727521 – EVOTION

DELIVERABLE No: D3.2

Public Health Policy Decision Models (PHPDM) v2

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List of Abbreviations

ANN	Artificial Neural Networks
ANOVA	Analysis of Variance
AT	Auditory Training
BDA	Big-Data Analytics
DALY	Disability-Adjusted Life-Year
DOW	Description Of Work
ED	Evotion Data
ENT	Ear Nose Throat Experts
GHABP	Glasgow Hearing Aid Benefit Profile
HA	Hearing Aid(S)
HADS	Hospital Anxiety And Disorder Scale
HL	Hearing Loss
MOCA	Montreal Cognitive Assessment
OWL	Web Ontology Language
PCA	Principal Component Analysis
PHP	Public Health Policy
PHPDM(s)	Public Health Policy Decision Model(S)
PTA	Pure Tone Audiometry
SIN	Speech In Noise
SPL	Sound Pressure Level(S)
TTS	Temporary Threshold Shift
WP	Work Package

Executive Summary

This document presents the second version of the Public Health Policy Decision Models (PHPDMs) implemented within Tasks 3.1-3.4 of Work Package 3 “Development of PHPDM models”.

The second version of these models provides their description, introduced in Deliverable D3.1 “Public Health Policy Decision Models (PHPDM) v1” (Katrakazas et al., 2017), using the Specification Language. This language is presented in Deliverable D4.1 “PHPDM model specification language” (Prasinos et al., 2017), and specified within the Specification Tool, the service of which is presented in Deliverable D4.2 “PHPDM model Specification Tool” (Basdekis et al., 2018).

All four models described here will consequently allow the validation of the language use in Work Package 7 “Validation of EVOTION platform”.

1 Introduction

1.1 Overview

Work Package 3 (WP3) in EVOTION focuses on the development of PHPDMs having a twofold objective:

- to identify factors related to the effectiveness of hearing loss (HL) treatments for different HL patients (with respect to their type of HL and other characteristics including possible co-morbidities of HL patients) in different contexts based on analysis of the EVOTION data, and
- to develop PHPDM incorporating simulation models to enable the exploration of the effects of the decisions that they generate.

The work under this WP is divided into four (4) tasks, each focusing on the different types of predictive and PHPDM models. The models defined are:

- a PHPDM for Prognosis of Effectiveness of Hearing Aid Usage (PHPDM1)
- a PHPDM for Prognosis and Prevention of Noise Induced Hearing Loss (PHPDM2)
- a PHPDM for Prognosis and Delivery of Effective Auditory Training Rehabilitation Services (PHPDM3), and
- a PHPDM for Hearing Loss Management and Overall Well-being of Hearing Impaired Individuals (PHPDM4)

Following the work presented in deliverable D3.1 "Public Health Policy Decision Models (PHPDM) v1" (Katrakazas et al., 2017), the aforementioned PHPDMs can be described based on a set of building elements consisting of: Goal(s), Objective(s), Decision Criteria, Data, Types of Analysis, Stakeholder(s) and Policy Action(s).

All four PHPDMs have been updated as far as their related data types are concerned, based on recent bibliography, and after using the Text-Mining Capabilities of the EVOTION Decision Support System shown in Deliverable D5.6 "Decision Support System and Simulation Component" (Katrakazas et al., 2018).

In the current deliverable, these models will be further described in the Specification Language developed in Deliverable D4.1 "PHPDM model specification language" (Prasinos et al., 2017) and specified within the Specification Tool, the service of which is presented in Deliverable D4.2 "PHPDM model Specification Tool" (Basdekis et al., 2018).

Before proceeding to the update of the documentation of the first version of the initial PHPDMs, we present a case study to show how these models can be used in terms of public health policy making.

1.2 A case study of EVOTION PHPDMs being used in Policy Making

Driven by the recent legislation passed by the French government regarding the decrease of the maximum sustained noise level by 3 dB[1] we present a case study to show how PHPDM2 can be used in terms of public health policy making.

As a regional-level public authority, EVOTION's member organisation Pazardzhik Regional Administration (PRA) is responsible for coordinating the implementation of all national public policies at regional level (art.31,(1)2, Law on administration[2]). In addition to this and among others, it also supervises the decisions of local (municipal) governments (12 in total in the Pazardzhik region) and exercises control functions on their adopted local acts (Ibid, art.31(1)5).

On the other hand, pursuant to the above and according to the Law on Regional Development (art.21[3]), PRA is also responsible for organizing the development and coordinating the implementation of the Regional Development Strategy for Pazardzhik region. This policy document (Ibid, art.12) identifies mid-term development goals and priorities for the region and also provides strategic guidance for the development of local (municipal) development plans (12 in Pazardzhik region).

This is organised according to a time-plan (7-year policy cycle[4]). Accordingly, the currently valid document which is in force for PRA is the Regional Development Strategy of Pazardzhik region 2014-2020[5]. This strategic policy document touches on the analysis of the economic and social development of the region and identifies goals and priorities for development in the period covered, in all spheres of public governance including public healthcare. Once in force, it serves as guidance for local authorities in drawing up their local municipal development plans and adopting local policy acts.

Based on the above background information and according to the current stage of the policy cycle, PRA is organizing the evaluation of the achievements of the current document and beginning preparations for the development of the next strategic policy document for Pazardzhik region for the period 2021-2027. This is an internal process followed for the development of this particular type of policy document as a whole according to the current stage of the policy cycle and is not limited to this case study. A specifically appointed Task group is responsible for these comprising internal policy experts at PRA and external subcontractors. Hence, based on evaluation findings/recommendations and PRA's experience gained in the past period including the EVOTION project, it is planned to substantiate and include as future public healthcare priorities targeted hearing health interventions based on evidence on noise-induced hearing impairment. This will then act as guidance to local authorities to plan and adopt such policy actions.

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[1] https://www.legifrance.gouv.fr/eli/decret/2017/8/7/SSAP1700132D/jo/texte
[2] https://lex.bg/bg/laws/ldoc/2134443520
[3] https://www.lex.bg/laws/ldoc/2135589285
[4] https://ec.europa.eu/regional_policy/en/newsroom/news/2018/05/29-05-2018-regional-development-and-cohesion-policy-2021-2027
[5] http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=984

In order to do this, members of the Task group will draft a proposal. This will be prepared by PRA staff who have participated in the EVOTION PHPDMs development and will draw on the expertise of EVOTION partners specifically responsible for PHPDM2 development. According to the methodological guidelines for the development of strategic documents provided by the Bulgarian Minister of Regional Development[6] and internal rules of procedure at PRA, this proposal will then be presented to all members of the Task group to include into the draft regional development strategy 2021-2027. It will further undergo the coordinated stakeholder approval and decision-making process laid down in the above-mentioned regulatory acts.

The proposal will draw on the outcome of the analyses carried out in EVOTION PHPDM2 in order to justify its inclusion in the new policy document. Additionally, individual items in the structure of the model correspond to structural elements of the policy document proposal and include:

- **Goal** (*corresponds to "Strategic Vision" in the PRA policy document structure*): To prevent noise-induced hearing impairment resulting from exposure to hazardous noise in public places affecting large numbers of people.
- **Rationale** (*corresponds to "Analysis of Economic and Social background" in the PRA policy document structure)*: The need to take policy measures on noise-induced hearing impairment based on the rationale for PHPDM2 and its research literature, as described in the first version of the model in D3.1 (Katrakazas et al., 2017). In addition, big data analytics may support the identification of groups of patients experiencing TTS in high noise/sound exposure levels in public places. Hence, a call for public health interventions by local governments to control hazardous noise exposure in specific public places.
- **Objectives** (*correspond to "Strategic Objectives" in the PRA policy document structure):* based on the PHPDM2 model for PTS/TTS prediction developed in EVOTION, the objective is to support prevention and decrease the frequency of TTS episodes by introducing local measures to control hazardous noise exposure
- **Policy Actions** (*correspond to "Priority Measures/Interventions" in the PRA policy document structure):* Based on local conditions, municipalities undertake regular monitoring of hazardous noise exposure in specific locations (concert halls, 3D cinemas, open stages during open events, live-music venues).
    - Local authorities undertake regular expert evaluations for hazardous noise exposure at their specific locations or events. Based on regular monitoring and expert recommendations, municipalities adopt local regulations on hazardous noise exposure to be observed by operators of specific NIHL-risk locations/events.
    - Local authorities adopt regulations for providing warnings to members of the public at risk locations or events, also especially targeted to HA users regarding potential risk of TTS or PTS. Provisions in this respect could be included in the contracts signed with venue operators or event organisers.
    - Local authorities adopt regulations for compulsory advice to the public at risk locations/events on wearing personal protective equipment. Provisions in this respect could be included in contracts with local authorities.

[6] https://www.mrrb.bg/static/media/ups/articles/attachments/7d3f7da880fa0e5a47bcdc92fbd7bbdc.pdf

Observing data access legal and ethical requirements, EVOTION PHPDM functionality will be used to underpin the above proposal based on the PHPDM2. The model specification Tool presented in Deliverable 4.2 and the EVOTION Decision Support System shown in Deliverable D5.6 will be used to demonstrate data correlations between location data and environment noise monitoring and how these lead to BDA outcomes that support/argue above policy actions and/or propose different ones. Therefore, EVOTION will be used as a tool to support experts in the Task group to come to a consensus as to whether to include specific policies or interventions around hazardous noise exposure in the draft regional policy document for the 2021-2027 period.

When this has been done, a draft will then be circulated for consultation to institutions and stakeholders according to the procedure envisaged under the above methodological guidelines for the development of strategic documents. Finally, after all feedback and other considerations have been taken into account and the draft version finalized accordingly, the final decision-making (voting) procedure will be performed (voted by Regional Development Council members).

Once the document is adopted, it is made widely available to the public, to all 12 local authorities in Pazardzhik region and other regional stakeholders. Municipalities will follow the guidance when drafting their local development plans and ideally, implement the recommended policy actions by adopting local policy acts. This process of implementation of PRA's regional strategy is monitored and evaluated in accordance with the procedure and time-line stipulated in the above mentioned legislation (Law on Regional Development, Art.30-37[7].

1.3 Purpose and scope of deliverable

The purpose of Deliverable 3.2 is to present the form of the building elements from each PHPDM using the Model Specification Language developed in deliverable D4.1 and specified within the Specification Tool of deliverable D4.2 with the definition of: GOAL(S); OBJECTIVES; POLICY ACTIONS (interventions); DATA TYPES (evidence variables); ANALYSIS TYPES; STAKEHOLDERS; and DECISION CRITERIA[8].

[7] https://www.lex.bg/laws/ldoc/2135589285

[8] Any criterion that is based on single predictor variables is potentially flawed. Analysis types provided in each PHPDM address this issue to some degree, though not perfectly. It is up to the consortiums data scientists' discretion on how to analyse and correlate the data types in order to produce the most accurate results.

2 PHPDM for Prognosis of Effectiveness of HA Usage

PHPDM1 will investigate whether hearing aid (HA) usage and satisfaction can be predicted based on ten specific measured and observed variables. These variables, which will support policy makers in the definition of actions targeted to specific HA users, are:

I. Environment (e.g. rural areas, city centers)
   - HA_ENVIRONMENT_DATA > LOCATION[9]

II. Age
   - PATIENT > DATEOFBIRTH

III. Hearing Loss (HL)
   - Q_DRMED table> HI_DEGREE_CURRHL_L, HI_DEGREE_CURRHL_R

IV. Encountered Acoustic Environment (e.g. noise levels)
   - REAL_TIME_HA > S_EN_PARA

V. Education Level
   - Q_DRMED > EDUC_PLACEM

VI. Gender
   - PATIENT > SEX field

VII. Presence of Significant Others
   - PATIENT > SIGNIFICANTOTHER

VIII. Personal Care
   - REFERRING_AGENT > PCG_ID

IX. Employment Status
   - Data found in Q_DRMED > LS_EMPL_SIT1, LS_EMPL_SIT2

X. Occupation
   - Data found in Q_DRMED > LS_EMPL_TYPE

In the following, we describe PHPDM1 using the Model Specification Language:

GOALS

- **Description**: Improve the effectiveness of HA usage (GOAL_1)
- **Description**: Improve HA usage and usage satisfaction (GOAL_2)

OBJECTIVES

1. Enhance clinical practice (OBJ_1) by monitoring potential variables that influence HA usage and user reported benefit negatively and positively.
2. Undertake actions to improve HA users' awareness and motivation to use their HAs (OBJ_2)

POLICY ACTIONS

1. Provide clinical practice guidelines based on identified potential variables that influence HA usage and user reported benefit and satisfaction (PA_1)
2. For each of the ten variables listed above, the following actions could be taken (PA_2) if a negative relation to HA usage/satisfaction is identified for that variable (see CRITERIA):

[9] The format shown as "XX > xx" refers to the xx field of the XX table found in the EVOTION Data repository (Deliverable D5.6 (Basdekis et al., 2017)).

I. Development of standards of HA clinical practice related to specific environments
II. Fitting at a younger/older/particular age according to findings
III. Development of standards of HA clinical practice related to time spent in specific acoustic environments
IV. Introduce obligatory training programmes at the stage of HA fitting for HL-profile users exhibiting low HA usage
V. Training and/or educational programmes specific to sub-populations of educational levels
VI. Raising awareness programmes/informational campaigns
VII. Introduction of measures aimed to help solitary individuals and cost-relief packages for subgroups
VIII. Development of standards of HA clinical practice related to working and non-working population
IX. Development of standards of HA clinical practice related to working conditions

STAKEHOLDERS

Representatives of:

- National/regional ENT-specialists' Advisory Committee (in their role as prescribing the use of HAs);
- National/regional Directorate for Social support (in their role as authorising financial support for purchasing HAs and performing follow-up on administration and use);
- National/regional structures of the Health Insurance Fund(s) (in their role as funding clinical pathways);
- Hearing Care Professionals (HCPs);
- Patients' association – national/regional representatives of patients and carers
- Associations of audiologists/clinical HL practitioners (in view of setting new standards in clinical practice)

CRITERIA

1. Only variables contributing significantly to prediction of HA usage or HA satisfaction ($p<0.05$) are monitored over time for each sub-population/individual (CRI_1)
2. Policy actions are undertaken based on variables contributing with a percentage (%) explained variance (CRI_2):
   a. Increase HA usage by a specific amount of time per day
   b. Increase satisfaction with using a HA by a specific percentage

DATA TABLES:

To reach the goals of this PHPDM, the following EVOTION data tables are needed (in arbitrary order):

- PATIENT
- Q_DRMED
- GHABP_ANSWERS
- AUDIOGRAMCURVE
- MOCA_ANSWERS
- HADS_ANSWERS

- HUI3_ANSWERS
- AUDITORY_TRAINING
- ENVI_DATA
- HA_ENVIRONMENT_DATA
- REAL_TIME_HA
- USER_PTA_TEST_RESULT
- DIGIT_RECALL_TEST_RESULT
- SPEECH_IN_BABBLE
- ORGANIZATION

ANALYSIS TYPES

- Aggregation of data-logs over time
- Classification of standard audiograms
- Linear Mixed modelling of the variables I. – X. (listed above)
- Analysis of Variance (ANOVA)

For a formal definition of PHPDM1 in Web Ontology Language (OWL), the following instances are needed:

- One instance of the `PolicyModel` class named "PM_1" with label "Prognosis of Effectiveness of HA Usage and Satisfaction"
- Two instances of the `Goal` class named "Goal_1" and "Goal_2" (see labels defined above under "GOAL(S)")
- Two instances of the `Objective` class named "Obj_1" and "Obj_2" (see labels defined above under "OBJECTIVES")
- Two instances of the `PolicyAction` class named "PA_1" annd "PA_2" (see labels defined above under "POLICY ACTIONS")
- Five instances of the `Stakeholder` class: one named "Stakeholder_1" with label "Regional ENT-specialists' Advisory Committee", one named "Stakeholder_2" with label "Regional Directorate for Social support", one named "Stakeholder_3" with label "Regional structures of the national Health Insurance Fund", one named "Stakeholder_4" with label "HA vendors/fitting experts" and one named "Stakeholder_5" with label "Regional representatives of patients"
- Two instances of the `Criterion` class named "CRI_1" with label "PvalueCriterion" and "CRI_2" with label "ExplainedVarCriterion"

Appendix A has the full PHPDM1 described in the Specification Language.

3 PHPDM for Prognosis and Prevention of Noise Induced Hearing Loss

PHPDM2 should investigate whether three specific measured and observed variables enable the prediction of new Noise-Induced Hearing Loss (NIHL) among the EVOTION participants. These variables, which will support policy makers in the definition of actions targeted to HA users of different degrees of hearing loss and experiencing different noise exposure levels, are:

I. Hearing Loss (HL)
II. Encountered Acoustic Environment (e.g. noise levels)
III. Time Spent in these Environments

In the following, we describe PHPDM2 using the Model Specification Language:

GOAL

- **Description**: Deliver public policy regarding the prevention of NIHL in HA and non-HA users
- **Rationale**: Decrease of the prevalence of NIHL in HA user groups exposed to noise including occupational settings, by providing a prediction model for PTS risk/TTS incidents, thus allowing the prevention and decrease the risk of TTS in HA users

OBJECTIVE

1. Development of predictive models for TTS incidents and PTS risk based on cumulative individuals' data

Note: PTS risk is related to occurrence of sound exposure high enough to cause permanent threshold shift after long-term exposure (≥1 year).
TTS episodes are related to occurrence of sound exposure high enough to cause temporary threshold shift after short-term exposure (up to 16 hours), although it does not mean that given exposure to risky noise eventually results in TTS in HA user.

POLICY ACTION

1. Suggest and set-up of standards related to individuals with and without HL regarding the time spent in specific environments according to their noise levels.

STAKEHOLDERS

Representatives of:

- National/regional ENT or Audiology -specialists' Advisory Committee (in their role as prescribing the use of HAs);
- National/regional Directorate for Social support (in their role as authorising financial support for purchasing HAs and performing follow-up on administration and use);
- National/regional structures of the Health Insurance Fund(s) (in their role as funding clinical pathways);
- Hearing Care Professionals (HCPs);
- Patients' association – national/regional representatives of patients

CRITERIA

1. Policy actions are to be undertaken:
   - for TTS - for cut-off values ≥10 dB predicted in normal hearing people;
   - For PTS - if daily noise exposure level normalized over 16-hour daily activity exceeds 77 dB (CR1)

   Notes:

- Sound pressure level (SPL) values, which are predicted to occur at the eardrum of HA user, are transferred back to free field conditions; Effective value of SPL is individual for every subject as it is the function of degree of hearing loss of HA user (i.e. audiometric hearing thresholds) and consecutively HA amplification.

- PTS risk and incidence of TTS episodes may be analyzed in reference to daily or long-term usage of HA usage. There are four combinations of possible outcomes for daily prediction of PTS risk and/or TTS episodes, i.e.:

  – 0 - neither PTS risk nor TTS episodes occurred during the HA usage,
  – 1 - PTS risk episode occurred during the HA usage period,
  – 2 -TTS episode occurred during the HA usage period,
  – 3 –both PTS risk and TTS episode occurred during the HA usage period.

  Results of daily monitoring of PTS risk and TTS episodes are stored in the PTS_TTS_RES in the RETRO_HA tables.
  If during the last month or quarter, the prevalence of PTS/TTS_RES>0 is greater than assumed limit value (e.g. 30%) specific predefined actions should be undertaken. The previously mentioned limit value might be determined after data analytics.

A detailed analysis of how this predictive model works can be found at Appendix B, whereas its impact for a large population was demonstrated in Deliverable D3.1 (Katrakazas et al., 2017).

DATA TABLES

To reach the goals of this PHPDM, the following EVOTION data tables are needed (in arbitrary order):

- AUDIOGRAMCURVE
- ENVI_DATA
- HA_ENVIRONMENT_DATA
- TTSNIHL_TEST_RESULT
- USER_PTA_TEST_RESULT

TYPES OF EVOTION ANALYSIS

- Aggregation of data-logs over time
- Time series analysis

- Binary logistic regression (e.g. increase of HT at 4 kHz (yes/no) = f(prevalence of PTS/TTS_RES>0))
- Spearman Correlation test

For a formal definition of PHPDM2 in OWL, the following instances are needed:

- One instance of the `PolicyModel` class named "PM_2" with label "Prognosis of NIHL"
- an instance of the Goal class named "Goal_1" (see labels defined above under "GOAL")
- Two instances of the `Objective` class named "Obj_1" and "Obj_2" (see labels defined above under "OBJECTIVES")
- one instance of the `PolicyAction` class: named "PA_1" with label "NIHL related ACTION: Suggest and set-up of standards related to individuals with and without HL regarding the time spent in specific environments according to their noise levels",
- Five instances of the `Stakeholder` class: one named "Stakeholder_1" with label "Regional ENT-specialists' Advisory Committee", one named "Stakeholder_2" with label "Regional Directorate for Social support", one named "Stakeholder_3" with label "Regional structures of the national Health Insurance Fund", one named "Stakeholder_4" with label "HA vendors/fitting experts" and one named "Stakeholder_5" with label "Regional representatives of patients"
- One instance of the `Criterion` class named "CRI_1" with label "VAFCriterion"

Appendix A has the full PHPDM2 described in the Specification Language.

4 PHPDM for Prognosis and Delivery of Effective Auditory Training Rehabilitation

PHPDM3 considers data analytics that will study whether Auditory Training (AT) rehabilitation tools have positive effects on hearing aid (HA) use and on mitigating cognitive and auditory skill deterioration taking into account:

(i) Education level
- Q_DRMED > EDUC_PLACEM

(ii) Engagement (time spent) in AT
- AUDITORY_TRAINING > TASK_COMPLETION_RATE, START_TIME, END_TIME

This is to support policy makers in the definition of actions targeted to (i) HA users of different educational levels and cognitive impairment and (ii) HA users with different degrees of engagement with AT.

In the following, we describe PHPDM3 using the Model Specification Language:

GOAL(S)

1. **Description**: Assessing AT effectiveness (GOAL_1)
   Rationale: The purpose of this PHPDM is to determine to what extent AT could improve HA use and mitigate cognitive and auditory processing deterioration in a population, in order to inform the optimisation of public health policies. AT effectiveness might depend on behavioural factors and individual traits of patients. Big data analytics may support the identification of groups of patients that would respond better to AT, this way improving a public health policy effectiveness based on providing AT to a selected sub-population of patients.

OBJECTIVES

1. Explore whether the education level of HA users receiving AT predicts their hearing aid satisfaction (as measured by Glasgow Hearing Aid Benefit Profile (GHABP) scores), the stability of cognitive function (as measured by MOCA) and Speech in Noise and HA daily/monthly use and take relevant action of necessary. (OBJ_1)
2. Explore whether the engagement (i.e. time spent) with AT of HA users affects the PP scores and HA daily/monthly use, the stability of MOCA and mobile Speech in Noise scores over a period of *x* years and take relevant action of necessary. (OBJ_2)

POLICY ACTIONS

1. Educational level related ACTION: (If AT is found to be significantly less effective at improving HA use and reducing cognitive decline in participants with lower educational levels, then) Failure to reach a particular educational level has to be addressed to improve AT effectiveness (PA_1)
2. Engagement related ACTION: (If AT effectiveness in improving HA use and in reducing cognitive decline is found to be significantly positively correlated with the amount of time

spent with AT, then) Poor engagement in AT has to be addressed to improve AT effectiveness. (PA_2)

<u>STAKEHOLDERS</u>

Representatives of:

- National/regional ENT-specialists' Advisory Committee (in their role as prescribing the use of HAs);
- National/regional Directorate for Social support (in their role as authorising financial support for purchasing HAs and performing follow-up on administration and use);
- National/regional structures of the Health Insurance Fund(s) (in their role as funding clinical pathways);
- Hearing Care Professionals (HCPs);
- Patients' association – national/regional representatives of patients and carers
- Associations of audiologists/clinical HL practitioners (in view of setting new standards in clinical practice)

<u>CRITERIA</u>

1. Only variables related to education of HA Users contributing significantly to positive effects for AT ($p<0.05$) are accounted over time for each sub-population (CRI_1)
2. Only variables related to engagement of HA Users contributing significantly to positive effects for AT ($p<0.05$) are accounted over time for each sub-population (CRI_2)

<u>DATA TABLES:</u>

- GHABP_ANSWERS, GHABP_RESULT
- MOCA_ANSWERS
- AUDITORY_TRAINING
- REAL_TIME_HA
- Q_DRMED

<u>ANALYSIS TYPES</u>

- ANOVA
- Clustering
- Statistical Correlation

For a formal definition of PHPDM3 in OWL, the following instances are needed:

- One instance of the `PolicyModel` class named "PM_3" with label "Prognosis and Delivery of Effective Auditory Training Rehabilitation Services"
- One instance of the `Goal` class named "Goal_1" (see labels defined above under "GOAL")
- Two instances of the `Objective` class named "Obj_1" and "Obj_2" (see labels defined above under "OBJECTIVES")
- Two instances of the `PolicyAction` class named "PA_1" and "PA_2" (see labels defined above under "POLICY ACTIONS")

- Five instances of the `Stakeholder` class: one named “Stakeholder_1” with label “Regional ENT-specialists’ Advisory Committee”, one named “Stakeholder_2” with label “Regional Directorate for Social support”, one named “Stakeholder_3” with label “Regional structures of the national Health Insurance Fund”, one named “Stakeholder_4” with label “HA vendors/fitting experts” and one named “Stakeholder_5” with label “Regional representatives of patients”
- Two instances of the `Criterion` class named “CRI_1” with label “EducationCriterion” and “CRI_2” with label “EngagementCriterion”

Appendix A has the full PHPDM3 described in the Specification Language.

5 PHPDM for Hearing Loss Management and Overall Well-being of Hearing-Impaired Individuals

PHPDM4 will investigate whether self-management of hearing health interventions on a population scale have positive effects on wellbeing and quality of life and on mitigating cognitive and auditory processing deterioration. These effects can be used by public health planners to develop policies targeted at individual users, making a difference at the population level. The effects may be predicted and enabled through data from the following variables:

1. Age
    - PATIENT > DATEOFBIRTH
2. Hearing Loss
    - Q_DRMED > HI_DEGREE_CURRHL_L , HI_DEGREE_CURRHL_R
3. Use of hearing aids
    - TIME_PERIOD
4. Acoustic environment
    - HA_ENVRIRONMENT_DATA > S_EN_PARA
5. Education level of user
    - Q_DRMED > EDUC_PLACEM
6. Social-economic background - post code
    - PATIENT > POSTALCODE
7. Presence of significant other (medical condition)
    - Q_DRMED > OTHER_MEDICAL_PROB
8. Hearing Coach Training (from mobile) – to provide data on training, self-managing and tracking achievements.
    - RECORD_DATE
9. DR Medical and Audiological History.
    - Q_DRMED > FAMILYHISTORY
    - Q_DRMED > HEARING_PROB
    - Q_DRMED > HI_BETTER_EAR
    - Q_DRMED > HI_DEGREE_CURRHL_L
    - Q_DRMED > HI_DEGREE_CURRHL_R
    - Q_DRMED > HI_HISTOR_COMMNT
    - Q_DRMED > HI_ONSET_COUSE_L
    - Q_DRMED > HI_ONSET_COUSE_R
    - Q_DRMED > HI_ONSET_YSTART_L
    - Q_DRMED > HI_ONSET_YSTART_R
    - Q_DRMED > HI_PRDEAF_L
    - Q_DRMED > HI_PRDEAF_R
    - Q_DRMED > HI_PRDEAF_YSTART_L
    - Q_DRMED > HI_PRDEAF_YSTART_R
    - Q_DRMED > HI_PRDEAF_YSTOP_L
    - Q_DRMED > HI_PRDEAF_YSTOP_R
    - Q_DRMED > HI_PREVHA_YSTART_L

- Q_DRMED > HI_PREVHA_YSTART_R
- Q_DRMED > OTHER_MEDICAL_DESC
- Q_DRMED > OTHER_MEDICAL_PROB
- Q_DRMED > OTH_CURR_MEDIC
- Q_DRMED > OTH_HEAD_INJUR

10. Environmental Data (from mobile) – number of steps
    - ENVI_DATA > STEPS
11. BIO Sensors – Blood pressure (to be confirmed)
    - BIO_SENSOR > BLOOD_PRESSURE
12. Social Media – Number of followers
    - SOCIAL_MEDIA > TARGET_NUMBER_FOLLOWERS
13. Occupation
    - a. Q_DRMED > LS_EMPL_TYPE
14. Employment status
    - Q_DRMED > LS_EMPL_SIT1, LS_EMPL_SIT2
15. MoCA (Montreal Cognitive Assessment) a rapid screening instrument for mild cognitive dysfunction.
16. GHABP (The Glasgow Hearing Aid Benefit Profile) for evaluation of the efficacy and effectiveness of rehabilitative services for hearing-impaired adults.
17. HUI3 (The Health Utilities Index) for a summary index of health-related quality of life.
18. HADs which measures anxiety and depression in both hospital and community settings.

In the following, we describe PHPDM4 using the Model Specification Language.

GOAL(S)

- **Description**: Mitigate cognitive decline and auditory processing deterioration in a population of HA users (GOAL_1)
  Rationale: To improve overall wellbeing and quality of HA users in a population

OBJECTIVES

1. Enhance clinical monitoring of variables that impact upon cognition and wellbeing via face-face visits and mobile app (OBJ_1) by:
    a. determining which of the variables are associated with improved wellbeing and quality of life, and with mitigation of cognitive decline and auditory processing deterioration
2. Introduce interventions to improve hearing loss management and self-management (OBJ_2) by:
    a. assessing to what extent self-management of hearing aids in a population of HA users improves wellbeing and quality of life, and mitigates both cognitive decline and auditory processing deterioration.
    b. demonstrating that implementation of self-management of HAs in a sample population of HA users improves wellbeing and quality of life scores by a certain defined percentage, and mitigation of cognitive decline and auditory processing deterioration by defined percentages respectively over a period of certain months

POLICY ACTIONS

1. For each of the variables listed above that influence wellbeing and quality of life, and mitigate cognitive decline and auditory processing deterioration, actions should be taken (PA1):
    i. Additional training/support for a subpopulation identified by educational level
    ii. Fitting at a younger/older/particular age according to findings; Raising awareness programmes/public information campaigns
    iii. Screening for hearing loss at particular ages
    iv. Introduction of further noise regulations and alerting patients to exposure
    v. Development of standards around HA clinical practice related to time spent in specific acoustic environments
    vi. Monitoring self-managed tests scores on an app and alerting clinics if any deterioration is suspected
    vii. Introduction of training programmes at the stage of HA fitting for HA users with a profile that is associated with low HA usage
    viii. Training and/or educational programmes specific to sub-populations of various particular educational levels
    ix. Cost-relief packages for subgroups who live in high-risk areas: Development of standards of HA clinical practice related to patient employment status
    x. Introduction of measures aimed to help solitary individuals
    xi. Development of standards of HA clinical practice related to relevant aspect of medical and audiological history.
    xii. Development of standards of HA clinical practice related to time spent in specific acoustic environments
    xiii. Introduction of measures aimed to help individuals with high blood pressure to reduce it/ and/or referral to appropriate medical clinic
    xiv. Introduction of measures aimed to help individuals increase social interaction
    xv. Development of standards of HA clinical practice and public health interventions related to working conditions (e.g. hearing conservation programmes where appropriate)
2. Provide clinical practice guidelines to enable self-management that would improve wellbeing and quality of life, and mitigate cognitive decline and auditory processing deterioration (PA2).

STAKEHOLDERS

Representatives of:

- National/regional ENT-specialists' Advisory Committee (in their role as prescribing the use of HAs);
- National/regional Directorate for Social support (in their role as authorising financial support for purchasing HAs and performing follow-up on administration and use);
- National/regional structures of the Health Insurance Fund(s) (in their role as funding clinical pathways);
- Relevant Government and NGO public health planners concerned with the development of public health policy for hearing health)
- Hearing Care Professionals (HCPs);

- Patients' association – national/regional representatives of patients and carers

CRITERIA

1. Only variables related to positive effects for cognition and wellbeing ($p<0.05$) are monitored over time for each sub-population (CRI_1):
    a. Edu_Level P < 0.05
    b. Engage_Level P < 0.05
    c. GHABP_Score P < 0.05
    d. MOCA_Score P < 0.05
    e. HUI3_Score P < 0.05
    f. FollowUp_Freq P < 0.05
2. Policy actions are undertaken based on variables contributing with a certain percentage explained variance (CRI_2)
    a. R2 square > 0.5
    b. Significance F < 0.05
    c. Significance F >= 0.05

DATA TABLES:

- GHABP (SCORE_Q1/2/3/4/5/6/7)
- MOCA_ANSWERS (TOTAL_SCORE)
- HADS_ANSWERS
- HUI3_ANSWERS (HUI3 SCORE_Q7/11/12/14)
- REAL_TIME_HA
- Q_DRMED
- PATIENT
- RETRO_HA
- ENVI_DATA
- BIO Sensors
- SOCIAL_MEDIA

TYPES OF EVOTION ANALYSES

- Multiple variable regression analysis
- Artificial Neural Networks (ANN) architectures
    - For classification
    - For actual variables prediction.
    - For generation missing data points after data clearing stage if needed.
    - Deep architectures (Autoencoder + ANN) in case unsupervised features selection process will be needed.
- Genetic algorithms in combination with classification rules (as an ANN alternative in case of poor performance on feature selection process)
- Correlation analysis
    - for actual analysis

- as part of Relevance analysis in order to extract knowledge for complicated classification models if needed

- Analysis of Variance (ANOVA)
- Factor analysis
- Clustering

For a formal definition of PHPDM4 in OWL, the following instances are needed:

- One instance of the `PolicyModel` class named “PM_4” with label “Introduction of self-management in hearing health interventions s”
- One instance of the `Goal` class named “Goal_1” (see labels defined above under “GOAL”)
- Two instances of the `Objective` class named “Obj_1” and “Obj_2” (see labels defined above under “OBJECTIVES”)
- Two instances of the `PolicyAction` class named “PA_1” and “PA_2” (see labels defined above under “POLICY ACTIONS”)
- Five instances of the `Stakeholder` class: one named “Stakeholder_1” with label “Regional ENT-specialists’ Advisory Committee”, one named “Stakeholder_2” with label “Regional Directorate for Social support”, one named “Stakeholder_3” with label “Regional structures of the national Health Insurance Fund”, one named “Stakeholder_4” with label “HA vendors/fitting experts” and one named “Stakeholder_5” with label “Regional representatives of patients”
- Two instances of the `Criterion` class named “CRI_1” with label “PValueCriterion” and “CRI_2” with label “VarianceCriterion”

Appendix A has the full PHPDM4 described in the Specification Language.

6 Demonstrator

The PHPDM model specification Tool presented in Deliverable 4.2 (Basdekis et al., 2018) will be used to demonstrate how a specific model (PHPDM2) is populated in the Specification Tool which can be found at the following URL: https://evotion.city.ac.uk/login.php.

After logging into the registered users' area with our credentials (Figure 1), we create the Workflow related to the Policy Model, hereby named DAW1, which is to be executed upon user action (Figure 2). After creating the workflow (Figure 3), the tool brings us back to the first screen (Figure 4) in order to create the policy model.

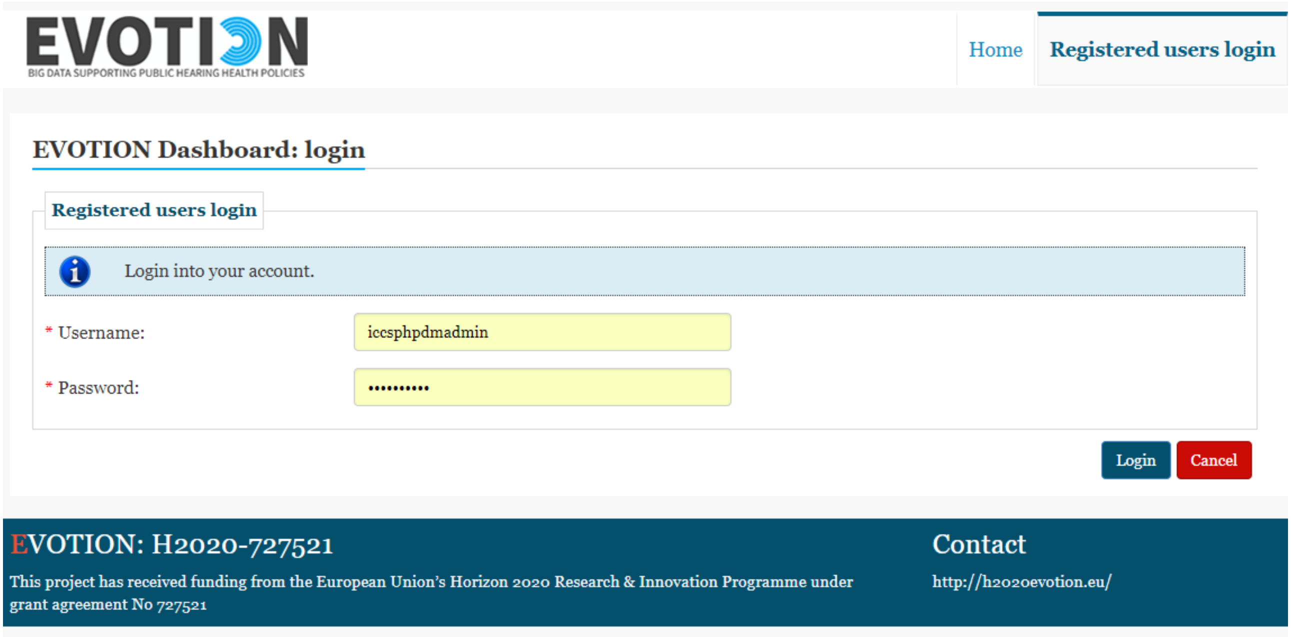

Figure 1 Starting Screen of the Specification Tool before Login

Upon pressing the "Create Policy" button, we fill up the form with the "Goal" and "Objective" Sections (Figure 5), as these were identified in PHPDM2. In the next screen, we are given the option to add policy action(s) connected to the specific objective (Figure 6) and the workflow we have already defined. Upon completing these tasks, we are going back to the starting screen, where we can see our created model (Figure 7).

We have to define now the data and types of data analysis to be used in the defined workflows. Pressing the DAW1 Workflow (Figure 8), we are presented with a screen where we can insert types of data needed into a data analytics task (Figure 9), select the Types of Analysis and the EVOTION Data (Figure 10) and choose whether some of the variables are to be dependent one another (Figure 11). After that step, we create and define the execution Criteria as these were described in PHPDM2 (Figure 12). Completing that step, brings us back to Figure 7, from where we can proceed with the refinement, altering and execution steps of the PHPDMs via the Specification Tool (part of WP3 Deliverable D3.3).

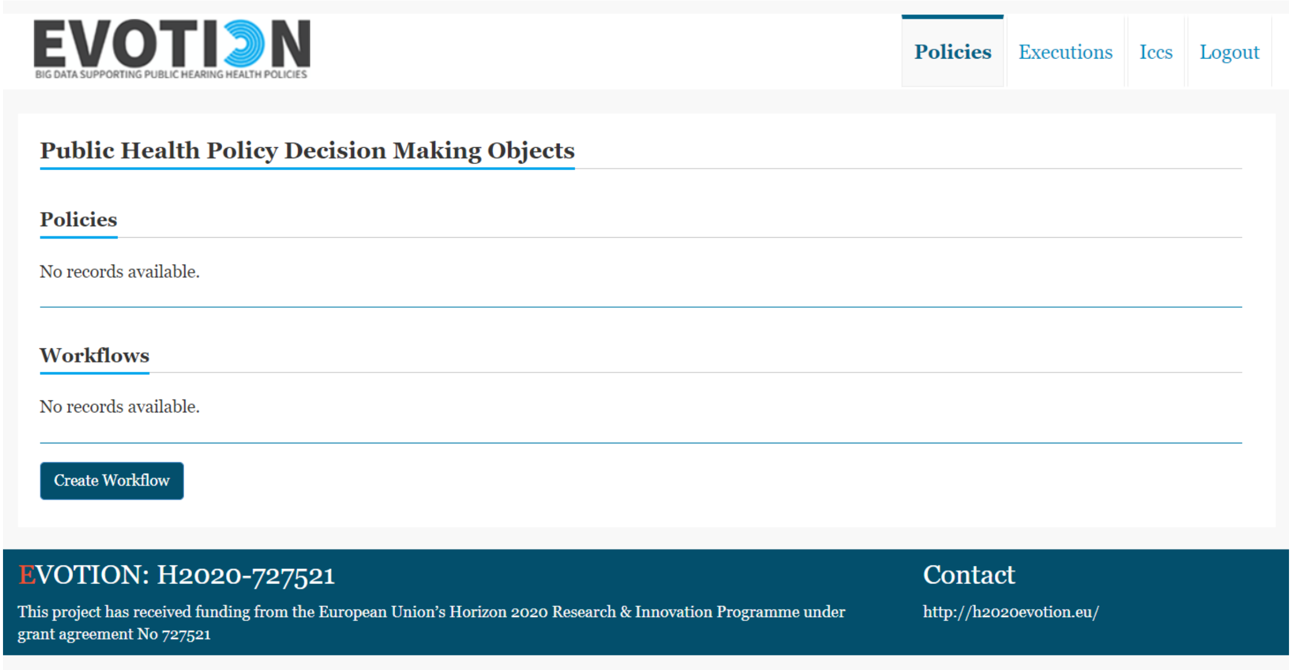

Figure 2 Starting Screen of the Specification Tool after Login

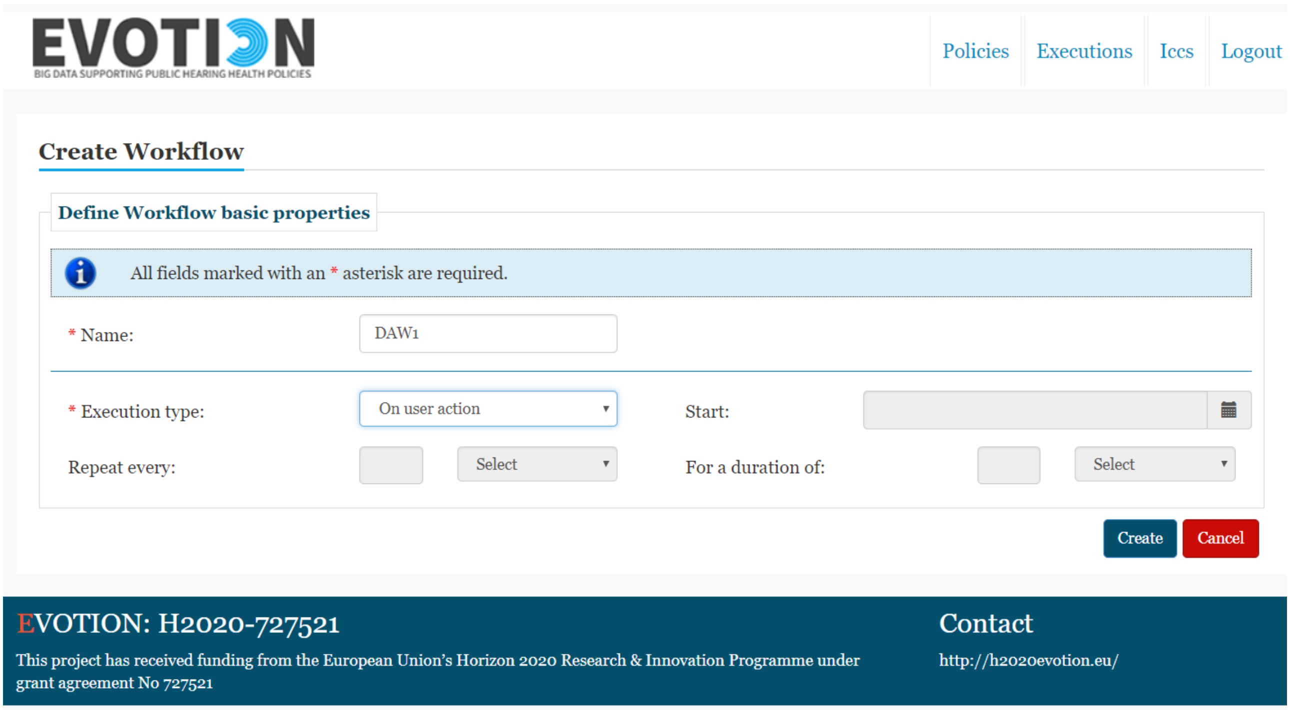

Figure 3 Definition of Workflow related to the Policy Model

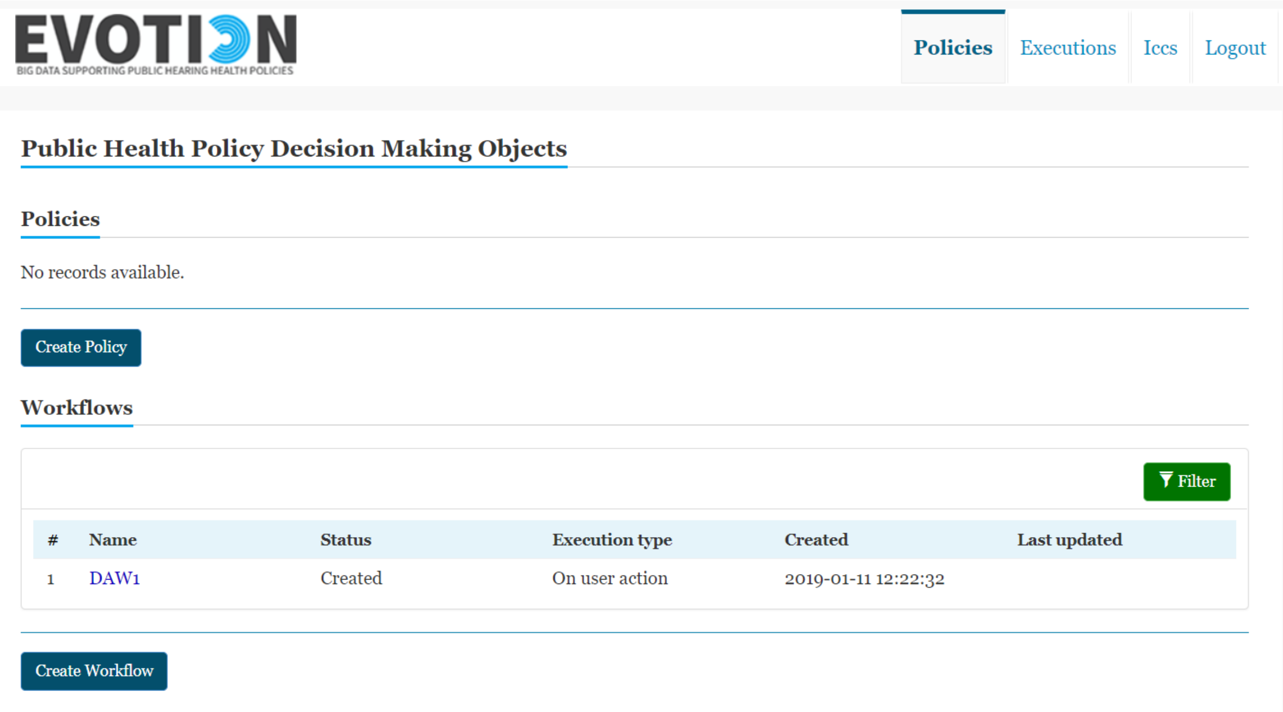

Figure 4 Return Screen after Workflow Creation

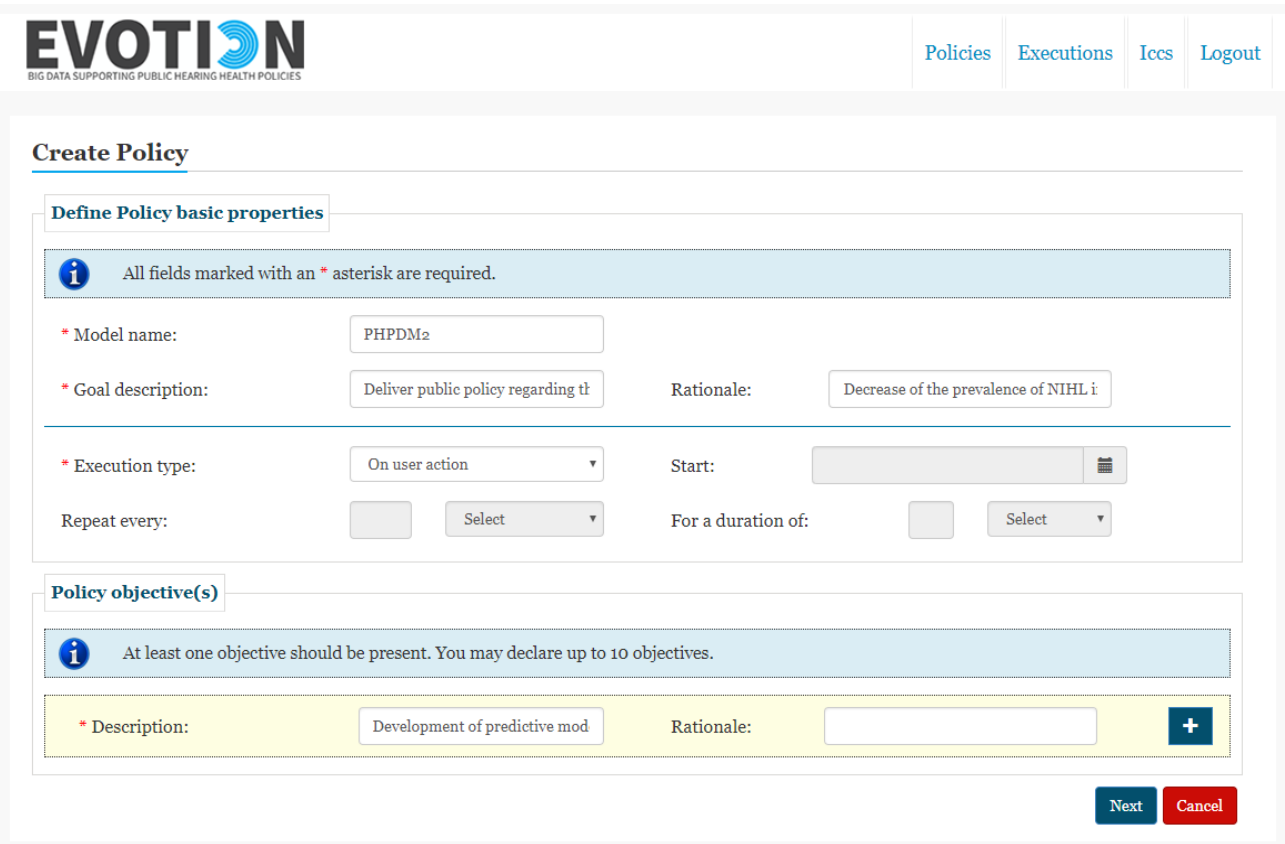

Figure 5 Goal and Objectives Screen

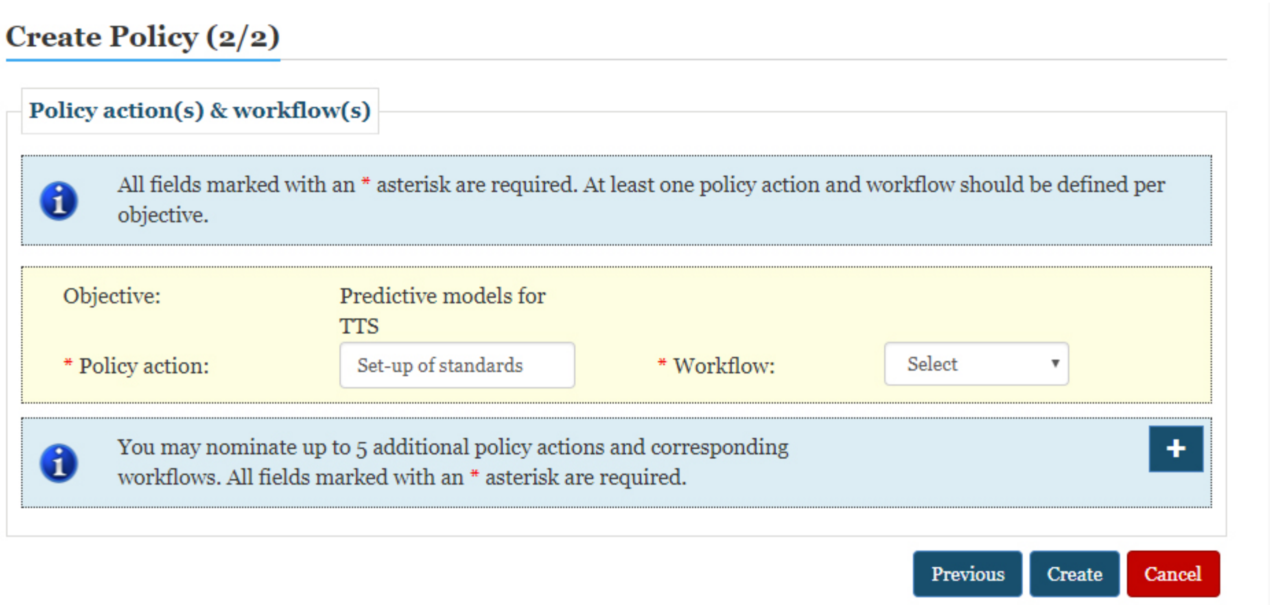

Figure 6 Policy Action(s) Screen

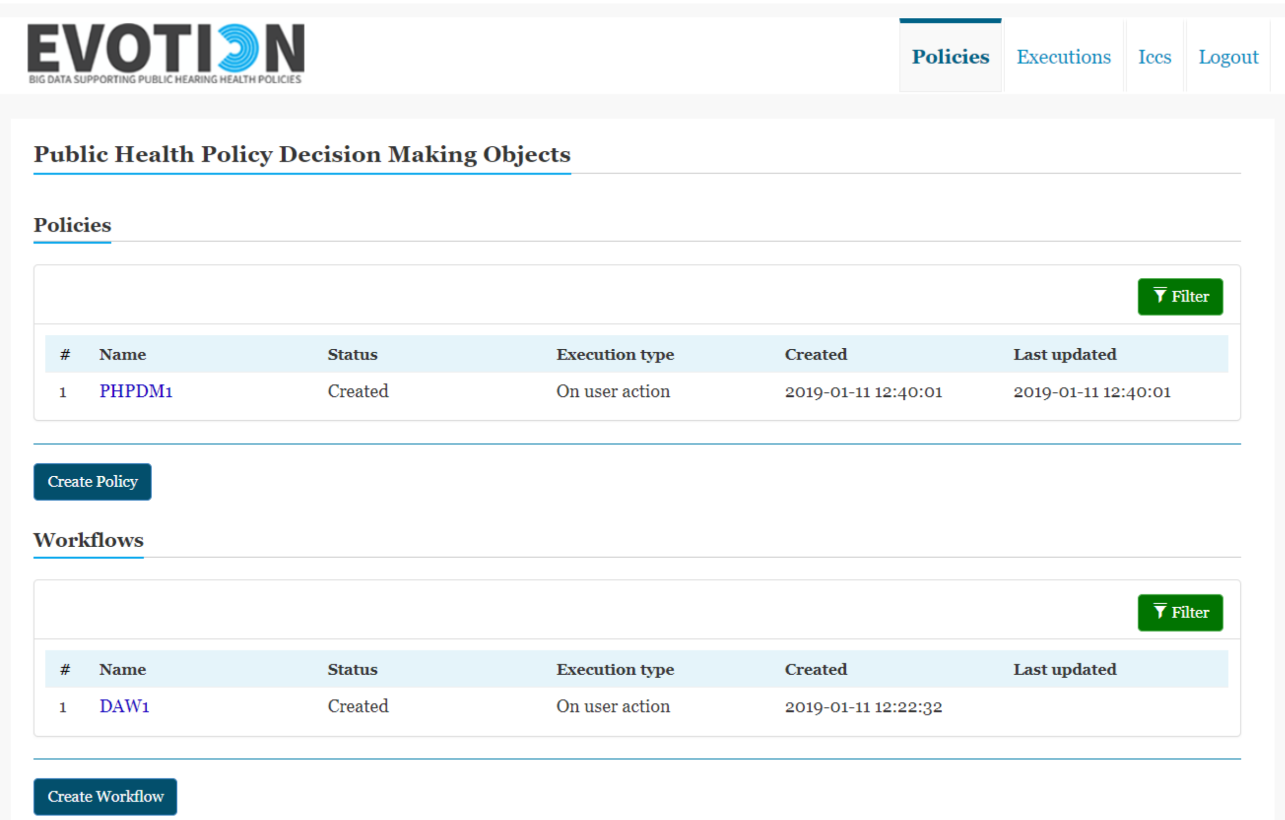

Figure 7 Created Model Screen

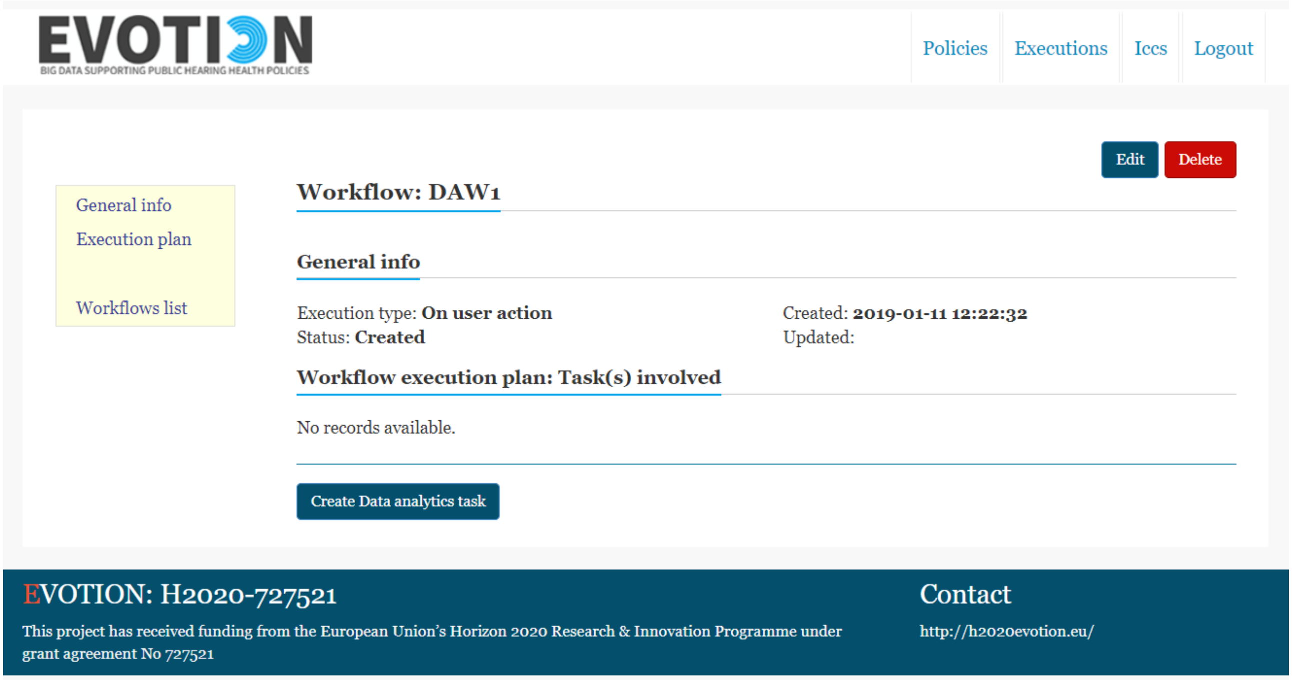

Figure 8 Workflow Editing and Data Analytics Task Creation Screen

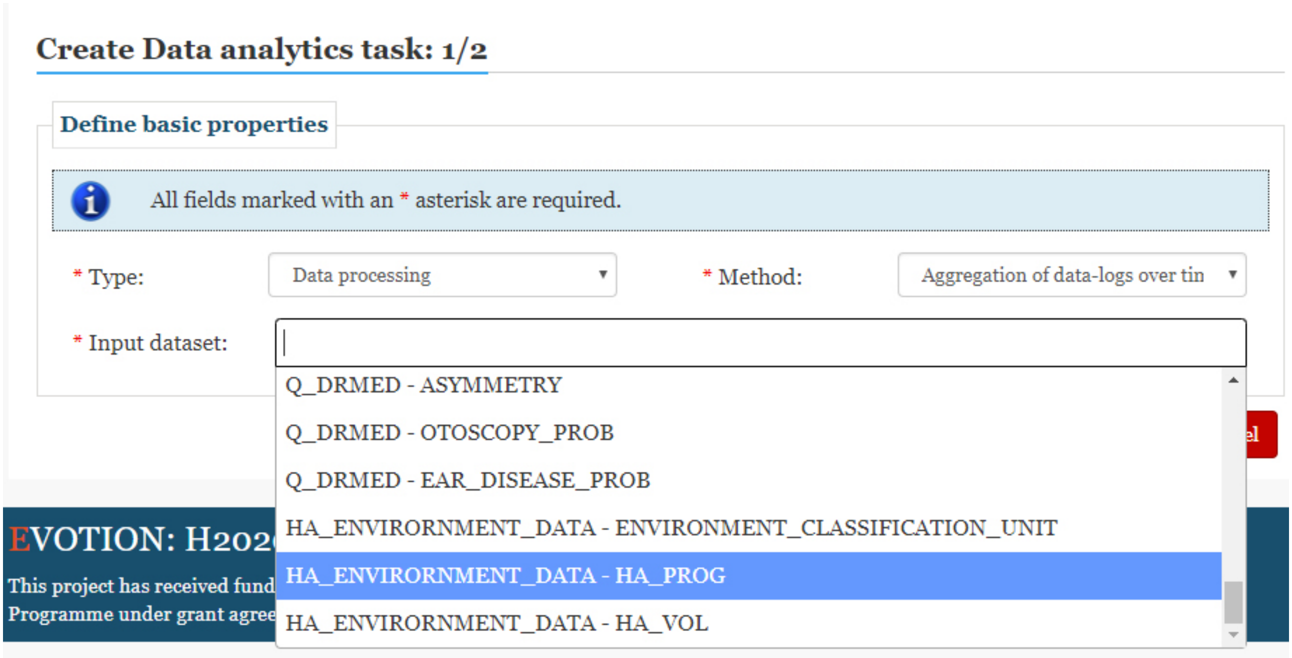

Figure 9 Data Analytics Task Definition Screen

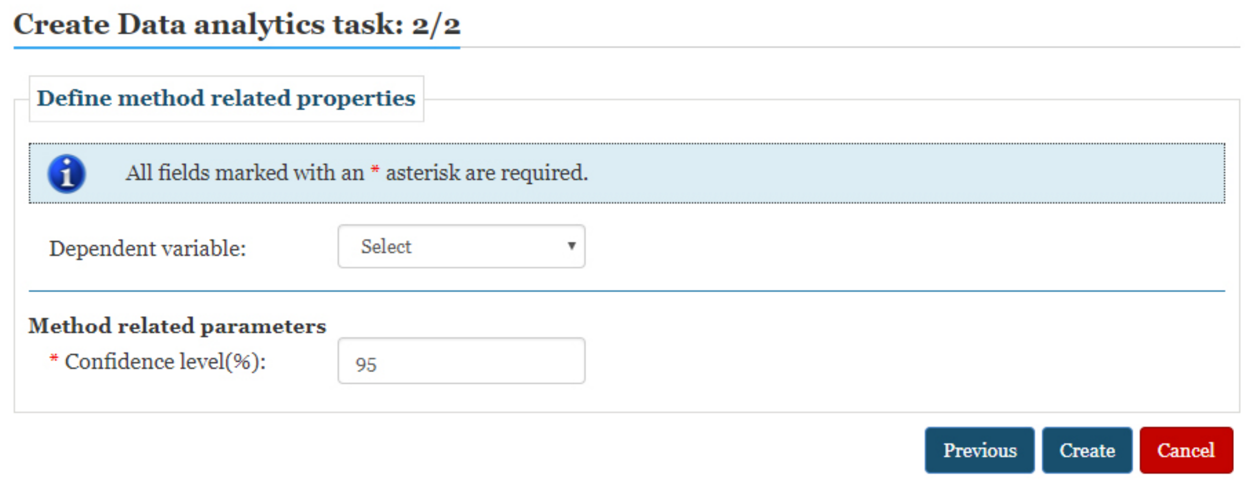

Figure 10 Data Definition Screen

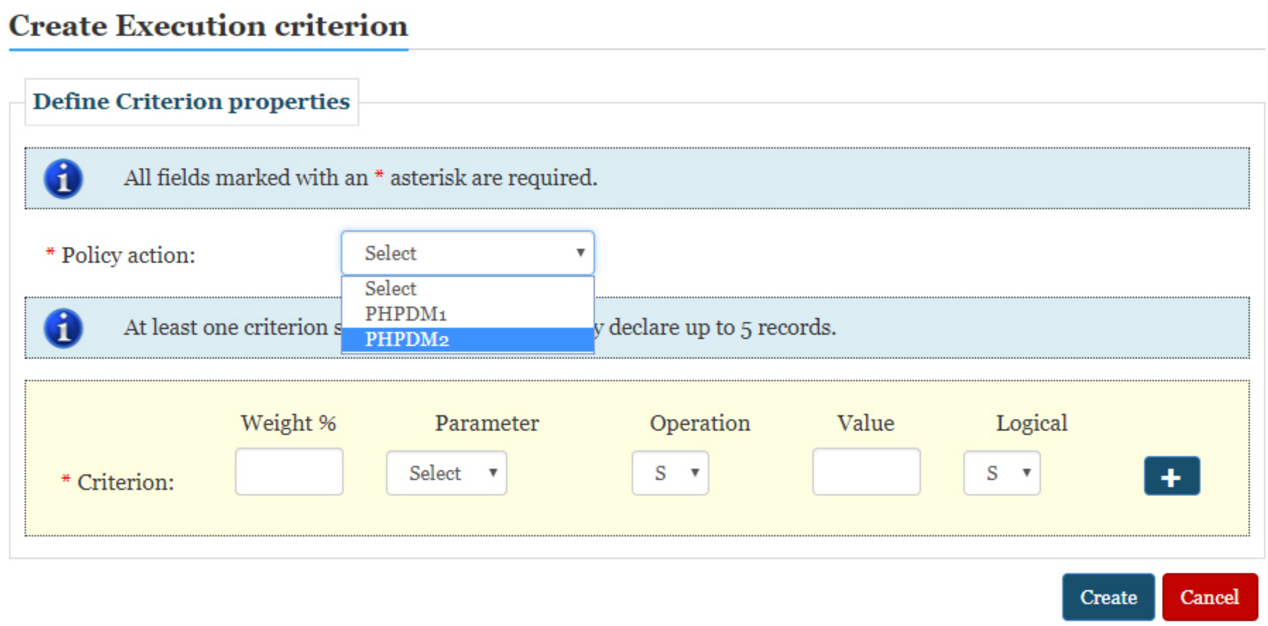

Figure 11 Policy Action related Criterion Screen

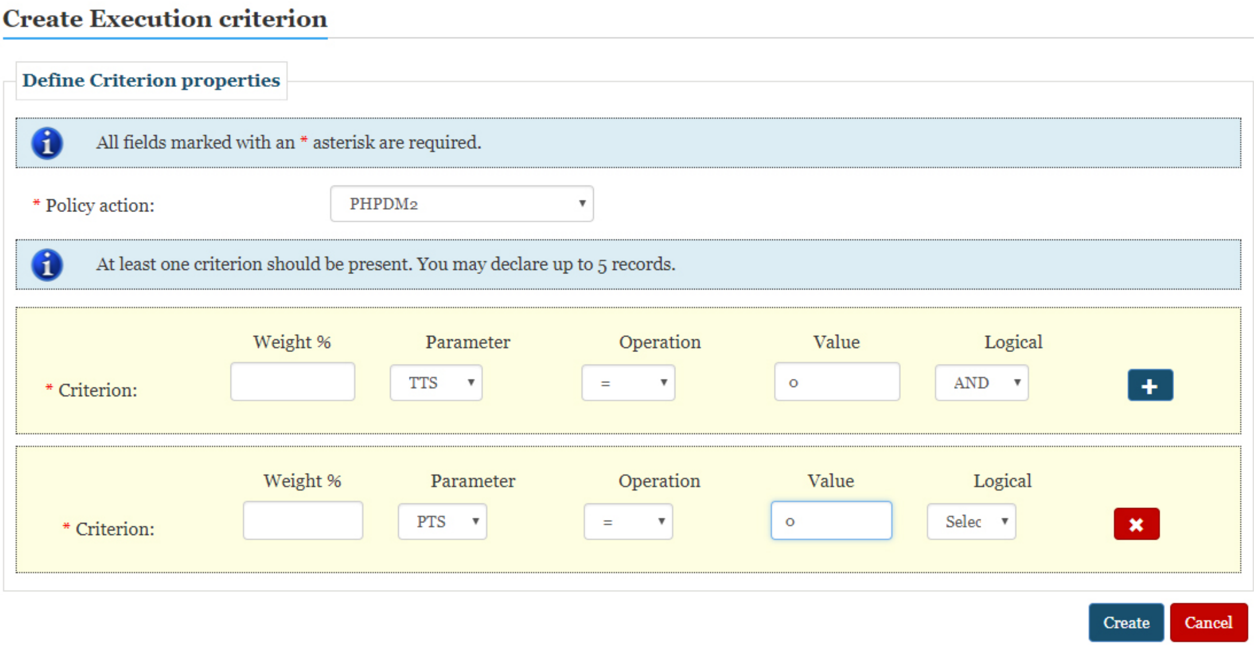

Figure 12 Criteria Definition Screen

7 Concluding Remarks

This report presents the second version of the PHPDMs, described in the Specification Language in order to be informed by big data analytics to support decisions related to policy making in key HL treatment and management areas. The focus of this deliverable is on the specification of PHPDM models in the language developed in EVOTION, which was demonstrated via the full description of the PHPDMs in the Specification Language (as found in the Appendix Section) and the example run via the Specification Tool (as found in the Demonstrator Section).

There are four PHPDMs described in this report:

1. Prognosis of Effectiveness of HA Usage (PHPDM1),
2. Prognosis and Prevention of Noise Induced Hearing Loss (PHPDM2),
3. Prognosis and Delivery of Effective Auditory Training Rehabilitation Services (PHPDM3) and
4. Hearing Loss Treatment/Overall Well-being of Hearing-Impaired Individuals (PHPDM4)

The four PHPDMs will reach their final format in Deliverable D3.3 where the remaining phases of (a) initial pattern recognition, (b) feature selection and dimensionality reduction, (c) development of the optimal prediction model and (d) finalization will take place.

The impact of having the PHPDMs specified in the language is to allow:

(a) the realization of evidenced based policy making practice related to HL treatment accountable and directly attributable to data
(b) the validation of tool support for public health policy making in HL, along with a language for defining new public PHPDM models,
(c) the specification of such processes that enable the execution of the policy decision making model that incorporates them with different (big) datasets and with datasets dynamically evolving in real time.
(d) the realization of sustainable HL policy decision making models that can be continually and automatically updated by connection to data streams with specific BDA estimators that can be re-executed as data updates require.

The next steps are:

(a) **Data cleaning.** A data cleaning strategy is to be implemented over the next months. EVOTION depends on complex real time data collected with WP7 from real hearing aid users (Kikidis et al., 2018). To ensure that the PHPDMs can deliver reliable and valid outputs, it is essential that data are validated. Clinical partners will identify data cleaning and validation criteria. This task interfaces with task of Clinical Evaluation under WP7. Technical partners will work with clinical partners to implement appropriate data cleaning operations. This activity will not only be of value in and of itself to ensure EVOTION data is valid, but also it will provide a basis for identifying appropriate cleaning operations and workflows that can subsequently be used to enrich the PHPDM language in a systematic manner.
(a) **Advanced data analytics.** Based on the BDA engine, advanced analytics will enhance the PHPDMs and bring out their full potential. The expected value of the information contained in each PHPDM is a good measure of its potential importance to the PHP makers. The

EVOTION Platform has a variety of tools, such as the Big Data Analytics engine (Anisetti et al., 2018) and the Decision Support System (Katrakazas et al., 2018) available to assist the analyst and user in better understanding the data held within it. Each tool does something different, and usually this implies a specific problem is best treated with a particular algorithm type. However, sometimes, different algorithm types can be used for the same problem. Most involve setting parameters, which can be important in the effectiveness of the method. Furthermore, output needs to be interpreted. Therefore, the sscalability of the PHPDMs as described here is very important, as streams of real-time data input can make more complex models difficult to monitor and understand.

(b) **Validation of the PHPDMs from the public health and technical perspectives.** The validation of the outcomes of the BDA analytics of EVOTION from a clinical perspective (WP7, Task 7.5) will allow the BDA outcomes related to correlations between hearing loss related factors and comorbidities to be validated by the clinical partners through comparison to existing clinical studies and related causal underpinning factors that may be established from existing clinical knowledge. Moreover, the technical validation of the performance, scalability, usability, privacy, security and accuracy of the BDA enabled decision making of the EVOTION platform (WP7, Task 7.4) and the validation of the EVOTION platform (WP7, Task 7.3) as a public health policymaking tool, through the active involvement of the consortium's PHP makers, will validate the PHPDMs' relation to steering policy direction. This will provide the necessary level of certainty and risk stratification of HL patients with different comorbidities and characteristics for making policy decisions/. It will also support in an effective, accountable and evidenced based manner the exploration and selection of alternative policy decisions making.

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APPENDIX A

PHDPM1 described in Specification Language

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ns#PlainLiteral">in their role as authorising financial support for purchasing HAs
and performing follow-up on ad-ministration and use</Literal>
       </AnnotationAssertion>
       <AnnotationAssertion>
           <AnnotationProperty abbreviatedIRI="rdfs:label"/>
           <IRI>#Stakeholder_2</IRI>
           <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Regional Directorate for Social support</Literal>
       </AnnotationAssertion>
       <AnnotationAssertion>
           <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
           <IRI>#Stakeholder_3</IRI>
           <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">in their role as funding clinical pathways</Literal>
       </AnnotationAssertion>
       <AnnotationAssertion>
           <AnnotationProperty abbreviatedIRI="rdfs:label"/>
           <IRI>#Stakeholder_3</IRI>
           <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Regional structures of the national Health Insurance
Fund</Literal>
       </AnnotationAssertion>
       <AnnotationAssertion>
           <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
           <IRI>#Stakeholder_4</IRI>
           <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">providing follow-up rehab</Literal>
       </AnnotationAssertion>
       <AnnotationAssertion>
```

```
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_4</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">HA vendors/fitting experts</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_5</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">regional representatives of patients</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_5</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Patients’ association</Literal>
        </AnnotationAssertion>
    <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_6</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Associations of audiologists/clinical HL practinioners</Literal>
        </AnnotationAssertion>
```

```
    <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
            <NamedIndividual IRI="#PM_1"/>
            <NamedIndividual IRI="#Stakeholder_1"/>
        </ObjectPropertyAssertion>
        <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
            <NamedIndividual IRI="#PM_1"/>
            <NamedIndividual IRI="#Stakeholder_2"/>
        </ObjectPropertyAssertion>
        <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
            <NamedIndividual IRI="#PM_1"/>
            <NamedIndividual IRI="#Stakeholder_3"/>
           </ObjectPropertyAssertion>
```

```
      <ObjectPropertyAssertion>
          <ObjectProperty IRI="#involvesStakeholders"/>
          <NamedIndividual IRI="#PM_1"/>
          <NamedIndividual IRI="#Stakeholder_4"/>
        </ObjectPropertyAssertion>
      <ObjectPropertyAssertion>
          <ObjectProperty IRI="#involvesStakeholders"/>
          <NamedIndividual IRI="#PM_1"/>
          <NamedIndividual IRI="#Stakeholder_5"/>
        </ObjectPropertyAssertion>
  <ObjectPropertyAssertion>
          <ObjectProperty IRI="#involvesStakeholders"/>
          <NamedIndividual IRI="#PM_1"/>
          <NamedIndividual IRI="#Stakeholder_6"/>
       </ObjectPropertyAssertion>
```

PHDPM2 described in Specification Language

```
  <Declaration>
          <NamedIndividual IRI="#PM_2"/>
      </Declaration>
      <ClassAssertion>
          <Class IRI="#PolicyModel"/>
          <NamedIndividual IRI="#PM_2"/>
       </ClassAssertion>
       <AnnotationAssertion>
          <AnnotationProperty abbreviatedIRI="rdfs:label"/>
          <IRI>#PM_1</IRI>
          <LiteraldatatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax
ns#PlainLiteral">      Prognosis  and  Prevention  of  Noise  Induced  Hearing  Loss
</Literal>
      </AnnotationAssertion>
  <Declaration>
          <NamedIndividual IRI="#Goal_1"/>
      </Declaration>
  <ClassAssertion>
          <Class IRI="#Goal"/>
          <NamedIndividual IRI="#Goal_1"/>
      </ClassAssertion>
  <AnnotationAssertion>
          <AnnotationProperty abbreviatedIRI="rdfs:label"/>
          <IRI>#Goal_1</IRI>
          <Literal           datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral"> Deliver public policy regarding the prevention of NIHL in HA users
</Literal>
      </AnnotationAssertion>
  <DataPropertyAssertion>
          <DataProperty IRI="#description"/>
          <NamedIndividual IRI="#Goal_1"/>
          <Literal           datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral"> Decrease of the prevalence of NIHL in HA user groups exposed to
noise including occupational settings, by providing a prediction model for PTS/TTS
incidents, thus allowing the prevention and decrease the risk of TTS in HA users
</Literal>
      </DataPropertyAssertion>
```

```
&lt;Declaration&gt;
        &lt;NamedIndividual IRI="#Obj_1"/&gt;
    &lt;/Declaration&gt;
&lt;ClassAssertion&gt;
        &lt;Class IRI="#Objective"/&gt;
        &lt;NamedIndividual IRI="#Obj_1"/&gt;
    &lt;/ClassAssertion&gt;
&lt;AnnotationAssertion&gt;
        &lt;AnnotationProperty abbreviatedIRI="rdfs:label"/&gt;
        &lt;IRI&gt;#Obj_1&lt;/IRI&gt;
        <Literal          datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral"> Development of a predictive model for PTS/TTS incidents based on
cumulative individuals' data &lt;/Literal&gt;
    &lt;/AnnotationAssertion&gt;
&lt;Declaration&gt;
        &lt;NamedIndividual IRI="#PA_1"/&gt;
    &lt;/Declaration&gt;
&lt;ClassAssertion&gt;
        &lt;Class IRI="#PolicyAction"/&gt;
        &lt;NamedIndividual IRI="#PA_1"/&gt;
    &lt;/ClassAssertion&gt;
&lt;DataPropertyAssertion&gt;
        &lt;DataProperty IRI="#description"/&gt;
        &lt;NamedIndividual IRI="#PA_1"/&gt;
        <Literal          datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">  Suggest and set-up of standards related to individuals with or
without HL regarding the time spent in specific environments according to their
noise levels. &lt;/Literal&gt;
    &lt;/DataPropertyAssertion&gt;
```

```
&lt;Declaration&gt;
        &lt;NamedIndividual IRI="#Stakeholder_1"/&gt;
    &lt;/Declaration&gt;
&lt;Declaration&gt;
        &lt;NamedIndividual IRI="#Stakeholder_2"/&gt;
    &lt;/Declaration&gt;
&lt;Declaration&gt;
        &lt;NamedIndividual IRI="#Stakeholder_3"/&gt;
```

```
        </Declaration>
    <Declaration>
            <NamedIndividual IRI="#Stakeholder_4"/>
        </Declaration>
    <Declaration>
            <NamedIndividual IRI="#Stakeholder_5"/>
        </Declaration>
    <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_1</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">in their role as prescribing the use of HAs</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_1</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">National ENT-specialists’ Advisory Committee</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_2</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">in their role as authorising financial support for purchasing HAs
and performing follow-up on ad-ministration and use</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_2</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Regional Directorate for Social support</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_3</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">in their role as funding clinical pathways</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
```

```
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_3</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Regional structures of the national Health Insurance
Fund</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_4</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">providing follow-up rehab</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_4</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">HA vendors/fitting experts</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_5</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">regional representatives of patients</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_5</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Patients’ association</Literal>
        </AnnotationAssertion>
```

```
    <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
            <NamedIndividual IRI="#PM_2"/>
            <NamedIndividual IRI="#Stakeholder_1"/>
        </ObjectPropertyAssertion>
        <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
```

```
        <NamedIndividual IRI="#PM_2"/>
        <NamedIndividual IRI="#Stakeholder_2"/>
    </ObjectPropertyAssertion>
    <ObjectPropertyAssertion>
        <ObjectProperty IRI="#involvesStakeholders"/>
        <NamedIndividual IRI="#PM_2"/>
        <NamedIndividual IRI="#Stakeholder_3"/>
      </ObjectPropertyAssertion>
    <ObjectPropertyAssertion>
        <ObjectProperty IRI="#involvesStakeholders"/>
        <NamedIndividual IRI="#PM_2"/>
        <NamedIndividual IRI="#Stakeholder_4"/>
      </ObjectPropertyAssertion>
    <ObjectPropertyAssertion>
        <ObjectProperty IRI="#involvesStakeholders"/>
        <NamedIndividual IRI="#PM_2"/>
        <NamedIndividual IRI="#Stakeholder_5"/>
      </ObjectPropertyAssertion>
```

```
  <Declaration>
          <NamedIndividual IRI="#PM_3"/>
      </Declaration>
      <ClassAssertion>
          <Class IRI="#PolicyModel"/>
          <NamedIndividual IRI="#PM_3"/>
       </ClassAssertion>
       <AnnotationAssertion>
          <AnnotationProperty abbreviatedIRI="rdfs:label"/>
          <IRI>#PM_1</IRI>
          <LiteraldatatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax
ns#PlainLiteral">Prognosis   and   Delivery   of   Effective   Auditory   Training
Rehabilitation Services</Literal>
      </AnnotationAssertion>
  <Declaration>
          <NamedIndividual IRI="#Goal_1"/>
      </Declaration>
  <ClassAssertion>
          <Class IRI="#Goal"/>
          <NamedIndividual IRI="#Goal_1"/>
      </ClassAssertion>
  <AnnotationAssertion>
          <AnnotationProperty abbreviatedIRI="rdfs:label"/>
          <IRI>#Goal_1</IRI>
          <Literal           datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Assessing AT effectiveness</Literal>
      </AnnotationAssertion>
  <DataPropertyAssertion>
          <DataProperty IRI="#description"/>
          <NamedIndividual IRI="#Goal_1"/>
          <Literal           datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral"> Assessing AT effectiveness . </Literal>
      </DataPropertyAssertion>
      <DataPropertyAssertion>
          <DataProperty IRI="#rationale"/>
          <NamedIndividual IRI="#Goal_1"/>
```

```
          <Literal          datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-ns#PlainLiteral"> The purpose of this PHPDM is to determine to what extent an AT could improve the HA use and mitigate cognitive and auditory processing deterioration in a population in order to inform the optimisation of public health policies. AT effectiveness might depend on behavioural factors and individual traits of patients. Big data analytics may support the identification of groups of patients that would respond better to AT, this way improving a public health policy effectiveness based on providing AT to a selected subpopulation of patients. </Literal>
    </DataPropertyAssertion>
  <Declaration>
          <NamedIndividual IRI="#Obj_1"/>
      </Declaration>
  <Declaration>
          <NamedIndividual IRI="#Obj_2"/>
      </Declaration>
  <Class IRI="#Objective"/>
          <NamedIndividual IRI="#Obj_1"/>
      </ClassAssertion>
      <ClassAssertion>
          <Class IRI="#Objective"/>
          <NamedIndividual IRI="#Obj_2"/>
      </ClassAssertion>
  <AnnotationAssertion>
          <AnnotationProperty abbreviatedIRI="rdfs:label"/>
          <IRI>#Obj_1</IRI>
          <Literal          datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-ns#PlainLiteral"> Explore whether the education level of HA users receiving AT affects their Glasgow Hearing Aid Benefit Profile (GHABP) scores, the stability of MOCA and Speech in Noise and HA daily/monthly use and take relevant action if necessary </Literal>
      </AnnotationAssertion>
      <AnnotationAssertion>
          <AnnotationProperty abbreviatedIRI="rdfs:label"/>
          <IRI>#Obj_2</IRI>
          <Literal          datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-ns#PlainLiteral"> Explore whether the engagement (i.e. time spent) with AT of HA users affects the GHABP scores and HA daily/monthly use, the stability of MOCA and
```

```
mobile Speech in Noise scores over a period of x years and take relevant action if necessary </Literal>
        </AnnotationAssertion>
        <Declaration>
            <NamedIndividual IRI="#PA_1"/>
        </Declaration>
    <Declaration>
            <NamedIndividual IRI="#PA_2"/>
        </Declaration>
    <ClassAssertion>
            <Class IRI="#PolicyAction"/>
            <NamedIndividual IRI="#PA_1"/>
        </ClassAssertion>
        <ClassAssertion>
            <Class IRI="#PolicyAction"/>
            <NamedIndividual IRI="#PA_2"/>
        </ClassAssertion>
    <DataPropertyAssertion>
            <DataProperty IRI="#description"/>
            <NamedIndividual IRI="#PA_1"/>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-ns#PlainLiteral"> If AT is found to be significantly less effective in improving HA use and in reducing cognitive decline in participants with low than those with high educational level, then failure to reach a particular educational level has to be addressed to improve AT effectiveness </Literal>
        </DataPropertyAssertion>
        <DataPropertyAssertion>
            <DataProperty IRI="#description"/>
            <NamedIndividual IRI="#PA_2"/>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-ns#PlainLiteral"> If AT effectiveness in improving HA use and in reducing cognitive decline is found to be significantly positively correlated with the amount of time spent with AT, then poor engagement in AT has to be addressed to improve AT effectiveness </Literal>
        </DataPropertyAssertion>
```

```
    <Declaration>
            <NamedIndividual IRI="#Stakeholder_1"/>
```

```
        </Declaration>
    <Declaration>
            <NamedIndividual IRI="#Stakeholder_2"/>
        </Declaration>
    <Declaration>
            <NamedIndividual IRI="#Stakeholder_3"/>
        </Declaration>
    <Declaration>
            <NamedIndividual IRI="#Stakeholder_4"/>
        </Declaration>
    <Declaration>
            <NamedIndividual IRI="#Stakeholder_5"/>
        </Declaration><Declaration>
            <NamedIndividual IRI="#Stakeholder_6"/>
        </Declaration>
    <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_1</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">in their role as prescribing the use of HAs</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_1</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Regional ENT-specialists’ Advisory Committee</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_2</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">in their role as authorising financial support for purchasing HAs
and performing follow-up on ad-ministration and use</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_2</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Regional Directorate for Social support</Literal>
```

```
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_3</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">in their role as funding clinical pathways</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_3</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Regional structures of the national Health Insurance
Fund</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_4</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">providing follow-up rehab</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_4</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">HA vendors/fitting experts</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:comment"/>
            <IRI>#Stakeholder_5</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">regional representatives of patients</Literal>
        </AnnotationAssertion>
        <AnnotationAssertion>
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_5</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Patients’ association</Literal>
        </AnnotationAssertion>
    <AnnotationAssertion>
```

```
            <AnnotationProperty abbreviatedIRI="rdfs:label"/>
            <IRI>#Stakeholder_6</IRI>
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Associations of audiologists/clinical HL practinioners</Literal>
        </AnnotationAssertion>
```

```
    <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
            <NamedIndividual IRI="#PM_1"/>
            <NamedIndividual IRI="#Stakeholder_1"/>
        </ObjectPropertyAssertion>
        <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
            <NamedIndividual IRI="#PM_1"/>
            <NamedIndividual IRI="#Stakeholder_2"/>
        </ObjectPropertyAssertion>
        <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
            <NamedIndividual IRI="#PM_1"/>
            <NamedIndividual IRI="#Stakeholder_3"/>
          </ObjectPropertyAssertion>
        <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
            <NamedIndividual IRI="#PM_1"/>
            <NamedIndividual IRI="#Stakeholder_4"/>
          </ObjectPropertyAssertion>
        <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
            <NamedIndividual IRI="#PM_1"/>
            <NamedIndividual IRI="#Stakeholder_5"/>
          </ObjectPropertyAssertion>
    <ObjectPropertyAssertion>
            <ObjectProperty IRI="#involvesStakeholders"/>
            <NamedIndividual IRI="#PM_1"/>
            <NamedIndividual IRI="#Stakeholder_6"/>
         </ObjectPropertyAssertion>
```

PHDPM4 described in Specification Language


```
  <Declaration>
          <NamedIndividual IRI="#PM_4"/>
      </Declaration>
      <ClassAssertion>
          <Class IRI="#PolicyModel"/>
          <NamedIndividual IRI="#PM_4"/>
       </ClassAssertion>
       <AnnotationAssertion>
          <AnnotationProperty abbreviatedIRI="rdfs:label"/>
          <IRI>#PM_1</IRI>
          <LiteraldatatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax
ns#PlainLiteral">Hearing Loss Management and Overall Well-being of Hearing Impaired
Individuals </Literal>
      </AnnotationAssertion>
  <Declaration>
          <NamedIndividual IRI="#Goal_1"/>
      </Declaration>
  <ClassAssertion>
          <Class IRI="#Goal"/>
          <NamedIndividual IRI="#Goal_1"/>
      </ClassAssertion>
  <AnnotationAssertion>
          <AnnotationProperty abbreviatedIRI="rdfs:label"/>
          <IRI>#Goal_1</IRI>
          <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Mitigate Cognitive Decline and auditory process deterioration in
a population of HA users </Literal>
      </AnnotationAssertion>
  <DataPropertyAssertion>
          <DataProperty IRI="#rationale"/>
          <NamedIndividual IRI="#Goal_1"/>
          <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral"> To improve wellbeing and quality of life in HA users in a
population </Literal>
      </DataPropertyAssertion>
  <Declaration>
          <NamedIndividual IRI="#Obj_1"/>
```

```
      </Declaration>
  <Declaration>
          <NamedIndividual IRI="#Obj_2"/>
      </Declaration>
  <ClassAssertion>
          <Class IRI="#Objective"/>
          <NamedIndividual IRI="#Obj_1"/>
      </ClassAssertion>
      <ClassAssertion>
          <Class IRI="#Objective"/>
          <NamedIndividual IRI="#Obj_2"/>
      </ClassAssertion>
  <AnnotationAssertion>
          <AnnotationProperty abbreviatedIRI="rdfs:label"/>
          <IRI>#Obj_1</IRI>
          <Literal           datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">Enhance  clinical  monitoring  of  variables  that  impact  upon
cognition and wellbeing via face-face visits and mobile app</Literal>
      </AnnotationAssertion>
      <AnnotationAssertion>
          <AnnotationProperty abbreviatedIRI="rdfs:label"/>
          <IRI>#Obj_2</IRI>
          <Literal           datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral"> Introduce interventions to improve hearing loss management and
self-management</Literal>
      </AnnotationAssertion>
  <Declaration>
          <NamedIndividual IRI="#PA_1"/>
      </Declaration>
  <Declaration>
          <NamedIndividual IRI="#PA_2"/>
      </Declaration>
  <ClassAssertion>
          <Class IRI="#PolicyAction"/>
          <NamedIndividual IRI="#PA_1"/>
      </ClassAssertion>
      <ClassAssertion>
          <Class IRI="#PolicyAction"/>
          <NamedIndividual IRI="#PA_2"/>
```

```
      </ClassAssertion>
  <DataPropertyAssertion>
          <DataProperty IRI="#description"/>
          <NamedIndividual IRI="#PA_1"/>
          <Literal           datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral"> For each of the variables listed above that influence wellbeing
and quality of life and mitigate cognitive decline and auditory process
deterioration, actions should be taken </Literal>
      </DataPropertyAssertion>
      <DataPropertyAssertion>
          <DataProperty IRI="#description"/>
          <NamedIndividual IRI="#PA_2"/>
          <Literal           datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral"> Provide clinical practice guidelines to enable self-management
that would improve wellbeing and quality of life, and mitigate cognitive decline
and auditory process deterioration </Literal>
      </DataPropertyAssertion>
```

```
  <Declaration>
          <NamedIndividual IRI="#Stakeholder_1"/>
      </Declaration>
  <Declaration>
          <NamedIndividual IRI="#Stakeholder_2"/>
      </Declaration>
  <Declaration>
          <NamedIndividual IRI="#Stakeholder_3"/>
      </Declaration>
  <Declaration>
          <NamedIndividual IRI="#Stakeholder_4"/>
      </Declaration>
  <Declaration>
          <NamedIndividual IRI="#Stakeholder_5"/>
      </Declaration><Declaration>
          <NamedIndividual IRI="#Stakeholder_6"/>
      </Declaration>
  <AnnotationAssertion>
```

```
            &lt;AnnotationProperty abbreviatedIRI="rdfs:comment"/&gt;
            &lt;IRI&gt;#Stakeholder_1&lt;/IRI&gt;
            <Literal datatypeIRI="http://www.w3.org/1999/02/22-rdf-syntax-
ns#PlainLiteral">in their role as prescribing the use of HAs&lt;/Literal&gt;
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and performing follow-up on ad-ministration and use&lt;/Literal&gt;
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APPENDIX B

Procedure of Monitoring TTS Episodes and PTS Risk

1. **Noise monitoring outside HA within EVOTION bands**
    a. Inputs:
    - Elapsed time from turning on HA in minutes (T) or sample number (n),
    - **00 SPL 0-1.3 kHz** → Mobile Application Interface NoiseMonitorig MAOP, from environmentDataHAOP
    - **01 SPL 1.3-4.1 kHz** → Mobile Application Interface NoiseMonitorig MAOP, from environmentDataHAOP
    - **02 SPL 4.1-10 kHz** → Mobile Application Interface NoiseMonitorig MAOP, from environmentDataHAOP
    - **21 Sound environment paramete**r → Mobile Application Interface NoiseMonitorig MAOP, from environmentDataHAOP

    b. A-weighted sound pressure levels outside HA ($L_A(n)$) will be determined every one minute using equation (1):

L_A=SPL dBA=10 log(0.4494x10.^(“0-SPL”/10)+1.3007x10.^(“1-SPL”/10)+0.8595x10.^(”2-SPL”/10)) (1)

    c. Sound pressure levels in EVOTION bands and A-weighted sound pressure levels ($L_A(n)$) are integrated every one minutes since the turning on the HA device to obtain the equivalent-continuous sound pressure level over elapsed time of the HA usage.

The A-weighted equivalent-continuous SPL ($L_{Aeq}(n)$) is determined using equations (2)-(3):

$$L_{A,eq}(1) = L_A(1) = SPL\ dBA\ (1) \qquad (2)$$

$$L_{A,eq}(n) = 10 \cdot log\left\{\frac{1}{n}\left[\left((n-1)\,10^{\frac{L_{A,eq}(n-1)}{10}}\right) + \left(10^{\frac{SPL\ dBA(n)}{10}}\right)\right]\right\} \qquad (3)$$

Note: $L_{A,eq}(n)$ =SPL LEQ-n dBA, $L_A(n)$= *SPL dBA(n)* = SPL dBA-n

Sound pressure levels in the EVOTION bands are integrated using similar equations.

$\mathbf{L_{Aeq}}$ is used for prediction of TTS episodes in subjects with normal hearing not using HAs.

    d. Determination of the noise exposure level normalized over 16-hour daily activity ($\mathbf{L_{EX,16h}}$) using equation (4):

$L_{EX,16h}$ (n)=L_{Aeq} (n)+10 log(n/960min)= SPL LEQ-n dBA**+**10 log(n/960min) (4)

$\mathbf{L_{EX,16h}}$ is used for prediction of PTS risk in subjects with normal hearing not using HAs.

e. Determination of the daily noise exposure level $L_{EX,16h,av}$ averaged over a number of days (e.g. corresponding a month or quarter) using equation (5):

$$L_{EX,16h,av} = 10 \times \log\left(\frac{1}{N}\sum_{i=1}^{N} 10^{0.1 \times L_{EX,16h,i}}\right) \quad (5)$$

Where $L_{EX,16h,i}$ is the noise exposure level for day *i*, *i* is the day number, *N* is the total number of days.

$\mathbf{L_{EX,16h,av}}$ can be used for determination of expected noise-induced permanet threshold shift (NIPTS) according to ISO 1999:2013 after assumed period of exposure (e.g. 1, 2 or 5 year) in subjects with normal hearing not using HAs.

2. **Calculation of the free-field related A-weighted equivalent-continuous SPL at the ear drum of HA's user** following the procedure outlined in the Demonstrator Section in Deliverable D3.1 (Katrakazas et al., 2017)).
   a. Inputs:
   - **audiometric hearing thresholds used for HA device fitting** (hearing thresholds – HTs in dB HL) → Pure-tone audiometry (PTA) test results used for HA fitting HA (F1) can be found in the AUDIOGRAMHEAD Table, and the daily time HA usage pattern (F2) can be found in the RETRO_HA Table.
   - equivalent-continuous SPLs in the EVOTION bands (Leq SPL) (see 1c)
   - Insertion gain function, open ear gain (OEG) leads to A-weighted Leq (standardized) as function of the **21 Sound environment paramete**r and **Audiogram**
   - current time (SPL sample number from the beginning of the record; from the last HA device was turned on.
   - standardized sound spectra for different environment conditions (ANSI 3.51 simplified speech, pink noise etc.)

   b. Equivalent-continuous SPL in the EVOTION bands (Leq SPLs) are recalculated into 1/3-octave bands ($L_{f\ 1/3\text{-oct, eq}}$) with respect to "**Sound environment parameter**" (i.e. pink noise, standard speech spectrum)
   c. Recalculation of $L_{f\ 1/3\text{-oct, eq}}$ in dB SPL into dB HL ($L_{f\ 1/3\text{-oct, eq (dBHL)}}$) according to ISO 389-7.
   d. Determination of the VAC insertion gain for given HTs and the $L_{f\ 1/3\text{-oct, eq (dBHL)}}$ values.
   e. Determination of equivalent free-field gained $L_{f,\ 1/3\text{-oct, eq,g,FF}}$ taking into account VAC insertion gain and open ear gain (OEG).
   f. Recalculation of $L_{,1/3\text{-oct,eq,g,FF}}$ into 1/1-octave bands $L_{,1/1\text{-oct,eq,g,FF}}$
   g. Determination of the free-field related gained A-weighted equivalent-continuous sound pressure level over elapsed time T in minutes ($\mathbf{L_{Aeq,g,\ FF}}$).

$\mathbf{L_{Aeq,g,\ FF}}$ is used for prediction of TTS episodes in subjects using HAs.

SPL $L_{Aeq,}$ (n) =**GainedSPL LEQ-n dBA** for elapsed time (based on the $L_{feq,g,FF}$ levels).

Note: The value of free field A-weighted SPL enhanced by HA device has to be greater than background A-weighted SPL. Calculations performed according to points b-g can lead to opposite results, especially in the case of low SPL values. In such cases, it is assumed that free field gained A-weighted SPL at time T is equal to background L_{Aeq} (t) (**SPL dBA-n**) of the background and calculation according to points b-g are not performed (see figure 1).

h. Determination of the free-field related gained noise exposure level normalized over 16-hour daily activity (**$L_{EX,16h,g,FF}$**) using equation (6):

$L_{EX,16h,g,FF}$ (n)=$L_{Aeq,g,FF}$ (n)+10 log(n/960min)= GainedSPL LEQ-n dBA+10 log(n/960min) (6)

$L_{EX,16 h,g, FF}$ is used for prediction of PTS risk in subjects using HAs.

i. Determination of the daily noise exposure level $L_{EX,16h,g,FF,av}$ averaged over a number of days (e.g. corresponding a month or quarter) using equation (7):

$$L_{EX,16h,g,FF,av} = 10 \times \log\left(\frac{1}{N}\sum_{i=1}^{N} 10^{0.1 \times L_{EX,16h,g,FF,i}}\right) \qquad (7)$$

Where $L_{EX,16h,g,FF,\,i}$ is the noise exposure level for day *i*, *i* is the day number, *N* is the total number of days.

$L_{EX,16 h,g, FF,av}$ can be used for determination of expected noise-induced permanet threshold shift (NIPTS) after assumed period of exposure (in years) in subjects using HAs.

3. Monitoring of PTS risk

a. Inputs
   - time elapsed from turning on HA (T)

Current elapsed time T in minutes equal to last sample number from the last HA device turning on. The total time of HA usage is equal to number of samples in **RETRO_HA Table.**

   - current daily noise exposure level normalized over 16-hour ($L_{EX,16h}$ (T)) (see 1d)
   - current free-field related gained daily noise exposure level normalized 16-hour (**$L_{EX,16h,g,FF}$**(T)) (see 1h).

b. Checking if the PTS episode may occur at current daily noise exposure level after elapsed time T, i.e.

if $L_{EX,16h}$(T) = $L_{EX,16h}$(n) >77 dB SPL, then there is a risk of PTS in subjects with normal hearing,

if $L_{EX,16h,g,FF}$(T) = $L_{EX,16h,g,FF}$(T)>77 dB SPL, then there is a risk of PTS in subjects with HL using HAs (see figure 13).

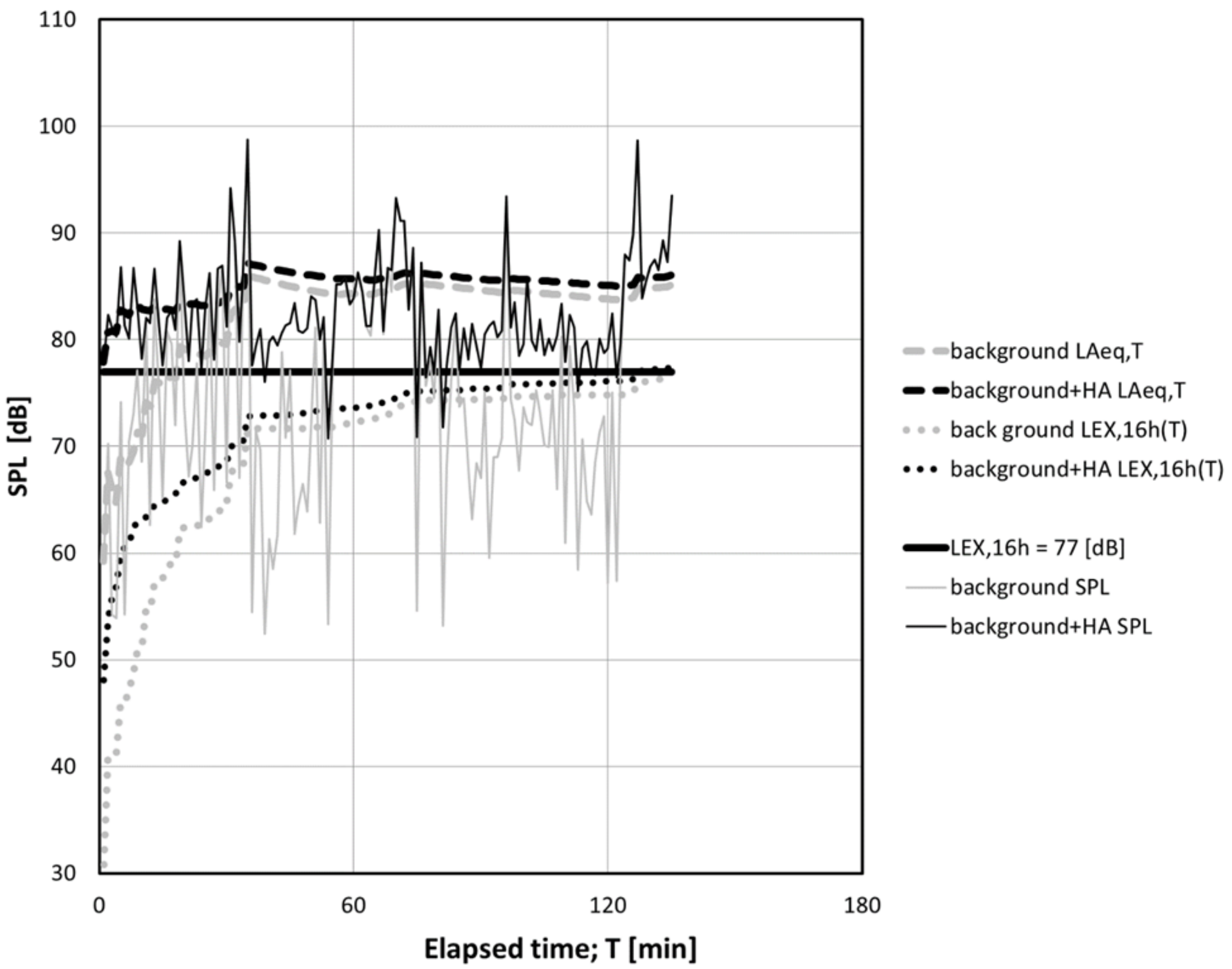

Figure 13 An example of analysis of the PTS risk occurrence which may be performed using mobile application[10].

4. **Monitoring of TTS episode**
   a. Inputs
      1. time elapsed from turning on HA (T)
      2. A-weighted equivalent-continuous SPL over elapsed time T outside HA ($L_{Aeq}(T)$)
      3. free-field related gained (processed by HA) A-weighted equivalent-continuous SPL over elapsed time T ($L_{Aeq,g,FF}(T)$),
      4. audiogram (hearing thresholds – HTs in dBHL) used for HA fitting

   b. Calculation of the temporary threshold shift (at 0.5, 1, 2 and 4 kHz) for subject with normal hearing according to equation (8):

[10] Calculations for HA fit to person with hearing threshold levels at 0.5, 1, 2, 4 kHz equal to 20. 18. 24 and 57 dBHL, respectively. Black point line crosses solid black line; it means that the PTS risk occurred due to surrounding noise gained by HA (***background+HA** corresponds to $L_{Aeq,g,FF}(T)$ and $L_{EX,16h,g,FF}(T)$*, ***background** corresponds to $L_{A\,eq}\,(T)$ and $L_{EX,16h}\,(T)$)*

$$TTS_n(L_{Aeq}(T)) = 1.7 \cdot \left\{ 10 \cdot log \left[\frac{\left(10^{\frac{L_{Aeq}(T)}{10}} + 10^{\frac{L_C}{10}}\right)}{10^{\frac{L_C}{10}}} \right] \right\} \cdot \left(1 - e^{-\frac{T}{t_o}}\right) \tag{8}$$

where L_c is a critical level equal to 78 dB for broadband noise, t_o is the time constant (t_o= 2 h).
Calculation of the temporary threshold shift (at 0.5, 1, 2 and 4 kHz) for subject with HL not using HA according to question (9):

$$TTS_{HL}(L_{Aeq}(T)) = 10 \cdot log \left\{ \left[\left(10^{\frac{TTS_n(L_{Aeq}(T))}{10}}\right)^P + \left(10^{\frac{HL}{10}}\right)^P - 1 \right]^{\frac{1}{P}} \right\} - HL \tag{9}$$

Where HL is the initial value (before sound exposure) of mean hearing threshold at frequencies 0.5, 1, 2, 4 kHz, in dBHL, P is the time constant equal to 0.2, TTS_n is the temporary threshold shift of person with normal hearing (see equation (8)).
Calculation of the TTS at 4 kHz for subjects not wearing HA with normal hearing and with hearing loss using the equations (9) and (10), respectively:

$$TTS_{4kHz,n}(L_{Aeq}(T)) = TTS_n(L_{Aeq}(T)) \cdot \frac{1{,}61}{4} \tag{9}$$
$$TTS_{4kHz,HL}(L_{Aeq}(T)) = TTS_{HL}(L_{Aeq}(T)) \cdot \frac{1{,}61}{4} \tag{10}$$

c. Calculation of the temporary threshold shift (at 0.5, 1, 2 and 4 kHz) for subject without and with HL, exposed to sounds at the $L_{Aeq,g,FF}(T)$ using equations (11)-(12):

$$TTS_n(L_{Aeq,g,FF}(T)) = 1.7 \cdot \left\{ 10 \cdot log \left[\frac{\left(10^{\frac{L_{Aeq,g,FF}(T)}{10}} + 10^{\frac{L_C}{10}}\right)}{10^{\frac{L_C}{10}}} \right] \right\} \cdot \left(1 - e^{-\frac{T}{t_o}}\right)$$

(11)

$$TTS_{HL}(L_{Aeq,g,FF}(T)) = 10 \cdot log \left\{ \left[\left(10^{\frac{TTS_n(L_{Aeq,g,FF}(T))}{10}}\right)^P + \left(10^{\frac{HL}{10}}\right)^P - 1 \right]^{\frac{1}{P}} \right\} - HL \tag{12}$$

where HL is the initial value of mean hearing threshold at frequencies 0.5, 1, 2 and 4 kHz, in dBHL, P is the time constant equal to 0.2.
Calculation of the TTS at 4 kHz for subjects not using HA with normal hearing and with hearing loss exposed to $L_{Aeq,g,FF}(T)$ using equations (13) and (14), respectively:

$$TTS_{4kHz,n}(L_{Aeq,g,FF}(T)) = TTS_n(L_{Aeq,g,FF}(T)) \cdot \frac{1{,}61}{4} \tag{13}$$
$$TTS_{4kHz,HL}(L_{Aeq,g,FF}(T)) = TTS_{HL}(L_{Aeq,g,FF}(T)) \cdot \frac{1{,}61}{4} \tag{14}$$

d. Comparison of the current value of TTS after elapsed time (T) with an assumed limit value (e.g. 10 dB).

If $TTS_{4kHz,n}\left(L_{Aeq}(T)\right) \geq 10\ dB$, then TTS episode is likely to occur in subject with normal hearing not using HA,

If $TTS_{4kHz,HL}\left(L_{Aeq}(T)\right) \geq 10\ dB$, then TTS episode is likely to occur in subject with hearing loss not using HA,
If $TTS_{4kHz,n}\left(L_{Aeq,g,FF}(T)\right) \geq 10\ dB$, then TTS episode is likely to occur in subject with hearing loss using HA,
If $TTS_{4kHz,n}\left(L_{Aeq}(T)\right) \geq 10\ dB$, then TTS episode is likely to occur in subject without hearing loss and not using HA but exposed to sound/noise at the $L_{Aeq,g,FF}(T)$ level (see figure 14).

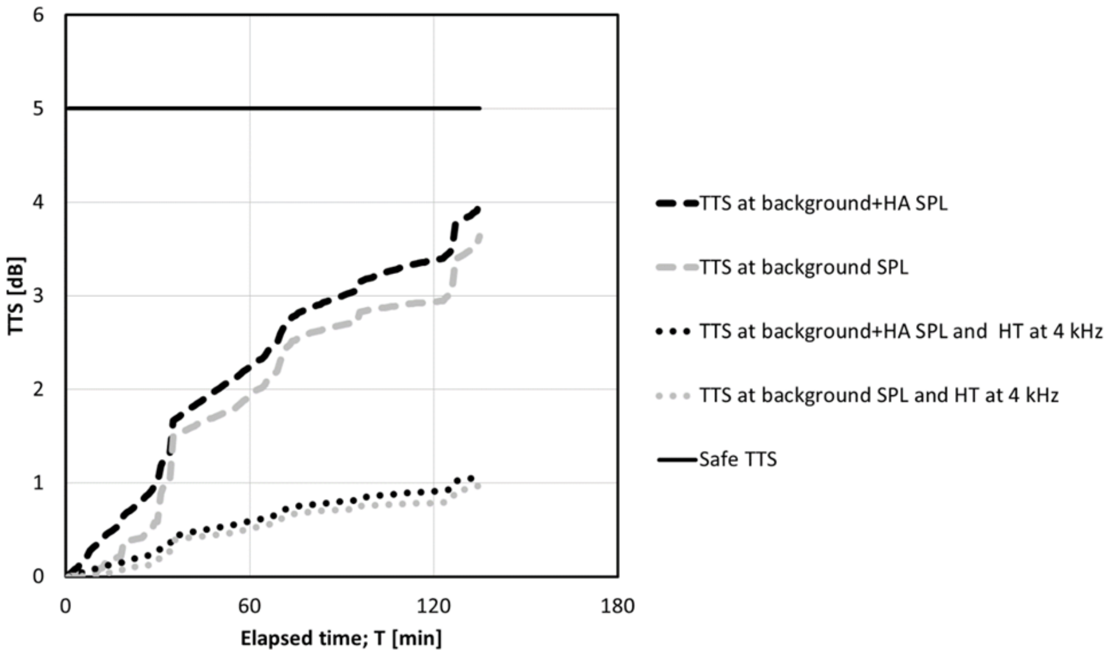

Figure 14 An example of analysis of occurrence of the TTS episode which may be performed using mobile application[11].

Note: Since TTS in subjects with hearing loss strongly depends on hearing thresholds (see figure 15). Thus, in the further analysis the TTS episodes will be only identified based on prediction for people with normal hearing, i.e. when

$$TTS_{4kHz,n}\left(L_{Aeq,g,FF}(T)\right) \geq 10\ dB \quad (15)$$

$$TTS_{4kHz,n}\left(L_{Aeq}(T)\right) \geq 10\ dB. \quad (16)$$

[11] Calculation for HA device fit to person with hearing threshold levels at 0.5, 1, 2, 4 kHz equal to 20, 18, 24 and 57 dB HL, respectively. Black dashed line does not cross solid black line; it means that there was no TTS episode caused by surrounding noise gained by HA (dashed lines for normal hearing, point lines for impaired hearing) (*a) **TTS at background +HA SPL** - TTS at 4 kHz in normal hearing person, calculated for $L_{A\,eq,g,FF}(T)$, b) **TTS at background SPL** - TTS at 4 kHz in normal hearing person, calculated for $L_{A\,eq}(T)$, c) a) **TTS at background +HA SPL and HT at 4kHz**- TTS at 4 kHz in person with HL, calculated for $L_{A\,eq,g,FF}(T)$, d) **TTS at background SPL and HT at 4kHz** - TTS at 4 kHz in person with HL, calculated for $L_{A\,eq}(T)$*).

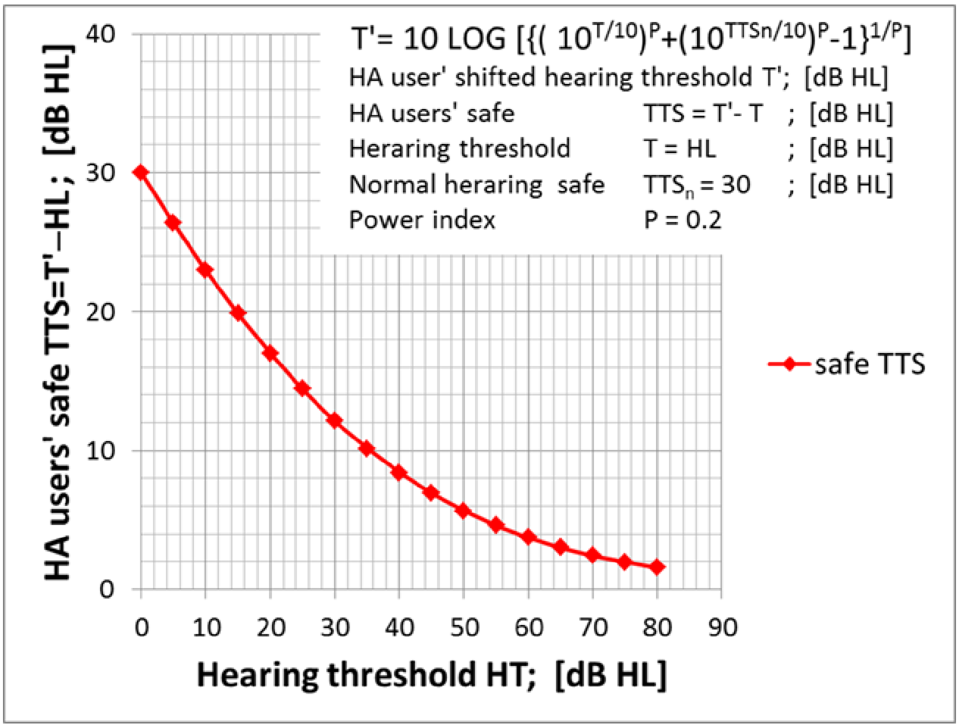

Figure 15 Safe limits of TTS in HA users as a function of the initial hearing threshold[12].

5. Prediction of NIPTS

a. Inputs:
   - daily noise exposure level $L_{EX,16h,av}$ averaged over a number of days
   - daily noise exposure level $L_{EX,16h,g,FF,av}$ averaged over a number of days

b. Calculations of the median potential noise-induced permanent threshold shift at 4 kHz in subjects using and not using HA are performed using equations (17) and (18), respectively:

$$NIPTS_{4kHz}(L_{EX,16h,g,FF,av}) = [0.025 + 0.025 \times \log(t/t_o)] \times (L_{EX,16h,g,FF,av} - 72)^2 \quad (17)$$

$$NIPTS_{4kHz}(L_{EX,16h,av}) = [0.025 + 0.025 \times \log(t/t_o)] \times (L_{EX,16h,av} - 72)^2 \quad (18)$$

Where t is the hypothetical time of the HA usage, in years(t≥1 year), to is 1 year.

c. Comparison of the of the median potential noise-induced permanent threshold shifts at 4 kHz in subjects using and not using HA.

6. Analysis of PTS risk and TTS episodes

The prevalence of PTS risk and TTS episodes may be analyzed in accordance to daily or long-time usage of HA usage. There are four combinations of possible outcomes for daily predicting of PTS risk and/or TTS episodes, i.e.:

- 0 - neither PTS nor TTS episodes occurred during the HA usage,
- 1 - PTS episode occurred during the HA usage period,
- 2 -TTS episode occurred during the HA usage period,
- 3 –both PTS risk and TTS episode occurred during the HA usage period.

[12] Based on (Macrae, 1994).

Results of daily monitoring of PTS risk and TTS episodes are stored as **PTS_TTS_RES** in the **RETRO_HA records.**

If during last month or quarter the prevalence of PTS/TTS_RES>0 is greater than assumed limit value (e.g. 30%) PM_2 will be undertaken. The aforesaid limit value might be determined after data analytics.

Optionally, the difference in the expected noise-induced permanent threshold shifts (NIPTS) between individuals using and not using HA's might be also analyzed.
If the difference $(NIPTS_{4kHz}(L_{EX,16h,g,FF,av}) - NIPTS_{4kHz}(L_{EX,16h,av}))$ is greater than assumed limit value (e.g. 5 dB) some preventive actions should be taken.
is greater than assumed limit value (e.g. 5 dB) PM_1 will be taken. The aforesaid limit value might be determined after data analytics.

Note: The daily analysis may be useful for HA users, while results of long period analyses may be useful for clinicians and other stakeholders, including health policymakers.