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Clinical audit: a useful tool for reducing severe postpartum haemorrhages?

Corinne Dupont, Catherine Deneux-Tharaux, Sandrine Touzet, Cyrille Colin, Marie-Hélène Bouvier-Colle, Jacques Lansac, Simone Thevenet, Claire Boberie-Moyrand, Gaëlle Piccin, Marie-Pierre Fernandez, et al.

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1 **Clinical audit: a useful tool for reducing severe postpartum haemorrhages?**

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6 **Abstract**

7 Objective. Reducing the rate of severe postpartum haemorrhage (PPH) is a major challenge in
8 obstetrics today. One potentially effective tool for improving the quality of care is the clinical audit,
9 that is, peer evaluation and comparison of actual practices against explicit criteria. Our objective was
10 to assess the impact of regular criteria-based audits on the prevalence of severe PPH.

11 Design. Quasi-experimental before-and-after survey

12 Setting. Two French maternity units in the Rhône-Alpes region, with different organisation of care.

13 Participants. All staff of both units.

14 Intervention. Quarterly clinical audit meetings at which a team of reviewers analysed all cases of
15 severe PPH and provided feedback on quality of care and where all staff actively participated.

16 Main outcome measures. The primary outcome was the prevalence of severe PPH. Secondary
17 outcomes included the global quality of care for women with severe PPH, including the performance
18 rate for each recommended procedure. Differences in these variables between 2005 and 2008 were
19 tested.

20 Results. The prevalence of severe PPH declined significantly in both units, from 1.52% to 0.96% of
21 deliveries in the level III hospital ($p=0.048$) and from 2.08% to 0.57% in the level II hospital
22 ($p<0.001$). From 2005 to 2008, the proportion of deliveries with severe PPH that were managed
23 consistently with the guidelines increased for all of its main components, in both units.

24 Conclusion. Regular clinical audits of cases severe PPH were associated with a persistent reduction in
25 the prevalence of severe PPH.

26 **Introduction**

27 Severe postpartum haemorrhage (PPH) is the main component of severe maternal morbidity in
28 developed countries, and reducing its rate is a major challenge in obstetrics today. In France, PPH is
29 the leading cause of maternal mortality, and data from the French Confidential Enquiries into maternal
30 deaths show that 80% of deaths due to PPH might have been prevented by timely and appropriate care
31 (1). The French College of Obstetrics & Gynaecology (CNGOF) issued the first national clinical
32 guidelines on PPH prevention and management in France in November 2004 (2). However, the
33 passive dissemination of guidelines is by itself insufficient to change professionals' practices (3).

34 Clinical audit is a quality improvement process that seeks to improve patient care and outcomes by
35 looking at current actual practices through the review of cases according to explicit criteria and uses
36 the findings to modify the organisation and the content of care if necessary (4, 5). Few studies have
37 assessed the impact of clinical audits in obstetrics (6,7,8), and none, to our knowledge, has focused
38 specifically on PPH. Information on the feasibility of clinical audits of deliveries with severe PPH and
39 the results that can be expected from this tool would be useful to clinicians (9).

40 The Pithagore6 trial was a cluster-randomised trial, with the maternity unit as the unit of
41 randomisation, to evaluate a multifaceted educational intervention for reducing the rate of severe PPH.
42 It included 106 French maternity units and finally found no significant difference in the severe PPH
43 rate between the hospitals with the intervention and the control hospitals (10). The intervention
44 included a clinical audit of deliveries with severe PPH in all maternity units in the intervention arm.
45 Two of these hospitals decided to continue the clinical audit meetings on a regular basis. The objective
46 of this report is to describe the change in the prevalence of severe PPH and in the quality of care
47 provided in these cases after the implementation of routine audits in two hospitals with different levels
48 and organisation of care.

49

50 **Methods**

51 A before-and-after survey was designed to assess the impact of the routine use of clinical audits.

52 ***Population***

53 The study was conducted in France in two maternity hospitals located in the Rhône-Alpes region. Both
54 were part of the Pithagore6 research program (10) and decided, after the study's conclusion, to
55 integrate the clinical audit into their routine practice. Croix-Rousse Hospital is a level III university
56 hospital, that is, a reference centre with an onsite neonatal intensive care unit and around 3000
57 deliveries a year. Valence Hospital is a level II hospital that has a neonatal unit and around 2000
58 annual deliveries. Both units have an anaesthetist and a junior and a senior obstetrician on site at all
59 times, as well as an onsite blood bank, arterial embolisation facilities and an adult intensive care unit.
60 They also have written protocols, consistent with national guidelines, for the management of obstetric
61 haemorrhages.

62

63 From 2005 through 2008, the obstetrics departments of both hospitals held clinical audit meetings
64 every three months to analyse all cases of severe PPH in the preceding quarter. Severe PPH was
65 defined as a PPH associated with one or more of the following: blood transfusion, arterial
66 embolisation, arterial ligation, other conservative uterine surgery, hysterectomy, transfer to an
67 intensive care unit, peripartum haemoglobin drop of 4 g/dl or more, or maternal death. Women with
68 transfusions during the postpartum period but not clinically diagnosed with PPH were not included.
69 Deliveries with severe PPH were prospectively identified and reported at the daily obstetric staff
70 meeting, and one midwife in each hospital was responsible for collecting cases and checking that all
71 pertinent information was included in the file.

72

73 ***Clinical audit***

74 In each unit, all cases of severe PPH that occurred during the previous 3 months were reviewed during
75 a quarterly meeting of the local clinicians. All members of maternity unit's medical staff (obstetricians,
76 midwives and anaesthetists) were asked to participate. Participation in this meeting was considered
77 working time. From 20 to 25 people attended each meeting. In each unit, a three-member audit team

78 — an obstetrician, a midwife and an anaesthetist — conducted the clinical audit. A member of the
79 team caring for the woman at the time the PPH occurred presented each case. The content of the
80 obstetric files was also available to the audit team.

81 The clinical audit included three steps. First, the appropriateness of the care provided was critically
82 analysed by the audit team in a discussion with the other clinicians. Management was assessed
83 according to explicit criteria derived from the main components of the national guidelines:
84 examination of the uterine cavity and/or manual removal of the placenta within 15 minutes of the PPH
85 diagnosis; instrumental examination of the vagina and cervix; intravenous administration of oxytocin;
86 and if PPH persisted and was due to uterine atony, intravenous administration of sulprostone (second
87 line oxytocic) within 30 minutes of the initial diagnosis. A standardised audit form (available on
88 request to the authors) was completed for each case and stated whether each recommended procedure
89 was performed.

90 At the end of this analysis, the audit team offered an oral synthesis of the practices, feedback about
91 what was done wrong and what was done well, and a consensus was then made by the audit meeting
92 on the global quality of care provided (optimal, suboptimal, non-optimal). Care was considered
93 optimal if the following four major components of recommended care were performed within the
94 required time: examination of the uterine cavity/manual removal of placenta; call for additional staff;
95 administration of oxytocin; and administration of sulprostone if uterine atony persisted. If at least one
96 of these major components was absent, care was considered non-optimal. Care was considered
97 suboptimal if all major procedures were performed but at least one was not done within the
98 recommended time or another minor component of care did not comply with the recommendations.

99 The second step of the audit consisted in an active discussion involving all meeting participants and
100 facilitated by the audit team to identify the specific reasons for sub- or non-optimal care, both in terms
101 of content and organization. Finally, the group analysed the reasons identified in the second step and
102 defined practical ways to improve the specific non-optimal aspects, in view of local constraints and the
103 specific context. One person, usually a senior midwife, was in charge of monitoring implementation of
104 the recommended actions. After the meeting, the senior midwife reduced these conclusions to writing

105 and sent them by email to each participant. They were also made available to all staff of the maternity
106 unit in the labour ward.

107

108 *Study variables*

109 The data routinely collected by the units includes characteristics of pregnancy and delivery known to
110 be risk factors for severe PPH: previous caesarean delivery, multiple pregnancy, placenta praevia or
111 accreta, mode of delivery, and foetal macrosomia (baby's weight > 4000 g), as well as any postpartum
112 haemorrhage (clinically assessed by the caregivers). These data were extracted for this study, together
113 with their proportions among annual deliveries (from each unit's annual report).

114 The primary outcome was the prevalence of severe PPH, calculated as the number of cases divided by
115 the total number of deliveries. Secondary outcomes included the rates of the principal recommended
116 interventions for PPH management, extracted from the data collected during the audits. Specifically,
117 we calculated the rate of calls for additional staff and administration of oxytocin for all cases. The
118 rates of examination of the uterine cavity within 15 minutes of diagnosis and of instrumental
119 examination of the vagina and cervix were assessed for severe PPH following vaginal delivery. Lastly,
120 the rate of administration of sulprostone within 30 minutes of the diagnosis was assessed for the cases
121 due to uterine atony.

122

123 *Analysis*

124 Differences between the before (2005) and after (2008) periods for primary and secondary outcomes
125 were tested with the chi-square test or Fisher's exact test, as appropriate, as were differences in the
126 prevalence of individual risk factors for severe PPH between these periods.

127

128 **Results**

129 The characteristics of parturient women did not change significantly from 2005 to 2008 in the level II
130 unit, although in the level III unit, the rate of instrumental vaginal deliveries increased significantly,
131 from 7.3% in 2005 to 10.5% in 2008, as did the rate of deliveries with PPH, from 4.0% of deliveries in
132 2005 to 6.1% in 2008 (Table 1). This global increase in the PPH annual rate resulted from the

133 combination of a decrease in PPH after spontaneous and instrumental vaginal deliveries (from 2.0% to
134 1.85% and from 7.9% to 3.5%, respectively) and a concomitant significant increase in the PPH rate
135 after caesarean deliveries, from 9.6% in 2005 to 20.4% in 2008.

136 A significant reduction in the prevalence of severe PPH occurred in both hospitals between 2005 and
137 2008, from 2.1% to 0.6% in the level II hospital and from 1.5% to 1.0% in the level III hospital (Table
138 2). In the level II unit, the prevalence of severe PPH decreased for both vaginal and caesarean
139 deliveries. In the level III unit, on the other hand, the prevalence of severe PPH after vaginal deliveries
140 fell significantly, but the prevalence after caesareans did not change.

141 The global quality of care provided to women with severe PPH improved in both units between 2005
142 and 2008, although the difference reached statistical significance only in the level III hospital (Table
143 3). The proportion of cases for which management was considered optimal increased from 47% to
144 73% in the level II unit and from 22% to 61% in the level III unit.

145 In both units in 2005, the main deviations from recommended care once PPH was diagnosed were no
146 or delayed examination of the uterine cavity (57% in the level II and 74% in the level III unit), the
147 absence of instrumental examinations of vagina and cervix (76% and 59% of severe PPH cases,
148 respectively), and no or delayed administration of second-line uterotonics when uterine atony persisted
149 (71% and 86%).

150 From 2005 to 2008, the proportion of deliveries with severe PPH that were managed consistently with
151 the guidelines increased for all of the principal components, in both units. In particular, this
152 improvement was statistically significant in both units for the components of care that were the most
153 inappropriate in 2005.

154

155 **Discussion**

156 This study shows that routine clinical audits can easily be implemented in obstetrics settings and that
157 their regular performance is associated with an improvement in PPH-related practices and with a
158 significant reduction in the prevalence of severe PPH.

159

160 Several limitations must be noted. First although the initial audit meeting was part of a research
161 programme, the routine use of the audit that followed was a local initiative in both units, and the
162 external validity of the results may thus be questionable. Our findings nonetheless suggest that clinical
163 audits are a simple and potentially effective tool for units willing to assess and improve the care they
164 provide.

165 The quality of care for PPH and the specific components of that care were analysed only in cases of
166 severe PPH. A complete assessment of the audit impact would theoretically have required us to
167 analyse practices in all cases of PPH, or in a representative sample of them, and not only in the most
168 severe cases. These data, however, were not available. It is possible that the improvement in practices
169 was actually greater than that observed in cases of severe PPH, since, by definition, the severe cases
170 have worsened and are thus more likely to have received inappropriate care.

171 The inherent limitations of our observational design prevent this study from proving that the regular
172 audits caused the reduction in the prevalence of severe PPH, and other factors external to the audit
173 may have contributed to this decrease. Obstetrics professionals in France have been focusing on the
174 issue of PPH since the late 1990s, and global improvement in PPH-related practices might have been
175 underway as part of this national context and could explain the decrease in the prevalence of severe
176 PPH found in the 2 units of our study. We consider this hypothesis seems unlikely, however. Firstly,
177 passive dissemination of recommendations for clinical practice has repeatedly been shown to be
178 insufficient to improve practices (11). Secondly, the dramatic reduction found here – with the
179 prevalence of severe PPH after vaginal delivery divided by three -- seems unlikely to have happened
180 in the absence of active intervention. Finally, a regional study in all maternity units of another French
181 region showed no significant decrease in the rate of severe PPH during this time period (12).

182 Another possible explanation of our results is that the proportion of women at risk for PPH decreased
183 over time. However, neither the prevalence of PPH risk factors among parturient women nor the
184 annual rate of all PPH decreased over this period. Indeed, an inverse trend was observed in the level
185 III unit, where the rates of two important risk factors increased between 2005 and 2008: the number of
186 instrumental deliveries and of women with previous caesareans. These changes may have contributed
187 to the increase in the PPH rate. Under these circumstances, the reduction we observed in the

188 prevalence of severe PPH suggests a decline in the proportion of the PPH that worsened and became
189 severe, probably due to better management of early PPH. The specific PPH-related practices used as
190 criteria for determining quality of care improved concomitantly. Finally, the implementation of routine
191 audits was associated with a significant reduction in severe PPH in two different maternity units
192 providing different levels of care in different settings. All these elements suggest that the organisation
193 of regular clinical audits is likely to have had a positive effect on the prevalence of severe PPH.

194

195 Although there are reports of interventions aimed at improving the global quality of care delivered to
196 mothers and children, or targeting other specific issues in obstetrics, previous studies of interventions
197 to decrease the rate of severe PPH are scarce (13-14). Because those few tested the impact of complex
198 or multifaceted interventions, they are not easily reproducible, and it is difficult to attribute the global
199 effect to one component or another. Only one reported a significant reduction in the rate of severe
200 PPH, obtained over a 3 year period in one centre (13). The present study provides a description of the
201 routine use of one specific tool, the clinical audit, and our findings suggest it has a significant impact
202 on the prevention of severe PPH through effective management of early bleeding. The precise
203 description of the agenda of the audit meetings should make them easily reproducible in other units. In
204 addition, the continuous monitoring of the prevalence of severe PPH and of the proportion of adequate
205 care provides evidence that the audit's impact is sustained over time.

206

207 A major strength of regular clinical audits is that they bring practitioners together frequently to discuss
208 the management of severe cases and to define relevant improvement objectives appropriate to the local
209 context and based on the audit's findings (15). Severe PPH is a very pertinent event for clinical audits,
210 because of the availability of management guidelines and its obviously multidisciplinary nature,
211 involving midwives, obstetricians, and anaesthetists. Such multidisciplinary meetings with a facilitator
212 team applying strategies to encourage collaboration, both at the meeting and during care, are likely to
213 increase the audit activity and to improve care.

214 In our experience, the results that can be expected from a clinical audit meeting depend on several
215 aspects of the audit process: institutional support, by treating participation in the meetings as actual

216 working time; respect for the facilitator team and their leadership skills; consideration for every
217 participant's words; objective assessment of care provided with the help of a standardised form;
218 analysis of the mechanisms that led to the severe event, focused not on individual mistakes, but on
219 understanding individual and collective decision-making processes; and conclusions expressed in
220 terms of improvement strategies. In addition, long-term repetition of the audit appears necessary for it
221 to improve practices and health outcomes. In the level III unit, clear improvement appeared only
222 during the third year of audits. This finding is consistent with the previous report from Rizvi et al of an
223 intervention to decrease the rate of severe PPH (13). This is also likely to explain why no significant
224 improvement was obtained in the Pithagore6 trial where only one audit meeting took place (10): a
225 single meeting is probably insufficient for identifying suboptimal care and its reasons and is certainly
226 insufficient for verifying its improvement.

227

228 An interesting finding is the differential changes in the prevalence of severe PPH for vaginal and
229 caesarean deliveries. Caesarean delivery is a recognized risk factor for severe PPH, and the baseline
230 rates of severe PPH in 2005 were higher for caesarean than vaginal deliveries in both units. During the
231 subsequent years and following the implementation of routine audits, the prevalence of severe PPH
232 after vaginal delivery fell quite appreciably in both units. However, severe PPH at caesarean deliveries
233 decreased only in the level II unit; it remained stable in the level III unit and these cases accounted for
234 most of the severe PPH in 2008. The clinical guidelines for PPH management offer more detailed
235 measures for dealing with bleeding after vaginal delivery; it is thus unsurprising that the audits might
236 have had a greater impact on this type of PPH. The concomitant increase in the rate of all PPH after
237 caesarean delivery found in the level III unit may indicate that the procedure itself was associated with
238 a higher risk of bleeding in 2008 than in 2005. Although the mechanisms and management of PPH at
239 caesarean deliveries include surgical issues that may be more difficult to standardise, the current
240 continuous rise in caesarean rates indicates that guidelines focusing on the management of bleeding at
241 caesarean delivery are needed.

242

243 The prevalence of severe PPH and the high proportion of inadequate management found at baseline in
244 the two units of this study suggest that room for improvement exists. Because passive dissemination of
245 guidelines does not change practices, specific interventions are required. One feasible tool is the
246 regular clinical audit of severe PPH, and in this study, it was associated with a persistent reduction in
247 the prevalence of severe PPH.

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250 **Disclosure of interests**

251 The authors have nothing to disclose

252 **Contribution to authorship**

253 CD and CDT participated in the design and the implementation of the study, the collection and the
254 analysis of the data and the drafting and revision of the paper.

255 ST, CC, MHBC and JL participated in the design of the study and the revision of the paper.

256 RR initiated the collaborative project, participated in the design and the implementation of the study,
257 the management of the audit meetings, the analysis of the data and the drafting and revision of the
258 paper.

259 ST, CB, GP, and MPF participated in the organisation of the audit meetings, the collection of the data
260 and the revision of the paper.

261

262 **Ethics approval**

263 Approval for the Pithgaore6 trial was obtained from the Sud Est III Institutional Review Board and
264 from the French Data Protection Agency (CNIL). No specific ethics approval for this ancillary study
265 was required because outcome data were routinely collected at maternity units and analysed in an
266 aggregate format.

267

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272 publication.

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Table 1: Characteristics of pregnancy and delivery in parturient women, 2005 to 2008, in the 2 units

Level II Unit	2005		2006		2007		2008		P*
	n	%	n	%	n	%	n	%	
All	1 538	100.0	1 469	100.0	1 552	100.0	1 899	100.0	
Previous caesarean	134	9,4	181	12,3	185	11,6	201	10,6	0.1
Multiple pregnancy	43	2,9	22	1,5	42	2,6	38	2,0	0.3
Placenta praevia	17	1,2	17	1,2	5	0,3	12	0,6	0.1
Caesarean delivery	386	26,3	356	24,2	363	22,7	461	24,3	0.9
Instrumental vaginal delivery	102	7.2	117	8.1	150	9.7	185	9.7	0.1
Fetal macrosomia	109	7.2	109	7.3	110	6.9	140	7.2	0.9
Postpartum haemorrhage	63	4.1	73	5	87	5.6	65	4.2	0.3
Level III Unit	n	%	n	%	n	%	n	%	P*
All	2 962	100	3 113	100	3 058	100	3 213	100	
Previous caesarean	219	7,5	342	11,0	354	11,5	353	11,0	<0.01
Multiple pregnancy	97	3,3	93	3,0	112	3,7	99	3,1	0.8
Placenta praevia	31	1,1	38	1,2	33	1,1	35	1,1	0.6
Caesarean delivery	636	21,8	691	22,2	682	22,3	706	22,0	0.8
Instrumental vaginal delivery	216	7.3	234	7.5	299	9.8	343	10.5	<0.01
Fetal macrosomia	210	6.9	221	6.9	215	6.8	218	6.6	0.6
Postpartum haemorrhage	121	4.0	131	4,2	190	6.2	196	6.1	<0.01

*Difference between 2005 and 2008

Table 2 : Number and Rate (% of deliveries) of severe PPH*, 2005 to 2008, in the 2 units

Level II Unit	2005		2006		2007		2008		P**
	n	%	n	%	n	%	n	%	
All Severe PPH	32	2.1	9	0.6	8	0.5	11	0.6	<0.01
Severe PPH at vaginal delivery	21	1.8	6	0.5	3	0.3	8	0.6	<0.01
Severe PPH at caesarean delivery	11	2.8	3	0.8	5	1.4	3	0.7	<0.01
Level III Unit	n	%	n	%	n	%	n	%	P**
All Severe PPH	45	1.5	41	1.6	33	1.1	31	1.0	0.05
Severe pph at vaginal delivery	27	1.2	25	1.0	16	0.7	9	0.4	<0.01
Severe pph at caesarean delivery	18	2.8	16	2.3	17	2.5	22	3.1	0.8

*severe PPH defined as a PPH associated with one or more of the following: blood transfusion, arterial embolisation, arterial ligation, other conservative uterine surgery, hysterectomy, transfer to an intensive care unit, peripartum haemoglobin delta of 4 g/dl or higher, or maternal death

**Difference between 2005 and 2008

Table 3 : Characteristics of care provided for severe PPH, 2005 to 2008, in the 2 units

Level II Unit	2005		2006		2007		2008		P*
	n	%	n	%	n	%	n	%	
	32	100	9	100	8	100	11	100	
▪ Global quality of care									
Optimal care	15	47	8	88	5	63	8	73	0.1
Sub-optimal care	17	53	1	22	3	37	3	27	
Non-optimal care	0	0	0	0	0	0	0	0	
▪ Specific components of management									
<i>All Severe PPH</i>	32	100	9	100	8	100	11	100	
Administration of oxytocin	27	84	9	100	8	100	11	100	0.8
Call for additional staff	28	88	8	89	8	100	10	91	0.9
<i>Severe PPH at vaginal delivery</i>	21	100	6	100	3	100	8	100	
Pharmacological prophylaxis	10	48	5	83	2	67	7	88	0.1
Examination of the uterine cavity	15	71	6	100	2	67	6	75	0.8
within 15 minutes of PPH diagnosis	9	43	5	83	2	67	5	63	0.6
Instrumental examination of vagina/cervix	5	24	6	100	3	100	7	88	<0.01
<i>Severe PPH due to uterine atony</i>	21	100	7	100	7	100	6	100	
Intravenous administration of sulprostone	8	38	6	86	6	86	5	83	0.1
within 30 min of PPH diagnosis	6	29	6	86	5	71	5	83	0.05
Level III Unit	n	%	n	%	n	%	n	%	P*
	45	100	41	100	33	100	31	100	
▪ Global quality of care									
Optimal care	10	22	9	22	14	42	19	61	<0.01
Sub-optimal care	24	53	27	66	18	55	11	35	
Non-optimal care	11	24	5	12	1	3	1	4	
▪ Specific components of management									
<i>All Severe PPH</i>	45	100	41	100	33	100	31	100	
Administration of oxytocin	43	96	36	88	32	97	31	100	0.9
Call for additional staff	43	96	41	100	31	94	30	97	0.9
<i>Severe PPH at vaginal delivery</i>	27	100	25	100	16	100	9	100	
Pharmacological prophylaxis	5	19	18	72	10	63	9	100	<0.01
Examination of the uterine cavity	19	70	23	92	16	100	8	89	0.5
within 15 minutes of PPH diagnosis	7	26	22	88	10	63	8	89	<0.01
Instrumental examination of vagina/cervix	11	41	18	72	9	56	8	89	0.03
<i>Severe PPH due to uterine atony</i>	35	100	29	100	14	100	19	100	
Intravenous administration of sulprostone	20	57	25	86	13	93	18	95	<0.01
within 30 min of PPH diagnosis	5	14	16	55	7	50	18	95	<0.01

* Difference between 2005 and 2008