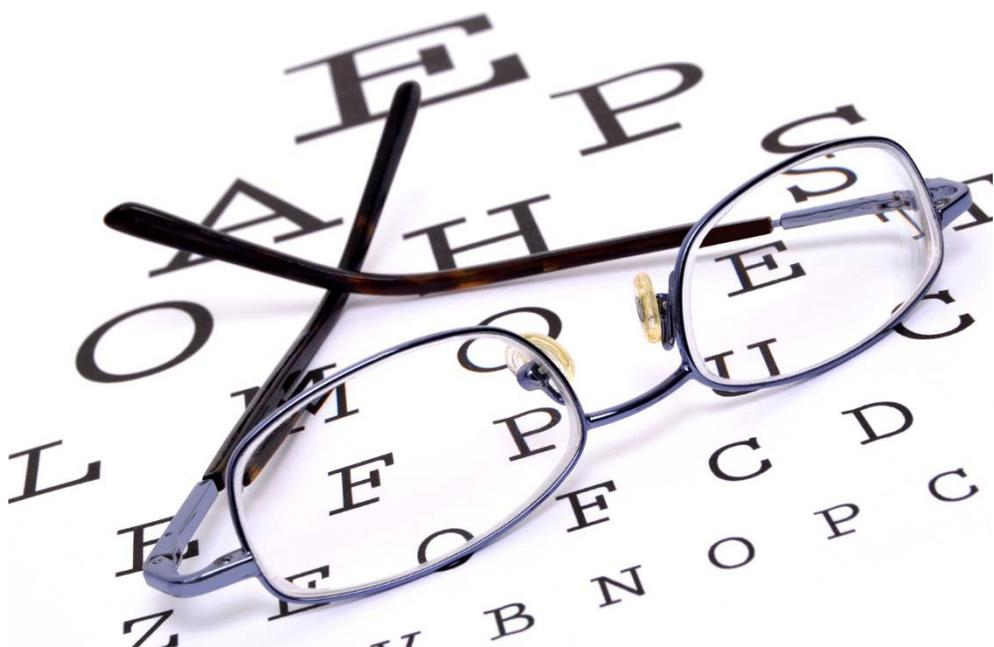


SYNTHESIS

CORRECTION OF REFRACTIVE ERRORS OF THE EYE IN ADULTS – PART 3: ORGANISATION AND LEGAL FRAMEWORK OF EXTRAMURAL SURGERY CENTRES





Belgian Health Care Knowledge Centre

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SYNTHESIS

CORRECTION OF REFRACTIVE ERRORS OF THE EYE IN ADULTS – PART 3: ORGANISATION AND LEGAL FRAMEWORK OF EXTRAMURAL SURGERY CENTRES

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COLOPHON

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■ FOREWORD

The diagnostic and therapeutic freedom is an important element in the professional identity of doctors. The fundamental value is that doctors must have the freedom to select the best option for their patient and should not be limited in this by the interests of a healthcare insurance company, an employer or any other stakeholder. This freedom is entrenched in medical practice and reflected in the way in which the medical profession is organised.

Equally obvious is that a profession that is so important to society has a foundation of deontology (obligation-based ethics). The basic principles of Hippocrates have survived nearly 2500 years and form the foundation of the trust with which a patient can surrender to his or her doctor.

More recently, in addition to these (inter) personal aspects, a fundamental engagement of society has been added, namely the willingness of our society to build a strong solidarity in healthcare. For example, we spend more than 10 % of our public funding on financing the healthcare insurance and healthcare system. It is unavoidable that this results in new limitations to the freedom to offer care and to new obligations in order to participate in this collective supportive care system.

But there is more: healthcare has undergone a radical evolution, from a noble profession focusing mainly on the doctor-patient confidentiality, to a system of complementary, multidisciplinary activities that are very diverse in nature, imbedded (ideally) in an integrated care system.

This is exactly the area that this report will focus on – using refractive eye surgery as an example: how should a health system deal with initiatives to remove certain forms of care from the “regular” hospitals and offer them in private, extra-mural centres? How to deal with (new) medical activities that take place out of the health insurance framework (unless complications occur)? In brief, what are the obligations to the patient and society with regards to the free organisation of care?

The perspective used is primarily the safety and the quality of care but then in a legal context with a European, national and regional/communal dimension. This legal context is also still fully evolving. Perhaps this will provide a window of opportunity to synchronise optimally the interests of care providers, patients and other partners in the care system with regards to this matter!

Christian LÉONARD
Deputy general director

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General director



■ ABSTRACT

Myopic, hypermetropic or astigmatic individuals have a choice between spectacles, contact lenses or surgery, so-called refractive surgery. Refractive surgery is an operation using laser techniques or intraocular lens implantation. This type of surgery is growing in popularity and is increasingly performed in extra-mural centres. These care facilities are set up as a private initiative and – contrary to the regular hospitals – are still not subjected to the stringent regulations regarding quality and safety of care. However, this does not mean that they operate in a legal vacuum. There are general standards such as fire safety in the building, waste regulations, the ISO standards, the compulsory use of medical devices with a CE brand and systems that offer basic guarantees for safety and quality of care. The legal framework in which doctors practice medicine also offers some guarantees, regardless of the setting in which they work. However, these standards are often not specific enough and also not subjected to periodic and systematic quality control inspections, as it is the case for the hospitals. As there is no obligation to register, there is currently no overview of the exact number of extramural centres, the number of doctors working in these centres or the volume of interventions performed.

As part of the Directive on patients' rights in cross-border healthcare, there is now a need to define a legal framework for quality and safety of care, regardless of the setting in which this care is provided. Other countries such as the Netherlands and Denmark already have a legal framework defining the quality and safety of care in extramural centres. In Belgium, various legislative initiatives have attempted to create such a framework; however, the implementation always encountered difficulties relating to the division of authority between the Federal State and the communities. After the transfer of powers due to the 6th state reform a good, efficient regulation and control of the extramural practices necessitate a collaboration between the federal government and the communities. The existing quality initiatives of professionals currently working in extramural centres – such as those by the Belgian working group for extra-mural eye surgery – can play a role in defining the quality and safety criteria.



The existence of extramural centres also raises the question of the impact on healthcare policy. A possible consequence of the growing popularity of these centres is that doctors could be more likely to opt for these centres due to the favourable working conditions: this could result in a shortage of doctors in certain specialisations in the hospitals. There is also a risk that only the patients with a favourable health profile will be treated in the extramural centres and that the “high risk” ones will be left to the hospitals, with negative financial consequences. If one wants to avoid these consequences, then a broader framework must be examined of the organisation of the healthcare facilities with equal remuneration of doctors.



■ SYNTHESIS

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1. CONTEXT AND OBJECTIVE OF THIS REPORT

This report is the last one of a KCE trilogy on refractive eye surgery. The growing popularity of refractive eye surgery gave rise to a number of questions on the effectiveness and safety of this intervention, as well as on the organisation of the expanding sector of extramural ophthalmology centres, where refractive surgery is increasingly performed.

The first report (KCE report 202) described the perception and experience of refractive error and the correction methods in the population. The second report (KCE report 215) was a health technology assessment on the techniques of refractive eye surgery with a review of their safety and effectiveness, an economic evaluation, a comparison of reimbursement policies in other countries and an overview of the patients' drivers and barriers to opt for refractive surgery.

This third report aims to analyse issues of quality and safety in extramural ophthalmology centres and to formulate policy options for their regulation. In contrast to public and private not-for-profit hospitals, extramural surgery centres are not subject to the same quality and safety guarantees. Today safeguarding safety and quality in extramural centres mostly relies on voluntary initiatives of health professionals. The case of extramural ophthalmology centres could be an illustration for the regulation of other extramural surgery centres. Refractive eye surgery is at the same time a starting point to open a broader discussion on the impact of the organisation of surgery in extramural centres on the organisation of care and public health policy in general.

2. QUALITY AND SAFETY: WHAT THE LEGAL FRAMEWORK GUARANTEES...

2.1. Strict regulation of hospitals with regard to quality and safety of care...

Hospitals are legally defined in the Belgian hospital law that outlines criteria for official recognition and hence grants the right to operate and claim reimbursement of intramural health care services by the compulsory national health insurance (Coordinated Hospital Law 10 July 2008). Hospitals, public or private not for profit, need to meet two general conditions: they need to fulfil official recognition criteria (e.g. hygiene, safety, quality of care) and they need to fit in the national planning, the programming. Programming is an estimation of the necessary capacity for a particular care establishment.

The notion 'hospital' is described in the hospital law. Key characteristics of hospitals are continuity of care, provision of basic care in medicine and surgery, multidisciplinary setting, appropriate organization and infrastructure, possibility to stay overnight, ability to react timely to the care needs. Furthermore, hospitals are required to provide care accessible for all citizens, independent of their age, gender, philosophical or religious belief, race or sexual orientation and without discrimination based on individual financial status (art. 3 § 1 Decree 17 October 2003 related to the quality of health care and wellbeing establishments).

Today, the Federal government is competent to set the recognition criteria for hospitals (services, care programs, hospital services, etc.) related to financing of the exploitation, the compulsory health insurance or the basic rules regarding programming and financing of the infrastructure. Apart from the recognition norms, there are other federal rules and initiatives targeting the promotion of quality of care in hospitals. Not only national but also regional legislation has imposed several quality norms for hospitals (for instance the Decree related to the quality of care and wellbeing establishments). Compliance with the recognition norms in hospitals is checked by the respective Community or regional governments. Hospitals in Flanders for instance get recognition for an unlimited period and a yearly thematic inspection will be performed. Additionally system inspection (on leadership, strategy and policy, safety management and the quality system) will be carried out for hospitals that are not already - on their own initiative -



accredited by internationally recognized bodies or institutes (e.g. Nederlands Instituut voor Accreditatie in de Zorg).

With the 6th state reform, the Communities will get, on top of the existing powers, the power to define the recognition norms hospitals and services (included psychiatric hospitals and psychiatric sections in hospitals), care programs, hospital services, etc. have to comply with to be recognised. Yet, they need to respect the organic legislation, the federal programming criteria and the federal power to regulate the practice of medicine. The financing of the hospitals (except for A1 (budget for the construction and the renovation of hospitals) and A3 (investment costs for heavy medical equipment such as MRI, PET scan, radiotherapy) of the budget financial means (BFM) of the hospitals, remain with the federal powers. If necessary, the federal government has a veto right against norms that have a negative impact (in the short or long term) on the budget of the federal government and social security.

2.2. Not applicable to extramural centres

2.2.1. Hospital-specific legislation related to quality and safety does not apply to extramural centres

There is no legal definition of the notion 'extramural (ophthalmology) centre'. This report uses the following working definition: "health care centres, other than hospitals as defined in the Belgian hospital law or a health care setting linked to a hospital, where any eye surgical or other invasive procedure requiring general or locoregional anesthesia, or sedation, including cryosurgery and laser surgery, but without the patients staying overnight, is performed by a physician. This definition excludes medical offices where only minor interventions are performed (i.e. included in the list of acts of general practitioners, dermatologists and dentists).

Since extramural centres do not fall within the scope of the definition of "hospital" in the sense of the hospital law, they do not have to comply with quality norms imbedded in the hospital law and with other rules that apply to the hospitals. There is no requirement for systematic registration, no recognition and physicians, or even business entrepreneurs, can start an extramural centre with neither approval nor inspection from the public health authorities regarding safety and quality.

The number of ophthalmology extramural centres is unknown given the absence of systematic and mandatory registration. Moreover, the number and the identity of the physicians working in these centres is a black box. In addition, there is no registration of interventions that are not reimbursed by the compulsory health insurance. Hence, there is a lack of data on the number, nature and quality of these interventions.

2.2.2. No legal central liability for extramural centres

The Belgian Patients' Rights act regulates the right to qualitative care, the right to information about his or her health status and its probable evolution, the right to free and informed consent, the rights to be assisted by a reliable person and to be represented by a representative, rights regarding the direct access to the patient file, the right to privacy, the right to pain relief, the right to freely choose a health care professional and the right to complain (Patients' rights act 22 August 2002).

Central liability of hospitals

The respect of patients' rights has been integrated in the Hospital law (art. 30 Hospital Law). Hospitals need to respect the relevant patients' rights and need to make sure that self employed health care professionals working in the hospital respect the patients' rights. Furthermore the hospital is liable for the breaches of the patients' rights committed by the health care professionals working at the hospital (self employed, employee or statutory), except if the hospital explicitly and priorly informed the patient that it will not be liable. The advantage of this so called "centralized liability" is that patients know to whom they can address a claim in case of presumed violation of their rights.



As extramural centres do not fall into the definition of hospitals, the obligation to respect the relevant patients' rights and the central liability formulated in the hospital law do not apply to these centres. Yet, since all physicians fall under the scope of application of the Patients' Rights act, patients treated in extramural centres "benefit" from patients' rights (cfr. 2.4). Furthermore civil and criminal liability rules apply to extramural centres. Extramural centres could for instance be held liable for violation of the 'general duty of care', if fault, damage and a causal link can be proven (art. 1382 Civil Code). The content of this general concept is interpreted by judges and could also contain elements of patients' rights. Moreover, extramural centers can be held liable for damage resulting from faulty acts of the personnel working there in subordination (art. 1384, al. 3 Civil Code).

2.3. Yet general norms apply to extramural centres...

The non-application of hospital specific legislation does not imply that extramural centres operate in a legal vacuum. Generic legislation that relates to safety and quality such as for instance fire prevention in buildings, environmental regulations, CE marking of medical devices, ISO norms... is applicable to extramural centres. Yet, these general regulations often lack the specificity needed for centres where patients undergo surgery. Another major drawback is the absence of proactive control of these norms as for quality norms in hospitals. General civil and criminal liability rules and liability rules for defective products, such as for instance medical devices or air flow systems apply to extramural centres but only when harm already occurred.

2.4. ... and to the physicians who work there

Quality of care in extramural centres is to some extent, indirectly guaranteed by general norms applying to all physicians in Belgium, irrespective of the setting where they work. Health care professionals have indeed to work according to several legally imposed requirements linked to the exercise of their profession (Royal Decree No. 78 on the exercise of the health professions, November, 10th 1967), to the patients' rights (Patients' Rights Act, August, 22nd 2002), to the protection of personal data (Act on the protection of privacy in relation to the processing of personal data, December, 8th 1992 and its implementing decrees) and to the deontological code. Moreover, civil and criminal liability rules apply if a patients suffers from an injury due to a medical intervention performed in an extramural center. Rules related to liability for defective products, as for instance

implants also apply, regardless of the setting where the intervention took place.

2.4.1. *General rules exist but further elaboration is often solely focused on the practice in a hospital setting*

The patient's record plays an important role for the continuity of care. Transitions between health care settings call for shared patient records to allow transparency in the patient's care trajectory. According to the patients' rights act (art. 9 § 1) all physicians are obliged to carefully keep and store a patient's record (hardcopy or electronic). Other legal and deontological rules (e.g. art. 46 and 47 deontological code) define duties related to the patient file for physicians. Yet, the minimal content of the patient file is solely defined for the hospital setting (Royal Decree 3 May 1999 regarding de definition of the general minimum requirements the medical file, as referred to in article 15 of the hospital law, coordinated on 7 August 1987, needs to comply with; Royal Decree of 28 December 2006 regarding the definition of the general minimum requirements a nursing file, as defined in art. 17quater of the hospital law, coordinated on 7 August 1987, has to comply with). In line with this, some modalities for the storage of the patient file are solely clearly defined for the hospital setting. The hospital law for instance defines that patient files need to be stored in the hospital under the responsibility of the chief physician (art. 25 § 1 hospital law).

2.4.2. *Specific protective patients' rights regarding aesthetic interventions*

Aesthetic medical interventions, surgical or not, are often performed in extramural centers. Refractive eye surgery cannot be considered as a purely aesthetic intervention as the intervention has a reconstructive as well as a therapeutic character. Aesthetic medical interventions and aesthetic surgery have been explicitly inserted in the field of application of the Patients' Rights Act and some patients' rights have been extended (Law regulating the qualifications required for interventions of non-surgical aesthetic medicine and aesthetic surgery, May, 23th 2013). The content of the informed consent statement prior to aesthetic surgery has been extensively defined (Art. 18). Moreover a reflection period of at least 15 days between the information and the date of the intervention is imposed (Art. 20).



Plastic surgeons and surgeons are competent to perform aesthetic surgical and non-surgical medical interventions in the orbito-palpebral region. Among the other specialists, ophthalmologists only are allowed to perform these interventions (art. 12, 1°). Still this restriction does not apply to refractive eye surgery that is not considered as a purely aesthetic intervention. In principle physicians have the competence to practice any medical act (the so-called ‘therapeutic freedom’ of the health care provider) but in practice mostly ophthalmologists will be involved.

2.5. Self regulation initiatives by the professional associations

Today safeguarding safety and quality in extramural centres mostly relies on voluntary self-regulation initiatives. The Belgian working group for extramural eye surgery has introduced a voluntary certification which guarantees compliance with norms predefined by this group. The audit is done by an independent instance accredited by the Belgian Accreditation Organisation BELAC and concerns architecture, equipment, sterility, personnel and responsibilities. A list of certified clinics is updated every 4 months. This list is primarily used by private insurers limiting reimbursement of refractive eye surgery to certified centres. In the near future the list will be available for patients. This self-regulation may impose higher quality norms than those formulated in legislation for hospitals but the compliance depends on voluntary participation of extramural centres as there is no legal obligation to obtain this certification to operate. Other norms in civil liability insurance contracts of ophthalmologists are for instance the compliance with the predefined minimal content of the medical patient file and the obligation for extramural eye surgery centres to notify their activities to the emergency department of a hospital.

2.6. European legislation calls for regulation on quality and safety in all settings

On the European level the guarantee for quality and safety in any healthcare setting has been a matter of concern for years.

The 2009 Recommendation on patient safety, including the prevention and control of healthcare associated infections invited member states to implement measures to reduce or prevent harm resulting from healthcare, such as the development of national programs on patient safety, patient empowerment and patient information.

In line with this Recommendation the 2011 Directive on patients’ rights in cross border healthcare imposes that member states should have a minimal framework of quality and safety norms for healthcare provided in the respective state (Directive 2011/24/EU, March, 9th 2011). Member States need to make sure that patients are informed on the supervision and assessment of health care providers. Furthermore these providers have to provide relevant information to help their patients to make an informed choice. This includes the treatment options, the availability, quality and safety of the healthcare that they provide. Patients should also receive clear information on prices, as well as on the health care professionals’ authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability. Furthermore, health care professionals should be obliged to provide transparent invoices for any health care intervention. The Directive had to be transposed in national legislation by the end of October 2013.

To be in line with the Directive, a legislative framework guaranteeing quality and safety framework for extramural centres is necessary. Furthermore, some existing patients’ rights need to be further elaborated and also need to apply to extramural centres. The duty to inform patients on the necessary elements to allow them to make an informed choice for instance, does not only apply to health care professionals but also to health care establishments, included extramural centres (art; 4, 2b) Directive). From the 1st of July on, hospitals need to publish information on their website regarding the offered care, the costs of stay and the convention status of the physicians working there (Art. 31-34 Law of February 7th 2014 regarding diverse dispositions related to the access of health care). This obligation does not apply to extramural centres, however.



2.7. The Netherlands and Denmark are examples of sound regulatory systems supporting quality and safety in extramural centres

2.7.1. The Netherlands

In the Netherlands, extramural centres have to comply with the same quality norms as public hospitals. Extramural centres are furthermore obliged to register in the Care register. Data on their activity and the patient characteristics are available at the Dutch Healthcare Inspectorate (Inspectie voor de Gezondheidszorg - IGZ) who is responsible for monitoring quality and safety in Dutch hospitals as well as in extramural centres. Each clinic needs to send every year the results of predefined quality indicators to the IGZ. Based on this information, clinics with the highest risk profile are selected for visitation whilst at random inspections are also carried out in other centres.

There are two types of quality indicators: general quality indicators for all care institutions and indicators for specific interventions such as refractive eye surgery. The norms at the basis of the assessment tool stem from legislation and from scientific professional associations. The results of the inspections are public. Furthermore the IGZ also analyses reported safety incidents.

At the level of the individual health care professional, quality control is implemented through registration and re-registration requirements. In order to renew his/her registration, a specialist needs to participate in the visitation program organised by his/her scientific association of medical specialists.

More specifically, for refractive eye surgery, the Nederlands Oogheelkundig Gezelschap (NOG) checks whether the ophthalmologists specialised in refractive surgery comply with their predefined norms. In addition, refractive eye surgery centres can get accreditation from the Association Zelfstandige Klinieken Nederland. If a refractive surgeon has a positive evaluation by the NOG, and the centre where he/she operates has obtained its accreditation, the IGZ considers that the centre complies with the requirement for qualitative care as set in the Dutch Quality Act.

2.7.2. Denmark

Extramural centres need an authorization and registration to operate. The register is public and contains not only identification data but also the supervision report from the inspection visits. Public health medical officers conduct the supervision in a 3 year cycle. Moreover, inspection might be triggered by specific events. The evaluation is based on predefined criteria related to hygiene, medication management, post-operative surveillance, aftercare, complication and emergency management, medication errors etc. The professional organisations have collaborated to define the set of criteria developed by the Danish Health and Medicines Authorities for every medical specialty. Complaints on physicians' interventions are listed by name on the website of the Danish Health and Medicines Authorities (only cases of confirmed malpractice).

2.8. Belgian legal framework in the pipeline?

2.8.1. The powers of the Federal Government and the Communities

In the past, several legal (draft) texts attempted to regulate the (practice in) extramural centres. Overall, none of them was ever implemented because the competences of the different authorities in this issue have been a major point of discussion. In principle, the Communities are competent for policy setting of health care provision in and outside the care institutions (art. 5 § 1, I, 1° special law of August, 8th 1980 regarding the reform of the institutions). An exception to this general rule, relevant for this issue, regards the regulations regarding the basic legislation for hospitals such as Hospital Law or regulation regarding care institutions to avoid or to diminish the length of hospital stays (organic legislation) which remains to the competence of the Federal Government. According to the Council of State the regulation of extramural settings cannot be considered as an application of this exception (Advice 49.795/VR/3 of June, 28th 2011, Parl. St. 2010-11, 5-62/2). The Federal government remains competent to regulate the practice of medicine, even though due to the 6th state reform the power to organise primary care, to support the primary care health care professionals and to recognise the health care professionals within the boundaries of the recognition requirements defined by the federal government, is transferred to the communities. The communities are also competent for setting the quota of the health care professionals, taking into account the global number



of persons that can access the respective health care profession that the federal government can annually set per community. With the 6th state reform, the Communities will also get, on top of the existing powers, the power to define the recognition norms hospitals and services (included psychiatric hospitals and psychiatric sections in hospitals), care programs, hospital services, etc. have to comply with to be recognised. Yet, they need to respect the organic legislation, the federal programming criteria and the federal power to regulate the practice of medicine. The financing of the hospitals (except for A1 (budget for the construction and the renovation of hospitals) and A3 (investment costs for heavy medical equipment such as MRI, PET scan, radiotherapy) of the budget financial means (BFM) of the hospitals, remain with the federal powers. A procedure for the evaluation of the impact of the recognition norms on the budget of the federal government and social security is foreseen and if necessary the federal competent ministers or the council of ministers can exercise a veto right.

A sound, efficient regulation and control of the extramural centres will necessitate a collaboration of the federal government and the communities, given their respective powers related to this issue.

2.8.2. Operational costs

If quality and safety requirements similar to those for hospitals are applied to extramural centres, the question can be raised whether it can be justified to finance the operational costs of hospitals with public means whereas this is not the case for extramural centres, in particular when it concerns medical interventions reimbursed by the compulsory health insurance. The European State aid rules can be violated when financing services of general interest, such as in hospital care. The EU state aid framework provides several rules to scrutinize whether the public financing of services of general economic interest can be considered as legal state aid or not. The recipient undertaking must actually have public service obligations to discharge, the obligations must be clearly defined and the parameters on the basis of which the compensation is calculated must be established in advance in an objective and transparent manner. Moreover the compensation needs to be proportional to the costs to cover entirely or partially the costs of the obligations.

Currently, the hospital law states that hospital are charged with a service of general interest. There is no clear definition, however, of this content of this concept. In the definition of the notion ‘hospital’ some guiding elements can be found (e.g. emergency service, multidisciplinary, the possibility to stay overnight,...). Today these elements are often not present in extramural centres. If (some of) these elements and recognition norms similar to those of hospitals would be required for extramural centres, it becomes even more important to clearly define the precise meaning of the services of general interest to justify their public financing. Besides the interpretation of the notion service of general interest, the transparency and proportionality of the compensation can be problematic. The elements characterising the hospitals, as mentioned above, are mainly financed by the BFM. It is not possible, however, to ventilate the compensation for each of these elements. Consequently it is impossible to check whether the compensation is proportional.

2.8.3. Bill of law regarding practice in healthcare

At the time of writing this report, the bill of law regarding the practice in healthcare, setting a minimal framework for quality and safety of medical practice, regardless of the setting, is pending for advice at the Council of State. Besides, a legal initiative is necessary to implement the Directive on patients’ rights in cross border healthcare in Belgian legislation. The bill of law is imbedded in the residual power of the federal government regarding the practice of medicine. According to the bill, health care professionals need to respect quality- and safety requirements related to the potential risks that can be linked to diagnostic and/or therapeutic interventions (general quality requirements and quality requirements linked to surgical interventions). These requirements apply regardless of the setting the healthcare professional is working in. The general requirements related to the experience and the competence of the healthcare professional, procedures for anxiolysis/hypnosis/anaesthesia, the environment in which the interventions take place, the personnel, electronic data exchange, quality framework, the guarantee for continuity of care and the distribution and storage of pharmaceuticals and implantable medical devices. Some risky interventions and interventions for patients with particular characteristics (e.g. high BMI, young age) can solely be carried out in a hospital setting.



Quality requirements for healthcare professionals performing surgical interventions include the collaboration with a hospital for the organisation of emergency cases, particular requirements with regard to the information duty and informed consent, a qualitative environment, internal quality control and external ad hoc quality control by peers and registration of the type of interventions and the place where the health care professional holds his/her practice. A preliminary positive accreditation by an accreditation commission is necessary to be registered.

Today, medical interventions can solely be performed if the respective healthcare professional is recognised; recognition criteria mainly include study and training. Currently, the criteria to maintain the recognition also include quality criteria. General practitioners for instance need to guarantee continuity of care and have to comply with duties related to the patient file to maintain the recognition.

3. BROADENING THE DISCUSSION ON EXTRAMURAL CENTRES: POSSIBLE CONSEQUENCES FOR PUBLIC HEALTH POLICY

3.1. Two parallel care circuits?

In contrast to hospitals, extramural surgery centres are not regulated by the hospital law and a.o. their operating costs (for instance utilities, consumables, intensive care, emergency department, the continuity of care during night and day, costs for infrastructure....) are not eligible for public financing. Yet, specialists practicing in these centres can perform both reimbursed and non-reimbursed procedures, although reimbursement of some of these might be restricted to recognized hospitals.

Reimbursement rules for surgical procedures

Any operating room (OR) procedure with a nomenclature code value coefficient equal to or superior to K 120 or N 200 or I 200 has to be performed in an officially recognized hospital, having at least one C service (= surgery department) or D service (=internal medicine).

However, from May 2009 onwards, the above mentioned hospital confinement rule does no longer apply to interventions listed in Article 14 h) of the nomenclature (ophthalmology), provided that (1) these procedures are performed in an extramural setting that meets the architectural standards of the day-care surgery function and (2) only if these procedures are done under local or topical anaesthesia, and (3) do not require sedation of the patient, (4) neither direct nursing care or aftercare.



The tariffs of non-reimbursed interventions can be set freely, irrespective of the setting. However, there is a tariff convention between the Werkgroep Extramuraal Oogheelkunde and the private insurers, conditioning the reimbursement of refractive eye surgery

It is assumed that extramural centres mainly provide aesthetic, non-reimbursed, non-urgent care. Yet, legally, some interventions eligible for reimbursement such as for instance cataract operations can also take place in extramural settings, if the above mentioned conditions are fulfilled. This is in line with art. 7 §1 Order July, 28th 2003 executing article 22, 11° of the law regarding the compulsory insurance coordinated July 14th 1994 stating that the entitled person can be admitted to the hospital if it is not possible to diagnose, treat ambulatory or if it is impossible to isolate a patient with an infectious disease.

3.2. Continuity of care: risk of brain drain and lacking after hours care

Extramural centres can be particularly attractive for health care providers because of the working conditions and the financial rewards. Most extramural centres have more favourable schedules than hospitals: in particular, they generally don't organize after-hours duties. Tariff setting is free and the working costs are predictable, since patients' severity of illness is often low with few co-morbidities (patient selection policy). The costs predictability of selected patient population limits the risk for budgetary deficits. This advantageous situation could supposedly lead to a brain drain of specialists from hospitals. Some of them can opt to work exclusively in an extramural centre; others will combine clinical work in a hospital with a job in an extramural centre (if allowed by their employment contract with the hospital). The risk of brain drain also applies to paramedical personnel.

3.3. Risk of patient selection

Extramural ophthalmology centres may be owned (or managed) by physicians who also work in a regular hospital (dual practice). Conflict of interest can arise if the services offered in the regular hospital are similar to those offered in the extramural centre. Some physicians may refer the less severe cases to the extramural centre. A possible consequence could be that hospitals concentrate the more severe cases and cases with more co-morbidities, at risk of complications and consultations during after-hours periods. It is obvious that this kind of evolution also has negative financial consequences for the hospitals. The absence of registration of interventions performed in extramural centres precludes from estimating the magnitude of the above-mentioned potential problems.

3.4. Regulating dual practice in Belgium: some trails?

In Belgium, dual practice is not regulated. Some hospitals adopt clauses prohibiting the referral to or the simultaneous work in a private practice or any other extramural setting during the period of their contract or even longer. It is doubtful, however, whether such clauses are in accordance with the rules of competition law. Another option would be to regulate this dual practice: the pros and cons are discussed below.

3.4.1. Different options, no panacea

A policy based on rewards, such as an exclusivity bonus remuneration for physicians working solely in regular hospitals does not seem advisable, because it is likely to be solely attractive to those physicians that have less opportunity to operate in extramural centres due to their particular specialty. If additional revenues from extramural practice were denied to physicians employed in recognized hospitals, some of them might permanently quit the public health circuit.

Making after hours and emergency duties financially more attractive is another option but its feasibility needs to be assessed in the wider context of hospital financing and financing of the hospital physicians. Limiting the number of hours that can be performed in extramural practice or limiting revenues obtained from private practice would only be realistic if working time and incomes were systematically registered.



3.4.2. Measures need to be conform to EU regulations

Restricting measures regarding care provided in extramural centres and professionals working in these centres or in relation to the establishment of extramural centres must conform to EU and national regulations on free movement of people and services and to the freedom of competition rules. Financial accessibility and continuity of care are clearly objectives that can be accepted as having a public health interest, hence justifying restrictive measures. Member States need to provide evidence, however, that the restricting measure is necessary to protect the public interest objective.

Therefore, data on extramural centres and physicians' activities in the public and the extramural settings are primordial to support the implementation of appropriate measures to regulate their activities.

3.4.3. The broader context needs to be assessed

The above-mentioned risks are not solely linked to the existence of extramural centres but need to be assessed in the broader context of the organisation and fair remuneration of medical professionals and hospitals. Implementing restrictive measures as such are thus not an optimal solution. The sequences of any restricting measure should be assessed in the wider context of the regulatory framework.



■ RECOMMENDATIONS^a

To the competent Ministers

The Directive on Patients' Rights in cross border healthcare imposes the Belgian State to implement quality and safety norms for health care interventions, regardless of the setting. The following recommendations focus on the definition of a legal framework for quality and safety in extramural centres.

- **Definition of extramural centre**
An official definition of extramural centres should be agreed upon.
- **Possible options to guarantee a quality framework for extramural centres and the medical intervention performed there:**
 - **Recognition of the extramural centres**
Extramural centres should be submitted to an official recognition process, granting them a license to operate. The recognition norms should ensure that minimum requirements for safety and quality of care are met. Differentiation of the recognition norms according to the practice profile of the centre is recommended. Collaboration between the communities and the federal government is necessary to avoid discussions regarding the powers for defining the recognition norms, in particular when it concerns the practice of medicine. Existing norms, for instance those drafted by the professional associations, such as the criteria for the voluntary certification of extramural ophthalmological centres, can be a valuable input for the definition of official recognition norms. The competent government needs to control the respect of the recognition norms. The results of the control need to be public.
 - **Quality- and safety requirements for the practice of health care professionals, regardless the setting they work in.**
It needs to be assessed, in collaboration with the communities, how the federal government within her powers regarding the practice of medicine can define quality- and safety norms health care professionals need to comply with. An option can be to extend the norms to maintain recognition of the healthcare professions. General as well as specific safety- and quality norms can be linked to the different medical activities.

^a The KCE has sole responsibility for the recommendations.



Special attention is needed for the duties of healthcare professionals with regard to:

- **Continuity of care**

Practitioners working in extramural centres can organise after hours in the centre or guarantee continuity of care in another way. A possible option is to have a formal agreement with a nearby hospital for the emergency and after-hours duties. The patient should be clearly informed on the organisation of the aftercare.

- **Patients' Rights**

The content of the information duty needs to be extended and specified according to the Directive on patients' rights in cross border care. The information duty also applies to extramural centres. By analogy with the legislation for hospitals, the duty to publish information regarding the offer of medical care, the costs, the fees and the convention status of the physicians working there, should also apply to extramural centres.

The minimal content of the patient file and the modalities of storage should be explicated in the patients' rights act. Details on the care trajectory, the medication scheme, the implants used etc. should be included.

- **Registration**

Extramural centres and the health care professionals working there should be registered. The Federale Databank van de Beoefenaars van de Gezondheidszorgberoepen / La Banque de Données Fédérale des Professionnels des Soins de Santé should be completed with the necessary information to enable the tracing of all physicians and their activities in all settings.

- **Nature of the medical interventions in extramural centres and possible compensation of the costs?**

The decision on a possible compensation of the costs will depend on the definite choice on the nature of the medical activity (day hospital or surgical day hospital versus ambulatory care) and will need to be integrated in the larger scope of the future reform of the hospital financing.

- **Liability**

Central liability should be regulated for health care provided in extramural centres.

- **A sound procedure for complaints against extramural centres needs to be elaborated.**

