Minutes EFAS WG SHS meeting 15NOV17, Leuven, Belgium

Present: Frans Coninx, Jacub Dršata, Jan de Laat, Vinay Swarnalatha Nagaraj, Emre Gürses, Wouter Dreschler, Lea Zupan, Limor Lavie, Tytti Willberg, Sam Denys, Michael Hofmann, Astrid van Wieringen (not), Jan Wouters (not)

Agenda

Tuesday 14nov17
19:30 Dinner together at Restaurant Notre Dame, Grote Markt 11, 3000 Leuven

Wednesday 15nov17
8:15   Get together at IBIS Brusselsestraat for pick-up and drive to meeting room ExpORL
9:00   Reiteration objectives of project (Jan)
        Schema of project (Jan)
9:20   Preparation of project (Sam)
                Development and evaluation SEC
                Pilot study adults
                Pilot study children
                now ready for sensitivity and specificity in adults
10:00 coffee break
10:30 information measurement setup (Michael)
11:00 Evaluation SEC drawings* (all)
11:15 Demo and Training, web version and tablets (all)
11:50 Each partner provides info of referral and in own country used tests for NHS & SHS*
                Israel (Limor Lavie)
                Finland (Tytti Willberg)
                Norway (Vinay Swarnalatha Nagaraj)
                Slovenia (Lea Zupan)
                Turkey (Emre Gürses)
                Czech Republic (Jakub Drsata)
                Germany (Frans Coninx)
                The Netherlands (Jan de Laat)
                Flanders/Belgium (Sam Denys)
13:00 lunch
13:30 test protocol of study (all)
        Number of subjects, conduction losses, other necessary info, …
15:30 data and publications (all)
16:30 end of meeting
18:30 Dinner together at Restaurant Klimop, Martelarenplein 5, 3000 Leuven

Tasks for partners before meeting 15nov17
*Evaluate methodology and drawings using web version and give feedback before meeting
*Provide info about referral and used tests in own country for NHS & SHS screening

Minutes

Jan Wouters
intro: welcome, purpose of the meeting, objectives and schema of the project, agenda, Additional points of meeting?
The project focuses on 2 research questions Q1 (Methodology SHS) and Q2 (Incidence SHS), at this stage we focus on a pilot study of this project, the pilot study has Part 1 and Part 2, Part 1 is focus in Spring and Summer 2018

Question Frans: What about participation Poland? Other countries?
Answer Jan: all info, every document is also sent to the Polish group. They are informed. No concrete response received.
The two countries Ireland (Theresa Pitt) and Romania (Madalina Georgescu) have expressed interest to collaborate in this project, but they could not make the meeting.

Sam Denys
Preparation of project

Second ear is better than first ear, training phase bilateral and test left and right after each other, if randomized left right then we should know which ear is tested first
acclimatization phase, entry phase, training phase and then test
whole staircase is recorded, SD can be used as a measure when child loses concentration

Question: Some discussion on the spectral and temporal properties of the sounds: do they cover the frequency range? Is there a risk that hearing impaired persons may use other cues to identify the sound?
Answer Wouter: all stimuli are more or less equivalent. High (up to 5kHz) and low frequencies are present. Discrimination to sound in noise more dependent on high frequencies than to low frequencies.

If you change a token (sound or word) in the list you need to start validation all over. And we already went from 9 to 8 sounds (-trumpet)

Need to do validation study in adults, study in hearing impaired persons (Leiden, Leuven), study to compare to DTT. Validation of SEC with adults is ongoing

Adaptation procedure in test?
2up-1down seems to be better, after 1 mistake then easier
after a wrong answer children may be a bit uncertain

Implementation of test
Limor: it is possible to click and get the test done without listening to the stimuli.
One can press very quickly many times and finish the test
We need to build in a prevention, to link the stimulus to the response.
Change test: answer is not accepted until sound is played (ask Michael to change)

To minimize possible differences in perception and recognition of the sounds in different countries, make sure before the test that the sounds are recognized by the child?
Loop the different sounds and do a recognition test at SNR=+10dB, until all sounds are recognized

How short should test be? training phase is important, max duration of total test time in 5-6y old: 5min training and 5min test
Some discussion on how to familiarize the sound with figure prior to testing.
Jan DL: present the test with signal and (little bit) of noise first (eg/ +10 dB SNR, bilateral)

Need for randomization of ears: small effect first –second ear, need to know sequence

Add color to figures?
Slight preference to start with black on white (cfr max contrast and issue of color blindness)

Discussion and Consensus about protocol
Acclimatization/Entry: bilateral + 10 dB SNR, performance check (correct the child in case of mistake). Stimulus will be presented once. As is implemented, if correct, the stimulus/figure will disappear. If incorrect the stimulus/figure will be repeated. (1 min)
Training: bilateral training descent, 8 stimuli, start-SNR=0, 12 steps, rule out procedure learning (1.5min)
Interim: YOU DID WELL! Now the real thing!
Test Ear 1 (random, now first Left and then Right), start at 0 dB SNR (3 min)
Test Ear 2 , start at 0 dB SNR (3 min)
This has all been implemented already.

Frans: Monte Carlo simulation of response, determine 'consequence' of not perceiving a certain sound, based on the adaptive response tracks. Can be done afterwards to check confusions.

Michael Hofmann
Describes internet based test, and measurement setup
Discussion about which identifiers in local database and which in SHS-database
Overall data (needs to be linked to identifier)

Frans: raises point of CE labelling, needed for medical devices. In current research (pilot phase) we need to comply with requirements of each local Ethical committee.

Lunch

Description of NHS and SHS in different countries
(every country: please add or correct the used criteria for SHS referral)

Israel (Limor)
NHS: Well-babies DPOAE/TEOAE, high risk babies also mandatory ABR. Overall referral 0.34% on average (Israëli Jews 0.2%, Israëli arabs: 0.6%)

SHS: Hearing screening @school in quiet room. First grade. Children with known S/N hearing loss are not screened. 500 Hz@25 dB HL; 1000, 2000, 4000 Hz @ 20dB HL. Refer when child cannot identify one or more frequencies. Single presentation.
many problems with this test and many human factors. Often too much environmental noise. About 17% fail on 1st screening test, 5%-10% of all children fail on the 2nd test (repeat on same day). Results are sent to parents

In pilot project the SEC will be compared to PTA protocol
JW: accessibility to NHS database? Limor will ask

Finland (Tytti)
Easy to track persons, because of databases in public health system (to which all persons belong)
NHS: OAE, only 1 ear tested! in maternity ward. In case of failure
Missing SSD and auditory neuropathy
Hearing screening is continued at child health clinics (free, most attend).
Hearing screening @9 months Ewing test)

SHS: at child health clinics: @4-5 years, and @6 years
Speech development is evaluated during each visit
PTA@20dBHL, 250Hz, 500 Hz, 1kHz, 2kHz, and 4kHz
In a quiet room with headphones
SHS @school, at 7 or 8 and 14 yrs, now also with 8 kHz
Nurse or doctor refers the child
Referral rate at 6 y: many false alarms, half are false alarms, 30% completely normal, 20% hearing problem
SSD caught at age 4
At this stage partner Finland will not contribute to Q1 but focus on Q2.

Slovenia (Lea)
NHS: TEOAE for well-babies and A-ABR for babies in NICU
Referral rate for medical and audiological assessment is 2% (400 infants)
SHS: PTA protocol 500, 1,2,3& 4 kHz, 20 dB HL in quiet room. A fail is when one frequency is not perceived. Want to do the study in 2 locations

Norway (Vinay)
NHS: TEOAE and, if needed AABR
Parent consent is essential
Staff at the maternity and neonatal units must have necessary expertise.
Professional guidelines for hearing screening
20 dB HL at 0.5, 1,2,and 4 kHz. Both ears, if 1 tone not heard then refer to ENT hospital
Hearing screening which show 'refer' should be registered in the medical history
Norway needs to apply research project at a central/school level in Trondheim. Needs to be done to get approval to carry out research.
NHS and HS are two separate database systems and difficult to connect, now collaborations

Turkey (Emre)
NHS: start in 2004, before leaving hospital before 72 hrs
Mandatory, TEOAE and AABR (for risk babies)
Website Ministry of health: 1.309.771 births, + 40.000 syrian babies.
Hearing loss at NHS: 2-3/1000

SHS: start in 2016, screening audiometry in schools at 20dB HL: 500, 1000, 2000, 4000 Hz + questionnaire to ask for risk factors
Problems: noisy environment in schools, not enough test battery equipment
1year and 5 grade (6 and 11 years of age): 6/1000 hearing loss

NHS and SHS two separate databases and data are not shared
Some hospitals require money for screening, some school do not have enough equipment

Czech Republic (Jacub)
NHS: methodologic recommendation but no legislative support, no central collection of data
1st level TEOAE, AABR for risk babies

Data are sent to regional databases; referral to specified ORL
2nd level: re-TEOAE, TM, history

SHS: pre-school children (pilot project 2015-2016)
5-6y, high level of non-compliance 50%! Written info to parents
methodology: 4 frequencies, @25 dB HL, presented once. If failed at one frequency then child is referred

Germany (Frans)
18 member states, each own autonomous ministry of education
Ongoing struggle between different disciplines and groups
NHS: every birth clinic has to take care for NHS, all babies
Method is not prescribed: OAE or ABR
No central database
SHS: School entry: 'kind of' PTA 0.25, 0.5, 1,2,4, and 6 kHz. 30 dB HL
For this study focus on nordrhein-westfalen

Netherlands (Jan de Laat)
More than 70 pages rules and guideline
NICU screening: AABR
Regular: OAE
99.5% attendance
No of births: 175,000/year, 200 referral
National database @RIVM

HS@5 yrs of age: 500, 1000, 2000, 4000 Hz at well-baby clinic
A threshold (in quiet room) is determined by a nurse, criterion is 35 dB HL
Contact moments @9,12, and 15 years of age

Flanders (Sam Denys)
NHS : high coverage
1st non systematic screening for risk-babies @2nd grade of kindergarten (1000 Hz, 4000Hz, threshold is determined)
1st systematic screening at 1st year of primary school
@11 yrs and @14-15 years of age (CLB)
Digit triplet test has been introduced for two years

Discussion points

Question Wouter: can we discuss resources for follow-up study?
Answer Jan: this study is in fact a pilot study and collaborating partners, if they want to be part of this pilot study, are supposed to have the necessary resources to successfully work out their part of the pilot project. The outcomes of this pilot project may be a stimulant to consider a large study across-Europe and application for an EU-project. The pilot study will provide very interesting information about methodology and prevalence, but most probably evoke a number of new questions to optimize and apply at large scale.
Pilot project will be covered with own resources of the partner, but resources needed for large EU follow-up project

Discuss and finalize test protocol with aspects: a common denominator for all (SEC), the usual country-specific SHS-test will as usual be administered (using the standard method)

Consensus on test protocol:
Acclimatization/Entry: bilateral + 10 dB SNR, performance check (correct child in case of mistake). Stimulus will be presented once. If correct, the stimulus/figure will disappear. If incorrect the stimulus/figure will be repeated. (1 min)
Training: bilateral training descent, 8 stimuli, start at SNR=0, 12 steps, rule out procedure learning (1.5min)
Interim message: YOU DID WELL! Now the real thing!
Test Ear 1 (random), start at 0 dB SNR (3 min)
Test Ear 2 , start at 0 dB SNR (3 min)
~8.5 min in total

Agreements about use of material: a number of measurement sets (with Sound Ear Check only) will be provided for partners in the pilot project. A price of x EUR per set will be requested for rent during the pilot project (x to be decided based on new tablet). The measurement sets remain property of partner Leuven and will be returned after the pilot project. Partners can make use of the test sets as long as project and collaboration runs. The measurement sets of calibrated headphone plus tablet with software installed, manual, training and supplementary info will be delivered, max 2 sets per partner

Agreements about data: some data are kept in one common general database and part of the data are kept in a local database (separate from each partners own national health database), all data will be anonymized according to common key, each partner (or organization in partner country) has transcription key of own children, each partner has the freedom to use the own data
Proposal of key for anonymized subject ID: countryname in 2 letters, tablet number in 2 digits, subject ID number in 5 digits
As an example BE0400010 for the 10th subject of the 4th tablet (the tablet number 2 of partner BE)

Data to be accumulated per child in database DB:
1)automatically stored per subject in tablet DB (general DB)
tablet ID: BE04 in the example above
test moment: date and time
test results per ear: ear R or L, SRT, SD, Staircase, test duration

2)information input by site collaborator, to be typed in on tablet DB (general DB)
6 last digits of key: 400010 in the example above
Gender: M or F (here or in excel-sheet?)
Age: as DD/MM/YYYY or as MM/YYYY or as age? (what can a child of 5y do? Only age is not sufficient because change in test skills happens between 4 and 6 years of age?)
3)information input by site collaborator in excel-sheet (proposal of excel-sheet will be provided)
Results of subject on local screening test: LP or LF (Left ear pass or fail), RP or RF (Right ear pass or fail)
Environment of test? (indicate on 5-point scale from quiet to loud ambient noise in the background)
Gender: M or F (here or input on tablet?)
Age: as DD/MM/YYYY or as MM/YYYY? (here or input on tablet?)
4)information input by site collaborator in clinical file of subject (local DB)
Risk factors: (we need to have common list; Jan de Laat will translate), Attention Deficits, Academic Achievements, native-non native, history of OME, risk upper respiratory problems, history ME problems, smoking parents, Attentional or developmental deficit, (non-)native speaker, **an example questionnaire (for parents) of risk factors is appended (can be added to local DB)**

AP2: agree with this proposal of database management structure?
AP3: info about gender and age input on tablet or in excel-sheet?
AP4: what is exact definition of Pass and Fail on the screening test in your country
AP5: agree on indicating acoustical environment of test?
AP6: agree to use questionnaire to add to local DB?
AP7: comments on data management?

Agreements about publication: each partner owns own data and can make use of them, collaboration Leuven-Netherlands can use complete dataset for analyses. An article about whole study will be used as a report of the EFAS WG SHS

Verification with audiogram is necessary to deduce info about sensitivity and specificity

How to exclude conduction loss?
Based on the attenuation-distortion model of speech recognition by Plomp
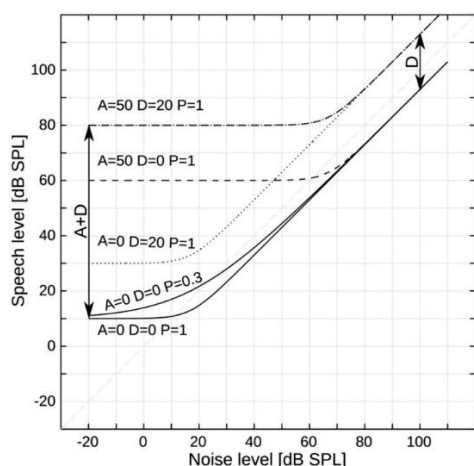
Speech recognition in noise is sensitive to sensorineural hearing loss. The SRT at 65dB SPL noise level is not sensitive to relatively small conduction loss. Speech recognition in quiet is sensitive to conductive and sensorineural hearing loss.
Our aim is to detect a conduction loss when it is above 20 dB HL

An additional test Speech recognition in quiet (adaptive SRT or at fixed level) would allow to estimate and disentangle possible contributions of conductive and sensorineural hearing loss. As an example, for a normal hearing child reference SRT in quiet (under optimal acoustical conditions) is at 25dB SPL then an SRT in quiet of 45 dB SPL would indicate that the conductive hearing loss is not higher than 20 dB. And 45 dB SPL is acoustically possible to administer in a quiet room using the proposed tablet/headphone system. The used headphones are the best ensemble set of circumaural headphones shielding interfering environmental sounds.

How to test conductive hearing loss? By additional test in quiet? By Tympanometry (necessary equipment not available in child health centers, and expensive)?
We have to decide if we will add this to the protocol, or leave this out for the pilot study, no reference data have been gathered up to now for Sound Ear Check in quiet

To get an estimate about the occurrence of conductive hearing loss components it is decided at the end of the meeting to split the pilot study in 2 parts.

Split pilot study in 2 parts
Part 1
Validation of test approach in own pediatric clinic first, then main study in schools
Administer SEC in noise and audiogram: air conduction and bone conduction (in booths, no problem with environmental noise background)
20-25 NH, 20-25 Sensorineural HL, 20-25 Conductive HL
Children between 5 and 7 years of age
N=500 for all centers together, before summer 2018 holidays
Pass/refer for SEC compared to pass/fail for tone audiometry
(cfr. Sam's validation study in adults is completed in March 2018)
Part 2
Test children at school? How many? 2000? Decide at a later stage, when outcomes of Part 1 known.

AP8: agree with split of pilot study in 2 parts, start with part 1 in pediatric clinic?
AP9: which partners agree to collaborate on part 1 of the pilot study, before the main pilot study?

Participating partners pilot study
The project has 2 research questions Q1 and Q2

Q1: Methodology: the Sound Ear Check (SEC) will provide an across-partner and across-languages reference measure
Q1-partners Part 1: Belgium/Flanders, The Netherlands, Israel, Turkey?, Romania?, Slovenia?, Norway?, Germany? (please confirm!)
Q1-partners Part 2: ?

Q2: Evidence/Incidence of SHS, in some countries the NHS and SHS data are in the same database:
Q2-partners Part 1: Finland, Ireland
Partners Finland and Ireland: please prepare a 1-2 page document explaining how in your country, a link between NHS and SHS databases is made, and how and with what efforts the prevalence of SHS can be estimated (based on numbers of SHS-pass and SHS-fail, given NHS-pass)
Q2-partners Part 2: (other partners later: Belgium/Flanders, …)

AP10: for the partners who will focus at Q2: agree to prepare by 01may18 a 1-2 page document explaining how in your country, a link between NHS and SHS databases is made, and how and with what efforts the prevalence of SHS can be estimated

Timing
Estimated start of pilot project
When agreement on the list of action points, then submit necessary documents for approval of local medical ethical committee: March/April 2018
Ready Q1 for implementation: 01May18
Ready Q2 document: 01May18
Start Pilot study Part 1: June/July 2018 + selecting & preparing schools that collaborate in Part 2.
Start Pilot study Part 2: September/October 2018
Report at EFAS 2018, September 27-28, Montpellier 2018: report Q1 Pilot study Part 1 and Q2
Report at EFAS 2019, May 22-25, Lisbon 2019: report Q1 Pilot study Part 2 and Q2

Action Points
AP1: do you agree on this consensus protocol?
AP2: agree with this proposal of database management structure?
AP3: info about gender and age input on tablet or in excel-sheet?
AP4: what is exact definition of Pass and Fail on the screening test in your country
AP5: agree on indicating acoustical environment of test?
AP6: agree to use questionnaire to add to local DB?
AP7: comments on data management?
AP8: agree with split of pilot study in 2 parts, start with part 1 in pediatric clinic?
AP9: which partners agree to collaborate on part 1 of the pilot study, before the main pilot study?
AP10: for the partners who will focus at Q2: agree to prepare by 01may18 a 1-2 page document explaining how in your country, a link between NHS and SHS databases is made, and how and with what efforts the prevalence of SHS can be estimated

Present at Workshop

Finland	Tytti Willberg	tytti.willberg@tyks.fi
Germany	Frans Coninx	f.coninx@ifap.info
Israel	Limor Lavie	lavielimor@gmail.com
Czech Republic	Jacub Dršata	jakub.drsata@fnhk.cz
Slovenia	Lea Zupan	Lea.zupan1@gmail.com
Turkey	Emre Gürses	gursess.emre@gmail.com
Norway	Vinay Swarnalatha Nagaraj	vinay.s.nagaraj@hist.no
Netherlands:	Wouter Dreschler	w.a.dreschler@amc.uva.nl
	Jan de Laat	J.A.P.M.de_Laat@lumc.nl
Belgium/Flanders:	Jan Wouters	jan.wouters@med.kuleuven.be
	Sam Denys	sam.denys@med.kuleuven.be
	Astrid van Wieringen	Astrid.VanWieringen@med.kuleuven.be
	Michael Hofmann	michael.hofmann@med.kuleuven.be

Apologies:		
Romania:	Madalina Georgescu	madalina.georgescu@gecad.com
Ireland:	Theresa Pitt	theresapitt@sky.com

Example questionnaire for parents to indicate risk factors of the tested children

PARENT QUESTIONAIRE

Child's Name: _____ Gender: _____ Date of birth: ___/___/___

Date of completion:

School Name: _____ Class: _____ ___/___/___

Country of birth (child): _____ Nationality: _____

This questionnaire assesses the language input, the language proficiency and development, general health and your childs hearing.Your answers are very important. Would you please fill out this questionnaire **as competely as possible**

1. What language / languages is / are spoken at home?
   - Parents together : _____
   - Mother with the children : _____
   - Father with the children : _____
   - Children together : _____
   - Children with the mother : _____
   - Children with the father : _____
2. What is the family language? What language is spoken at the table?_____
3. What is you mother tongue?
   - Mother : _____
   - Father : _____
4. How well do you control your (**circle**, 0 = not at all 5 = sufficient 10 = good):

	Mother	Father
Mother tongue		
COMPREHENSION	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10
SPEECH	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10
READING	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10
WRITING	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10
Dutch ↳*fill in if not your mother tongue*		
COMPREHENSION	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10
SPEECH	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10
READING	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10
WRITING	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10

5. How well does your child controls his

Mother tongue	
COMPREHENSION	0 1 2 3 4 5 6 7 8 9 10
SPEECH	0 1 2 3 4 5 6 7 8 9 10
Dutch ↳*fill in if not your mother tongue*	
COMPREHENSION	0 1 2 3 4 5 6 7 8 9 10
SPEECH	0 1 2 3 4 5 6 7 8 9 10

6. Are you concerned about your child's development in terms of language and speech (**circle**) Yes / No
7. Are you concerned about the academic performance of your child (**circle**) Yes / No
   ↳*If yes*, please clarify: _____
8. Does your child have major health problems (**circle**)
   ↳*if yes, please clarify*: _____
9. Does your child have a documented learning disability (dyslexia, dyscalculia, AD(H)D or an autism spectrum disorder? Yes / No
   ↳*if yes, please clarify*: _____
10. Was the child born prematurely? We mean at 32 weeks gestation or earlier (**circle**) Yes / No
11. Has the mom during pregnancy had a CMV (cytomegalovirus) infection? (**circle**) Yes / No
12. Has your child suffered bacterial meningitis (**circle**) Yes / No
13. Has your child had a serious head injury (eg. By falling or bumping) (**circle**) Yes / No
14. Has your child suffered repeated ear infections? (**circle**)
    ↳*If so, was your child treated with grommets or similar*? Yes / No
    ↳*If so, the child currently has grommets or those recently failed (**circle**)* Yes / No
15. Was your child's hearing screened shortly after birth (kind & gezin) (**circle**) Yes / No
16. Do you think your child has hearing loss (**circle**) Yes / No
17. Does hearing loss run in the family (**circle**)

This questionnaire was completed by the father / mother / guardian (**circle**) of the child.

Your email adres / telephone numer: _____

signature: