

SNP data to the general population Experiences from the MIDIA Study

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MIDIA-Miljøårsaker til type 1 diabetes

MIDIA STUDY

Purpose:

Find environmental triggers of type 1 diabetes

How:

Screen 100,000 children to find the 2,1 % who have the high-risk genotype with mouth swabs

Follow-up 2,000 children with the high-risk genotype for 15 years



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Regulations for Scientific Projects

- Based on informed consent
- Approval from the Regional Committee for Medical Ethics, 1999
- Approval from the Data Inspectorate, 2001



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Additional evaluations

- The National Committee for Medical Ethics
- The Directorate for Health and Social Affairs
- The Department for Health and Care Affairs
- The Biotechnology Committee





A mother and father with a HR child

- 
- Visited their local physician
- 
- She complained to the Committee for Medical Ethics,
The Norwegian Medical Association
- 



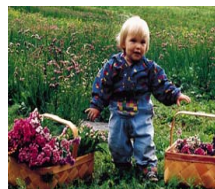
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- Another mother wrote an anonymous letter to Journal of the Norwegian Medical Association



- Aftenposten 28.06.07



- The head of the Biotechnology Committee:
"The MIDIA Study is performing genotyping against the Biotechnology Law",
Aftenposten, 29.06.07



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The Norwegian Biotechnology Law

Predictive Genetic testing

- Counseling has to be given before, during and after the testing

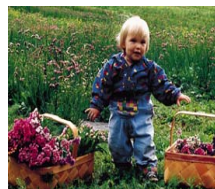


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The Norwegian Biotechnology Law

- Genetic testing of a child < 16 years is not allowed if circumstances can't be detected that can give health benefit for the child
- The Dept. can under certain conditions make exceptions







- Stopping of MIDIA from July 2, 2007
- Meeting with the Directorate for Health and Social Affairs, July 4.
- We could apply for exception, getting certification for genotyping, no reason to stop MIDIA in the meantime

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- Committe for the Biotechnology law:
"MIDIA is against the law"



-The National Committe for Social
and Health Affairs: "6 went for a closed
study design, 5 said that it could
continue in it's present form"



-The Committee for Medical Ethics:
"Only ethical to test 1. degree relatives"

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- The MIDIA Study was stopped by The Directorate for Health and Social Affairs December 10, 2007.
- Participants should be followed-up in a good medical and suitable form



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- The Data Inspectorate, December 13, 2007: Illegal to use the already collected data in MIDIA.

- But data belongs to the participants in MIDIA

- We could apply to the Regional Committee for Medical Ethics and the Data Inspectorate once more

- Ask for a new Informed consent

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- Complaint to Shdir

Participants should be followed-up in a good medical and suitable form???



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- Shdir rejected the Complaint of Dec. 22, 2007
March 30, 2008.
- The Department for Health and Social Affairs,
letter of April 26, 2008, would give their own
evaluation of the MIDIA project,
important health political decisions has to go to
HOD before Shdir can make a decision
(the roles for management by Shdir from HOD
of January 2005)

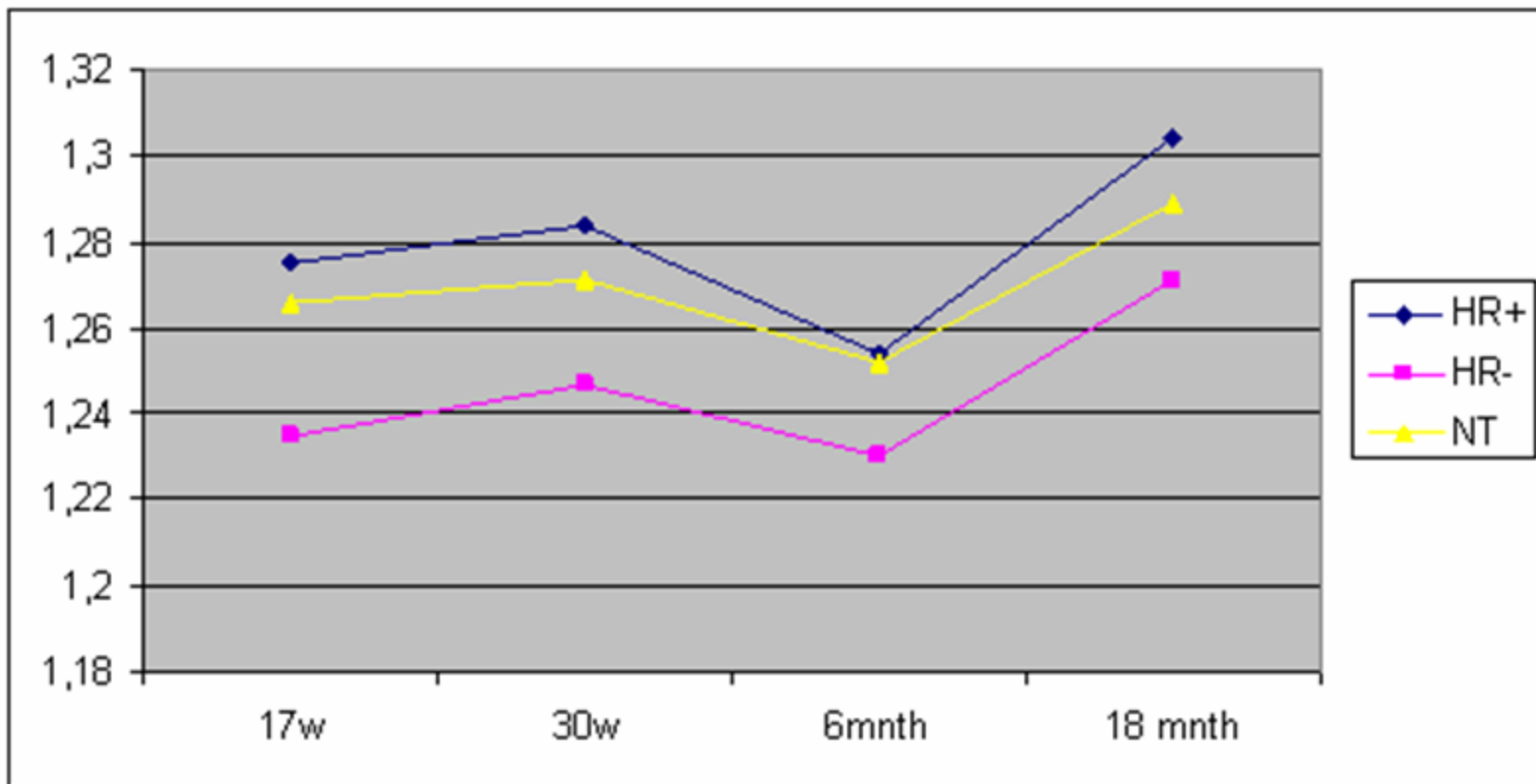
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The revised National Budget

- The government wanted the follow-up of participants in MIDIA to continue as before
- Final decision in the parliament June 20, 2008
- Letter from HOD June 23, 2008, research in MIDIA could continue



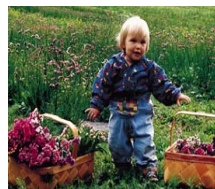
Effect of risk information



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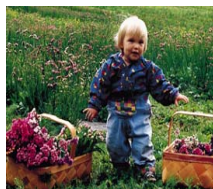
Psychosocial effect of risk information



Thinking about T1D risk, Questionnaire 3 mnd (n=927)	Never N (%)	Sometimes N (%)	Often N (%)	Daily N (%)	Not answered N (%)
Mother	126 (13.6)	576 (62.1)	136 (14.7)	55 (5.9)	34 (3.7)
Father	233 (25.1)	520 (56.1)	63 (6.8)	18 (1.9)	93 (10.0)

Psychosocial effect of risk information

Thinking about T1D risk, Questionnaire 12 mnd (n=663)	Never N (%)	Sometimes N (%)	Often N (%)	Daily N (%)	Not answered N (%)
Mother	209 (31.5)	385 (58.1)	32 (4.8)	6 (0.9)	31 (4.7)
Father	317 (47.8)	266 (40.1)	16 (2.4)	3 (0.5)	61 (9.2)





- Primary intervention
omega-3 fatty acids
- Secondary intervention
GAD vaccine

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Thank you very much for your attention!



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