Executive summary

Health Council of the Netherlands. Towards a sustainable tissue supply chain. The Hague: Health Council of the Netherlands, 2014; publication no. 2014/04

Medical treatments in the Netherlands involving human tissue

In the Netherlands, medical treatment involving various types of human tissue is being administered. This mainly involves the transplantation of cornea, skin, heart valves, cardiac tissue, bone tissue and tendon tissue. Such human tissue is usually obtained from deceased donors. Bone material from living donors can sometimes be used (or re-used), following hip replacement surgery, for example. Organs have to be transplanted into patients as soon as possible after donation. Tissues, however, are removed, processed and then stored. Later on, they are implanted into a recipient. This process is facilitated by a number of tissue banks, the first of which was established in the Netherlands in the mid-1970s. The Netherlands currently has two cornea banks, a skin bank, a heart valve bank and a bone bank, all of which are fully accredited tissue banks. There are also numerous institutions that have accreditations/permits for the limited handling of human tissue.

Recent changes in the organisation of the tissue supply chain

In recent years, there have been frequent debates about the best way to coordinate the national tissue supply system. The tissue supply chain consists of a group of small organisations, between which there is a limited degree of cohesion and cooperation. As an organ centre, the Dutch Transplant Foundation

(NTS) has the statutory duty of giving direction to the national tissue supply system and of fostering cooperation within the tissue supply chain. Until recently, however, the legal and administrative instruments at its disposal were not entirely fit for purpose. In recent years, however, a change pathway has been put in place. As part of this process, the Ministry of Health, Welfare and Sport has assigned “central control” of the tissue supply chain to the organ centre. New arrangements have also been made regarding cooperation between that organ centre and the tissue banks. The organ centre’s tasks include the initial screening and acceptance of tissue donors. The tissue banks collect tissues, check them for safety and quality, then process and store them in accordance with good practice. In the final tissue distribution stage, a distinction is drawn between material that is assigned to individual patients due to scarcity and specific medical properties (tissue that is subject to an allocation requirement, to be assigned by the organ centre), and tissue that can be distributed to patients without any differentiation (tissue that is not subject to an allocation requirement, the responsibility of tissue banks). This division of labour has been in effect since 1 January 2012.

Is the tissue supply chain “future-proof”?

The Minister of Health, Welfare and Sport has asked the Health Council of the Netherlands whether the tissue supply chain’s new structure is sufficiently future-proof. For instance, can it cope with new and expected developments, such as the use of human tissue material to prepare advanced medicinal products or the insertion of tissues into medical devices (Advanced Therapy Medical Products - ATMPs)? In this advisory report, the Health Council concludes that while the recent reallocation of duties and responsibilities has indeed generated some improvments, there is still some way to go.

Fragmentation of rules

The procedures for organ and tissue donation are embedded in a national legal framework: the Organ Donation Act (WOD) and the Body Material (Safety and Quality) Act (WVKL). These laws, in turn, have been brought into line with EU guidelines pertaining to the donation and transplantation of tissues and organs. The WOD focuses mainly on the consent procedure for donation, while the WVKL primarily regulates the safety, quality, and traceability of human tissue. The WOD also stipulates how the various organisations in the Netherlands must cooperate with one another in receiving, storing, processing, and allocating tissues and organs. A pivotal role has been assigned to the Dutch Transplant

Foundation, which cooperates with Eurotransplant International Foundation and with the various tissue banks.

The Committee takes the view that the current situation (in which the tissue supply system is regulated by two different laws) is not ideal, in terms of transparency. These laws are not entirely mutually compatible, which results in a fragmentation of the rules. The conceptual framework underpinning these laws is neither clear nor consistent, nor does it adequately reflect the specific character of the tissue process. The system by which the control of donated tissue is currently regulated, for example, focuses exclusively on implantation and the associated areas of scientific research. However, this fails to do justice to the broader therapeutic uses of tissue and to related areas of research. Current legislation needs to be amended to take account of these issues.

Current legislation cannot cope with the latest scientific developments

The Committee has conducted a brief survey of scientific developments relating to the use of human tissue, and in particular to its medical application in Advanced Therapy Medical Products (ATMPs). In the short term, these are unlikely to have any major impact on standard tissue transplants, or on the way in which the tissue supply chain is organised. In the medium term, however, this situation is expected to change. In terms of the adequate regulation of human tissue destined for the preparation of ATMPs, the current legal framework (WOD and WVKL) has a number of shortcomings. This is particularly true of material that is not obtained via the usual post-mortem donation procedure. The Committee calls for better regulation of control, a greater focus on safety and quality, and improvements in the channeling of this tissue.

Dutch tissue banks have to operate in an international market

The Minister of Health, Welfare and Sport has asked whether the Netherlands needs to be self-sufficient with regard to tissues. The Committee, however, calls for a stronger orientation on, and greater participation in, the European market for tissue products. Dutch tissue banks are already substantially involved in international mediation processes for donated tissue, and in the associated export/exchange procedures. Closer cooperation can help to augment the national tissue supply system and to generate efficiency improvements.

In addition, modern tissue banks will increasingly have to operate and compete in an international tissue market. This means that they must also be able to develop commercial activities, which can then act as an incentive to boost

operational efficiency. However, such commercial activities must be subject to strict limits, to ensure that public interests are not adversely affected. For instance, commercial activities must neither undermine public confidence nor people's willingness to donate. Rather than being distributed to shareholders, any revenues from commercial activities must be used to benefit the public tissue supply system itself. Furthermore, operating in the international tissue market (tissue exports, medical product development) must not take place at the expense of implantation-oriented applications. Finally, in the international exchange of tissue material, the effective monitoring of safety and quality must always take priority over any other considerations.

The pursuit of profit could endanger unpaid donation

The principle of non-profit donation is enshrined in our legislation, as well as in European regulations. Accordingly, tissue banks in the Netherlands are non-profit institutions, which are not permitted to make profits and pay dividends. At the same time, the processing and storage of tissues does involve significant costs. The therapeutic end result is therefore expensive, but it also has great added value (quality and safety). The tissue banks (and their commercial partners that perform processing work) must, of course, be compensated for these expenses, by means of the cost price charged for the tissue product in question. Without this, it would not be possible to maintain either the tissue process or the tissue supply chain. For this reason, tissue donation and transplantation public information campaigns will stress that an efficient business operation and entrepreneurship are not the same thing as the pursuit of profit. The revenues from commercial transactions (including those at international level) must flow back into the tissue supply chain, to improve quality and safety, and to benfit research and innovation. This is the only way to avoid undermining public confidence and people's willingness to donate. Incidentally, tissue institutions that are not accredited tissue banks are not subject to the prohibition on profit making. These institutions are not currently subject to the control and supervision arrangements that operate in the tissue supply chain.

The tissue supply chain needs tighter controls

The process of change launched by the Ministry of Health, Welfare and Sport and the Dutch Transplant Foundation does have more robust controls. The aim of this process is to create an effective and efficient tissue supply chain capable of meeting high standards of quality and safety, both now and in the future. Its goals

include safeguarding the effectiveness of the tissue supply system, and serving the public interest (sustaining people's willingness to donate). Other goals are responding to scientific innovation in the area of tissues, and developing the capacity to operate in a field characterised by increasing commercialisation, competition and internationalisation.

While the newly launched process is indeed a step in the right direction, the control function (as presently configured) will not be able to cope with the anticipated developments and challenges that lie ahead. At the very least, the following conditions must be met in order to create a future-proof, efficiently managed tissue supply chain:

- A clearer legal basis than is presently the case, plus a clear description of the position, role and powers of the directing authority with respect to the tissue banks on the one hand and the Minister of Health, Welfare and Sport on the other.
- A clear separation of the control tasks (strategy development) and executive tasks (allocation).
- Clear lines of information and accountability between the directing authority and the executive organisations, while retaining the latter bodies' broad discretionary policy (within the agreed frameworks and subject to the agreed preconditions).
- Closer cooperation between tissue banks, resulting in a single, common point of contact.
- A clear funding structure tailored to the way in which the tissue supply chain is organised.

It's time for a new organisational model

With the above constraints in mind, the Committee has put forward a proposal for a modified organisational model. A new "donor centre" will be set up and given the powers needed to act as a directing authority. This centre will represent the interests of organ/tissue donors, and will translate these into tasks for the organ supply chain or tissue supply chain, as the case may be. The donor centre will act as a link between donors and society on the one hand, and the parties in the organ and tissue supply chains on the other. In the interests of public confidence and people's willingness to donate, it is essential that donors (and future donors) are convinced that their rights and interests will be in good hands at the donor centre. The donor centre will be responsible for the screening and acceptance of all donors. It will also have formal control over the allocation of all

donated human tissue. The donor centre will authorise two other organisations to carry out the executive tasks:

1 The “organ centre”, will deal with the actual allocation of organs and of tissues that are subject to an allocation requirement. In the case of organs this will involve waiting list management and allocation in close collaboration with Eurotransplant, as is presently the case. For tissues, this involves the allocation of tissues that have either been categorised as scarce and/or that must be allocated to a specific patient (just as the Dutch Transplant Foundation does at present).
2 The “tissue centre” will be responsible for the screening and acceptance of tissue material that is not subject to an allocation requirement. It will also deal with the removal, storage, processing and issuance of such tissue. The tissue centre will act as an umbrella organisation for existing tissue banks, which will acquire the status of departments or divisions in this context. Within the frameworks agreed with the donor centre, the tissue centre will be free to establish contacts or partnerships with research centres, medical technology industries, pharmaceutical industries, or tissue organisations outside the Netherlands. The tissue centre will also handle the import/export of tissues, and maintain contact with the other accredited tissue institutions with regard to the channeling of human tissue obtained outside the context of the Organ Donation Act (WOD).

As a new administrative entity, the donor centre must be based on the WOD, and its duties and powers as a directing authority must be clearly defined. The duties which the donor centre authorises the organ centre and the tissue centre to perform will also require a legal basis of this kind.