

# BMJ Open European List of Essential Medicines for Medical Education: a protocol for a modified Delphi study

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## ABSTRACT

**Introduction** Junior doctors are responsible for a substantial number of prescribing errors, and final-year medical students lack sufficient prescribing knowledge and skills just before they graduate. Various national and international projects have been initiated to reform the teaching of clinical pharmacology and therapeutics (CP&T) during undergraduate medical training. However, there is as yet no list of commonly prescribed and available medicines that European doctors should be able to independently prescribe safely and effectively without direct supervision. Such a list could form the basis for a European Prescribing Exam and would harmonise European CP&T education. Therefore, the aim of this study is to reach consensus on a list of widely prescribed medicines, available in most European countries, that European junior doctors should be able to independently prescribe safely and effectively without direct supervision: the European List of Essential Medicines for Medical Education.

**Methods and analysis** This modified Delphi study will recruit European CP&T teachers (expert group). Two Delphi rounds will be carried out to enable a list to be drawn up of medicines that are available in ≥80% of European countries, which are considered standard prescribing practice, and which junior doctors should be able to prescribe safely and effectively without supervision.

**Ethics and dissemination** The study has been approved by the Medical Ethics Review Committee of VU University Medical Center (no. 2020.335) and by the Ethical Review Board of the Netherlands Association for Medical Education (approved project no. NVM0-ERB 2020.4.8). The European List of Essential Medicines for Medical Education will be presented at national and international conferences and will be submitted to international peer-reviewed journals. It will also be used to develop and implement the European Prescribing Exam.

## INTRODUCTION

Prescribing is a core task of junior doctors, who are responsible for most hospital prescriptions.<sup>1 2</sup> With an ever-expanding therapeutic arsenal and an increasing number of patients with comorbidity and polypharmacy, safe and effective

## Strengths and limitations of this study

- To our knowledge, this will be the first study to reach consensus on a European List of Essential Medicines for Medical Education.
- The Delphi method is the most suitable method to reach consensus anonymously with a large group of experts working in different countries.
- The European List of Essential Medicines for Medical Education will help to harmonise clinical pharmacology and therapeutics (CP&T) education in Europe.
- There is already strong collaboration between European Association for Clinical Pharmacology and Therapeutics and WHO Europe, and the members are recognised experts in the field of CP&T education.
- Recruiting a sufficient number of participants from all European countries will be a challenge.

prescribing has become an increasingly complex task. International studies have shown that junior doctors are responsible for a substantial number of prescribing errors<sup>1 3</sup> and that at the time of graduation, junior doctors not only feel insufficiently prepared to prescribe safely and effectively but also have insufficient knowledge and skills to perform this task.<sup>4–8</sup>

This has prompted various national and international projects to reform teaching in clinical pharmacology and therapeutics (CP&T) in the undergraduate medical curriculum. For example, in the UK and the Netherlands a prescribing assessment has been introduced for final-year students, to ensure that they have acquired the necessary knowledge before graduation.<sup>9–11</sup> Other European countries might benefit from a similar initiative. As many countries do not have the time and resources to implement an assessment at a national level, we initiated an Erasmus+



project (2019-1 - NL01 - KA203-060492) to develop, test and implement a standardised prescribing assessment on safe prescribing (including knowledge and skills) for undergraduate medical students studying at medical schools in the European Union (ie, European Prescribing Exam (EuroPE<sup>+</sup>)). See <http://www.prescribingeducation.eu/> for more information.

The assessment will be based on the ‘essential diseases in prescribing’ derived from a Delphi consensus study held in 2018.<sup>12</sup> However, there is no consensus list of medicines that European junior doctors should be able to independently prescribe safely and effectively without direct supervision. This list will form the basis of the European Prescribing Exam (especially the skills part), and together with country-specific adjustments to reform educational programmes in CP&T in all European countries. This will complement the wish of the European Association for Clinical Pharmacology and Therapeutics (EACPT) to harmonise European training in CP&T<sup>13</sup> and will be included in a future revision of the Guide to Good Prescribing of the WHO.<sup>14</sup> Previous studies of such lists have been based on the opinions of individuals or small groups of experts or were specific to one country.<sup>15–18</sup> Therefore, the aim of this study is to reach consensus on a list of medicines that are widely prescribed and available in Europe and which European junior doctors should be able to independently prescribe safely and effectively without direct supervision, that is, the European List of Essential Medicines for Medical Education.

## METHODS AND ANALYSIS

A modified Delphi method will be used as it has been shown to be an effective and successful method for reaching consensus on content of a CP&T curriculum.<sup>12 19–23</sup> As the availability of medicines differs between European countries, it is not possible to develop an all-encompassing list, but one that can be considered as a basis for European CP&T education. Subsequently, each country can adjust the list based on the availability of medicines in its country. The study will start in October 2020 and will comprise three phases: phase I—creating a drug list, selecting an European expert panel and developing a web-based questionnaire in Castor Electronic Data Capture; phase II—sending a questionnaire to appointed coordinators and phase III—Delphi consensus.

### Patient and public involvement

No patient involved.

### Phase I

#### Drug list

On the basis of the WHO Model List of Essential Medicines,<sup>24</sup> guideline therapies for the ‘essential diseases in prescribing’ (see online supplemental appendix

1), a literature review<sup>15–18</sup> and a drug list from the EuroPE<sup>+</sup> project,<sup>25</sup> a questionnaire will be developed regarding an extensive list of possible medicines that European junior doctors should be able to prescribe safely and effectively without supervision directly after graduation (online supplemental appendix 2). This list will be categorised into diseases. For each drug, the most commonly used routes of administration will be listed separately.

### Expert panel

Through the Education Working Group of the EACPT and the affiliated Network of Teachers in Pharmacotherapy, all coordinators (n=393) from all European medical schools (n=297) who are responsible for teaching CP&T to medical students will be approached to participate in the study. The coordinators will be asked to participate in the study themselves and to select a group of experts within their own centre, using the following criteria:

- ▶ Two experienced (≥3 years of teaching experience) teachers explicitly engaged in CP&T education for medical students, of which at least one teacher is registered as a clinical pharmacologist.
- ▶ At least five healthcare professionals, preferably a surgeon (eg, general surgeon); an internist (eg, general internist, gastroenterologists, pulmonologist and cardiologist); a general practitioner; a specialist in geriatric medicine or geriatrician and a (hospital) pharmacist.
- ▶ Two recently graduated junior doctors (graduated ≤1 year ago) who prescribe drugs on a daily basis.

There will be no restrictions regarding the work environment of the respondents (academic or community hospitals). The principal investigator will invite the experts to participate via email, providing an information letter and a link to the online survey. Prior to participation, the experts will be asked to sign a digital informed consent form.

Based on previous studies with this dedicated group of experts,<sup>22 26</sup> we expect a response rate of 25% for the coordinators, representing all European countries. Assuming 5–6 recruited experts per coordinator and a response rate of 25% as well, we expect in total 200–250 experts to complete the study.

### Phases II and III

#### Study design and data collection

In phase II, the coordinator(s) of each university will receive the list of medicines developed in phase I and will be asked to indicate which medicines are available in his or her country. On the basis of this information, a second questionnaire will be drawn up consisting of the medicines that are available in Europe. This questionnaire will be used for phase III, a two-round Delphi study. In round 1, all experts will be asked to evaluate two statements for each medicine (item): (1) ‘In my country, it is standard practice to

prescribe this medicine to patients' and (2) 'A junior doctor should be able to independently prescribe this medicine safely and effectively without direct supervision'. Respondents will score both statements using a 5-point Likert scale (1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree and 5=strongly agree). Respondents will also be able to add missing medicines that they consider should be included in round 2, and to add arguments for their choices in an open text box.

The questionnaire for round 2 will have the same structure as in round 1, but will also include the average group score per medicine from round 1, the suggested medicines and the arguments for their inclusion. The coordinator will be asked an additional question about the availability of the suggested medicines in his or her country: 'In my country, this medicine is available to prescribe to patients'.

To minimise participant drop-out, the list of medicines will be structured and participants are allowed to complete a portion of the survey and return later to finish the remaining part. The list must be completed within 2 weeks, a reminder will be sent after 1 week.

### Statistics

A medicine will be included in the second questionnaire if that medicine is available in  $\geq 80\%$  of the European countries. In accordance with previous studies,<sup>12 22</sup> a medicine will be included in the final European List of Essential Medicines for Medical Education if both statements about this medicine are scored 4 or 5 by  $\geq 80\%$  of the respondents. If one statement about a medicine is scored 4 or 5 by  $\geq 80\%$  of the respondents but the other statement is scored 4 or 5 by  $\geq 50\%$ – $<80\%$  of the respondents, then this medicine will be reassessed in Delphi round 2. This also applies to suggested medicines. Medicines from round 2 will be included in the European List of Essential Medicines for Medical Education if both statements regarding a medicine are given a score of 4 or 5 by  $\geq 80\%$  of the respondents. Medicines suggested by respondents should also be available in  $\geq 80\%$  of European countries.

### ETHICS AND DISSEMINATION

Prior to participation, all experts will be asked to give their informed consent and provide the following information: email address, medical school, profession with background, and years of clinical and teaching experience. The data will be coded and stored for a maximum of 10 years in a secure folder on the hard disk of the Amsterdam UMC, location VUmc. Participation will not be professionally advantageous or disadvantageous and there will be no compensation for participation. Respondents can end their participation at any time, without giving a reason. The study has been approved by the Medical Ethics Review

Committee of Amsterdam UMC, location VUmc (no. 2020.335) and by the Ethical Review Board of the Netherlands Association for Medical Education (approved project no. NVMO-ERB 2020.4.8).

The results of the study will be presented at national and international conferences and will be submitted to international peer-reviewed journals. The final European List of Essential Medicines for Medical Education will be used to develop and implement the European Prescribing Exam.

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**Appendix 1**

All guideline medicines to treat the 'essential diseases', ordered alphabetically. When note down more than once, means that there is more than one indication.

Acenocoumarol	Diazepam
Acenocoumarol	Diclofenac
Acetylsalicylic acid	Diclofenac
Acetylsalicylic acid	Diclofenac
Alendronic acid	Diclofenac
Aluminium acetotartrate -eardrip	Digoxin
Aluminum hydroxide/magnesium hydroxide	Diltiazem
Amitriptyline	Diltiazem
Amlodipine	Dipyridamole
Amoxicillin	Domperidone
Amoxicillin	Domperidone
Amoxicillin	Doxycycline
Amoxicillin	Doxycycline
Amoxicillin/clavulanate	Doxycycline
Amoxicillin/clavulanate	Doxycycline
Amoxicillin/clavulanate	Emollients (e.g. Cremor vaselini cetomacrogolis)
Atorvastatin	Emollients (e.g. Cremor vaselini cetomacrogolis)
Azithromycin	Emollients (e.g. Cremor vaselini cetomacrogolis)
Azithromycin	Emollients (e.g. Cremor vaselini cetomacrogolis)
Azithromycin	Enalapril
Azithromycin	Enalapril
Beclometasone	Epinephrine (adrenaline)
Betamethasone	Epinephrine (adrenaline)
Butylscopolamine	Esomeprazole
Carbasalate calcium	Ethinylestradiol/levonorgestrel (oral)
Chloramphenicol	Etonogestrel (s.c. Implant)
Ciprofloxacin	Ferrous fumarate
Citalopram	Flucloxacillin
Clarithromycin	Flucloxacillin
Clarithromycin	Flucloxacillin
Clarithromycin	Fluconazole
Clemastine	Fluticasone
Clemastine	Fluticasone
Clomipramine	Folic acid (vitamin b9)
Clopidogrel	Formoterol
Clopidogrel	Fosfomycin
Clotrimazole	Fusidic acid
Codeine	Gliclazide
Colchicine	Glucagon
Colecalciferol (with/without) calcium	Glucose solution
Desloratadine	Glycerol trinitrate (nitroglycerine)
Desloratadine	Haloperidol
Desloratadine	Hydrochlorothiazide
Desogestrel (oral)	Hydrocortisone
Dexamethason	Hydrocortisone
Dexamethason	Hydrocortisone/acetic acid

Hydroxocobalamin (vitamin b12)	Omeprazole, pantoprazole, esomeprazole
Ibuprofen	Ors (oral rehydration solution)
Ibuprofen	Ors (oral rehydration solution)
Ibuprofen	Oxazepam
Ibuprofen	Oxycodone
Influenza vaccine	Pantoprazole
Insulin aspart	Paracetamol
Insulin glargine	Paracetamol
Ipratropium bromide	Paroxetine
Ipratropium bromide	Perindopril
Isosorbide dinitrate	Pheneticillin
Isosorbide mononitrate	Pheneticillin
Ispaghula (psylla seeds)	Pheneticillin
Lactulose	Phenprocoumon
Levocabastine	Phenprocoumon
Levocetirizine	Prednisolone
Levocetirizine	Prednisolone
Levocetirizine	Prednisolone
Levonorgestrel (iud)	Prenisolone
Levothyroxine	Propranolol
Lidocaine creme	Ranitidine
Lisinopril	Risedronic acid
Loperamide	Rosuvastatin
Loperamide	Salbutamol
Lorazepam	Salbutamol
Losartan	Salbutamol
Macrogol	Salbutamol
Macrogol	Salbutamol
Mebeverine	Salbutamol
Medroxyprogesterone (s.c. Depot)	Salmeterol
Menthol in aqueous cream	Simvastatin
Menthol in aqueous cream	Sodium chloride solution
Metformin	Spirolactone
Metocloperamide	Temazepam
Metocloperamide	Tetanus toxoid
Metoprolol	Thiamine (vit b1)
Metoprolol	Tiotropium bromide
Metronidazole	Tramadol
Miconazol	Triamcinolone
Midazolam (i.m.)	Triamcinolone/acetic acid
Mometasone	Trimethoprim
Nadroparin	Trimethoprim/polymyxine b
Nadroparin	Trimethoprim/sulfamethoxazole
Naproxen	Trimethoprim/sulfamethoxazole
Naproxen	Trimethoprim/sulfamethoxazole
Naproxen	Verapamil
Naproxen	Verapamil
Nitrofurantoin	Xylometazoline nasalspray
Omeprazole	Xylometazoline nasalspray
Omeprazole, pantoprazole	Zolpidem

List of medicines	Route of administration	Route of administration	Route of administration	Route of administration
Miconazole	Oral			
Aluminium hydroxide/magnesium hydroxide	Oral			
Magnesium hydroxide	Oral			
Ranitidine	Oral			
Misoprostol	Oral			
Omeprazole	Oral			
Pantoprazole	Oral			
Esomeprazole	Oral	IV		
Mebeverine	Oral			
Atropine	IV			
Butylscopolamine	Oral			
Metoclopramide	Oral	IV	Rectal	
Domperidone	Oral			
Ondansetron	Oral	IV	Rectal	
Bisacodyl	Oral	Rectal		
Ispaghula husk	Oral			
Lactulose	Oral			
Macrogol	Oral			
Nystatin	Oral			
Oral rehydration solution (ORS)	Oral			
Loperamide	Oral			
Insulin	SC			
Insulin aspart	SC			
Protamine (novomix)	SC			
Insulin glargine	SC			
Metformin	Oral			
Gliclazide	Oral			
Glimepiride	Oral			
Acarbose	Oral			
Pioglitazone	Oral			
Sitagliptin	Oral			
Linagliptin	Oral			
Exenatide	SC			
Liraglutide	SC			
Canagliflozin	Oral			
Empagliflozin	Oral			
Repaglinide	Oral			
Cholecalciferol	Oral			
Thiamine (vit B1)	Oral	IV		
Calcium/vitamin D	Oral			
Potassium chloride	Oral			
Fenprocoumon	SC			
Acenocoumarol	SC			
Heparin	IV			

Enoxaparin	SC	
Nadroparin	SC	
Clopidogrel	Oral	
Dipyridamole	Oral	
Carbasalate calcium	Oral	
Prasugrel	Oral	
Dabigatran	Oral	
Rivaroxaban	Oral	
Apixaban	Oral	
Fondaparinux	SC	IV
Tranexamic acid	Oral	IV
Vitamin K	Oral	IV
Prothrombin complex concentrate	IV	
Ferrous fumarate	Oral	
Hydroxocobalamin (vitamin B12)	SC	IM
Folic acid (vitamin B9)	Oral	
Glucose solution	IV	
Potassium chloride	IV	
Digoxin	Oral	IV
Flecainide	Oral	
Amiodarone	Oral	IV
Epinephrine (adrenaline)	IM	
Nitroglycerine	SL	
Isosorbide dinitrate	Oral	SL
Isosorbide mononitrate	Oral	
Methyldopa	Oral	
Hydrochlorothiazide	Oral	
Chlorthalidone	Oral	
Furosemide	Oral	IV
Bumetanide	Oral	IV
Spirolactone	Oral	
Propranolol	Oral	
Sotalol	Oral	
Metoprolol	Oral	IV
Atenolol	Oral	
Bisoprolol	Oral	
Labetolol	Oral	IV
Amlodipine	Oral	
Nifedipine	Oral	
Barnidipine	Oral	
Lercanidipine	Oral	
Nicardipine	IV	
Verapamil	Oral	IV
Diltiazem	Oral	
Enalapril	Oral	
Lisinopril	Oral	



Perindopril	Oral	
Ramipril	Oral	
Fosinopril	Oral	
Losartan	Oral	
Valsartan	Oral	
Irbesartan	Oral	
Candesartan	Oral	
Simvastatin	Oral	
Pravastatin	Oral	
Atorvastatin	Oral	
Rosuvastatin	Oral	
Gemfibrozil	Oral	
Colestyramine	Oral	
Ezetimibe	Oral	
Evolocumab	SC	
Miconazole	Cutaneous	
Emollients (e.g. Cremor vaseline cetomacrogolis)	Cutaneous	
Zinc oxide	Cutaneous	
Petroleum jelly	Cutaneous	
Lidocaine creme	Cutaneous	
Menthol in hydrophilic ointment	Cutaneous	
Fusidic acid	Cutaneous	
Hydrocortisone	Cutaneous	
Triamcinolone	Cutaneous	
Betamethasone	Cutaneous	
Mometasone	Cutaneous	
Clobetasole	Cutaneous	
Clotrimazole	Cutaneous	
IUD with progestogen	IUD	
Ethinylestradiol/levonorgestrel	Oral	
Medroxyprogesterone (s.c. Depot)	SC	
Etonogestrel (s.c. Implant)	SC	
Desogestrel	Oral	
Levonorgestrel	Oral	
Estradiol	Oral	
Oxybutynin	Oral	
Solifenacin	Oral	
Tamsulosin	Oral	
Finasteride	Oral	
Betamethasone	Oral	IV
Dexamethasone	Oral	IV
Prednisolone	Oral	IV
Hydrocortisone	Oral	IV
Levothyroxine	Oral	
Glucagon	IM	

Doxycycline	Oral				
Amoxicillin	Oral	IV			
Feneticillin	Oral	IV			
Flucloxacillin	Oral	IV			
Amoxicillin/clavulanic acid	Oral	IV			
Meropenem	IV				
Trimethoprim	Oral				
Co-trimoxazole	Oral	IV			
Trimethoprim/sulfamethoxazole	Oral	IV			
Erythromycin	Oral	IV			
Clarithromycin	Oral	IV			
Azithromycin	Oral	IV			
Gentamycin	IV				
Ciprofloxacin	Oral	IV			
Vancomycin	IV				
Fusidic acid	Oral				
Nitrofurantoin	Oral				
Fosfomycin	Oral				
Fluconazole	Oral	IV			
Rifampicin	Oral	IV			
Acyclovir	Oral	IV			
Valaciclovir	Oral				
Oseltamivir	Oral				
Tetanus toxoid	IM				
Methotrexate	Oral	IV	IM	SC	
Diclofenac	Oral				
Ibuprofen	Oral				
Naproxen	Oral				
Ibuprofen	Cutaneous				
Diclofenac	Cutaneous				
Allopurinol	Oral				
Colchicine	Oral				
Alendronic acid	Oral				
Risedronic acid	Oral				
Denosumab	SC				
Fentanyl	IV				
Lidocaine	SC				
Epinephrine (adrenaline)	SC				
Morphine	Oral	IV	SC		
Oxycodone	Oral	SC			
Fentanyl	Oral	Cutaneous	Nasal	SL	
Tramadol	Oral	Rectal			
Piritramide	SC				
Acetylsalicylic acid	Oral	IV			
Calcium carbasalate	Oral	IV			
Paracetamol	Oral	IV	Rectal		

Sumatriptan	Oral	Nasal	SC
Valproic acid	Oral	IV	
Levetiracetam	Oral	IV	
Pregabalin	Oral	IV	
Haloperidol	Oral	IV	
Clozapine	Oral		
Olanzapine	Oral		
Quetiapine	Oral		
Lithium	Oral		
Risperidone	Oral	IM	
Diazepam	Oral	Rectal	
Oxazepam	Oral		
Lorazepam	Oral	IM	IV
Temazepam	Oral		
Midazolam	Oral	IV	
Zolpidem	Oral		
Clomipramine	Oral		
Amitriptyline	Oral		
Nortriptyline	Oral		
Fluoxetine	Oral		
Citalopram	Oral		
Paroxetine	Oral		
Sertraline	Oral		
Escitalopram	Oral		
Mirtazapine	Oral		
Venlafaxine	Oral		
Metronidazole	Oral	IV	
Xylometazoline	Nasal		
Levocabastine	Ocular		
Beclomethasone	Nasal		
Budesonide	Nasal		
Mometasone	Nasal		
Fluticasone	Nasal		
Salbutamol	Inhalation		
Salmeterol	Inhalation		
Formoterol	Inhalation		
Beclometasone	Inhalation		
Budesonide	Inhalation		
Fluticasone	Inhalation		
Ciclesonide	Inhalation		
Ipratropium bromide	Inhalation		
Tiotropium bromide	Inhalation		
Tiotropium	Inhalation		
Codeine	Oral		
Clemastine	Oral	IV	
Meclozine	Oral		

Levocetirizine	Oral	
Desloratadine	Oral	
Chloramphenicol	Ocular	
Fusidic acid	Ocular	
Erythromycin	Ocular	
Trimethoprim/polymyxin B	Ocular	
Dexamethasone (Ocular)	Ocular	
Prednisolone (Ocular)	Ocular	
Levocabastine	Ocular	
Aluminium acetate	Ear	
Miconazole	Oral	
Hydrocortisone/acetic acid	Ear	
Triamcinolone/acetic acid	Ear	
Protamine	IV	
Naloxone	IV	
Flumazenil	IV	
Ticagrelor	Oral	IV
Cefuroxime	IV	
Cefotaxime	IV	
Ceftriaxone	IV	
Ceftazidime	IV	
Clindamycin	Oral	IV
Sodium chloride	IV	
Ringer's lactate	IV	