**Challenges and Barriers facing the Current G-BA Directive on Newborn Screening – One Year experience from Newborn Screening Heidelberg**

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**Introduction**

The revised G-BA directive for paediatric newborn screening was implemented in January 2025. It requires (highly) abnormal findings to be communicated directly by the laboratory physician to parents within 72 hours after blood draw. Furthermore screening laboratories must ensure timely referral to a specialised pediatric center for further diagnosis and treatment. This marks a major change to current practice. This project documents the challenges and barriers faced by laboratory physicians at the Heidelberg Screening Centre during the first year of the revised directive.

**Methods**

The impact of the legal requirements on the Heidelberg Screening Centre was evaluated retrospectively during the first year of implementation (15$^{th}$ Jan 2025- 15$^{th}$ Jan 2026), using the novel introduced documentation forms.

**Results**

Between 15/01/2025 – 15/01/2026, a total of 132,506 children underwent newborn screening in Heidelberg. In 417 cases, abnormal findings required telephone contact with parents and specialised centres. Suspected diagnoses were CAH (20), PCH (65), MCADD (13), VLCADD (3), MSUD (3), LCHADD/MTP (2), GA-I (6), PKU (12), IVA (45), GALT (6), HT-I (2), CPT I-D (1), SMA (20), SCD (26), SCID (14) and CF (179). 14 % were hospitalized. Major challenges when contacting parents were unavailability (up to 15 contact attempts), missing or incorrect phone numbers (6 %) and language barriers (8 %). Police assistance was required in six cases. Specialised centres contacted families for some target diseases, particularly SMA (85 %), SCID (21 %), MCADD (7 %), CAH (5%), CF (5 %) and PCH (5%).

**Conclusion**

The implementation of the revised G-BA directive has expanded the role of screening laboratories beyond diagnostics to direct patient communication and coordination of care. While early and direct parental notification may accelerate diagnosis and treatment, it creates challenges, including unreliable contact, communication barriers, and increased resource demands. Our findings highlight

the need for standardized communication pathways, improved data quality and additional structural support to ensure effective and equitable implementation of the directive.

**Referenzen:**


1. Kinder-Richtlinie - Gemeinsamer Bundesausschuss (https://www.g-ba.de/richtlinien/15/)