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► To cite this version:

M. Bucchiotty, S. El Morabit, Y. Hammou, R. Gallouj, N. Messaadi, et al.. Effect of a postpartum prescription for pertussis vaccine: a before-and-after study. *Journal of Gynecology Obstetrics and Human Reproduction*, 2021, *Journal of Gynecology Obstetrics and Human Reproduction*, 50 (4), pp.102050. 10.1016/j.jogoh.2020.102050 . hal-04502523

HAL Id: hal-04502523

<https://hal.univ-lille.fr/hal-04502523v1>

Submitted on 22 Jul 2024

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1 **Effect of a postpartum prescription for pertussis vaccine: a before-**
2 **and-after study**

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19

20 **Abbreviation**

21 dTpa-IPV : diphtheria tetanus acellular pertussis poliomyelitis

22

23 **Funding**

24 This research did not receive any specific grant from funding agencies in the public,
25 commercial, or not-for-profit sectors.

1 **Effect of a postpartum prescription for pertussis vaccine: a before-and-**
2 **after study**

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21

22 **Summary**

23

24 **Background:** Among the strategies to encourage pregnant women to be vaccinated against
25 pertussis in the postpartum period, that of giving them a prescription has been evaluated only
26 sparsely.

27 **Objective:** To measure the effect of giving women who are not immunized against pertussis a
28 prescription for the vaccine at discharge from the maternity unit.

29 **Material and methods:** Single-center before-and-after study (2011: before; 2015: after). All
30 women received both oral and written information about vaccination against pertussis. During
31 the after period, they were also specifically asked their immunization status during pregnancy.
32 Those currently unimmunized received a written prescription for it at discharge.

33 **Results:** Among the women unimmunized at delivery, the percentage who were vaccinated
34 postpartum climbed from 17 to 42% between 2011 and 2015 ($p<0.001$), while the percentage
35 of their unimmunized partners who were vaccinated remained stable (27 and 29%, $p=0.74$).
36 During this time, the percentage of women immunized against pertussis at the beginning of
37 pregnancy rose from 32 to 52% ($p<0.001$). Finally, the percentage of all women protected
38 against this disease postpartum climbed from 44 to 72% between these two periods ($p<0.001$).

39 **Conclusions:** In the postpartum period, giving a prescription for pertussis vaccine to women
40 unimmunized is accompanied by a significant elevation in their vaccination rate.
41 Nevertheless, this rate remains low and better strategies have to be implemented.

42

43 **Key words:** vaccination, pertussis, pregnancy, postpartum, prescription, cocooning strategy.

44

45 **INTRODUCTION**

46

47 Pertussis, commonly known as “whooping cough”, is a highly contagious respiratory
48 infection caused by a type of bacteria called *Bordetella Pertussis*.

49 It is still a major health issue to this day and affect people of all ages, but it is definitely more
50 serious for young children and babies (1). The average annual infant mortality rate due to
51 Pertussis is 2% (2–5). There are 40 million estimated cases which lead to 300 000 deaths each
52 year (6).

53 Since the 1990s and despite mass vaccination, Pertussis infection rates have been rising in
54 developed countries. It is probably due to the decrease of vaccinated persons. It can also be
55 explained by the use of the acellular vaccine, which showed an early waning of vaccine-
56 induced immunity (7–10). Pertussis spreads from person to person by coughing/sneezing or
57 sharing enclosed space. In most cases, infants get infected by their parents or close family
58 (11–13).

59 While many countries have chosen to vaccinate women during their pregnancy (14,15), some
60 use the cocooning strategy instead. As a matter of fact, France has been doing it since 2004
61 (4). This program provides protection to infants too young to be vaccinated by targeting the
62 family members or caregivers for vaccination. Its goal is to prevent and interrupt Pertussis
63 transmission (16). However, mothers have to get vaccinated as soon as they give birth (17).

64

65 Nonetheless, this recommendation is difficult to carry out (13), and debates about incentive
66 strategies for mothers who are recovering from childbirth are still going. Leboucher *et al.*
67 reported that oral and written instructions, followed by a prescription and advice at discharge

68 from the maternity unit, was accompanied by a coverage rate of 69% at 8 weeks postpartum
69 (18). However, Bonneau *et al.* found that this combination strategy resulted in a change of the
70 immunization status for only 38% of women (19).

71

72 In 2012, our department chose to adopt this strategy which consists in giving a prescription
73 for pertussis vaccine to unimmunized women at discharge after delivery. Therefore, we made
74 the decision to perform a before-and-after comparative study to evaluate the effect of this
75 postpartum prescription.

76

77 **MATERIAL AND METHODS**

78

79 **A/ Study goal:**

80 The objective of this study was to measure the trend between 2011 and 2015 in the rate of
81 pertussis vaccination in postpartum women and their partners who had not been vaccinated
82 within the previous 10 years.

83 The principal endpoint was parental vaccination among this unimmunized population at 8
84 weeks postpartum.

85 Two other secondary outcomes were also measured: the vaccination coverage rate observed
86 during pregnancy, that is, the percentage of parents immunized at the beginning of pregnancy,
87 and that measured postpartum, that is the total parental vaccination rate postpartum.

88 These three criteria were measured with a closed questionnaire during a telephone interview
89 at 8 to 10 weeks after discharge. During this telephone interview, the women were asked to
90 look at their own portable health or vaccination records. Women who did not have these
91 records were asked to remember when they had last received this vaccine. Similarly, they
92 were asked to describe their partner's vaccination status. Women and partners whose vaccine
93 status was unknown were arbitrarily considered to be not currently immunized.

94 In 2011, evidence of the resulting low vaccination coverage led us to modify this strategy as
95 of January 2012. After that change, in addition to the oral and written information that we had
96 always provided, we asked women during their pregnancy to report their immunization status,
97 by completing a self-administered questionnaire. Moreover, the form advised them to discuss
98 their vaccinations with their general practitioner. After delivery, the women who had reported
99 an uncertain or not up to date immunization status received a prescription for the quadrivalent
100 vaccine at discharge (DTPa-IPV).

101

102 **B/ Type of study design:**

103 This is a before-and-after observational study. This study took place in one center, a French
104 university hospital (level III).

105

106 **C/ Study population:**

107 Women were eligible if they had just given birth to one or more liveborn infants, regardless of
108 gestational age at delivery. They were excluded, however, if they were younger than 18 years
109 of age, if their telephone number was unknown, if they had been transferred *in utero* to our
110 hospital just before their delivery, or if court action concerning the child was underway. They
111 were also excluded if they refused to participate, if language difficulties prevented effective
112 communication on this subject, if the telephone number in their records appeared to be wrong,
113 or if we were unable to reach them by telephone after four attempts.

114 In this comparative study we selected two different populations at both time period.

115 All women provided oral consent at the beginning of the telephone interview. Women's
116 medical and socioeconomic data were recorded from the obstetric files (telephone number,
117 age, educational level, date of delivery, type of delivery, parity, breastfeeding at discharge,
118 and date of discharge).

119

120 **D/ Periods studied:**

121 The previous strategy for pertussis vaccination in our maternity ward dated from 2005; we
122 provided oral and written information about the need for up-to-date immunization from the
123 beginning of pregnancy for the family – father, siblings, grandparents, and other persons in
124 regular contact with the newborn – and very early in the immediate postpartum period for the
125 mother.

126

127 The exploratory "before" period, intended to estimate vaccination coverage from a sample of
128 around 100 women, was scheduled to take 14 days. The after period was chosen to be able to
129 show an increase in vaccination coverage between the two periods. Demonstrating a 17%
130 immunization rate postpartum in unimmunized women in 2011 allowed us to estimate that the
131 inclusion of 200 women in 2015 would enable us to detect a possible doubling of this rate
132 ($\alpha=5\%$, $1-\beta=20\%$, bilateral risk). The inclusion period in 2015 was therefore twice as long as
133 in 2011: 28 days.

134 In practice, the survey and data collection covered all women who gave birth between
135 September 5 and 18, 2011, and from March 26 to April 22, 2015.

136

137 **E/ Statistical analysis:**

138 The computerized data were anonymized. Our study was reported under the simplified
139 procedure to the National Data Protection Authority (CNIL) as number DEC 16-49.

140 The data were recorded and analyzed with Epi Info software (Version 3.1, Epidata
141 Association, Denmark).

142 Comparisons of percentages used the Chi-2 test or Fisher's exact test when appropriate.
143 Means were compared with Student's t test. The percentages were rounded to the closest
144 whole number and are reported in parentheses. We report the means with their standard
145 deviations. Differences were considered significant when $p<0.05$.

146

147 **RESULTS**

148

149 During the 2011 study period, 147 women gave birth, and during the 2015 period, 364. After
150 application of the exclusion criteria (women without a telephone number, late transfers,
151 minors, and those whose child had been placed by a court), the percentage of eligible women
152 was 91% (n=134/147) in 2011 and 95% (n=347/364) in 2015 ($p=0.07$).

153 After we counted the interviews that were impossible because of failure to reach the woman
154 by telephone four times, or wrong telephone numbers, or communication (language)
155 difficulties, interviews were possible for 65% (n=95/147) in 2011 and 76% (n=278/364) in
156 2015 ($p=0.06$). The percentage of participants rose significantly between 2011 and 2015 (64%
157 (n=94/147) vs 74% (n=270/364), $p=0.02$).

158 The women during both study periods were comparable for their general characteristics
159 (Table 1). Specifically, they did not differ by period for mean age, parity, educational level,
160 vaginal delivery rate, or breastfeeding rate at discharge.

161 Table 2 presents their vaccination status by study period. Among the women unimmunized
162 during pregnancy, the percentage vaccinated postpartum rose significantly between 2011 and
163 2015 (17% (n=11/64) vs 42% (n=54/130), $p<0.001$), regardless of parity. The percentage of
164 women up to date for this immunization at the beginning of pregnancy also rose from 32%
165 (n=30/94) in 2011 to 52% (n=140/270) in 2015 ($p<0.001$). This increase too was significant
166 simultaneously in nulliparous and parous women. Overall, the percentage of women up to
167 date for their pertussis vaccination in the postpartum period rose very significantly between
168 2011 and 2015 (from 44% (n=41/94) to 72% (n=194/270), $p<0.001$), with an amplitude
169 almost identical in nulliparas and paras.

170

171 Finally, the vaccination status for partners initially unimmunized but vaccinated in the
172 postpartum period remained stable between the two periods (27% (n=18/68) vs 29%
173 (n=39/136), $p=0.74$). The percentage of partners immunized at the beginning of the pregnancy
174 did rise significantly – from 26 % (n=24/92) to 45% (n=109/245) between 2011 and 2015
175 ($p<0.008$), but only among paras. Finally, the total percentage of immunized partners
176 postpartum increased significantly between 2011 and 2015 (from 46% (n=42/92) to 60%
177 (n=148/245), $p<0.001$); again, this increase occurred only among partners of parous women.

178

179 **DISCUSSION**

180

181 In our before-and-after study, giving women a prescription for pertussis vaccine at their
182 discharge from the maternity unit allowed to observe in a significant elevation in the rate of
183 vaccination postpartum.

184 This is a before-and-after study with all of the possible biases associated with this study
185 design. The method of the survey itself can be criticized, since vaccine status was collected by
186 telephone. We nonetheless limited this measurement bias by asking all women to have their
187 vaccination records in front of them at the time of the interview. All surveys about this
188 vaccine coverage are, like ours, self-reported (20–23).

189 The before-and-after nature of our study does not allow us to be certain that the increased
190 vaccination rate observed between 2011 and 2015 is really due to giving a vaccine
191 prescription to these unimmunized mothers. We observed a significant increase from 32 to
192 52% of women already immunized during pregnancy – regardless of parity – indicates that
193 adherence to pertussis immunization guidelines by healthcare professionals improved notably
194 between 2011 and 2015. This effect was also observed in partners, whose coverage during
195 pregnancy rose from 26 to 45% during the same period, although the increase was significant
196 only among partners of parous women. It is nonetheless probable that this better involvement
197 of healthcare professionals in pertussis vaccination between 2011 and 2015 does not fully
198 explain the increase in the postpartum vaccination rate that we observed in the unimmunized
199 women. That is, the stability of postpartum vaccination of partners – who did not receive a
200 prescription –between 2011 and 2015 while the rates of the mothers rose from 17 to 42%
201 during the same period suggests strongly of a positive effect due to the prescription itself.

202 The vaccination coverage rates measured in our study during the postpartum period are in line
203 with those measured in France in similar conditions (18,20,21). At the Angers University
204 Hospital maternity ward, Leboucher *et al.* reported in 2009 that after they provided women
205 with oral and written information and a prescription for the vaccine, the coverage rate reached
206 69% in mothers and 62% in their partners (18). A study at the maternity ward at Quimper
207 Hospital, published in 2011, found that the provision of oral and written information and a
208 vaccine prescription was associated with coverage rates of 65% in mothers and 59% in their
209 partners (20). In our study, these rates in mothers and their partners were respectively 44 and
210 46% in 2011 and then 72 and 60% in 2015.

211 In 2015, despite the strategy of vaccine prescriptions, the postpartum vaccination rate of 42%
212 observed among the women in our study unimmunized at delivery appears low, especially
213 compared with the 61% rate observed with the same strategy in Quimper in 2011 (21). It is on
214 the other hand, similar to the 38% measured at Tenon Hospital, a university hospital in Paris,
215 in 2009 (19). We have no clear explanations for these low vaccination rates despite
216 prescriptions from university hospital maternity units, but we can suggest two hypotheses. On
217 the one hand, it is possible that the conditions in which the prescription is given are as
218 important as the prescription itself. That is, we know that the healthcare professional's
219 convictions play an essential role in vaccination adherence and we have observed that
220 insufficient recommendations by the physicians and midwives who give the prescriptions can
221 diminish women's desire to be vaccinated (24–26). On the other hand, the multiplicity of
222 information delivered at discharge from maternity unit, the fear of vaccination during
223 breastfeeding, and the lack of time inherent in the postpartum period are all factors that can
224 negatively influence the likelihood of vaccination (18–21).

225 This vaccination rate, finally fairly low despite the prescription at discharge, has led some
226 teams to offer the mother this vaccination during her postpartum hospitalization. This strategy
227 has resulted in maternal coverage rates reaching 65% in North Carolina (US) (27) and even
228 75% in Texas (US) (28), but only 47% in Montreal (Canada) (23). Its superiority compared
229 with the simple prescription of vaccine has not been proved. On the one hand, a before-and-
230 after study in France has showed the superiority of vaccination in the maternity department,
231 compared with prescription alone, with a modest but significant progression from 53 to 64%
232 vaccination coverage of parents six weeks after discharge (21). On the other, this strategy
233 faces the costs associated with purchasing the vaccine – approximately 20 € per dose – and
234 with the supplementary time needed to perform the vaccination, which would have to be
235 integrated into the cost of hospitalization. Rather than purchase by the hospital, a family
236 member could purchase it at a pharmacy. Nonetheless, the complexity of this solution
237 presents a risk of failure. The teams at Saint-Julien-en-Genevois and Caen observed refusal
238 rates of 60 and 50%, respectively (21,22). Besides, this strategy of vaccination in the
239 maternity unit does not prevent the prescription of the vaccine if the patient refuses
240 immunization during hospitalization (21,22).

241 A vaccination strategy called cocooning for parents has appeared in the French guidelines
242 since 2014 (16) and seems to result in coverage rates at six weeks postpartum of 64% for
243 parents (21) and even 83% in mothers (22).

244 Lastly, these results cannot be discussed without mentioning those of another strategy:
245 immunization of pregnant women with the pertussis vaccine at the beginning of the third
246 trimester. This strategy is aimed at directly protecting infants against pertussis through their
247 transplacental receipt of maternal antipertussis antibodies (4,14,15). This strategy is an
248 alternative to the “cocoon” approach. Cocooning appears reduce the incidence of infantile

249 pertussis only when at least 65% of family members are immunized (29), a rate that the
250 countries that have adopted this strategy, such as France, Switzerland, and Canada (23,30), do
251 not appear to have reached. In our study, among the women vaccinated postpartum, 24% did
252 not have this injection until were more than a month after they left the maternity unit. This
253 delay limits still further the effectiveness of this strategy (data not shown) (31).

254 Moreover, the cost-effectiveness interest of the cocooning strategy – which must address
255 several adults to protect one child – turns out to be poorer than vaccination of the pregnant
256 woman only during pregnancy (4,32), now recommended in several countries, including the
257 United States, United Kingdom, Argentina, New Zealand, Belgium, and Israel (4). The
258 vaccination rate for pregnant women reached 82% in Massachusetts in 2013 (US) (33) and
259 62% in England in 2014 (34); vaccination effectiveness for pertussis may reach 91% in
260 England (35,36).

261 In conclusion, the results of our study shed important light on the prescription of pertussis
262 vaccine to unimmunized women in the postpartum period. Despite its observational character,
263 our study strongly supports the positive role of this prescription. Nonetheless, it increased the
264 vaccination rate only from 17 to 42% in this population and thus requires that we envision
265 other strategies. Beyond vaccination at the maternity unit, which could give better results,
266 pregnant women can help protect newborns by getting vaccinated during pregnancy, via
267 transplacental transfer of maternal pertussis antibodies to the infant (37,38). This strategy
268 appears the most cost-effective for preventing pertussis in infants. It has been recommended
269 since 2014 by the World Health Organization (36,39) and should be studied as an alternative
270 to the cocooning vaccination still in force in France. If pregnant women would accept a new
271 vaccination during pregnancy, it should certainly improve the rate of protection of newborns
272 during their first months of life (40).

273

274 **Declarations of interest:** none

275

276 **Acknowledgements:**

277 We are grateful to Jo Ann Cahn who helped us in translating this paper and reviewing
278 different drafts.

279 .

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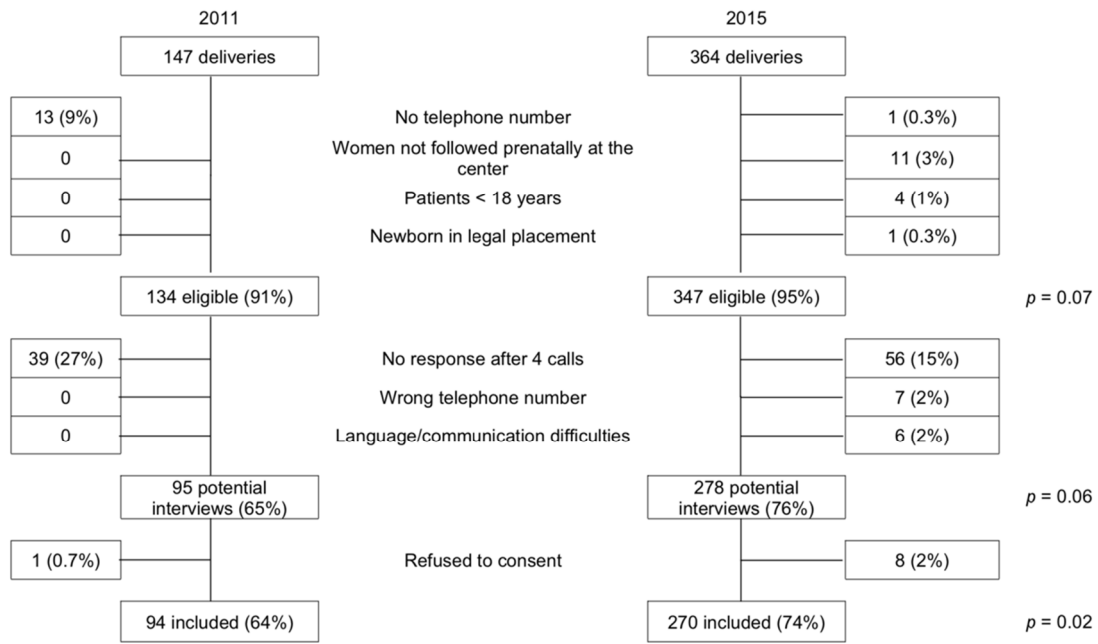
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Figure 1: Flow chart



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Table 1: Women's characteristics by study period

	2011	2015	<i>p</i>
	n=94	n=270	
Age (years)	30.0 ± 5.6	30.3 ± 5.0	0.65
Nulliparous	44 (47)	110 (41)	0.30
Educational level ≥ baccalaureate exam	76 (81)	200 (74)	0.44
Vaginal delivery	75 (80)	224 (83)	0.49
Breastfeeding on D4	62 (66)	200 (74)	0.13

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Table 2: Vaccination status of women by study period

	2011	2015	<i>p</i>
Postpartum vaccination among unimmunized women	11/64(17)	54/130(42)	<0.001
- Nulliparous	7/31(23)	31/59(53)	0.006
- Parous	4/33(12)	23/71(32)	0.028
Immunized women at the beginning of the pregnancy	30/94 (32)	140/270 (52)	<0.001
- Nulliparous	13/44 (30)	51/110 (46)	=0.05
- Parous	17/50 (34)	89/160 (56)	0.008
Total immunized women postpartum	41/94(44)	194/270(72)	<0.001
- Nulliparous	20/44(45)	82/110(75)	<0.001
- Parous	21/50(42)	112/160(70)	<0.001

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Table 3: Vaccination status of partners by study period

	2011	2015	<i>p</i>
Vaccination during or after pregnancy among unimmunized partners	18/68(27)	39/136(29)	0.74
- Nulliparous	13/34(38)	29/65(45)	0.54
- Parous	5/34(15)	10/71(14)	0.93
Immunized partners at the beginning of the pregnancy	24/92(26)	109/245(45)	0.008
- Nulliparous	10/44(23)	33/98(34)	0.19
- Parous	14/48(29)	76/147(52)	0.007
Total immunized partners postpartum	42/92(46)	148/245(60)	<0.001
- Nulliparous	23/44(52)	62/98(63)	0.22
- Parous	19/48(40)	86/147(59)	0.02

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