FARMAKOVIJILANS İNDIKATÖRLERI REHBERI_EN

Pharmacovigilance Indicators Manual TURKISHMEDICINESANDMEDICALDEVICESAGENCY 23.08.2022

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2 1.Introduction Pharmacovigilancehasattainedthematurityandextentofadisciplinethathasa significantimpactonpatientcareandpublichealth.Therefore,therehasbeenaneedfor developmentofreliableindiceswhichwillenablecomparisonwithinandbetweencountries orregions,allowforanassessmentorquantificationofthegrowthandperformanceof pharmacovigilanceandprovideabaseline. 1.1.DefinitionofPharmacovigilance Pharmacovigilanceisdefinedastheactivitiesandscientificstudiesrelatingtothe detection,assessment,understandingandpreventionofadversereactionsandanyother medicine-relatedproblems. 2.PharmacovigilanceIndicators 2.1.Definitions Indicatorsarespecificobjectivemeasuresthatallowtheevaluationofthecurrentsituation, theprogressinsystems,theservicesandtheinterventions.Pharmacovigilanceindicatorsare measuresofinputs,processes,outputs,outcomes,andimpactsofdevelopmentprojects, programmesorpoliciesrelatedtohealthsystemsandservices.Theyprovideinformationfor measuringhowwellapharmacovigilanceprogrammeisachievingitsobjectives. 2.2.RationaleandObjectivesofPharmacovigilanceIndicators Theindicatorsshouldmeasuretheexistenceandperformanceofkeypharmacovigilance structuresandprocessesandbeabletoidentifythestrengthsandweaknesses,aswellas revealingtheachievements,growthorlackofgrowthofthepharmacovigilancesystems.They shouldalsomeasurethedegreeofattainmentofsetstrategicobjectives.Themainobjectiveof thepharmacovigilanceindicatorsistoensuretheassessmentofpharmacovigilanceactivities andtheirimpactgloballyatalllevelsofthehealth-caresystem,withaviewtoensuringpatient safety.Theavailabilityofthesepharmacovigilanceindicatorswillalsoprovideobjective indicestomeasureperformanceinthisarea.Keyoutputsofusingpharmacovigilance indicators areasfollows: totakeobjectivemeasurestodescribethepharmacovigilancesituationinacountry;

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toassesspharmacovigilanceactivitiesatthenational,regionalandhealthcarefacility levels
toassesspharmacovigilancecapacityattheselevels
toprovidetoolsforsupervisionandmonitoringofpharmacovigilanceactivities
toassessprogressandenabletheprioritizationofinterventionsbasedonthis assessment
toenablecomparisonofpharmacovigilanceactivitiesbetweengeographicalregions
andhealthcarefacilitiesatagiventimeandatdifferenttimes
toprovidetoolsformeasuringtheimpactofinterventions
toprovideinformationforgovernmentsandotherstakeholderstoenablethemtotake
appropriateactioninensuringmedicinesafety 2.3.CharacteristicsofIdealPharmacovigilanceIndicators
Theseindicatorsareintendedtohavefourimportantcharacteristics.Theyshould:
besimpletounderstand notrequiregreatexpertisetomeasureandinterpret bereproducible
3 bespecificandsensitivesothattheyareabletodetectpharmacovigilance
problemsthatrequireattentionaswellaschangesinthepharmacovigilance systems
2.4.ClassificationofPharmacovigilanceIndicators
Somequantitativeinformationisneededbeforeusingpharmacovigilanceindicators(see
Annex1).Thisinformationwilldefineanddescribetheenvironmentwherethe
pharmacovigilanceactivitiestakeplaceandotherfactorslikelytohaveimpacton
pharmacovigilance.Theinformationobtainedwillcoverdemographics,economics,the
health-caresystemandthepharmaceuticalscenario.Thepharmacovigilanceindicatorsare
classifiedintothefollowingthreegroups: Structuralindicators Processindicators
Outcomeorimpactindicators 2.4.1.StructuralIndicators
Thestructuralindicatorsassesstheexistenceofkeypharmacovigilancestructures,
systemsandmechanismsinthesettingbeingstudied.Availabilityofbasicinfrastructureis
requiredtoconductpharmacovigilanceoperations.Theseindicatorsassesstheelementsthat
givevisibilitytopharmacovigilance.Theyalsoassesstheexistenceofapolicyandregulatory
frameworkwhichenablepharmacovigilancetooperate.Theseindicatorsareessentially qualitative.
2.4.2.ProcessIndicators Theprocessindicatorsassesstheextentofpharmacovigilanceactivities.
Theyfocusonthechainofactivitieswhichdescribethemechanismofpharmacovigilance
(thecollection,analysisandevaluationofadversereactionreports).Theyalsoconsiderother
activitieswhichinfluencethoselistedabove.Thesearemeasuresthatassessdirectlyor
indirectlytheextenttowhichthesystemisoperating. 2.4.3.OutcomeandImpactIndicators
Theoutcomeandimpactindicatorsmeasuretheeffects(resultsandchanges)of
pharmacovigilanceactivities.Theymeasuretheextentofrealizationofthepharmacovigilance
objectiveswhich,inessence,constituteensuringpatientsafety.
3.WorldHealthOrganizationPharmacovigilanceIndicators
Thetwosuggestedcategories(CoreandComplementaryIndicators)areexplainedbelow.
Eachofthecategoriesincludethreetypesofindicators(structural,processandoutcomeor
impact).Additionally,asetofindicatorshavebeenselectedtoaddresspublichealth
programmes.However,thiswillnotbeaddressedinthismanual.
1.Coreindicators(C)arethoseconsideredtobeimportantandusefulincharacterizing
pharmacovigilance.
2.Complementaryindicators(T)areadditionalmeasurementsconsideredtoberelevant
anduseful.Theyservetofurthercharacterizethepharmacovigilancesituationinthestated
settingbutneednotbeusedinallinstances. 3.1.CorePharmacovigilanceIndicators
Thereare27corepharmacovigilanceindicators:10structural,9processand8outcome
orimpactindicators.
4 3.1.1.CoreStructuralIndicators Thereare10corestructuralindicators(CSTs).
CST1.Existenceofapharmacovigilancecentre
CST2.Existenceoflegalinfrastructure(nationalpolicy,legislation)forpharmacovigilance
CST3.Existenceofamedicinesregulatoryauthorityormedicinesagency
CST4.Existenceofregularstatutorybudgetforthepharmacovigilancecentre

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CST5.Thepharmacovigilancecentrehassufficienthumanresourcestocarryoutitsfunctions duly
CST6.Existenceofastandardadversereactionreportingforminthehealthcarefacilities
Subsetindicators:Thestandardformenablesreportinginthefollowingsituations.
CST6a:Suspectedmedicationerrors
CST6b:SuspectedcounterfeitorsubstandardmedicinesCST6c:Therapeutic ineffectiveness
CST6d:Suspectedmisuse/abuseofand/ordependenceonmedicinesCST6e:Adverse
reactionsreportedbythegeneralpublic
CST7.Availabilityofaprocessforcollection,recordingandanalysisofadversereaction reports
CST8.Incorporationofpharmacovigilanceintothenationalcurriculumofvarioushealthcare
professionals Subsetindicators: CST8a:Formedicaldoctors CST8b:Fordentists CST8c:Forpharmacists
CST8d:Fornursesormidwives CST8e:Forothers(tobespecified)
CST9.Existenceofanewsletter,informationbulletinand/orwebsiteforpromulgationof
informationrelatedtopharmacovigilance CST10.Existenceofapharmacovigilanceadvisorycommittee
3.1.2.Coreprocessindicators Thereare9coreprocessindicators(CPs).
CP1.Totalnumberofadversereactionreportsreceivedinthepreviouscalendaryear(also
expressedasthenumberofadversereactionsper100.000personsinthepopulation)
CP2.Currenttotalnumberofreportsinthenationaldatabase
CP3.Percentageoftotalannualreportsacknowledgedand/orissuedfeedbackfor
CP4.Percentageoftotalreportssubjectedtocausalityassessmentinthepreviouscalendar year
CP5.Percentageoftotalannualadversereactionreportswithrelevantsections
satisfactorilycompletedandsubmittedtothenationalpharmacovigilancecentrein
thepreviouscalendaryear
SubsetindicatorCP5a:ofthereportswithrelevantsectionssatisfactorilycompleted
andsenttothenationalpharmacovigilancecentre,percentageofreportssenttothe WHOdatabase
CP6.Percentageoftotalreportsattributedtotherapeuticineffectivenessreceivedinthe
previouscalendaryear CP7.Percentageofreportsonmedicationerrorsreportedinthepreviousyear
5 CP8.Percentageofregisteredpharmaceuticalcompanieshavingafunctional
pharmacovigilancesystem
CP9.Numberofactivesurveillanceactivitiesinitiated,ongoingorcompletedduringthe
pastfivecalendaryears 3.1.3.Coreoutcomeorimpactindicators
Thereareeightoutcomeorimpactindicators.
C01.Numberofsignalsdetectedinthepastfiveyearsbythepharmacovigilancecentre
C02.Numberofregulatoryactionstakeninthepreviousyearasaconsequenceofnational
pharmacovigilanceactivities C02a:NumberofSmPC/PILchanges(variation)
C02b:Numberofsafetywarningsonmedicines: (i)Healthcareprofessionals (ii)Generalpublic
C02c:Numberofmedicineswithdrawn C02d:Numberofotherrestrictionsonuseofmedicines
C03.Numberofmedicine-relatedhospitaladmissionsper1000admissions
C04.Numberofmedicine-relateddeathsper1000personsservedbythehospitalperyear
C05.Numberofmedicine-relateddeathsper100.000personsinthepopulation
C06.Averagecostoftreatmentofmedicine-relatedillnesses
C07.Averageduration(days)ofmedicine-relatedextensionofhospitalstay
C08.Averagecostofmedicine-relatedhospitalization 3.2.Complementaryindicators
Thereare36complementaryindicators:11structural,13processand12outcomeorimpact
3.2.1.Complementarystructuralindicators
The11complementarystructuralindicatorsaregivenbelow.
ST1.Existenceofcomputer(s)dedicatedtopharmacovigilanceactivities
ST2.Existenceofasourceofdataonconsumptionandprescriptionofmedicines
ST3.Existenceoffunctioningandaccessiblecommunicationfacilitiesinthe pharmacovigilancecentre
ST4.Existenceofalibrary/referencesourcetoreachinformationonmedicinesafety
ST5.Existenceofacomputerizedcasereportmanagementsystem
ST6.Existenceofaprogramme(includingalaboratory)formonitoringthequalityof

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pharmaceuticalproducts
SubsetindicatorST6a:Theprogramme(includingalaboratory)formonitoringthe qualityofpharmaceuticalproductscollaborateswiththepharmacovigilance programme.
ST7.Existenceofanessentialmedicineslistwhichisinuse
ST8.Systematicconsiderationofpharmacovigilancedatawhendevelopingthemain standardtreatmentguidelines ST9.Thepharmacovigilancecentreorganizestrainingprogrammes

ST9a:forhealthcareprofessionals ST9b:forgeneralpublic
ST10.Availabilityofweb-basedpharmacovigilancetrainingtools ST10a:forhealthcareprofessionals ST10b:forgeneralpublic
ST11.Existenceofrequirementsthatmandatemarketauthorizationholderstosubmit periodicbenefit/riskevaluationreports 3.2.2.Complementaryprocessindicators
The13complementaryprocessindicatorsaregivenbelow.
P1.Percentageofhealthcarefacilitieshavingafunctionalpharmacovigilanceunit(i.e. submitting≥10reportstothepharmacovigilancecentre)inthepreviousyear
P2.Percentageoftotalreportssentinthepreviousyearbydifferentstakeholdersincludes:
P2a:percentageoftotalreportssentbymedicaldoctors P2b:bydentists P2c:bypharmacists P2d:bynursesormidwives P2e:bythegeneralpublic P2f:bymarketingauthorizationholders
P3.Totalnumberofreportsreceivedpermillionpopulationperyear
P4.Averagenumberofreportspernumberofhealthcareprofessionalsperyear P4a:bymedicaldoctors P4b:bydentists P4c:bypharmacists P4d:bynursesormidwives
P5.Percentageofhealthcareprofessionalsawareofandknowledgeableaboutadverse reactionsperhealthcarefacility
P6.Percentageofpatientsleavingahealthcarefacilityasawareofadversereactions
P7.Numberofface-to-facetrainingsinthefieldofpharmacovigilanceorganizedinthe previousyear P7a:forhealthcareprofessionals P7b:forgeneralpublic
P8.P8.Numberofindividualswhoreceivedface-to-facetrainingonpharmacovigilancein thepreviousyear P8a:Numberofhealthcareprofessionalstrainedinthepreviousyear P8b:Numberofindividualsfromthegeneralpublictrainedinthepreviousyear
P9.Totalnumberofnationalreportsforaspecificproductpervolumeofsalesofthat productinthecountry(productspecific)fromtheindustry
P10.Numberofregisteredproductswithapharmacovigilanceplanand/orariskmanagement strategyamongthemarketingauthorizationholdersinthecountry
SubsetindicatorP10a:Percentageofregisteredproductswithapharmacovigilanceplan and/orariskmanagementstrategyofthemarketingauthorizationholdersinthecountry
P11.Percentageofmarketingauthorizationholderswhosubmitperiodicbenefit/risk evaluationreportstothemedicinesregulatoryauthority(TurkishMedicinesand MedicalDevicesAgency)asstipulatedinthecountry
P12.Numberofmedicinalproductsvoluntarilywithdrawnbymarketingauthorization holdersbecauseofsafetyconcernsinthepreviousyear
SubsetindicatorP12a:NumberofSmPCsupdatedbymarketingauthorizationholders becauseofsafetyconcernsinthepreviousyear
P13.Numberofreportsreceivedinthepreviousyearfromeachpharmaceuticalcompany registeredwithpharmacovigilancecentre

3.2.3.Complementaryoutcomeorimpactindicators
The12outcomeorimpactindicatorsaregivenbelow.
01.Percentageofpreventableadversereactionsreportedinthepreviousyearoutofthetotal numberofadversereactionsreported 07.Costsavingsattributedtopharmacovigilanceactivities
02.Numberofmedicines-relatedcongenitalmalformationsper100.000births
03.Numberofmedicinessupposedtobeassociatedwithcongenitalmalformationsinthe past5years
04.Percentageofmedicinesinthepharmaceuticalmarketthatarecounterfeitorsubstandard
05.Numberofpatientsaffectedbyamedicationerrorinhospitalper1000admissionsinthe previousyear

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06.Averageworkorschooldayslostduetodrug-relatedproblems
08.Healthbudgetimpact(annual)attributedtopharmacovigilanceactivity Rationaluseofmedicines
09.Averagenumberofmedicinesperprescription
010.Percentageofprescriptionswithmedicinesexceedingthedoserecommendedbythe manufacturer
011.Percentageofprescriptionformsprescribingmedicineswithpotentialforinteraction
012.Percentageofpatientsreceivinginformationontheuseoftheirmedicinesandon potentialadversereactionsassociatedwiththosemedicines 4.Descriptionofcoreindicators
4.1.Corestructuralindicators CST1:Existenceofapharmacovigilancecentre Definition
Thepresenceofaspacespecificallydedicatedtopharmacovigilanceactivities Descriptionanduses
Theexistenceofacentreforpharmacovigilanceactivityprovidesthenecessaryvisibility forpharmacovigilanceandameetingpointforinteraction.Italsoindicatespoliticaland administrativecommitmenttowardsachievingpharmacovigilanceobjectives.
Thecentreshouldhavethebasicofficeequipmentandfacilitiesrequiredtocollect, analyzeandtransmitindividualcasesafetyreports(ICSRs)toWorldHealthOrganization UppsalaMonitoringCentre(WHO-UMC)andtoprovidethenecessaryfeedbackand communication.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Theindicatorisqualitativeandthepresenceorabsenceofcentreisnoted.Thesourceof informationshouldbetheMinistryofHealthofthecountryconcernedsinceitplaysa supervisoryroleforallmattersofhealth.Thepharmacovigilancecentremustberecognized and/oraccreditedbytheMinistryofHealth. Limitations
Non-functionalpharmacovigilancecentresarenottakenintoaccount.
CST2:Existenceoflegalinfrastructure(nationalpolicy,legislation)forpharmacovigilance Definition
Thepresenceofastatutoryprovisionissought.
 Descriptionanduses
Thisindicatorshoulddescribethespecificsfortheauthoritiesempoweredtocarryout pharmacovigilanceactivitieswithwell-definedrolesandresponsibilities.
Theexistenceofthisindicatorhighlightsthecommitmentofthegovernmenttoensuring thesafeuseofmedicines.Itthereforeenablestheoperatorstocarryouttheirworkwith convictioninthecentre. Sourcesandmethodsofdatacollectionandindicatorcalculation
Theindicatorisqualitativeandthepresenceorabsenceofcentreisnoted.Thesourceof informationshouldbetheMinistryofHealthofthecountryconcernedsinceitplaysa regulatoryandsupervisoryroleforallmattersofhealth. Limitations
Themerepresenceofanenablinginstrumentdoesnotindicateafunctional pharmacovigilancesystem. Also,theexistenceoflegislationdoesnotimplythatitisspecificandcomprehensiveorup-to- date.
CST3:Existenceofamedicinesregulatoryauthorityormedicinesagency Definition
Theexistenceofanorganresponsibleforregulatingthelegislationonthemedicines Descriptionanduses
Theindicatorisqualitativeandthepresenceorabsenceofamedicinesregulatory authorityisnoted.Thepresenceofaregulatoryandsupervisoryagencyindicatesthe availabilityofaregulatoryframeworkformedicinalproductsforhumanuseasanimportant stakeholderandfocalpointforpromotingpharmacovigilance.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Theinformationonthepresenceofamedicinesregulatoryagencyshouldbeobtainedfrom theMinistryofHealth. Theinformationisqualitative,andthepresenceorabsenceisnoted. Limitations
Thelimitationofthisindicatorisitsinabilitytoexpressthefunctionalstatusand effectivenessoftheoperationsconcerningpharmacovigilance.
CST4:Existenceofregularfinancialbudgetforthepharmacovigilancecentre Definition
Afinancialarrangementspecifictothepharmacovigilancecentrereferstotheprovision ofaregular(e.g.yearly)andsustainedfundingsourcetoenabletherunningofthefacility.
Descriptionanduses
Thisindicatordenotesthepresenceorabsenceofastatutorybudgetandfundingsource.
Theavailabilityoffundingrepresentsthepossibilityforthecentretocarryout

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pharmacovigilanceactivities.Italsosignifiesthegeneralimportancegivento pharmacovigilance.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Theinformationregardingtheprovisionoffundingshouldbeobtainedfromthe pharmacovigilancecentre.Theinformationisqualitative,andthepresenceorabsenceisnoted.
Limitations Thelimitationofthisindicatoristhattheactualbudgetaryallocationorthetotalamount availabletothecentretofinanceitsactivitiesisnotstated.Therefore,itisnotpossibletostate whetherthefundingissufficienttoensuretheeffectiveoperationofthecentre.
CST5:Thepharmacovigilancecentrehassufficienthumanresourcestocarryoutits functionsduly
Definition Theavailabilityinthepharmacovigilancecentreoftrainedstafftocarryoutallessential
9 functionsduly. Descriptionanduses
Thisindicatorsuggeststhepresenceofhumanresourcesinthepharmacovigilancecentreto takeonthevariousdutiesandresponsibilitiesexpected.Itprovidesameasureofthenumberof staffrequiredforeffectiveoperationofapharmacovigilancecentre
Sourcesandmethodsofdatacollectionandindicatorcalculation
Thepharmacovigilancecentreshouldberequestedtosupplythedataforthisindicator.
Theinformationobtainedshouldalsoincludethenumberofstaffinthecentre.Thenumberof full-timeandpart-timestaff,ifany,shouldbenotedandrepresentedasfull-timeequivalents.
Thisinformationshouldbecomparedwiththeexpectedtotalfull-timeequivalentsrequiredto enablethepharmacovigilancecentretofulfillallitsdutiesandresponsibilities.The informationobtainedisqualitative,andthepresenceorabsenceofadequatestaffisnoted. Limitations Themainlimitationofthisindicatorisitsinabilitytoassessandstatethelevelof expertiseofthepersonnelandthismayaffectthestandardsofthecentre.
CST6:Existenceofastandardadversereactionreportingforminthehealthcarefacilities
Subsetindicators:Thestandardadversereactionformprovidesforreporting:CST6a: Suspectedmedicationerrors CST6b:Suspectedcounterfeitorsubstandardmedicines
CST6c:Therapeuticineffectiveness
CST6d:Suspectedmisuse/abuseofand/ordependenceonmedicines
CST6e:Adversereactionsreportedbythegeneralpublic Definition
Thisindicatorrelatestotheuseofastandardadversereactionreportingform. Usesanddescription
Theindicatormeasuresthepresenceofadatacollectiontoolforpharmacovigilance operations.Itstatesthatthetoolrequiredforcollectingcriticalinformationonasuspected medicine-relatedadversereactionhasbeenfullyintegratedintothepharmacovigilancesystem.
Theadversereactionreportingformshouldcontainallelementsnormallyrequiredto enablecausalityassessmentofacasebasedonclinicalevidence.
Thesubsetindicators(CST6a–CST6d)includetherelevantsectionsofadversereaction formtoenableandtoencouragehealthcareprofessionalstoreportonallthareascoveredby pharmacovigilance.ThesubsetindicatorCST6ereferstotherecognitionofthegeneralpublic asstakeholdersinpharmacovigilanceanditalsomeasuresthepreparednessofahealthcare facilitytosupportreportingofadversereactionsbythegeneralpublic.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Theinformationshouldbeobtainedfromthepharmacovigilancecentre.Theinformation obtainedisqualitative,andthepresenceorabsenceisnoted. Limitations
Thelimitationofthisindicatoristhatitreportsthepresenceinthesystemofareporting formanddoesnotprovideinformationonhowitisputtouse.Thefunctionalityistherefore notassessed.
Theinformationcoveredbythefoursubsetindicators(CST6a–CST6d)mayalsobecollected byinformationmanagementtoolsotherthanthereportingforms(e.g.medicalrecords),and theinformationisthensenttothepharmacovigilancecentre.Thismayleadtoduplication.
CST7:Availabilityofaprocessforcollection,recordingandanalysisofadversereaction reports Definition
10 Thisreferstotheexistenceofachainofactivitiesrelatingtothecausalityassessment, feedbackandsubmissiontoWHOUppsalaMonitoringCentre'sdatabaseofadversereaction reports.
Descriptionanduses

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Theresponseisqualitativebutwillassessthepresenceofareportmanagementprocess withprovisionforfeedback,causalityassessmentandanelectronicdatabase.Thisindicatoris ameasureofthefunctionalityandpresenceofanoperationalprocessinthe pharmacovigilancecentre.Sourcesandmethodsofdatacollectionandindicatorcalculation Theheadofthepharmacovigilancecentrewillsupplythenecessarydataforthisindicator. Aqualitativeresponseisobtained,i.e.presenceorabsenceoftheprocess. Limitations Themainlimitationofthisindicatoristhatitisaqualitativemeasureofthepresenceor absenceofacasemanagementsystemandprovidesnoinformationontherelevantprocess. CST8:Incorporationofpharmacovigilanceintothenationalcurriculumofvarious healthcareprofessionals CST8a:Formedicaldoctors CST8b:Fordentists CST8c:Forpharmacists CST8d:Fornursesormidwives CST8e:Forothers(tobespecified) Definition Thisindicatorassesseswhetherpharmacovigilancehasbeenincorporatedintothe nationalcurriculumofthevarioushealth-careprofessions. Descriptionanduses Theincorporationofpharmacovigilanceintothenationalcurriculumfortraining healthcareprofessionalsimpliesanearlylearningofpharmacovigilancebythevarious categoriesofpersonnelengagedinthecareofpatients.Thisprocesssensitizesthehealthcare professionalsearlyintheircareertoissuesregardingthesafetyofmedicines.Itisanessential stepinintegratingpharmacovigilanceintothehealthcaresystem.Theabsenceof pharmacovigilanceinthetrainingcurriculumsuggestsalackofpreparednessofthehealthcare professionalsforcareerchallengesonissuesofsafetyofmedicines. Sourcesandmethodsofdatacollectionandindicatorcalculation Theinformationshouldbeobtainablefromtherelevantprofessionalregulatorybodiesfor medicaldoctors,pharmacists,nursesandotherrelatedprofessionsuponrequest. Theresponseisqualitative(Intheformofyes/noforeachprofessionalcategory). Limitations Itisnotpossibletoobtaininformationaboutthequalityoftrainingwiththisindicator: Themainlimitationofthisindicatorisitsinabilitytoelicittheextentofimplementation. CST9:Existenceofanewsletter,informationbulletinand/orwebsiteforpromulgationof informationrelatedtopharmacovigilance Definition Thisindicatorreferstothepresenceofasystemfortheregulardisseminationof informationonmedicinessafetytohealthcareprofessionalsandtothepublic(newsletter and/oraninformationbulletinand/orawebsite). Descriptionanduses Oneoftheexpectedfunctionsofanationalpharmacovigilancesystemistoprovide effectivecommunicationonaspectsrelatedtosafetyofmedicines.

11 Aclearstrategyforroutinecommunicationandcommunicationduringcrisesisoneofthe minimumrequirementsforafunctionalnationalpharmacovigilancesystem. Sourcesandmethodsofdatacollectionandindicatorcalculation Theinformationregardingtheexistenceofthiskindofcommunicationtool(s)shouldbe obtainablefromthepharmacovigilancecentre.Theinformationisqualitativeandthepresence orabsenceofthetool(s)isnoted. Limitations Thequalityandfrequencyofthecommunication(includingthevalidityofitscontent,the relevancetotheaudience,theeffectivenessandefficiencyofthemediachosen)arenot assessed.Thisindicatordoesnotassessthepreparednessandeffectivenessofthe pharmacovigilancecentreincommunicatingintheeventofacrisisanditcannotmeasurethe impactoftheinformationonprofessionalbehaviour. CST10:Existenceofapharmacovigilanceadvisorycommittee Definition Thisindicatorreferstotheexistenceofaqualifiedcommitteethatcanprovideadviceand technicalassistanceoncausalityassessment,riskassessment,riskmanagement,case investigationand,wherenecessary,crisismanagementincludingcrisiscommunication. Descriptionanduses Theresponseisqualitativeandindicateswhetherpharmacovigilancecentrestaffisable toachievesufficientcompetencetosupportallthemainfunctionsofapharmacovigilance

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system.Acommitteeshouldbecomposedofaminimumofthreepeoplewithdifferent professionalbackgroundsinhealthcareandshouldmeetregularly.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Thedatashouldbeobtainablefromthepharmacovigilancecentre.Aqualitativeresponse isobtained:presentorabsent. Limitations
Themainlimitationofthisindicatoristhatitdoesnotmeasurethebreadthordepthofthe competenciesrepresentedinthecommittee,thefrequencyofitsmeetingsortherelevanceof itsadvicetothepharmacovigilancecentre. 4.2.Coreprocessindicators
CP1:Totalnumberofadversereactionreportsreceivedinthepreviouscalendaryear
100.00(alsoexpressedasthenumberofadversereactionperpersoninthepopulation) Definition
Thisindicatorstatesthenumberofadversereactionreportsreceivedannuallybythe centre.Itisanindicatorofthevolumeofreportsgeneratedwithinthepopulation. Descriptionanduses
Theindicatorservestomeasurethepharmacovigilanceactivity,itsawarenessandthe awarenessandthewillingnessofhealthcareprofessionalstoreport.
Validcasereportsshouldcontainthefourcoredataelements,asperICH-E2A: Reporter Identifiablepatient Suspectedmedicines Adversereaction
Whenexpressedinrelationtothepopulation,itallowsforcomparisonbetweencountries, andwithinfacilities,regionsorzoneswithinacountry.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Themainsourceofdataisthedatabaseatthenational,orotherrelevant pharmacovigilancecentrewhererereportsarereceivedandcollated. Thevaluesofthisindicatorare Absolutenumberofreportsand
12 thenumberofreportsper100.000peopleinthepopulation(Usefulforcomparative purposes).
Limitations Thequalityofthedocumentationorrelevanceforsignalidentificationwillnotbemeasured.
CP2:Currenttotalnumberofreportsinthenationaldatabase Definition
Thisindicatorreferstothecurrenttotalnumberofreportsintherelevantdatabase. Descriptionanduses
Theindicatorisameasureofcumulativereportsinthedatabasesinceitsinception.Itis alsoameasureofpharmacovigilanceactivitiesandthestrengthofthedatabase.Thesizeofa databaseanditspaceofgrowthovertime(obtainedfromCP1),canbeusedforcomparative purposesandprovidesusefulinformation.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Themainsourceofthedataisthedatabaseintherelevantpharmacovigilancecentre.The datacanbeobtainedfromtheheadofthepharmacovigilanceunit. Limitations
Themainlimitationofthisindicatoristhatwhileitconsidersthesizeofthedatabase, thereisnoinformationonthequalityofreports.Therationalebehindreportingtrends (investigatedthroughCP1)cannotbedeterminedthroughthisindicator.
CP3:Percentageoftotalannualreportsacknowledged/issuedfeedback Definition
Thisindicatorreferstotheproportionofthereportsforwhichtheadversereaction reportersreceivedacknowledgementorinformationfromtheofficialsofthe pharmacovigilancecentre.
Descriptionanduses
Itisexpectedthatinresponsetoreceivinganadversereactionreport,thepersonnelinthe pharmacovigilancecentrewillprovideaninformedacknowledgementtothereporting healthcareprofessionals.Thenumberofreportsprovidedwiththisfeedbackisdocumented.It isameasureoftheresponsivenessofthecentretosubmittedreports.
Ahighpercentagesuggestsacommendablelevelofresponsebythepersonnelatthe pharmacovigilancecentre.Lowfeedbackratesplayadissuasiveroleforhealthcare professionals.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Themainsourceofthedataisthepharmacovigilancecentrewhichshouldproviderecords ofthenumberofreportsprovidedwithfeedbackandthetotalnumberofreports.The indicatorcanthenbecalculatedasfollows:
Numberofreportsforwhichfeedbacksprovidedwithinoneyear×100

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Numberofreportsintotalreceivedinoneyearperiod Limitations Thelimitationofthisindicatoristhatitdoesnotassessthequalityofthecontentorthe delayinprovidingthefeedback.

CP4:Percentageoftotalreportssubjectedtocausalityassessmentinthepreviouscalendar year Definition Theindicatorreferstotheproportionofreportssubjectedtocausalityassessmentinthelast calendaryear.

13 Descriptionanduses Thecharacterizationofareportanddeterminationofitsqualityiscarriedouttoalarge extentduringthecausalityassessment.Itisameasureoftheactivitiesofthenationalcentre staffandthoseoftheadvisorycommitteesresponsibleforcarryingoutthisassignment.The proportionofreportsassessedinthecentreisanindicatoroftheleveofcommitmentto processingthesafetydataandensuringitsquality,especiallywhensendingreportstothe WHOdatabase.Lowvaluesmightsuggestalackofthenecessaryexpertisetocarryout causalityassessmentandaweakpharmacovigilancesystem.Insomecentreswithlarge databases,causalityanalysisiscarriedoutsubsequenttostatisticalanalysisofalargenumber ofreportssubmitted.Theindicatorwillhavealowvalueinthesecircumstancesaswell.

Sourcesandmethodsofdatacollectionandindicatorcalculation Thedataforcalculatingthisindicatorshouldbeobtainedfromthepharmacovigilance centrerecords.Thisshouldincludethenumberofreportssubjectedtocausalityassessmentin theyearunderconsiderationandthetotalnumberofreportsreceivedinthesameperiod. Theindicatorvaluecanbecalculatedasfollows:

Numberofreportssubjectedtocausalityassessmentduringtheyear×100 Totalnumberofreportsreceivedinthesameperiod Limitations Alimitationofthisindicatoristhatitdoesnotstatethequalityofcausalityassessment.

CP5:Percentageoftotalannualadversereactionreportswithrelevantsectionssatisfactorily completedandsubmittedtothenationalpharmacovigilancecentreinthepreviouscalendar year SubsetindicatorCP5a:Ofthereportswithrelevantsectionssatisfactorilycompletedand senttothenationalpharmacovigilancecentre,percentageofthosesenttotheWHOdatabase. Definition Thisindicatorreferstotheproportionoftotalreportsreceivedannuallyatthe pharmacovigilancecentrethathaveallthereleventfieldsforcausalityassessment satisfactorilyfilledin.Then,thesubsetindicatorCP5areferstothosereportssenttotheWHO databasemanagedbyUMC(satisfactorilycompletedatthepharmacovigilancecentreand sent).

Sourcesandmethodsofdatacollectionandindicatorcalculation Thedatarequiredtocalculatethisindicatorvalueshouldbeavailableatthe pharmacovigilancecentre.Itscalculationwillentailareviewofallthereportsinthe pharmacovigilancecentredatabasetoevaluatewhetherthevariousfieldsintheadverse reactionreportingformwerefilledin.Forthesubsetindicator,itisnecessarytocheck whetherthecompletedreportsweresenttotheWHOdatabase.Wherethepharmacovigilance centredatabaseislarge,evaluationshouldbemadeusingsystematicrandomsamplingofthe reports. Thevalueisobtainedasfollows: Numberofreportscompletedsatisfactorilywithintheyear×100 Numberoftotalreportsreceivedinthesameperiod

ThevalueofthesubsetindicatorCP5aisobtainedasfollows:

14 Numberofreportscompletedsatisfactorilyand numberofreportssenttotheWHOdatabaseduringtheyear×100 Numberoftotalreportsreceivedinthesameperiod Limitations Onelimitationisthetimeandeffortrequiredtoinitiatetheprocessofdevelopingthis indicatorinagivensetting.Onceestablishedandincorporatedintotheroutineofthecentre, theprocessbecomeslesscumbersome.

CP6:Percentageoftherapeuticineffectivenessreportsreceivedinthepreviousyear Definition Thisindicatoridentifiesfailedtreatmentsduetoineffectivenessofmedicinesusedinthe healthcaresystem. Descriptionanduses

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Thetotalnumberofreportsreceivedinthepharmacovigilancecentreisdocumented.
Failedtreatmentcasesinthehealthsystemattributabletomedicinessuggesttheexistenceof pharmaceuticalortherapeuticissuesthatneedtobeaddressed.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Thedatacanbeobtainedfromthepharmacovigilancecentredatabaseandthetotal numberoftreatmentfailuresforagivenyearshouldbedocumented.Thisisexpressedasa proportion(percentage)oftotalreportsinthedatabase. Theindicatorisanalyzedasfollows:
Numberoftherapeuticineffectivenessreportswithintheyear×100
Numberoftotalreportsreceivedinthesameyear Limitations
Themainlimitationofthisindicatoristhatitdoesnotreallycapturethemagnitudeandthe typeoftheprobleminthesettingsincetherapeuticineffectivenesscanberelatedtovarious factors,suchasthequalityofmedicines,emergenceofdrugresistance,interactions,irrational use,orlackofpharmacologicalefficacy.Theinformationobtainedmayalsooverlookissues suchasthequalityofreporting.However,itisausefulmeasureforfollowingthetrends.
CP7:Percentageofreportsonmedicationerrorsreportedinthepreviousyear Definition
Thisindicatoridentifiesthefailureintreatmentprocessesthatresultedinharmtopatients.
Descriptionanduses Thetotalnumberofmedicationerrorsreportedtothepharmacovigilancecentreis documented.Theoccurrenceoftheseerrorsindicatestheexistenceoffundamentalsystemic issueswhichshouldbeaddressedtoensurepatientsafety.However,areviewofthepatterns andprofileovertimewillbeusefulinidentifyingproblemsrelatingtomedicationerrorsthat requireattention. Sourcesandmethodsofdatacollectionandindicatorcalculation
Thedataforthisindicatorcanbeobtainedfromthepharmacovigilancecentredatabase bydocumentingthetotalnumberofpreventableadversereactionsforagivenyear.Itmaybe necessarytocarryoutanin-depthreviewofreportsinthedatabasetoidentifymissed medicationerrorsreportedsolelyasadversereactions.
Absolutenumbersshouldbedocumentedandthetrendovertimeshouldbenoted.Thisvalue mayneedtobeexpressedasaproportionoftotalreports(adversereactions+allother reports),especiallywherethereisaunifiedreportingsystem.
15 Limitations
Themainlimitationofthisindicatoristhatitdoesnotreallycapturethemagnitudeofthe medicationerrorssincethisisinfluencedbymanyotherfactors.However,itisauseful measureinfollowingthetrendsinreportingmedicationerrorsandthefactorsthatimpacton thisactivity.
CP8:Percentageofregisteredpharmaceuticalcompanieshavingafunctional pharmacovigilancesystem Definition Thisindicatorstatestheproportionofregisteredpharmaceuticalcompaniesthathavea functionalpharmacovigilancesystem. Descriptionanduses
Thefunctionalpharmacovigilancesettingdescribestheprovisionofastandardregulation, theengagementofaqualifiedpersonforpharmacovigilance(Pharmacovigilanceofficial),an effectivereportingsystem,developmentandsubmissiontotheAgencyofperiodic benefit/riskassessmentreports(PBRERs),andotherrelevantpharmacovigilanceactivities.
Theindicatorprovidesinformationontheproportionofindustriesthatcontributetoensuring thesafetyofmedicines.Therefore,lowvaluesofthisindicatorsuggestalessthanacceptable levelofinvolvementofthepharmaceuticalcompaniesinpharmacovigilanceactivities.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Therelevantinformationcanbeobtainedfrombooththepharmaceuticalcompaniesandthe pharmacovigilancecentre. Theindicatorvaluecanbeobtainedasfollows:
Numberofpharmaceuticalcompanieshavingafunctional pharmacovigilancesystem×100
Numberoftotalregisteredpharmaceuticalcompaniesinthesetting Limitations
Themainlimitationoftheindicatorstemsfromthechallengeinassessingthe functionalityofthepharmacovigilancesystemofthepharmaceuticalcompanies.Thus,the extentofpharmacovigilanceactivityintheindustrieswillneedtobeconsideredas appropriateornot(“functionalornot”)bythepharmacovigilancecentre.Thisindicator

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requiresthepharmacovigilancecentretohaveaclearandsystematicassessmentschemefor evaluatingthepharmacovigilancesystemsofpharmaceuticalcompaniesandtouseit consistently. CP9:Numberofactivesurveillanceactivitiesinitiated,ongoingorcompletedduringthepast fivecalendaryears Definition Thisindicatorreferstothenumberofactivesurveillanceeffortsthatareongoingorthat wereconductedinthesettinginthepastfiveyears. Descriptionanduses Theindicatormeasuresthenumberofactivesurveillanceefforts(e.g.phase4clinical trials,cohorteventmonitoring,targetedspontaneousreporting,pregnancyexposureregistry orotherepidemiologicalstudies)thatareorwereimplementedinthesetting.Suchactive surveillanceeffortsmaybecriticalwhenintroducingnewproductsforthetreatmentoflarge populations,tocharacterizespecificadversereactionsortofocusonspecificpopulationsor problems.Thevalueofthisindicatorreflectsthedynamismofpharmacovigilanceand regulatoryactivitiesaswellastheawarenessofthepharmacovigilancecentre. Sourcesandmethodsofdatacollectionandindicatorcalculation Themainsourcesofthedataarethepharmacovigilancecentre,thenationalmedicines regulatoryagencies,thepublichealthprogrammesandthemedicinemanufacturingindustry. Limitations

16 Themainlimitationofthisindicatoristhatitdoesnotprovideanyinformationaboutthe qualityofsuchstudies.Also,thepharmacovigilancecentremaynotbeawareofallstudies conducted. 4.3.Coreoutcomeorimpactindicators

C01:Numberofsignalsdetectedinthepastfiveyearsbythepharmacovigilancecentre Definition Thisindicatorreferstothenumberofsignalsidentifiedfromthenationaldatabaseinthe precedingfiveyears. Descriptionanduses Thisindicatorcontributestomeasuringtheabilityofthepharmacovigilancesystemto ensurethesafetyofmedicines.Theabilityofthepharmacovigilancesystemtodetectsignals underscoresitsimportanceinensuringthesafeuseofmedicines. Theinferencesthatcanbedrawnfromthisindicatorincludethestatusandqualification ofthedatabase,theexpertiseofthepharmacovigilancestaff,thedynamicsofthe pharmaceuticalsystemandreportingofadversereactionsduetothemedicines,theirquality andtheiruse. Sourcesandmethodsofdatacollectionandindicatorcalculation Necessarydocumentationanddetailsareobtainedfromthepharmacovigilancecentre. Theindicatorshouldbestatedastheabsolutevaluesofthenumberofsignalsdetectedinthe precedingfiveyears. Limitations Thelimitationofthisindicatoristhatitdoesnotreflectthesubtletiesthatexistinthe detectionofsignalsandthefactthatcausalityisnotimplied.Itprovidesnoinformationabout thetimelaginthepharmacovigilancesystembeforeasignaliscreatedbasedontheadverse reactioninformationthathasbeencollected. Thequalityofthesubsequentcommunicationtothetargetaudience(healthcare professionalsand/orthepublic),andtheanswertothequestionofwhether,andifso,howthe healthcareprovidersusetheinformationarenotcaptured.

C02:Numberofregulatoryactionstakeninthepreviousyearasaconsequenceofnational pharmacovigilanceactivities Subsetindicators: C02a:NumberofSmPC/PILchanges(variation) C02b:Numberofsafetywarningsonmedicines C02b(i):Healthcareprofessionals C02c(ii):Generalpublic C02c:Numberofmedicineswithdrawn C02d:Numberofotherrestrictionsonuseofmedicines Definition Thisindicatorreferstothenumberofregulatoryactionstakenintheprecedingyear. Descriptionanduses Thisindicatorisameasureoftheregulatorydecisions,basedonpharmacovigilance activities,takentoensuresafetyofmedicines.Italsomeasuresthefunctionalityofthe pharmacovigilancecentreandtheinterfaceoftheactivitiesofthepharmacovigilancecentre withthoseoftheregulatoryagency.

Theissuanceofadviceandtakingofappropriatemeasuresbytheregulatoryauthoritiesis

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amajoroutputofthepharmacovigilancesystemthathassignificantimpactonsafeuseof medicines.Absenceofthesemeasuresindicatesnon-functionalpharmacovigilancesystemor medicinesregulatoryagenciesandalackofmonitoringofmedicinesforsafety.
Sourcesandmethodsofdatacollectionandindicatorcalculation
17 Theinformationonthisindicatorcanbeobtainedfromtheregulatoryagencyrecords. Thenumberandcharacteristicsoftheregulatoryactionsaredocumented.Regulatory measurestakensolelyonthebasisofinformationordatafromothercountriesarenotcounted.
Limitations Thelimitationofthisindicatoristheinabilitytodeduceitsappropriatenessforpublic healthintheshortterm.Itshouldalsobenotedthatregulatoryactionsmaybeaffectedby factorsotherthanthestrictscientificevidence.
C03:Numberofmedicine-relatedhospitaladmissionsper1000admissions Definition Thisindicatorreferstothenumberofpeopleadmittedtohospitalasaresultofevents associatedwithmedicinesandtheiruse. Descriptionanduses Thisindicatorisameasureofinjurytohealthresultingfromtheuseofmedicines (Adversereactions,medicationerrors,misuseorabuseofmedicines,counterfeit/substandard medicines,andpoisonings).Toalargeextent,itmeasurestheeffectivenessofprovisionsput inplacetosafeguardhealththroughsafemedicinesandtheirsafeuse.
Ahighvalueofthisindicatorsuggestslackofeffectivemechanismstoensurethesafety andthesafeuseofmedicines.Thetrendinthisindicatorcanbeusedtomonitortheimpactof anyinterventionputinplacetoensurepatientsafety.Itisalsoameasureoftheburdenof medicine-relatedadmissionstohospitalandshouldservetoidentifyproblemsthatneedtobe addressed.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Thedatarequiredtocalculatethisindicatorshouldbeobtainedfromhospitalrecordsand shouldinclude: Thenumberofpeopleadmittedasaresultofamedicine-relatedillnessduringthestudy period Thetotalnumberofpeoplewhowenttothesame hospitalduringthesameperiod. Numberofindividualshospitalizedduetoamedicine-relateddisease×1000 Numberoftotalindividualsadmittedtothesamehospitalorsetting
Itissuggestedtouseastandardandpeer-reviewedstudyprotocoltoimprovethe qualityofthemeasuresandtoensurereliabletrendanalyses. Limitations Thelimitationofthisindicatoristhedifficultyinestablishingwithcertaintythecausal linkbetweenamedicineandanadversereaction.Furthermore,exceptincaseofpoisoning,a medicine-relatedeventisseldomconsideredastheunderlyingcauseofahospitaladmission andisthereforenotrecordedatthetimeofhospitalvisit.Itisbelievedthatthenumberof casesofmedicine-relatedillnessisgrosslyunderestimatedowingtoalowindexofsuspicion andlackofawarenessofsuchproblems.
C04:Numberofmedicine-relateddeathsper1000personsservedbythehospitalperyear Definition Theindicatorreferstothenumberofmedicine-relateddeathsinrelationtothenumberof patientsservedbythehospital.
18 Descriptionanduses Thisindicatorisameasureoftotalnumberofdeathsresultingfrommedicines.Such deathsmayincludeindividualswhowereoutpatientsanddiedasaresultoftheuseof medicines–duetoadversereactions,medicationerrors,misuseorabuseofmedicines, dependence,interactions,counterfeit/substandardmedicines,orpoisonings.Or,thereported deathsmaybeofinpatientswhowereadmittedtohospitalasaresultofamedicine-related eventandlaterdied,orthoseinpatientswhodevelopedamedicine-relatedeventwhilein hospitalanddied. Theindicatorwillbeameasureoftheharmfuleffectsofmedicinesonpatientsinthe community,inhospitalorpatientswhoarenotinhospital.Ithighlightsthesafetyof medicinescirculatinginthehealthcaresystem,theappropriatenessoftheirusebyhealthcare professionalsandtheeffectofthepharmacovigilancesystemandregulatorymechanismsin ensuringsafeuseofmedicines.Suchamortalityfigurerevealssystemicproblemsthatneedto beaddressedtoreducetheburdenonthesocietyandonthehealthcaresystem.

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Trendsinthisindicatorareusefulinmonitoringinterventionsandinplanningstrategy.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Themainsourcesofdataforthisindicatorarehospitalrecords.Therelevantdatatobe obtainedaretherecordsofmedicine-relatedhospitaldeathsandtotalnumberofhospital admissionsduringtherelevantperiod. Theindicatorvalueiscalculatedasfollows: Numberofmedicine-relateddeaths(outpatient-inpatient)x1000
Totalnumberofin-patientsandout-patientsadmittedtothehospitalwithintheperiod Limitations
ThelimitationsnotedforCO3alsoapplytoCO4.Themainlimitationontheuseofthis indicatoristhedifficultyinfollowingupthedeathsofoutpatientsandconsequentlythe underestimationofthevalue.Inaddition,medicinesortheirabsencemightcontributeto deathsratherthandirectlycausingthem.
Astandardstudyprotocolshouldbeusedovertimetoensurereliabletrendanalyses.
Benchmarkingbetweensettingscouldbeaffectedbydifferencesinaccesstohospital care,andthusmaynotbevalidinsomeinstances.
C05:Numberofmedicine-relateddeathsper100.000personsinthepopulation Definition
Thisindicatorreferstothemedicine-relatedmortalityinthepopulation. Descriptionanduses
Theindicatormeasurestheharmfuleffectsofmedicinesusingmortalityastheend-point. Itmeasuresdeathsthatarerelatedtopoorpracticesalongtheentirechain,fromthe manufactureofthemedicinetoitsuse.Itisanaggregatemeasureoftheharmfuleffects includingadversereactionstomedicines,medicationerrors,counterfeit/substandard medicines,misuseorabuseofmedicinesandpoisonings,andhelpswithplansforaddressing theseproblems. Sourcesandmethodsofdatacollectionandindicatorcalculation
Itisdifficulttoobtainthisdata. Limitations
Themainlimitationisusuallythepoorqualityofthedata.Obtainingdataofsuitable qualityforthisindicatorischallenging,bothintermsofresources(budget,time)and expertise.
Tobeabletodocumentthisindicator,thepharmacovigilancecentresareencouragedto collaboratecloselywithrelevantnationalauthorities(healthstatistics),andinsomeinstances

alsowithotherstakeholderssuchasuniversities,researchinstitutionsandpublichealth programmes. C06:Averagecostoftreatmentofmedicine-relatedillnesses Definition
Thisisameasureofthecostoftreatingmedicine-relatedillnessesinasetting. Descriptionanduses
Thisindicatorisanestimateofthefinancialburdenimposedbymedicine-related illnesses.Itprovidesinformationontheimpactonthehealthcaresystemofmedicine-related illnesses.Italsosupportstheevaluationofthecostsofinterventionsandtrendanalyses.It providesusefulinformationinplanningforhealthcare.Highvaluesofthisindicatorsuggest majorfinanciallossesduetomedicine-relatedillness.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Thisindicatorcanbeobtainedbyexperiencedhealtheconomists,usingcost-of-illness models.
Limitations Themainlimitationisthecomplexityofthecalculationsneededtoobtaintherequired informationandtodevelop(and/orreplicate)anappropriatemodel.Otherlimitationsmay includethelikelihoodofnon-recognitionofmedicine-relatedillness,resultinginlowvalues.
Astandardstudyprotocolshouldbeusedovertimetoensurereliabletrendanalyses.
C07:Averageduration(days)ofmedicine-relatedextensionofhospitalstay Definition
Thisindicatorreferstohospitalstaysresultingfrommedicine-relatedillnesses. Descriptionanduses
Theindicatormeasurestheperiodofhospitalizationasaresultofnoxiousorinadvertent effectsofmedicines.Patientsmaybehospitalizedowingtoamedicine-relatedeventand/or havetheirhospitalstayprolongedasaresultofcertaineventsrelatedtomedicinesthatwere administeredinhospital.Theprolongationofhospitalstayhasimportantmedicaland economicconsequences.Theoccupancyofhospitalbedsbypatientswithmedicine-related illnessesdeprivespatientswithotherdiseasesofbedspaceforinpatientcare.Theindicatoris ausefultoolforhealthplanningpurposes.Itislikelytoprovideinformationovertimeonthe impactofmedicine-relatedillnessesonthehealthcaresystemandalsotoenableevaluationof

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theimpactofinterventionmeasures.Withinahospital,itcanalsobeusedtoevaluatethe treatmentmethods.Lowerindicatorvaluesmightsuggestbetterhospitalcareoradecreased occurrenceofmedicine-relatedillness. Sourcesandmethodsofdatacollectionandindicatorcalculation Thesourcesofthedataaremainlyhospitalsandthedatashouldbeobtainedinthecourse ofawell-designedstudy,throughappropriatesampling.Allinformationrelatedtothe medicine-relatedhospitalstayshouldbeobtainedinconjunctionwiththedatarequiredto documentindicatorCO8. Limitations Animportantlimitationofthisindicatoristhepersonnel,timeandcostrequiredtocarry outasurvey.Anotherlimitationisthatitisimpossibletobeabsolutelycertainofacausallink betweenamedicineandanadversereaction.Expertiseofhealthcareprofessionalsonthis matterisrequiredtoobtainreliablevalues.Also,itisbelievedthatthenumberofcasesof medicine-relatedillnessisgrosslyunderestimatedowingtoalowindexofsuspicionanda lackofawarenessofsuchproblems.

20 Itissuggestedthattherequiredinformationbeobtainedfromastandardandpeer-reviewedstudyprotocoltoensuretheavailabilityofthedata,toimprovethequalityofthe measuresandtoensurereliabletrendanalyses. C08:Averagecostofmedicine-relatedhospitalization Definition Thisindicatorreferstothecostofhospitalizationfollowingamedicine-relatedillness. Descriptionanduses Thisindicatorisameasureofthefinancialburdenonahospitalattributabletomedicine-relatedillness.Thisshouldbeseenfirstlyasthecostsofhospitalizationnecessitatedbya medicine-relatedillnessandsecondlyascostsresultingfromprolongationofhospitalstay followinganadversereactionexperiencedbyaninpatientwhichdevelopedinconnection withamedicine-relatedillness.Itisanimportantmeasureoftheimpactofamedicine-related illnessonthehealthcaresystem.Thehospitalizationofapatientwithamedicine-related illnessdeprivesotherpatientsofhospitalfacilities.Theeconomicsofhospitalstayalsotake intoconsiderationthecostofpersonneltoprovidecareandmayalsoreflectthetreatmentcost. Thevaluesofthisindicatorwillbeusefulinmonitoringthetrendsinhospitalizationovertime andtheeffectsofinterventionmeasures.
Sourcesandmethodsofdatacollectionandindicatorcalculation
Thedatashouldbeobtainedfromthehospital,fromstudies,orhospitalresearchin regionsorcountries.Awell-designedstudyshouldobtaindetailedinformationonhospital staysofpatientswithmedicine-relatedillnessindesignatedfacilities. Limitations Themainlimitationofthisindicatoristhecumbersomeprocessofobtainingtherelevant dataregardingtheengagementofpersonnel,andonthetimeandcostinvolved.

21 Appendix1: Quantitativeinformationrequiredbeforeusingpharmacovigilanceindicatorsareasfollows:
BG1.Totalpopulation(country,regionorfacility) BG2.Genderandagestructureofpopulation a.Male:Female b.Lifeexpectancy c.Proportionofthoseinneedofcare
BG3.Totalnumberofmedicinemanufacturingunitsinthecountry
BG4.Totalnumberofpharmaceuticalcompaniesinthecountry
BG5.Totalnumberofpharmaciesinthecountry BG6.Totalnumberofregisteredmedicines
BG7.Totalnumberofmedicinesincludedinthenationalessentialmedicineslist
BG8.Percentageofmedicinessoldinshadowindustry
BG9.Percentageofcounterfeit/substandardmedicinesinthepharmaceuticalmarket
BG10.Totalnumberofhospitalsandclinics a.State b.Private
BG11.Totalnumberofhealthcareprofessionalsineachcategory a.Doctors b.Dentists c.Pharmacists d.Nurses e.Others Source:
1.WHOPharmacovigilanceindicators:Apracticalmanualfortheassessmentof pharmacovigilancesystems,2015.

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