A Framework for Genomic Newborn Screening

Symposium on Final Results of the NEW_LIVES Project (“Genomic Newborn Screening Programs – Legal Implications, Value, Ethics and Society”)

Location: Marsilius-Kolleg, Im Neuenheimer Feld 130.1, 69120 Heidelberg (Germany)
Date: 18.07.2025
Time: 11:00–17:00 (GMT+2), Symposium & 18:00–19:00 (GMT+2): Panel discussion
(The events can be attended separately; no registration required for panel discussion.)
Language: English

The event will also be streamed online (link can be requested during registration). Participation is free, but places for the symposium are limited, **please register in advance by email to lars.neth@med.uni-heidelberg.de** and indicate whether you want to participate in person or listen online. The panel discussion can be attended in person without prior registration, for online participation please contact Lars Neth (see email above).

Description

Newborn screening (NBS), established more than 50 years ago, is one of the most successful public health programs for disease prevention. It aims at early detection, and early treatment of children with selected severe diseases. The implementation of genome sequencing in the context of NBS opens the possibility of genomic newborn screening (gNBS). At present, gNBS is investigated in pilot studies around the world, but not yet integrated to population-wide NBS programs.

On July 18, 2025, the **project NEW_LIVES**: “Genomic **NEW**born screening programs – **L**egal **I**mplications, **V**alue, **E**thics and **S**ociety” (http://gnbs.ukhd.de), funded through the ELSI funding line of the German Federal Ministry of Research, Technology and Space is cordially inviting participants to a conference in Heidelberg which discusses the ethical, legal, and societal implications (ELSI) of a potential gNBS program, as well as associated medical implications.

At the center of the event will be the presentation, explanation, and discussion of recommendations for the selection of target diseases and program management as well as regulatory changes for a possible future gNBS program in Germany. These recommendations will also be published in a position paper issued at the time of the symposium in print as well as online: “Empfehlungen zu ethischen, rechtlichen, sozialen und medizinischen Rahmenbedingungen für ein genomisches Neugeborenen-Screening-Programm in Deutschland. Stellungnahme der Projektgruppe NEW_LIVES ‘Genomic NEWborn screening programs – Legal Implications, Value, Ethics and Society’” (forthcoming).

Besides **specialists from related fields**, the event is aimed at the **public**, **media**, and **representatives from society and politics**.

Program

10:30 Registration desk opens

11:00–12:00

Part I: Why Are We Discussing Genomic Newborn Screening?

Chair: Prof. Dr. Dr. Eva Winkler (Institute for Medical and Data Ethics, Heidelberg University; NEW_LIVES, subproject ethics)

11:00–11:15

Welcome and Introductory Notes (Prof. Dr. Dr. Eva Winkler)

11:15–11:40 (15 min + 10 min discussion)

Newborn Screening and Genomic Newborn Screening (gNBS) – Introduction and Current Research on Potential Medical Gains of gNBS (Prof. Dr. Ulrike Mütze, subproject pediatrics, Division for Neuropediatrics and Metabolic Medicine, Pediatric Clinic I, Heidelberg University & Dr. Heiko Brennenstuhl, subproject human genetics, Institute of Human Genetics, Heidelberg University)

11:40–12:00 (15 min + 5 min discussion)

Role of Patient Representation in the Research Project NEW_LIVES (Tobias Hagedorn, patient representative, Deutsche Interessengemeinschaft Phenylketonurie und verwandte angeborene Stoffwechselstörungen, DIG PKU e.V.)

12:00–12:10 Short break

12:10–13:00

Part II: Societal Perspectives – Results of Socio-Empirical Studies in the NEW_LIVES Project

Chair: Prof. Dr. Beate Ditzen (Institute of Medical Psychology, Heidelberg University; NEW_LIVES, subproject medical psychology)

12:10–12:15

Brief Introduction to Parts II and III – ELSI of gNBS (Prof. Dr. Beate Ditzen)

12:15–13:00 (30 min + 15 min discussion)

Empirical Work in NEW_LIVES on German Population and Parental Attitudes Towards gNBS (Elena Doll & Dr. Julia Mahal, subproject medical psychology, Institute of Medical Psychology, Heidelberg University)

13:00–14:00 Lunch break

14:00–15:30

Part III: Ethical and Legal Grounds of Genomic Newborn Screening

Chair: Prof. Dr. Ralf Müller-Terpitz (Department of Law, University of Mannheim; NEW_LIVES, subproject law)

14:00–14:25 (15 min + 10 min discussion)

Current Legal Regulation of Genomic Newborn Screening (Hannah Straub, subproject law, Department of Law, University of Mannheim)

14:25–14:50 (15 min + 10 min discussion)

Ethical Framework for Genomic Newborn Screening (Karla Alex, Lars Neth & Prof. Dr. Dr. Eva Winkler, subproject ethics and project coordination, Institute for Medical and Data Ethics, Heidelberg University)

14:50–15:30 min (25 min + 15 min discussion)

Genomic Newborn Screening from an International ELSI Perspective (Dr. Amicia Phillips, University of Exeter Medical School)

15:30–16:00 Coffee break

16:00–17:20

Part IV: Recommendations for a Genomic Newborn Screening Program of the NEW_LIVES Project Group (Criteria for Target Disease Selection and Program Management & Regulatory Recommendations)

Chair: Prof. Dr. Stefan Kölker (Division for Neuropediatrics and Metabolic Medicine, Pediatric Clinic I, Heidelberg University; NEW_LIVES, subproject pediatrics)

16:00–16:45 (30 min + 15 min discussion)

Criteria for the Selection of Target Diseases – Clinical, Diagnostic, and Therapeutic Criteria (NEW_LIVES Criteria 1–11) (Karla Alex, subproject ethics, Institute for Medical and Data Ethics, Heidelberg University; Dr. Elena

Schnabel-Besson, subproject pediatrics, Division for Neuropediatrics and Metabolic Medicine, Pediatric Clinic I, Heidelberg University & Dr. Nicola Dikow, subproject human genetics, Institute of Human Genetics, Heidelberg University)

16:45–17:20 (20 min + 15 min discussion)
Criteria for Program Management (NEW_LIVES Criteria 12–18)
& Recommendations for Legal Reform (Prof. Dr. Ralf Müller-Terpitz, subproject law, Department of Law, University of Mannheim; Dr. Julia Mahal & Elena Doll, subproject medical psychology, Institute of Medical Psychology, Heidelberg University)

17:20–18:00 Break

18:00–19:00
Panel Discussion on Genomic Newborn Screening – Status Quo and Next Steps (Current state of NBS and gNBS, NEW_LIVES recommendations for gNBS, next steps)

Moderator:
- Dr. Jens Foell

Panellists:
- Prof. Dr. Beate Ditzen
  - Institute of Medical Psychology, Heidelberg University
- Tobias Hagedorn
  - DIG PKU e.V. (patient representative NEW_LIVES)
- Prof. Dr. Georg Hoffmann
  - Department of General Pediatrics, Neuropediatrics, Metabolism, Gastroenterology, Nephrology, Heidelberg University (advisory board NEW_LIVES)
- Dr. Amicia Phillips
  - University of Exeter Medical School
- Prof. Dr. Christian Schaaf
  - Institute of Human Genetics, Heidelberg University
- Prof. Dr. Dr. Eva Winkler
  - Institute for Medical and Data Ethics, Heidelberg University

Organized by the project group NEW_LIVES (http://gnbs.ukhd.de); funded by the German Federal Ministry of Research, Technology and Space (BMFTR).
(Fortbildungspunkte wurden bei der Landesärztekammer beantragt.)