Author's response to reviews

Title: Cost effectiveness of total knee arthroplasty from the health care providers' perspective before and after introduction of an interdisciplinary clinical pathway - is investment always improvement?

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Author's response to reviews: see over
Dear Editors of BMC Health Services Research!

First let us thank you for the opportunity of submitting a revised version of our manuscript „Cost effectiveness of total knee arthroplasty from a health care providers’ perspective before and after introduction of an interdisciplinary clinical pathway – is investment always improvement?” (BMC manuscript no 3067616635058181 )

which has now been uploaded in combination with this cover letter and the respective point to point replies to reviewers 1 and 2.

Please note that the rather invasive recommendations of reviewer 2 meant some deeper changes in the discussion section and partially throughout the manuscript. Nevertheless, as both reviewers recommendations were quite constructive and explicit we felt it necessary to oblige to their suggestions whenever possible. The point to point replies indicate the extensions of the presentation and its various changes.

We would be delighted, if the manuscript could now be taken into consideration for acceptance and publication by BMC Health Services Research!

Best regards,
Frank Krummenauer, Klaus-Peter Günther & Stephan Kirschner
Dear Prof Vanhaecht,

we greatly appreciate your constructive suggestions and the encouraging overall estimation of our manuscript. Unfortunately, due to some technical problems with the electronic manuscript handling system, we received these comments rather late, so that our revision took some time. Nevertheless we hope that we could meet your proposals satisfactory despite this delay.

Best regards, Frank Krummenauer, Klaus-Peter Günther and Stefan Kirschner

point 1 (design)

A new Figure 1 has now been incorporated into the overall presentation, which demonstrates the sequential cohort design and the split-up of the post pathway cohort 2 into two sub cohorts in terms of individual attendance of the briefing offer as part of the implemented pathway.

point 2 (setting)

A brief description of the Dresden University Hospital’s Orthopedic Surgery Department has now been incorporated into the Methods Section with special regard to the aspect „locally available competences and facilities“.

point 3 (pathway description)

To avoid lengthening of the presentation at hand, we added two recent publication references of our team, which focus on to details of the implemented TKA pathway and ist derivation. Note that these publications do not interfere with the manuscript at hand, as the latter merely concentrates on the clinical and economical evaluation of the pre / post pathway implementation data, whereas the added references primarily concentrate on process information and patient satisfaction according to pathway changes.

Your presumption that the pre pathway implementation cohort already passed a rather structured „underlying“ informal pathway, is certainly true as can be seen by the rather small median hospital stays before pathway implementation (which in fact did not change after the pathway implementation). We added a corresponding point into the Discussion section.

point 4 (Discussion)

a) In fact we did not measure the personal views and acceptance profiles of our staff concerning the positive and negative effect of the pathway implementation – by intention: The pathway implementation was thoroughly declared and understood a an improvement in quality assurance and thereby discussion was only restricted to the pathway’s development and implementation. Although this may sound a bit harsh, but we did not want to catalyse an overall Department discussion on a quality assurance tool, which could become colloquially discussed in the context of cost reductions. However, after 3 years of experience with this pathway we shall now take your advice as an encouragement for an independent assessment of the staff satisfaction with the pathway driven health care situation at hand (with special regard to its putative benefit in particular for „young doctors“ as a teaching device).
b) „pathway as a complex intervention“: we punctually refer to this point by means of the additional two new references of our team, which concentrate on pathways from this explicit process management designing perspective. In order to keep the presentation at hand rather strictly orientated to its clinical and health economic evaluation course, we hope you will be in accordance with this decision. Furthermore, we feel that this important – but complex – issue seems to deserve its own conceptual manuscript from a joint multidisciplinary perspective. We would be delighted if you would be interested in such a joint activity?

c) „pitfalls due to enthusiasms in pathways“: thanks for encouraging this perspective, which is not appreciated by too many publications. We added a Discussion on the cost consideration of implementation and maintenance of clinical pathways both with regard to the cost loss proportional to the expetable number of patients „not elegible for a critical pathway“ and with regard to the local specificity of pathways and the resulting difficulties due to any Department changes: „In terms of a cost–cost balance, surgical department coordinators may feel warned…”

point 5 (Statistics)

The corresponding author (FK) is a medical statistician, so that formal and factual statistical competence may have been met in this area. 😊
Dear Prof van Herck,

we greatly appreciate your constructive suggestions and the encouraging overall estimation of our manuscript. Unfortunately, due to some technical problems with the electronic manuscript handling system, we received these comments rather late, so that our revision took some time. Nevertheless we hope that we could meet your proposals satisfactory despite this delay.

Best regards, Frank Krummenauer, Klaus-Peter Günther and Stefan Kirschner

Replies to your comments and suggestions:

1. done
2. done; the Results section of the abstract now furthermore reports the findings for the primary endpoint (now also announced in the abstract’s Methods section). Note that we decided to thoroughly retain the primary endpoint chosen to design and power the investigation. We appreciate your recent review on alternative endpoint choices, but found it more favourable in terms of a confirmatory investigation to cling to the a priori planning information and assumptions. The same holds for the definition of the primary endpoint alongside an heuristic cost effectiveness cut point, but has now been commented on in the Discussion section (see below).
3. done
4. done, the Results summary is now directly related to the primary endpoint’s choice
5. done, the conclusion of the abstract now directly cites the manuscript’s setting
6. done; the Introduction now states: Note that this investigation will not focus on a reduction of the TKA patients’ individual or median length of stay as concentrated on by most recent literature: when the investigation was designed, it could already be assumed, that the Orthopedic Surgery Department has implemented standard processes achieving a somewhat short median overall length of stay by previous process optimization steps. As a consequence the critical pathway under consideration was designed to rather introduce patient-related features such as preoperative information on postoperatively expectable gain in health and mobility – and thereby to address compliance related issues rather than the underlying health care process itself. Nevertheless, since introduction of these pathway components had to be fully accomplished by the Orthopedic Surgery Department “at its own costs”, we decided to retain the Department’s perspective for the overall cost effectiveness consideration of implementing the clinical pathway.
7. Crucial point – thanks for figuring that out !!! After an initial shock on that issue we now feel a bit re-assured, that the timing bias may not have influenced the functional outcome too much: note that the three sub cohorts hardly differ in the preoperative WOMAC assessment (41% versus 44% for the overall and 41% versus 44 – 46% for the sub cohorts). This difference is far from being significant or clinically relevant as it corresponds to only minor rating differences in one or two of the overall score’s 24 items. If the timing issue would have introduced major bias, we should have expected a larger difference, which should even be in the different direction (note that the preoperative WOMAC ratings rather increase with the amount of individual preoperative briefing!). Nevertheless, you figured out a potential design flaw, which may implied biases beyound this primary endpoint assessment and is now critically commented on in the Discussion section: Note, however, that the design at hand may...
have introduced a different kind of bias due to the choice of time for the main intervention: the clinical pathway proposal under consideration mainly concentrates on patient-related information by means of written material and personal briefing and thereby addresses the area of patient compliance and awareness. As a matter of fact, this central part of the intervention was implemented before (!) the preoperative WOMAC assessment of the post pathway cohort, i.e. the preoperative functional assessment of this post-intervention cohort may have been biased in contrast to the corresponding ratings in the pre-intervention cohort. This bias may then also have been introduced into the marginal cost effectiveness estimates and thereby into the primary endpoint evaluation. On the other hand, Table 3 indicates, that all three subcohorts showed comparable preoperative median WOMAC scores (not differing locally significantly), with preoperative medians increasing proportionally to the amount of individually achieved information. Whether this gradient in preoperative score distributions is rather an indication of intervention-related bias in the above meaning or rather represents a consequence of different recruitment patterns among the pre and post pathway implementation cohorts (also relating to the willingness to undergo personal or written briefing) cannot be quantified by means of the data at hand.

8. The manuscript now references two recent references (19, 20) of our project group, which directly focus on the details of the underlying pathway and its conception as well as its process monitoring documentation. With regard to the increasing length of the paper and its clinical and health economic focus we decided to omit further details here. More information on the pathway’s nature in contrast to classical “LOS dimmers” is now provided in the Introduction and Discussion sections.

9. see above, now picked up in the Discussion section

10. The offer of a personal briefing attendance was held voluntary with regard to the patients age and socioeconomic status: note that TKA patients usually will require the help of relatives (requiring a lift etc) to attend the briefings. We found it unethical to force trial participants to attend the briefings by all means (which might have introduced severe bias into recruitment patterns and preoperative ratings!). The Discussion section now comments this issue directly.

11. done; as we did not properly quantify these human resources-related costs (which would been confounded by the costs of the trial implementation and conductance!), we restricted to only few cost components such as for the written material: Note that this primary estimation did not involve direct human resource-related costs for the implementation and maintenance of the pathway by the Department members, but only direct costs related to the patient-related intervention constituents such as the written material and the reimbursement of personal briefing attendances.

12. now specified more clearly in the Methods section in terms of the concentration on “total costs” (necessary to calculate cost effectiveness endpoints). On a more bilateral note we must admit, that the University Hospital’s administration went a bit unhappy with our initial intention of publishing cost sum details such as the radiology and physiotherapy cost constituents. The restriction to cost sums was somewhat of a “political compromise”…

13. see above

14. Here you raise an important issue, which was also discussed by our local Independent Ethics Committee: As our investigation was considered kind of “interventional” the local IEC recommended conductance according to the requirements of Good Clinical and Good Epidemiological Practice, which calls for the formal definition and confirmatory presentation of a primary endpoint such as chosen by the 100 € per gained percentage point criterion. With regard to this recommendation we formally
powered our investigation according to standards of clinical trials and therefore ended in a more or less difficult sample size calculation scenario. As a consequence, the sample size and power considerations rather reflect an a priori discussion on what is achievable based on billing informations in 2005 (then amounting to 4500 €) than a grounded discussion on what we know now in 2011. However, in terms of scientific correctness, we retained the original planning phase’s arguments, but now tried to figure out that the 4500 – 4000 reduction is rather an example for power illustration.

15. done (see Table 3) in the abstract and the Results section
16. done
17. done
18. see above; we tried to incorporate this crucial point into the Discussion section, but do not feel that there is was a notable (=measurable) bias involved. Unfortunately we do not have any further data on this available from the investigation under consideration. As we were not able to interview patients after ending the investigation (ethic committee’s vote!) we must admit that this question will have to be solved in a future punctual interview design on the short-term effect of the personal briefing.

19. The “minus” signs indicating ranges “from – to” have now been changes to “from ; to” and the remaining minus signs in fact correspond to extreme value outcome, that means individuals reporting a decrease in behaviour. Note that our inclusion criteria were in no way related to success criteria of the TKA itself but rather to its patient-related outcome in practically relevant situations (including failure patients).

20. As already commented above, we felt it necessary to oblige to the interventional character of the investigation and thereby to adhere to the analysis and reporting standards of GCP and GEP as also recommended by our local independent ethics committee. As a consequence the confirmatory question of the investigation was put in front and its exploratory re-evaluation was presented in terms of additional (and then hypotheses generating) information. In fact we found, that the baseline WOMAC score noshed up most of the explaining variability in this logistic regression modelling step (again indicating the relevance of your “time issue” argument above). On the other hand one must accomplish, that the modelling fit of these regressions was not too convincing with a Nagelkerke coefficient of only 68%. We now mention this in the Result section as a slight motivation of our reporting priority.

21. done
22. see above, the 68% goodness of fit indicate confounders beyound our model variables
23. That was an unlucky terminology of ours, now being re-formulated as “it may therefore be considered as having arisen from a somewhat asymmetric regression to the mean effect within the sub cohorts due to a slight (non significant) sub cohort difference in the preoperative WOMAC scores”. There may have occurred regression to the mean in all three sub cohorts due to the un-controlled sequential cohort design, but this effect may have been asymmetric due to the gradual preoperative WOMAC score differences.

24. We refered this statement to one explicit outlet of Rotter et al, whose conclusions were quite optimistic and – unfortunately – yet present one of the best-known and most-cited reviews in this area. The same would hold for the older review of Kim el al (2003), so that we felt in need of a somewhat “louder” statement of contrast. At the time being, the number of publications presenting pessimistic findings on critical pathways in surgery is still limited. We now explicitly re reference Rotter et al in this intention.

25. As the recent presentation concentrates on a cost-effectiveness scenario, we did not want to concentrate on this cost-cost evaluation here too much, but rather emphasized the problem of “underlying” human ressource costs for pathway implementation and
maintenance. The 25,000 € package is an estimate based on the assumption of an annual 50% employment for a medical documentation assistance (18,000 €), the loss in human resources among the Orthopedic Surgery Department staff for regular meetings during the conception phase and the human resources in experienced medical staff for supervising the development and implementation phase. As these estimates correspond to rather delicate and hardly reproducible retrospective calculations, we decided to restrict to this mimunum annual investment estimate. The topic has now been re-formulated as “As a broad initial estimation the latter will amount to not less 25,000 € per year and pathway (and certainly more during the conception and implementation phase), and will thereby crucially reduce the nominal cost reductions described above”.

26. sorry for that, you’re quite right here. The statement has now been weakened to “may not necessarily result in cost reduction, but can even end up in increased human resource investment”
27. sentence has been deleted, since the abstract concentrates on the pre / post cohorts
28. done
29. done (see also above)
30. done; the statement now explicitly refers to the WOMAC endpoint. As a bilateral information: We have also measured health-related quality of life by means of the EuroQol questionnaire and found even less cohort differences by means in the WOMAC endpoint. However, regarding the length of the presentation in mind, we omitted this additional data here.
31. done (“research intention” instead of “purpose”)
32. reformulated
33. as most of the literature still concentrates on LOS as the dominant surrogate of critical pathway evaluation (e.g. Rotter et al) and thereby meet larger benefit from pathway implementation as we found here based on patient-related information, we felt obliged to at least comment on the LOS issue.
34. The Introduction has been extended for several issues now.
35. … we tried our best…”