Benchmarks voor lage rugpijn in de huisartsenpraktijk: elektronische AUDIT van INTEGO

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1 Abstract

1.1 Nederlands

Achtergrond. Lage rugpijn (LRP) is één van de meest frequente aanmeldingsklachten in de huisartsenpraktijk. Resultaten uit de literatuur tonen echter een lage adherentie met bestaande behandelingsrichtlijnen. Audit en feedback is een frequent gebruikte strategie om zorg te sturen naar een op evidentie gebaseerde aanpak. Benchmarking is een belangrijke stap in het audit & feedback proces. Het doel van deze studie was om data-gestuurde benchmarks te bepalen voor LRP-kwaliteitsindicatoren.

Methode. Vier elektronisch-medisch dossier extraheerbare kwaliteitsindicatoren werden geselecteerd door middel van en gemodificeerde Delphi procedure door CEBAM, een onafhankelijk, multidisciplinair en interuniversitair medisch wetenschappelijk instituut in België. Data van 2021-2022 van INTEGO, een huisartsgeneeskundig registratienetwerk, werd gebruikt als *data sample* om de benchmarks te berekenen. De benchmarks werden berekend door middel van de Achievable Benchmark of Care methode waarbij de benchmark gedefinieerd werd als de gemiddelde performante van de 10% best presterende praktijken.

Resultaten. Volgende benchmarks werden bepaald: 4.20% voorschrift voor medische beeldvorming, 15.1% voorschrift voor opioïden versus niet-steroïdale anti-inflammatoire middelen, paracetamol of opioïden, 37.7% voorschrift voor kinesitherapie en 11.9% voorschrift voor arbeidsongeschiktheid.

Conclusie. Benchmarks voor vier elektronisch medisch dossier-extraheerbare kwaliteitsindicatoren werden bepaald. Ze kunnen worden gebruikt voor het ontwikkelen van een elektronische audit & feedback tool voor huisartsenpraktijken in Vlaanderen of andere kwaliteitverbeterprojecten.

1.2 Engels

Benchmarks for quality of care for low back pain in general practice in Flanders: electronic audit of INTEGO

Background. Low back pain (LBP) is one of the most frequent reasons for encounter in general practice. Yet results from literature show adherence to clinical practice guidelines is low. Audit & feedback is a well-known strategy to improve adherence to guidelines. Benchmarking is an important step in the audit & feedback process. The objective of this study was to develop data-derived benchmarks for low back pain quality indicators.

Methods. Four electronic health record extractable quality indicators were selected using a modified Delphi method by CEBAM, an independent, multidisciplinary and interuniversity medical scientific institute in Belgium. Data from 2021-2022 from INTEGO, a general practice morbidity registry, were used to calculate benchmarks for the four quality indicators. The Achievable Benchmark of Care methodology was used to create benchmarks based on the performance of the 10 % best-performing practices.

Results. The following benchmarks were derived: 4.20% prescription for medical imaging, 15.1% prescription for opioids versus for non-steroidal anti-inflammatory drugs, acetaminophen or opioids, 37.7% prescription for physical therapy and 11.9% prescription for work absenteeism.

Conclusions. Benchmarks for four electronic health record-extractable quality indicators have been established. They can be used for an electronic audit & feedback tool in primary practice in Flanders or other quality improvement initiatives.

2 Background

Low back pain (LBP) is one of the most frequent reasons for encounter in general practice. The mean prevalence is estimated to be 18.3%, and one-month prevalence 30.8% [1]. It's also the leading cause of years lived with disability worldwide (7.4% of years lived with disability) [2]. LBP can be caused by a specific pathology such as infection, tumour, osteoporosis, lumbar spine fracture, structural deformity, inflammatory disorder, radicular syndrome, or cauda equina syndrome; but most cases of LBP are non-specific low back pain (NSLBP) [3–5]. NSLBP is in most cases a self-limiting disease and most patients improve regardless of treatment [6]. Thus, clinical practice guidelines recommend avoiding routine imaging and other diagnostic tests, and recommend nonpharmacological treatment as the first choice [4,6,7]. Yet one quarter of patients who present with LBP in primary care are referred for imaging [8], and many patients receive a prescription for analgesics (48% in the UK and 61% in Australia) [9–11]. This shows that there is still a long way to go before these clinical practice guidelines will be achieved in actual practice.

Audit and feedback (A&F) is frequently used as a strategy to improve professional practice. A Cochrane systematic review defined A&F as "summary of clinical performance over a specified period of time." [12] Systematic reviews of the topic showed that it can effectively improve quality of care [12,13]. A&F is most effective when baseline performance is low, when provided by a supervisor and when it is provided continuously [12]. Manual A&F however can be time-consuming and costly. The evolution in electronic health records (EHRs) with EHR-extractable quality indicators allows for this auditing process to be automated and implemented on large scale. This can make electronic A&F (eA&F) a cost-effective alternative to manual A&F [14–16]. A similar initiative has already been developed for diabetes care in Belgium where each practice receives an automated report on a regular base for some EHR-extractable quality indicators for diabetes care (the "diabetes barometer") [17].

An important step in providing the feedback is to set a standard of care ("benchmark") [18]. Setting a benchmark is important as it sets a goal for quality improvement. It allows for

reporting and comparison between countries. The Achievable Benchmarks of Care (ABC™) approach is a benchmarking method that sets "real world" goals. It defines "top performance" using the 'pared mean', defined as the average performance of the subset of those providers with the highest scores for the indicator under consideration. The subset includes the top-ranked providers down to the point whereby at least 10% of the patient pool across all providers is selected [19]. The use of achievable benchmarks has been shown to be effective [20–22].

The aim was to develop data-derived benchmarks for low back pain quality indicators that can be used in an electronic audit & feedback tool for low back pain in primary care practice in Flanders. The benchmarks may also be used for reporting and quality improvement in patients with low back pain in other countries since benchmarks, and especially achievable benchmarks are an important tool for quality improvement.

3 Methods

3.1 Data source

INTEGO, a general practice morbidity registry in Flanders (Belgium), consists of a large pool of patient data, that are systematically collected from electronic healthcare systems of general practitioners and corresponds to more than 6.23% of the Flemish population in 2022. The data were pseudonymized and followed national privacy legislation [23]. The overall project was approved by the Research Ethics Committee UZ/KU Leuven (MP018709). Patient characteristics and individual consultation data were collected. Some data is further encoded such as diagnosis in International Classification of Primary Care - 2nd edition (ICPC-2) [24], medication in Anatomical Therapeutic Chemical Classification (ATC) code [25], specifics about prescriptions for medical imaging, absence and physical therapy [23].

3.2 Data sample

Patients aged eighteen years or older with a global medical record (GMR) in the practice and with LBP were identified. LBP was defined as at least one consultation with the ICPC-2

diagnostic codes: L02, L03, L84 or L86. Data for 2021 and 2022 were extracted from INTEGO. Only practices that contributed more than ten cases of LBP were included in the analysis. Practices with a zero value for two or more indicators were excluded for all indicators because this may indicate the data is not valid.

3.3 Low back pain quality indicators

Based upon existing indicator sets (National Institute for Health and Care Excellence [NICE], Institut für Qualitätssicherung und Transparenz im Gesundheitswesen [IQTIG], Nederlands Huisartsen Genootschap (NHG), Healthcare Effectiveness Data and Information Set [HEDIS] and International Consortium for Health Outcomes Measurement [ICHOM] guidelines) using a modified Delphi method Belgian Centre for Evidence-Based Medicine (CEBAM), an independent, multidisciplinary and interuniversity medical scientific institute [26] and Federaal Kenniscentrum voor de Gezondheidszorg (KCE) defined a list of quality indicators for low back pain. Table 1 lists the four quality indicators that can be evaluated in EHR among the nine quality indicators that were withheld [27]. For the second quality indicator "Proportion of adults with low back pain and a prescription for opioids versus adults with low back pain with a prescription for non-steroidal anti-inflammatory drugs or acetaminophen" we slightly had to alter the definition for practical reasons. The original definition allowed for zero-values in the denominator which can result in calculation problems. So, we redefined it to "Proportion of adults with low back pain and a prescription for opioids versus adults with low back pain with a prescription for non-steroidal anti-inflammatory drugs, acetaminophen or opioids."

Indicator	**Type of indicator**
1. Proportion of adults with low back pain where imaging is requested	process
2. Original definition: Proportion of adults with low back pain and a prescription for opioids versus adults with low back pain with a prescription for non-steroidal anti-inflammatory drugs or acetaminophen	process

Altered definition: Proportion of adults with low back pain and a prescription for opioids versus adults with low back pain with a prescription for non-steroidal anti-inflammatory drugs, acetaminophen or opioids	
3. Proportion of adults with low back pain with a physical therapy prescription or with "back school" prescriptions	process
4. Proportion of adults with low back pain on medical leave	process

Table 1 Electronic medical record extractable quality of care indicators for low back pain

Quality of care indicators for low back pain that are extractable from electronic medical record in Flanders. Filtered from the initial set of indicators as defined by CEBAM in 2021 using a modified Deplhi method using existing indicator sets **[27]**.

3.4 Statistical analysis

A script was developed in the programming language R to automatize the data analysis process. The INTEGO database was filtered to select consultations for LBP. Each consultation received a PASS or FAIL score for each of the quality indicators. Figure 1 shows more in detail how the INTEGO database was filtered, and which criteria were used to evaluate each of the quality indicators. Consultations were then grouped per patient because it was impossible to evaluate whether different consultations were part of the same episode of LBP. If patients had multiple consultations for LBP the best score for each quality indicator was used. The data were pooled for each practice and a score for each quality indicator per practice was calculated by counting the number of patients that had a PASS value divided by the total number of patients with the diagnosis LBP in the practice.

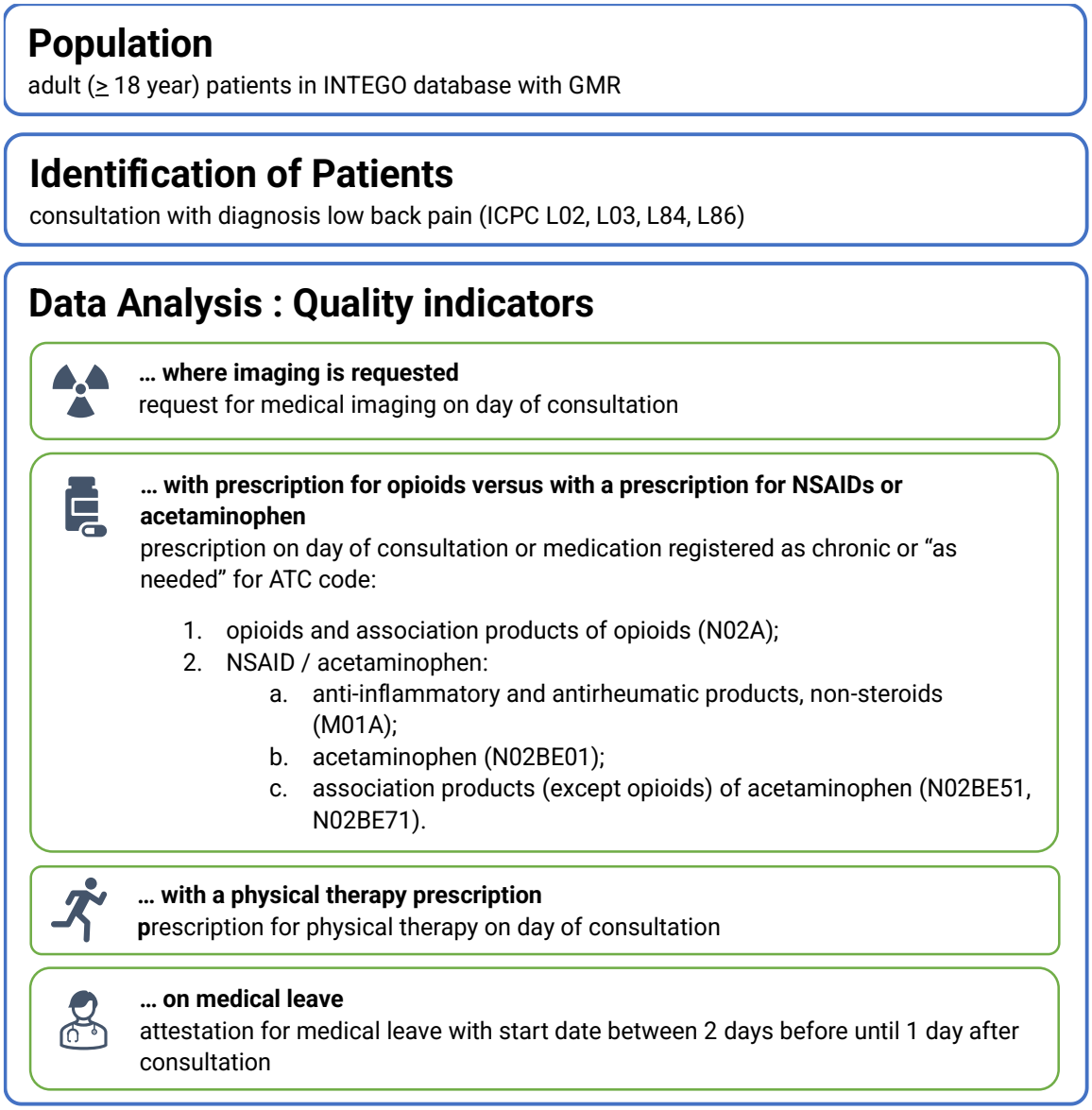


Figure 1 Summary of the R script developed for the INTEGO database

Summary of the R script developed for the INTEGO database with specifics about how the quality indicators were calculated.

NSAIDs: non-steroidal anti-inflammatory drugs; ICPC-2: International Classification of Primary Care - 2nd edition; ATC: Anatomical Therapeutic Chemical Classification

The data was then further analysed in IBM SPSS Statistics (Version 29). The normality of the distribution was evaluated using the Kolmogorov-Smirnov test, QQ-plot, skewness and histogram. The ABC™ methodology was used to calculate benchmarks for the four quality indicators. The overall indicator performance was assessed using Kiefe et al.'s algorithm to determine the minimum sufficient denominator (MSD) (i.e. eligible patients). If needed a

Bayesian adjustment was used to calculate the practice's adjusted performance fraction [19,21,28]. The benchmark was calculated as the mean of the practices in the 10th upper percentile of performance. This was used as an alternative to Weissman's original definition of the ABC™ benchmark because it is easier to implement for continuous feedback and because the benchmark did not significantly differ from the original method of calculation ($p > 0.05$ for Independent Samples Student t-test and Levene's Test for Equality of Variances). For each of the quality indicators is reported (1) the mean, standard deviation (SD) and 95% confidence interval (95% CIs), (2) the ABC™ benchmark and the amount of practices at or above the benchmark, (3) descriptive statistics (N, median, range, 10^{th}, 25^{th}, 75^{th} and 90^{th} percentile of the practices included in the benchmark calculation and (4) the practices in the audit with patient samples below the MSD.

4 Results

The INTEGO database included 132 practices for 2021 and 2022. Nine practices were excluded from further analysis because of incomplete data in the INTEGO database (ex. no coded diagnosis for LBP, incomplete consultation data…). Any practice with less than 10 patients with LBP or with two or more indicators without data (zero-values) was excluded (15 practices). Table 2 describes the characteristics of the patients included in the INTEGO low back pain audit from 2021-2022. The total GMR population was 318,744 GMR patients for the 108 practices. The prevalence of LBP was 144.1 patients / 1,000 GMR patients (n = 45,938). There was a slight overweight of female patients (54.5%).

There was a wide range of performances for all four quality indicators. The overall performance for prescription for physical therapy was 19.5% (SD 1.08; 95% CI 16.3 to 21.6). The performance for quality indicators where the target value is zero percent ranged from 28.7% for prescription for opioids (SD 0.69; 95% CI 27.3 to 30.0), 23.2% for medical leave (SD 0.66; 95% CI 22.9 to 24.5) to 16.0% for prescription for imaging (SD 0.73; 95% CI 14.5 to 17.4). Using the MSD a Bayesian adjustment was applied to the performance factor for three

practices for prescription for imaging and for two practices for prescription for physical therapy.

The target benchmarks using the ABC™ methodology ordered from highest target to lowest are 4.20% for prescription for medical imaging, 11.9% for prescription for medical leave, 15.1% for prescription for opioids, and 37.7% for prescription for physical therapy. Only approximately 5 to 10% of all the practices reached the ABC™ benchmark indicating that the gap between the overall performance and the benchmark target was large (Table 3). The included number of practices for each calculation was 11 practices. The number of patients included in the benchmark calculation (eligible patients) per practice varies strongly (range 13 to 464 patients). Only for prescriptions for physical therapy some bigger practices were included (range 44-1542) (Table 4).

We should note that only 64.9% of patients with LBP received a prescription for opioids, NSAIDs or acetaminophen (SD 1.44; 95% CI 62.0 to 67.7). The number of patients receiving analgesics was also significantly lower in the benchmark group compared to the overall performance (two-sided independent Student t-test $p < 0.05$) with a mean of 53.4% (SD 3.87; 95% CI 44.8 to 62.05) in the benchmark group compared to a mean of 66.1% (SD 1.15; 95% CI 63.2 to 69.1).

Characteristic	**N (%)**
Patients consulting with LBP	45,938 (144.12[a])
Patient sex	
Male	20,923 (45.5)
Female	25,011 (54.5)
Unknown	4 (0.00)
Age	
18-24	2,452 (5.3)
25-34	6,574 (14.3)

35-44	8,585 (18.7)
45-54	8,470 (18.4)
55-64	8,562 (18.6)
65-74	5,737 (12.5)
> 75	5,558 (12.1)

Table 2 Characteristics of patients and practices

Characteristics of practices included (N = 108) and patients (N = 318,744) in INTEGO low back pain audit 2021-2022. Nine practices were excluded because of incomplete data. 15 practices were excluded because they had less than 10 patients with LBP or because they had no patients for 2 or more benchmark scores.

LBP: low back pain

[a] *Prevalence (/ 1,000 GMR patients)*

Low back pain quality indicator	Overall performance			Benchmark	
	Mean (%)	SD (%)	95% CI (%)	ABC™ (%)	Number of practices at or above the ABC™ benchmark
1. Imaging	15.97	0.73	14.51-17.42	4.20	6
2. Opioids	28.68	0.69	27.32-30.04	15.13	5
3. Physical therapy	19.47	1.08	16.32-21.63	37.67	6
4. Medical leave	23.16	0.66	21.85-24.47	11.87	7

Table 3 Achievable Benchmark of Care in INTEGO low back pain audit 2021-2022

The ABC™ benchmark was calculated as the 10% best performing practices (N = 11). For each benchmark the amount of practices that reached the benchmark is reported of the total of 108 practices. The overall performance of the whole population is also reported as a mean and 95% confidence interval.

[a] *Eligible patients is the total number of patients with LBP receiving NSAIDs, acetaminophen or opioids*

LBP: low back pain; NSAIDs: non-steroidal anti-inflammatory drugs; 95% CI: 95% confidence interval; ABC™: Achievable Benchmark of Care; SD: Standard deviation

Descriptive	1. Imaging	2. Opioids	3. Physical therapy	4. Medical leave
N	1,991	1183	5,933	1,980
Range	23-455	13-333	44-1,542	16-464
10th percentile	23.4	13.8	56.2	18.2
25th percentile	27.0	20.0	178.0	44.0
Median	86	70	393	193
75th percentile	393.0	200.0	679.0	228.0
90th percentile	446.0	309.8	1532.4	451.0

Table 4 Distribution of Eligible Patient Volume per practice in INTEGO low back pain audit 2021-2022

Descriptive statistics of the Eligible Patient Volume. This is the volume of patients included in the ABC™ benchmark calculation.

5 Discussion

This study provides benchmarks using the ABC™ methodology for four low back pain quality indicators that can be measured in the EHR in Flanders. Adjustments were made for practices with small numbers of eligible patients. To allow replication of our work we included detailed indicator definitions. To assess precision of the benchmarks we reported the median and range of eligible patients within the practices included. These benchmarks are derived from a representative sample of patients presenting with low back pain in primary care in 108 general practices in Flanders representing a GMR population of more than 300,000 patients.

The four quality indicators we defined are key-messages in most guidelines [4–7,29]. The results on overall performance for these quality indicators in literature varies strongly because of difference in definition and method of analysis used [8,30–39]. This makes comparison to previous literature difficult. To our knowledge this study is the first to define benchmarks for LBP. We defined our benchmarks using existing indicator sets in other countries so it can be used in other countries to reproduce and compare results. This could allow for a more

223 international approach in the treatment for LBP and more targeted interventions as it would
224 help in evaluating region-based trends and evolutions in treatment of LBP.

225 Unfortunately, we could not extract data for 5 other quality indicators that were selected by
226 CEBAM because currently they are not extractable in the available Belgian EHRs for primary
227 care. And while the INTEGO database is under constant review for validity of data, quality
228 indicators extracted from EHRs are prone to error since they may leave error for context and
229 not-encoded data compared to manual A&F [14–16]. As such, we had to exclude 15 practices
230 because they failed to report data for 2 or more quality indicators indicating that there could
231 be a problem with the data extraction in those practices. For absenteeism we could also not
232 extract data for patients on disability benefit or patients with a special type of attestation
233 (government employer, self-employed, etc.). Moreover, our method also did not allow us to
234 link a specific quality indicator to the diagnosis of low back pain but rather to the same period
235 of consultation for low back pain. Patients could very well be receiving attestation for work, a
236 prescription for medical imaging or physical therapy for a different medical problem than low
237 back pain. Regarding prescriptions for medication, there is a law in Belgium that mandates
238 encoded prescribing (except for some specific cases) [40]. Most prescriptions for medication
239 should thus be encoded in the EHR, and these data should be least prone to error.

240 However, as our quality indicators are EHR-extractable in Belgium context, it allows for a cost-
241 effective, repeatable and easy scalable way of evaluating the quality of care for LBP locally (but
242 also regionally, nationally and maybe internationally) [14]. Because of the size of the data
243 sample (with only a few practices not reaching the MSD target) it also allows to calculate a
244 representative benchmark for each quality indicator. Many other benchmarking studies
245 struggle with a small sample size of patients [19,21,28]. The benchmarking target set for the
246 quality indicators is also an achievable one and prior studies using the ABC™ method shows
247 that it has higher improvement rates than those receiving feedback where median
248 performance was used [41]. Another advantage of the ABC™ method is that when all practices
249 improve and recalibration leads to higher standards, the goals will remain achievable [28].

Since we programmed a script for calculating our benchmarks, the process of recalibration and A&F could also be automated, thus allowing for continuous feedback.

6 Conclusions

Our study is one of the first to define benchmarks for low back pain in general practice based upon a sample of 108 Flemish practices. Although data extractability was one of the biggest challenges, we could include a large sample size of practices widely spread in Flanders. Transparency of the patient and practice sample size allow the credibility of the benchmarks to be assessed. The script developed for the benchmarking can be used to implement an electronic audit & feedback tool in primary practice in Flanders. The benchmarks may also be used for reporting and quality improvement in patients with low back pain in other countries since benchmarks, and especially achievable benchmarks are an important tool for quality improvement. Further research is needed to examine the benchmarks that are content derived or lack specificity.

7 Reflection

Voorbije jaren zijn zonder twijfel anders verlopen dan hoe ik het gepland had. Initieel startte ik deze thesis met Dr. Charlotte De Clercq met een totaal verschillend onderwerp: een kwaliteitsverbeterproject voor lage rugpijn in 2 groepspraktijken. Dit evolueerde naar de ontwikkeling van een elektronische AUDIT voor INTEGO en eindigde voor mij bij het benchmarken van 4 kwaliteitsindicatoren voor lage rugpijn. Het is hoe dan ook één van de mijn interesses en motivaties gebleven doorheen de voorbije jaren.

Dit ondanks een tumultueus verloop in mijn privé en professioneel leven. Het laatste vooral gestuurd door het eerste. Dit heeft mijn thesispartner een uitdagende situatie bezorgd en ik apprecieer dat ik steeds op haar begrip en respect heb kunnen rekenen. We deden samen onze literatuurstudie en voor Charlotte haar thesis ondersteunde ik haar in de datacollectie. In de mate van het mogelijke heb ik haar proberen blijven ondersteunen tijdens haar thesis, zelfs wanneer ik mijn eigen HAIO traject onderbroken heb. Toen ik mijn HAIO traject hervatte had zij reeds haar thesis afgewerkt. Mijn thesis kadert binnen hetzelfde domein van het onderwerp "benchmarking", maar vormt een volgende stap in het geheel.

Voor mij was mijn pauze een noodzakelijke onderbreking. Mijn privéleven was zo chaotisch geworden dat ik even een uitweg nodig had. Spijtig genoeg kreeg ik van de erkenningscommissie slechts een fractie van de tijd die ik nodig had en diende ik mijn traject te herbeginnen in volle chaos. Graag had ik deze thesis gemaakt in rustigere en stabielere omstandigheden, waardoor de impact op mijn thesispartner kleiner was geweest. Al ben ik heel tevreden met de nieuwe opportuniteiten die het mij opgeleverd heeft. Ik kijk er naar uit mijn werk verder te zetten binnen INTEGO, alsook de nieuwe opportuniteiten welke mij daar wachten. Ik zou dit traject niet kunnen doorlopen hebben zonder de steun van mijn promotor Prof. Dr. Bert Vaes en mijn praktijkopleider Dr. Siegfried Geens en ben hun dan ook heel dankbaar.

8 List of abbreviations

LBP: Low Back Pain

NSLBP: Non-Specific Low Back Pain

A&F: Audit and feedback

eA&F: electronic Audit and feedback

EHRs: Electronic Health Records

ABC™: Achievable Benchmarks of Care

NSAIDs: Non-Steroidal Anti-Inflammatory Drugs

ICPC-2: International Classification of Primary Care - 2nd edition

ATC: Anatomical Therapeutic Chemical Classification

NICE: National Institute for Health and Care Excellence

IQTIG: Institut für Qualitätssicherung und Transparenz im Gesundheitswesen

NHG: Nederlands Huisartsen Genootschap

HEDIS: Healthcare Effectiveness Data and Information Set

ICHOM: International Consortium for Health Outcomes Measurement

CEBAM: Belgian Centre for Evidence-Based Medicine

KCE: Federaal Kenniscentrum voor de Gezondheidszorg

MSD: Minimum Sufficient Denominator

95% CI: 95% confidence interval

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10 Appendix

10.1 OBC Protocol

GROEP BIOMEDISCHE WETENSCHAPPEN
Academisch Centrum voor
Huisartsgeneeskunde
HERESTRAAT 49, O&N II – BUS 700
BE-3000 LEUVEN

MASTERPAPER PROTOCOL: RETROSPECTIVE STUDY

1. APPLICANTS

*This application can be prepared in **Dutch** or in **English**. The blue text boxes with explanation can be deleted when submitting the application. See the website for examples and text suggestion for the various sections. (https://med.kuleuven.be/nl/obc/Documents_en)*

***Every resubmission or amendment** should be done in '**track changes' or in 'highlight'** in order to identify the changes. The file name must also be changed to 'resubmission_MP###_version#' or 'amendment_MP##_version#'. The MP-number can be found via SCONE (overview master thesis), the version number is up to you: starting at 1 and increasing by 1 each time you are asked to make new changes.*

Protocol - full title	Low back pain in general practice: design and evaluation of an automated clinical audit: Imaging, farmacotherapy and physical therapy
Version 1: Date submission	Date:Click here to enter a date.
Version 2: Date resubmission	(to add in case of resubmission) Date:Click here to enter a date.
Version 3: Date third submission	(to add in case of third submission) Date:Click here to enter a date.
Principal Investigator – Promoter	Name: Bert Vaes, MD, PhD
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	Telephone: +32 (0)16 37 72 78
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	Student number: 0901134
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	Name: Charlotte De Clercq, MD
	Student number: r0380440
	Telephone: +32 (0)496 38 94 44
	Email: csdeclercq@gmail.com

2. BACKGROUND AND RATIONALE

Oliveira et al. [1] define non-specific low back pain (LBP) as “low back pain not attributable to a known cause” [1]. 90-95 % of LBP cases are non-specific [1,2]. These cases of LBP generally don’t lead to absence from work and for those it does, three quarters of them return to work within 4 weeks. However a small part develop long-lasting LBP which leads to long-term absence from work [2,3]. Additionally LBP is the leading cause of years lived with disability [1]

An estimated 60 to 90 % of the Western population will experience at least one episode of low back pain (LBP) during their lifetime, of which 30 % has a second episode within the year [4–6]. In Flanders low back pain is part of the top 10 diseases that general practitioners diagnose each year (incidence 43,7 per 1,000 patients in 2015) [7].

An evidence-based approach to the management of LBP may decrease the amount of imaging requested and reduce the amount of prescriptions for physiotherapy, opioids and nonsteroidal anti-inflammatory drugs (NSAID) while resulting in the same outcome [8]. In Belgium the KCE, *Federaal kenniscentrum voor de gezondheidszorg*, implemented new guidelines for the management of LBP in 2019 aiming to improve the quality of care for LBP [3]. The adherence to these guidelines, and more generally the quality of care of the management of low back pain, in Flanders is however unknown.

Commonly, audit and feedback (A&F) is used to promote the implementation of evidence based medicine. Ivers et al.[9] define audit and feedback (A&F) as: “providing a recipient with a summary of their performance over a specified period of time.” Giving practitioners feedback on their current practice may improve adherence to evidence based medicine by self-assessment or self-monitoring [9]. However, the results of A&F are variable ranging from a relatively large, positive effect on quality of care (one-quarter) to a negative or null effect (one-quarter) [9,10]. In medicine we generally speak of a clinical audit, which is a continuous “quality loop” aiming to highlight the discrepancies between actual practice and standard of care. This “quality loop” consists of: choosing a topic, setting criteria and a standard of care, collecting data followed by data analysis and change implementation and, finally, checking for improvement and maintaining it [11,12]. The evolution in electronic medical records the past years allows for the opportunity to do these audits electronically which allows general practitioners (GP) to do these audits more time-efficiently and also make these results reproducible. This allows comparison of the results between GPs [9].

Currently no electronic clinical audits are available in Belgium to evaluate the management of low back pain in general practice. In this master dissertation we will aim to create an electronic clinical audit for the management of low back pain and check the validity of this clinical audit for use in daily practice. The clinical audit “quality loop” will be used in this process.

3. STUDY OBJECTIVES

Development of an electronic clinical AUDIT for the evaluation of low back pain in general practice in Flanders and evaluate the validity of this AUDIT. In total 4 quality indicators will be implemented in the AUDIT. These quality indicators were defined by CEBAM, the Belgian Centrum for Evidence-Based Medicine (https://www.cebam.be/). These quality indicators are:

1. % of adults with low back pain where imaging is requested
2. % of adults with low back pain that get a prescription for opioids compared to the amount of adults with low back pain that get a prescription for non-steroidal anti-inflammatory drugs (NSAID)
3. % of adults with low back pain where revalidations is prescribed
4. Employment status of people with low back pain

4. RESEARCH METHOD

Present the methodologies and explain potential ethical implications of the planned methodologies.

Based upon the quality indicators defined earlier a protocol will be developed that allows data collection from the electronic medical record software CareConnect General Practitioner from Corilus using the Statistics module. However, we know that the Statistics module available in CareConnect has limitations. Therefore, this protocol will be further refined and custom programmed in CareConnect as a standardized electronic AUDIT to collect all information correctly. In a second step each included patient will be reviewed manually by one of the researchers using the same protocol to evaluate if the data collected by the electronical AUDIT is correct. All data will be collected by general practitioners in training who also work in the participating practice where the data is collected. No information on individual patients will be exported out of the EMD (for example date of birth, name, place of residence). Only aggregated data will be exported and reported for the participating practices. An ethical implication may be that this AUDIT will only be developed in CareConnect. However a general protocol will be developed, which can also be used by other EMD software developers to implement this clinical AUDIT. The performance of each GP practice will be compared to a benchmark in the literature. Since the population profile in private practices can influence the result further subgroup analysis will be done (age, gender…) to compensate for these differences in population.

5. DATA COLLECTION

Specify the source and method of the data to be collected / obtained and specify the time period that will be studied.
Note: As this concerns a retrospective study, the past will be examined using already rightfully collected data from files that are:
- medical files of the study participants

- other accessible data files/bases with collected personal data of the study participants, e.g. pharmaceutical files, vaccination data bases, RIZIV data bases, disease registers, …

The data will be collected in 2 general practitioner practices in Flanders, "Groepspraktijk Huisartsen Harelbeke" and "Huisartsenpraktijk Nieuwenhoven". The data is collected retrospectively using consultation reports between 01/10/2020 and 30/09/2021. Only aggregated data will be reported for the participating practices. No data on individual patients will leave the GP practice. Data analysis using individual patient data will be performed within the GP practice.

Contact information:

- Groepspraktijk Huisartsen Harelbeke, Kortrijksesteenweg 28, 8530 Harelbeke, Dr. Stijn Torbeyns, groepspraktijk.harelbeke@skynet.be, 056 71 54 41
- Huisartsenpraktijk Nieuwenhoven: Nieuwenhovenlaan 4, 1600 Sint-Pieters-Leeuw, Dr. Siegfried Geens, mail@siegfriedgeens.be, 02/377.51.78

6. ANALYSIS

Describe the measures taken to avoid, or at least minimize, biases. Give the number of participants to be enrolled, together with the rationale for the sample size. Describe also methods for data analysis.

The two datasets (electronic and manual AUDIT) in each practice will be further analysed using MathWorks MATLAB R2018a. The table below lists all collected data and the statistical analyses applied to the data. A significance level of 0.05 will be used. Before each test the requirements for the test will be checked. All variables are unpaired. Since this project is a pilot project no specific minimal sample size is defined, however the sample size should suffice for the necessary statistical analysis since 2 private practices will be evaluated with an estimated number of active global medical record patients of close to 5000 patients each.

Indicator
Demographic information • Gender • Age • Nationality
Medical background information • Comorbidities • Chronic medication

- Number of previous episodes of low back pain

Indicator 1: % of adults with low back pain where imaging is requested

- Imaging requested?
  Descriptive statistics
  Chi²-test with H_0: there is no difference between the amount of people that received imaging between the manual AUDIT and the electronic AUDIT population
  Two proportion Z-test with H_0: the amount of imaging requested in the manual AUDIT population (respectively electronic AUDIT population) is comparable to the benchmark found in literature.
- Type of imaging requested
  Descriptive statistics
  If Gaussian distribution criteria are met: unpaired parametric Student's t-test, otherwise Mann-Whitney U-test, with H_0: there is no difference between the type of imaging request between the manual AUDIT and the electronic AUDIT population
  Two proportion Z-test with H_0: the type of imaging requested in the manual AUDIT population (respectively electronic AUDIT population) is comparable to the benchmark found in literature.

Indicator 2: % of adults with low back pain that get a prescription for opioids compared to the amount of adults with low back pain that get a prescription for non-steroidal anti-inflammatory drugs (NSAID)

- Medication prescribed?
  Descriptive statistics
  Chi²-test with H_0: there is no difference between the amount of people that received a prescription for medication between the manual AUDIT and the electronic AUDIT population
  Two proportion Z-test with H_0: the frequency of medication prescribed in the manual AUDIT population (respectively electronic AUDIT population) is comparable to the benchmark found in literature.
- Which medication?
  Descriptive statistics
  If Gaussian distribution criteria are met: unpaired parametric Student's t-test, otherwise Mann-Whitney U-test, with H_0: there is no difference between the type of medication prescribed between the manual AUDIT and the electronic AUDIT population
  Two proportion Z-test with H_0: the amount of opioids (respectively NSAID) prescribed in the manual AUDIT population (respectively electronic AUDIT population) is comparable to the benchmark found in literature.

Indicator 3: % of adults with low back pain where physiotherapy is prescribed

- Revalidations prescribed?
  Descriptive statistics
  Chi²-test with H_0: there is no difference between the amount of people that received physiotherapy between the manual AUDIT and the electronic AUDIT population
  Two proportion Z-test with H_0: the frequency of the physiotherapy prescribed in the manual AUDIT population (respectively electronic AUDIT population) is comparable to the benchmark found in literature.
- Type of Revalidations: physical therapy vs group sessions in hospital
  Descriptive statistics
  If Gaussian distribution criteria are met: unpaired parametric Student's t-test, otherwise Mann-Whitney U-test, with H_0: there is no difference between the type of physiotherapy prescribed between the manual AUDIT and the electronic AUDIT population
  Two proportion Z-test with H_0: the amount of physiotherapy prescriptions in the manual AUDIT population (respectively electronic AUDIT population) is comparable to the benchmark found in literature.

Indicator 4: Employment status of people with low back pain

- Certificate of absence prescribed?
  Descriptive statistics
  Chi²-test with H_0: there is no difference between the amount of people that received a certificate of absence between the manual AUDIT and the electronic AUDIT population
  Two proportion Z-test with H_0: the frequency of incapacity prescribed in the manual AUDIT population (respectively electronic AUDIT population) is comparable to the benchmark found in literature.
- Duration of incapacity
  Descriptive statistics
  If Gaussian distribution criteria are met: unpaired parametric Student's t-test, otherwise Mann-Whitney U-test, with H_0: there is no difference between the duration of incapacity prescribed between the manual AUDIT and the electronic AUDIT population
  Two proportion Z-test with H_0: the duration of incapacity prescribed in the manual AUDIT population (respectively electronic AUDIT population) is comparable to the benchmark found in literature.

7. DATA HANDLING AND MANAGEMENT

7.1 Data storage and management

Explain which type of data you are using, how the privacy of the participants is being protected (e.g. coding or anonymization), how the data is safely stored, and what will happen to the data at the end of the project.

The data will be collected in 2 general practitioner private practices in Flanders. Only patients with an active global medical file registered to one of the GPs of the practice will be included. The data collected using the electronic AUDIT is anonymized automatically upon export out of CareConnect since no individual patient data is exported, only practice wide data is exported. The data collected manually will be collected by 2 medical doctors who are bound by medical privacy and who are the 2 primary researchers of this master dissertation. They will anonymize the data within the private practice so no data that can identify a patient (i.e. name, date of birth, national register numbers, …) will leave the electronic medical record (Careconnect). The anonymized data will be further analyzed using statistical software. The anonymized data will be kept for 2 years after analysis and deleted afterwards. Only the processed data will be used in this master thesis.

7.2 Declaration of Confidentiality and Careful Management of Information and Personal Data

In the framework of his / her Master's thesis, the student(s) will have access to all kinds of data, information, results and documents, including personal data which is not exclusively limited to patient data (the "Information"). In order to ensure the confidentiality of this Information and the privacy of those involved, within the framework of his / her Master's thesis the student(s) should always deal with the Information with the greatest care and discretion.

Data collected in the framework of a Master's thesis, in particular research related to patients and including the collection and analysis of personal data, requires the utmost of care and discretion. Therefore, at all times the student must observe complete confidentiality with respect to the Information he / she has collected during the course of his / her Master's thesis.

In performing this research, the student(s) commit(s) him/herself to the following confidentiality obligations:

- *He / she accepts, during and after the completion of the Master's thesis, the obligation to strictly observe the confidentiality of the Information he / she has collected and the activities to which he / she has participated, and regarding the patients, healthy volunteers and the staff members with whom he / she comes into contact;*
- *He / she will only process and collect data that is relevant and necessary for his / her Master's thesis;*
- *He / she will not share information with persons not directly involved within the framework of his / her research;*
- *He / she will take all necessary steps to protect the confidentiality of Information and the privacy of those involved;*
- *He / she will handle with care and responsibility the Information and the access granted to him/her to information systems and digital media.*

  All investigators shall treat all information and data relating to the study as confidential and shall not disclose such information to third parties or use such information for any purpose other than the performance of the study. The collection, processing and disclosure of personal data, such as participants' health and medical information, is subject to compliance with applicable personal data protection legislation.

8. APPROVAL

Hereby we confirm that data collection is performed with approval of the head of the respective unit(s) or department(s) where data collecting is taking place. The data will be collected in 2 private practices of general practitioners.

9. PUBLICATION POLICY

Publications will be coordinated by the Principal Investigator. Authorship to publications will be determined in accordance with the requirements published by the International Committee of Medical Journal Editors and in accordance with the requirements of the respective journal.

10. DIRECT ACCESS TO SOURCE DATA AND DOCUMENTS

The investigator(s) and the institution(s) will permit study-related monitoring, audits, ethical review and regulatory inspections (where appropriate) by providing direct access to source data.

11. REFERENCES

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10.2 OBC Approval

GROEP BIOMEDISCHE WETENSCHAPPEN
HERESTRAAT 49, O&N II – BUS 700
BE-3000 LEUVEN

English version below.

Ons kenmerk: MP018709
Uw kenmerk: Masterproef studie: Low back pain in general practice: design and evaluation of an automated clinical audit: Imaging, farmacotherapy and physical therapy
Leuven, 21-12-2021

DEFINITIEF GUNSTIG ADVIES

Geachte Bert Vaes
Geachte Charlotte De Clercq, Rico Paridaens

De Ethische Commissie Onderzoek UZ/KU Leuven verleent hierbij een gunstig advies aan de voorgestelde studie, zoals ze werd beschreven in het protocol. De Commissie is van oordeel dat er vanuit ethisch standpunt geen bezwaren zijn bij de voorgestelde studie. De studie werd goedgekeurd op 21-12-2021

De Onderwijs-Begeleidings-Commissie voor Medische Ethiek (OBC) heeft in delegatie van het EC Onderzoek UZ/KU Leuven het vermeld protocol onderzocht en besproken op haar vergadering.

(Goedkeuring) This is a retrospective observational study ai

Aangezien het om een Masterproefproject binnen de Groep Biomedische Wetenschappen van de KU Leuven gaat, werd de aanvraag tot de Ethische Commissie Onderzoek UZ/KU Leuven ingediend via de Onderwijs-Begeleidings-Commissie.

De Commissie heeft geen bezwaar tegen het project mits vertrouwelijke behandeling van de gegevens en naleving van de Belgische wetgeving omtrent privacy. De Ethische Commissie Onderzoek UZ KU Leuven wenst de hoofdonderzoeker/promotor van de studie te wijzen op zijn/haar verantwoordelijkheid betreft de privacy van de persoons-/patiënt-gegevens bij contact met levende personen, patiënten en/of inzage in het elektronisch medisch dossier, inclusief de correcte implementatie hiervan door medewerkers en studenten.

Dit gunstig advies betreft de indiening van 01-12-2021 en wordt gegeven voor de duur van de Masterproef van de betrokken student(en). Elke wijziging aan het protocol doet dit gunstig advies vervallen. U dient in dat geval tijdig een amendement voor advies voor te leggen aan de commissie die eerder uw dossier goedkeurde.

De Commissie bevestigt dat ze werkt in overeenstemming met de ICH-GCP principes (International Conference on Harmonization Guidelines on Good Clinical Practice), met de meest recente versie van de Verklaring van Helsinki en met de van toepassing zijnde wetten en regelgeving.

De Commissie bevestigt dat in geval van belangenconflict, de betrokken leden niet deelnemen aan de besluitvorming omtrent de studie.

Met vriendelijke groet,

Prof. dr. Minne Casteels
Voorzitter

Ethische Commissie Onderzoek UZ/KU Leuven

Prof. dr. Pascal Borry
Voorzitter
Onderwijs-BegeleidingsCommissie voor Medische Ethiek KU Leuvenv

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Aandachtspunten (indien van toepassing)

De Ethische Commissie UZ KU Leuven wenst de hoofdonderzoeker/promotor van de studie te wijzen op zijn/haar verantwoordelijkheid betreft de privacy van de persoons-/patiëntgegevens bij contact met de patiënt en/of inzage in het elektronisch medisch dossier, inclusief de correcte implementatie hiervan door medewerkers en studenten. Het EC verwijst naar de richtlijnen van ICH/GCP hierover op de website, en benadrukt dat een GCP-opleiding van elke hoofdonderzoeker verwacht wordt voor studies die vallen onder de Wet op Medische Experimenten. Het EC verwijst tevens naar de Belgische wetgeving (Wet van 8/12/1992 ter bescherming van de persoonlijke levenssfeer en Wet van 22/8/2002 betreffende de rechten van de patiënt), en de Algemene Verordening Gegevensbescherming (van toepassing op 25 mei 2018).

Bij gebruik van elektronisch medische gegevens is een formeel akkoord van de dienstraad vereist. De opdrachtgever is verantwoordelijk voor de conformiteit van de anderstalige documenten met de Nederlandstalige documenten.

Onderzoek op embryo's in vitro valt onder de wet van 11 mei 2003. Voor dergelijk onderzoek is er naast een positief advies van het EC Onderzoek UZ/KU Leuven ook een goedkeuring van de Federale Commissie voor medisch en wetenschappelijk onderzoek op embryo's in vitro noodzakelijk vooraleer dit onderzoeksproject kan doorgaan.

Vooraleer u dierexperimenten mag opstarten is een goedkeuring vereist van de Ethische Commissie Dierproeven (ECD). U dient zich bijgevolg aan te melden bij deze commissie voor het onderdeel met dierproeven en hun adviezen te volgen. Gelieve te noteren dat u het onderzoek pas mag starten nadat u een definitief gunstig advies van deze commissie heeft verkregen.

Onderzoek op humane kadavers vereist een goedkeuring van het Ethisch Comité voor Zorg en Begeleiding. U dient zich bijgevolg aan te melden bij deze commissie en hun adviezen te volgen. Gelieve te noteren dat u het onderzoek pas mag starten nadat u een definitief gunstig advies van deze commissie heeft verkregen

Dit gunstig advies van de Commissie houdt niet in dat zij de verantwoordelijkheid voor de geplande studie op zich neemt. U blijft hiervoor dus zelf verantwoordelijk.
Bovendien dient u, als betrokken hoofdonderzoeker, erover te waken dat de resultaten van dit onderzoek, correct worden weergegeven in publicaties, rapporten voor de overheid enz.

U wordt eraan herinnerd dat bij klinische studies iedere door u waargenomen ernstige verwikkeling onmiddellijk zowel aan de opdrachtgever (desgevallend de producent) als aan het EC Onderzoek UZ/KU Leuven moet worden gemeld, ook al is het oorzakelijke verband met de studie onduidelijk.

Our reference: MP018709
Your reference: Master's thesis study: Low back pain in general practice: design and evaluation of an automated clinical audit: Imaging, farmacotherapy and physical therapy
Leuven, 21-12-2021

DEFINITIVE FAVOURABLE ADVICE

Dear Bert Vaes
Dear Charlotte De Clercq, Rico Paridaens

The Research Ethics Committee UZ/KU Leuven hereby grants favourable advice to the proposed study, as it was described in the protocol. The Commission is of the opinion that from an ethical standpoint there are no objections to the proposed study. The study was approved on 21-12-2021

De Onderwijs-Begeleidings-Commissie voor Medische Ethiek (OBC) heeft in delegatie van het EC Onderzoek UZ/KU Leuven het vermeld protocol onderzocht en besproken op haar vergadering.

(Goedkeuring) This is a retrospective observational study ai

Given that the study takes the form of a Master's thesis within the Group Biomedical Science, the application to the Research Ethics Committee UZ/KU Leuven was submitted to the Educational-Support Committee.

The Committee has no objection to the project on the basis of confidential treatment of the data and compliance with the Belgian legislation concerning privacy. The Research Ethics Committee UZ/KU Leuven wishes for the head researcher / promoter of the study to be aware of their responsibilities with regard to the privacy of personal / patient details, when in contact with living persons, patients, and / or contained within electronic medical records, including the correct implementation by employees and students.

This favorable advice concerns the submission of 01-12-2021 and is given for the duration of the Master's thesis of the student(s) concerned. Any amendment to the protocol will invalidate this favorable advice. In that case, you must submit an amendment for advice to the committee that previously approved your file.

The Committee confirms that they work in accordance with the ICH-GCP principles (International Conference on Harmonisation Guidelines on Good Clinical Practice), with the most recent verison of the Helsinki Declaration, and with applicable laws and regulations.

The Committee confirms that in case of a conflict of interest, the members concerned have not participated in decision regarding the study.

Kind regards,

Prof. dr. Minne Casteels
President / Chairperson
Research Ethics Committee UZ/KU Leuven

Prof. dr. Pascal Borry
President / Chairperson
Education-Support Committee for Medical Ethics KU Leuven

Points of Interests (if applicable)

The Research Ethics Committee UZ/KU Leuven wishes for the head researcher / promoter of the study to be aware of their responsiblities with regard to the privacy of personal / patient details, when in contact with living persons, patients, and / or contained within electronic medical records, including the correct implementation by employees and students. The Ethics Committee refers to the guidelines of the ICH/GCP here on the website, and emphasises that GCP-training is expected from every head-researcher for studies that come under the Law on Medical Experimentation. The Ethics Committee refers at the same time to the Belgian legislation (Law from 8/12/1992 for the protection of personal privacy and Law from 22/8/2002 regarding the rights of the patient), and the General Data Protection Regulation (which comes into effect on May 25th 2018).

For use of electronic medical data, a formal agreement from the clinical board is required. The study promotor is responsible for the conformity of foreign language documents with the Dutch language version.

In vitro research on embryos comes under the Law of 11 May 2003. For such research, besides positive approval from the Ethics Committee, approval by the Federal Committee for Medical and Scientific Research on Embryos In Vitro is also necessary before a project can commence.

Before you may commence animal experimentation, approval is required from the Animal Ethics Committee. You must register with this committee for the animal testing component and follow their advice. Please note that you may start the investigation only after you have obtained a definitive favorable opinion from this committee.

Research on human cadavers requires approval of the Care and Support Ethics Committee. You must therefore register with this committee and follow their advice. Please note that you may start the investigation only after you have obtained a definitive favorable opinion from this committee.

This favorable opinion from the Commission does not mean that it takes responsibility for the planned study. You remain responsible for this yourself. In addition, as the principal investigator, you must ensure that the results of this research are correctly displayed in publications, reports for the government, etc.

You are reminded that any serious complication you observe must be reported immediately to both the study promotor (if applicable, the producer) and the Ethics Committee, even if the causal link with the study is unclear.