


Feasibility of the long-term data collection on infant development in the BELpREG registry in Belgium

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Background and Objectives


Long-term infant risks following maternal medication use in pregnancy are understudied for most medications. The longitudinal **LIFETIME Framework**, developed within the IMI Project ConcePTION, initiated and streamlined data collection efforts in Europe. However, its success depends on the **volume and completeness of the collected data**.

 Our aim was to assess the **feasibility of long-term data collection** in the BELpREG registry in Belgium.

Methods

 A **descriptive evaluation** was conducted using data from the **BELpREG registry in Belgium**.

 **BELpREG participants** enroll during pregnancy, are ≥18 years and receive healthcare in Belgium.

 The BELpREG questionnaires at 6 and 12 months postpartum include the **Ages & Stages Questionnaires (ASQ)**, assessing five subdomains: **communication, gross and fine motor, problem solving, and personal-social development**, each with a **maximum score of 60**.

 Data collection started in **November 2022**, and data were extracted on **November 28th, 2024**.

A total of **1843 participants** had **consented to receive the BELpREG questionnaire at 6 and 12 months**.

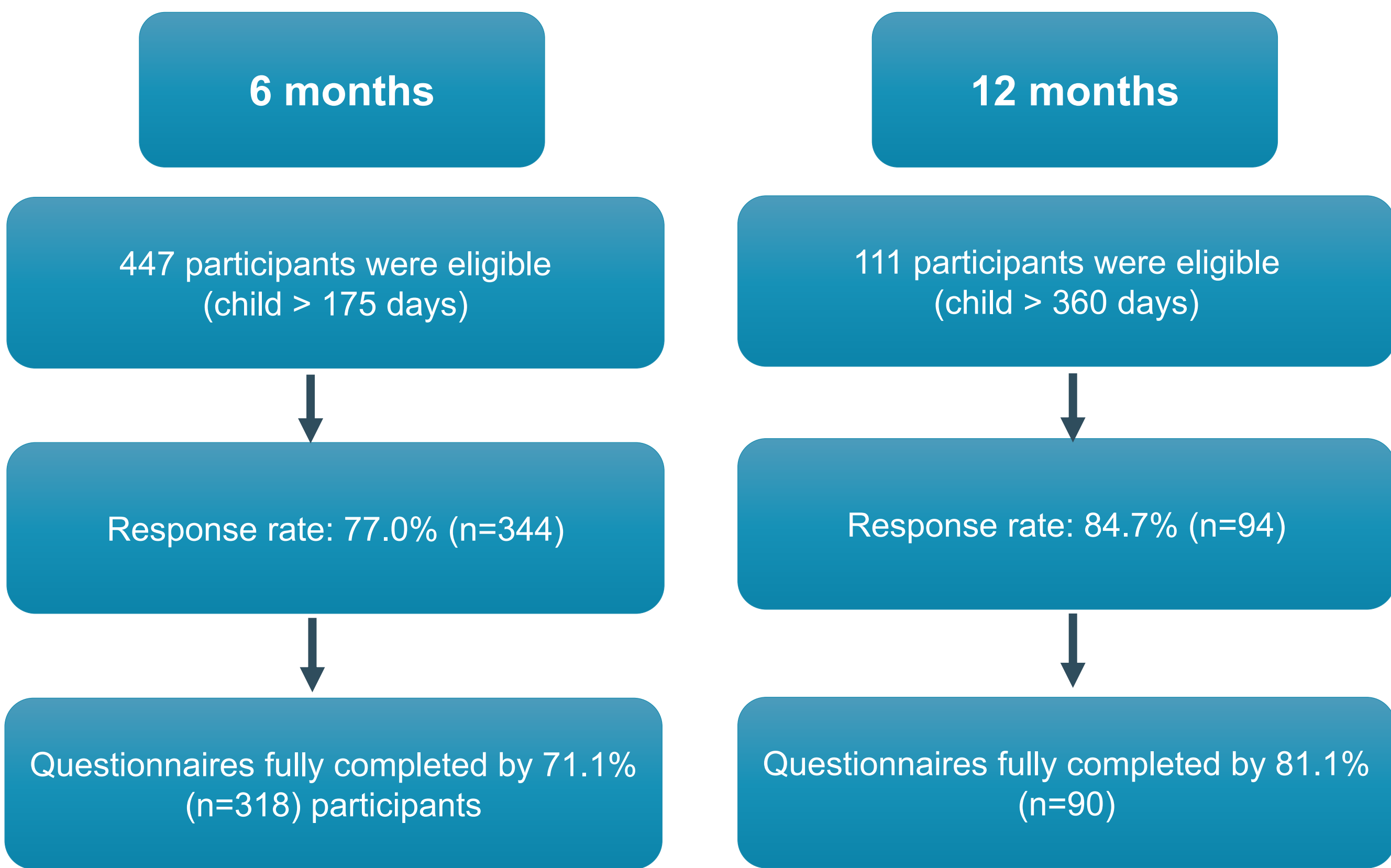


Figure 1: Overview of the participants for the questionnaires at 6 and 12 months postpartum

Table 2: ASQ scores and percentages of participants below the cut-off scores at 6 and 12 months

ASQ subdomains	6 months		12 months	
	Mean ASQ scores	N (%) below cut-off	Mean ASQ scores	N (%) below cut-off
Communication	46.2	0.0	40.9	0.0
Gross motor	36.2	11.4	35.4	21.3
Fine motor	43.2	18.4	50.1	3.2
Problem-solving	48.8	4.3	43.0	10.0
Personal-social	41.6	9.0	40.9	6.7

Results

Table 1: Characteristics of participants who filled in the questionnaire at 6 and 12 months

	6 months (n=318) N (%)	12 months (n=90) N (%)
Maternal age		
<25 years	9 (2.8)	21 (6.7)
25-35 years	279 (87.7)	265 (83.3%)
>35 years	30 (9.5)	32 (10.0%)
Speaks Dutch at home	270 (84.9)	286 (90.0)
Belgian nationality	303 (95.3)	300 (94.4)
Maternal education*		
Low	3 (0.9)	10 (3.3)
High	315 (99.1)	308 (96.7)
Annual gross household income		
Low (< 30.000 euro)	16 (5.0)	19 (6.1)
High (≥ 30.000 euro)	302 (95.0)	299 (93.9)
Gravidity		
1	149 (46.9)	166 (52.2)
>1	169 (53.1)	152 (47.8)

*High education is defined as any degree obtained in higher education or university.

Compared to the 6-month questionnaire, the **12-month questionnaire** was more often completed by participants who spoke **Dutch at home** and were **primigravida**.

Conclusion



The BELpREG registry and self-reported data show strong potential for research on medication safety in pregnancy and long-term infant development, illustrated by the **high and complete response rates of the questionnaires at 6 and 12 months after delivery** (with 818 and 470 completed questionnaires so far).

In addition, **infant follow-up in the BELpREG registry** has been **expanded with two additional ASQ questionnaires at 24 and 48 months** after delivery.

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