Newborn Hearing Screening - How to get it implemented?

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Prevalence of Permanent Hearing Loss in Neonates which needs treatment

Region-dependent:
1.8/1000 (Australia; bilateral), ~1/1000 (Brazil; bilateral; Sweden), 1-3/1000 (China; bilateral) and ~5/1000 (unilateral), 2.3 /1000 Germany (1.6/1000 bilateral, 0.7/1000 unilateral); 1.61/1000 of at-risk infants (India; bilateral); 1/1000 (Serbia; bilateral) and 0.3/1000 (unilateral), 1.05/1000 (Colorado; bilateral) and 0.45/1000 (unilateral), 1.83/1000 (Washington D.C.), 3/1000 (Philippines)

Range: 1/1000 – 6/1000

Which Consequences Does an Infant Hearing Loss Have?

- Disturbed development of hearing, speech and language, learning, reading and spelling
- Emotional and cognitive disturbances
- Consequences for the families
- education and
- professional performance

Mean loss of income for life of persons with congenital hearing disorders:

300.000 – 500.000 $

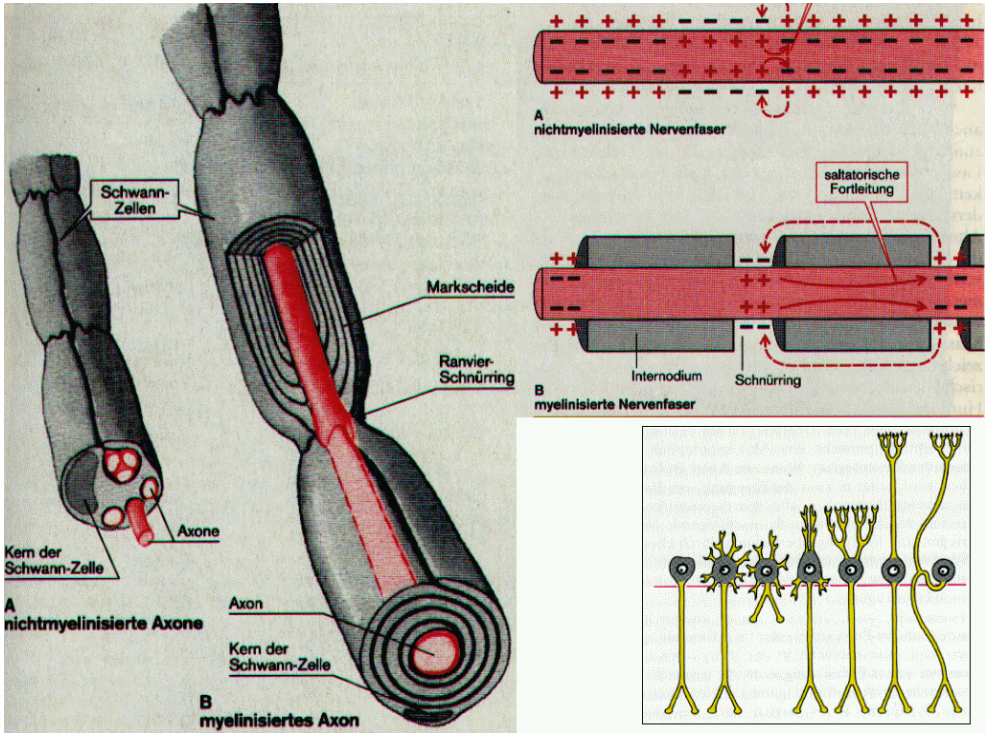
(Northern and Downs, 1991, USA)

Development of the Auditory System

Basic processes mainly during the last prenatal weeks and first postnatal months

Sensitive time windows for maturation of the Auditory Pathway

- dendritogenesis completed after 40 weeks (Lenarz, 1997)
- myelinization of the axons of the auditory nerve up to the inferior colliculus completed up to the end of the first year (Moore, 1995)



No Earlier Diagnosis and Treatment in Regions with Sporadic Newborn Hearing Screening!

German Central Register of Infant Hearing Disorders (Gross, 2001):

→ **A sporadic or regional screening is not enough.**

Screening program was required, which includes from the first beginning certain quality criteria

Screening results have to be judged by answering the question:
Do children with neonatal hearing disorders indeed receive an earlier therapy as so far?

Newborn Hearing Screening in Germany mandated since Jan. 1, 2009

Every newborn has the right to receive a NHS.

Written information for parents, disagreement needs to be signed by a parent

detection of a bilateral permanent childhood hearing loss (PCHL) from **35 dBHL** on

to be **diagnosed** up to the end of the **3rd month** of life

Therapy start up to the end of the **6th month** of life

Financing: Health insurances

Methods:

TEOAE and in case of failing AABR (two-stage) or **AABR alone**

failing the primary screening (TEOAE or AABR) → control-AABR (same day recommended, but up to 10th day of life latest)

failing control-AABR → pediatric-audiological diagnostics

at-risk babies: obligatory AABR

binaurally

Time frame of the screening: up to the 3rd day of life recommended, latest until 10th day of life

in-patient screening: before delivery

preterm newborns: latest up to the calculated birth date

severely ill babies: NHS considering additional diseases, but up to the end of the 3rd month of life latest

Responsibility:
must be clearly defined

in-patient screening: physician who is responsible for the maternity ward

out-patient birth: midwife or the physician who guided birth reponsible for the initiation of the screening

out-patient screening: by ENT, pediatrician, or phoniatrician/pediatric audiologist

pediatric-audiological diagnostics: phoniatricians/pediatric audiologists or pediatric-audiologically qualified ENTs

Quality Assurance

Coverage rate of the NHS in the hospital 95%

At least 95% of the babies who failed the primary screening should get a control-AABR

(a) before delivery from the maternity ward (in-patient screening)

(b) in the same practise where the screening has been performed (out-patient screening)

Proportion of children who need a pediatic-audiological confirmation diagnostics should not be higher than 4% (also for practises)

Defined follow-up diagnostics after a failed primary and control screening

Two steps:

Step1: Repeated and extended screening

→ 90% pass

Step 2: Full pediatric-audiological diagnostics

Every child undergoes regular pediatric examinations during the first 6 yrs. of life, documented in a booklet
→ ensures minimal tracking

Disagreement of parents /sign

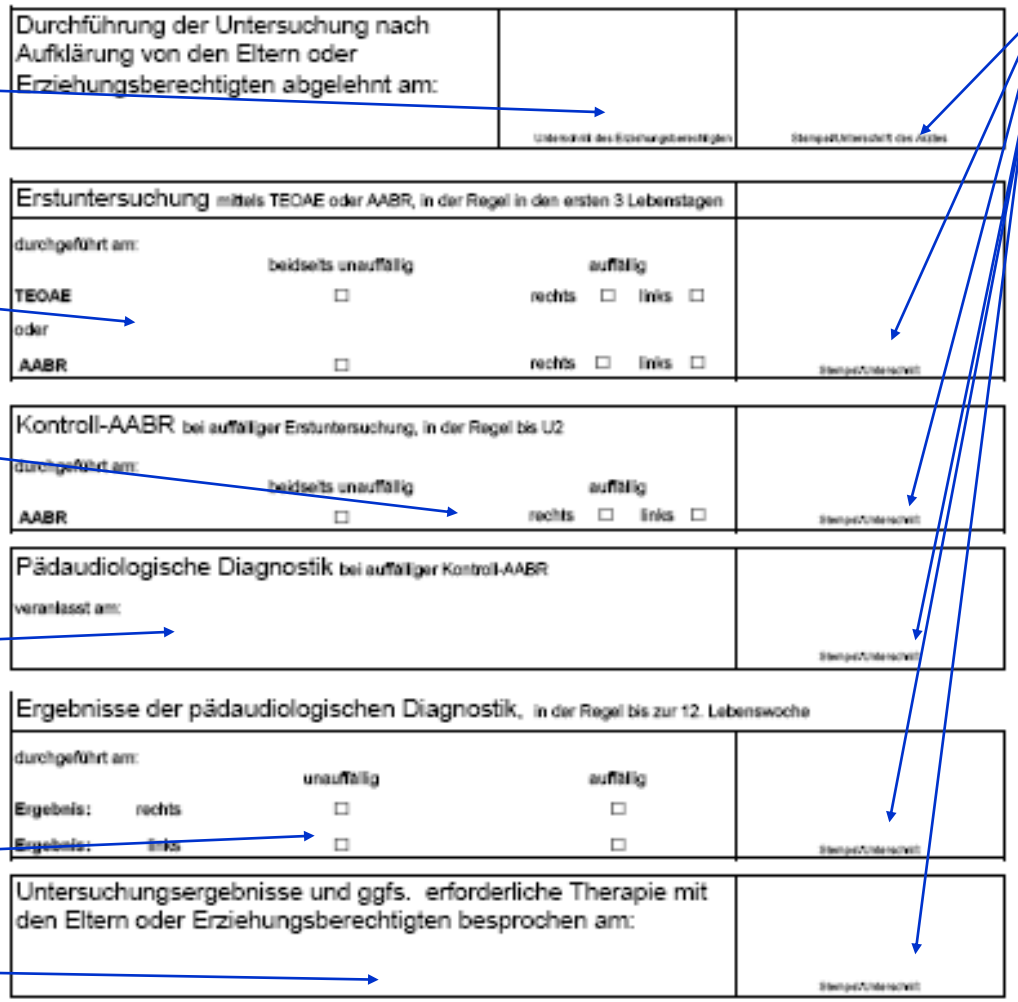
Primary screening (TEOAE / AABR passed or failed?

Control-AABR passed or failed?

Pediatric audiological diagnostics initiated? When?

Results of a Pediatric audiological diagnostics? Hearing loss? Ear?

Talk with the parents about the results of the examaintions?



Sign of Pediatrician

+ annual statistics of the birth clinics

Data from Germany from 2005, 2006, and 2010 (German Registry of Childhood Hering Loss, DHZ)

- 11 of 16 German federal states send regular reports to the DHZ.
- **74%** of the 245 children born in year **2005** who were identified with a permanent hearing loss and were reported to the DZH were diagnosed by a NHS, in **2006** this percentage increased to **85%.**
- mean age at diagnosis of the **screened** children: **4.7 mos. in 2005**

  4.2 mos. in 2006

  of the **not screened** children: **16.5 mos. in 2005**

  12.5 mos. in 2006
- **42%** of the children received **intervention before 6 mos. of age** in 2005 and **61% in 2006**
- **After implementation of a nation-wide NHS:** mean age at diagnosis of a permanent infant hearing loss **(screened and not screened children**) decreased to **12 mos. In 2010**

Problem: Financing of regional screening centers and tracking

Neumann et al. Hearing impaired children in Germany. 5 years' review and outlook Shanghai, 2010

Hessen, Germany

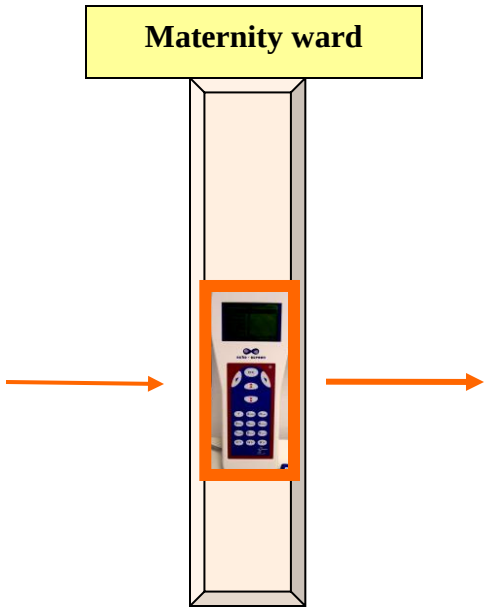
- 51,000 deliveries per year
- 83 birth clinics: NHS in all clinics
- 74 clinics: electronic data transfer to a screening center → tracking
- 9 clinics: no central data collection → no tracking
- 1650 trained examiners with certificate (2008)

Neumann. NHS in Hesse and Germany. WHO, Geneve, 2009.

Hessian NHS progran: meets Iinternational quality criteria:

1. coverage rate 95 % → in-patient screening √
2. < 4 % babies fail the primary screening → two-stage screening protocol; TEOAE-AABR√
3. follow-up rate ≥ 95 % → after a failed primary screening babies directly referred to pediatric-audiological institutions (√)
4. clear organization of follow-up → parents provided with addresses of pediatric audiological follow-up institutions√
5. diagnostics finished within 3 mos., therapy starts within 6 mos. → first pediatric-audiological consultation within 2 weeks, tracking with reminder letters and telephone calls in two-week intervals √
6. further quality standards: central data processing, tracking, certified training and supervision of the screening staff √

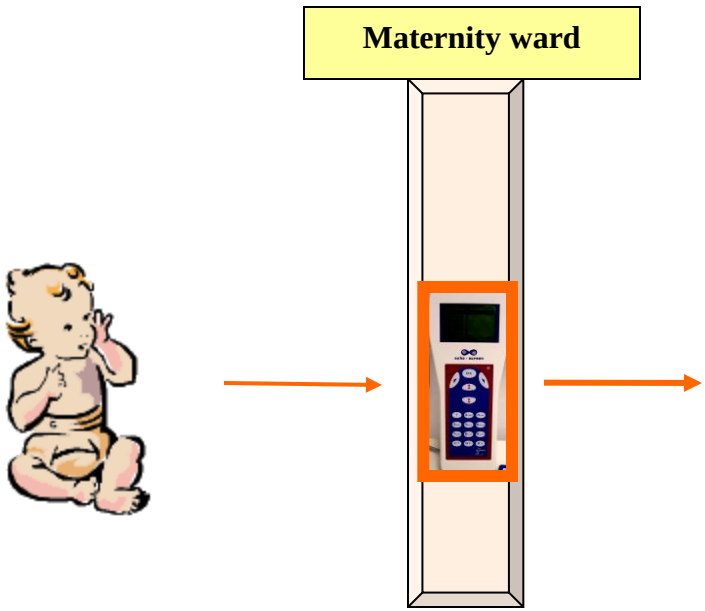
Electronic data collection, database, tracking



first German NHS-Programm with automated data transfer and qualiy assurance
(Neumann et al., 2006)

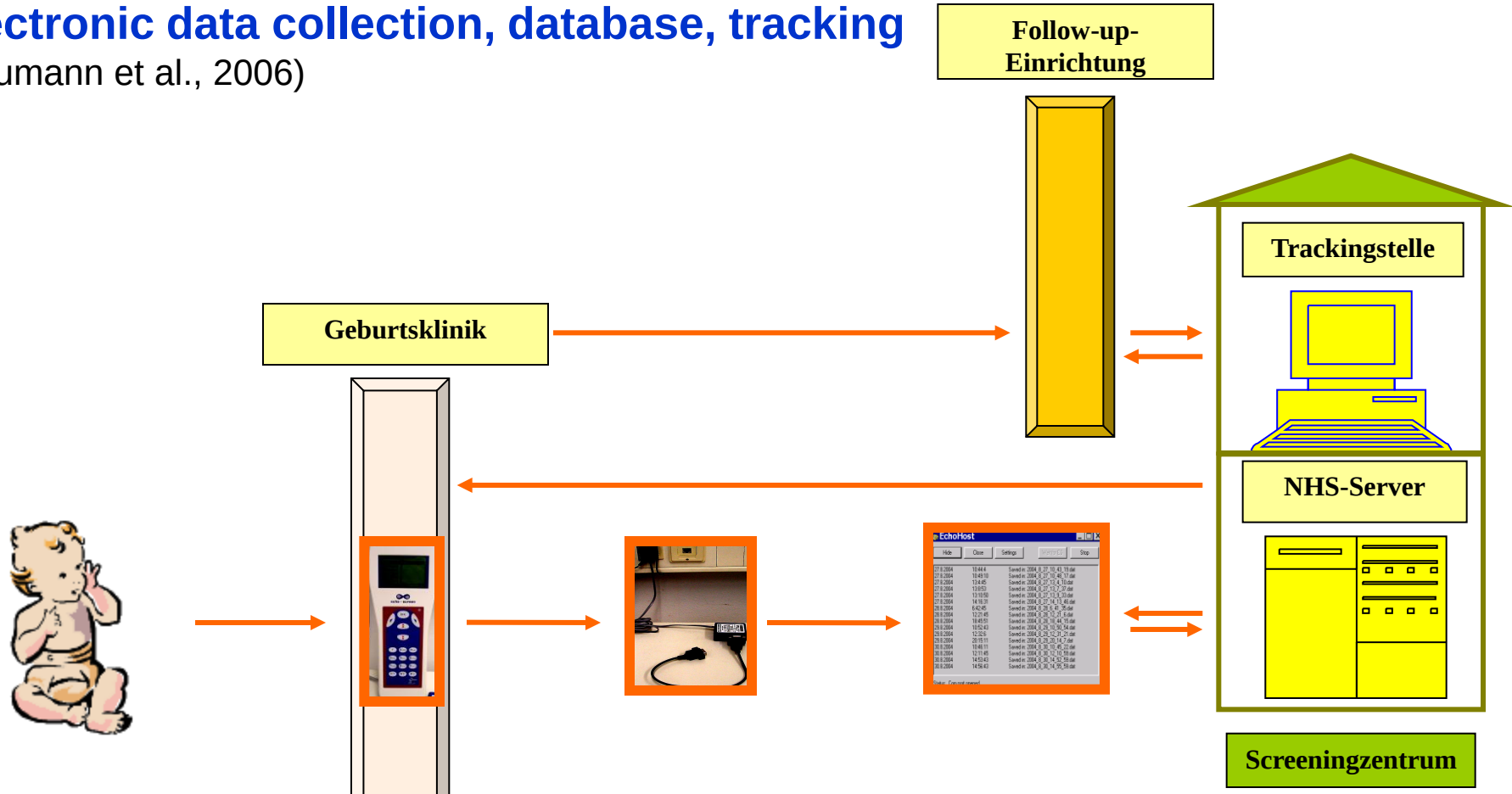
Electronic data collection, database, tracking

(Neumann et al., 2006)



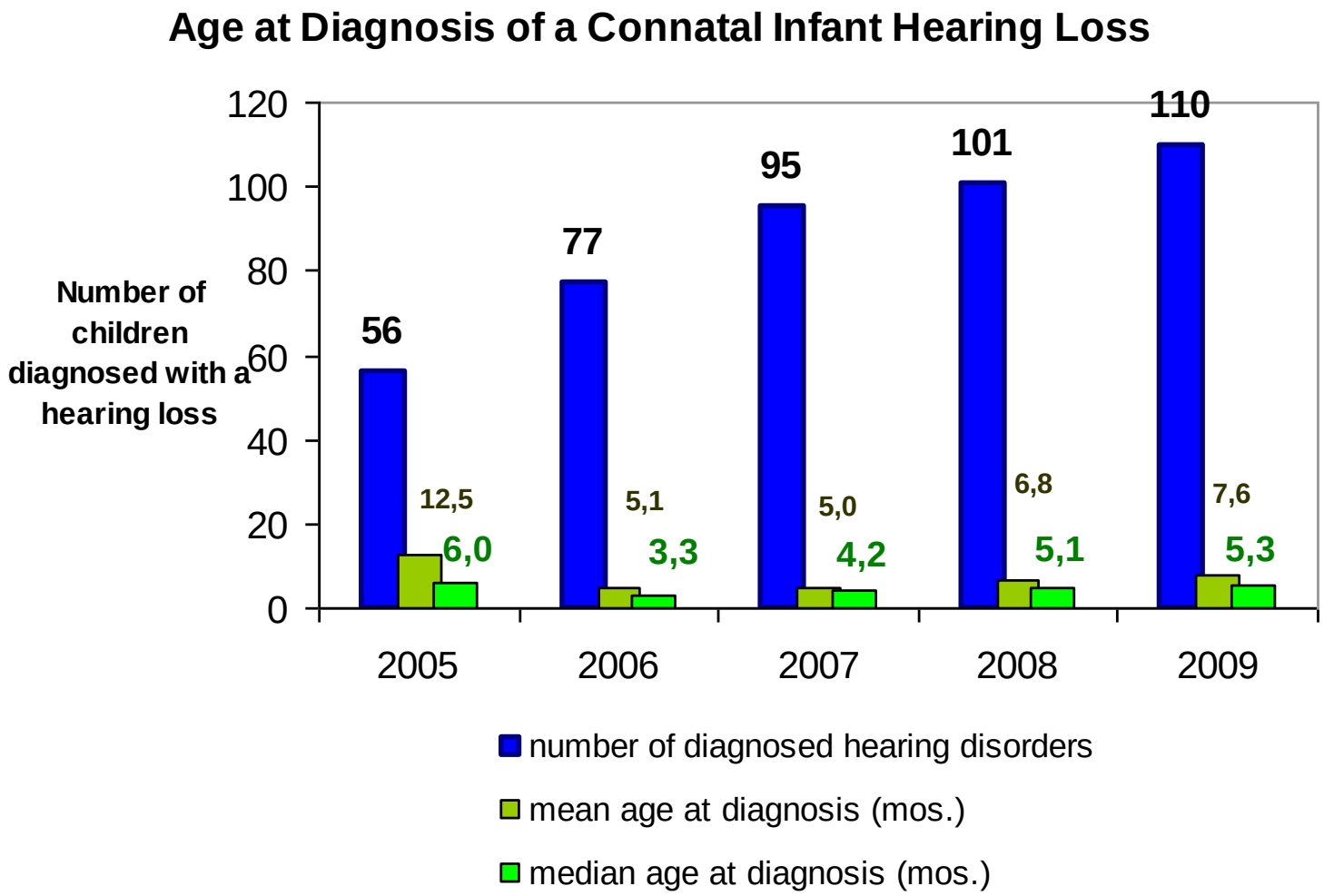
Electronic data collection, database, tracking

(Neumann et al., 2006)



State of Hesse: Age at Diagnosis in the Hessian NHS program

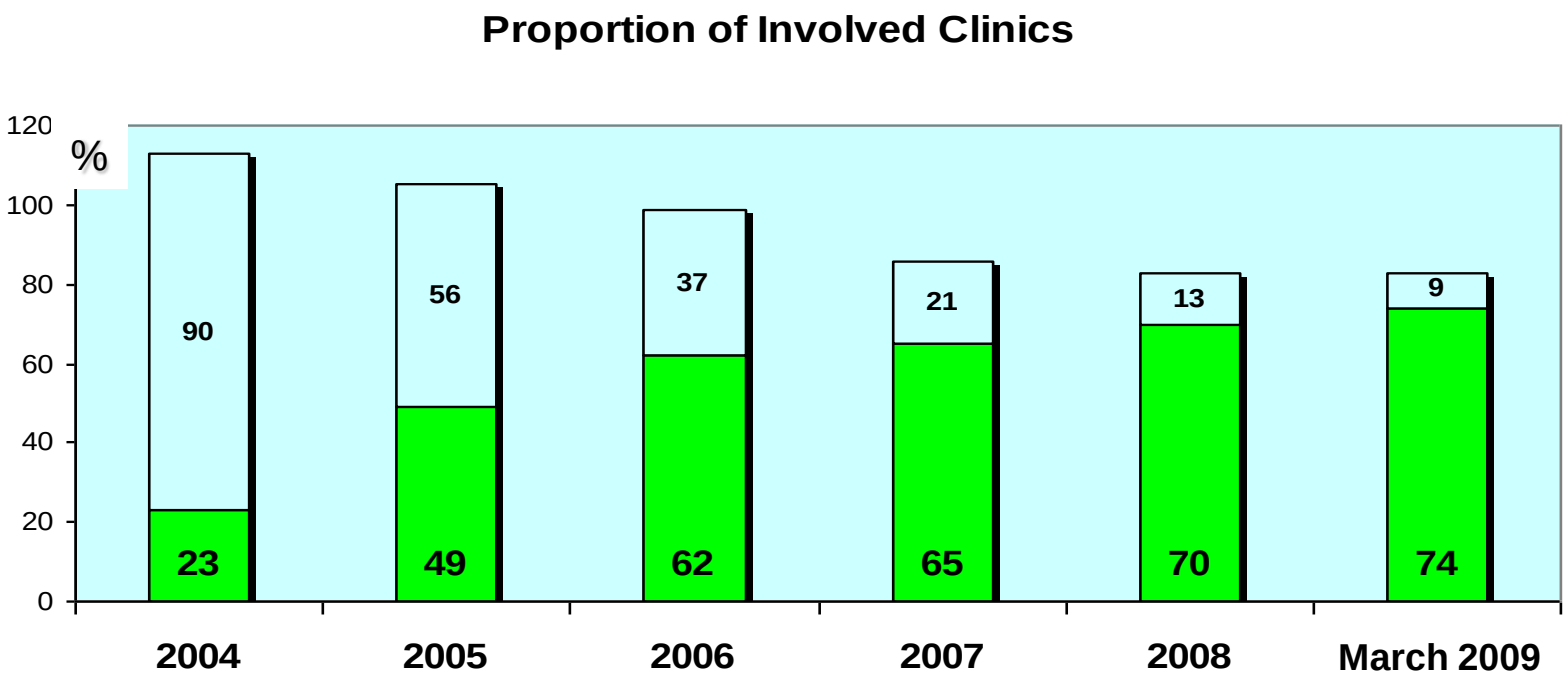
Database comprises datasets of 210.870 children at current



Increase of age at diagnosis by lacking follow-up capacity?

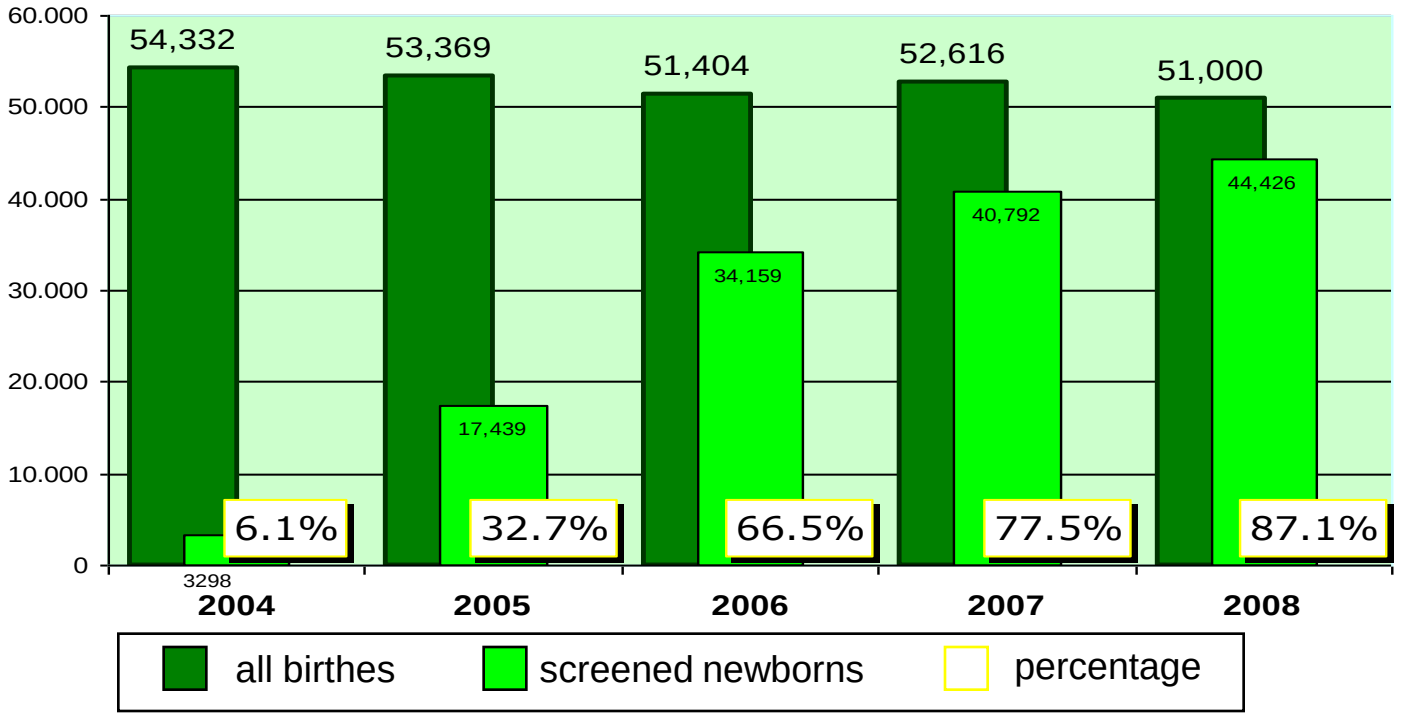
Neumann et al. Hearing impaired children in Germany. 5 years' review and outlook Shanghai, 2010

Implementation of a UNHS in the Hessian Birth Clinics



Neumann. NHS in Hesse and Germany. WHO, Geneve, 2009.

Development of Coverage Rates in the Hessian NHS Program



Coverage rates in clinics involved in the Hessian NHS program in 2008: 97.2%

Neumann. NHS in Hesse and Germany. WHO, Geneve, 2009.

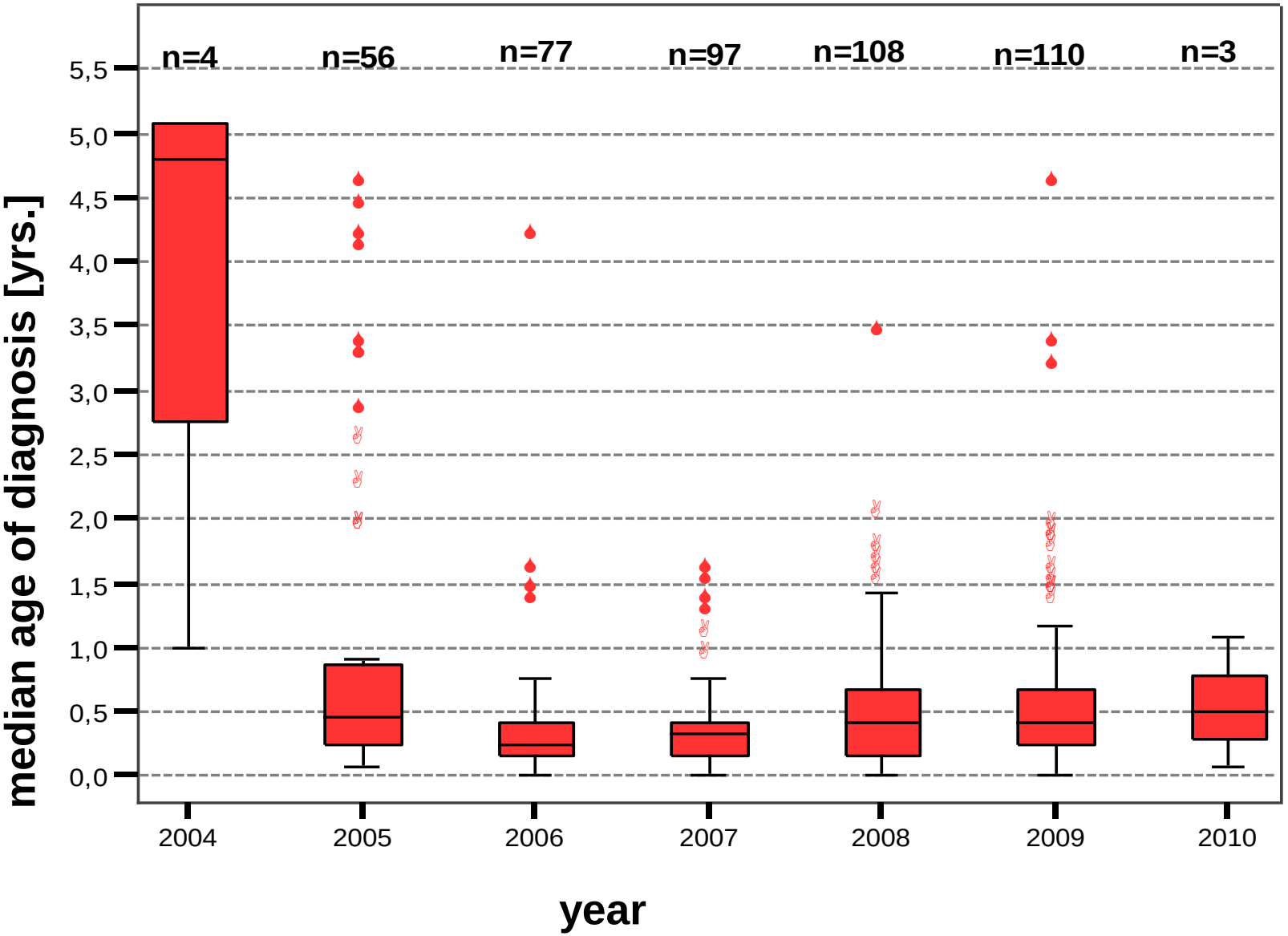
Outcome Hessen: NHS Database 2005 and 2006
data of 34,129 babies

Prevalence (incl. monaural hearing impairments)		2.1-2.8 / 1000
Median age at diagnosis (detected by screening)	2005	3.1 mos.
	2006	3.2 mos.
(not detected by screening)	2006	16.7 mos.
Median age at therapy start (detected by screening)	2005	3.5 mos.
(not detected by screening)	2005	49.5 mos.
Program specificity	2005	97.2 %
	2006	96.5 %
Hessen 2005: Median age at diagnosis of all hearing impaired children		6.3 mos.
	2006	3.9 mos.
Germany: Median age at diagnosis	2005	39 mos.

→In 2005 64% of all children with hearing loss in Hessen detected by a NHS, in 2006 already 93%!

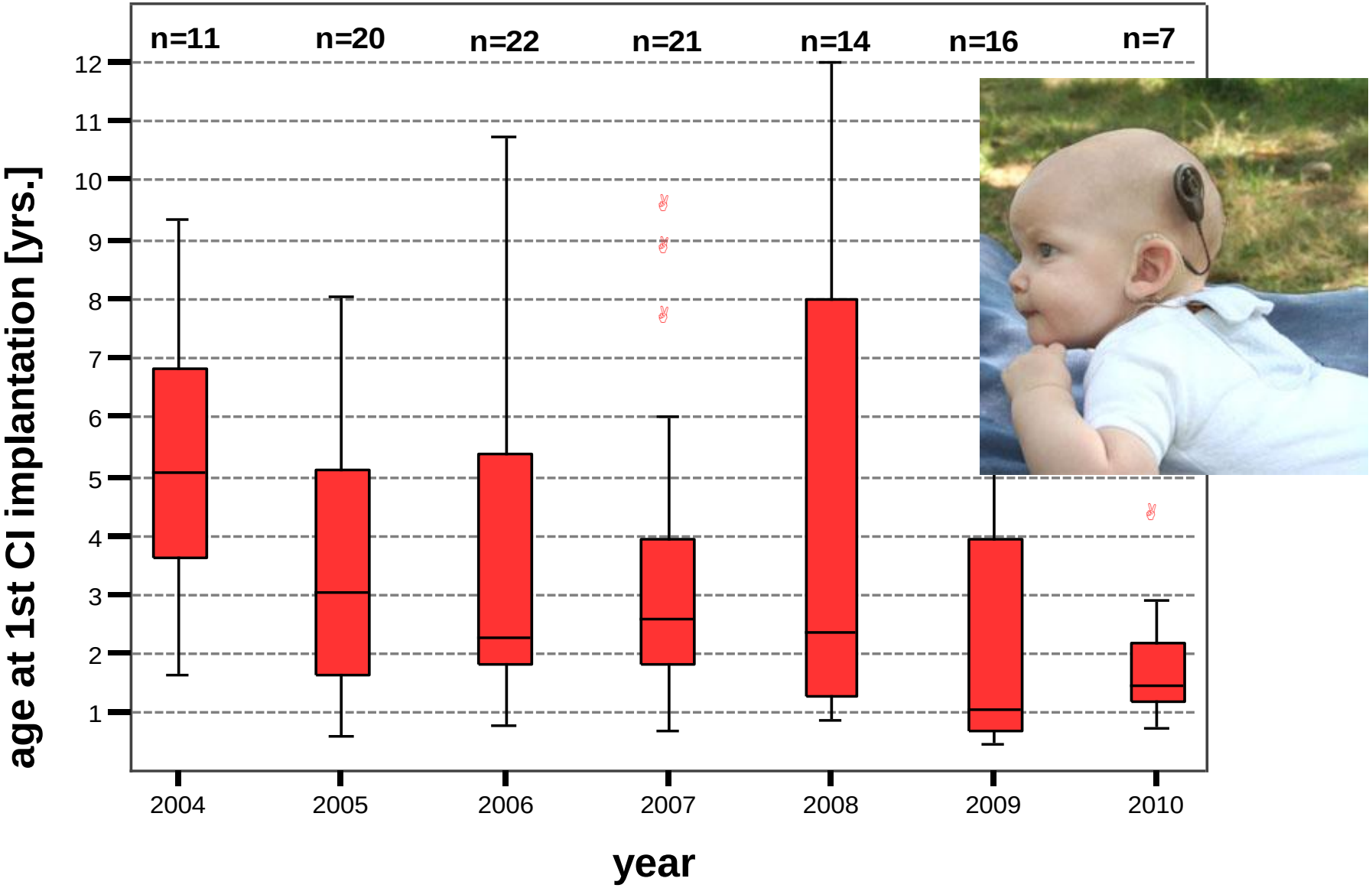
Less than one month delay between detection and therapy start

Development of age medians of diagnosing an permanent infant hearing loss in the state of Hesse, Germany



Neumann et al. Hearing impaired children in Germany. 5 years' review and outlook Shanghai, 2010

Development of age medians of 1st CI implantation (University of Frankfurt)

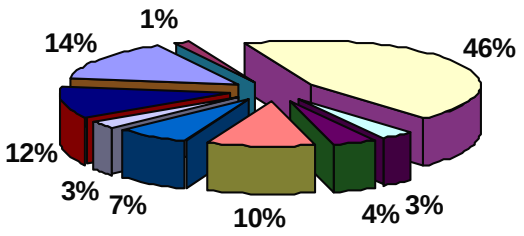


Neumann et al. Hearing impaired children in Germany. 5 years' review and outlook Shanghai, 2010

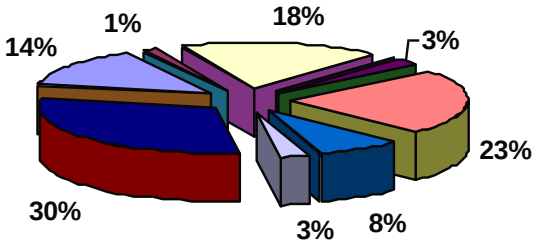
Education of children implanted with CI (Diller, 2006)

- 56 % of the Hessian children, who received a CI between 3 and 6 yrs. Of age were educated in 2006 in schools of the deaf or special schools
- only 24 % of the children who got a CI before their 3rd birthday were educated in schools of the deaf or special schools

Late implanted



Early implanted



Tracking

Quality assurance and evaluation of the EHDI (Neumann et al., 2009)

Regional Screening center

1 per federal state

Tracking of babies who failed the screening or had incomplete measurements (follow-up tracking)

Tracking of babies who missed the screening (completeness tracking, related to a birth cohort, region, or institution)

Screening center stores the regional data

Transfers data to nation-wide institution of UNHS quality assurance

Informs maternity wards quarterly about the screening results

Responsible for training and retraining of the screening staff

Assures continuity of the screening

Central data processing and analysis

Domains

1. transmission of screening data from the birth clinic to a screening center
2. transmission of follow-up data from the follow-up institution to a screening center
3. data analysis and tracking (follow-up and completeness) by the screening center
4. feedback information from the screening center to the maternity wards (important for keeping motivation) and follow-up institutions
5. provision of statistics/epidemiology

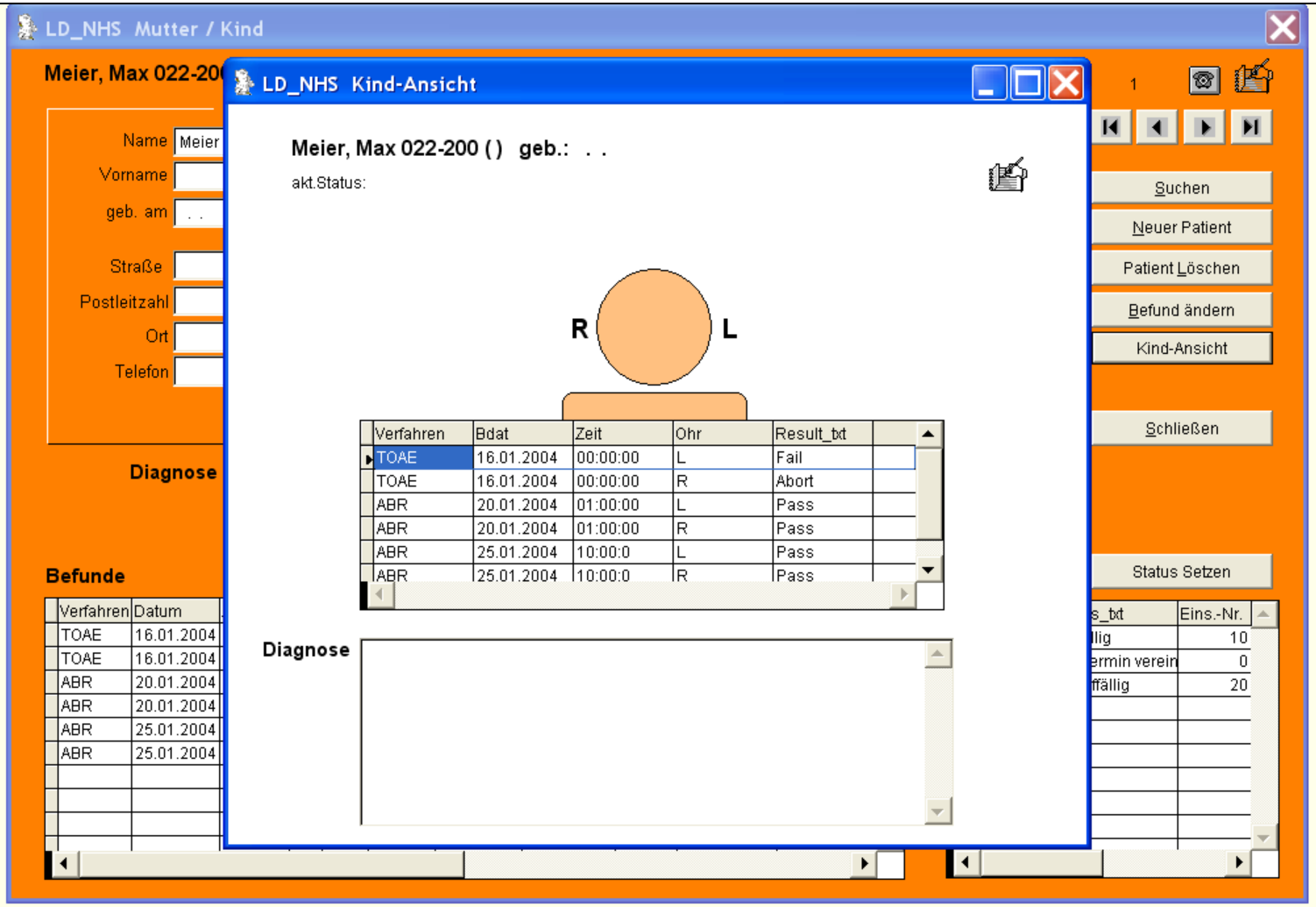
Software

developed by the Clinic of Phoniatrics and Pediatric Audiology of the University of Frankfurt together with Labodat, Dresden

experience of internationally approved NHS software is integrated

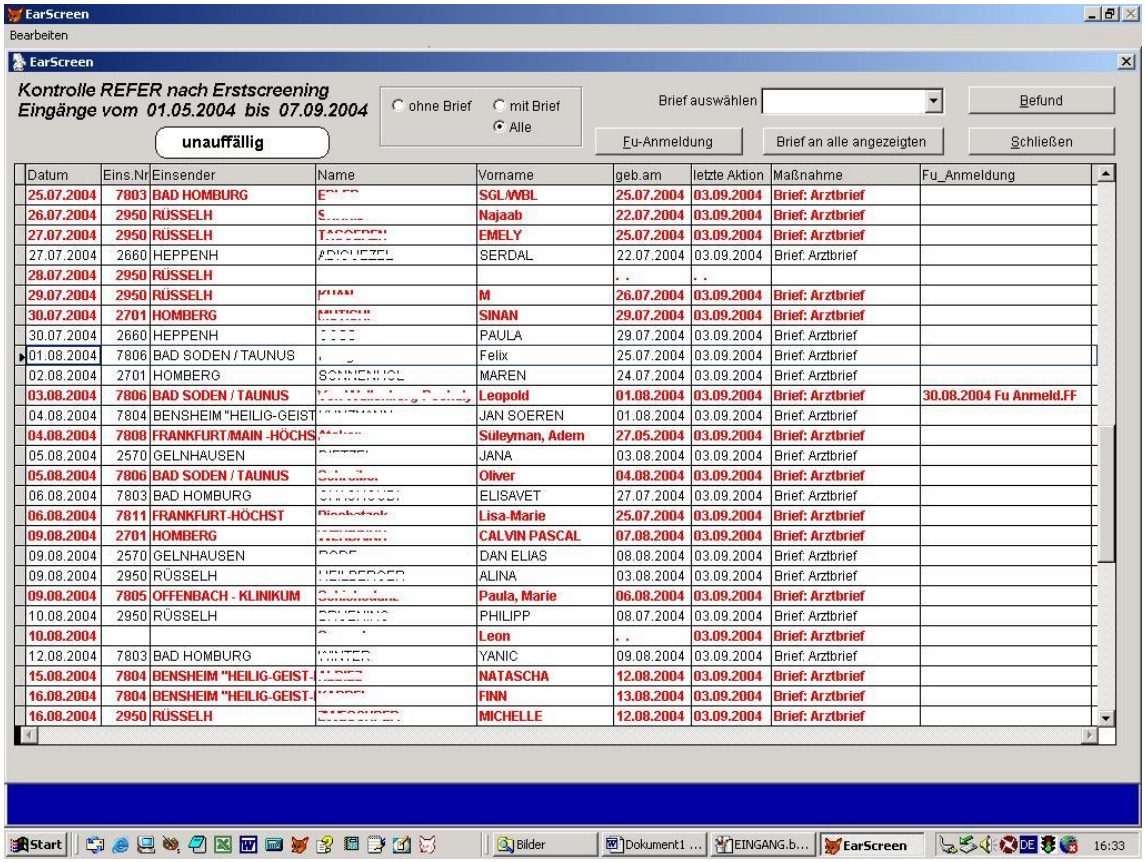
working also in China

View of Child



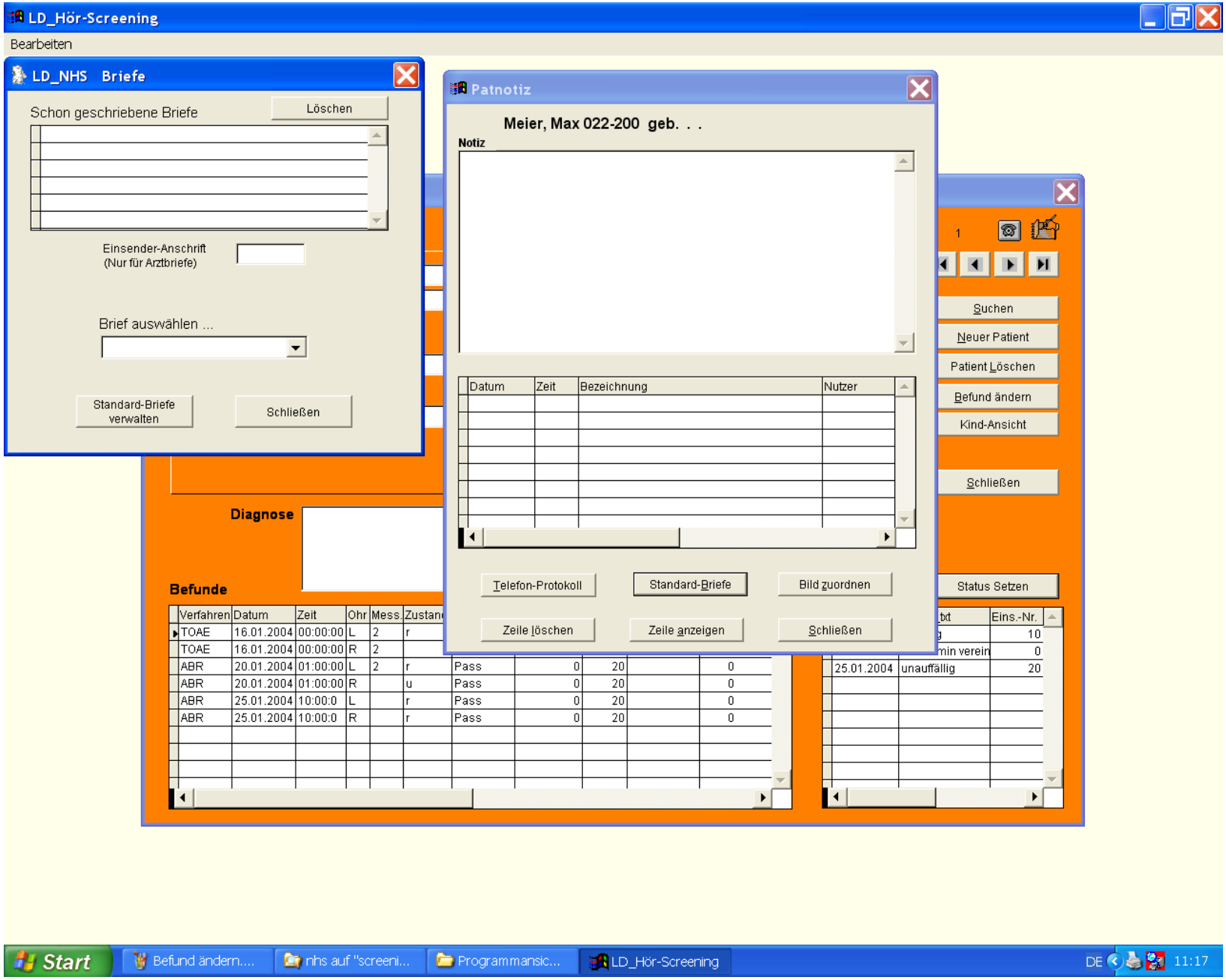
TRACKING OF FAILS

done by the screening center

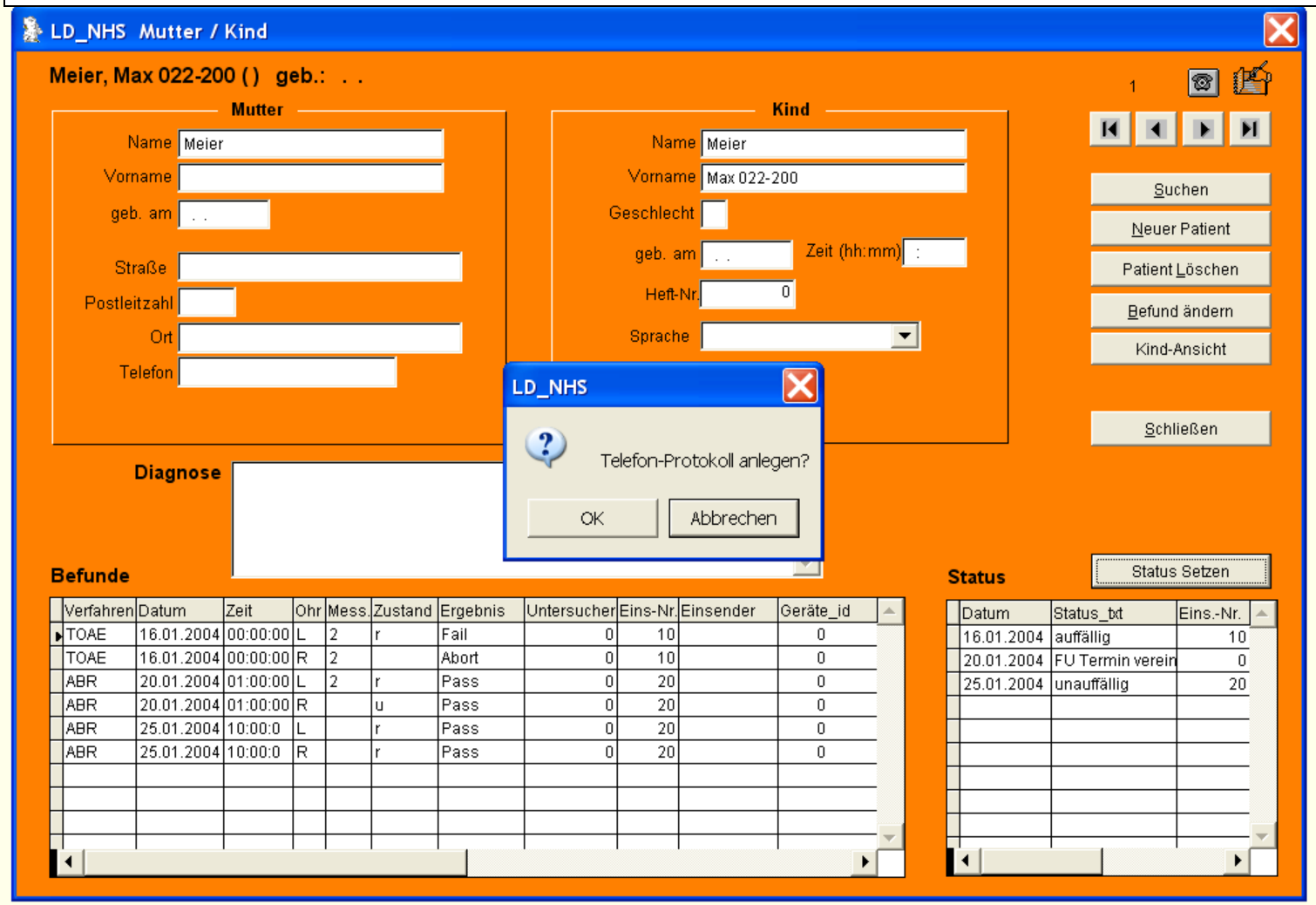


- list of children who failed the primary screening
- last action of the screening center (letter, telephone call)
- appointment for follow-up
- detailed data per child can be shown and selected for the follow-up institution

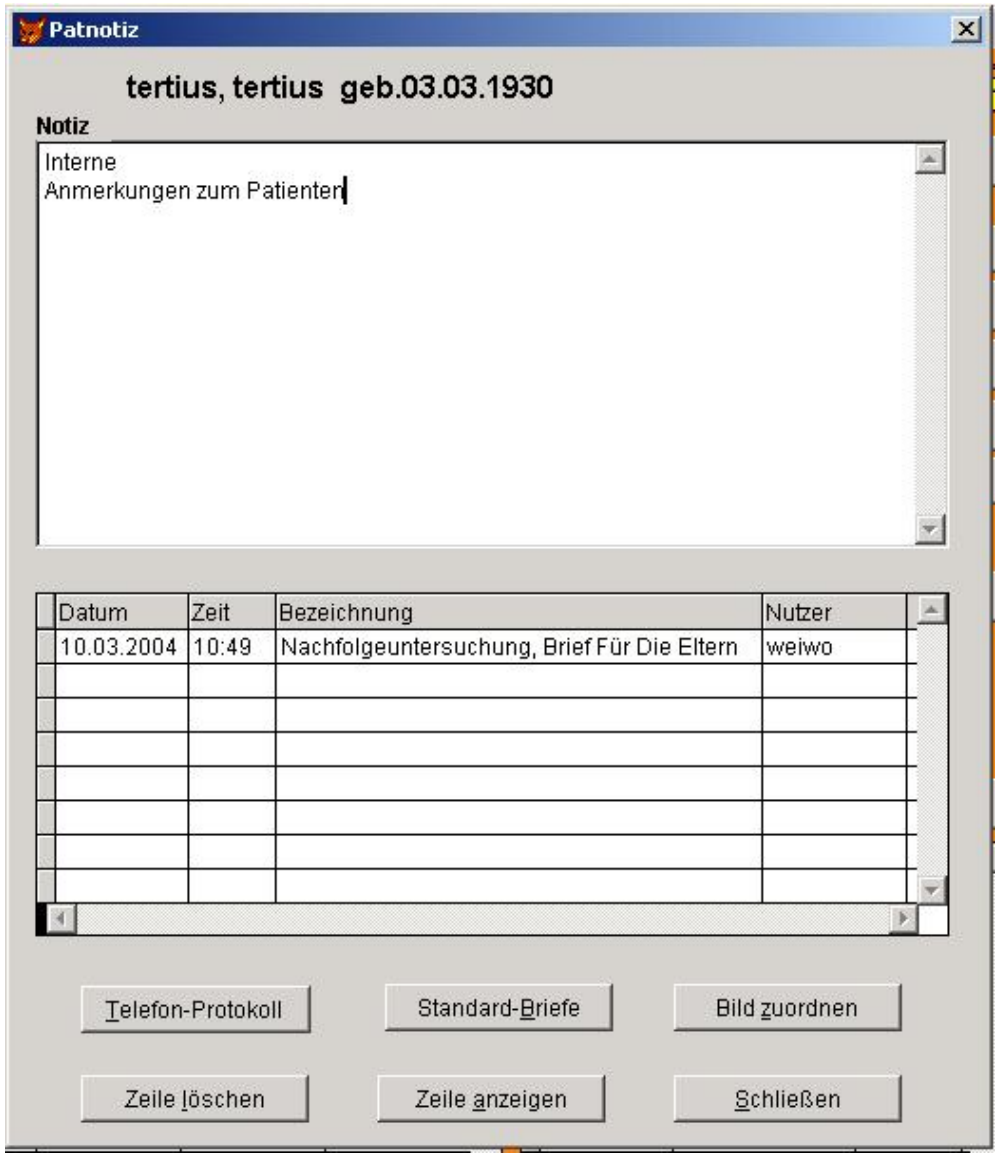
Standard letters



Telephone protocol

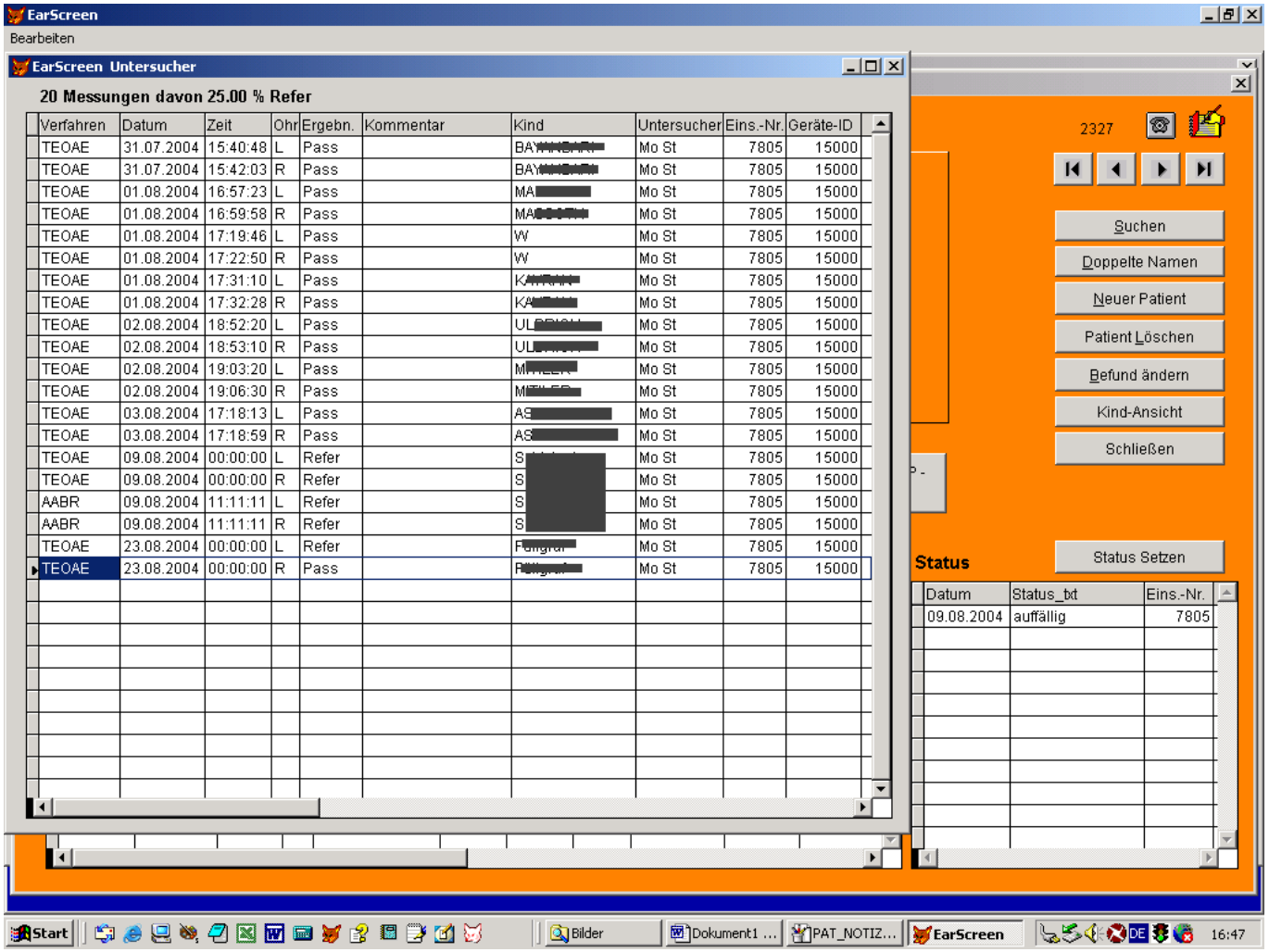


Remarks on a child

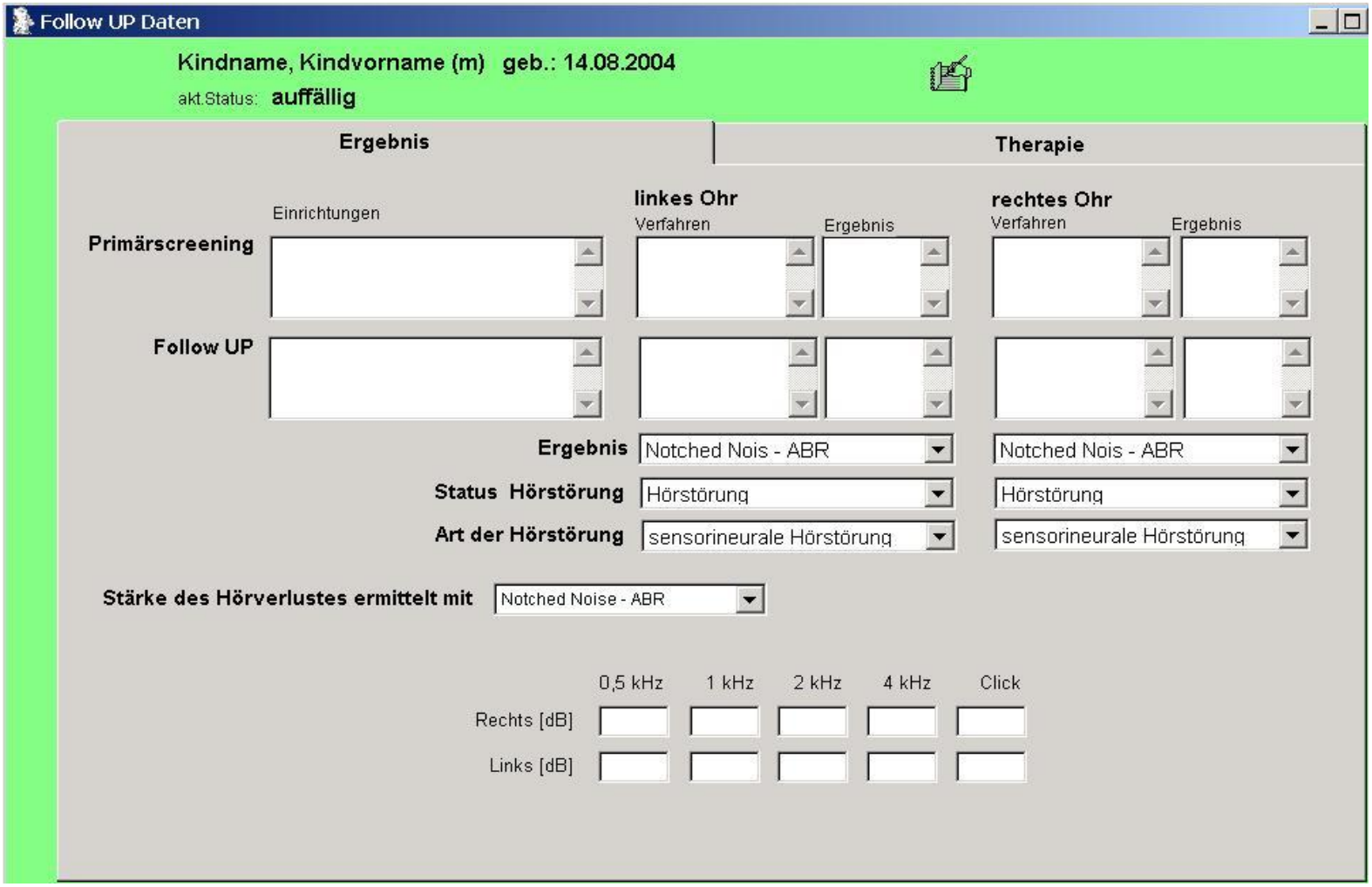


Screener

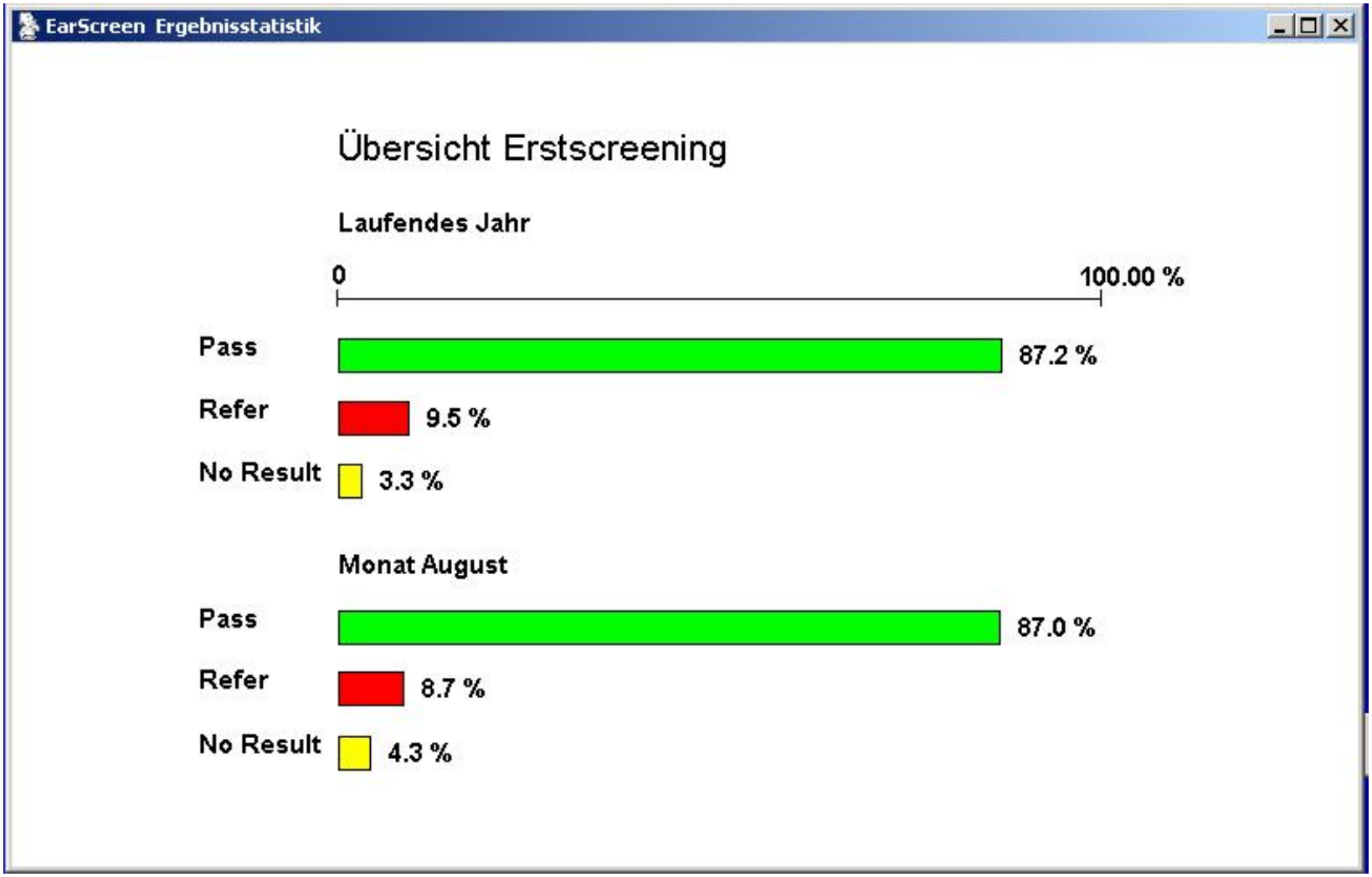
Coded with a number,
Re-training required?



Follow-up data

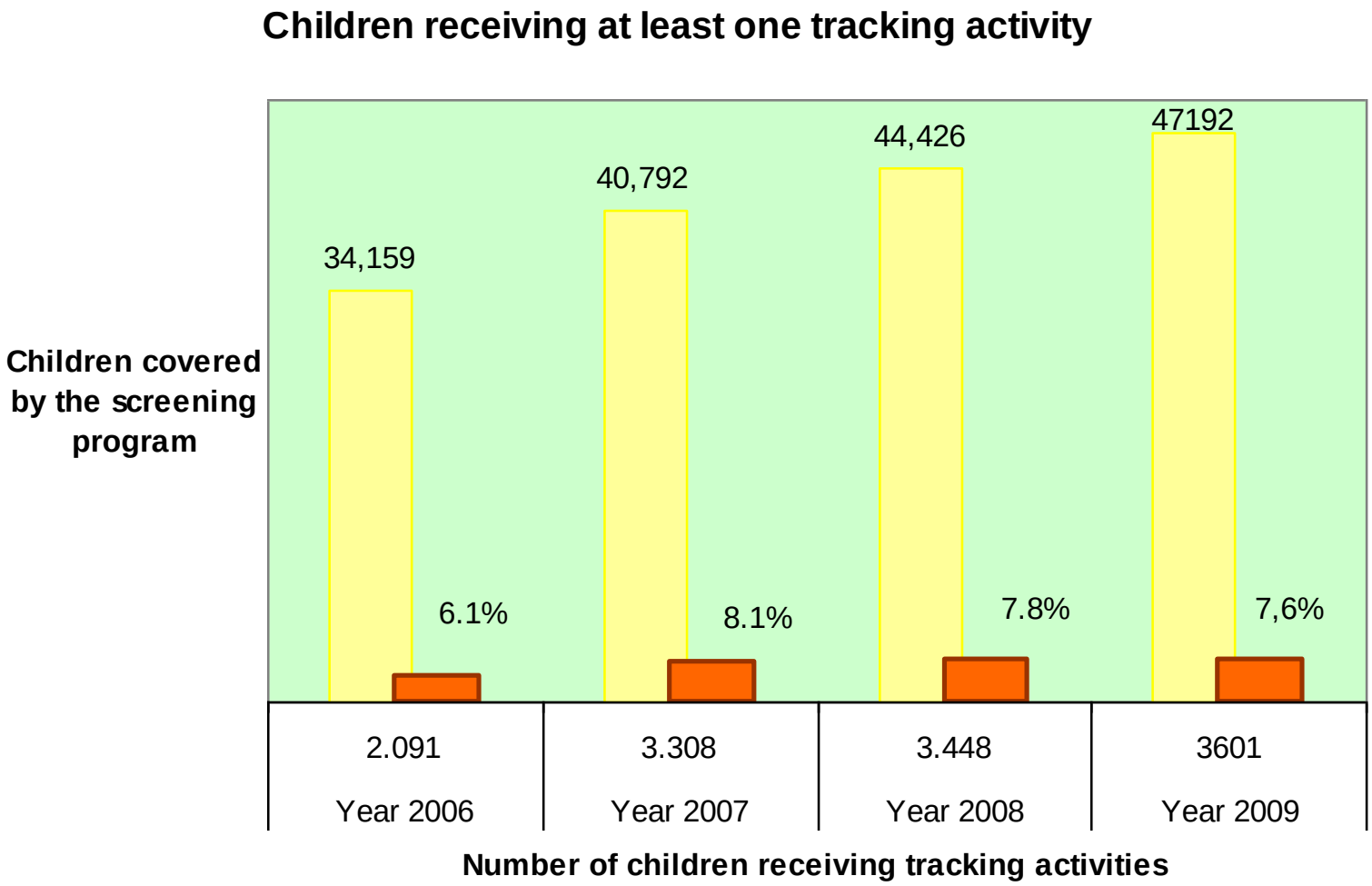


Statistics, Epidemiology

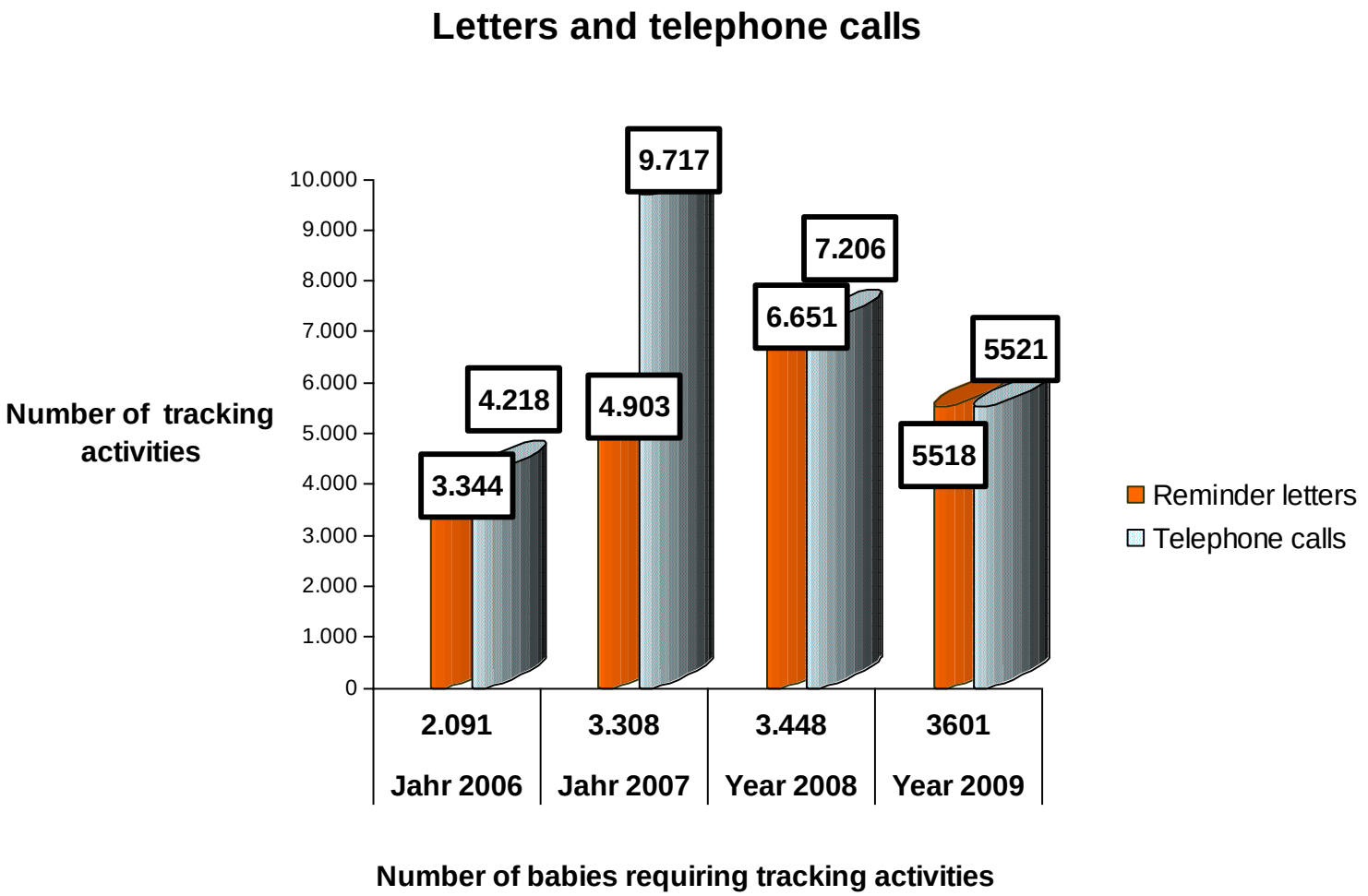


Annual Statistics

State of Hesse: Tracking Effort



Tracking Effort for a Follow-up Tracking + a Completeness Tracking (Neumann et al., 2009)



The effort of a tracking largely exceeds that one of a tracking which searches only for babies who have failed the screening.

Tracking Effort

Babies who needed at least one tracking action in 2008 had 6 days after birth…	Frequency	Percentage
…been screened without result (e.g. screening abort)	108	3.1
…been transferred to another ward	64	1.9
…failed the screening	1367	**39.6**
not yet been enrolled or only information received (e.g. long-term NICU)	833	24.2
…passed the screening (e.g.incomplete information)	806	23.4
…completed follow-up elsewhere	1	<0.1
…not received a screening (e.g. out-patient birth)	253	7.3
…screening declined	12	0.3
…been lost to follow-up	1	<0.1
…become a finished case (e.g. baby died)	3	0.1
Total	3448	100

Quality Influencing Factors: Example „Qualification of Examiner“

Examiner	Number of trials	Number REFERs	REFERs %	Screening aborts	% aborts	Calibration errors	% calibration errors	% useless trials
An Qu	151	10	6,6	87	57,6	3	2,0	66,2
Ko Ap	60	18	30,0	14	23,3	0	0,0	53,3
St Bu	53	14	26,4	9	17,0	4	7,6	50,9
Bä Mi	47	2	4,3	12	25,5	8	17,0	46,8
Ch Se	43	3	7,0	22	51,2	0	0,0	58,1
Be Ko	34	11	32,4	1	2,9	0	0,0	35,2
He Bu	31	1	3,2	12	38,7	2	6,5	48,3
Sa Sc	29	11	37,9	3	10,3	3	10,3	58,6
Gu Sc	28	13	46,4	6	21,4	4	14,3	82,1
Ut Ge	26	2	7,7	10	38,5	1	3,9	50,0
El Bu	16	0	0,0	4	25,0	0	0,0	25,0
Pe Sc	14	8	57,1	0	0,0	1	7,1	64,2

Conclusion

A UNHS protocol which is implemented should consider from the first beginning on the requirements of evidence-based medicine and quality assurance.

A completeness tracking and a tracking of the children who have not passed the screening is necessary and must be organized and financed by the overhead structures.

An ongoing education of the screening staff must be guaranteed. Pedaudiological services which deal adequately with treatment and reghabilitation of very young children must be established.

Devices

…must be affordable
Senti (Path medical): ~1200 € preschool/school screening (adaptive pure tone audiometry, OAE, AABR; from age 4 on)

for Newborn Hearing Screening: affordable TEOAE device (~1000 €) planned, given that enough devices are sold
developer: GNOtometrics+Path medical+University of Frankfurt, Germany

…must face battery/power supply problems
→solar charger

…must face humidity problems

…must be accessible? OAE via mobile phones (mostly distributed technical device in the world)?

…local evidence required that the equipment is functioning correctly

Thank you for your attention!

WHO informal consultation on neonatal and infant hearing screening.
WHO Headquarters, Geneva, Switzerland, 09-10 November, 2009