Improving management of breech presentation at term

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Cost-effectiveness of improving implementation of external cephalic version for term breech presentation.

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ABSTRACT

Objective To assess cost-effectiveness of two implementation strategies developed to improve the external cephalic version rate compared to care as usual.

Design Economic evaluation based on the results of a randomised controlled trial on the implementation of two strategies to improve external cephalic version rates. Clusters were randomised to the client strategy (information leaflets and decision aid), a care provider strategy (one day counselling course focussed on knowledge and counselling skills), or to both strategies combined. For this economic evaluation, the baseline implementation rate of external cephalic version in each cluster was used as comparator.

Setting 25 clusters, each consisting of a hospital and referring midwifery practices in the Netherlands.

Population Pregnant women with a breech presentation from 32 weeks onwards.

Methods Model based cost-effectiveness analysis from a hospital perspective.

Main outcome measures We estimated direct medical costs in euros per client, associated with healthcare utilisation from start of the implementation strategies until the version attempt, and until birth. We calculated the incremental cost-effectiveness ratio as costs per extra version attempt, and per prevented caesarean section.

Results The combination of the client and care provider implementation strategy has the best potential to improve external cephalic version rates (mean increase 7%, range among clusters 3-44%). The extra costs per client associated with the implementation strategy were €83, the incremental cost-effectiveness ratio to gain one ECV attempt was €1,119 (range €190 - €2,659). If the effect of the implementation strategy sustains for two years after implementation, the extra costs per patient would decrease to €64 (incremental cost-effectiveness ratio €865 (range €147 – €2,055)). As ECV attempt rates were only modestly improved due to poor adherence to implementation strategies, caesarean section rates were more or less unaffected.

Conclusions Implementation of external cephalic version rates can be improved by a strategy focussing on both clients and care providers. Whether this strategy is cost-effective depends on the societal willingness to pay for an additional attempt, and the sustainability of the effect of the implementation strategy.
INTRODUCTION
Breech presentation occurs in 3 to 4% of all term pregnancies. Since the publication of the Term Breech Trial results, the majority of breech presentations at birth are managed by elective caesarean section. This randomised controlled trial reported a significant increased neonatal morbidity and mortality during planned vaginal breech delivery.\(^1\) This has led to elective caesarean sections rates up to 90% in the UK and 96% in Australia.\(^2,3\) The downside of these caesarean sections is the increased maternal and neonatal morbidity and mortality in subsequent pregnancies due to the scarred uterus.\(^4-6\) Whether the gain in neonatal outcome due to planned caesarean section for breech presentation outweighs the neonatal risks in the subsequent pregnancy, is still a topic of debate Thus, prevention of breech presentation at birth should have a high priority in every obstetric unit.

External cephalic version (ECV) is an effective and safe treatment to prevent breech presentation at birth.\(^7,8\) It is proven to be a cost effective intervention when compared to the planned caesarean section, if success rates of ECV are above the 32% (society’s perspective, USA).\(^9\) However, recommendation of ECV in professional guidelines, has not automatically led to an optimal implementation of this intervention.\(^10-13\)

We have developed two implementation strategies to improve the ECV implementation rate in the Netherlands.\(^14-16\) The aim of this economic evaluation study was to estimate the costs associated with these implementation strategies and the incremental costs in order to achieve an extra ECV attempt, and to prevent a caesarean section.

METHODS

Study design
A model based economic evaluation was performed, where results from a cluster randomised controlled trial (RCT) of the implementation of ECV were used to estimate parameters in the model.\(^14-16\) This trial compared the effectiveness of two implementation strategies (a client and a care provider strategy) on the ECV rate within clusters (a hospital and the referring midwifery practices). Clusters were randomised in a two-by-two factorial design meaning that they were assigned to either the client strategy, the care provider strategy, both implementation strategies, or care as usual. Within the client strategy, clients received an information leaflet on ECV and...
a decision aid on ECV.\textsuperscript{17} During a two hour kick-off meeting, all participating care providers received the user instruction; they were asked to hand out the leaflet and decision aid to all women with a breech presentation from 32 weeks onwards and to schedule an extra counselling appointment. The care provider strategy contained a one day counselling course. Participants were informed on the contents of national guidelines and relevant literature emphasising the importance, benefits and risks of ECV.\textsuperscript{18,19} Furthermore, participants were trained in counselling by a counselling coach. After enrolment of the implementation strategies within the clusters, data on all consecutive women with a singleton breech presentation from 32 weeks onwards, eligible for ECV, over a period of nine months were collected; in total 1,613 women from 25 clusters. We will briefly describe the results of this cluster RCT to introduce the choices we made for the model parameters within this economic evaluation. The main outcome of this trial was the effect of the implementation strategy on the ECV rate compared to those clusters who were not exposed to the implementation strategy. The overall implementation rate was 72\% (1,169 of 1,613 eligible clients) with a range between clusters of 8-95\%. Neither the client (OR 0.64 (95\% CI 0.30-1.39)) nor the care provider strategy (OR 1.98 (95\% CI 0.72-4.47)) showed significant improvements. As it was unclear, whether contamination occurred, positively affecting the results in the control group (e.g. increased awareness through participation, Hawthorne effect), and because of the large intra-cluster variation of implementation of ECV, we performed a retrospective baseline measurement within the participating clusters. Therefore, we identified all consecutive breech deliveries from 36 0/7 weeks gestation and onwards from hospital birth registers between the 1st of January 2008 and the 31st of December 2009. We reviewed patient files to collect data on ECV attempts or reasons why no ECV was offered or performed. ECV registers are missing in most clusters and therefore we were not able to collect data on successful ECV attempts. Estimates for model parameters are derived from data on 2,077 breech presentations. In this economic evaluation, we compared changes in the implementation rate of ECV between the baseline measurement and the outcomes of the strategies evaluated in the cluster randomized controlled trial, after adjusting for the missing 37\% successful ECV attempts (mean ECV success rate in the cluster RCT).
Model parameters
Outcomes
The following outcome parameters were used in our model: the percentage of women counselled for ECV, percentage opting for ECV, the overall ECV attempt rate, the mean ECV success rate, adherence rate of care providers to the implemented strategy and caesarean section rates among women with a cephalic presentation after successful ECV, breech presentation after failed ECV and breech presentation without an ECV attempt.
Parameters estimates are provided in Table 1. Estimates and ranges reflecting their uncertainty are based on the results of the baseline measurement and cluster RCT. For those parameters influencing the ECV implementation rate (percentage counselled, opting and overall ECV attempt) we calculated the mean of clusters assigned to one strategy with a range representing the worst and best achieving cluster within that strategy. For all other parameters (ECV success rate and CS rates) we used mean and range values for all clusters, irrespective of strategy.

\[ \text{Table 1. Model parameters of outcomes based on results of study cohort} \]

<table>
<thead>
<tr>
<th></th>
<th>Baseline measurement</th>
<th>Cluster RCT</th>
<th>Δ improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adherence to strategy</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Client</td>
<td>-</td>
<td>0.24</td>
<td>-</td>
</tr>
<tr>
<td>Care provider</td>
<td>-</td>
<td>0.21</td>
<td>-</td>
</tr>
<tr>
<td>Combined</td>
<td>-</td>
<td>0.23</td>
<td>-</td>
</tr>
<tr>
<td>ECV attempts</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Client</td>
<td>0.74</td>
<td>0.68</td>
<td>-0.05</td>
</tr>
<tr>
<td>Care provider</td>
<td>0.68</td>
<td>0.66</td>
<td>-0.02</td>
</tr>
<tr>
<td>Combined</td>
<td>0.78</td>
<td>0.86</td>
<td>0.07</td>
</tr>
<tr>
<td>CS without ECV</td>
<td>0.91</td>
<td>0.91</td>
<td>-</td>
</tr>
<tr>
<td>CS after failed ECV</td>
<td>0.78</td>
<td>0.78</td>
<td>-</td>
</tr>
<tr>
<td>CS after successful ECV</td>
<td>0.14</td>
<td>0.14</td>
<td>-</td>
</tr>
<tr>
<td>Overall CS rate</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Client</td>
<td>0.67</td>
<td>0.67</td>
<td>0.01</td>
</tr>
<tr>
<td>Care provider</td>
<td>0.68</td>
<td>0.68</td>
<td>0.00</td>
</tr>
<tr>
<td>Combined</td>
<td>0.66</td>
<td>0.65</td>
<td>-0.01</td>
</tr>
</tbody>
</table>
*Ranges represent the worst and best achieving cluster on ECV within one strategy*
*^Including the successful ECV attempts (37% of all ECV attempts)*
Costs
Estimates for cost parameters were calculated from a health care perspective. All costs were expressed in 2012 euros and inflated where appropriate according to the consumer pricing index. Costs were divided into implementation costs (costs related to deploying the strategy into clinical practice) and operational costs (costs related to counsel a client according to standard care or the implementation strategy, and the costs of an ECV attempt). The baseline estimates, range and references of cost parameters are presented in Table 2. We accounted for suboptimal adherence of care providers to the implementation strategy. Adherence rates were 24%, 21% and 23% for the client, care provider and combined strategy respectively. Thus we only included extra operational costs of the implementation strategy into account for those clients actually counselled according to the strategy (adherence rate). For the remaining women, we included the baseline costs of counseling.

Analyses

Cost-effectiveness
The primary measure of effectiveness was the change in ECV attempts, and expressed as the increase/decrease in the probability that a woman presenting with a breech presentation will have an ECV attempt. The associated costs were estimated as the average costs per woman presenting with a breech presentation. Secondary outcomes were change in caesarean section rate (increased/decreased probability of a CS) and associated costs per client presenting with a breech presentation. While costs of the ECV attempt itself were not included in the cost per change in ECV rate (to avoid double counting), these costs were taken into account in the cost per change in CS rate.

The incremental cost-effectiveness ratios (ICER) combines costs and clinical outcomes in a single figure, and is defined as ratio of the difference in effectiveness and the difference in costs, as compared to a reference strategy. ICERs for each of the three implementation strategies reflect the costs needed to obtain one extra ECV or to prevent one caesarean section, as compared to the care as usual strategy.
Table 2. Estimated costs of implementation strategies and standard care (2012 €)

<table>
<thead>
<tr>
<th>Units</th>
<th>Baseline Estimate €</th>
</tr>
</thead>
</table>

### Implementation costs

**Client**
- Two-hour introduction session
  - Midwife (n=89) per hour: 37€
  - Gynaecologist (n=24) per hour: 76€
  - Project leaders (n=1) per hour: 15€
  - Overall costs per session: 10,264€

**Care provider**
- Training course of 8 hours
  - Midwife (n=41) per hour: 37€
  - Gynaecologist (n=5) per hour: 76€
  - Project leaders (n=2) per hour: 15€
  - Consultant (counselling) (n=1) per hour: 125€
  - Actress (n=1) per hour: 85€
  - Overall costs per session: 17,096€

**Combined**
- Training course of 9 hours
  - Midwife (n=41) per hour: 37€
  - Gynaecologist (n=5) per hour: 76€
  - Project leaders (n=2) per hour: 15€
  - Consultant (counselling) (n=1) per hour: 125€
  - Actress (n=1) per hour: 85€
  - Overall costs per session: 19,023€

### Operational costs

**Client**
- Decision aid per client: 0.84€
- Information leaflet per client: 0.73€
- Counselling appointment per client: 254€
- Extra counselling appointment per client: 254€
  - Overall costs per client: 510€

**Care provider**
- Counselling appointment per client: 254€
  - Overall costs per client: 254€

**Combined**
- Decision aid per client: 0.84€
- Information leaflet per client: 0.73€
- Counselling appointment per client: 254€
- Extra counselling appointment per client: 254€
  - Overall costs per client: 510€

**ECV attempt**
- Per client: 843€

Sensitivity and scenario analysis
Robustness of our findings was evaluated in several sensitivity analyses. The lower and upper limit of the confidence interval of effectiveness and ICER are based on the analyses where the mean probabilities are replaced by the probabilities of the worst and best achieving clusters in the RCT. In addition to the base case model (model 0), using the most probable estimates for all model parameters, we evaluated the consequence of different assumptions in effectiveness and cost estimates in the following seven analyses. In model 1 and 2, we have assessed the impact of respectively an overestimation or underestimation of the overall costs by 10%, which corresponds to the range in costs among different sources. In model 3, we assumed that the observed effects of the implementation strategies sustain for two years (instead of nine months) after introduction of the strategies. As a consequence the implementation costs per client were decreased in this scenario. In the fourth model, we assumed that a second introduction session of the implementation strategy would double the effect on adherence to the implementation strategy as more care providers are reached. In the fifth analysis, both scenarios were combined; a sustained effect and a repeated implementation.

All statistical analyses to calculate model parameters from primary study data were performed using SPSS version 18.0 (Chicago, IL, USA), and MICROSOFT EXCEL 2003 was used to develop the model and perform sensitivity analyses.

RESULTS

Cost-effectiveness of change in ECV attempts
Results of our economic evaluation are presented in Table 3. After using the client strategy, on average the percentage ECV attempts decreased by 5% (range -37% to +32% among different clusters). On average, costs per client in the client strategy increased by €45. After the care provider strategy, the percentage of ECV attempts decreased by 2% (range -70% to +44%). The care provider strategy resulted in a cost decrease of €5. Combining both strategies increased the ECV rate by 7% (range +3 to +44%). The additional costs per client were €83.

The client as well as the care provider strategy led to less ECV attempts against higher costs (inferior strategies, with non-informative ICERs). Only the combined strategy led to increase in ECV attempts against higher costs
In the base case, the costs to achieve one extra ECV attempt were €1,119 (range among clusters €190 to €2,659).

Sensitivity analyses
The differences in outcomes, costs and ICERs for the different sensitivity analyses are presented in Table 4 and Figure 1 and 2. Varying implementation and operational costs (sensitivity analyses, model 1 and 2) led to a range from €1,007 to €1,213 around the mean of €1,119 per extra ECV attempt. Model 3 presents the scenario that the effect of our implementation strategies will reach beyond the nine month follow up of the cluster RCT. If the effect would maintain for two years, the ICER of the combined strategy would be lowered to €865 (range €147 – €2,055). Model 4 evaluate scenarios were ECV implementation rates would be further increased; repeated implementation courses to improve adherence of care providers to the implementation strategies would still not lead to an overall increase of ECV attempts in the client or care provider strategy. The implementation rate within the combined strategy would be improved by 15%, but against costs of €495 per patient, resulting in an ICER of €3,320 (range €564 – €7,888). If both sustained effect and repeated courses were taken into account (model 5), the ICER would be €1,602 (range €272 – €3,806).

(with ICERs indicating costs associated per unit in health gained).
Table 4. Sensitivity and scenario analyses for the combined strategy (2012 €)

<table>
<thead>
<tr>
<th>Model</th>
<th>Description</th>
<th>Strategy</th>
<th>Δ improvement ECV</th>
<th>Δ improvement CS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>%</td>
<td>min - max</td>
</tr>
<tr>
<td>Univariate sensitivity analyses</td>
<td>0. Base case</td>
<td>Client</td>
<td>-0.05</td>
<td>-0.37 - 0.32</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Care provider</td>
<td>-0.02</td>
<td>-0.70 - 0.44</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Combined</td>
<td>0.07</td>
<td>0.03 - 0.44</td>
</tr>
<tr>
<td></td>
<td>1. 10% Higher implementation and operational costs</td>
<td>Client</td>
<td>-0.05</td>
<td>-0.37 - 0.32</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Care provider</td>
<td>-0.02</td>
<td>-0.70 - 0.44</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Combined</td>
<td>0.07</td>
<td>0.03 - 0.44</td>
</tr>
<tr>
<td></td>
<td>2. 10% Lower implementation and operational costs</td>
<td>Client</td>
<td>-0.05</td>
<td>-0.37 - 0.32</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Care provider</td>
<td>-0.02</td>
<td>-0.70 - 0.44</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Combined</td>
<td>0.07</td>
<td>0.03 - 0.44</td>
</tr>
<tr>
<td>Scenario analyses</td>
<td>3. Sustained effect of implementation strategies up to two years</td>
<td>Client</td>
<td>-0.05</td>
<td>-0.37 - 0.32</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Care provider</td>
<td>-0.02</td>
<td>-0.70 - 0.44</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Combined</td>
<td>0.07</td>
<td>0.03 - 0.44</td>
</tr>
<tr>
<td></td>
<td>4. Repeated implementation to double adherence</td>
<td>Client</td>
<td>-0.03</td>
<td>-0.18 - 0.64</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Care provider</td>
<td>-0.01</td>
<td>-0.35 - 0.88</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Combined</td>
<td>0.15</td>
<td>0.06 - 0.88</td>
</tr>
<tr>
<td></td>
<td>5. Repeated implementation, sustained effect</td>
<td>Client</td>
<td>-0.03</td>
<td>-0.18 - 0.64</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Care provider</td>
<td>-0.01</td>
<td>-0.35 - 0.88</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Combined</td>
<td>0.15</td>
<td>0.06 - 0.88</td>
</tr>
</tbody>
</table>

The ICER of ECV are the extra costs per ECV attempt. The ICER can be positive or negative valued based on the effect on ECV attempts or CS rates. If positive, the scenario leads to more ECV attempts against more costs. If negative, the scenario leads to less ECV attempts against more costs.

*The ICER for this scenario means that there were less ECV attempts against less costs

^The ICER for this scenario means that there were more CS against more costs.
The results are also summarized in a cost-effectiveness plane (shown in Figure 1). Points located in the upper right quadrant represent those strategies are more effective (i.e. result in more ECV) but at higher costs. Points in the upper left quadrant represent inferior strategies, as they are less effective (i.e. decreased ECV rate) but at higher costs. This figure clearly visualises that only the combined strategy could be a cost-effective alternative to improve ECV attempt rates, if society is willing to pay the additional costs to achieve this improvement in ECV attempt rate. If the effect of that strategy last up to two years, the costs are €64 per client to achieve a mean increase of 7% in ECV attempt rates.

Cost-effectiveness of change in planned caesarean sections
As a result of these limited effects of implementation strategies on the ECV attempt rate, caesarean section rates were more or less unaffected. In the client strategy the caesarean section rate increased with 1% (range -5% to 6%), in the care provider strategy the caesarean section rate remained unchanged (0%, range -7 to 11%) and in the combined strategy the caesarean
section rate was reduced with 1% (range -7 to 0%). The additional costs per client presenting with a breech presentation were €83, €73 and €221 for respectively the client, care provider and combined strategy in the caesarean section model (costs of ECV were taken into account). Due to the minor change in mean caesarean section rates, the incremental cost-effectiveness ratios were very high (Table 3). the ICER for the combined strategy was €19,119 (range €3,248-€45,418) per prevented caesarean section. The difference in direct medical costs between a caesarean section compared to a vaginal breech delivery is approximately €1500,21 and the break-even point for the combined strategy to become cost effective is a 95% increase in ECV rate. The results with planned caesarean sections as an outcome are also visualised in a cost effectiveness plane (Figure 2).

Figure 2. Cost-effectiveness plane. Each point in the cost-effectiveness plane represent the additional costs per patient and change in planned caesarean delivery rate for the different strategies and different sensitivity and scenario analyses (the points are numbered according to the corresponding analysis).

The points in the upper right quadrant, represent those strategies which led to more planned caesarean deliveries are performed against additional costs. The points in the upper left quadrant represent strategies which decreased the caesarean section rate against more costs. If society is willing to pay the considerable costs to prevent one caesarean section, the combined strategy could become cost-effective.
DISCUSSION
This study evaluated the cost-effectiveness of different implementation strategies to improve ECV rates within clusters. The economic analysis was performed from a health care perspective, based on results of the cluster randomised controlled trial on the implementation of ECV, and the baseline measurement performed within the participating clusters. Our analyses showed that the combined strategy (client and care provider strategies together) has the best potential to increase ECV implementation rates. Only in those regions with the highest increase in ECV rates, the incremental cost effectiveness ratios (costs per additional ECV) could be considered acceptable. However, in terms of improving planned caesarean section rates, the costs per prevented planned caesarean section always largely exceed the costs savings resulting from the intervention prevented. The wide range in effect of the client strategy and care provider strategy to improve ECV implementation rates is mainly due to those clusters which contributed the least amount of patients and could be defined as outliers. Costs are estimated on reliable sources, but the costs per ECV attempt and counseling are relatively high compared to the costs per strategy and have a great influence on the outcome of the cost effectiveness analyses to prevent a caesarean section. If these costs could be lowered (for instance by more efficient organization or group-counseling), the strategies might become more cost effective.

Strength and limitations
A strength of our study is the accuracy of the model parameters which were based on the prospective data gathering within the cluster randomised controlled trial; the effects of the implementation strategies on ECV attempts and mode of delivery. The baseline measurement, made it possible to deal with the wide range of ECV implementation rates among clusters and evaluate the effect of the implementation strategies within clusters and not only between the clusters assigned to the different strategies. The scenario analyses shed light on the potential opportunities of the strategy, beyond the study protocol of the cluster randomised controlled trial. Sustained effectiveness of the implementation strategies would decrease the costs per gained ECV attempt, but the willingness to pay needed for the combination strategy to be considered cost-effective remained high. The break-even point of a 95% improvement can only be reached in those clusters with very poor baseline implementation rates. The break-even point could be lower
in other settings (countries) with higher CS rates for breech presentation at birth, as the effect of ECV at the CS rate would be more distinct. (The break-even point might also be lower if downstream costs are taken into account; prevention of CS leads to less repeated CS and less complications in subsequent pregnancies. Repeated implementation efforts to increase the uptake of ECV only led to an increase of the incremental cost effectiveness ratios.

Limitations of this study are similar to those of any cost-effectiveness analysis. In our analysis we have assumed that ECV success rates are equal among all clusters (we took the average rates). We made this assumption to reflect the effect of the implementation strategy on planned caesarean section rates in an unbiased way. We know from other studies that assuming a mean ECV success rates of 37% is a reasonable assumption for the Dutch setting. But some regions with high ECV implementation rates, also achieved ECV success rates up to 60%. If implementation strategies were developed, not only to increase the quantity (amount of attempts) but also the quality (success rates) of the ECV attempt, these might be more effective in prevention of CS. Our model could be further refined by taking these effects into account, if more data become available in future studies on the topic of improvement of ECV success rates.

A potential bias in our study is the time window between the baseline measurement within the clusters (2008-2009) and the cluster randomized controlled trial (2011-2012). During the trial, we did not have any clues to suspect another change in ECV policy among clusters, which could have caused the measured effect of the combined strategy. Potential bias could be caused by the so called Hawthorne effect: care providers might have put more effort in the counselling for ECV as they knew they were being monitored during the study period. If this has played any role in the outcome, it probably would have influenced the results of certain regions more (best performing regions) compared to others (decrease in ECV implementation rates). The mean effect of the strategies and results of best performing clusters might be slightly overrated due to this effect.
Relation to other studies
To our knowledge, this is the first study to evaluate the cost-effectiveness of different strategies to improve the implementation of ECV. Our results show the difficulties to change common practice and the effort and costs needed to achieve minimal change. This is contrary to societies expectations that care providers work according to state of the art guidelines, and only differ if it can be argued.

CONCLUSION

An implementation strategy focusing on both patients and care providers can improve ECV implementation rates, but against considerable costs. Whether this strategy is cost-effective depends on the societal willingness to pay for an additional attempt, and the sustainability of the effect of the implementation strategy. None of the strategies was cost-effective to improve planned caesarean section rates.
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Chapter 11 Cost-effectiveness of improving implementation


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Chapter 11 Cost-effectiveness of improving implementation


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