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Consensus Derived Clinical Decision Rules to Guide Advanced Imaging Decisions for Pulmonary Embolism in Pregnancy and the Post-partum Period

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**Word Count:** 433 words

**Synopsis:** Three consensus derived expert clinical decision rules are presented to guide advanced imaging decisions for pulmonary embolism in pregnancy and the post-partum period

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**Competing interests:** None.

**Synopsis:** Expert consensus derived clinical decision rules (CDRs) are presented to guide imaging decisions for PE in pregnant and post-partum patients.
Pulmonary Embolism (PE) is a leading cause of death during pregnancy and the postpartum period. Current clinical decision rules (CDRs) to guide imaging decisions in PE include d-dimer testing, which has been shown to be unreliable in pregnancy. Current guidelines consequently recommend that all pregnant or postpartum women with suspected PE should receive advanced diagnostic imaging. However this non-selective approach results in very low rates of detected PE, risks radiation exposure and reaction to contrast media, is inconvenient for patients, and incurs costs for the health services.

The Diagnosis of Pulmonary Embolism in Pregnancy (DIPEP) study is a prospective cohort study including pregnant and postpartum women with diagnosed and suspected PE in the UK. The aim of the current study was to develop expert CDRs to guide imaging decisions in PE for validation in the DIPEP dataset.

Three expert clinical decision rules were developed, each with a contrasting focus: (1) balancing sensitivity and specificity (primary CDR) (2) optimising sensitivity and (3) optimising specificity. To reduce biases arising from the subjectivity of expert views, and maximise content and face validity a two stage consensus process, guided by best practice guidelines, was conducted. Ethical approval was given by a University of Sheffield ethics committee. All participants provided written informed consent.

In the first stage, a web based Delphi survey was conducted to identify candidate clinical predictors of PE. Purposive sampling was used to recruit a heterogeneous group of 20 experts. The open first round of the classical Delphi approach was replaced with a systematic literature review to identify possible PE predictors. Participants were then asked to rate the predictive value of each variable on a 1 to 5 Likert scale and justify their opinion. In subsequent Delphi iterations, participants were provided with quantitative and qualitative results of the previous round, and a summary of their previous opinions.

In the second stage, the Nominal Group Technique (NGT) was used to formulate the content and scope of the three expert clinical decision rules. A series of face-to-face meetings, including rating rounds and structured group discussions, were conducted with a consensus panel consisting of DIPEP co-
Investigators, facilitated by an independent researcher experienced in the NGT. Moderately or strongly predictive variables identified during the Delphi survey were considered for inclusion.

The systematic literature review identified 45 potential variables for evaluation in the Delphi Survey. Three Delphi rounds were then conducted before stability of opinion was evident. Twenty four variables felt to be moderately or strongly predictive of PE were carried forward for consideration in the NGT meetings. Consensus was subsequently achieved for inclusion of 13 predictors in the final CDRs, with variable weightings and cut-point differing according to the focus of individual rules. The scope of the CDRs, including inclusion and exclusion criteria, were also confirmed. The final CDRs are presented in Table 1. The performance of these rules now requires testing in appropriate populations, such as the DIPEP sample, prior to any introduction into clinical practice.
Table 1. Consensus Derived CDRs to Guide Advanced Imaging Decisions for Pulmonary Embolism in Pregnancy and the Post-partum Period

The CDRs apply to pregnant or post-partum women presenting with symptoms that prompt consideration of pulmonary embolism (e.g. chest pain, shortness of breath). The rule does not apply if: critically ill and/or in need of resuscitation; a clear non-PE diagnosis is identified by clinical assessment, including ECG, chest x-ray and blood tests where appropriate (e.g. chest infection); or an uncommon, but powerful, VTE risk factor exists, e.g. thrombophilia, intravenous illicit drug misuse.

<table>
<thead>
<tr>
<th>INCLUDED VARIABLES:</th>
<th>PRIMARY CDR</th>
<th>SENSITIVE CDR</th>
<th>SPECIFIC CDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemoptysis</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Pleuritic chest pain</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Previous VTE</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Family history of VTE in first degree relative</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hospital admission, surgery or significant injury within 90 days</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>[excluding Normal vaginal delivery or caesarean section]</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstetric complication*</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Active medical co-morbidities†</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Post partum or third trimester</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Raised BMI ≥30</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Clinical symptoms or signs of DVT**</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Oxygen sats&lt;94% on room air</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Tachycardia &gt;100bpm (in 1st or second trimester, or post-partum) / Tachycardia &gt;110bpm (in third trimester)</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Increased respiratory rate &gt;24 b/m</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

CDR CUT POINT: 3 1 4

VARIABLE WEIGHTING§

*Obstetric complications - Apply once if any of the following are present: Pre-eclampsia in current pregnancy. Assisted reproductive technology (antenatal only), multiple pregnancy, Caesarean section in labour, elective caesarean section, mid-cavity or rotational operative delivery, prolonged labour (> 24 hours), post-partum haemorrhage (> 1 litre or transfusion), preterm birth < 37+0 weeks in current pregnancy, stillbirth in current pregnancy, hyperemesis, Ovarian hyper-stimulation syndrome (first trimester only). †Active medical co-morbidities - Apply once if any of the following are present: cancer, heart failure; systemic lupus erythematosus, inflammatory polyarthritis or inflammatory bowel disease; nephrotic syndrome; type I or type 2 diabetes mellitus with nephropathy; sickle cell disease. **Patients presenting with symptoms and / or signs of DVT and suspicion of PE would initially undergo Duplex ultrasound of the leg(s). If positive patients would be treated for DVT and presumed PE. Negative leg imaging does not rule out DVT and these patients would still be considered higher risk for PE. §The scoring systems for the primary and specific rules allow the three rules to be presented alongside each other. In practice these scores can be simplified by removing zero scoring variables.
References


3. Royal College of Obstetricians and Gynaecologists (2015) Thrombosis and Embolism During Pregnancy and the Puerperium, the Acute Management of (Green-top 37b); Available at: https://www.rcog.org.uk/globalassets/documents/guidelines/gtg-37b.pdf [Accessed 2nd May 2017]


