Facilitating Translational Research

Would a carpenter be asked to manage building a new housing development? Probably not. More likely, a real estate developer with the skills, experience and knowledge of the local market and trades, including carpentry, would manage such an undertaking. Good developers anticipate and address the challenges of building and selling homes. Delivering attractive, appropriately priced homes on time and on budget requires that developers use their knowledge, experience, and judgment to make numerous decisions that engage the right talent at the right time to balance development risks and costs.

Likewise, would musicians form an orchestra without a conductor? Again, probably not. Despite the considerable skills of even the very best musicians, they collectively create their best music when guided by a conductor.

If real estate developers and orchestra conductors are needed to facilitate their respective resources to get the best outcomes, why is the complex process of translational medical research in academia often led by a person with deep expertise in only one of, or at best a few of, the disciplines required to create viable solutions to important unmet medical needs?

Usually, the responsibility for managing translational research in an academic setting falls to a researcher designated as the "Principle Investigator" (PI). Academic healthcare institutions are very familiar with the role of PI as the responsible party for the conduct of all aspects of basic or applied research. A PI may be technically oriented and conceive of novel solutions, or be clinically oriented, with the savvy and commitment to appreciate the possible impact and champion the implementation of an innovation. Some PI's can do both and some can also raise venture funds and start a business, but they are the exceptions.

The traditional role of most PIs may not be ideal for translational research. Unlike the rigorous training they obtained in their specific discipline, PIs typically learn to conduct translational research by trial and error, inevitably making mistakes and experiencing failures along the way. Many failures are due to avoidable mistakes, such as not anticipating the potential consequences of decisions. Others result from the PI relying too heavily on his or her own, often limited experience. It is unusual for a PI to even consider taking work in a direction outside of their area of expertise if a major roadblock is encountered mid-stream. As the saying goes, "when the only tool you have is a hammer, everything looks like a nail."

In contrast to the traditional approach, one strategy for overcoming the challenges in translational medical research can be adapted from the approaches taken by the successful developer and conductor: focusing responsibility on an experienced coach or facilitator. The facilitator's role is to synergize, harmonize and synchronize the work of diverse professionals to achieve a shared vision of success through a journey with multiple, inter-related steps. This strategy should be even more valuable in translational medical research due to its complexity. It inherently entails more unknowns and risks, as well as unique requirements, such as adherence to strict constraints to protect animals from undue suffering or patients from harm. Even more than their counterparts on a housing project or in an orchestra, academic researchers often have very different motivations that can vary with the stage of their career, personal objectives and/or their institutional policies. In addition, while all industries are highly competitive, healthcare related businesses today face particularly difficult dynamic competitive and regulatory environments.

For over 15 years, the Consortia for Improving Medicine with Innovation and Technology (CIMIT) has learned, in essence, how to be the equivalent of a developer or conductor to create solutions to pressing unmet medical needs. CIMIT has learned to orchestrate the isolated pockets of expertise and misaligned incentives that impede translational research within academic medical centers to accelerate innovations to patient care.

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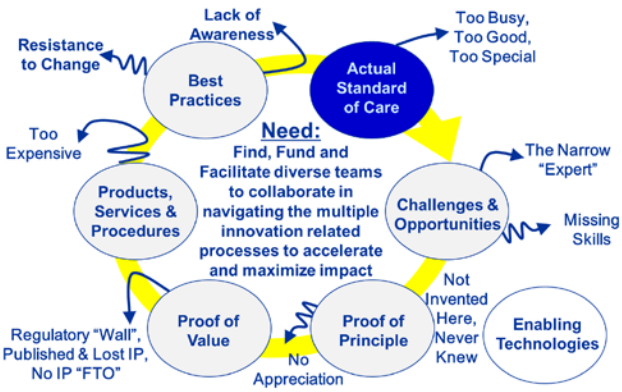

Figure 1: Typical Issues Encountered in the Healthcare Innovation Cycle
The Cycle begins with a stakeholder, who may be a clinician, patient, administrator, supplier, or other participant, observing how care is actually delivered – the actual standard of care. From that observation, the individual can describe challenges to address and/or opportunities available to improve care. Inventors create potential solutions and attempt to demonstrate the feasibility of the underlying principles. Information on challenges and opportunities can also inform basic science and the development of enabling technologies that can later be incorporated into proposed solutions. Robust prototypes are then developed and tested to determine whether the solution will create sufficient value under practical considerations and constraints to attract commercial investment in a product or service, or a healthcare provider to implement a new procedure. Evidence is gathered to demonstrate that the product, service or procedure enables a "best practice" that should be replicated. At that point, the work is still not completed; the solution needs to be broadly disseminated and made widely available before it can become the new standard of care. When the cycle operates at its best, it is indeed a spiral, arriving at the end of each rotation at a higher standard of care, awaiting future medical insights and innovations for further enhancement.

CIMIT is a consortium of 13 academic medical centers and universities in the greater Boston area with a growing network of national and international affiliates. CIMIT focuses on products, procedures, and clinical systems (see www.cimit.org.) It has supported the development of more than 250 potential solutions to important unmet needs through over 600 peer-reviewed projects. After identifying an important unmet medical need—perhaps the most critical of all starting points—CIMIT funds and facilitates teams through the challenging journey that comprises the innovation process. CIMIT has achieved what we believe to be an enviable success rate, particularly given that its support starts at the very early stages of development: more than 17% of CIMIT-supported teams have brought solutions to patient care and an overlapping 27% have transitioned to commercial partners, with most of the remaining teams still active.

CIMIT has termed the process of creating innovative products, procedures, and care delivery systems as the "Healthcare Innovation Cycle." (Figure 1) Representing this process as cyclical rather than linear highlights a key lesson learned: start with clinical problems rather than technology solutions and keep a focus on the result of improving patient care. While the steps in the process are clean and neat in theory, the cycle is very difficult to implement in practice, even with considerable expertise. Many mistakes occur during the innovation process causing promising ideas to fail needlessly.

For example, to share an insight or discovery with the world, a PI may describe results in an abstract or present them at a conference before properly protecting the underlying intellectual property (IP). While disseminating new knowledge is aligned with academic objectives, it needs to be coordinated with the commercial imperative to protect IP so that an economically motivated company or venture capitalist will be willing to invest. Further, many PIs have the misperception that a patent gives them broad rights to the invention it covers, whereas it only gives them the right to preclude others from using it. This possibly subtle distinction has huge potential ramifications– if decisions are made such that an invention requires the use of IP owned by others to work (i.e., no "freedom to operate" or "FTO"), investors will likely not even consider it unless a very robust license agreement is in place with those who control the other IP.

Unlike the immediate bad outcome if there is poor coordination between an electrician and a framer in building a house, an error in the healthcare innovation cycle may not come to light for years, wasting time and money. Even worse, the ramifications of a mistake may never be seen or appreciated by the responsible group, making "learning by doing" inefficient and arguably impractical. For example, in the case that IP is lost or there is no clean FTO, most investors will not even consider the opportunity. The team may only be told that an investor was "not interested", but never know the reason.

The core approach behind the CIMIT Model is to find, fund, and facilitate multi-disciplinary teams through the innovation cycle to speed and maximize the impact of an innovation on patient care. The fact that CIMIT is multi-institutional increases the opportunities to access the ideal experts as team members. Like a developer or conductor, CIMIT facilitators enable team members to focus on what they do well in contributing to the process.

Effective facilitation is not cheap. It requires seasoned individuals with considerable experience who are seen by PIs as peers, at least. It also requires that the facilitators allocate the time needed to be actively involved in the project. Assigning junior people to manage a portfolio of projects is not sufficient. CIMIT facilitators usually commit at least 25% and often more than 50% effort to a single project. Just as an orchestra with world-class musicians invests in a world-class conductor, CIMIT has shown that it is a very good investment to engage a team of skilled facilitator to make the most of the available resources and teams.

The facilitator must understand and manage the different motivations and incentives that exist among members of the research teams. Clinicians are likely to focus on issues that most affect the care they can provide to their own patients, whereas scientists and technologists may value the potential novelty of solutions and entrepreneurs motivated by profit potential. Rather than try to change existing motivations or incentives, an experienced facilitator can chart a path and show team members it aligns multiple objectives in such a way to meet everyone's needs and interests over time. Success requires constantly synchronizing the skills and composition of the team to meet the challenges at any point in the process, much like the accomplished developer and conductor.

However, whereas a successful developer or conductor generally receives the acclaim for their work, the credit for success of the healthcare innovation goes to the research team and especially the designated PIs, not the individuals who facilitate the cycle. Therefore, finding people with the required skills and experience who are willing to facilitate the success of others can be a significant challenge. Further, finding sources of funding that understand the value that such facilitation brings is a challenge. Fortunately, the situation is changing in part due CIMIT's track record of success and that of organizations adapting and using the CIMIT Model.

Substantial institutional investment is initially required to put the CIMIT model in place, including support for the facilitation team and seed grant funding to attract innovators and clinician researchers. CIMIT has documented its clinical, academic and commercial metrics of success to understand and improve the short and long-term value of the investment. In looking at just the financial return to member institutions, within a few years their investment is more than fully repaid through grants and associated overhead, with further downstream financial return in licensing fees and royalties. Since CIMIT entered a steady state, for every dollar CIMIT institutions invest in the infrastructure of CIMIT, they receive $3.50 directly back from CIMIT that year to fund potential solutions. In addition, each dollar of CIMIT-funded projects results in an additional $10 of funding to the institutions from outside sources, usually at full indirect cost. The result is more than a 35:1 multiplier of funds to advance solutions initiated with CIMIT support. Commercial investments are in addition and are of similar magnitude, and may generate licensing and royalty payments.

We conclude that translational medical research can be significantly enhanced through active facilitation and treating it as a learnable, dynamic process. It is enhanced by having the flexibility to assemble the most appropriate teams from many organizations to address the specific demands of a potential solution in each stage of its development. While some contend that academic institutions should eschew steps in the innovation cycle beyond pure discovery, we believe this approach is too wasteful of excellent clinical observations that would otherwise never lead to advancements in patient care. In fact, the CIMIT model imbeds business expertise throughout the innovation cycle.

The CIMIT Model works well in the resource-rich environment in Boston. It has also been shown to work well elsewhere when adapted, such as in Manchester, United Kingdom, and Singapore (ref IEEE article). It has the potential to create even more impact as the CIMIT network expands, linking medical innovation hubs across the world to enable enhanced access to assemble the best teams to address the ever-present critical challenges of improving patient care. Recent expansion of CIMIT's scope to develop pharmacological solutions will reveal whether the same applies to therapeutics.

CONFLICT OF INTEREST

The authors state no conflict of interest.

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