Grant Application Form

Van Rens Foundation 2017

1a. Study title (max. 25 words)
What makes a best performing hospital in hip and knee replacement? Quality improvement using joint registry data

1b. General information project leader	
Title	
Initials	
Name	
Position	
Institute/organisation	
Contact address	
Contact email	
Contact telephone	

1c. Other project members involved		
1	Name Position Institute	
2	Name Position Institute	
3	Name Position Institute	
4	Name Position Institute	
5	Name Position Institute	

Please add the Curriculum Vitae of the project leader to the grant application

See attached file

1d. Project characteristics		
Is this application a resubmission?	Yes / no No	submitted in
Type of researcher	Post-doc / PhD / other, specify PhD MD	
Duration in months 48 months	months	
Expected starting date (not sooner than January 1, 2017, not later than March 1, 2017)	March 1, 2018	

1e. List of 5 key words
1. Hospital variation
2. Performance measures
3. Quality improvement
4. Effectiveness
5.

1f. Scientific summary (max 1000 words, no tables/figures)

Background
Several studies have shown variation in hospital performance after hip and knee replacement, both in outcomes and costs, thereby suggesting that improvement may be possible. In the Dutch joint registry, data are available on 300,000 hip and knee arthroplasties since 2007. The variation in outcomes between hospitals is visible in their annual report e.g. on the case-mix adjusted 1-year revision rates. However, other outcomes (e.g. readmission and length of stay) may be relevant and interrelated so that these outcomes need to be considered together and integrated into a composite outcome (or hospital performance profile), not yet available for orthopaedic surgery. Furthermore, data needs to be available continuously for hospitals to use this information effectively to improve quality of care, as shown by audits in other surgical fields to be associated with better guideline adherence and improved outcomes. This requires orthopaedic surgeons to be educated on how to use this information to figure out where and how to improve.

Objectives
Aim of this study is to gain more insight into the extent of hospital variation in outcomes after primary hip and knee replacement as well as in explanatory factors, and to test whether a strategy of education combined with more frequent feedback of data, results in more effective use of joint registry data, more quality improvement activities as well as better outcomes.

Methods
The study is designed as a randomized controlled trial to test the effectiveness of the multifaceted strategy, within the Dutch joint registry to estimate both the extent of hospital variation and to monitor the outcomes in the trial.

First we will assess the extent of variation in hospital performance after hip and knee replacement for all hospitals in the Netherlands using anonymous LROI data. All patients undergoing a hip or knee replacement in the period 2014-2016 will be included, regardless of type of prosthesis. We will use joint registry outcomes regarding revision (overall and by cause) as well as PROMs to indicate performance (adjusted for case-mix: age, gender, ASA class, BMI, smoking and Charnley comorbidity score) and estimate the extent of hospital variation as well as reliability of ranking.
Then we will invite all hospitals performing hip and knee replacement to participate in this study. Participation means that they agree their joint registry data to be linked to data from other sources (length of stay, readmission, quality indicators) to obtain the composite outcome and to be randomized in a study to improve performance based on these data. The composite outcome is defined as: survival, no revision within 1 year or emergency readmission within 30 days, a normal length of stay and an increase in PROMs in the upper quartile. Power calculation has shown that 18 hospitals are needed to detect a difference of 70% versus 80% in the composite outcome between randomized groups with 80% power and 95% reliability. For each hospital and each outcome we will assess whether the hospital has a better, average or worse performance based on the funnel plot, to assess whether the different outcomes are correlated so that some hospitals perform good on all outcomes or that there are mostly mixed profiles. Potential explanatory factors (e.g. pre- and postoperative processes, structural factors like teaching status, experience of orthopaedic surgeons and fast track protocols) explaining the variation in performance between hospitals, will be assessed through a survey among orthopaedic surgeons and interviews.
Participating hospitals will be randomized to an early versus late group, stratified by teaching status as this might influence the time available for quality improvement versus production parameters. In the first period, the early group will receive the intervention and will be compared with the other group receiving usual care. In the second period, the early group should be able to sustain the intervention in daily practice (so not actively supported anymore) and will be compared with the late group now receiving the intervention. In addition, we will be able to compare the first and second period within each group. The intervention will consist of education on how to use joint registry data for quality improvement, create more awareness, regular feedback on outcomes from the joint registry and other data sources, linking to another hospital with better outcomes to exchange information on how this is achieved. We will monitor improvement on the composite outcome but also on intermediate outcomes (number of quality improvement activities undertaken, knowledge about performance among orthopaedic surgeons, number of people attending quality meetings etc).

Expected outcomes
Expected outcomes of this study include knowledge on the extent of variation in outcomes after primary hip and knee replacement between all hospitals in the Netherlands, and the influence of case-mix and explanatory factors. In addition, a composite outcome measure will be created which can be used after the study is completed for instance within the existing audit by the Dutch Orthopaedic association, similar to other scientific associations. In addition, if the intervention is effective, this can be further implemented in other hospitals to further expand the use of the joint registry for quality improvement in daily practice.

1g. Short lay summary of the project (max 100 words)

Patient outcomes after hip or knee replacement may vary between hospitals. Part of this variation is due to some hospitals treating more complex patients, but part cannot be explained and may be due to the quality of care delivered to these patients. Therefore hospitals can use information on whether the outcomes in their patients are better or worse than in other hospitals to improve their care. The present study will gain information on how much variation there is between Dutch hospitals, which factors may explain this and test a strategy to use this information to improve patient outcomes.

Research proposal

2a. Research question (max 150 words)

Aim of the present study is

1) to gain more insight into variation in hospital performance on different outcomes after primary hip and knee replacement, combined into hospital performance profiles

2) the extent to which this variation is explained by differences in patient-mix, type of prostheses, pre-and post-operative processes or other factors

3) to test whether an intervention, consisting of education and frequent feedback of data results in more effective use of joint registry data, more quality improvement activities as well as better outcomes

2b. Background (max 1000 words)

Hip and knee replacement are frequently performed worldwide [1,2] and the number of procedures is expected to increase exponentially in the coming decades, due to the ageing of the population and the increasing prevalence of obesity. [3-5] This will increase the burden on health care systems and have considerable societal and economic consequences. [6] Although these procedures are very effective in reducing pain and improving functionality, it becomes increasingly important to deliver both high value care for patients and reduce costs while the number of procedures increases. In recent years, several studies have shown variation in hospital performance after hip and knee replacement both in outcomes and costs [7-9], thereby suggesting that there may be room for improvement. To inform hospitals and drive quality improvement, data are needed on the extent of variation in performance.

In the Netherlands, the nationwide joint registry comprises data from over 300,000 hip and knee arthroplasties since 2007, with complete coverage of all hospitals attained in 2012 and completeness of at least 95%. [10] The joint registry produces an annual report in which the variation between hospitals is visible, particularly recently when case-mix adjusted funnel plots on 1-year revision rates after hip and knee replacement were added. [11] These data are now also available on the secured part of the website, where hospitals can see how their performance relates to others. However, additional case-mix variables (smoking and BMI) have become available but not yet used for case-mix adjustment, whereas these may have different risks on revision or complications. [12-14] Furthermore, outcomes are aggregated for all types of prosthesis bearings, whereas it may be appropriate to report these separately or to adjust for differences in procedure mix between hospitals as outcomes may differ. [15] Variation in other outcomes such as long length of stay, readmissions or patient reported outcomes has not been routinely reported in the Dutch joint registry. Not all of these outcomes are available in the joint registry, but are available in other data sources which may be linked.

Hospitals can use information on variation in outcomes as a starting point for quality improvement initiatives, particularly if this information shows that their hospital has worse outcome than other comparable hospitals. However, a hospital can have a good performance on one outcome and needs to improve on another, but as the different outcomes are also likely interrelated, these need to be considered together. In previous research we have already defined such a composite outcome for other specialties [16-18], also known as textbook outcome and used by insurers [19], but this is not available for orthopaedic surgery in the Netherlands. So the information on different outcomes after hip and knee replacement need to be integrated into a composite outcome (or hospital performance profile) but also needs to be available continuously for hospitals to use this information effectively to improve quality of care, as shown by audits in other surgical fields to be associated with better guideline adherence and improved outcomes. [20] This requires orthopaedic surgeons to be educated on how to use this information to figure out where and how to improve.

2c. State of the art of the work field (max 500 words)

Most studies reporting on variation in hospital performance after hip and knee replacement are from the United States (US), which were performed particularly in the context of the recent introduction of bundled payment for hip and knee replacement. [8,9,21] Bundled payment was introduced to reduce variation in costs and outcomes between hospitals. Therefore studies performed in such a context are likely to have both a better average performance (e.g. on length of stay, or readmissions) but also smaller hospital variation as particularly hospitals with worse outcomes are forced to improve. In addition, outcomes like length of stay are already know to be much lower in the US than Europe, as patients are discharged quickly to rehabilitation centres, so that results from US studies may not be generalised. Only one European study was found, showing considerable variation in return to theatre (RTT) and suggesting this may be used as a quality performance measure [22]. However, the question is how this RTT adds to revision surgery which is mostly used as a performance measure, as different surgeries including revision, dislocation, debridement are now all combined into one reoperation variable. Furthermore, all these studies were based on administrative data and acknowledged this to be a limitation, whereas the availability of clinical variables would allow for better adjustment for case-mix. Research into explanatory factors explaining the variation in outcome is scarce.

The present study will add the perspective from another European country, without bundled payment or payment for performance present, and use more clinical variables for risk-adjustment available in the joint registry. By linking to other data sources, case-mix adjustment is likely to be optimized and to give a more comprehensive view on quality of care. Innovative elements of this proposal include that joint registry data will be used to not only show the variation between hospitals in outcomes, but also to investigate explanatory factors and to actively engage professionals to use this information for quality improvement in daily clinical practice and to test the effectiveness on improving outcomes for patients in a randomized study.

Methodology

3a. Methodology – Variables, data sources and data collection methodology (max 300 words)

The study is designed as a randomized controlled trial nested within the joint registry (LROI). We will first analyse the hospital variation in case-mix adjusted outcomes after hip and knee replacement performed in 2014-2016 using all data from the joint registry and create a composite 'textbook' outcome. Then we will ask hospitals to participate in a randomized controlled trial in which they will get more regular feedback regarding their performance both on the composite and individual outcomes, combined with education on how to use these data to improve their quality. The feedback information will be based both on data available in the joint registry (e.g. revision) as on data available through linkage with other data sources (e.g. readmission). Hospitals are randomized to an early versus late group, with the early group receiving regular feedback combined with education in the first period followed by a second period in which they continue to receive the regular feedback but without the active support and education, to test whether they have been able to sustain this in daily clinical practice. The late group receives usual care (i.e. the current situation) in the first period, followed by a second period in which they receive regular feedback and education (as the early group received in the first period).

Available LROI data will be used, linked to hospital supplied data on quality indicators and administrative data. Data on potential factors explaining the hospital variation in outcomes will be retrospectively collected in participating hospitals, using record review among a sample of patients, surveys and interviews among professionals. In addition, we will monitor prospectively both the quality improvement activities undertaken and the outcomes in participating hospitals using data from the LROI and survey data, both before, during and after the intervention.

3b. Methodology – Study population (persons, implants, time period, inclusion and exclusion criteria) (max 200 words)

All patients undergoing a hip or knee replacement in the period 2014-2016 are included, regardless of type of prosthesis, to assess the extent of variation and potential explanatory factors (research question 1 and 2). This period was chosen given the additional availability of relevant case-mix factors (smoking and BMI) and still allow for sufficient follow-up time for all patients to calculate 1-year revision rates. To answer research question 3, we will include more recently treated patients, to be able to monitor the effect of quality improvement activities on outcomes in the participating hospitals.

3c. Methodology – Work plan (max. 1750 words (including tables and figures))

All hospitals

First we will assess the extent of variation in hospital performance after hip and knee replacement for all hospitals in the Netherlands using anonymous LROI data. All patients undergoing a hip or knee replacement in the period 2014-2016 will be included, regardless of type of prosthesis. The hospital variation will be assessed per year and for the entire period to increase power. The following outcomes will be used:

- Overall revision within 1 year
- Revision for infection within 1 year
- Revision for loosening within 1 year
- Revision for dislocation within 1 year
- Increase in Patient Reported Outcome Measure (PROM) after versus before hip/knee replacement (measured by the EQ-5D, HOOS-PS and KOOS-PS)

For the different PROM dimensions (e.g. pain or functionality) we will first calculate quartiles of increase in PROM based on all patients from all hospitals, separately for hip and knee replacement. Consequently, being in the upper quartile of PROMs increase (yes/no) will be calculated as an additional variable for each patient to indicate performance, as this is what both patients and doctors strive for. Separate case-mix models will be created for each outcome using backwards logistic regression, starting with the entire set of patient characteristics (age, gender, ASA class, BMI, smoking and Charnley comorbidity score) as independent variables and using $p<0.10$ for inclusion in the model. Using the coefficients from this multivariate model, the expected probability on the outcome is calculated for each patient. Aggregating these probability at the hospital level results in the expected number of events for a hospital, to be compared with the observed number. The risk-adjusted outcome rate in the funnel plot will be calculated by dividing the observed number by the expected number and multiplying by the average rate across all hospitals.

The extent of variation between hospitals will be expressed as the median rate with the interquartile range, as well as the number of outliers (both above and below the 95% confidence interval). Exact Poisson 95% confidence intervals will be calculated. The reliability of ranking hospitals (rankability) will also be calculated (see 3d - statistics). As a separate step, we will add different prosthesis characteristics to the model (e.g. cemented or uncemented, manufacturer etc.) as these may be determinants of the outcomes and explain part of the variation, but can be changed and are thus part of possible quality improvement initiatives. We will assess whether adding these variables will change both the overall model fit (assessed by the C-statistic) and the number of outliers to indicate possible consequences for hospitals.

Participating hospitals

All hospitals in the Netherlands will be approached to participate using an online survey to the head of the orthopaedic department, combined with news feeds on the LROI secured site and the general Dutch Orthopaedic Association site with a direct link. Participation means that they agree their LROI data to be linked to data from other sources to obtain the composite outcome and to be randomized in a study to improve performance based on these data. LROI data will be linked to the following additional data sources:

- Administrative data, routinely collected in all hospitals, containing admission data to calculate length of stay and readmissions following primary hip and knee replacement

If possible, cost data will also be requested.
- Annual quality indicators partly based on LROI data but with data added by the hospital e.g. on the number of surgeons performing the hip and knee replacements and percentage of surgical site infections.

Linkage will be done according to the following procedure (see also 7c for more detail). After agreement for participation, we will approach the LROI to select the appropriate hospitals and patients from the total dataset into a new dataset. Each hospital can convert the anonymous patient identifiers to the local unique patient number for their own patients, which can be used to add the following variables:
- Admission and discharge data in hospital
- Any subsequent admissions for this patient, whether this was an emergency admission or not, and the primary diagnosis for these admissions
- Date of death or patient still alive

Each hospital will send this additional information linked to the anonymous patient identifier back to the coordinating centre. The new dataset will be used to conduct the same analyses as for all hospitals to assess whether results are similar. Differences between participating and non-participating hospitals in outcomes and patient characteristics will be tested using chi-square tests for categorical variables and t-tests for continuous variables. As described above, case-mix models will be built to adjust hospital variation for the additional outcomes:
- All readmissions within 30 days
- Emergency readmissions within 30 days
- Long length-of-stay, defined as a length of stay in the upper quartile
We will create the following composite outcome: survival, no revision within 1 year or emergency readmission within 30 days, a normal length of stay and an increase in PROMs in the upper quartile. This is indicated for each patient as a yes/no variable and aggregated to the hospital level to calculate the observed number. Using similar procedures as described above, a case-mix model can be build and funnel plots can be created. For each hospital and each outcome we will assess whether the hospital has a better, average or worse performance based on the funnel plot, to assess whether the different outcomes are correlated so that some hospitals perform good on all outcomes or that there are mostly mixed profiles.

Potential other factors (in addition to patient and prosthesis characteristics) explaining the variation in performance between hospitals, will be based on literature review and expert advice and depend on the outcome considered. For instance, for differences in revision for infection we will consider factors such as antibiotic prophylaxis, both timing and general policy (single vs multiple shot). These factors will be assessed in the survey among all orthopaedic surgeons performing hip and knee replacement in the participating hospitals, and added as hospital level explanatory factor in the statistical model. In addition to questions on pre- and postoperative processes, some more general structural characteristics will be assessed such as teaching status, experience of orthopaedic surgeons and fast track protocols. We will also conduct interviews to assess in a qualitative way how hospitals act based on feedback information provided from the joint registry as well as to provide context regarding factors explaining difference in performance. Multilevel logistic regression models will be used with some variables assessed at

the hospital level (e.g. from the survey or teaching status) and taking into account patients clustering within these hospitals.

Randomized trial – using data on variation to improve hospital performance
A pragmatic randomized controlled trial will be conducted with hospitals randomized to an early versus late group, stratified by teaching status as this might influence the time available for quality improvement versus production parameters. Randomization will be done using a computer generated randomization table in a 1:1 ratio. When agreeing to participate, the hospital supplies a list with names and email addresses of orthopaedic surgeons who perform hip and knee replacements to be used to send information and schedule meetings. The intervention will consist of the following components:
- Create more awareness about actual performance: all orthopaedic surgeons performing hip and knee replacement will receive their own LROI account to be able to look at their performance. In the current situation, only the head of the department and a datamanager have access.
- Education on how to use the information from the LROI to identify in which area a specific hospital can improve.
- Add feedback data from other sources as well as from the survey, combined with education on how to use this information for improvement. This will be send quarterly by email to the intervention group to prevent contamination bias for the control group (receiving this intervention at a later point in time).
- Link a hospital in need for improvement on a certain outcome (defined as outside the 95% confidence interval of the funnel plot) to another similar hospital to enable learning from each other by exchanging in more detail how they treat these patients and achieve a better performance on this outcome. As it is likely that most hospitals will have mixed profiles, this will probably go both ways i.e. that hospital 1 learns from hospital 2 on a certain outcome but vice versa on another outcome. To facilitate this learning, meetings will be organized at respective hospital sites or linked to the bi-annual meetings of the Dutch Orthopaedic Association. The local datamanagers of hospitals will be included in these meetings as they will be the contact for monitoring the effect on outcomes and to support the orthopaedic surgeons in correctly interpreting the LROI data.
- Prepare for sustainment: discuss at the meetings how this can be incorporated in daily clinical practice.

During the trial, we will conduct quarterly measurement on intermediate outcomes showing whether the intervention reaches the target group (process evaluation). The following measurements will take place:
- Knowledge among orthopaedic surgeons on their recent performance and how that relates to others
- Number of quality improvement activities undertaken directed at improving a certain outcome.
- Planned improvement activities (e.g. record review to figure out why performance is not as good as in other centers) together with who is responsible and by which time
- Number of people attending the meetings, number of times a specific account has accessed the LROI site to ensure that information has reached the target group.
- Survey among orthopaedic surgeons at the end of the intervention period on knowledge learned and the extent to which they think this is sustainable in daily practice. We will analyse the data using statistical process control techniques, based

on quarterly data (monthly if feasible), particularly suitable to signal whether outcomes have improved. This will be done both for the outcomes from the LROI data and the intermediate outcomes within the group receiving the intervention. In addition we will compare the outcomes between the early group and the late group (control group because they receive usual care in first period) to test the effectiveness of the intervention, using the appropriate regression techniques. In the second period we will test the sustainability of this approach in daily practice by comparing the outcomes within the early group with the first period, and compare with the late group to test whether outcomes in the sustainability phase are similar as when actively supported.

3d. Methodology – Statistics / power calculation (max 500 words)

For the first part of the study, funnel plots will be used to assess the variation between hospitals in outcomes adjusted for case-mix. Expected probabilities for each outcome and patient will be calculated using logistic regression models and all available patient characteristics (age at primary procedure, gender, ASA class, BMI, smoking and comorbidity (Charnley score)) as independent variables. These are aggregated per hospital to be able to compare observed with expected numbers. Exact Poisson 95% confidence intervals will be calculated. We will also calculate the reliability of ranking hospitals for each outcome, a measure to indicate which part of the total variation is due to real hospital differences as opposed to chance. [23-25] This will be done for different outcomes as these might have different explanatory factors (e.g. revision for infection versus revision for dislocation) and for different types of prosthesis besides overall as it may direct towards using a different type of prosthesis if it would be associated with better outcomes.

For the randomized controlled trial, at least 18 participating hospitals (9 in each arm) are needed to be able to detect a difference in performance on the composite outcome of 70% versus 80% with 80% power and 95% reliability (assuming an intra-hospital correlation of 0.02 and a median of 100 procedures per hospital, separately for hip and knee replacement). Based on previous multicentre studies conducted by our group [26] and the presence of the research collaborative CORE now at the Dutch Orthopaedic Association expected to further facilitate multicentre studies, inclusion of this number of hospitals is feasible (9 hospitals have already agreed or shown interest at this point). We will then perform the same analyses as in the first part to check whether participating hospitals may be a selection of hospitals, looking at both patient characteristics, extent of variation and structural factors like teaching status. Additional collected data for these hospitals (e.g. on pre-and postoperative processes) will be added to test whether these explain part of the hospital variation (e.g. different antibiotic prophylaxis policy might explain part of differences in revision for infection).

3e. Methodology – Limitations of study design, data sources and analytical methods (max 300 words)

Even though a randomized controlled trial is the highest level of evidence attainable, some limitations of the overall project can be noted. First, showing the magnitude of the variation in outcomes between hospitals may be hampered by insufficient case-mix adjustment or large random variation. Insufficient case-mix adjustment will remain an issue because we can never obtain all relevant variables, but the available variables are likely to be the most relevant ones. Large random variation is particularly an issue for low frequent outcomes, which is why we have chosen to combine several outcomes in a composite outcome with the advantage of increasing power. In addition we will calculate the reliability of ranking hospitals to signal the ability to identify hospital variation from random noise (signal to noise ratio). A limitation for the randomized controlled trial might be that the intervention period in which professionals receive education and frequent feedback, may be too short to show results in patient outcomes. For this reason we have also included a process evaluation containing intermediate outcomes such as the number of quality improvement activities undertaken, which are likely to result in improved patient outcomes in the long run. Finally, a limitation may be that orthopaedic surgeons sometimes work in different hospitals, that both participate in the randomized controlled trial but are assigned to different arms. We will check for this possibility even though chances are low, by comparing names and email addresses of orthopaedic surgeons within participating hospitals.

3f. Methodology – Timeline (max 500 words)

Year 1: Analysis variation all hospitals using anonymous LROI data, invite hospitals to participate, survey on explanatory factors, request additional hospital data and create queries to regularly extract this data

Year 2: Analysis variation participating hospitals, linkage data, create composite outcome, preparation RCT

Year 3: In first 6 months feedback and education in early hospitals (organisation of meetings, frequent feedback, data collection on number of quality improvement initiatives and outcomes), in last 6 months in late hospitals.

Year 4: Evaluation of effectiveness of intervention, writing publications

Outcome

4a. Expected outcome / end product and impact (max 200 words)
Outcomes of this study include knowledge on the extent of variation in outcomes after primary hip and knee replacement between all hospitals in the Netherlands, and the influence of case-mix and explanatory factors. In addition, a composite outcome measure will be created which can be used after the study is completed for instance within the existing audit by the Dutch Orthopaedic association, similar to other scientific associations. The method to be used to link the joint registry data to other data sources can be implemented nationwide, as well as the strategies to improve quality of care on specific outcomes (if shown to be effective in the current study). Other end products include education material and formats for feedback of data which will be made available to the joint registry after completion of the study. As such, the study is likely to expand use of joint registry data and consolidate its use in routine clinical practice to patients.

4b. Plans for communicating results and dissemination (max 200 words)
Results from this study are particularly relevant for those professionals caring for hip and knee replacement patients, but also for datamanagers who might become increasingly important to help monitoring the hospital specific outcomes and to signal any changes that occur. We therefore aim to also disseminate our results by organizing a workshop alongside the scientific conferences of the Dutch Orthopaedic association which non-participating hospitals can attend to also learn about how to effectively use joint registry data for quality improvement. In this workshop we hope to involve professionals from participating hospitals as our champion experts, thereby creating a growing quality improvement network among orthopaedic surgeons, nurses and datamanagers. On the external joint registry website, an extract of study results will be made available for patients and insurers.

4c. Contribution of the project to the quality of orthopaedic care (max 300 words)

The project will both show the extent of variation in outcomes between hospitals, and thereby the potential for quality improvement. Whether this is attainable in practice will depend on the importance of case-mix and explanatory factors. In addition, for hospitals participating in the randomized controlled trial the project will directly contribute to their activities to improve quality of care.

5. Structure and cooperation research group (max 200 words)

Within the LUMC and the present research group, the departments of Orthopaedic Surgery and Medical Decision Making have successfully collaborated on a large number of multicentre studies and cohorts (eg LISBOA study, pragmatic RCT in 21 hospitals, LOAS, Vespa and Paprika cohort). In addition, Prof Nelissen is the founder of the Dutch joint registry and still active in both national and international joint registries. Dr Marang-van de Mheen is one of the editors of BMJ Quality & Safety, has ample experience in working in large (international) consortia trying to reliably compare hospital outcomes (e.g. dr Foster Global Comparators), running large multicentre studies and large databases, as well as connecting routinely used data to quality improvement initiatives. Furthermore, extensive knowledge and experience in implementation research among orthopaedic surgeons is available (van Bodegom-Vos & Hofstede), thereby being able to create effective strategies for quality improvement by professionals. Besides the 5 orthopaedic departments already involved in writing this application, another 4 have already indicated their interest to participate. As such, the present study will be able to benefit both from a large existing network of hospitals as well as from extensive knowledge on registry data, reliably comparing hospital outcomes and quality of care.

6. References (max 1 page)

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Data storage

7a. Information governance (max 100 words)
The study will be presented to the Medical Ethics committee for a waiver, but in this way the procedure for governance of data will be checked. Data will be stored on the secured server of the LUMC in anonymised format, with the key to patient identifiable information remaining in individual hospitals. Only researchers involved in the project will have access to the data. The handling of data will comply with Dutch law on privacy of patients and hospitals.

7b. Patient identifiable data (max 100 words)
Any patient identifiable data will remain in individual hospitals or in the joint registry.

7c. Linking to patient identifiable data from other sources (max 100 words)
Data will be linked to other sources using the procedure as described above in more detail. Linkage will be done within participating hospitals so that any patient identifiable information will remain there and only anonymous data will be send to the coordinating centre to be analysed. The procedure will also be presented to the Medical Ethics committee for approval to comply with relevant Dutch laws.

Budget

8a. Co-financing (max 400 words)
Co-financing will be requested to cover the material costs in this project (estimated at 20.000 euro). Material costs include data retrieval from participating hospitals, building a dedicated database for participating hospitals, organising meetings in hospitals during the trial and travel costs to visit the hospitals. If not found, these will be covered by department of the project leader or by the participating hospitals (e.g. hosting the meetings).

8b. Budget					
	Proportion (fte)	**Starting date**	**Finishing date**	**Duration (in months)**	**Budget**
Personnel[1] Junior researcher / PhD / post-doc / other, specify	0.9 junior researcher			48	226.068
Junior researcher / PhD / post-doc / other, specify	0.1 project coordination			48	31.673
Congress visit[2]					4.000

[1] Max. 1.0 fte in total; [2] Including administration fee, travel and hotel expenses, excluding NOV congress.

8c. Motivation of requested budget (max 300 words)

The project will be carried out by a junior researcher who preferably has a MD and will enter a PhD trajectory. In addition, given the multicentre character of the study and linkage of data to other sources, both epidemiological and project management expertise is required to coordinate the project. Conference costs to present results at an international conference are included.

Part of the required project coordination costs will be contributed by the department, so that the total budget requested is 240.000 euro.

8d. Contact person financial administration (max 100 words)

Dhr. Frans van den Broek
Email: fvdbroek@lumc.nl
Phone: 071-5298298

Review and conflicts of interest

9a. Suggested (international) referees (minimal 5)[1]			
	Name	**Position and organisation**	**Email address**
1.	Alma Pedersen	Post doctoral scientist, Department of Clinical Epidemiology, University of Aarhus	abp@clin.au.dk
2.	Ton Tran	Director of Orthopaedic Surgery, Monash Health	Ton.Tran@monashhealth.org
3.	Andrew Gordon	Consultant Orthopaedic surgeon, Sheffield teaching hospitals	a.gordon@sheffield.ac.uk
4.	Andrew Carr	Nuffield Professor of Orthopaedics, Director of the Oxford Musculoskeletal BRU, Di	andrew.carr@ndorms.ox.ac.uk
5.	Sten Rasmussen	Orthopaedic surgeon and associate professor, Aalborg University Hospital	sten.rasmussen@rn.dk
6.			
7.			
8.			
Comments (max 100 words)			

[1] Please provide at least 5 (international) possible referees who are not directly involved in this or comparable research projects within your research group. Prevent 'hot shots', since they are generally too busy to judge your project. This information will only be used internal and not send to external referees.

9b. Conflicts of interest (max 100 words)
All project members declare to have no conflicts of interest.

Specification of data application LROI

Specification of data application					
Joint		**Procedure type**		**Patient demographics**	
Hip	X	Primary	X	Gender	X
Knee	X	Revision	X	Age at procedure	X
Shoulder (available since 2014)		Linked Primary-revision	X	Smoking (available since 2014)	X
Elbow (available since 2014)				BMI (available since 2014)	X
Ankle (available since 2014)				ASA Grade	X
				Charnley score (hip/knee) (available since 2014)	X
				Walch class (shoulder) (available since 2014)	
				Previous operations of affected joint	X
Procedure details		**Implant data**		Anonymous hospital number!!	
Year of procedure	X	Manufacturer	X		
Side	X	Name of implant	X		
Indication for primary procedure	X	Material of implant	X		
Approach	X	Type of implant	X		
Type of prosthesis	X				
Fixation	X				
Articulation	X				
Reason for revision	X				

Data is provided on the level of detail needed to answer the research question. Data will not contain any patient identifiable data and is made untraceable to physician(s) and hospital(s). Traceability of data on the level of the physician or hospital will only be performed after approval of the concerning hospital(s) or physician(s).

Please fill in the form in English and save the definitive Application Form Van Rens Foundation as a PDF file. Please sent this grant application form (as PDF) including the Curriculum Vitae of the project leader (as PDF) and a motivation letter (as PDF) to vanrensfonds@orthopeden.org.