

Reference: \_\_\_\_\_ Date of data extraction: \_\_\_\_\_ Reviewer:  KH

**PART 1: Study eligibility and characteristics of the study**

	<b>Exclusion criteria</b>	<b>Characteristics of the study</b>	
<b>Type of publication</b>	<input type="checkbox"/> Not a peer-reviewed original research article, e.g. commentary, editorial, letter, report, guidelines or conference or meeting proceedings <input type="checkbox"/> Not published in English	-	
<b>Study design/ type of study</b>	<input type="checkbox"/> Case report <input type="checkbox"/> Conceptual paper <input type="checkbox"/> Other: _____	<input type="checkbox"/> Observational <input type="checkbox"/> Intervention	<input type="checkbox"/> Retrospective <input type="checkbox"/> Prospective <input type="checkbox"/> Cross-sectional
<b>Data source</b>	<input type="checkbox"/> Pre-existing material on drug-related morbidity without evaluation of drug-related morbidity in the current study	<input type="checkbox"/> Case records <input type="checkbox"/> Interview <input type="checkbox"/> Reports <input type="checkbox"/> Survey <input type="checkbox"/> Other: _____	
<b>Setting</b>	<input type="checkbox"/> Care unit(s) for patients with specific disease or disease class	<input type="checkbox"/> Inpatient setting <input type="checkbox"/> Outpatient setting <input type="checkbox"/> Residential facility <input type="checkbox"/> Community setting <input type="checkbox"/> Academic teaching facility <input type="checkbox"/> Other setting: _____ <input type="checkbox"/> No setting restrictions	<input type="checkbox"/> Africa <input type="checkbox"/> Eastern Mediterranean <input type="checkbox"/> Europe <input type="checkbox"/> North America <input type="checkbox"/> South America <input type="checkbox"/> South-East Asia <input type="checkbox"/> Western Pacific
<b>Sampling frame</b>	Sampling frame represents patients <input type="checkbox"/> with a certain medical condition <input type="checkbox"/> receiving a certain treatment, preventive health intervention or procedure	<input type="checkbox"/> Health facility <input type="checkbox"/> Insurance scheme <input type="checkbox"/> Population-based	
<b>Characteristics of participating patients</b>	Participants <input type="checkbox"/> with a certain disease, disease class, symptom or other medical condition <input type="checkbox"/> receive a certain treatment, e.g. specific medication, medication group, herbal product, vaccine or medical procedure <input type="checkbox"/> receive a certain preventive health intervention or diagnostic procedure	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Both	Age group: <input type="checkbox"/> ≤17 years <input type="checkbox"/> 18-65 years <input type="checkbox"/> ≥66 years <input type="checkbox"/> No age limitation
<b>Outcome measures and results</b>	Do <u>not represent</u> <input type="checkbox"/> Prevalence/incidence/frequency of drug-related morbidity (or synonymous concepts) <input type="checkbox"/> Preventability of drug-related morbidity <u>Represent exclusively</u> <input type="checkbox"/> potential, not actual, morbidity <input type="checkbox"/> specific medical conditions <input type="checkbox"/> effects of chemical compounds (other than medicines), human transmitters, nutrients, nutritional product, alcohol, tobacco or illicit substances <input type="checkbox"/> pharmacodynamic, pharmacokinetic or pharmacogenetic measures	Prevalence/incidence/frequency of drug-related morbidity (or synonymous concepts) <input type="checkbox"/> Mentioned as an outcome measure <input type="checkbox"/> Not mentioned as an outcome measure, but can be interpreted Preventability of drug-related morbidity <input type="checkbox"/> Mentioned as an outcome measure <input type="checkbox"/> Not mentioned as an outcome measure, but can be interpreted	
<input type="checkbox"/> <b>One or more exclusion criteria fulfilled</b> → <b>ARTICLE EXCLUDED</b>		<input type="checkbox"/> <b>None of the exclusion criteria fulfilled</b> → <b>ARTICLE INCLUDED</b> → <b>proceed to page 2</b>	

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Reviewer: KH**PART 2: Methods for prevalence and preventability assessment of drug-related morbidity (DRM)**

<b>Aim of the study</b>		
<b>Definition(s) of drug-related morbidity (DRM)</b>		
<input type="checkbox"/> Adverse drug event (ADE) <input type="checkbox"/> Adverse drug reaction (ADR) <input type="checkbox"/> Drug-related morbidity(DRM) <input type="checkbox"/> Drug-related problem (DRP) <input type="checkbox"/> Medication error (ME) <input type="checkbox"/> Other: _____  <input type="checkbox"/> Not defined	<input type="checkbox"/> According to reference(s) <input type="checkbox"/> Modified from reference(s) <input type="checkbox"/> Own definition (no reference) Description (+ relevant references): _____ _____ _____ _____  <input type="checkbox"/> No definition	
<b>Assessment method of prevalence/incidence/frequency/causality of drug-related morbidity (DRM)</b>		
<b>Measurement:</b> <input type="checkbox"/> Incidence <input type="checkbox"/> Prevalence <input type="checkbox"/> Other frequency measure: _____ _____ <input type="checkbox"/> Not defined	<b>Assessor(s):</b> <input type="checkbox"/> Researcher(s) <input type="checkbox"/> Health professional(s) <input type="checkbox"/> Computer programme <input type="checkbox"/> Other(s) Describe: _____ _____ _____ _____ <input type="checkbox"/> Not defined	<b>Assessment of causality</b> (medication therapy → adverse outcome): <input type="checkbox"/> According to reference(s) <input type="checkbox"/> Modified from reference(s) <input type="checkbox"/> Own definition (no reference) Description (+ relevant references): _____ _____ _____ _____ <input type="checkbox"/> Method not specified (no reference)
<b>Additional description, e.g. information on <u>validity</u> or <u>reliability</u> testing:</b>		
<b>Assessment method of preventability</b>		
<b>Reference:</b> <input type="checkbox"/> Bates et al. 1993/1995 <input type="checkbox"/> Chan et al. 2001 <input type="checkbox"/> Dubois and Brook 1988 <input type="checkbox"/> Hallas et al. 1990 <input type="checkbox"/> Hartwig et al. 1992 <input type="checkbox"/> Hepler and Strand 1990 <input type="checkbox"/> Leape at al. 1995 <input type="checkbox"/> Schumock and Thornton 1992 <input type="checkbox"/> Other reference: _____ _____ <input type="checkbox"/> No reference	<b>Assessor(s):</b> <input type="checkbox"/> Same as above ↑ <input type="checkbox"/> Researcher(s) <input type="checkbox"/> Health professional(s) <input type="checkbox"/> Other(s) Describe: _____ _____ _____ _____ <input type="checkbox"/> Not defined	<b>Description of the method:</b> <input type="checkbox"/> According to reference(s) <input type="checkbox"/> Modified from the reference(s) <input type="checkbox"/> Own method (no reference) Description (+ relevant references): _____ _____ _____ _____ _____ <input type="checkbox"/> Method not specified (no reference)
<b>Additional description, e.g. information on <u>validity</u> or <u>reliability</u> testing:</b>		
<b>Additional notes</b>		
<i>(Please continue writing here in case of shortage of space in any parts of the sheet.)</i>		

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<b><i>Standardising the assessment process</i></b>	
Performing pilot	Yes No
Use of operational manual/guidelines/protocol	Yes No
<b><i>Assessors</i></b>	
Profession	Pharmacist(s) Physician(s) Nurse(s) Not reported
Training for/ experienced in assessment	Yes No
Number of assessors per case	1 $\geq 2$ Not reported
Blinding assessors (if multiple assessors, cat $\geq 2$ from above)	Yes No
Managing conflicting assessments (if multiple assessors, cat $\geq 2$ from above)	Discussion until consensus Discussion and reassessment, consensus not required One assessor interpretation determines assessment Additional assessor(s) Not reported
<b><i>Evaluation of assessment method</i></b>	
Reliability of preventability assessments	Yes, in same article Yes, reference to another article No
Sensitivity of preventability assessments	Yes, reported in same article Yes, reference to another article No
Specificity of preventability assessments	Yes, reported in same article Yes, reference to another article No