IMI2 821520 - ConcePTION

ConcePTION

WP5 – Dissemination and education for HCPs, pregnant and breastfeeding women and general public

D5.5 Report with planned training programmes, learning goals, target audience

Lead contributor	Brian Cleary (27-ENTIS) Stéphanie Tcherny-Lessenot (39-Sanofi)
Other contributors	Anke van Mil (30-Elevate Health) Eline Borsboom (30-Elevate Health) Lean Rolfes (9-LAREB) Benedikte Cuppers (9-LAREB) Hedvig Nordeng (14-UOSL) Maya Berlin (27-ENTIS) Ludivine Douarin (39-Sanofi) Chantal El-Haddad (39-Sanofi) Michael Steel (10-Novartis) Charlotte Owens (48-Abbvie) Ida Niklson (10-Novartis) Hildrun Sundseth (16 – EIWH)

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Abstract

This report describes the content and development of the training plan in ConcePTION for healthcare professionals (HCPs). This plan was designed within task 5.4 for the purpose of training HCPs about teratology and long-term outcomes of drug exposure during pregnancy, and methods of evidence generation and how they can translate this into effective messages for women and their families on drug use during pregnancy or breastfeeding.
In this task an e-learning training programme, which can be used for continuous education of HCPs in English language, will be built. The focus will be on the basic principles of teratology and rational therapeutics in pregnancy and breastfeeding, knowing where to find the right information, and how to interpret it for patient-centered, evidence-based shared decision making.
The course design described in this report will be used to build the e-learning programme.

Introduction

Studies have shown that HCPs find it challenging to explain possible risks of medication use during pregnancy and breastfeeding. HCPs are the most accessible to prescribe or to provide advice but there is evidence of lack of knowledge about medication safety during pregnancy and breastfeeding. Lack of training may be associated with conflicting advice or decisions provided by different HCPs due to personal experiences (Jayawickrama et al, 2010).
In a study conducted in Switzerland in 2010, only 35% of HCPs reported having received specific training on drug use during pregnancy in the past five years. This low level of training was correlated with overestimation of the risk associated with drug use during pregnancy (Csajka et al, 2014). To optimise medication advice and medication use during pregnancy and breastfeeding, HCPs need more structured and increased training or continuing education programs on safety of medicines used in this context (Hussainy and Dermele 2011). A recent review of medical training programmes in Ireland confirmed that the majority of these programmes do not cover specifically the management of drugs and therapeutics in pregnancy and breastfeeding (McCarthy & Donnelly, internal report).
The overall purpose of the training programme is to train HCPs about teratology and long-term outcomes of drug exposure during pregnancy, on the methods of evidence generation and how they can effectively translate this into clear communication with women on the safe and effective use of medicines in pregnancy and breastfeeding.
This report presents how the training plan was developed as well as the final course design.

Development of training plan

Analysis of the landscape and determination of target audience

Inventory of training curriculum

Existing training courses on medications during pregnancy and breastfeeding were collected from task participants and were summarized in a table with information on responsible organization, country and language, content and learning objectives, target audience, and format.

The inventory of 24 training courses across Europe is displayed in **Appendix 1** of the report.

Definition and knowledge of target audience

The target audience includes all HCPs who interact frequently with pregnant or lactating women and who have to provide advice about medication use during pregnancy and breastfeeding. The HCPs in the target audience are:

- general practitioners,

- pharmacists,

- midwives,

- obstetrician/gynaecologists.

Different levels of experience were considered for each: beginner, advanced and expert.

In order to better understand the HCPs in our target audience, focus groups were conducted with representatives of each group to define a series of theoretical profile "personas" for each category. A sample persona profile is provided in **Appendix 2**.

The key findings on these personas in terms of personal profile, job features, learning habits and needs are summarized in the table below.

Table 1: Key findings about the target audience HCP profile

Audience	Personal	Job	Learning
Midwives	Very dedicated to their job and patients	Hands on tasks in the beginning	Are familiar with e-learning, but like the interaction with each other (intervision)
	Are afraid of making mistakes	Are under supervision of more experienced mentor	There is a lot of mentoring, supervisors shape the trainee
		Not much experience in collaboration with others	In the beginning they want knowledge, after that the application of that knowledge in their work practice
Obstetricians/ gynaecologists	Very dedicated to their patients to deliver excellent care	Starts with work on a training scheme	Find it difficult to find new information
		Very busy job	Value clear communication from coworkers
		Regular medical encounters with pregnancy and breastfeeding	Have experience with e-learning and group work, like team based small group learning
			Limited time for learning
Pharmacists	Want to be challenged and support best outcomes for patients	Reviews and consults with some pregnant patients	Have experience with e-learning, self-directed learning
		There is some coverage about women's health in their study	Like to be engaged
General Practitioners	Is careful of patients, wants appropriate information to share with patients	Looks for external resources for information	Makes time for training, finds it important
All HCPs	Dedicated and want to learn new things	Busy schedules	Experience with e-learning
		Do not learn together yet with other professions	Hands-on, case based
		Not much information about pregnancy, breastfeeding and women health during training	Limited time for learning; short learning blocks
		Looking for interaction	Like to have small digestible learning elements
		All in direct contact with (female) patients	

Definition of learning needs

A preliminary list of topics of interest was developed (Table 2) and then further work was done to identify for each topic the aim, and what the target audience needs to know for each topic (Table 3).

Table 2: List of topics of interest

Historical context
Principles of teratology
Principles of therapeutics in pregnancy
Medicines in breastfeeding
Information sources / Interpreting information / Study designs
Risk communication & Benefit risk assessment
Contribute to more data about safety with drugs in pregnancy and breastfeeding, reporting of information
Patient experiences/views/behaviours, adherence, risk perceptions of patients (women telling their own stories)

Table 3: Structure of learning outcomes development by topic

Subject	Aim	Need to know
Historical context	Understand the relevance and importance of safe and effective use of medicines during pregnancy and breastfeeding. Importance of being vigilant.	Past examples of harmful medication use in pregnancy. Why it's important to be alert. Understanding the folk memory/awareness of dangers of medication use in pregnancy and how this may impact women's decision making
Principles of teratology	Understand the principles of teratology and how they affect decision making on medication use in pregnancy	Principles of embryology Basic risks/causes of malformations Timing, exposure First trimester, second trimester Window of susceptibility Which drugs can cross the placenta Dose-effect Difference between species Indirect and direct embryotoxic effects
Principles of therapeutics in pregnancy	Understand the principles of therapeutics in pregnancy and apply these through the decision-making framework	Background (prevalence of medication use, indications for use) PK/PD in pregnant women Risk of untreated/ undertreatment of maternal disease/ drug risk Decision-making framework/pathway Pregnancy Prevention Programmes
Medicines in breastfeeding	Apply principles of maternal, infant and drug characteristics to decision-making on therapeutics during breastfeeding	Maternal Characteristics- underlying condition, therapeutic alternatives Infant characteristics- Age, prematurity, other conditions Drug Characteristics-PK in milk, relevant infant dose (RID), milk plasma ration M/P Galactagogues

Subject	Aim	Need to know
Information sources Interpreting information on drugs Study design understanding	How to find information How to interpret information Deal with contradictions	Type of sources + differences between them Risk assessment SmPC vs. clinical guidelines Dealing with contradictory findings Confounders Bias Critical appraisal
Risk communication & Benefit risk assessment	Communicating effectively about risks Conducting a risk assessment for a patient and supporting shared decision making	Risk communication How to express the risk (balanced framing) Potential role of decision-aid
Contribute to safety data on drugs in pregnancy and breastfeeding	Encourage HCPs to play an active role in ensuring the safety of medicine in pregnancy and breastfeeding	Contribute to research/registries Contribute to pharmacovigilance reporting Contribute to recording medication exposure and pregnancy outcome data in a structured way
Patient experiences/views/ behaviours, risk perceptions of patients (women telling their own stories)	Realize that stories and experiences are very valuable and insightful	Understanding patients' perspective Understanding non-adherence Hear patients' stories and experiences of medication use in pregnancy

Design

Determination of learning objectives

Bloom's taxonomy describes different levels of learning that can be achieved. Different verbs that align with the aimed level of learning were used to formulate detailed learning objectives for each topic of interest (Armstrong, 2010). For all topics, a list of learning objectives was constructed and is presented in the overview of the final course design.

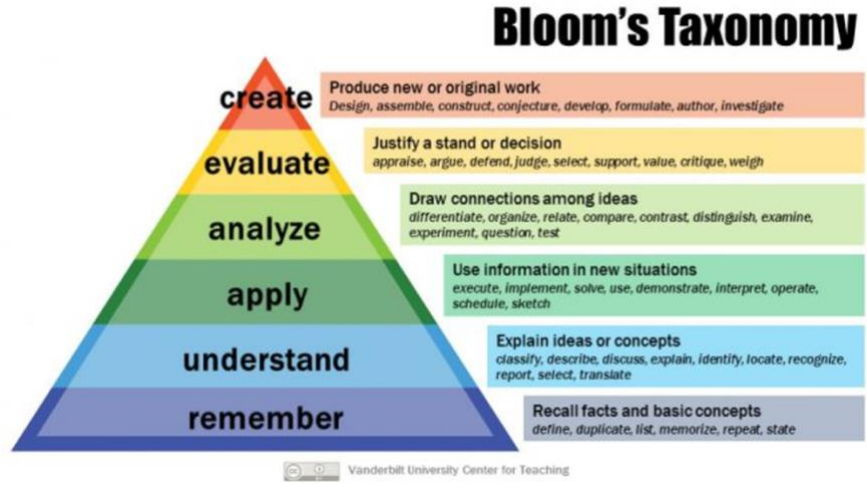

Figure 1: Bloom's taxonomy of training objectives

Overall structure of the course

Determination of level of content by target audience: The learning objectives were categorized according to levels, including basic, advanced, and skills. There was consensus that the majority of the course content was required learning for all participants, with some content being categorised as advanced. After categorization, the different learning objectives were combined with a variety of learning methods, including both passive and active learning tools. Examples of passive learning include reading and/or watching videos, whilst examples of active learning include problem solving through cases.

The skills classification includes learning objectives that don't result in knowledge transfer, but actual skill practice. These are further categorized to basic- and advanced-level skills, and entail for example learning to find and interpret scientific literature on specific topics.

The overall structure of the different topics includes:

- learning introduction including pre-test
- classification of learning objectives by level: basic or advanced level skills
- common structure by chapter
    - introduction with a case example and background
    - presenting basic theory
    - practice assignments on the basic theory
    - presenting advanced theory (when applicable)
    - practice assignments on advanced theory
    - test to evaluate achieving learning objectives

Overview of final course design

The table below describes the full course design with detailed information for each learning unit, each learning activity in the learning unit, whether it is required, and related learning objective, level and description of activity.

The total number of learning units is expected to be 3 at minimum and 11 at maximum. The total number of learning activities per learning unit is expected to be 3 at minimum and 16 at maximum.

Table 4: Course design elements

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
0. Introduction to the course	Welcome	Yes		Basic	Welcome message; start with spark (practical example or case)
	What is ConcePTION	Yes		Basic	Short introduction to the concept/project. Introduction of IMI and ENTIS
	About the course	Yes		Basic	Overview of course organiser (structure) and explanation of different levels
	What do you already know?	Yes		Basic	Pre-test of all chapters (basic knowledge)
	Navigation	Yes		Basic	Navigation explanation and key terms information

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
1. Historical context	1.1	Yes	Get motivated to start and understand learning process of this chapter	Basic	Start with spark. Provide overview of the chapter (use of organiser).
	1.2	Yes	1.2.1 Summarize early teratology awareness (rubella/ thalidomide) 1.2.2 Explain consequences for pharmacovigilance 1.2.3 explain on basis of 1.2.1 why it is important to be aware of danger of medication exposure in pregnancy.	Basic	Provide theory for basic level
	1.3	Yes	Summarize the history of harmful medications (e.g. thalidomide, Diethylstilbestrol and valproate) - Understand how past issues with the safety of medicines in pregnancy may affect decision making by pregnant women	Skill (basic)	Skill/practice with basic level knowledge
	1.4	No	Understand historical context and explain why it is important to critically appraise regulatory decision-making, evidence and interpretation of drug harms (pyridoxine/doxylamine/ondansetron)	Advanced	Theory advanced
	1.5	No	Describe the regulatory reaction occurred for valproate in relation to neurodevelopmental effects	Skill (advanced)	Skill/practice with advanced level knowledge
	1.6	Yes	Interpret the cumulative impact of the historical context on 1. regulators and 2. patients/the public. Balance stories of harm with examples of medicines where benefits outweigh risks. Understand potential impact of only considering the harms and what has gone wrong in the past.	Skill (advanced)	Skill/practice with advanced level knowledge
	1.7 Test your knowledge	Yes	Get insight into own learning/progress of basic knowledge	Basic	Test your knowledge for basic level

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
2. Principles of embryology and teratology, part 1	2.1	Yes	Get motivated to start and understand learning process of this chapter	Basic	Start with spark. Provide overview of the chapter (use of organiser). Structure chapter: 1. embryology 2. teratology
		Yes	Summarize the basic principles of embryology (as relevant to the occurrence of birth defects)	Basic	
	2.2	Yes	Summarize the 6 basic principles of teratology (Wilson)	Basic	Theory (including definitions) with assignment (for example drag and drop)
	2.3	Yes	- Know the basic background risks and causes of malformations. Summarize different teratogens. Give definitions of teratology and teratogen. - Describe the causes of malformation, regarding timing (e.g. first, second trimester), giving examples of medications and other environmental exposures	Basic	Theoretical information. Summarising assignment
	2.4	Yes	Describe potential mechanisms of teratogenicity and give examples	Basic	Theory with assignment (for example drag and drop, deciding on the order of mechanism)
	2.5	Yes	Describe the potential range of teratogenic defects and give examples	Basic	Theory (in animated video?)
	2.6 Test your knowledge	Yes	Get insight in own learning progress of basic knowledge	Basic	Test your knowledge for basic level

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
3. Principles of embryology and teratology, part 2	3.1	Yes	Get motivated to start and understand learning process of this chapter	Basic	"Start with spark, practice with informing through scenario tool (dialogue trainer?). Provide overview of the chapter (use of organiser). Structure chapter: 1. medicines & susceptibility 2. the placenta 3. dose-effect
	3.2	Yes	Explain the importance of the window of susceptibility to teratogens and how medicine pharmacokinetic properties / administration route affect risk of birth defects - to inform a pregnant woman about window of susceptibility	Basic	
	3.3	Yes	Outline the differences between a teratogen and a medication that causes fetal toxicity	Basic	Theory with checklist
	3.4	No	Analyse window of susceptibility and advise pregnant women on decision making	Advanced	Case with questions, regarding susceptibility and the correct steps in advising on decision-making. Examples: ibuprofen (exposure beyond 30 weeks), enalapril/valsartan (exposure beyond 20 weeks)
	3.5	No	Principles of placental physiology, describe the role of the placenta and medication pharmacokinetic properties in terms of placental passage.	Advanced	Theory
	3.6	Yes	Explain the importance of knowing which drugs can pass the placental barrier for decision making	Basic	Theory with animation or infographic

	3.7	Yes	Demonstrate where you can find medicines information regarding placental passage	Skill (basic)	1. Provide checklist with tips on how to find appropriate information 2. Assignment: find information regarding specific case
	3.8	No	Describe the relative placental passage of TNF-alpha antagonists and potential neonatal/infant impact	Advanced	Theory + case assignment (quiz questions) - describe the difference with certolizumab
	3.9	Yes	Describe examples of associations between medication exposures and specific adverse outcomes	Basic	Theory with an assignment (matching exposure with outcome)
	3.10	Yes	Describe the principles for deciding if an association between a medication and an adverse pregnancy outcome is causal	Basic	Theoretical information on causality principles (Shepard)
	3.11	Yes	Describe the differences between species and within species Developmental and reproductive toxicology (DART) studies and where to find additional information e.g. thalidomide and fluoroquinolones or corticosteroids	Basic	Case-based differences between and/or within species (basic level)
	3.12	No	Recognize and detect the differences between species and within species and where to find additional information e.g. thalidomide and fluoroquinolones or corticosteroids	Advanced	Case-based differences between and/or within species (more advanced level cases)
	3.13	Yes	Explain the importance of knowing the dose-effect relationship for decision making	Basic	Theory through expert interview video (dose-effect regarding teratology, e.g. valproic acid, some antiepileptic examples. Fetal Alcohol Syndrome and/or PKU as other examples)
	3.14	Yes	Cite and critically appraise specific studies regarding the dose-effect	Skill (basic)	Practice with case examples (quiz questions)
	3.15	Yes	Inform a pregnant woman about the usage of drugs and their dose-effect	Basic	How to inform in different scenario's (with different drugs/dose-effects). Dialogue trainer?
	3.16 Test your knowledge	Yes	Get insight in own learning progress of basic knowledge	Basic	Test your knowledge for basic level

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
4. Principles of therapeutics in pregnancy	4.1	Yes	Get motivated to start and understand learning process of this chapter - MBBRACE (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries) vignettes	Basic	Start with spark (practical example or case). Provide overview of the chapter (use of organiser). Structure chapter: 1. provide support with decision-making using different perspectives of reasoning: 1. principles (PK/PD), 2. ethical considerations 2. you're using medication: how to deal with (possibly dangerous) medication
	4.2	Yes	Describe the prevalence and the reason for drug use during pregnancy- examples including SSRI antidepressants, antiepileptics and biologics	Basic	What considerations are in place for rational use of drugs during pregnancy
	4.3	Yes	Describe the physiological effect of pregnancy on Pharmacokinetics (PK)/Pharmacodynamics (PD) Analyse and interpret PK/PD in pregnant women for application in decision-making	Basic	Theoretically explain PK/PD whilst using case(s). Assignment includes the interpretation of PK/PD (lamotrigine, methadone)
	4.4	Yes	Identify ethical considerations that may arise in making decisions around therapeutics in pregnancy	Basic	Poll activity, scenario with poll on response (poll visible for others, all anonymous)
	4.5	Yes	Explain the need to counterbalance risk for mother and fœtus not to treat (or benefit for mother and baby to treat) and risk of harm from medication - Propose an example of maternal disease with potentially important consequences for the fetus if untreated during pregnancy e.g., biologics for management of inflammatory bowel disease in pregnancy.	Basic	Theoretical explanation (pillars of treat/not to treat) and apply to a clinical scenario. 2 scenarios, one with intention to treat, and one without

	4.6	Yes	Know what a Pregnancy Prevention Program entails and summarize some examples	Basic	
	4.7	Yes	Describe the challenges of conducting randomized clinical trials (RCTs) of medications in pregnancy and why there is such a dependence on observational research in this context	Basic	Theoretical explanation + assignment regarding differences RCT/observational study in pregnancy Give example of RCT in pregnancy (COVID-19 vaccines)
	4.8	No	Analyze important steps in therapeutic drug monitoring (TDM) throughout pregnancy	Advanced	Theoretical explanation Give example : lamotrigine
	4.9	No	Formulate a treatment plan/options for a patient case	Skill (advanced)	Theoretically explanation how to formulate a treatment plan and put the theory to practice in a patient case
	4.10	No	Describe how to support an appropriate therapeutic decision with a pregnant woman	Skill (advanced)	How to respond on different scenarios. Dialogue trainer?
	4.11 Test your knowledge	Yes	Get insight in own learning progress of basic knowledge	Basic	Test your knowledge for basic level

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
5. Medicines and Breastfeeding	5.1	Yes	Get motivated to start and understand learning process of this chapter - be aware of controversial medications and recommendations (due to cultural reasons and/or individual perception)	Basic	Start with spark (with controversial medications). Provide overview of the chapter (use of organiser). Structure chapter: 1. explanation in breastfeeding 2. basic principles of drug transfer 3. breastfeeding and medication (compatible/not compatible-controversy) 4. advanced: principles of therapeutics and skill learning
	5.2	Yes	Breastfeeding fundamentals and benefits	Basic	theoretical information + infographic regarding benefits of breastfeeding
	5.3	Yes	- Describe the 3 questions regarding breastfeeding: (1) does the drug enter the breast milk (2) how high is the child exposure (3) are there adverse effects for the child reported?	Basic	
	5.4	Yes	Interpret the Milk:Plasma ratio, relevant infant dose (RID) and average infant dose in µg/kg/day.	Basic	2 case based scenarios with RID versus µg/kg/day
	5.5	Yes	- Describe examples of medications compatible with breastfeeding - Describe examples of medications not compatible with breastfeeding	Basic	Compare cases and scenario's
	5.6	Yes	Describe basic principles for drug transfer into breastmilk - describe the physico-chemical characteristics of the drug	Basic	Animation of content
	5.7		Interpret evidence gained from pre-clinical studies	Basic	

	5.8	No	Demonstrate where you can find relevant sources of information for breastfeeding	Skill (advanced)	1. Provide checklist with tips on how to find information 2. Assignment: find information.
	5.9	No	Apply principles of rational therapeutics in breastfeeding Explain difficulty in interpretation of information sources and/or studies: study design, obtaining milk samples at different times, no sources or limited sources, why animal studies are not sufficient	Advanced	Apply knowledge of compatible/not compatible to case
	5.10Test your knowledge	Yes	Get insight in own learning progress of basic knowledge	Basic	Test your knowledge for basic level

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
6. Information sources	6.1	Yes	Get motivated to start and understand learning process of this chapter	Basic	Start with spark: example of situation where poor access to information may lead to an adverse outcome Structure chapter: 1. How the critically appraise information sources 2. Practice with examples
	6.2	Yes	- Describe publicly accessible and subscription based information sources and outline how they differ. - Evaluate a situation where the prescribing information differs between sources. e.g., summary of product characteristics recommends not using a medication in pregnancy and/or during breastfeeding and consensus guidelines/medicines in pregnancy resources recommend its use.	Skill (basic)	1. Provide checklist on how to find the right information. What makes a source valid? 2. Offer series of example situations where information differs between sources, make a choice for the 'right' sources (critically appraise information sources)
	6.3	Yes	Describe strengths and limitations of different study designs	Advanced	Infographic of (methodological) overview of study design differences, accompanying with available literature (e.g. Teratology primer from the Teratology Society or Källén, B. A. (2005). Methodological issues in the epidemiological study of the teratogenicity of drugs. Congenital Anomalies (Kyoto), 45(2), 44-51. doi:CGA62 [pii] 10.1111/j.1741-4520.2005.00062.x)
	6.4 Test your knowledge	Yes	Get insight in own learning/progress of basic knowledge	Basic	Test your knowledge for basic level

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
7. Risk communication	7.1	Yes	Understand general principles of risk communication around medicines in pregnancy or breastfeeding. Understand the utility of using absolute risk in comparison to relative risk when communicating about the use of medicines in pregnancy.	Basic	Start with spark. Provide overview of the chapter (use of organiser). Structure chapter: 1. what is risk communication (absolute vs relative) 2. risk communication tools 3. examples with different drugs 4. critical appraisal and justification of benefit/risk assessment
	7.2	Yes	- Use risk communication tools to facilitate communication of absolute risk - Existing communication tools for Marketing Authorisation Holders and Regulators about important safety risk of drug exposure during pregnancy.	Basic	Assignment regarding the use of the different tools. How do they work and what can you use/learn?
	7.3	Yes	Example of Pregnancy Prevention Programme in place for a teratogenic drug (e.g. educational materials for HCPs and patients in place for valproate) and guideline on management of epilepsy in pregnant women to support decision making	Basic	Example, formulated as an infographic or video
	7.4	Yes	Critically analyze/appraise pharmacovigilance /post marketing surveillance and providing transparent communication regarding what is known and what is not known regarding safety of medicines during pregnancy or breastfeeding (sample case-valproate)	Basic	Case description and assignment on steps in communication
	7.5	Yes	Justify the use of a medicine in pregnant or breastfeeding women per labeling but without sufficient level of evidence to support its use during pregnancy or breastfeeding from teratology information service (TIS)	Basic	Application of previous learning objectives, checklist, benefit/risk assessment with 2 cases (one with positive and one with negative

			perspective, considering positive benefit-risk balance ("express the risk (balance framing)").		benefit-risk balance). Example: ondansetron, valsartan
	7.6	No	Describe a real-life example a physician can meet in their day-to-day practices requiring benefit-risk assessment and decision-making for a patient planning to become pregnant and treated by a teratogenic treatment for a severe chronic medical condition	Advanced	Scenario (MS-patient) with decision-making steps.
	7.7	No	Review decision aids, and consider how decision aids can improve shared decision-making.	Advanced	Scenario-based with examples, using COVID-vaccines, NVP and antidepressants
	7.8 Test your knowledge	Yes	Get insight in own learning progress of basic knowledge	Basic	Test your knowledge for basic level

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
8. Reporting information	8.1	Yes	Get motivated to start and understand learning process of this chapter	Basic	Start with spark. Provide overview of the chapter (use of organiser). Structure chapter: 1. Why is reporting important 2. What to report 3. How to report
	8.2	Yes	- Explain the importance of recording exposure to drugs, timing and pregnancy outcome. Recording reason of exposure. - Explain which data are important to record for research	Basic	Infographic (example Pregnancy Prevention Program)
	8.3	Yes	Describe the registries that exist (Industry, local Pregnancy registries, Scandinavian registries)	Basic	Provide list of registries and links
	8.4	Yes	Describe how to report drug exposure during pregnancy or breastfeeding	Basic	Theory and assignment to practice with reporting
	8.5	Yes	Describe how the reported information are managed to produce useful information	Basic	
	8.6 Test your knowledge	Yes	Get insight in own learning progress of basic knowledge	Basic	Test your knowledge for basic level

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
9. Patient experiences	9.1	Yes	Get motivated to start and understand learning process of this chapter	Basic	Start with spark: case with example that shows importance. Provide overview of the chapter (use of organiser). Structure chapter: 1. Why are patient beliefs and risk perceptions important? 2. How are patient beliefs and risk perceptions influenced? 3. Women telling their own stories 4. Show why communication and education are important
		Yes	Explain the importance of patient beliefs and risk perceptions regarding medicine use during pregnancy and breastfeeding, and impact on decision making and medicine adherence	Basic	
	9.2	Yes	Describe the factors influencing patient perspectives, including patient belief and risk perception and consequences of non-adherence	Basic	Infographic of the different factors
	9.3	Yes	Example of patients telling their stories: Positive stories of women having received the required information on the risk of medicine use during pregnancy or breastfeeding or the risk of not using the medicine and how this have impacted the decision making. Negative experiences of women not receiving the required information on the risk of medicine use during pregnancy or breastfeeding and the impact on the decision making e.g. management of hyperemesis gravidarum.	Basic	Combination of videos, audios (podcast) and (short) written stories Examples: http://realtalkwithrealmums.ie/ https://soundcloud.com/user-920613307/episode-9-mental-health

	9.4	Yes	- Explain the importance of communication between patients and HCPs regarding risk perception, information received from other sources (social media, family and friends, blogs,...) (Women playing a proactive role in discussions with HCPs and in decision making) - Explain the importance of the development of educational tools to better inform women on what is known about the risks to the fetus/breastfed child from taking the medication but also the risk of not taking the medication (especially in chronic disease)	Basic	Explain importance in text, show some examples and let participants brainstorm over possible tools for communication and education
	9.5 Test your knowledge	Yes	Get insight in own learning progress of basic knowledge	Basic	Test your knowledge for basic level

Title Learning Unit	Title Learning Activity	Required activity?	Learning Objective(s)	Level	Activity Description
10. Course closure	Course summary	Yes		Basic	Provide summary of entire course (use course organiser?).
	Final exam	Yes		Basic	Final quiz to show mastering of course topics (basic knowledge)
	Evaluation	Yes		Basic	Questionnaire about course experiences
	Course certificate	Yes		Basic	Farewell message, future references, how can I get involved with ENTIS, how can I access live courses on medicines in pregnancy and breastfeeding how can I contribute to research on medicines in pregnancy and course certificate

Overview of next steps

The main next steps will include:

- Training content development,
- International accreditation from Accreditation Council for Continuous Medical Education (ACCME),
- Development of sustainability plan.

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Appendices

Appendix 1: Inventory of training curriculum on medicines during pregnancy and breastfeeding

Program name	Organization	Country/language	Learning objectives	Target audience	Format	Quiz/Test	Comment
The human teratogen course	OTIS	USA English	- Identify exposures which confer teratogenic risk to embryo, fetus, or infant. - Discuss the magnitude of risk to embryo or fetus associated with maternal conditions during pregnancy or preconception. - Discuss the magnitude of risk to pregnancy associated with maternal medication exposures during pregnancy or preconception - Discuss the magnitude of risk to embryo or fetus associated with maternal illicit drug use during pregnancy or preconception. - Determine magnitude of risk associated with paternal exposures. Assess risks to infants associated with exposures during breastfeeding.	Obstetricians Maternal Fetal Medicine Specialists Genetic Counselors Pharmacists Allied Health Professionals	Class room (3 days)	No	
	APOKUS	Norwegian	Breast feeding and Medicines Antibiotics in pregnancy Medicines in pregnancy and breastfeeding Pregnancy and Medication	Pharmacists	On-line	Yes	
PAO course: Medicines during pregnancy and breastfeeding	TIS	Netherlands Dutch	know the 6 basic principles of teratology know on the basis of these principles how to take drug use during pregnancy in consideration Can argue whether a medicine can or can't be used during pregnancy understand the factors that play a role in the transition of a drug in breast milk can argue whether a women can safely breastfeed know how to communicate about drug use during pregnancy and breastfeeding with other healthcare providers and patients understand the considerations of drug use by man wish to become parent.	Pharmacists	Class room (1 day)	no	
Medicines during pregnancy and breastfeeding	Tis	Netherlands Dutch	same as PAO course	Students (pharmacy midwives and medicine)	Classroom (1-1,5 hour)	Test at the end	

Program name	Organization	Country/language	Learning objectives	Target audience	Format	Quiz/Test	Comment
Under-graduate midwifery	CHHS, SU	Wales English	Epidemiology of anomalies in Wales including Prevalence. Detection of anomalies and the antenatal detections rates of key anomalies. Role of Folic acid in prevention of neural tube defects Risk factor for congenital anomalies. Monitoring and surveillance of anomalies. Management of clusters. International comparisons including the work of EUROCAT and ICBDSR. Recent research projects	Future midwives	2 hour lecture per cohort	no	
Graduate entry medicine	Swansea University Medical School	Wales English	Lectures on the ethics of ante-natal screening (3h), and predication and testing for genetic diseases (3h), as well as ICM scenarios on Down's syndrome etc (half a day).	Future doctors	Lectures and integrated clinical methods (ICM) / clinical skills sessions	Exam questions are integrated into main assessments.	
Under-graduate nursing	CHHS SU	Wales English	Understand associations with AEDs	Future nurses	5-10 minutes in the AED lecture	no	
Undergraduate pharmacy (MPharm)	Swansea University Medical School	Wales English	Teratology will crop up in different areas, e.g. optical isomerism in the pharmaceutical chemistry theme and thalidomide. But teratology will be discussed in the context of various clinical and ethical scenarios	Future pharmacists	~2 hours over a 4 year taught programme	Not directly	
Medications and pregnancy	Faculté de Médecine Université Toulouse III Service de Pharmacologie	France Toulouse (Régional area) French	Identify medications which confer teratogenic risk to embryo, fetus, or infant. Discuss the magnitude of risk to pregnancy associated with maternal medication exposures during pregnancy or preconception Evaluate the benefit/risk balance of the prescription of a medication during pregnancy	Medical students (3rd year, 6th year) Residents	Class room Interactive with clinical cases (3 hours each group) Participation to the monthly work meeting of the Information Unit on Medications and Reproduction + conference with patient association (DES network France)	Exam at the end of the year	Separate courses and format according to the students
Medications and Reproduction	Centre hospitalier Universitaire de Toulouse (CHUT) Unité « Medicaments, reproduction, Grossesse et allaitement »Pharmacovigilance and Information service	France Toulouse (Régional area) French	How to answer to a health professional or a patient asking a question about medication and reproduction to the Information service	residents (physcians, pharmacists)	2 Half-day workshops (Scientific basis, available databases, etc…) +Participation to the monthly work meeting of the Information Unit on Medications and Reproduction	No	Every 6 months

Program name	Organization	Country/language	Learning objectives	Target audience	Format	Quiz/Test	Comment
Medications/drugs and pregnancy and breastfeeding	Ecole de sages-femmes Université Toulouse III Service de Pharmacologie	France Toulouse (Régional area) French	Identify medications which confer teratogenic risk to embryo, fetus, or infant. Discuss the magnitude of risk to pregnancy associated with maternal medication exposures during pregnancy or preconception Evaluate de benefit/risk balance of a medication during pregnancy Evaluate de benefit/risk balance of a medication during breastfeeding Assess risks to infants associated with exposures during breastfeeding	Midwives students. Each year : 2nd, 3rd, 4th, 5th	Class room In each course on medications + 1h30 dedicated course + Interactive workshops with clinical cases (1h30 each group) + conference with patient association (reseauDES France) + Participation to the monthly work meeting	Exams at the end of the year	
Diplôme Universitaire de Pédiatrie en Maternité Risks of « in utero exposure to medications" for children	Service de Pharmacologie	France French	Identify in utero exposure to medications which induce defects or pathologies in infants. Assess risks to infants associated with exposures during breastfeeding Evaluate de benefit/risk balance of a medication during breastfeeding	Paediatricians	Classroom	Test at the end	
Diplôme Universitaire de Santé Genetique Medications and Reproduction	Service de Pharmacologie	France Toulouse (Régional area) French)	Medications and reproduction : Pharmacological basis	General practitioners, Gynaecologists and midwives	Classroom 4hours	Test at the end	
DIU de Formation Complémentaire en Gynécologie Obstétrique (réservé aux Médecins Généralistes) Medications and Reproduction	Service de Pharmacologie	France Toulouse (Régional area) French	Identify medications which confer teratogenic risk to embryo, fetus, or infant. Discuss the magnitude of risk to pregnancy associated with maternal medication exposures during pregnancy or preconception Evaluate the benefit/risk balance of a medication during pregnancy Evaluate the benefit/risk balance of a medication during breastfeeding Assess risks to infants associated with exposures during breastfeeding	General practitioners	Classroom 2hours	Test at the end	
Master 1	Service de Pharmacologie	France Toulouse (Régional area) French	Methods for evaluation of teratogenic risk	Pharmacy, scientific, medical and vet. students	Classroom (2h)	Exam	
Master2 pro	Service de Pharmacologie	France Toulouse (Régional area) French	Pharmacological basis of teratogenicity Evaluating the teratogenic/ fetotoxic risks of drugs	Pharmacy, scientific, students	Classroom (2h) + workshop (2h)	Exam	

Program name	Organization	Country/language	Learning objectives	Target audience	Format	Quiz/Test	Comment
Post university training	Service de Pharmacologie	France Toulouse (Régional area) French	Identify medications which confer teratogenic risk to embryo, fetus, or infant. Discuss the magnitude of risk to pregnancy associated with maternal medication exposures during pregnancy or preconception Evaluate the benefit/risk balance of a medication during pregnancy Assess risks to infants associated with exposures during breastfeeding Evaluate the benefit/risk balance of a medication during breastfeeding	General practioners Pharmacists Midwives	Evening meetings (3hours) + Workshops during annual meetings (half day on saturday) organised by the Pharmacology ward “les Matinales de la Pharmacologie Toulousaine”	Pre and Post test	There are several workshops like that all along the year
Faculty of Pharmaceutical Sciences Master of Science in Pharmaceutical Care	KU Leuven	Belgium, Leuven Dutch	Fertility, pregnancy and breastfeeding : theoretical aspects Teratogenicity Transplacental passage + passage into breastmilk using PK parameters Benefit/risk balance of medicines; commonly used and ‘safe’ prescription and over-the-counter medicines during pregnancy and breastfeeding Counselling on preconception and pregnancy matters, including folic acid, while dispensing pregnancy tests Pharmacological discussion on the medicines used for pregnancy-related conditions	Fifth-year pharmacy students (Master 2)	Class room where theoretical principles are explained while using practical cases (4h) + workshops with 8-10 students where students present a case, followed by an interactive discussion (4h)	Written exam at the end of the semester using cases + evaluation of case presentation and discussion	
Post university training Advanced course on pregnancy and breastfeeding	Institute for Continuous Education for Community Pharmacists (IPSA) in Flanders, Belgium (Dutch speaking part of Belgium)	Belgium, Flanders Dutch	Theoretical aspects of fertility, pregnancy and breastfeeding TeratogenicityTransplacental passage + passage into breastmilk using PK parameters Benefit/risk balance of medicines; commonly used ‘safe’ prescription and over-the-counter medicines during pregnancy and breastfeedingCommunication in pharmacy practice (OTC questions, dispensing of pregnancy tests)Appropriate sources and how to use them properly	Licensed community pharmacists	1 class room teaching (2h) +e-learning (4h)+Workshop where cases are solved and discussed in small groups while using appropriate sources (2h)+2 webinars on breastfeeding issues and formula feeding (4h)	Attending all course elements is currently sufficient to receive the accreditation; some non-binding test questions are included in the course	This course was organized in 2019 and 2020; but this will probably not occur annually
Clinical Teratology	Hebrew University Hadassah Medical School Jerusalem	Israel Hebrew	The course provides knowledge about teratological damages that can be caused due to drugs or teratogenic agents, maternal infections or diseases to the baby and the different time point during pregnancy and breastfeeding. The aims of the course are to familiarize the student with the potential damages that can be associated with drug treatment infections or maternal diseases and how to advice the patient and the caregiver about avoiding these issues.	Pharm D Students	Class room 5 day clinical rotation	Presentation and exam	

Program name	Organization	Country/language	Learning objectives	Target audience	Format	Quiz/Test	Comment
Embryology and Teratology	Hebrew University Hadassah Medical School Jerusalem	Israel Hebrew	The development of the human embryo. Effect of teratogenic agents on the human embryo/fetus. Understanding the biological processes that are involved in normal embryonic development. Knowledge of environmental exposures during pregnancy associated with increased risk for anomalies.	Nursing students	Classroom 10 academic 2 hour sessions	Exam	
Post university training (but with option to classify as for master CU)	University of Southampton + European Society of Pediatric Research	UK English	Placental and maternal pharmacology, fetal and neonatal relevance specific submodule on maternal-placental-fetal pharmacology, as part of a module on neonatal clinical pharmacology	Neonatologists and neonatologists in training	Formal training module, ICTS, CU available, online lectures, and workshops	Formal evaluation (master CU)	Module within the Neonatal Online Training and Education (NOTE) initiative
Safe Prescribing in Pregnancy	Royal College of Physicians in Ireland	Ireland English	Historical Context Teratogens and determinants of teratogenicity General Principles of medication use in pregnancy Predicting human pregnancy risk Communicating teratogenic risk Case based learning – antidepressants and antiepileptics	Obstetricians	1 Hr E-Learning 1 Hr case-based classroom learning	Discussion of cases	
Medication Use In Pregnancy and Breastfeeding	Royal College of Surgeons in Ireland	Ireland English	Explain the historical context of medication use in pregnancy Understand the general principles of medication use in pregnancy Interpret/analyse evidence on the use of medicines in pregnancy Synthesise information for patients based on currently available evidence Understand common conditions and therapeutics in pregnancy Advocate for safe and effective use of medicines in pregnancy Case based learning – antidepressants and antiemetics Pharmacokinetics in Pregnancy Common/pre-existing conditions in pregnancy Hot topics in medicines in pregnancy Women with epilepsy Medications and breastfeeding	Future Pharmacists	5 Hr Lectures 1 Hr case-based classroom learning	Exam	

Appendix 2: Example of filled persona sheet

General practitioner advanced

<table>
<tr><td colspan="2">PERSONAL
Name: Marie Robert
Age: 42 y.o
Highest level of education: MD
Hobbies: scuba diving, traveling, cycling
Pets/relationships/children: married, 3 children
Place of residence: Paris area, France</td></tr>
<tr><td>JOB: FACTS
Job description: general practitioner in medical center
Responsibilities/tasks: primary care medical exams, make diagnosis and drug prescriptions
Experience with medicines in pregnancy and breastfeeding: experience of queries of pregnant women on maternal health and food, managing chronic treatment with support of specialists (e.g. endocrinologists, neurologists)
Relationship to/experience with pregnant/breast feeding women: coming across pregnant or lactating <omen at least once a week. Significant amount of exposure to women of childbearing potential</td><td>JOB: OPINION
Values: relationship, patient service, scientific knowledge, transmission of knowledge
Needs: precise and reliable information source (e.g. le CRAT), competence with pregnancy related queries and update on new information in all domains (not only pregnancy related)
Wants: more time for engagement with patients
Challenges/fears: need to maintain accurate and update on all domains (be up to date on everything!)</td></tr>
<tr><td colspan="2">LEARNING EXPERIENCE
Experience with learning on the job:
Regular face to face training program, service staff discussions, national conferences/congresses
Favorite learning method/tool: face-to-face, discussion with peers
Limited experience with e-learning. Prefers interactive tools
Time available for learning: very limited, competes with clinical and personal commitments
Experience/comfort with technology for learning: comfortable but limited time available</td></tr>
</table>