KCE

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d''Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

ANNUAL REPORT 2019

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About us

Who we are

The Belgian Health Care Knowledge Centre (KCE) is an independent federal research centre that focuses on the organisation, financing and reimbursement of health care and on health technology assessment. It also develops guidelines for the clinicians.

The scientific studies it produces are usually asked by public authorities, universities and professional associations, but in fact all citizens, patients or patient organisations can submit a research proposal (see “Propose a topic”).

Each KCE study results in recommendations for competent authorities and health care stakeholders. However, KCE has no decision-making power and the policy choices arising from the reports it publishes are not within its remit. It may nevertheless be required to intervene in implementation phases when its technical skills are an of essential added value.

KCE is a type B parastatal organisation. This status guarantees total independence from the subsidiary powers, who essentially are the federal authorities (NIHDI for 75% and Federal Public Services Health and Social Security, together for 25%). In addition, some specific European subsidies cover KCE’s involvement in international research networks and projects.

The acronym KCE is a contraction of the words:
Kenniscentrum (Dutch) and Centre d’Expertise (French)

Our values

Independant

Meticulous

Transparent

Our mission: to defend care that is

Effective

Of high quality

Secure

Patient-centered

Accessible

Durable

What we do

The KCE activities encompass five areas of expertise:

- **Health Services Research (HSR):** the organisation and financing of health care in the broadest sense
- **Health Technology Assessment (HTA):** the evaluation of medical technologies
- **Evidence-Based Practice:** the production of clinical practice guidelines adapted to the new scientific developments and participation in the Belgian network of Evidence-Based Practice
- **KCE Trials programme:** the coordination of the Belgian non-commercial clinical research programme
- **Methods:** the creation of accurate and robust methodological manuals to establish validated working methods for all health care and public health researchers

In 2019, the KCE published 18 reports (see “Study programme of the KCE”) and the KCE Trials programme funded 18 clinical trials (see “KCE Trials programme”).

Our Board of Directors

Our Board of Directors (hereinafter, the “Board”), consists of representatives of the public authorities and the most important actors in healthcare, health insurance and patient associations, in a balanced composition. At each Board meeting our new finalised reports are presented. The scientific content is in principle not subject to modification, except on the basis of quantifiable methodological arguments. The political recommendations, based upon the scientific work, are then discussed, sometimes nuanced, but only on the basis of scientific arguments from the report. When voting turns out to be necessary, the reports are approved by a simple majority. Finally, KCE is legally obliged to publish all of its results within one month of their approval by the Board, which is an additional guarantee for our independency and transparency.

Our team

The healthcare domain is very complex. There is no scientific training that comprises all its numerous aspects. That is why at KCE we have opted for a truly cross-disciplinary approach. No research is conducted by a single researcher; on the contrary, each research question is examined from a medical, economic, social, legal and/or ethical perspective, depending on the needs. This is highly appreciated, both by the users of the studies and by the researchers themselves.

KCE staff members active on December 31st, 2019

	in full-time equivalent
Chairman	**0,2**
Management	**3,0**
General Management	2,0
Programme Management	1,0
Studies	**43.3**
Physicians, nurses, dentists, physiotherapists,…	23,9
Health economists	7,2
Sociologists, lawyers	3,7
Data analysts, statisticians and specialists in scientific information	5,6
Experts in dissemination and knowledge management	2,9
Support	**16.5**
Project facilitator	1.8
Secretariat and layout	7,3
ICT, website and library	2,0
Legal advice and Human Resources Management	3,4
Budget and accountancy	2,0
TOTAL	**63.0**

The KCE experts can be divided into five different categories:

- researchers with a **clinical or biomedical** background: physicians, nurses, physiotherapists, dentists, psychologists, all who have acquired complementary skills (usually a PhD) in subjects such as public health, epidemiology, methodology for the development of guidelines, analysis and data management, etc.

- researchers with a background as **health economist**. Thanks to their expertise, we are able to conduct very thorough economic assessments, including Health Technology Assessments (HTA). Their contribution is also essential for our studies on the organisation and financing of health care, an area for which KCE is increasingly solicited.

- researchers with a background in other **human sciences**. Sociologists conduct qualitative studies: they collect data from field experts, patients, stakeholders, etc.) and ensure their rigorous processing. Other researchers allow us to discuss the possible legal or ethical aspects of the varied research questions.

- **data analysts, statisticians and specialists in scientific information**. They extract from international and Belgian data the pertinent information and figures for our research. They also scrupulously ensure that while using the sometimes very sensitive data, the privacy legislation is respected, that all useful information is identified and that the figures are interpreted correctly. In this way we can collect very precise statistics.

- specialists in **dissemination and knowledge management**. The first group of specialists adapts the language of our reports to the different target groups and ensures that the message reaches the appropriate audience. Thanks to the second group, all our experts can maintain and develop their expertise, and the quality of our work is guaranteed thanks to meticulous work procedures.

Some of these experts were or are still academically or clinically active (which enhances their understanding of the field), others have committed themselves to full-time research at KCE.

Performant support services

KCE functions in a very horizontal organisation on a human scale where working procedures are well organised and decisions are efficiently taken after deliberation. The experts are supported by sharp and efficient support services (project coordination, ICT, webmaster, library, layout, secretariat, legal advice and human resources management, accountancy, etc.).

All together they form a united and enthusiastic team of 70 people, motivated by the same goal: to provide the studies needed to maintain or improve an effective, safe, quality, accessible and sustainable health care system.

Our external collaborations

We regularly appeal for external expertise to support us in the design and execution of certain parts of our studies. We also call upon external experts for the validation of each report. Finally, we are part of European and global networks of expertise.

Subcontractors

Despite an in-house team with many skills, the KCE does not always have the necessary internal expertise or the time to perform all of the studies itself. This is why some studies are fully or partially outsourced by public tender to, for example, university teams, specialised consultants or other public services. However, in these cases, KCE always retains responsibility for the coordination, the supervision and the final results of the projects.

External experts and stakeholders

KCE doesn't work in an ivory tower. For each project, field experts are called in. These people, mostly specialists on the study subject, provide feedback on the research questions, the methodology and the key points to be taken into account for a better acceptance in the field. Patients are also increasingly involved as experts with lived experience (see "Around the patient").

Similarly, in each of its studies, KCE also invites interested stakeholders for consultations to gather their opinions on the subjects concerned. Stakeholder opinions are always taken into consideration, but are identified as such and are distinguished from the research results.

Each external participant is requested to sign a declaration of potential conflicts of interest (see below).

Thanks to these external collaborations, the communication between researchers and caregivers, patients and decision-makers in health care can be improved and professionalised.

The validators

All KCE reports are subject to internal and external scientific validation. For the latter, KCE invites three external experts, at least one of whom is foreign. In this way, the KCE benefits from critical, constructive external views on its work, and this contributes to the relevance and the scientific rigour of its reports.

In the course of the years, these external validations have enabled KCE to build a very rich network with highly specialised national and international experts in a wide range of fields.

Conflict of Interest Policy

KCE is absolutely committed to its independence and neutrality. Therefore its policy on conflicts of interest is clear and transparent:

- **KCE researchers are not authorised to engage in other professional activities that may give rise to conflicts of interest;**
- **All external experts, subcontractors or validators who are involved in a KCE-study have to sign a declaration of possible conflicts of interest, which will be included in the colophon of the report.**

Our international network

KCE has excellent relationships with other scientific institutions conducting similar research in other countries such as **NICE (United Kingdom), ZIN (the Netherlands), HAS (France), IQWIG (Germany) or the Norwegian Institute of Public Health (Norway)**.

Due to its reputation of scientific rigour the KCE receive many requests to participate in working groups, congresses and symposiums on an international level. It is an active member of several international networks such as **EUnetHTA (European network for Health Technology Assessment), GIN (Guidelines International Network) or INAHTA (International Network for Health Techology Assessment)**. KCE is also the Belgian representative by the European Observatory on Health Systems and Policies, which publishes the **HiT (Health in Transition)** Report and is involved in European projects, such as **PREFER (IMI)** an initiative aiming at the development of a method which takes into account the preferences of the patient in the making of new drugs.

Propose a topic

For the KCE studies year programme

Each year, before summer, KCE launches a call for study proposals for the work programme of the following year. Any citizen, organisation, institution or policy maker can submit a study proposal.

Proposals can be submitted between July and September. The work programme is then composed, based upon the following criteria:

- The **potential** of the proposed subject to improve health care decisions
- The **frequency** of the health problem
- The **severity** of the health problem
- The **potential to improve** the health problem
- The **feasibility** of the study

Each criterion is individually analysed by members of management and a dozen KCE experts. The results are discussed by all the evaluators and the rejections are systematically justified according to the criteria. At the end of this procedure, KCE's research capabilities are taken into account. In order for this evaluation process to proceed as neutrally as possible, all proposals are anonymised. Each applicant is informed individually of the reasoned decision of the KCE. However, if a proposal is withheld, this does not mean that the submitter may carry out the study himself/herself. The KCE will do this itself, or outsource parts of it, after an open tender procedure (see 'External collaboration').

If you wish to be kept informed on our calls for projects, please register on the website via 'receive news'

For the clinical trials programme (KCE Trials)

The KCE Trials programme also solicits input from clinicians, patients, and others for its clinical trial topics. But in contrast to KCE's annual study program, the KCE Trials program has no fixed schedule for its calls. You can ask to be kept informed on calls and other information from KCE Trials by subscribing on the KCE website.

There are three types of calls for study proposals:

- Within the '**investigator led workstream**': the study subjects are proposed by the researchers themselves (and their institution will also take the role of study sponsor);
- Within the '**commissioned work stream**': the study subjects are proposed by the KCE, or by the NIDHI, the Federal Public Health administration, the Minister(s) of Health, or by members of the Priority Group of the KCE Trials programme. Interested research teams may apply to conduct them;
- Within the '**international workstream**' : they offer Belgian teams different possibilities to collaborate in international trials. The topics are proposed by the team that will take on the role of coordination centre for Belgium.

You may find more information about the call for clinical trials on the KCE website.

Our visibility

KCE is legally obliged to publish each report on its website after approval by the Board of Directors. Via its website, press releases and the social media, each report is disseminated to all stakeholders including policy makers, the health care sector and the general public.
Our researchers are also regularly invited to present their reports at symposia and meetings. They also publish articles in scientific, peer-reviewed journals.

KCE

Our website

For each published report, a specific page is created, with a short introductory text. Different documents can be downloaded from this page, which are tailor-made to the needs and degree of interest of each reader:

- The **scientific report** describes the performed research, with the methodological details and results. It is always written in English, since it is the language of the scientific community (Belgian and international) and of our research teams, whose members often speak different languages.
- A **20 to 30 page summary**, which outlines in a clear and accessible language the context of the study, the main results and the final recommendations. The summary is available in French and Dutch as it is addressed to all interested citizens, but above all to health care professionals and the concerned decision-makers. It is sometimes completed by a **short report**, written in English, which summarises the research work and contains the discussion of the results.
- A press release, a two-page text written for journalists that can also serve as a quick introduction to the subject. It is published in French and Dutch.

Website traffic in 2019

235 826
visitors

1 189 209
Visited pages

38 834
Video views for
a total of 70 140 minutes

Our followers

We are also present on social media **Twitter, LinkedIn** and **Facebook**, which enables us to broaden our visibility and add immediate interactivity to our communication. Our videos are available on our **YouTube** channel .

2217
Followers on Twitter

3630
subscribers on LinkedIn

444
Followers on Facebook

Our website also contains other information on:

calls for study proposals, information about KCE Trials, public tenders, job vacatures, etc. This information is also systematically sent to everyone who wishes to be kept informed on our activities by registering on our website..

Today, about 5750 subscribers and some 325 journalists regularly receive our mailings.

KCE
study programme

Accessibility of care

The word “accessibility” appears frequently in the KCE [Belgian Health Care Knowledge Centre] recommendations. It is a key aspect of a care system like ours, which is firmly committed to tackling health inequalities.
It may involve financial accessibility, in its strict sense, as in Report 309 on social protection measures, or Report 315 on the reimbursement procedures for enteral and parenteral nutrition. But, often, accessibility is also a question of how care is organised, as shown in two reports that deal with access to care for particularly vulnerable populations, such as asylum seekers (Report 319) or people with mental health problems (Report 318).

Report 309 : Cost sharing and protection mechanisms in health

The Belgian compulsory health insurance is not only an insurance scheme that reimburses health costs; it is also a solidarity system designed to reduce inequalities. It does this through two mechanisms: by income redistribution (high-income groups contribute more than low-income groups) and by cross-subsidies from low to high health risks. However, the Belgian health insurance system is also characterised by patient cost sharing, such as co-payments or supplements. This personal contribution is, on average, 20-25% of total health costs.

A number of social protection measures were introduced to limit patient cost sharing in order to make health care more accessible to the most vulnerable groups. These measures are either targeted at specific categories of patients (for example, those with chronic illnesses), or at certain socioeconomic groups (for example, those entitled to an integration allowance for handicapped persons or to increased reimbursement of healthcare costs). At the request of the NIDHI [National Institute for Health and Disability Insurance], KCE has calculated the budgetary impact and the redistributive effect of the policy measures taken between 2012 and 2016 which have had an impact on patient cost sharing, and has assessed the impact of a series of hypothetical changes to the current protection measures.

Report 315: Organisation and reimbursement of enteral and parenteral nutrition in and outside the hospital in Belgium

In this country, 33% of hospital patients, 16% of residential care residents, and nearly 13% of elderly people living at home suffer from malnutrition. For people who are not or no longer capable of feeding themselves normally, food must be administered via a tube into their digestive tract (enteral nutrition), or via a drip directly into their blood stream (parenteral nutrition).

In Belgium, the reimbursement rules for these two types of nutrition are not always logical. Thus, in hospital, nutrition via a tube costs the patient nothing, whereas, at home, it costs them between €11 and €28 per day. Conversely, parenteral nutrition costs a hospital patient around €11 per day, but is practically free at home. KCE recommends changing the reimbursement procedures so that the costs payable by patients are similar, regardless of where they are being treated and what type of nutrition they require.

Full reimbursement would represent a budget increase for health insurance of around €16 million.

Report 318: Organisation of mental health care for adults in Belgium

Mental health services have undergone a number of reorganisations, all of which are characterised by a desire to discharge patients from hospital to enable them to live in the community.

KCE was given the task of mapping the current landscape for these services and identifying their shortcomings and possible overlaps. But since the needs of the Belgian population are not known – as there are no reliable figures on the subject – KCE has not been able to verify whether the services provided meet those needs. Priority must therefore be given to implementing efficient encoding systems for data relating to mental health problems, the care services needed, the services provided and how these services are used, their costs, their quality, etc.

The number of care access points must also be increased and made more accessible from a financial point of view. The access points could be general practitioners, medical centres, health services in the workplace, Public Welfare Centres (CPAS/OCMW), etc. Several networks are already tackling this. In addition, all the information on the provision of mental and physical health services should be combined online in a single portal.

The provision of adapted dwellings must be increased significantly in order to promote social reintegration and prevent institutionalisation. Lastly, preventing mental health problems and managing them early cannot be achieved without their destigmatisation, both in the general population and among employers and the care providers themselves.

Report 319: Asylum seekers in Belgium: options for a more equitable access to health care

Any migrant who arrives in Belgium and seeks asylum automatically receives access to healthcare for the duration of the asylum procedures. However, several Belgian and international reports have highlighted the fact that access to this care is not equal for all asylum seekers. KCE was asked to propose solutions to rectify this situation which is putting Belgium at odds with the international treaties it has signed.

The crux of the problem is that the funding of this healthcare is dependent on different bodies according to whether the asylum seeker is housed in a collective reception centre or in a local reception initiative (ILA/LOI) managed by a Public Welfare Centre (CPAS/OCMW). KCE recommends simplifying the organisation of access to the care by incorporating it all into a single overall budget. Who will manage this budget? There are several possibilities; KCE has analysed them, but the final decision rests with the public authority.

Safety of care

It goes without saying that healthcare must be completely safe. However, this requires constant vigilance since practices that were once considered safe may no longer be so in the light of today's standards. Or, conversely, the fascination with new technologies may cause certain safeguards to be overlooked by some people as they are too busy to implement them.
This year, however, we have been focusing on two practices where safety issues are no longer in doubt: the unreasonable use of antibiotics (Report 311) and the shortage of nursing staff in our hospitals (Report 325). These are two areas in which our healthcare can – and must – improve.

Another way to tackle safety is to check whether certain interventions are being properly targeted at those patients for whom they are proven to be beneficial. That is what we have done with our study on bariatric surgery (Report 316).

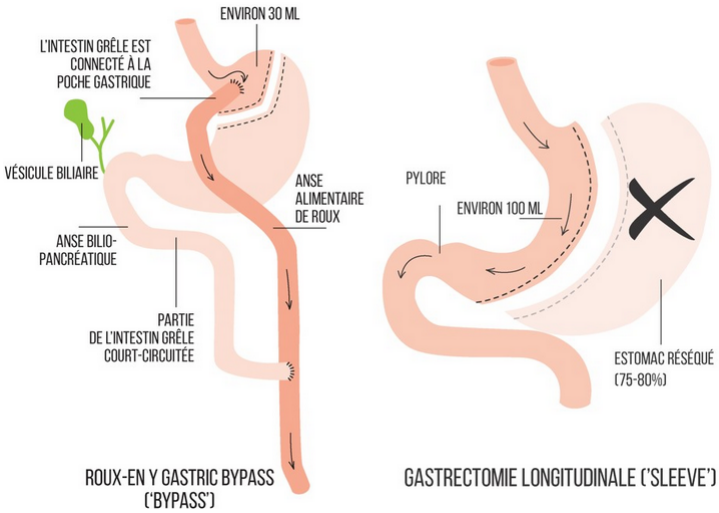
Report 311: Proposals for a more effective antibiotic policy in Belgium

The inappropriate use of antibiotics has led to an increasing resistance to bacteria, to the extent that all the benefits of these drugs risk being wiped out. To tackle this resistance problem, the prudent use of antibiotics is a priority. And because human, animal and environmental health are closely linked, this problem must be addressed through a "One Health" approach in which the different sectors collaborate.

In Belgium, we use more antibiotics than the European average in the ambulatory sector (especially in general medicine), in care homes and in the veterinary sector. The KCE has put forward 21 recommendations to improve this situation. The first of these recommendations is to develop a national "One Health" action plan to tackle antimicrobial resistance, involving all the relevant stakeholders in both human and veterinary medicine.

Other recommendations include strengthening "antibiotic stewardship" in acute care hospitals and developing it in the ambulatory sector and in nursing homes. The KCE also suggests authorising pharmacists to sell the exact number of tablets required for the prescribed treatment. This would prevent people from keeping "leftovers", with the associated risks of self-medication and environmental pollution. Moreover, the use of antibiotics in domestic animals also warrants greater attention: at present, there are few data on the subject, yet we know that they too can transmit resistant bacteria to their owners, and vice versa.

Report 316: Bariatric surgery: an HTA report on the efficacy, safety and cost-effectiveness



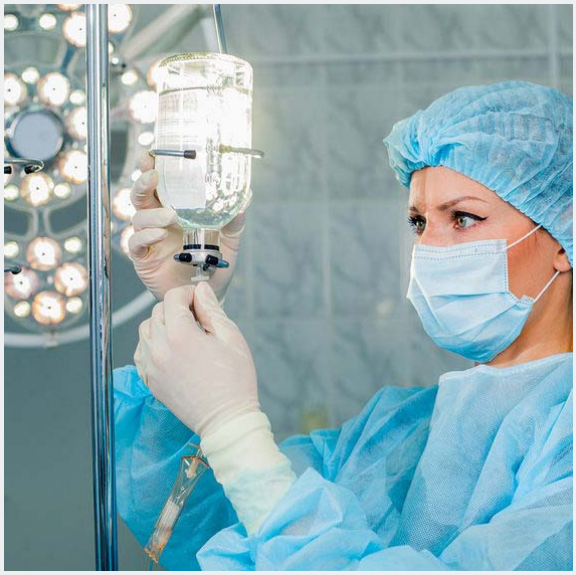
Bariatric operations (i.e. for the purpose of losing weight) have increased by more than 80% over the last seven years. In the majority of cases, these operations result in significant and lasting weight loss, along with a reduction in the risk of obesity-related death and an improvement in diabetes, which is often present in obese people. However, it is important to note that these are major, often irreversible operations which can cause serious complications. They involve a radical change in how a person eats, a lifelong medical monitoring, and the intake of food supplements to prevent nutritional deficiencies.

Currently, bariatric surgical operations are reimbursed only above the age of 18, with some rare exceptions. The first question put to KCE was whether it was appropriate to extend this reimbursement to include adolescents. When they become seriously obese, a condition often accompanied by high blood pressure or diabetes, their life expectancy is clearly shortened. KCE has concluded that such operations must remain exceptional and reserved for cases where the medical need is great.

Another question concerned people with diabetes (type 2). These individuals can usually obtain reimbursement if their body mass index (BMI) is at least 35, but the question is whether this threshold should be lowered to 30. KCE recommends authorising reimbursement at this level but linking it to a requirement to record data so that a subsequent assessment can be made on whether the improvement obtained is genuine and lasting.

This report will be followed up, in 2020, with the publication of a detailed care plan for the overall care of patients undergoing bariatric surgery.

Report 325: Safe nurse staffing levels in acute hospitals



At the international level, it is generally accepted that patient safety in hospitals cannot be guaranteed when there are more than 8 patients per nurse. However, in Belgian hospitals, nurses have to look after 9.4 patients on average. That is already better than 10 years ago, when a study carried out by KU Leuven found that there was 1 nurse per 11 patients. But the current situation is still not acceptable, particularly because the intensity of care has increased over the past ten years, so patient safety is not guaranteed in many services in which KCE undertook the study, particularly in geriatrics (where, nearly 70% of the time, the patient/nurse ratio is above what is regarded as safe).

The nurses themselves are aware of the risks presented by this situation. Due to a lack of time, they are increasingly unable to perform the necessary care, particularly because they have to carry out numerous other tasks (serving meals, transporting patients within a hospital) which could just as easily be carried out by auxiliary nurses or non-medical staff.

Not only is this situation dangerous and/or uncomfortable for patients, but it also contributes to the increasing dissatisfaction of nurses: one in four is dissatisfied with their work, 36% run the risk of burnout, and 10% are even considering quitting the profession.

The study concludes with a number of recommendations, the first of which is that a maximum number of patients per nurse needs to be laid down by law, and that the necessary resources must be invested in order to improve the nurses' working conditions and the safety of care. Swift elimination of clearly dangerous situations would require a staffing increase of 1,629 full-time equivalents, in other words an additional annual budget of nearly 118 million euro. In the longer term, and just for surgery, internal medicine, geriatrics, rehabilitation and paediatrics, a further 5,527 full-time nurses would be required, with an additional annual budget of more than 403 million euro.

Around pregnancy and birth

Of the 18 reports published in 2019, three deal with pregnancy and childbirth, although from very different perspectives. Report 326 proposes a prenatal care plan for all pregnant women, Report 323 recommends reorganising maternity hospitals to increase their efficiency while maintaining their accessibility across Belgium, and Rapport 312 looks at how midwifery will evolve over the next 25 years.

Report 312 : Alternative scenarios for the forecasting of the midwifery workforce

In 2018, the Planning Unit for the Healthcare Professions (Cellule Planification de l'Offre des Professions des Soins de Santé / Cel Planning van het Aanbod van de Gezondheidszorg-beroepen) published a future scenario on the evolution of midwifery staffing levels for the period 2014-2039. This scenario was developed based on the trends observed in the past. KCE was tasked with supplementing this base scenario by incorporating the new challenges that this profession is likely to face over this 25-year period.

To respond to this request, we developed a ground-breaking methodology, combining foresight analysis and scenario generation involving the actors on the ground. Three future scenarios were developed. The first envisages pregnancy and birth being managed mainly by gynaecologists, which more or less reflects the current situation. The second describes a care organisation centred around hospital-based midwives, and the third, a mainly outpatient care organisation, run by frontline actors (midwives and general practitioners). According to these three scenarios, the demand for midwives will increase by 11.4%, 12.0% and 17.4% respectively by 2026, and the midwives' employment status – hospital employees, self-employed or mixed – will also change according to the care model that becomes dominant

Report 323: Organisation of maternity services in Belgium

Excess capacity of Belgian maternity services was calculated in KCE report 289 and amounts to about 1 000 beds. Hence, a reduction in the number of maternity services was recommended. This is in line with an international trend to close smaller maternity services and transfer their activities to larger services in order to reduce the average cost per delivery. Even in maternity services with low activity, minimum levels of midwives, nurses, doctors and equipment are necessary, which is expensive.

As part of the ongoing reform of the hospital sector, KCE was asked to define criteria for closing maternity services. We calculated that a maternity service should perform at least 557 deliveries per year to have a cost per delivery at the level of the more efficient maternity services, without compromising the quality or safety of the care provided. However, in addition to efficiency, there is another, crucial criterion: accessibility. Every woman must be able to reach a maternity service within a certain length of time (we used 30 minutes by car as time limit.). Currently, 80% of women has access to 8 or more maternity services within 30 minutes. KCE recommends that 17 of the 104 maternity services in Belgium could be closed because their number of deliveries is too low. An additional 4 maternity services also have less than 557 deliveries per year, but because of accessibility reasons they should not be closed.

Report 326: Towards integrated antenatal care for low-risk pregnancy

In Belgium, the provision of prenatal care is varied, is provided by qualified professionals, and is accessible in various settings (hospitals, private clinics, etc.). The downside is the complexity of the care supply. We also observed that parents to-be sometimes do not find their way in the health system maze and are not always able to find answers to their many questions. In addition, some pregnant women still slip through the net whereas others are over-monitored.

For this reason, we have developed a proposal for a “prenatal care pathway” similar to what exists in other countries. This pathway would be supported by a professional network, the composition of which would be adapted according to her specific medical, psychological or social needs and risks. A new type of consultation so-called “individual counselling consultations” (ICC) would allow to develop a care plan in collaboration with the pregnant women. This plan would detail all the important stages of the pregnancy follow-up and implement additional interventions where vulnerabilities are identified. A single contact person would be appointed to coordinate the entire pathway. In this way, parents to-be will have everything they need for informed management of the pregnancy, the birth and the first few weeks of their child’s life.

Around the patient

Healthcare services are rapidly changing and are now more and more being organised around the patient, who is becoming a "partners" in his/her care. It goes without saying that certain aspects of this more egalitarian vision of the care relationship need to be adjusted and questioned. KCE was the first Belgian public institution to look at ways to increase the level of patient involvement in its research (Report 320). But a dialogue between patients and carers is only possible if each is able to understand the other. This is what is referred to as "health literacy" (Report 322).

Report 320: Position of KCE on patient involvement in health care policy research

Around the world, the tendency is to involve patients in scientific research projects aimed at providing guidance to healthcare policy -makers. Patients, who are faced with the physical, emotional and financial consequences of their illness, have specific knowledge which researchers do not have (or which are not described in the scientific literature). This is what is referred to as “expertise by experience”. It is therefore logical to take their point of view into account. In Belgium, KCE is the first public institution to examine this issue.

Our researchers have studied the scientific literature and consulted the opinions of Belgian experts and institutions similar to KCE in other countries, taking into account the ethical and philosophical aspects associated with patient involvement. We have also discussed and researched the matter internally, questioning our own culture, opinions and experiences. As a result of this in-depth exercise, we have put forward 18 positions on the subject.

Investing in time and in additional resources will be the main challenge for the researchers. They will also have to look closely at the emotional burden that this involvement will represent for patients and researchers, and at the possible conflicts of interest, just as they do for the other stakeholders. The next step will be to develop a methodological guide offering practical recommendations.

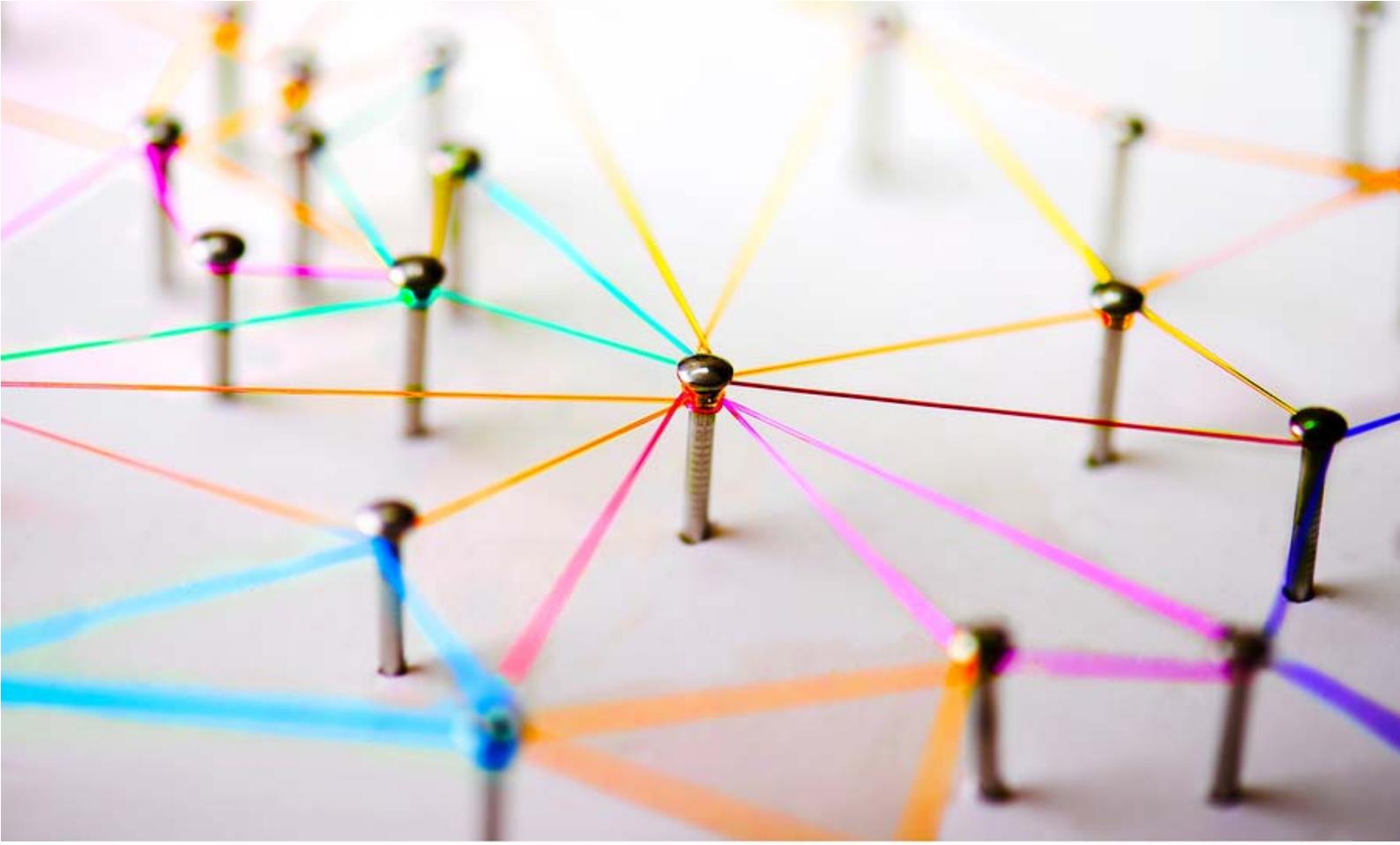
Report 322: Health literacy: what lessons can be learned from the experiences of other countries?

The term “health literacy” describes a person’s ability to understand health information so that they can maintain or improve their health and their quality of life. People who have a low level of health literacy find it hard to interact properly with health professionals, understand the how and the why of their health condition, talk to professionals about the steps to be taken, understand drug leaflets, and follow their treatments correctly. In Belgium, the health literacy level appears problematic for 30 to 45% of the population.

However, health literacy does not depend on individuals alone; the way health information is designed and health care is organised also has a part to play. Indeed, the more complex a health system is, the more difficult it is for its users to interact with it as “competent” individuals. Health literacy must therefore be seen as a shared responsibility between individuals and the health system in which they operate.

Many countries have implemented action plans to improve the health literacy of their population. KCE was tasked with analysing some of these plans in order to learn the lessons for developing a possible plan for Belgium. It appears that the “ideal” plan would need to mobilise all sectors of society (education, employment, etc.), but certainly first and foremost all health professionals and organisations.

Our country can already rely on a wealth of health literacy expertise and a number of actors who are very sensitive to the issue at all levels and in all sectors, but the subject still needs to be coordinated more effectively as a whole. In short, the proposals involve identifying the driving forces, assessing the current actions and reflecting together on how to optimise our efforts in future.



The Belgian Evidence-Based Practice network

All healthcare professionals need to be guided in their daily practice so that they can give due consideration to continually evolving science. This is the role of the clinical practice recommendations (or guidelines), which summarise the latest evidence-based scientific data. Today, using such data is an essential care quality standard in all western countries.

For several years, an ambitious project to create a Belgian Evidence-Based Practice (EBP) Network has been taking shape in Belgium. It aims to provide, on a single online portal (www.ebpnet.be), all the guidelines and other evidence-based materials used by ten primary care health professions. Report 317 describes the latest stage in the implementation of this network. The KCE has also completed its first year as coordinator of the prioritisation unit within this network.

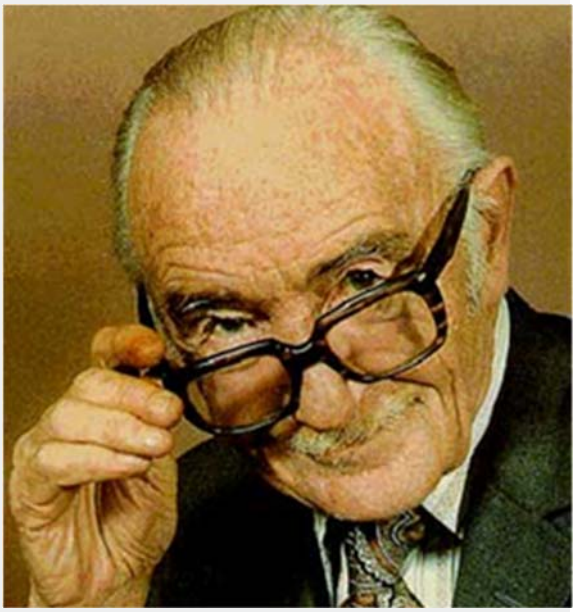
Regarding EBP, we have also this year developed guidelines on diagnosing and treating two sexually transmitted infections (STIs), gonorrhoea and syphilis (Report 310), and two interactive tools to assist medical consultation, one on STIs (Report 321), the other on statins in primary prevention (Report 324).

What is Evidence-Based Practice or EBP ?

Evidence-based practice (EBP) can be defined as "the conscientious, explicit and judicious use of the best recent scientific evidence when making decisions about the care of individual patients".

For a health professional, practising EBP means combining, in their daily practice, three elements of equal importance:

- their own clinical expertise, which covers their accumulated experience, their training and their clinical skills;
- the preferences, concerns, expectations and values of each individual patient;
- the "proof" or "evidence" available in the form of guidelines, which are themselves based on clinical research that meets the highest quality standards.



Sir Archibald Cochrane (1909-1988), founder of the EBP

Setting up the Belgian EBP network is a lengthy project whose foundations have been entrusted to KCE. Since 2016, we have been working on this project in close collaboration with the Antwerp Management School, and we have updated you on its progress in our successive annual reports. But 2019 will remain a historic year: the year of take-off! After identifying and contacting all the EBP actors in Belgium, after getting them together to consider the best ways to coordinate and organise their respective activities to enable them to work harmoniously, after drafting a common "charter" documenting all these interactions, and after thoughtfully considering the optimum forms of governance for coordinating the network and outlining the various phases of its operationalisation, we are, at last, able to announce that the network is well and truly up and running.

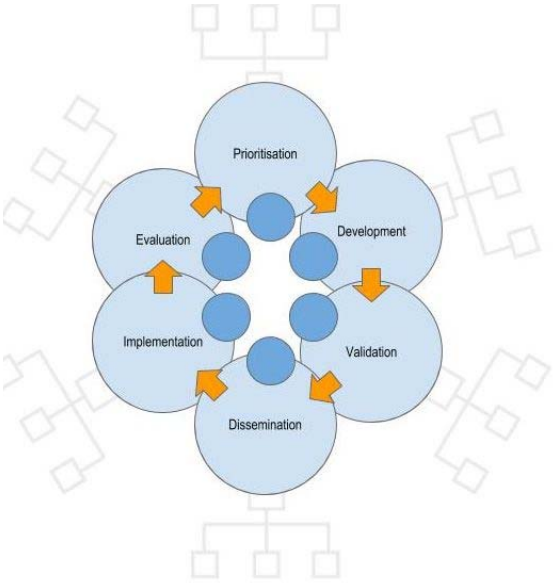
For further information on the background and the previous reports, see on the KCE website

Report 317: Towards an integrated plan for Evidence-Based Practice in Belgium – Part 3

The latest phase of developing the EBP network has involved drafting a Charter describing the missions and visions of the network, the type of collaborations and interactions between the various partners, and the role and responsibilities of each. This drafting process has involved all the actors and users of the future network (44 professional and patient organisations).

In parallel, each work cycle unit has drafted detailed descriptions of its processes, both internal (ongoing within the unit) and external (to be implemented between the various units). These procedures, processes and information flows have all been pooled so that the network becomes “self-learning”, with cogs turning completely transparently, in a coordinated way and based on common procedures. The other structures that are part of the network (Steering committee, Network coordination, etc.) have been configured and implemented.

However, the network will only be fully operational once its database has been supplemented with guidelines intended for the 10 professions mentioned, in other words, in addition to general practitioners who are already well provided for, pharmacists, nurses, midwives, physiotherapists, occupational therapists, speech therapists, podiatrists, dentists, and dieticians.



Activities of the Prioritisation Cell

Within the EBP network, KCE was given the task of selecting the subjects to be addressed by the network as a priority. Given that the health minister wanted the network’s initial activities to focus on implementing the existing guidelines, the selection was made from the guidelines published in Belgium in recent years. After initially selecting two subjects in 2018 (treating low back pain and radicular pain, and intermittent claudication), two other projects were prepared in 2019:

- implementing the clinical practice guide on chronic pain management
- implementing the clinical practice guide on chronic kidney failure.

The specification documents were drafted and the calls for tenders issued. The panels deliberated at the end of 2019 and the projects have now been awarded (partly).

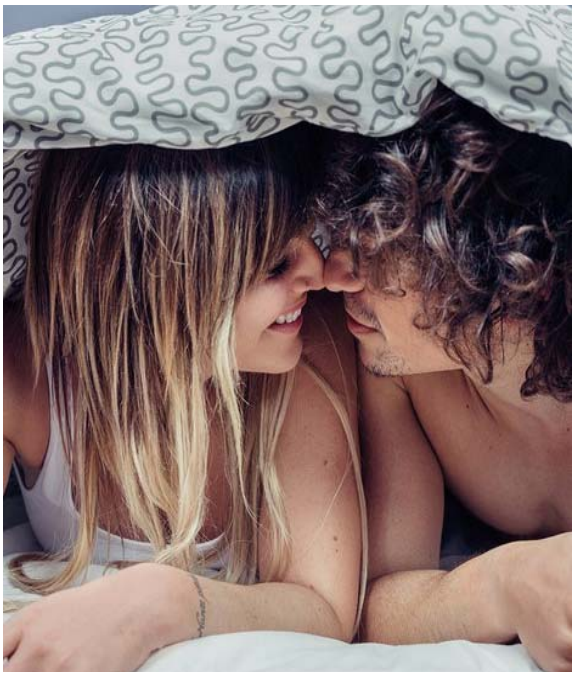
The prioritisation unit has also gathered the priorities for the public and scientific authorities for 2020-2021. It received 12 project proposals from professional, scientific and patient associations; several priority projects were recently selected by the federal steering committee and will be launched in 2020.

Report 310: Diagnosis and management of gonorrhoea and syphilis

Report 321: Online tool to assist healthcare practitioners with Sexually Transmitted Infections

Along with its involvement in the Belgian EBP network, KCE is continuing its mission to develop guidelines and/or tools for implementing guidelines. In 2019, a clinical practice guide for the diagnosis and management of gonorrhoea and syphilis was published, while our partner, the Belgian Working group "Development of Primary Care Guidelines", published a guideline on the diagnosis and management of chlamydia infections. The gonorrhoea-syphilis guideline is the ultimate primary care guideline that KCE will publish for use in primary care since this task will now be handled by the EBP network. KCE will, however, continue to develop guidelines for specialists. To implement the guidelines, we developed an interactive tool designed to support primary care – mainly general practitioners – in how to introduce testing for an STI during the consultation. The tool also indicates the correct management of an STI. This tool is based on the two sets of guidelines mentioned above, but also includes information to assist with diagnosis and to direct people diagnosed with HIV and Hepatitis A, B and C towards the appropriate specialists. It is available in French, Dutch, German and English.

Interactive tool: www.sti.kce.be/en

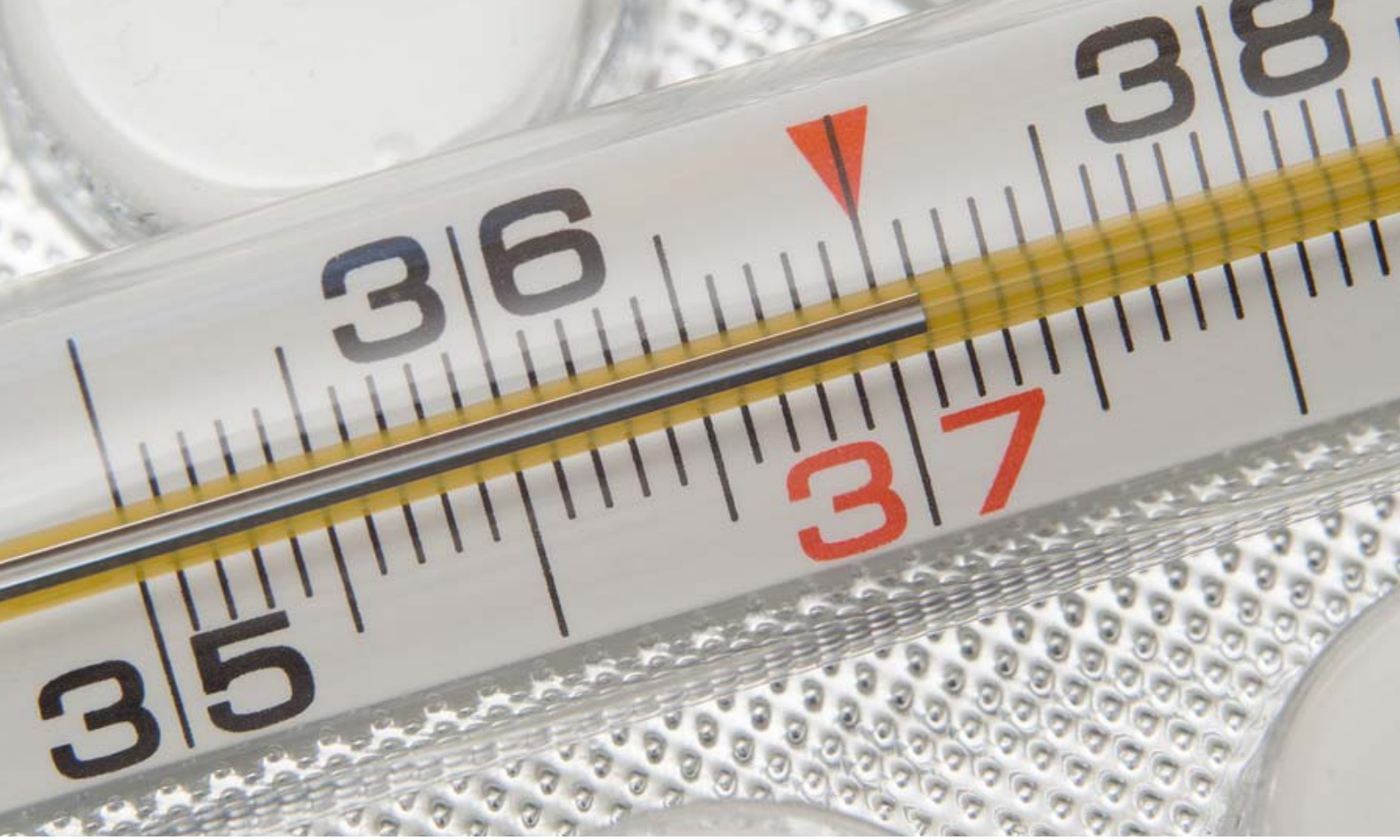


Report 324: Statins in primary prevention: an online tool for shared-decision making

In a previous report published in 2018, KCE revealed that a quarter of Belgians over the age of 40 take a statin-class drug to lower their cholesterol level. However, although the benefit of these drugs is clear for people who have already had cardio-vascular problems (heart attack, stroke), it is less clear for people who have never had such problems. Moreover, the side effects of these drugs can be significant. It is therefore necessary to weigh up the pros and cons, on a case-by-case basis, before prescribing them. To that end, we have developed an interactive tool allowing the visualisation of the comparative benefits and the risks of statins. This tool is aimed mainly at general practitioners to help them talk to their patients about whether they should take these drugs. As a matter of fact, the decision on whether to prescribe a statin or not should ideally be taken after a shared decision-making process between the doctor and the patient since it is for the patient him/herself to define what he/she considers to be an acceptable balance between the advantages and disadvantages of this treatment.

Interactive tool: www.statines.kce.be (available in French, Dutch or German)

Our website devotes a specific page to all the medical consultation support tools published by KCE.



Performance of the health care system

All European countries in the World Health Organisation (WHO) have pledged to carry out regular check-ups on the performance of their healthcare systems. The approach is referred to as the Health System Performance Assessment.

This check-up consists of a series of measurable indicators which, together, offer a comprehensive, transparent and responsible view of the performance of a health system, meaning that its progress can be monitored over time. This process allows the authorities in the various countries to plan their health strategy, establish comparisons between countries and set targets to be met. The final objective is to be able to offer the population a high quality health system at an affordable cost.

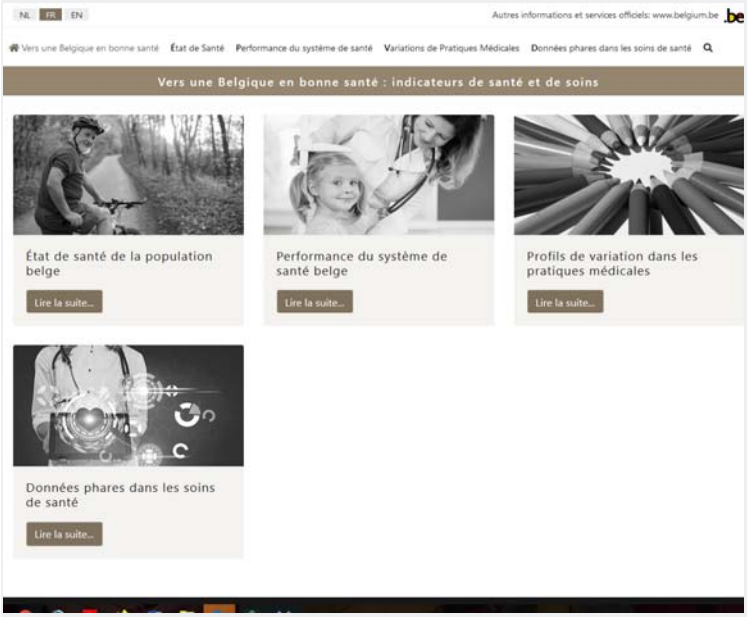
KCE is responsible for this for Belgium, in collaboration with Sciensano, the NIDHI (National Institute for Health and Disability Insurance) and the Federal Public Service for Health. Their "Performance of the Belgian health system" report is published every four years.

Report 313: Performance of the Belgian healthcare system – 2019

The fourth edition of the Belgian Performance Report was published in 2019. It analyses our health system according to five dimensions: accessibility, quality, efficiency, sustainability and equity of care. In addition, five specific care topics have been examined: preventive care, mental health care, care for the elderly, end-of-life care, and care for mothers and newborns. The result is a dashboard containing 121 indicators.

The report highlights the strengths and weaknesses using “green lights” and “red lights”. In 2019, for example, green lights were used for the 5-year survival rate after colorectal cancer, neonatal mortality, and the use of low cost medications. Red lights alerted us to the overconsumption of antibiotics, the decrease in influenza vaccination coverage among the elderly, and the turnover forecasts in general medicine.

A new website: healthybelgium.be



The NIDHI, the Federal Public Service for Health, Sciensano and the KCE are four major institutions in the Belgian health and healthcare landscape. Each of these institutions produces data or indicators that are invaluable to anyone interested in the population’s state of health and the functioning of the healthcare system. For this reason, they have joined forces to create a common website that offers all citizens an evolving overview of the health and care indicators for Belgium: healthybelgium.be/ belgiqueenbonnesante.be/gezondbelgie.be

This site currently has four sections:

- a section on the state of health of the Belgian population (Health Status Report), written by Sciensano;
- a section presenting the report on the performance of the Belgian health system, written by the KCE;
- a section on the variation patterns in medical practices, written by the NIDHI;
- a section on the key healthcare data, written by the Federal Public Service for Health.

This website will be updated regularly by the four partners. This means that anyone will be able to obtain first-hand information on the progress of a range of parameters, and even download the relevant data based on dynamic graphs. A mine of information for public health researchers, policy-makers, journalists, students and anyone interested in the subject.

Insurance law

The Insurance Law of 4 April 2014 created an Office for the monitoring of insurance rates, whose mission is to examine premium surcharge proposals or cases where payment protection insurance is refused for people who have been treated for serious illnesses. The same law stated that KCE was to be a scientific reference regarding the development of medical techniques and healthcare in the main diseases covered by this law. An initial report (Report 314) was published in 2019 in this context; it concerns people with diabetes.

Report 314: Life expectancy of individuals with type 1 diabetes (Rapid review)

The request at the origin of this study was to assess, on the basis of the international scientific literature, the risk of increased mortality and the life expectancy of patients with this disease.

It appears that these risks are very hard to estimate. The characteristics of the individual patients are extremely variable; it is therefore not possible to apply an average estimate to them based on a global population of people with type 1 diabetes. However, the data in the literature shows a positive trend towards improvement in the overall survival rate among these patients on account of the continuous improvement in the care and technologies implemented.

In conclusion, even though, overall, diabetes remains responsible for excess mortality, the latest scientific data indicates that patients who take an active role in managing their diabetes have a life expectancy that is similar to that of the general population.

KCE Trials programme

Since 2016, KCE has been responsible for managing a programme of non-commercial and practice-oriented clinical trials, "KCE Trials programme", similar to those existing in England and the Netherlands. These clinical trials address issues that are usually neglected by industry despite their high societal importance, such as comparing treatment options with each other (e.g. two surgical techniques) or studying the effect of existing drugs on populations that are rarely considered in commercial studies, such as children or the elderly. KCE focuses primarily on comparative effectiveness studies.

KCE is responsible for selecting, funding and following-up the trials but is not the sponsor. Each year, the KCE Trials programme issues a call for study proposals ("Call"). In 2019, the fourth Call attracted 14 study proposals, which are currently being evaluated. If you would like to be kept informed about the activities of KCE Trials including these Calls, you can register on the website.

KCE TRIALS

2265

patients recruited in

52

hospitals

12 932

patients recruited by

470

general practioners

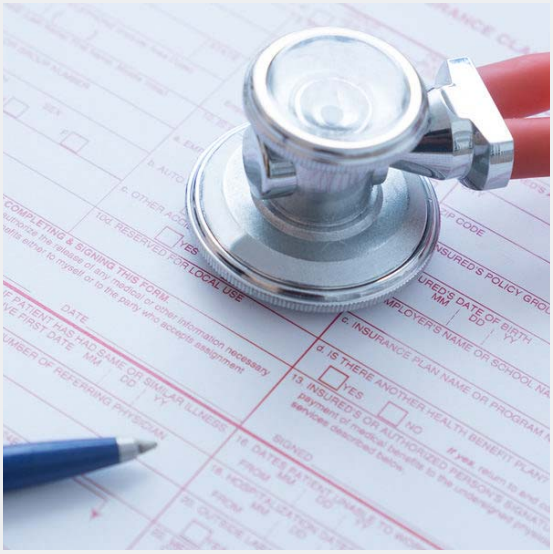
Median budget per trial

2

million euros

The KCE clinical trials are:

- **non-commercial**
- **results-oriented and focused on practice**: unlike commercial trials, these involve patients treated under real-life conditions
- **comparative**: they compare the efficacy of treatments which have already been used but which have never been directly compared to one another
- potentially able to lead to **cost savings for health insurance**
- **not limited to drugs or medical devices**: they can also involve medical devices, lifestyle modifications, diets, psychotherapies, diagnostic tests, surgical interventions, etc.
- guaranteed to generate **"public" databases**, that is, made available to public authorities to be able to conduct detailed and independent cost-effectiveness studies.



18 clinical trials are running at the end of 2019:

3 clinical trials are in the analysis phase of the results:

- Effect of evidence-based decision support for ordering laboratory tests in family practice (ELMO)
- Use of a silicone adhesive multilayer foam dressing as prevention for pressure ulcer development in hospitalised patients
- Vincristine-Induced Neuropathy in Children with Cancer (VINCA – international study)

11 clinical trials are ongoing:

- Diet Or Medication in Irritable bowel syndrome (DOMINO)
- COBRA-Slim with or without fast access to TNF blockade for remission induction in early rheumatoid arthritis (CareRA 2020)
- Diuretic effects of Acetazolamide (Diamox ®) in patients with Decompensated heart failure and Volume OveRload (ADVOR)
- Localized neuropathic pain: a study to compare topical treatment versus systemic treatment (PELICAN)
- Early treatment versus expectative management of patent ductus arteriosus in preterm infants (BeNeDuctus – international study)
- Blended Care Psychodynamic Therapy or Cognitive Behavioral Therapy versus Face-to-Face Psychotherapy for Depression (BLENDED)
-
- Effectiveness of a blended care program for the discontinuation of benzodiazepines use for sleeping problems in primary care (BIG BIRD)
- HYALOBARRIER® GEL ENDO versus no HYALOBARRIER® GEL ENDO following operative hysteroscopy for improving reproductive outcome in women with intrauterine pathology wishing to become pregnant (AGNOHSTIC)
- Metformin as RenoProtector in Non-Diabetic Patients with Progressive Chronic Kidney Disease (RenoMet)
- OptiMEDs intervention for multidisciplinary medication review in nursing homes to evaluate the appropriateness of prescribing – a pilot study (OptiMEDs)
- Continuous beta-lactam infusion compared with intermittent beta-lactam dosing in critically ill patients – phase III study (BLING III)

4 clinical studies are ready to start recruitment in 2020:

- Dose reduction of the new generation biologics (IL17 and IL23 inhibitors) in psoriasis (BeNeBio – BeNeFIT)
- Bronchodilators for wheeze in young children presenting to primary care (KIWI – BeNeFIT)
- Randomized Evaluation of Surgery in Elderly with Traumatic Acute SubDural Hematoma (RESET – BeNeFIT)
- Evaluation of a treatment based on near-infrared spectroscopy monitoring versus treatment as usual in premature infants (SAFEBOOSC III)

Some of these studies (VINCA, BeNeDuctus, BLING III and SafeBoosc) are carried out within the framework of international multi-centre collaborations. In these cases, a Belgian hospital takes over the coordination of the research for the whole of Belgium and acts as the single point of contact for the project at the international level. Three other studies are carried out within the framework of the BeNeFIT project (see below).

The 52 participating Belgian hospitals; the size of their name is proportional to the number of KCE Trials run in the hospital.

BeNeFIT

KCE is co-financing certain trials with its Dutch counterpart ZonMw within the scope of a joint appeal called BeNeFIT (Belgium-Netherlands Funding of International Trials). Numerous issues relating to healthcare are in fact relevant for both countries; the development of joint selection processes and exchanges of good procedures between researchers helps strengthen the expertise of both teams and obtain results more quickly. Five BeNeFIT studies are currently ongoing and will start recruiting patients in the two countries in 2020.

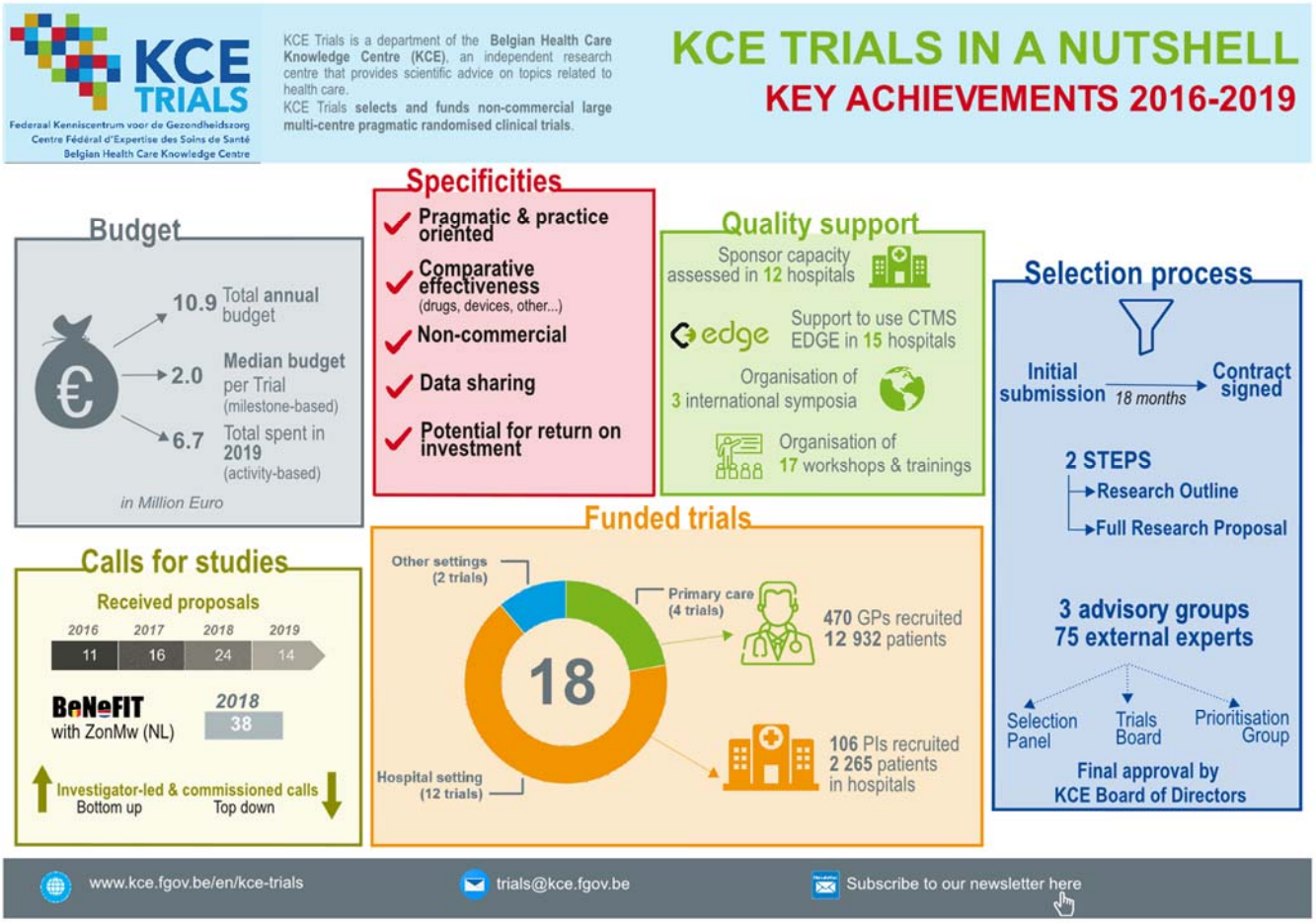
Raising the overall quality of clinical research in our country

KCE Trials also supports Belgian clinicians in the conduct of large-scale pragmatic clinical trials. After performing a GAP assessment in the Clinical Trials Units (Clinical Research Units) of the main Belgian hospitals, the KCE Trials team organises training courses for Clinical Trials Units and Investigators several times a year. In 2019, these workshops focused on the development of data management plans, the responsibilities of the study sponsors according to Good Clinical Practice and the implementation of quality audits in the research units. Over the years, the KCE Trials team has also developed and optimised a tool to estimate the budget of a pragmatic multi-centre randomised clinical trial. The use of this "budget tool" ensures that all clinical studies in the programme are funded in the same way. The tool has been published in open-access in the journal 'Trials'.

KCE Trials is also continuing to roll out EDGE online software, which enables real-time monitoring of patient recruitment in all ongoing hospital trials. It is now being used in the Clinical Trials Units of 15 Belgian hospitals and is being implemented in the remaining hospitals, significantly improving the day-to-day management of the KCE Trials programme. In 2019, KCE Trials also started to publish dynamic dashboards on its website to enable everyone to track patient recruitment in KCE Trials (in hospitals) almost in real-time. In November 2019, the third international symposium of the KCE Trials programme was held. It brought together a large number of participants representing all stakeholders to discuss "Hot Topics in Clinical Trials": Developing Research Agendas, New Methods in Trials and Data Sharing, and to meet with colleagues and collaborators interested in publically funded pragmatic trials.

Actively involving patients

Since the start of the KCE Trials programme, major emphasis has been placed on patients' point of view. Their representatives are involved in the selection of study subjects and also in the follow-up of the trials: they are indeed best able to judge the feasibility of a study or the relevance of its results. Thus, for example, for studies such as BIG BIRD (support for stopping benzodiazepines) or BLENDED (treatment for depression using online tools), numerous patients have participated in the thinking regarding the design of the research, questionnaires, and electronic tools which are to be tested. They helped introduce improvements to the structure of the tools themselves as well as to the language used and to the communication with future study participants.


KCE TRIALS
Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre
KCE Trials is a department of the Belgian Health Care Knowledge Centre (KCE), an independent research centre that provides scientific advice on topics related to health care.
KCE Trials selects and funds non-commercial large multi-centre pragmatic randomised clinical trials.
KCE TRIALS IN A NUTSHELL
KEY ACHIEVEMENTS 2016-2019
Budget
10.9 Total annual budget
2.0 Median budget per Trial (milestone-based)
6.7 Total spent in 2019 (activity-based)
in Million Euro
Specificities
Pragmatic & practice oriented
Comparative effectiveness (drugs, devices, other...)
Non-commercial
Data sharing
Potential for return on investment
Quality support
Sponsor capacity assessed in 12 hospitals
Support to use CTMS EDGE in 15 hospitals
Organisation of 3 international symposia
Organisation of 17 workshops & trainings
Selection process
Initial submission
18 months
Contract signed
2 STEPS
Research Outline
Full Research Proposal
3 advisory groups
75 external experts
Selection Panel
Trials Board
Prioritisation Group
Final approval by KCE Board of Directors
Calls for studies
Received proposals
2016 2017 2018 2019
11 16 24 14
BeNeFIT with ZonMw (NL)
2018
38
Investigator-led & commissioned calls
Bottom up
Top down
Funded trials
Other settings (2 trials)
Primary care (4 trials)
470 GPs recruited
12 932 patients
18
106 PIs recruited
2 265 patients
in hospitals
Hospital setting (12 trials)
www.kce.fgov.be/en/kce-trials
trials@kce.fgov.be
Subscribe to our newsletter here

@KCETrials

Financial statements 2019

BALANCE

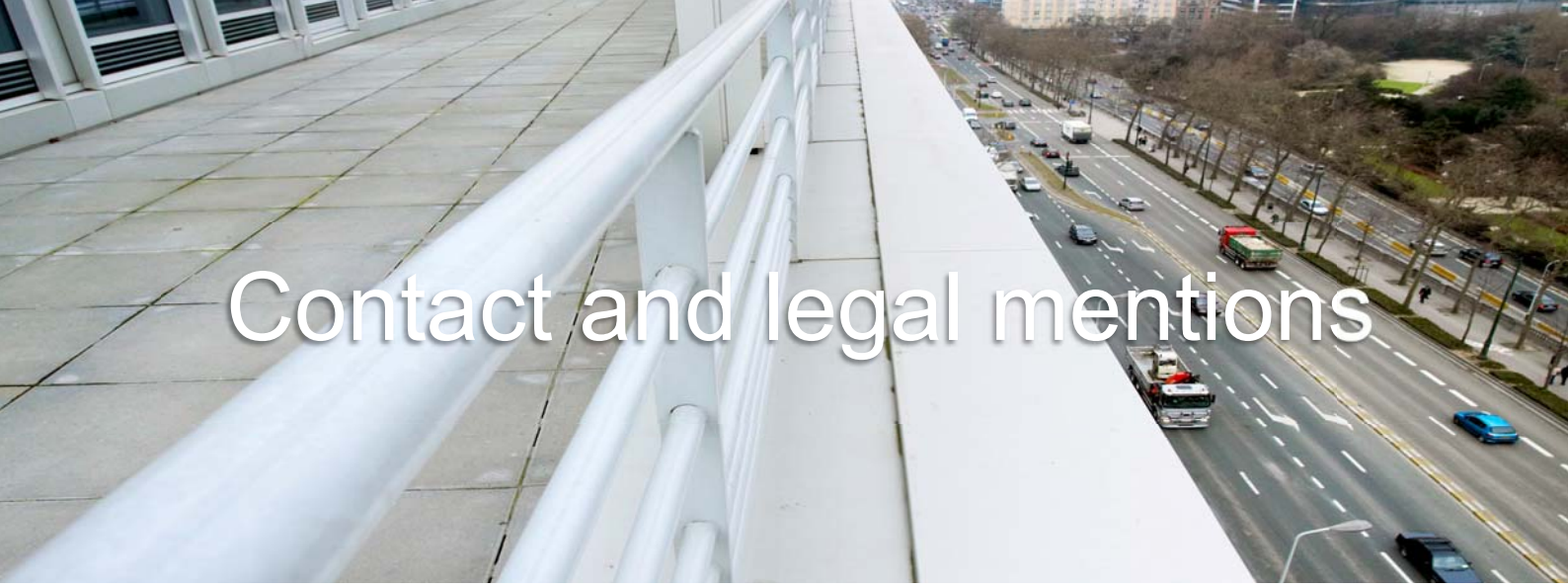
Part 1 ASSETS	31/12/2019	31/12/2018
FIXED ASSETS	**131,462.14**	**145 920.53**
I. Formation expenses		
II. Intangible fixed assets	**18,605**	**70 774,00**
III. Tangible fixed assets	**104,254**	**73 605,03**
A. Land and buildings	32,176	
B. Plant, machinery and equipment	46,294	57 242,14
C. Furniture and vehicles	25,785	16 362,89
D. Leasing and similar rights		
E. other tangible fixed assets		
F. Assets under construction and advance payments		
IV. Financial fixed assets	**8,603**	**1 541,50**
CURRENT ASSETS	**14,341,219.32**	**18 277 944,96**
V. Amounts receivable after more than one year	**1588**	
A. Trade debtors		
B. Other amounts receiva	1588	
C. Claims from subsidies		
VI. Stocks		
VII. Amounts receivable within one year	**161,532**	**17 902 127,92**
A. Trade debtors		
B. Other amounts receivable	161,532	17 902 127,92
VIII. Current investments		
IX. Cash at bank and in hand	**14,062,101**	**353 276,20**
X. Deferred charges and accrued income	**115,998**	**22 540,84**
TOTAL ASSETS	**14,472,681**	**18 423 865,49**

Part 2 LIABILITIES	31/12/2019	31/12/2018
EQUITY	**6,234,630**	**6 214 945,29**
I. Capital		
III. Revaluation surpluses		
V. Accumulated profits (losses)	**6,234,630**	**6 214 945,29**
VI. Investment grants		
PROVISIONS AND DEFERRED TAXES		
VII. Provisions for liabilities and charges		
A. Pensions and similar obligations		
B. Taxes		
C. Major repairs and maintenance		
D. Other liabilities and charges		
AMOUNTS PAYABLE	**8,238,051.00**	**12 208 920,20**
VIII. Amounts payable after more than one year		**0,00**
A. Financial debts		
1. Credit institutions, leasing and other similar obligations		
2. Other loans		
B. Trade debt		
C. Advanced received on contracts in progress		
D. Bails received in cash		
E. Other amouts payable		
IX. Amounts payable within one year	**8,237,611.00**	**12 208 920,20**
A. Current portion of amounts payable after more than one year falling due within one year		
B. Financial debts		
1. Credit institutions		
2. Other loans		
C. Trade debts	1,662,879.98	**2 107 262,14**
D. Advanced received on contracts in progress	22,265.00	**22 265,00**
E. Taxes, renumerations and social security		
1. Taxes	1,077,021.46	**1 062 659,21**
2. Renumerations and social security	5,475,444.56	**9 016 733,85**
F. Other amounts payable		
X. Deferred charges and accrued income	**440**	
TOTAL LIABILITIES	**14,472,681**	**18 423 865,49**

PROFIT AND LOSS ACCOUNT

RESULTAAT	31/12/2019	31/12/2018
I. Operating income I. Operating income I. Operating income	**20,760,058**	**20 196 476,02**
A. Turnover		
B. Stocks: increase (decrease)		
C. Own construction capitalized		
D. Intern billing		
E. Other operating income	**20,760,058**	**20 196 476,02**
II. Operating charges	**15,279,116**	**14 959 320,52**
A. Purchases and stocks		
B. Services and other goods B. Services and other goods	7,110,017	**7 287 817,51**
C. Renumerations, social security costs and pension	8,042,531	**7 478 981,42**
D. Depreciation of and other amounts written down formation expenses, intangible and tangible fixed assets	126,568	**192 521,59**
E. Amounts written down stocks, contracts in progress and trade debtors: appropriations (write-backs)		
F. Provisions for risks and charges		
G. Other operating charges		
H. Operating charges carried to assets as restructuring costs		
III. Operating profit (loss)	**5,480,942**	**5 237 155,50**
IV. Financial income	**0,00**	**0,00**
A. Income from financial fixed assets		
B. Income from current assets		
C. Other financial income		
V. Financial charges	**222**	**0,58**
A. Debt charges		
B. Amounts written down on current assets except stocks, contracts in progress and trade debtors		
C. Other financial products	**222**	**0,58**
VI. Profit (losses) on ordinary activities before taxes	**5,480,720**	**5 237 154,92**

VII. Extraordinary income	**15.304**	**0,00**
A. write-back of depreciation and of amounts written down intangible and tangible fixed as		
B. Write-back of amounts written down financial fixed assets		
C. Write-back of provisions for extraordinary liabilities and charges		
D. Gains and disposal of fixed assets	15.304	
E. Other extraordinary income		
VIII. Extraordinary charges	**5,476,340**	**5 278 544,61**
A. Extraordinary depriciation of and extraordinary amounts written down formation expenses, intangible and– tangible fixed assets		
B. Amounts written down financial fixed assets		
C. Provisions for extraordinary liabilities and charges		
D. Losses on disposal of fixed assets	**895**	
E. Other extraordinary charges	**5,476,340**	**5 278 544,61**
F. Extraordinary charges carried to assets as restructuring costs		
IX. Gain (loss) of the period	**19,684**	**-41 389,69**
A. Profit to be appropriated (+)		
Loss to be appropriated (-)		
1. Gain to be appropriated (+)		
Loss to be appropriated (-)		
2. Profit (loss) brought forward		
a. Profit brought forward		
Loss brought forward (+)		
b. Accumulated deficit from the previous year (-)		
D. Profit (loss) to be carried forward		
1. Profit to be carried forward (+)		
2. Loss to be carried forward (-)		



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