EUnetHTA WP7: Implementation Report November 2019

Contents

Abbreviations

AAZ: Agency for Quality and Accreditation in Health Care (now Croatian Ministry of Health)
AEMPS: Agencia Española de Medicamentos y Productos Sanitarios
AETSA: Andalusian Agency for Health Technology Assessment
AETS-ISCIII: Health Technology Assessment Agency-Institute of Health Carlos III
AGENAS: The National Agency for Regional Health Services
JAZMP: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
AIFA: Agenzia Italiana del Farmaco
AOTMiT: Agency for Health Technology Assessment and Tariff System
AQuAS – Agència de Qualitat i Avaluació Sanitàries de Catalunya
ASSR-RER: Agenzia Sanitaria e Sociale Regionale-Emilia-Romagna
AVALIA-T – Galician Agency for Health Technology Assessment
AWTTC: All Wales Therapeutics and Technology Centre
CGM: Continuous glucose monitoring
CRP POCT: C-reactive protein point of care testing
DPA: Directorate Pharmaceutical Affairs DPA), Malta
EC: European Commission
EUnetHTA: European Network for Health Technology Assessment
EU REA: EUnetHTA Relative Effectiveness Assessment
FIMEA: Finnish Medicines Agency
FLACS: Femtosecond laser-assisted cataract surgery
FOPH: Federal Office of Public Health
FUCANIS: Canary Foundation for Health Research
GOeG: Gesundheit Österreich GmbH
GRADE: Grading of Recommendations Assessment, Development and Evaluation
HAS: Haute Autorité de Santé
HIFU: High-intensity focused ultrasound
HILA: Pharmaceuticals Pricing Board
HIS: Healthcare Improvement Scotland
HIQA: Health Improvement and Quality Authority
HTA: Health Technology Assessment
HTW: Health Technology Wales
INFARMED: National Authority of Medicines and Health Products
JA: Joint Action
JA2: Joint Action 2
JA3: Joint Action 3
KCE: Belgian Health Care Knowledge Centre
LBI: Ludwig Boltzmann Institute
MOH SI: Ministry of Health, Slovenia
NCPE: National Centre for Pharmacoeconomics
NHS: National Health Service
NICE: National Institute for Health and Care Excellence
NIPHNO: Norwegian Institute of Public Health
NIPT: Non-Invasive Perinatal Testing
NIPN: National Institute of Pharmacy and Nutrition
NOMA: Norwegian Medicines Agency

NSPHMPD: National School of Public Health, Management & Professional Development
OSTEBA – Basque Office for Health Technology Assessment
PICO: Population, Intervention, Comparator, Outcome
PICOTS: Population, Intervention, Comparator, Outcome, Timing, Setting
POP Database: Planning and Ongoing Projects Database
PT: Pharmaceutical Technologies
PTJA: Pharmaceutical Technologies Joint Assessment
OT: Other technologies
OTCA: Other Technologies Collaborative Assessment
REA: Relative Effectiveness Assessment
rTMS: Repetitive Transcranial Magnetic Stimulation
RWD: Real World Data
RWE: Real World Evidence
SBU: Swedish Agency for Health Technology Assessment and Assessment of Social Services
SHTG: Scottish Health Technologies Group
SMC: Scottish Medicines Consortium
SmPC: Summary of Product Characteristics
SNHTA: Swiss Network for Health Technology Assessment
SUKL: State Institute for Drug Control
TAVI: Transcatheter Aortic Valve Implantation
TLV: Dental and Pharmaceutical Benefits Agency
UCSC: Università Cattolica del Sacro Cuore
UNIBA: Comenius University in Bratislava
UK: United Kingdom
UTA: University of Tartu, Estonia
VASPVT: State Health Care Accreditation Agency, Lithuania
WCD: Wearable Cardioverter Defibrillator
WP: Work Package
ZIN: Zorginstituut Nederland

Introduction

This is the 4th Work Package 7 (WP7) implementation report. The report presents the latest implementation data on the uptake of joint and collaborative assessments published under JA3. Comparison is made with data from previous implementation reports and with JA2 where appropriate and feasible.

WP7 implementation reports are produced bi-annually. Previous WP7 implementation reports are available on the EUnetHTA website:

https://www.eunethta.eu/national-implementation/implementation-reports

This is the final scheduled WP7 implementation report. A further update of the implementation data will, however, be provided in the final WP7 deliverable 7.2 in May 2020.

Methods

Implementation data are collected by WP7 for all published EUnetHTA joint and collaborative assessments. Agencies provide data through completion of an implementation survey (intranet version for EUnetHTA partners, internet version for non-partners). The implementation survey is sent out after the publication of each assessment. The survey is predominately multiple choice but with some free-text responses (questions ask about whether the assessment was used, if so, how it was used, and factors that prevented or limited use). Respondents are expected to revise / update responses if their status changes.

Implementation data are downloaded, 'cleaned' and analysed by WP7 for inclusion in the bi-annual implementation reports. The implementation data in this report are as reported up to 20th November 2019.

Summary of key findings

- Since the last implementation report was published in May 2019, no new PT assessments have been published on which implementation data can be collected. Consequently, we see very little change in the implementation data for PT assessments. In contrast 5 new OT assessments have been published since the last implementation report on which there has been sufficient follow-up time to collect implementation data, and consequently we see much more change in the implementation data for OT assessments.

- 220 examples of use of JA3 assessments have been reported to date (as at 20th November 2019). There have been 56 uses of the 3 published PT assessments, rising from 54 in May 2019. The number of uses of OT assessments since May 2019 has increased significantly from 105 to 164.

- Of the 220 uses, 117 uses (53%) are in assessment procedures and 103 uses (47%) are dissemination. In the last implementation report a greater percentage of uses were in assessment procedures (60%). The majority of uses in dissemination continue to be OT assessments (n = 91 – 92%).

- Uses of PT assessments under JA3 continues to exceed reported use under JA2. For the PT assessments published under JA3 the median number of uses in assessment procedures is 15 (range = 4), compared with a median number of uses of 6.5 for the PT assessments published under JA2 (range = 12).

- For the OT assessments published under JA3 the median number of uses in assessment procedures is 3.5 (range = 9), compared with a median number of uses of 6.5 for the OT assessments published under JA2 (range = 8). However, a number of these OT assessments are only recently published and with a longer follow-up period we will hopefully see levels of use for OT assessments rise to that similar under JA2.

- For PT assessments 19 countries have now reported using a JA3 assessment rising from 18 in May 2019 and up from 10 countries in the 1st implementation report in May 2018. For OT assessments 20 countries have now reported use of a JA3 assessment rising from 19 in May 2019, and up from 9 in May 2018.

- The key issues limiting or preventing use of EUnetHTA assessments continue to be timing (particularly for OT), relevance, language and reporting. The extent to which specific factors are reported to limit or prevent assessments in countries is presented in figures 18 to 33 (pages 29 to 33).

Results

Published assessments

As at 20th November 2019, 22 joint or collaborative assessments have been published under JA3, 18 OT assessments and 4 PT assessments. Implementation data on 19 of these assessments are presented in this report (3 PT and 16 OT). No implementation data is presented on sotagliflozin (PTJA04), as this product has not yet been launched in Europe. No data is presented on 2 of the OT assessments (OTCA18 and OTCA20), as there has not yet been sufficient follow-up time to collect accurate implementation data. Information on these assessments will be included in WP7 final deliverable (7.2) in May 2020.

The publication date (shown in table 1 overleaf) should be born in mind when considering the results of the implementation data. At the time of writing this report, 5 of the OT assessments have been published for 9 months or less (OTCA10, OTCA11, OTCA14, OTCA15 and OTCA19). This is unlikely to be adequate time to fully capture implementation data on the use of these assessments. Conversely, all the PT assessments have been published for 2 years and, therefore, the majority of use of these assessments is already likely to have been captured.

Response rates

Table 1 overleaf details the total response rate by agency for all published JA3 assessments, including both responses of use and non-use of assessments[1]. The response rates for PT assessments are good and range from 83% (PTJA03) to 85% (PTJA01, PTJA02), with no change from the last implementation report. The response rates by agency for OT assessments range from 28% (OTCA19) to 90% (OTCA03). The response rate for the most recently published assessments can be expected to increase over time with a longer follow-up period (OTCA10, OTCA11, OTCA14, OTCA15 and OTCA19).

Table 2 (p. 10) details the response rate by country for JA3 assessments[2]. Response rates by country for PT also remain high and show no change from the last implementation report, ranging from 87% (PTJA03) to 93% (PTJA01 and PTJA02). Response rates for OT are also good ranging from 32% (OTCA19) to 92% (OTCA01, OTCA02, OTCA03, OTCA04 and OTCA05). Again, the response rates for the most

[1] Calculated based on 39 agencies currently using HTA to assess non-pharmaceutical technologies and 47 using HTA to assess pharmaceutical technologies. Data on use of HTA was collected by WP7 in their research and analysis of HTA and reimbursement processes in EUnetHTA partner countries and from partners in the implementation network. Please note these figures have been updated to include agencies in Greece, where there is now an established HTA system.

[2] Calculated based on 25 countries currently using HTA to assess non-pharmaceutical technologies and 30 using HTA to assess pharmaceutical technologies. Data on which countries use different types of HTA was collected by WP7 in their research and analysis of HTA and reimbursement processes in EUnetHTA partner countries and from partners in the implementation network. Please note these figures have been updated to include Greece, an HTA process has now been established.

recently published OT assessments can be expected to increase over-time with longer follow-up.

The data in table 2 (overleaf) also shows that country response rates have improved across several assessments since the last implementation report in May 2019 (where comparable data is available).

Table 1: Response rate by agency – JA3 assessments

Assessment	Publication Date	Responses from expected agencies – November 2019	
		Number (N)	Percentage (%)
OTCA01 (Wearable cardioverter-defibrillator)	Nov-16	34 of 39	87%
OTCA02 (Antibacterial-coated Sutures)	Apr-17	31 of 39	79%
OTCA03 (NIPT)	Feb-18	35 of 39	90%
OTCA04 (MammaPrint)	Jan-18	31 of 39	79%
OTCA05 (Magnetic stimulation)	Apr-17	32 of 39	82%
OTCA06 (TAVI)	Dec-18	21 of 39	54%
OTCA07 (FLACS)	Oct-18	21 of 39	54%
OTJA08 (Glucose monitoring)	Jul-18	29 of 39	74%
OTCA09 (HIFU ablation)	Apr-18	29 of 39	74%
OTCA10 (Stool DNA testing)	Jul-19	15 of 39	38%
OTCA11 (3D Implants)	Apr-19	18 of 39	46%
OTCA12 (CRP POCT)	Jan-19	24 of 39	62%
OTCA14 (Robot assisted surgery)	May-19	19 of 39	49%
OTCA15 (Irreversible electroporation)	Jul-19	19 of 39	49%
OTCA16 (Bioresorbable stents)	Jan-19	24 of 39	62%
OTCA19 (Screening for osteoporosis)	Sep-19	11 of 39	28%
PTJA01 (Midostaurin)	Nov-17	40 of 47	85%
PTJA02 (Regorafenib)	Oct-17	40 of 47	85%
PTJA03 (Alectinib)	Jan-18	39 of 47	83%

Table 2: Response rate by country – JA3 assessments

Assessment	Responses from expected countries – May 2019		Responses from expected countries –November 2019	
	Number	Percentage (%)	Number	Percentage (%)
OTCA01 (Wearable cardioverter-defibrillator)	23 of 25	92%	23 of 25	92%
OTCA02 (Antibacterial-coated Sutures)	23 of 25	92%	23 of 25	92%
OTCA03 (NIPT)	22 of 25	88%	23 of 25	92%
OTCA04 (MammaPrint)	22 of 25	88%	23 of 25	92%
OTCA05 (Magnetic stimulation)	23 of 25	92%	23 of 25	92%
OTCA06 (TAVI)	15 of 25	60%	19 of 25	76%
OTCA07 (FLACS)	16 of 25	64%	17 of 25	68%
OTJA08 (Glucose Monitoring)	22 of 25	88%	22 of 25	88%
OTCA09 (HIFU Ablation)	21 of 25	84%	21 of 25	84%
OTCA10 (Stool DNA testing)	N/A	N/A	13 of 25	52%
OTCA11 (3D Implants)	N/A	N/A	16 of 25	64%
OTCA12 (CRP POCT)	18 of 25	72%	19 of 25	76%
OTCA14 (Robot assisted surgery)	N/A	N/A	15 of 25	60%
OTCA15 (Irreversible electroporation)	N/A	N/A	14 of 25	56%
OTCA16 (Bioresorbable Stents)	18 of 25	72%	21 of 25	84%
OTCA19 (Screening for osteoporosis)	N/A	N/A	8 of 25	32%
PTJA01 (Midostaurin)	28 of 30	93%	28 of 30	93%
PTJA02 (Regorafenib)	28 of 30	93%	28 of 30	93%
PTJA03 (Alectinib)	26 of 30	87%	26 of 30	87%

Topic relevance

As with the previous implementation reports, the data for November 2019 continues to show that EUnetHTA is generally choosing topics that are within an agency's remit. As shown in table 3 below, agencies indicating that OT topics were not within remit ranged from 0% (OTJA08) to 16% (OTCA14). For all 3 PT assessments published to date 6 agencies (15%) indicated that the topic was not within their remit.

For a number of agencies, although the topic area chosen by EUnetHTA is within their remit, the agency is not currently planning to assess the technology meaning the EUnetHTA topic may not be aligned with agency priorities. The assessment topics for OT continue to show higher levels of topics being within an agency remit but not in the work programme compared to PT. In the final WP7 deliverable 7.2 we will explore the impact on implementation of specific changes that EUnetHTA has introduced to improve topic selection and prioritisation, including the Topic Identification, Selection and Prioritisation (TISP) pilots and the EUnetHTA Prioritisation List.

Table 3: Work status in the topic area subject to EUnetHTA assessment

Assessment	Work on this topic is……			
	Not in our remit	In our remit but not currently planned	Planned but not started	Ongoing or complete
OTCA01 (Wearable cardioverter-defibrillator)	2 (6%)	22 (65%)	1 (3%)	9 (26%)
OTCA02 (Antibacterial-coated Sutures)	5 (16%)	20 (65%)	0 (0%)	6 (19%)
OTCA03 (NIPT)	3 (9%)	17 (49%)	1 (3%)	14 (40%)
OTCA04 (MammaPrint)	2 (6%)	14 (45%)	2 (6%)	13 (42%)
OTCA05 (Magnetic stimulation)	3 (9%)	20 (63%)	0 (0%)	9 (28%)
OTCA06 (TAVI)	1 (5%)	8 (38%)	3 (10%)	9 (31%
OTCA07 (FLACS)	1 (5%)	16 (76%)	0 (0%)	4 (19%)
OTJA08 (Glucose Monitoring)	0 (0%)	10 (34%)	1 (3%)	18 (62%)
OTCA09 (HIFU)	3 (10%)	14 (48%)	1 (3%)	11 (38%)
OTCA10 (Stool DNA testing)	2 (13%)	10 (67%)	0 (0%)	3 (21%)
OTCA11 (3D Implants)	1 (6%)	12 (67%)	0 (0%)	5 (28%)
OTCA12 (CRP POCT)	2 (8%)	11 (46%)	1 (4%)	10 (42%)
OTCA14 (Robot assisted surgery)	3 (16%)	10 (53%)	1 (5%)	5 (22%)
OTCA15 (Irreversible electroporation)	1 (5%)	11 (58%)	1 (5%)	6 (32%)
OTCA16 (Stents)	1 (4%)	16 (67%)	0 (0%)	7 (29%)
OTCA19 (Screening for osteoporosis)	1 (9%)	8 (73%)	0 (0%)	2 (18%)
PTJA01 (Midostaurin)	6 (15%)	12 (30%)	3 (8%)	19 (47%)
PTJA02 (Regorafenib)	6 (15%)	16 (40%)	1 (3%)	17 (42%)
PTJA03 (Alectinib)	6 (15%)	7 (18%)	2 (5%)	24 (62%)

Overview of use of EUnetHTA assessments

Implementation data is collected on two principal types of use[3]:

1. Support for or as an alternative to the agency's existing HTA procedures
2. Dissemination of EUnetHTA assessments to support awareness of the availability of reports and/or evidence informed decision making

As shown in table 4 and figure 1 overleaf, 220 examples of use of JA3 assessments have been reported to date, up from 159 in the May 2019. The assessments where there has been a change in use since May 2019 are bolded in table 4.

The number of uses ranges from 22 uses for PTJA03 (Alectinib) to 7 uses for OTCA9 (HIFU Ablation). For the PT assessments the median number of uses is 18 (range = 6). For the OT assessments the median number of uses is 10.5 range (range = 6). Of the 220 total reported uses, 117 were uses in assessment procedures (48 for PT and 69 for OT) and 103 were sharing via dissemination (8 for PT and 95 for OT).

Unsurprisingly the data shows little change in the use of PT assessments since the last implementation report. No new PT assessments have published since the last implementation report on which implementation data is currently being collected. The number of uses of PT assessments has risen from 54 in May 2019 to 56 in November 2019. The new reported uses are for PTJA01 (Pharmaceuticals Pricing Board – Finland) and PTJA03 (Directorate for Pharmaceutical Affairs – Malta).

A significant increase in use of OT assessments has been reported since the last implementation report, with the number of uses of OT assessments rising from 105 in May 2019 to 164 in November 2019. This increase has principally been driven by the publication of 5 new OT assessments since the last implementation report.

There were 97 responses to the survey question on whether the use of assessments was national or regional, 89 (91%) were reported to be national and 8 (9%) were reported to be regional, again consistent with the findings from the last implementation report. EUnetHTA assessments are frequently reported to inform agency procedures used for reimbursement, although this continues to be more likely for PT than OT.

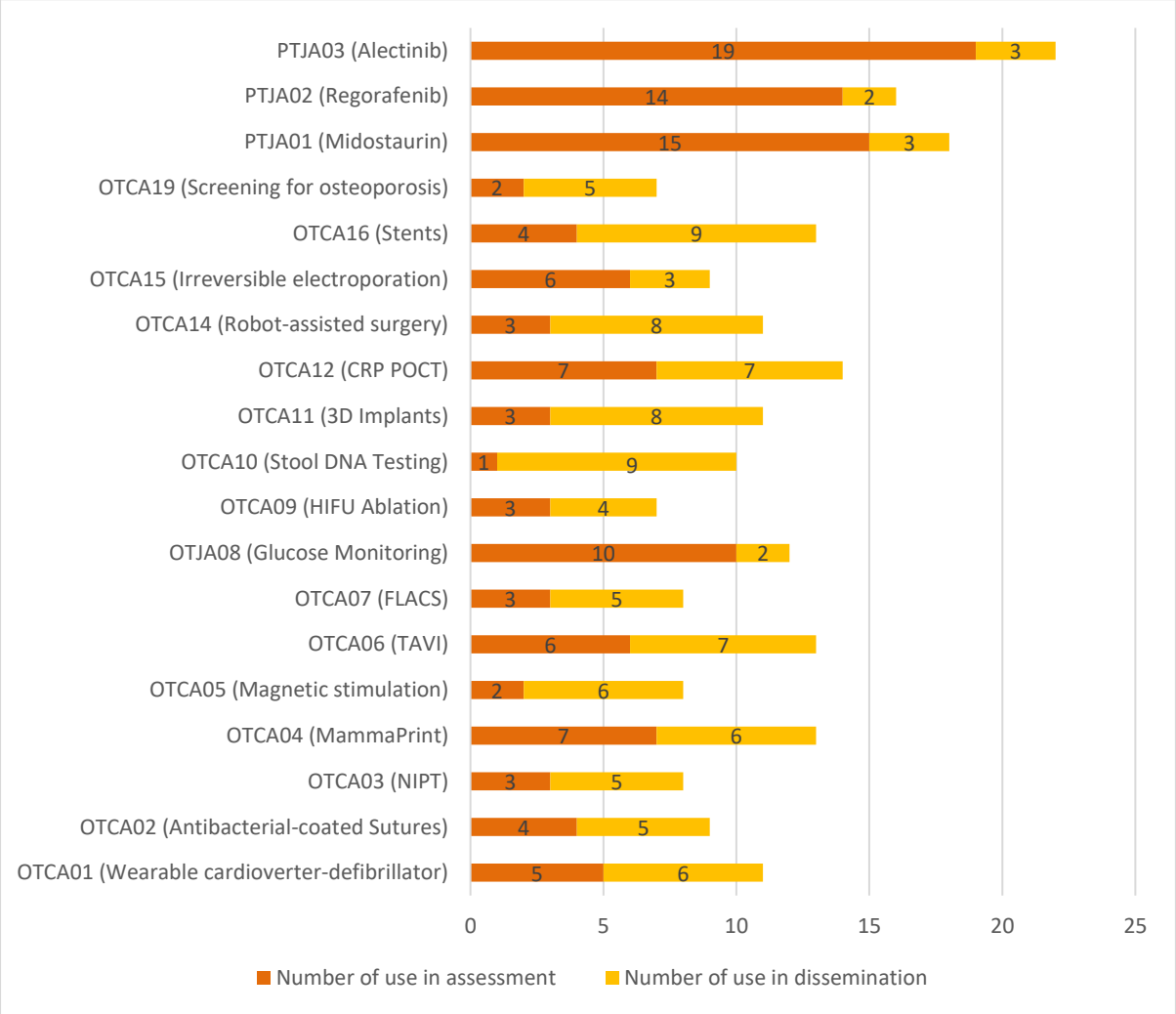
A summary of agencies reporting use of EUnetHTA assessments in assessment procedures are provided in **appendix 1** (PT assessments) and **appendix 2** (OT assessments).

[3] In the count of use each agency is only counted once for each assessment. Agencies reporting both use and dissemination for an assessment are counted once under use only.

Table 4: Use of the EUnetHTA JA3 assessments

	Number of uses in assessment	Number of uses in dissemination	Total number of uses of the EUnetHTA assessment
OTCA01 (Wearable cardioverter-defibrillator)	5 (45%)	6 (55%)	11
OTCA02 (Antibacterial-coated Sutures)	4 (44%)	5 (56%)	9
OTCA03 (NIPT)	3 (38%)	5 (62%)	8
OTCA04 (MammaPrint)	7 (54%)	6 (46%)	13
OTCA05 (Magnetic stimulation)	2 (25%)	6 (75%)	8
OTCA06 (TAVI)	6 (46%)	**7 (54%)**	**13**
OTCA07 (FLACS)	3 (38%)	**5 (62%)**	**8**
OTJA08 (Glucose Monitoring)	**10 (83%)**	2 (17%)	12
OTCA09 (HIFU Ablation)	3 (43%)	4 (57%)	7
OTCA10 (Stool DNA Testing)	**1 (10%)**	**9 (90%)**	**10**
OTCA11 (3D Implants)	**3 (27%)**	**8 (73%)**	**10**
OTCA12 (CRP POCT)	**7 (54%)**	**7 (50%)**	**14**
OTCA14 (Robot-assisted surgery)	**3 (27%)**	**8 (73%)**	**11**
OTCA15 (Irreversible electroporation)	**6 (67%)**	**3 (33%)**	**9**
OTCA16 (Stents)	**4 (21%)**	**9 (79%)**	**13**
OTCA19 (Screening for osteoporosis)	**2 (29%)**	**5 (71%)**	**7**
PTJA01 (Midostaurin)	**15 (83%)**	3 (17%)	**18**
PTJA02 (Regorafenib)	14 (8%)	2 (12%)	16
PTJA03 (Alectinib)	**19 (86%)**	3 (14%)	**22**
Total	**117 (54%)**	**103 (46%)**	**220**

Figure 1: Use of the EUnetHTA JA3 assessments



Countries reporting use of EUnetHTA assessments

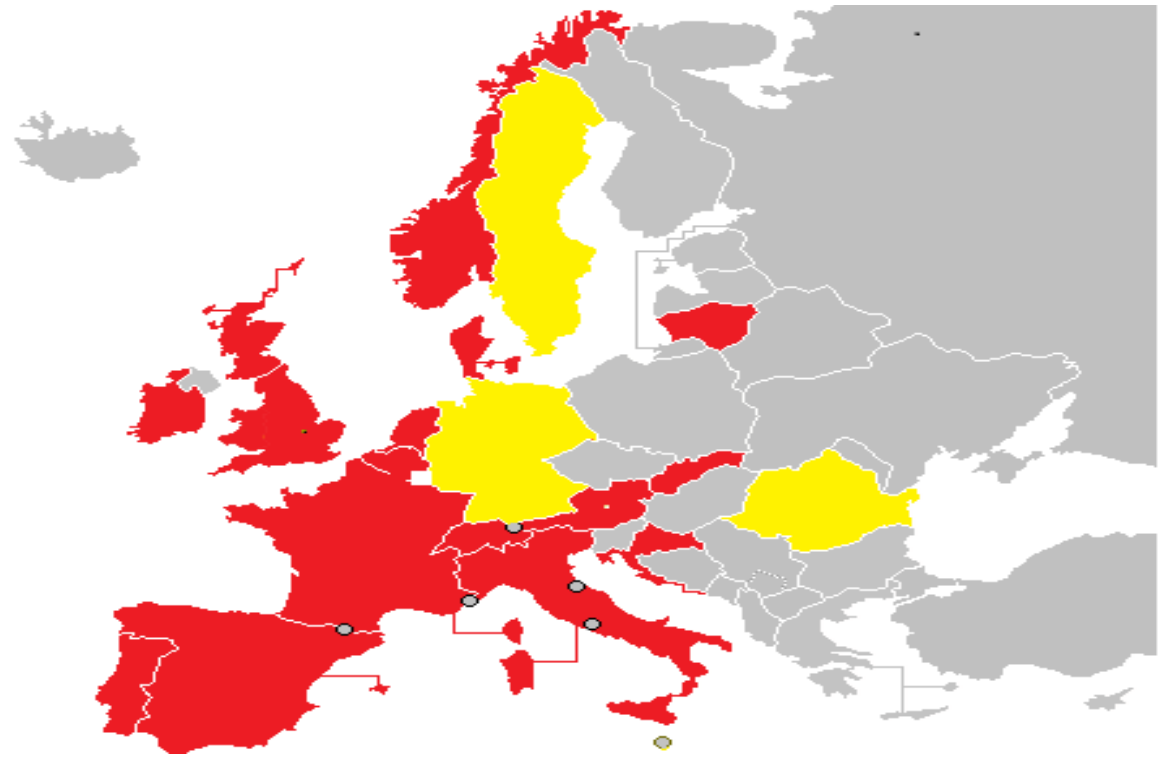
The maps overleaf (figure 2 for PT assessments and figure 3 for OT assessments) illustrate the countries reporting use of JA3 assessments. Red shading represents countries that reported use in assessment activities, yellow shading represents use in dissemination activities only.

For PT assessments 19 countries have now reported using a JA3 assessment. All 19 countries reported use in assessment activities and 5 of those countries also reported use in dissemination activities. This demonstrates an increase in the number of countries reporting use of PT assessments from 18 in May 2019, with Malta being the new country reporting use since the last (3rd) implementation report. Since the 1st implementation report in May 2018 the number of countries reporting use of EUnetHTA PT assessments has risen from 10.

For OT assessments 20 countries reported using a JA3 assessment. Of those, 17 reported use in assessment activities and 14 of those countries also reported use in dissemination activities. A further 3 countries reported use in dissemination only. The countries reporting use in dissemination only are shaded yellow. Since the last implementation report in May 2019 the number of countries reporting use of EUnetHTA assessments has increased from 19, with Germany being the new country reporting use (through dissemination) since the last implementation report. Since the first implementation report in May 2018, the number of countries reporting use of OT assessments has risen from 9.

Figure 2: Countries reporting use of at least one PT assessment

Figure 3: Countries reporting use of at least one OT assessment



Key: Red = reported use in assessment activities, Yellow = reported use in dissemination activities only

Figure 4 (PT) and figure 5 (OT) below provide colour coded maps illustrating the number of uses of EUnetHTA assessments in assessment procedures. The darker the shading indicates the more uses in each country. The analysis of PT assessments is based on data from PTJA01, PTJA02 and PTJA03. The analysis OT assessments is based on the first 9 OT assessments: OTCA01, OTCA02, OTCA03, OTCA04, OTCA05, OTCA06, OTCA07, OTCAO8 and OTCA09. Updated maps for the other published OT assessments will be provided once there has been a longer follow-up period to collect implementation data.

Figure 4: Number of uses of PT assessments – analysis by country

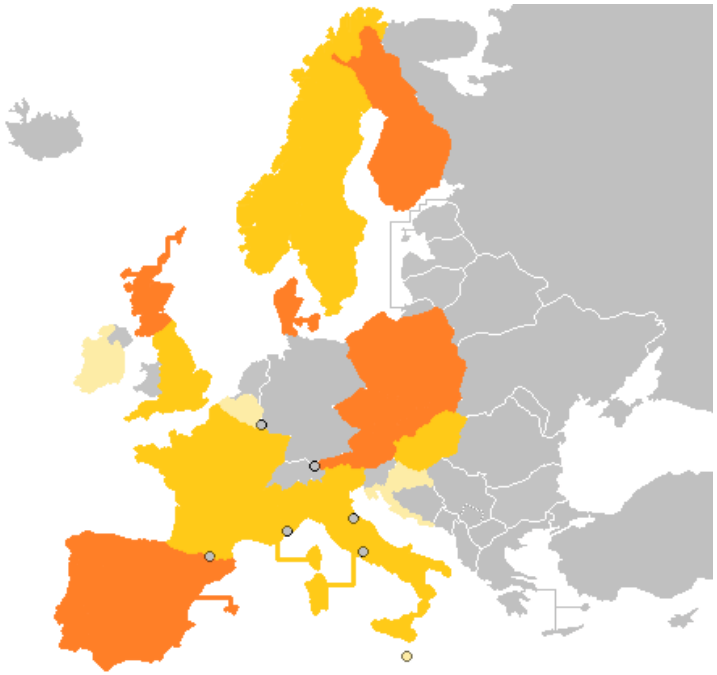
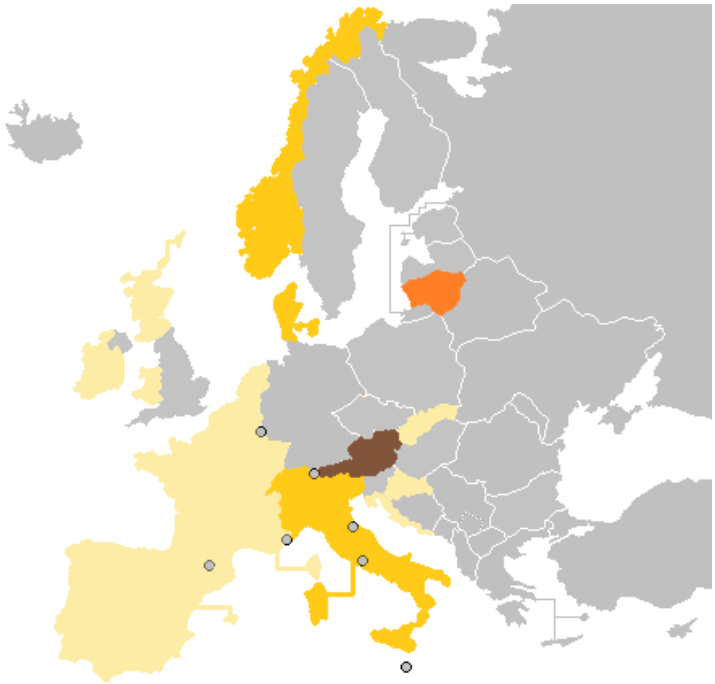


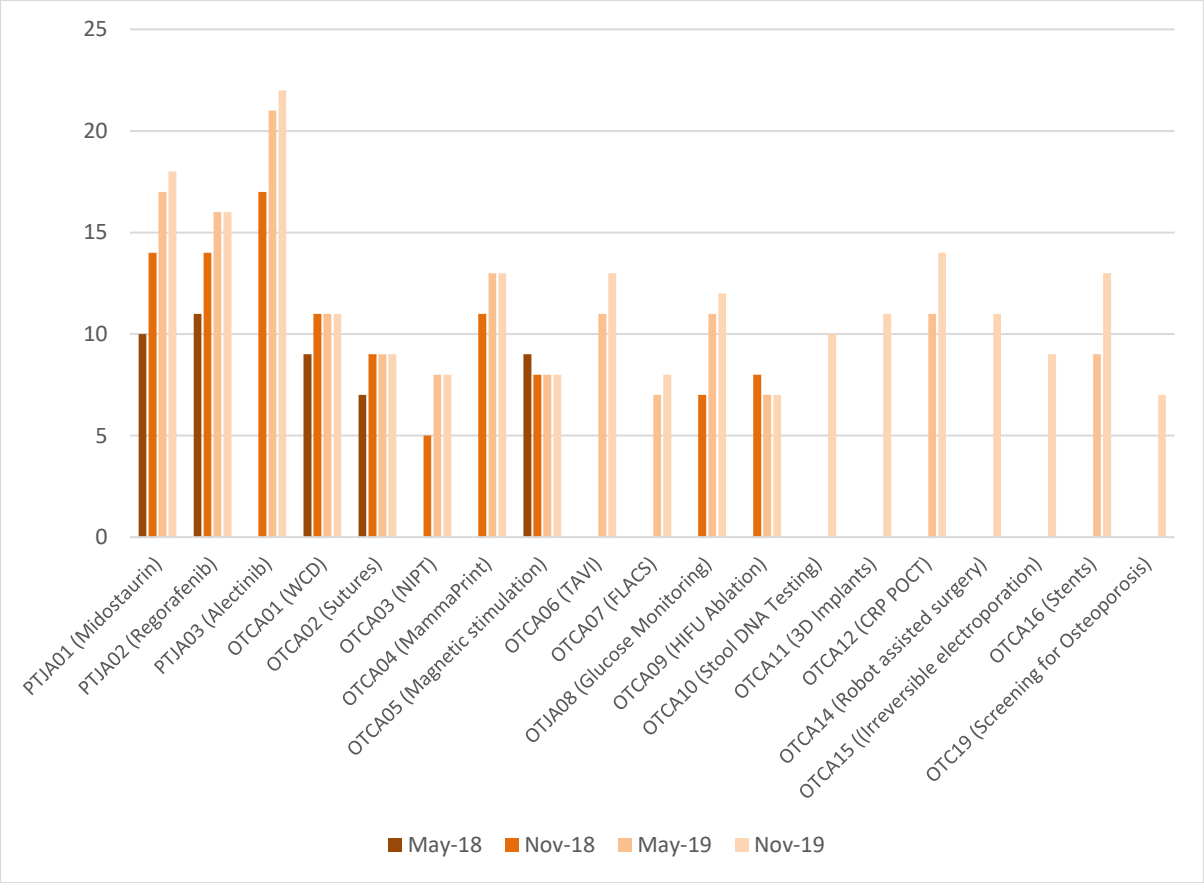
Figure 5: Number of uses of OT assessments – analysis by country



Comparison of use of JA3 assessments – May 2018 to November 2019

Figure 6 below details the total number of uses of JA3 assessments, comparing reported use for the 4 time points captured within the 4 implementation reports (May 2018, November 2018, May 2019 and November 2019). The graph continues to show that the majority of data is reported in the first year following publication of the assessment. The publication of 5 new OT assessments since the last implementation report means that we see a substantial increase in the use of OT assessments.

Figure 6: Use of JA3 assessments – May 2018 to November 2019

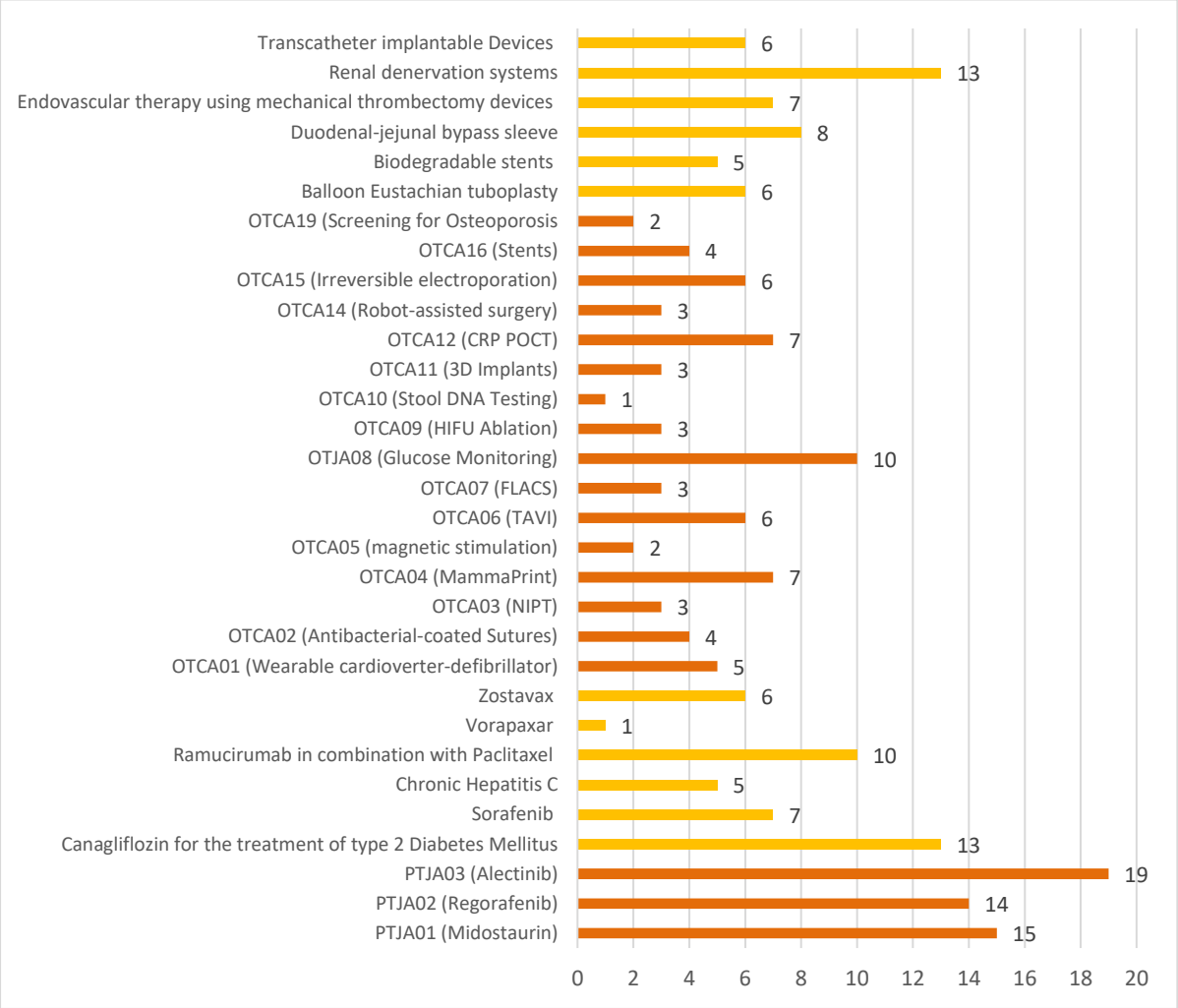


Comparison of use of JA3 assessments in assessment procedures with JA2

Figure 7 below compares the number of reported uses of JA3 assessments in assessment procedures (dark orange) with JA2 assessments (light orange). Comparison is only made on use in assessment procedures (rather than total use) because JA2 data was predominately focussed on use in assessment procedures (not dissemination).

For the PT assessments published under JA3 the median number of uses is 15 (range = 4), compared with a median number of uses of 6.5 for the PT assessments published under JA2 (range = 12). For the OT assessments published under JA3 the median number of uses is 3.5 (range = 9), compared with a median number of uses of 6.5 for the OT assessments published under JA2 (range = 8). The data for some OT assessments shows that use is lower in JA3 than in JA2, but with a longer follow-up period this data will hopefully show comparable use.

Figure 7: Use of EUnetHTA assessments in national assessment procedures – Comparison between JA3 and JA2



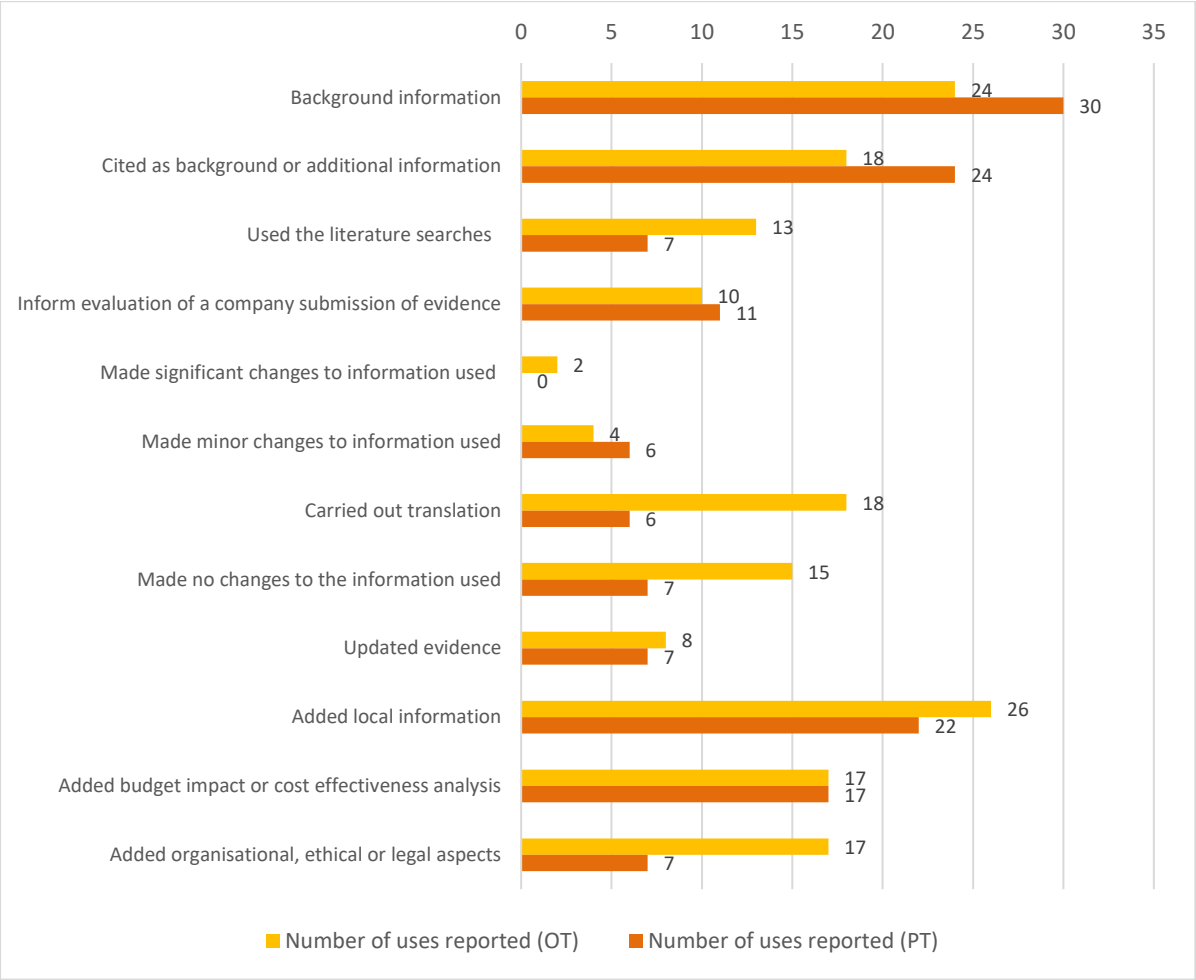
Key: JA3 assessments are shaded dark orange, JA2 assessments are light orange.

Type of use of JA3 assessments

Figure 8 below details the type of use of assessments published under JA3. As with the previous implementation reports, use of PT and OT assessments varies considerably. Most frequently the assessment is read for background information or cited in the agency report as background or additional information. Agencies also frequently reported using the assessments and adding local information, budget impact or cost-effectiveness analysis, and organisational, legal or ethical aspects. PT assessments are also frequently used to inform the evaluation of a company submission.

The data continues to show that more agencies use OT assessments with no changes or carry out translation only compared to PT assessments. In general, agencies assessing OT are more frequently able to use EUnetHTA assessments to replace agency work.

Figure 8: Type of use of JA3 assessments

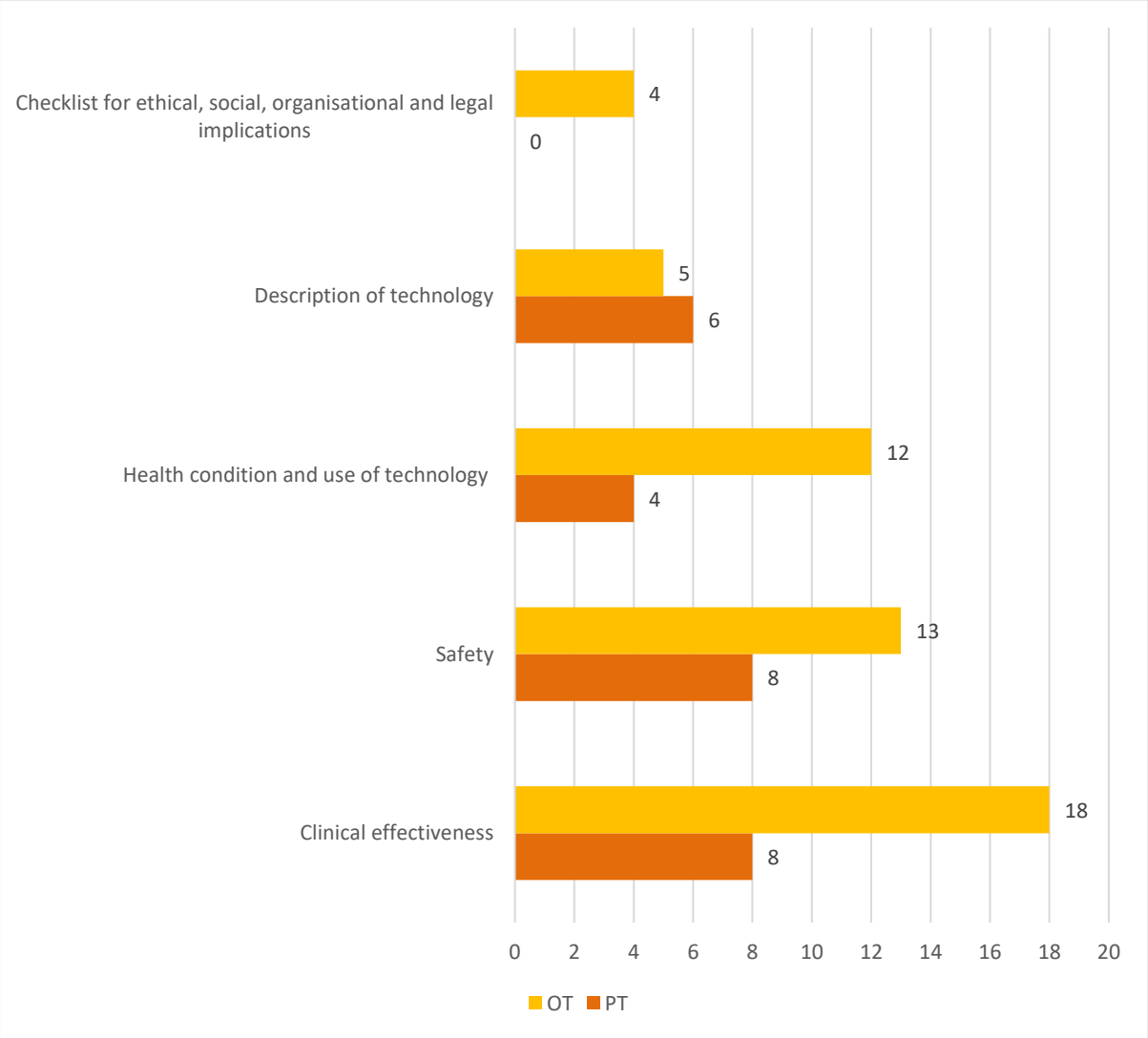


Sections of the assessments used

Where agencies have used EUnetHTA assessments in their assessment procedure, they are asked within the implementation survey to report which sections of the assessments they have used. In 69 cases (70%) agencies reported using all sections of the assessment and in 29 cases (30%) specific sections were used (a number of agencies did not respond to this question). Of the 69 cases of an agency reporting using all sections of a EUnetHTA assessment, 20 were for PT and 49 were for OT. Of the 29 cases of an agency using specific sections of an assessment, 19 were for PT and 10 were for OT. The findings in this implementation report are consistent with the findings from the last implementation report.

Where agencies did use specific sections, the results are again consistent with the last implementation report. The sections reported to be used most frequently were clinical effectiveness (PT = 8, OT = 18) and safety (OT = 13, PT= 8), as illustrated in figure 9 below.

Figure 9: Sections of assessments used



Limiting Factors

Agencies that used a JA3 assessment in their assessment processes are asked in the implementation survey whether there were any factors that limited their ability to use the assessment (see figure 10 overleaf).

For PT assessments 78 examples limiting use have been reported, a small increase from 75 in the last implementation report. The most frequently identified limiting factors are the same as in the last implementation report, namely:

- the requirement to prepare reports in their national language (n = 19)
- the requirement to use a specified report structure (n = 16)
- the timing of the availability of the EUnetHTA assessment (n = 11)
- different content information needed (n = 11)

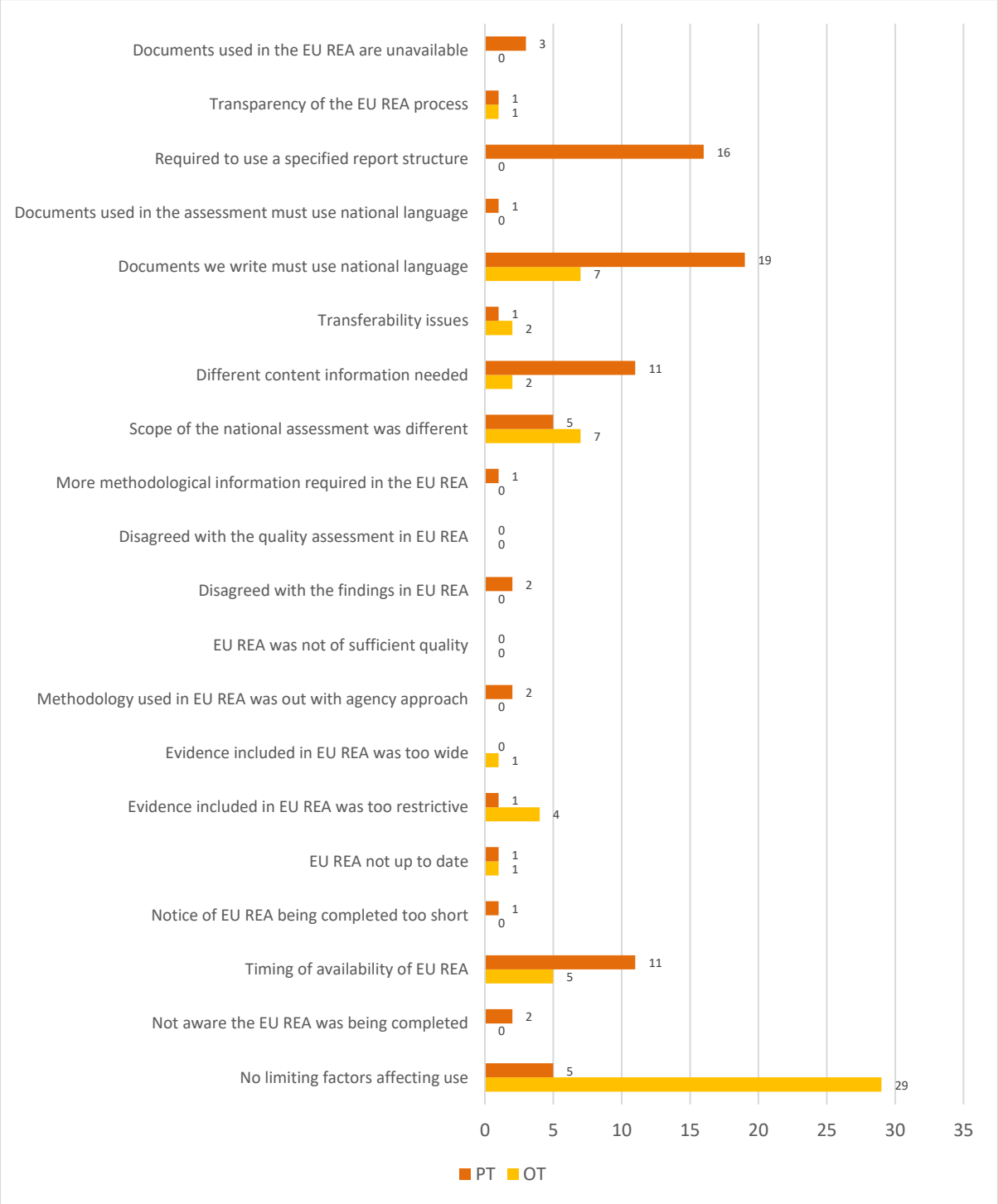
Users of OT assessments are much less likely to identify factors limiting use than users of PT assessments. 29 responses to the implementation survey reported that there were no limiting factors affecting use (compared to just 5 for PT). 34 examples limiting use of OT assessments were reported, up from 26 in the last implementation report. The main factors limiting use of OT assessments have also not changed the last implementation report, they still are:

- the requirement to prepare reports in their national language (n = 7)
- scope of the national assessment was different (n = 7)
- the timing of the availability of the EUnetHTA assessment (n = 5)
- evidence included in the EUnetHTA assessment was too restrictive (n = 4)

Figure 11 (PT) and figure 12 (OT) overleaf aggregate the limiting factors reported into categories: awareness; timing; evidence and methodology; reliability; relevance; transferability; language; reporting and accountability. In this analysis the data are aggregated where an agency identified 2 or more factors as limiting use within the same category (e.g. timing or relevance) for the same assessment this was only counted once. Consequently, the numbers in figures 11 and 12 do not exactly match with those in figure 10.

Again, the grouped limiting factors identified by users of PT assessments show no significant change since the last implementation report. The most commonly identified limiting factors are language (27%); reporting (21%); relevance (19%); and timing (17%). For OT the factors limiting also show little change, the key factors identified as limiting use of OT assessments continue to be language (27%), relevance (23%), timing (23%), and evidence and methodology (15%).

Figure 10: Factors limiting use of JA3 Assessments (n)



Limiting factors (aggregated into categories)

Figure 11: Factors that limited use of PT assessments (%)

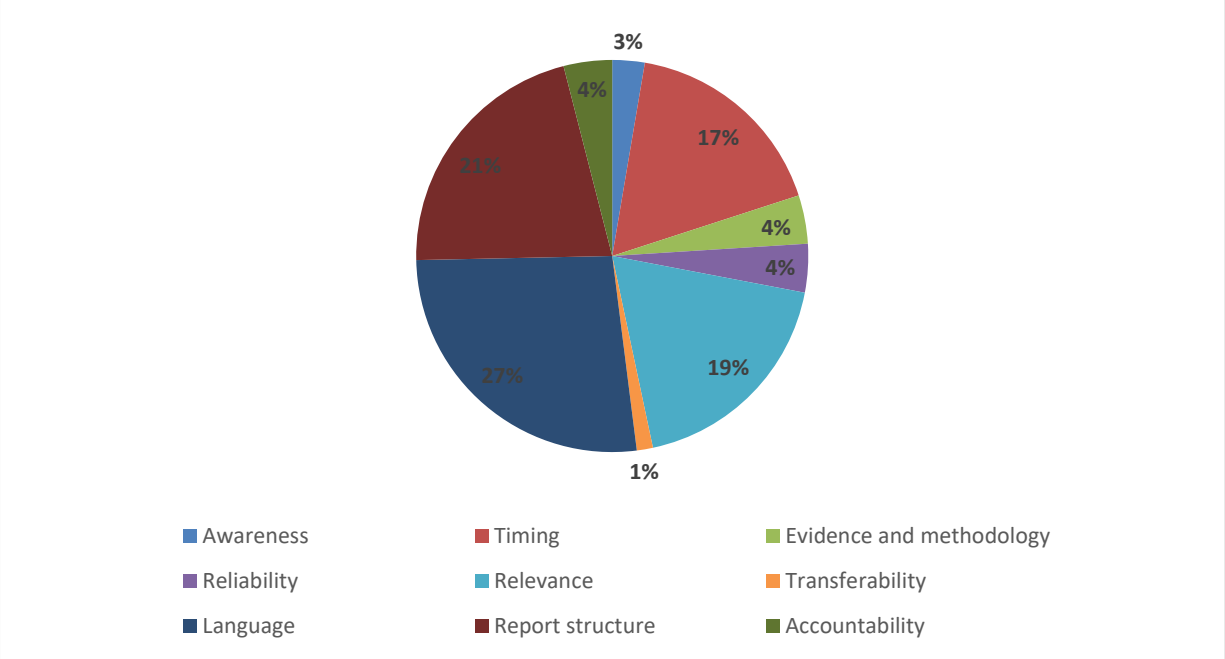
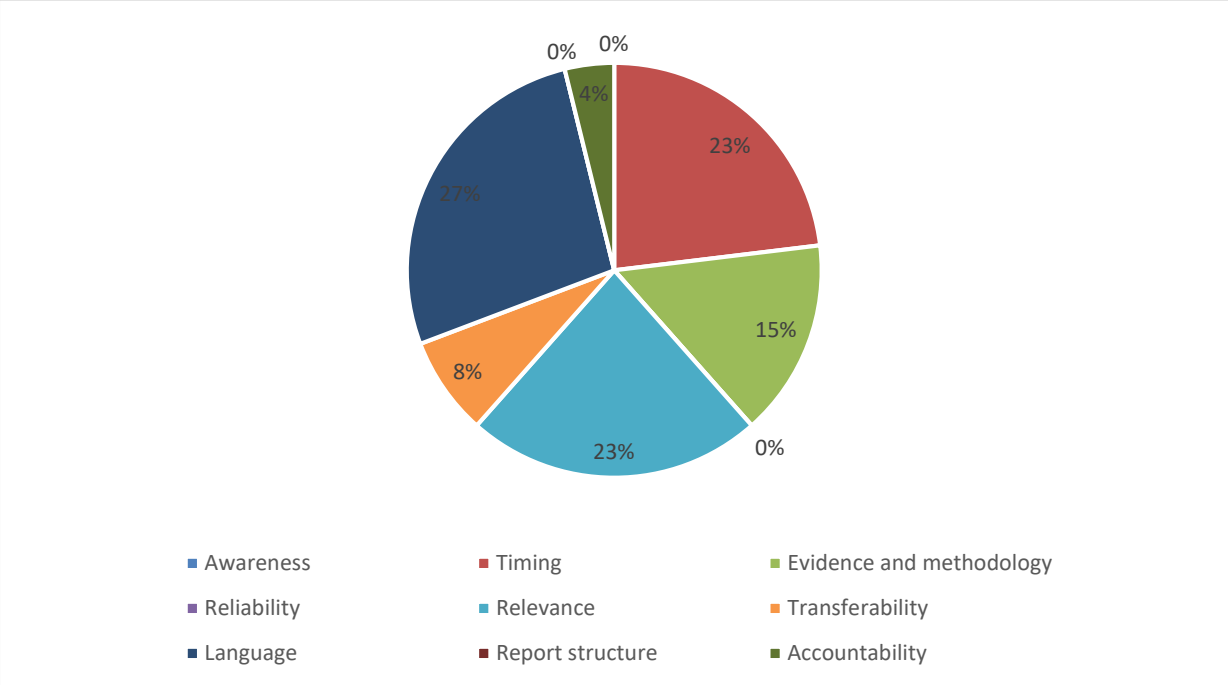


Figure 12: Factors that limited use of OT assessments (%)



Non-use of assessments

As shown in table 5 overleaf for the 16 OT assessments published to date under JA3 there have been 56 cases of an agency working on the topic but **not** using the EUnetHTA assessment, ranging from 0 examples for OTCA15 (Irreversible electroporation) and OTCA19 (Screening for osteoporosis) to 11 examples for OTCA3 (NIPT).

The data shows little change since the last implementation report. The OT assessments with the lowest numbers of reported non-uses are generally the most recently published assessments and the assessments with the lowest response rate to the implementation survey. The number of reported non-uses for these assessments may increase over-time with a longer follow-up period. As with the last implementation report OTCA03 (NIPT) remains the assessment with the highest number of non-uses.

For the 3 PT assessments published under JA3 there have been 11 cases of an agency working on a topic but not using the EUnetHTA assessment. This shows no change from the last implementation report. As previously documented, in the final WP7 deliverable 7.2 we will explore the impact on implementation of specific changes that EUnetHTA have made to the assessment process.

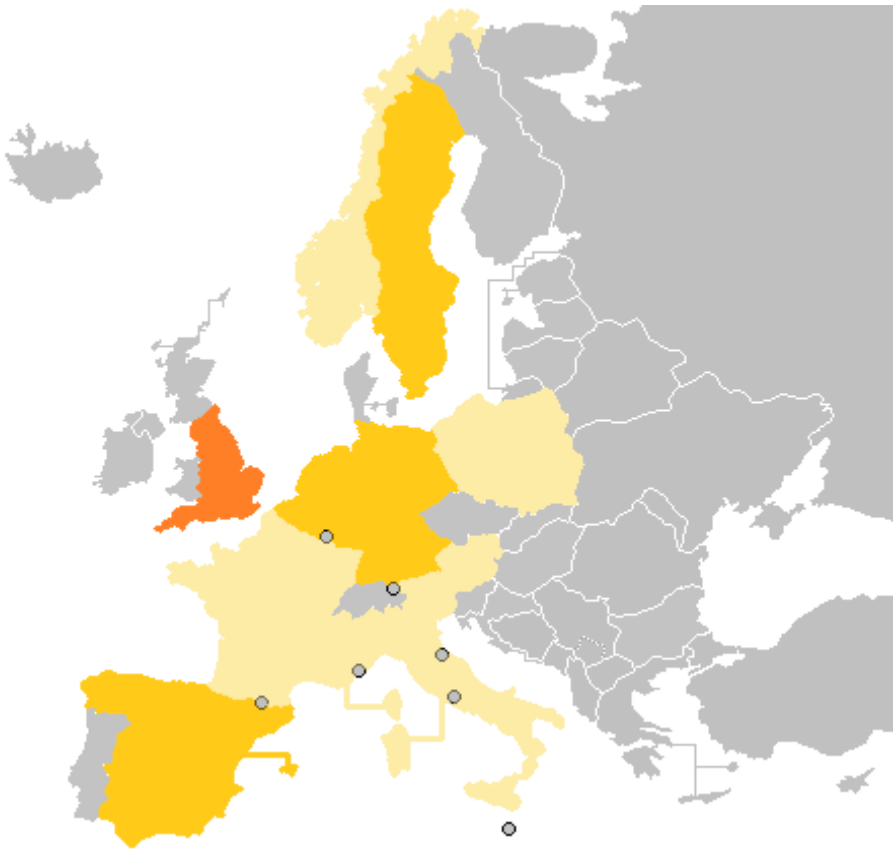
Table 5: Non-use of assessments by agencies working on topic area

	Worked on the topic but did not use the EUnetHTA assessment
OTCA01 (Wearable cardioverter-defibrillator)	4
OTCA02 (Antibacterial-coated Sutures)	2
OTCA03 (NIPT)	11
OTCA04 (MammaPrint)	6
OTCA05 (Magnetic stimulation)	7
OTCA06 (TAVI)	2
OTCA07 (FLACS)	1
OTJA08 (Glucose Monitoring)	8
OTCA09 (HIFU Ablation)	8
OTCA10 (Stool DNA Testing)	1
OTCA11 (3D Implants	1
OTCA12 (CRP POCT)	2
OTCA14 (Robotic Surgery)	1
OTCA15 (Irreversible electroporation)	0
OTCA16 (Stents)	2
OTCA19 (Screening for Osteoporosis)	0
OT Total	**56**
PTJA01 (Midostaurin)	4
PTJA02 (Regorafenib)	2
PTJA03 (Alectinib)	5
PT Total	**11**
Total (PT and OT)	**67**

Figure 13 (PT) and figure 14 (OT) overleaf provide colour coded maps detailing which countries report doing HTA on the topic area but not using the EUnetHTA assessment. The data is presented by the country and the darker shading indicates higher levels of non-use. The analysis of PT assessments is based on data from PTJA01, PTJA02 and PTJA03. Again, the analysis of OT assessments is based on the first 9 OT assessments OTCA01, OTCA02, OTCA03, OTCA04, OTCA05, OTCA06, OTCA07, OTCAO8 and OTCA09. Updated maps for the other OT assessments will be provided once there has been a longer follow-up period. It is underlined that non-use doesn't usually arise because an agency has made a conscious decision not to use a EUnetHTA assessment, in the majority of cases it arises because the EUnetHTA assessment is not available at the time the agency is asked to work on the topic (figure 15).

Figure 13: Number of non-uses of PT assessments – analysis by country

Figure 14: Number of non-uses of OT assessments – analysis by country –



Preventing factors

Agencies who didn't use the EUnetHTA assessment are asked about the factors that prevented them from using the assessment. Users of OT assessments identified 68 examples of factors preventing use of OT assessments, up from 56 in the May 2019 implementation report. As shown in figure 15 below for OT assessments the timing of the availability of the EUnetHTA REA (n = 46) is, as with the last implementation report, still clearly identified as the main factor preventing use of OT assessments. The next factor most frequently identified preventing use of OT assessments is the scope of the assessment being different from the one in the EUnetHTA assessment (n = 7).

Users of PT assessments remain less likely to identify preventing factors (n = 28). For PT assessments the timing of the availability of the EUnetHTA REA is also still identified as the main factor preventing use of PT assessments (n = 5), followed by: the scope of the national assessment being different from the EUnetHTA assessment; the EUnetHTA REA not being of sufficient quality (n = 3); and documents used in the EU REA were not available (n = 3).

Figure 15: Factors that prevented use of assessments

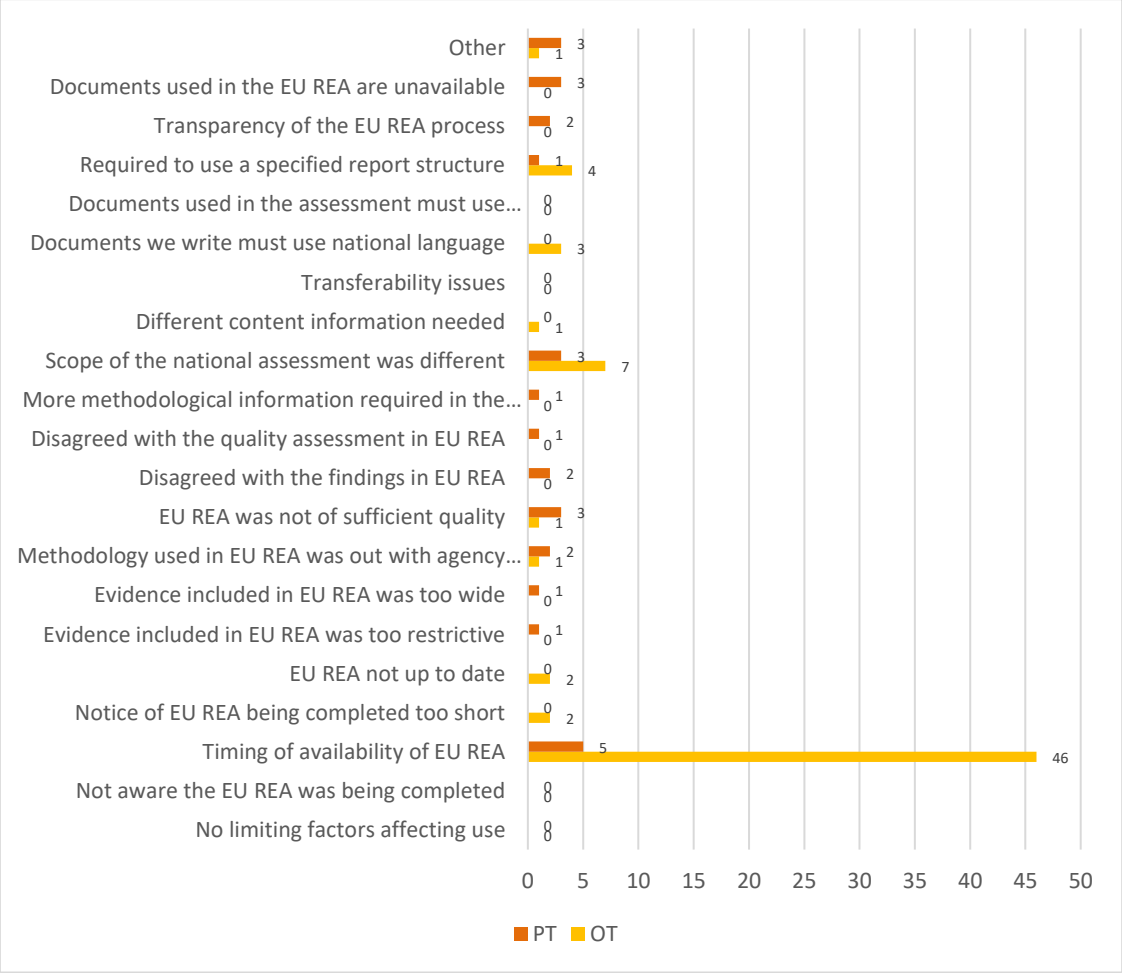


Figure 16 (PT) and figure 17 (OT) overleaf aggregate preventing factors into categories and present them in percentage (%) terms. In this analysis where an agency identified 2 or more factors as limiting use within the same category (e.g. timing or relevance) for the same assessment this was only counted once. Consequently, the numbers in figures 16 and 17 do not exactly match with those in figure 15.

For PT assessments the factors identified as preventing use are varied, with the most commonly identified factor being, as with the last implementation report, timing (28%). This is followed by accountability, reliability and relevance (all with 17%). For OT assessments the main preventing factor use, as with the last implementation report, continues overwhelmingly to be timing (83%).

Figure 16: Factors that prevented use of PT assessments (%)

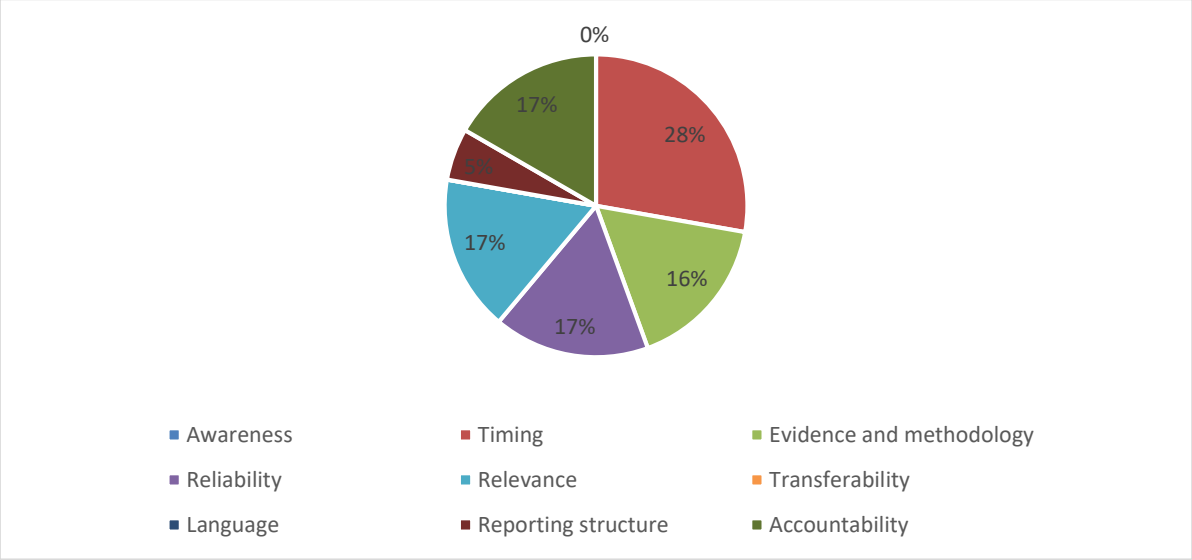
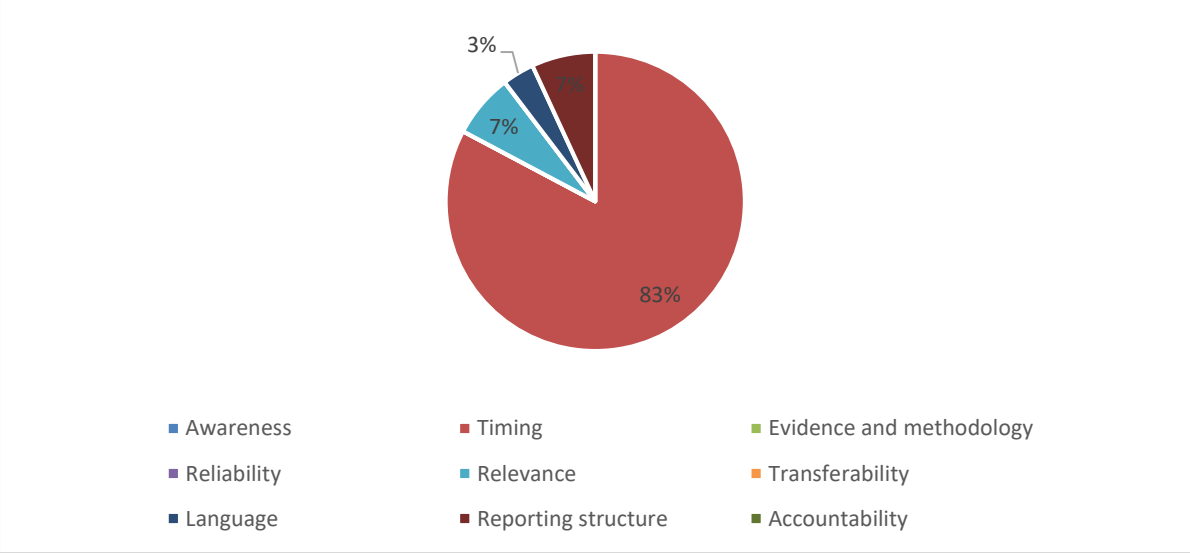


Figure 17: Factors that prevented use of OT assessments (%)



Limiting and preventing factors – analysis by country

The maps in the following pages provide an analysis of the factors reported to limit or prevent use of EUnetHTA assessments – presented by country. The data underpinning this analysis is presented in **appendix 1** (PT assessments) and **appendix 2** (OT assessments).

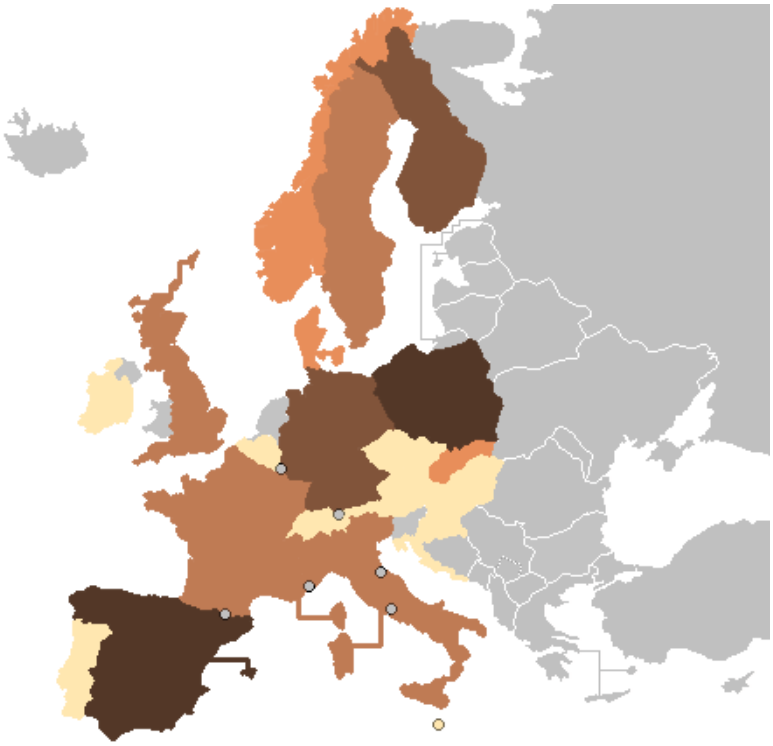
The analysis of PT assessments is presented first and is based on data from PTJA01, PTJA02 and PTJA03. The analysis of OT assessments is then presented, again based on the first set of published OT assessments: OTCA01, OTCA02, OTCA03, OTCA04, OTCA05, OTCA06, OTCA07, OTCAO8 and OTCA09. Maps for all the other published OT assessments will be presented once there has been a longer follow-up period.

In each map the darker the shading indicates that a country reports more limiting and preventing factors.

Factors limiting or preventing use of PT assessments

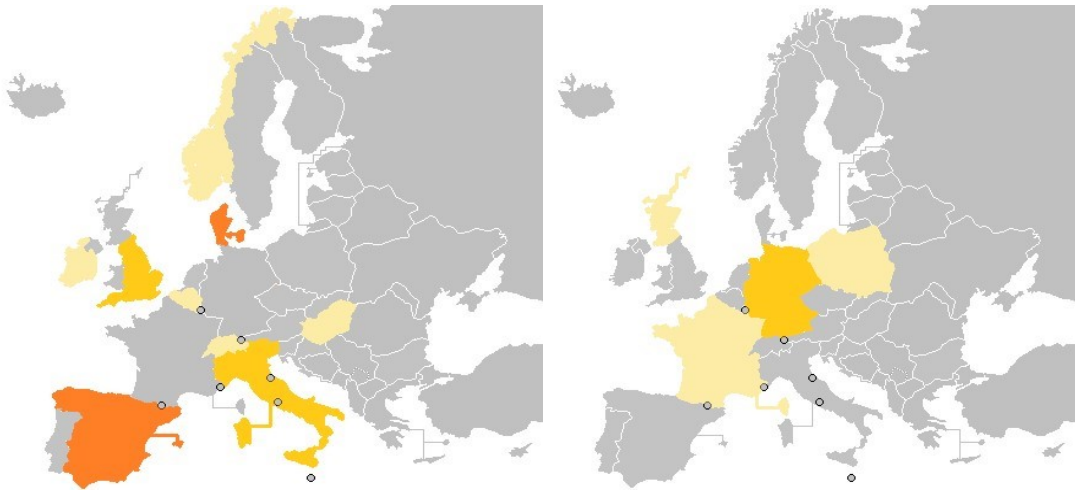
This section of the report presents the analysis of limiting and preventing factors for **PT** assessments. Figure 18 below presents data by country for all limiting and preventing factors reported, figures 19-25 (pages 30-31) break this down by category. Two countries (Austria and Croatia) report use of EUnetHTA assessments and no factors that limit or prevent their use.

Figure 18: Total number of limiting or preventing factors by country – PT

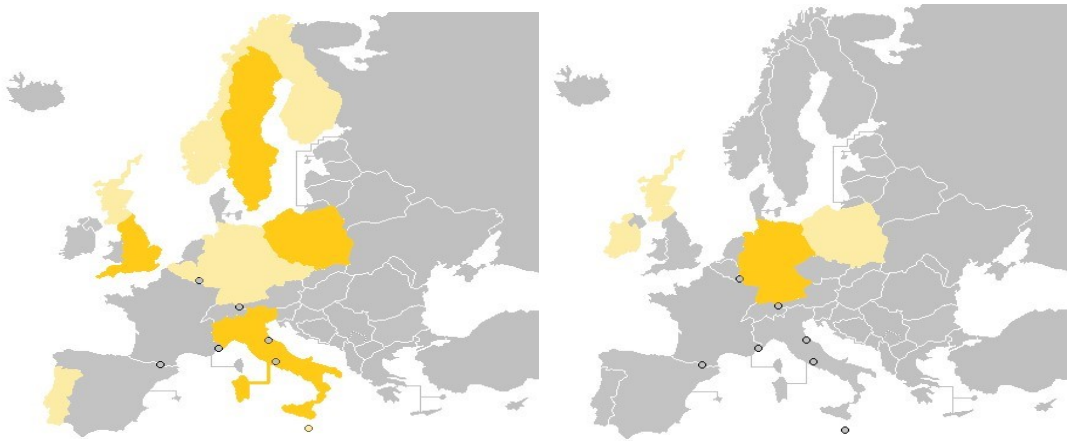


Figures 19-25: Countries reporting each type of limiting / preventing factor (PT)

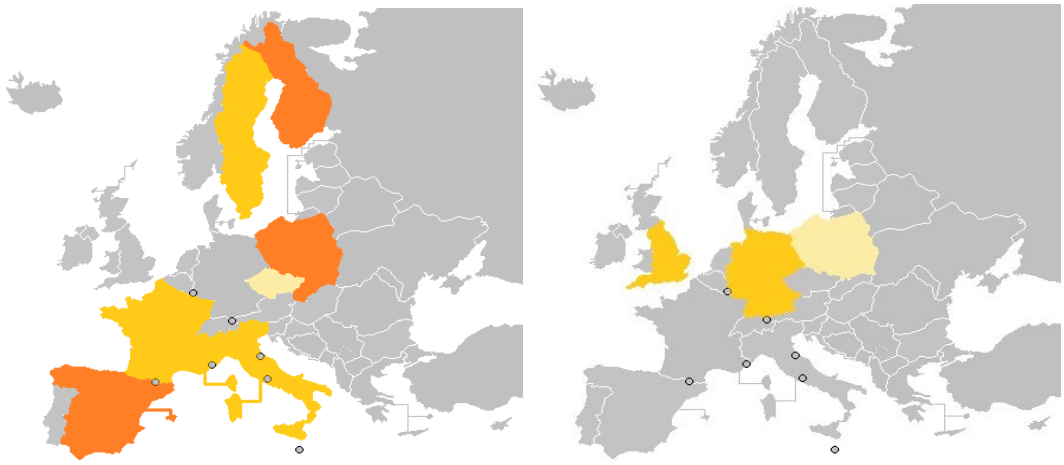
Timing (left) Reliability (right)



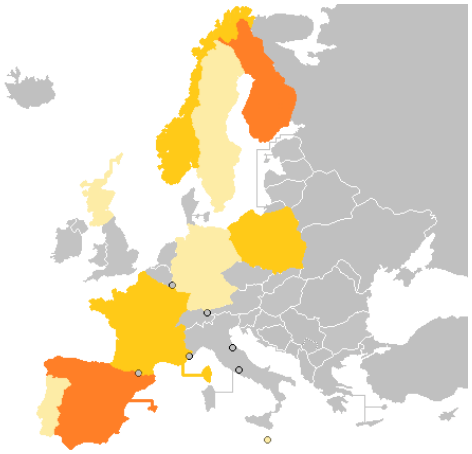
Relevance (left), Evidence and methodology (right)



Language (left), Accountability (right)



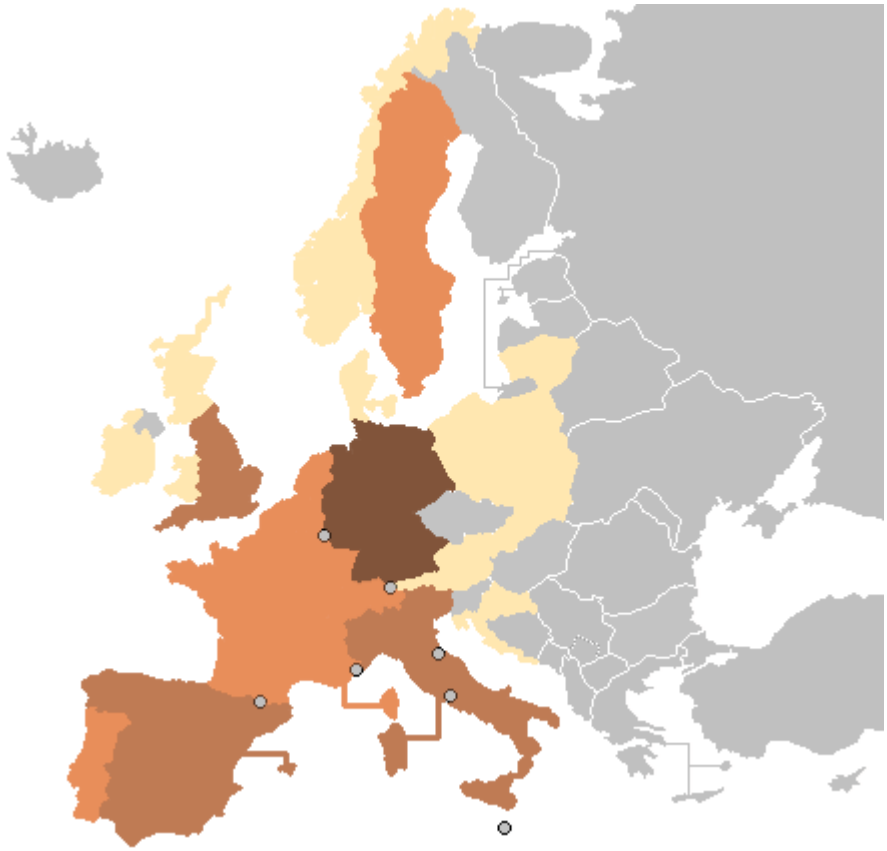
Reporting structure



Factors limiting or preventing use of OT assessments

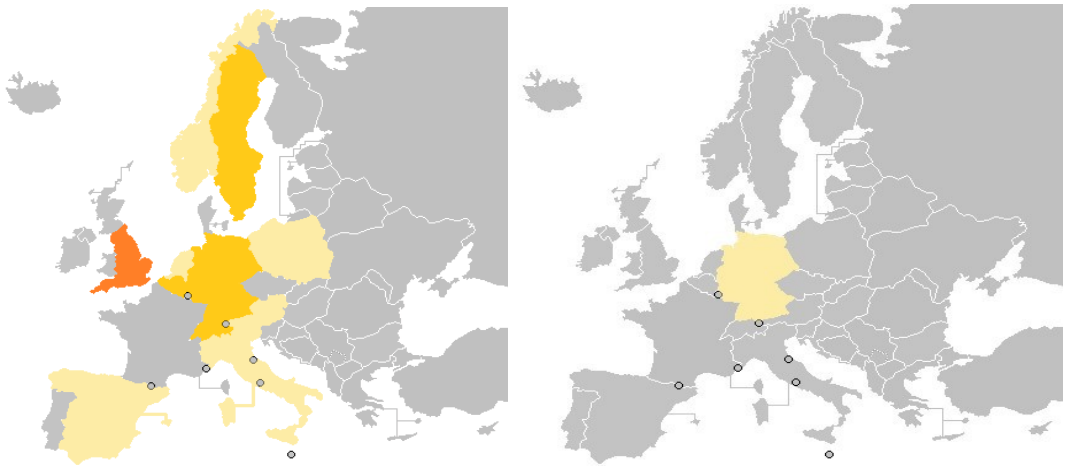
This section of the report presents the analysis of limiting and preventing factors for **OT** assessments. Figure 26 below presents data by country for all limiting and preventing factors reported, figures 27-33 (pages 32-33) break this down by category. Five countries (Lithuania, Denmark, Ireland, Wales and Scotland) report use of EUnetHTA assessments and no factors that limit or prevent use.

Figure 26: Total number of limiting or preventing factors by country – OT

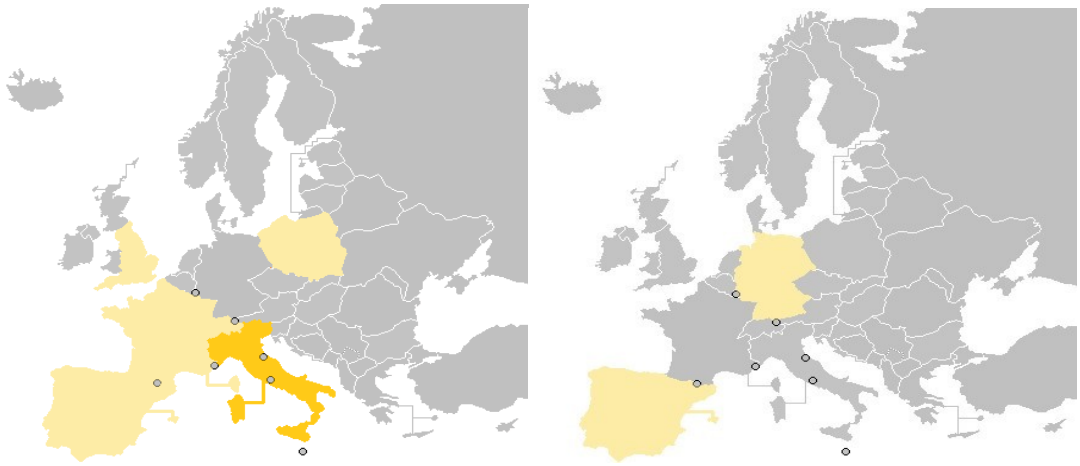


Figures 27-33: Countries reporting each type of limiting / preventing factor (OT)

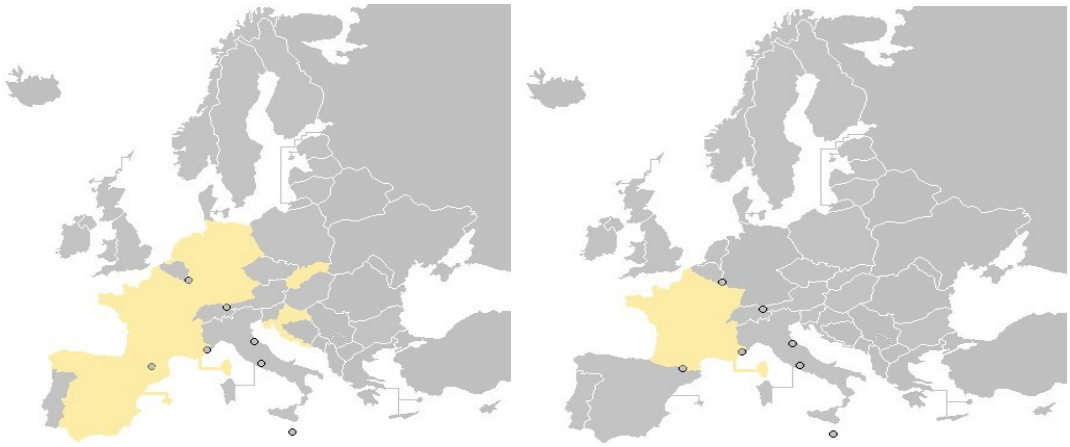
Timing (left), Reliability (right)



Relevance (left), Evidence and methodology (right)



Language (left), Accountability (right)



Reporting structure