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Corporate overview

Innovative products for medically supervised settings

March 2024

Forward-looking statements and non-GAAP financial measures

Forward-Looking Statements

Some of the information in this presentation is not historical in nature and may constitute forward-looking statements, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as “believes,” “expects,” “anticipates,” “may,” “will,” “should,” “seeks,” “approximately,” “intends,” “plans,” “estimates,” or the negative of these words or other comparable terminology. The discussion of financial trends, strategy, plans or intentions may also include forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied by such statements. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described in the Company’s annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the Securities and Exchange Commission (SEC). You are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date such statements were first made. To the degree financial information is included in this presentation, it is in summary form only and must be considered in the context of the full details provided in the Company’s most recent annual, quarterly or current report as filed or furnished with the SEC. The Company’s SEC reports are available at www.acelrx.com under the “Investors” tab. Except to the extent required by law, the Company undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

Non-GAAP Financial Measures

To supplement AcelRx’s financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), the company uses certain non-GAAP financial measures in this presentation, in particular, excluding stock-based compensation expense from its operating expenses. The company believes that this non-GAAP financial measure provides useful supplementary information to, and facilitates additional analysis by, investors and analysts.

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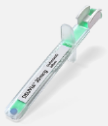
Portfolio overview

Approval

Product	Administration	Phase 1	Phase 2	Phase 3	NDA submitted	Next anticipated milestone
Nafamostat product candidates						
Niyad™	Anticoagulation of the extracorporeal circuit–CRRT/IHD regulated as device					Top-line data read-out expected in Q3 2024 with PMA submission expected in Q4 2024
LTX-608	Various indications regulated as drugs *					
Pre-filled syringe product candidates						
Fedsyra™ 	Ephedrine hydrochloride 10 ml ready to use pre-filled syringe					NDA ready; submission timing being evaluated
PFS-02 	Phenylephrine hydrochloride 10 ml ready to use pre-filled syringe					NDA submission timing being evaluated

DSUVIA® (sufentanil) sublingual tablet 30 mcg (II) 

Divested to Alora Pharmaceuticals, and due **15%** royalties on commercial sales; **75%** royalties on sales to the Department of Defense, and up to **$116.5M** in milestone payments; Transaction closed in April 2023; Partial monetization of royalty/milestone stream in January 2024 with XOMA Royalty

* Post-toxicology study, expect to be in phase 2 development

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Talphera investment highlights

1. Late-stage pipeline assets with near-term commercial potential in medically supervised settings
2. Lead asset Niyad has FDA Breakthrough Designation with potential peak sales of $200M
3. Single registrational study for Niyad planned to begin enrolling in April 2024; 166 total patient study, top-line data read out expected in Q3 2024 followed by PMA submission in Q4 2024; we believe high probability of success
4. Fedsyra™, ephedrine pre-filled syringe, NDA-ready, submission timing being evaluated
5. Recent financings completed in Q1 2024 are expected to provide sufficient cash to a potential Niyad approval in H1 2025

Nafamostat portfolio

Niyad™ and LTX-608

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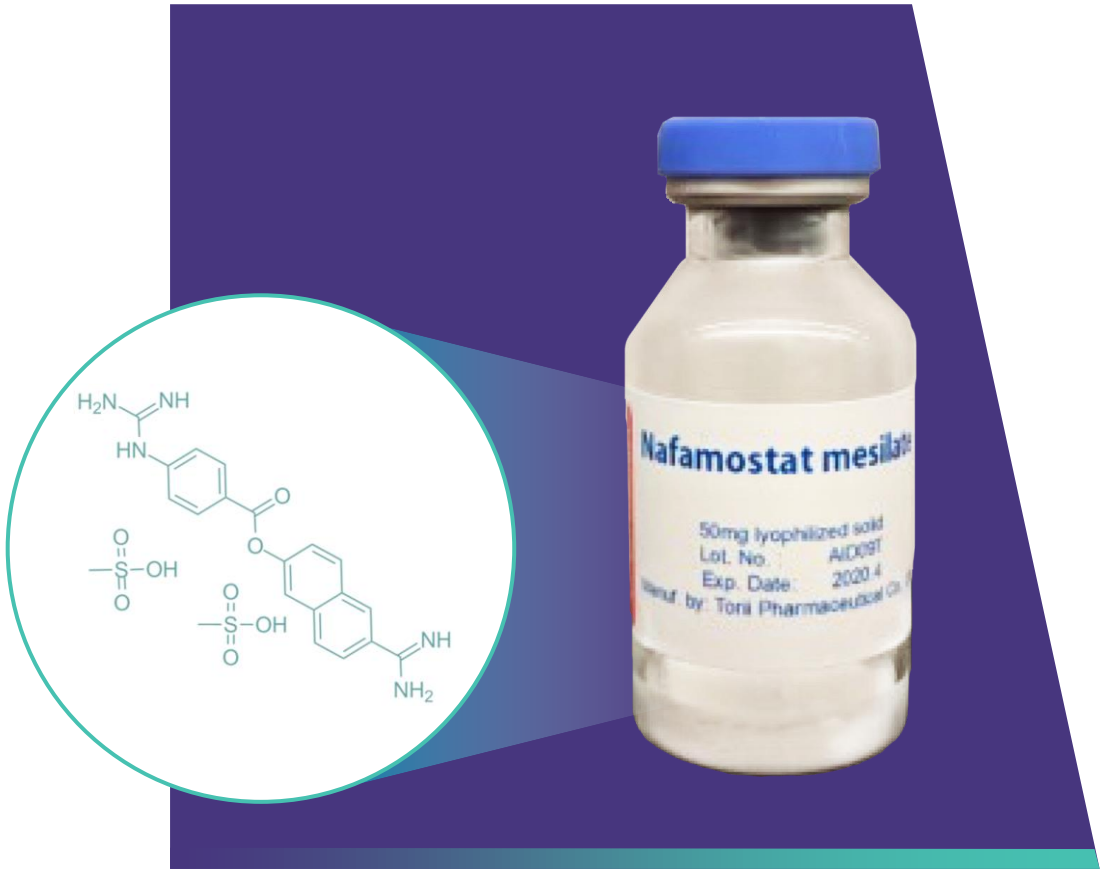
What is nafamostat?

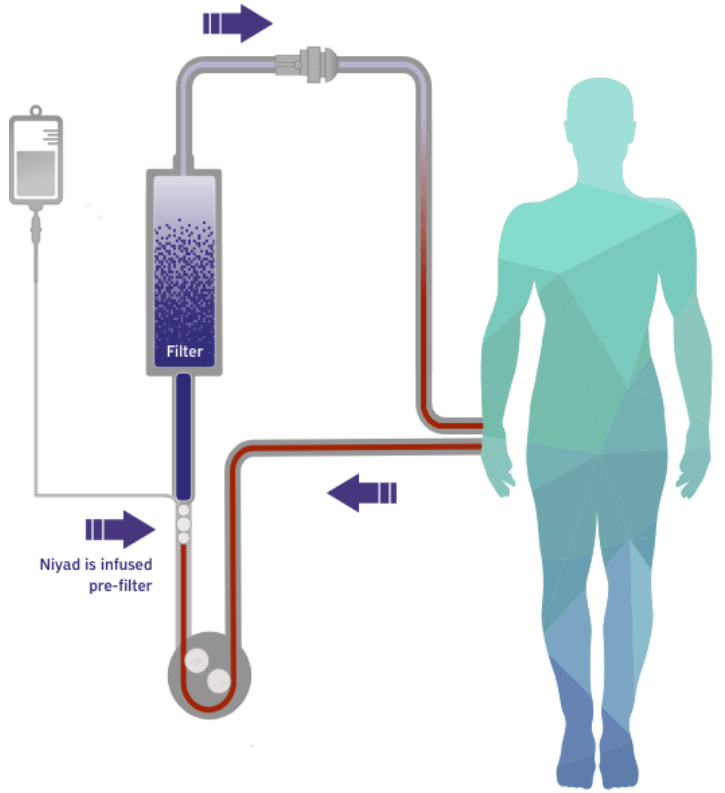
- An investigational broad-spectrum serine protease inhibitor with anticoagulant, anti-inflammatory, mucus clearing and potential anti-viral activities
- Half-life of 8 minutes
- Multiple potential indications given its proposed mechanism of action
- Approved and used in Japan and South Korea for over 30 years
  - Anticoagulation of the extracorporeal circuit
  - Disseminated intravascular coagulation (DIC)
  - Acute pancreatitis
- Various studies performed outside the U.S. for COVID, Acute Respiratory Distress Syndrome (ARDS), Dengue fever and numerous other diseases



Niyad™ is our lead nafamostat product candidate

Talphera is evaluating nafamostat as an anticoagulant for the extracorporeal circuit (blood path outside patient)

- ✓ Niyad has numerous potential **benefits** compared to the standard of care
- ✓ There are **no FDA-approved** regional anti-coagulants for the extracorporeal circuit
- ✓ Niyad is being regulated as a device (works in the circuit)
  - Granted **FDA Breakthrough Device Designation** status for use as a regional anticoagulant in patients receiving CRRT that cannot tolerate heparin or are at a higher risk of bleeding, providing regulatory and developmental benefits
- ✓ Approval for a **single registrational study** planned to start in April 2024 with endpoints agreed with the FDA
- ✓ ICD-10 CMS procedural code already received to support **reimbursement**
- ✓ Niyad peak sales estimated at more than **$200 million**



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Exposure of blood to the dialysis filter causes clotting

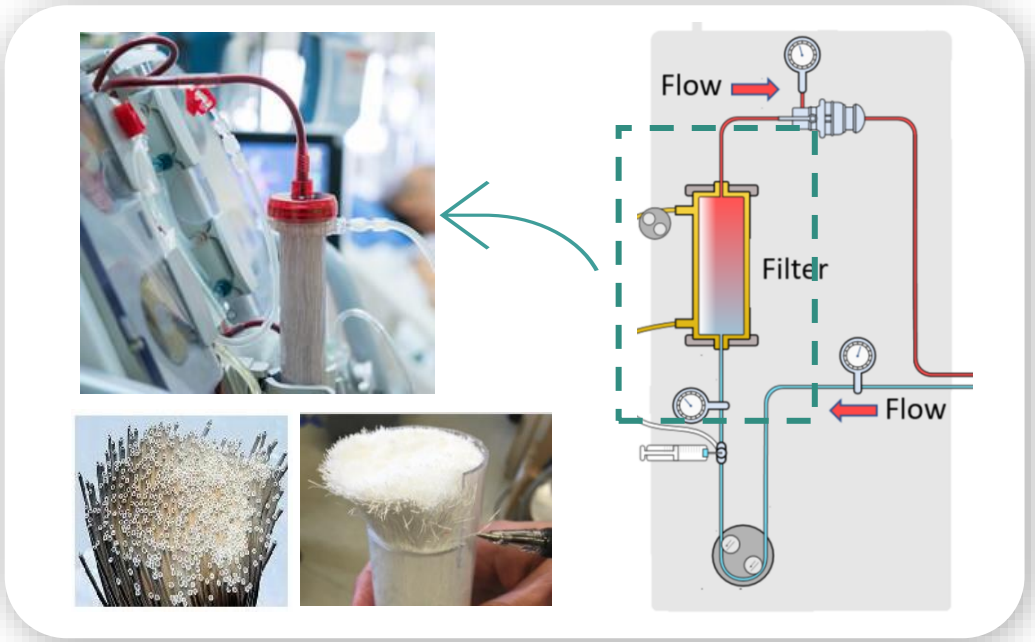
Clotting of the dialysis filter during CRRT is a major limitation to care, as it leads to inefficient dialysis, causes blood loss, and depletes limited resources[1]. Circuit clotting is the most frequent cause of therapy interruption circuit dialysis[2]

More frequent filter changes required to ensure efficacy

Increased blood loss; increased platelet transfusions

Delayed/ prolonged treatment time

Burden on healthcare professional



1. Uchino S, Fealy N, Baldwin I, Morimatsu H, Bellomo R. Continuous is not continuous: the incidence and impact of circuit “down-time” on uraemic control during continuous veno-venous haemofiltration. Intensive Care Med. 2003;29:575–578. Zhang Z, Ni H, Lu B. Variables associated with circuit life span in critically ill patients undergoing continuous renal replacement therapy: a prospective observational study. ASAIO J. 2012;58:46–50
2. 2. Clinical review: Patency of the circuit in continuous renal replacement therapy.Joannidis M, Oudemans-van Straaten HMCrit Care. 2007; 11(4):218.

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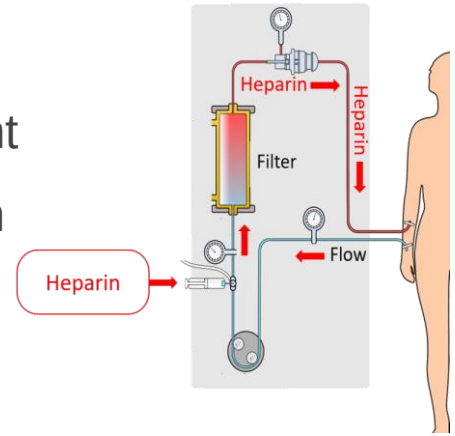
Current standards for anticoagulation have many disadvantages

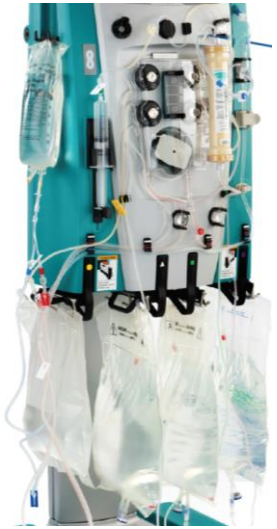
Heparin

- Systemic anticoagulant
- Prolonged half-life up to 3 hours makes it difficult to titrate
- Clinicians fear over anticoagulating the patient
- Significant safety concern for patients at risk of bleeding
- Thrombocytopenia



Citrate

- Citrate chelates calcium, which inhibits the generation of thrombin
- Using citrate requires infusing calcium on the return side of filter (back to patient)
- Extensive, complicated protocol
- Frequent blood draws to measure calcium are time-consuming and expensive
- Rapid changes in calcium levels which can cause hypotension, ventricular fibrillation, and possibly cardiac arrest.
- Even more complicated in patients with liver failure



1) Ohtake Y. Nafamostat as Anticoagulant in Continuous HD. Contrib Nephrol. 1991;93;215-217.

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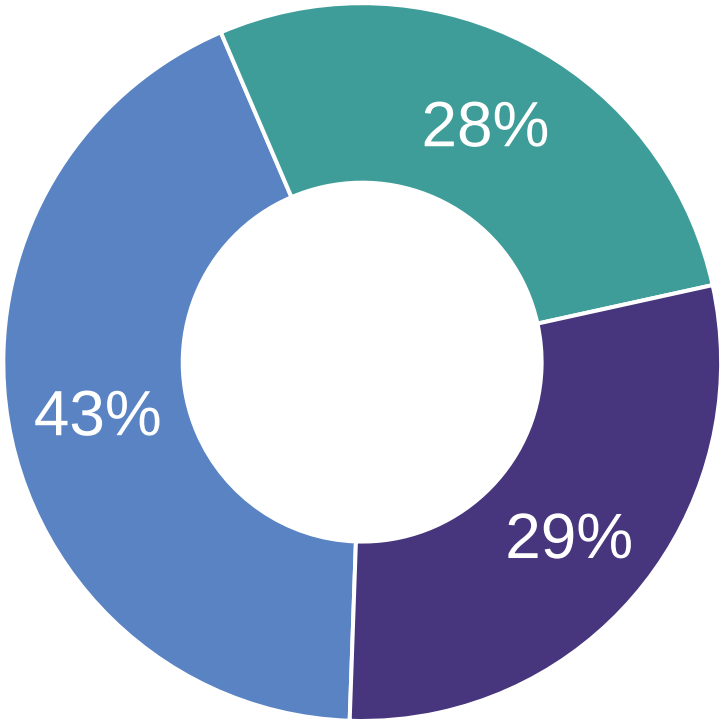
The current market landscape for anticoagulants used during continuous renal replacement therapy (CRRT)

Anticoagulants used in CRRT

Heparin – 43%
(systemic anticoagulant – anticoagulation of the patient and the circuit)



Citrate – 28%
(regional anticoagulant – anticoagulant for circuit only; used in U.S. under an Emergency Use Authorization)

No anticoagulant
29% is unfortunately the default when physicians are concerned with safety of heparin or citrate

Source: Boldt, et al. Anticoagulation practices for continuous renal replacement therapy: a survey of physicians from the United States, Renal Failure, 2023; https://doi.org/10.1080/0886022X.2023.2290932

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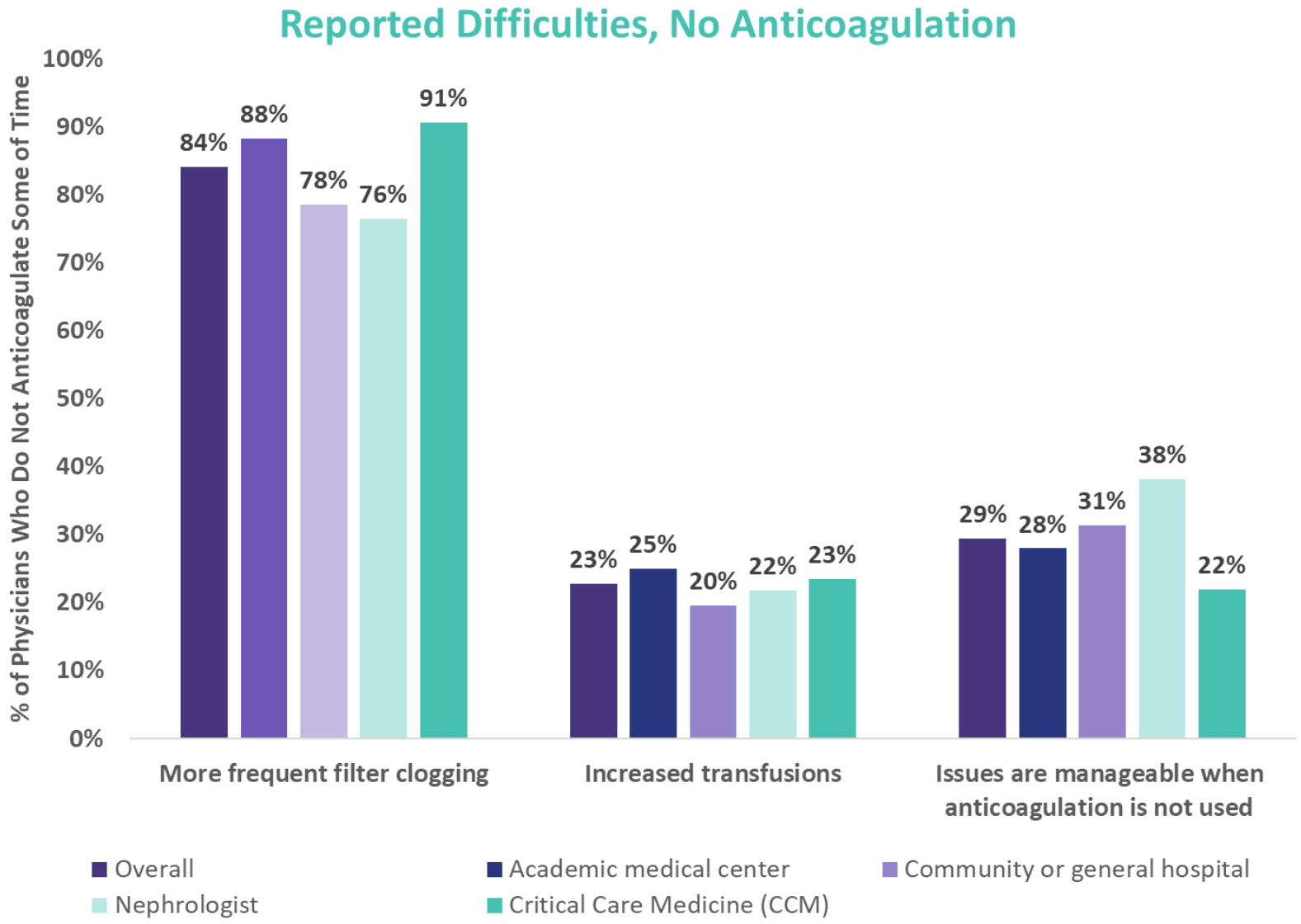
When not using an anticoagulant for CRRT, frequent filter clogging was the most common issue, with 20-25% stating increased transfusions were needed



Source: Boldt, et al. Anticoagulation practices for continuous renal replacement therapy: a survey of physicians from the United States, Renal Failure, 2023;https://doi.org/10.1080/0886022X.2023.2290932

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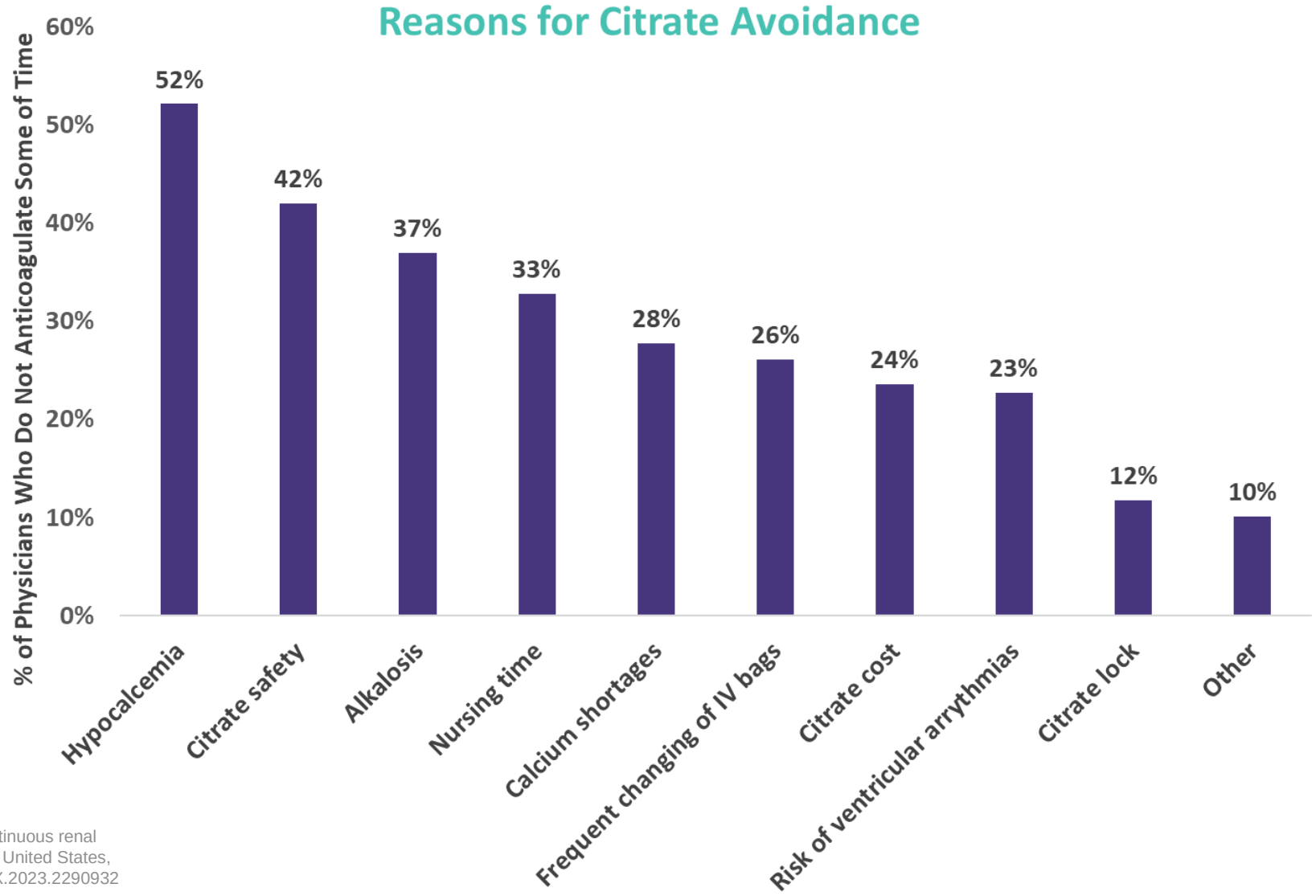
Market research indicated a number of reasons why physicians decide not to use citrate as an anticoagulant during CRRT despite it being given an EUA



Source: Boldt, et al. Anticoagulation practices for continuous renal replacement therapy: a survey of physicians from the United States, Renal Failure, 2023;https://doi.org/10.1080/0886022X.2023.2290932

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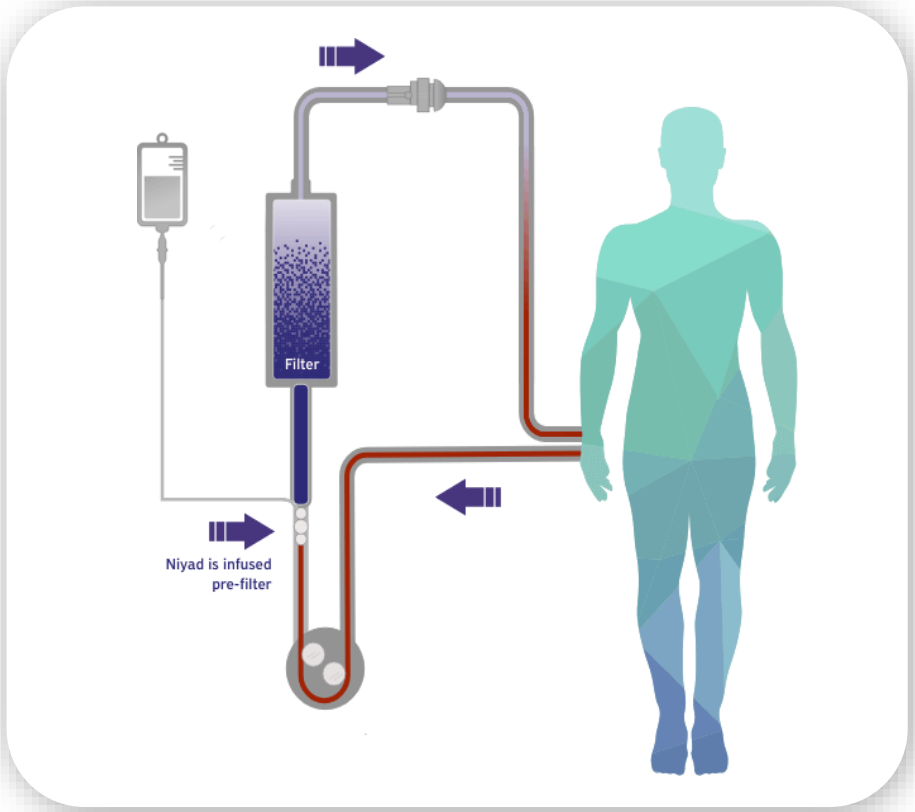
Potential benefits of using Niyad in the dialysis circuit

- Standardized international guidelines recommend using an anticoagulant during renal replacement therapy (RRT)
- Niyad is designed to provide a short half-life, titratable, regional anticoagulation without the shortcomings of heparin or citrate
- Potential advantages of Niyad:
  - Niyad designed to be used in patients at risk of bleeding, whereas heparin is limited
  - Niyad designed to be used easily in patients with liver failure – whereas citrate is limited
- Compared to no anticoagulation: potential for fewer filter changes, fewer transfusions, more importantly – lower cost of doctor and nursing time



	Heparin	Nafamostat
Incidence of Bleeding[1]	**66.7 %**	**4.3 %**

1) Ohtake Y. Nafamostat as Anticoagulant in Continuous HD. Contrib Nephrol. 1991;93;215-217.

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Decades of use outside the U.S. and numerous studies support the benefits of nafamostat as an anticoagulant for the extracorporeal circuit

An independent, meta-analysis published in 2022 on the use of nafamostat as an anticoagulant in the extracorporeal circuit demonstrates the efficacy and safety compared to conventional therapy

11 Studies

2,723 Patients

Mortality

25% lower with nafamostat vs. conventional therapy (31% lower vs. no-anticoagulant)

Bleeding Risk

45% higher risk of bleeding complications on conventional therapy vs. nafamostat

Filter life

10.5 hours longer filter life compared to no-anticoagulant

Source: Yao Lin, et al; RENAL FAILURE, 2022, VOL. 44, NO. 1, 1263–1279, https://doi.org/10.1080/0886022X.2022.2105233

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FDA feedback on emergency use authorization (EUA) for Niyad

Although an EUA for Niyad was not considered an FDA priority due to lack of FDA resources, correspondence with FDA provided us with encouraging feedback

FDA opined on 8/24/21:

"We believe that your device has the potential to address an unmet need in patients who cannot tolerate heparin or….who are treated in facilities that are ill-equipped for use of a citrate anticoagulant."

"Additionally, we recognize that there may be an unmet need for patients…who also cannot tolerate citrate due to another condition such as liver disease."

"We believe that you have provided significant evidence demonstrating that the potential benefits of the Niyad device could be greater than the reasonably foreseen risks."

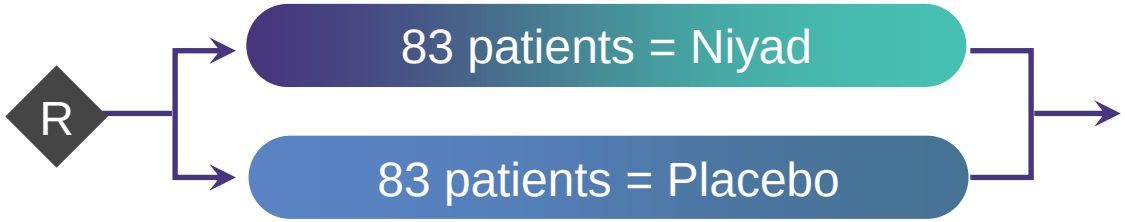
Single registrational study on Niyad

Prospective, randomized, placebo-controlled study at up to 10 clinical sites

Randomization

166 adult patients undergoing RRT who cannot tolerate heparin or are at risk for bleeding

Dosing period (7 days)



Safety:

Bleeding, electrolyte disorders, 28-day all-cause mortality

Primary Endpoints:

- Mean post-filter activated clotting time (ACT) over first 24 hours versus placebo

Key Secondary Endpoints:

- Mean post-filter ACT over 72 hours
- Filter lifespan
- Number of filter changes over 72 hours
- Number of transfusions over 72 hours
- Dialysis efficacy (based on urea concentration) over first 24 hours

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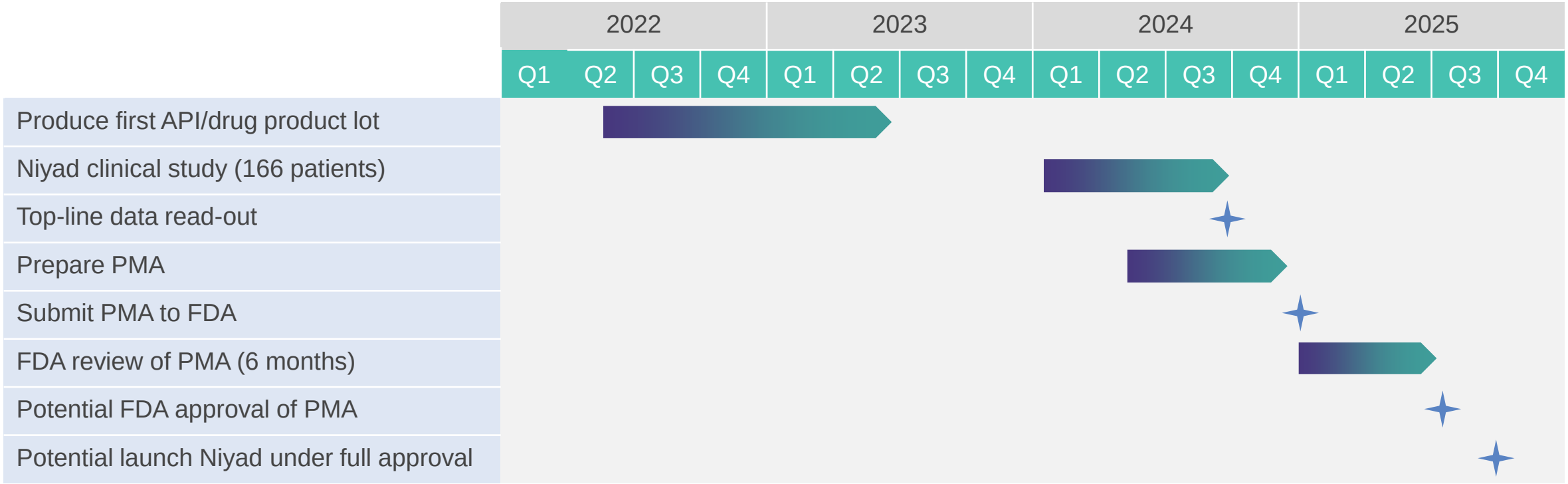
Anticipated timeline to PMA approval for Niyad™

FDA review of IDE is complete with approval for a single study of 166 patients with primary and secondary endpoints established



* Pending successful completion of IDE study

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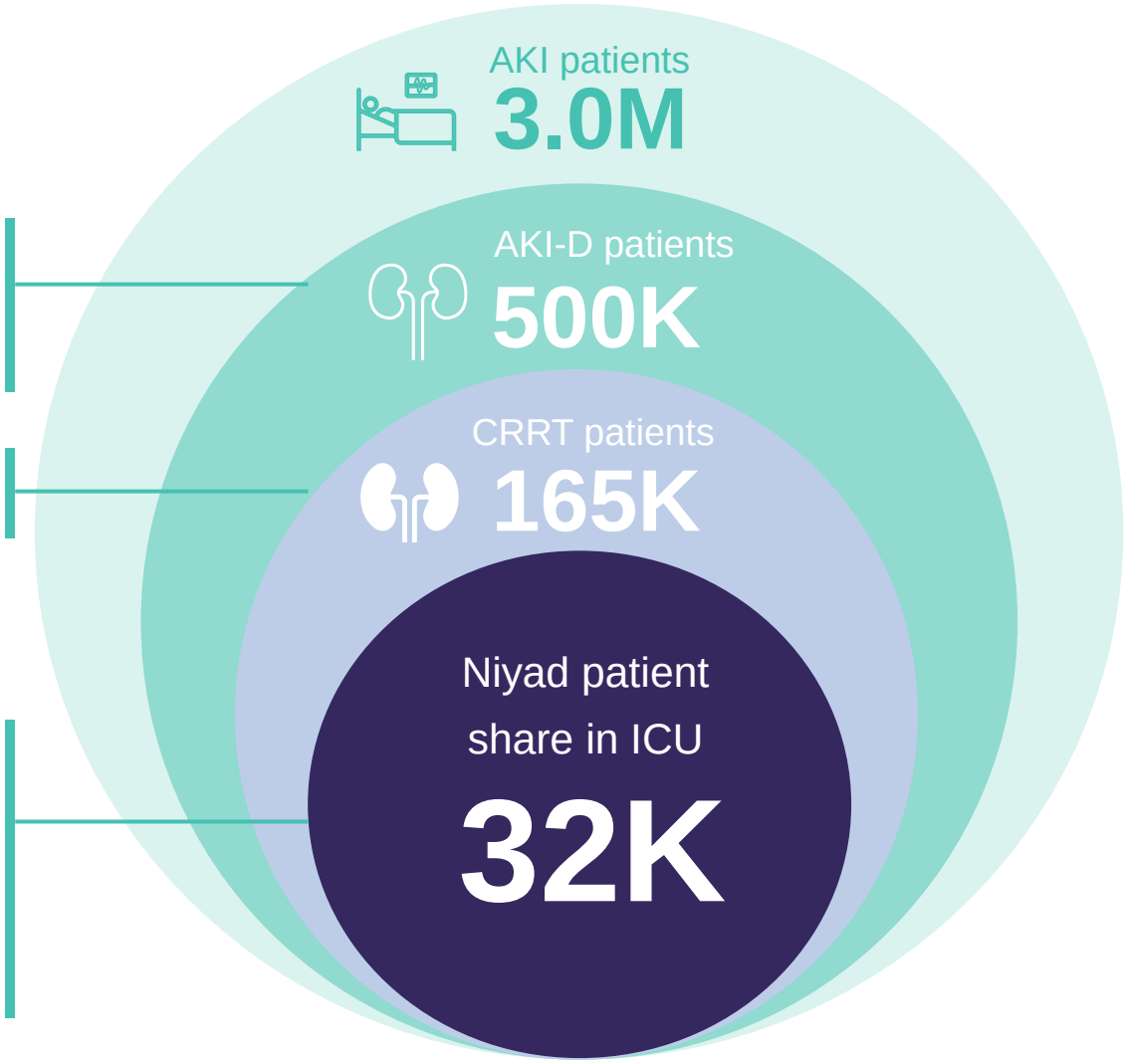
Niyad™ market opportunity in CRRT

If approved, Niyad would be the only FDA approved regional anticoagulant for the extracorporeal circuit



Some patients receive intermittent hemodialysis (IHD) and others continuous (CRRT)

5-7 days average CRRT; then possible transition to IHD

Estimated 19.5% share taken from (a) no anticoagulant used because of safety with current products; (b) some from heparin and (c) some from citrate.

Total patient numbers excludes other in-hospital anticoagulation of extracorporeal circuits (ECMO, CRRT outside of ICU)

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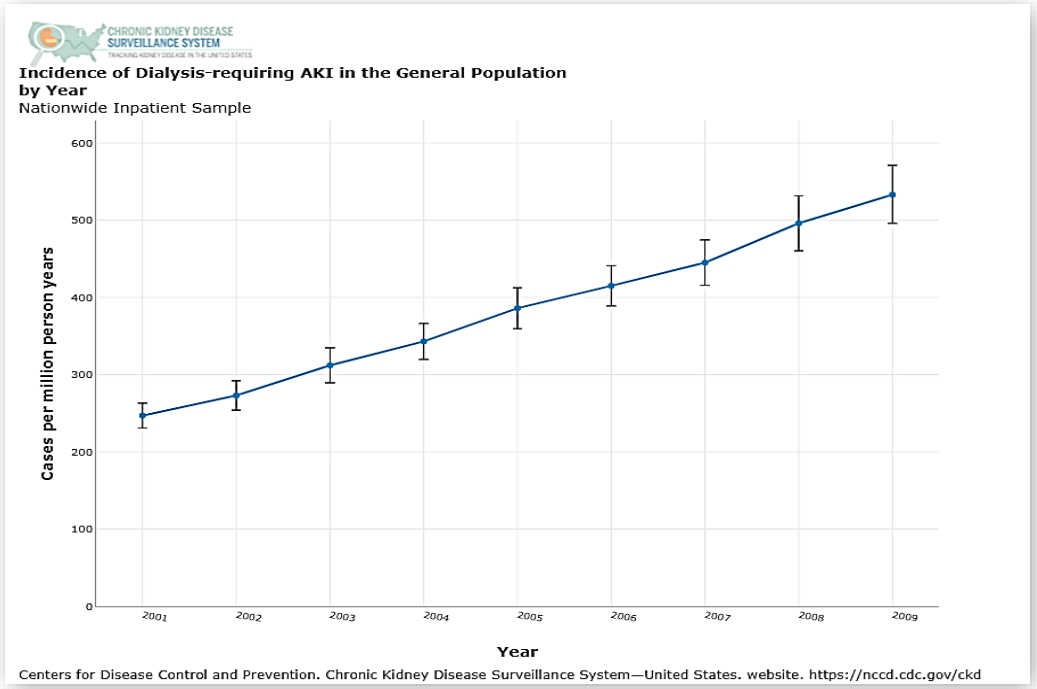
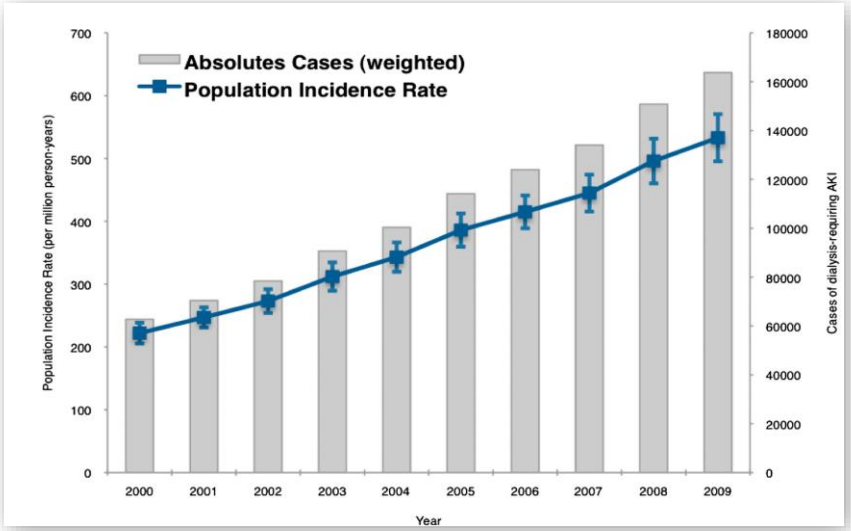
Acute kidney injury rates are rapidly increasing

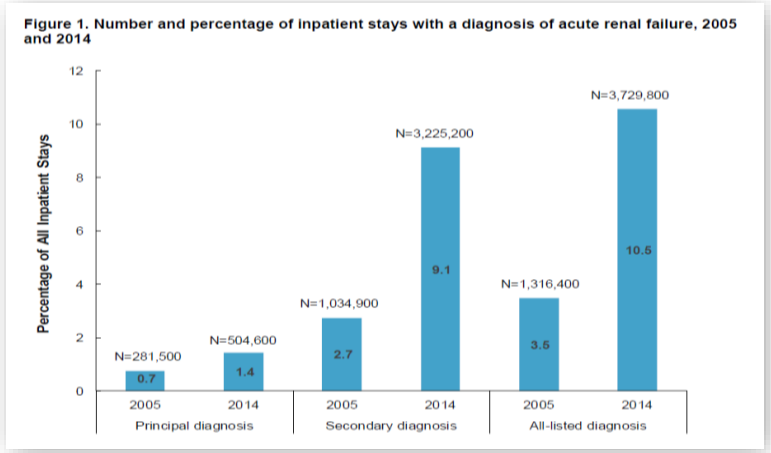




Hsu RK, McCulloch CE, Dudley RA, Lo LJ, Hsu CY. Temporal changes in incidence of dialysis-requiring AKI. J Am Soc Nephrol. 2013;24(1):37-42.

Acute kidney injury (AKI) is defined by a rapid increase in serum creatinine, decrease in urine output, or both. AKI occurs in approximately 10-15% of patients admitted to hospital, while its incidence in intensive care has been reported in more than 50% of patients.[1]

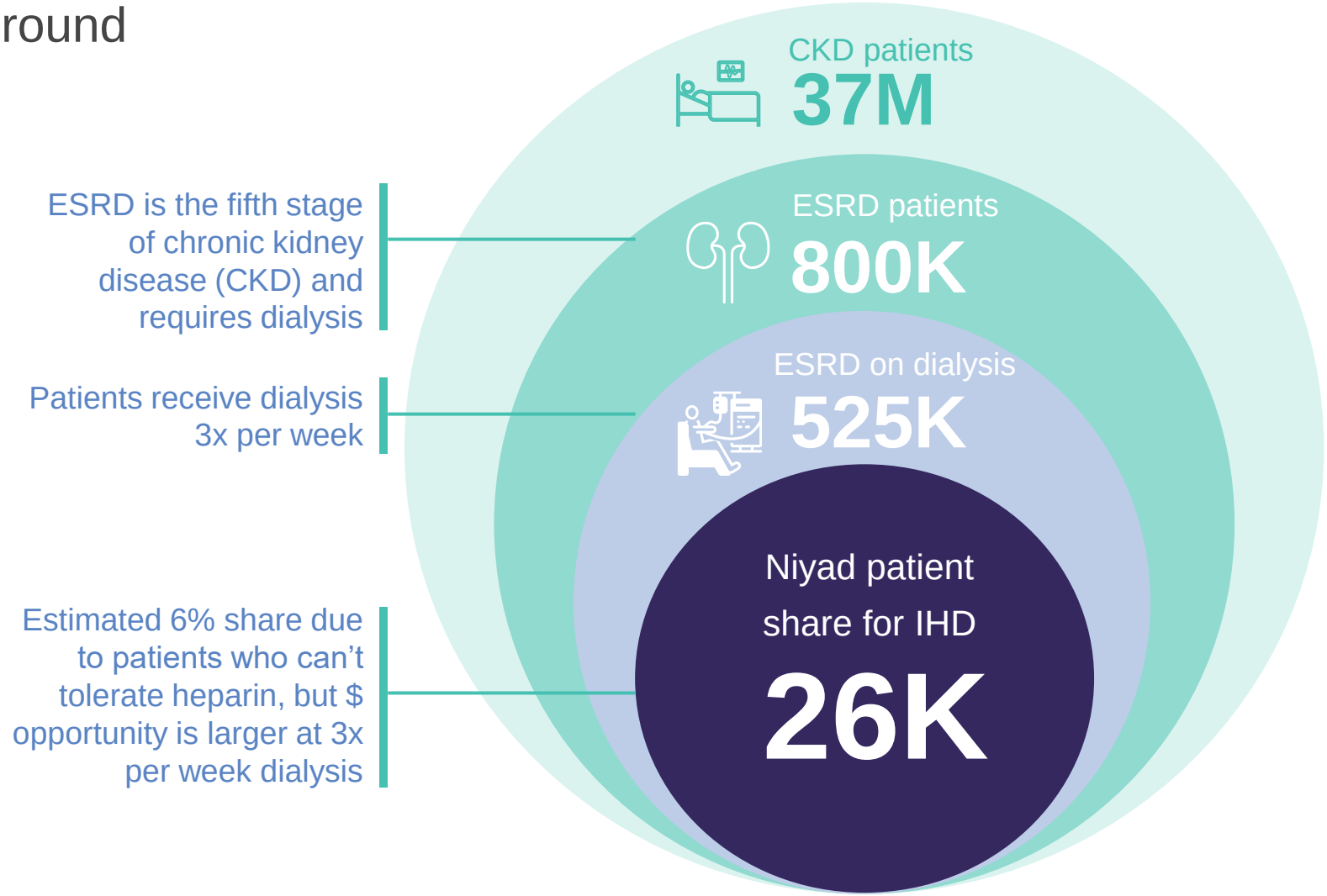
Note: Diagnoses were identified using the Clinical Classifications Software (CCS). Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National (Nationwide) Inpatient Sample (NIS), 2005â€“2014



1. Acute kidney injury. Lancet. 2019; 394(10212):1949-1964 (ISSN: 1474-547X), Ronco C; Bellomo R; Kellum JA

Niyad™ market opportunity in IHD

Intermittent hemodialysis is shorter in duration than CRRT, however, frequency of the procedure is 3x per week, year-round



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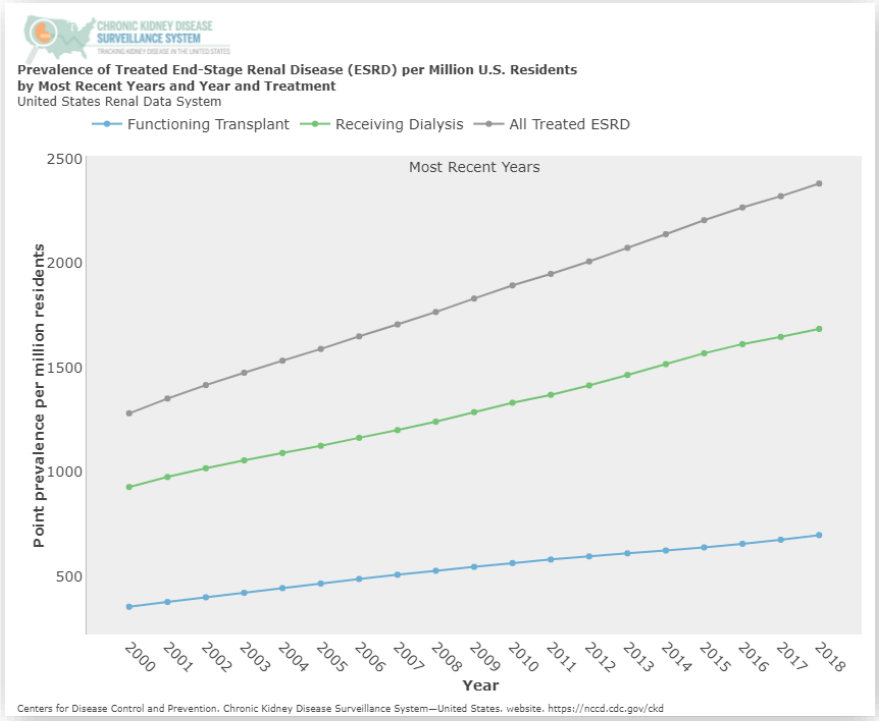
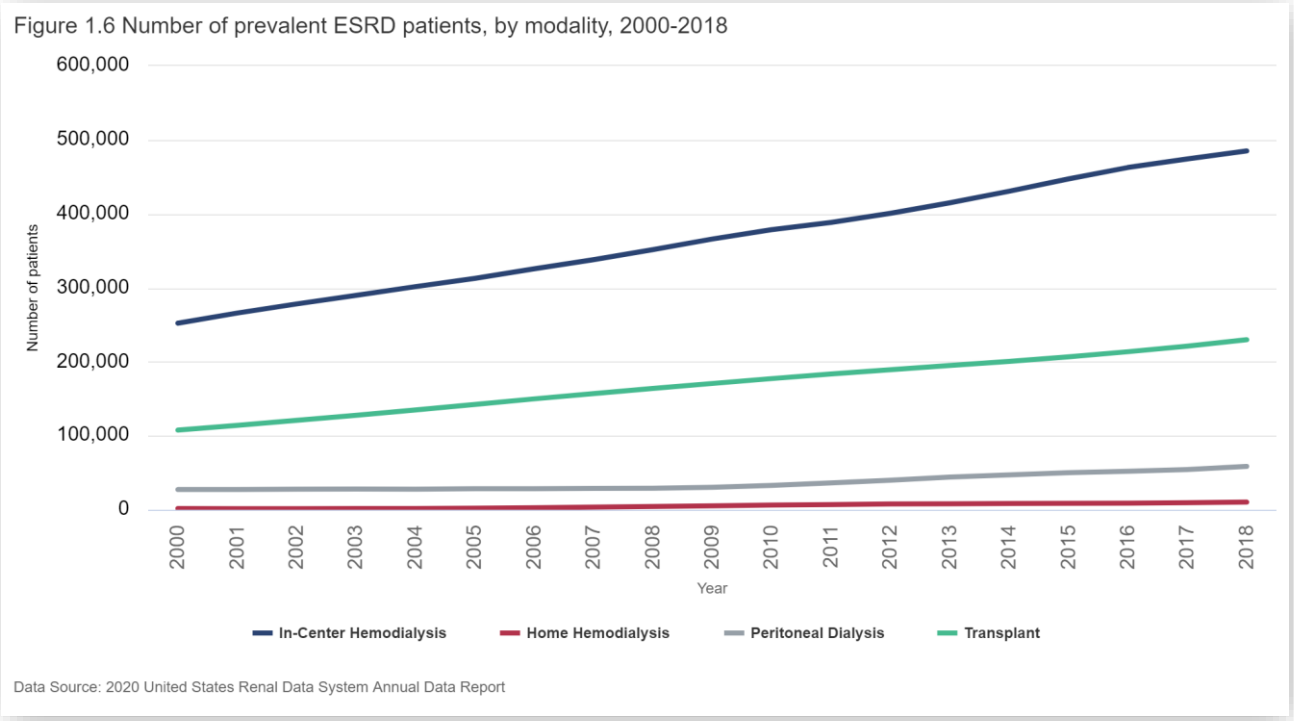
End stage renal disease (ESRD) and outpatient dialysis continues to increase





End stage renal disease (ESRD) is the fifth stage of chronic kidney disease (CKD) and requires dialysis or transplant; The prevalence of ESRD has more than tripled since 1990[1]

1. Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States.website. http://www.cdc.gov/ckd

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LTX-608: the other nafamostat opportunity with broad potential

Nafamostat is a "pipeline in a product" that has potential beyond Niyad

Disseminated intravascular coagulation (DIC)

Approved indication in Japan and South Korea; intellectual property protection will focus on method of use patents based on the complexity of DIC treatment

COVID treatment

Various ex-US studies have demonstrated positive results; publications support development as a potential COVID treatment by inhibiting TMPRSS2; A potent broad-spectrum serine protease inhibitor that blocks host protease activation of the viral spike protein [1]

Acute respiratory distress syndrome (ARDS)

A life-threatening lung injury that allows fluid to leak into lungs; Nafamostat potential modes of action of anticoagulation, anti-inflammation and sustaining endothelial barrier function/preventing vascular leak could support exploring development

Acute pancreatitis

Approved indication in Japan and South Korea

1. B. F. Niemeyer, C. M.Miller, C. Ledesma-Feliciano, J. H. Morrison, R.Jimenez-Valdes,C.Clifton,E.M.Poeschla,K.H.Benam, Nano Select □□□□,

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Nafamostat intellectual property status and data exclusivity

Potential for six years data exclusivity upon Niyad PMA approval before issuance of pending patents

Niyad™ patent pending

Claims drawn to priming of the extracorporeal circuit and blood flow when using nafamostat.

LTX-608 (nafamostat) multiple patents pending

Claims drawn to use of nafamostat in disseminated intravascular coagulation (DIC), as an antiviral agent (e.g., COVID treatment), in acute respiratory distress (ARDS) and other conditions.

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Pre-filled syringe portfolio

Fedsyra™
Ephedrine 10 ml pre-filled syringe

PFS-02
Phenylephrine 10 ml pre-filled syringe

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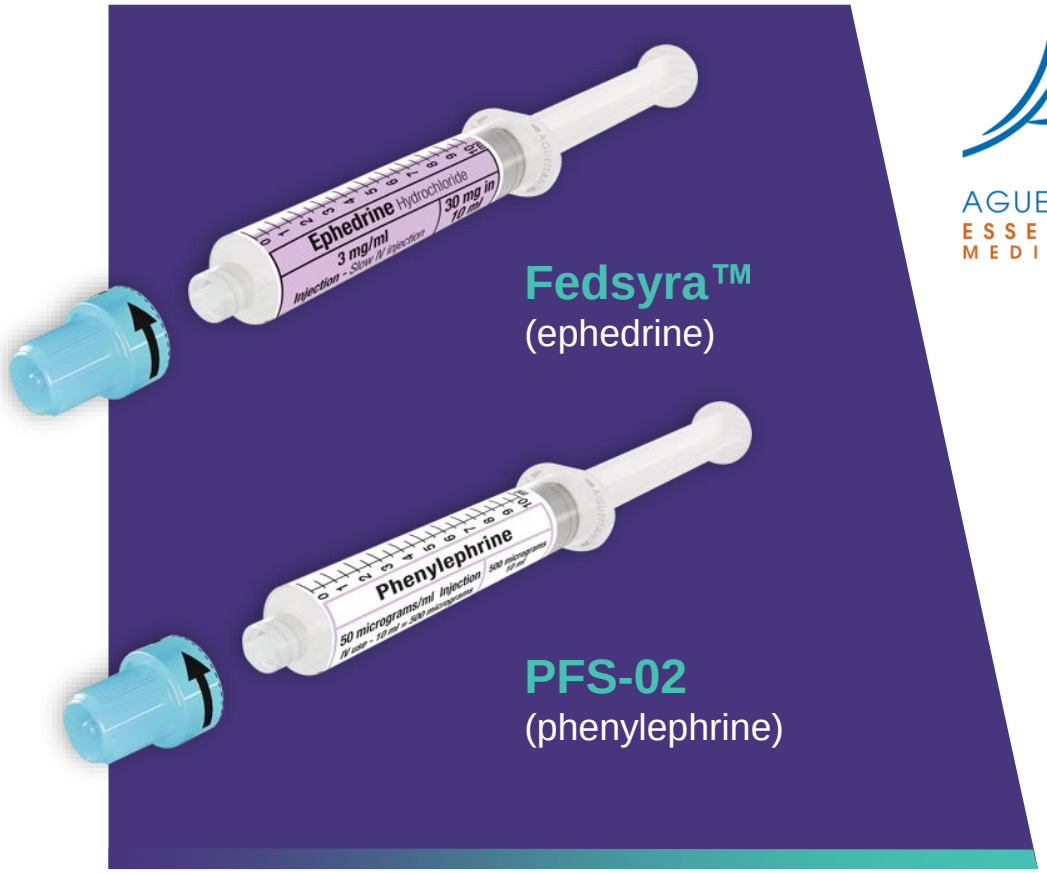
Two complementary pipeline products added in July 2021 through a licensing agreement with France-based pharmaceutical company Laboratoire Aguettant

- Pre-filled, ready-to-use syringes of commonly used products for acute care
- Pre-filled, ready-to-use ephedrine and phenylephrine syringes combined market opportunity is estimated at over $100 million
- Minimal expected cost to get the products through NDA submissions and potential approval
- Fedsyra is NDA ready and we're evaluating submission timing; phenylephrine is expected to be one year behind Fedsyra
- Approved and marketed products in Europe and other regions outside the U.S.



AGUETTANT
ESSENTIAL MEDICINES

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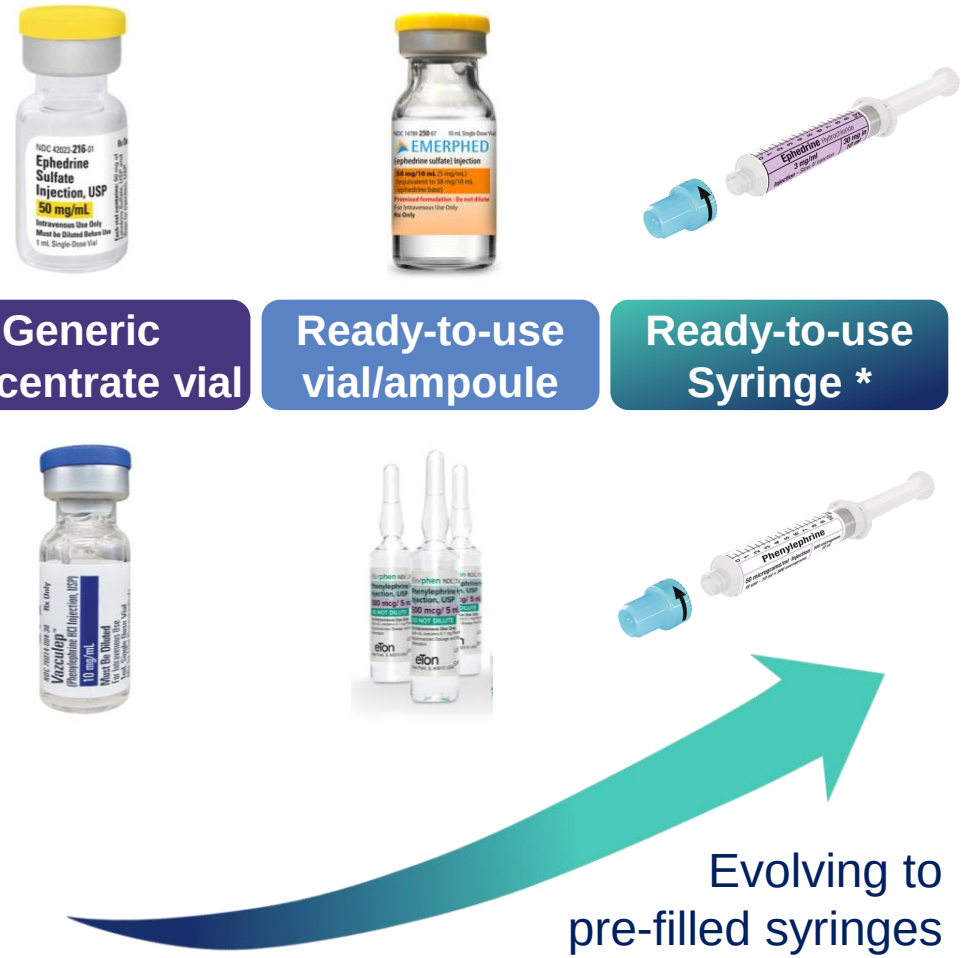
Ephedrine and phenylephrine: commonly used medicines in the perioperative settings for hypotension

Ephedrine is a first-line treatment for hypotension under general anesthesia[1]

Ephedrine is an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia

Phenylephrine is a first line treatment for hypotension for obstetrics and spinal anesthesia[2]

Phenylephrine is an alpha-1 adrenergic receptor agonist for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia



1. Lonjaret et al. Integr Blood Press Control. 2014;7:49-59.
2. Bishop et al. Anesth Analg. 2017;125(3):904-906.

* Not an FDA approved product; Aguettant pre-filled syringe and AcelRx's formulations of ephedrine and phenylephrine are investigational in the U.S.

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Aguettant pre-filled syringes are focused on delivering commonly used medicines safely and efficiently

Pa Patient Saf Advis 2018 Dec;15(4).

Perioperative Medication Errors: Uncovering Risk from Behind the Drapes

Authors

Kayla H. Ciemiak, PharmD, MS, BCPS
Medication Safety Analyst

Michael J. Gaunt, PharmD
Sr. Medication Safety Analyst

Matthew Grissinger, RPh, FISMP, FASCP
Manager, Medication Safety Analysis

Pennsylvania Patient Safety Authority

Corresponding Author
Matthew Grissinger

Abstract

Medication use in the perioperative setting presents u
settings. For example, perioperative medication prescr
checks, such as electronic physician order entry with d
administration, and multiple nursing checks at the time
events associated with the perioperative settings (e.g.,
identified by analysts in event reports to the Pennsylva
2017. More than half (54.6%, n = 621) of reported even
of events were attributed to a breakdown in the comm
procedures. Other common contributing factors involv
improper handling of medications leading to mix-ups a
Organizations may use this data to inform proactive ef
prevent similar errors from occurring.

Introduction

Although medication errors are preventable, they occu
$600,000 to upwards of $5.6 million per hospital each
constraints and high-stress surgical procedure manag
compared with general medical-surgical patient care a

PERIOPERATIVE MEDICINE

Evaluation of Perioperative Medication Errors and Adverse Drug Events

Karen C. Nanji, M.D., M.P.H., Amit Patel, M.D., M.P.H., Sofia Shaikh, B.Sc., Diane L. Seger, R.Ph., David W. Bates, M.D., M.Sc.

ABSTRACT

Background: The purpose of this study is to assess the rates of perioperative medication errors (MEs) and adverse drug events (ADEs) as percentages of medication administrations, to evaluate their root causes, and to formulate targeted solutions to prevent them.

Methods: In this prospective observational study, anesthesia-trained study staff (anesthesiologists/nurse anesthetists) observed randomly selected operations at a 1,046-bed tertiary care academic medical center to identify MEs and ADEs over 8 months. Retrospective chart abstraction was performed to flag events that were missed by observation. All events subsequently underwent review by two independent reviewers. Primary outcomes were the incidence of MEs and ADEs.

Results: A total of 277 operations were observed with 3,671 medication administrations of which 193 (5.3%; 95% CI, 4.5 to 6.0) involved a ME and/or ADE. Of these, 153 (79.3%) were preventable and 40 (20.7%) were nonpreventable. The events included 153 (79.3%) errors and 91 (
51 (55.3%) led to an observed ADE and an
(64.7%) were serious. 51 (55.3%) were signi
Conclusions: One in 20 perioperative medi
MEs led to observed ADEs, and the remaini
those reported by retrospective surveys. Spec
else MEs. (ANESTHESIOLOGY 2016; 124:27

MEDICATION administration in th
setting presents particular patient s
compared with other hospital settings.[1] Unl
tient hospital ward setting, perioperative me
istration today often bypasses standard safe
as electronic physician order entry with d
pharmacy approval of specific drugs bef
tion, and multiple nursing checks at the tim
administration. Furthermore, the high-stres
nature of operating room care may lead to b
of medication errors (MEs) and errors of hig
Perioperative syringe swaps, ampoule ex
dose errors can all cause serious harm.[2] In fa
quently cited critical incidents in anesthesia
istration errors.[3] However, the literature on t
ME rates is sparse and contains largely self-r
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ISMP
Institute for Safe Medication Practices
200 Lakeside Drive, Suite 200 · Horsham, PA 19044-2321
Tel: 215.947.7797 · www.ismp.org · www.consumermedsafety.org

NEWS RELEASE

March 18, 2021

CONTACT
Renee Brehio, ISMP Public and Media Relations
rbrehio@ismp.org • 614-376-0212

ISMP Launches Perioperative Medication Safety Self Assessment

New Tool Will Help Surgery Sites Evaluate, Document Compliance, Compare Scores Horsham, Pa. – Medication errors happen in all phases of perioperative care, often due to the complexity and fast-paced nature of the setting, as well as the multiple handoffs of care. The Institute for Safe Medication Practices (ISMP) has released a new assessment to help hospitals, ambulatory surgical centers, and other surgery settings evaluate their medication safety practices and identify specific challenges and opportunities for improvement.

The **ISMP Medication Safety Self Assessment**® **for Perioperative Settings** also offers providers a way to document compliance with risk assessment and performance improvement requirements from various state and federal regulatory and accrediting agencies. Participating organizations that submit their assessment findings to ISMP anonymously will be able to compare their individual experiences with the aggregate experiences of demographically similar facilities nationwide—**the data submission deadline is August 31, 2021**.

"We urge perioperative service providers to get involved in this unique effort to not only advance their own safety initiatives, but also to benefit the entire healthcare community," says ISMP President Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP. "The assessment will allow ISMP to detail our nation's baseline efforts to prevent patient harm in this setting and develop and share effective prevention strategies."

The self assessment is being conducted under a contract from the U.S. Food and Drug Administration (FDA). ISMP has conducted multiple other medication safety self assessments for specific care settings and focus areas, including for hospitals, community/ambulatory pharmacies, high-alert medications, oncology, and antithrombotic therapy. Several national medication safety initiatives have been created based on data from ISMP's previous self assessments, and other countries have adopted some of the assessment tools to gather information and goals for their own safety efforts.

Facilities can participate anonymously via a secure, password protected website, and will have unlimited opportunity to view and download their own weighted scores during the data collection period. Participants are encouraged to attend a free ISMP webinar on **May 25, 2021,** to learn more about the self assessment and how to obtain the most valuable, accurate, and useful results.

For more information and to register for the free webinar, visit: www.ismp.org/node/18027.

About the Institute for Safe Medication Practices:
The Institute for Safe Medication Practices (ISMP) is the nation's first 501c (3) nonprofit organization devoted entirely to preventing medication errors. ISMP is known and respected for its medication safety information. For more than 25 years, it also has served as a vital force for progress. ISMP's advocacy work alone has resulted in numerous necessary changes in clinical practice, public policy, and drug labeling and packaging. Among its many initiatives, ISMP runs the only national voluntary practitioner medication error reporting program, publishes newsletters with real-time error information read and trusted throughout the global healthcare community, and offers a wide range of unique educational programs, tools, and guidelines. In 2020, ISMP formally affiliated with ECRI to create one of the largest healthcare quality and safety entities in the world, and ECRI and the ISMP PSO is a federally-certified patient safety organization by the U.S. Department of Health and Human Services. As an independent watchdog organization, ISMP receives no advertising revenue and depends entirely on charitable donations, educational grant, newsletter subscriptions, and volunteer efforts to pursue its life-saving work. Visit www.ismp.org and follow @ismp_org to learn more.

A nonprofit organization

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Prefilled Syringes Are the Preferred Choice

Waste reduction, time-savings and increased safety are among the benefits of purchasing preloaded medications.

Sheldon Sones

Publish Date: April 8, 2021 | Tags: Supply Management (/outpatient-surgery/search#sort=date%20descending&f:@osmtopicfacet=[Supply Management])

QUICK DRAW Prefilled syringes allow you to bypass the time-consuming task of drawing up medications and complying with safe labeling practices. | *Pamela Bevelhymer*

TALPHERA

Financial information/metrics

$9.4M
December 31, 2023 cash

$14.0M
Initial combined proceeds from Jan 2024 royalty financing and first closing of equity offering

$23.4M
Proforma cash at December 31, 2023 (1)

$4.6M
Q4 2023 combined R&D and SG&A(2)

$17.5M
FY 2023 combined R&D and SG&A(2)

$21-23M
FY 2024 estimated cash operating expense (excludes stock-based compensation)

(1) December 31, 2023 cash plus $14 million of proceeds received in January royalty financing and first closing of equity offering (excluding $12 million of committed proceeds should the company achieve the Pivotal Milestone and Price Milestone as disclosed in the January 18, 2024 press release)
(2) Cash operating expense: Combined R&D and SG&A including $0.3M and $1.7M of non-cash stock-based compensation in Q4 and FY 2023, respectively

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