Potential for 21st Century’s Academic Health Centers to Revolutionize Healthcare

Lessons to be Learned from Tampere, Finland
Abstract

Academic health centers (AHC) play a significant role in innovation. New revolutionary fields in healthcare, like regenerative medicine (RM), however bring challenges to traditional AHCs in terms of organizing research and innovation. The author conducted an in-depth case study in Tampere, Finland where the author studied how AHC is organized in order to succeed in the RM sector, and found that combinations of technology and basic research, focus on products and applications, relevance to clinicians, commercial awareness and mission orientation are needed. It is argued that in order to be successful in RM research and applications, AHCs should focus on developing an innovative environment for new therapies, bringing commercial awareness to research, and be organized towards a common mission.

Keywords

Academic health center, AHC, regenerative medicine, innovation
1 Introduction

Academic health centers (AHC) in America are one of the success stories of the 20th century1. In the decades following WWII, a growth in federal funding for biomedical research and medical education strengthened the role and position of AHCs2 that are still a central part of today’s healthcare, also in Europe. For example in 2009, the UK announced that they granted official academic health science center (AHSC) status to 5 partnerships between universities and National Health Services, as they saw the potential to compete globally with established AHCs, for example in the U.S., Canada, Singapore, Sweden and the Netherlands3. However, a sufficient funding is a major challenge nowadays for AHCs45.

AHCs have three things in common: involvement in clinical and biomedical research, commitment to specialized patient care, and commitment to teaching6. As medical innovation depends on interactions between universities, especially AHCs, and industrial firms2, in healthcare there is a growing role with AHCs in innovation and the development of new devices, drugs, and applications7. One of the proposed new roles for AHCs are to act as an integrator in the discovery-care continuum in translational medicine8. AHCs play an important role in the innovation process because they are focused on treating patients and advancing healthcare7.

Aim in this study was to show the potential role and structure of AHCs in development of the new regenerative medicine (RM) sector in healthcare, and what managerial and policy implications it brings along. RM can be defined as follows: ‘Regenerative medicine replaces or regenerates human cells, tissue or organs, to restore or establish normal function’9. In this study, RM is associated with stem cell related applications and accessory technologies, even though in pharmaceutical, biotechnology and medical device industries there are RM applications too. This study is based on data gathered in Tampere, Finland. Finland has not granted any official AHC/AHSC statuses as such
for the combinations of universities and hospitals, but the five university hospitals in Finland are generally combinations of university institutes and hospitals comprising the main building blocks of the Finnish healthcare system and by definition are AHCs. In Tampere, a joint institute of two major universities (BioMediTech) are working together with a university hospital (AHC) in order to provide both needed accessory technologies for stem cell research and stem cell applications in the RM sector. It will be discussed in this study how these traditionally distinctive organizations (BioMediTech and university hospital) are essential in the development of RM sector and for the sake of RM should be understood as a one loosely connected AHC from the operational point of view.

2 Innovative responsibility of AHCs

In the literature, academic medical centers (AMC), AHSCs and AHCs are used more or less as synonyms and even though teaching, clinical patient care and research in medicine are building blocks of AHC there is no widely accepted precise definition for it\(^6\). Lately, a conceptual framework was proposed for AHCs adding following four dimensions to building blocks: health, innovation, community, and policy\(^10\). Indeed, innovation fostering environment is important aspect of AHCs\(^11\) and AHC’s roles as innovator and advancer of healthcare are widely acknowledged:

- Co-creation of medical innovation\(^2\)
- Foster entrepreneurial culture\(^7\)
- System integrator in translational medicine\(^8\)
- Focus on treating patients and advancing healthcare\(^7\)
- AHCs or commercial entities are usually responsible for running clinical trials with an aim to reach regulatory approvals\(^12\)
Evolution of new therapy is dependent on progress in co-evolving pathways of clinical experience, medical devices and biomedical scientific understanding and thus, AHCs are fruitful places for new therapies because expertise in clinical medicine, basic sciences and technology exist there in contrast to university-based innovation in medicine where only basic science and technology expertise are available. AHCs are involved in innovation in medicine and there are four identified tasks for AHCs regarding medical innovation:

- development of new technologies, techniques and applications
- adoption of new devices, therapies and procedures
- evaluation and assessment of emerging and established technologies and practices
- advice to public and private sectors

Straightforwardly, the responsibilities for AHCs include development to adoption and evaluation of emerging technologies to societal informing. Innovation in medicine is interdisciplinary and thus, old structures where different disciplines in academia are divided into separate departments might hinder innovation, and by breaking these borders, a new innovative environment could emerge where accidentally significant innovations could also occur as different knowledge is combined. While the juridical relationships with hospitals, medical schools and other components of AHCs might vary, e.g. medical schools and hospitals might be inside a university under shared ownership, or medical and other professional schools are part of universities and hospitals as a separate corporation, actual operations of AHCs are more important.

AHCs work with start-up companies, pharmaceutical companies and medical device companies in order to transfer academic inventions into commercial products and have a societal impact. Processes by which new technologies are generated, and background conditions for innovation, are assumed to be very different in fields of healthcare. Fields such as biotechnology and pharmaceuticals produce
science-based technologies\textsuperscript{17}, and in these fields, medical innovation is stimulated by potential demand for health improving technologies and advances in scientific and engineering knowledge, while it requires interdisciplinary research and involves the crossing of institutional boundaries\textsuperscript{2}. Thus, the future paths of healthcare are highly dependent on the structure and competencies that are found from entrepreneurial and innovation fostering environments inside and outside AHCs.

3 Methodology

3.1 Context

In Tampere, which is the case examined here, the first official RM focused institution, Regea, was established 10 years ago in 2005 by University of Tampere together with Tampere University of Technology, Pirkanmaa Hospital District, Pirkanmaa University of Applied Sciences, and Coxa, the Hospital for Joint Replacement\textsuperscript{18}. Thus, in Regea there was at the ownership level a connection between clinical medicine and academic research from the beginning. Later in 2011, Institute of Biosciences and Medical Technology (BioMediTech) was established as a joint research institute combining parts of University of Tampere and Tampere University of Technology, as a successor to Regea. Combined expertise from these universities make it possible to develop innovations where different technologies and disciplines are needed. University Hospital of Tampere is one of Finland’s central hospitals working with the medical school of Tampere University. There is a lot of medical research in the University Hospital of Tampere, but stem cell based research is mostly in BioMediTech. Clinical operations with stem cell products, however, are conducted in the university hospital.

BioMediTech was established at the same time as the Finnish Funding Agency for Technology and Innovation (TEKES) granted strategic research funding for BioMediTech. With this funding, a
research program Human Spare Parts was established focusing on RM in order to address unmet needs of medicine with stem cells. Together eight groups were included in the program of which four were technology focused groups and four were stem cell biology focused groups. In addition to these groups, there are several other groups in BioMediTech that are not included in the Human Spare Parts program, and also in the schools of medicine and health sciences there are several different groups working with several health related topics. However, the focus here was in the Human Spare Parts program and the RM sector. From the establishment of Regea, tens of millions of euros have been invested in RM research and research facilities in Tampere area, and thus the expectations are high too.

3.2 Method

As an exploratory case study conducted in Tampere, Finland, data was gathered mostly from two organizations, BioMediTech and University Hospital of Tampere. In the Human Spare Parts program, RM is mostly based on stem cells and related technologies. In this qualitative study, 24 persons were interviewed in order to draw an in-depth systemic picture of the RM sector development and ecosystem in Tampere. Interviews were focused on the Human Spare Parts program, even though there are other programs and research groups in BioMediTech focusing on human health. Main themes in the interviews were research environment, finance, market environment, end-value and use of RM technologies. In BioMediTech, 15 interviews were conducted, in University Hospital of Tampere 3 interviews were conducted, and others were in local and regional development agencies, Ministry of Employment and the Economy, TEKES, and a local firm with a RM focus.
4 AHC striving for the future of medicine in Tampere, Finland

In the following themes, important elements of RM found in the Human Spare Parts program were studied with regard to AHC and its new potential multidisciplinary RM function: 1) combination of technological and stem cell research, 2) motivation towards products and applications, 3) clinical expertise in the stem cell groups, 4) commercially savvy groups, and 5) common goal and mission.

4.1 Combination of basic research and technology development

Basic research with stem cells is essentially important because it is in the core of the RM from which all the potential future applications occur. In the Human Spare Parts program, the focus is on different areas of human biology and clinical aspects, i.e. bones and tissues, neurology, ophthalmology and cardiology, where stem cells could be used in the future either directly or indirectly in order to improve health of patients. These groups are not located in the school of medicine nor university hospital, but in BioMediTech. However, there are also clinicians involved in the work of these stem cell research groups, and without this clinical link, it would be difficult to focus research effectively and wisely, or to conduct clinical experiments.

In addition to stem cell groups, four other groups in the Human Spare Parts program focus on biomaterials, biosensors, biomimetic environments, and imaging and signals. As technology and stem cell groups are in the same program with shared funding, it is natural for them to interact with each other. Interaction and collaboration is the key for development of new therapies and supporting tools. Stem cell groups are focusing on applications while technology groups focus on other tasks for the development of tools for stem cell groups.

This interactive work and feedback between technology and stem cell groups enables iterative development. It is essential because research in this field is in the frontline and commercial tools in
the market do not always fulfil the needs of research groups. Thus, it is a great advantage to be able to produce tailored tools within academia. However, in the end all advances are based on high competency in the field.

4.2 Focus on products and applications

Even though it is mostly basic research that is conducted in academia, in BioMediTech there is also a clear focus on products and applications. Existing examples can be found from adult stem cells group where clinical operations are conducted with real patients. The therapy is targeted to facial and cranial bone tissue regeneration from patient’s own fatty tissue, and first operations were conducted already in 2007 and today over 25 operations have been conducted. This stem cell based therapy developed in Regea and continued in BioMediTech has been used in several university hospitals in Finland in order to treat patients. The latest operations have been conducted in Tampere University Hospital located on the same campus with BioMediTech.

Regarding this microvascular reconstruction of the maxilla\textsuperscript{19}, the hospital has a significant role. In the published process, first abdominal fat was harvested in the operating room (OR) for in vitro cell isolation and expansion in laboratory for two weeks. In the OR, after cells were placed in a custom-made titanium cage, the cage was inserted in the left rectus abdominis of the patient for 8 months. Then after several months, grown bone particle was inserted in the facial area. Together there were two surgeries first in the abdomen and then in the facial area.

There are no official clinical trials running regarding this therapy. Instead, these operations are conducted under hospital exemption within the Advanced Therapy Medicinal Product (ATMP) regulation in EU. ATMP hospital exemption is definitely the advantage that EU countries have in contrast to some other countries. This experimental therapy has no officially (in clinical trials) proven safety nor efficacy, and thus without ATMP hospital exemption it would not be possible to provide
this kind of patient care. The other remark is that without a connection between BioMediTech and Finland’s university hospitals there are no possibilities for this kind of operation.

Therefore, within this kind of extended AHC it is possible to provide patient care with applications that are proven in the laboratory but not scientifically in clinical trials. However, without clinical trials, it is not possible to commercially exploit this as a product. To do so, clinical trials are needed to obtain product approval.

4.3 Relevance to clinicians and hospitals

RM research is mostly academia centered but there are several important aspects regarding hospitals too. RM constitutes a new stream in healthcare and it is inspired by current unreached needs of medicine. Thus, experience and expertise of clinical practitioners are a focal point of emergence in this field. Before any official clinical trials, hospitals are places for clinical experiments that are not otherwise possible to conduct. Hospitals are also the places for clinical trials. It is not a task for hospitals to commercialize new therapies, but they might have a significant role in acquiring first business references, obviously in clinical trials and also hospitals are able to find proper patients. It is also beneficial for hospitals as it allows them to be at the frontline regarding new treatments and drugs.

The role of the clinicians was significant in establishing Regea, which was the predecessor of BioMediTech. The first director was a clinician and there was a clinical need to grow bone, which was one of the reasons why development of this stem cell based therapy started. As development of this application occurs in academia, clinical operations are conducted in hospitals where the clinician is needed to do surgery. There are also other staff in the hospital, e.g. nurses that are needed in stem cell therapy operations. In Finland, the good thing is that even though the clinician has all the
responsibility to do the clinical operation correctly, hospitals take the responsibility for the outcome. This makes it easier for clinicians to join medical experiments.

4.4 Commercial savviness

In the cases of innovations that have a significant value for human beings but are not commercially viable, AHCs might play a role in funding, conducting clinical trials, and distribution of therapies. However, the main role for the current technology market is to spread those innovations that are commercially viable for global use. Regarding these commercially viable innovations, AHCs should collaborate with firms by enabling trials and regulatory approval. AHCs should also be proactive towards industries when they have developed an innovation and have some proof that it actually works. However, in doing all this, AHCs should be aware of commercial opportunities. They should also be able to deliver proven concepts. As researchers are not commercially aware naturally, maybe there would be place in the culture of AHCs where some training would be provided.

BioMediTech is active in finding commercial possibilities for research they are conducting and has employed IPR specialists to serve research groups to support this goal. In addition, researchers are trained to be aware of business opportunities regarding their research. Even though they are not business people themselves, they are able to talk and think about possible business opportunities and assist with IPR protection and initial market research, for example.

Regarding commercial applications there are identified short-term and long-term opportunities. Short-term opportunities include, for example, technologies that are developed for stem cell groups while long-term opportunities include stem cell therapies, where clinical trials are needed before commercial use. For example, therapy conducted under ATMP hospital exemption is a non-commercial product and product approval is not possible to obtain before successful clinical trials.
However, because of several clinical operations, there is some proof and understanding about the technological viability and limits of the concept being useful in the translational activities later.

### 4.5 Mission

All the groups involved in the Human Spare Parts program are dedicated to the mission of developing new therapies and drugs, because they obtain some funding and interesting applications in the field from it. This is also a fundamental reason why RM research in BioMediTech exists: a mission to find new ways to cure people. In the end, there are several levels where value is added with RM research and applications. For individuals, there is a clear value as they receive new kinds of treatments that are not possible otherwise to receive. For society, RM based therapies could enable longer working periods for their citizens and could reduce breaks in careers because of serious illness or trauma.

There are good reasons why RM should be developed.

The environment where technology, stem cell research and clinical experience meet is crucial for innovation in the RM sector and thus organizations should have a common goal in order to develop a needed innovation environment and actual innovations. However, not all of these groups are focused on health related issues, and traditionally they would not be part of the work community of AHC. With the mission, it is possible to reorganize operations in meaningful ways and it allows teams to reach common goals. However, sufficient and wisely managed funding is an important aspect of succeeding in this mission. It allows those groups whose discipline is advantageous in the RM sphere to work alongside groups having their primary applications in the RM sphere. With the mission, it is also justified to focus on potential commercial applications too, because in many cases this is the only way to advance the sector.
5 Managerial and policy implications

It is fundamental for AHCs to be places where innovations occur and thus there is a need for breaking old department structures and promoting interdisciplinary research\(^1\) in order to achieve innovative objectives. The revolution RM sector could bring to AHCs lies not only in the new techniques how patients can be treated but also in how these new opportunities are integrated into AHC. Especially cell therapy products possess a great opportunities beside pharmaceutical products, biopharmaceutical products and medical devices. If something is broken in the patient, it might be possible to regenerate new tissue or organ and repair the problem. Also some disorders that are not curable with medicines might in the future be possible to cure with, for example, stem cells.

As the RM sector is still in the early phases as a field of scientific, the development of new applications happens mostly in the academia. In the RM sector, disciplines outside health sciences are needed to develop and eventually provide new therapies. This is comparable to the medical device industry where innovation is really outward-looking by nature and is dependent on progress in several disciplines such as electronics, optics, computers and material sciences\(^2\). Regarding RM in Tampere, BioMediTech and University Hospital of Tampere together constitute a loose collaborative organizational structure where not only medical and biomedical research and clinical operations are conducted, but also complementary research and technology development. This is essentially important for the progress of the RM sector.

However, the loose organizational structure brings many challenges to the management of innovation as clinical operations and RM research are in the different organizations. Individual researchers collaborate easily across organizational borders and it is even possible that new experimental treatments emerge from these collaborations, as has happened in Tampere. Nevertheless, collaboration and ongoing dialogue are needed also in the management level of these organizations,
both in the strategic level and in the very practical level, e.g. in the calculation of the cost of a
treatment as several human and material resources are needed in the operations, in the allocation of
needed human resources, or in the training of involved personnel.

It would be beneficial to have a common strategy for organizations involved in the RM research and
subsequent applications. In Tampere, for example, actors involved in the health sector research and
medical operations have proposed that a research organization should be founded to unite existing
medical and health research related departments and the university hospital through common services
and research programs. Even though this is actually a general strategic initiative in the Tampere region
and not intended specifically for the RM sector, this loose organization called Tampere Health
Research Center Kauppi would have its own research strategy, in which RM is identified as one of
the spearheads. Certainly, it would promote and facilitate communication between different
departments and research programs.

6 Concluding remarks

Hospitals are needed for the provision of health services for human beings and in healthcare
advancement of science and technology has been remarkable over the last century\textsuperscript{20}. Through
advancement of technology, there are more healthcare services available than ever. In the same time,
the decision about what hospitals are able to offer is more and more difficult, as not all the possible
treatments can be provided because of limited resources. Regarding RM products there is still a long
journey to become regular hospital services.

As an emerging sector in healthcare RM demands a diversified knowledge base and thus would
benefit if old department structures in the university could be passed and close collaboration between
complementary technology development and stem cell biology could be connected in AHCs. In the
case studied here, most of the technology and stem cell expertise exist outside traditional medical research. In some sense, traditional AHC has no other role than taking responsibility of surgery and providing healthcare facilities for it, even though it should be the place, where innovations occur.

A lesson to learn from the Human Spare Parts program is that of combining different kinds of expertise. For example, technology groups bring expertise that can be utilized in RM research, too. They collaborate with stem cell groups and are essential in solving problems arising in stem cell research. In the organizational level, collaboration and communication are the most important aspects in an emerging field like RM. If RM will be institutionalized in hospitals more profoundly, there might appear collaborations that is more formal. When RM will be an institutionalized method to treat patients, most likely there will be a specific RM department in the AHC. However, what really constitutes AHCs in the future is a more difficult question, as different sectors aiming towards human health are dependent on different disciplines.
References


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