

Mixed Methods Research to Understand Disease Burden and Unmet Need in HDFN and FNAIT

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BACKGROUND

- Hemolytic disease of the fetus and newborn (HDFN) is a rare and potentially life-threatening condition that occurs when the blood types of the pregnant adult and the fetus are incompatible and the pregnant adult develops alloantibodies against an antigen on fetal red blood cells. During pregnancy, the maternal alloantibodies cross the placenta and bind to fetal red blood cells, causing destruction and anemia in the fetus or the newborn¹
- Fetal and neonatal autoimmune thrombocytopenia (FNAIT) is a rare disease resulting from human platelet antigen (HPA) incompatibility between a pregnant adult and their fetus. In FNAIT, maternal immunoglobulin G antibodies against fetal HPA cross the placenta and destroy fetal and neonatal platelets, resulting in thrombocytopenia²
- Both HDFN and FNAIT are associated with significant morbidity and mortality for developing fetuses and neonates; however, they are asymptomatic for mothers
- There is a lack of available literature from the patient perspective to describe the disease burden and unmet need of these 2 rare pregnancy-related alloimmune conditions

OBJECTIVE

- To advance the understanding of the impacts associated with the experience of a pregnancy affected by HDFN or FNAIT from the patient perspective

METHODS

- Qualitative, semistructured interviews were conducted with mothers who had ≥1 pregnancy diagnosed with either HDFN (n = 10) or FNAIT (n = 8; **Table 1**)

TABLE 1: Demographic characteristics

	HDFN (n = 10)	FNAIT (n = 8)
Sex, n (%)		
Female	10 (100)	8 (100)
Age, years		
Mean (SD)	35.5 (4.58)	41.0 (4.84)
Median (Q1, Q3)	35.5 (32.0, 37.0)	40.5 (38.0, 43.5)
Minimum, maximum	30.0, 46.0	34.0, 50.0
Race/ethnicity, n (%)		
Non-Hispanic White or Caucasian	7 (70)	8 (100)
Black or African American	1 (10)	–
Asian or Asian American	2 (20)	–

FNAIT, fetal and neonatal autoimmune thrombocytopenia; HDFN, hemolytic disease of the fetus and newborn; Q1, first quartile; Q3, third quartile; SD, standard deviation.

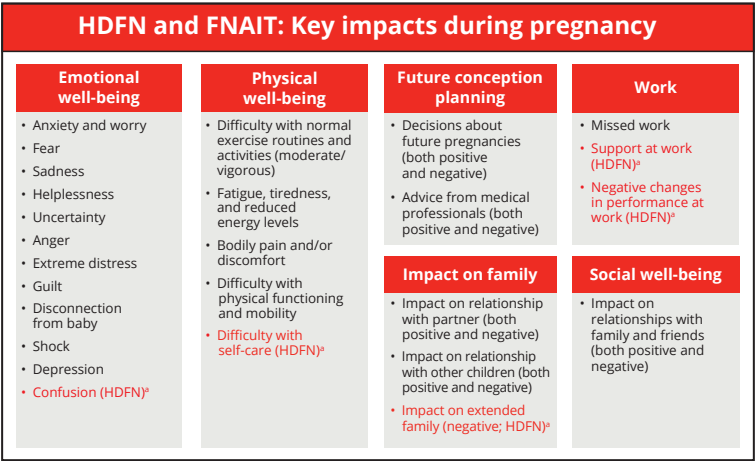
- All participants were recruited from the United States via a research partner following institutional review board approval
- Eligible participants had ≥1 previous pregnancy with a diagnosis of HDFN or FNAIT, were able to complete the interview in English, and were willing and able to give informed consent and to comply with study procedures; there were no exclusion criteria
- The Mother-Generated Index (MGI) was mailed to participants to complete and return in their own time. The MGI is a 3-step patient-reported outcome measure that assesses antenatal and postnatal quality of life. Mothers are asked to record, in a free-text field, up to 8 areas of their lives that have been impacted by having a baby. For the purposes of this study, mothers were instructed to complete the MGI while thinking about their most recently affected pregnancy with HDFN or FNAIT
- Interviews were audio recorded and transcribed verbatim. Transcripts and MGI data were analyzed using thematic analysis methods

¹Janssen Global Services, LLC, a Johnson & Johnson company, Raritan, NJ, USA; ²Clinical Outcomes Solutions, Tucson, AZ, USA.

RESULTS

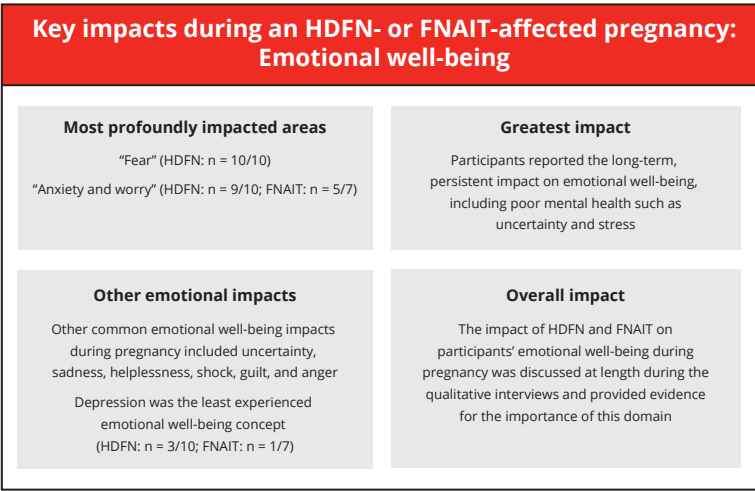
- Participants reported an HDFN- or FNAIT-affected pregnancy encompassed several impacts, including those associated with diagnosis, making time for and tolerating treatments, and uncertainties during the neonatal period
- The most frequently reported impacts of HDFN or FNAIT experienced during pregnancy included negative impacts on emotional well-being (HDFN: n = 10/10, 100%; FNAIT: n = 8/8, 100%), such as anxiety, worry, or fear; physical well-being (HDFN: n = 8/10, 80%; FNAIT: n = 5/7, 71%), such as fatigue, tiredness, and reduced energy levels; and social well-being (HDFN: n = 8/10, 80%; FNAIT: n = 5/7, 71%), with respect to relationships with family and friends (**Figures 1-3**)
 - Concept-level findings for FNAIT were based on a total of 7 participants as 1 participant was diagnosed after giving birth and, therefore, was not able to report impacts during pregnancy

FIGURE 1: Combined disease experience visualization: impacts during pregnancy



FNAIT, fetal and neonatal autoimmune thrombocytopenia; HDFN, hemolytic disease of the fetus and newborn.

FIGURE 2: Greatest emotional well-being impacts during an HDFN- or FNAIT-affected pregnancy

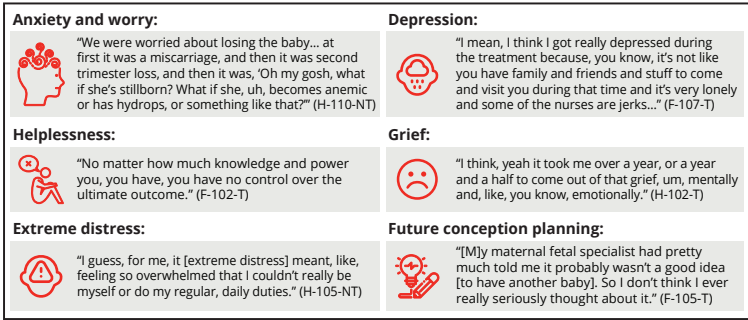


FNAIT, fetal and neonatal autoimmune thrombocytopenia; HDFN, hemolytic disease of the fetus and newborn.

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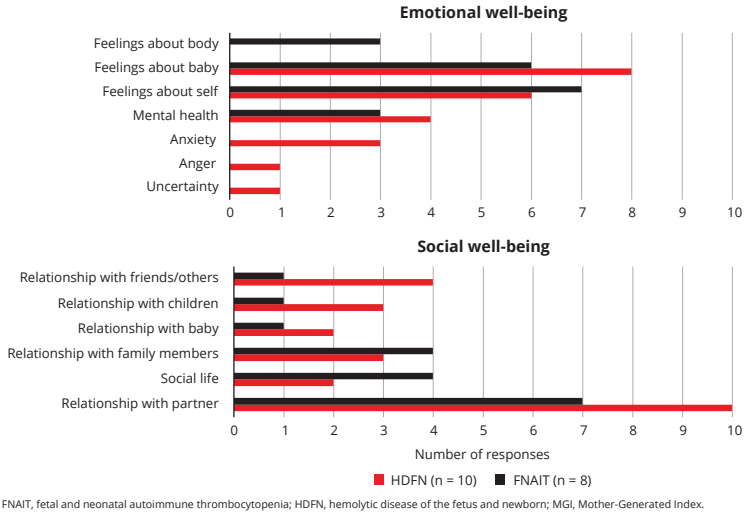
FIGURE 3: Exemplary quotes from participants with HDFN and FNAIT*



FNAIT, fetal and neonatal autoimmune thrombocytopenia; HDFN, hemolytic disease of the fetus and newborn. *Quotes are represented by "H" for participants with HDFN, "F" for participants with FNAIT, "T" for participants who received treatment during pregnancy, and "NT" for participants who did not receive treatment during pregnancy.

- Postnatally, participants reported they also face long-term challenges as a result of their experience with HDFN or FNAIT, including decisions regarding whether or not to pursue future pregnancies and persistent emotional well-being impacts
- Participants recorded MGI areas that were important to them, allowing for a deeper understanding of what is relevant to pregnant individuals impacted by HDFN or FNAIT. MGI data were consistent with and confirmed the results generated by the qualitative interviews, with social well-being and emotional well-being impacts indicated as the most relevant to the experiences of participants (**Figure 4**)

FIGURE 4: Important areas of life affected by HDFN and FNAIT as recorded on the MGI



FNAIT, fetal and neonatal autoimmune thrombocytopenia; HDFN, hemolytic disease of the fetus and newborn; MGI, Mother-Generated Index.

KEY TAKEAWAY

- Primary research with individuals who had either an HDFN- or FNAIT-affected pregnancy demonstrated the profound impact diagnosis and treatment have on maternal emotional, social, and physical well-being

CONCLUSIONS

- The results of this study contextualize significant impacts that mothers experience during and after an HDFN- or FNAIT-affected pregnancy
- The qualitative interviews with mothers indicated that several areas of well-being were affected, which were affirmed by MGI data
- This research provides important insights into disease areas with limited patient-generated information and direction for future studies on the assessment of health and well-being in these high-risk pregnancies

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DISCLOSURES

SP, MLT, and KS are employees of Janssen Global Services, LLC. PM, SH, and JR are employees of Clinical Outcomes Solutions, which received funding from Janssen for this analysis. SD is a former employee of Janssen Global Services, LLC.

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