BONEBANK

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OVERVIEW AND COMPARISON OF HEALTH AND REIMBURSEMENT SYSTEMS RELEVANT FOR EXPLOITATION OF STEM CELLS

Author: Anna Eckers, Imke Schneemann, Thomas Frahm,
Life Science Nord Management GmbH

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1. Management Summary

This document provides an overview and relevant comparison of the Danish and German health and reimbursement systems focussing on basic information and systems with relevance for stem cell recovery and innovations. Within the Danish-German cross border BONEBANK project, stem cells will be isolated from routine surgeries. It will be analysed if these cells have osteogenic potential and would be sufficient for therapeutic use in the future. However, at the current situation, requirements analysis showed that the cells cannot be used for reinfection within the project runtime. Nevertheless, it is of interest how the landscape of therapeutic usage, storage and reimbursement system look like in the programme region of this Interreg A project. This *status quo* will support future activities for development of stem cells suitable for therapy and identify lacks in policy and health care systems relevant to this.

2. German Health Care and Reimbursement System

Health insurance is mandatory for the whole population in Germany. Two systems exist side by side – the statutory health insurance (SHI) and the substitutive private health insurance (PHI), the latter of which covers a much smaller number of insured persons: Around 86 % of the German population receive their primary coverage through SHI, which was already set up in 1883. Military members, police, and other public-sector employees are covered under special programs. Regulatory details and decisions on e.g. SHI benefits are specified in directives issued by the *Gemeinsamer Bundesausschuss* (Federal Joint Committee). It consists of representatives of sickness fund associations, physicians/dentists, hospitals, and three independent members. Each employee is compulsorily insured, if his or her salary does not exceed a certain limit. If this occurs (or s/he becomes self-employed or enters civil service), the employee can either leave the SHI system (to get private health insurance) or s/he continues his/her membership voluntarily. In the latter case, a written consent has to be given to the SHI. The benefits of the statutory health insurance are, for example, outpatient (ambulatory care) and inpatient medical treatment, dental care, drugs and sickness benefit. Payment for the SHI is covered by a specific percentage of the salary, respectively the social insurance pension, and therefore does not depend on the age of the insured person. The contribution is paid equally by the employee and the employer. Family members (spouse and children) are insured without additional contribution, if their income can be neglected. The system is managed by health insurance funds (under public law). Since every person has to have a health insurance, the system runs without competition aspects.

In Germany, patients are free to choose physicians or hospitals and do not receive an invoice for treatment - the costs are directly paid by the fund.

In contrast to the SHI, a person has to apply for private insurance. Employees exceeding the contribution assessment ceiling, self-employed persons and civil servants are allowed to apply. After approval, the policy holder and the insurance company sign a contract, in which many packages and combinations are possible. As a result, the insured person can choose the coverage and its amount. The insurance companies are either stock companies or mutual insurance companies - about fifty companies compete in this market. PHI contributions depend on individual health risks and the commission paid by the PHI is higher than the one paid by the SHI.

The disadvantage, however, is that a return from the PHI to the SHI is restricted – i.e. the person has to be younger than 55 or they must have had a salary decrease. Like in the SHI, the patient is free to choose physicians or hospitals. Unlike the SHI, the patient receives an invoice and has to apply for reimbursement to the insurance. Whereas in the SHI a contract exists between the physician or hospital and the insurance, this does not apply to the PHI companies. In addition, payment for a physician in ambulatory care is higher for PHI patients than for SHI patients. This makes the PHI patients financially more attractive and thus leads to concerns of equity resulting in longer waiting times for SHI patients.

Regarding health expenditure, Germany spends more money than any other country in the EU (Germany: 11.2% vs. EU average 9.9%). It also has the highest bed per patient ratio, with 813 beds per 100,000 population. This results in a low nurse/doctor per patient ratio, even if the numbers of physicians have been increasing over the last decades. However, since other countries have reduced beds, Germany’s ratio is one of the highest in the EU (813 beds per 100 000 population). On average, each citizen visits a physician ten times a year, which is more often than in the rest of the EU.

The separation between ambulatory and hospital care, as well as primary and specialist care is, compared to other countries, relatively strong. Moreover, quality information is nearly unavailable for the ambulatory care in comparison to hospital quality in general. Due to the resulting lack of continuity and exchange, management programs have been set up, especially for chronic diseases, to improve care. Better care and prevention are not only a topic on the policy level itself – SHI insurances, for example, have initiated programs for better fitness or anti-smoking, from which policy holders benefit. Another example, established by the Federal Ministry of Health is a funding priority to promote research in the field of childhood obesity.

3. Danish Health Care and Reimbursement System

As in Germany, health insurance is compulsory for citizens. People who work in Denmark and pay their taxes are automatically medically insured. However, there is only one SHI with two variants, citizens can choose from: The first one, which is selected by most (98%) people, is the model to register with a doctor in the radius of 10 km. Outpatient treatments are free of charge and referrals to specialists are required. The second model allows a free choice of doctors, referrals to specialists are not required. Doctors are not bound by tariffs. The patient has to pay the difference.

In contrast to the German healthcare system, the Danish system also strongly involves political and administrative levels: the state itself, the regions and the municipalities (national, regional and local levels). Regulations and supervision of health and elderly care is managed by the national government. This means: Legislation on the organization and provision of health and elderly care services, patients´ rights, healthcare professionals, hospitals and pharmacies, medical products, vaccinations, quality control, maternity care and child healthcare. The five regions are primarily responsible for the hospitals including emergency care, the general practitioners, service delivery and for psychiatric care. Denmark has 98 municipalities that are responsible for local health and elderly care services (such as disease prevention and health promotion, rehabilitation outside hospital, home nursing, school health services, child dental treatment, child nursing, physiotherapy, alcohol and drug abuse treatment, home care services, nursing homes). In addition, municipalities co-finance regional rehabilitation services and training facilities. As mentioned, anyone has access to the public healthcare system, and most services are provided free of charge. The system is financed by tax revenues. Citizens pay around 16% for drugs, dental care and other medicinal products, including rehabilitation.

Similar to Germany, health expenditure is also high, mainly public and above EU average: 10.3% of GDP – up from 9.1% in 2005. As mentioned, some countries have reduced hospital beds in the last year, therefore, Denmark has relatively few hospital beds (half of the EU average of 5.1 per 1 000 population) and a short length of stay.

Information and Communication Technology (ICT) applications are increasing in health care and have the ability to transform current health care and to improve the overall status. In contrast to Germany, Denmark is strongly using ICT in the primary health care sector thus being the frontrunner on EU level. For example, Denmark introduced a shared electronic medical record system through which all health care providers across sectors can view, change and prescribe recipes.

4. Comparison of the German and Danish health care and reimbursement systems

In summary, the hospital in Germany rather compares to a profit centre, whereas in Denmark it is more a social institution. Germany has over 200 health insurances, in contrast to Denmark with only one insurance. Private insurances are important for Germany – in Denmark it is an "add-on". Hospitals in Denmark are centrally controlled and guided, and focus more on quality control than in Germany. Due to the high use of ICT in Denmark, processes are easier to monitor.

5. The German and Danish Cell Therapy and Innovation Landscape

Both in Denmark and Germany, a lot of basic and clinical stem cell research is done. Different stem cell types are used, from pluripotent stem cells (ESC and iPSC) to adult stem cells (e.g. HSC and MSC). Research focus is e.g. on differentiation or regulatory mechanisms, which are linked to specific diseases. The group of Professor Moustapha Kassem (Research Unit for the Department of Endocrinology (KMEB) in Odense) was established in 2001 and is also a partner within the BONEBANK project. The group primarily focuses on basal and clinical research on mesenchymal stem cells (MSCs) with a focus on MSC differentiation into osteoblasts and bone formation. The group has been involved in several clinical trials both in Denmark and abroad and was coordinator of the first clinical stem cell trial for vascular regeneration in Denmark.

Companies, in contrast to research facilities of universities, often focus on diseases like cancer and heart diseases which are under the TOP10 causes of death. The reasons for this is cost efficiency, but there are also products in the pipeline for rare diseases because of lower regulatory hurdles, as these products can enter the market much easier than orphan drugs.

Innovative and new therapies are more cost-intensive than conventional therapies and drugs. Resources (staff, money, time) are high, therefore production costs are, compared to chemical synthesis. It is even more expensive to produce stem cells for allogenic therapy, than for autologous therapy. Moreover, logistics are challenging, available products on the market have a life time ranging between 24 to 40 hours. Technical innovation (e.g. stem cell reactors), increasing markets and competition will decrease costs in the future, and a full regulatory overview will increase the pressure to companies for reducing costs as well.

In 2012, the Danish Stem Cell Society (DASCS) was established as an independent network for stem cell researchers in Denmark. Denmark has twelve stem cell research centres located in four Universities: Copenhagen, Southern Denmark, Aarhus and Aalborg.

In Germany, the reimbursement status depends whether they are used in an outpatient or inpatient setting and whether they are considered a medicinal product and are reimbursed by law, or as part of a therapy. If it is part of an outpatient therapy, the Federal Joint Committee has to decide on funding on a case-by-case basis before the reimbursement status can be applied. In addition, some (only very few) German health insurances started to offer discounts for Vita 34 – it is one of the largest umbilical cord blood bank. It was founded in 1997 and acquired the Danish stem cell bank StemCare.

Stem Cell donation is organized e.g. by Cellex/CMS in Germany. This competence center regulates all organizational steps for the donor, from required examinations to the billing of the health insurance provider. Of note is that health insurances of the donor do not reimburse the treatment, but the insurance of the recipient.

However, development of stem cell products with high market share which replace conventional therapies are of need for the future – therapeutic effectiveness is often still low or not completely proven and costs for production are high. However, the BONEBANK project and its future activities will follow the aim to support and achieve efficiency of therapeutical usage of these cells.

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