



Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of
patient summary and electronic prescription

D1.4.1 EED SERVICES including use cases for all services

Use-cases description.

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ABSTRACT
<p>The document describes use cases for:</p> <ul style="list-style-type: none"> - extension of the epSOS Core Services - Patient Summary and ePrescription - Additional Service EHIC to illustrate how to improve coordination between epSOS core services and health administration processes - Additional Service 112 Emergency - Additional Service Access for Patients

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149 1 Introduction

150 The document **D1.4.1 EED SERVICES including use cases for all services - Use case**
151 **description** contains the fourth version of use – cases descriptions.

152

153 The first version was commented by TPM and after incorporating TPM comments and
154 recommendations the work resulted in the second version of the document. The second
155 version of the document was commented by

156

- 157 • National epSOS Coordinators (NEPC) in 23 participation nations,
- 158 • KT 1.4.10 experts (29 experts commented),
- 159 • Semantics WG

160

161 The incorporation of all mentioned comments on the second version into the document
162 resulted in the third version of the document. The third version of use case description arose
163 on the basis of comments and recommendation from above listed three groups of reviewers.
164 The third version of the document was commented by NEPC and KT 1.4.10 experts.
165 Afterwards use-case description from the third version together with comments and proposals
166 from last two rounds of reviews were analysed and evaluated at the TPM meeting which took
167 place in Copenhagen on 31.8 – 1.9.2011.

168

169 At the meeting in Copenhagen TPM concluded principles on which the decision on scope of
170 specification work will be made.

171

- 172 • No intrusion into national eHealth systems but opportunity to influence national
173 transpositions of the Directive 2011/24/EU.
- 174 • epSOS is not aiming at a federated pan-European database.
- 175 • epSOS is aiming to support each PN retaining its own responsibility for eHealth.
- 176 • In principle each PN has responsibilities under the Directive 2011/24/EU as a country
177 of affiliation with respect to its own citizens, therefore:
 - 178 – epSOS access to patient’s data is only possible through the country of affiliation.
 - 179 – Each country of treatment must provide means to transfer epSOS encoded
180 medical information about the patient to the country of affiliation.

181

182 Applying those principles and considering analysis of the UCs by WP2.1, WP3.A, WP1.4 and
183 lessons learnt in epSOS 1, the scope of service specification work was detailed and use-cases
184 appropriate to be further specified by KTS 1.4.6/7/8/9 were selected by all TPM.

185

- 186 • UC.PS.4 “Patient Summary of Country A always updated” is to be changed to “patient
187 information will be made available by country B to country A”.
- 188 • UC.PS.1-3 “Several PSs” and “PS in country B” are covered if information is included
189 in country A through UC.PS.4.
- 190 • UC.PS.5 “Automatic Update” does not correspond to the defined assumptions.
- 191 • UC.MED.2 “medicine newly prescribed in country B” will be an extension to the eP
192 service.
- 193 • UC.MED.1 “Role specific access to medication related overview” (UC.MED.2 is
194 prerequisite).
- 195 • UC.EHIC will be analysed in a service specification with a recommendation for the
196 future.
- 197 • UC.112 will be covered by one service specification incl. data set and supporting
198 processes.
- 199 • UC.PAC.1 “Patient Access to country A information in country B language” will be
200 developed in a service specification and covers as well UC.PAC.2 “Patient Access to

201 country B information in country A language” if information is included in country A
202 through UC.PS.4 and UC.MED.2.
203

204 In next chapters only use cases which were selected for further processing in the specification
205 phase are described. There is one Patient Summary use case description in chapter 2, then
206 two use cases for Medication in chapter 3, one use case for 112 Emergency in chapter 5 and
207 one use case for Patient Access in chapter 6.
208

209 One use case – UC.EHIC, see chapter 4 - will also proceed for further processing but the
210 result will not be in the form of specification but will end in the form of recommendation
211 concerning possible future application.
212

213 Detailed description of use cases can be found in Annex. On the base of this detailed
214 description the reader can see the definition process of basic use cases and their development
215 into a larger set where the above described process of selection was applied.
216

217 The last, fourth version of the Document and of the use cases description resulted from
218 applying above mentioned principles and also from the harmonising process based on TPM
219 meeting comments and comments received during the last review round. The wording of use
220 case descriptions was aligned to the Directive 2011/24/EU wording.
221

222 In the document we use the abbreviation **UC.xxx.y**, where **UC** means use-case. **XXX** means
223 PS for patient summary, MED for medication, EHIC for use-cases connected to EHIC, 112 for
224 use-cases connected with the 112 Emergency, PAC for patient access to his data and **y**
225 means serial number of the use case in the use case group.
226

227 The basic approach we used was to start defining the use case in the way it is performed
228 inside one country and then to try and find all actors and activities that could apply in the
229 usage of the use case in the foreigner country. The combinations of foreign actors and
230 activities inside the use-cases provided us with the possible variations of use-cases. As not all
231 variations are based on common sense we described only use-cases that could occur in the
232 reality with some meaningful level of probability.
233

234 For those familiar with the UML language we have to say that understanding of the term “use
235 case” in this document is slightly different from the understanding of the term “use case” from
236 the UML language. We hope that this difference will not make any problem of understanding
237 the content of this document.
238

239 ***Feature: The epSOS services only provide access to clinical information by way***
240 ***of the Country of Affiliation.***
241

242 A key decision was made by the epSOS PSB on Sep 7, 2011 saying that epSOS services will
243 only provide access to clinical information (PS or eP) by way of the patient’s **country of**
244 **affiliation** (Country A). If clinical information is produced in other countries (Country B), they
245 can only be accessed through epSOS services if Country of Affiliation (Country A) can provide
246 that access, either by incorporating the information into the Country of Affiliation (Country A)
247 **medical records** or by other means. The rationale for this restriction is that only Country of
248 Affiliation (Country A) can always guarantee unequivocal identification of the patient, and that
249 a distributed model of the Patient Summary runs a serious risk to the continuity and coherence
250 of the clinical information.
251

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253

254 **2 Patient Summary related use case for the epSOS extension**

255

256 KT1.4.1, Michiel Sprenger, Nictiz, Kea Task Leader, sprenger@nictiz.nl, Wouter Tesink, Nictiz
257 Juan Nuñez, Indra (IT)

258

259 September 15, 2011

260

261 **Use Case Patient Summary Extension:**

262 **Patient information will be made available by country B to country A**

263

264 The detailed analysis and rationale for the epSOS Patient Summary Extension (UC.PS.6) is
265 described in the Annex. The Patient Summary extension service is built upon and enhances
266 the already specified epSOS Patient Summary service.

267

268 **Actors**

269 The actors involved in this Use Case are:

270

271 • The patient: the patient concerned in this use cases is always seen by a health
272 professional, in country other than his/her home country (country A).

273

274 • The health professional at the point of care (PoC) in any country other than the home
275 country of the patient.

276

277 **Goals**

278 This use case focuses on ways to make known to physicians in the home country details
279 about the treatment or diagnosis of the patient whilst travelling outside his or her home
280 country.

281

282 **Steps of the UC.PS.6**

283 The patient visits a health professional in country B

284

285 1) The health professional in country B requests the patient summary from country A.

286

287 2) The health professional in country B records encoded medical information about the
288 patient's treatment event.

289

290 3) The health professionals notifies country A of the treatment event in country B and the
291 availability of encoded medical information, and offers means to transfer this information
292 to country A. At this moment it is not further specified how to do this. Analysis will be done
293 in KT.1.4.6.

294

295 4) Based on this information, the patient summary in country A can be updated according to
296 its own policies.

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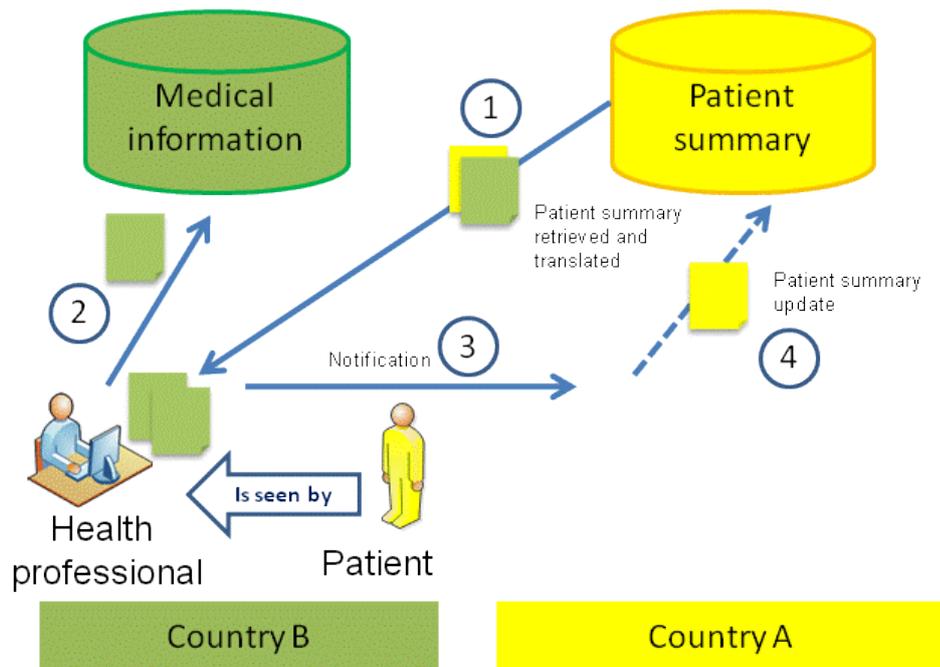
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296 **2.1 Feasibility of the proposed uses case**

297 The means to transfer the encoded medical information from country B to country A have not
 298 been defined. The following has to be taking into account for further analysis

- 299
- 300 • Information can only be sent to the country of affiliation in a security context, as long as
 301 this context exists. Once the context is suspended, the information cannot be
 302 exchanged with guaranteed data security, integrity etc.
 - 303 • Country B, the country of the point of care has to make the information of the foreign
 304 patient available. Some countries might not be able do that for foreign patients, and
 305 this can possible involve intrusion into national systems.
 - 306 • Sending information to country A can give legal responsibilities for (health professionals
 307 in) country A.
- 308

309

310 **3 Medication related use cases for the epSOS extension**

311

312 KT1.4.1, Michiel Sprenger, Nictiz, Kea Task Leader, sprenger@nictiz.nl, Wouter Tesink, Nictiz
313 Juan Nuñez, Indra (IT)

314

315 September 15, 2011

316

317

318 The detailed analysis and rationale for the epSOS ePrescription Extension (UC.MED.1 and
319 UC.MED.2) is described in the Annex. The ePrescription extension service is built upon and
320 enhances the already specified epSOS ePrescription service.

321

322 **Actors**

323 The actors involved in these Use Cases are:

324 • The patient: the patient concerned in these uses cases is always seen by a health
325 professional, either in his/her own country or in country other than his/her home country
326 (country A).

327 • The health professional at the point of care (PoC) in any country, home country or
328 abroad.

329

330 **Goals**

331 The development of cross-border solutions for medication serves two major goals:

332 • Improving the continuity of care by providing solutions for the cross-border validity of
333 medication prescriptions;

334 • Improving patient safety by supplying relevant information to all actors in the
335 medication process, wherever the patient resides. The safety is increased most and for
336 all by the prevention of adverse drug events. We call this consulting the medication
337 related overview.

338

339 **Steps of the UC.MED.1:**

340 **Medication Related Overview available for dispenser in country B**

341 A patient from country A is visiting country B. The patient has a prescription that is not fully
342 dispensed yet. The patient needs medication to be dispensed, based upon this prescription.

343 The patient goes to a pharmacy in country B. The pharmacy in country B obtains, from country

344 A, the medication history of the patient which includes the unfulfilled prescription and the

345 medication related overview. The medication related overview is obtained in a form and

346 richness common in country A (how country A normally informs a pharmacist). The pharmacist

347 checks the medication to be dispensed against the medication related overview to check for

348 possible adverse reactions and / or other unwanted effects. When the pharmacist can assume

349 that medication can be safely and legally dispensed, the medication is handed to the patient or

350 the person representing the patient (e.g. a family member). The pharmacist in country B

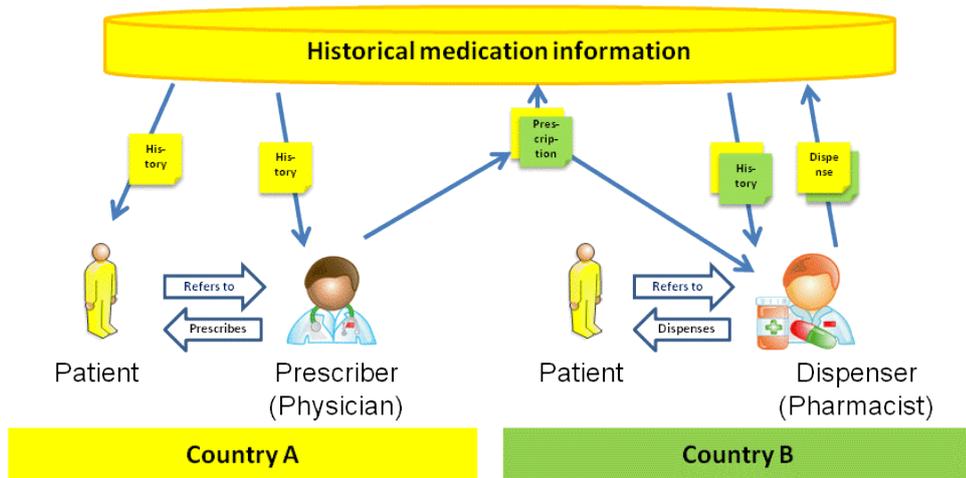
351 makes the dispensation information available, which then is transferred to the home country

352 for inclusion into the medication history in country A, and for updating the status of the

353 prescription in country A, i.e. lowering the remaining amount of possible dispenses from that

354 prescription.

355



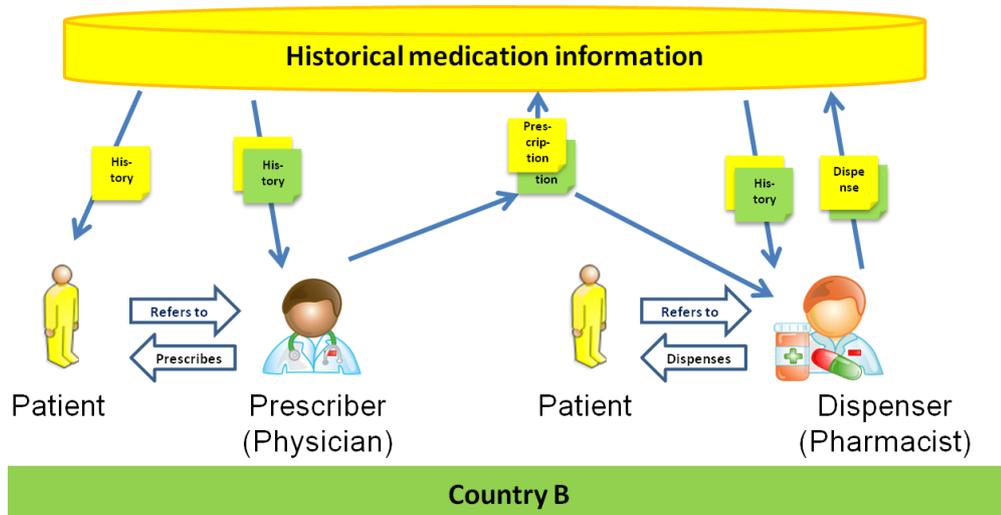
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Steps of the UC.MED.2:

Medication newly prescribed and dispensed in foreign country

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A patient from country A is visiting country B. The patient needs care and visits a physician in country B. The physician and the patient conclude that the patient needs medication. The physician in country B consults the medication history (i.e. medication related overview) from country A, and based upon that history and the current situation (illness) of the patient, issues a prescription. That prescription is sent to country A for inclusion into the medication history in country A, for future reference. The patient goes to a pharmacy in country B. The pharmacy in country B obtains, from country A, the medication history of the patient which includes the unfulfilled prescription and the medication related overview. The medication related overview is obtained in a form and richness common in country A (how country A normally informs a pharmacist). The pharmacist obtains the electronic prescription from the physician in country B, through the regular Country B procedure. The pharmacist checks the medication to be dispensed against the medication related overview, to check for possible adverse reactions and / or other unwanted effects. When the pharmacist can assume that medication can be safely and legally dispensed, the medication is handed to the patient or the person representing the patient (e.g. a family member). The pharmacist in country B makes the dispense information available in electronic form, which then is transferred to the home country for inclusion into the medication history in country A.



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3.1 Feasibility of the proposed uses cases

- In 50% of the countries medication related overview is available, in half of these countries the MRO is available for different actors (all include the pharmacist). This means that both prescriber and disperser could access this information in these countries. It is foreseen that in 2013 fourteen countries will have a medication related overview electronically available as an individual document. It is reasonable to expect that this number of countries will be reached, because already thirteen countries have medication related overview available at the moment.
- In some countries the medication related overview is part of the Patient Summary. It must be kept in mind that in some countries a pharmacist is not allowed to view the PS.
- From the remaining countries a large part uses free text for their elements or still have a lot elements not applicable. A relative small part of the elements is coded and therefore at the moment useable for translating information in the epSOS setting. The codes that are used differ greatly between countries.

398 **4 Use cases for the epSOS additional services – EHIC**

399

400 KT 1.4.2, Andrzej Strug, NFZ (PL), Key Task Leader, Andrzej.Strug@nfz.gov.pl

401 September, 16, 2011

402

403 **4.1 General introduction**

404 The aim of EHIC business case study was to investigate possibilities of including the functions
405 concerning patient identification and healthcare entitlement verification, being based on the EU
406 social security coordination system, into epSOS project pilot.

407

408 Initial assessment of this problem presented by the Key Task Leader and discussed on the
409 TPM level concluded with the decision not to implemented EHIC use cases within the scope of
410 epSOS II. The main reason for this is that on the one hand it is not feasible to repeat the work
411 done or being done in the other EU projects (EESSI, NETCARDS), and on the other hand
412 there are still no sustainable outcomes of these projects that could be reused as the parts of
413 epSOS solution. There are also certain limitations arising from regulations regarding EHICs
414 and general social security coordination system that don't facilitate computerization of these
415 areas.

416

417 EHIC use cases analysis display current situation. In accordance with the TPM decision,
418 results of the EHIC use cases analysis will be taken into consideration to prepare
419 recommendation about changes in ICT environment of the healthcare sector, that would allow
420 for an implementation of the more advanced eHealth solutions.

421

422 Detailed clarification and analysis of EHIC related scope is described in Annex.

423

424 **4.2 Basic process of EHIC usage**

425 Basic process of EHIC usage starts with capturing data from EHIC handed over by foreign
426 patient to the HCP representative in order to get a medical treatment on the basis of EU social
427 security coordination system (which means in brief on the same conditions like domestic
428 patient). It aims at receiving reimbursement for this kind of medical treatment. It should be
429 noticed, that aside of EHIC the Provisional Replacement Certificate (PRC) exists, that is a
430 paper document issued on request when an insured person needs medical treatment (cross-
431 border healthcare) in (Member State of treatment) and does not have EHIC with him. PRC
432 plays the same role as EHIC, but differs in the way of acquiring.

433

434 In the course of analysis the following business cases related to the EHIC process were
435 specified:

436

437 **UC.EHIC.1 - Data capture from EHIC (or from PRC)**

438 This use-case describes the main function of EHIC card which is a carrier of information about
439 identification of a patient, his/her insurer (called Competent Institution in regulations) and an
440 expiry date of the card. This information has to be captured by HCP in order to identify the
441 patient and to present them later in reimbursement process of cost claiming. A patient may
442 come to HCP with Provisional Replacement Certificate (PRC) instead of EHIC.

443 There are 3 groups of data on the EHIC (PRC) that are important:

444

- identification of a patient (and a card)

445

- identification of the Competent Institution responsible for the financing of the treatment

446

- information about expiry date of the card

447 Mentioned above 3 groups of data are create the main issues that should be solved on EU
448 level in order to computerize cross border eServices.

449

450 **UC.EHIC.2 - Requesting the PRC**

451 This use-case describes a situation when a patient is insured but has not his/her EHIC with
452 him/her. According to the regulations of the European systems coordination it is possible to
453 apply for Provisional Replacement Certificate (replacing EHIC) from abroad in order to prove
454 an entitlement in country B. After obtaining PRC from relevant Competent Institution (CI-A), it
455 can be used in line with scenario described in the previous use-case.

456 Up to now, there is no pan European procedure to exchange electronically data between the
457 actors of this use case. Only in the scope of EESSI system the relevant flows (with elementary
458 SEDs – Structured Electronic Documents) between institutions in Country A and B are defined.
459 Only implementation of legal, organizational and technical measures to solve these issues will
460 enable computerization of the process.

461

462 **UC.EHIC.3 - Using the captured data for reimbursement process**

463 After acquisition of the patient's data, what was described in the first use-case, the data are
464 used in the process of reimbursement. Healthcare Provider (HCP) must send a proper set of
465 data to the Institution of Temporary Stay (CI-B), to obtain a reimbursement for the treatment
466 delivered to the patient. Afterwards this institution gets the reimbursement from the Competent
467 Institution (CI-A).

468 Information from HCP may be required only in a paper version, then a copy of EHIC (PRC) is
469 expected, or, in case of countries with electronic exchange of data, a HCP has additionally to
470 deliver electronic version of the data, captured from EHIC.

471 The HCP has to add data items captured from EHIC (PRC) to the data describing the service
472 provided to the patient and send them together to the proper institution in Country B in
473 accordance with domestic regulations. If only an expiry date from the EHIC is valid, the claim
474 has to be reimbursed regardless of other data taken form EHIC.

475 But the most common issue arises in CI-A when the claim sent from Country B contains valid
476 expiry date copied form EHIC, but the patient used it lawlessly at HCP because he/she lost the
477 entitlement or changed the insurer after getting EHIC. Again, according to the EU regulations
478 the CI-A has to pay the claim from Country B. Later it may start a procedure to recover the
479 costs of claim from the patient or from the new patient's insurer accordingly. It may be very
480 time-consuming and costly procedure.

481

482 **4.3 EHIC Use Cases Conclusion**

483 The above use cases describe the currently running situation concerning EHIC data
484 exchange, performed in a different organizational context and a set of actors or tools involved.
485 But if we look at the problem from another, more analytical perspective, we can enumerate
486 several basic functions that are needed to reach the goals of these EHIC related use cases:

- 487 • identification of the patient
- 488 • identification of the insurer (institution that will finally bear the costs of the treatment)
- 489 • determination of the patient's entitlement status
- 490 • proving patient's health insurance document presence (EHIC or PRC) at the HCP
- 491 • capturing data into electronic form for farther computer processing

492

493 Proposals of certain changes to present solutions regarding EHICs and their usage to facilitate
494 implementation of eHealth systems will be included as the result of the Key Task 1.4.7.

495 **5 Use-case for Additional Services 112 Emergency**

496

497 epSOS II, Key Task 1.4.3, Oskar Kadlec, NHIC, Slovakia, Key Task Leader,
498 kadlec@posam.sk, Christina Lumbreras, Marcello Melgara, Carlos Bermell, Vesna
499 Lesnik Sefotic, Gottfried Heider

500

501 September, 2011

502

503 **5.1 General introduction**

504 In accordance with the Directive of Cross-border Health Services (Directive 2011/24/EU),
505 epSOS will develop a service providing the patient access to key information in his or her own
506 medical record, when seeking or receiving healthcare abroad (outside his/her Country of
507 Affiliation, Country A). The **epSOS Additional Services 112 Emergency (112)** are built upon
508 and enhances but does not replace any National Emergency services within the Participating
509 Nations.

510

511 epSOS 2 will assess and test how 112 emergency services can be included in epSOS
512 services. The aim is to allow European emergency services (112) and in particular the
513 Emergency Medical Services to securely - and legally - access a patient summary to improve
514 the quality of the intervention.

515

516 In accordance with the epSOS Description of Work (ref: DoW), this service should provide
517 access to a Patient Summary (PS).

518

519 As per this limitation, all other information, including detailed medical records notes,
520 reimbursement and billing data, pharmaceutical information about the actual drug prescribed,
521 or general (not patient-specific) medical information about the disorders treated, will be out of
522 scope. Also, patient input of clinical data will not be included in these specifications (is out of
523 scope).

524

525 According to the general approach in epSOS, only structured and coded data will be subjected
526 to translation, restricting the use for unstructured data to a copy of the original document in its
527 original language (Ref: Deliverable D3.5.2/D3.9.1-Appendix B1).

528

529 **5.2 Basic process of Additional Services 112 Use Cases**

530 **Actors in the Use Cases for Additional Services 112 are:**

531

532 **Primary actors:**

533

- Patient

534

- Caller

535

536 **Secondary actors:**

537

- 112 call – taker

538

- Health Care Professional acting as Health Care Provider in the 112 call centre

539

- Health Care Professional acting as Health Care Provider in the ambulance (Point of Care)

540

541

- Health Care Professional acting as Health Care Provider in the first aid department (Point of Care)

542

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Information used

The information used in the Use Cases for Additional services 112 is:

- The Patient Summary (PS)

Goals in the Additional Services 112

The goals of the actors in the Use-Cases are:

The Patient

The Patient wants to have improved quality of intervention provided by 112 Emergency services (included in epSOS services), securely and legally.

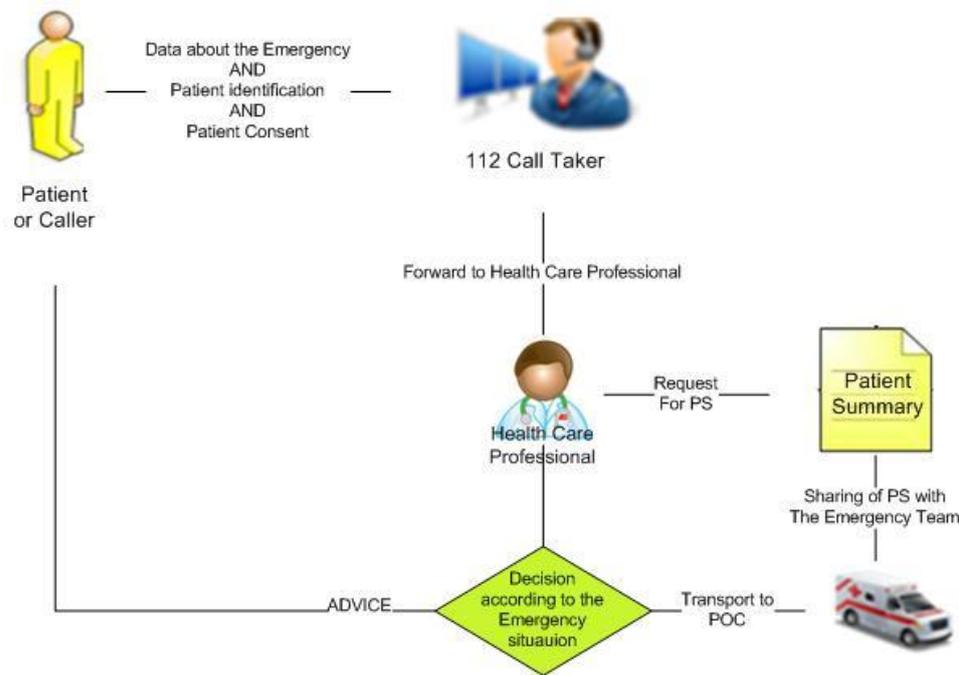
The Health Care Professional

The Health Care Professional Wants to receive all relevant information about the Patient in the different processes provided by Emergency teams to increase of Patient safety and quality of services in the emergency situations.

Steps of Additional services 112 process

The basic process of provision Additional services 112 is outlined in Diagram 1.

Diagram 1: Additional services 112 Basic process:



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The general overview of the medical emergency handling process can be divided into three steps. In the first one, the emergency call is received in 112 Emergency Call Centre, first data about the situation are taken and medical resources are dispatched. In the second step, health professionals arrive to the emergency place and take care of the patient. The last step is when the patient arrives to the first aid department.

579 **6 Use cases for the epSOS additional services – Patient Access**

580

581 Key Task 1.4.4: Matti Mäkelä, THL, Finland, key task leader, matti.makela@thl.fi, Montse
582 Meya, Ismael Cerda, Elie Lobel, Gergely Heja, Mustafa Yuksel, Miguel Roldan

583

584 October, 2011

585

586 **6.1 Use Case for Additional Services - Patient Access**

587 The detailed analysis and rationale for the **epSOS Patient Access Service (epSPA)** is
588 described in the Annex. The epSPA service is built upon and enhances but does not replace
589 any National Patient Access service within the Participating Nations. Therefore, it always
590 conforms with the national policy for Patient Access.

591

592 The single Use Case for Patient Access (UC.PAC.1) is dependent on electronic patient access
593 to a Patient Summary or ePrescription in the patient's country of affiliation (country A). The
594 epSOS Patient Access service provides a translation of the coded elements in the documents
595 to be accessed. This use case serves two principal needs:

596

- a patient in Country A, who is not fluent in the language of the PS/eP, needs Language B access to his/her own clinical documents, and

597

- the patient wishes to consult someone in Language B on the basis of his/her PS or eP, for instance during an encounter with a Health Professional in Country B. Both needs are widespread, and the potential demand for this Use Case service is high.

600

601

602

Actors

603

The actors involved in the epSPA Use Case are:

604

605

Primary actors

606

- The Patient

607

Secondary actors

608

- The Health Professional, acting as a Healthcare Provider, producing the medical information used in the document to be accessed

609

610

- The Health Professional at a new encounter (New Health Professional)

611

- Patient identification, authentication & role authorization service

612

- The epSPA translation service

613

614

Goals

615

The goals of the main actor, the patient, in UC.PAC.1 is to access and understand what the Health Professional has recorded in the PS or eP, in order to:

616

617

- participate in his or her own care, and/or to
- improve the information he or she gives to a New Health Professional

618

619

620

The Steps of the UC.PAC.1

621

622

The process of Patient Access is outlined in Diagram 1.

623

- The Health Professional updates/produces the medical information used in the PS or eP on the basis of an encounter (i.e. the existence of a PS or eP is a precondition for the successful Patient Access Use Case)

624

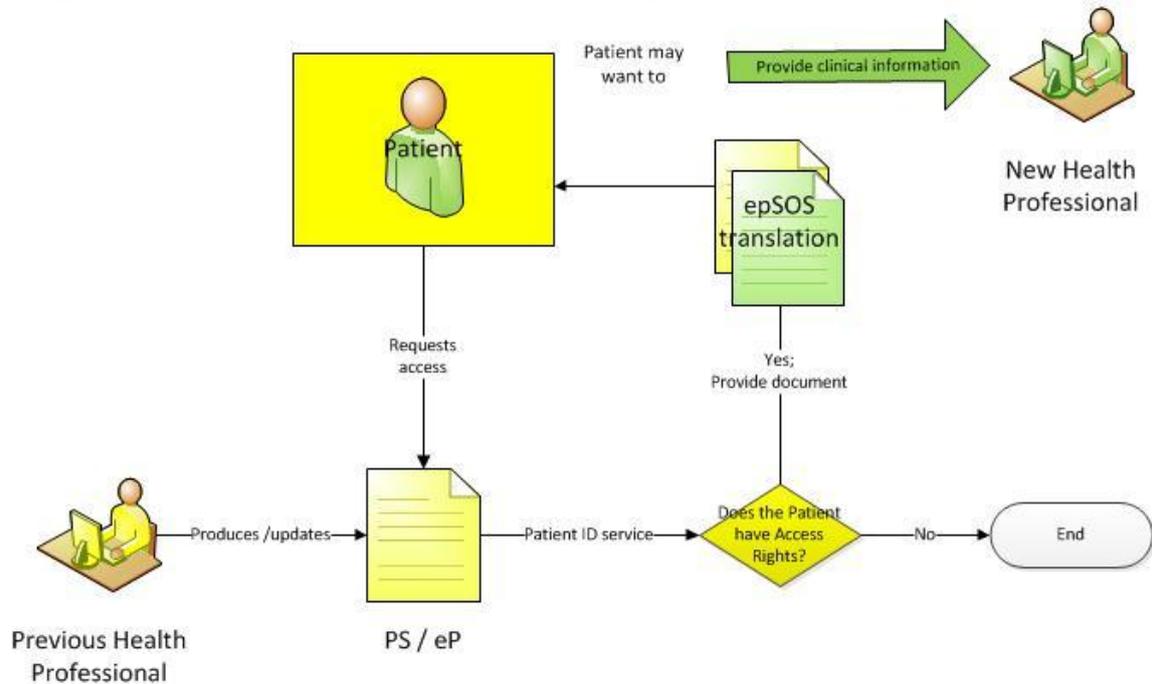
625

- The Patient requests his or her PS or eP from the National Patient Access Service

626

- 627 • The National Patient Access Service (including Patient Identification, authentication
628 and role authorization) verifies that he or she has access rights to the information,
629 including that his or her age is sufficient to allow access.
- 630 • The National Patient Access Service provides the requested document
- 631 • The epSPA service is invoked to produce a translation of (the coded content of) the
632 document into Language B. The epSPA service uses the MTC for Language B,
633 produced by Country B.
- 634 • The Patient receives the translated document.
- 635 • The Patient reads, copies, uses and distributes the document as he or she considers
636 appropriate.
 - 637 ○ One possible way the Patient may want to distribute the information to is a new
638 Health Professional at a new encounter, scheduled or unscheduled. This step is
639 relevant only if the Health Professional does not, for some reason, have access
640 to the PS or eP.

642 **Diagram 1: Patient Access to Patient Summary or e-Prescription – UC.PAC.1**



643
644

645 **6.2 Recognized liability and trust issues**

646 The translation to Language B requested in this case relies on the semantic service of Country
647 B. It is not controlled by the NCP or the National Authority in Country A. Therefore, the Patient
648 should be aware that the semantic content is not necessarily authorized in Country A.
649
650
651

652 **7 Conclusions.**

653 There were more use-cases described at the beginning of the use case definition process –
654 you can find them in the Annex, where the process of defining use cases and the development
655 of use cases can be traced.

656
657 It is clear that not each PN will pilot every use case in the future. The final decision on which
658 new use-cases will be piloted during the next phase of project epSOS will be based on the
659 feedback from stakeholders. That was reason that the part of the review of use case version 2
660 and version 3 was also small questionnaire concerning the piloting tendency. We ask NEPCs
661 following questions:

662
663 Could you please check which of these use cases are the ones that contribute the most to
664 quality of care in cross border situations ?

665
666 Could you also check which ones would be most easily accepted by health care professionals
667 and patients ?

668
669 Is there any other advice you could give us from your point of view ?

670
671 In the table below you can see the
672 **“Summary of the PN responses on their interest in piloting and implementing for
673 selected use cases”**.

674 There are combined responses to version 2 and version 3.

675 Interpretation was made by Matti Mäkelä. Note: many responses were not easily interpreted

676
677

	Interested in piloting		Interested in use case	
	A-pilot	B-pilot	A-pilot	B-pilot
UC.PC.4	4	5	11	12
UC.MED.1	5	4	9	9
UC.MED.2	4	4	9	10
UC.112.1	1	1	8	5
UC.PAC.1	6	6	12	14

678
679

680 In epSOS1 there was an agreement on basic use-cases in the beginning of the project and all
681 agreed use-cases were taken to the piloting phase. In the actual financial situation maybe not
682 every country will be interested to pilot all new use-cases. The discussion on how many
683 countries are necessary to start the concrete use-case piloting did not start yet. But we all
684 perceive that the information on how many countries will plan to pilot the particular use-case is
685 the most important information for deciding to proceed (not proceed) to the specification and to
686 the further implementation of the use-case in the piloting process.

687

688

689 **8 GLOSSARY**

690 **112** (pronounced one-one-two)

691 The principal emergency telephone number that can be dialed free of charge from any
692 telephone or any mobile phone in order to reach emergency services (ambulances, fire-
693 fighters and the police) in the European Union (EU), its candidates for accession, members of
694 the EEA agreement, as well as several other countries in the world. It was established by a
695 decision of the EU Council on 29 July 1991.

696

697 **Basic Process.**

698 A description of a service process in general terms, including the actors, goals and information
699 flow, possibly with a flowchart diagram. In epSOS, the basic process description also includes
700 an analysis of cross-border distributions of actors.

701

702 **Competent Institution (CI-A, CI-B)**

703 The insurance institution that insures the patient in his/her home country (CI-A) or is
704 competent for reimbursements in country of patient's temporary stay (CI-B).

705

706 **Cross-border distribution.**

707 A logical analysis of the possible ways a basic process can occur over national or language
708 borders, and what each situation in the distribution means for use case development

709

710 **eDispensation**

711 Acronym:Electronic Dispensation

712 eDispensing is defined as the act of electronically retrieving a prescription and administering
713 medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is
714 administered, the dispenser sends an electronic report on the dispensed medicine(s).

715

716 **EENA - European Emergency Number Association.**

717 EENA is the largest network of emergency services professionals in Europe with more than
718 270 representatives from 112, EMS, police and fire organizations from 32 European countries.
719 The association also gathers the leading solution providers that equip a large majority of the
720 112 and emergency medical services in Europe.

721

722 **Emergency resources.**

723 Assets available and anticipated for operations. They include people, equipment, facilities and
724 other things used to plan, implement, and evaluate public programs whether or not paid for
725 directly by public funds.

726

727 **ePrescription**

728 Abbreviation:eP, ePrescription means a medicinal prescription, i.e. a set of data like drug ID,
729 drug name, strength, form, dosage and/or indication(s), provided in electronic format.

730

731 **epSOS Patient Access Service.**

732 The service that enables the Patient to access and understand what the HCP has recorded in
733 the PS or eP in a country different from the Patient's country of affiliation or a language
734 different from the original language of the PS or eP.

735

736 **epSPA.**

737 epSOS Patient Access Service

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Historical medication information.

A general term we use for the information that is preserved from medication related events. The content may differ per country appreciably. In the most general approach it contains historical prescriptions and the dispenses that have been issued from these prescriptions, in relationship to each other. Furthermore it may contain information related to allergies and other adverse drug events. It also may contain recordings of pharmaceutical advices.

Language A.

Language (of Country A) in which the original documents (on which the epSOS Patient Summary and electronic Prescription are based) are created and stored by Country A.

Language B

Language different from Language A, into which the PS or eP are translated by an epSOS service.

Medication related overview

Many countries constitute certain overviews of relevant aspects for patient care, especially for safety reasons. Implementations vary widely from country to country, and also the content of this overview might vary from user to user: prescribers and pharmacists do not in all countries the same overview.

Patient Identification Service.

A service that provides an identification of the Patient, possibly with authentication.

Patient Summary (PS)

A Patient Summary (PS) is a concise clinical document that provides an electronic patient health data set applicable both for unexpected, as well as expected, healthcare contact. A PS provides an health professional with essential information needed for healthcare coordination and, in case of an unexpected need, for the continuity of care, or when the patient consults an health professional other than his regular contact person (e.g. the general practitioner he/she is registered with).

The epSOS PS does not include a detailed medical history, details on clinical conditions or a full list of all prescriptions and dispensed medicines. It is rather a standardized set of basic health data containing the following information:

General Information about the patient (e.g. name, birth date, gender, etc.).

A Medical Summary consisting of the most important clinical patient data (e.g. allergies, current medical problems, medical implants, or major surgical procedures during the last six months).

A list of the current medication including all prescribed medication that the patient is currently taking.

Information about the Patient Summary itself (e.g. when and by whom was the Patient Summary

Semantic interoperability

Means ensuring that the precise meaning of exchanged information is understandable by any other system or application not initially developed for this purpose. Also: Ability of two or more systems or components to exchange information and to use the information that has been exchanged.

789
790



Person, actor



Information



Process flow



Information flow



Optional Information flow



Translation (epSOS)



Information flow not possible

791
792

793 *Borrowed from D2.1.2 (needs to be updated along the way)*

794

9 ABBREVIATIONS

CA	Certificate Authority
CAB	Change Advisory Board
CC	Competence Centres
CI	Configuration Items
CMDB	Configuration management Database
ConfigM	Configuration management
CoT	Circle of Trust
DP	Data Protection Authority
DPA	? 7.2.4
DPD	Data Protection Directive
D.x.y.z	Deliverable from WPx.y
ECJ	European Court of Justice
eD	Electronic Dispensation
EHR	Electronic Health Records
eP	Electronic Prescription
epSOS	Smart Open Services for European Patients
EU	European Union
F2F	Face to face meeting
FR	Functional Requirement
FWA	Legal Framework Agreement
GP	General Practitioner
HW	Hardware
HC	Health Care
HCO	Health Care Organisation
HCP(O)	Health Care Professional Organisation
ICT	Information and Communication Technology
ID	Identity
IPSec	Internet Protocol Security
IT	Information Technology
JWG	Joint Working Group WP3.8/3.9
LSP	Large Scale Project
MS	Member State
MVC	Master Value Catalogue
NAB	National Authority Beneficiary
NCP	National Contact Point
NCP-A	National Contact Point in country A
NCP-B	National Contact Point in country B
NDA	Non-disclosure Agreements
PD3	Project Domain 3
POC	Point of Care
PR	Public Relations
PS	Patient Summary
PSB	Project Steering Board
QA	Quality Assurance
SLA	Service Level Agreement
SOA	Statement of Applicability
SP	Security Policy
SPOC	Single Point of Contact
SSL	Security Socket Layer
SW	Software
TPM	Technical Project Management

UPS	Uninterruptible Power Supply
WG	Working Group
WP	Work Package

796
797

798 **ANNEX - detailed use cases description**

799

800 **1 Introduction**

801

802 In chapters 2,3,4,5,6 can be found detailed description of use case as they had developed
803 from the first version to the last, when the process of use case selection for the specification
804 period started. Only selected use cases were described in the condensed form above.

805

806 The methodology of use cases description was long discussed in WP 1.4 and also inside
807 epSOS TPM. We decided for the template which uses three basic hierarchical levels:

808

809 **1st level - Basic process**

810 5 basic processes are defined:

811 Medication services, PS, EHIC, 112 emergency, Patient access

812 **2nd level - Cross border distributions of the basic processes**

813 **3rd level - Use Cases**

814

815 The use case description in this document has the following structure:

816

817 General introduction to the basic process

818 Basic process description (Actors, Goals, Information used, Process Steps)

819 Cross border distribution

820 Use cases description

821 Recommendation concerning basic process

822

823 Anyway it was not so simple to implement the methodology in the reality. In the document
824 below you can find some small variations of the described template.

825

826

827 **2 Patient Summary related use cases for the epSOS extension**

828 September 16, 2011

829 KT1.4.1

830 Juan Nuñez, Indra (IT)

831 M. Sprenger, Nictiz

832 W. Tesink, Nictiz

833 Version 0.4

834 sprenger@nictiz.nl

835

836 **2.1 Introduction**

837 This chapter treats the possible patient summary use cases in the cross-border distributions.
838 In epSOS phase I the use case to be piloted is the situation where the patient is in a foreign
839 country (country B in the common epSOS terminology), while in his home country - Country of
840 Affiliation (Country A) a patient summary is available, which is transferred and translated
841 (transcoded) to country B for the physician in B.

842

843 For the epSOS extension (phase II) it was agreed to focus on facilitating the sharing or
844 updating of pertinent patient summary information from countries different from country A.
845 Thus, focus on ways to make known to physicians in the home country and/or other countries
846 details about the treatment or diagnosis of the patient whilst travelling outside his or her home
847 country. This means that the patient can be at a point of care in his or her home country or in
848 any other country.

849

850 In the context of the epSOS distributions, “translation” of the patient summary relies on the
851 standard semantic services of epSOS, where the source patient summary from a country is
852 converted to an epSOS patient summary, which in turn is converted to the target patient
853 summary in a different country.

854

855 Below a first analysis is given of the most prominent distributions including two or three
856 countries. This analysis leads to proposals for the choices of use cases to be further
857 developed in epSOS.

858

859 **2.1.1 Basic process of patient summary use cases**

860 **Actors**

861 The actors involved in the patient summary use cases are the following:

862

863 • The patient: the patient concerned in these uses cases is always seen by a health
864 professional, either in his/her own country or in country other than his/her home country
865 (country A).

866 • The health professional at the point of care (PoC) in any country, home country or
867 abroad.

868

869 **Information used**

870 The information used in the Use Cases for patient summary is:

871

872 • The Patient Summary (PS)

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Steps of Patient Summary process

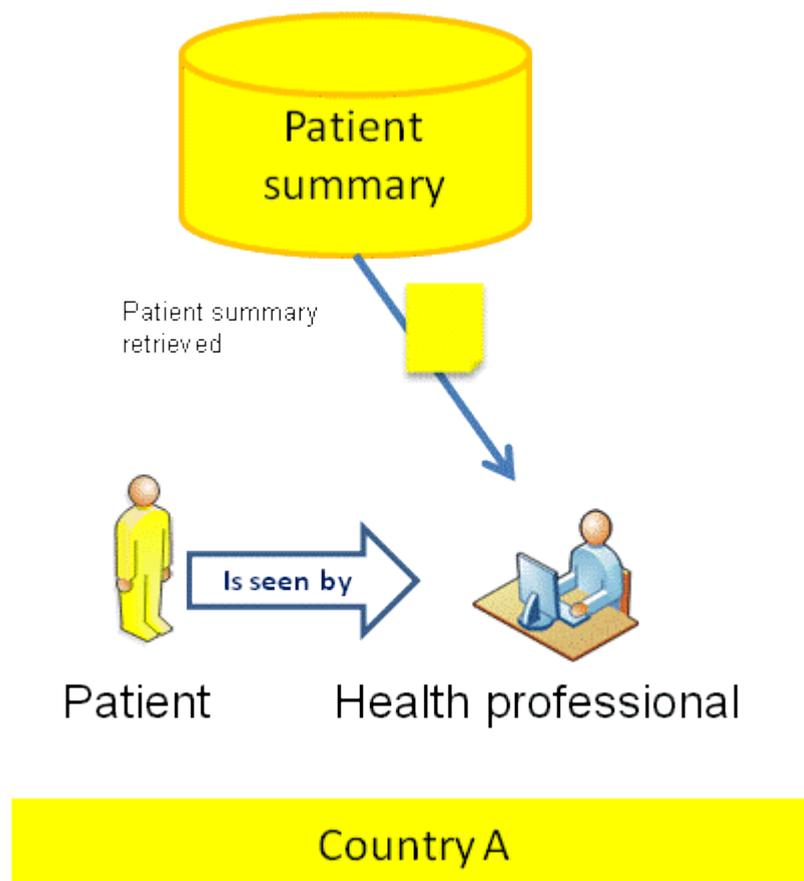
The steps in the common Patient Summary process are the following:

- The Patient is seen by a health professional that desires to consult the patient summary of the patient in order to improve the healthcare provided.
- The update of the Patient Summary is done in the country of affiliation, according to its own design and policies.

Note: Profound differences exist in the various countries in the design and implementation of the patient summary mechanism. The most prominent two approaches are:

- A patient summary can be in a single repository centrally managed by one health care provider or organization. Health professionals then insert or copy, on a regular basis, information elements of agreed nature to that central patient summary.
- A patient summary is constructed on the fly upon request by a central service that knows which information systems to query, and that combines information into one summary for transfer to the requester.

Moreover, the involvement of healthcare providers in the content of this Patient Summary varies: in some countries the general practitioner is supposed to be the healthcare provider that has all information, in other countries hospitals play a crucial role.



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903 **2.2 Analysis of the cross border distributions of the basic process**

904 When looking at the possibilities for cross border distributions in the handling of patient
 905 summaries, the following table displays the main possibilities (we are assuming the patient is
 906 always from country A):
 907

Cross border distribution	Country where patient summary is available	Country where the patient summary is displayed	Is patient summary updated?	Comment
1	A	A	Yes, in country A	Regular situation, non epSOS use case
2	A	B	No	Use case piloted in epSOS I
3	B	A	No	Patient of country A has a patient summary (summaries) in country B. The patient summary in country B is displayed in country A. The complexity resides in the identification of a foreign patient and its legal implications
4	B,C	A	No	Several patient summaries from different countries (other than the home country) exist. There is a need for displaying several patient summaries
5	A, B	C	No	Several patient summaries consulted from anywhere
6	A	B	Yes in country A	Patient summary in home country always up to date
7	A, B	C	Yes in countries A&B	Several patient summaries consulted from anywhere and updated simultaneously

908
 909
 910 **Cross border distribution 1** is the regular one where everything happens in the same
 911 country (not an epSOS scenario).
 912

913 **Cross border distribution 2** corresponds to the use case piloted in epSOS 1, i.e., patient
 914 summary from country A is displayed in country B.
 915

916 **Cross border distribution 3** is slightly different from distribution 2 since a patient summary
 917 exists in country B and is consulted from country A (the patient being from country A). The
 918 complexity of this distribution is related to the creation of a patient summary for a foreign
 919 patient and the ability to retrieve it when required from the home country, since there might not
 920 be a link between the identification code of the patient in country A and country B's
 921 identification code of the same patient. Furthermore, in some countries if a foreign patient is
 922 seen by different healthcare facilities, each facility may use a temporary ID that is not shared
 923 with other facilities. This makes very difficult the creation of a patient summary of a foreign
 924 patient. In this context, foreign patient means a patient that is not a regular beneficiary of the
 925 healthcare system and is from another country.
 926

927 **Cross border distribution 4** represents the situation where in several countries patient
 928 summaries of the same patient exist, next to the patient summary in country A. The difference
 929 compared to Cross border distribution 3 lies in the need for displaying somehow these patient
 930 summaries.
 931

932 **In Cross border distribution 5** several patient summaries (at least country A's & country B's)
 933 are consulted from any country (generally speaking, country C). There is a need for displaying

934 several patient summaries and proper identification of the patient in several countries in
935 distribution.

936

937 The always up-to-date patient summary in country A is represented by **cross border**
938 **distribution 6** where health professionals outside the borders of country A send “updates” to
939 this patient summary. As mentioned earlier, very likely update in this context means adding
940 new information to the patient summary and not modifying data already registered (such as
941 allergies) in the patient summary.

942

943 **Cross border distribution 7** represents the situation where there are several patient
944 summaries of the same patient that are updated from any country, generally speaking country
945 C.

946

947 The following sections contain diagrams that explain these distributions.

948

949 2.2.1 epSOS Patient Summary Use cases

950 2.2.1.1 Use Case UC.PS.1: Patient Summary in country B displayed in country A

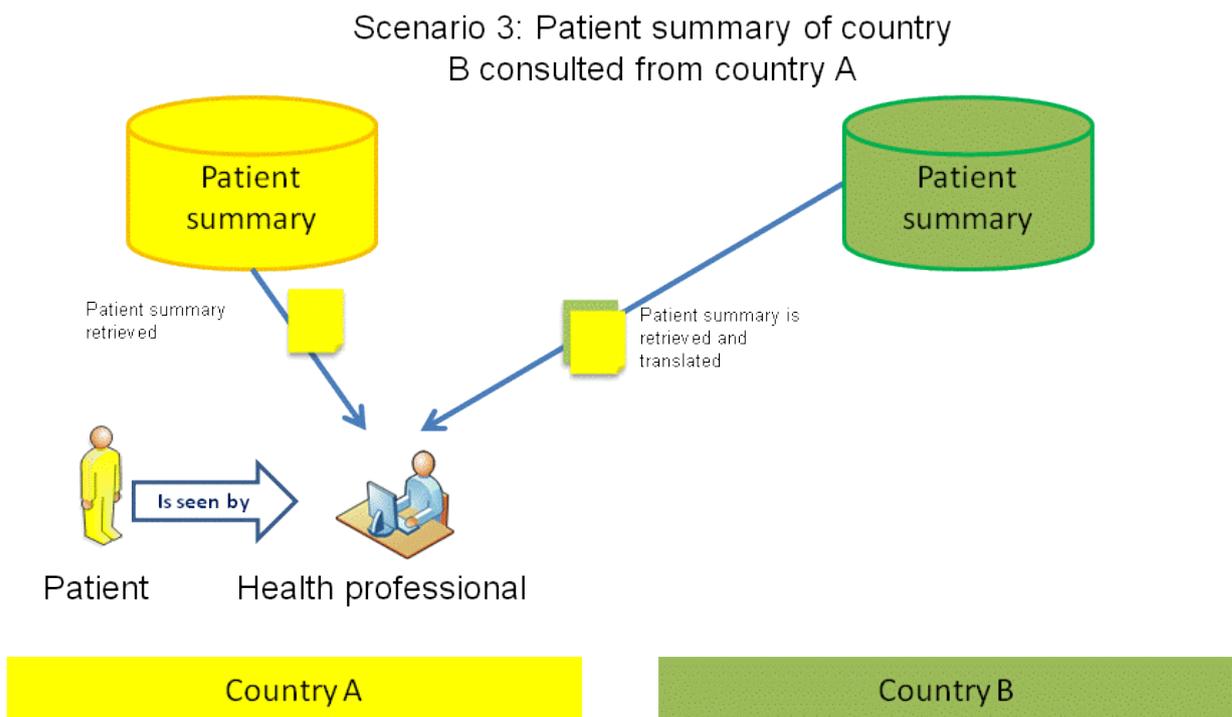
951 The following figure represents the use case where the patient summary from country B is
952 consulted by a health professional in country A. This situation may arise when a patient
953 spends time split in two countries, such as in case of seasonal migration, or even when
954 travelling for any reason, and a patient summary with relevant information is created in country
955 B.

956

957 In this picture, we are assuming that there is also a patient summary in country A, which
958 seems most natural and likely.

959

960 Depending on how countries manage the creation of patient summaries for foreigners (e.g.
961 whether they assign a permanent code to identify the patient or not, if several encounters in
962 different facilities/regions result in several patient codes) the retrieval of this information can be
963 feasible.



964

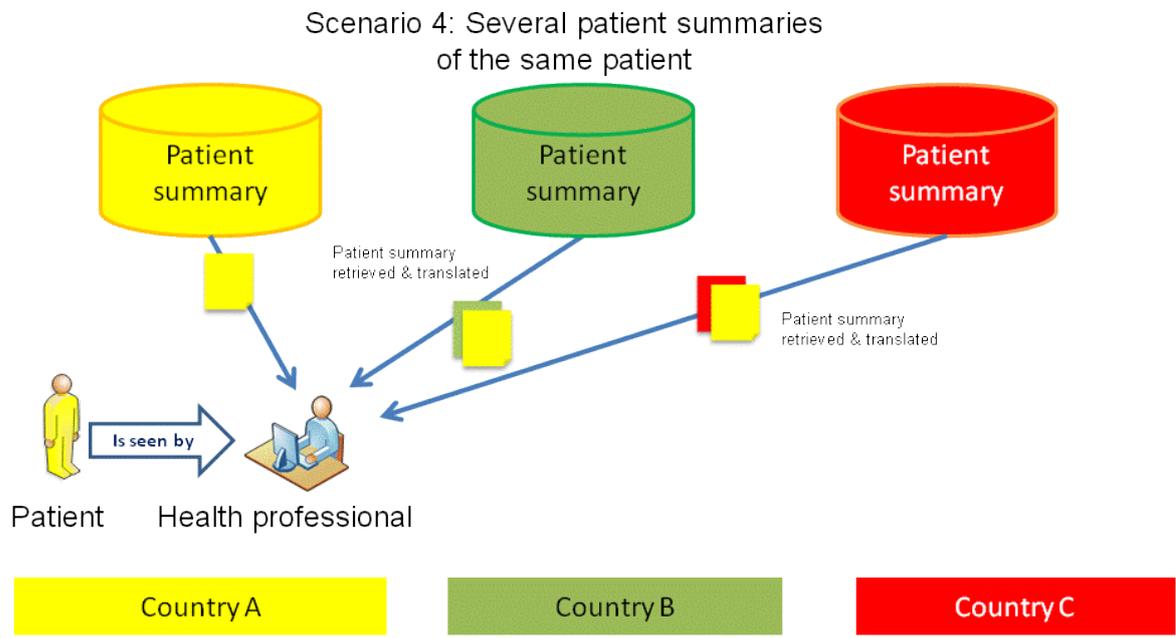
965

966 Since there will, most probably, also be a patient summary in country A, there is a need for
 967 displaying somehow patient summaries (one from country A and another from the country B).
 968 The main challenge presented by this compilation or aggregation basically consists in the
 969 difficulty of acquiring information from several patient summaries and presenting it in a way
 970 that is useful to the health professional. Several alternatives may be considered, such as:

- 972 • Displaying independent patient summaries to the health professional who navigates
 973 them. This is a simpler approach but consumes more time of the health professional.
 974 The advantage of this approach however is, that the originating country is visible to the
 975 health professional when information originating from Country B/C is be clearly tagged
 976 as such..
- 977 • Reorganizing all information into one single patient summary placing every item from
 978 all patient summaries in its respective category. This alternative is technically more
 979 complex although, if well performed, saves time to the health professional.

982 **2.2.1.2 Use Case UC.PS.2: Several patient summaries of the same patient**

983 This use case corresponds to the situation where several patient summaries of the same
 984 patient exist, in different foreign countries (B & C) and are consulted from country A. The main
 985 difference with regards to the previous use case is that instead of one “foreign” country there
 986 might be several, which introduces further complexity, particularly regarding the identification
 987 of the patient, since many identification codes of the patient may be involved (even several
 988 identification codes in the same country).
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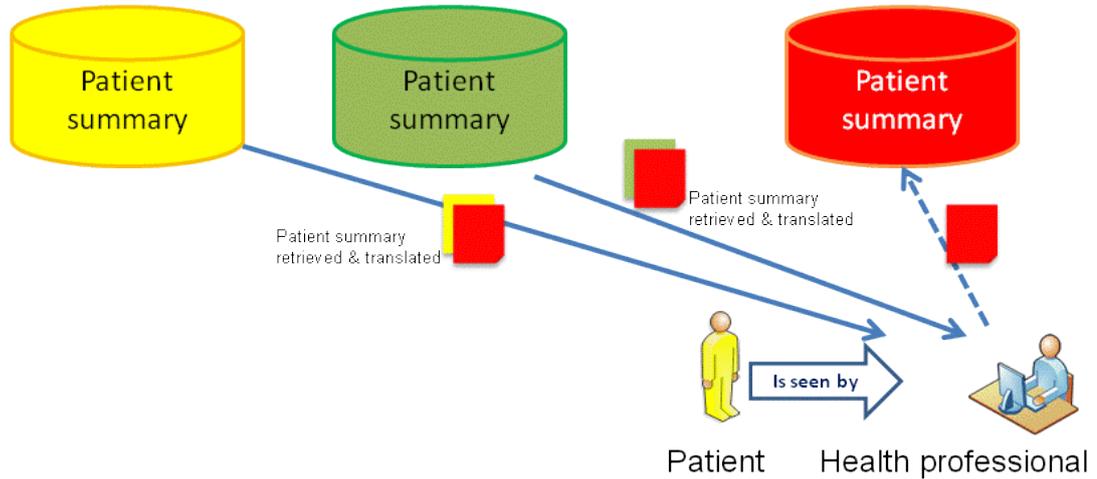
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2.2.1.3 Use Case UC.PS.3: Several patient summaries from the same patient consulted from anywhere

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The following figure represents the use case where several patient summaries of the same patient have been created and are consulted from any country (generally speaking, country C). The dotted line represents an option. In this particular case, it is a possible creation or update of the patient summary in country C, performed by the health professional.

Scenario 5: Several patient summaries of the patient consulted from anywhere



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Again, the complexity of this use case lies in the identification of the patient and the aggregation of information from several patient summaries.

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2.2.1.4 Use Case UC.PS.4: Patient Summary of country A always updated

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This use case represents the situation where one single patient summary, in country A, is kept always up-to-date, and, therefore, integrates somehow the updates sent from health professionals from any other country, country B. The dotted line represents an option. In this particular case, it is a possible creation or update of the patient summary in country B, performed by the health professional.

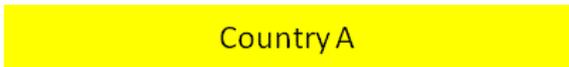
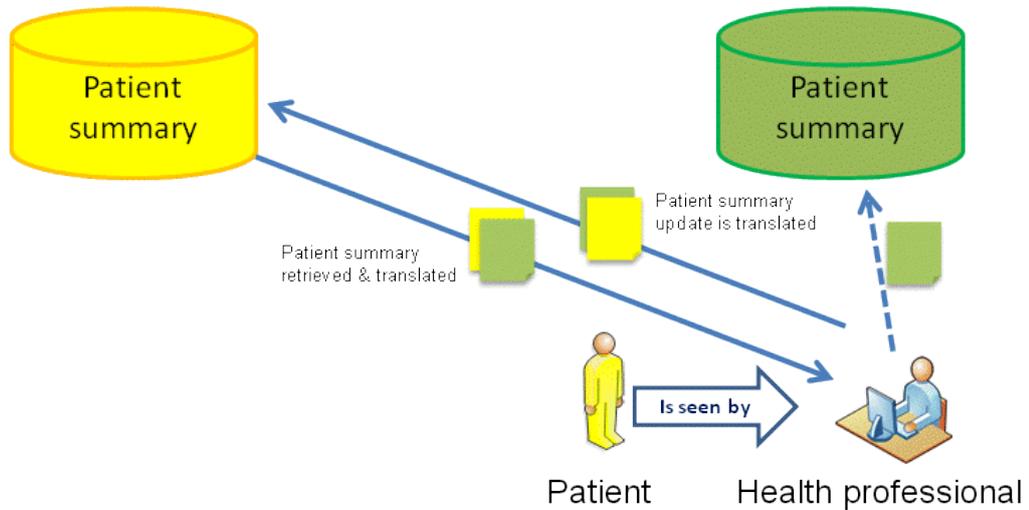
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Several organizational issues challenge the feasibility of this use case that requires the updating of the patient summary from outside the national/regional borders. Some of these difficulties are present if:

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- The patient summary is the result of the compilation of information from several sources in Country A. Updating this type of patient summary is more complex than updating a patient summary hosted in one single location. Moreover, the information systems that contains these pieces of the patient summary need to be able to accept the same patient summary pieces from another information system, which might not be the case in every country (different data structure and coding systems, lack of validation mechanisms, etc.).
- There is not one single health professional responsible for the patient summary of the patient. In this case, the health system has to decide if it accepts the information from another country without the supervision of a health professional (of the patient's own country).

Scenario 6: Patient summary of country A always updated



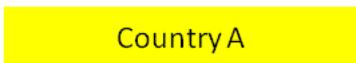
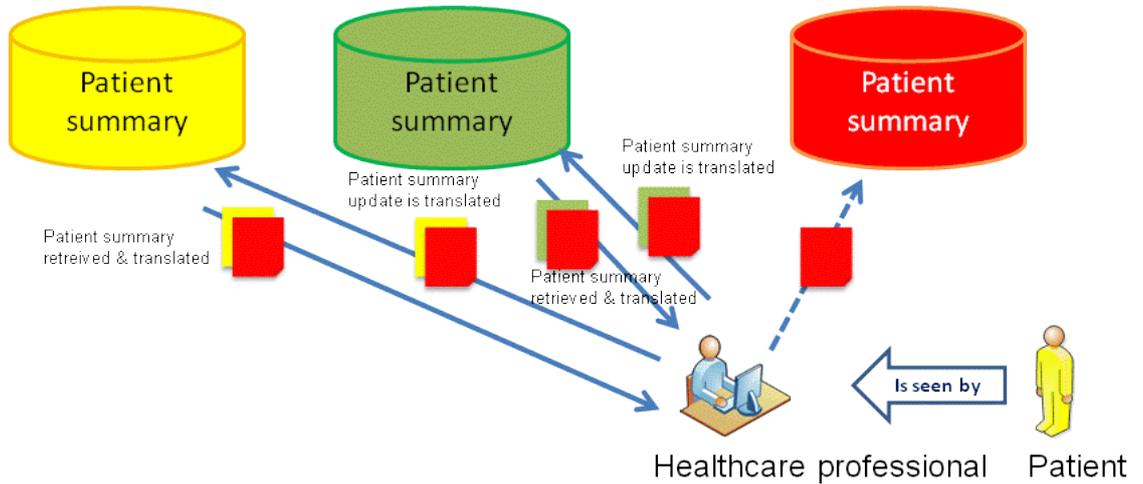
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2.2.1.5 Use Case UC.PS.5: Several patient summaries of the patient all updated

In this use case, the patient summaries are updated by any health professional (independently of the country where the patient is being seen).

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Scenario 7: Several patient summaries of the patient, all updated



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This use case combines the challenges from the previous ones since it requires the compilation and displaying of information coming from several patient summaries and the updating of all of them.

1038 **2.3 Proposed use case for the patient summary in the epSOS extension**

1039 The following epSOS principles (see also in chapter 1 Introduction) should be applied on the
1040 use case descriptions above:

- 1041 • No intrusion into national systems but opportunity influence national transpositions of
1042 the directive.
- 1043 • epSOS is not aiming at a federated pan-European database.
- 1044 • epSOS is aiming to support each participating nation retaining its own responsibility for
1045 eHealth.
- 1046 • In principle each participating nations has responsibilities under the directive as a
1047 country of affiliation with respect to its own citizens, therefore:
 - 1048 ○ epSOS access to patient's data is only possible through the country of
1049 affiliation.
 - 1050 ○ Each country of treatment must provide means to transfer epSOS encoded
1051 medical information about the patient to the country of affiliation

1052

1053 Applying these principles results in that all use cases where the Patient Summary is retrieved
1054 from any other country than country A, are not supported by epSOS. UC.PS.5 is therefore out
1055 of scope for further analysis. In order to comply with all these principles and still support the
1056 distributions, UC.PS1-4 are merged into the proposed use case UC.PS.6 below.

1057

1058 Note that in comparison to the use case descriptions above, in the UC.PS.6 context, country B
1059 does not have a Patient Summary of foreign patients, but only some medical information of
1060 foreign patients that have had a treatment event.

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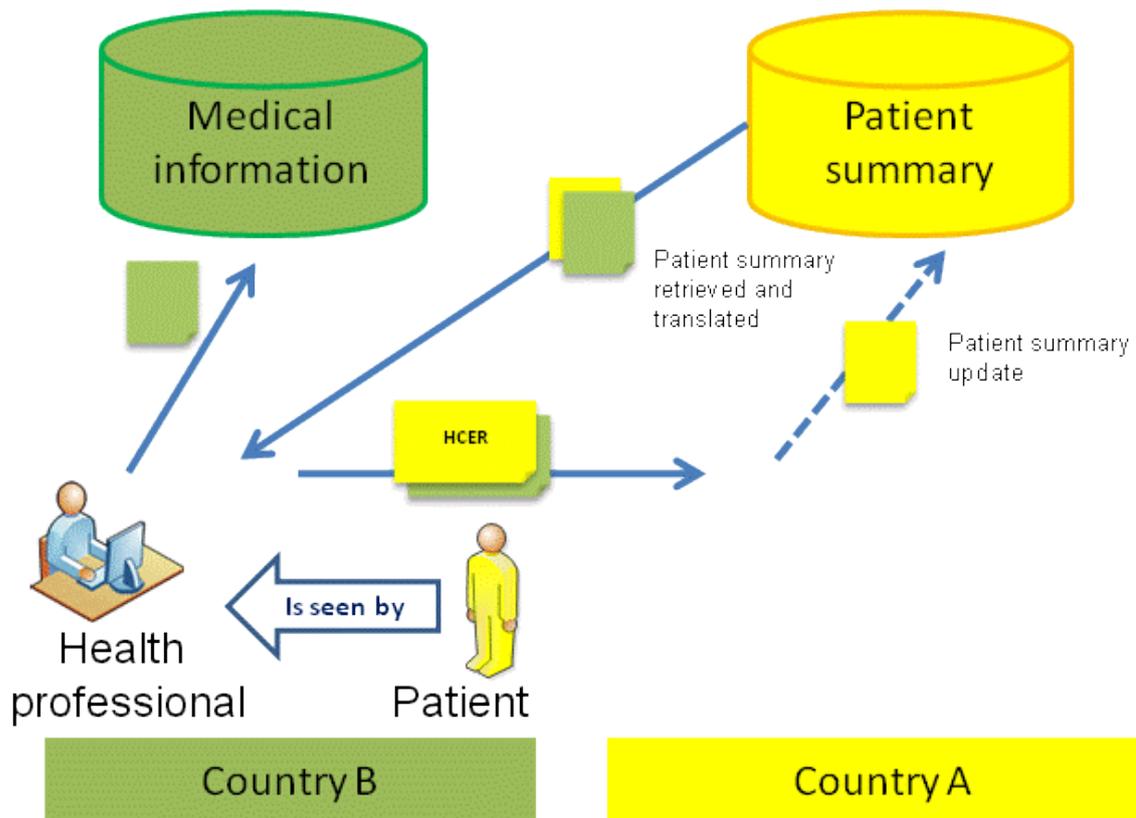
1062 **2.3.1 UC.PS.6 healthcare encounter report is send to country A**

1063 The patient visits a health professional in country B

- 1064 1) The health professional in country B requests the patient summary from country A.
- 1065 2) The health professional in country B records encoded medical information about the
1066 patient's treatment event.
- 1067 3) The health professionals sends country A a Healthcare Encounter Report (HCER) to
1068 country B
- 1069 4) Based on the information in the HCER, the patient summary in country A can be updated
1070 according to the own policies of country A.

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1075 **2.3.2 Feasibility of the proposed uses cases**

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- Information can only be sent to the country of affiliation in a security context, as long as this context exists. Once the context is suspended, the information cannot be exchanged with guaranteed data security, integrity etc.
- Sending information to country A can give legal responsibilities for (health professionals in) country A. In those cases it could be an option for country A to store the received HCER in a Personal Health Record of the patient.

1084

1085 **3 Medication related use cases for the epSOS extension**

1086

1087 August 3, 2011

1088 KT1.4.1

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1090 Wouter Tesink, Nictiz

1091 Juan Nuñez, Indra (IT)

1092 Version 0.5

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1095 **3.1 Introduction**

1096 This chapter concentrates on the various cross-border distributions for the medication-related
1097 processes, and describes within these distributions the possible use cases. Furthermore a
1098 proposal is presented for which use cases to include into epSOS II.

1099

1100 First we will show our interpretation of the basic medication-related process and actors. This
1101 interpretation is general enough to be applicable to the situation within all participating nations.
1102 Then we will, based upon this process description show the distributions that can be
1103 distinguished when not all actors and/or information elements are situated within one country,
1104 thus showing the various epSOS distributions. Finally we will do proposals for use cases to be
1105 developed within these distributions and describe them in wording and schemes.

1106

1107 **3.1.1 Business goals for cross border use cases**

1108 The development of cross-border solutions for medication serves two major goals:

1109

- 1110 • Improving the continuity of care by providing solutions for the cross-border validity of
1111 medication prescriptions;
- 1112 • Improving patient safety by supplying relevant information to all actors in the
1113 medication process, wherever the patient resides. The safety is increased most and for
1114 all by the prevention of adverse drug events. We call this consulting the medication
1115 related overview.

1116

1117 **3.2 Medication Related Overview**

1118 To accommodate the business goals described in the previous paragraph, three sets of
1119 medication related information are needed. Two of these are already defined in epSOS, which
1120 are the ePrescription (eP) and eDispensation (eD). The new set of information is needed to
1121 support improving patient safety, which we call the medication related overview (MRO). These
1122 three information sets are all part of the 'historical medication information', that is kept up to
1123 date in country A.

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1125 The availability of the medication related overview of the patient to the different actors is
1126 generally considered to be crucial for the safety aspects, in order to prevent adverse drug
1127 events.

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Two types of medication safety checks exist:

- Drug-drug interaction checking
- Drug-patient interaction checking, in the ICA triple check for:
 - Intolerances
 - Contra-indications (other diseases, special conditions like pregnancy, etc)
 - Allergies

What information the medication related overview should consist of is at this stage not decided, but in WP1.4.5 (Country status outline) the following data elements were considered as relevant:

- a) Allergies and other adverse reactions
- b) Intolerances
- c) Contra indications
- d) History of past illness
- e) Immunization
- f) List of surgeries
- g) List of current problems/diagnosis
- h) Medical devices
- i) Health Maintenance Care Plan
- j) Functional Status
- k) Social History
- l) Pregnancy History
- m) Physical findings (e.g. blood pressure)
- n) Diagnostic tests (e.g. blood group)
- o) Lab results
- p) Prescriptions (including fulfilled prescriptions)
- q) Actually dispensed medication information

1160 **3.2.1 Relation with the Patient Summary**

1161 Although all nations in Europe agree on the importance of consulting the medication related
1162 overview, implementations and roles vary widely. In some countries prescribers, dispensers
1163 and administrators are all informed on the medication history, in some other countries the
1164 prescribers have the whole responsibility for dispensation of appropriate medication on the
1165 basis of their prescription information. Any epSOS solution supposed to be instrumental in
1166 implementation of medication related overview will have to take these differences into account.

1167
1168 The medication related overview is not always a (single) separate set of information. A subset
1169 of the information in the medication related overview is in some countries part of the Patient
1170 Summary, which is in its turn not always accessible by all actors involved in the medication
1171 process. In the epSOS context the medication related overview is seen as a single document.
1172 It is up to the participating nations if this document is derived from the patient summary or not.
1173 In cases the medication related overview is derived from the Patient Summary, prescription
1174 (and dispense) information reported back to country A should also be incorporated into the
1175 Patient Summary.
1176

1177

1178 3.3 Basic medication process and actors

1179 Figure 3.1 shows the general process flow with its actors and information elements. The
1180 human actors are:

1181

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- The **patient**, who is referred to (or reports himself to) a physician.
- When the decision is made that the patient has to take medication for treatment the physician, in his role as **prescriber**, issues a medication prescription that can be seen both as an order to a pharmacist as well as the agreement between the physician and the patient on the specific treatment with this medication. For doing this, the prescriber receives relevant historical medication information.
- The pharmacist, in his role as a **dispenser** of medication, receives the prescription, in some countries he receives relevant historical medication information, and dispenses the medication. The pharmacist then issues information about the dispensation, which serves two goals: it is added to the historical medication information, and it is used to update the status of the prescription (in some cases it lowers the amount of remaining items that can be given out from the prescription).
- The **patient** again, finally, receives the medication and takes care of the administration, with or without the intervention of family members and/or nurses.

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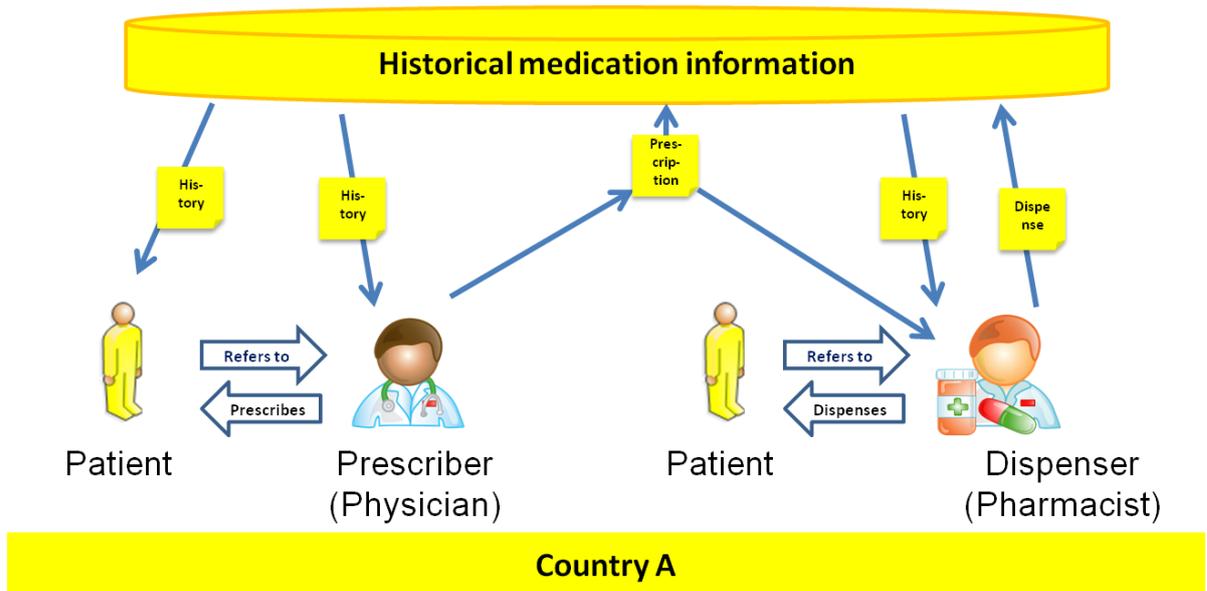
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Figure 3.1: process flow and related information for the generalised medication process

In figure 3.1, this process is shown in the lower half, and the flows of information are shown in the upper half. Directly related to the process are the prescription and the dispense information, both are, in general terms, also included into the medication history of the patient. This general description of the medication process will be used below to analyse the various possibilities of cross-border situations, when all actors or all information elements are not in the same country.

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Some limiting remarks apply to this scheme:

- Some countries do not implement this process fully. For instance, certain countries do not grant patients access to their own medication history.
- The history information supplied to the different actors is not necessarily identical for all actors. In some countries limitations may occur, e.g. for pharmacists, who are in certain countries prohibited to see information that is considered to be of medical nature, like allergies;
- Some countries include a step called Pharmaceutical Advice, between prescription and dispense;
- This process is not fully supported electronically in all countries and regions; but in a vast majority of the nations in Europe developments take place to do so in the near future;
- This process applies to community pharmacy only; clinical pharmacy (within the hospital) is not considered here. This is done because medication prescribed for outpatients is not to be dispensed in the hospital. ePrescription can only over the prescription of medication to a patient in the hospital (in emergency, or in an external consultant or when the patient is discharged), but only if this is dispensed in a community pharmacy.

1231 **3.3.1 Cross border distributions for the medication process**

1232 When looking at the process scheme of figure 3.1, five distributions exist for spreading the
1233 three different actors over one, two or three countries. Table 3.1 gives these possible
1234 distributions. These are the distributions described in the epSOS I specifications. Accessing
1235 the medication related overview is not included in this table and is described in table 3.1a.
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Db	Home	Prescribing	Dispensing	Comment
1	A	A	A	Regular situation, process in home country, not epSOS
2	A	A	B	Medication already prescribed in home country
3	A	B	B	Medication newly prescribed and dispensed in foreign country
4	A	B	A	Medication prescribed in B, dispensed in home country
5	A	B	C	Two foreign countries involved

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Table 3.1: distributions for the occurrence of the prescription-dispensation chain spread over possible different countries (A, B and C) in relation to the home country of the patient (A).

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The following observations apply:

- Distribution 1, of course, is the regular situation within the home country, see figure 3.1.
- Distribution 2 and distribution 3 will be discussed below; the epSOS I ePrescription use case is within distribution 2
- Distribution 4: our assumption is that in most cases a patient, when returning home, will go to his own GP or specialist to obtain a local, country A prescription.
- Distribution 5 is uncommon: in most cases a patient in C will refer to a prescriber in C, thus reverting to distribution 3.

In addition to the above distributions we can add the possible distributions when the medication related overview is being accessed. As this information could be accessed and in some countries even generated by both prescriber and dispenser, it is more an issue of in which country the information is accessed and from which country/countries this information is retrieved.

Db	health professional	Source of medication related overview	Comment
I	A	A	Regular situation, process in home country, not epSOS
II	B	A	Prescribing or dispensing HCP in country B
III	A	(A+)B	A subset of the medication related overview is available in country B. Proposal: out-of-scope.
IV	B	(A)+B	Somewhat similar as distribution III: the medication related overview is partly in country B and all the involved healthcare professionals are in country B. This would be an addition to distribution 3 and 5. Proposal: out-of-scope.

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Table 3.1a: distributions for the occurrence of where the medication related overview is accessed and retrieved from over possible different countries (A and B).

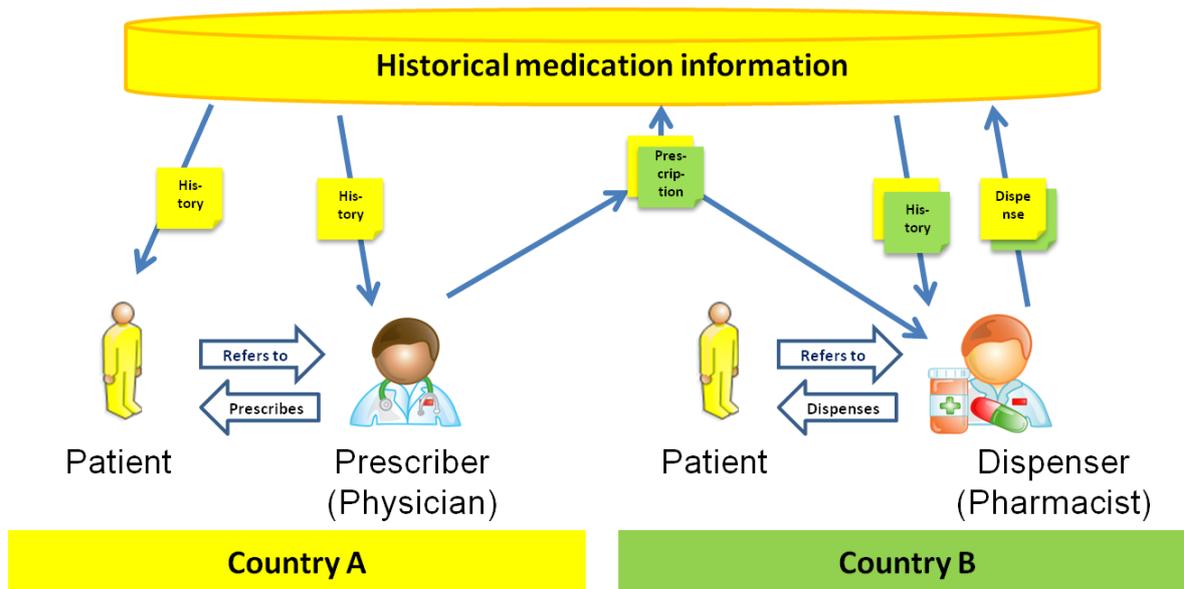
The following observations apply:

- Distribution I, of course, is the regular situation within the home country and won't be further discussed.
- Distribution II will be discussed below as part of distributions 2 and 3.
- Distribution III could be a possibility if, for instance, new allergies are discovered in country B. This distribution adds a lot of complexities as multiple source countries are involved and, on top of that, there is a strong relation with the extension of the Patient Summary. So for now, the proposal is to leave this distribution out of scope of epSOS II and therefore is further not discussed.
- For the same reasons as distribution III, distribution IV is also placed out of scope and therefore not further discussed.

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3.3.2 Distribution 2 + II: “Medication already prescribed in home country”

In this distribution a patient will go to a pharmacy in country B, the country where he or she is visiting, in order to obtain medication on the basis of a prescription from the home country. Typically this use case occurs with patients who have repeating prescriptions (prescriptions that lead to multiple dispenses) from their home country. Diabetes patients might form the largest group here. Figure 3.2 gives the modified scheme for this process, showing the actors and information elements in the colours also used in Table 3.1 and 3.1a.



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Figure 3.2: process diagram of the medication distribution 2 (eP and eD) + distribution II (medication related overview).

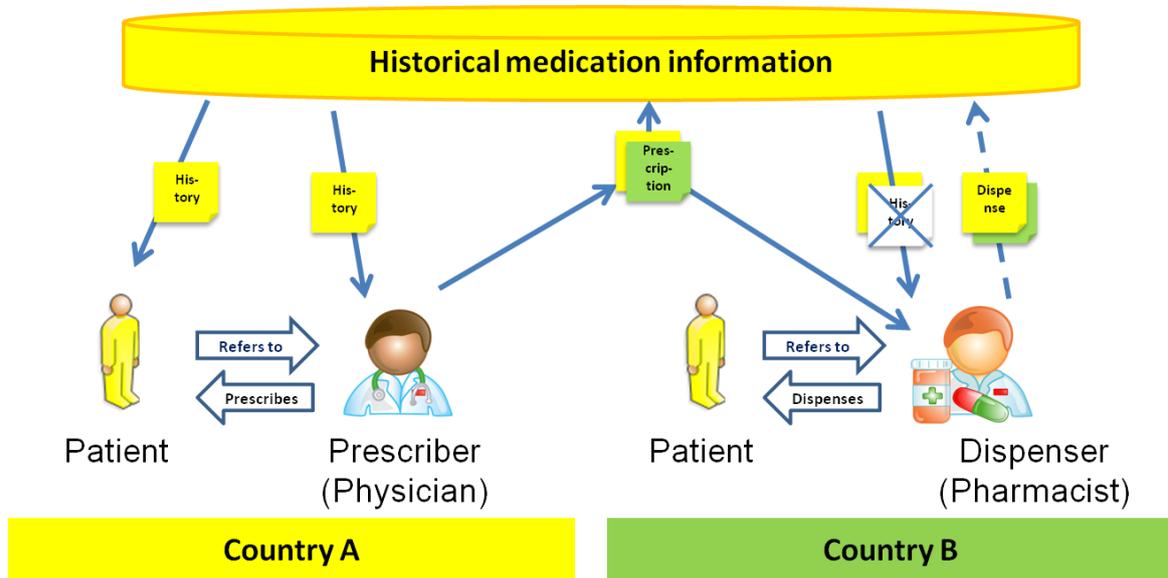
epSOS translation services are needed for:

- Making the available prescriptions from country A usable for the pharmacist in B;
- Making the Medication Related Overview of the patient from country A usable for the pharmacist in B
- Feeding back the dispense information from the pharmacist in B into the history in country A, from which also the status of the prescription in country A is updated.

The epSOS I specification and piloting has the first translation as a requirement, does not implement the second, and has the third to be implemented by epSOS for Country B, but it is left to Country A decide how to update the historical medication information (depicted by the dotted arrow).

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Thus the process scheme for the epSOS I implementation looks like figure 3.3. We call this use case UC.MED.0.



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Figure 3.3: Process flow for the use case as implemented in epSOS I .

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We propose to implement in epSOS II the full distribution 2 for the epSOS I specifications together with distribution II for the medication related overview, seen in figure 3.2. We call this use case UC.MED.1. This implicates two extensions to the epSOS1 use case as seen in figure 3.3:

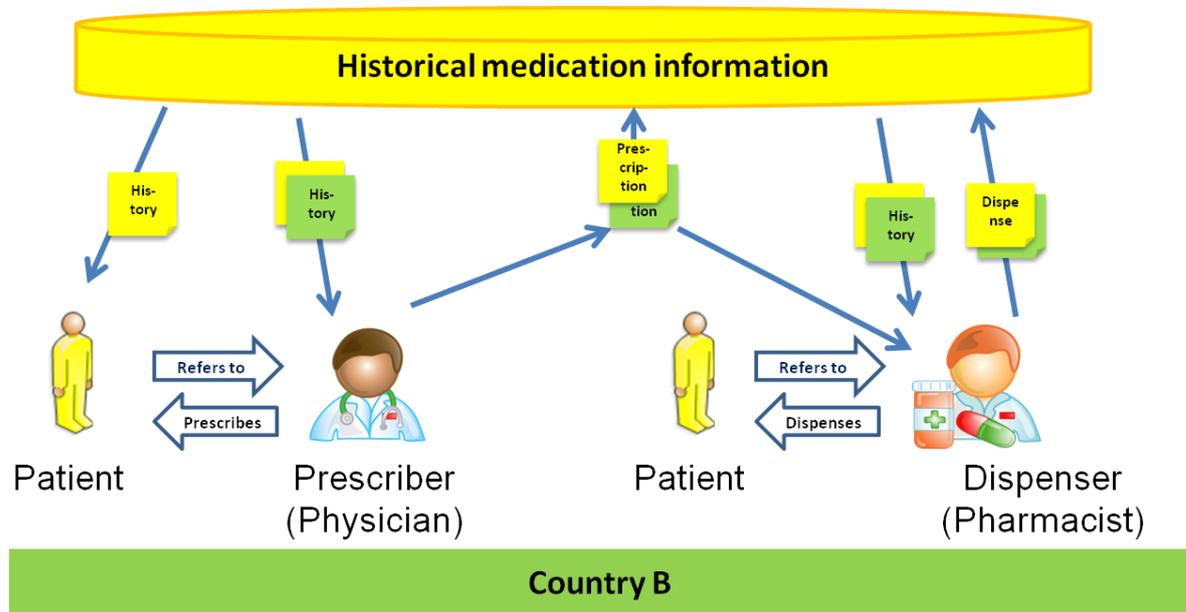
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- Fully implement the translation and feed-back of dispensed medication information to country A for inclusion into the history, until now country A could decide to ignore the eDispensation from country B (dotted arrow in figure 3.3) and not include this in the historical medication information.
- Make the Medication Related Overview from country A available to the pharmacist in country B, for the purpose of patient safety. This cannot be a unique solution, since countries have different policies for making information available to pharmacists. Here the maximum approach should apply, and not the common minimum: through epSOS the information should be made available to pharmacists in B that the country A considers appropriate for the safety of its patients. Thus, this information is not uniquely specified but will have a range of possible enhancements, depending upon the policy of country A.

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3.3.3 Distribution 3: “Medication newly prescribed and dispensed in foreign country”

Figure 4.4 gives the diagram for distribution 3 (eP and eD) + distribution II (medication related overview).



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Figure 4.4: diagram for the medication use case of distribution 3 (eP and eD) + distribution II (medication related overview), full implementation

For distribution 3, four epSOS translation and transfer services are needed:

- Translation of the Medication Related Overview from country A to the prescriber in country B¹
- The Medication Related Overview also goes to the dispenser in country B (not necessarily the same set as the set provided to the prescriber)²
- Translation of the prescription to be included in the medication history in country A³
- Translation of the dispensed medication from the pharmacist in country B to be included in the history in country A.

We call the full implementation of distribution 3 (together with distribution II for the medication related overview) use case UC.MED.2

¹ part of information could be overlapping with information from the Patient Summary from country A

² note that distribution IV from table 3.1a is out of scope. This means that there is no feedback loop back to the historical medication history in country A (other than a possible Patient Summary update described in chapter 2).

³ the dispenser gets the unfulfilled prescription via the prescription process of country B – not from country A via epSOS

1362 **3.3.4 Proposed use cases for the epSOS extension, medication related**

1363 Here we describe the use cases as being proposed for the epSOS extension in a narrative
1364 way. They are given as full implementations of the distributions 2 and 3, together with the
1365 additional distribution II for the medication related overview, in the terms and limitations
1366 described above. In words we will once again phrase them:
1367

1368 **3.3.4.1 UC.MED.1:**

1369 *A patient from country A is visiting country B. The patient has a prescription that is not fully*
1370 *dispensed yet. The patient needs medication to be dispensed, based upon this prescription.*
1371 *The patient goes to a pharmacy in country B. The pharmacy in country B obtains, from country*
1372 *A, the historical medication information of the patient which includes the available prescriptions*
1373 *and the medication related overview. The medication related overview is obtained in a form*
1374 *and richness common in country A (how country A normally informs a pharmacist). The*
1375 *pharmacist checks the medication to be dispensed against the medication related overview to*
1376 *check for possible adverse reactions and / or other unwanted effects. When the pharmacist*
1377 *can assume that medication can be safely and legally dispensed, the medication is handed to*
1378 *the patient or the person representing the patient (e.g. a family member). The pharmacist in*
1379 *country B makes the dispensation information available, which then is transferred to the home*
1380 *country for inclusion into the medication history in country A, and for updating the status of the*
1381 *prescription in country A, i.e. lowering the remaining amount of possible dispenses from that*
1382 *prescription.*
1383

1384 **3.3.4.2 UC.MED.2:**

1385 *A patient from country A is visiting country B. The patient needs care and visits a physician in*
1386 *country B. The physician and the patient conclude that the patient needs medication. The*
1387 *physician in country B consults the historical medication information (i.e. the medication*
1388 *related overview) from country A, and based upon that history and the current situation*
1389 *(illness) of the patient, issues a prescription. That prescription is sent to country A for inclusion*
1390 *into the medication history in country A, for future reference. The patient goes to a pharmacy in*
1391 *country B. The pharmacy in country B obtains, from country A, the historical medication*
1392 *information of the patient which includes the medication related overview (and any available*
1393 *prescriptions). The medication related overview is obtained in a form and richness common in*
1394 *country A (how country A normally informs a pharmacist). The pharmacist obtains the*
1395 *electronic prescription from the physician in country B, through the regular Country B*
1396 *procedure. The pharmacist checks the medication to be dispensed against the medication*
1397 *related overview, to check for possible adverse reactions and / or other unwanted effects.*
1398 *When the pharmacist can assume that medication can be safely and legally dispensed, the*
1399 *medication is handed to the patient or the person representing the patient (e.g. a family*
1400 *member). The pharmacist in country B makes the dispense information available in electronic*
1401 *form, which then is transferred to the home country for inclusion into the medication history in*
1402 *country A.*
1403

1404 Table II finally lists the proposals done in this document for the various distributions.
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 1407

Db	Home	Prescribing	Dispensing	Source of medication related overview	Comment
1 & I	A	A	A	A	Regular situation, process in home country, not epSOS
2 & II	A	A	B	A	Medication already prescribed in home country. Partly implemented in epSOS I., UC.MED.0 Proposal: full implementation in epSOS II, UC.MED.1
3 & II	A	B	B	A	Medication newly prescribed and dispensed in foreign country: Not implemented in epSOS phase I Proposal: full implementation in epSOS II, UC.MED.2
4 & III	A	B	A	(A+)B	Medication prescribed in B, dispensed in home country Proposal: Out-of-scope in epSOS I&II, UC.MED.3
5 & IV	A	B	C	(A+)B	Two foreign countries involved Proposal: Out-of-scope in epSOS I&II, UC.MED.4

1408
 1409 Table 3.2, proposal for the use cases to be developed in epSOS
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1412 **3.3.5 Feasibility of proposed use cases**

1413 In a short questionnaire the different member states answered if the proposed use cases
 1414 above could be piloted in their respective countries. Nine countries responded on this
 1415 questionnaire, and only a few said that they could support a pilot. The following use cases are
 1416 feasible:

- 1417
- 1418 • UC.MED.1 as country A : 3 countries
- 1419 • UC.MED.1 as country B : 3 countries
- 1420 • UC.MED.2 as country A: 1-2 countries
- 1421 • UC.MED.2 as country B: 2 countries
- 1422
- 1423

1424 Also work is done in KT1.4.5 to get information on if and when medication related overview is
 1425 available, but at the time of writing only preliminary conclusions are available from this study.
 1426 From these preliminary conclusions it seems that

- 1427
- 1428 • In 50% of the countries medication related overview is available. It is foreseen that in
 1429 2013 fourteen countries will have a medication related overview electronically available
 1430 as an individual document. It is reasonable to expect that this number of countries will
 1431 be reached, because already thirteen countries have medication related overview
 1432 available at the moment.
- 1433 • From the countries that have a medication related overview more than fifty percent
 1434 have an overview that is available for different actors (all include the pharmacist). This
 1435 means that both prescriber and dispenser could access this information.
- 1436 • Only four countries can request and retrieve a medication related overview for all of
 1437 their patients at the moment. In the future it is foreseen that only five PN will be able to
 1438 do this.
- 1439 • Nine Participating Nations answered that none of the elements are applicable at the
 1440 moment. This means that nine countries can't translate the different elements of the
 1441 dataset of the medication related overview in another language. Because only coded
 1442 text can be translated.

- 1443
- 1444
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- 1446
- 1447
- 1448
- 1449
- In some countries the medication related overview is part of the Patient Summary. It must be kept in mind that in some countries a pharmacist is not allowed to view the PS.
 - From the remaining countries a large part uses free text for their elements or still have a lot elements not applicable. A relative small part of the elements is coded and therefore at the moment useable for translating information in the epSOS setting. The codes that are used differ greatly between countries.

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There is also the issue of the available time for creating the specifications for the medication related overview. This process took for over a year in epSOS I for the patient summary and ePrescription (WP3.1 and WP3.2). The amount of time available according to the epSOS II planning (KT1.4.6) is only 2 months.

1455 **3.3.6 Semantics**

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To enable the full implementation of the use cases described above, it is necessary to extend the limits of epSOS I on the semantic level. The limitation decided on in epSOS 1, that the semantic services only support information on "medicinal products intended for human use, elaborated from an industrial process, prescribed for out-patients (not to be dispensed in the Hospital), and dispensed in Community Pharmacies. These medicinal products must be produced by a registered pharmaceutical manufacturer and hold a current 'marketing authorisation' (licence)". In addition, narcotics were excluded. Even if these limitations are continued for the eDispensation use cases, they should not apply to the medication related overview. Information about allergies and previous medication history should include active ingredients not necessarily included in the epSOS Active Ingredient valueset.

1468

1469 **4 EHIC related use-cases analysis**

1470

1471 September, 16, 2011

1472 KT 1.4.2

1473 Task Leader: Andrzej Strug, Andrzej.Strug@nfz.gov.pl

1474 Beneficiary: NFZ (PL)

1475

1476 **4.1 Introduction to EHIC related use-case analysis**

1477 **4.1.1 General introduction**

1478 The aim of EHIC business case study was to investigate possibilities of including the functions
1479 concerning patient identification and healthcare entitlement verification, being based on the EU
1480 social security coordination system, into epSOS project pilot.

1481

1482 Initial assessment of this problem presented by the Key Task Leader and discussed on the
1483 TPM level concluded with the decision not to implemented EHIC use cases within the scope of
1484 epSOS II. The main reason for this is that on the one hand it is not feasible to repeat the work
1485 done or being done in the other EU projects (EESSI, NETCARDS), and on the other hand
1486 there are still no sustainable outcomes of these projects that could be reused as the parts of
1487 epSOS solution. There are also certain limitations arising from regulations regarding EHICs
1488 and general social security coordination system that don't facilitate computerization of these
1489 areas.

1490

1491 This decision influences also the content of this document in the part describing EHIC related
1492 processes. The common for other use cases chapter with recommendations is replaced with
1493 chapter containing critical analysis of the today's EHIC use cases.

1494

1495 Suggestions about enhanced future EHIC use cases will be presented and discussed in a
1496 separate document (chapter) that will be prepared in the scope of the Key Task 1.4.7. In
1497 accordance with the TPM decision, results of the EHIC use cases analysis will be taken into
1498 consideration to prepare recommendation about changes in ICT environment of the healthcare
1499 sector, that would allow for an implementation of the more advanced eHealth solutions.

1500

1501 **4.1.2 European Health Insurance Card**

1502 Having regard to Administrative Commission Decision No 189 of 18 June 2003, the European
1503 health insurance card (EHIC) progressively replaced the forms provided for by Regulations
1504 (EEC) No 1408/71 and (EEC) No 574/72. EHIC – as personal and not-transferable document
1505 – provides a minimum set of “eye-readable” data to be used in a Member State of temporary
1506 stay (B) – EEA countries and Switzerland – other than the Member State of insurance or
1507 residence (A) for identifying the insured person, the Competent Institution and the card in
1508 order to state the entitlement for receiving unplanned medical treatment for free or at a
1509 reduced cost.

1510

1511 The EHIC is to be issued by the institution of the competent State or the State of residence.
1512 The period of validity of the European cards is determined by the issuer institution itself, taking
1513 into account the presumed duration of the insured person's entitlement.

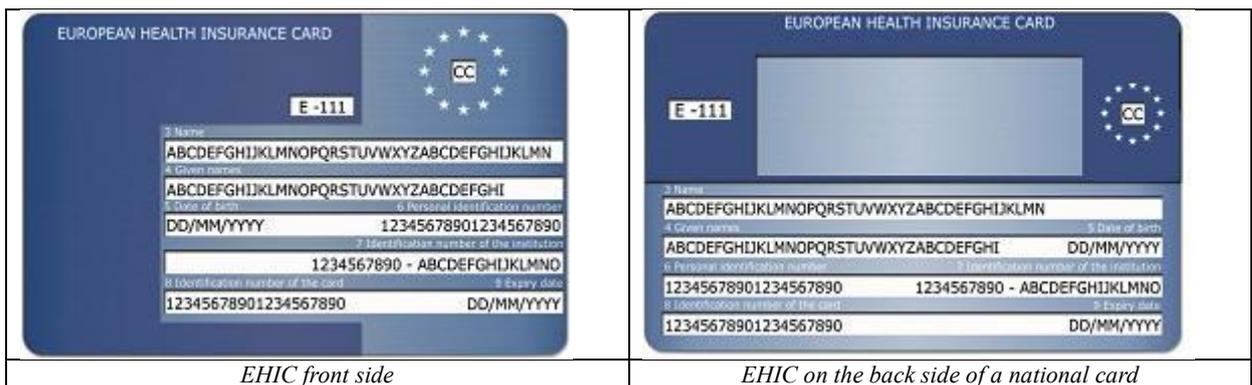
1514

1515 The EHIC must conform to a single model defined by the Administrative Commission,
 1516 which should both facilitate access to health care and help to prevent irregular, abusive or
 1517 fraudulent use of the card.
 1518

1519 In particular, the information which must be visible on the EHIC is defined in Article 6 of
 1520 Administrative Commission Decision No 189:
 1521

- surname and forename of the card holder,
- personal identification number of the card holder or, when no such number exists, the number of the insured person from whom the rights of the card holder derive,
- date of birth of the card holder,
- expiry date of the card,
- ISO code of the Member State issuing the card,
- identification number and acronym of the Competent Institution,
- logical number of the card.

1531 The layout of the EHIC is defined by technical specifications contained in Administrative
 1532 Commission Decision No 190 of 18 June 2003. Since the use of health or social insurance
 1533 cards differs widely from one country to another, the EHIC should be introduced initially in a
 1534 format in which the data necessary for the provision of health care and reimbursement of the
 1535 costs can be read with the naked eye.
 1536

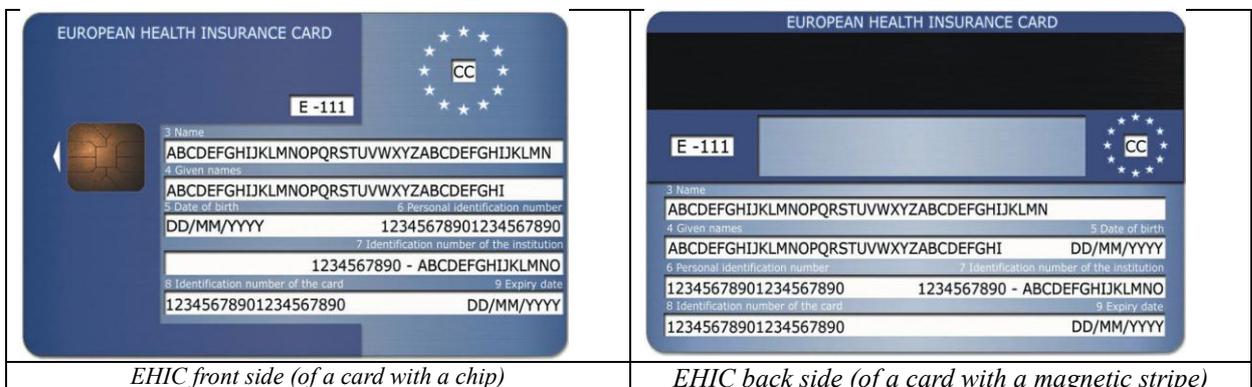


EHIC front side

EHIC on the back side of a national card

1537
 1538 **Picture 1: The layout of EHIC without electronic medium**

1539 This information may additionally be incorporated in an electronic medium. The use of an
 1540 electronic medium will furthermore become generalized at a later stage in the introduction of
 1541 the EHIC. But it has not been done yet.
 1542
 1543



EHIC front side (of a card with a chip)

EHIC back side (of a card with a magnetic stripe)

1544
 1545 **Picture 2: The layout of EHIC containing electronic medium**

1546

1547 When exceptional circumstances – i.e. theft or loss of the EHIC or departure at notice too
1548 short for a EHIC to be obtained – prevent the person concerned from producing the EHIC, a
1549 provisional replacement certificate (PRC) of limited validity should be issued.
1550

1551 **4.2 Basic process of EHIC usage**

1552 **4.2.1 Description**

1553 Basic process of EHIC usage starts with capturing data from EHIC handed over by foreign
1554 patient to the HCP representative in order to get a medical treatment on the basis of EU social
1555 security coordination system (which means in brief on the same conditions like domestic
1556 patient). It aims at receiving reimbursement for this kind of medical treatment. It should be
1557 noticed, that aside of EHIC the Provisional Replacement Certificate (PRC) exists, that is a
1558 paper document issued on request when an insured person needs medical treatment (cross-
1559 border healthcare) in (Member State of treatment) and does not have EHIC with him. PRC
1560 plays the same role as EHIC, but differs in the way of acquiring.

1561
1562 In the course of analysis the following business cases related to the EHIC process were
1563 specified:
1564

1565 **Data capture from EHIC (or from PRC)**

1566
1567 This use-case describes the main function of EHIC card which is a carrier of information about
1568 identification of a patient, his/her insurer (called Competent Institution in regulations) and an
1569 expiry date of the card. This information has to be captured by HCP in order to get
1570 reimbursement for the treatment provided to the patient. A patient may come to HCP with
1571 Provisional Replacement Certificate (PRC) instead of EHIC.
1572

1573 **Requesting the PRC**

1574
1575 This use-case describes a situation when a patient is insured but has not his/her EHIC with
1576 him/her. According to the regulations of the European systems coordination it is possible to
1577 apply for Provisional Replacement Certificate (replacing EHIC) from abroad. After obtaining
1578 PRC from relevant Competent Institution (CI-A), it can be used in line with scenario described
1579 in the previous use-case.
1580

1581 **Using the captured data for reimbursement process**

1582
1583 After acquisition of the patient's data, what was described in the first use-case, the data are
1584 used in the process of reimbursement. This allows the Healthcare Provider (HCP) to get
1585 a payment for the treatment delivered to the patient, from the Institution of Temporary Stay (CI-
1586 B). Afterwards this institution gets the reimbursement from the Competent Institution (CI-A).
1587

1588

1589 **4.2.2 Cross border distributions of EHIC basic process**

1590 Data printed on EHIC are used in the situation when a person insured in country A (Member
1591 State of affiliation) needs a medical treatment in country B (Member State of treatment), on the
1592 basis of EU social security coordination system. Data concerning entitlement for cross-border
1593 healthcare are gathered in Member State of affiliation (country A) and the final reimbursement
1594 will be done by Competent Institution in country A, therefore only one scenario of cross-border
1595 data capture is possible.

1596
1597

Country of the competent institution responsible for the patient	Country where the patient needs a treatment and EHIC may be used	Comments
A	B	<i>The situation exists in accordance with regulations of EU social security coordination system</i>

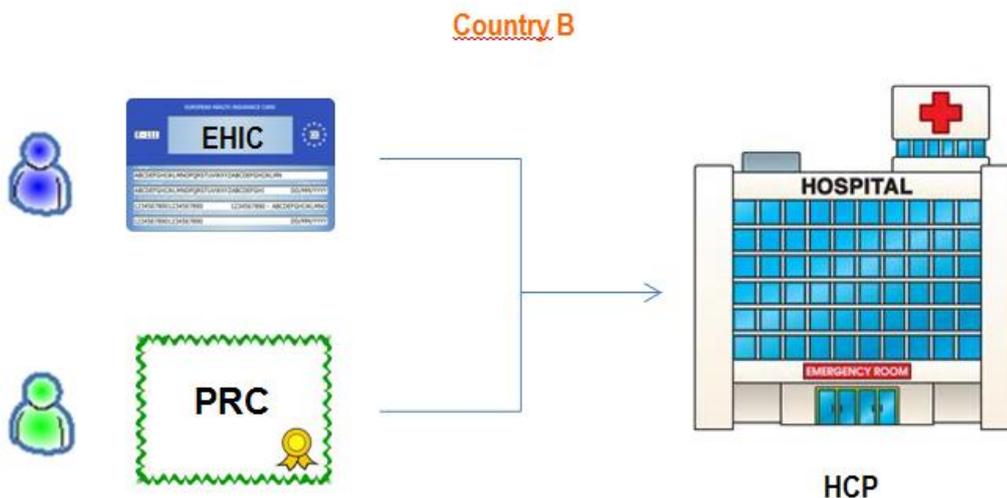
1598
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1600 **4.2.3 EHIC Use Cases**

1601 **4.2.3.1 UC.EHIC.1 – Data capture from EHIC (or PRC)**

1602 **4.2.3.1.1 Use case story (UC.EHIC.1)**

1603
1604



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1607

Picture 3: Data capture from EHIC (or PRC)

1608
1609 Patients from abroad can obtain medical services (cross-border healthcare) on the same
1610 conditions like domestic patients only with either EHIC or PRC, according to European
1611 regulations on the coordination of social security systems. EHICs are acquired by the patients
1612 in Member State of affiliation (Country A) from the proper Competent Institution. If patient goes
1613 abroad (to Country B) without EHIC he/she can apply for PRC in accordance with the
1614 UC.EHIC.2.

1615
1616 When the patient comes to the HCP, patient's EHIC (or PRC) has to be copied (onto paper) by
1617 HCP.

1618
1619 If electronic reimbursement procedure exists in Country B, the HCP usually captures data from
1620 the document into his local computer (database) in the scope of this use case.

1621
1622 Later, these data are used in a reimbursement procedure as described in UC.EHIC.3.
1623
1624

1625 **4.2.3.2 Use case definition (UC.EHIC.1)**

1626

1627 **Goal**

1628
1629 HCP has to collect data from patient's EHIC (or PRC) in order to identify the patient and to
1630 present them later in the process of costs claiming.

1631

1632 **Actors**

- 1633
- 1634 • patient;
 - 1635 • HCP's representative (receptionist, clerk, nurse, doctor etc.) from Country B.
- 1636

1637

1638 **Preconditions**

- 1639 • patient needs a medical service in a Country B;
 - 1640 • patient has his/her EHIC card (or PRC document);
 - 1641 • HCP is obliged to act under the European regulations on the coordination of social
1642 security systems.
- 1643

1644

1645 **Success condition**

1646 The use case can be considered as successful one when the data set from EHIC, required for
1647 reimbursement process, is collected by HCP.

1648

1649 **Failure condition**

1650
1651 The use case can be considered as a failure when all precondition are fulfilled (the process
1652 described by the use case starts) but a validity date on EHIC (or PRC) has expired or no data
1653 can be acquired because e.g. the data on the document are unreadable.

1654

1655 **Trigger**

- 1656
 - 1657 • patient comes to HCP in order to receive the medical service
 - 1658 • in effect of an accident the patient requires medical service that is provided by an
1659 emergency service
- 1660

1661

1662 **Critical analysis**

1663 The data needed for reimbursement process are printed on the document a patient should
1664 have with him (in both cases: EHIC and PRC). In accordance with the domestic legal and
1665 organizational solutions, HCP is obliged either only to make a paper copy of EHIC (or PRC) or
1666 additionally to collect these data for the use in reimbursement process. It means the HCP has
1667 to type again the data into the computer application.

1668
1669 The process of typing data is prone to mistakes and it cannot be verified if it was done
1670 correctly. There is no possibility to get on-line access to remote databases functioning in
1671 Competent Institutions in Member State of affiliation where these data are stored.

1672
1673 There are 3 groups of data on the EHIC (PRC) that should be analyzed separately:

- 1674
- 1675 • identification of a patient (and a card)
- 1676 • identification of the Competent Institution responsible for the financing of the treatment
- 1677 • information about expiry date of the card
- 1678

1679 There is no way of an authentication of the document (EHIC, PRC) and the patient. Even the
1680 simplest thing – EHIC card number verification – cannot be done because there is no relevant
1681 eService available.

1682
1683 The HCP doesn't have an opportunity to verify the Competent Institution ID code (acronym).
1684 Even though there is the Code List Database (CLD) available, it is not updated sufficiently
1685 well. But what is more important, EC doesn't want the HCPs to be accountable for the data
1686 verification of the Competent Institution in Country A (CI-A) printed on EHIC. It is Institution of
1687 Temporary Stay (CI-B) and Liaison Body in Country B to solve the potential inconsistencies at
1688 a later stage of the reimbursement process.

1689
1690 In a new EESSI environment there will be the Master Directory database available to all users,
1691 with all institutions updated more thoroughly because of its use in routing procedures, but
1692 responsibilities of the stakeholders seem not to be changed.

1693
1694 The expiry date printed on an EHIC is a convenient solution from the point of view of the
1695 patient and HCP. And it is why the EC is supporting it strongly. But for the patient's Competent
1696 Institution (CI-A) it may be a costly approach. In countries with health insurance system,
1697 patients can change their insurer or lose an insurance at all. But as long as the expiry date
1698 printed on EHIC is still valid, Competent Institution has to pay the bill. Later it can start the
1699 procedure of costs recovery from the new Competent Institution responsible or from the
1700 patient but it may be a very costly procedure.

1701

1702

Current issues
• human errors (copy loss, typing errors, confusing unfamiliar foreign fonts)
• time to collect the info (copying or typing)
• card validity (institution ID, falsification)
• entitlement validity (printed expiry date vs. actual entitlement)

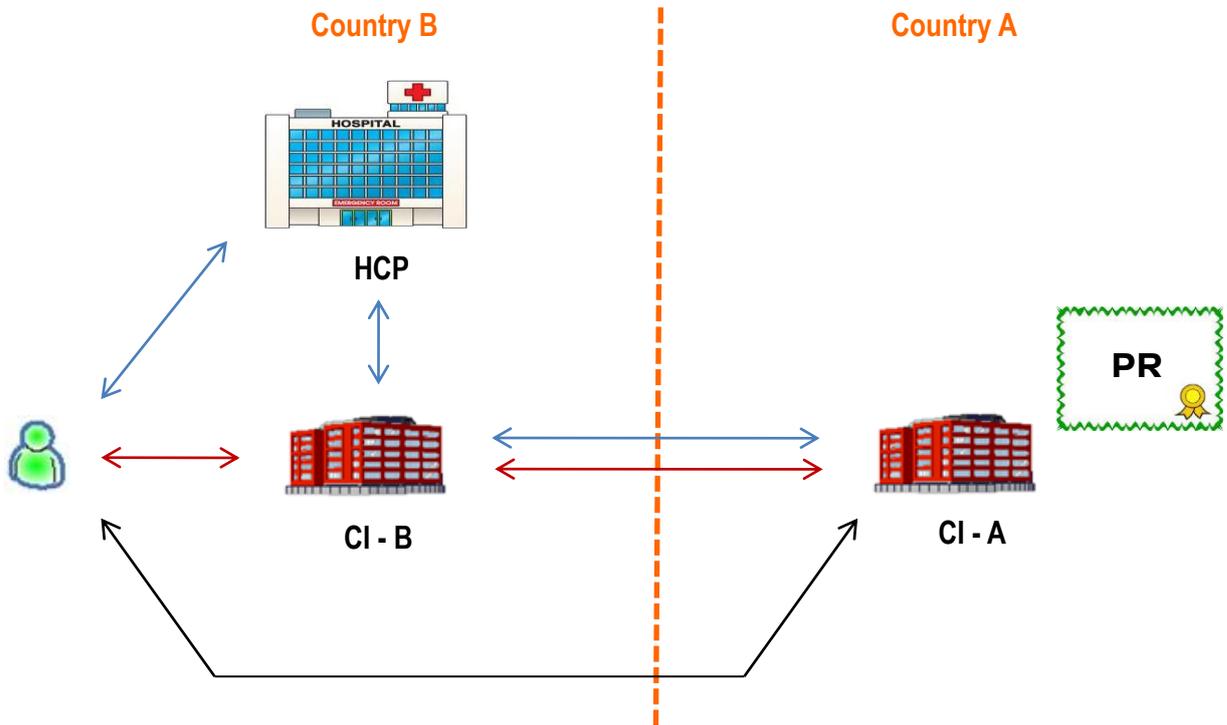
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1704

1705 **4.2.3.3 UC.EHIC.2 – Requesting the PRC**

1706 **Use case story (UC.EHIC.2)**

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Picture 4: Requesting the PRC

When a patient needs cross-border healthcare but has not a valid EHIC with her/him, it is possible to apply for the Provisional Replacement Certificate. The easiest way for the patient to do it is to ask a HCP, where he needs a treatment, to initiate a procedure.

The HCP should verify patient's identification document (passport etc.), decide on the needed period of an entitlement confirmation, and then contact the proper Institution of Temporary Stay in Country B (CI-B) capable to acquire a PRC from Competent Institution in Country A (CI-A). There is no European procedure defining this process on a domestic level. Usually it is done by phone and fax or mail (as a scanned attachment).

When the Institution of Temporary Stay in Country B (CI-B) gets a request from his domestic HCP it asks CI-A to prepare and send PRC for the patient whose ID document's copy obtained from HCP is sent again by fax or mail. Delivered PRC is conveyed to HCP.

A patient may come directly to Institution of Temporary Stay in Country B (CI-B) with the request to acquire a PRC for him, but usually it is not so obvious for a patient from the Country A, how to find proper institution's office, so it is easier for him to start a procedure at HCP's premises or apply for PRC directly to his insurer (CI-A). In this last case, again, the phone, fax or mail are used.

Use case definition (UC.EHIC.2)

Goal

To request a PRC document from CI-A to use it as a proof of entitlement in Country B.

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Actors

- patient;
- HCP's clerk;
- clerk from Institution of Temporary Stay in Country B (CI-B);
- clerk from Competent Institution of Country A (CI-A).

Preconditions

- patient needs cross-border healthcare in the Country B;
- patient is insured but he/she doesn't have EHIC with him/her.

Success condition

The use case can be considered as successful when the patient receives the PRC from his/her insurer on time to get medical service in accordance with European systems coordination.

Failure condition

The use case can be considered as failed when the patient doesn't receive the PRC on time (e.g. due to delay in administrative procedures).

Trigger

- patient asks HCP, Institution of Temporary Stay (CI-B) or CI-A for PRC;
- HCP's clerk contacts Institution of Temporary Stay on behalf of the patient (unconscious) and asks for PRC.

Critical analysis of the authorization service among CI-A and CI-B

Up to now, as it was described above in "Use case story", there is no pan European procedure to exchange electronically data between the actors of this use case. Only in the scope of EESSI system the relevant flows (with elementary SEDs – Structured Electronic Documents) between institutions in Country A and B are defined. This solution should be put into operation in May 2012 (but it is the success scenario and this date is expected to be delayed).

Two things are still not decided in the scope of EESSI:

- EESSI system connection to the national databases of entitlement;
- the way of giving access to these data from HCP's systems.

Even with EESSI in operation, CI-A is not obliged to answer immediately to the request of CI-B. It is because in many countries there is neither central database with entitlement information nor a web service to get this information on-line from local, dispersed databases.

And till an CI-B will not be able to get an electronic dataset about an entitlement from CI-A, it will not be interested in implementation of the internal (domestic) web service to pass the acquired information to the HCPs. It is also not quite clear what confidentiality rules should apply in this electronic request for entitlement status procedure.

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Only implementation of legal, organizational and technical measures to solve these issues will enable computerization of the process.

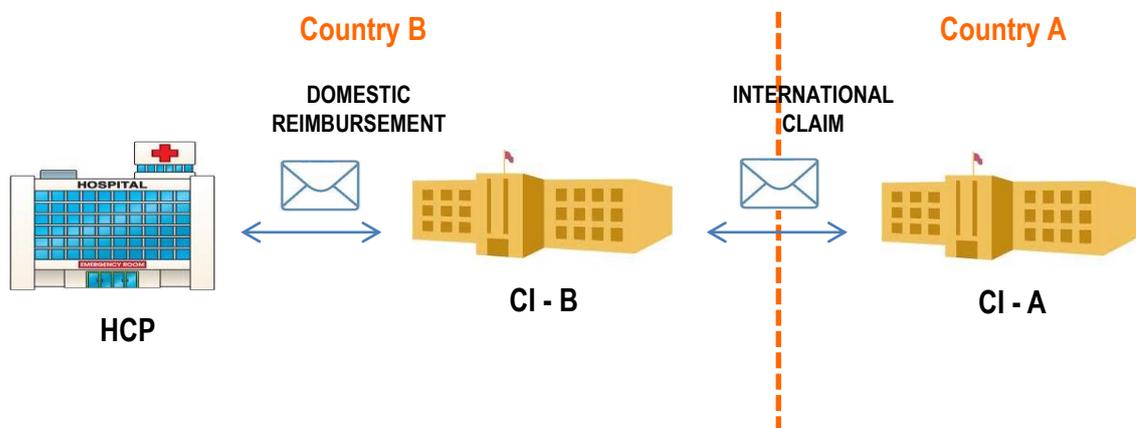
Current issues
<ul style="list-style-type: none">• there is no on-line solution to get the PRC in an electronic form
<ul style="list-style-type: none">• present procedure is prone to confidentiality breaks

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1795

1796 **4.2.3.4 UC.EHIC.3 – Using the captured data for reimbursement process**

1797 **Use case story (UC.EHIC.3)**

1798



1799
1800

Picture 5: Using the captured data for reimbursement process

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1802

1803 To obtain reimbursement for the treatment delivered to the foreign patient, HCP has to submit
1804 a financial information about the treatment together with information from EHIC (or PRC) to the
1805 institution accountable for the payment of such claims in accordance with domestic
1806 regulations. In some countries this role is played by an institutions accountable also for
1807 domestic patients. In others, there are special institutions appointed only for clearing the
1808 claims in EU coordination framework.

1809

1810 Regardless of the above, information from HCP may be required only in a paper version, then
1811 a copy of EHIC (PRC) is expected, or, in case of countries with electronic exchange of data,
1812 a HCP has additionally to deliver electronic version of the data, captured from EHIC.

1813

1814 This use case is focused on the HCP sending electronic data.

1815

1816 The HCP has to add data items captured from EHIC (PRC) to the data describing the service
1817 provided to the patient and send them together to the proper institution in Country B in
1818 accordance with domestic regulations. If only an expiry date from the EHIC is valid, the claim
1819 has to be reimbursed regardless of other data taken form EHIC.

1820

1821 To be quite precise, the data exchange between Institution of Temporary Stay (CI-B) and CI-A
1822 is actually done through Liaison Body in Country A and B but it doesn't change the principles.
1823 To avoid clumsiness of the picture they are not depicted.

1824

1825

1826 **Use case definition (UC.EHIC.3)**

1827

1828 **Goal**

1830 To send a proper set of data to the Institution of Temporary Stay (CI-B), to guarantee
1831 a reimbursement to HCP.

1832

1833

1834 **Actors**

1835

- 1836 • HCP's clerk;
- 1837 • clerk in Tnstitution of Temporary Stay in Country B (CI-B);
- 1838 • clerk in Competent Institution of Country A (CI-A).

1839

1840 **Preconditions**

1841

- 1842 • treatment was provided to the patient who had EHIC or PRC;
- 1843 • use case "Capture the data from EHIC (or PRC)" had been completed successfully.

1844

1845 **Success condition**

1846

1847 The use case ends with success when the Institution of Temporary Stay in Country B accepts
1848 the data sent by the HCP.

1849

1850 **Failure condition**

1851

1852 The use case fails when the claim from the HCP will be rejected by the Institution of Temporary
1853 Stay in Country B (CI-B).

1854

1855 **Trigger**

1856

1857 Sending the data for reimbursement claims (according to domestic regulations it can happen
1858 after various amount of time).

1859

1860

1861 **Critical analysis about the impact in the reimbursement**

1862 The HCP who is initiating this use case is in a strong position in comparison to the other
1863 actors. If he sends for reimbursement the data that were precisely captured from EHIC (PRC),
1864 he has to get paid by proper institution in Country B (if only the other data about the service
1865 provided are compliant with domestic regulations). The only additional burden put onto him is
1866 a necessity of keeping a paper copy of EHIC (and sending another one to CI-B).

1867

1868 The data from EHIC should theoretically comply with the formats defined in relevant EC
1869 Decision but if they were printed wrongly on the EHIC, and the HCP can prove it by showing
1870 its copy, they must be accepted by proper institution in Country B (and later by CI-A).

1871

1872 What's more, even if the EHIC was fake, what might be discovered at the end of the process
1873 in CI-A, this institution according to coordination rules has to pay the claim sent by institution in
1874 Country B.

1875

1876 But the most common issue arises in CI-A when the claim sent from Country B contains valid
1877 expiry date copied form EHIC, but the patient used it lawlessly at HCP because he/she lost the
1878 entitlement or changed the insurer after getting EHIC. Again, according to the EU regulations
1879 the CI-A has to pay the claim from Country B. Later it may start a procedure to recover the

1880 costs of claim from the patient or from the new patient's insurer accordingly. It may be very
1881 time-consuming and costly procedure.
1882

Current issues
<ul style="list-style-type: none">• HCP has to make and to store paper copies of EHICs (PRCs)
<ul style="list-style-type: none">• Because data captured from EHIC are not verified on-line, Competent Institution bearing the costs of the treatment is exposed to frauds

1883
1884

1885 **4.3 EHIC Use Cases Conclusion**

1886 Like it was said in Introduction chapter, the above analysis will be supplemented with
1887 additional document (chapter) recommending certain changes to present solutions regarding
1888 EHICs and their usage to facilitate implementation of eHealth systems. It will be the result of
1889 the Key Task 1.4.7.
1890
1891
1892

1893 **5 Use-case for Additional Services 112 Emergency**

1894 epSOS II, Key Task 1.4.3

1895 September, 2011

1896

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1900 Carlos Bermell

1901 Vesna Lesnik Sefotic

1902 Gottfried Heider

1903 **5.1 Introduction to Additional Services 112 Emergency**

1904 **5.1.1 General introduction**

1905 In accordance with the Directive of Cross-border Health Services (Directive 2011/24/EU),
1906 epSOS will develop a service providing the patient access to key information in his or her own
1907 medical record, when seeking or receiving healthcare abroad (outside his/her Country of
1908 Affiliation, Country A). The **epSOS Additional Services 112 Emergency (112)** are built upon
1909 and enhances but does not replace any National Emergency services within the Participating
1910 Nations.

1911

1912 epSOS 2 will assess and test how 112 emergency services can be included in epSOS
1913 services. The aim is to allow European emergency services (112) and in particular the
1914 Emergency Medical Services to securely - and legally - access a patient summary to improve
1915 the quality of the intervention.

1916

1917 In accordance with the epSOS Description of Work (ref: DoW), this service should provide
1918 access to a Patient Summary (PS).

1919

1920 As per this limitation, all other information, including detailed medical records notes,
1921 reimbursement and billing data, pharmaceutical information about the actual drug prescribed,
1922 or general (not patient-specific) medical information about the disorders treated, will be out of
1923 scope. Also, patient input of clinical data will not be included in these specifications (is out of
1924 scope).

1925

1926 According to the general approach in epSOS, only structured and coded data will be subjected
1927 to translation, restricting the use for unstructured data to a copy of the original document in its
1928 original language (Ref: Deliverable D3.5.2/D3.9.1-Appendix B1).

1929

1930 **5.1.2 Basic process of Additional Services 112 Use Cases**

1931 **Actors in the Use Cases for Additional Services 112 are:**

1932

1933 **Primary actors:**

1934

- Patient

1935

- Caller

1936

1937 **Secondary actors:**

1938

- 112 call – taker

1939

- Health Care Professional acting as Health Care Provider in the 112 call centre

- 1940 • Health Care Professional acting as Health Care Provider in the ambulance (Point of Care)
- 1941
- 1942 • Health Care Professional acting as Health Care Provider in the first aid department (Point of Care)
- 1943

1944
1945

Information used

1946 The information used in the Use Cases for Additional services 112 is:

- 1947 • The Patient Summary (PS)
- 1948

1949
1950

Goals in the Additional Services 112

The goals of the actors in the Use-Cases are:

1951
1952

The Patient

1953 The Patient wants to have improved quality of intervention provided by 112 Emergency services (included in epSOS services), securely and legally.

1954
1955

The Health Care Professional

1957 The Health Care Professional Wants to receive all relevant information about the Patient in the different processes provided by Emergency teams to increase of Patient safety and quality of services in the emergency situations.

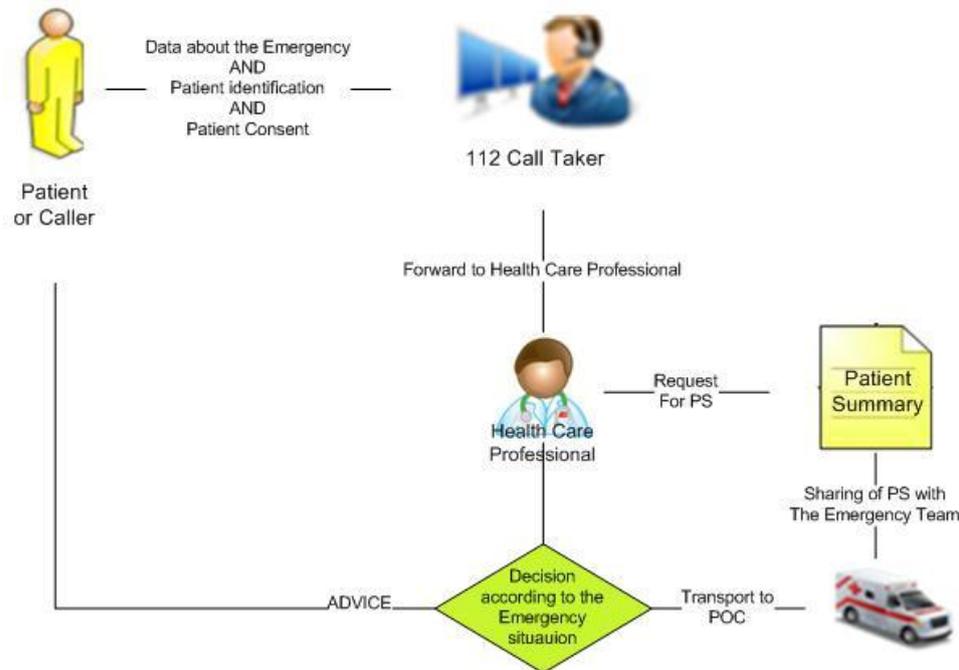
1959
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Steps of Additional services 112 process

1962 The basic process of provision Additional services 112 is outlined in Diagram 1.

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Diagram 1: Additional services 112 Basic process:

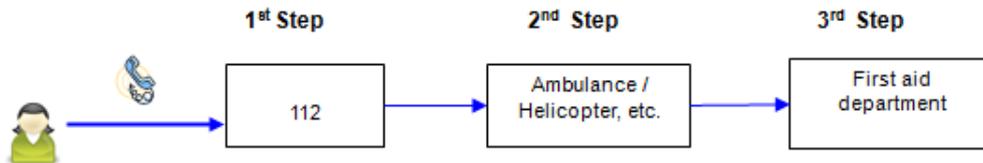


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The general overview of the medical emergency handling process of can be divided into three steps. In the first one, the emergency call is received in 112 Emergency Call Centre, first data about the situation are taken and medical resources are dispatched. In the second step, health professionals arrive to the emergency place and take care of the patient. The last step is when the patient arrives to the first aid department.

1974

1975 **5.1.2.1 1st Step**



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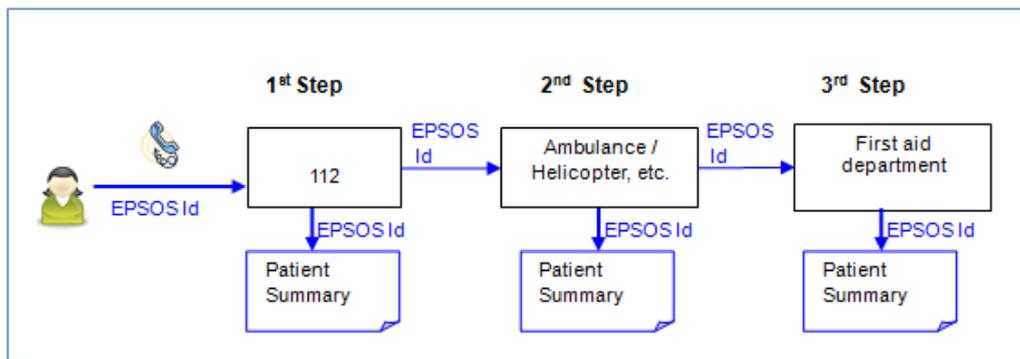
1984

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A citizen (it can be the patient or not) dials 112. Data about the emergency (situation, location, etc.) are taken by the call-taker. In some cases, the call is forwarded to health care professionals before it is decided to send an ambulance (or other means of transportation) or not to the location of the emergency. The 112 call-taker asks to the caller the epSOS compatibility.

Data flow:



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1-st Step – Service process 1: the call is forwarded to health care professionals

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In case that the caller needs medical services for himself or for another person, the 112 call is always forwarded to health care professionals. The 112 call-taker forwards the epSOS identification of the patient to the health care professionals with the call.



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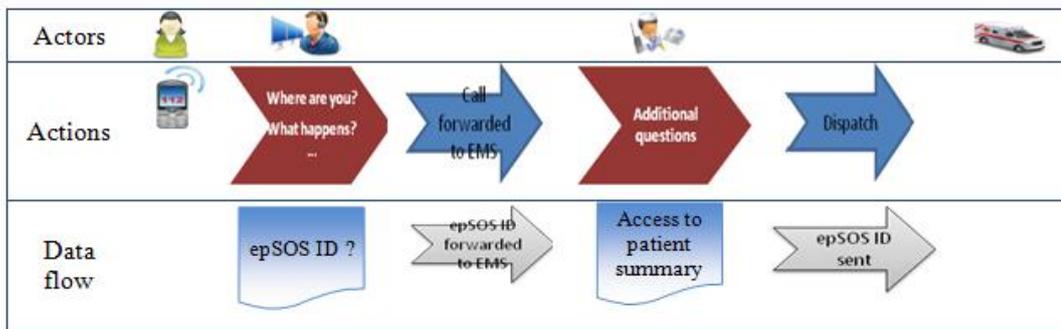
The call is then handled by a health care professional. It could be:

- Physician
- Nurse
- Paramedic

They receive the epSOS patient identification information and can access the Patient Summary, if allowed by their role. This information might be used to take a better decision about the medical resources to be sent. There will be unique emergency epSOS identifier subject of discussion in the phase of design of services (Key Task 1.4.8).

Data flow:

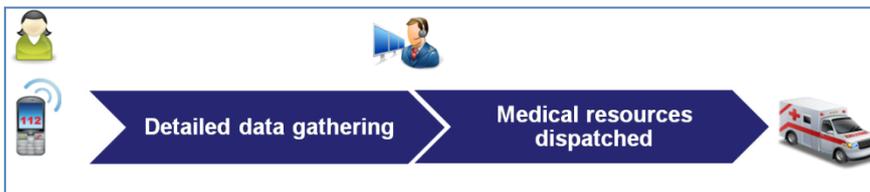
In case that the caller needs medical services, the 112 call is always forwarded to medical emergency services. They can have access to the patient summary and send it to the ambulance.



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1-st Step - Service process 2: the call is not forwarded to health professionals

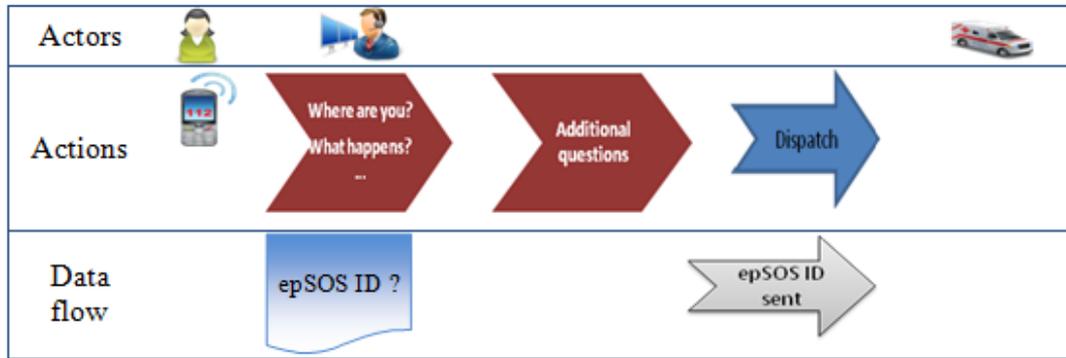
The 112 call is not forwarded to the medical emergency services. The 112 call taker that is not a health care professional dispatches medical resources. The epSOS identification information is then sent to the medical resources that are going to emergency place.



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Data Flow:

If the call is not forwarded to medical emergency services, the 112 call taker is the one who dispatches medical resources. As he is not a health professional, he/she is not allowed to see the patient summary. The epSOS identification is sent to the ambulance.



2044
2045
2046

2047 **5.1.2.2 2nd step**

2048

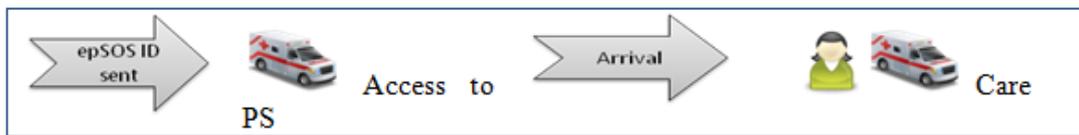
2049 **2-nd Step - Service process 1: health professionals in the ambulance receive the epSOS**
2050 **identification before their arrival to the emergency place**

2051

2052 Health professionals in the ambulance (or other means of transportation) receive information
2053 about the emergency situation and the epSOS identification of the patient previously to their
2054 arrival to the emergency place. They can access the patient summary before their arrival.
2055 Once they arrive to the emergency place, health professionals take care of the patient and if
2056 needed, transport the patient to the first aid department of a hospital.

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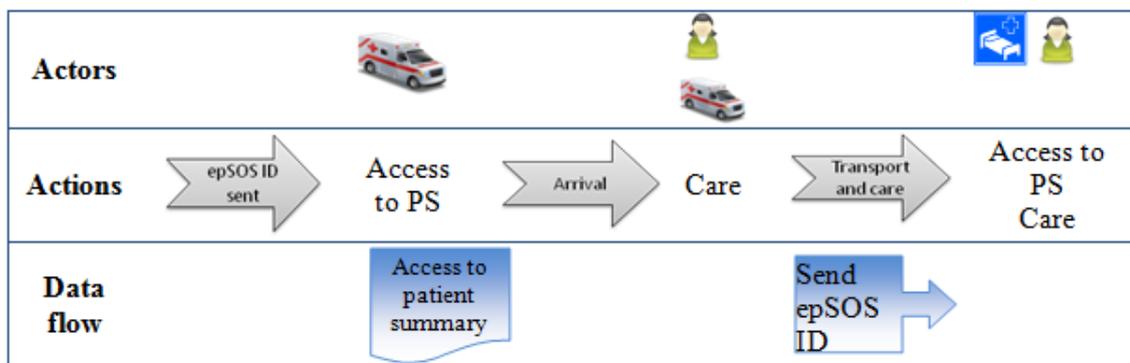
2059

2060 **Data flow:**

2061 Health care professionals in the ambulance (or other means of transportation) receive
2062 information about the emergency situation and the epSOS identification of the patient
2063 previously to their arrival to the emergency place. They can access the patient summary
2064 before their arrival. Once they arrive to the emergency place, health professionals take care of
2065 the patient and if needed, transport the patient to the first aid department of a hospital.

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2nd Step - Service process 2: health professionals in the ambulance do not receive the epSOS identification before their arrival to the emergency place

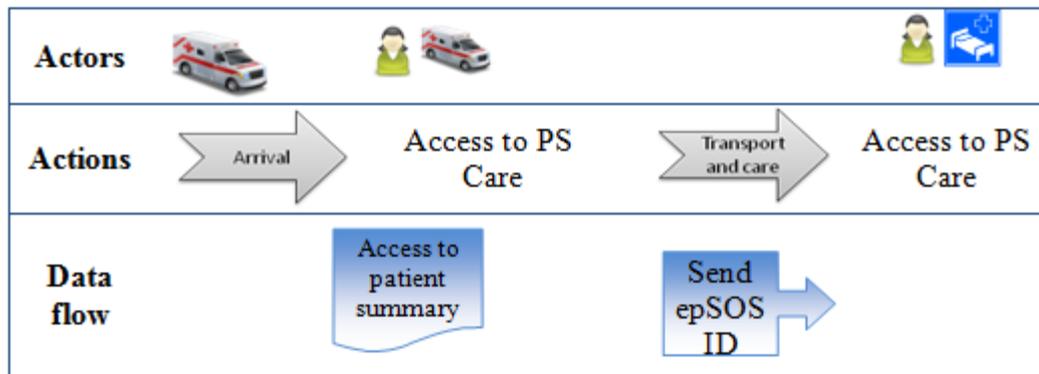
Health care professionals in the ambulance (or other means of transportation) receive information about the emergency situation. Once they arrive to the emergency place, the patient gives the epSOS identification and health care professionals access to his/her patient summary. Health professionals take care of the patient and if needed, transport the patient to the first aid department of a hospital.



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Data flow:

Health professionals in the ambulance (or other means of transportation) receive information about the emergency situation. Once they arrive to the emergency place, the patient gives the epSOS identification and health professionals access to his/her patient summary. Health professionals take care of the patient and if needed, transport the patient to the first aid department of a hospital.



2092
 2093
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 2095

2096 **5.1.2.3 3rd step**

2097

2098 **3-rd Step - Service process 1: the first aid department receives the patient's epSOS identification before the patient arrival**

2099 The ambulance sends the patient's epSOS identification to the first aid department.

2100

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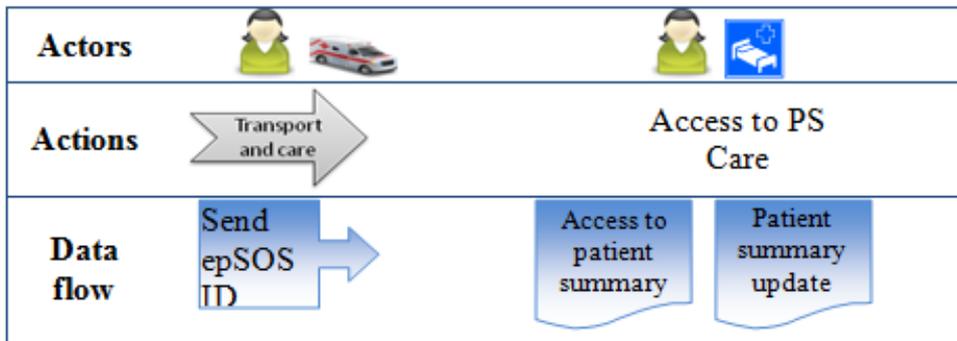
2105 **Data flow:**

2106

2107 The ambulance arrives to the first aid department

2108

2109



2110

2111

2112

2113 **3rd Step - Service process 2: the first aid department does not receive the patient's epSOS identification before the patient arrival.**

2114

2115 The ambulance arrives to the first aid department. The patient gives his/her epSOS identification and the health care professionals have access to the patient summary.

2116

2117

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2121

2122 **Data flow:**

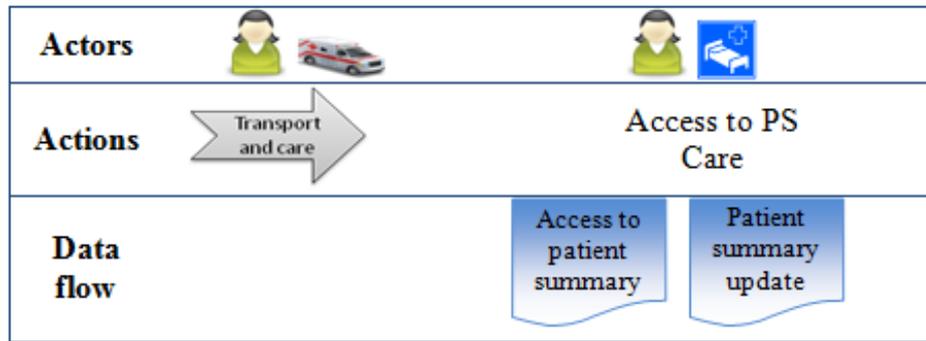
2123

2124 The ambulance arrives to the first aid department

2125

2126

2127



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2129

2130 **5.1.3 Analysis of the cross-border distributions of the actors**

2131 Most service processes foresee the presence of actors of different countries along the process
2132 (Call Center, Ambulance, 1st Aid Dep.) regardless the Patient Country of affiliation.

2133

2134 The basic concept it should be enforced is that every Actor is connected to his own NCP that
2135 provide him the Patient Summary of the involved citizen in the language understood by the
2136 Healthcare professional acting in that moment.

2137

2138 Hence the process should analyze the different situations, assuring the patient identification
2139 data and the patient current status are passed.

2140

2141 The functional requirement already stated in epSOS basic PS service that the PS has to be
2142 provided to the HC in a format and language he can understand, remains unchanged.

2143

Service Process	Home	112 calls emergency call centre	Resources (ambulance, helicopter, etc.)	Hospital	Comments
1	A	A	A	A	<i>Regular situation</i>
2	A	B	-	-	<i>No emergency case, just medical advice. No ambulance is needed.</i>
3	A	B	B	B	<i>epSOS case, occasional visit and season migration</i>
4	A	A	B	B	<i>epSOS border regions</i>
5	A	A	A	B	<i>epSOS border regions</i>
6	A	B	C	C	<i>The call has arrived to a 112 call centre that is in the border country</i>

2144

2145 ■: in epSOS extension

2146

2147 **5.1.4 Business case for the basic process of Additional Services 112 Emergency**

2148 In the extension of epSOS in 2011, additional services are to be specified. One of them is the
2149 integration with 112 emergency services. This is described in the DoW as follows:

2150

2151 The objective of this task is the basic description of functions related to additional service
2152 based on 112 Emergency, which will be distinguished and illustrated in the form of use – case
2153 diagrams. The task is being meant to be a preparatory work for KT1.4.8

2154

2155
2156 To conclude, we can say that the business case incorporates epSOS product – patient
2157 summary into different processes provided by health care providers and Emergency teams,
2158 which work under the umbrella of 112 Emergency Services in different countries. It enables the
2159 health care professionals to access the patient summaries. It also defines conditions for
2160 activities leading to an increase of patient safety and quality of services provided in the
2161 emergency situations.
2162

2163 Following the Council Decision in 1991, European member countries have implemented the
2164 112 emergency European Number. As it is a national competence, each country has decided
2165 to organize emergency calls handling with a different approach; but the purpose of all of them
2166 is the same, that is, to save lives and protect properties. Not only the Universal Service
2167 Directive has an impact on 112 organizations but also data protection and privacy concerns
2168 have to be taken into account.
2169

2170 In an emergency situation, to access and consult a high amount of data can be not impossible.
2171 It may be needed to revise the content of Patient Summary and adapt it to emergency
2172 healthcare services specifications.
2173

2174 The below-mentioned outline of processes provides the country representatives with
2175 information necessary to decide on application of such services in their country conditions.
2176

2177 **5.2 epSOS Additional Services 112 Use Cases**

2178 **5.2.1 UC 112.1 Patient from Country A dials 112 in Country B for medical advice**

2179 **Actors:**

- 2180 • The Patient
- 2181 • Caller
- 2182 • 112 Call Taker
- 2183 • Registered Health Care Professional with the right to obtain Patient summary

2184 **Preconditions:**

- 2185 • A Patient Summary exists in Country A
- 2186 • The epSOS translation service covers languages A and B
- 2187 • Patient consent legal issue solved

2188
2189
2190
2191 The patient is not in his home country (A) and dials 112 in a foreign country (B). The 112 call is
2192 handled by the emergency call centre from country B. The health care professional in the
2193 emergency call centre accesses the patient summary. This information can help him to
2194 determine that sending medical emergency resources is not needed and gives medical advice
2195 or other instructions to the patient.
2196



2197
2198

2199 **5.2.2 UC 112.2 Patient from Country A dials 112 in Country B using emergency**
2200 **resources and POC of Country B**

2201 **Actors:**

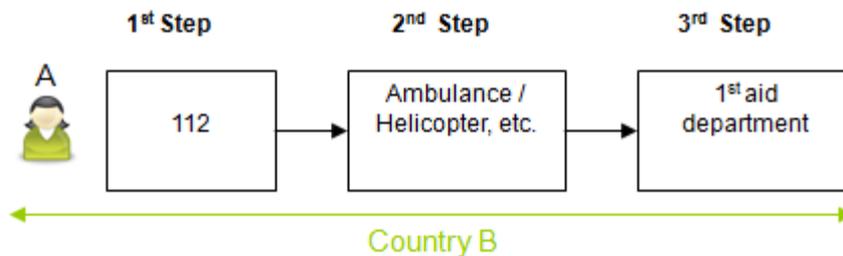
- 2202 • The Patient
- 2203 • Caller
- 2204 • 112 Call Taker
- 2205 • Registered Health Care Professional with the right to obtain Patient summary

2206 **Preconditions:**

- 2207 • A Patient Summary exists in Country A
- 2208 • The epSOS translation service covers languages A and B
- 2209 • Patient consent legal issue solved
- 2210 • Bilateral agreement (regulation) between Country A and Country B exists

2211
2212
2213 The patient is not in his home country (A) and dials 112 in a foreign country (B). The 112 call is
2214 handled by the emergency call centre from country B. The health care professional in the
2215 emergency call centre accesses the patient summary. This information can help him to
2216 determine that medical emergency resources have to be sent. Emergency medical resources
2217 from country B arrives to the place. Previously, they access the PS and this information helps
2218 them to prepare better his intervention. If needed, the patient is driven to the first aid
2219 department in country B where the health professional access also the PS.

2220
2221



2222
2223
2224

2225

2226 **5.2.3 UC 112.3 Patient from Country A dials 112 in Country A – Emergency resources**
2227 **from Country B are used**

2228 **Actors:**

- 2229 • The Patient
- 2230 • Caller
- 2231 • 112 Call Taker
- 2232 • Registered Health Care Professional with the right to obtain Patient summary

2233

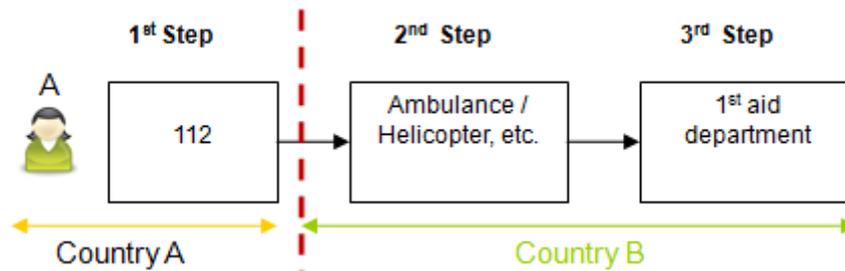
2234 **Preconditions:**

- 2235 • A Patient Summary exists in Country A
- 2236 • The epSOS translation service covers languages A and B
- 2237 • Patient consent legal issue solved
- 2238 • Bilateral agreement (regulation) between Country A and Country B exists

2239

2240

2241 The patient is in his home country (A). He dials 112 in his country and speaks with the
2242 emergency call centre in country A. The health care professional in the emergency call centre
2243 accesses the patient summary. This information can help him to determine that medical
2244 emergency resources have to be sent. Resources from country B are the most appropriate to
2245 be dispatched (e.g., they are closer, etc.). Health care professionals in country B receive the
2246 requirement from country A that their medical emergency resources are needed. They can
2247 access the patient summary and, this way, better prepare their intervention.
2248



2249

2250

2251

2252 **5.2.4 UC 112.4 Patient from Country A dials 112 in Country A. Emergency 112 is**
2253 **transferring Patient to the POC in Country B**

2254 **Actors:**

- 2255 • The Patient
- 2256 • Caller
- 2257 • 112 Call Taker
- 2258 • Registered Health Care Professional with the right to obtain Patient summary

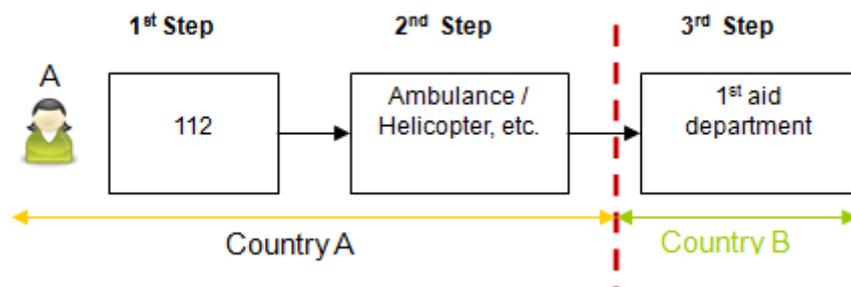
2259 **Preconditions:**

- 2261 • A Patient Summary exists in Country A
- 2262 • The epSOS translation service covers languages A and B

2263
2264

2265 The patient is in his home country (A). He dials 112 in his country and speaks with the
2266 emergency call centre in country A. The health care professional in the emergency call centre
2267 accesses the patient summary. This information helps him to determine that medical
2268 emergency resources have to be sent. Resources from country A are dispatched and arrive to
2269 go to the emergency location. It is determined that the most appropriate first aid department to
2270 is from country B (e.g., specialized, etc.). Health care professional in the first aid department in
2271 country B can access the patient summary and, this way, they can better prepare their
2272 intervention..

2273



2274
2275

2276

2277 **5.2.5 UC 112.5 Patient from Country A dials 112 in Country C, Call is handled by 112**
2278 **Call Center in Country B and resources from Country Care sent after**
2279 **recognition of the Patient.**

2280 **Actors:**

- 2281 • The Patient
- 2282 • Caller
- 2283 • 112 Call Taker
- 2284 • Registered Health Care Professional with the right to obtain Patient summary

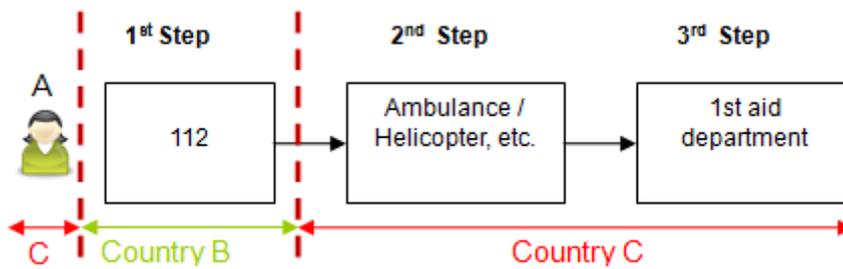
2285
2286 **Preconditions:**

- 2287 • A Patient Summary exists in Country A
- 2288 • The epSOS translation service covers languages A and B
- 2289 • Patient consent legal issue solved
- 2290 • Coordination between 112 Emergency services between Country C and Country B
- 2291 exists.

2292

2293 The patient is in a foreign country (C). He dials 112 in country C. Due to mobile network
2294 inaccuracy, the call arrives to a 112 call centre that is not in country C, but in country B (border
2295 country). The health care professional in the emergency call centre accesses the patient
2296 summary. This information helps him to determine that medical emergency resources have to
2297 be sent. Resources from country C are dispatched and arrive to the emergency location. It is
2298 determined that the most appropriate first aid department to go to from country C. Health care
2299 professional in the first aid department in country C can access the patient summary and, this
2300 way, better prepare their intervention.

2301



2302

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2305 **5.3 Recommendations and items to be developed elsewhere**

2306 **5.3.1 Interaction with reduction of Patient Summary content (Emergency Data Set)**

2307 Already in the design process of use-cases it was clear, that existing content of epSOS patient
2308 summary contains information that is not immediately relevant to the provision of Emergency
2309 services. For the purposes of Emergency services will need to specify a specific set of data
2310 (Emergency Data Set) containing the relevant data necessary for the efficient provision of
2311 Emergency Services. This data set will be specified in collaboration with experts actively
2312 working in an environment providing Emergency Services. Given that the project epSOS has
2313 own group of clinical experts, will be necessary to cooperate with this group closely to define
2314 of appropriate EDS containing relevant information.

2315

2316 Responsible: 1.4.8, 1.4.10 (Semantic working group)

2317

2318 **5.3.2 Interaction with Patient consent / legal setup**

2319 Given that in the case of Emergency services cannot be always used the classic scenario of
2320 consent given by patient. It will therefore be necessary to allow the team intervening in the
2321 situation Emergency access to patient data relevant to the provision of Emergency services in
2322 special situations. In these situations will be needed to calculate with the alternative, that the
2323 patient cannot communicate, respectively communicates on behalf of another person. It will
2324 also be taken into account the fact that Emergency services are provided outside the reach of
2325 technical infrastructure enabling express of patients consent. Draft procedure for these
2326 situations will be needed to consult with the legal experts.

2327 **5.3.3 Interaction with Patient identification**

2328 Identification of patients in an Emergency 112 services will be subject of special handling.
2329 Often it is a situation in which the Patient is identified with the help of another person or
2330 Communicate via telephone. It will therefore be necessary to set up the service to allow
2331 reliable verification of identity of the patient in an Emergency 112 services.

2332
2333 Responsible: Identity management
2334

2335 **5.3.4 Legal consideration**

2336 For proper function of epSOS Emergency services 112 will be need to configure services in
2337 every Participating nation environment. For each implementation will be needed individual
2338 assessment of integration into existing 112 Emergency services epSOS. Given that in Europe
2339 are 112 Emergency services not standardized, it will be necessary to define the optimum level
2340 of integration to enable the use of epSOS 112 Emergency Services respecting local
2341 legislation.

2342
2343 Responsible: WP 2.1
2344

2345 **5.4 Conclusion**

2346 Based on research of interest to implement use-cases in the environment of the participating
2347 nations, we can conclude that we have received positive feedback indicating interest of
2348 participating nations to implement the described use-cases. Detailed information containing
2349 the conditions under which the service will be implemented across participating nations will be
2350 prepared after finalization of the use-cases. Through the feedback received from the NEPC's
2351 we got a lot of inspiration that we can use for next period - service definition (KT. 1.4.8).
2352

2353 **6 Use cases for the epSOS additional services – Patient Access**

2354

2355 epSOS II, Key Task 1.4.4

2356

2357 September, 2011

2358

2359 Matti Mäkelä, THL, Finland, key task leader, matti.makela@thl.fi

2360 Montse Meya

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2362 Elie Lobel

2363 Gergely Heja

2364 Mustafa Yuksel

2365 Miguel Roldan

2366

2367 **6.1 Introduction to Additional Services - Patient Access Use Cases**

2368 **6.1.1 General introduction to Patient Access Use Cases**

2369 In accordance with the Directive of Cross-border Health Services (Directive 2011/24/EU),
2370 epSOS will develop a service providing the patient access to key information in his or her own
2371 medical record, when seeking or receiving healthcare abroad (outside his/her Country of
2372 Affiliation, Country A). The **epSOS Patient Access Service (epSPA)** is built upon and
2373 enhances but does not replace any National Patient Access service within the Participating
2374 Nations.

2375

2376 In accordance with the epSOS Description of Work (ref: DoW), this service should provide
2377 access to a Patient Summary (PS) and/or to an electronic Prescription (eP).

2378

2379 As per this limitation, all other information, including detailed medical records notes,
2380 reimbursement and billing data, pharmaceutical information about the actual drug prescribed,
2381 or general (not patient-specific) medical information about the disorders treated, will be out of
2382 scope. Also, patient input of clinical data will not be included in these specifications (is out of
2383 scope).

2384

2385 Second, according to the general approach in epSOS, the epSPA must be in accordance with
2386 the Patient Access policy of the country controlling the Patient Summary / ePrescription to be
2387 accessed (Ref: Deliverable D.2.1).

2388

2389 Third, according to the general approach in epSOS, only structured and coded data will be
2390 subjected to translation, restricting the epSPA for unstructured data to a copy of the original
2391 document in its original language (Ref: Deliverable D3.5.2/D3.9.1-Appendix B1).

2392

2393 **6.1.2 Basic process of Patient Access Use Cases**

2394 **Actors**

2395 The actors in the Use Cases for Patient Access are:

2396

2397 *Primary actors*

- 2398 • The Patient

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2450

Secondary actors

- The Health Professional, acting as a Healthcare Provider, producing the medical information used in the document to be accessed
- The Health Professional at a new encounter (New Health Professional)
- Patient identification, authentication & role authorization service

Information used

The information used in the Use Cases for Patient Access is:

- The Patient Summary (PS)
- Electronic Prescription (eP)

Goals in the Patient Access Use Cases

The goals of the actors in the Use Cases are:

The Patient wants to access and understand what the Health Professional has recorded in the PS or eP, in order to:

- participate in his or her own care, and to
- improve the information he or she gives to another Health Professional

The Health Professional producing the medical information used in the document to be accessed wants to provide the Patient with information he or she needs to fulfil the care plan.

The new Health Professional wants to receive all relevant information about the Patient in his/her encounter

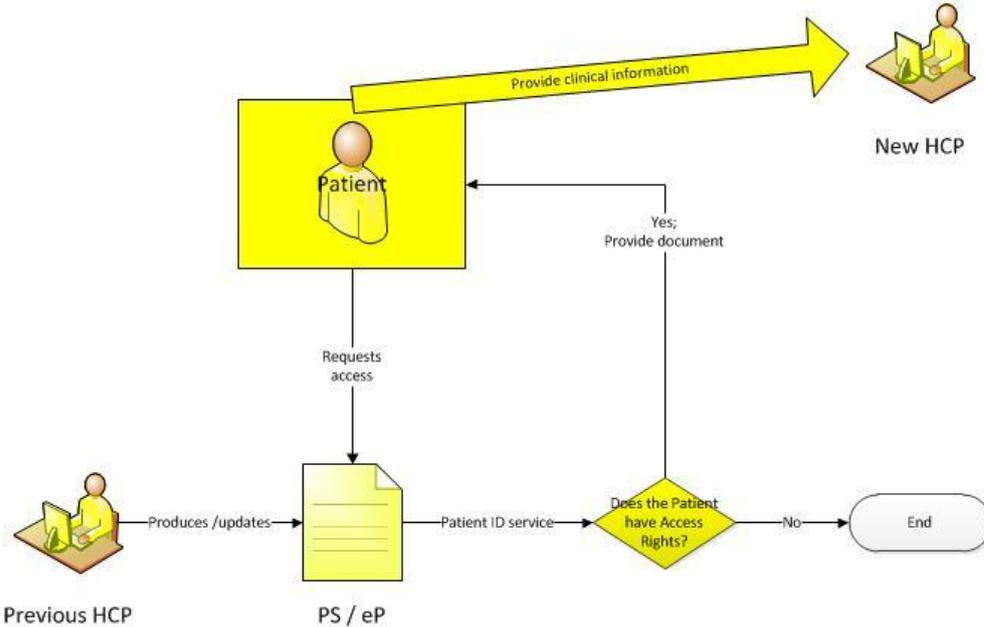
The Patient ID service wants to ensure appropriate data protection and access to sensitive information only for authorized users

Steps of Patient Access process (of which the epSPA is a special case)

The basic process of Patient Access is outlined in Diagram 1.

- The Health Professional updates/produces the medical information used in the PS or eP on the basis of an encounter (i.e. the existence of a PS or eP is a precondition for the successful Patient Access Use Case)
- The Patient requests his or her PS or eP from the Patient Access Service
- The Patient Access Service (including Patient Identification, authentication and role authorization) verifies that he or she has access rights to the information, including that his or her age is sufficient to allow access.
- The Patient Access Service provides the requested document
- The Patient reads, copies, uses and distributes the document as he or she considers appropriate.
 - One possible actor the Patient may want to distribute the information to is a new Health Professional at a new encounter, scheduled or unscheduled. This step is relevant only if the Health Professional does not, for some reason, have access to the PS or eP.

2451 **Diagram 1: Patient Access to Patient Summary or e-Prescription – the general case**



2452
2453

2454 **6.1.2.1 Feature: Identification of the Health Professional and Healthcare Provider only as they**
2455 **are contained in the original document**

2456 Although epSPA services may be used in the presence of a Health Professional, the use case
2457 definitions cannot be dependent on any role authentication of the Health Professional, either in
2458 Country A or Country B, since the same epSPA service must be available also without the
2459 presence of a Health Professional. Thus, in contrast to the original epSOS services, which
2460 provide translated access to Patient Summary and e-Prescriptions to Health Professionals, the
2461 only roles to be identified and authenticated in the epSPA are those of the patient, the NCPs,
2462 and the holders of the PS/eP documents.

2463 **6.1.3 Analysis of the cross-border distributions of the actors**

2464 The epSOS Patient Access Service (epSPA) enhances any National Patient Access Service
2465 by improving understanding over national (language) boundaries. The epSPA does not alter
2466 the Access Rights of the Patient. The key service provided by epSOS is therefore the
2467 translation of the PS or eP. As defined in D3.5.2/D3.9.1-Appendix B1, the translation is
2468 dependent on the NCP in the country of the previous Health Professional transforming a
2469 national PS or eP to a transcoded pivot document, which is translated according to the
2470 standard epSOS process by the NCP controlling the semantic translation table to the target
2471 language.

2472
2473 All the relevant cross-border distributions of the actors in the epSPA are presented in Table 7.1

Sc	Patient's home*	Country of Previous Health Professional**	Patient's language***	Country of new Health Professional**	Comment
0	A	A	A	A	National Patient Access, no epSOS services required
1	A	A	B	A	Use of epSOS services for translation of PS or eP for foreign-language patients
2	A	A	A	B	Translation of PS or eP, when the new Health Professional in country B is not an epSOS-community member
3	A	B	A		Translation of PS or eP for the Patient, empowerment of Patient in self care
4	A	B	A	A	Translation of PS or eP when the new Health Professional (in country A) is not an epSOS-community member
5	A	B	A	C	Not covered by this Use Case Description

2474 *: Country of affiliation of the Patient

2475 **: Country controlling the document to be accessed

2476 ***: Country responsible for the translation

2477

2478 The cross-border distributions lead to two possible epSPA use cases. The first use case
2479 covers the actor constellations 1 and 2, where both the Patient and the Previous Health
2480 Professional (and therefore the document to be accessed) are affiliated with country A, but the
2481 goal of the Patient is that the PS or eP document is translated into language B. The second
2482 use case arises from constellations 3 and 4, where the Patient affiliated with country A has
2483 received care in country B and wants to access a document in his own language (that of
2484 country A). Based on the principle of epSOS access only through Country A, this use case is
2485 only possible if the information produced in Country B is made accessible through the Country
2486 A National Patient Access Service.

2487 **6.1.4 Business case for the basic process of Patient Access**

2488 The importance of patient empowerment is widely recognised, and is thought to lead to
2489 improvements in patient safety and healthcare quality. In many countries, a national Patient
2490 Access is a priority development in eHealth.

2491

2492 The goal of the main actor, the Patient, in a Patient Access service is to access and
2493 understand what the Health Professional has recorded in the PS or eP, in order to participate
2494 in his or her own care. As a secondary use, and an added benefit, the Patient may (or may
2495 not) use the same information to improve the information he or she gives to another Health
2496 Professional.

2497

2498 There are large patient populations for which a national Patient Access service is not sufficient,
2499 because they are in one or another situation of the cross-border distribution. Such patient
2500 groups include migrant workers (situations 1 and 3), populations in the border regions,
2501 travellers with unscheduled healthcare encounters, and seasonal migration populations. The
2502 potential for a cross-border Patient Access service to result in improvement of healthcare
2503 quality and patient safety is large, but very much dependent on the existence and popular
2504 acceptance of national Patient Access services.

2505

2506

2507 **6.2 epSOS Patient Access Use cases**

2508 **6.2.1 UC.PAC.1 Patient Access to PS or to eP in Country A with translation to**
2509 **Language B**

2510 **Actors:**

- 2511 • The Patient,
- 2512 • the previous HCP in country A,
- 2513 • the Patient Identification, Authentication and Authorization Service in Country A
- 2514 • the epSOS translation service

2515

2516 **Preconditions:**

- 2517 • A Patient Summary or electronic Prescription exists in Country A
- 2518 • A National Patient Access Service exists in Country A
- 2519 • the epSOS translation service covers languages A and B

2520

2521 **Notes:**

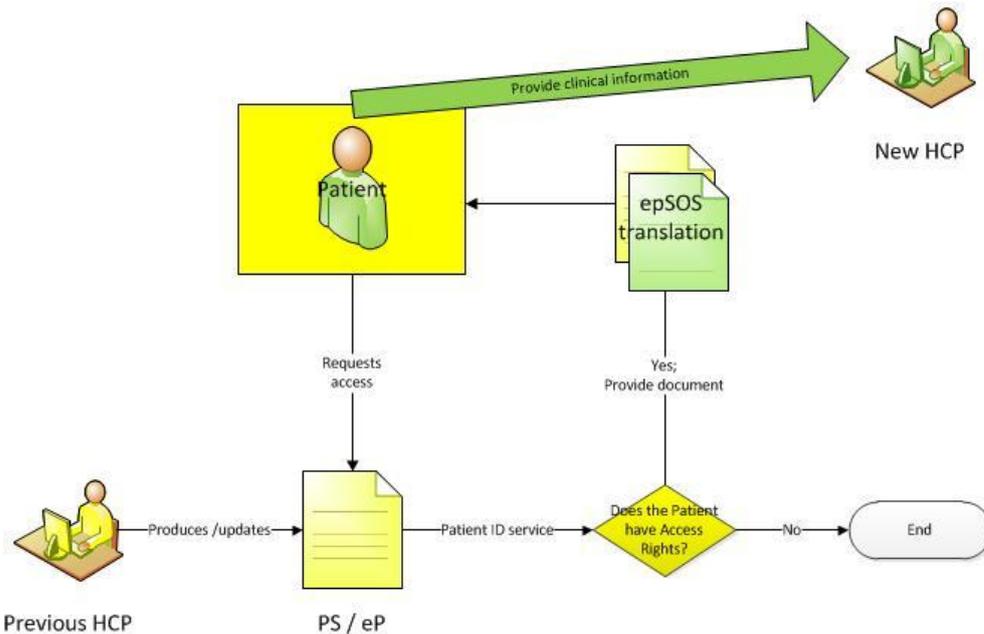
2522 The first use case is, strictly speaking, not covered by the DoW, since the documents to be
 2523 accessed are not “*Patient Summaries generated and kept in other countries (different from country A)*”, but
 2524 all patients in Country A are not necessarily fluent in the language of the PS/eP, and it is
 2525 conceivable that a patient could benefit from an epSOS-based translation of the Patient
 2526 Summary or ePrescription to his/her own language (denoted as Language B), even if this is
 2527 only a subset of what might be accessible by the National Patient Access in Country A. It is
 2528 also foreseen that for many Participating Nations, this use case is much easier to implement
 2529 than the Use Case UC.PAC.2.

2530

2531 **Diagram 2. Patient Access in Use Case UC.PAC.1**

2532

2533



2534

2535

2536 **Cross-border distribution 1. Patient Access to Country A PS or eP, with translation to**
2537 **Language B, for own use**

2538 Foreign language patients are by no means rare in any country. The potential for a widespread
2539 demand for the Use Case services is high, but the uptake may be rather slow.

2540

2541 **Cross-border distribution 2. Patient Access to Country A PS or eP, for use in an**
2542 **encounter with a Health Professional in Country B**

2543 The service process is the same as Use Case UC.PAC.1 in cross-border distribution 1, except
2544 for the final stage, where the Patient passes the epSPA document to his/her Health
2545 Professional -B. Also, the language of the epSOS translation may be dictated by the language
2546 of the New Health Professional, not necessarily that of the Patient. Therefore, this situation
2547 can also be seen as a workaround for the situation where the Country B Health Professional
2548 HCP does not have access to the regular epSOS PS/eP documents – possibly even outside
2549 Europe. However, the Use Case still requires the semantic support for Language B, provided
2550 by an epSOS NCP.

2551

2552 The potential need for the Use Case for this situation is very high, as it might be used to
2553 enhance the healthcare of migrant workers. Also, the present semantic solution in epSOS, with
2554 a terminology database designed for professional use, may require further development if lay
2555 understandability is to be achieved.

2556

2557 **6.2.2 UC.PAC.2 - Patient Access to PS or eP in Country B with translation to**
2558 **Language A**

2559 **Actors:**

- 2560 • The Patient,
- 2561 • the previous HCP in country B,
- 2562 • the Patient Identification, Authentication and Authorization Service in Country B
- 2563 • the epSOS translation service

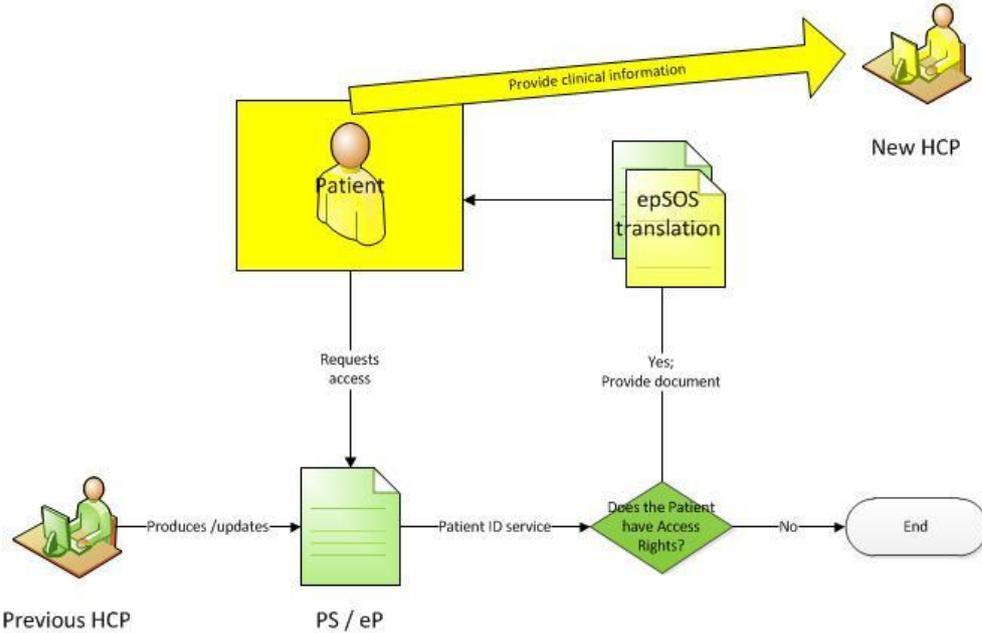
2564

2565 **Preconditions:**

- 2566 • A Patient Summary or electronic Prescription exists in Country B
- 2567 • A National Patient Access Service exists in Country B
- 2568 • The National Patient Access and the Patient Identification, Authentication and
2569 Authorization Service in Country B can be accessed by the Patient from Country A
- 2570 • the epSOS translation service covers languages A and B

2571

2572 **Diagram 3. Patient Access in Use Case UC.PAC.2**



2573
2574

2575 **Cross-border distribution 3. Patient Access to PS or eP generated or kept in Country B**

2576

2577 This is the situation described in the DoW. By default, the PS/eP is in Language B, and not
2578 readily understandable by the Patient or his/her Health Professional in Country A.

2579

2580 This situation for the Use Case UC.PAC.2 is probably reasonably prevalent, as soon as
2581 patients are confident users of their National Patient Access services. In fact, the need for
2582 Patient Access is higher in this case than in the regular (non-epSOS) Country A – Country A
2583 case, because the language barrier makes it more likely the Patient does not fully understand
2584 what the HCP has told him/her during the encounter.

2585

2586 An added complication compared to Use Case UC.PAC.1 is that the Patient does not usually
2587 have access to the National Patient Access Service of Country B, either by Country B
2588 legislation or because Country B Patient Authentication is not available to foreign patients. In
2589 such cases, the use case falls apart (epSOS abides by the existing rules of both Country A
2590 and Country B). Therefore, a precondition for this use case is that the Patient has a way to
2591 authenticate his/her electronic ID in Country B. Since this is usually not possible, the epSOS
2592 pilot will not provide a service of this kind.

2593

2594 A completely different approach to the cross-border distribution 3 is if the epSOS Patient
2595 Summary in Country B is used to update (possibly even create) a Patient Summary in Country
2596 A, as described in the Patient Summary extension UC.PS.4. If such a consolidation of the
2597 Patient Summaries is achieved, the Use Case UC.PAC.1 covers the Patient's needs in cross-
2598 border distribution 3 (and 4).

2599

2600 **Cross-border distribution 4. Patient Access to PS or eP generated or kept in Country B,
2601 for use by Health Professional in Country A**

2602

2603 This is the second situation described in the DoW. By default, the PS/eP is in Language B, and
2604 not readily understandable by the Patient or his/her Health Professional in Country A.

2605

2606 The Use Case UC.PAC.2 for cross-border distribution 4 is meaningful only if the Health
2607 Professional in Country A does not have epSOS access to the Patient's PS/eP in Country B.
2608 This may occur even if the epSOS translation service for PS/eP exists, and Country A (or

2609 another country providing the Language A translation resource) therefore is already within the
2610 epSOS community. This could be the case if a) the Health Professional is not connected to the
2611 epSOS services, or b) the Use Case for epSOS-PS/eP in Country B is not established.

2612

2613 The service process is the same as for Use Case UC.PAC.2 in cross-border distribution 3,
2614 except for the final stage, where the Patient passes the epSPA document to his/her Health
2615 Professional -A.

2616

2617 This is probably a rare case, since it is based on the exception where the Country A epSOS
2618 service exists but Patient Access is needed because the Health Professional is not connected
2619 to it.

2620

2621

2622 **6.3 Recommendations and items to be developed elsewhere**

2623 **6.3.1 Adoption of Use Case UC.PAC.1**

2624 After considerations regarding the difficulty of unequivocal identification of foreign patients,
2625 and the risks involved in maintaining the information quality if Patient Summary information is
2626 distributed in countries other than the country of affiliation, the epSOS PSB has decided that
2627 epSOS services only support access to medical records through the patient's country of
2628 affiliation (Country A). Therefore, specifications are needed only for UC.PAC.1.

2629
2630 Responsible: KT 1.4.9
2631

2632 **6.3.2 Interaction with Extension of Patient Summary content**

2633 The value of the Patient empowerment is especially high in the care of chronic conditions
2634 (diabetes, COPD, depression, atrial fibrillation, etc.). For these cases, the present epSOS
2635 Patient Summary content is insufficient, and added fields should be developed to describe
2636

- 2637
- 2638 • the care plan,
 - 2639 • physiological measurements & tests to be monitored (blood pressure, weight, PEF,
2640 etc.),
 - 2641 • lab results to be monitored,
 - 2642 • the functional state (disability) and
 - 2643 • assistive devices.

2644 The KT 1.4.4 recommends that the content of epSOS Patient Summary and e-Prescription
2645 services are developed to better serve patients with chronic conditions.

2646
2647 Responsible: Semantic Working Group (KT 1.4.10)
2648
2649

2650 **6.3.3 Patient Access to input health information (“Write Access”)**

2651 Once national solutions are developed for consolidating patient-produced data with the current
2652 professional Electronic Health Records, the need for an epSOS-like service for such Personal
2653 Health Records will arise. As of now, commercial solutions for patient-maintained health
2654 information exist (Microsoft Health Vault, etc.), and do not require epSOS-like support.

2655
2656 The KT 1.4.4 recommends that no patient input service is developed within the epSOS project.
2657

2658 **6.3.4 Supplemental Information external to PS or eP**

2659 The needs of the Patient may not be satisfied with the information received through the Use
2660 Cases described, since the information content of PS and eP is primarily meant to be read and
2661 interpreted by professionals. The Patient might want to access supplementary information, e.g.
2662 about the diagnoses or the prescribed/dispensed (foreign and unfamiliar) medications, or
2663 decision support. At this time, no processing of such information is suggested within epSOS.

2664 **6.3.5 Additional services where the Patient Access interface may be useful**

2665 **6.3.5.1 Maintenance of Patient Consent**

2666 The way the Use Cases UC.PAC.1 and UC.PAC.2 are described, patient consent is not an
2667 issue, since the Patient is accessing the content himself/herself. However, the Patient might
2668 want to use the Patient Access interface to give or withdraw consent to a Health Professional
2669 accessing his or her PS/eP. At least some National Patient Access services are implementing
2670 similar components for the maintenance of national patient consent (for sharing of electronic
2671 health records). As an epSOS service, this is only meaningful for the epSOS consent.
2672

2673 This is in effect a third Use Case, and one that was not specified in the planning process for
2674 epSOS nor described in the DoW. However, time and other resources do not permit the full
2675 development of this Use Case within epSOS.

2676 **6.3.5.2 Patient Access to access logs**

2677 It has been suggested that patients might want to use the epSOS Patient Access interface to
2678 monitor who has accessed their PS/eP via epSOS. At least some National Patient Access
2679 services are implementing similar components to let patients monitor who has accessed their
2680 EHR. When time and resources permit to incorporate this feature into Patient Access service it
2681 could enhance the contribution of Patient Access service.

2682 **6.3.5.3 Searching for epSOS sites (PoCs)**

2683 It has been suggested that patients might want to use the epSOS Patient Access interface to
2684 search for epSOS sites (PoC:s) to enable them to contact HCP:s who could provide them with
2685 the best possible cross-border service.
2686

2687 This is in effect a fifth Use Case, and one that was not specified in the planning process for
2688 epSOS nor described in the DoW. Such a list might, however, be a relatively straightforward
2689 service that could be specified as a functional component of the Use Cases UC.PAC.1, even if
2690 the information requested is quite different and separate from the information handled in these
2691 Use Cases. If possible, the specifications of such a searching and listing service will be
2692 included in the work of KT1.4.9.
2693
2694

2695 **6.3.6 Legal considerations**

2696 The most problematic question is how the Patient affiliated with Country A is identified and
2697 possibly authenticated within Country B services in the Use Case UC.PAC.2, cross-border
2698 distributions 3 and 4. As mentioned above, if the Country B healthcare encounter information
2699 can be returned to Country A so that the Country A PS is fully updated, no Country B
2700 identification is needed for Patient Access. Where this cannot be achieved, the fulfilment of
2701 Patient Access in cross-border distributions 3 and 4 would require identification and
2702 authentication of the Patient by Country B criteria, and this solution (and therefore UC.PAC.2)
2703 will not be developed in epSOS. Development of a unified European approach to this problem
2704 may be facilitated by the development of a common European electronic identity within the
2705 STORK project and its extension STORK 2.0.
2706

2707
2708 An unexplored legal consideration arises from the fact that epSOS is based on a B2B model
2709 based on the Circle of Trust and governed by the FWA. Which implications the direct patient
2710 access has on this B2B model? One possible implication is a liability that arises in Use Case
2711 UC.PAC.1, cross-border distribution 1. The translation to Language B requested in this case
2712 relies on the semantic service of Country B. It is not controlled by the NCP or the National
2713 Authority in Country A. Therefore, the Patient should be aware that the semantic content is not
2714 necessarily authorized in Country A.

2715
2716 The same reliance on a foreign semantic authority is seen in the situation 2 of Use Case
2717 UC.PAC.1, where the HCP in Country B receives a translation of the Country A PS from the
2718 patient, possibly in Language C. Here, the HCP is of course responsible for his/her own
2719 clinical decisions, but the chain of trust now includes a new actor, and the consequences of
2720 this must be considered.

2721
2722 Responsible: WP 2.1

2723
2724
2725