PainWeek

ADVANCED EDUCATION

CERTIFICATION SERIES

Methadone Madness: Part 1

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Titles and Affiliations

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Disclosures

Learning Objectives

- List risk stratification strategies prior to starting methadone therapy
- Describe appropriate candidates for methadone therapy
- Describe inappropriate candidates for methadone therapy
- Describe the pharmacodynamic properties of methadone
- Describe the pharmacokinetic properties of methadone including absorption, distribution, metabolism, and excretion
- Explain common drug interactions with methadone
- Recommend a methadone dose in an opioid-naïve patient

Methadone Stats

- Long and variable half-life
- Potential drug interactions with multiple medications
- Variability in equianalgesic dose ratios
- Association with prolongation of QTc
  - “Proportion of methadone-associated deaths related to arrhythmia is likely to be small relative to the proportion related to accidental overdose, though reliable estimates are not available”

Chou, Weimer, Herr; APS. silo.tips/download/the-methadone-safety-guidelines-a-live-webinar.

Pharmacodynamics of Methadone

- Synthetic opioid developed over 50 years ago
- Used to treat opioid dependent patients
- Many characteristics making it ideal for chronic pain patients (long duration of action, efficacy, low cost)
- Racemic mixture of R- and S-methadone
  - R-methadone is 8-50 times more potent than S-methadone
- Mu, kappa, delta agonist
- NMDA receptor antagonist (MAYBE, and probably at very high doses)
- Inhibits reuptake of serotonin

Pharmacokinetics of Methadone

- Absorption
  - Oral, rectal, IV, IM, SQ, epidural,* intrathecal*
  - Basic, lipophilic drug
  - Onset 15-45 minutes after oral, peaks in 2.5-4 hours
  - Oral bioavailability 70%-80% (range 36%-100%)

* Not FDA approved

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Pharmacokinetics of Methadone

- Distribution
  - Widely and quickly distributed throughout
    - Brain, gut, kidney, liver, muscle, lung
  - Retained in tissues and slowly released back into plasma during redistribution and elimination; contributes to long half-life
  - Binds to alpha 1-acid glycoprotein; less so to albumin and globulin
    - Free fraction varies 4-fold among patients

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Pharmacokinetics of Methadone

- Metabolism – extensively metabolized
  - N-demethylation
  - Cytochrome P450 – 3A4, 2B6, 2C8, 2C9, 2C19, 2D6
  - Primarily in the liver, also in the gut
  - Pharmacologically-inactive metabolites, eliminated in urine and feces
  - Involved in numerous drug interactions

silo.tips/download/the-methadone-safety-guidelines-a-live-webinar.

Pharmacokinetics of Methadone

- Elimination
  - Inactive metabolites are eliminated in urine and feces
  - Elimination half-life is 5-130 hours; AVERAGE 24 hours
  - Takes 4-10 days to achieve steady state
    - When initiating drug therapy
    - With dosage changes

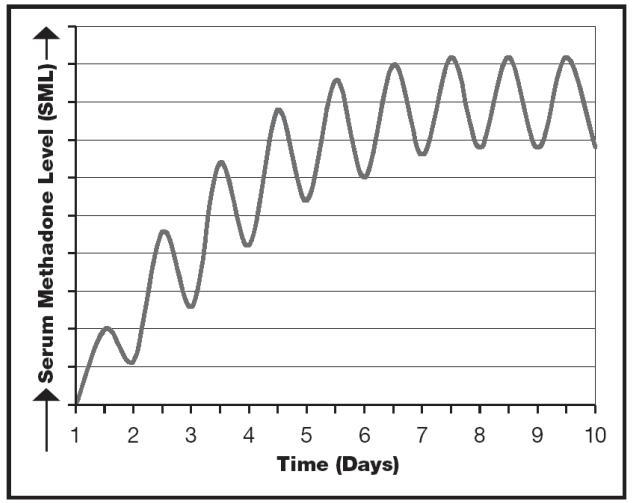
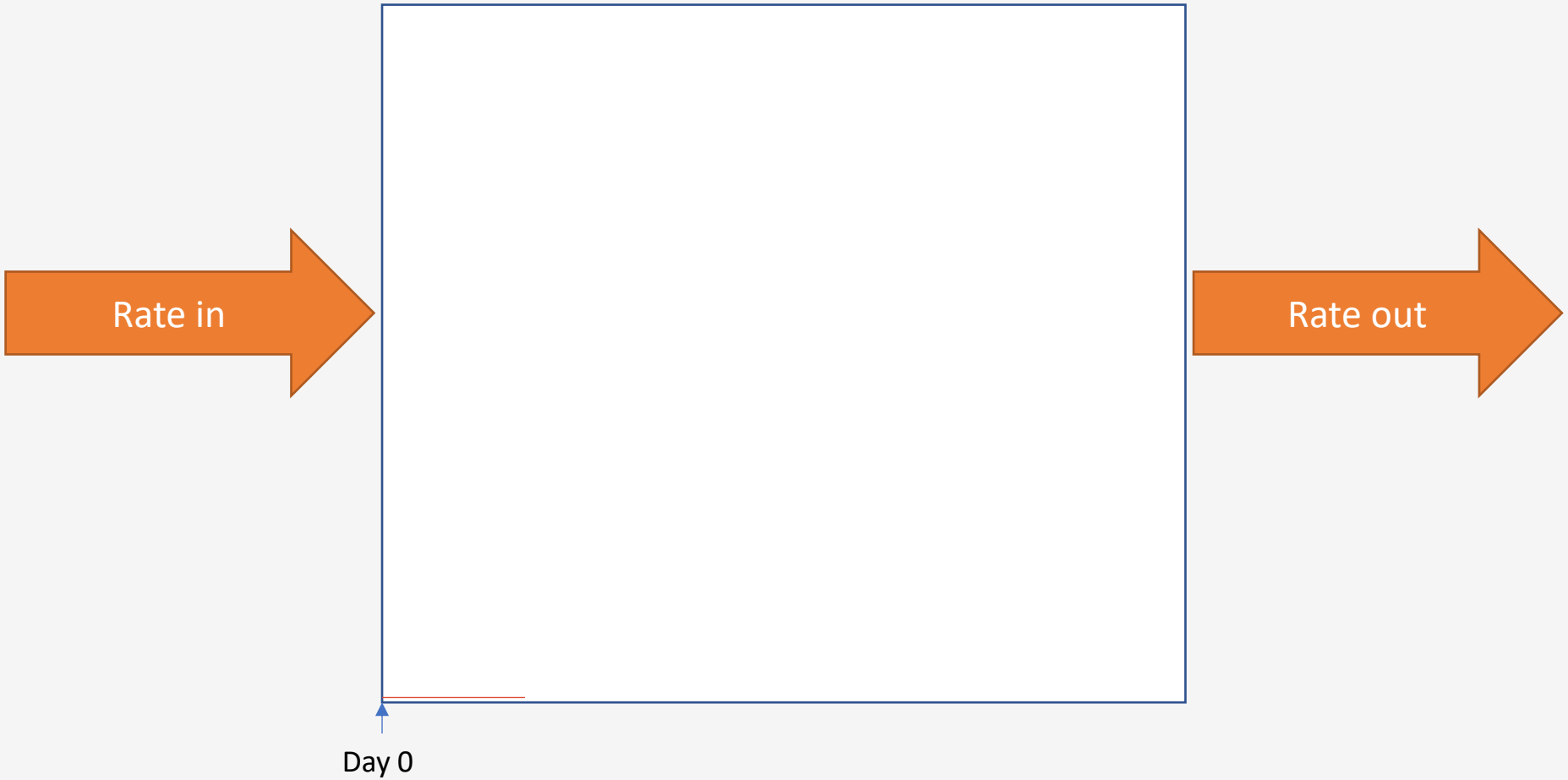


Figure 6-1. Steady-state methadone concentration reached in about 5 days. *Source:* Addiction Treatment Forum: Methadone Dosing and Safety in the Treatment of Opioid Addition, Stewart B. Leavitt, PhD.

silo.tips/download/the-methadone-safety-guidelines-a-live-webinar

Used with permission

Achieving Steady State



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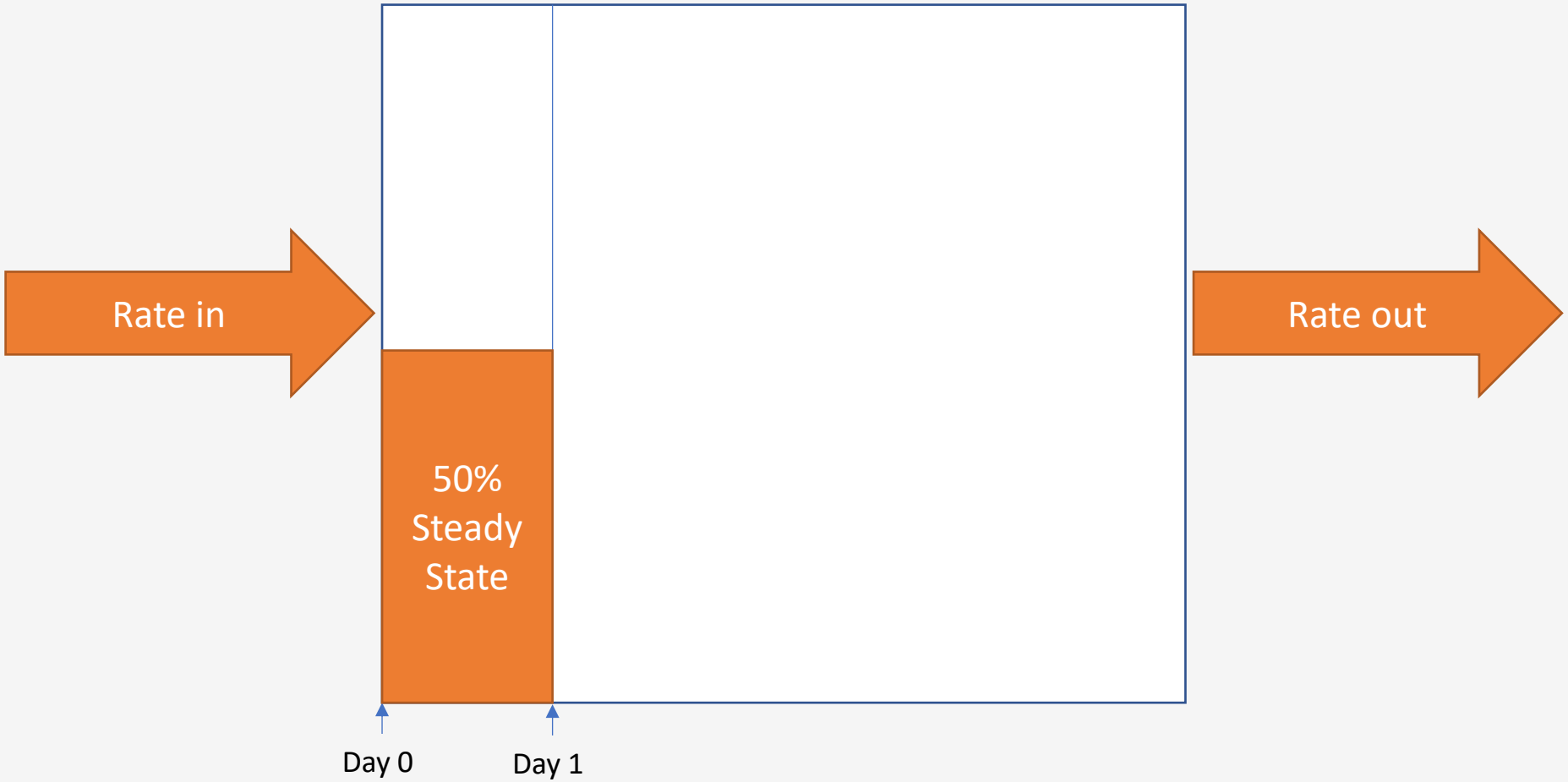
Achieving Steady State



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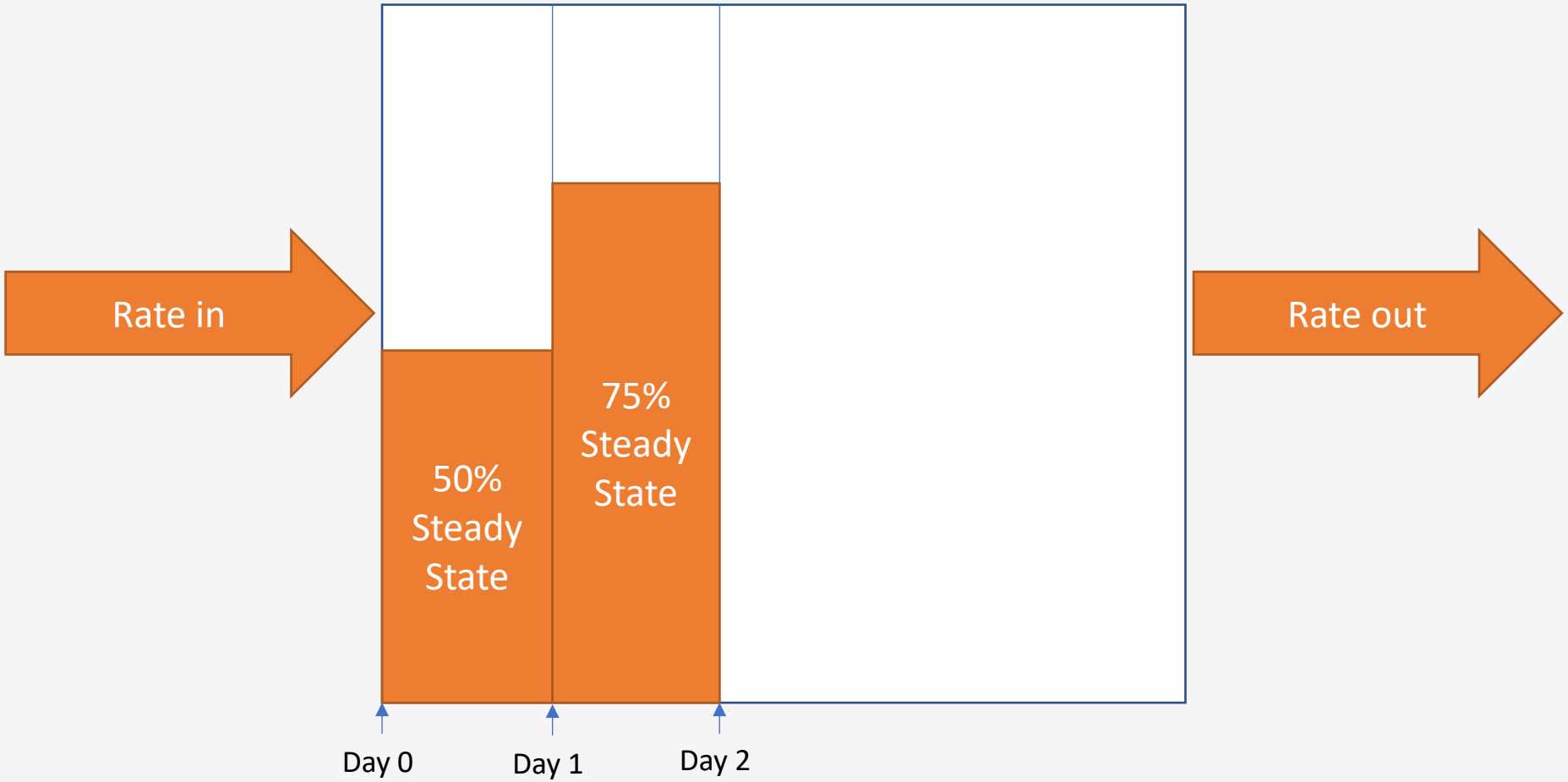
Achieving Steady State



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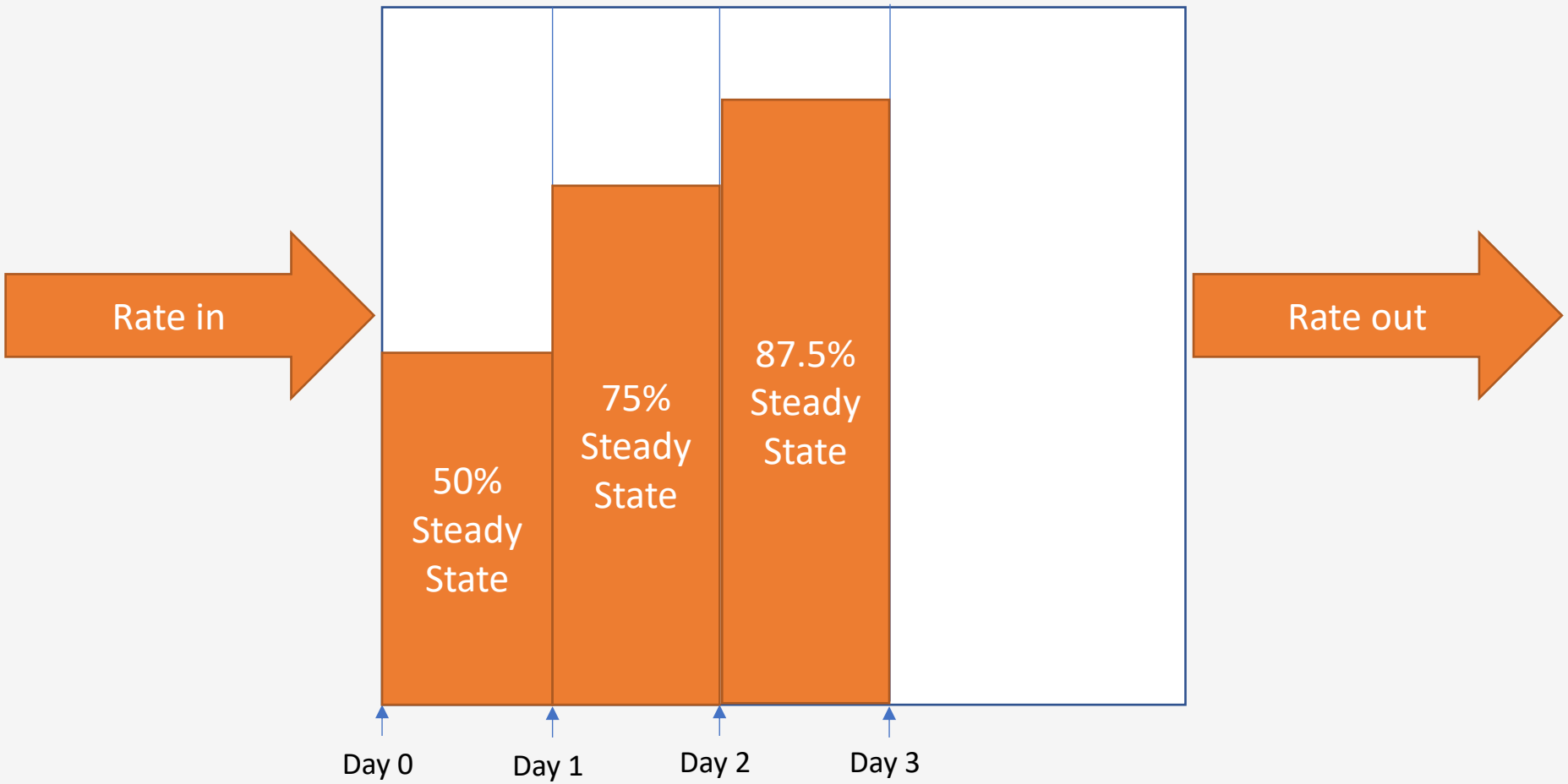
Achieving Steady State



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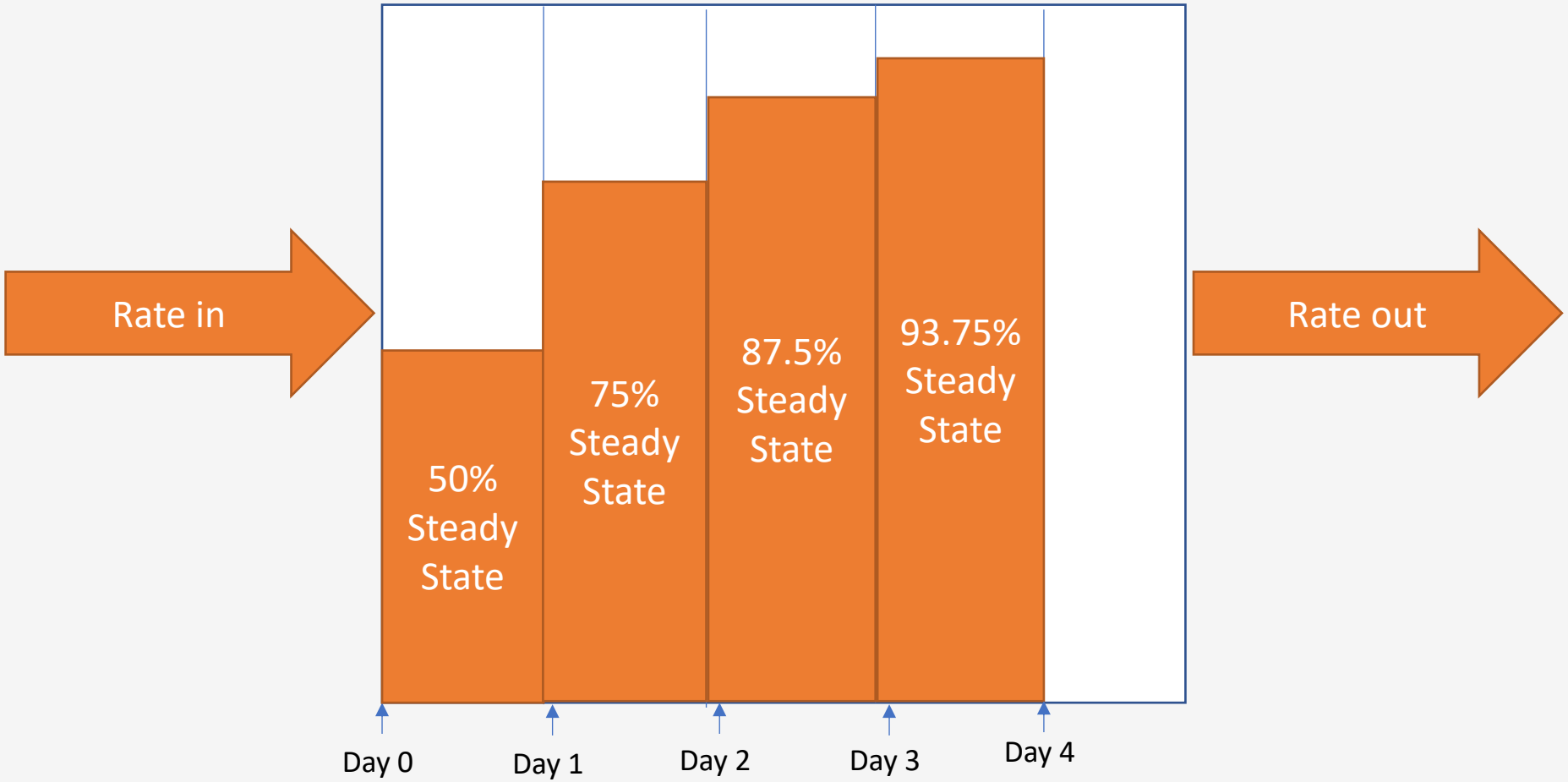
Achieving Steady State



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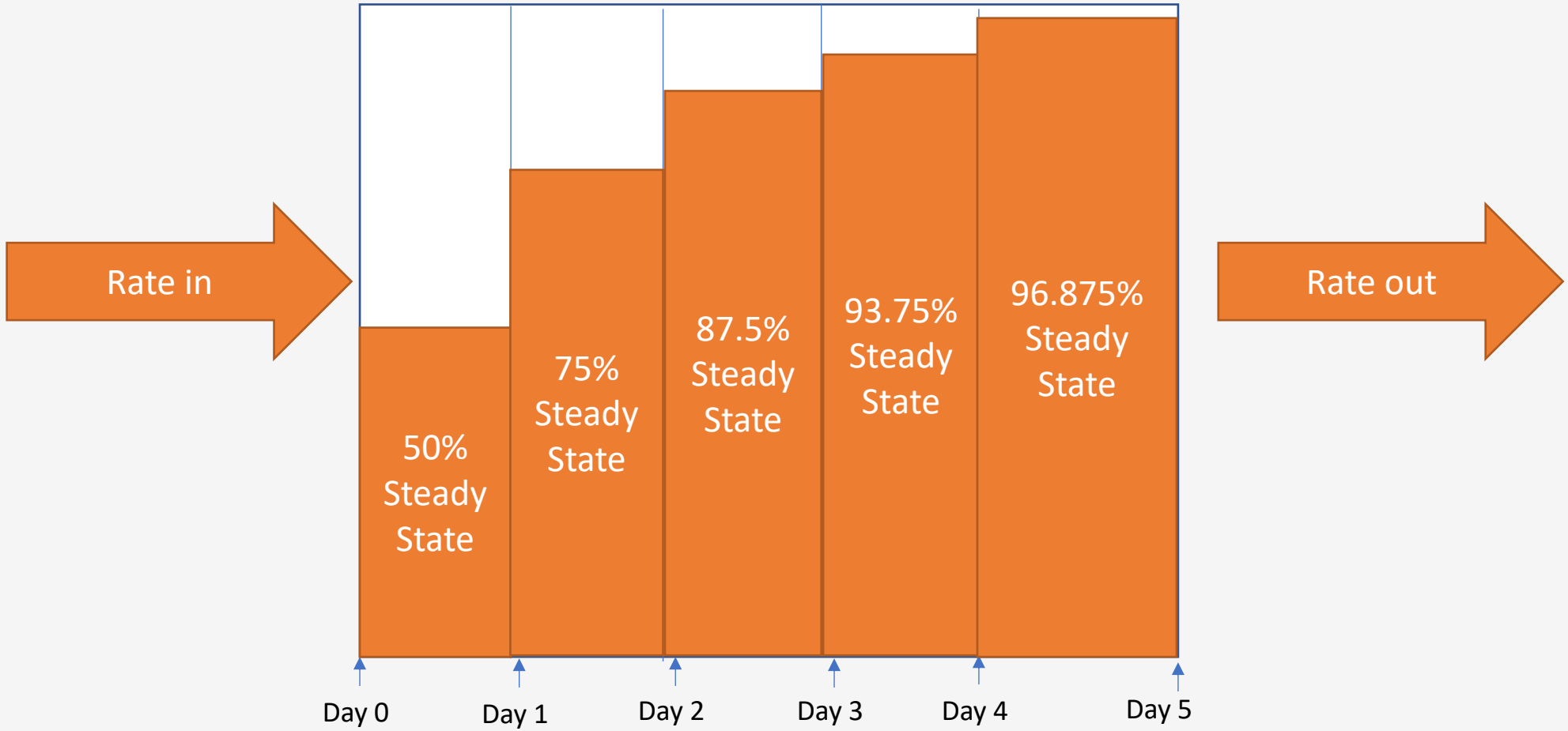
Achieving Steady State



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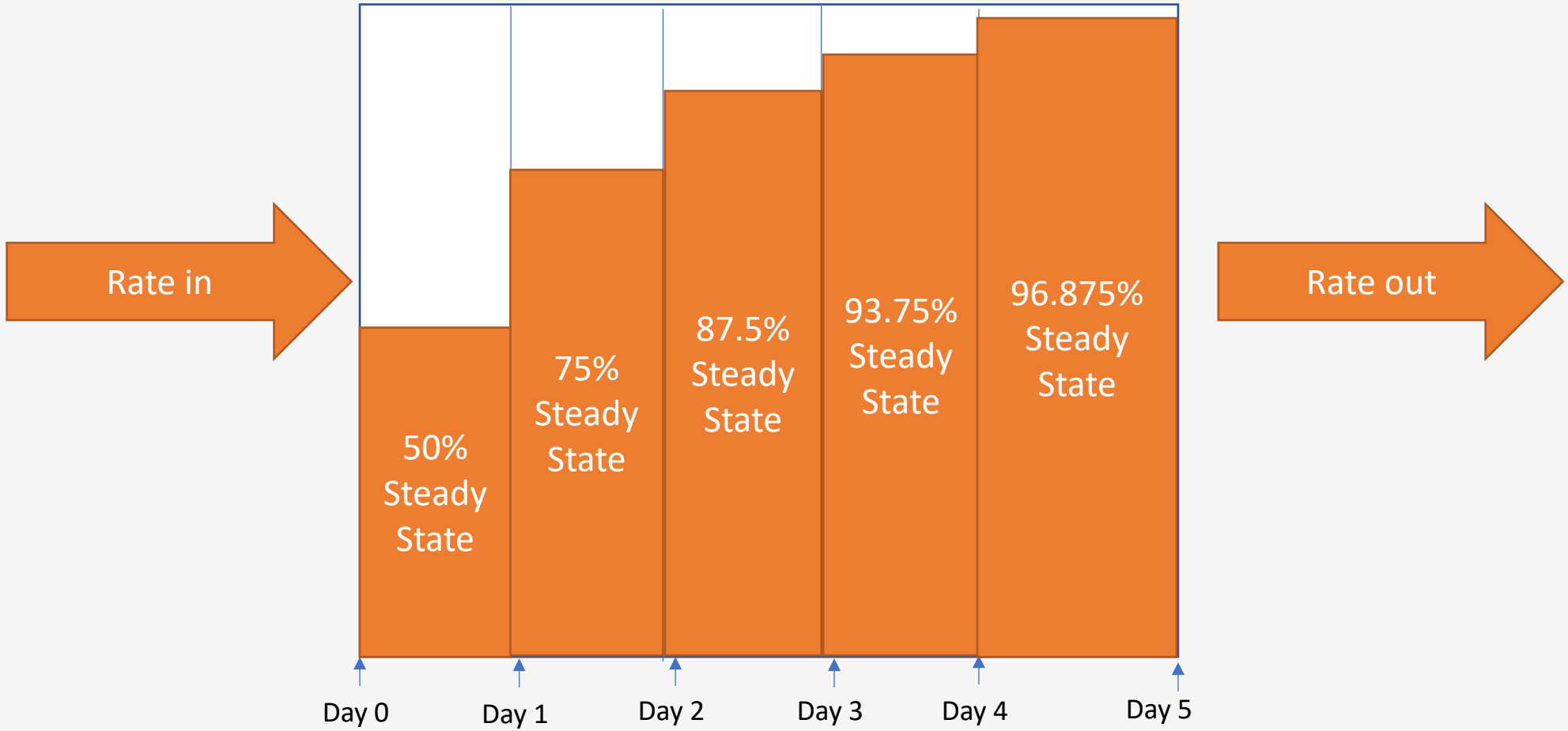
Achieving Steady State ($t_{1/2}$ = 24 hours)



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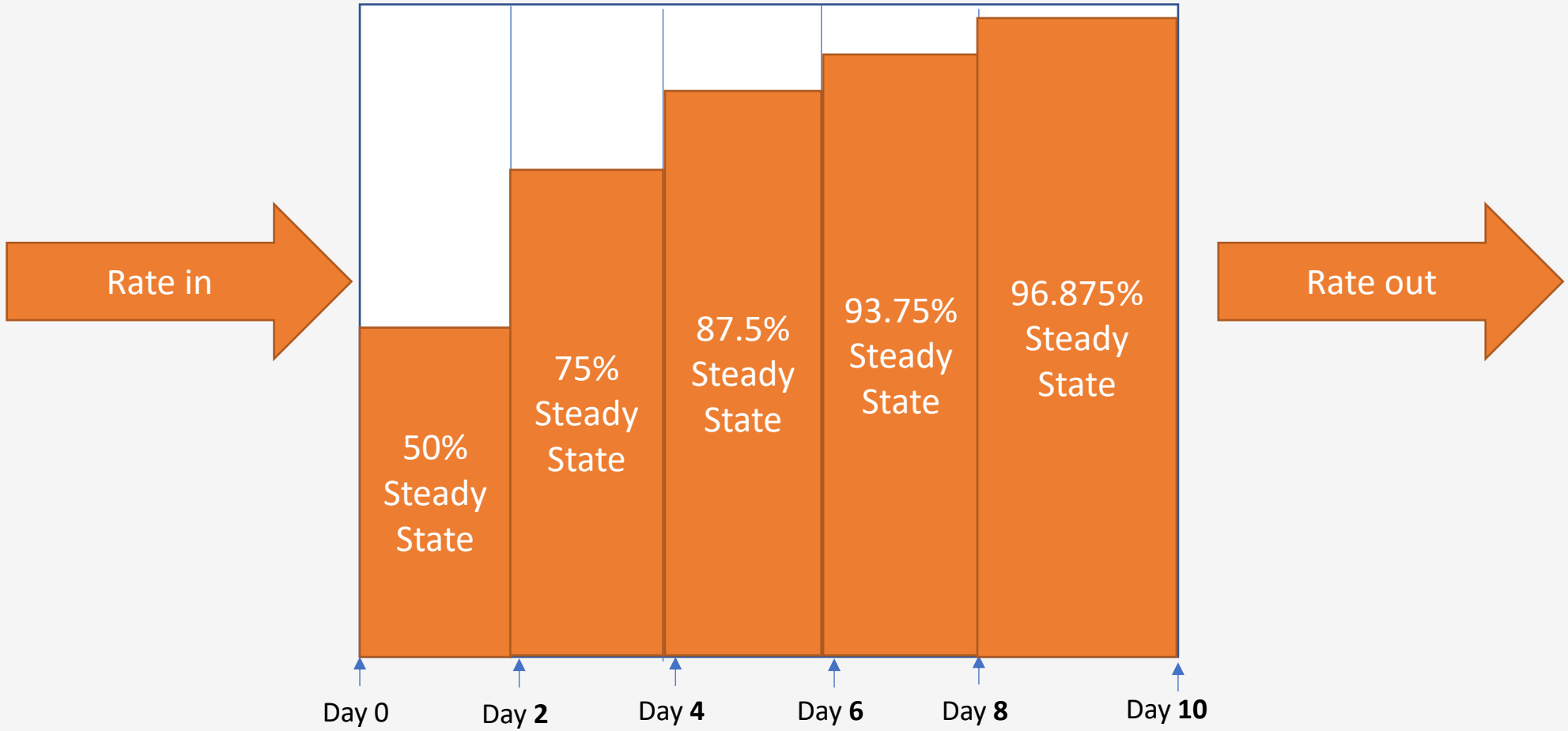
Achieving Steady State ($t_{1/2}$ = 48 hours)



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Drug Interactions with Methadone

- Drug interaction
  - A clinical scenario where one drug alters the pharmacologic effect of another drug given at the same time (eg, in the same drug regimen)
  - Drug interactions can alter the pharmacokinetics of a drug
    - Absorption, distribution, metabolism, excretion
  - Drug interactions can alter the pharmacodynamics of a drug
    - Increased or decreased therapeutic effectiveness of either drug
    - Increased or decreased adverse effects of either drug

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Pharmacodynamic Drug Interactions

- Methadone and other opioids
  - Increased analgesia
  - Additive toxicities – increased risk respiratory depression and sedation
- Methadone and alcohol, neuroleptics, benzodiazepines, antidepressants, etc
  - Increased CNS depression
- Methadone and other medications that prolong QT interval (antiarrhythmics, antipsychotics, antidepressants, etc)

www.medsafe.govt.nz/profs/PUArticles/June2018/Methadone.htm.

Pharmacokinetic Drug Interactions

- Distribution
  - Competition for protein binding sites
  - May increase methadone free fraction
  - TCA and neuroleptic medications compete with methadone for binding on alpha 1-acid glycoprotein

Pharmacokinetic Drug Interactions

- Metabolism
  - Extensively metabolized in intestines and liver
  - Primarily by 3A4 enzyme system
  - 30-fold difference in liver 3A4 enzymes among individuals
  - 11-fold difference in intestinal 3A4 enzymes among individuals

  - Other medications can *induce* (increase) activity of enzymes
  - Other medications can *inhibit* (reduce) activity of enzymes
  - These other medications affect the serum level of the object drug being metabolized – methadone – known as the *substrate*

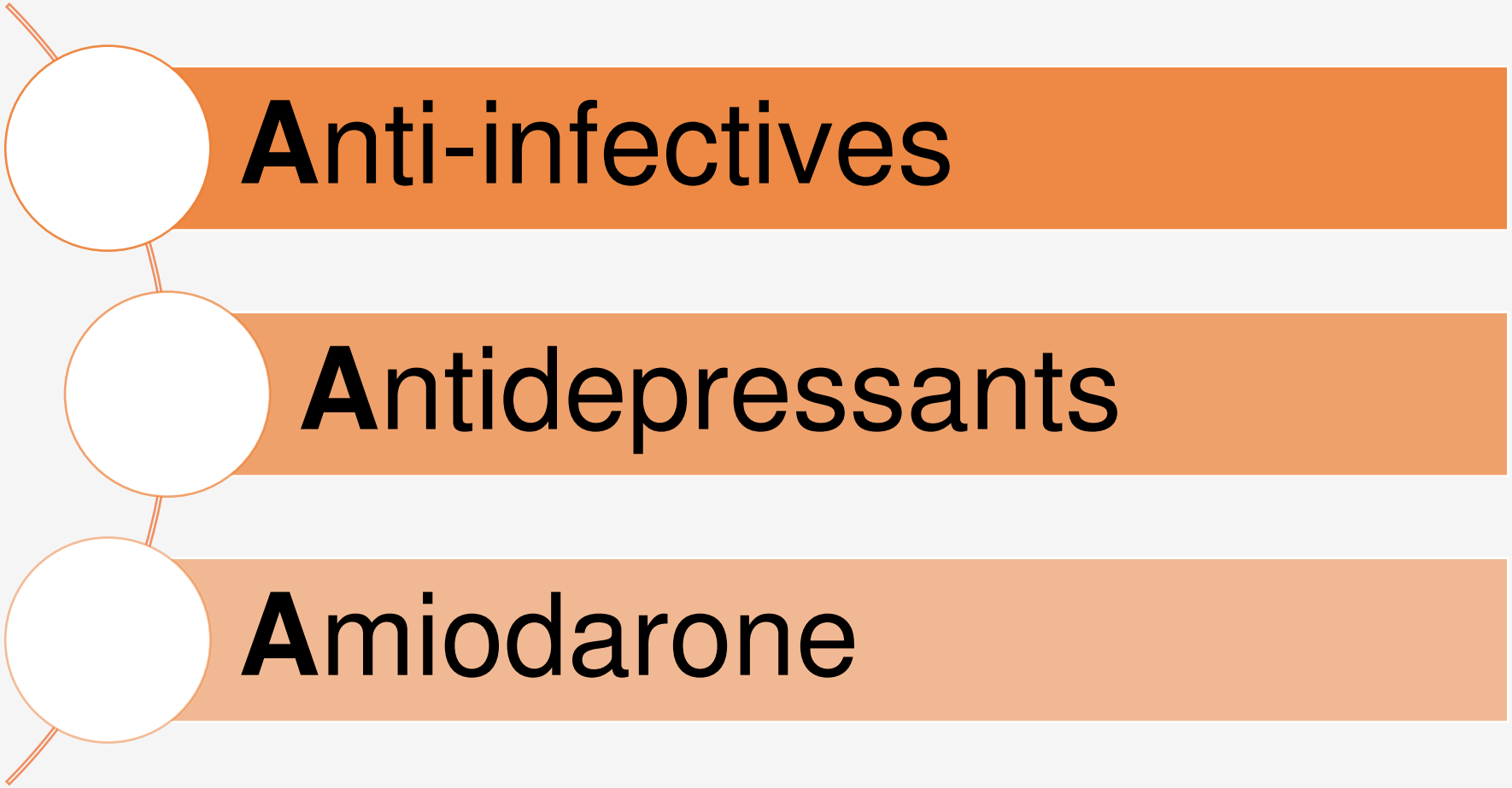
Pharmacokinetic Drug Interactions

- Metabolism
  - Enzyme *induction* usually takes 1-2 weeks
    - May take 1-2 weeks to see a reduction in methadone serum levels and increase in pain
  - Enzyme *inhibition* occurs much more quickly (1 or 2 days)
    - See an increase in methadone serum levels and possibly adverse effects within 1 or 2 days

Effect of Enzyme Inhibitors/Inducers

What's the situation?	What happens in this situation?	What does this mean for my patient?	What should I do about it?
Taking methadone with medications known to be enzyme inhibitors	Slowed metabolism of methadone, resulting in increased methadone serum level	The patient may become toxic from a methadone overdose	Reduce calculated methadone dose by 25% or more Encourage use of rescue opioid
Taking methadone with medications known to be enzyme inducers	Increased metabolism of methadone, resulting in decreased methadone serum level	Dose of methadone may be insufficient and patient can experience increased pain	Use calculated methadone dose but strongly encourage use of rescue opioid Increase methadone if appropriate once at steady-state

Drugs that Inhibit Methadone Metabolism



Enzyme Inducers	Enzyme Inhibitors	
Rifampicin / rifampin	**Amiodarone**	Ketoconazole
Rifabutin	Fluconazole	Erythromycin
Phenobarbital	Fluoxetine	Troleandomycin
Phenytoin	Paroxetine	Citalopram
Spironolactone	Sertraline	Desipramine
Nevirapine	Ciprofloxacin	Clarithromycin
Efavirenz	Fluvoxamine	Telithromycin
Amprenavir	Amitriptyline	Itraconazole
Nelfinavir		
Ritonavir		
Carbamazepine		
St. John's Wort		

medicine.iupui.edu/clinpharm/ddis/.

Anti-infectives
- Antibiotics
- Antifungals
- Antivirals

Antidepressants
- SSRIs
- TCAs

Amiodarone

Self-Assessment!

- JR is a 72 year old man with end-stage lung cancer, maintained on methadone 7.5 mg by mouth every 12 hours with good effect. He has developed oral thrush and his prescriber added fluconazole 150 mg by mouth once daily for 7 days. How quickly will this drug interaction be apparent, and what will the outcome be?

A. Fluconazole will induce methadone metabolism, effect seen in about a week resulting in lower methadone serum level
B. Fluconazole will inhibit methadone metabolism, effect seen in a day or two resulting in higher methadone serum level
C. Fluconazole will induce methadone metabolism, effect seen in a day or two resulting in lower methadone serum level
D. Fluconazole will inhibit methadone metabolism, effect seen in about a week resulting in lower methadone serum level

Self-Assessment!

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C. Fluconazole will induce methadone metabolism, effect seen in a day or two resulting in lower methadone serum level

D. Fluconazole will inhibit methadone metabolism, effect seen in about a week resulting in lower methadone serum level

Appropriate Methadone Candidates

- True morphine allergic (or other mu agonist)
- Significant renal impairment
- Neuropathic pain
- Opioid-induced adverse effects
- Pain refractory to other opioids or uncontrolled pain
- Cost is an issue
- Long-acting opioid preferred (especially oral solution)
- Any opioid-requiring patient???

Inappropriate Methadone Candidates

(at least use caution)

- Very limited prognosis (less than a week)
- Numerous drug interactions with methadone
- History of syncope or arrhythmias
- Lives alone, poor cognitive functioning, unreliable, noncomprehending instruction
- History of nonadherence to therapy

More Methadone Statistics

- Methadone accounted for 1.7% of opioid prescriptions in 2009, and 9.0% of morphine equivalents
- Methadone was associated with 31% of opioid related deaths and 40% of single-drug deaths

MMWR. 2012;61:493-497.

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Methadone Safety Guidelines

Methadone Safety: A Clinical Practice Guideline From the American Pain Society and College on Problems of Drug Dependence, in Collaboration With the Heart Rhythm Society

Roger Chou,* Ricardo A. Cruciani,† David A. Fiellin,‡ Peggy Compton,§ John T. Farrar,‖ Mark C. Haigney,¶ Charles Inturrisi,** John R. Knight,†† Shirley Otis-Green,‡‡ Steven M. Marcus,§§ Davendra Mehta,‖‖ Marjorie C. Meyer,¶¶ Russell Portenoy,† Seddon Savage,*** Eric Strain,††† Sharon Walsh,‡‡‡ and Lonnie Zeltzer§§§

Commissioned an interdisciplinary expert panel to develop a clinical practice guideline on safe prescribing of methadone for treatment of opioid addiction and chronic pain

Special Article

Safe and Appropriate Use of Methadone in Hospice and Palliative Care: Expert Consensus White Paper

Mary Lynn McPherson, PharmD, MA, MDE, BCPS, CPE, Kathryn A. Walker, PharmD, BCPS, CPE, Mellar P. Davis, MD, FCCP, FAAHPM, Eduardo Bruera, MD, Akhila Reddy, MD, Judith Paice, PhD, RN, Kasey Malotte, PharmD, BCPS, Dawn Kashelle Lockman, PharmD, MA, Charles Wellman, MD, Shelley Salpeter, MD, Nina M. Bemben, PharmD, BCPS, James B. Ray, PharmD, CPE, Bernard J. Lapointe, MD, and Roger Chou, MD

University of Maryland School of Pharmacy (M.L.M., K.A.W.), Baltimore, Maryland, USA; MedStar Health (K.A.W.), Baltimore, Maryland, USA; Geisinger Medical Center (M.P.D.), Danville, Philadelphia, USA; Palliative, Rehabilitation & Integrative Medicine Department (E.B.), University of Texas MD Anderson Cancer Center, Houston, Texas, USA; F. T. McGraw Chair in the Treatment of Cancer (E.B.); The University of Texas MD Anderson Cancer Center (E.B., A.R.,), Houston, Texas, USA; Division of Hematology-Oncology (J.P.); Feinberg School of Medicine (J.P.), Northwestern University, Chicago, Illinois, USA; Advanced Practice Pharmacist Supportive Care Medicine Cedars-Sinai Medical Center (K.M.), Los Angeles, California, USA; Hospice & Palliative Care (D.K.L.), University of Iowa College of Pharmacy; Internal Medicine-Palliative Care Program (D.K.L.), Iowa City, Iowa, USA; Hospice of the Western Reserve (C.W.), Cleveland, Ohio, USA; Stanford University School of Medicine (S.S.), Stanford, California, USA; Mission Hospice and Home Care (S.S.), San Mateo, California, USA; Wolters Kluwer (N.M.B.), Chicago, Illinois, USA; University of Iowa College of Pharmacy (J.B.R.), Iowa City, Iowa, USA; Supportive and Palliative Care Consult Service (J.B.R.), University of Iowa Hospitals and Clinics, Iowa City, Iowa, USA; Eric M. Flanders Chair in Palliative Medicine (B.J.L.), McGill University; Chief Supportive and Palliative Care Division (B.J.L.), Jewish General Hospital, Montreal, Canada; and Division of General Internal Medicine and Geriatrics (R.C.), OHSU, USA

Patient Assessment, Selection, Education

- Perform an individualized medical and behavioral risk evaluation to assess risks and benefits of methadone
- Educate and counsel patients regarding risks and benefits prior to first prescription and periodically while taking methadone

- Appropriate Candidates (HPM)
  - True morphine (phenanthrene allergy)
  - Significant renal impairment
  - Pain refractory to other opioids
  - Opioid-induced adverse effects not other easily managed
  - LA opioid needed, but oral solution preferred
  - Patients with high opioid tolerance

Chou, Weimer, Herr; APS.
AAHPM Methadone Working Group (HPM).

Patient Assessment, Selection, Education

- Potentially inappropriate candidates (HPM)
  - Poor prognosis (eg, <1 week)
    - Consider using methadone as adjuvant
  - Risky situation
    - Poor cognitive functioning, lack of reliable caregiver, lack of knowledgeable HCP on transfer, possibly drug abuse by patient/family/caregiver, patient otherwise unreliable or poor adherence to drug therapy
  - More risky business
    - Transplant patients, patients on phase I/experimental trials, clinical instability, multiple transitions in care
  - Medically at risk
    - Liver failure, interacting drugs, electrolyte abnormalities, disordered breathing syndrome, heart disease

AAHPM Methadone Working Group (HPM).

ECG Monitoring (Chou, APS)

- Obtain baseline ECG prior to initiation of methadone in patients with:
  - Risk factors for QTc prolongation
  - History of QTc prolongation
  - History of prior ventricular arrhythmia
- Consider obtaining a baseline ECG in patients not known to be at higher risk of QTc prolongation
  - ECG within 12 months is sufficient

ECG Monitoring (Chou, APS)

Baseline QTc Interval	Recommended Action
> 500 ms	Recommend against use of methadone
≥450 – 500 ms	Recommend considering alternatives to methadone; evaluate and correct reversible causes of QTc

Consider buprenorphine for patients treated for opioid addiction who have risk factors or known QTc interval prolongation

Follow-Up ECG Monitoring (Chou, APS)

Clinical Situation	Recommended Action
• Patients with risk factors for QTc interval prolongation • Any prior ECG with QTc >450 ms • History of syncope	• Perform follow-up ECG 2-4 weeks after initiation of methadone • Follow-up ECG after significant dose increases
• Any patient who reaches total daily methadone dose of 30-40 mg/day • Any patient who reaches total daily methadone dose of 100 mg	• Repeat ECG
• Any patient with new risk factors for QTc interval prolongation • Signs or symptoms suggestive of arrhythmia	• Repeat ECG

Follow-Up ECG Monitoring (Chou, APS)

Clinical Situation	Recommended Action
• Methadone-treated patient has QTc ≥500 ms	• Switch to an alternate opioid or immediately reduce methadone dose • Evaluate and correct reversible causes of QTc; repeat ECG after dose reduced
• QTc ≥450-500 ms	• Consider switching to an alternative opioid or reducing methadone dose • If patient won't/can't switch, discuss potential risks of continuing with patient • Evaluate and correct reversible causes of QTc; repeat ECG after dose reduced

Table 3

ECG Monitoring and Action Steps

Level of Vigilance	Goals of Care	Methadone Role	Baseline ECG	Follow-Up ECG
High	Curative, life-prolonging	First line	Obtain baseline ECG: • Positive risk factors[a] • Prior QTc >450 ms • History suggestive of prior ventricular arrhythmia Consider baseline ECG: • No risk factors • QTc <450 ms in the previous year Recommendation: • QTc >500 ms—do not use methadone • QTc 450–499 ms—consider alternate opioid (or correct reversible causes of QTc prolongation and reassess)	Obtain ECG within two to four weeks: • Positive risk factors • Prior ECG with QTc > 450 ms • History of syncope Obtain additional ECG: • TDD methadone reaches 30–40 mg • TDD methadone reaches 100 mg • New risk factors or signs/symptoms suggesting arrhythmia Recommendation: • QTc > 500 ms—switch to alternative opioid or reduce methadone dose • QTc 450–499 ms—consider switching to alternative opioid or reduce methadone dose
Moderate	Curative, life-prolonging	Second line	• Discuss risks and benefits with patient/family in light of goals of care	• Reinitiate discussion of risks/benefits if goals of care change
	Comfort measures only	First line	• Routine baseline ECG monitoring not recommended; may consider ECG depending on patient's risk status, wishes, and goals of care (e.g., curative) • Document informed consent if no ECG • If ECG obtained, follow recommendations above	• Routine follow-up ECG monitoring not recommended; may consider ECG depending on patient's risk status, wishes, and goals of care • Document informed consent if no ECG • If ECG obtained, follow recommendations above
Low	Comfort measures only	Second line	• No ECG unless compelling indication • If ECG obtained, follow recommendations above	• No ECG unless compelling indication • If ECG obtained, follow recommendations above

[a]Clinical risk assessment is always indicated and may alter recommendation for ECG monitoring. Risk factors include hypokalemia, hypomagnesemia, impaired liver function, structural heart disease (congenital heart defects, history of endocarditis, or heart failure), and genetic predisposition including patient or family history of congenital QTc syndrome, use of QTc-prolonging medications.[3]

ECG Monitoring (HPM)

Level of Vigilance	Goals of Care; Methadone Role	ECG Monitoring Recommendation
High	Curative, life-prolonging Methadone 1st line opioid	• Obtain baseline ECG with positive risk factors, prior QTc >450 ms, history suggestive of prior ventricular arrhythmia • Consider baseline ECG if no risk factors, prior QTc <450 ms in previous year
Moderate	Curative, life-prolonging Methadone 2nd line opioid Or Comfort measures only Methadone 1st line opioid	• Discuss risks and benefits with patient/family in light of goals of care • Routine baseline ECG monitoring not recommended; may consider obtaining ECG based on patient's risk status, wishes, and goals of care • Document informed consent if no ECG
Low	Comfort measures only Methadone 1st or 2nd line opioid	• No ECG unless compelling indication

Ok, let’s get our hands dirty!

Case 1

- BL is a 54 year old woman with a 10 year history of low back pain, now failed back
  - Did not respond to acetaminophen, NSAID
  - Adverse effects to gabapentin and duloxetine
- Not taking any medications that interact with methadone, and is opioid-naïve
- Doesn't want a short-acting opioid because she works in an office and is afraid of "peak" effect
- PCP asks for dosing recommendation

What do YOU think?

- 54 years old, ambulatory, opioid-naïve
- Starting dose of methadone?
  - A. 1 mg by mouth every 12 hours
  - B. 2.5 mg by mouth every 12 hours
  - C. 2.5 mg by mouth every 8 hours
  - D. 5 mg by mouth every 12 hours
  - E. 5 mg by mouth every 8 hours

Case 1

- No interacting medications, and she is younger (54 years old)
- Possible recommendations:
  - 2.5 mg by mouth q12h (half of a 5 mg tablet)
  - 2.5 mg by mouth q8h (possibly switch to q12h dosing later)
- Rescue opioid?
  - If appropriate, morphine or oxycodone 5 mg by mouth every 4 or 6 hours as needed for additional pain

Case 2

- FA is an 89 year old man admitted to hospice with a diagnosis of protein-calorie malnutrition, complaining of generalized aches and pains
- Patient is ambulatory and frail
- Has a history of bleeding ulcer, PCP does not want to prescribe a NSAID; did not respond to acetaminophen
- PCP would like you to recommend a methadone dose
- No interacting medications

Case 2

- No interacting medications, but he is elderly and frail
- Possible recommendations:
  - 1 mg by mouth qam or qhs
  - 1 mg by mouth q12h
  - 2.5 mg by mouth qam or qhs
- Rescue opioid?
  - Morphine or oxycodone 2.5 to 5 mg by mouth every 2, 3 or 4 hours as needed for additional pain

Initiating Methadone (Chou, APS)

- Start at low dose
  - In opioid-naïve patients, or converting from low doses of other opioids (eg, <40-60 mg OME/day) – do not exceed methadone 2.5 mg by mouth every 8 hours
    - Dose increases no more than 5 mg/day every 5-7 days
  - Converting from higher doses of other opioids, start methadone at 75%-90% less than calculated equianalgesic dose
    - Do not exceed methadone 30-40 mg by mouth qd
    - Dose increases no more than 10 mg/day every 5-7 days

OME – oral morphine equivalent

Initiating Methadone (HPM)

- In opioid-naïve patients, or ≥40-60 mg OME/day – do not exceed methadone 2-7.5 mg by mouth per day in 2-3 divided doses
  - 1 mg by mouth q12h (oral solution)
  - 2 mg by mouth q12h (oral solution)
  - 2.5 mg by mouth q12h (tablet or oral solution)
  - 2.5 mg by mouth q8h (tablet or oral solution)
- Reduce calculated dose by 25%-33% if enzyme inhibiting medication on board
- Dose increase no more than 5 mg/day every 5-7 days

OME – oral morphine equivalent

JOURNAL OF PALLIATIVE MEDICINE
Volume 16, Number 6, 2013

DOI: 10.1089/jpm.2012.0612

The Use of Very-Low-Dose Methadone for Palliative Pain Control and the Prevention of Opioid Hyperalgesia

Shelley R. Salpeter, MD, FACP,[1] Jacob S. Buckley,[2] and Eduardo Bruera, MD[3]

- Reviewed EMR of patients admitted to hospice from 7-1-11 to 4-1-12, with data collected until hospice DC or until 4-30-12
- Morphine 5 mg q4h prn prescribed (OME)
  - Once ≥2 doses needed daily, methadone initiated at 2.5 mg by mouth once daily, and titrated up by 2.5 mg per day, every 4-7 days, to a MDD of 15 mg qd
  - Patients on another LA opioid converted to methadone 2.5-15 mg by mouth qd
  - Haloperidol used adjunctively

Results

- All patients received SA opioids (morphine 5 mg dose)
- 40% of patients received methadone 5 mg by mouth qd median dose
  - Half of those also received haloperidol
- Median pain score = 0; mean peak <3
- Low dose methadone with adjuvants resulted in excellent pain control without dosage escalation or opioid-induced hyperalgesia in both cancer and noncancer patients

Self-Assessment!

- When starting a patient on methadone (both opioid-naïve and opioid-tolerant patients), after you determine the optimal dose, what adjustment should be made (if any) if the patient is receiving an enzyme inhibiting medication?
  - A. No adjustment to methadone dose needed
  - B. Reduce the calculated methadone dose by 25%-33%
  - C. Reduce the calculated methadone dose by 75%
  - D. Increase the calculated methadone dose by 50%

Self-Assessment!

- When starting a patient on methadone (both opioid-naïve and opioid-tolerant patients), after you determine the optimal dose, what adjustment should be made (if any) if the patient is receiving an enzyme inhibiting medication?
  - A. No adjustment to methadone dose needed
  - B. Reduce the calculated methadone dose by 25%-33%
  - C. Reduce the calculated methadone dose by 75%
  - D. Increase the calculated methadone dose by 50%

What did we do in this module?

1. List and interpret risk stratification strategies prior to starting methadone therapy
2. Describe appropriate candidates for methadone therapy
3. Describe inappropriate candidates for methadone therapy
4. Describe the pharmacodynamic properties of methadone
5. Describe the pharmacokinetic properties of methadone including absorption, distribution, metabolism, and excretion
6. List and explain common drug interactions with methadone
7. Recommend a methadone dose in an opioid-naïve patient

PainWeek

ADVANCED EDUCATION

CERTIFICATION SERIES

Methadone Madness: Part 1

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