



JOHNS HOPKINS
BLOOMBERG SCHOOL
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Case Studies in Drug Utilization

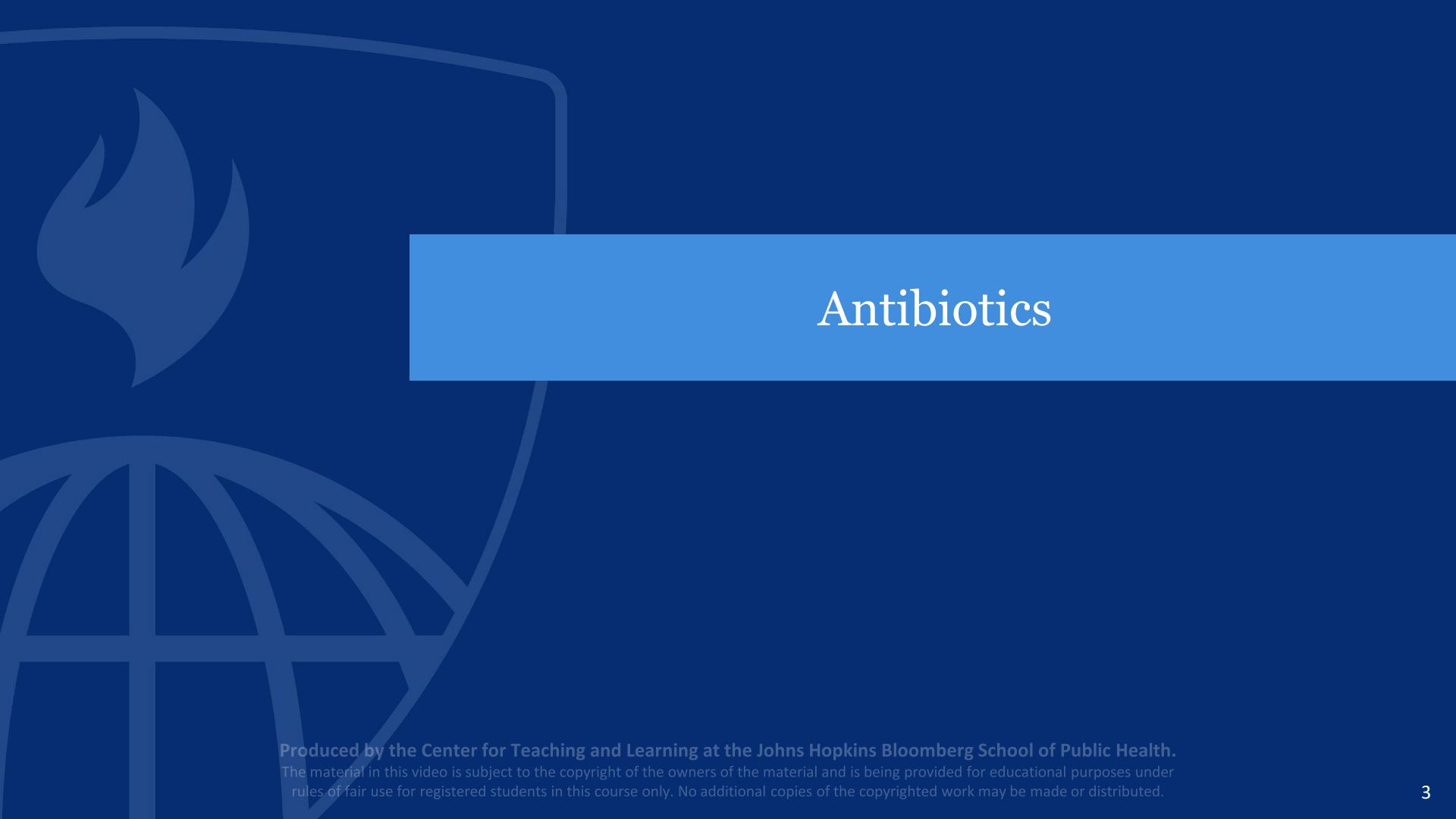
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Outline

- ▶ Antibiotics
- ▶ Prescription opioids
- ▶ Anticoagulants
- ▶ Generics and biosimilars



Antibiotics

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Prescription Drugs Are Not Inherently Good or Bad!



Image source: Hammer: Evan-Amos. (2010). A standard household claw hammer. [Graphic]. Own work. <https://commons.wikimedia.org/wiki/File:Claw-hammer.jpg>; duct tape: Evan-Amos. (2010). A roll of silver, Scotch-brand duct tape. [Graphic]. Own work. <https://commons.wikimedia.org/wiki/File:Duct-tape.jpg>. Public domain.

Many Factors Have Contributed to Harms

WHO reports widespread overuse of antibiotics in patients hospitalized with COVID-19

Many Factors Responsible for Antibiotic Overuse for UTIs

HEALTH TECH
Telehealth providers can drive antibiotic overuse — or choose to combat it

STAT+

Countries renew efforts to tackle antimicrobial resistance with a strong focus on curbing the misuse and overuse of antibiotics

‘Just in case’ antibiotics widely overused during COVID-19, says UN health agency

Rise Seen in Inappropriate Antibiotic Use



Magnitude of Overuse—1

- ▶ Antibiotic overuse is enduring and common, especially for upper respiratory infections such as rhinosinusitis or acute bronchitis
- ▶ Depending on data source, study design, cohort derivation, outcomes, and other study features, anywhere from about one quarter to about one half of antibiotics are inappropriately prescribed (Chua et al., 2019)
- ▶ Broad-spectrum antibiotics are also often prescribed instead of more narrow-spectrum drugs

Magnitude of Overuse—2

- ▶ Antibiotic overuse is enduring and common, especially for upper respiratory infections such as rhinosinusitis or acute bronchitis
- ▶ Depending on data source, study design, cohort derivation, outcomes, and other study features, anywhere from about one quarter to about one half of antibiotics are inappropriately prescribed (Chua et al., 2019)
- ▶ Broad-spectrum antibiotics are also often prescribed instead of more narrow-spectrum drugs

Why are antibiotics
so commonly
overused?

What is driving this
nonrational
prescribing?

Prevalence of Inappropriate Antibiotic Prescriptions

Table 4. Mean annual antibiotic prescribing rates in 2010–2011 US NAMCS/NHAMCS vs estimated appropriate antibiotic prescribing annual rates per 1000 population by age group and diagnosis

	Rates per 1000 Population		Potential Reduction in Annual Antibiotic Prescription Rates, %
	2010-2011 Weighted Mean Annual Rate of Antibiotic Prescriptions (95% CI)	Estimated Appropriate Annual Rate of Antibiotic Prescriptions ^a	
0-19 y			
All acute respiratory conditions ^b	421 (369 to 473)	278 ^c	-34
Sinusitis	65 (51 to 79)	59	-9
Suppurative otitis media	154 (131 to 177)	138	-10
Pharyngitis	91 (76 to 105)	60	-34
Asthma or allergy; bronchitis or bronchiolitis; influenza; nonsuppurative otitis media; viral URI; and viral pneumonia ^e	90 (71 to 108)	0	-100
Pneumonia	22 (16 to 27)	22	0
Other conditions ^d	225 (197 to 252)	180 ^f	-20
Urinary tract infection	23 (17 to 28)	23	0
Miscellaneous bacterial infections	20 (13 to 26)	20	0
Remaining other conditions ^g	182 (160 to 205)	137	-25
Total ^h	646 (571 to 721)	458	-29
All Ages			
All acute respiratory conditions ^b	221 (198 to 245)	111	-50
Other conditions ^d	284 (256 to 313)	242	-15
Total ^h	506 (458 to 554)	353	-30

Source: Table 4. In: Fleming-Dutra, K. E., Hersh, A. L., Shapiro, D. J., et al. (2016). Prevalence of inappropriate antibiotic prescriptions among US ambulatory care visits, 2010-2011. *JAMA*, 315(17), 1864–1873. <https://doi.org/10.1001/jama.2016.4151>

Economic and Clinical Consequences of Overuse

- ▶ Increase in antimicrobial resistance
- ▶ Increase in more severe diseases
- ▶ Increase in the length of disease
- ▶ Increase in risk of complications
- ▶ Increase in mortality rate
- ▶ Increase in health care costs
- ▶ Increase risk of adverse effects, some being life-threatening
- ▶ Increase re-attendance due to infectious diseases
- ▶ Increased medicalization of self-limiting infectious conditions



Tipping the Balance Toward Fewer Antibiotics

"Unfortunately, physician educational efforts have had little effect Almost all physicians already know that avoiding antibiotics for viral conditions is the right thing to do, and physicians' knowledge of guidelines has no association with their likelihood of prescribing an antibiotic."

"The overuse of antibiotics is not a knowledge problem or a diagnostic problem; it is largely a psychological problem."

—Mehotra and Linder, 2016

Box. The Imbalance in Factors Related to Antibiotic Prescribing

Factors Driving Antibiotic Prescribing: Immediate and Emotionally Salient

- Belief that a patient wants antibiotics
- Perception that it is easier and quicker to prescribe antibiotics than explain why they are unnecessary
- Habit
- Worry about serious complications and "just to be safe" mentality

Factors Deterring Antibiotic Prescribing: More Remote and Less Emotionally Salient

- Risks of adverse reactions and drug interactions
- Recognizing the need for antibiotic stewardship
- Desire to deter low-value care and decrease unnecessary health care spending
- Prefer to follow guidelines

Approaches to Reducing Overuse

- ▶ Clinician and patient education
- ▶ Communication training
- ▶ Rapid diagnostics
- ▶ Clinical decision support
- ▶ Delayed prescriptions

Why Are Antibiotic Stewardship Programs Valuable?

- They are multifaceted
- They are data driven
- They are dynamic and nimble to changing settings on the ground
- They include reporting to provide transparency and accountability
- They are inclusive, and they include stakeholders such as pharmacists and clinicians, among others

Core Elements of Hospital Antibiotic Stewardship Programs



Hospital Leadership Commitment

Dedicate necessary human, financial, and information technology resources.



Accountability

Appoint a leader or co-leaders, such as a physician and pharmacist, responsible for program management and outcomes.



Pharmacy Expertise (previously "Drug Expertise"):

Appoint a pharmacist, ideally as the co-leader of the stewardship program, to help lead implementation efforts to improve antibiotic use.



Action

Implement interventions, such as prospective audit and feedback or preauthorization, to improve antibiotic use.



Tracking

Monitor antibiotic prescribing, impact of interventions, and other important outcomes, like *C. difficile* infections and resistance patterns.



Reporting

Regularly report information on antibiotic use and resistance to prescribers, pharmacists, nurses, and hospital leadership.



Education

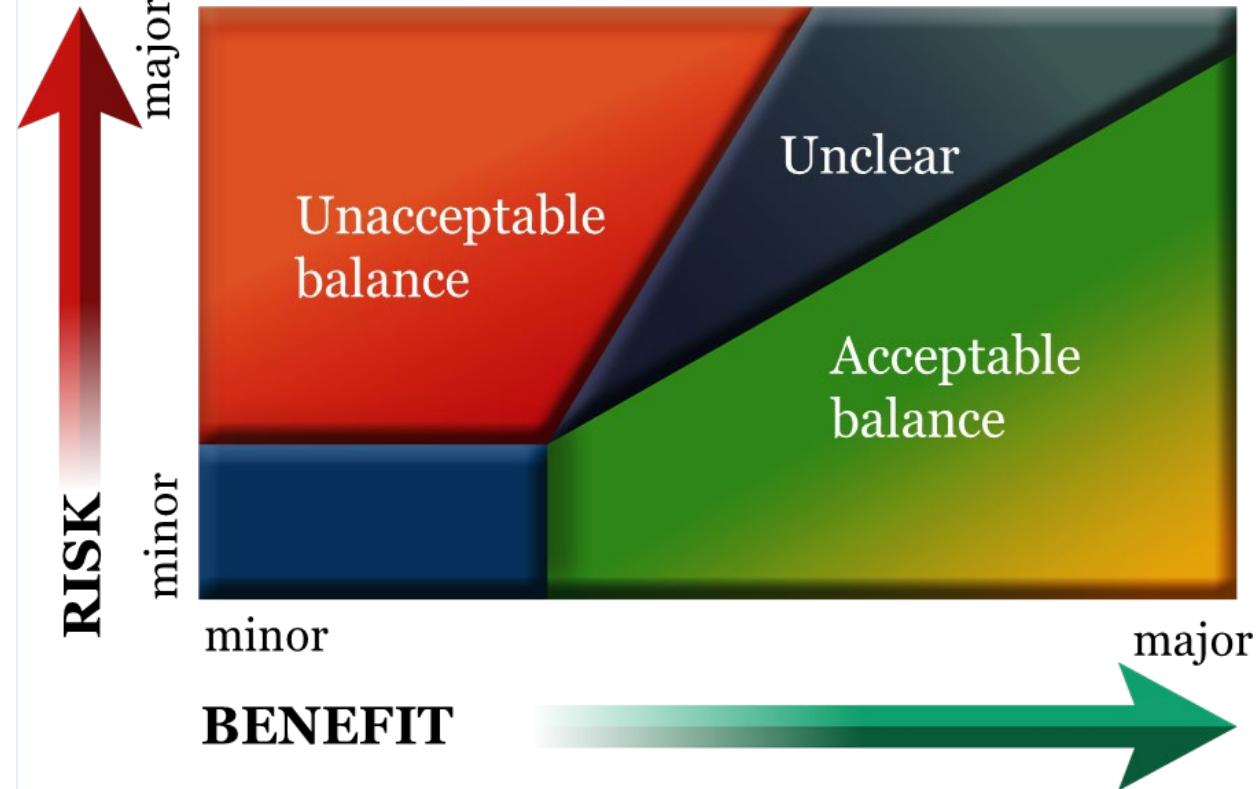
Educate prescribers, pharmacists, nurses, and patients about adverse reactions from antibiotics, antibiotic resistance, and optimal prescribing.



Prescription Opioids

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Benefit–Risk Ratio



Faces of the Epidemic



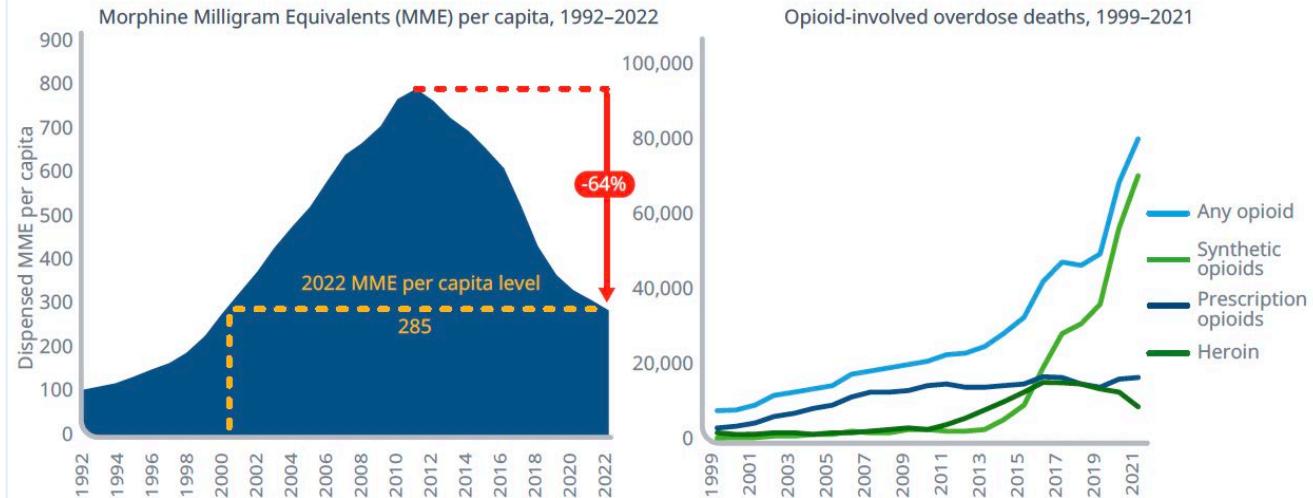
Sources: *Left:* Holley, P. (2016, September 24). 'Heartbreaking' video captures toddler trying to wake mother after apparent overdose. *Washington Post*. <https://www.washingtonpost.com/news/true-crime/wp/2016/09/24/heartbreaking-video-captures-toddler-trying-to-wake-mother-after-apparent-overdose/>; *right:* Haidet, R. (2016, September 9). Police share images of adults they say overdosed with child in car. *USA Today*. <https://www.usatoday.com/story/news/nation-now/2016/09/09/police-share-images-adults-they-say-overdosed-child-car/90138800/>

Proximal Source of Harms Has Changed Over Time

MEDICINE USE

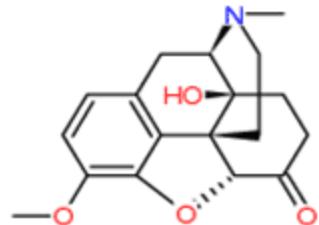
Per capita prescription opioid use continues to decline to levels seen in 2000, however overdose deaths continue to rise

Exhibit 18: Prescription opioid use overall and opioid-involved overdose deaths

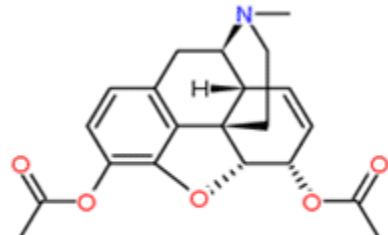


Source: IQVIA Xponent, IQVIA National Prescription Audit, Sep 2022; IQVIA Institute, Mar 2023; National Institute on Drug Abuse, Feb 2023.

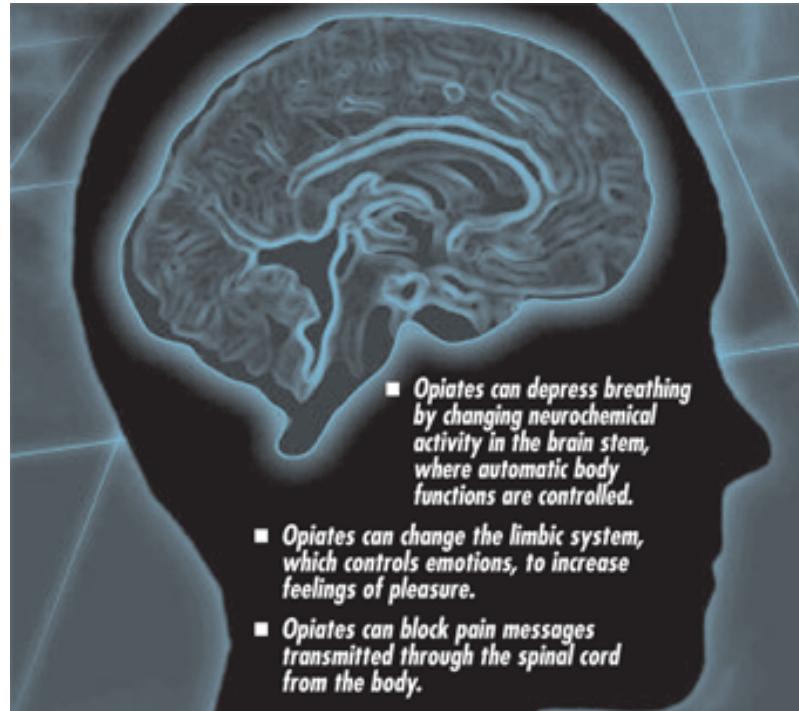
Prescription and Illicit Opioids Are More Similar Than Different!



OXYCONTIN (OXYCODONE)



HEROIN



Many Factors Have Contributed to Harms

- ▶ Pain common, undertreated
- ▶ Products heavily marketed, far beyond evidence
- ▶ Opioids addictive, also diverted
- ▶ Prescriptions fueled robust heroin and fentanyl market
- ▶ Many stakeholders, rare agreement
- ▶ Powerful economic interests (\$\$\$ billions)
- ▶ Regulatory failures
- ▶ And so on ...

Frequency of Overdose Among People Prescribed Opioids

Study	Population	Outcome	Frequency	Follow-up
Bohnert, 2011	Veterans Health Affairs patients with pain	Opioid-related overdose (fatal)	1 in 2500	Up to 5 years
Dunn, 2010	Adult managed care patients with chronic non-cancer pain	Opioid-related overdose (fatal or non-fatal)	1 in 195	Up to 119 months; mean 42 months
Dunn, 2010	Adult managed care patients with chronic non-cancer pain	Opioid-related overdose (fatal)	1 in 1657	Up to 119 months; mean 42 months
Gomes, 2011	Publicly insured Canadians ages 15–64 with non-malignant pain	Opioid-related death	1 in 415	Up to 113 months
Kaplovitch, 2015	Ontario patients ages 15–64 with chronic non-cancer pain	Opioid-related death	1 in 550	Up to 13 years (median 2.6 years from 1 st Rx to death)
Kaplovitch, 2015	Ontario patients ages 15–64 with chronic non-cancer pain escalating to high-dose opioids (>200 MME)	Opioid-related death	1 in 32	Up to 13 years

Sources: Bohnert, A. S. B., et al. (2011). Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*, 305(13), 1315–1321. <https://doi.org/10.1001/jama.2011.370>; Dunn, K. M., et al. (2010). Opioid prescriptions for chronic pain and overdose: A cohort study. *Annals of Internal Medicine*, 152(2), 85–92. <https://doi.org/10.7326/0003-4819-152-2-201001190-00006>; Gomes, T., et al. (2011). Opioid dose and drug-related mortality in patients with nonmalignant pain. *Archives of Internal Medicine*, 171(7), 686–691. <https://doi.org/10.1001/archinternmed.2011.117>; Kaplovitch, E., et al. (2015). Sex differences in dose escalation and overdose death during chronic opioid therapy: A population-based cohort study. *PloS One*, 10(8), e0134550. <https://doi.org/10.1371/journal.pone.0134550>

Chronic Opioids: Nonmedical Use and Addiction Are Common!

- ▶ Many systematic reviews have examined risks of chronic prescription opioids, producing a wide range of estimates of resultant nonmedical opioid use or addiction (OUD)
- ▶ Studies vary with respect to populations sampled, study designs, sample sizes, statistical controls, and methods of defining and ascertaining nonmedical opioid use or OUD
- ▶ Many reviews have common limitations that should be considered
 - ▶ Combined behaviors (e.g., nonmedical use) or diseases (e.g., OUD) into single measure
 - ▶ Used studies excluding individuals with current or former drug use
 - ▶ Used administrative or clinical data rather than structured interviews and tox testing
 - ▶ Reported only ranges rather than weighted pooled estimate
 - ▶ In single best analysis, Vowles et al. estimated range of means for misuse (21–29%) and OUD (8–12%), and report weighted average prevalence of misuse (21%) and OUD (8%)

Relationship Between Prescription and Illicit Opioid Use

- ▶ A small proportion of chronic prescription opioid users transition to illicit opioids
 - ▶ A small proportion of a big number is a big number
 - ▶ Illicit opioid initiation rates much higher than among non-prescription opioid users
- ▶ The likelihood of prior prescription opioid use among illicit opioid users has increased markedly over time
- ▶ A variety of factors influence illicit opioid use, including purity and cost
- ▶ Many individuals transition between prescription and illicit opioids
- ▶ Despite highly safe and effective treatments, there is widespread undertreatment of both prescription and illicit opioid use disorder, and a unified perspective is critical

Evidence-Based Review

- ▶ “Opioids are associated with small improvements versus placebo in pain and function, and increased risk of harms at short-term (1 to <6 months) followup; evidence on long-term effectiveness is very limited, and there is evidence of increased risk of serious harms that appear to be dose dependent.”
- ▶ “At short-term followup, evidence showed no differences between opioids versus nonopioid medications in improvement in pain, function, mental health status, sleep, or depression.”
- ▶ “Evidence on the effectiveness and harms of alternative opioid dosing strategies and the effects of risk mitigation strategies is lacking, although provision of naloxone to patients might reduce the likelihood of opioid-related emergency department visits, a taper support intervention might improve functional outcomes compared to no taper support, and co-prescription of benzodiazepines and gabapentinoids might increase risk of overdose.”
- ▶ “No instrument has been shown to be associated with high accuracy for predicting opioid overdose, addiction, abuse, or misuse.”

Opioid Abatement

- ▶ Informing action with evidence
 - ▶ Scaling up evidence-based interventions
 - ▶ Rapidly implementing and evaluating promising policies and programs
- ▶ Intervening comprehensively
 - ▶ All along supply chain
 - ▶ Clinic, community, and addiction treatment settings
 - ▶ Primary, secondary, and tertiary prevention
 - ▶ Creating synergies across different interventions
- ▶ Promoting appropriate and safe opioid use
 - ▶ Reducing overuse
 - ▶ Focus on safe use, storage, and disposal
 - ▶ Optimizing use in accordance with best practices



Anticoagulants

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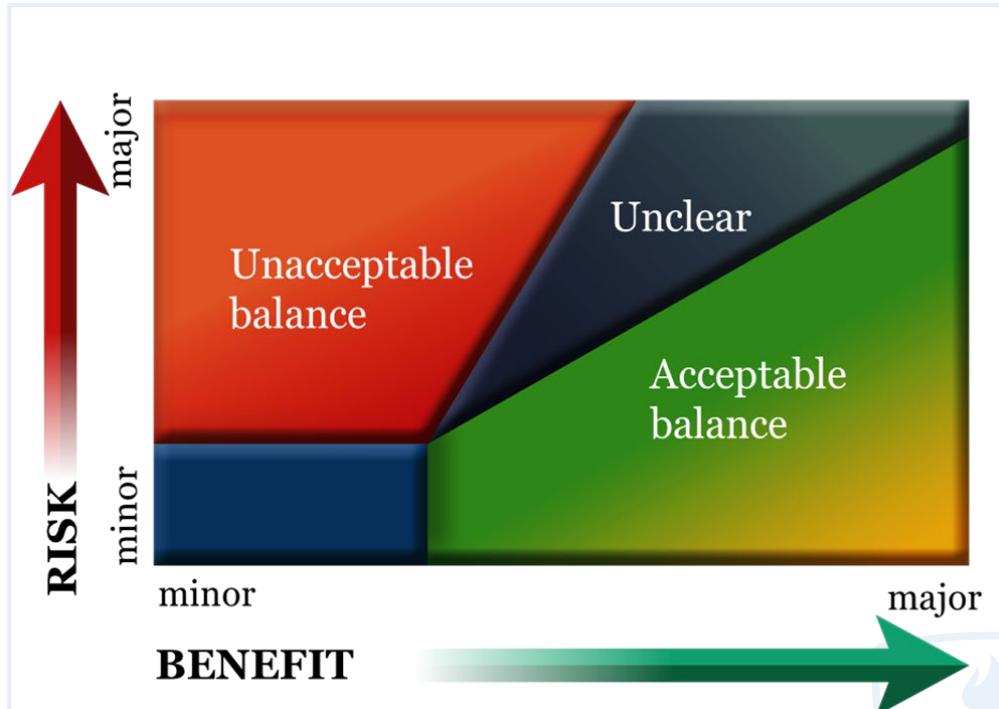
Clinical Science of Anticoagulants

- ▶ Decrease body's ability to form clots, available as intravenous, oral, and subcutaneous injections
- ▶ Related to, but distinct from, antiplatelets (e.g., aspirin) and thrombolytics (e.g., plasminogen activators)
- ▶ Three main groups: heparins, vitamin K antagonists (warfarin), and direct-acting oral anticoagulants (direct thrombin inhibitors and factor Xa inhibitors)
- ▶ Major role in managing common and costly conditions, including atrial fibrillation, deep venous thrombosis, and pulmonary embolism



Balancing Risks and Benefits

- ▶ Anticoagulants, more so than many therapeutic classes, draw the issue of risks and benefits into sharp focus
- ▶ This is because both the risks and benefits of anticoagulants have been very well studied—more so than many other products where they may be harder to enumerate using standard pharmacoepidemiologic approaches



HAS-BLED Score Predicts Clinical Risk

Letter	Clinical Characteristic	Points
H	Hypertension	1
A	Abnormal renal/liver function	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs	1
E	Elderly	1
D	Illicit drug or alcohol use	1 or 2

HAS-BLED score	Bleeds per 100 patient-years
0	1.13
1	1.02
2	1.88
3	3.74
4	8.70
5	12.5

Source: Pisters, R., Lane, D. A., Nieuwlaat, R., de Vos, C. B., Crijns, H. J. G. M., & Lip, G. Y. H. (2010). A novel user-friendly score (HAS-BLED) to assess 1-year risk of major bleeding in patients with atrial fibrillation: The Euro Heart Survey. *Chest*, 138(5), 1093–1100. <https://doi.org/10.1378/chest.10-0134>

CHA₂DS₂-VASc Score Predicts Clinical Benefit

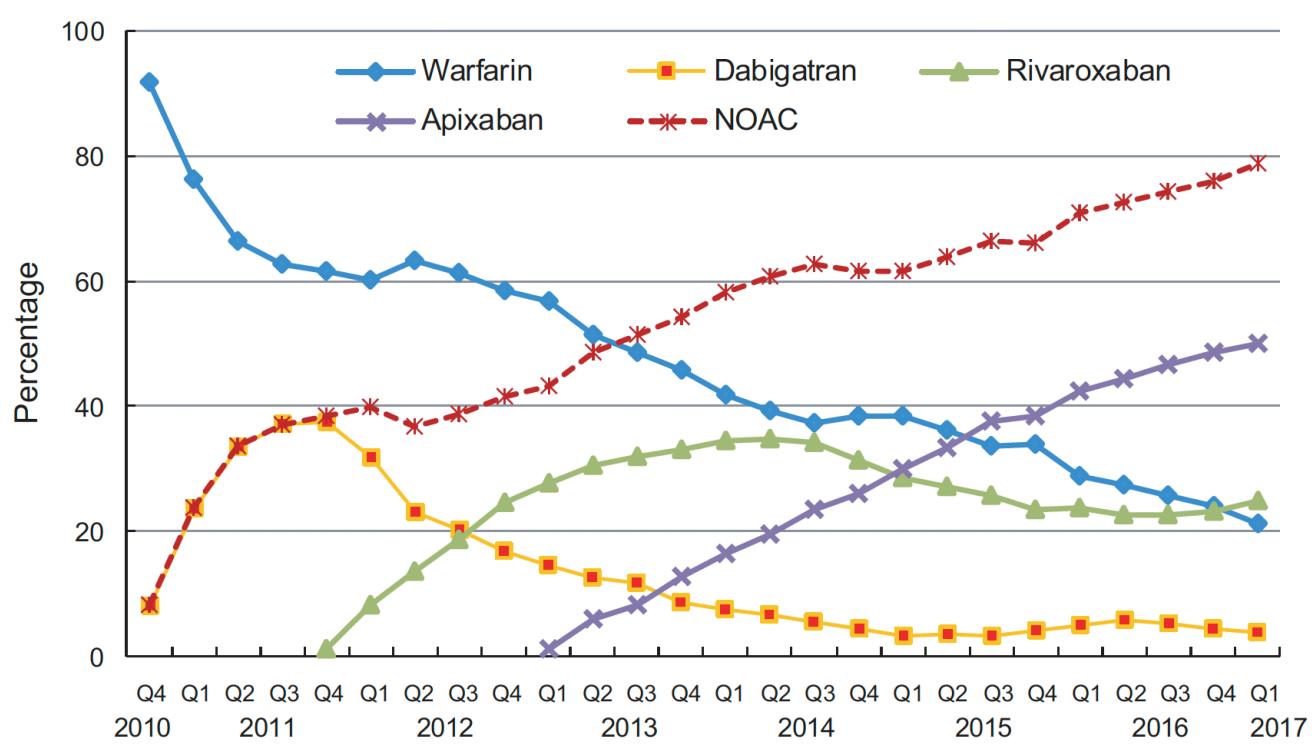
	Condition	Points
C	Congestive heart failure (or left ventricular systolic dysfunction)	1
H	Hypertension: blood pressure consistently above 140/90 mm Hg (or treated hypertension on medication)	1
A ₂	Age 75 or older	2
D	Diabetes mellitus	1
S ₂	Prior stroke or TIA or thromboembolism	2
V	Vascular disease (e.g., peripheral artery disease, myocardial infarction, aortic plaque)	1
A	Age 65–74 years	1
Sc	Sex category (i.e., female sex)	1

CHA ₂ DS ₂ -VASc score	Annual stroke risk (%)
0	0.0 (0.0-0.0)
1	0.6 (0.0-3.4)
2	1.6 (0.3-4.7)
3	3.9 (1.7-7.6)
4	1.9 (0.5-4.9)
5	3.2 (0.7-9.0)
6	3.6 (0.4-12.3)
7	8.0 (1.0-26.0)
8	11.1 (0.3-48.3)
9	100 (2.5-100)

Source: Lip, G. Y. H., Nieuwlaat, R., Pisters, R., Lane, D. A., & Crijns, H. J. G. M. (2010). Refining clinical risk stratification for predicting stroke and thromboembolism in atrial fibrillation using a novel risk factor-based approach: The euro heart survey on atrial fibrillation. *Chest*, 137(2), 263–272. <https://doi.org/10.1378/chest.09-1584>

Profound Changes in Anticoagulant Utilization Over Time

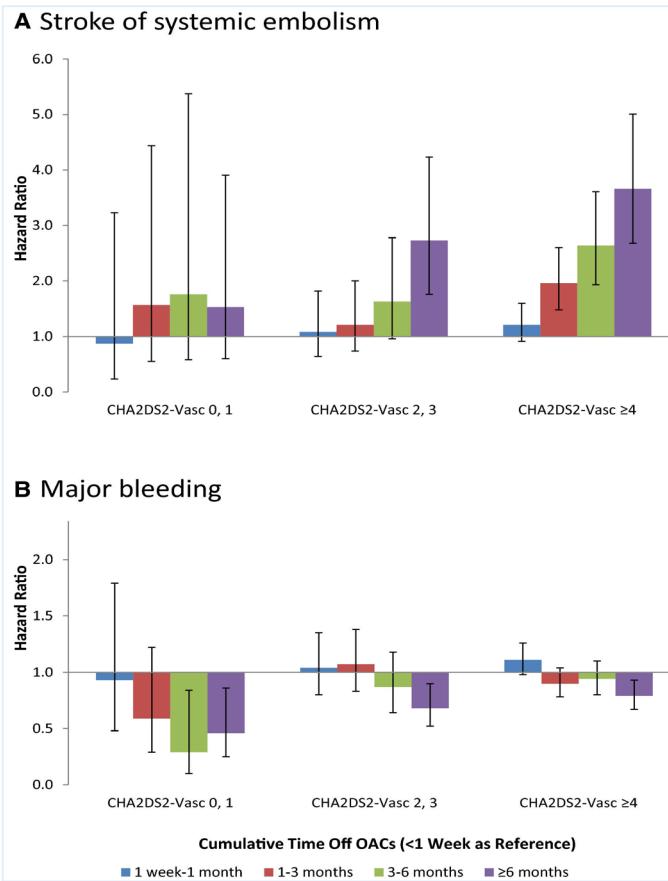
Figure 2. Quarterly trends in oral anticoagulant prescriptions for atrial fibrillation, from the fourth quarter of 2010 (2010 Q4) to the first quarter of 2017 (2017 Q1). Y-axis refers to the percentage of incident oral anticoagulant users prescribed a specific oral anticoagulant.



OAC = oral anticoagulant; NOAC = non-vitamin K antagonist oral anticoagulants, including dabigatran, rivaroxaban, and apixaban.

Source: Figure 2. In: Zhu, J., Alexander, G. C., Nazarian, S., Segal, J. B., & Wu, A. W. (2018). Trends and variation in oral anticoagulant choice in patients with atrial fibrillation, 2010-2017. *Pharmacotherapy*, 38(9), 907-920. <https://doi.org/10.1002/phar.2158>

Risk of Stroke and Bleeding With Anticoagulants



Source: Figure 1, "Hazard ratio for primary outcomes stratified by CHA₂DS₂-VASc (risk based on the presence of congestive heart failure, hypertension, age 65–74 y, age ≥75 y, diabetes mellitus, prior stroke or transient ischemic attack, vascular disease, sex category) score." In: Yao, X., Abraham, N. S., Alexander, G. C., Crown, W., Montori, V. M., Sangaralingham, L. R., Gersh, B. J., Shah, N. D., & Noseworthy, P. A. (2016). Effect of adherence to oral anticoagulants on risk of stroke and major bleeding among patients with atrial fibrillation. *Journal of the American Heart Association*, 5(2), e003074. <https://doi.org/10.1161/JAHA.115.003074>

Conclusion: "Adherence to anticoagulation is poor in practice and may be modestly improved with NOACs. Adherence to therapy appears to be most important in patients with CHA₂DS₂-VASc score ≥2, whereas the benefits of anticoagulation may not outweigh the harms in patients with CHA₂DS₂-VASc score 0 or 1."

Utilization of Anticoagulants in Clinical Practice

- ▶ Major changes in treatment over past two decades
- ▶ Nonadherence is common (drugs don't work in people who don't take them)
- ▶ Use of warfarin, a mainstay of anticoagulation, is fraught
 - ▶ Many individuals spend lots of time outside therapeutic range
 - ▶ Drug–drug interactions are common and may be quite serious
- ▶ Direct-acting oral anticoagulants pose their own challenges

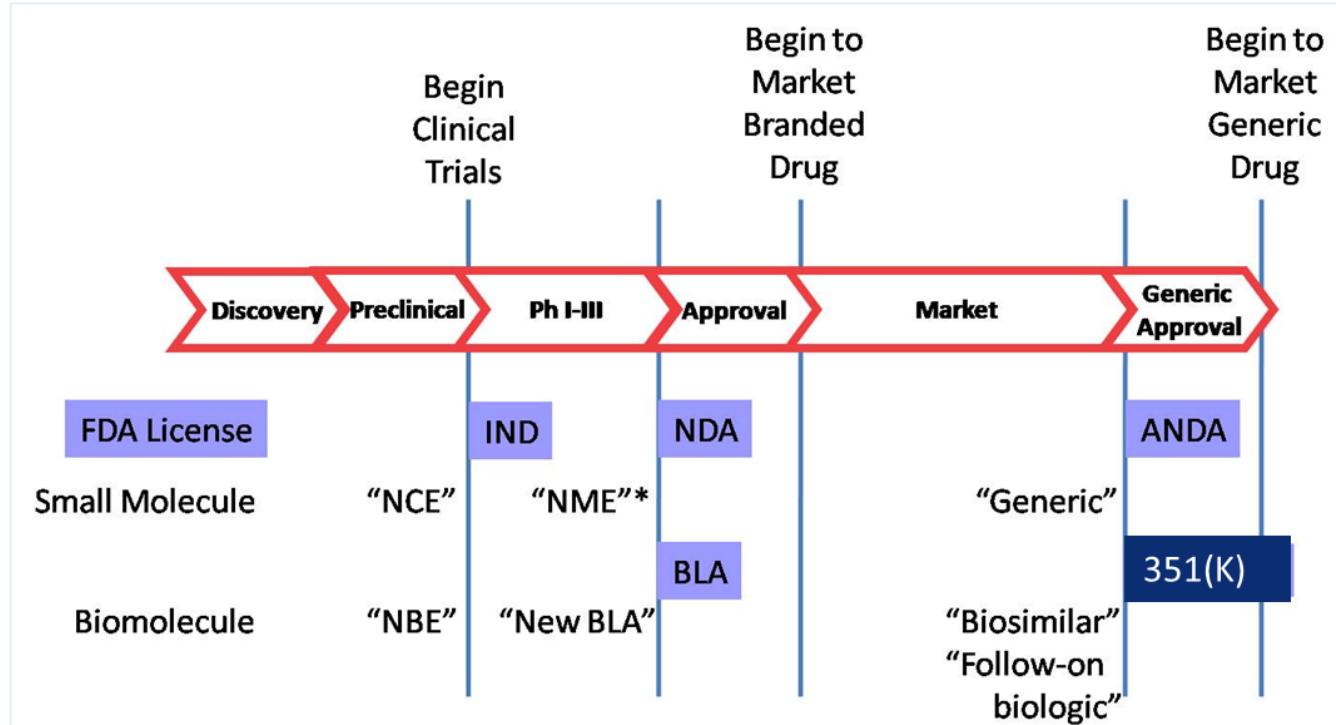


Generics and Biosimilars

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Drug Patent Life Cycle

Small molecules and biomolecules can take on different names over the lifetime of drug discovery and development and marketing

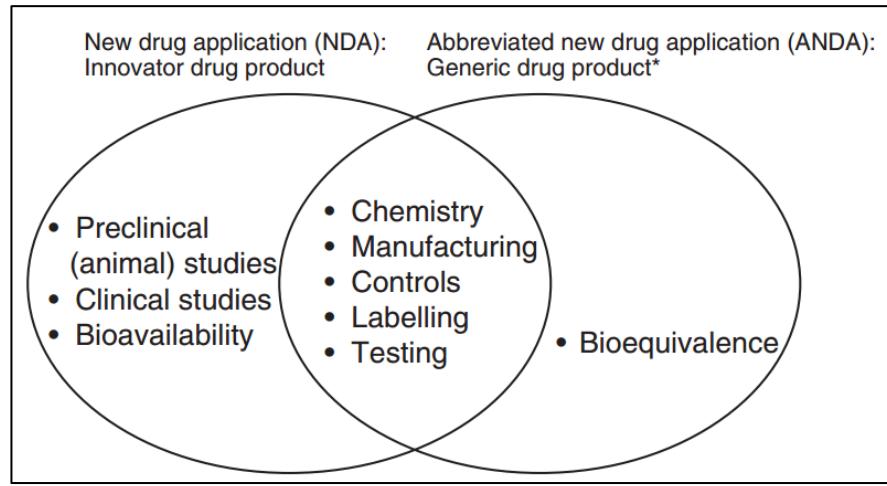


ANDA = abbreviated new drug application; BLA = biologics license application; IND = investigational new drug; NBE = new biological entity; NCE = new chemical entity; NDA = new drug application; NME = new molecular entity.

Adapted from: Crasto, A. (2014, February 28). Drug discovery. *New Drug Approvals*. <https://newdrugapprovals.org/2014/02/28/drug-discovery/>

Conditions for Approval of Generic Drugs

- ▶ Generic drugs are approved by FDA if:
 - ▶ Pharmaceutically equivalent to approved safe and effective reference product
 - Contains identical amounts of active drug
 - Meets standards of strength, quality, purity, identity
 - ▶ Bioequivalent to reference product
 - Does not present bioequivalence problem and meets acceptable in vitro standards
 - Meets bioequivalence standards
 - ▶ Adequately labeled
 - ▶ Manufactured in compliance with Good Manufacturing Practices

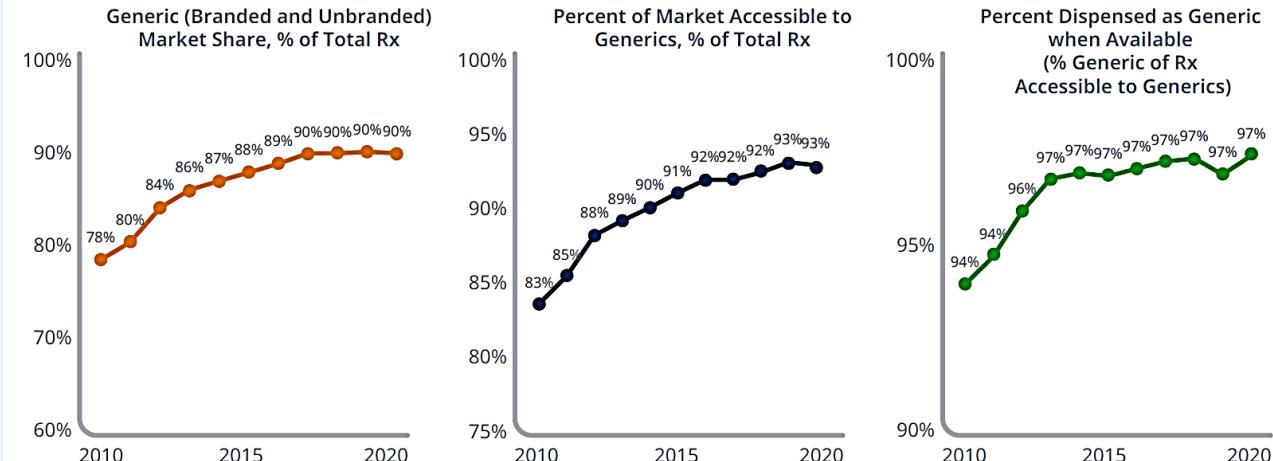


Sources: Davit, B. M., Nwakama, P. E., Buehler, G. J., et al. (2009). Comparing generic and innovator drugs: A review of 12 years of bioequivalence data from the United States Food and Drug Administration. *The Annals of Pharmacotherapy*, 43(10), 1583–1597. <https://doi.org/10.1345/aph.1M141>; Image: Figure 1, "Comparison between regulatory requirements for NDAs with innovator versus ANDAs with generic drug products." In: Meredith, P. A. (2009). Potential concerns about generic substitution: Bioequivalence versus therapeutic equivalence of different amlodipine salt forms. *Current Medical Research and Opinion*, 25(9), 2179–2189. <https://doi.org/10.1185/03007990903116867>

Generic Drug Market Dynamics

Generics are 90% of dispensed prescriptions, up from 72% 10 years ago, and dispensed 97% of the time when possible

Exhibit 32: Generic Shares of Dispensed Prescriptions, Accessible Market and Generic Share when Available

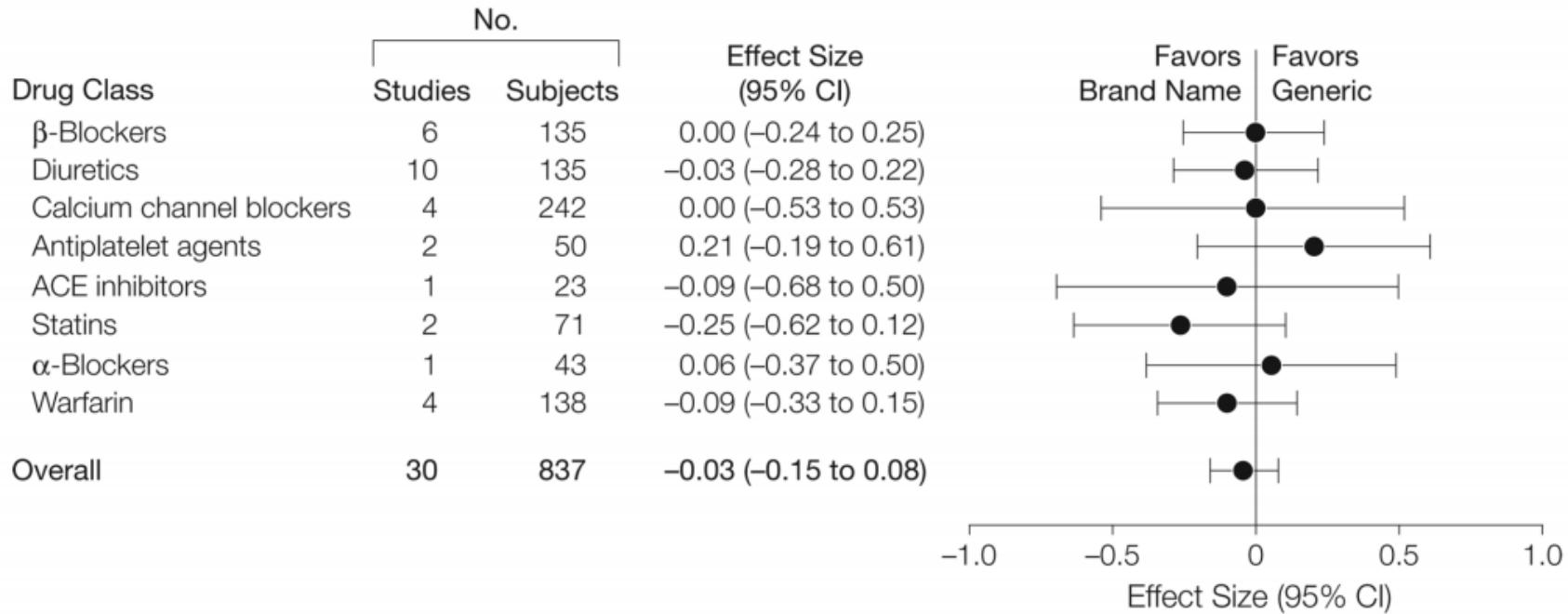


Source: IQVIA National Prescription Audit, Dec 2020

Many Questions for Drug Utilization Researchers

- ▶ How commonly are generic drugs used, overall and for multi-source products? How has this changed over time?
- ▶ To what degree, if at all, are generic drugs less safe or effective than their branded counterparts?
 - ▶ What about for drugs that have a narrow therapeutic index (NTI)?
 - ▶ What about drugs with disputed bioequivalence standards?
- ▶ How does coverage and reimbursement affect generic drug utilization?
- ▶ How do biosimilars pose unique scientific and clinical challenges?

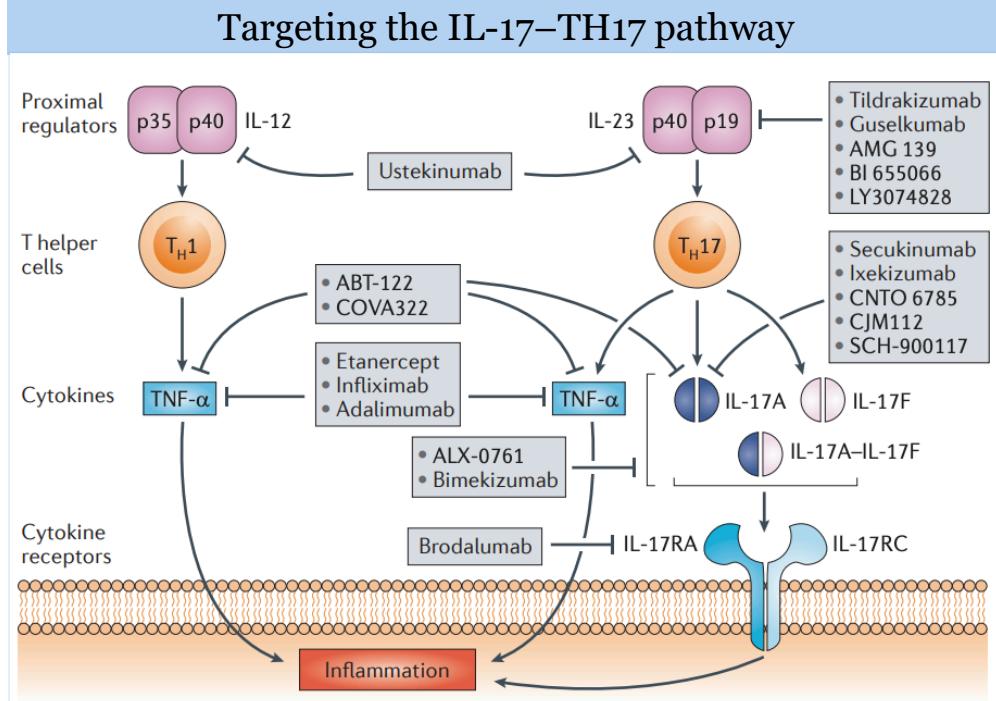
Drug Class and Aggregate Meta-Analyses of Trials Comparing Generic and Brand-Name Drugs Used in Cardiovascular Disease



Source: Figure 2, "Drug class and aggregate meta-analyses of trials comparing generic and brand-name drugs used in cardiovascular disease." In: Kesselheim, A. S., Misono, A. S., Lee, J. L., Stedman, M. R., Brookhart, M. A., Choudhry, N. K., & Shrunk, W. H. (2008). Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: A systematic review and meta-analysis. *JAMA*, 300(21), 2514–2526. <https://doi.org/10.1001/jama.2008.758>

Biologics and Biosimilars

- Xultophy (insulin degludec/liraglutide)
- Xermelo (telotristat ethyl)
- Dupixent (dupilumab)
- Ocrevus (ocrelizumab)
- Bavencio (avelumab)
- Trulance (plecanatide)
- Siliq (brodalumab)

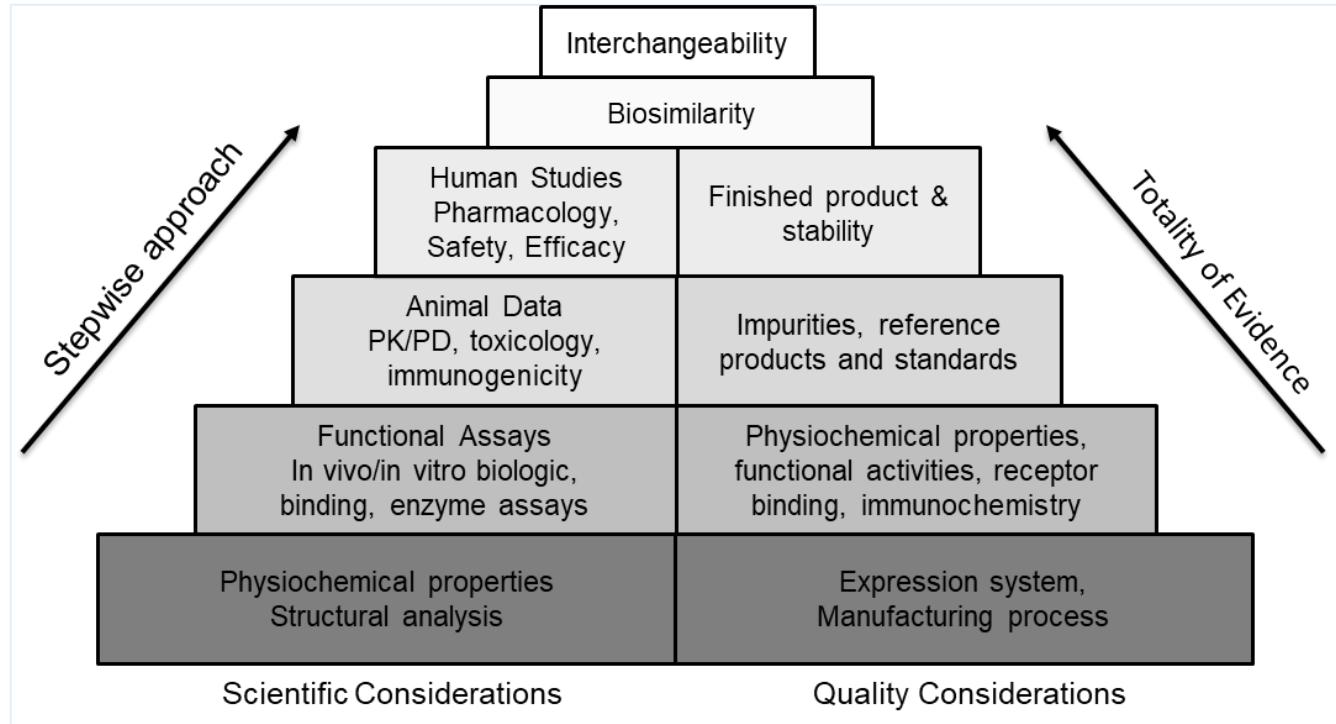


Source: Figure 1, "Targeting the IL-17–TH17 pathway." In: Bartlett, H. S., & Million, R. P. (2015). Targeting the IL-17–TH17 pathway. *Nature Reviews Drug Discovery*, 14(1), 11–12.
<https://doi.org/10.1038/nrd4518>

Comparison of Small-Molecule Medications and Biologics

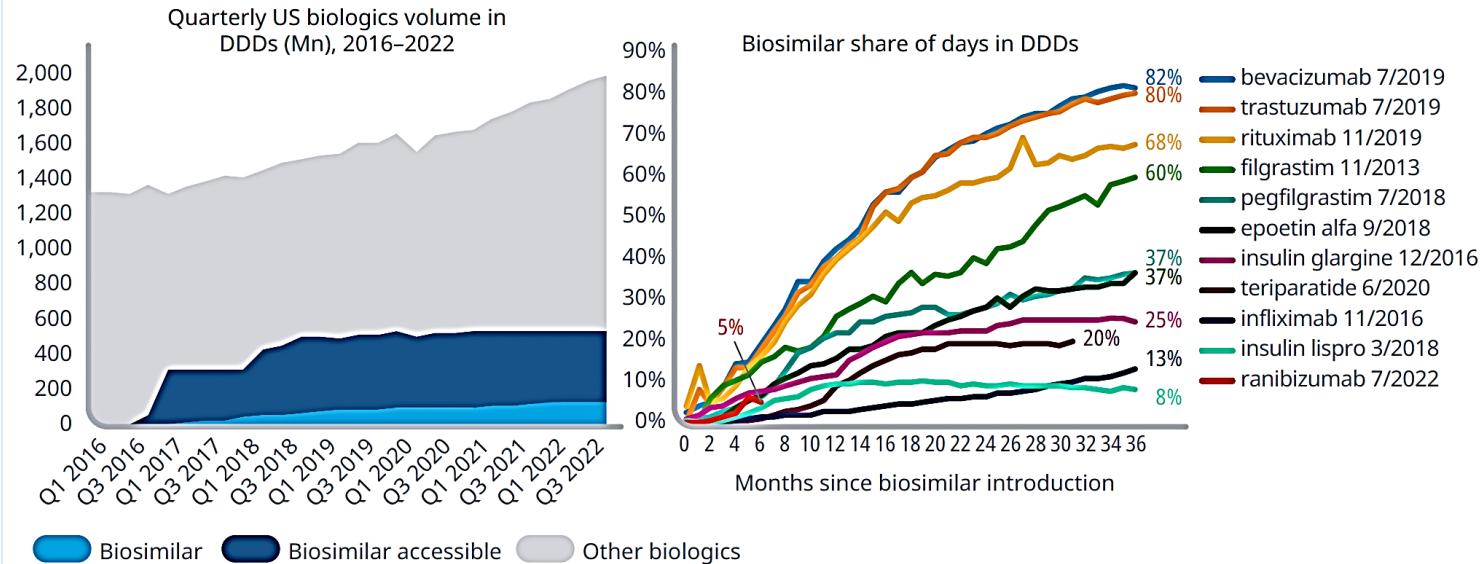
Characteristic	Small-Molecule Drugs	Biologics
Production	Chemical synthesis	Through biotechnology and host cell lines
Size	Low molecular weight	High molecular weight
Physiochemical properties	Well defined and stable	Complex, sensitive to heat, sheer stress (aggregation)
Manufacturing	Single entity, high chemical purity, standards well established Not affected by slight changes in production process and environmental conditions	Heterogeneous mixture, broad specifications which may change during development, difficult to standardize Highly susceptible to changes in production process and environmental conditions
Analytic assays	Completely characterized by analytic methods	Difficult to characterize, assays not standardized
Decontamination	Easy to purify	Lengthy and complex purification process
Quality assurance and detection	Contamination can be avoided and easily detected and removable	High possibility of contamination, detection hard, and removal impossible
Pharmacokinetic properties	Administered through different routes Distributes to any organ and tissue Rapidly enters systemic circulation through capillaries	Parenteral route of administration most common Distribution limited to plasma and extracellular fluid Larger molecules enter circulation through lymphatic system, subject to proteolysis and lymphatic transit
Toxicity	Organ specific toxicity	Mostly receptor mediated toxicity
Allergenicity	Often not antigenic	Usually antigenic

US Food and Drug Administration Regulation of Biosimilars



Biologics Market Continues to Grow Faster Than Nonbiologics on an Invoice Basis

Exhibit 11: Biologics volume and biosimilar share by molecule in Defined Daily Doses (DDDs)



Source: Biosimilars in the United States 2023–2027: Competition, Savings, and Sustainability. January 2023. Report by the IQVIA Institute for Human Data Science.

Dynamic Policy Milieu Governing Generics and Biosimilars!

National Geographic

Do generic drugs work as well as brand name? Here's what to know.

Around nine out of 10 prescriptions filled in the United States are for a generic version of a drug rather than the brand name manufactured...

3 weeks ago



Generic Drugmaking Firms Fall Short for Poorest Patients

- Analysis examined 50 medicines from five large manufacturers
- Some essential drugs still inaccessible despite price declines

By [Chris Kay](#)

26 September 2023 at 04:00 GMT-4

Updated on 26 September 2023 at 08:58 GMT-4

SEPTEMBER 22, 2023

WSJ The Wall Street Journal

WSJ News Exclusive | Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them

The cancer drug Gleevec went generic in 2016 and can be bought today for as little as \$55 a month. But many patients' insurance plans are...

1 month ago



VAN HOLLEN, BLUMENTHAL, BROWN, COONS INTRODUCE BILL TO PROTECT CONSUMERS USING GENERIC MEDICATIONS

Today, U.S. Senators Chris Van Hollen (D-Md.), Richard Blumenthal (D-Conn.), Sherrod Brown (D-Ohio), and Chris Coons (D-Del.) announced the introduction of the Updated Drug Labeling for Patient Safety Act, legislation to allow all prescription drug manufacturers to revise medication labels to provide accurate, up-to-date warnings to consumers. Current federal law mandates that generic drug labels must match those approved by the Food and Drug Administration (FDA) for their brand-name equivalents. This bill will enable drug companies to update labels for generic medications independently – ensuring patients have the latest information about the potential side effects and risks associated with their prescriptions.

Summary Across the Case Studies

- ▶ These four cases—antibiotics, opioids, anticoagulants, and generics/biosimilars—highlight the valuable role that drug utilization research plays in helping to optimize the use, safety, effectiveness, and value of therapeutics
- ▶ The cases also underscore many of the themes that we have discussed
 - ▶ The drug life cycle
 - ▶ A dynamic policy milieu
 - ▶ Drivers of drug utilization
 - ▶ Overuse, underuse, misuse
 - ▶ Context of use that shape value
 - ▶ Need for bright and committed pharmacoepidemiologists!