	Strong							
	1.13. If capmatinib or tepotinib is not available, clinicians may offer standard first-line therapy following the nondriver alteration guidelines	Low	Strong							
	(continued on following page)									



Guideline-driven
Evidence
Generation

Evidence-driven
Data
standardization

Evidence-driven
Open Source
Development

Evidence-driven Collaborative Education



Guideline-driven Evidence Generation Evidence-driven
Data
standardization

Evidence-driven
Open Source
Development

Evidence-driven Collaborative Education

Dry January:	Phenotype Phebruary:	March to Data Fitness:					
Guideline review to determine evidence needs where RWE could potentially contribute	Develop/evaluate cohorts needed to support filling the evidence gaps	Evidence network to determine which partners are appropriate to generate which evidence					
Analysis April:	Meta-analysis May:	Journey to June:					
Prepare protocol and analysis specification to initiate network execution	Collaborative interpretation of results from across network	Mid-year reflection on evidence generation process and progress					
Spread-the-Word Second Half: Focus on Evidence Dissemination							
July: OHDSI EU	August:	September:					
October: OHDSI Global (tbd)	November:	December: OHDSI APAC					



# Breadth and depth: where can OHDSI make an impact?

- Anesthesiology
- Cardiology
- Dermatology
- Digestive/liver disease
- Emergency Medicine
- Endocrinology
- Hematology
- Infectious disease
- Neurology
- Nephrology
- Obstetrics/Gynecology
- Oncology

- Ophthalmology
- Otolaryngology
- Orthopedic surgery
- Palliative care
- Pediatrics
- Pulmonary
- Psychiatry
- Rheumatology
- Radiology
- Rehabilitation and regenerative medicine
- Surgery
- Urology





- Topics
- My Posts
- Review
- Admin
- More
- Categories
- General •
- Implementers
- Developers
- Researchers •
- CDM Builders •
- Tags
- cdm
- atlas •
- vocabularies •
- patientprediction •
- webapi

## Guideline-driven evidence generation opportunities 🎤

General



1m

Clinical guidelines are extremely helpful, not only for providing guidance not only for providers on how to best treat their patients, but also for highlighting to the research community where there are open questions and evidence gaps. Some of these evidence gaps can be filled reliably through proper analysis of real-world data, as we aim to conduct across the OHDSI Evidence Network.

To help stimulate discussion and prioritize our community's collaborative activities in 2025, I'm opening up this thread with a specific ask for anyone who is interested in leading or participating in an OHDSI network study, or simply are interested in seeing an OHDSI study conducted by the community on a topic that's of interest to you:

Post a link to a current clinical guideline about a disease/topic of interest. Review the guideline and share what evidence gaps you see that could be potentially filled with real-world evidence.

We'll use the input and interest from the community on this thread to guide us toward collaborative evidence generation activities this year.









https://forums.ohdsi.org/t/guideline-driven-evidencegeneration-opportunities/23029



Guideline-driven Evidence Generation Evidence-driven
Data
standardization

Evidence-driven
Open Source
Development

Evidence-driven
Collaborative
Education

### 2025 Priorities:

- 1. Evidence Network engagement
  - Data partner organizations with source data converted to OMOP CDM v5.4 are encouraged to become part of OHDSI Evidence Network
  - We will conduct Evidence Network evaluations of 'fitness-for-use' based on evidence needs identified by the community
- 2. OHDSI Standardized Vocabularies community contributions
  - OHDSI Vocabulary team has defined 2025 roadmap for February and August releases
  - We are seeking community contributions to expand vocabulary content (concepts) and improve mapping (relationships), and to improve our own processes for incorporating community contributions



Guideline-driven
Evidence
Generation

Evidence-driven
Data
standardization

Evidence-driven
Open Source
Development

Evidence-driven
Collaborative
Education

## 2025 Priorities:

- 1. Harden Strategus and associated HADES packages to enable improved user installation and execution experience
- 2. Improve OHDSI packages based on the user needs and experience from Guideline-driven Evidence Generation study teams
- 3. Redesign ATLAS with focus on improving the experience of cohort design and evaluation



Guideline-driven Evidence Generation Evidence-driven
Data
standardization

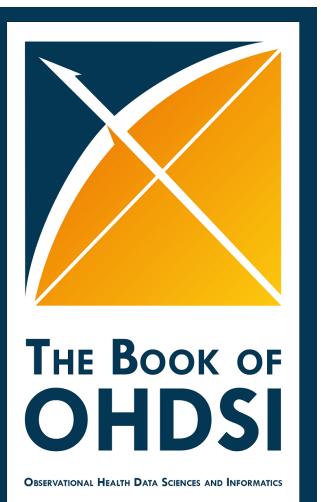
Evidence-driven
Open Source
Development

Evidence-driven
Collaborative
Education

## 2025 Priorities:

- 1. Refresh 'Book of OHDSI' to align with current practice and increase emphasis on evidence generation and dissemination for evidence *generators*
- 2. Lean into JACC Partnership to promote best practice to evidence *consumers*





### **Weekly Recordings & Updates**

- + Dec 17: Holiday-Themed Goodbye to 2024
- + Dec 10: How did OHDSI do in 2024 (Ryan)
- + Dec 3: Recent OMOP/OHDSI Publications (Fruchart, Prats-Uribe, Eisman, Tong)
- + Nov. 26: OHDSI 2024 Collaborator Showcase Honorees (Hallaj, Tekumalla, Alvarez, Patnoe, Blacketer)
- + Nov. 19: Evidence Network in Action: The Semaglutide Study (Cai, Zhang, Nagy, Sena, Westlund, Martin)
- + Nov. 12: Next Steps in Evidence Dissemination (Ryan, Schuemie, Pratt)
- + Nov. 5: Meet the 2024 Titans! (Janetzki, Cai, Zhuk, Zhang, Adulyannukosol, Blacketer, Camprubi, Katzman, Lavallee)
- + Oct. 29: Welcome to OHDSI (Hripcsak, Sachson)
- + Oct. 15: Global Symposium Mad Minutes and Final Logistics
- + Oct. 8: Advances in Methodological Research + 2024-25 Vocabulary Roadmap (Che, Hripcsak, Chattopadhyay, Davydov)
- + Oct. 1: DARWINEU® Update & Progress (Rijnbeek, Moinat, Prieto-Alhambra, Verhamme)
- + Sept. 24: Recent Publications (Mateus, Patterson, Ostchega, Golozar)
- Sept. 17: Book of OHDSI, 5 Years Later (Authors from The Book of OHDSI)

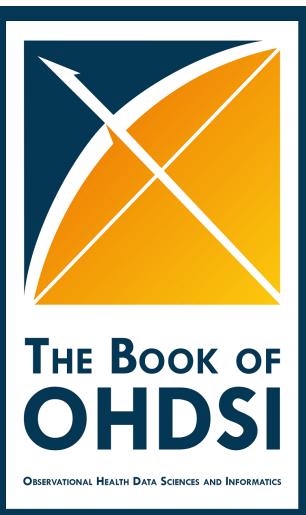
The Sept. 17 community call featured the Book of OHDSI. Published in 2019, the Book of OHDSI (book ohdsi.org) was developed by community volunteers to be a central knowledge repository for OHDSI, and it focuses on describing our community, data standards, and tools. It recently celebrated its fifth anniversary, and it remains one of the most frequently used educational resources for both newcomers and veterans.

### **Community Updates**

 Congratulations to the team of Jung-Joon Cha, Yunjin Yum, Yong Hyun Kim, Eung Ju Kim, Yoon Chan Rah, Euyhyun Park, Gi Jung Im, Jae-Jun Song, Sung-Won Chae, June Choi, and Hyung Joon







### Structure of the Book

This book is organized in five major sections:

- I. The OHDSI Community
- II. Uniform data representation
- III. Data Analytics
- IV. Evidence Quality
- V. OHDSI Studies

Each section has multiple chapters, and, as appropriate, each chapter follows the sequence: Introduction, Theory, Practice, Summary, and Exercises.

- I The OHDSI Community
- 1 The OHDSI Community
- 2 Where to Begin
- 3 Open Science
- II Uniform Data Representation
- 4 The Common Data Model
- 5 Standardized Vocabularies
- 6 Extract Transform Load
- III Data Analytics
- 7 Data Analytics Use Cases
- 8 OHDSI Analytics Tools
- 9 SQL and R
- 10 Defining Cohorts
- 11 Characterization
- 12 Population-Level Estimation
- 13 Patient-Level Prediction
- IV Evidence Quality
- 14 Evidence Quality
- 15 Data Quality
- 16 Clinical Validity
- 17 Software Validity
- 18 Method Validity

V OHDSI Studies

- 19 Study steps
- 20 OHDSI Network Research



# 2025 Workgroup support



### 2025 Resolution:

- 1) All workgroup leaders will provide their purpose and 2025 Objectives and Key Results by end of January
- All workgroups will present on a community call in February to encourage participation
- 3) Workgroups should clearly define which 2025 Focus Area(s) they are contributing to, and how



Patrick Ryan



## Which OHDSI 2025 Focus Area do you plan to contribute to?

(A) Guideline-driven Evidence Generation (Design and implement network study to fill evidence gap)	
	0%
(B) Evidence-driven Data standardization (Evidence network and community vocabularies contributions)	
	0%
(C) Evidence-driven Open Source Development (analytics tools to support evidence needs)	
	0%
(D) Evidence-driven Collaborative Education (Book of OHDSI, Symposium Tutorials, JACC partnership)	00/
	0%
(E) None of the above	00/
	0%