Author’s response to reviews

Title: The increasing importance of a continence nurse specialist to improve outcomes and save costs of urinary incontinence care: an analysis of future policy scenarios

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Author’s response to reviews:

Response of the authors to the reviewer reports:

Reviewer Carlos KH Wong (Reviewer 3)

Thank you for opportunity to review the statistical and methodological aspect of this submission. This is a modelling study simulating the cost-effectiveness and budgetary impact of optimum continence service specification (OCSS), based on incidence, prevalence data, effectiveness data from multiple data sources, and previously adapted decision analytic modelling on the cost-effectiveness of including nurse specialist in primary care urinary continence services.

The effectiveness estimates of continence nurse specialist were sourced from parent publication (ref#18) which assessed the ‘behavioral therapy group’ in a RCT design over a study period of 6 weeks. The evidence from this RCT provided short-term efficacy data so the observed data beyond 6 weeks and long-term data after implementation seem unavailable. In predicting long-term benefit of continence nurse specialist, how did authors extrapolate the effectiveness estimate beyond 6 weeks up to three years which is the time frame of model? Please specify the methodology of data extrapolation, if any.

Response of the authors:

We thank Carlos Wong for taking time to provide valuable feedback on our manuscript. We considered the comments and revised the manuscript accordingly.

We used in the model the following data regarding the effectiveness estimates of Subak et al.: mean and standard errors of reported % of cases treated initially by NP with improvement (mean 21%) and % cases treated initially by NP with success (mean 31%). Therefore, we assumed that
the benefits that were observed in the trial would hold. We assumed that there would be no relapses but also no late responders. Because of the uncertainty of the long term effects, we only modelled the outcomes over a three-year time horizon and not over a life time horizon.

We adapted the text as follows: “Effectiveness estimates of care provided by the nurse specialist in terms of improvement of the condition (mean 21%) and successfully treated (mean 31%) were based on a randomised controlled trial (RCT) by Subak et al. [18].”

As stated in statistical analyses and uncertainty analyses, quality-adjusted life-year (QALY) is the main outcome of this study, and is contributed by the estimates of health utility scores of patients with urinary incontinence. However, health utility scores of each health state simulated in model, and their corresponding data sources were uncertain. The possible health states in model were detected urinary incontinence, never detected urinary incontinence, incontinence after treatment, improvement after treatment, remission of incontinence after treatment. Were the health utility scores observed value from EQ-5D/SF-6D measures or estimated based on assumption? Without those information, the total QALYs shown in Table 3 were not convincing to readers.

Response of the authors:

Thank you very much for your feedback. We agree with the reviewer that the description on the model and the input parameters are limited in this manuscript. This was because we used the cost-effectiveness model which was previously published (Holtzer-Goor et al. 2015) including an extensive description of the model and all input parameters. In the manuscript we refer to this publication also for all input parameters that were identical to the previous model.

Table 5 in the publication of Holtzer-Goor et al. provides the utility scores and their source. The utility score for the “success health state” was 0.8595 and for the “failure health state” 0.8246. Both were based on the publication by Slieker-ten Hove et al. (2010). The utility score for the “improvement health state” was 0.84205, this was based on an assumption. In specific, the utility score was the mean of the other two health states (success and failure).

To provide more information on the input parameters without the need for accessing the publication of Holtzer-Goor et al., we added an extensive table for the online appendix describing the input parameters for PSA, including base-case setting, probability distribution and their source.

In addition, the distributions assigned to each parameter in PSA were unclear. Authors used a range of +/- 20% of the mean value as lower and upper bound used in PSA. How come cost parameters were not assigned log-normal distribution? ‘A uniform distribution was assumed for the remaining input parameters’ - what are the remaining input parameters?

Response of the authors:

The probability parameters were modelled following Beta distributions. Also utilities were modelled following Beta distributions.
We agree with the reviewer that it is standard practice to use a log normal or a gamma distribution for cost parameters. However, we had no information on the uncertainty of the cost outcomes, thus no standard errors or other type of uncertainty information. Therefore a range of ±20% was used as in the prior publication. To model this lack of data, we applied an uniform distribution. This is a more conservative approach as it brings more uncertainty in the model than a Gamma distribution would.

As described above, we added an extensive table for the online appendix describing the input parameters for the PSA, including base-case setting, probability distribution and their source.

In table 5, authors showed the probability of new care being more effective, probability of new care being cost-saving, and probability of new care being dominant strategy. I realized that authors took the term 'cost-saving' to mean less costly. Terms of 'dominant' and 'cost-saving' are usually interchangeable in health economics literature. I would recommend authors to use 'less costly' instead of 'cost-saving' to avoid confusion.

Response of the authors:

Thank you for your feedback. We agree with the reviewer that the terms ‘dominant’ and ‘cost-saving’ are usually interchangeable in the health economics literature. To avoid any confusion, we replaced at several place in the text the term ‘cost-saving’ with ‘less costly’. We also replaced cost-saving with less costly in table 5 as suggested by the reviewer.

Minor comments out of statistical scope:

P9 line50 will authors explain the rationale of converting ICPC-2 diagnosis codes to ICPC-1 codes?

Response of the authors:

Thank you for this, this may indeed seem somewhat unclear. The ICPC-2 codes were based on an Australian paper, however, the NIVEL database in the Netherlands still works with ICPC-1 codes, therefore, we had to make this conversion in order to combine data from both sources. We adapted the text in the manuscript as follows: “The definition of chronic disease was based on an existing list of the International Classification of Primary Care (the ICPC-2 codes of O'Halloran [20] were recoded to ICPC-1 codes used by the Dutch database).“

P9 line58: Table 1 is mentioned in text "Table 1 shows the key characteristics of the patient population in the model“ but the caption of table 1 is "Overview of the settings of the current situation and the scenarios for 2030" which caption describe Table 1?

Response of the authors:
Thank you for pointing out this inconsistency. We adapted the caption of Table 1 to: “Key characteristics of the patient population and overview of the settings of the current situation and the 2030 scenarios”

P10 line 11. "The model captures the complete pathway of Dutch patients as identified by healthcare experts". which types of healthcare experts helped to identify treatment pathway?

Response of the authors:

The treatment pathway was identified in the previous project by a series of interviews. We agree with the reviewer that this is important information also for the current project. Therefore we adapted the text as follows: “The model captures the complete pathway of Dutch patients as identified by a series of interviews with healthcare experts (3 GPs, 3 pelvic physiotherapists, 2 continence nurses, 3 gynaecologists, 2 surgeons, 2 urologists, a geriatric specialist, a gastroenterologist, and a pharmacists [16]).”

Reviewer Mark Harris (Reviewer 4)

The study explores the economic consequences of the specifications to provide specialist continence nursing in primary care (OCSS) in the Netherlands based on a number of different healthcare policy scenarios in an ageing population. The OCSS is a key focus of the study but description is quite limited. This is well described in reference 15 by Wagg et al but requires the reader to search for the publication (because there is no URL). There should be a diagram such as Fig 6 in the reference included in the paper.

Response of the authors:

We would like to thank Mark Harris for his effort to provide valuable feedback on our manuscript.

The reviewer may have misunderstood that we operationalised the OCSS new care strategy as the appointment of a nurse specialist at the master level, specifically taking care of urinary incontinence care within the GP practice. For usual care, no nurse specialist was assumed to be available within the GP practice. Therefore, there is no specific description of this nurse-led service determined, such a service is not yet implemented in The Netherlands. It was not the aim of this project to further develop or specify such a service as conducted by Wagg et al. Therefore it is not possible to provide diagram comparable to the diagram (Figure 6) by Wagg et al. In case such as service will be implemented, it will be important to further specify the description of the tasks of this nurse led service which should be based on the components as described by Wagg et al.

To ensure that readers understand the operationalisation of the OCSS strategy correctly, we amended the text as follows: “The OCSS strategy is not yet implemented in The Netherlands. Therefore, it was operationalised in our model as the appointment of a nurse specialist (at a master level) who is responsible for urinary continence care within the GP practice in the Dutch
primary care setting. The implementation of this new care strategy compared to usual care includes the following changes to the current delivery of care: i) more active case detection; ii) initial assessment and treatment by a continence nurse specialist; and iii) improved case coordination [15]. The appointed nurse specialist can either be specialised in continence care visiting several GP practices or specialised in various chronic conditions (e.g., incontinence, stoma and wound care) and appointed within one GP practice. The type of nurse specialist proposed in this evaluation is responsible for urinary continence care and is specially trained to carry out physical examinations, prescribe drugs and containment products, and refer patients to specialist care.”

The authors wording in the introduction seems to suggest that the authors have prejudged their study (page 7 line 57-59, page 8 line1). [The line numbers throughout the manuscript do not line up with the text lines]. These comments are referenced to [16] (Holtzer-Goor et al) which is a cost effectiveness study on the OCSS. It should be more clearly stated that these are findings of that study. It is also important to explain how the current paper adds to this previous study which concludes that under the new OCSS"a QALY gain of 0.005 per patient is achieved while saving €402 per patient over a 3 year period from a societal perspective”.

Response of the authors:

Thank you for your feedback. We had no intention to prejudge our study and refer to the findings previously reported. We have adapted the text in the introduction as follows: “This implies that postponing the implementation of the OCSS new care strategy costs health and money. Extrapolation of the results of Holtzer-Goor et al. [16] suggest that if the new strategy would not be implemented within the next 15 years, over €145 Million and €585 Million of savings could be forgone in health care and society, respectively. However, mainly due to ageing of the population, it is expected that the number of urinary incontinence affected individuals will rise in the future [17]. Consequently, healthcare and societal costs of continence care most likely further increase, which implies that even greater potential savings could be achievable. Moreover, there is an ongoing trend in (Dutch) healthcare policymaking to shift formal care (covered by insurance) to informal care and to lower the degree of institutionalisation. These demographic and policy changes, in combination with the impact of the condition on the quality of life of patients and the role of informal care givers, make it increasingly important to improve urinary incontinence treatment pathways for community-dwelling elderly. There is, however, no evidence on the future costs and budgetary consequences of continence care.”

The methodology is complex and should be reviewed by a health economist. Effectiveness estimates are based on one RCT by Subak et al. published in 2002 of the effect of behavioural therapy on urinary incontinence involving 152 women in the US. This found a 50% reduction in mean number of incontinent episodes recorded on a 7-day urinary diary compared with a 15% reduction for controls. A number of systematic reviews have concluded that behavioural interventions are effective but that there are few high-quality studies. The authors acknowledge on page 24 that other studies have not shown such large effects. Technology assessments in other jurisdictions (eg Canada) have been more cautious than the authors. This deserves more discussion.
Response of the authors:

Thank for your comment. We have added to this section in the discussion the following:

“Furthermore, previous results of the model published by Holtzer-Goor et al. [16] showed that the new care strategy still yielded QALY gains and resulted in lower costs even in case the new care strategy was assumed only to impact the detection rate and not the effectiveness rate. Our extreme case scenarios further underline the robustness of our results.”

The discussion is focused on the economic case for the OCSS in the Netherlands. To be relevant to readers of the Journal, the paper should discuss the implications for implementation in primary care. There is a brief reference on page 9 to the model which may involve either a specialist continence nurse visiting several general practices or being appointed within only one practice but having other roles. This should be discussed in more detail. The two models would have quite different logistic and cost implications as well influencing the extent to which they will be seen either as a visiting practitioner or as a member of the practice team. It is unclear what the financing mechanism would be for these two models.

Response of the authors:

This feedback is very much related to the first point of the reviewer. The reviewer may have misunderstood that we operationalised the OCSS new care strategy as the appointment of a nurse specialist specifically taking care of urinary incontinence care within the GP practice. For usual care, no nurse specialist was assumed to be available within the GP practice. This means that it is especially relevant for this journal because it concerns primary care practice and in specific potential cost savings within primary care. As this nurse-led service is not yet implemented in The Netherlands, further specifications of the tasks and logistics are to be determined in a later phase and are beyond the scope of this manuscript. We agree with the reviewer that the logistics will be different in case the nurse specialist visits several GP practices or will be appointed within one GP practice (and for example also be responsible for other nurse specialist care). However, the costs for the implementation of this service are mainly determined on the training (master level) of the nurse(s) and wage rates, which were both taken into account as implementation costs. These implementation costs were relatively small compared to all potential savings of such a service (as can be seen in our results in the tables and figures). We believe that it is beyond the scope of this manuscript to discuss the financing mechanism of the primary care settings. We only show that on the national level large savings (in healthcare costs as well as societal costs) are possible in case such a program would be implemented, irrespectively of healthcare context.

We added to the discussion section: “Although beyond the scope of our study, in case the new care strategy will be implemented, the description and details of this nurse led service and its finance mechanism should be further developed based on the components as described by Wagg et al. [15] taking into account context specific healthcare policies and organisation.”