Surgical management of tubal pregnancy
Mol, Femke

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Guideline adherence in ectopic pregnancy management

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CHAPTER 3

ABSTRACT

BACKGROUND: Evidence-based guidelines have been issued for ectopic pregnancy (EP), covering both diagnostic and therapeutic management. In general, guidelines aim to reduce practice variation and to improve quality of care. To assess the guideline adherence in the management of EP, we developed guideline-based quality indicators and measured patient care in various hospitals.

METHODS: A panel of experts and clinicians developed quality indicators based on recommendations from the Dutch guideline on EP management, using the systematic RAND-modified Delphi method. With these indicators, patient care was assessed in six Dutch hospitals between January 2003 and December 2005. For each quality indicator, a ratio for guideline adherence was calculated. Overall adherence was reported, as well as adherence per hospital type, i.e. academic, teaching and non-teaching hospitals.

RESULTS: Out of 30 guideline-based recommendations, 12 quality indicators were selected covering procedural, structural and outcome aspects of care. For 317 women surgically treated for EP, these aspects were assessed. Overall adherence to the guideline was 75%. The highest adherence (98%) was observed for performing transvaginal sonography during the diagnostic workup. The lowest adherence (21%) was observed for performing salpingotomy in case of contra-lateral tubal pathology. Wide variance in adherence (0–100%) existed between academic, teaching and non-teaching hospitals.

CONCLUSIONS: The overall guideline adherence was reasonable, with ample room for improvement in various aspects of care. Further research should focus on the barriers for guideline dissemination and adherence, to further improve the management of EP.
INTRODUCTION

Ectopic pregnancy (EP) is nowadays mostly a benign condition, which lends itself to conservative management. However, if the diagnosis is delayed or missed altogether, tubal rupture with intra-abdominal bleeding may occur as a potentially life-threatening complication, requiring emergency surgery (1). Despite the awareness of these hazards among clinicians, the maternal mortality rate (MMR) for EP has remained low but static since 1985 at a rate of 0.5 per 100,000 maternities in the UK (2). In The Netherlands, the MMR is very similar (3). Obviously, the clinical challenge is to avoid tubal rupture by making a correct and timely diagnosis, thereby optimizing fertility prospects. In the UK, a key recommendation of the Centre for Maternal and Child Enquiries is to develop guidelines for pain and bleeding in early pregnancy to increase awareness and diagnostic accuracy among clinicians to prevent first trimester maternal deaths (2). In 2001, the Dutch Society of Obstetrics and Gynaecology issued an evidence-based guideline on diagnosis and management of EP (4). The guideline was accepted by the members of the society in their annual meeting. Hereafter, the guideline was published online (www.nvog.nl) and sent as a paper version to all the members of the society. However, the implementation of evidence-based guidelines in daily practice is often problematic (5-7). Passive dissemination of information alone is generally ineffective and in daily practice only 60–70% of all patients receive care based on scientific evidence (8).

It is unknown to what extent the recommendations from EP guidelines have been implemented in clinical practice. To answer this question, we developed a set of quality indicators. These indicators were then used to assess the quality of actual care for women with EP.

MATERIALS AND METHODS

Indicator development

The systematic RAND-modified Delphi method was used to develop quality indicators based on the Dutch guideline on the management of EP (9-12). This stepwise method consists of three expert consensus rounds with independent expert ratings and repetitive feedback. The expert panel comprised a representative diversity of eight experts in the field and clinical guideline users working at academic and teaching hospitals in The Netherlands. They were either gynaecologist subspecialists in Reproductive Medicine, gynaecologists working in Early Pregnancy Units or residents with a PhD in early pregnancy complications. In Step 1, recommendations from the guideline were extracted separately by two authors (F.M. and P.J.H.). In Step 2, the extracted recommendations were presented to the members of the expert panel who individually scored each recommendation on a five-point Likert scale (ranging from 1 = hardly relevant to 5 = extremely relevant) in terms of health gain,
efficacy, measurability and the presence of any room for improvement of care. We then
asked the expert panel to prioritize the recommendations being ‘most important’ and/
or ‘representative’ using a top-ten ranking. Recommendations ranked as 1 were given
10 points, ranked as 2 were given 9 points and so on. A maximum score of 80 points per
recommendation could be obtained when all experts ranked this recommendation as
number 1. Recommendations were rated as valid if they matched the Campbell criteria
(13). This means that consensus on high scoring recommendations was defined as a mean
individual score of ≥4 on the Likert scale per recommendation. Of these highly scoring
recommendations, only those with a top 10 ranking above the fifth percentile of the
maximum top 10 score were selected for the set of potential key recommendations. In
Step 3, the ranking of recommendations was plenary discussed in the expert panel, and
compared with the member’s individual scores until consensus was reached. Two authors
(F.M. and P.J.H.) evaluated the individual scores and rankings in terms of measurability and
potential for improvement (Step 4). In the last feedback round, the final set of 12 quality
indicators was presented to the expert panel (Step 5) and accepted with general consensus
by all its members.

Measurement of actual care

The guideline contains a diagnostic algorithm that combines transvaginal sonography (TVS)
findings with serial serum hCG measurements (Fig. 1).

Figure 1 Flowchart of the diagnostic algorithm as in the Dutch Guideline.
This non-invasive diagnostic algorithm enables an early and reliable diagnosis of EP (14, 15). The algorithm eventually classifies women as having a definite EP, an intrauterine pregnancy or a failing pregnancy of unknown location. Whenever the diagnosis definite EP is indicated by the algorithm, treatment should be performed the same or following day. In case of inconclusive TVS, a follow-up visit after 2 days for re-evaluation is mandatory.

The set of 12 quality indicators was used to assess actual care in women surgically treated for a tubal EP between January 2003 and December 2005 in six Dutch hospitals, i.e. two academic hospitals (Academic Medical Centre Amsterdam, University Medical Centre Utrecht), two teaching hospitals (Onze Lieve Vrouwe Gasthuis, Amsterdam and Máxima Medical Centre, Veldhoven) and in two non-teaching hospitals (Boven IJ Hospital, Amsterdam and Amstelveen Hospital, Amstelveen). Women were identified from the hospitals’ surgical and financial registries. Clinical data of women with EP were retrospectively collected from the medical charts, and scored according to the set of 12 quality indicators. The adherence per indicator was expressed as a ratio (percentage), i.e. the number of women submitted to a specific test or intervention, divided by the number of women in whom this test or intervention should have been performed under ideal circumstances according to the 12 quality indicators. The overall adherence per indicator and the mean adherence per hospital type were calculated. Chi squared test or Fisher’s exact test were used for statistical analysis to detect differences between hospital types. For continuous data, the Mann – Whitney-U or Kruskal – Wallis test was used in case of non-normality (Kolmogorov–Smirnov test).

RESULTS

Indicator development

Thirty recommendations were extracted from the guideline on EP (Step 1). All eight members of the expert panel participated in the questionnaire round, and all questionnaires were completed for evaluation. From this, 12 recommendations were selected for further analysis and prioritization by the expert panel. Two new recommendations were suggested by the expert panel and scored: first, the success criteria of systemic methotrexate (MTX) treatment and second, the counselling of women on the risk for repeat EP (Step 2). In the consensus meeting, the prioritization was agreed upon (Step 3). Measurability and capacity for improvement of care were evaluated (Step 4). In the end, the two newly suggested recommendations by the expert panel were not selected because of the lack of measurability. Thus, a set of 12 quality indicators was approved by the expert panel as the final set to assess the quality of care for women with EP (Step 5). We identified process, structural and outcome indicators (Table 1).

Process indicators included all aspects of the diagnostic algorithm (Fig. 1) and the detection of any persistent trophoblast after salpingotomy by serum hCG measurement (n=7). Structural indicators (n=2) included laboratory and operation theatre availability. Outcome indicators (n =3) dealt with surgical treatment only.
Measurement of actual care

Between January 2003 and December 2005, 317 women with EP were identified from the six hospital registries: 96 in the academic hospitals, 167 in the teaching hospitals and 54 in the non-teaching hospitals. The mean age of women was 33 years (Table 2).

Figure 2. A step-wise RAND-modified Delphi method to develop quality indicators for EP.
Table 1. Final set of quality indicators for the management of EP per type of indicator.

<table>
<thead>
<tr>
<th>Quality indicators</th>
<th>Diagnostic/therapeutic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process indicators</strong></td>
<td></td>
</tr>
<tr>
<td>Perform a hCG urinary test in case of suspected EP</td>
<td>Diagnostic</td>
</tr>
<tr>
<td>Perform transvaginal ultrasound in case of suspected EP</td>
<td>Diagnostic</td>
</tr>
<tr>
<td>Measure serum hCG in case of an ‘inconclusive TVS’</td>
<td>Diagnostic</td>
</tr>
<tr>
<td>Schedule treatment if the diagnosis is ‘EP’ according to algorithm</td>
<td>Diagnostic</td>
</tr>
<tr>
<td>Plan follow up after 2 days if the diagnosis is ‘no EP’ according to algorithm</td>
<td>Diagnostic</td>
</tr>
<tr>
<td>Complete serum hCG follow up after salpingotomy until undetectable</td>
<td>Therapeutic</td>
</tr>
<tr>
<td>Administer anti-D immunoglobulin to rhesus negative women</td>
<td>Therapeutic</td>
</tr>
<tr>
<td><strong>Structural indicators</strong></td>
<td></td>
</tr>
<tr>
<td>Arrange a 24/7 serum hCG laboratory service availability</td>
<td>Diagnostic</td>
</tr>
<tr>
<td>Perform same type of surgery (salpingotomy) during office and non-office hours</td>
<td>Therapeutic</td>
</tr>
<tr>
<td><strong>Outcome indicators</strong></td>
<td></td>
</tr>
<tr>
<td>Attempt a laparoscopy in case of haemodynamically stable women</td>
<td>Therapeutic</td>
</tr>
<tr>
<td>Attempt a salpingotomy in case of contra-lateral tubal pathology</td>
<td>Therapeutic</td>
</tr>
<tr>
<td>Treat persistent trophoblast with systemic</td>
<td>Therapeutic</td>
</tr>
</tbody>
</table>

Table 2. Characteristics of women treated for EP (2003-2005) in six hospitals

<table>
<thead>
<tr>
<th></th>
<th>All (n=6)</th>
<th>Academic (n=2)</th>
<th>Teaching (n=2)</th>
<th>Non-teaching (n=2)</th>
<th>X²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women with EP (n)</td>
<td>317</td>
<td>96</td>
<td>167</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Mean age (year)</td>
<td>32.7</td>
<td>32.8</td>
<td>33.0</td>
<td>31.4</td>
<td>NS</td>
</tr>
<tr>
<td>Nulliparity</td>
<td>44%</td>
<td>38%</td>
<td>50%</td>
<td>20%</td>
<td>NS</td>
</tr>
<tr>
<td>Risk factors for EP (≥1)</td>
<td>43%</td>
<td>40%</td>
<td>47%</td>
<td>33%</td>
<td>NS</td>
</tr>
<tr>
<td>Vaginal bleeding and/or pain</td>
<td>43%</td>
<td>40%</td>
<td>47%</td>
<td>33%</td>
<td>NS</td>
</tr>
<tr>
<td>Signs of haemorrhagic shock</td>
<td>8%</td>
<td>10%</td>
<td>8%</td>
<td>7%</td>
<td>NS</td>
</tr>
<tr>
<td>Serum hCG (IU/L)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>3215</td>
<td>3828</td>
<td>3063</td>
<td>3178</td>
<td>NS*</td>
</tr>
<tr>
<td>Mean</td>
<td>8140</td>
<td>8187</td>
<td>8833</td>
<td>5518</td>
<td>NS*</td>
</tr>
</tbody>
</table>

EP, ectopic pregnancy; risk factors for EP were history of EP, genital Chlamydia trachomatis infection, pelvic inflammatory disease, tubal pathology, pregnancy after IVF. *Kruskal–Wallis test P = 0.685.

Risk factors for EP were present in 43% of women. Virtually all women presented with some abdominal pain or vaginal bleeding, whereas 8% presented with signs of haemorrhagic shock. Population characteristics and serum hCG levels showed no significant differences between hospital types. The median and mean serum hCG concentrations were 3215 and 8140 IU/l, respectively.
Adherence (%)

A flowchart of the diagnostic workup and adherence to the diagnostic algorithm is shown in Fig. 3. Of the 317 women identified, 26 (8%) presented with signs of hypovolemic shock and were all correctly admitted and treated. Of the 291 haemodynamically stable women, we found complete reports in 261. In four women, no TVS was performed (98% adherence to indicator 2). Based on the visualization of an ectopic sac, the diagnosis definite EP was instantly made in 33 women (13%). The other 228 women (87%) were labelled as having ‘an inconclusive TVS’ and serum hCG was measured in 197 women (87% adherence to indicator 3). Based on the diagnostic algorithm (TVS and serum hCG measurement), 129 of these 197 women had a definite EP. Of the 162 (33 + 129) women diagnosed with EP, 122 were surgically treated the same or following day (75% adherence to indicator 4). The other 40 women were not treated according to the guideline and had expectant management (25% no adherence).

**Figure 3.** Flowchart of the diagnostic work up and the adherence to the algorithm.


**Mann–Whitney-U test P=0.30.
Based on the diagnostic algorithm (TVS and serum hCG measurement) 68 of the 197 women had ‘no suspected EP’, and of these 68 women, only 23 had the recommended follow-up visit after 2 days (34% adherence to indicator 5). The majority of women (n=45) were managed otherwise: immediate surgical intervention (n=25; 37%) or expectant management with delayed re-evaluation up to 1 week (n=15; 22%), whereas a few women were already evaluated the next day (n=5; 7%) (combined non-adherence of 66%). No significant differences in serum hCG levels were found between the adherence group versus the non-adherence (P = 0.09 and P = 0.30). Eventually, all women had surgery with a confirmed EP.

Blood was typed for rhesus factor in 95% of women while only 56% of the confirmed rhesus negative women received anti-D immunoprophylaxis (56% adherence to indicator 7). In the non-teaching hospitals, none of the women received anti-D immunoprophylaxis, while in two academic hospitals all women received anti-D immunoprophylaxis.

Structural and outcome indicators showed a great variance in adherence. Round-the-clock laboratory services for serum hCG measurement were not available in one academic and one non-teaching hospital out of the six hospitals (67% adherence to indicator 8). Laparoscopy was the type of surgery of first choice in 98% of women and succeeded in 89% of these, while a conversion to laparotomy was necessary in 10% (89% adherence to indicator 10). Laparoscopy was significantly more often successful in teaching hospitals; no differences between office and non-office hours were observed. There were 25% of women who had contra-lateral tubal pathology. In these women, a salpingotomy was attempted in 30%. A conversion to salpingectomy was accomplished in 21% of women with contra-lateral tubal pathology (21% adherence to indicator 11). Attempts for salpingotomy or conversion rates to salpingectomy did not differ between hospital types. Also, no differences were observed in attempted and successful salpingotomy between office hours and non-office hours or at night time (see Table III for adherence to indicator 9). In women undergoing salpingotomy, serum hCG follow up was carried out in 78% and adherence was not influenced by the serum hCG level prior to surgery (78% adherence to indicator 6, P=0.57). In these women, the persistent trophoblast rate was 10%. Treatment of this complication with systemic MTX had an overall adherence of 88% (88% adherence to indicator 12). Only one case had surgery for persistent trophoblast.

The overall adherence to the guideline was 75% and varied per indicator from 21 to 98%. The results of the adherence per indicator and per indicator type are presented in Table III. (The process indicator ‘Perform a hCG urinary test in case of suspected EP’ could not be measured, most likely due to registration inconsistencies (adherence to indicator 1 NA). Urinary tests performed on the clinical ward were not automatically reported and uploaded in the electronically available hospital laboratory results program. The overall adherence was comparable between hospital types (75, 76 and 72%, respectively). The adherence to process, structural and outcome indicators was 84, 43 and 76% respectively (Table 3). The adherence to structural indicators was significantly lower in the teaching hospitals.
compared with the academic hospitals, but the adherence to outcome indicators was higher in the teaching hospitals.

DISCUSSION

There are often major discrepancies between best evidence and daily practice. This results in large practice variation between professionals and care for patients that is not always based on evidence (6, 14-16). Guidelines might close this gap between research and practice, but implementation of guidelines is known to be challenging. Therefore, it is recommended that alongside new guidelines, quality indicators are developed to make these guidelines immediately available for quality assessment of care.

Our study describes the first steps in the process of guideline implementation in the management of women with EP. We developed a set of quality indicators according to the standard implementation format of the systematic RAND-modified Delphi method, and put this set through a practice test. The overall adherence to the guideline ranged from 21 to 98%. Concerning the diagnostic process, we found that the adherence was particularly low in haemodynamically stable women with an inconclusive scan and serum hCG levels under the cut off levels of the algorithm. In these women, only 34% had the recommended follow-up visit, 37% had (potential over-) treatment, 22% had a delayed follow up and 7% were evaluated too soon. A higher adherence was observed for women diagnosed with EP, 75% had treatment as recommended by the guideline; thus the other 25% did not receive appropriate care, i.e. expectant management. A high adherence was found for successful laparoscopy, but salpingotomy was only attempted in the minority of women with contra-lateral tubal pathology. The conversion rate to salpingectomy was high, leaving these women with a successful salpingotomy rate of only 21%, independent of the time of the day. A persistent trophoblast was observed in only 10 women and overall well treated with systemic MTX. On the other hand, the detection of persistent trophoblast by serum hCG follow up was not complete in 22%. Only half of the women with a negative blood type received anti-D to prevent erythrocyte immunisation.

Characteristics of our study were that we included women who were surgically treated for tubal EP, which represent the mainstream treatment in The Netherlands; MTX as primary treatment is estimated to be as low as 5% (17, 18). Limiting the study to women surgically treated for EP also ensured complete coverage considering the precise surgical registry in The Netherlands. In other words, our study population is representative for the majority of EP patients and with a complete coverage. Of the women, 8% presented with signs of hypovolemic shock. It is not clear whether this percentage is high or not, as only women who were surgically treated for EP were included in the current study. This percentage, which reflects clinical practice, is not comparable with other data as most studies on EP
### Table 3. Adherence per indicator (%), per hospital type (%)

<table>
<thead>
<tr>
<th>Process indicators</th>
<th>All (n=6)</th>
<th>Academic (n=2)</th>
<th>Teaching (n=2)</th>
<th>Non-teaching (n=2)</th>
<th>X2 or FE</th>
</tr>
</thead>
<tbody>
<tr>
<td>hCG urinary test</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>TVS</td>
<td>98</td>
<td>98</td>
<td>100</td>
<td>98</td>
<td>NS</td>
</tr>
<tr>
<td>Serum hCG measurement</td>
<td>87</td>
<td>91</td>
<td>91</td>
<td>74</td>
<td>NS</td>
</tr>
<tr>
<td>Treatment if diagnosis “EP”</td>
<td>75</td>
<td>84</td>
<td>68</td>
<td>80</td>
<td>NS</td>
</tr>
<tr>
<td>Follow up if no diagnosis</td>
<td>34</td>
<td>38</td>
<td>38</td>
<td>23</td>
<td>NS</td>
</tr>
<tr>
<td>Post-operative serum hCG follow up</td>
<td>78</td>
<td>90</td>
<td>75</td>
<td>71</td>
<td>NS</td>
</tr>
<tr>
<td>Anti-D immunoglobulin</td>
<td>56</td>
<td>50</td>
<td>100</td>
<td>0</td>
<td>P=0.005 b</td>
</tr>
</tbody>
</table>

**Structural indicators**

| 24/7 serum hCG laboratory services | 67        | 50            | 100           | 50                 | NS      |

**Perform salpingotomy**

<table>
<thead>
<tr>
<th>office hours versus non office hours</th>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>- attempt</td>
<td>27 vs. 30</td>
<td>15 vs. 36</td>
<td>18 vs. 31</td>
<td>67 vs. NA</td>
</tr>
<tr>
<td>- successful</td>
<td>20 vs. 19</td>
<td>8 vs. 18</td>
<td>18 vs. 23</td>
<td>50 vs. NA</td>
</tr>
</tbody>
</table>

8.00-23.00 versus 23.00- 8.00h

| - attempt                                   | 28 vs. 30 | 23 vs. 50     | 26 vs. 25     | 44 vs. NA         | NS      |
| - successful                                | 18 vs. 27 | 9 vs. 50      | 21 vs. 22     | 33 vs. NA         | NS      |

**Outcome indicators**

| Successful laparoscopy                      | 89        | 83            | 95            | 82                 | P=0.014 d |
| Successful salpingotomy in women with contra lateral tubal pathology | 21        | 11            | 26            | 33                 | NS      |
| MTX for persistent trophoblast             | 88        | 100           | 100           | 0                  | NS      |

**Adherence per indicator type (%)**

| Process                                     | 84        | 87            | 85            | 76                 | NS      |
| Structural                                  | 43        | 50            | 34            | 58                 | P=0.005 e |
| Outcome                                    | 76        | 65            | 83            | 73                 | P=0.003 f |
| All indicators                              | 75        | 75            | 76            | 72                 | NS      |

TVS, transvaginal sonography; EP, ectopic pregnancy; MTX, methotrexate; FE, Fisher’s exact test; NA, not applicable.

a Teaching versus non-teaching P < 0.02, academic versus non-teaching P < 0.02.
b Teaching versus non-teaching P = 0.00.
c No difference in % successful laparoscopy was observed between office hours versus non-office hours.
d Academic versus teaching P = 0.009, teaching versus non-teaching P = 0.015.
e Academic versus teaching P = 0.02, teaching versus non-teaching P = 0.003.
f Academic versus teaching P = 0.001.
report on haemodynamically stable women only or describe women with tubal rupture without mentioning the presence of hypovolemic shock. By including women with EP from different hospital types in three different cities in both urban and suburban areas in the actual assessment of care, the whole range of hospital settings and professionals involved in early pregnancy care were covered.

Despite these standardized and thorough procedures, some limitations should be considered. It can be argued that the Dutch guideline on the management of EP used to develop the indicators is outdated and needs revision. However other international guidelines, e.g. those of the American College of Emergency Physicians (2003)(19), the Royal College of Obstetricians and Gynaecologists (2004)(20) and the American College of Obstetricians and Gynaecologists (2008)(21) recommend a similar non-invasive diagnostic approach. We therefore consider the final set of quality indicators to be realistic, clinically relevant, and up-to-date.

So far, only one other implementation study in the field of Reproductive Medicine has been published. This study involved guidelines on subfertility diagnosis and treatment. It showed a low adherence (< 50%) in a third of the indicators and a variation in performance between the clinics up to 100% (22). These findings together with the results of our study confirm our suspicion of a structural problem with adherence to guidelines in early pregnancy and fertility care.

Specifically for women with EP, the indicators diagnostic algorithm, salpingotomy in case of contra-lateral tubal pathology and administration of anti-D in rhesus negative women were poorly adhered to. Concerning the diagnostic algorithm, low adherence was observed in the planning of a follow-up visit after two days in case of ‘an inconclusive TVS’ and serum hCG levels below the cut-off levels of the algorithm. On one hand, this resulted in unnecessary surgery and thus indicates room for improvement, especially if one considers morbidity and costs (hospital admission and surgery). On the other hand, delayed follow up may have jeopardised women by delaying a correct diagnosis and appropriate treatment. Moreover, candidates for medical treatment with systemic MTX, i.e. women with low-serum hCG levels, were withheld this treatment option. We observed that in this group of asymptomatic women, clinicians responded in two ways: either by immediate intervention or by a delayed follow-up visit. The first might reflect uneasiness among clinicians and women on the small risk of tubal rupture or the urge to deal with a medical problem instantly. The second might be a sign of unfamiliarity or disagreement with the guideline. Another possible explanation for the low adherence might be the serum hCG level. In case of a low-serum hCG level, clinicians might consider the risk of tubal rupture or the likelihood of an EP lower and are thus more likely to postpone treatment or follow up. In a sub-analysis, we found that the adherence to the diagnostic algorithm is independent of the serum hCG level (Fig. 3). Another possible explanation for the low adherence may be the lack of a 24/7 serum hCG laboratory.
service. Only in the teaching hospitals, this service was offered on a 24/7 basis. Although the scientific evidence underpinning this recommendation is lacking, we feel that in line with emergency service standards of practice, a 24/7 serum hCG service is recommended and nowadays easily available (RCOG, Good clinical practice guideline no 9, 2009). Furthermore, the structural indicator on 24/7 serum hCG service is a necessary step to be able to adhere to the process indicators on serum hCG measurements. If the preconditions are not fulfilled, proper adherence to other parts of the guideline is never achievable.

Concerning salpingotomy, this technique was only attempted in 30% of women with contra-lateral tubal pathology, while conversion to salpingectomy was necessary in one-third of these. This may be explained by the low level of evidence (II-2), lack of surgical skills or personal barriers such as dislike for this more complex and time consuming technique compared with a quick salpingectomy. However, the finding of similar rates of salpingotomies during out-of-office hours did not strengthen this hypothesis. Post-operative serum hCG follow up after salpingotomy was performed in 78% of women, but significantly less frequently in non-teaching hospitals. The only case of persistent trophoblast in a non-teaching hospital was treated surgically instead of with systemic MTX. We have no follow-up data on the other women in whom serum hCG follow up was not carried out for persistent trophoblast.

Concerning anti-D administration, we observed a variance in adherence between hospital types. A 0% adherence in the non-teaching hospitals in the administration of 375 IE anti-D in rhesus negative women is unexpected, especially since its administration is also recommended in the guideline ‘Erythrocyte immunisation and pregnancy’ (Dutch Society of Obstetrics and Gynaecology NVOG, 2002) (23). A potential bias could be a registration problem in the medical charts, although administration of blood and plasma products should be registered (Dutch Institute for Healthcare Improvement, 2004) (24). We have no data on rhesus immunisation in the following pregnancies of women who did not receive anti-D.

The overall adherence to the guideline ranged from 21 to 98%. It is unclear what degree of adherence should be regarded as acceptable. In the manual for the ESHRE guideline development, published by the Special Interest Group Safety and Quality in ART, no recommendations were provided for the minimal and/or optimal percentage of adherence to aim for as a benchmark. In another implementation study in the field of Reproductive Medicine, the authors stated that a 100% adherence score may not always be a viable goal but professionals should at least aim to rival the best scoring clinic, which indeed might be a realistic benchmark (22).

In our study, three types of indicators (process, structural and outcome) were used for actual care measurement. We observed an intermediate overall adherence of 76% to the three outcome indicators. Outcome indicators are easily measurable but are quite likely affected
by factors unrelated to the quality of care, e.g. by case mix variation that cannot be adjusted for (25). Outcome indicators also seem to lack information about how future improvements should be made (26), and can lead to stigmatization if used for external reporting (27).

Process indicators may have advantages over outcome indicators. In our study, we found the highest overall adherence of 84% to the seven process indicators. Process indicators encourage action from all organizations or individuals with room for improvement, not just a small proportion of outliers. Also, these indicators are more useful when any subsequent adverse events are markedly delayed, e.g. in case of rhesus sensibilization in the following pregnancy due to failure to administer anti-D to rhesus negative women in the index EP (26). Adherence to structural indicators, such as the 24/7 serum hCG laboratory service, can be easily improved.

In this study, the first two steps out of four in the process of guideline implementation for EP were completed: indicator development and measurement of actual care. The developed 12 quality indicators enabled the assessment of EP care. The overall adherence was found to be 75%, but also revealed room for improvement, especially in the adherence to the diagnostic algorithm. In general, deviations from a guideline are difficult to explain from a retrospective collection of clinical data. Specific reasons for not following the guideline are usually not stated in the medical charts. In a sub-analysis, we did not find that the serum hCG level influenced the adherence to the diagnostic algorithm. Whether or not the level of evidence of an indicator influenced the level of adherence could not be analysed since these evidence levels are not reported in this guideline. Disagreement, unfamiliarity with the content of the guideline or the fact that the diagnostic algorithm might be regarded as complicated by its users, might also be the explanations for non-adherence. However, identification of these barriers was beyond the scope of this study and needs to be further investigated in qualitative research. Therefore, the next steps to be taken are the identification of barriers and facilitators and the development of an implementation strategy to improve guideline adherence in EP care.

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