From the Ground Up: Building a Pediatric Orthopaedic Clinical Research Program

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Abstract: The purpose of this editorial is to provide an approach to building a successful clinical research program in pediatric orthopaedics. Simple early steps and early success will build momentum. Advertise your program locally to recruit help from residents, students, departments, and hospitals. Utilize available local resources that often come with little to no cost. Solicit support from key stakeholders such as hospital systems, universities, and academic departments. Once your program gains some momentum and financial support, you can begin to add key personnel. It is then time for your mature research program to begin national and international collaborations and seek out large grants.

Key Concepts:

- Start small and achieve early success in a new clinical research program.
- Improve your research skills by serving as a reviewer for research proposals, manuscripts, and grants.
- Collaborate as often as possible both within your institution and around the globe.
- Promote your program's research success to build momentum and recruit talented people.

Introduction

What is the goal? Build a clinical research program? Publish in the highest quality, peer-reviewed journals? Build prestige for yourself and your program? Build your curriculum vitae? Obtain grant funding? Increase your income? Gain academic stature, maybe even tenure? Mentor young minds? Find answers to those clinical conundrums that puzzle, frustrate, and annoy? Or simply, do what you can to make the practice of pediatric orthopaedics a little better for the next patient? It isn't easy. It won't just happen. Data won't rain down like mana from heaven and manuscripts won't appear like inscriptions on stone tablets. It will take some effort. At times, it will take

Guru says…

Start with "Why"—Why do you want/need to have a research program?"

— *Steve Frick*

quite a bit of effort, but once the clinical research train gets rolling down the track, the momentum can be nearly impossible to stop.

Guru says…

The most important aspect of any research endeavor is, "What question are you trying to answer?"

—Steve Frick

A couple of key innate ingredients must be present before the construction of a clinical research program can begin; the rest can be learned, acquired, or built. First, there must be curiosity, the ability to ask the next unanswered question, or the boldness to challenge dogma. The best clinician scientist is the one who asks the next great question. Second, there must be a willingness to begin to carve out time from some aspect of your very busy life to take the first steps. The successful clinician scientist is the one who dedicates at least some time to the pursuit of new knowledge.

We will not claim to be experts on this, but we have learned some things, and we know we have a great deal more to learn. There are many who have done this better, bigger, bolder, and with profoundly greater acclaim than us. Thousands of our predecessors and contemporaries could have penned these words and likely could have done so with greater insight and wisdom. The following is by no means the only way forward but are a few thoughts that have helped us to ask questions, find answers, and share what we have learned.

Guru says…

Perfect is the enemy of good. Start where you are, usually with small retrospective studies, and try to get better every day. Contributing to established multicenter groups also is a good way to start. Take care not to take on huge projects like a randomized trial to determine if surgery is helpful in LCPD—especially if you don't have the numbers of patients to prove an effect.

—Steve Frick

Step 1: Start Moving

Guru says…

One of the most prolific researchers I know took 2 years to write his first case report with near constant harassment from an attending. It was initially bad, but with edits, he learned. Once he had a taste, however, he sought more training and more projects and hasn't stopped. He currently has over 1500 publications.

—Shawn Gilbert

You cannot wait for all the pieces to be in place. Although some authors on this topic will have you believe that funding comes first, followed by developing a team, then starting your project(s) (Clin Colon Rectal Surg 2014;27:65–70.), a fully formed and fully funded clinical research machine will not simply appear complete with coordinators, statisticians, grant writers, chart miners, and medical copy editors. No matter how much you badger, demand, beg, or manipulate those holding the purse strings, the resources won't begin to flow in your direction until you begin to show effort, likely not until you begin to show results. Find a friend or mentor who shares your desire to see your program's clinical research reach the next level, whatever that level may be. Set a schedule to meet consistently to discuss ideas, monitor progress, and overcome obstacles.

Guru says…

Good research is deep work. It has to be on the calendar and protected from the jealous mistress—clinical activities.

—Shawn Gilbert

We recommend meeting monthly for at least one hour. Any less than that and enthusiasm wanes, and early momentum grinds to a halt. Dedicate that time to research and research alone. Don't make it a subsection of other business because whenever something needs to be cut to make room for "more important" matters, it is almost always research that gets the ax. Establish small goals.

Ask one question that you are pretty sure you have the ability to answer all on your own if no one else is willing or able to help you. Ideally, this should be a simple

Guru says…

Monthly meetings with colleagues or a mentor are very useful. They can serve as internal deadlines to move projects forward. The small group can work to brainstorm next steps, refine study questions, edit manuscripts, and give feedback on presentations. Co-author opportunities also can be helpful motivation.

—Jennifer Laine

clinical question about a patient care scenario that you frequently encounter so that you know the data will be readily available and easier to collect. Design a simple study that can be evaluated with retrospective data to have some early success. A double-blinded, randomized multicenter evaluation of the surgical management of a rare condition should not be your first project. Lead author on the lead article in the highest impact factor journal in orthopaedics should not be your first goal. Hope to publish in a middle-tier, peer-reviewed, subspecialty journal; then set some loftier goals. As the meetings and publications begin to accumulate, consider some more complex studies.

Guru says…

Explore whether your institution will allow broadly written or "umbrella" IRBs. If so, once the initial IRB is approved, you may only need to submit amendments or modifications when starting a new study within that same topic or field. This can help streamline the process of study start-up significantly.

—Jennifer Laine

Collaborate with colleagues who are at a similar place in their careers and harness the power and wisdom of a larger group. Include some study type variability. Include Quality Improvement (QI) projects, case reports, retrospective studies, and maybe even a single-center prospective study idea or two. Studies with varying complexity will yield results over various timelines. Simple projects may take only a few months to complete and submit, while others may take years. All the while, you see successes. And successes yield motivation for continued endeavors and more success.

Step 2: Advertise and Recruit Help

It will be hard at first. There is a great demand for research support. And fellows, residents, and students come with motivations to get their names in lights and get them there quickly. They want to be able to put publications and podium presentations onto their applications for the next big step in life, and they will seek out research programs that can give them the best chance at accomplishing that goal. Most often, they will work for the glory of authorship alone; no additional funding is required. They may be hard to find at first, but you can find them if you ask around. Maybe there is an advance practice provider in your group who has some research interest and/or experience, or maybe you occasionally have a junior level medical student rotate through your clinic, or maybe you are fortunate enough to have large numbers of fellows, residents, and students work in your practice month after month, but you have never been the go-to person for research success. Ask them, discuss ideas with them, listen to them to ask a question that doesn't yet have a solid answer in

Guru says…

The first project will take so much more time. You have to look at it as learning to jump through the hoops. Everything is new–the IRB forms, designing the database, doing the stats, writing the paper, learning to put together all the "other" materials for journal submission. Save everything because when you have done it once, a lot of it is cut-and-paste with changes just in key details.

—Shawn Gilbert

Guru says…

'Help' those who are helping your research. In doing so, you will create a win-win that is gratifying and, occasionally, you will find a future superstar who will be a thought leader.

—Steve Frick

Guru says…

Once the literature review is complete, consider looking for opportunities to co-author a review article or chapter on the subject with the trainee. This is something that can be achieved while awaiting IRB approval and data collection on your study. If the trainee becomes very comfortable with the literature on this topic, the literature review can also be transitioned into a grand rounds presentation. These opportunities will help you build your relationship with the trainee, help both of you become established within this particular field, and help build your CVs.

—Jennifer Laine

the medical literature and then challenge them to help you find the answer. Just because you are new to clinical practice, or just because you haven't been the research powerhouse in the past, doesn't mean that you can't offer them what they want, and it doesn't mean that they can't partner with you to help you get what you want. Invite them to your next research meeting. Have them start a literature search on the topic. Challenge them to actually write up the results of their literature review, reference their statements, and generate a bibliography. The basic literature review then becomes the copy used again and again in protocols, IRB submissions, meeting abstracts, and manuscript introductions and discussions. This is a key first step in "capturing" the energy of junior researchers and starting a project on the road to success.

Guru says…

Once you find an interested team member, such as a research coordinator, invite them to educational opportunities on the subject. Consider giving them articles to read, inviting them to didactic lectures given to residents, or having them observe cases in the operating room. The more they learn about the topic of study, the more likely they will be engaged and interested in the study just like you.

—Jennifer Laine

Step 3. Utilize Available Resources

A study on clinical trials concluded that clinician scientists contribute only about 9% of the overall time required to conduct a large clinical trial (J Clin Oncol 2003;21:4145-4150). This percentage is likely true of other study designs if you have access to support staff. How much will you have to contribute without help? What do you need? What do you want? Well, you want it all. You want research coordinators—that's right, coordinators (plural). You want research nurses, health information officers, bioinformatics experts, programmers, basic scientists, biomechanical engineers, histologists, research pharmacists, data miners, statisticians, medical editors, librarians, graphic artists, grant writers, research mentors, and mentees. If you had all those personnel resources, imagine the research you could crank out! But you don't have ready access to all those people. Even in the largest academic centers, only some of those skill sets are available to each clinician scientist at one time. You don't have them all, and you will probably never will, but you DO have some of them. Maybe just one or two at most but you do have access to some of the skills and talents you don't personally possess—utilize them. In many cases, it is their job to help you; it is a job for which they are paid a salary, perhaps even a salary paid by someone other than your institution. Meet with them. Find out their abilities and motivations. Maybe their goals align with yours. Maybe their goals merely complement yours. They can be part of your team, and you can be a part of theirs. Momentum starts to build. Many hands make light work.

Guru says…

Keep in mind, many full-time researchers are looking for clinician collaborators who can help bring clinical relevance and translational skills to the team. You may be contacted about projects that aren't in your wheelhouse but may be opportunities to learn new skills and build new collaborations.

—Shawn Gilbert

Guru says…

Visibility–at all levels–can be very important.

Internally, look for ways to promote ongoing research studies and the research successes of you and your partners/team. If you had a poster presented at a conference, consider finding an appropriate place to display it within your hospital or department. Consider including a research update in your staff meetings about ongoing studies and recent successes. If you or one of your partners had a manuscript published or an abstract accepted for presentation, tell people about it! Openly discussing these achievements–which otherwise can easily go unnoticed–can be helpful in creating a culture of research and in directing trainees and resources. Additionally, it can help you and your partners translate some of these research findings back to the clinical setting.

—Jennifer Laine

If your department or hospital has a salaried staff statistician, then maybe you won't have to beg, borrow, and steal stats support. If you already have access to a librarian, you can focus your attention on other parts of the project aside from literature review and rare article procurement. If you know of a motivated biomechanical engineer or histologist, then maybe you can come up with a research interest of yours that can utilize their knowledge and resources. Get creative. The more partners you can find, the less of each step of the process you have to do on your own.

Step 4: Solicit Support from Stakeholders

You are not the only one who wants you to succeed. There are others who want to share in your academic accomplishments. Your hospital may want to promote research success to gain national and international acclaim through outlets such as *U.S. News and World Report*. They may wish to grow departments or build clinical programs and may believe that research will play a vital role in that growth. If you are part of an academic department, they will most assuredly want to claim research successes in the form of publications, presentations, and ultimately in philanthropic or grant support. And, if you are in a for-profit private system, research can mean prestige in the local and regional community, fodder for advertisement, a way to rise above the competition, and ultimately, a means to attract more patients to some of the more lucrative aspects of the organization. The point is that some have a financial interest in your academic success, and they understand or can be encouraged to understand the potential return on a monetary investment in your research efforts. Reach out to leaders of your hospital, academic department, or practice organization. Excite them with your vision. Explain the steps you have already taken (Step 1). Provide them with details on the partnerships you

Guru says…

Lots of resources can greatly assist in getting research completed. BUT the main driver of good pediatric orthopaedic research is from curious surgeons who want to find a better way to take care of patients, and who are intrinsically driven to improve our surgical and nonsurgical treatments.

—Steve Frick

Guru says…

Hospital or departmental communications departments or teams are often looking for content in order to keep websites, blogs, social media, and mailers updated, active, and relevant. Consider reaching out to communication teams with updates on current research projects and achievements. This can draw internal attention and resources, can spark external thoughts of funding from donors, and can also draw patients and families to your institution since you have a dedicated interest in a certain field.

—Jennifer Laine

Guru says…

Some institutions have clinical trials support centers that have centralized work pools and you can contract part of an FTE without the long-term commitment of hiring a permanent person.

—Shawn Gilbert

have already established (Steps 2 and 3). Describe your plans for future growth. Then ask for their support to take your vision to the next level by providing funding for the next key team member that you may be missing, or an institutional grant to start the next project, or maybe just the travel budget for you and a couple of members of your team to attend the next big meeting where your work will be presented. Start small and then grow the partnership. As they begin to see a return on their investment, they are likely to increase their support.

Step 5: Add Key Personnel

You are off and running, moving in the right direction. You have had a bit of success. Maybe you have published a couple of papers and presented them at meetings. You have a mentor or two who are celebrating your early triumphs. Those in charge of the money have started turning their heads in your direction. You have a small team that is still meeting regularly. Your catalog of ongoing studies continues to grow. There are multiple projects in various stages of completion. Now is the time to add that next team member. Maybe you have limited your efforts to small retrospective studies because the statistical analysis is fairly simple. Larger studies will need more than your college Stats 101 course and a few hours in Microsoft Excel; you really need access to dedicated statistical expertise for the larger studies. Maybe you have been able to "borrow" 10% of a full-time research coordinator's time from another department to help you navigate the IRB, but you are tired of trying to answer all those provisos on your own and you need your own dedicated research coordinator. Maybe you have submitted a few small grants but have fallen short on securing any funds and wish you had a skilled grant writer to help close the gap between your efforts and actually bringing home the bacon. Whatever your next need may be, it is time to ask for it. After all, you have earned it. You have demonstrated your dedication to the research effort. Those in a position to help cannot deny your ambition. Ask them for their support—maybe even demand it. Explain to them that you can continue at the current level indefinitely, but if they want to see the research grow, if they want to see larger, more impactful studies, if they want to see their institution's name in more prestigious journals or hear their institution's name spoken at larger meetings, it is time to make a sizeable financial commitment to your—no, "our" research team. Give them the glory. They are partnering with you. Make it "our" team, not just your team; heck, make it "their" team. Get that next team member, gain more success, publish more papers, present more abstracts, get more grants, and then go back and get the next team member and repeat the cycle over and over again.

Guru says…

As one of my friends' dad used to say, "Do something not a lot of people can do." If the group is struggling to get someone to take on a certain role or task, step up to be that person. Suddenly, you are the go-to on that topic and become a key cog in the big machine.

—Shawn Gilbert

Guru says…

Everyone says they want to participate in research. Actually doing it significantly narrows the field. If you volunteer, try to "never miss a deadline." You will be a remarkable outlier if you can accomplish this.

—Steve Frick

Step 6: Collaboration

You are there. You are now an established academician. People know you. When your name appears in the authorship line, they stop and read at least the abstract. After all, they know you have something important to

Guru says…

The big questions in our field require collaboration and multicenter studies to provide enough power and must demonstrate the generalizability of the results.

—*Steve Frick*

say. You ask great questions, you have scientific integrity, you are an authority in the field, you get things done, and you are to be respected academically. They might even consider a collaboration with your team. The questions are harder. Rare diseases or rare injuries are very difficult to study at a single institution. It is just impossible for a single institution to build up enough numbers to statistically analyze many of the challenging questions that continue to plague our patients. Why not partner? You might think you are ready to start your own prospective multicenter study complete with data usage agreements, regulatory variability among IRBs, grant support distribution, and all the rest, but start small. Learn the ropes from someone else who has done this before. Let them battle all the regulatory monsters while you gain from their experience. Find a study group with clinical interests similar to yours. Contribute some of your patient data to a retrospective arm of a larger study. Let your team shine by turning in your completed data set ahead of the deadline. Volunteer to write up the results. Harness the skillset of one of your team members that the study group may be lacking. Do what it takes to gain authorship credit for you and your team members. As your knowledge and comfort with multicenter research grows, set your sights on being the host site for the next big collaboration.

Guru says…

If you anticipate writing or even being a co-investigator on grants, it can be helpful to have your NIH Biosketch ready to go so that it only needs minor updates or edits. This information can be entered and stored through: https://www.ncbi.nlm.nih.gov/sciencv/

Many grant applications require this format.

—*Jennifer Laine*

Step 7: Grants

These steps are not linear. It is true that you are unlikely to build a large research team until you have demonstrated your dedication to clinical research by garnering some early success, but many of these steps will overlap. This is never truer than when it comes to grant support. As has been previously discussed, don't start off with the hopes of being awarded the next big National Institutes of Health (NIH) or Department of Defense (DOD) prize. The big grants typically go to those who have previously been awarded other big grants, so start small. Apply for local institutional grants. The applicant pool will be much smaller, and the application process will be much less daunting. In some cases, these local, institutional grants may go unclaimed. You might be the only applicant for financial support that sits as a line item on budgets year after year just waiting for a reasonable idea to arrive. Get a couple of those under your belt. Learn the language of grant applications. Understand what grant reviewers are looking for then set your sights on societal grants or industry grants. Go after some larger philanthropic funds. Get some of those bigger dollars next. Build up a portfolio of financial support. Learn how to utilize those more difficult dollars when strings are attached and when funds can only be used for certain

Guru says…

If you volunteer your expertise to review, reading the other reviewers' comments about the paper is a great way to learn.

—*Steve Frick*

Guru says…

"Grantsmanship" is definitely a thing. A great way to learn it is to utilize mock study sections at your institution or to volunteer to review grants locally or for a foundation (like POSNA).

—*Shawn Gilbert*

purposes or very defined sets of questions. Once you can show that grant money is safe in your hands, you can go after that really big money with a reasonable chance of taking home the prize.

Step 8: Continually Improve Your Skills

You want to be a better writer of scientific manuscripts—sign up as a reviewer for a few journals. Learn what makes for a good paper and see where others make mistakes. You want to increase your chances of being awarded a grant—agree to serve on a grant committee and review some grants proposals. Learn the language of successful grants. You want to be a more gracious and grateful mentee—look for opportunities to mentor others. You want to learn how to be a better leader of a research organization—put yourself in positions where you are led by others. Volunteer to head a subcommittee of a multicenter collaboration and watch a great leader manage your efforts. You want to ask better questions and design higher quality studies—voraciously consume scientific literature. You will develop into a mature clinician scientist. What began as a goal of maybe producing one publication a year may grow into a thriving research machine that supports the research efforts of dozens of students, residents, and fellows and provides salary support for maybe a dozen or more others.

Guru says…

If you are not part of a journal club, join one or start one.

—*Steve Frick*

Conclusion

A successful clinical research program in pediatric orthopedics won't just happen. It takes work and time commitment. But, thoughtful planning, realistic early expectations, and a few key initial steps can get you on the road to research success. Don't wait for all the pieces to be in place before you begin—utilize available resources early, engage key stakeholders, advertise your program and your successes to build momentum and recruit more talented, motivated people. Hone your writing skills by reviewing research proposals, manuscripts, and grants. Add key research personnel once your program begins to grow financially. Collaborate locally, regionally, nationally, and internationally. Seek out small attainable grants and grow to much larger research prizes. For those who enjoy the scientific process and enjoy asking questions and seeking answers, a successful clinical research program can be one of the most rewarding aspects of a pediatric orthopaedist's career.

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