Publishing Scientific Manuscripts: A Primer for Pharmacists

OhioHealth Pharmacy Resident Workshop Series

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Learning Objectives (Pharmacists & Pharmacy Technicians)

- Develop a toolkit for getting started with publishing scholarly work
- 2. Apply effective strategies for scholarly productivity
- **3**. Discuss various strategies for responding to peer review
- 4. Navigate the publication process from pre-work through final publication

The resident research graveyard



Why publish?



https://researchforevidence.fhi360.org https://anchor.fm/s/54831478/podcast/play/49807992 https://anchor.fm/s/54831478/podcast/play/51193982/ https://mcdn.podbean.com/mf/web/bhieb6/VerifiedRx-PracticaltipsforPublishing_Final.mp3

What makes a project publishable?

FINER criteria

Is it replicable?

Is it worth replicating?

Who stands to benefit?

https://scientific-publishing.webshop.elsevier.com/research-process/finer-research-framework/

When NOT to Publish

Insufficient methods

- Not aligned with professional standards
- Not replicable
- No control for major confounders
- Untrustworthy data

No/limited novelty

- Inappropriate or unnecessary comparison
- Research question already answered

No/limited external application

Do I need IRB approval to publish?

Research vs quality improvement (QI) IRB processes

Research vs QI: Largely a matter of intention

Research

- Add to literature
- Hypothesis-testing in human subjects
- Prospective IRB approval
- IRB protocol submission

Quality Improvement

- Improve a process
- Applying best practices
- OHSP review if intention to disseminate, not required to conduct internally
- Brief application for QI determination

Do I need IRB approval to publish?

- YES (in some form or another)
- Research vs QI IRB processes
- OHRI is here to help!
 - Full out an <u>IRP</u> and <u>submit a ticket</u>
 - Follow this map
- <u>Bottom line</u>: conducting research and presenting research or QI projects outside the organization requires regulatory review

Regulatory Review Statements

- "This project was approved by the OhioHealth Institutional Review Board ..."
- "This project was reviewed by the OhioHealth Office of Human Subjects Protections as a Quality Improvement Determination ..."

Does it cost money to publish?



Traditional Journals vs. Open Access Journals

Traditional

- Usually no required cost to authors
- Paid by subscription and/or advertising
- May be more trustworthy and universally accepted
- No one likes paywalls
- Journal usually retains copyright

Open Access

- \$500-\$5000 per article
- Paid by authors/depts, sometimes grants
- Perceived as less legitimate by some
- May allow more freedom /creativity
- 个Readers, 个citations?
- Authors may retain rights

Other Publishing Options

Hybrid – traditional journals offer open access option

New/innovative journals, e.g. Cureus

Nontraditional platforms, e.g. blogs, podcasts, newsletters...





NO LIST TO RULE THEM ALL

Assessments of which journals are likely to be predatory or legitimate do not tally, and titles can appear in both categories. There is no way to know which journals were considered for a list but left off, or which were not considered.





https://www.nature.com/articles/d41586-019-03759-y

Does it cost money to publish?

Generally, no
Options that do incur \$:
Open access
Preprints
Color printed figures
Extra journal copies

Can I make money publishing?



Not really

- Authors, peer reviewers, and most editorial board members do not make money throughout the publication process to limit bias
- Suspect predatory journal if payments offered
- Indirect incentives

Publishing Process – Get Started



Establish/refresh professional online presence

Determine authorship early



Classify study/article type and pull reporting guidelines for initial checklist



Pick 2 ideal target journals



Find 2 similar articles in journal to **template**

Your (and Your Work's) Professional Online Presence

ORCID[®] ID <u>https://orcid.org/</u> X/Twitter[®] <u>https://accpjournals.onlinelibrary.wiley.com</u> Google[®] Scholar h-Index LinkedIn[®] Altmetrics[®] / PlumX Metrics[®]

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Periop	erative P	ain Management and Opioid Stev	wardship: A Practical Guide		2021		

CLINICAL PHARMACY FORUM

Perioperative clinical pharmacy practice: Responsibilities and scope within the surgical care continuum

Gourang P. Patel Pharm.D., M.Sc.¹ | Sara J. Hyland Pharm.D² | Kara L. Birrer Pharm.D³ | Rachel C. Wolfe Pharm.D⁴ | Jenna K. Lovely Pharm.D⁵ | April N. Smith Pharm.D^{6,7} | Russell L. Dixon Pharm.D⁸ | Eric G. Johnson Pharm.D^{9,10} | Marian L. Gaviola Pharm.D¹¹ | Amanda Giancarelli Pharm.D³ | William R. Vincent III Pharm.D¹² | Carole Richardson Pharm.D¹³ | Richard H. Parrish II Ph.D., FCCP¹⁴ |



4 Monchel

Since 2016

EDIT

ICMJE Authorship Criteria

Substantial contributions to conception or design of the work; or the acquisition, analysis, or interpretation of data

<u>AND</u>

Drafting the work or revising it critically for important **intellectual content**

<u>AND</u>

Final approval of the version to be published

<u>AND</u>

Agreement to be accountable for all aspects of the work

http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-roleof-authors-and-contributors.html

CRediT Taxonomy for Author Roles

Conceptualization Resources Data curation Software **Formal Analysis Supervision Funding acquisition** Validation Investigation Visualization Methodology Writing – original draft **Project administration** Writing – review & editing

Authors vs. Acknowledgements

"The authors gratefully acknowledge the contributions of..."

Authors vs. Acknowledgements

Who are <u>authors</u> and who are <u>acknowledgements</u> on your publication?

Name	Criterion 1	Criterion 2	Crit. 3	Crit. 4	Author or Acknow.?
SJ	Conceptualization, data curation, investigation, Validation	Visualization, Writing – original draft	Yes	Yes	Author
JD	Data curation, formal analysis	Writing – original draft	Yes	Yes	Author
CY	Conceptualization, supervision	Writing – review and editing	Yes	Yes	Author

Reporting and Style Guidelines

Equator Network

Enhancing the QUAlity and Transparency Of health Research

https://www.equator-network.org/reportingguidelines/

https://www.nlm.nih.gov/services/research_re port_guide.html



Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	<u>SPIRIT</u>	PRISMA-P
<u>Diagnostic/prognostic</u> <u>studies</u>	<u>STARD</u>	TRIPOD
Case reports	CARE	Extensions
<u>Clinical practice</u> g <u>uidelines</u>	AGREE	<u>RIGHT</u>
Qualitative research	<u>SRQR</u>	<u>COREQ</u>
<u>Animal pre-clinical</u> <u>studies</u>	ARRIVE	
<u>Quality improvement</u> <u>studies</u>	<u>SQUIRE</u>	
Economic evaluations	CHEERS	

Reporting and Style Guidelines

Which <u>reporting</u> <u>guidelines</u> will you adhere to? Download/save them now!

https://www.equatornetwork.org/reporting-guidelines/

https://www.nlm.nih.gov/services/research_ report_guide.html



Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	<u>SPIRIT</u>	PRISMA-P
Diagnostic/prognostic	STARD	TRIPOD
studies		
Case reports	CARE	Extensions
Clinical practice	AGREE	<u>RIGHT</u>
<u>guidelines</u>		
<u>Qualitative research</u>	<u>SRQR</u>	<u>COREQ</u>
Animal pre-clinical	ARRIVE	
studies		
Quality improvement	<u>SQUIRE</u>	
studies		
Economic evaluations	CHEERS	

Publishing Process -Get Started

Establish/refresh professional online presence

Determine authorship early



Classify study/article type and pull reporting guidelines for initial checklist



Pick 2 ideal target journals



Find 2 similar articles in journal to **template**

Journal Selection

- "MUSTs?" = peer-reviewed and indexed
- Impact Factor
 - <u>https://www.scimagojr.com/journalrank.php</u>
 - Probably unimportant to you at this point
- Key Driver = target audience
- Ultimate Drivers = published and findable

JANE Tool for Journal Selection

Journal/Author Name Estimator Insert title/keywords \rightarrow find journals to submit to

http://jane.biosemantics.org/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6300233/



These journals have articles most similar to your input: "orthopedic clinical pharmacist service"

Confidence	Journal	Article Influence 2	Articles
	International journal of clinical pharmacy Medline-indexed	0.4	Show articles
	Journal of the American Pharmacists Association : JAPhA Medline-indexed	0.3	Show articles
	Journal of pharmacy practice Medline-indexed		Show articles
	Am J Health Syst Pharm Medline-indexed PMC	0.5	Show articles
	European journal of hospital pharmacy. Science and practice PMC	0.1	Show articles
	Research in social & administrative pharmacy : RSAP Medline-indexed	0.4	Show articles
	J Oncol Pharm Pract Medline-indexed		Show articles
	The Annals of pharmacotherapy Medline-indexed	0.7	Show articles
	Integrated pharmacy research & practice High-quality open access PMC		Show articles
	Pharmacy (Basel, Switzerland) High-quality open access PMC		Show articles
	BMC health services research High-quality open access Medline-indexed PMC	0.8	Show articles
	Pain practice : the official journal of World Institute of Pain Medline-indexed	0.7	Show articles
	Emergency medicine Australasia : EMA Medline-indexed	0.4	Show articles
	The Senior care pharmacist		Show articles
	Journal of clinical pharmacy and therapeutics Medline-Indexed	0.5	Show articles
	Journal of pain & palliative care pharmacotherapy Medline-indexed		Show articles
	Journal of patient safety Medline-indexed	0.9	Show articles
	Federal practitioner : for the health care professionals of the VA, DoD, and PHS PMC		Show articles
	Einstein (Sao Paulo, Brazil) High-quality open access Medline-indexed PMC		Show articles
	Pharmacotherapy Medline-indexed	0.7	Show articles

http://jane.biosemantics.org/

Finding "Template" Articles

Similar topic

Similar methodology/rigor

Can't find? → Reassess journal selection

Found? → Consider structure, style, length, etc.

Publishing Process – Get Going



Gather and update **references** - Use a reference manager!



Pull journal Instructions for Authors



Setup your **draft** manuscript per **journal requirements**

Q

Visualize the publication **process**



Set timeline, goals

Reference Managers

EndNote[®] Zotero® **Mendeley**[®] PaperPile[®]

\leftrightarrow \rightarrow C \triangle $$ paperpile.com/app		
Paperpile		
• Add Papers •	Search your papers Select V	
ALL PAPERS (1286)		[1–15]
 STARRED (1) FOLDERS NMB (141) LABELS SHARED FOLDERS periop pain/opioid stewarship (36) TRASH (17) 	 Prothrombin Complex Concentrates for Bleeding in the Perioper Setting Ghadimi K, Levy JH, Welsby IJ Anesth Analg, 2016 – Review E Prothrombin complex concentrate in cardiac surgery for the treat of non-surgical bleeding Hayes K, Fernando MC, Young L, Jordan V, Cochrane Heart Group Cochrane Database Syst Rev, 2020 – Journal Article E The outcomes of emergency pharmacist participation during act myocardial infarction Acquisto NM, Hays DP, Fairbanks RJ, Shah MN, Delehanty J, Nobay F, Guido J, Haa J Emerg Med, 2012 – Journal Article E ASHP Guidelines on Emergency Medicine Pharmacist Services Ortmann MJ, Johnson EG, Jarrell DH, Bilhimer M, Hayes BD, Mishler A, Pugliese RS Boberson TA. Slocum G. Smith AP. Yabut K. Zimmerman DE 	 Paperpile citation Thygesen K, Alpert JS, Jaffe AS, Chaitman BR, Bax JJ, Morrow DA, et al. Fourth Universal Definition of Myocardial Infarction (2018). J Am Coll Cardiol. 2018;72: 2231–2264. doi:10.1016/j.jacc.2018.08.1038 Meyers EP, Weingart MDS, Smith FS. The OMI Manifesto. [cited 22 Feb 2021]. Available: https://www.albanycritcare.net/s/The-OMI-Manifesto-PDF-32918.pdf Ibanez B, James S, Agewall S, Antunes MJ, Bucciarelli-Ducci C, Bueno H, et al. 2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: The Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC). Eur Heart J. 2018;39: 119–177. doi:10.1093/eurhearti/ehx393 O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;127: e362–425. doi:10.1161/CIR.0b013e3182742cf6 Levine GN, Bates ER, Blankenship JC, Bailey SR, Bittl JA, Cercek B, et al. 2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for
		 the Management of ST-Elevation Myocardial Infarction. J Am Coll Cardiol. 2016;67: 1235–1250. doi:10.1016/j.jacc.2015.10.005 Levine GN, Bates ER, Bittl JA, Brindis RG, Fihn SD, Fleisher LA, et al. 2016 ACC/AHA Guideline Eccused Lindete on Duration of Dual Antiplatelet Therapy in Patiente With

Coronary Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery, 2012

Setting Up Your Draft

Carefully read journal requirements
 Font type, size, spacing
 Section headers

Leave comments containing journal specs

- Max word counts
- Number of keywords
- Max references
- General guidance for each section

Journal Submission Guidelines Examples

https://accpjournals.onlinelibrary.wiley.com/hub/journal/18759114/forauthors .html

https://academic.oup.com/ajhp/pages/General Instructions

https://journals.lww.com/ccmjournal/Pages/informationforauthors.aspx

Your Turn

Which journal will you target first?
 Locate and save "Information for authors"
 Drop comments in your manuscript draft:

 Max abstract word count
 Max manuscript word count
 Max reference count

Publishing Process – Get Going



Gather and update **references** - Use a reference manager!



Pull journal Instructions for Authors



Setup your **draft** manuscript per **journal requirements**

Q

Visualize the publication **process**



Set timeline, goals
The Publication Process



Like watching grass grow...

Submissions Being Processed for Author Page: 1 of 1 (<u>1 total submissions</u>)			Results			
Action 🗖 🔽	Manuscript Number 🔺	Title 🔺	Initial Date Submitted	Status Date ▲	Current Status 🔺	
View Submission Author Status Correspondence Send E-mail			07/07/2021	01/20/2022	Undergoing peer review	

Tips for Academic Productivity

Critical appraisal of competing priorities

Scheduling tasks

Specifying tasks – "micro-listing"

Choose active collaborators and seek mentorship

Writing efficiency α writing volume

Language services

Done well >>> not done, but perfect

Micro-listing and Scheduling Tasks



To do Tuesday:

-Write Methods section -Prep for Wed meeting -Get gas on the way home



Setup for Success

Tuesday calendar:

Write Methods section – study design, participants and timeline section

1430 for 1 hr



Active Collaborators

Complementary skills or perspectives

Genuine interest

Capacity for commitment

Effective mentors

Tips for Academic Productivity

Critical appraisal of competing priorities

Scheduling tasks

Specifying tasks – "micro-listing"

Choose active collaborators and seek mentorship

Writing efficiency α writing volume

Language services

Done well >>> not done, but perfect

Publishing Process – Get Done



Finalizing Manuscript Draft



Finalizing Manuscript Draft

DO NOT SUBMIT UNTIL ALL HAVE BEEN MET:

- Complete, polished, publication-worthy
- 100% adherent to journal specifications and interests
- NO grammatical/spelling errors, formatting issues, or tracked changes
- Approved by ALL authors

So you think you're ready to submit?

Title page • Author names, credentials, affiliations	Abstract, keywords	Conflict of interest (COI) forms, IRB forms
Author contributions and attestations	 Final (de-identified?) main text file Abstract, main text, tables, figure legends? 	Separate figure files in correct format?
Acknowledgements	Cover letter	Checklist (from EQUATOR and/or journal)

Submission Component Tips

Cover letter – address to editor/team

- Briefly introduce impetus for your work and sell why of interest to journal audience
- IRB approval, attestations
- Keywords use to maximize findability!
 - Use PubMed MESH terms
- Log in to submission portal in advance

Editorial Manager®



Publishing Process – Get Done



Submission Complete!



5

Refresh

your

growth

mindset



Prepare for onslaught of review...

Tracing the Decision Process



Desk and Editorial Review

- Journal editorial staff
- Technical screen
 - Formatting and components to specs
 - Strong, concise, coherent writing
 - Appropriate methods and references
- Journal aims and scope
- Ethical standards

Desk or Editorial Rejections

XIncomplete and/or error-ridden draft XInadequate prose or English X Methods/analysis not appropriate X References outdated and/or unbalanced XNot novel/of interest to journal audience XInsufficient rigor for journal impact **X**Ethical concerns

Tracing the Decision Process



- Unpaid, external reviewers
- Published/practicing experts in field
- Assess scientific merit of work + if manuscript is worthy of publication in that journal
 - Provide recommendations to authors to improve their work
 - Make recommendation to editor
- Single- or double-blind process



should be significantly expanded (*reviewer 3 sells odd shaped windows) @redpenblackpen

https://twitter.com/redpenblackpen/status/1173797

approach



Your published manuscript

$\Box \nabla$







Response to Reviewers



Be meticulous and courteous



Cite specific location of changes in resubmitted manuscript file



All comments must be addressed, but not all suggestions must be accepted



Follow journal instructions carefully but often an open/"letterlike" format

Response to Reviewers



Guy R. Hasegawa, PharmD Senior Editor American Journal of Health-System Pharmacy Kellie L.E. Musch, PharmD, MS Pharmacy Manager OhioHealth

November 20th, 2018

Dear Dr. Guy Hasegawa,

Please consider the revised manuscript entitled: "Characteristics of postgraduate year two (PGY2) ambulatory care pharmacy residency programs in the United States" for publication in your esteemed journal. A point-by-point response to editor and reviewer comments is included below.

Editor 1

 A colleague here at ASHP suggests the following corrections. First, in Results, paragraph 3, end of sentence 2, there are no PGY1 Ambulatory Care Residency Programs; these may be PGY1 programs in an ambulatory setting. Second, in Results, last paragraph, next-to-last sentence, the terminology "Residency Learning System" is obsolete; this is now called "Residency Program Design and Conduct."

Response: While ASHP may not recognize a subtype or PGY1 programs as Ambulatory Care, it was an option to select on our survey for program designation. Therefore the authors believe we should leave as noted in the manuscript. Thank you for the term correction, "Residency Learning System" was updated to "Residency Program Design and Conduct" workshop.

Challenges with Peer Review

- Conflicting feedback/requests
- Unproductive criticism
- Feedback would result in exceeding journal requirements
- Feedback you disagree with /would change intention





https://twitter.com/redpenblackpen/status/1173797747872239616

Challenges with Peer Review

- Conflicting feedback/requests
- Unproductive criticism
- Feedback would result in exceeding journal requirements
- Feedback you disagree with /would change intention

- →Seek guidance from journal editor
- →Seek and respond to intention
- →Reassess other sections for opportunities
- → Reassess presentation rather than content
- →Provide rationale for declining

Resubmission

01

Maintain attention to detail

 Including authorship details

02

Reengage all collaborators and independent reviewers for "fresh eyes"

03

Cross-check all reference numeration, table and figure legends/data labels, etc.

Rejection after Peer Review



Thank editorial team and reviewers









Assess next target journal



Pursue process as per "Accepted with Revisions"



Comprehensive revision addressing review



Acceptance

From: ajhp@msubmit.net <ajhp@msubmit.net> Sent: Thursday, February 14, 2019 8:31 AM Subject: 2018AJHP0544R Decision Letter

Dear Dr. Musch:

Thank you for revising the referenced manuscript as suggested. We are pleased to accept it for AJHP Residents Edition.

Per standard procedure, your paper will be edited with the goal of achieving optimum readability and conformance with our style conventions. You will have an opportunity to review these editing changes when our publishing partner, Oxford University Press, sends galley proofs to you. Because of our large backlog of accepted papers, this may not occur for several months. Your careful review and prompt return of this material will be appreciated. Please keep me informed of any changes in your contact information.

Thank you for your contribution to the American Journal of Health-System Pharmacy. If you have any questions, feel free to contact me.

Sincerely,

Guy R. Hasegawa, <u>Pharm.D.</u>, Senior Editor American Journal of Health-System Pharmacy 301-664-8740 <u>ghasegawa@ashp.org</u>

Final Steps



Acceptance

Scelebrate!

Disseminate







Serve as a peer reviewer

Many other ways to publish


OhioHealth Pharmacy's Publication Boom



OhioHealth Pharmacy's Research Quality

Non-Pharmacist Winners
Pharmacist Research Competition Winners



Summary and Encouragement



- Community health-system pharmacists face many challenges to publishing our research and QI projects, but many resources and strategies exist to support those interested in scholarship
- Mentorship and active collaborators are key, along with advanced time-management skills and persistence
- We are doing great work it deserves to be seen!

Part 2: Writing Your Research Manuscript



Scientific Writing Backbone



Elliott C, Sainani K, Harwell D. "Active vs. Passive voice in scientific writing". ACS Webnars.

The Authors' Responsibilities

===





Primary obligation = convey information clearly, concisely, and objectively Clean writing promotes clear interpretation Simple, straightforward writing should be the goal

Voice: to fluff or not fluff

Active Voice

Passive Voice

- The subject acts
- "We found a strong correlation..."
- Using "I", "we", etc.
- Shift to preference from journals
- Promotes more direct, clear writing
- Places more responsibility on the author than the content

- The subject is acted upon
- "A strong correlation was found..."
- <u>Historically</u> preferred in scientific writing... until it wasn't
- Still appropriate to use, though at a lesser frequency than the active voice



Thou shall

- Outsource your *labor* to AI, not your *thinking*
- Use AI as your research *assistant*, not your supervisor
- Use AI to create *structure*, not *content*
- Use your common sense

Polishing Your Writing with Al

Please write a _____ for this paragraph

- Topic sentence
- Transition sentence

Please rewrite this paragraph as...

- An introduction
- A conclusion

Limitations

- ChatGPT can be used as a supplement and should not be relied upon entirely
- Spelling or nuances in language
- Limits with understanding complex concepts and nuances in language
- Unable to cite (accurately at least...)

Manuscript Writing Structure

Section	Paragraphs	Words	Refs
I	2-3	250-500	5-16
Μ	4-10	350-750	0-5
R	3-9	250-1000	N/A
D	5-11	750-1500	8-30

J Am Coll Clin Pharm. 2020; 3: 818–824; Arq Bras Cardiol. 2014 Feb; 102(2): e21-e23.

Introduction = 2 or 3 Paragraphs

Put your research topic in broad context Concisely describe what is known Contrast with what is **not** known End with study question, hypothesis, or goal

Introduction / Background: Working Smarter not Harder

- Most consistent piece of the research process
- Use what you have already done, but change it for your new audience

Background Process Example

Critically ill patients may experience pain and agitation in the intensive care unit (ICU), requiring analgesia and sedation. Causes for pain and agitation include underlying injury or illness, surgical/invasive procedures, and noxious stimuli caused by interventions.¹ Intensive procedures such as mechanical ventilation, while often necessary for patients, can cause pain and agitation. While current guidelines recommend a multimodal approach to treating pain in the ICU, opioids remain a mainstay of pharmacotherapy.

Caring for patients in the critical care setting requires a focus on activities necessary to sustain life. Protecting a patient's airway is paramount in this endeavor. Mechanical ventilation becomes necessary when patients are no longer able to maintain their airway or provide adequate oxygenation secondary to compromised lung function, difficulty in breathing, or acute respiratory distress syndrome (ARDS).² Critically ill, mechanically ventilated patients experience acute pain related to their illness or injury that is subsequently associated with many negative physical and emotional consequences.³ While some patients tolerate mechanical ventilation with an endotracheal tube without sedation, some require the IV administration of sedatives and analgesics to minimize pain, agitation, and anxiety.

The 2018 Pain, Agitation/sedation, Delirium, Immobility, and Sleep (PADIS) Guidelines recommend opioids as a first-line treatment option for non-neuropathic pain, as well as sedation. Strategies include analgesia-first and analgesia-based sedation, prioritizing pain management and preferentially using intravenous opioids before administration of continuously infused sedatives such as propofol or dexmedetomidine.¹ For patients receiving continuous infusions of opioids for multiple days who are unable to tolerate abrupt cessation, enteral opioids may be used to reduce intravenous demands and prevent acute opioid withdrawal. A common weaning strategy involves the use of oral opioids to reduce intravenous opioid demands.⁴³ Providing sufficient analgesia to ICU patients while preventing opioid dependence and withdrawal is essential to promote comfort and rehabilitation. Current best practices include the use of the ABCDEF (A2F) Bundle, as a method of implementing evidence based care. The critical importance of managing pain in ICU patients is highlighted in the first step of this bundle, with "A," meaning, "assess, prevent, and manage pain." The use of the A2F bundle is associated with clinically meaningful improvements in outcomes including survival, mechanical ventilation use, coma, delirium, restraint-free care. ICU readmissions and nost-ICU discharge

Kram et. al. set out to determine the pro prescription for an around the clock enteral opic continuous opioid infusion in the ICU. The study weaning strategy may lead to prolonged and po with 30.6% of patients receiving a new prescript determine the appropriateness of medications p were one of the most common and potentially i discharge.⁷ In fact, the study found that 73% of actually inappropriate.⁷ Although analgesia-first sedation is recommended to provide comfort in mechanically ventilated adults, the occurrence of downstream effects like ICU-acquired physical dependence on opioids is unclear.² Prescription opioid abuse remains an epidemic in the United States, and is particularly alarming in the State of Ohio. In 2017, Ohio had the second highest rate of drug overdose deaths involving opioids in the United States (39.2 deaths per 100,000 Ohioans vs. 14.6 deaths per 100,000 Americans).⁸

This research provides the opportunity to investigate the effects of current best practice in sedating mechanically ventilated patients and the effects of post discharge opioids. Additionally, further research is needed to elucidate the impact of opioid prescribing in the ICU on the prescription opioid epidemic. Finding a balance between the appropriate use of opioids and the opioid epidemic requires heightened ICU clinician attention and focused research.² The objective of this study is to determine the incidence of ICU patients receiving continuous opioid infusions versus intermittent opioid dosing during their stay who subsequently receive an opioid prescription upon discharge.

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Background Example – QI Project

Infectious complications of total joint arthroplasty (TJA), especially prosthetic joint infections (PJI), are associated with significant morbidity and decreased quality of life for affected patients, in addition to conferring an estimated economic burden of over \$1.62 billion annually [1]. Antimicrobials play an important role in the delivery of safe and effective surgical care and are utilized in myriad ways across the care continuum in elective TJA procedures. While essential to avoiding surgical site infections (SSIs), inappropriate or excessive use of antimicrobials can lead to deleterious outcomes, including toxicity, growth of resistant organisms, superinfections (including C. difficile infection), and unnecessary costs [2]. Unfortunately, limited high-quality data exist to guide many of the antimicrobial modalities used in TJA, creating a need for comprehensive antimicrobial stewardship program (ASP) implementation and evaluation [1,3,4].

Antimicrobial stewardship is defined as "[optimizing] antimicrobial use to achieve the best clinical outcomes while minimizing adverse events and limiting selective pressures that drive the emergence of resistance," while also attempting to reduce excess costs attributable to suboptimal antimicrobial use [5]. Robust institutional antimicrobial stewardship programs (ASPs) are required to meet metrics imposed by the Centers for Medicare and Medicaid Services (CMS) and are strongly encouraged by the Centers for Disease Control and Prevention (CDC) [6,7]. ASPs have demonstrated value to hospitalized patients and institutions [8], yet application to elective surgical populations, including TJA, remains limited.

To address these needs, our institution formed a comprehensive, multidisciplinary orthopedic surgery antimicrobial stewardship program ("Ortho ASP") with the goal of identifying the highest quality antimicrobial interventions to improve surgical outcomes and decrease the burden of adverse effects related to antimicrobials, all while controlling expenditures. We pursued a pre- and post-implementation assessment in all TJA patients at our urban, community teaching hospital, with the primary outcome being the rate of optimal preoperative antibiotic selection. We hypothesized that a collaborative Ortho ASP would optimize antibiotic use in TJA, as indicated by increased utilization of high-value antibiotics, a reduction in unnecessary or overly toxic antibiotic exposures, improved or neutral effects on postoperative SSI and acute kidney injury (AKI) rates, and reduced direct and/or indirect costs to the institution.

Background Example – 2 Paragraphs

Sugammadex is a novel chelating medication for non-depolarizing aminosteroidal neuromuscular blocking agents (NMBAs) and is indicated for the reversal of paralysis caused by rocuronium or vecuronium [1-3]. While sugammadex has been used routinely by anesthetists across the globe for over a decade, it has more recently been employed in emergency department (ED) and intensive care unit (ICU) settings to facilitate timely neurologic assessments in patients who have received NMBAs, such as after rapid sequence intubation (RSI) for severe traumatic brain injury (TBI). This approach has merit in facilitating a more efficient and accurate neurologic assessment as compared to delaying exam for NMBA clearance or proceeding with care plans despite the possibility of residual neuromuscular blockade, which persists longer than clinicians discern [2,4]. Additionally, detecting critical neurologic worsening in hospitalized TBI patients is imperative to initiating emergent management, and delays are associated with increased mortality [5,6]. Hastening neurologic diagnosis, prognosis, and treatment of the critically brain-injured could confer significant benefit to patients, providers and hospitals.

To date, very limited studies have described patient outcomes and clinical considerations associated with sugammadex use outside of anesthesia settings [7–12]. While known to be well-tolerated across diverse surgical populations [13–15], sugammadex administration carries an infrequent risk of severe bradycardia, hypotension, and even asystole [16–22]. These risks may be more prevalent and more deleterious in the neurocritically ill than in the elective surgical populations in which sugammadex has been studied, and need to be better understood before this practice can be recommended routinely. The purpose of this study is to assess the use of sugammadex to facilitate neurologic assessment in brain-injured patients previously exposed to NMBAs at a high-volume Level 1 trauma center and to provide practical guidance to neurocritical care clinicians pursuing this modality.

Your Turn

Outline your 2-3 paragraph intro
 Paste the background for your IRB protocol into your manuscript draft

Remove excess material and paste to your discussion section

Methods

Subsections in logical, predictable order

- Consult "template" article
- Journal requirements
- EQUATOR checklist

Painfully concise and clear prose

Your Turn

- Paste your methods from your IRB protocol into your manuscript draft
- Adjust for conciseness, past tense
- Remove excess material and paste to a supplemental materials document
- Leave comments for items to come back to
 Statistical analysis- power calc, descriptive stats, inferential statistical tests used

Results

Subsections in logical, predictable order

- Consistent order across sections

Figures and table predominate

Limited text - do not comprehensively restate tables or graphics

Your Turn

Paste your figures and tables into your manuscript draft in proper order Patient flowchart if applicable Demographic variables table Primary/secondary analyses tables/charts Reformat for print vs presentation Remove excess content to supplement Leave comments for what to come back to

Writing a Compelling Discussion Section

Rita N. How to write a strong discussion in scientific manuscripts and other online resources. BioScience Writers, 2014. https://www.biosciencewriters.com/How-to-Write-a-Strong-Discussion-in-Scientific-Manuscripts.aspx

Literature Examples Used

•

#1: Comparative
Effectiveness and Safety
of Ticagrelor versus
Prasugrel in Patients
with Acute Coronary
Syndrome: A
Retrospective Cohort
Analysis.

Pharmacotherapy. 2019 Sep;39(9):912-920. doi: 10.1002/phar.2311. #2: Clinical Pharmacist Service Associated With Improved Outcomes and Cost Savings in Total Joint Arthroplasty.

J Arthroplasty. 2020 Sep;35(9):2307-2317.e1. doi: 10.1016/j.arth.2020.04.022

Discussion Part 1

Summarize knowledge gap Relates to (*≠* repeats) intro 1 **brief** paragraph vs. sentence End with statement of **problem** + significance Why is this important? How will answering this specific research question contribute to addressing the larger stated opportunity?

Example Discussion Part 1-#1

This study is among the <u>first observational cohort</u> <u>analyses</u> to assess the **long-term effectiveness and safety of ticagrelor compared with prasugrel in patients with ACS** based on <u>real-world data in the United States</u>. ...

Example Discussion Part 1-#2

Postoperative complications and readmissions after elective TJA are subject to increasing scrutiny by payors, institutions, and patients. While an interprofessional approach has known benefits in improving care quality and reducing costs (15-17), a comprehensive pharmacotherapy service aimed at improving TJA outcomes has not been described. Quantifying clinical pharmacist impact will contribute to evidence-based strategies for avoiding complications in this population and may inform institutional decision-making regarding quality improvement and resource allocation.

Discussion Part 1 – Your Turn

Summarize knowledge gap Relates to (*≠* repeats) intro 1 **brief** paragraph vs. sentence End with statement of **problem** + significance Why is this important? How will answering this specific research question contribute to addressing the larger stated opportunity?

Discussion Part 1

Adaptations:

-First paragraph of section

-Consolidated into first sentence of first paragraph

-Skipped initially and used as closing

Good place to start - helps drive subsequent writing and target audience decisions

Discussion Part 2

Set up critical analysis of findings Relates to (*≠* repeats) results section Start with stating approach + main results What was your strategy for trying to answer this research question and what did you find? 1 paragraph Active voice

Example Discussion Part 2-#1

...In this **large propensity score–matched cohort** of patients in the general ACS population, the use of <u>ticagrelor was associated with a significantly lower risk of</u> <u>recurrent nonfatal CVD and major bleeding events</u> <u>compared with prasugrel</u>. Our findings were consistent <u>regardless of patients' age, presence of baseline diabetes,</u> <u>use of PPIs, or baseline renal impairment</u>. We also found a <u>reduced risk of minor bleeding events with ticagrelor</u> <u>compared with prasugrel</u>.

Example Discussion Part 2-#2

In this study, we implemented a comprehensive orthopedic clinical pharmacist service and assessed its impact through a sequential cohort analysis of reported institutional outcomes from the affected fiscal years. We then used literature-reported healthcare expenditures to explore its potential effects on total costs of care. In the pre- and post-implementation assessment, the orthopedic clinical pharmacist service was associated with significant improvements in institutional rates of postoperative complications and readmissions. These lower rates of costly adverse events drove substantial institutional return on investment in the economic analysis.

Discussion Part 2 – Your Turn

Set up critical analysis of findings Relates to (*≠* repeats) results Start with stating **approach** + main results What was your strategy for trying to answer this research question and what did you find? 1 paragraph Active voice

Discussion Part 3

Critical analysis of findings in context of current/prior knowledge

How do your results fit with existing literature on this topic? What may explain differences?

Include/address both supporting AND contrary prior work

~2-4 paragraphs

Discussion Part 3

[Update lit review of all related studies and distill to most recent and relevant]

Start with main findings then proceed to additional findings (i.e. maintain prior order)

Start writing process with topic sentences + associated references

Expand each to comment on **why** results are similar or different to yours

Example Discussion Part 3-#1

- The findings from our study regarding the lower risk of recurrent CVD and major bleeding events are somewhat different than the results of the PRAGUE-18 study, observational studies, and meta-analyses of RCTs.^{10-13, 26-28}
- Other retrospective observational studies supported the effectiveness and safety profile in favor of prasugrel over ticagrelor.^{12, 13}
- Evidence from meta-analyses of RCTs has been conflicting.^{10, 11}
- In addition, a recent study using data from the UK showed no significant difference in mortality among patients receiving prasugrel versus ticagrelor (HR 0.81, 95% CI 0.61–1.10).³⁰
- Prior interventional cohort studies and recent reviews have demonstrated the value of the interprofessional perioperative surgical home to TJA patients. (15-20)
- As discussed in a recent review, clinical pharmacist roles and value in care pathways for orthopedic patients are wellfounded and promising, but supporting literature is in its infancy. (21-25)
- Previous cohort studies of direct clinical pharmacist collaboration with orthopedic surgical teams have yielded positive results in focused care domains. (5, 9-10, 26)
- Minimal and conflicting prior literature exists regarding the economic impact of clinical pharmacy services on orthopedic surgery departments. (10.27-28)

Discussion Part 3 – Your Turn

- [Update lit review of all related studies and distill to most recent and relevant]
- Start with main findings then proceed to additional findings (i.e. maintain prior order)
- Start writing process with topic sentences + associated references
- Expand each to comment on **why** results are similar or different to yours

Discussion Part 4

Discuss limitations and their implications Identify confounding variables + how they may have influenced your findings Identify sources and types of bias + how they may have influenced your findings Discuss what these limitations mean for your study's internal and external validity

Review of Bias, Errors

Bias in medical research https://first10em.com/bias/ Identifying and avoiding bias in research https://pubmed.ncbi.nlm.nih.gov/20679844/ Ten categories of statistical errors https://pubmed.ncbi.nlm.nih.gov/15010353/ Assessing bias: the importance of considering confounding

https://pubmed.ncbi.nlm.nih.gov/23236300/

Discussion Part 4

What other factors (beyond your intervention) could have influenced your results? How did you account for them?

How do <u>confounding factors and potential</u> <u>sources of bias</u> influence the **interpretation** and **generalizability** of your findings?

Our analysis, however, is not without limitations. First, we did not have access to data on over-the-counter medications (e.g., aspirin, nonsteroidal antiinflammatory drugs) that may contribute to the bleeding risk observed in this study. However, we expect this to have a minimal impact on the observed estimates because prior studies reported that aspirin adherence is unlikely to be the differential between groups receiving the different agents.29

Second, we cannot rule out the possibility of residual confounding due to missing data on some lifestyle variables (e.g., smoking status), although we used propensity score matching to adjust for observed differences. Third, selection bias is a possibility because physicians' decisions to treat patients with ticagrelor or prasugrel might be influenced by other factors not captured in the data.

Fourth, there is the potential for <u>exposure</u> <u>misclassifications</u> when information regarding antiplatelet medications used during the hospital stay was absent from the current data and may have been different from the long-term agent the patient received.

Finally, deaths occurring in the outpatient setting and cause of death are not captured in the Truven database, and therefore deaths due to CVD or bleeding events could not be considered in our composite end points. We assume that most of such deaths would coincide with a hospitalization that was captured in our end points and was similar between the prasugrel and ticagrelor groups.

Our analysis suffers from a number of limitations, the most significant being those inherit to a nonrandomized, non-controlled design. In pursuing a sequential cohort analysis we could not control for the effects of other process improvement initiatives and practice changes occurring throughout the study timeframe, though we attempted to describe and discuss these as comprehensively as possible in the retrospective complications cause assessment.

Additionally, because many of the targeted outcomes represent very rare events, exceedingly large sample sizes would be needed to support causality of a given intervention on the results. While our study was determined to have 90% power to detect a 3% reduction in readmission rate at a=0.05, this determination was not made a priori for the primary outcome, and the secondary outcomes analyses were again limited to hypothesis-generation in terms of statistical rigor.

Furthermore, only institution-level data rather than patient-level data was able to be used in these comparisons, on account of limited institutional resources to support large-scale data collection. This created various patient populations for the included outcomes owing to external organization-defined outcomes measures, further contributing to difficulty in assessing the effects of the intervention.

While these limitations decrease internal validity by increasing the risk of type I error in our study, ...

Discussion Part 4 – Your Turn

Discuss limitations and their implications Identify confounding variables + how they may have influenced your findings Identify sources and types of bias + how they may have influenced your findings Discuss what these limitations mean for your study's internal and external validity

Discussion Part 5

Discuss strengths and future directions What subsequent studies are needed to finish addressing the original knowledge gap? How would you design subsequent studies to answer the research question more completely than your study did/could?

Our analysis had several strengths. First, we used a longer follow-up time that allowed examination of recurrent nonfatal CVD event risk up to an average of ~6 months. Second, our large sample size allowed for the assessment of select subgroups of patients with ACS (e.g., patients with type 2 diabetes) who may respond differently to antiplatelet therapy than the general ACS population.

Third, we restricted the analysis to patients initiating the study drugs within 7 days after discharge to minimize the potential for confounding by disease severity. Fourth, we used validated definitions for both the study outcomes and the confounders to minimize measurement biases and residual confounding resulting from using administrative claims databases.

Our study results are **generalizable** to patients with ACS who are covered by commercial or Medicare supplementary insurance.

..., we stand by the **clinical significance** of our findings from the patient and institutional perspective. Considering the catastrophic morbidity, mortality, and costs of postoperative complications and readmissions, any intervention associated with improved outcomes is likely worthy of further exploration. This is especially true for more complex patient populations and reimbursement-vulnerable institutions such as ours.

Indeed, the use of **population-level**, **external organization-defined outcomes strengthens the study's generalizability** since all American centers completing TJA are compelled to collect these data to inform process improvements in the same manner.

Future studies at resource-rich centers should be pursued to definitely assess the impact of comprehensive clinical pharmacy services on TJA outcomes in a prospective, randomized controlled fashion utilizing single population patient-level data.

Discussion Part 5 – Your Turn

Discuss strengths and future directions What subsequent studies are needed to finish addressing the original knowledge gap? How would you design subsequent studies to answer the research question more completely than your study did/could?

Discussion Part 6

Overall conclusion and major impact Relate to Part 1 to "close the loop" What is your study's main contribution? What practice changes or research to you recommend based on your results? What is your main takehome message to your audience? Strong but concise final paragraph (2-4 sentences)

In this population-based cohort of patients with incident ACS, the use of ticagrelor was associated with a lower risk of recurrent nonfatal CVD events, major bleeding events, and minor bleeding events when compared with prasugrel. The beneficial effect of ticagrelor remained consistent in our analyses of subgroups stratified by age, baseline diabetes, baseline renal impairment, and use of baseline PPIs.

In this sequential cohort analysis at a large surgery center serving a complex TJA patient population, the implementation of a comprehensive clinical pharmacy service was associated with improved institutional rates of postoperative readmissions and complications. Additionally, pharmacist discharge counseling was associated with positive indicators of patient understanding and satisfaction. We estimate a \$1.80 ROI for similar institutions adopting this type of service.

While definitive conclusions of causality are limited by a non-controlled design, clinical pharmacy services have established benefits to patient outcomes across myriad practice areas. Based on this study and prior literature, clinical pharmacists should be explored as valuable partners in improving TJA patient outcomes by orthopedic surgeon teams and institutions.

Discussion Part 6 – Your Turn

Overall conclusion and major impact Relate to Part 1 to "close the loop" What is your study's main contribution? What practice changes or research to you recommend based on your results? What is your main takehome message to your audience? Strong but concise final paragraph (2-4 sentences)

Publishing Scientific Manuscripts: A Primer for Pharmacists

OhioHealth Pharmacy Resident Workshop Series

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Recommended Resources

- Hammond, DA, Rech, MA. A "how-to" guide for effectively writing a publishable research manuscript. J Am Coll Clin Pharm. 2020; 3: 818–824. <u>https://doi.org/10.1002/jac5.1190</u>
- Publishing Biomedical Research and Reviews: Guidelines and Advice for Authors. Author C. Lindsay DeVane, Pharm.D., FCCP, FACNP
- Viglianti EM, Admon AJ, Carlton EF, et al. Publishing a Clinical Research Manuscript: Guidance for Early-Career Researchers With a Focus on Pulmonary and Critical Care Medicine. *Chest*. 2019;156(6):1054-1061. doi:10.1016/j.chest.2019.06.014
- Roederer M, Marciniak MW, O'Connor SK, Eckel SF. An integrated approach to research and manuscript development. Am J Health Syst Pharm. 2013 Jul 15;70(14):1211-8. doi: 10.2146/ajhp120167. Erratum in: Am J Health Syst Pharm. 2013 Oct 1;70(19):1650.
 PMID: 23820457.
- Steen RG. Writing for publication in a medical journal. *Indian J Endocrinol Metab*. 2012;16(6):899-903. doi:10.4103/2230-8210.102988
- Equator (Enhancing the QUAlity and Transparency Of health Research) Network www.equator-network.org International Committee of Medical Journal Editors (ICMJE) <u>www.icmje.org/</u>
- Consolidated Standards of Reporting Trials (CONSORT) <u>www.consort-statement.org/consort-statement/</u>
- STrengthening the Reporting of Observational studies in Epidemiology (STROBE) www.strobe-statement.org/Support.html
- National Library of Medicine (NLM) Research Reporting Guidelines and Initiatives www.nlm.nih.gov/services/research_report_guide.html
- American Society of Health-System Pharmacists (ASHP) Research and Education Foundation. American Journal of Health-System Pharmacy series: Research Fundamentals
- Roederer M, et. Al. An integrated approach to research and manuscript development. Am J Health-Syst Pharm—Vol 70 Jul 15, 2013
- ACCP Annual Mtg Scientific Writing Workshop Activity Number: 0217-0000-17-195-L01-P materials. Oct 2017
- Rita N. How to write a strong discussion in scientific manuscripts and other online resources. BioScience Writers, 2014. https://www.biosciencewriters.com/How-to-Write-a-Strong-Discussion-in-Scientific-Manuscripts.aspx
- Elliott C, Sainani K, Harwell D. "Active vs. Passive voice in scientific writing". ACS Webnars. Apr 9 2015. Available from: https://www.acs.org/content/dam/acsorg/events/professional-development/Slides/2015-04-09-active-passive.pdf

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- 4. Scan QR code with your phone's camera. Enter activity **17937** and follow the prompts.



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