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Orthopaedic clinical research: building a team that lasts

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- Medical progress, including in the orthopaedic surgery field, depends on the interaction and collaboration between: physicians, with their expertise on the clinical setting; scientists, with their expertise on the research setting; and professionals who are skilled in both settings (clinical scientists). This leads to the need to develop research approaches which involves people who are committed and support the process, strategic planning, and a cohesive team that can execute the tasks. All these interactions must be supported financially in order to maintain the long-term viability of such team.
- Time management is crucial for the clinical research team. To ensure success, the research team must be flexible in order to adapt to dynamic clinical and surgical schedules. It is especially important that surgeons have regular, dedicated quality research time to maintain a consistent interaction with the team.
- Building a successful and productive orthopaedic clinical research programme involves many challenges in creating proper leadership, obtaining funding, setting proper resources, establishing necessary training, and providing guidance and insight around the importance of each role that every member plays on the team.

Keywords: clinical research; orthopaedics; team building

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Introduction

Clinicians are often faced with the challenging task of where to begin when starting a research programme or interacting with a team that does research. Many clinicians may be starting from scratch when embarking on this undertaking of building a research team on their own. Each clinician's needs will vary depending on the infrastructure already available in their practice or institution and how much time can be devoted to research. Nonetheless, a shared first approach is to understand the organizational network of a research team. Fig. 1 offers clinicians a brief overview of how a team network works through dynamic interaction.

In the domain of *research*, your part could be one of many diverse roles including primary and coinvestigator, scientist, physician, nurse, pharmacist, research study coordinator, statistician, research fellow and other health professionals. In the domain of *surgery*, your role could range from being a staff surgeon, anaesthesiologist, physician assistant, nurse, resident or fellow. Altogether, people from various backgrounds are involved and interact in wide-ranging research collaborations and projects extending from clinical trials to population-based studies, or from theoretical cost-analysis models to applied research on the optimization of health care services. Regardless of role and career stage, each individual holds a fundamental position that allows the system to work. The programme's ultimate success depends upon productive interaction in a healthy established environment that has a focused commitment to shared strategic goals for the group. A well-rounded research team typically consists of a diverse group with different roles capable of filling different research niches. Table 1 presents a list of roles that are useful to establish staff when building a research team. As the team matures, each role may be covered by one or more individuals by cross-training and sharing best practices within the research programme. It is the goal of this review to provide an overview of the structure and workflow of an orthopaedic clinical research programme and the team organizational network.

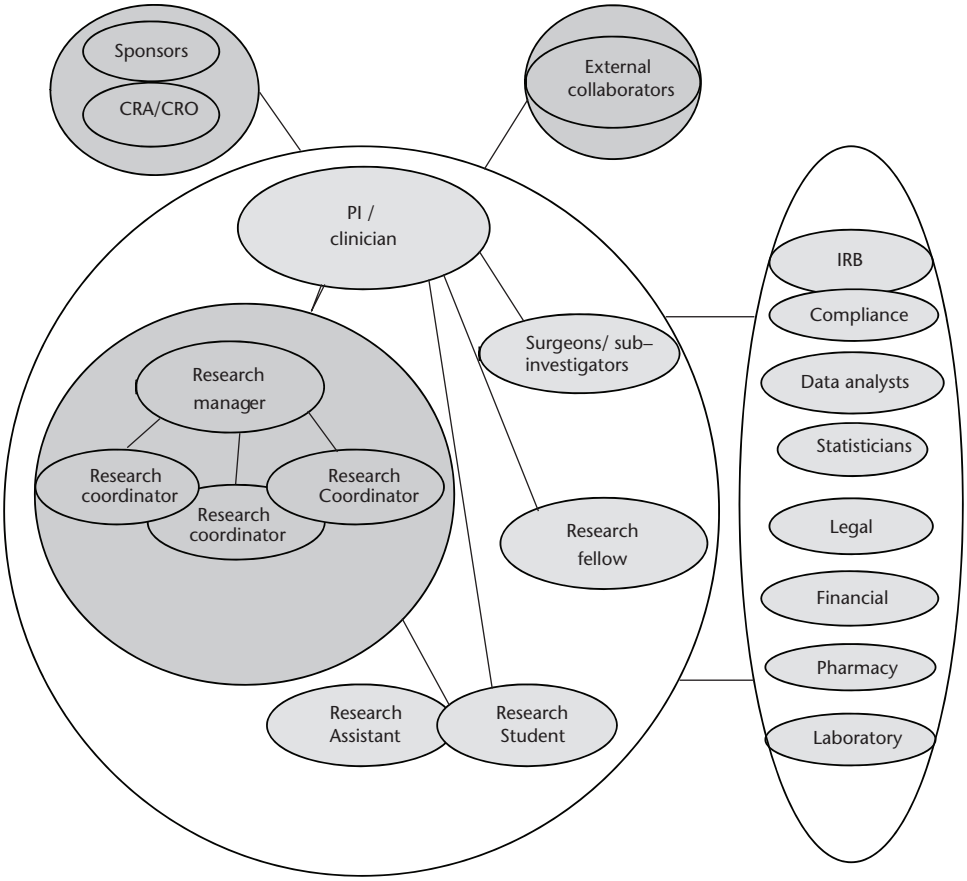

Fig. 1 Network of a team.

Note. CRA, clinical research associate; CRO, contract research organization; PI, primary investigator; IRB, institutional review board.

Table 1. Orthopaedic clinical research team roles

Role	Description
Primary investigator	Responsible for executing the clinical research project as outlined in the protocol
Orthopaedic surgeon/s	Physician responsible for diagnosing, treating, operating and educating
Research manager Research coordinator/s	Protocol development; subject recruitment; informed consent development; obtaining consents; collect and maintain clinical data; serve as the main contact for personnel and subjects during a clinical trial/project
Data analysist	Organizes study data to analyse using available statistical software; advises the team how to best utilize database information; edits, organizes and maintains computerized study data
Statistician/s	Consults with investigators to determine questions of interest and data needed; writes statistical methods sections of manuscripts and abstracts for publications or presentations based on study data; ensures studies are properly powered, appropriately designed, and that necessary confounding variables are collected
Research fellow/s	Produces research publications; serves as co-investigator or coordinator; assists with surgical or operational roles
Legal	Responsible for tracking and producing invoices for clinical trials as well as assuring all appropriate fees are collected from the sponsor; contract negotiation
Compliance	Responsible for providing information, training and support to ensure adherence to the laws, regulations and policies governing research; oversees the institutional compliance programme related to all aspects of research; relies on the combined efforts of researchers, support staff, study participants and others as well as collaboration among operational, departmental, collegiate and central units
Institutional review board	Responsible for the review and approval of applications to conduct research involving human subjects to assure that risks to research participants are minimized and participating by these subjects is done so in a voluntary, informed manner; protects the rights, safety and welfare of individuals recruited to participate in research activities
Financial	Works in the review and analysis of protocols for financial feasibility; prepares and tracks quarterly reports; invoices; ensures appropriate billing for IRB (initial, amendments, renewals and terminations review services); monitors all research expenses and charges within Administrative Account; maintains clinical research financial records for all externally and internally funded department protocols

Team members

The leader of any study is ultimately the primary investigator (PI), who is the individual responsible for the design, conduct, compliance, administration, and dissemination of the research. In most countries, anyone with a medical license can serve as a PI of a clinical trial, regardless of whether or not he or she has had previous training or experience in clinical research. The surgeon who is leading the research team as the research director must rely on his/her partners to participate as PIs on research projects as they fit individual interests and skills. It is important that he/she selects individuals with a similar commitment to the goals of the programme, and that these people are reliable, responsive and committed members of the team. Equally important is the infrastructure throughout the department, and the orthopaedic surgery team should adapt a culture of clinical research so all team members can support all primary investigators in the department. While establishing roles, it is important to highlight the importance of time management. The surgeon's priorities will vary greatly from other team members, and an optimal way to ensure that time is being managed well is to commit to weekly meetings with all members of the team. This regular, dedicated quality research time is vital to maintain a consistent interaction with the team and research.

Although physicians are vital in creating a culture promoting and fostering research, non-physician staff, such as the research programme manager and coordinators, are imperative to the overall success and sustainability of the programme. An American Society of Clinical Oncology (ASCO) study completed in 2003 found that physicians accounted for only 9% of the overall time required to conduct a clinical trial, whereas nurses and data managers contributed more than 30% each. At least one dedicated research staff member is critical to ensuring studies receive necessary attention. The clinical research associate or coordinator is responsible for daily research study tasks and assuring all deadlines are met. Study success relies heavily on this person because they are responsible for everything from screening patients to data collection regulatory compliance. These individuals commonly serve as the main source of interaction with study patients, which can substantially influence participant enrolment and retention. A research manager is a worthwhile investment, particularly when the research team expands to include more than one or two coordinators. This person helps oversee all aspects of the research programme, assists with dissemination of the research findings, and provides a level of stability important to ensuring the longevity of the group.

Training staff is imperative when developing a research team and should combine on-the-job instruction with formal training. Training within the institution should include mentorship from senior staff, active observation of study tasks, participation during study site initiation visits, and involvement during monitoring/audit preparation. Formal research training can be obtained through professional societies, universities, and online. To note, the latest version of the Declaration of Helsinki, dated October 2013, states that 'medical research must be conducted by individuals with appropriate training and qualifications in clinical research'.[1] In different countries, minimum requirements are established for those who participate in research. For example, the Collaborative Institutional Training Initiative (CITI) Program is a research enterprise that provides courses in research, ethics, regulatory oversight and the responsible conduct of research. The Innovative Medicines Initiative's PharmaTrain project developed shared standards and guidelines for the development of postgraduate diploma and master's courses in medicines development and related fields, raising the quality of education in Europe.[2] Ultimately, uniform high-level training and education in Europe will make the drug development process faster, more economical, and more tailored to patients' needs, and will give Europe a global advantage in developing new innovative medicines. For physician investigators, clinical research coordinators (CRCs) and clinical research associates (CRAs), there are other highly regarded certification programmes, offered through organizations such as the Association of Clinical Research Professionals (ACRP) and The Society of Clinical Research Associates, Inc. (SOCRA), but there are no formal regulations that define the educational or experiential requirements, and personnel certification is not mandated. Several additional clinical research educational resources are also available to help researchers through the American Academy of Orthopaedic Surgeons (AAOS), Orthopaedic Research Society (ORS), the European Orthopaedic Research Society (EORS), and the European Clinical Research Infrastructure Network (ECRIN). Although most researchers in the orthopaedic field are self-taught, there are numerous research career pathways offered through elite programmes, such as from the National Institute of Health (NIH) and the Innovative Medicines Initiative (IMI), e.g. PharmaTrain (an IMI programme on training in medicines development). The Orthopaedic Research and Education Foundation (OREF), offers fellowship training and opportunities for graduates to postdoctoral programmes and residency career paths. Their mission is to identify and support promising researchers whose work will have a practical impact on orthopaedic patient care.[3]

Overall, if the research programme is new, it may be helpful to gradually build the research portfolio so the research members have time to properly learn the many responsibilities associated with specific research projects and clinical trials. If newly hired research coordinators begin during actively running studies, consider initiating

incremental advancements so that responsibilities can increase over time. In either situation, the goal should be to provide achievable goals that lead to job satisfaction and research success. Considering that it make take up to 6 to 12 months to fully train research staff, frequent job turnover can affect data quality and impede programme development.[4] Longevity in a team member instils knowledge and general information about the way the team operates, which in return can be exemplified when recruiting and training new recruits. The goal in team member retention is perpetuating research team success.

Recently, several research professional groups formed and named the Joint Task Force (JTF) in an effort to establish a high-level set of standards that could be adopted worldwide and serve as a framework for defining professional competency throughout the clinical research enterprise.[1] For the first time, a globally relevant framework exists that identifies the associated cognitive skills necessary to conduct a high-quality, ethical and safe clinical trials. Logically, not all members of the clinical research team require the highest level of competency, but these harmonized core competencies can provide a basis for developing more specific statements of knowledge, skills and attitudes required by clinical research professionals for more focused purposes.[1] The categorization of competencies from novice to expert, or by professional role, can be a next step in this endeavour. Competency-based curricula or job descriptions can lead to standardization in training requirements, standardization and accreditation of educational programmes, and better definition of career tracks and performance evaluations.[1]

Once the team is in place with roles fulfilled, we turn to four principles that clinicians can use to serve as a framework for building a strong clinical research programme: (1) Leadership; (2) Dynamics of the culture; (3) Funding and disclosures (revisiting the practices within the practice); and (4) Team building.

Leadership

In any health care setting, leadership's first priority is to be accountable for effective care while protecting the safety of patients. This is no different in orthopaedic research. Trust and respect should permeate the team. A ship, like an organization, is a complex system, and it has a captain who decides on direction, but it is the crew working together that reaches the destination. Many people have heard the saying 'Employees join companies but leave managers'. There is strong evidence to show that this remains factual throughout several different organizations.[5,6] Strong leadership from research managers and investigators builds the foundation for a solid research team. Empirical data suggest that establishing clear, transparent trust between manager and employee, especially in handling mistakes, is of the utmost importance in the working relationship and progress for future success in the organization.[7,8] Mistakes, lapses, omissions and other human errors are opportunities for improvement, and lessons learned from them should be shared.[8] Punishing, terminating or failing to support an employee who makes a mistake during the course of an adverse event can erode leadership's credibility and undermine organizational safety culture.[8] Clinical experience is not often sufficient to foster the necessary skills in leadership for surgeons.[9] Data have suggested that surgeons are not always readily equipped with the skill sets required to be efficient business leaders or research managers.[9] It is important to recognize that these capabilities and talents must be cultivated in order to establish a successful and enduring orthopaedic research programme.

A process for vetting new research projects must be established and followed by each PI, to be reviewed and approved by the research director. This feasibility step must incorporate a review of past procedures to obtain accurate enrolment projections, rather than relying on anecdotal estimates which are most often inflated. An integral part of starting clinical trials is using a well-structured feasibility checklist designed to determine the readiness of the site and staff, assess anticipated regulatory or ethical challenges, and help the site think through operation aspects, such as subject recruiting. Feasibility questionnaires are essential for helping investigators evaluate the realistic expectations of being successful in fulfilling project requirements. Most importantly, this step helps ensure that studies will be conducted ethically and according to good clinical practice guidelines. Accepting a leadership position includes having to make difficult choices, and being able to accept that someone else may come up with better ideas and actions at times which require effective listening competence.[1] A great leader makes choices based on the team's best interests, not his/her own, and is there to serve not to be served. In the work environment, the concept of serving can be unsettling as it seems to turn the chain of command upside-down. In a traditional hierarchy, the customer and staff are on the bottom 'looking up' at leaders, now they work side by side.[6] Serving side by side matters because it engages employees. Engaged employees maintain clients, which increases productivity for the business.[6] Learning what motivates an individual employee leads to a boost in employee engagement and allows leaders to do more with less. This is a win-win for the leader, the staff, and the organization.[6]

Culture

Every successful professional group, including orthopaedic research teams, establishes a corporate culture. It seems obvious that nothing guarantees constant turnover more than below-market wages and subpar benefits.

Several studies have pointed out the high cost of employee turnovers and the real value of employees as a valuable asset.[10–12] The solution seems obvious too: make sure salary and benefits are in line with your local area and industry. And if we love what we do, work like we do not need the money, simple. Not so much.

Over the past several decades, there has been an emergence of workforce trends and challenges.[13] Employees view their careers from a different perspective than before. Not as a static choice to ride out to retirement, but rather as a fluid ebb and flow with the opportunity to make adjustments as needed to best suit their personal needs at different phases of their careers. These employee choices can leave employers coping with employees who do not hesitate to move on at the slightest provocation or when presented with even a marginally 'better' opportunity. Of course, the research setting in which an individual applies for work will present many different challenges and opportunities when one considers employment within an organization.[13] Academic and private institutions will vary greatly based on the industry and foundation or government support they receive, which can play a role in the research trials and projects that the research personnel will partake in. Academic institutions will require more expenses and steps to perform research, whereas private institutions are likely to be faster or more dynamic in starting projects. Nonetheless, academic institutions often are accredited with more recognition and have appeal for opportunity in publication and further innovation. It is important for managers and leaders to consider their recruits' objectives and career goals, and to continue to support their growth within the team. Growing together through mentorship promotes stability, trust, and employee satisfaction.[1]

Ultimately, orthopaedic surgery departments should acquire a culture of clinical research which would potentially impact the quality of patient care. Such an approach would require strategic planning that expands well beyond individual persons or projects. Health research provides high value to society, as it is vital to record and assess outcomes in clinical practice in order to develop best practices and to ensure high-quality patient care.[14] The field of orthopaedic surgery will have to continue strengthening its research training throughout orthopaedic residencies, its commitment to research programmes and partnerships with scientists who have expertise in clinical outcomes research, so the quality and quantity of orthopaedic research will increase.[15]

Funding and disclosures (practices within the practice)

Research programmes require funding to support research personnel and any patient care associated with the research. There is some inter-institutional variability in grant policies and funding strategies. Each institution separately defines their own missions, scientific priorities, budgets, and funding strategies; one size does not fit all. There are different approaches to grant funding, the types of organizations that are eligible to apply for funding, and the types of grant programmes that are offered. Researchers must work closely with legal teams and grant administrators when available for guidance in navigating application processes and developing budgets. Institutions have the responsibility to conduct research according to State and Federal-mandated practices, especially when it involves human subjects. Industry sponsors have a major responsibility of ensuring that institutions follow good clinical practice (GCP) compliance. Institutions will risk losing funding if they do not meet these standards. Each individual in research, regardless of his/her role, must be familiar with GCP guidelines that surround the ethical conduct of clinical trials, to protect the rights, safety and welfare of humans in research. Each institution must utilize an institutional review board (IRB) – independent, central, or local – to approve and oversee research protocols and to ensure that research members have been properly trained.

There are practices beyond standard GCP that should be utilized, and each individual must understand and comply with the regulations. For example, the Fellowship of the American Academy of Orthopaedic Surgeons (AAOS) adopted Standards of Professionalism (SOPs) on Orthopaedist-Industry Conflicts of Interest.[16] They focus on practices that enable orthopaedic surgeons to serve the best interests of the patient and the profession while participating in academic or commercial ventures. In recent years, legislative measures at the state and national level have been implemented to make relationships between physicians and industry more transparent.[17] Orthopaedic surgeons receive a disproportionately small share of funding from the National Institute of Health, but they receive the largest amount of funding from industry sources.[1,2,18,19] Physicians have faced increased scrutiny for financial ties to pharmaceutical companies and medical device manufacturers.[20] Consequently, in an effort to bring transparency to the financial relationships between physicians and industry, the Physician Payments Sunshine Act was enacted in 2010 along with the Affordable Care Act. Several recent studies have analysed the financial ties between physicians and industry, asking the important questions such as 'Who is receiving how much for what purpose, and what does this mean?'[20] In essence, this act empowers patients and allows them the knowledge of payments made by the medical industry to physicians and hospital staff, in terms of gifts, research funding, medical education, or consultancy that must be reported to the Centers for Medicare and Medicaid Services (CMS).

Equally important are disclosure requirements between physicians and medical journals. Over the past 25 years, it has become standard practice in medical journals to require authors to disclose relationships with industry.[21] However, the requirements vary across journals and often lack specificity. It is left to authors to determine the appropriate period for disclosure or the relevance of a financial relationship to a submitted article. As a result, disclosures may be inconsistent, with neither reviewers nor readers being fully informed of the ties between authors and industry.[21] To promote full transparency, journals could consider adopting ways to link and publish information contained in a national database, such as the way recent health care legislation did with the Physician Payments Sunshine Act.

Team building

With all of the leadership, practices, and dynamics at play in establishing an orthopaedic research programme, team building presents a unique set of challenges. Orthopaedic research managers are responsible for establishing and enabling the communications of their team. They anticipate and resolve conflicts, and also motivate and encourage their group. The success of any business, whatever the industry, rests to a great extent on the people employed within it. The research team leader needs to be confident that team members have, or can develop, the necessary skills and knowledge for the research in hand. The research leadership should demonstrate an area of general knowledge in understanding the role each research member plays, not only to ensure that a qualified individual fulfils that role, but also to ensure that the duties of that role are being achieved. The research leadership should also possess quality 'people skills' and recognize those who are dedicated, and help find balance for those who are struggling. Clinical research projects can involve so many different aspects, from finance to data collection, networking and data entry, to audits and surgery, that it is not uncommon for some members to assume multiple roles. The study coordinators collaborate with data analysts, the Research Fellows coincide with coinvestigators, legal contacts the grant administrators, and there is an ever long chain of communication among all aspects of the clinical research team. The research leadership has the challenging task of overseeing all of this as part of their role, and diffusing any escalating situations that could transpire between the team. According to a recent systematic review, teamwork is a daily practice and involves integration, synergy, availability, reliability, balance between autonomy and interdependence of professions, collaboration, and responding to the patient's integral care needs.[22] Communication is necessary for teamwork and the realization of inter-disciplinary environments. It involves: being open, understanding that it is necessary to listen and talk, informal meetings and frequent meetings, common language of the team.[22] A successful clinical research team must dedicate time to regularly scheduled weekly meetings to discuss study progress and to address any inefficiencies or issues with an open exchange of ideas. As with any field that requires continued performance at a very high level, research can have its setbacks. Enrolment goals may not be met, publications may be rejected, a grant could be denied and mistakes will be made. The team as a whole should strategize and develop corrective actions plans when needed.

Overall, we work with people, and every person we work with is different. They each react differently to us, and we react differently to each of them. This is what makes life and our work careers interesting. There is always the autonomy of the individual; choice exits, no matter what education, societal, or diverse background; what separates an individual from a team player is the decision they make to be a team player. It is up to each team member to make contributions and up to a great leader to acknowledge the contribution that each team member makes for the team. Ultimately, being a leader is a privilege, and as such you have a moral obligation to conduct yourself with honour and conviction. It is all about the right people.

Conclusion

Orthopaedic clinical research programmes function through a dynamic team organizational network that requires training, skills, funding, and compliance. Such programmes start with a physician who is committed to research and who builds a team that is dedicated and shares the same goals. Orthopaedic surgery departments should acquire a culture of clinical research and focus on the positions of research managers and coordinators, which will ensure success and positively impact patient care.

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ICMJE CONFLICT OF INTEREST STATEMENT

WKB reports consultancy for Stryker, employment by HOPCo, Cleveland Clinic, payment for lectures including service on speakers' bureaus from Stryker, that they are the Editor in Chief of the *Journal of Hip Surgery*, royalties from Custom Orthopedic Solutions, Stryker, Thieme and Arthrex, stock/stock options in Custom Orthopaedic Solutions, Capsico Health, Peerwell, PT Genie, Sight Medical, Stryker and Beyond Limits, travel/accommodation/meeting expenses unrelated to activities listed from Stryker and HOPCo, all outside the submitted work.

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