

The Recipe

A practical guide to scholarly activity



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Foreword

Jeffrey Quinlan, MD, FAAFP

How times have changed!! When I was a resident, very few of my colleagues were involved in scholarly pursuits. If someone did happen to get involved, it was typically in the form of a case report, based on one of their clinic or hospitalized patients. I can't remember a single resident who even tried to do a review article let alone do research. Several years later, I clearly remember as a junior faculty member struggling to understand how to get started and where to turn for help. Written guidance was sparse, and we largely relied on the insight of more senior faculty who had likewise struggled on their own when they were more junior.

A mere 25 years later, the ACGME now requires that both residents and faculty participate in scholarly activities. Faculty are expected to participate in two activities every five years, on average, and residents are expected to participate in two activities before graduation. Unfortunately, until now the quintessential "how-to" manual has been lacking, and many residency programs have continued to be overwhelmed by the requirement.

Fortunately, Drs. Rutherford, Lennon, and Seehusen now present an intuitive text that outlines the steps that any residency program can follow in order to take the fear out of the words "scholarly activity." The steps that they present are both well researched and draw on the successes that they have seen at their own residency programs.

In Chapter 1, Dr. Sanchack outlines why the pursuit of scholarly activity is important in a residency program. He presents both the FINER criteria and "five components" pathway. Dr. Rutherford then discusses the importance of a Resident Research Coordinator and how to select one who will embrace peer leadership in Chapter 2. Chapter 3, authored by Dr. Lennon, describes the steps required to perform a thorough and focused literature search, which is essential for every scholarly work. In Chapters 4 through 9, they provide step-by-step guidance on how to do a Case Report (Chapter 4, Dr. Seehusen), Photo Quiz (Chapter 5, Dr. Lennon), Poster Presentation (Chapter 6, Dr. Hoedebecke), Letter to the Editor (Chapter 7, Dr. Asplund), Lay Medical Article (Chapter 8, Dr. Larson), and a Process Improvement Project (Chapter 9, Dr. McDermott). The text concludes with chapters on how to navigate the IRB Process (Dr. Smith) and how to write a grant application (Dr. Stephens).

In addition to the resources outlined in this text, I would also draw your attention to another great resource that is available to Military Family Medicine Residency Programs, the Military Primary Care Research Network (MPCRN). Hosted by the Department of Family Medicine at the Uniformed Services University, the MPCRN's mission is to promote physician inquiry, discovery and improvement to enhance patient care. For more information, visit their website at www.usuhs.edu/mpcrn.

I hope you find these resources as useful as I have!

Preface

When Rob Lennon came to me with the proposition that I help teach research to our follow residents, my brain rang with excuses. I was a new intern at the time and struggling to handle my clinical responsibilities. In response to my pleading, he dropped an empty filing cabinet, all his current notes, and various scholarly projects (all at different points of completion) on my desk. After getting over my initial shock, I found that I truly enjoyed helping my fellow residents to accomplish their scholarship goals.

The title and concept of this book, “The Recipe,” came from my mother’s persistently patient attempts to teach me to cook. When I first became a resident research coordinator, I found that many of my colleagues struggle with scholarly activity the way I do cooking (Yes, there have been fires.)

By writing small little “how to do” sheets for common questions and problems, I was able to break down what they considered to be a huge task into smaller, achievable projects. This text is a compilation of scholarly recipes dedicated to helping people achieve their scholarship goals. Trust me, if I can be taught to make a breakfast casserole, anything is possible.

Anna Rutherford MD

I recall a more orderly transition...

I created the Resident Research Coordinator (RRC) position at the Jacksonville Family Medicine Residency Program (JFMRP) because I believed that peer leadership would be the best way to overcome what I perceived was the biggest obstacle to residents conducting research and pursuing scholarly activity: their belief that such pursuits were too hard. Through peer leadership, the RRC lowered the activation energy of scholarly pursuit for residents, increasing scholarly output by over an order of magnitude. By breaking down various activities into recipes, Anna built longevity into our system and made it portable. We hope you and your program will find these techniques as useful as we have!

Robert Lennon MD, JD, FAAFP

Introduction

The goal of this text is to enhance scholarly activity in a way that is reliable, reproducible, and sustainable. By giving easy-to-follow, step-by-step instructions, we believe it will serve to lower the activation energy associated with scholarly activity. It can be used alone or within an existing teaching curriculum.

Several interventions have been associated with increased scholarly activity including:

Requiring resident research, granting protected [research] time, providing biostatistical and research support personnel, appointing a residency research director (also called a faculty research coordinator), assigning [research] mentors, appointing a resident research coordinator, building a resident research team, incentive awards, elective research rotations, research lectures and research problem based learning discussions.

At a minimum we recommend that any attempt to improve scholarly activity through curricular reform include the position of a faculty research coordinator (a faculty member who has an interest in research), a resident research coordinator (a resident who is enthusiastic about learning, helping their fellow residents reach their goals, and is willing to be available for questions), and a scholarly point system (see Chapter 2.)

Scholarly activity references:

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Chapter 1. Why pursue scholarly activity? Building a Framework

Kristian Sanchack, MD

“The progress of science and the scientific or intelligent practice of medicine employ, therefore, exactly the same technique. To use it, whether in investigation or in practice, the student must be trained to the positive exercise of his faculties; and if so trained, (the medical school) begins rather completes his medical education.” – Abraham Flexner

Objective: To build a framework that facilitates the learner’s ability to conceptualize the historical significance, purpose, and importance of scholarly activity in advancing medical science enabling the learner to answer the question “why pursue scholarly activity?”

Why pursue scholarly activity?

Scholarly Activity is often an intimidating prospect to junior residents and sometimes even junior faculty. It may feel like there are many obstacles to completing scholarly projects and thus the sheer amount of work involved stops some people before they ever start. That same trepidation may lead people to question, “Why pursue scholarly activity at all?” An easy first response to this question is that scholarly activity is an important component of graduate medical education requirements. But this only addresses extrinsic motivation to pursue scholarly activity. Intrinsic motivation to pursue scholarly activity comes from an understanding that such pursuits enhance life-long learning, provide a greater understanding of the changing landscape of medicine, and enable an environment of curiosity in the practice of medicine. This intrinsic motivation also addresses physicians who might say, “I just want to see patients.” You will become a better clinician if you understand the literature in a more informed way. Over 100 years ago Flexner recognized that understanding and practicing with a scientific approach was critical to clinical medicine. Scholarly activity is defined as a contribution to the knowledge available for the discipline of medicine, and is subject to peer review. Scholarship therefore is truly a component of practice-based learning and professionalism.

What are the requirements?

The Accreditation Council for Graduated Medical Education (ACGME) includes scholarly activity as a component of the Common Program Requirements. Scholarly activity is currently covered in section IV.B.2 via the statement “Residents should participate in scholarly activity.” Different specialties have other specific requirements. Family Medicine, for example, requires residents to complete two scholarly activities, at least one of which should be a quality improvement project.

The ACGME allows multiple avenues to complete scholarly activity that can be broken into specific types of scholarship. The four types of scholarship, as originally put forth by Boyer, are Discovery, Integration, Application and Education. The options to fulfill scholarly activity in these areas allow a tremendous amount of flexibility for completion of the ACGME requirement.

Discovery is the generation of new knowledge and sharing that knowledge with our community. Examples include bench, clinical, and epidemiological research. At the Resident level this can be presented via poster or publication at local conferences, a residency newsletter, or at regional (or higher) levels.

Integration is taking that knowledge and synthesizing it into something that is useful for physicians to use in practice. Examples of this that count towards ACGME goals include presenting a case study with literature review at a local or regional venue, presenting reviews of a chronic condition at a local or regional conference, and publications such as a newspaper article on a public health concern or a letter to editor analyzing the results of paper published.

Application is putting the knowledge into practice. Resident examples include describing a patient education program on risk behavior or chronic disease management in a residency newsletter, or serving as chair of a local or state medical society committee and publishing a report of that committee's accomplishments in a medical society newsletter.

Teaching as a form of scholarly activity includes the development of educational programs or resources to educate stakeholders such as students, healthcare professionals or the public. Options here range from presenting to faculty members and peers on a topic of interest based upon a needs assessment to creating an enduring curriculum for use in a residency educational program.

Start with curiosity

Perhaps one of the most underrated attributes of a physician is curiosity. That intrinsic drive to seek knowledge and gratify the mind with new information is crucial to engagement during education. Encouraging inquiry rather than supplying information can promote self-directed learning as well as generate research questions. Practice improvement is also included in scholarly activity; current processes or lack thereof are good subjects of study to the curious mind.

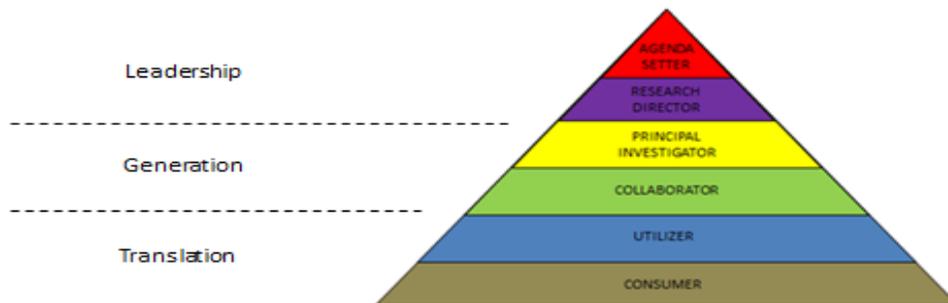
In our average day of practice an engaged and mindful physician could likely create many questions, particularly in a field as broad as family medicine. A colleague once recommended trying to write down at least one a day. During a three year residency, over 1,000 questions might be generated. While many of those might be answered with a literature review, some may

warrant further investigation to compile or create new information to share. Faculty modeling curiosity throughout the education process will support education and training, develop scholarly activity and may enhance practice through process improvement.

Build a Team with Research Roles

Throughout this guide you will be recommended to work with a mentor and build a team. All faculty, residents and practicing physicians should be reading and “consuming” current evidence. Our learners and faculty move up the research pyramid by starting to engage the use of evidence-based medicine directly in their practice and collaborate on scholarly projects. Beyond the truism that “many hands make light work,” having a team member experienced in clinical research (someone who has been a Principal Investigator or is a Research Director) allows your research to be in better alignment with current research trends. The Principle Investigator can be supported by our learners on projects and meet the goals of leadership who set the agenda and remove obstacles to enhance the teams experience.

Research Roles Pyramid



This pyramid depicts the spectrum of roles faculty can perform when it comes to medical research. The bottom two levels represent continuous learning about, and the translation of, new medical knowledge. All faculty participate in research through consumption of the literature and all those that provide patient care participate by being direct utilizers of research findings. The middle two levels represent actual participation in the generation of knowledge. Ideally, a robust number of faculty will actively collaborate in the research generation in order to produce broadly applicable findings. A smaller number, with significant experience and interest, will become principal investigators answering their own questions. The top two levels represent leading others in the generation of new knowledge. Those researchers with the most and broadest experience will become positioned to lead research programs or even to set research agendas for institutions and broad networks of researchers.

*Research Roles Pyramid image courtesy of Dr. Seehusen

Pursue your projects using the FINER criteria and “five components” pathway

A simple screen for clinical questions to pursue is the FINER criteria advocated by Hulley. Optimal research questions are: **F**easible, **I**nteresting, **N**ovel, **E**thical, and **R**elevant. Steps to perform meaningful scholarship include: 1. Begin with a scholarly question (using the FINER criteria); 2. Perform a systematic search for existing knowledge; 3. Gather, analyze and synthesize the data; 4. Present your findings. Following the chart below provides a mental model from taking your project from start to finish.

Type of Project	Begins with a scholarly question	A systematic search for existing knowledge	Gather data	Analyze and synthesize data	Present findings
Case report	What does this case add to the existing literature?	Literature search, discussion with experts	Collate previous cases, comparing and contrasting	Generate lessons learned, advice for other providers	Published paper, poster or oral presentation
Research	How are these variables related?	Literature search focused on prior research in the area	Outcomes data generated through scientific method	Statistical analysis of relationship between variables	Published paper, poster or oral presentation
Process Improvement Project	Can “X” outcome be improved by making “Y” change?	Literature search, discussions with peers, existing best practices	Outcomes data generated through scientific method	Analysis (may not be statistical) of relationship between variables	Presentation could result in publication (may need to get retrospective IRB approval)

Summary

We have dispelled the concern that only original institutional review board approved studies are acceptable. Our learners can start at a level that sets them up for success, in an area that speaks to their interests. Modelling curiosity will spark the learner’s intrinsic drive in a much more satisfying approach than simply working to meet requirements. The flywheel of success

encourages higher level engagement as the glass wall of trepidation is broken. Educators have the onus to encourage, coach and mentor via engagement in scholarly activity, and setting the example for our future colleagues. The recipes contained in the following chapters will help organize your approach to developing your residents and faculty team. The information spans creation of case reports to drafting investigational review board and grant applications. The book includes structural methods like creating a peer leader as resident research coordinator, which has been proven to increase production of scholarly activity. As Program Director for the Naval Hospital Jacksonville Family Medicine Residency Program, I have seen these recipes work, and am confident they will enhance your program!

Summary Points:

- ❖ Scholarly Activity contributes to the knowledge available to the discipline of medicine and is subject to peer-review
- ❖ Scholarly activity is a requirement of graduate medical education
- ❖ There is a wide range of scholarly activities that can be pursued and should be tailored to each learner's interests
- ❖ Curiosity should be supported and modeled to residents
- ❖ Use the FINER criteria and five component pathway to frame your work
- ❖ Remember that Flexner wanted physicians to do research because it encourages life-long learning and helps avoid stagnation via empiricism

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Chapter 2. Resident Research Coordinator

Anna Rutherford, MD

“Great things are accomplished by talented people who believe they will accomplish them.” – W.G. Bennis

Objective: To create a resident research coordinator position and educate him or her how to teach, mentor, and guide their fellow residents allowing for an increase in research output, to include presentations in local, regional, and national research conferences and publications in peer reviewed journals, over the course of a 1 to 2 year period.

Job description

First and foremost, you can do this! Convincing your sleep deprived, over-caffeinated, overworked, colleagues to take on further responsibilities can be a daunting task, but if you have a passion for research it is a worthy challenge. The key is to remember that all obstacles to research can be broken down into smaller, more manageable pieces.

The job of a resident research coordinator is to be an advocate for your fellow residents. You will be a facilitator of interdepartmental research, the “go to” person for finding regional, local, and national research conferences, a sounding board for new ideas and the instigator for collaborative efforts.

This book is designed to help you with this task, but should in no way be considered a comprehensive guide. The most important part of your job is to make research feasible and accessible. A great deal of creativity and various, sometimes crazy appearing, approaches may be necessary to mold your individual program, but remember you can do this!

Tracking conferences

One of the first things you will find in residency is that deadlines are a key motivator to exhausted minds. For this reason, it is important to know the major times and due dates for research conferences. They can usually be found on their individual web sites and are often emailed to department heads. They contain the rules for submission, appropriate word count, and often examples of previously accepted work.¹ Remember, they want your participation. It is not a research conference without research. Once you have a handle on the major conferences for your specialty, you need to follow when abstracts are due. About a month prior to the due date of an abstract, you should ask all the residents who are participating to show you a copy of their work. This accomplishes two things. It lets you see who has actually started their project, and it lets you edit ahead of time. Having all of the case reports on your desk for edits the day before they are due can be a heart stopping day.

This laminated poster hangs in the Jacksonville Family Medicine Residency Program (JFMRP) conference room. It has the major due dates of our most popular conferences, updated with a dry erase marker every year as dates are announced.

Research Conferences

Conference	Abstract Date	Presentation Date
USAFP		
Portsmouth		
Safety Symposium		
AAFP – Residents and Medical Students		
AAFP – Scientific Assembly		
Florida Med Society		
Duval County Medical Society Meeting		



Tracking individual projects

One way to help your fellow residents complete scholarly activity through publication is by setting goals. To that end, you need to help with due dates and keep track of who has done what. This can be best done with a spreadsheet; I also used a dry erase board placed conveniently outside the department head’s office. Residents place a check mark next to each step they complete. Never underestimate the enjoyment of checking something off a list – especially on a highly visible medium.

Friendly competition

One of the ways to help your colleagues go above and beyond is to post who the champions are at any given moment. We adopted a point system from Seehusen et al. and use it to foster a friendly competitive spirit.² One resident – determined to set the bar – accumulated 153 points in her effort to top the previous leader’s 120 point score. (Note that 10 points = graduation!)

I created a large laminated poster with places for each year and the top three residents overall. Below is an example of my poster. They can be made at most office stores for a relatively small amount of money and has a big impact when placed where residents will see it on a daily basis. The graduating resident at JFMRP with the most points is given a research award at graduation.

Number of points awarded for scholarly activity

Completion of an IRB approved research project or a publishable well-conducted process improvement project journal	10
Acceptance of a manuscript describing a case report, clinical review or research project in a peer reviewed medical journal	8
Acceptance for publication of an FPIN Clinical Inquiry	7
Submission, acceptance and presentation of a podium or poster presentation at a regional, national or international medical conference for a case report or original research	6
Acceptance for publication of an FPIN Help Desk Answer or EMedRef	5
Submission without acceptance of a manuscript describing a case report, clinical review or research project in a peer reviewed medical journal	5
Acceptance for publication of a letter to the editor in a peer-reviewed journal	3
Being recognized at a local, regional, national or international conference	3
Publications for lay public such as newspaper or magazine articles on medical topics	2
Presentation of scholarly activity at the JFMRP Annual Academic Scholarship Day	2
Presentation of a Grand Rounds/TIMM conference to the hospital staff	1
Submission without acceptance of a presentation at a regional, national or international conference	1
Presentation of case at Tumor Board	1
Completion of CITI /IRB training	1

Scholarly activity points system adapted from Seehusen et al's



RESEARCH POINT LEADERS!





R3

1
2
3
4
5

R2

1
2
3
4
5

R1

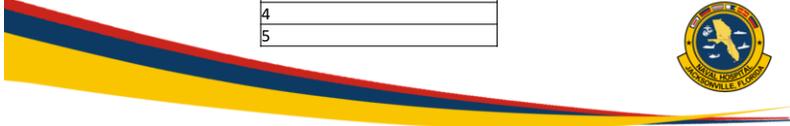
1
2
3
4
5

Number 1#

Number 2#

Number 3#





The Leaderboard

Keeping “How To” guides in easy reach

Make easy “how to” guides for things you want to help your residents do. Remember that when a person is tired, trouble finding a website can make them drop something back to the bottom of their “to do” pile. Some of the ones I have made are included with this book, but there are many more to be made for an individual hospital or program. Whenever I wanted residents to submit their research for a particular competition I would make a “how to” guide for that competition. This would include the website name, how to apply, problems associated with the application process, and the due date for the application. I would stick one version on my office door and leave easy to reach copies in a folder next to it. This was very effective and people started saying “I don’t know, go look at Anna’s door.”

Before you start

Anyone wishing to participate in ANY research with human subjects (even survey studies) must obtain their Collaborative Institutional Training Initiative (CITI) certification (or equivalent) and be up to date on their Health Insurance Portability and Accountability Act (HIPAA) training.

CITI certification can be done through a free online course (www.citiprogram.org) that teaches learners about the ethical responsibilities of human subject researchers. Each institution sets its own level of certification required to be a primary investigator – make a how-to guide to get your people there. EVERY MEMBER of a team working on a project must have certification in order for the Institutional Review Board (IRB) to approve the project. At JFMRP we followed Seehusen et al’s practice of awarding 1 scholarly activity point for completing CITI training. It is also very useful to keep a paper and electronic copy of all CITI certificates.

HIPAA training is institution specific. If you haven’t already done HIPAA training, ask your Program Director for your institution’s policy. A HIPAA overview and details can be found on HHS.gov (www.hhs.gov/hipaa/for-professionals/training/index.html).

Creating a Research Symposium

It may be difficult to find local and regional conferences to accept scholarship for all of the residents in your program. Don’t let your residents get discouraged. We started a resident research symposium where cases were printed out on posters and judged by the faculty. This helped residents and faculty to become familiar with common judging criteria, and helped residents practice presentations before giving them at regional and national conferences. It was later made into a competition, which the residents praised highly. The goal is to help every resident learn how to find, create, and present research. Some programs make presentation a graduation requirement and give scholarly activity points for presentation. You can also raise the stakes a little and increase everyone’s pride by inviting outside experts to help judge projects. It is all about FEASIBILITY. Make scholarly activity and research fun, applicable, and feasible, and you will change the culture of your residency.

Directions for Starting CITI:

Go to: www.citiprogram.org

1. “**Welcome**” screen: Click on “New Users Register Here” (it is in red and underlined)
2. “**Select Your Institution or organization**” screen:

Participating Institutions: From the drop-down menu select “Department of the Navy”
3. Complete the next two sections “Select User Name and Password” and “Enter your email address”, then Submit.
4. Continue registration on new screen:
 - Complete all the required information – marked with *
 - For “**Your Command**,” select the Navy Command where you are currently stationed.
 - If you do not belong to a Navy Command, select “DON Extramural Performers”.
 - Complete remaining fields and Click on ‘Submit’
5. “**Select Curriculum**” screen and answer the questions that apply.
 - There are multiple screens that will lead you to describe your involvement. Select the best one. If later you change your mind, you may go back through these screens and change your answers (use the browser Back arrow.)
 - To the question, “are you required to complete the CITI Good Clinical Practice course for the Department of the Navy?” Select, “No, not at this time.”
 - To the question, “Are you required to complete the CITI Responsible Conduct of Research (RCR) for the Department of the Navy?” Select, “No, not at this time.”
6. **Main Menu**

When you have completed the series of analytical questions, you will be taken to the Main Menu where you can review your enrollment. On this screen is a very good guide to taking the training. Please open and read “View the Department of the Navy instructions page”.

Under **My Courses** you may **begin your training**. You will be able to take the training in multiple sessions so you don’t have to block out large amounts of time.
7. Upon completion **print your certificate** and give a copy to Dr. Rutherford.

Guide to getting a CITI certificate; this was for JFMRP, so includes Command information – your institution will be pre-programmed for what is needed

Submitting for publication

As the resident research coordinator, people will come to you prior to publication or attempting to get things published. Tips to avoid common pitfalls:

- Please WARN THEM that a person can submit to only ONE journal at a time. When an article is submitted for publication, the submitter signs away their copyright for the duration of that review process.
- Stand by with warm tea, coffee, chocolate etc. when that resident receives their response letter – it is important to let them know that rejection is common and there is no such thing as a paper that gets accepted without edits/changes requested by the editor.
- Please also ALWAYS CHECK THE CITATIONS prior to submission.
- Some of the more common reasons for a journal to reject a work include formatting errors, too many words, and poor citations/mismatched citations. It is easy for these to be messed up during the research project and they should always be check just prior to submission.

Summary Points:

- ❖ A resident research coordinator is a resident with a passion for research who is willing to be an advocate and facilitator of research for their fellow residents.
- ❖ Following the abstracts and due dates for major conferences and keeping them easily visible will help your tired colleagues remember to turn their projects in.
- ❖ Creating a sense of competition by keeping track of the research points acquired by different residents can help inspire people to go above and beyond the minimum required research at your program.
- ❖ Determining obstacles in the pathway of research and making simple, easy to read recipes/guides to help overcome them can increase research productivity and output.

Resources and reference

- 1) 2013 USAFP Research Competition “Call for Papers Kit”
- 2) Seehusen DA, Asplund CA, Friedman M. A Point System for Resident Scholarly Activity. *Fam Med.* 2009; 41(7):467-469
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How to make a Resident Research Coordinator

For this recipe you will need:

❖ *An individual with an interest in research and a desire to teach others.*

Step 0: Make sure your Program Director is fully supportive, and that she and you agree on funding constraints for project development including poster printing and conference attendance.

Step 1: Develop the position of resident research coordinator. This individual should have a strong interest in research and helping others. A background in research is helpful, but not required. Motivation and perseverance are essential, as is a commitment from your program director to support this position.

Step 2: YAY! You're the research coordinator. Now that you have been elected (or voluntold ;)) into this position where do you begin? Start by evaluating the current research support/network that your residency has in place. (For example; do you have a medical librarian? A faculty research coordinator? Does your program have research or scholarly activity requirements beyond Accreditation Council for Graduate Medical Education (ACGME) requirements?)

Step 3: Place all the research resources in a readily available place and advertise its location. (Ask yourself what the common questions are going to be and make the answers easy to find. This author had them taped to her door with copies in folders right next to them.)

Step 4: Ask your faculty what some of the major conferences are for your specialty and determine which ones allow presentation of research (particularly those with a resident research category).

It is all in the ADVERTISING! Find a public way to announce these upcoming conferences/events and research teaching. Never underestimate the power of telling a fellow resident they can get time away from residency to go to Las Vegas to present their work ;).

Step 5: Start a competition! People love to compete. Try to make the award something official/snazzy sounding that can be placed on a CV.

Step 6: As conferences and competitions come up, make easy guides for people to follow that make submission easier. Feel free to shamelessly model it after these recipe sheets. Get creative and don't be discouraged – it may take several attempts before you get the right method of promotion for your program.

Chapter 3. A literature search/review

Robert Lennon, MD, JD, FAAFP

“Searching is half the fun: life is much more manageable when thought of as a scavenger hunt as opposed to a surprise party.” – Jimmy Buffett

Objective: To teach a practical way of doing literature searches that will allow the learner to obtain a sufficient, as defined by at least four, resources to begin formulating a research idea and to outline current resources available to further aid their search.

When in doubt, ask your medical librarian for help.

What is a literature search? A methodical search for all of the literature published on a topic.

Why do a literature search? Literature published on your topic will identify how others approached it and what they found. This information is valuable for several reasons.

- What has been done can guide how you build your research plan, from sample size to how results are defined or measured. Even if your study has already been done, it may still be worth repeating. Expanding the breadth (more end points) or depth (larger sample) of your original plan might take it from simple reproduction (less likely to get published) to advancing the knowledge base (more likely to get published.) Using terms as commonly defined in the literature makes your work more accessible, hence, more likely to get published (see MeSH, *infra*).
- Many authors will end their conclusions with recommendations for future research – which can give insight into questions about your topic that your community wants answered, and may lead you to modify your project to include them.
- The search results are also a list of journals that are interested in your topic, hence more likely to publish your work.
- Authors that have published on your topic can make ideal co-investigators and also be identified as potential reviewers.

What is a source of information?

A primary source provides direct evidence; in medicine typically results of direct observation or experiment outcomes. Citations in a published work should almost always be from a primary source. A secondary source is that which discusses or evaluates someone else’s primary source. These can give insight into how other research has been critiqued, and sometimes give a very

good overview of a topic. If you are explicitly referencing the analysis a secondary source is an appropriate reference. If there is data in a secondary source that you wish to reference, follow that source's references to the primary source; make sure that source actually says what it was reported to have said, and reference the primary source.

Where to search for sources?

There are many specialty-specific databases; the (not exhaustive) list below includes some of the more commonly used general databases.

Google (<http://scholar.google.com/>) The (giant) new kid on the block. Google's search engine includes many peer-reviewed journals across many disciplines, but not every publisher allows their content to be searched in this way. This should not be your only search, but can be useful in getting started, broadening a search for very rare things, and for identifying non-medical disciplines that may have published on your topic.

PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>) A data base that includes the MEDLINE database (MEDLINE is the U.S. National Library of Medicine (NLM) premier bibliographic database), life science journals and online books. It has easy-to-use tutorials (<https://learn.nlm.nih.gov/rest/training-packets/T0042010P.html>).

The Cochrane Library (<http://www.thecochranelibrary.com>) A database of systematic reviews; considered very strong for finding evidence-based clinical practice recommendations.

EMBASE (<https://www.elsevier.com/solutions/embase-biomedical-research>) A biomedical literature database; considered very strong in pharmacology, drug research and toxicology.

Trip! (<https://www.tripdatabase.com/>) A clinical search engine that uses a ranking algorithm to search a limited number of "highest quality" sources.

Ovid (<http://www.ovid.com/site/index.jsp>) A commercial publisher and vendor of various research databases – used by many University systems.

What are keywords and MeSH?

These are the language of searching. Keywords represent a primary concept. These can be generated from your research question. For example, if my research question is, "Is there a difference in glycemic control between intravenous detemir and glargine in the elderly," keywords might include: "glycemic control", "detemir", and "glargine." For this question, there are several implied keywords that might be useful, like "diabetes management" or "hyperglycemic management." Keep in mind synonyms (e.g. "old person", "geriatric", "geriatric

patient” are all synonyms of “elderly”), and acronyms (e.g. “DM2”, “T2D” are acronyms of type two diabetes.)

Medical Subject Headings (MeSH) (<https://www.nlm.nih.gov/mesh/>) are hierarchically-organized terms used by PubMed and other U.S. National Library of Medicine databases. These make searches easier, and help ensure common terminology for a given issue. You may be asked to provide MeSH identifiers (or just keywords) for your article; these should be similar to terms used by published articles on your topic. That makes sure people searching your topic will find your publication. The MeSH website has useful tutorials on how to use MeSH for better results. Many authors will also clearly describe their literature search by including MeSH used in their searches.

How do I search?

See the step-by-step guide at the end of this chapter – it’s that easy and there’s no need to duplicate it.

How do I expand the search?

Sometimes a search will yield zero or few results. If zero results, make sure you are not using operators (like “and”); these are great filters, but decrease results. You can also repeat your search in a broader database, ultimately simply searching the internet using Google. Returns on these searches may give you other, more search-friendly terms to describe your topic. They may also identify authors or speakers who are considered experts on the topic. A PubMed Author Search of those persons may identify articles on your topic.

If the search yields at least one but not enough results, enter more terms related to your topic, make sure you are using terms from the MeSH library, and enter synonyms for your topic. You may also find more searchable terms by reading articles cited in the results you do get. If using PubMed, click the “Similar Articles” link.

How do I contract the search?

Sometimes a search will yield too many results to be useful. In this case, replace general terms with specific ones (e.g. “diabetes mellitus type 2” instead of “hyperglycemia”). You can also simply add more terms to your search, or add operators like “and” to your search. Using an operator limits search results to those articles that meet all the criteria you define (e.g. [“diabetes mellitus type 2” AND detemir AND glargine AND management] requires each of those elements and will yield fewer results than “diabetes.”) Search engines have other operators that can require two words next to each other or within a certain number of words from each other, an exact phrase, or specific terms in different parts of an article.

Abstract vs article

Often the abstract is presented, but the full article is retained by the original publisher. You must read the entire article before citing the publication as a reference! Your institution's medical librarian will have access to the full work; just send her an email with the citation and ask for a copy. You may also be able to access the article for free through the journal's web page or through a university library account you may have access to through your university or medical school. You can also limit your searches to those with "free full text" available (can be useful for getting started but by itself is **NOT** an adequate literature search.)

Citations

Identify the style of references used by your preferred journal of publication. Keep detailed, accurate citations in that format as you search. It is useful to record all authors even if your preferred publication limits the number of authors to list. Although you will have to go back and remove some when you submit, this prevents a lot of re-work in the event you ultimately submit to a journal that requires all authors to be listed.

Keep copies of each paper you may use. This is particularly useful when a reviewer requests further information about a citation or challenges the work cited.

Keep an electronic worksheet of outcomes you are interested in with the citation. When you are done writing your paper, cut and paste the citations into your reference section as you cite them.

Summary Points:

- ❖ A literature search is a methodical search for all the literature published on a topic.
- ❖ Medical databases have different strengths and weaknesses; choosing the best suited will make for a better search.
- ❖ Describing a topic in MeSH terms makes a literature search easier; publishing work using MeSH terms makes it more accessible.
- ❖ Search results can be expanded, modified, and filtered to ensure a usable amount of relevant search results.
- ❖ Tracking key points from each article with that articles' proper citation will help organize concepts and limit the need to re-read articles.
- ❖ When in doubt – ASK YOUR MEDICAL LIBRARIAN!

References

All web sites accessible as of July 2017

[https://www.ncbi.nlm.nih.gov/books/NBK3827/#pubmedhelp.How do I search PubMed](https://www.ncbi.nlm.nih.gov/books/NBK3827/#pubmedhelp.How_do_I_search_PubMed)

<https://www.nlm.nih.gov/mesh/>

<https://www.tripdatabase.com/>

<https://www.elsevier.com/solutions/embase-biomedical-research>

<http://www.thecochranelibrary.com>

<http://www.ncbi.nlm.nih.gov/pubmed>

<http://scholar.google.com/>

How to perform a Literature Search – Using PubMed

For this recipe you will need:

- ❖ *Access to a computer with internet capabilities*
- ❖ *A subject that you wish to know more about or a scholarly question*
- ❖ *An email address*
- ❖ *The location of the nearest medical librarian to whom you may have access*

Step 1: Identify the key concepts for your search.

Example: What role does pain have in sleep disorders?

The key concepts are:

1. Pain
2. Sleep Disorders

Step 2: Go to: <https://www.ncbi.nlm.nih.gov/pubmed/>

Step 3: Enter the terms (or key concepts) in the search box.

Step 4: Look at the suggestions that display as you type your search terms. Is it what you are looking for? You may be able to click one to give you a better search.

Step 5: Click “Search”.

Step 6: Select “Filters” on the left hand side of page

Examples: 5 years, Human, English (There are many filters available. These can be used as tools to narrow your search results.)

Step 7: Select articles you want by clicking in box next to article title.

Step 8: Click on “Send to” (upper right corner of page).

Step 9: Select “Clipboard”, then “Add to Clipboard” (This enables you to run other searches on the same topic and add selected titles to the Clipboard- before saving to your email. (The clipboard only holds items for 12 hours so you need to send them to your email when you finish so you don’t lose them).

Step 10: When finished searching your topic, click on “Clipboard” (upper right corner of page).

Step 11: Click on “Send to” (just to left of Clipboard).

Step 12: Select “Email”; click on “Number to send” and make sure the number is higher than the number of titles you selected; type in your email address and enter a subject title in Subject box. (If you register as a user on PubMed you also have the option of sending to a “collection” for personal use.)

Step 13: Check your email for your search.

Step 14: Keep detailed records of all your searches so that you can reproduce them.

** Note: this is a very basic recipe using PubMed to get started. Work with your medical librarian to develop how-to guides for other databases.

Chapter 4. A Case Report

Dean Seehusen, MD, MPH

“To study the phenomena of disease without books is to sail an uncharted sea, while to study books without patients is not to go to sea at all.” – Sir William Osler

Objective: To outline a straight forward method by which a learner may adapt, write and work to obtain publication of a case report in 3 to 6 months.

Why write a case report?

There are many potential reasons why one might write a case report. Educating your peers is the most obvious. Case reports are an excellent mechanism to bring a novel clinical experience to the attention of a wider audience¹. It is through them that many important clinical entities come to be recognized². When Meyer and Lundberg published *Fifty-one Landmark Articles in Medicine*, 5 of the 51 pieces of literature they identified were case reports³. Published experience with a difficult scenario or rare complication may serve as a guide for future clinicians facing similar circumstances. Lastly, case reports are a great way to break into the medical literature serving as an important addition to your professional resume.

What makes a case report?

Case reports are not always, in fact are not usually, the very first described case of a new disease. We have all heard the adage that a case report is “a rare presentation of a common disease or a common presentation of a rare disease”. But this definition is too narrow.

The use of a novel therapy for an old disease, or a previously unpublished complication for a common therapy would also constitute a case report. A case report could focus on a new technique for performing a procedure or performance of a procedure for new indication. Cases that prove to be exceptions to clinical “rules” or that defy currently accepted theory would certainly qualify as case reports. An unusual combination of diseases in the same patient would also make a good case report because they may represent a common underlying pathway.

While some case reports are a record of rare events that could never be studied, some good case reports suggest a scholarly question amenable to inquiry. The most important case reports suggest either a change in practice, or a best practice, related to a particular medical condition.

What should I do if I think I have a case report?

If you are faced with a clinical scenario that may qualify as a case report, there are several important steps you should take. First, obtain permission from the patient to write the case up. Most patients, if they understand that the purpose is to advance the science of medicine, will be willing participants. Obtain a written consent from the patient – your institution will have a

standard consent form; many medical journals and conferences require these to even submit case reports. In the event of a patient's death, the next of kin can sign the consent form.

Second, it is important to make sure that your diagnosis is correct. Any alternative diagnoses should be explored in detail. This may mean doing a few additional tests in order to more definitively establish your diagnosis. This is acceptable within limits. However, it would be unethical to perform additional expensive or invasive tests just to make your case report stronger. For similar reasons, your history and physical examination should be even more thorough than usual. Obtain a good contact number in case additional information is needed later. Editors or reviewers may ask questions that you had not considered.

Third, perform a literature search (see chapter 3) to confirm that the scenario is as unique as you think it is. The search should be thorough but focused. Keep a detailed record of the exact search strategy you use so you can recreate it later and print it if desired by the journal. Next, combining the facts of your case with the literature review, formulate a hypothesis about the case. Determine what you think is the cause of the clinical scenario or how it adds to medical science. This hypothesis is the ultimate reason you feel the case warrants publication. Continue to refine this hypothesis until it is as simple and clear as possible.

Lastly, pick the journal to which you want to submit the case report. The best way to do this is to browse through a few back issues of candidate journals. Read the instructions for authors for guidance on the types of cases the journal is likely to publish. Look at case reports they have published recently and determine if you can envision your case among them. Your program director and your institution's medical librarian will also help find suitable journals. The table below lists several journals that frequently publish case reports.

Journals that frequently publish case reports:	
Archives of Dermatology	Clinical Geriatrics
Journal of Infectious Diseases	American Journal of Medicine
Medical Journal of Australia	Postgraduate Medical Journal
Southern Medical Journal	Family Practice
Journal of the American Board of Family Medicine	Military Medicine
American Journal of Obstetrics and Gynecology	Obstetrics and Gynecology
Journal of Abnormal Psychology	Mayo Clinic Proceedings
Journal of the American Osteopathic Association	Annals of Pharmacotherapy

The most difficult part of writing up a case report, or any type of medical literature, is getting started. Getting the first word on the page can be incredibly difficult for most people. I call this phenomenon “the inertia of the blank page”. Once this inertia is overcome, the rest of the manuscript will likely follow easily. Therefore, when writing the first draft, don’t worry much about grammar, punctuation or spelling. Just get your ideas on the page. There will be plenty of time to do revisions.

Make a timetable for completing your manuscript. Determine some landmarks along the way to publication such as “first draft written”, “first revision done”, “final draft done”, “submitted to journal” and assign deadlines to them. Backwards planning works well for this. These deadlines will serve as motivation to complete that step. For most case reports, it is reasonable to expect 3 to 6 months until you can submit your manuscript although this will depend on many factors including the complexity of the case and how busy you are with other responsibilities.

An outline is an extremely helpful tool for completing a case report. I use an outline modified from McCarthy and Reilly⁴. Filling out this worksheet will insure that you have addressed the important aspects of the case. It also serves as a complete but concise outline for writing your manuscript. By the time you turn the bullets on the worksheet into sentence and paragraph form, you will have a well-organized, nearly complete manuscript.

CASE REPORT WORKSHEET

Title _____

Abstract

Clinical question or problem _____

Analysis of literature review _____

Summary _____

(Continued next page)

(Case Report Worksheet, Continued)

Case history

Description of patient _____

History of presenting condition _____

Physical Exam _____

Relevant lab/X-ray/other tests _____

Initial diagnosis and treatment _____

Case outcome _____

Literature search

Search engine _____

Search strategy _____

Results of search _____

Discussion

Relevant literature _____

Relationship of this case to literature _____

Hypothesis _____

Diagnostic process/course of illness _____

Outcomes _____

Significance of case _____

Conclusion

Lessons learned _____

Recommendations _____

Areas of future research _____

References _____

When you compose your title, try to use MeSH terms so that your case report is more easily found using search engines like MEDLINE⁵. Some journals will request an introduction rather than an abstract. If given your choice, however, an abstract is preferable. Abstracts are included in a MEDLINE reference while introductions are not. Having the abstract available increases the chances others will read your work. Focus on pertinent positives and negatives when writing the case history and only include significant laboratory and radiographic data⁶. Always document what therapy was initiated and what the outcome of the case was. Cohen has published a terrific list of considerations if your case describes a new medication interaction or side effect.⁷

It is best to include your exact search strategy in the manuscript so that editors, reviewers and readers can reproduce it if they wish. Avoid doing a comprehensive literature review in the discussion phase. Only describe how the case fits into the existing medical literature or changes how we should think about a condition. In describing your hypothesis about the case, be brief and clear. Your conclusion should focus on lessons learned. You may also choose to make recommendations to clinicians who see similar cases or suggest areas of future research. Never conclude with “every physician should be aware of this condition”. That is a tempting, but unrealistic, conclusion for a unique case.

Expect that you will have to perform at least 3 or 4 revisions. Between revisions, put the manuscript aside and don't think about it for at least 48 hours. After, you will read your work with a fresh set of eyes and be able to identify areas needing improvement that you previously missed. Focus on repeated phrases and making sentences more concise. It is also important to find one or two independent peers to review the manuscript. It is important that these reviewers are honest and willing to provide constructive feedback. Reread the instructions for authors to insure you have conformed to the journal's standards, including word count, before you submit the manuscript.

Statistically speaking, it is not unusual to have even good case reports rejected by the first journal you send it to. If you get rejected, simply pick another journal. Use any feedback you get to improve your product and resubmit after reformatting to meet the new journal's standards.⁸

Summary

Family physicians are uniquely positioned to find case reports because of their breadth of knowledge and the high volume of patient they see. Published case reports are valuable additions to the medical literature and are excellent career development tools. Using the worksheet provided in figure 1, a case report can easily be ready for submission within a few months.

Summary Points:

- ❖ Case reports are an excellent mechanism to inform a wider audience about a clinical experience, aid in the identification of new clinical identities, and break into publishing in the medical literature.
- ❖ The definition of a case report is broad and includes cases that suggest a change in practice, a best practice for a particular medical condition, a previously unpublished complication of a common therapy, a rare presentation of a common disease or a common presentation of a rare disease.
- ❖ When writing a case report realize that your first draft is just that, a draft, and just get started writing (worry about grammar, punctuation and spelling later).
- ❖ Your presentation of the case should be brief and clear, and your conclusion should focus on lessons learned.

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How to make a Case Report

For this recipe you will need;

- ❖ *A Case (this can be defined in many ways)*
- ❖ *A journal you wish to publish in or a conference you wish to attend*
- ❖ *The directions for a case report from the location to which you wish to submit it*

Step 1: Find a clinical case that shows a novel therapy for an old disease, a previously unpublished complication of a common therapy, an exception to a clinical rule, an unusual combination of disease, or something that will inspire a scholarly question or clinical inquiry.

Step 2: Obtain formal consent (your hospital or the journal/conference will have a form) from the patient

Step 3: Confirm that your diagnosis is correct

Step 4: Perform a literature search to confirm that it is unique. A medical librarian can be very helpful here. A basic search is outlined in chapter 3.

Step 5: Pick where you want to publish or present

Step 6: Write it up. Look up the guidelines specific to your venue. Common requirements are listed below. For a specific examples, look at the Journal of the American Medical Association's Clinical Challenge guidelines at: <https://jamanetwork.com/journals/jama/pages/instructions-for-authors/#SecClinicalChallenge>, or the British Medical Journal's instructions for case report authors at: <http://casereports.bmj.com/site/about/guidelines.xhtml>.

- 1. Introduction/Objective** - This is your HOOK. You need to get them interested, snare their attention. SELL IT.
- 2. Case Presentation** - This is your HPI. It is where you are going to have the most trouble with your 300 word count. This is where you put data that makes your case stand out.
- 3. Discussion** – This is where you prove that you have done a literature search and explain why your case adds to our current research or stands out from it.
- 4. Scholarly Question** – “What question(s) does our case report raise?” For example, what future research questions, policy questions, ethical questions etc. are raised by your case? When this section is required you need to have at least one question.
- 5. Conclusion** - What are the implications of your case? It is best to avoid concepts like “increasing physician’s knowledge.” Show how this may change patient care, change how you practice, change how you look for an illness etc.

Chapter 5. A Photo Quiz

Robert Lennon, MD, JD, FAAFP

“Use a picture. It’s worth a thousand words.” – Arthur Brisbane

Objective: To teach the learner the definition, common pitfalls, development, and writing of a photo quiz allowing them to efficiently create their own using examples and overlays provided.

Objective

This chapter is designed to be used while you are writing a Photo Quiz. Prepare a case with a thorough history and physical, a detailed analysis with a differential of four to five possible diagnoses, a list of references that allow you to parse the differential, and your picture(s). Cut and paste the sample Photo Quiz at the end of this chapter and type over it with your case. You'll have a solid first draft in short order.

Common pitfalls

Before you start, make sure you have your patient's (or patient’s guardian's) written permission to use their case and image. Your hospital will have a specific form for this; most journals have a sample consent that is universally acceptable. (American Family Physician’s consent form can be found at: <http://www.aafp.org/dam/AAFP/documents/journals/afp/PQpatientconsent.pdf>.) Your institution may also have specific requirements about how your image is collected; with permission you can always use an image the patient took of themselves. (Patient's always have the right to take and maintain their own medical imaging and records.) Most institutions will have a research office or public affairs office that can help you navigate these requirements.

Creating a Photo Quiz

A Photo Quiz is a case-based tool for educating on a clinical topic. It often involves dermatology because skin makes a good canvas, but good images can also be found in ophthalmology, radiology (X-rays, CTs, MRIs, sonograms), pathology and electrocardiograms. This chapter is geared towards the Photo Quiz published by American Family Physician (AFP). (See: http://www.aafp.org/journals/afp/authors/guide/departments.html?cmpid=_van_640). AFP emphasizes educating on common clinical topics. Other journals are more open to esoteric presentations. There are numerous venues for publishing your Photo Quiz; tweak the format based on the author guide for the journal to which you are submitting.

A photo quiz has many elements in common with a case report or a poster. This makes it easy to turn a case report into a photo quiz and then a poster. They are both visually appealing versions of a case presentation. (See the Poster version of the sample Photo Quiz at the end of this chapter.)

Photo Quiz	Case Report	Poster
Title	Title	Title
Authors	Authors	Authors
History of present illness	Introduction	Introduction
Question	Case Report	Case Report
Discussion	Discussion	Images
Summary Table	Conclusion	Discussion
References	References	References

What makes a good Photo Quiz? A case that is interesting and educational. Your case is good if it accomplishes one or more of the following:

- Changes the course of medical science
- Illustrates a new principle, or offers a particularly good illustration of an established principle
- Supports or refutes a current theory
- Presents a previously misunderstood condition or response
- Identifies an unreported adverse response to drug therapies
- Shows an unrecognized cause-and-effect disease presentation
- Had a significant impact on the patient, physician or both
- Caused you to re-evaluate how you care for patients
- Suggests opportunities for patient education
- Presents as an unusual series of events that caused confusion or treatment dilemmas
- Is a new observation of the impact of one disease on another
- Shows an unexpected outcome of the treatment of one condition on a different condition

Title and author

An ideal Title hints at, but does not give away, the answer. This is your hook - a catchy title will get people to start reading. Don't spend more than five minutes on this at first; your title will likely evolve as you write, and journal editors may offer suggestions.

Always check the journal for specific authorship details. AFP, for example, never allows medical students or residents to be first author. Always define the author order, work expected, and timeline for all participants before you start. The first author is generally the one who does the most work; the last author is generally the senior / overseeing participant.

History of present illness

This is a very brief history. You do not need a formal introduction. Think of this as a concise but informative expert consultation -- ten sentences or less. The work here is to cut the chaff from your detailed history. Cut anything that does not directly impact your question and answers below. If you are having trouble here, whittle this section as much as you can in fifteen minutes, and then re-visit it after you complete your Question and Discussion. Because the Question and Discussion narrow your focus, once they are complete it is usually obvious what parts of your History are not needed. Reference your Images here.

Images

One to four pictures. High quality images that catch the reader's eye and help them answer the Question. The Title is your hook, the pictures set it. Many journals give guidance on resolution requirements and formatting. AFP recommends 300 ppi. Poor picture = poor chance of acceptance. AFP requires original images. Other journals, very rarely, may allow a previously published picture. You must obtain written permission first from the copyright holder of the picture and from the journal editor.

Taking multiple pictures up front from different angles and distances increases your chance of getting the "right" image. Putting an object for size reference (i.e. a penny or ruler) improves the appeal of your image. If at all possible, avoid faces or other identifying features; although a properly executed consent may still allow publication, editors are sensitive to minimizing patient information exposure.

The question

This is your differential diagnosis in multiple choice format. The Question is often about the diagnosis, but can be anything that gets at the crux of the case -- what therapeutic choice, what diagnostic test, what you would expect the pathology to show. The answer choices should represent a good, but not exhaustive, differential. Typically there will be one correct answer and three or four incorrect answers. Incorrect choices should be challenging but not impossible, and can be grouped as a class of answers for brevity. (I.e., in the template below, there is a single choice for thrombocytopenic purpura instead of one choice for idiopathic thrombocytopenic purpura and another for thrombotic thrombocytopenic purpura.) Consider running your proposed question and answers by peers to make sure the question is neither too easy nor too hard.

Discussion

The second page of the Photo Quiz starts with the Discussion. The first paragraph is the correct answer with an explanation. The second paragraph fleshes out the answer, and answers the question, "Why should I care?" Each incorrect answer is then addressed in its own paragraph. This is a brief analysis of each item in your differential. Each answer should have its own

citation, typically of a peer reviewed source that clarifies how to distinguish this choice from the answer. The Discussion of all answer choices makes the Photo Quiz more educational than merely informative. Most journals limit the Discussion to 500 words.

Summary table

This is the conclusion for your Photo Quiz. It is a simple table of how to parse your differential. The Summary Table should be something that a practicing clinician would find useful in a clinical setting. In order to be complete, this sometimes means that your Summary Table will have more bullets than appear in your Discussion. For the most part, however, it is a graphic representation of a condensed discussion. Cut, paste, shorten, done; fifteen minutes, tops.

References

Standard formatting applies. Most venues restrict Photo Quizzes to ten references, which should be more than adequate. PubMed citation is appropriate; some journals want full author lists, some limit the authors in a citation. When researching, keep track of your references with all authors and then modify as needed.

Summary Points:

- ❖ A photo quiz is a case-based tool for education on a clinical topic.
- ❖ A large variety of clinical cases can be used as photo quizzes and include but is not limited to cases that; change the course of medical science, illustrate a new principal, shows an unrecognized cause- and –effect disease presentation, or is a new observation of the impact of one disease on another.
- ❖ The key components of a photo quiz include; Title and author, History of present illness, Question and discussion, Summary table, and References.
- ❖ A photo quiz and a poster presentation share many key elements and can often be adapted to each other.

References

See Photo Quiz specifics for AAFP at:

<http://www.aafp.org/journals/afp/authors/guide/departments.html>

See Photoclinic specifics for PediatricsConsultantLive at:

<http://imaging.ubmmmedica.com/consultantlive/photoclinic/SubmissionGuidelines.pdf>

How to write a Photo Quiz

For this recipe you will need:

- ❖ *A Case (this can be defined in many ways)*
- ❖ *A journal in which you wish to publish*
- ❖ *Patient consent*
- ❖ *The directions for a photo quiz from the location to which you wish to submit*
- ❖ *A high quality, interesting or highly educational photo*

Step 1: Find an interesting case with good physical exam finding and take a picture (or have the patient take a picture and send it to you.)

Step 2: Discuss the use of the picture with the patient. Confirm that they understand it may be seen by many people and obtain their signed consent for the picture. Use the journal's (or your institution's) consent. AFP's consent form can be found at:

<http://www.aafp.org/dam/AAFP/documents/journals/afp/PQpatientconsent.pdf>

Step 3: Get a good history and physical exam on the patient. Make sure it is thorough. (When you actually write the photo quiz the HPI it will be brief, but you want to be able to reference a comprehensive history if asked by your peers.)

Step 4: Create a differential diagnosis for your exam finding. You want to have 3 to 4 good alternatives.

Step 5: Do a literature research for your answers (both correct and incorrect). (See Chapter 3!) Find a good reference for each alternative diagnosis.

Step 6: Write a brief paragraph about each diagnosis (both correct and incorrect.)

Step 7: Create a summary table that includes the conditions (the answer and the other 3 to 4 choices) in one column and the characteristics in the second column.

Step 8: Format your references to the journal's specifications.

Step 9: Format your Photo Quiz to the journal's specifications. (If rejected, reformat to the next journal's specs.) Submit!

Sample Photo Quiz

Spontaneous Hematomas in a 61-Year-Old Woman

John Yosay, MD, LT, MC, USN; Robert Lennon, MD, JD, LT, MC, USN; James Keck, MD, CDR, MC, USN.

Naval Hospital Jacksonville, Jacksonville, Florida

A 61 year old female presented with a one month history of easy bruising, progressing to spontaneous, painful, and diffuse bruises covering approximately 10 percent of her body. The patient had a history of severe depression, migraines, coronary artery disease and two prior episodes of transient ischemic attacks. For these conditions her medications included fiorinal, aspirin, and clopidogrel, all of which she had been taking at the same dose for years, and desvenlafexine, which had recently been added to treat her refractory depression. In addition to prescribed aspirin, the patient endorsed using additional over the counter aspirin (in the form of Goody's Headache Powder) several times per week. The patient denied recent illness, fevers, or other pain.

Physical examination revealed diffuse hematomas (on all aspects of her body including the face, neck and forearms), notable for their size (*Figure 1*). Also remarkable was the rapid development of hematomas in the Emergency Room with minor pressure (*Figure 2*) and spontaneously during evaluation (*Figure 3*).

Question

Based on the patient's presentation, medication history, physical examination and Emergency Department course, which one of the following is the most likely diagnosis?

- A. Physical abuse
- B. Hemophilia
- C. Senile purpura
- D. Iatrogenic coagulopathy
- E. Thrombocytopenic purpura

Discussion

The answer is D: Iatrogenic coagulopathy. Coagulopathy with clopidogrel and aspirin is well described. (1,2) Selective Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) are known to increase bleeding in patients receiving concurrent antiplatelet therapy. (3) A new generation of active metabolite formulations of SNRIs has been developed to reduce side effect profiles and

drug-drug interactions. (4) However, the improved side effect profile of these new formulations may not extend to bleeding risk.

As the prevalence of SNRIs as part of our patients' medication profile is steadily increasing, it is important for primary care physicians to recognize their potential for interaction with anti-platelet therapies, and to closely monitor patients on these medications, especially at times of initiation and dose changes. Treatment remains discontinuation of the pathologic combination.

Physical abuse of the elderly is not uncommon, and can often present with unexplained bruises or welts. (5) Other signs include malnutrition, open sores, dehydration, sudden onset patch-like hair loss, and unexplained fractures. (6) Absence of other signs and spontaneous bruising under observation point away from abuse in this case.

Hemophilia is a generic term that covers a group of hereditary genetic disorders that prevent appropriate coagulation. (7) The spectrum of hemophilia runs from mild – typically only found after surgery or trauma, to severe – often evident at birth. Moderate disease can (rarely) present later in life with spontaneous bleeding, but typically presents with pain in weight bearing joints.

Senile purpura are dark, irregularly shaped hemorrhagic areas due to abnormal skin mobility that tears small blood vessels. (8) Aging causes this through gradual atrophy of perivascular connective tissue, almost exclusively on the extensor surfaces of the hands and arms.

Thrombocytopenic purpura could refer to either the idiopathic (ITP) or thrombotic (TTP) etiology. (9, 10) Both are characterized by thrombocytopenia, but can be clinically anticipated with a history of recent viral exanthema, upper respiratory illness, malignancy, and antiplatelet drugs. ITP is rare in adults, and TTP typically presents with other clinical signs to include neurologic findings, decreased renal function and fever. Diagnosis can be excluded with normal platelet count, but absence of supporting clinical evidence prevents delay in alternative diagnosis.

Address correspondence to James Keck, MD, at James.keck@med.navy.mil. Reprints are not available from the authors.

Author Disclosure: Nothing to disclose. The views of this article are those of the authors and do not necessarily reflect the views or policy of the Department of the Navy, the Department of Defense, the United States Government, or Naval Hospital Jacksonville.

Summary Table

<i>Condition</i>	<i>Characteristics</i>
Physical abuse	Unexplained bruises, particularly in combination with one or more of the following: malnutrition, open sores, dehydration, patch-like hair loss and unexplained fractures.
Hemophilia	Onset typically at birth or after surgery or trauma, in moderate cases the presenting symptom is typically pain in weight bearing joints.
Senile Purpura	Typically limited to extensor surfaces of hands and arms.
Iatrogenic coagulopathy	Can present on achieving therapeutic dosage of any standard anti-platelet therapy. Over time presents more commonly with changes in dose or addition of interactive medications. SNRIs and their newer metabolite formulations increase risk.
Thrombocytopenic Purpura	ITP typically presents in the young after viral illness, TTP typically with one or more other symptoms to include neurologic findings, decreased renal function and fever.

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Photo quiz as a poster

Spontaneous Hematomas Attributable to Interaction Between Clopidogrel and Desvenlafaxine



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Introduction

Desvenlafaxine is marketed as an effective alternative to Venlafaxine for treatment of Major Depressive Disorder (MDD) with fewer drug-drug interactions. We present a case of coagulopathy manifesting with spontaneous, cutaneous hemorrhages secondary to interaction between Desvenlafaxine and Clopidogrel. This case demonstrates that the reported decreased side effect profile of Desvenlafaxine may not extend to bleeding risk.

Case Report

A 61 year old female presented to Naval Hospital Jacksonville with a one month history of easy bruising, progressing to spontaneous, painful, and diffuse hematomas covering approximately 10% of her body. Her medications included Clopidogrel 75mg and Desvenlafaxine 100mg once daily, as well as Fiorinal and Aspirin as needed for headaches. Spontaneous bleeding ceased 24 hours after discontinuing Clopidogrel, Desvenlafaxine, Fiorinal and Aspirin. Given her history of difficult to control MDD and Transient Ischemic Attacks (TIA), therapy with both Desvenlafaxine and Clopidogrel was resumed with strict precautions against Aspirin use. Two days after discharge, patient presented to another local Emergency Department with recurrence of hematomas and new TIA symptoms. After evaluation by staff Hematologist, discontinuation of combination therapy, and subsequent monotherapy with Clopidogrel was recommended. This intervention resulted in resolution of symptoms.

Imagery

Photo 1:

Left Anterior Shoulder



Hematoma that developed over course of 30 minutes between initial evaluation by Family Medicine Intern and subsequent evaluation by Family Medicine Attending Physician.

Photo 2:

Left Ventral Forearm



Ecchymosis that developed as a result of gentle pressure applied to forearm during placement of peripheral intravenous catheter.

Photo 3:

Left Mandible



Ecchymosis noted at presentation to Emergency Department.

Photo 4:

Left Flank



Ecchymosis noted at presentation to Emergency Department.

Discussion

Selective Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) are known to increase the risk of bleeding in patients receiving concurrent anti-platelet therapy. This phenomenon is attributable to decreased platelet serotonin levels, which, combined with standard anti-platelet therapy, can lead to pathologic coagulopathy. Active metabolite formulations of these medications are being developed to reduce side effect profiles and drug-drug interactions. Our case demonstrates that the improved side effect profile of these new formulations may not extend to bleeding risk. Treatment remains discontinuation of the pathologic anti-platelet combination.

Conclusion

The prevalence of serotonin reuptake inhibitors as part of a patient's medication profile is steadily increasing in the United States. Newer SNRI formulations continue to present significant bleeding risks, particularly when combined with anti-platelet therapies. It is important for Primary Care Physicians to recognize the potential for interactions. Patients prescribed serotonin reuptake inhibitor agents and especially patient's in whom combination anti-platelet therapy is initiated warrant regular bleeding risk monitoring in both the acute and long-term setting.

The views expressed in this article are those of the author(s) and do not reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

*Article and poster courtesy of Dr. Lennon

Chapter 6. Poster Presentation

Kyle Hoedebecke, MD, MBA, MPA, MS, FAAFP

“Our work is the presentation of our capabilities.” – Edward Gibbon

Objective: To identify the key components of a successful poster presentation and teach the learner how to set goals for presentation types, locations, and submission categories with emphasis on knowing submission deadlines, unique requirements, and abstract grading criteria allowing the learner to work towards being accepted and successfully presenting at a research conference.

Why should you present at medical conferences?

A manuscript can only be published in a peer-reviewed medical journal once, but it may be presented at numerous conferences, allowing for increased exposure of your work. Furthermore, journals accept only completed works while many conferences allow presentations of “works in progress” (i.e. incomplete or on-going projects). Initially, novice authors may feel more comfortable presenting a single poster together; however, as one becomes more experienced, it has been my experience that attending conferences alone and presenting solo has offered more opportunities to network with other attendees. This also allows for the team as a whole to save money while still getting the desired exposure level. Besides networking opportunities, contacts made at conferences tend to offer novel ideas in reference to your scholarship that were not previously considered. Lastly, presenters may receive further offers to present at other conferences – both national and international – or publication suggestions by influential attendees.

Where to start

Pick a conference from the poster board maintained by your Resident Research Coordinator (see Chapter 2). For first-time presenters, local and regional conferences are great places to start. Those who are more ambitious or more experienced may decide to aim for national or international conferences as they offer the greatest prestige.

Once you have decided where you would like to submit your work, review the abstract format, grading criteria, and preferred submission categories (i.e. by students/residents, unpublished, case reports vs. original research vs. process improvement, multicenter projects) for the specific conference. Standard sections for the abstract include: Background, Methods, Results, and Discussion/Conclusion. Abstract submissions tend to be 100-300 words and do not include graphs, photos, or sources. Review the abstract yourself and have another experienced individual do so as well in order to find any last minute errors or offer final suggestions. Of note, most conferences pick poster presentations based the abstract alone without ever seeing an actual

poster. The conference organization should contact you within weeks to months (depending on the conference) concerning your abstract submission acceptance or denial.

Once accepted, the next step is to create the poster itself. Visit the conference website again and find out the correct poster size. In the US, most locations accept 4 feet wide x 3 feet tall, but international and local conferences may have different dimensions. Standard sections for the poster mirror those of the abstract: Background, Methods, Results (to include graphs and photos), and Discussion/Conclusion. Sometimes separate section for sources and contact information are included as well. Unlike written manuscripts that contain all of the minute details, posters only highlight key points of the scholarly activity. The reader should be able to get a basic understanding of what occurred in your project and why it is important (i.e. why should he/she care?) Similar to PowerPoint ® slides, limit your words and the number of lines used. Too many words makes the poster look cluttered and can be confusing whereas pictures and a title in large font tend to draw people towards your poster. Ensure that attendees can read your information clearly from 3-6 feet away. Another tool to focus the reader is to consider highlighting words, numbers, or figures that you will discuss in any oral presentation in order to better tie your talk to poster. This also serves to focus the reader to the key points in the poster. Do not forget that the poster should augment your presentation. *Don't read off of poster!* Lastly, it is recommended that you bring business cards and 8.5"x11" copies of the poster for your guests.

Where should you print your poster? Luckily, most academic institutions have print shops that will make the poster free of charge. If this is not available, printing shops in the community can be found and multiple locations in most areas. Finally, online stores like Zazzle.com or Shutterfly.com will print and deliver your posters for a reasonable price.

Make sure you understand how you are expected to hang your poster. The two most common methods are push-pins on a board or Velcro. The veteran presenter will often bring a handful of push-pins, 8 2-inch Velcro strips (these are pre-packaged, and have self-adhesive on the backs of each side, allowing you to hang your poster on virtually any flat surface) and a roll of duct tape just to cover all bases.

How to make your poster stand out

With so many posters, how can you make yours stand out among the crowd? Some potential suggestions include:

- Use a central picture/photo and outline that image with the poster's text.
- Use a large singular background photo or watermark. This offers a distinguishable image from a distance, which may perk curiosity and draw them to your poster. Ensure that those who are drawn in by the photo at a distance will still be able to read the poster's text when viewed from a closer distance.

- Place pictures/graphs in middle line with lines near the left and right borders – allowing the reader to focus on the images

- Most posters will have 3-4 columns, with 0-1 images per column. Colors should have good contrast and avoid red and green (15% of people have some degree of red/green color blindness). Up to four references can fit comfortably on most posters; lengthy reference lists take up too much room. If you choose to not list references, have a printed list of references available. Most conferences will have previous winning posters available to reference as this can help choose the style of your poster.

-Wear something different! Uniformed service members such as military, police, etc. can show off their uniform. While at an international conference, you can wear clothing or accessories that represent your country. Additionally presenters can set up additional pieces of “flair” to their presentations by including flags, candy, portable videos, or small “knick-knack” gifts.



*Image courtesy of Dr. Hoedebecke

At the WONCA World Council in Prague, Czech Republic. Notice the great set up by our New Zealand colleagues. Their shirts match their poster. They are also representing their country with the “All Blacks” headbands/wristband, 2 flags above the poster, and the lanyards that they handed out to attendees. All of these things made this presentation one of the most interesting that I have ever seen!

Family Medicine Organizations with Poster Presentations

(NOT all-inclusive)

WONCA (World Organization of Family Doctors)

WONCA Polaris (North American Young Doctors Movement)

American Academy of Family Physicians (AAFP) national and state chapters

Society of Teachers of Family Medicine (STFM)

NAPCRG (North American Primary Care Research Group)

American Osteopathic Association

American College of Sports Medicine

Canadian Family Medicine Forum (FMF)

Summary Points

- ❖ Presenting your scholarly works in poster format allows the learner to have increased networking and exposure to public speaking, new and novel ideas about their research suggested by people who view their work, and additional offers for future presentations allowing the learner to further the dissemination of their ideas.
- ❖ Obtain knowledge about the location, abstract due date, and submission categories well in advance to the conference you wish to attend.
- ❖ Once accepted to a conference, confirm the poster size and dimensions required by that conference.
- ❖ Work to make sure that your poster stands out using methods such as a central picture/photo, background photos, or wearing something a little different.

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How to make a Poster Presentation

For this recipe you will need:

- ❖ *A Case or a scholarly project (this can be defined in many ways)*
- ❖ *A conference at which you wish to present*
- ❖ *The conference's specific directions for presentation*

Step 1: Determine what your institutions poster printing capabilities are. Find out if there is funding set aside for scholarly activity or if you are going to have to pay for your poster yourself. Getting to go to a big conference in a snazzy city can be totally worth it ;), but it is nice to know about the expense ahead of time. (You can usually ask your faculty or resident research coordinator.)

Step 2: Decide the conference at which you wish to present.

Step 3: Go to the official website and download their directions for presentation. Most sites will require a submission of an abstract prior to acceptance for presentation.

Step 4: Read the abstract format and grading criteria. It is VERY important that your abstract match their grading criteria. Many wonderful ideas have been turned down because the directions are not followed.

Step 5: Submit your abstract. The deadlines for abstracts are almost always absolute. Make sure you know the deadline ahead of time. It is usually at least 6 months prior to the time of presentation.

Step 6: Get Accepted. YAY!! Go back to the website and find the poster directions.

Step 7: Determine if your institutions public affairs office has a specific layout that they prefer to be used. In addition to these being a wonderful starting point, they are usually designed by people who have degrees in art and advertising and can be very appealing.

Step 8: Make sure that your poster is going to be printed prior to your presentation. Do not put this off to the last minute! It can cause a great deal of stress that you can easily avoid by doing it early.

Step 9: Present the poster at a conference. Have fun and network!

Sample poster



A Life Saving Near – Drowning

LT Patricia Reichert, DO
Naval Hospital Jacksonville, Florida



BACKGROUND

A near – drowning in an otherwise healthy individual should prompt evaluation of underlying causes.

Causes to consider include head trauma, cervical spine injury, arrhythmia, seizure, basic injury, hypoglycemia, syncope, toxins, suicide or homicide, and marine envenomation.¹

CASE

A 24 year old petty officer was tubing behind a friend's boat, when he suddenly fell off.

Concern started when friends noticed the young male made no effort to swim, nor keep his face out of water. He was cited to be "bobbing" and "spitting water out of his mouth." "looking disoriented." A life vest was keeping him above water. Initial assessment in the water noted a weak, thready pulse and agonal respirations.

He lost his pulse and respirations on the boat ride to shore and CPR was initiated. An AED detected a shockable rhythm; 2 subsequent shocks were delivered. CPR was continued during transport to the ED.

TREATMENT/COURSE

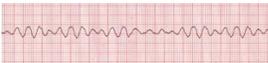
- Upon arrival to the ED the patient was comatose, but breathing spontaneously. Cardiac monitoring revealed atrial flutter
- CT of the head, cervical, thoracic and lumbar spine were unremarkable.
- UDOA and ethanol level were negative for toxins
- A spot glucose was 217
- The patient was intubated for airway protection and admitted to the ICU



- Due to atrial flutter with RVR and hypotension, patient was deemed unstable and a DC cardioversion performed - NSR was restored
- The patient was extubated on day 2
- Neurological assessment revealed no deficits with the exception of persistent amnesia for the event
- An EEG was unremarkable
- The patient was discharged on day 5 with Toprol XL and aspirin

RESULTS/DISCUSSION

- Following discharge, potential neurological and cardiac causes were sought out
- A normal physical exam, EEG and MRI revealed no obvious neurologic cause
- Sudden cardiac arrest was evaluated with a cardiac MRI, ambulatory telemetry, CT angiography, EP interrogation and implantable loop monitoring – all were unremarkable
- Interrogation of the AED at the initial scene reported ventricular fibrillation



- A sudden cardiac arrest genetics panel found the patient heterozygous for congenital polymorphic ventricular tachycardia (CPVT)
- Definitive treatment involved placement of an ICD, and the patient will continue on a beta blocker lifelong

SCHOLARLY QUESTIONS

- When does a cardiology sudden death workup have to be initiated in near drowning?
- Is testing is now indicated for his 3 year old son?

CONCLUSIONS

- The above case seeks to demonstrate although zebras are rare, they are still out there
- In a drowning or near drowning the possibility of head trauma, cervical spine injury, arrhythmia, seizure, basic injury, hypoglycemia, syncope, and toxins should all be evaluated
- For those found to have a cardiac cause for an arrhythmia, ICD placement can be lifesaving

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The views expressed in this poster are those of the authors and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense or the U.S. Government.

*Image courtesy of Dr. Lennon

Chapter 7. A letter to the editor

Chad Asplund, MD

“The art of art, the glory of expression and the sunshine of the light of letters, is simplicity.” – Walt Whitman

Objective: To learn how to define, write and submit a Letter to the Editor with the assistance of a step-by-step checklist for submission.

Introduction

A letter to the editor (LTTE) provides a method of communication between the author (reader) and the editor, as well as the greater medical community as a whole. Letters allow the reader to voice their opinion regarding a previously published article. A letter to the editor may provide new insight, make corrections, offer alternative theories, or request clarification about content printed in the particular journal. For many journals, LTTEs have the highest acceptance rates of any of their submission categories.

Types of Letters to the Editor

1. Identification of an error
2. Provide an alternate theory
3. Offer additional evidence
4. Use the letter as an avenue to provide more information to the readership
5. Provide a counterpoint

Tips from top journals

Length no more than 200-400 words
Submit within 1 month of publication of article
No more than 1 table or figure
No more than 5 references
Make 1 (no more than 2) points
Clarity and brevity are paramount

How to write

Before sitting down to write, it is recommended to read the instructions for authors for the particular journal that you intend to write. Some journals have specific requirements or restrictions, being aware of these limitations in advance will be very helpful. Many journals have a time limit from when the original article appears and when the letter to the editor regarding that article will be accepted.

Brevity is the key – the ability to say a lot with as few words as possible is a skill and is greatly appreciated by editors. Keep your points simple and focused – avoid personal comments. Key points should be backed by references when possible. Opinion not supported by facts is much less likely to be accepted for publication by an editor.

Before submission

Review submission to confirm that your letter meets the content and technical specifications of the journal.

After submission

The editor will screen the letter for essential components: Was the letter submitted in a timely fashion? Does it provide evidence for the statements made? Does it add value – meaningful clarification, enlightenment, or correction to previous publication?

After acceptance

Once you have received an acceptance letter, there is still work to be done. Before the article is published, you will receive page proofs of your letter (a formatted version of how your article will look in the print journal). These proofs may have questions for you to answer, or if your letter has been shortened or edited, may ask if the edits are in the spirit of your original idea. Most journals require a quick (48hr) turn-around time once you receive your page proofs – so it is very important to reply quickly.

If you contradict the original author or provide a different viewpoint, the original author will be given a chance to respond to your letter, which may also require a response.

Conclusion

Letters to the editor have a valuable place in the medical literature, and journals further the field by including select letters in response to recently published papers. A concise, timely letter is a valuable addition to the body of literature.

Checklist for Submission

Content:

- Are the grammar and spelling correct?
- Is the message short and to the point?
- Does the letter focus on a clear purpose?
- Is the purpose clearly stated in the letter's introduction?
- Is the information relevant, accurate, and appropriate?
- Does it contribute to the literature?
- Are points supported by citable evidence (referenced works)?
- Have you ensured there are no disparaging/derogatory comments?
- Did you avoid repeating the original article?
- Have you checked to make sure your letter does not duplicate previous letters?
- Have you had a colleague or mentor review?

Technical:

- Are letter author's names and affiliations correct?
- Have you completed a cover letter that lists conflicts, competing interests, and guarantee that your letter has not been previously published?
- Have you filled out the copyright form?
- Are you submitting within the timeframe required of the journal? Is your letter within word limits for the journal?

*Adapted from Johnson et al

Summary Points

- ❖ A letter to the editor provides a method of communication between the author, editor, and the greater medical community as a whole providing for new insight, corrections, alternative theories, and clarification requests in a particular journal.
- ❖ Before writing a letter to the editor it is advised that the learner looks up the directions provided by that journal for letters to the editor.
- ❖ After your acceptance you receive a proof which you need to look over to review changes by the editor and determine if the final is still in keeping with the original idea.

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*(Adapted from: Johnson C, Green B. Helpful hints: writing effective letters to the editor. *J Manipulative Physiol Ther* 2006; 29: 415-416.)

How to write a Letter to the Editor

For this recipe you will need;

- ❖ *An idea for a letter to an editor*
- ❖ *A journal you wish to publish your letter in*
- ❖ *The directions for a letter to the editor from that journal downloaded from that journals website*

Step 1: Figure out what type of letter to the editor you have: identification of error, alternate theory, additional evidence, counterpoint?

Step 2: Make sure a version of your letter does not already exist. (This is why it is important to address an article very soon after its publication preferably within a month.)

Step 3: Brevity is key! Most Journals want a length no more then 200-400 words, avoid personal comments and back up key points with references when possible (but no more than 5 references.)

Step 4: Check over your letter to make sure you avoided any disparaging or derogatory comments. Remember the journal in which you want to publish your letter chose to publish the article first!

Step 5: Have a colleague review your letter for content. Have a language lover review your paper for spelling, grammar, and language style.

Step 6: Write a cover letter that lists any conflicts or competing interests and assures the publication that this letter has not previously been written.

Step 7: Double check that your letter has followed all the directions for formatting and word count.

Step 8: Fill out the journal's copyright format. There is a special section for your signature if you are a federal employee.

Step 9: Submit!! Make sure your submission is within a month of the article's publication.

Chapter 8. How to write a lay medical article

Job Larson, MD

Objective: To describe the value and process of writing a lay medical article.

Why write a lay medical article?

The primary objective of a lay medical article is to educate patients about common medical conditions or questions. This not only disseminates important information, but ensures that medical information consumed by the public is accurate. Lay medical articles are an ideal opportunity to educate patients about common questions such as what makes a skin lesion concerning or when should someone with a cough be evaluated by a physician? It is also an excellent forum to advocate for effective public health measures.

One of the most effective methods of ensuring understanding of a topic is to teach it. Writing a lay medical article is therefore an effective method of self-education. Presenting the material in a lay fashion helps ensure the physician understands the topic well enough to present it in an accessible way to a patient.

Writing lay medical articles also presents a venue to mentor medical students and residents in the education and scholarly process. A resident collaborating with a medical student to write a lay article is an ideal way to challenge a medical student to take the learning process one step further, help them build their resume, and at the same time introduce the resident to an academic mentorship role.

Before you start

Your institution may have specific requirements for publishing an article. Ask first to avoid disappointment later. The hospital public affairs officer will be the best individual to describe the protocol you will need to follow. Do not look at this as a barrier! The people who occupy a public relations office within your institution have a wealth of experience in getting something published in local news media. Not only will they know good publication venues, they will help with proofreading and formatting.

Pick a preferred venue with back-ups before you start. This allows you to more easily make sure your article matches what their venue wants to publish.

Pick a topic

The first step is to pick a topic. The ideal topic is one that is of interest to the general population. Doctors hear these topics all the time – they are the most common “oh by the way” questions heard during clinic. Other good topics are those in recent news cycles; multiple news segments on a topic demonstrate consumer interest in it. Match your topic to your venue. Consider contacting the editor of your preferred venue to make sure there is interest.

Draft an outline

Once you have your topic, identify 3-5 key points that you want the reader to take away. The scope of a lay medical article must be fairly limited and to the point. This is not an in-depth analysis to be presented to colleagues, but rather a quick, bite sized and easily digestible overview of a topic with answers to common questions. Minimize statistics, equations and other complexity; take to heart an axiom of scientific book writing, “Every equation halves your book sales.”

Once you have your main points mapped out it is time to flesh out your article, to make it interesting, and to draw the reader in.

The Draw and the Hook

There are several ways to draw readers into your article. Graphics and catchy titles are good “draws” to pull the reader’s eye to your article. Color pictures and titles that are a play on words or pose common questions are ideal draws. The “hook” is your first sentence and serves to get the reader sufficiently engaged that they will read the remainder of the article. The hook convinces the reader that the article is important to them. Personal stories about someone in the community make a good hook.

The sample article uses each of these elements – there are color pictures to attract a reader’s eye, and a title that many patients have asked themselves. These draw the reader to start reading. The first sentence points out how important the subject of the article is, hooking the reader to read the entire article.

To increase the value of your article, consider including contact information for support groups for any specific disease mentioned or other local resources relevant to your topic.

Each key point should have its own short paragraph. For longer articles, consider each topic sentence as a fresh hook to keep the reader engaged.

Revision

Second only to facing down the initial blank page, one of the hardest parts of writing an article is revising it. The goal of revision is to ensure that all key points are made, that the article reads smoothly, and that the article is accessible to the reader. Like any self-critique, revision is challenging. To make it easier, seek feedback from others. Ask for simple, direct evaluations – was the article interesting? Was it easy to read? What did you get out of it? Peer review will ensure that your article is factually correct; non-medically trained reviewers can help make sure the article is accessible to lay readers. Similar to handouts that you may use in clinic, or send home with a patient after a hospitalization, your article should be geared to be read at the 8th grade reading level. After years of training in formal presentation this can be challenging for physicians, but it is an imperative part of ensuring your article is accessible. Non-medical reviewers will make sure that the information presented is digestible to a lay audience.

Revision should be a reiterative process of reviewer feedback and correction. After two or three rounds, put the article aside for a week so that your final approach is with a fresh set of eyes.

Publishing

When your revisions are complete and your institution has signed off, send it in! Pay particular attention to the method of submission; each paper, magazine or journal has its own preferred method and additional requirements. Things they may require include: a cover letter, word count, author forms, copyright forms and disclosure forms. They may have specific requirements on word count, font, and spacing. Improve your chance of success by following these to the letter – an administrative assistant will typically check for adherence to rules before sending your submission to an editor.

If an editor requests revision, be prompt and courteous. Remember that the publication venue is theirs and they know their audience best. By carefully selecting a publication venue (by working with your public affairs office) your chance of acceptance is much higher for a lay article than a peer review article. If your article is rejected, take any editorial feedback into consideration and try the next venue.

Beyond publication

Once you've published a lay article, help others follow in your footsteps. Mentoring others on publishing these articles is a rewarding way to encourage scholarship and engagement with rotating medical students and residents. This is a particularly good way for residents to demonstrate teaching and leadership ability.

Summary Points:

- ❖ Lay medical articles are an excellent opportunity to engage your local community and disseminate important medical information while bolstering your academic credentials
- ❖ Use these articles to address common primary care questions or medical hot topics such as vaccination safety or infectious disease outbreaks
- ❖ Design your article with visuals, a catchy title, and a hook to draw in your audience
- ❖ Be sure your article is accessible to your audience; aim for an 8th grade reading level.
- ❖ Use these articles as a way to engage medical students and residents in the education and mentoring process.

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How to write a Lay Medical Article

For this recipe you will need;

- ❖ *A topic: Pick something that patients frequently ask about or are consistently misinformed about*
- ❖ *A proof reader: Ideally someone who is not in the medical field and can give a lay perspective*
- ❖ *A publisher: pick a local news source that is likely to be read by your patient population in which to publish your article*
- ❖ *A partner: find a junior resident or a rotating medical student to help you write the article, help them build their resume, and help yourself develop your mentorship skills*

Step 1: Work with your Program Director and/or public affairs office to identify suitable lay-article venues and any publication requirements your institution has.

Step 2: Pick a topic. This can be a frequent patient question, a topic in the news, or a topic of seasonal interest (flu vaccines, summer safety)

Step 3: Draft an outline from a few key points that you wish to convey. Remember: your article needs to be concise, with a clear take home message.

Step 4: Capture your readers' attention. Use a combination of pictures, a catchy title, and an opening hook to pull your readers to and through your article.

Step 5: Revise, revise, and revise. Rework your article to ensure that it is accessible to your readers. Aim for an 8th grade reading level and avoid medical jargon. Get a non-medical friend or family member to read your article and give you a lay-person's perspective on what you have written. Is it clear? Is it understandable? Is it interesting? Is what they take away from reading the article what you intended? Your final revision should be proof reading and formatting by your public affairs office.

Step 6: Pick one of the venues you identified in Step 1. Make sure your article meets any guidelines they have. Send it in!

Step 7: Use your new expertise in publishing lay medical articles to mentor your colleagues. Become the leader in your institution!

Sample Lay Medical Article

The A-B-C-D-E's of detecting skin cancer: when should I go to the doctor?

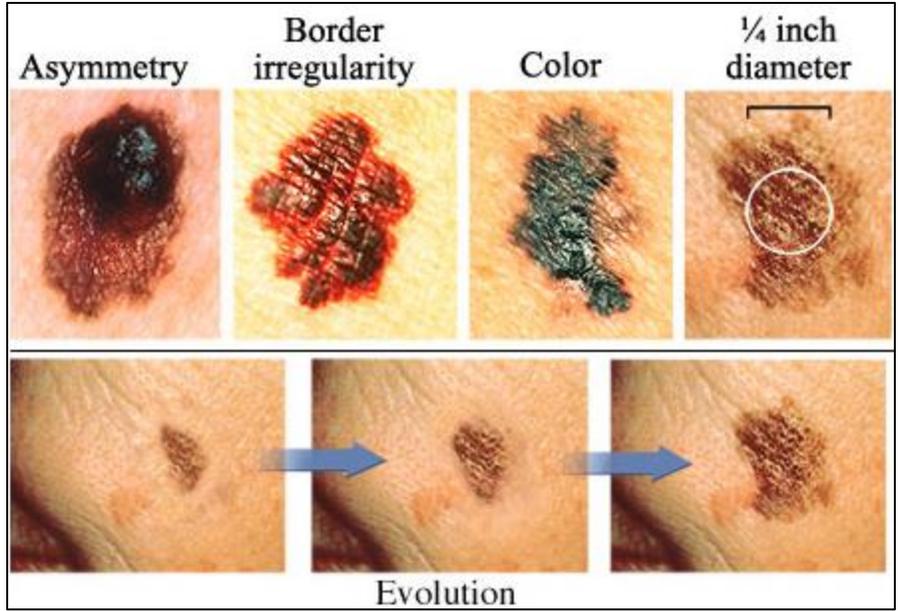
By: 2LT Thomas J. Peterson, Uniformed Services University of the Health Sciences, LT Job P Larson, PGY1 Jacksonville Naval Hospital

Did you know that 1 in 5 Americans will develop skin cancer within their lifetime? With summer upon us and more people spending time outdoors, now is a perfect time to discuss skin health!

It is important to do a yearly skin check on yourself to identify any concerning moles or growths (called "lesions" by your doctor). Early identification and treatment of skin cancer leads to better outcomes. Don't forget to check some of the more difficult to spot places like in the hairline, the armpits, the back, bathing suit areas, and the soles of the feet. If you have difficulty looking at your own back, try using a mirror or asking a close friend or spouse for help!

The ABCDE model is an easy to remember way to identify concerning lesions. ABCDE stands for Asymmetry, Border, Color, Diameter, and Evolution. First, identify the shape of the skin lesion and determine if it is symmetrical. A perfect circle would be an example of a symmetric shape. An irregular shape would be abnormal. Second, determine the border of the skin lesion. A normal border would be a smooth, consistent line. Again, think of a perfect circle. If the border is jagged or uneven, that is abnormal. Third, look at the color. A single, uniform color is normal. Multiple colors within the same skin lesion is abnormal. Fourth is size, if the diameter (distance measured across) is over 6mm wide, or about 1/4th an inch (roughly the size of a pencil eraser), that is abnormal. Finally, is evolution, or changes over time. If the skin lesion is growing or changing colors over time, that is abnormal. One good way to measure this is to take a picture of it to monitor over time. If you have any of these skin changes in ABCDE, you should schedule an appointment with your primary care doctor to have it investigated.

Additionally, you can use the "ugly duckling" rule of skin lesions. That is, if you have a bunch of moles but one, or a few, of them stick out as being different somehow from the others, this may be of concern. If you are unsure if a skin lesion is abnormal or not, schedule an appointment with your doctor!



Images are Public Domain from National Cancer Institute Visuals Online. <http://visualsonline.cancer.gov/about.cfm>

*Sample article courtesy of Dr. Larson

Chapter 9. Process Improvement Projects

Andrew J. McDermott, MD

“Unplanned process improvement is wishful thinking.” – Watts Humphrey

Objective: To review opportunities for process improvement and guide clinicians on the importance of and steps needed to create meaningful process improvement projects.

Why do Process Improvement?

In addition to keeping up with current medical information, it is important that clinicians maintain vigilance on how we deliver care and ways that can improve the quality, the efficiency, and the safety of the care we deliver. Process improvement allows clinicians to better own not only the direct delivery of care, but the manner in which this occurs, as well as a more global understanding of how the health care system operates. Investment in process improvement projects permits clinicians to better understand the patient experience of care and empathize with the inherent vulnerabilities of being a patient. Process improvement is also an integral part of ACGME requirements for residents and Maintenance of Certification for faculty providers.

How to select a Process Improvement project

Most Process Improvement projects arise from an event in which a deficiency in care was observed. These are mostly systems-based deficiencies, but can also occur at the individual level. When selecting a process that needs improvement, it is helpful to identify what aspect of health care delivery is being addressed. While there are endless opportunities of process improvement, below are some high-yield areas to consider.

Clinical benefit

There are certain processes that require improvement as a result of poor clinical outcomes. For example, constructing a project to improve HEDIS/Population Health metrics hypothetically incurs a clinical impact from the aspect of promoting wellness. Typically, these projects use clinical data and values, like hemoglobin A1c, as an objective, disease-oriented metric. These projects are useful for population-based improvement.

Patient-oriented benefit

This type of improvement addresses the patient experience of care. Addressing shortcomings in the wait time in an outpatient clinic or the overall time taken to discharge a patient drastically affect the patient’s experience with downstream implications of patient compliance with follow-up recommendations, patient satisfaction, and patients’ overall confidence in the medical system. The amount of pain experienced during an outpatient procedure can also be a patient-oriented outcome. There is an increasing push in healthcare to better assess the patient reported outcomes

since theoretically improving these outcomes should lead to better clinically relevant outcomes (this is at the heart of value-based care methodology).

Cost savings

Many process improvement projects are aimed at opportunities to decrease costs involved with delivering healthcare without sacrificing the quality of the care delivered. Approaches to addressing cost improvement can be measured in metrics such as differences in cost from using one medication compared to another, decreasing the amount waste that is generated through certain clinical processes, or establishing a cost avoidance that can be gained from a process improvement. There are numerous ways to measure cost impact with process improvement; here are three common projects.

- Medication costs: Using a preferred medication in the system's formulary over another, such as preferentially using pantoprazole (\$0.33 per pill) instead of esomeprazole (over \$3 per pill). If the safety and overall outcomes are similar, then there is a substantial savings to be incurred to the system. While the impact is minimal for 1 patient, if you apply this savings to tens of thousands of patients, the collective benefit is substantial.
- Decreasing waste: Not only medical waste, but administrative waste can be targeted for improvement. For example, decreasing the amount of paper printed for a typical outpatient encounter. If IT systems can be safely and efficiently integrated into daily operations, then the amount of money spent on paper and subsequent waste is measurable. Using a reliable IT system for collection of 3rd party insurance forms can save a great deal of waste in time and data entry compared to older, paper-heavy processes. When considering paper reduction, don't forget to include saved costs of document destruction.
- Cost-avoidance: This is largely a theoretical cost savings since the metric used is typically a calculation of how much money would have been spent. For example, if a medical system chooses to provide care to an eligible patient population so that the costs will not be incurred through a separate 3rd party system, cost avoidance can be calculated comparing the cost of care delivered through the process improvement compared to the cost that would have been incurred through the network. This typically requires a lot of assumptions and theoretical calculations.

Typically, cost savings projects are best suited for a Lean project (from Lean-Six Sigma methodology). The heart of Lean projects is reducing waste.

Patient safety

Patient safety projects almost always generate interest since this is a major focus of High Reliability Organizations. Many projects on improving patient safety result from a poor outcome or a near-miss. All near-misses should have some form of process improvement considered no matter the scale of the impact.

These projects lend themselves well to the Six Sigma methodology in which the aim of the project is to improve the reliability/accuracy of the process. An example of a simple patient safety driven project would be improving the manner in which patient sign-out handoff is conducted. Most medical systems suffer from opportunities for mistakes in the patient hand-off and projects aimed at improving this process can pay major dividends. The metrics for this will be determined by the setting, but could be number of wrong-site procedures, number of post-operative infections, provider rated quality of hand-off given, or medication errors.

There is a large amount of focus on these efforts from medical systems' governing bodies such as the Quality Council/Management and the Joint Commission.

Process efficiency

Many providers are frustrated at how inefficiently we deliver care. As such, this remains a great opportunity for process improvement. Projects can range from how patients are checked in, to how data is recorded in the electronic medical record on different wards, to how quickly a patient is discharged, to how satisfied physicians are working in a particular practice. This typically lends itself to a Lean project since most inefficiencies are a result of non-value-added steps.

How to generate your project

Successful projects have SMART objectives – that is, objectives that are **S**pecific, **M**easurable, **A**ttainable/**A**chievable, **R**elevant, and **T**ime bound. Keep these in mind as we go through the step-by-step process of project generation.

Identify the problem

What is the problem at hand? Identify the baseline process and map it out. Identify some baseline data that can objectively show why the process needs improvement and subsequently what metrics can be used to show benefit from your project. The more **S**pecific you are, the better your project will be. A problem of “patients are unhappy” is much more challenging than a problem of “patients are unhappy because they must wait an average of 15 minutes past their appointment time to be seen.”

Identify the stakeholders

Projects that fail to include the major stakeholders in the process are likely to fail. For example, if the issue identified is the time it takes to get IV antibiotics administered to an inpatient, failure to engage the pharmacy would be a critical mistake. Usually by mapping out the process on paper you can identify all parties involved in the process of interest. Again, you want to be as **S**pecific as possible. Patients are non-specific stakeholders; adult patients presenting to the emergency department with chest pain are **S**pecific.

Set reasonable goals

Make sure your goals are **SMART**. While we always shoot for perfection, it is understandable that most processes will never be 100% effective. Likewise, asking for 50% accuracy on medication delivery is simply an unsatisfactory expectation. Many governing bodies or licensing bodies set targets; when no obvious benchmark exists, an early task of the stakeholders is to agree upon a target efficacy. Define the **R**elevance of the goal in terms of the stakeholders. Stakeholders will become better engaged when they understand why the goal is relevant to them.

Set a time frame

Trying to implement change over too short of a time period can lead to frustration due to lack of results. Setting a goal too far out risks losing a project's momentum. Statistics show that most process improvement goals should be aimed at improvement over a 3-9 months period of time, with 6 months seeming to be the sweet spot as a **T**ime boundary.

Choose methodology

There are many methodologies to choose from; some lend themselves more readily to specific types of improvement. For example:

- 4DX (4 Disciplines of Execution): A very engaging methodology, 4DX uses scoreboards and places heavy emphasis on accountability. It can be used for most types of projects and typically requires a good deal of frequent engagement on the project (weekly).
- Lean Six Sigma: A great forum for large, statistic driven projects. These tend to require a lot of statistical analysis, and tend to get high-level visibility. They are usually split between a Lean project which deals with making things more efficient/reducing waste and Six Sigma which works to improve accuracy of a process.
- PDSA (Plan Do Study Act): Good for smaller scale projects, PDSAs are easily implemented and can go through multiple cycles to better refine a process.
- Other Process Improvement: Sometimes, you just want to make a process better with no particular methodology. This can be as simple as adding some focused training to solve a problem. Data is not always necessary, but does help to objectively monitor your successes.

Most institutions have a preferred methodology – ask your Program Director for yours.

How to measure your Process Improvement

For most projects, choosing a metric is the key to objectively measure success. Many projects will have multiple metrics.

Lagging measures

These are typically the goal measurement of the project with data resulted well after the process has been completed. A great example would be HEDIS data. Most of the data reported is three months old or more. It is a great metric to measure your long term successes, but hard to see immediate impact while the process is being implemented.

Leading Measures

The theory behind a leading measure is that there is something measurable daily or weekly that can effectively predict what will happen to your lagging metric. For example, if we refer to the HEDIS example and want to improve Cervical Cancer Screening, getting data back from three months ago doesn't tell me if the right things are being done today. However, establishing a leading measure of number of Pap smears per week allows for immediate assessment and can predict the lagging data. It can be challenging to find a leading measure that correlates well with the lagging measure; if your leading measure does not seem to be matching up to your lagging measure, adjust until you find a leading measure that does correlate.

Accountability to your measures

Accountability is paramount. Many systems with true, robust efforts at process improvement have weekly or even daily meeting to discuss their projects. The data is transparent and each member of the team is forced to face the data amongst their peers. Harboring this culture is essential if the culture of accountability is to be sustained. Systems with poor process improvement typically have poor accountability.

In Lean Six Sigma projects, a Control Plan is generated that outlines intervals in which the project is addressed, reviewed, and metrics assessed. This applies to implementation of the project as well as the sustainment phases of the project. They will typically include a sustainment trigger metric which is when the process needs to be revisited due to dropping metrics.

Creating a culture

Making daily and weekly discussion regarding process improvement part of the clinical lingo is the easiest way to change culture. The goal of Process Improvement is to implement change so that it becomes the new behavior and is sustainable. This is only possible through making an environment of palpable process that involves all members of the team.

How to submit your Process Improvement project for recognition

There is usually an individual in most systems that is responsible for process improvement and can help guide how to get the project appropriately presented/written up. Lean Six Sigma Greenbelt projects are great opportunities for many projects, but some projects may even lend themselves to poster presentation or mainstage presentations at various forums.

References:

DISCLAIMER: quality/process improvement is a **BIG** business. Many methodologies are developed by for-profit enterprises. The links below will let you learn about these methodologies and concepts, but should **NOT** be taken as an endorsement of a particular product or a recommendation to spend money on any program(s) referenced or offered.

1. Learn more about Lean Six Sigma here: <http://asq.org/learn-about-quality/six-sigma/overview/overview.html>

2. Learn more about the 4 Disciplines of Execution here: <https://www.franklincovey.com/Solutions/Execution/4-disciplines.html>

3. Learn more about the Plan Do Study Act model here: <http://www.ihl.org/resources/Pages/HowtoImprove/default.aspx>

4. Learn more about Changing Cultures here:

Business perspective: <https://executiveeducation.wharton.upenn.edu/thought-leadership/wharton-at-work/2011/09/four-steps-culture-change>

<https://www.forbes.com/sites/johnkotter/2012/09/27/the-key-to-changing-organizational-culture/#32d6fe8b5509>

iSixSigma perspective: <https://www.isixsigma.com/implementation/change-management-implementation/making-journey-toward-culture-change-healthcare/>

and

<https://www.isixsigma.com/implementation/change-management-implementation/not-just-statistics-implementing-cultural-change/>

5. Doran GT. (1981). "There's a S.M.A.R.T. Way to Write Management's Goals and Objectives", Management Review, Vol. 70, Issue 11, pp. 35-36.

How to generate a Process Improvement Project

For this recipe you will need;

- ❖ *A process you want improved*
- ❖ *Patience and perseverance!*

Step 1: Clearly identify the problem you wish to address and why that problem warrants improvement

Step 2: Identify the stakeholders

Step 3: Set reasonable goals

Step 4: Set a time frame

Step 5: Choose a methodology and clearly articulate leading and lagging metrics that will be measured

Step 6: Set reasonable goals

Step 7: Set a time frame

Step 8: Ensure stakeholders are holding each other accountable

Step 9: Revisit leading metrics to assess how well they correlate to lagging metrics, adjust as needed

Step 10: Consider venues for sharing your project – within your institution, at conferences, or through publication

Chapter 10. An institutional review board (IRB) application

Dustin K. Smith, DO

“Somewhere, something incredible is waiting to be known.” – Carl Sagan

Objective: To describe the purpose of and IRB and a general approach to completing an IRB-approved research project.

What is an IRB?

Human subject research has led to what we know about the current practice of medicine and is the reason that medicine has evolved so dramatically over time. An Institutional Review Board (IRB) is a committee established to protect human research subjects. An IRB must review and approve any federally funded or regulated research that involves human subjects to ensure the rights and welfare of those human subjects is protected, and most institutions require IRB approval for any research. According to federal regulations, an IRB has the authority to approve research, disapprove research, modify research, conduct continuing reviews, observe/verify changes, suspend or terminate approval, and observe the consent process and research procedures.

An IRB is made up of at least 5 members which includes members of both sexes. The members should have varied professional backgrounds. At least one member should be from a nonscientific area, one member from a scientific area, and one member with no affiliation with the organization. When research is being reviewed that includes vulnerable populations, there should be inclusion of an individual with an understanding of the vulnerable population being studied.

Why do we have IRBs?

“Atrocities are not less atrocities when they occur in laboratories and are called medical research.” – George Bernard Shaw

A discussion of IRBs and their role in the protection of human subjects of research would be incomplete without an understanding of some key ethical principles and a brief history of human subject research. Vaccination trials in the 1700s were some of the first human subject experiments to be documented. Research was conducted on humans with no oversight, often putting human at significant risk for minimal prospective gain. Although there were some calls for better human research oversight from the medical community, widespread understanding and demand for human subject protection did not occur until World War II, when Nazi doctors and scientists were put on trial for murder in Nuremberg. Ten key elements for conducting human research were included in the legal judgement and sentences handed down at the trial, known as the Nuremberg Code.

However, there remained little formal oversight of human subject research, which was often conducted on the most vulnerable populations. Dr. Henry Beecher wrote an article for the New England Journal of Medicine in 1966 which brought to light some research studies conducted by reputable researchers and published in major journals that were governed by controversial ethics. With the Beecher article, the public became increasingly aware of the ethics of research.

One of the most controversial human subject studies, and the one that was most influential in leading to governmental change, was the Public Health Service (PHS) Syphilis Study. The study included hundreds of men with and without syphilis and was begun before there was a known treatment for syphilis. These men were followed over time and subject to unnecessary testing, including spinal taps. Penicillin was found to be an effective treatment for syphilis in the 1940s but these men were denied antibiotic treatment and the study continued to track them until 1972, when it first appeared in the national press.

Congress subsequently formed a panel which immediately stopped the study but also recommended the design and implementation of federal regulations to protect human subjects in future research. Human research in the United States is now governed by 45 Code of Federal Regulations 46. Through the authorization of Congress, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research was formed in 1974. In 1979 the National Commission published the Belmont Report which identifies three basic principles that underlie all human subject research – respect of persons, beneficence, and justice. These ethical principles are what guide the evaluation of a study by the IRB.

What are the different types of IRB review?

There are three different types of IRB review: full committee review, expedited review, and review for exemption status. A full review requires that a quorum of IRB members be present at a convened meeting to review the application. The members present must include a nonscientific member and should also include a physician. For approval, a majority of the members present must approve the research. The IRB can decide to approve, modify, or disapprove of the research presented. Disapproval is typically done because the IRB does not believe a project is feasible or that it violates an ethical principle. If your project is disapproved, set up a meeting with the IRB Chair to discuss the reasons and to determine if the objections can be overcome.

The expedited IRB review process can be used for research involving no more than minimal risk to subjects or when the research project is done in specific, federally defined categories. Table 1 delineates the seven categories for a new expedited review. An expedited review can be performed by the IRB chair or one or more experienced IRB members designated by the chair. The reviewer(s) can approve the research, require modifications, or refer to the full IRB meeting; they may not disapprove the research.

The exempt IRB review process can be used for research that involves no human subject risk and is exempt from the other provisions of the regulations. Table 2 outlines the six categories of research that is eligible for exemption status.

What do I do if I think I have a good research project that would require IRB approval?

Starting an IRB research project can be a daunting task, but as with many aspects of research, the most difficult part of completing a research project is getting started. Once you have a framework for a good study you should start writing the IRB application. Each institution has a unique IRB application form, but all of them will include the following sections: objective of the study, review of the literature to date (which may help better refine the study framework), and a basic description of the research design. The how-to guide below includes the common elements required for an IRB application.

Contact your local IRB or research coordinator to better understand the process of routing an IRB application. You may find that your local IRB has specific/unique requirements that are helpful to understand before completing the application. Also, be sure to collaborate with colleagues. Research projects requiring IRB approval can be labor and time intensive so find others with similar interests/passions to help share the work. Many organizations also have employees specifically tasked to help with research applications. If not, you may be able to find someone who has been through the process before and can help mentor you along the way.

Do not get discouraged! Your IRB application is likely going to be returned requiring modifications at least once. Start the process with that as an expectation, and use the comments made by the IRB to improve your project. Keep in mind that many of the IRB members have extensive research experience.

Summary

Doing an IRB research project can be a daunting task; consider starting with IRB exempt or expedited research projects. Build on early successes and learn from failures.

Summary Points

- ❖ Human subject research is the backbone of our continuously evolving medical practice and IRBs are an essential part of this process – to ensure that the rights of those human subjects are protected.
- ❖ An IRB can decide to approve, modify, or disapprove of a research study.
- ❖ Depending on the risk to human subjects, IRB review can be exempt, expedited, or require full review.
- ❖ Institutions often have unique IRB applications although they all include common elements – objective of the study, background (review of the literature to date), and a basic description of the research design.

Table 1: Expedited IRB categories

Category	Description
1	Studies on drugs or medical devices for which an investigational new drug (IND) application or investigational device exemption (IDE) is not required Studies with a cleared/approved medical device that is being used in accordance with its approved labeling
2	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
3	Prospective collection of biological specimens for research purposes by noninvasive means
4	Collection of data through noninvasive procedures routinely employed in clinical practice (with some qualifications)
5	Research involving data, documents, records, or specimens that have been collected, or will be collected solely for nonresearch purposes
6	Collection of data from voice, video, digital, or image recording made for research purposes
7	Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Protection of Human Subjects, 45 C.F.R 46. 2009.

Table 2: Exempt IRB categories

Category	Description
1	Research conducted in established or commonly accepted educational settings, involving normal educational practices
2	Research involving educational tests, survey procedures, interview procedures, or observation of public behavior unless the information is recorded in a way that the subjects can be identified and disclosure of responses could reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation
3	Research involving educational tests, survey procedures, interview procedures, or observation of public behavior not exempt as above, if the human subjects are elected or appointed public officials or if federal statute requires without exception the confidentiality of the identifiable information
4	Research involving the collection or study of existing data if these sources are publically available or the information is de-identified
5	Research and demonstration projects conducted by heads of government departments or agencies designed to study, evaluate, or examine multiple aspects of public benefit or service programs
6	Taste and food quality evaluation and consumer acceptance studies

Protection of Human Subjects, 45 C.F.R 46. 2009.

References:

1. Protection of Human Subjects, 45 C.F.R 46. 2009.
2. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: ethical principles and guidelines for the protection of human subjects of research. Bethesda, Md.: The Commission, 1978.
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How to write an IRB

For this recipe you will need;

- ❖ *An idea for a research project*
- ❖ *Your institution's IRB application*
- ❖ *Patience, perseverance, and ideally an experienced mentor!*

Step 1: Clearly define the question(s) your research seeks to answer.

Step 2: Tell your colleagues about your project and solicit assistant investigators.

Step 3: Clearly identify roles, responsibilities, and timeline expectations with your co-investigators, including anticipated author order on the paper you will write to publish your findings. Put this in writing and make sure everyone has a copy.

Step 4: Complete this research outline (easiest to break it up into parts among your group):

Title: Be concise, don't capitalize every word

Subject Population: a brief description

Age of Subjects: Specify in particular the follow age ranges: newborns, 0-17, 18-65, over 65

Collection of Subject Demographics: What are you collecting? I.e., ages, gender and race

Population: Who are you studying?

Does the project involve active subject recruitment? If you'll recruit subjects, you'll need to describe in detail how you will do this.

Control / experimental / total subjects: Describe each group.

Abstract: This gives the IRB a good idea of what you are trying to study and how you plan to go about it. Put effort into this – with minimal modification this is the abstract to the article you'll publish about this project!

Research Plan: This is where you build a detailed outline of your project

1. Objectives / Specific Aims What clinical question are you trying to answer? What is your null hypothesis?

2. Background and Significance Why is this important? To whom is it important?

3. Research Design / Methods / Subject Justification Specify your research design. Is it retro- or prospective? How many arms? Cross over? Briefly describe your methods (you'll go into detail later). Will you pull data from an established database? Recruit subjects? Give a justification for your subject selection. This is particularly important if your subjects are considered vulnerable populations.

a. General Approach

i. Research Objective What clinical question are you trying to answer? What is your null hypothesis?

ii. Detail how many groups or Arms are in the Study and what each receives Be complete and concise.

iii. Randomization procedures How will you randomize? If you are not randomizing, why not?

b. Methods and materials Again, complete and concise. Be sure to include all actions the researchers will take, all anticipated interactions with subjects, and all tools/surveys/equipment you plan to use.

i. Experimental Procedure Step by step, what are you planning to do?

ii. If collaborative, what occurs at each institution Be explicit. Your IRB may require a formal data-sharing agreement or memorandum of understanding.

iii. Research material to be collected Be concise and complete. Anything not listed to the IRB cannot later be collected (unless you later submit and receive approval for a waiver before you collect it.) Here you can also specify PII vs non-PII data. Studies without PII may be eligible for an "expedited" review.

iv. Data collection tools Forms, surveys, databases, equipment etc.

v. Protection and security of data and identifying information Physically or electronically how will information be secured and who will have access to it?

vi. Disposition of data and identifying information at end of project Be specific – for how many years will information be retained. How will physical and electronic information be destroyed or archived?

vii. Gender and ethnicity Will this information be collected and if so, why?

c. Subject population

i. Subject inclusion and selection criteria How will you identify appropriate subjects for inclusion?

ii. Subject exclusion What, if any, are your exclusion criteria?

iii. Subject recruiting methods Be thorough – signs, mailers, booths, commercials, emails? Be explicit in subject compensation if any – money, time, promotional items. Your recruiting materials will be reviewed and should clearly address how the study might (or, better, will not) impact the subjects’ access to care or quality of care.

iv. Informed consent procedures Be thorough, and be sure to address potential barriers like language, legal ability to consent, subjects’ ability to revoke consent (your consent forms should include instructions on how to revoke consent), and again address how the study might (or, better, will not) impact the subjects’ access to care or quality of care

v. Justification for use of this subject population The more vulnerable your subjects, the more potential harm of your intervention, the stronger your justification must be.

vi. Vulnerable populations Clearly identify all “vulnerable” subjects. Vulnerable populations explicitly include: children, minors, pregnant women, fetuses, human in vitro fertilization, prisoners, employees, military persons, students in hierarchical organizations, terminally ill, comatose, physically and/or intellectually challenged individuals, visual or hearing impaired, ethnic minorities, refugees, international research, economically and disabled and healthy volunteers. Vulnerable populations also include *any other* population that might be at risk for exploitation.

vii. Number of subjects and justification Justification comes from your statistical modeling – this allows the IRB to see that you are not subjecting an unnecessary number of subjects to your intervention.

i. List and document risks Be broad – if data you collect (including that the subject is involved in your study) were available to all persons, what might happen? Loss of insurance? Loss of job? Embarrassment? If the intervention or lack of intervention were to cause harm, what would that harm be? Side effects? Loss of function(s) permanently or temporarily? What are the chances of harm with your intervention – are there animal studies, previous human trials, theoretical models, analogous interventions that allow estimation? Don’t forget every aspect of your intervention. For example, treatment with intramuscular agent X includes not only the effects of X, but the risk of injection alone.

ii. Justification of risks What might subjects in particular and the field of medicine in general gain?

iii. Minimization of risks Be thorough – address every risk listed above and clearly describe risk minimization process and procedures. This includes pre-screening subjects, intervention technique, and post-intervention monitoring.

e. Benefits What does the world gain from this study?

f. Cost to subjects Typically time and money, but also may be physical limitations (including driving, reading, sports) or mental limitations (fatigue, focus) depending on your interventions.

4. Adverse event management and reporting The next step to risk mitigation strategies above. If something goes wrong, what happens? Describe how an adverse event would be identified, to whom it would be reported, and what possible outcomes an event might trigger – risk amelioration, dropped from study, study on hold, study shut down, anything else. Also note that this must include how the researchers will notify the IRB.

5. Statistical analysis What analysis will you perform? Why? Make sure your model fits your anticipated data. Describe in detail power, confidence intervals, and sample sizes. Consider the impact of smaller sample sizes/drop-outs on your confidence intervals.

6. Significance to your institution Some institutions will explicitly ask this. It is a way for their IRB and internal leadership to make sure researchers are meeting the needs of their employers.

7. Patent disclosures/inventions Are you testing for your patent or invention? Disclose here.

8. Potential hazards to the research team Detail.

9. Anticipated enrollment time Include an estimate of how many subject per year over how many years your study will run.

10. Bibliography for background section/ research plan Some IRBs will direct you to cite in a specific style. You should have a great bibliography – See Chapter 3 for how to do a literature search. Be thorough – this will be the foundation for the References in the article you'll publish about this project.

Step 5: Cut and paste from the outline into your institution's IRB form.

Step 6: Submit your IRB!

Chapter 11. A grant proposal

Mark Stephens, MD, MS, FAAFP

“All that wealth can’t fill the hole in Gatsby’s heart – but it probably makes it easier to bear.” – F. Scott Fitzgerald

Objective: To introduce the concept of grant funding and identify the critical elements and steps necessary for grant writing and enable the learner to write their own grant proposal by use of an included outline/ overlay.

While Gatsby did not live in the world of academia, Fitzgerald’s words hold true for those of us who do. There are two primary financial resources in modern academic medicine: 1) Income generated from a clinical practice plan and 2) Grant funding.

In general, there are two primary sources of grant funding: 1) Intramural and 2) Extramural. Intramural funds come from within an institution. For military physicians, this could be from an individual hospital/MTF, from USU or from the Department of the Navy (or Army/Air Force). Intramural funds are traditionally used to ‘seed’ good ideas. Specifically, intramural projects are smaller and designed to create preliminary data for a larger extramural trial. Extramural funding comes from sources outside of the institution. The National Institutes of Health (NIH) has long served as the bellwether for extramural funding. When submitting to NIH, extramural proposals can be either investigator-initiated (i.e. you have an idea and take a chance that the NIH will like it and want to fund your work) or in response to specific requests for proposals/applications (RFP/RFA).

What follows is a very general guide to the grant writing process. The resource section includes several helpful websites with much more detail about NIH and foundational funding.

Extramural grants

1. Identify the sponsor. The sponsor is who pays the bills. This could be a government source (e.g. NIH), industry source (e.g. Pharma) or foundation source (e.g. AAFP Foundation). Knowing who is interested in funding what types of research is a key first step in deciding what money to go after. Common sources of funding for primary care include:

- a. HRSA: <http://www.hrsa.gov/grants/index.html>
- b. CHRT: <http://www.chrt.org/publications/price-of-care/affordable-care-act-funding-an-analysis-of-grant-programs-under-health-care-reform/>
- c. AAFP Foundation
<http://www.aafpfoundation.org/online/foundation/home/awards-and-grants.html>

2. Read the sponsor’s rule book and then read it again. You must follow the rules. Know what is required in terms of deadlines and formats. If you don’t adhere to the format, you’re out.

3. Assemble your team. Research is a team sport. If you go it alone, you will likely die of starvation. Find individuals who complement you and lay out clear roles in advance. No one likes devoting their time to a project and then being left out in the cold. Determine things like roles (Principal Investigator; Associate Investigator; Consultant) up front. Define what you will ‘pay’ your team (either monetarily or in terms of academic attribution). Determine authorship up front.

4. Prepare your proposal. There are plenty of “go-bys” out there. It is helpful to find someone who has had success with the sponsor and ask to see a copy of their proposal. Many people are more than willing to share (particularly if your line of research is not in direct competition). Having a successful boilerplate goes a long way in terms of shaping and managing your writing expectations.

5. Your research plan. If you are preparing an NIH RO1 grant, the research plan consists of the following subsections: **Significance, Innovation, Approach**. One way to frame this is to begin with a specific aim page (significance) that helps to shape the entire project. If reviewers only read one thing, this is often the only section they peruse. Make it a good one! A sample is available at <http://www.niaid.nih.gov/researchfunding/grant/Documents/Parrishresplan.pdf>

a. **Significance**/Specific Aims. This is arguably the most important element of your proposal. State what it is you propose to do clearly and concisely. Hypothesize directly.

i. Our long-term goal is to understand _____. The specific objective of this proposal is to _____. The central hypothesis is that _____. We formulated this hypothesis, in part, based upon our strong preliminary data, which shows that _____. The rationale for the proposed research is that once it is known how _____. We will pursue these studies in three Specific Aims:

- Aim 1 INSERT TEXT. Our working hypothesis for this Aim is that _____.
- Aim 2 INSERT TEXT. We will test the hypothesis _____.
- Aim 3 INSERT TEXT.

In these studies, we will examine the prediction that _____. The proposed work is innovative because it capitalizes on _____. At the completion of this project, we expect that the combined work proposed in Aims 1 and 2 will _____. We also expect that Aim 3 will establish _____.

b. **Innovation**. Reviewers prefer new and innovative work. Stating your case in this context is important.

c. **Approach**. This is your methodology. Make sure you consult a statistician and a librarian up front. Having a sound plan of analysis and a thorough review of the literature is important.

6. Know your local IRB rules. Some IRBs want you to submit up front. Other institutions have offices of research to help along the way. Still others use “just in time” processes (submitting to the IRB only if/when funding appears likely). Ask early and err conservatively—involving (rather than alienating) the IRB is important.

Here is some guidance on how to craft a competitive NIH grant proposal from Dr. Steve Kaminsky:

Significance (1 page limit):

- Introduction paragraph: *(purpose is to convince all reviewers that there is a problem, issue or gap)*
 - Opening sentence
 - Knowns
 - Unknowns
 - Frame the problem

- What, why, & whom paragraph: *(purpose is to convince all reviewers that we are the solution to the problem)*
 - Long-range goal(s)
 - Objective of this section
 - Central hypothesis
 - Rationale

- Aims: *(purpose is to describe what we are going to accomplish)*
 - Specific aims (2 to 4 at the most)
 - 1-2 sentences each (brief, focused and limited in scope)
 - Each must carry an eye-catching headline
 - Each aim should be related to the others but not dependent upon a particular outcome of another
 - Logical flow
 - Must collectively fill the need (central hypothesis)

- Payoff paragraph: *(purpose is to inform reviewers what the return on investment will be and why this will be of value to NIH)*
 - Innovation (novelty of approach)
 - Expected outcomes (one for each aim)
 - Positive impact (significance – national?)

Innovation: (purpose is to: 1) convey that we know what we are doing, 2) understand the technology and road ahead, 3) possess the intellectual and physical capacity, and 4) will to follow-through in this serious endeavor)

- Current state of the functional area (who we are)
- Accomplishments to date and why they are important (what we are doing)
- Include data that allowed us to form central hypothesis
- Include only salient data and arrange in order you can present logically and persuasively
- *Tip: This should lead reviewers to believe that you have competitive advantage when you undertake infrastructure plan (next section)*
- *Tip: Present data in such a way as to lead reviewers to establish the connections (to the other functions) that you want to happen.*

Approach (purpose is to win the \$\$ - what's the plan? What will be accomplished during the funding period?)

- This is where you expand (in detail) on your specific aims
- This section should be written around each of the specific aims using steps:
 - Repeat your specific aim (exactly as written in specific aims page)
 - What is to be done? (rationale)
 - What are the means that will be used to accomplish the aim? (design)
 - What you expect to happen? Why is this important (expected outcomes)
 - What might go wrong? If it does, what are alternative strategies? (predicting potential problems & alternatives to accomplish aim)
- Literally lay out as identified above:
 - Specific Aim #1: Exact title
 - Rationale: (no more than ½ page)
 - Design (key processes)
 - Expected Outcomes
 - Potential Problems and Alternative Strategies
- **Rationale paragraphs** for each specific aim should include an overview, objective(s) supporting the specific aim, how objective and aim will advance working hypothesis, rationale, summary of expected outcomes.
- After all specific aims are addressed include a **master timeline** (or timetable) for accomplishment
- Wrap-up this piece with **future directions**. (where you expect to be in future)

Summary Points

- ❖ Stay very clear and concise in your writing. For clarity use simple declarative sentences and avoid complicated words, unusual abbreviations, and tortuous syntax.
- ❖ Avoid discontinuities in reading that interrupt the concentration of reviewers and “weak words” that convey doubt.
- ❖ Keep emphasized text (e.g. bold, italicized, underlined) to a minimum.
- ❖ Make a case on how the various pieces of the grant relate.

References:

http://www.ninds.nih.gov/funding/write_grant_doc.htm accessed 19Nov2013.

<http://www.hfsp.org/funding/art-grantsmanship>

http://foundationcenter.org/getstarted/tutorials/shortcourse/prop1_print

How to write an Extramural Grant Proposal

For this recipe you will need;

- ❖ *A choice of sponsor for your grant (examples include NIH, HRSA, CHRT, and AAFP)*
- ❖ *A downloaded copy of the sponsor's rule book for grant funding*
- ❖ *A research plan – if you don't know where to start here, see Chapter 10*
- ❖ *A team of collaborators and ideally an experienced mentor.*

Step 1: Find an example of a grant proposal from place you wish to submit. The NIH has good examples on their website.

Step 2: Review the key elements that you will need to write your proposal. Some of them have the elements of background and significance, preliminary studies, progress report, research design and methodology. The newer variations have subsections such as significance, innovation, and approach. Determine what your elements will be.

Step 3: Write the Significance/aims – this is a single page section.

- a. The first paragraph is your introduction it states what you know, what you don't know and frames the problem. (Make sure you have a strong opening sentence.)
- b. The next 1 to 2 paragraphs give the what, why and whom. Convince people that you are the solution to the problem framed in the first paragraph!
- c. Next state the AIMS of the project. An Aim is the objective or end point of your project and should relate to the hypothesis you are trying to prove. **(If you are feeling overwhelmed, remember you are not reinventing the wheel! There are MANY examples of what to do out there. Consider it like a CV. You already know what you want to say, you just have to make sure you say it the *right* way.)**
- d. End this section with a conclusion paragraph that explains why this is a good investment on their dollar, reaffirm your expected outcomes, and explain why they will be significant.

Step 3: Write the innovation section. This is where you explain who you are, what you are doing, and that you *know* what you are doing.

Step 4: Write the approach. Lay it out exactly as below;

Specific Aim #1: Exact title - This is EXACTLY what it was in your above paragraph

Rationale: (no more than ½ page) – this is where you have an overview, an objective, how this objective will support/prove your hypothesis and what you believe will be the outcomes. You want a time table and the moving forward/future directions part here.

Design (key processes) – explain what you are going to do to accomplish this aim/what means do you have to accomplish it.

Expected Outcomes – here you would put what you expect to happen and why what you expect to happen is important.

Potential Problems and Alternative Strategies Here you list things that may go wrong. Other strategies that are not part of your goal.

Step 5: Go back and look at the directions for the grant again. A basic ability to follow directions implies to the people reading your request that your science is sound. Sloppy application = sloppy science.

Step 6: Determine if your institution requires your IRB to be done and complete prior to a request for funding. The members of the IRB board are good people to know, and they will keep you out of trouble. For more information on IRBs see the IRB chapter.

Step 7: Double check that there are no issues with your use of this funding for this purpose with the people you work with and for.

Step 6: Go get the money!