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TITLE: A model for integrating clinical care and basic science research, and pitfalls of performing complex research projects for addressing a clinical challenge

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ABSTRACT

The collaboration of clinicians with basic science researchers is crucial for addressing clinically relevant research questions. In order to initiate such mutually beneficial relationships, we propose a model where early career clinicians spend a designated time embedded in established basic science research groups, in order to pursue a postgraduate qualification. During this time, clinicians become integral members of the research team, fostering long term relationships and opening up opportunities for continuing collaboration.

However, for these collaborations to be successful there are pitfalls to be avoided. Limited time and funding can lead to attempts to answer clinical challenges with highly complex research projects characterised by a large number of “clinical” factors being introduced in the hope that the research outcomes will be more clinically relevant. As a result, the complexity of such studies and variability of its outcomes may lead to difficulties in drawing scientifically justified and clinically useful conclusions. Consequently, we stress that it is the basic science researcher and the clinician’s obligation to be mindful of the limitations and challenges of such multi-factorial research projects. A systematic step-by-step approach to address clinical research questions with limited, but highly targeted and well defined research projects provides the solid foundation which may lead to the development of a longer term research program for addressing more challenging clinical problems.

Ultimately, we believe that it is such models, encouraging the vital collaboration between clinicians and researchers for the work on targeted, well defined research projects, which will result in answers to the important clinical challenges of today.

What this topic is about

In this article we present a model for the successful integration of clinicians into a basic science research program. We list the advantages of the collaboration between clinicians and basic science researchers, but also highlight challenges. In particular, we outline some of the common pitfalls, based on our experiences, associated with attempts to address clinically relevant research questions within highly complex research projects. We are emphasizing that a clinical problem, just like any other scientific problem, requires a systematic approach to be solved successfully.

Common problems and challenges

The collaboration of clinicians/clinician researchers (in the following described as “clinicians”) with basic science researchers (described as “researchers” or “scientists”) is essential for addressing clinically relevant research questions. In ideal cases, this cooperation results in a mutually beneficial collaboration.

The researchers profit tremendously from direct contact with clinicians and the clinic. This may include logistical advantages, such as access to real patients, or the possibility to collect tissue samples from patients, but mainly comes from the awareness that the research conducted is addressing a real clinical need or problem. Without this interaction between researchers and clinicians, the danger exists for research to be conducted for the *sake of research* without any clear implications for the greater public. The ultimate goal for successful collaborations is the translation of research outcome into clinical practice, “from bench to bedside”. If this is achieved, the reward obtained from the knowledge to have contributed to a patient’s improvement exceeds the one received from the cheer of the individuals’ own research community by far.

Clinicians conducting experimental research, in turn, are dependent on a well functioning research support network that is usually already established at universities

or research institutes to solve scientific problems. Regardless of whether the challenge relies on expertise in biology, biochemistry, material science or biomechanics, advanced research methods and instruments used in these areas require the highly specific skill-set of trained researchers. This ensures that optimal results are obtained from the methods applied. Through access to necessary equipment, expertise and established research methods, this support network therefore saves valuable time for the clinician, who is often already time-restricted through clinical commitments and thus has only limited time for active research.

However, the initial integration of clinicians into a basic science research program can be challenging. In every country and medical specialty, the incorporation of a research agenda into the educational curriculum for clinicians is treated differently. At our university, we have been successful with a model, where early career clinicians spend a designated time at the university, performing full time research to obtain a postgraduate qualification. During this time, typically one or two years, they are embedded in an established research group and are supervised by a senior researcher. The clinicians are thoroughly trained in the scientific methods necessary for the completion of the particular research project. A tightly planned and controlled time schedule assures the timely completion of the main experimental and evaluative phase of the research project. During the time at the university, the clinicians become integral members of the research team. We believe that this is the key advantage of this model as it fosters a long term relationship between the research group and the clinicians that continues after their return to the clinic. Furthermore, through the concentrated work on a research topic in their field of interest, clinicians are given the opportunity to establish a research niche which can be pursued during the further clinical and research career. Since the implementation of this model at our university in 2004, ten young clinicians have entered the postgraduate research program, five have already completed and the research outcomes have been documented in more than 20 journal publications.

Even after successful integration of clinicians into established research programs, and despite the obvious advantages derived from close collaboration between clinicians and researchers, there does exist a “double-edged sword”. Limited time and funding can lead to attempts to answer clinical challenges with highly complex, multi-factorial research projects. In such cases, a large number of factors and parameters are then introduced to make the research model as similar as possible to a clinical scenario. This complexity is introduced in the hope that the research outcomes are more “clinically relevant” but often results in a high degree of variability in the measured outcome parameters. Consequently, differences between outcome parameters often cannot be confirmed statistically. However, even if any measured differences are statistically significant, it may be impossible to draw clinically important conclusions from the results of the study, as it is unclear which of the many confounding factors has contributed to the outcome, or to what extent. This not only clouds the clinical impact of the study, which is frustrating for the researchers and clinicians, but it also makes it extremely difficult to publish the results in a reputable scientific journal. Careful planning of the study design with statistical modelling for the calculation of appropriate sample size is therefore essential.

Research scientists are trained to analyse complex problems, to divide them into “bite sized” sub-problems and then address these with targeted research studies. The outcomes of these individual studies, when combined, enable conclusions to be drawn with a high degree of confidence, in response to the original clinical challenge. Unfortunately, with the prospect and excitement of the possibility to be contributing to solving a clinical challenge, this strategy can be forgotten.

Despite the potential pitfalls of the collaboration between clinicians and researchers for addressing clinically relevant research questions, we still champion

these vitally important relationships. However, we stress that it is the scientist AND the clinician's obligation to be mindful of the limitations and dangers of such multi-factorial research projects. Furthermore, we promote the interaction between researchers and research-experienced senior clinicians, who may be involved as mentors, in order to develop clearly defined research questions with a clinical focus and the choice of the most appropriate research methods, being defined from the outset.

Alternatively, if it is not possible to divide the clinically relevant research questions into achievable sub-studies, it must be considered whether a clinical study (e.g. a randomized controlled trial) may be the most appropriate path for answering the question posed.

Tips for researchers

1. As an early career clinician who is interested in doing research, look for an established research group at a university or research institute in your area of interest. Approach them about the possibilities to get involved, but be prepared to spend a significant time with this group. This is an investment into your future career and demonstrates your true commitment to research.
2. Once the contact with a group is established and a research project is being defined, do not try to make your research project more clinically relevant by adding more clinical components, variables and parameters.
3. Do your research and check for existing literature in your area of interest and look for gaps in the current knowledge. Then pick one aspect that *you want* to and, most importantly, *can contribute* to answer this problem with the research methods and support available to you.

4. Keep your study design simple and make sure that sample size, research methods and experimental model are appropriate for answering your research question.
5. If it is your goal to address a highly complex clinical problem, the development of a longer term research program with a logical sequence of individual, well defined, achievable research projects is essential.
6. Once you have completed your clearly defined, targeted research study, be careful not to draw conclusions for the clinic that go beyond the scope of your project.

Conflict of interest

The authors have no conflicting interests to declare.