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Invited Editorial

Challenges in Clinical Research

Introduction

Clinicians are often faced with the challenging task of where to begin when starting a research programme. Many clinicians may be starting from scratch when embarking on research. Each clinician's needs will vary depending on the infrastructure already available in their practice or institution and the amount of time that can be devoted to research. Most successful researchers have achieved their success through building robust and sustainable research teams. Hence, it is important to understand the organizational network of a research team.

The Research Team

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. The surgeon who is leading the research team must rely on his/her partners to participate in 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 study, 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.

In academic units in developed countries most of the logistics related to research is handled by research program managers and coordinators. However, in resource limited settings this responsibility lies with the clinicians involved in conducting research.

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 and involvement during monitoring. Formal research training can be obtained through professional societies, universities, and online. 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'.

Leadership

In any health care setting, leadership's first priority is to be accountable for effective care while protecting the safety of patients. Trust and respect should permeate the team. Strong leadership from research managers and investigators builds the foundation for a solid research team. Establishing clear, transparent trust between the leader and other members of the team, especially in handling mistakes, is of the utmost

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importance in the working relationship and progress for future successes. Mistakes, lapses, omissions and other human errors are opportunities for improvement, and lessons learned from them should be shared. Punishing, terminating or failing to support a junior researcher who makes a mistake during the course of an adverse event can erode the leadership credibility and undermine current and future research. Clinical experience is not often sufficient to foster the necessary skills in leadership for surgeons. Data have suggested that surgeons are not always readily equipped with the skill set required to be research managers. It is important to recognize that these capabilities and talents must be cultivated in order to establish a successful and enduring orthopaedic research programme.

Research Culture

Orthopaedic surgery departments should acquire a culture of doing clinical research which would have an impact on 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. The field of orthopaedic surgery will have to continue strengthening its research training throughout orthopaedic training, and beyond to 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.

Funding

Research programmes require funding to support research personnel and any patient care associated with the research. There is some inter-institutional variability in policies and funding strategies. Each institution separately defines its own mission, scientific priorities, budgets, and funding strategies. There are different approaches to funding, and the types of organizations that are eligible to apply for funding. Industry sponsors also have a responsibility of ensuring that institutions follow good clinical practices. 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 the guidelines that relate to the ethical conduct of clinical

trials, to protect the rights, safety and welfare of patients involved in research. Each institution must utilize an Ethical Review Committee independent, central, or local – to approve and oversee research. Physicians have faced increased scrutiny for financial ties to pharmaceutical companies and medical device manufacturers. Several recent studies have analysed the financial ties between physicians and industry.

Equally important are disclosure requirements between physicians and medical journals. In recent years, it has become standard practice in medical journals to require authors to disclose relationships with industry. 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.

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. Lead clinicians are responsible for establishing and enabling the communications of their team. They anticipate and resolve conflicts, and also motivate and encourage their group. 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 support 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 research leadership has the challenging task of overseeing all of this as part of its role, and diffusing any escalating situations that could transpire within the team. Teamwork is a daily practice and involves integration, synergy, availabil-

ity and reliability. Communication is necessary for teamwork and the realization of inter-disciplinary environments. A successful clinical research team must dedicate regular time to schedule 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, submissions may be rejected, a research grant could be denied and mistakes will be made. The team as a whole should strategize and develop corrective action plans when needed.

It is up to each team member to make contributions and up to a good leader to acknowledge the contri-

bution that each team member makes for the team. Ultimately, while being a leader is a privilege, and as such one has a moral obligation to conduct oneself with honour and conviction.

Conclusion

Orthopaedic clinical research programmes function through a dynamic organizational team network that requires training, skills, funding, and compliance. Such programmes start with a surgeon 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.

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