# Human tissues and cells: application by private clinics and oral implantologists in The Netherlands

M.S.E. Bergers, M.J Happel, P.Y. Zijlker-Jansen, A.G. Bokhorst

TRIP National hemovigilance and biovigilance office

#### Introduction

Hemo-en biovigilantie

The National Hemovigilance and Biovigilance Office TRIP performed a survey of the use of human tissues and cells by private clinics (private hospitals) and licensed implantologists. This survey aimed to complement information from the hospitals in order to obtain a comprehensive overview of institutions that apply allogeneic human tissues and cells subject to the EU Directives 2004/23/EC and 2006/86/EC on quality and safety of human tissues and cells.

## Method

Based on the Dutch Healthcare Register, the Private Clinic Quality Register, search engine Google and a list provided by the Healthcare Inspectorate, TRIP compiled a comprehensive list of private clinics in The Netherlands. Clinics were included if they offered plastic surgery, orthopaedic surgery, oral and dental surgery, ophthalmology and ENT surgery. In addition the register of licensed oral implantologists was consulted. In all 620 addresses were contacted by letter with a questionnaire about use and source of human tissues and cells.

### Results and comment

- In total 401 responses were received (n=620, response 64.7%).
- In all, 64 clinics and implantology practices stated that they apply autologous, allogeneic or xenogeneic tissues and cells (table 1). Autologous tissues used in the same procedure and xenogeneic tissues (23 clinics and implantology practices) are outside the scope of the EU directives.
- The following applications of human tissues were reported: ocular tissue (cornea and sclera) for corneal transplantation or other opthalmic surgery, allogeneic bone tissue used by implantologists in the reconstruction of the jaw, allogeneic skin tissue for the covering of gingival recession and in the treatment of burns and allogeneic tendons for the reconstruction of the anterior cruciate knee ligament.
- Xenogeneic tissues (medical devices) were sometimes erroneously classified as human. This shows that the origin of applied tissues is not always clear.

Table 1: Application of tissues and cells in The Netherlands (2013).

Application of tissues and cells	Private clinic	Dental implantology practice	Total	Percent
No human tissues and cells applied	135	201	336	54.2%
Autologous tissues and cells	4	11	15	2.4%
Allogeneic tissues and cells	9	32	41	6.6%
Xenogeneic tissues and cells (medical device)		8	8	1.3%
No answer ticked		1	1	0.2%
No response	99	120	219	35.3%
Total	247	373	620	100.0%

#### Conclusions

- The majority of private clinics and implantology practices do not apply human tissues and cells.
- In total 41 (6.6%) private clinics and implantology practices do apply allogeneic human tissues and cells.
- These clinics and practices should be included in the annual inventory of all Dutch hospitals and clinics for the provision of figures on use of human tissues and cells and number of recipients for the annual report to the European Commission.