

SCOPE Joint Action

Work Package 4

Improving capabilities for ADR reporting

Stakeholder Event
London, 21 September 2015



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WP4: Topics

TOPIC	LEAD
1. Audit of national reporting systems	HR
1a. Medication errors	HR
2. Patient reporting	HR
3. Awareness levels	UK
4. Reporting forms	UK
5. Review of IT systems and special form of reports	HR

WP4.1: Key survey findings

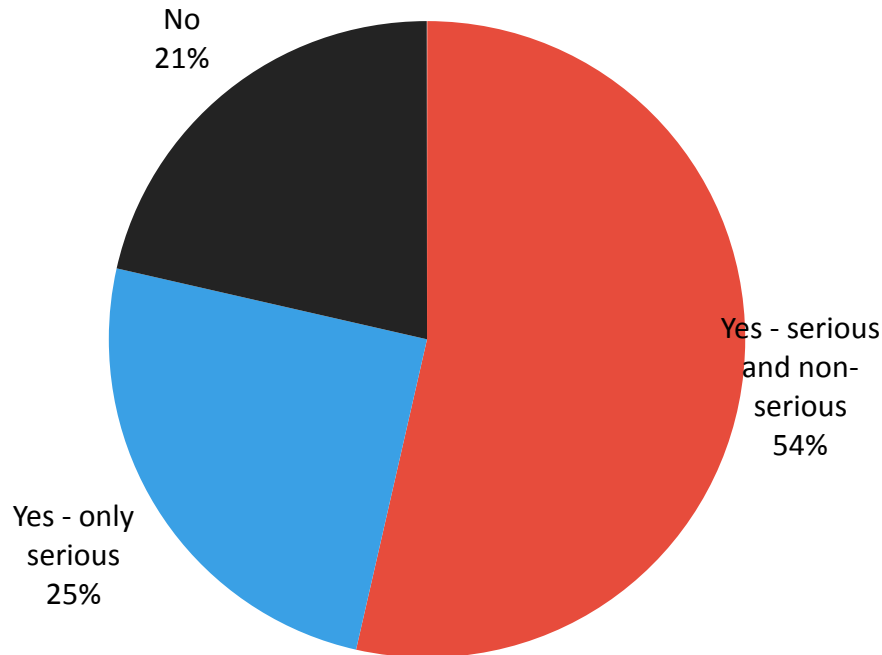


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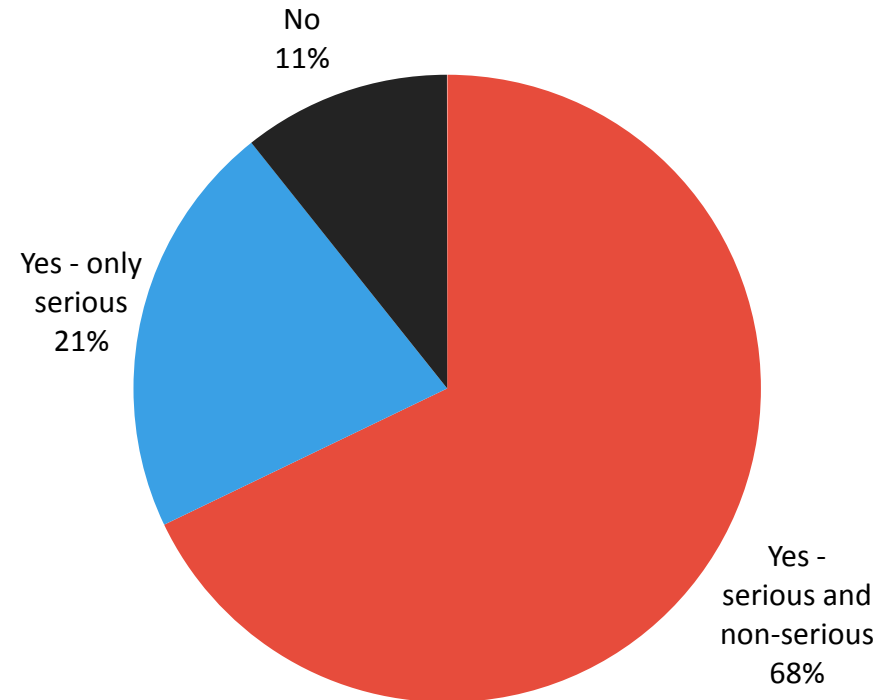
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Is ADR reporting for medicinal products/vaccines for healthcare professionals mandatory in your MS?

Medicinal products



Vaccines



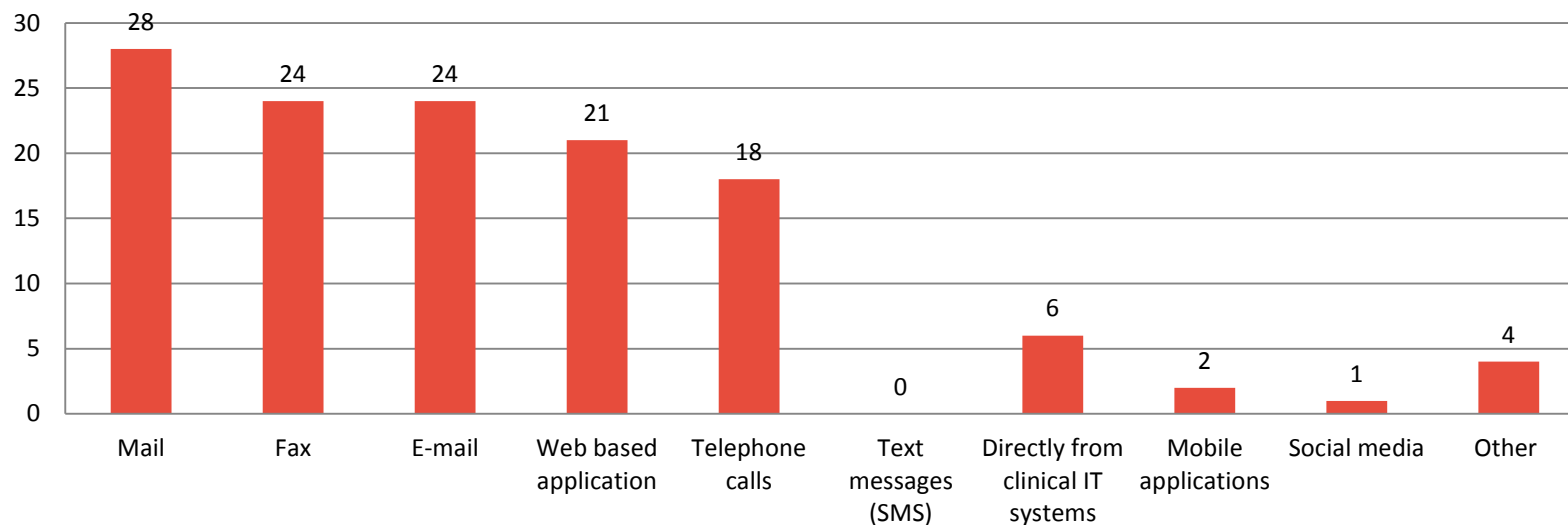
Response rate: 28 MSs

WP4.1: Key survey findings

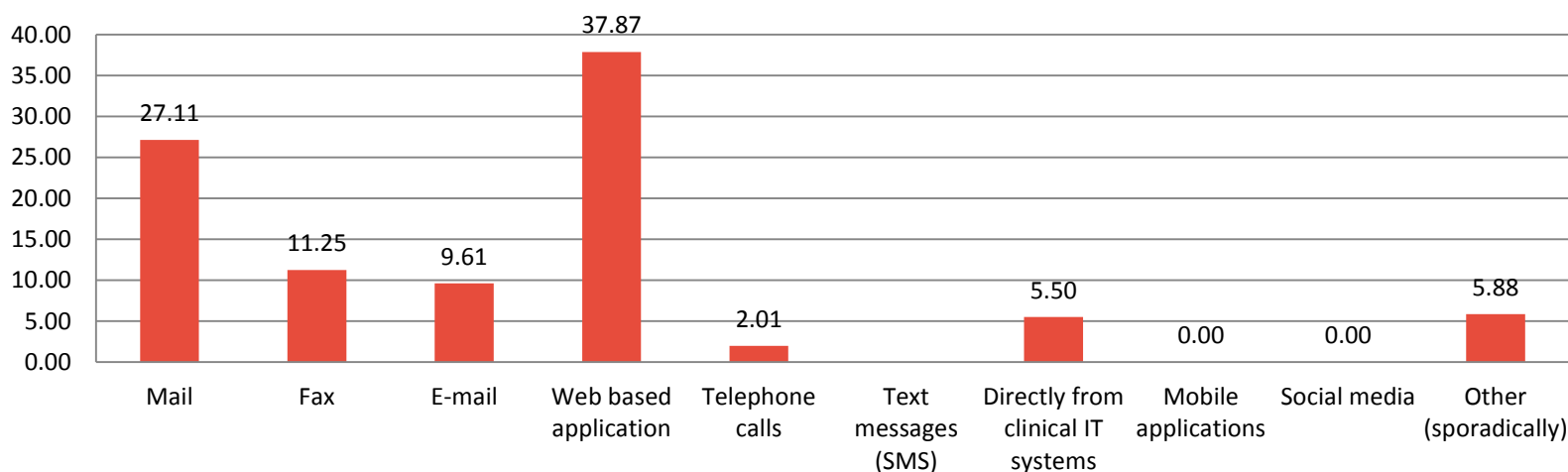


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Available ADR reporting channels www.scopejointaction.eu



Percentage of ADRs received in 2013

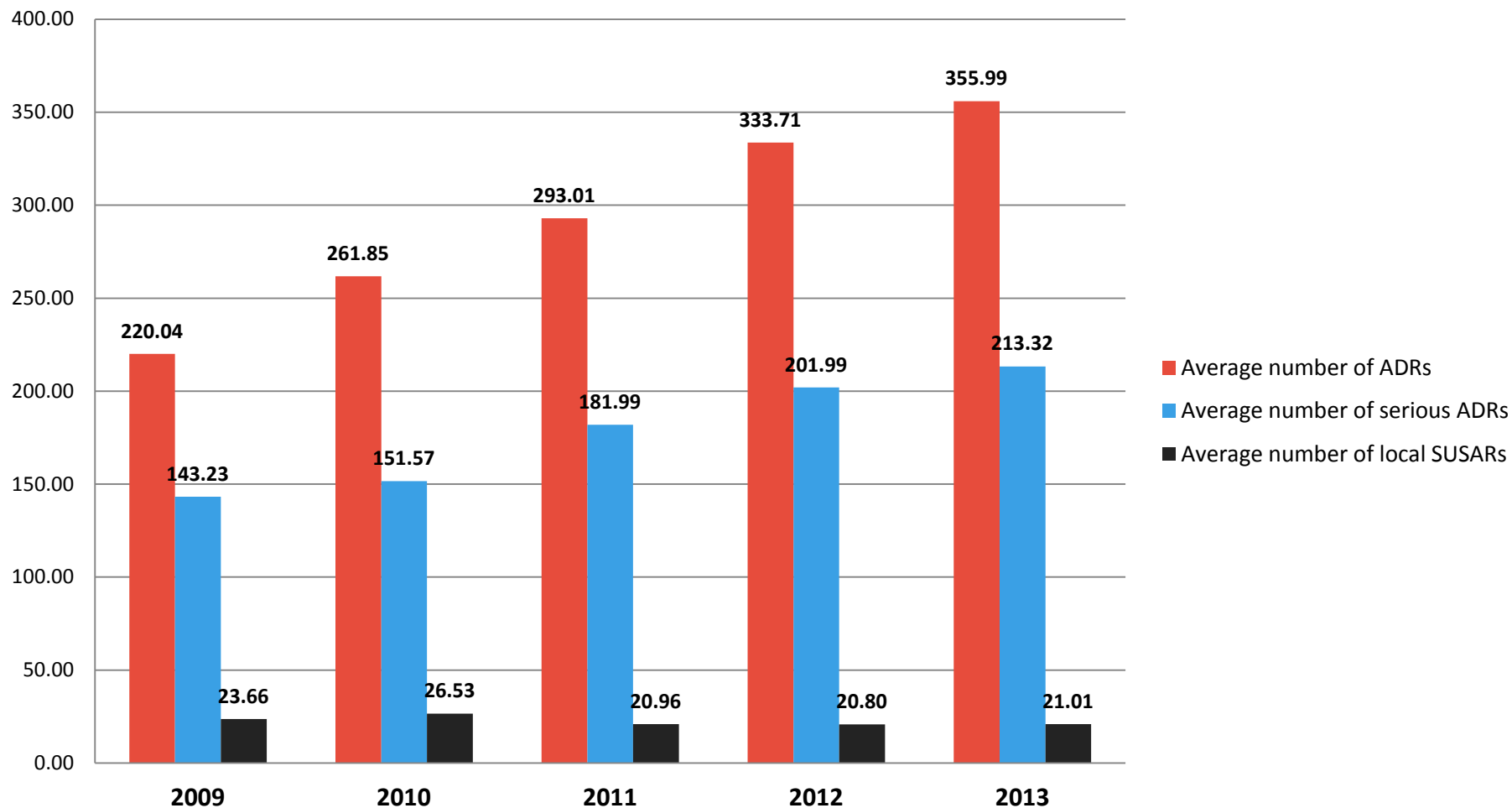


WP4.1: Key survey findings



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Average number of ADRs, serious ADRs and local SUSARs in period 2009 -2013 - on million inhabitants



WP4.1: Key survey findings

How many Full Time Equivalents (FTEs) are dedicated to ADR processing?

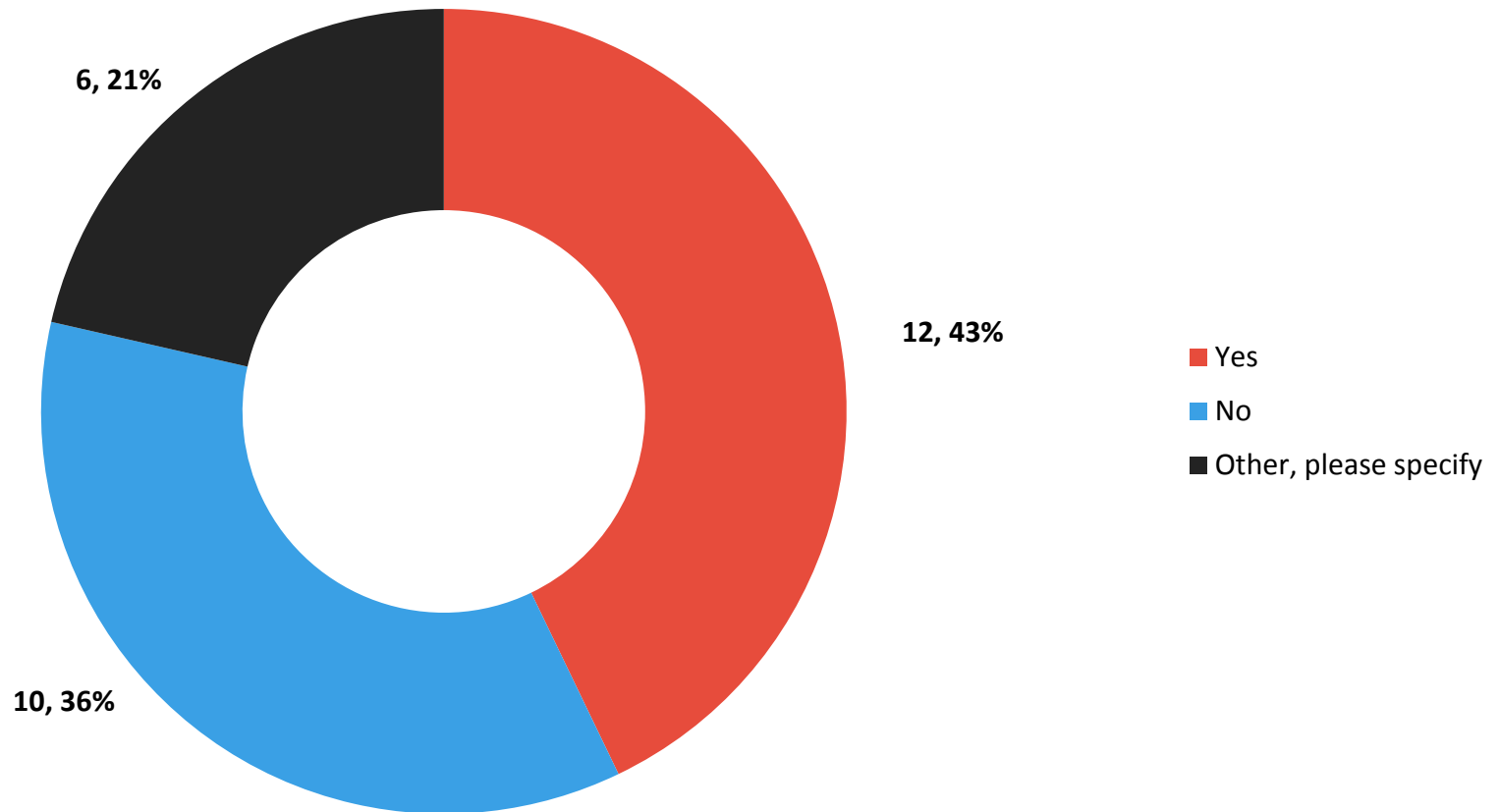
Validation	
	FTEs
Mean	2,9
Median	0,75
Cumulative (all respondents)	31,1

Data entry	
	FTEs
Mean	7,0
Median	2,0
Cumulative (all respondents)	77,4

Assesment	
	FTEs
Mean	9,4
Median	0,3
Cumulative (all respondents)	103,4

WP4.1a: Key survey findings

Are HCPs in your MS exempt from liability when reporting cases of ME?



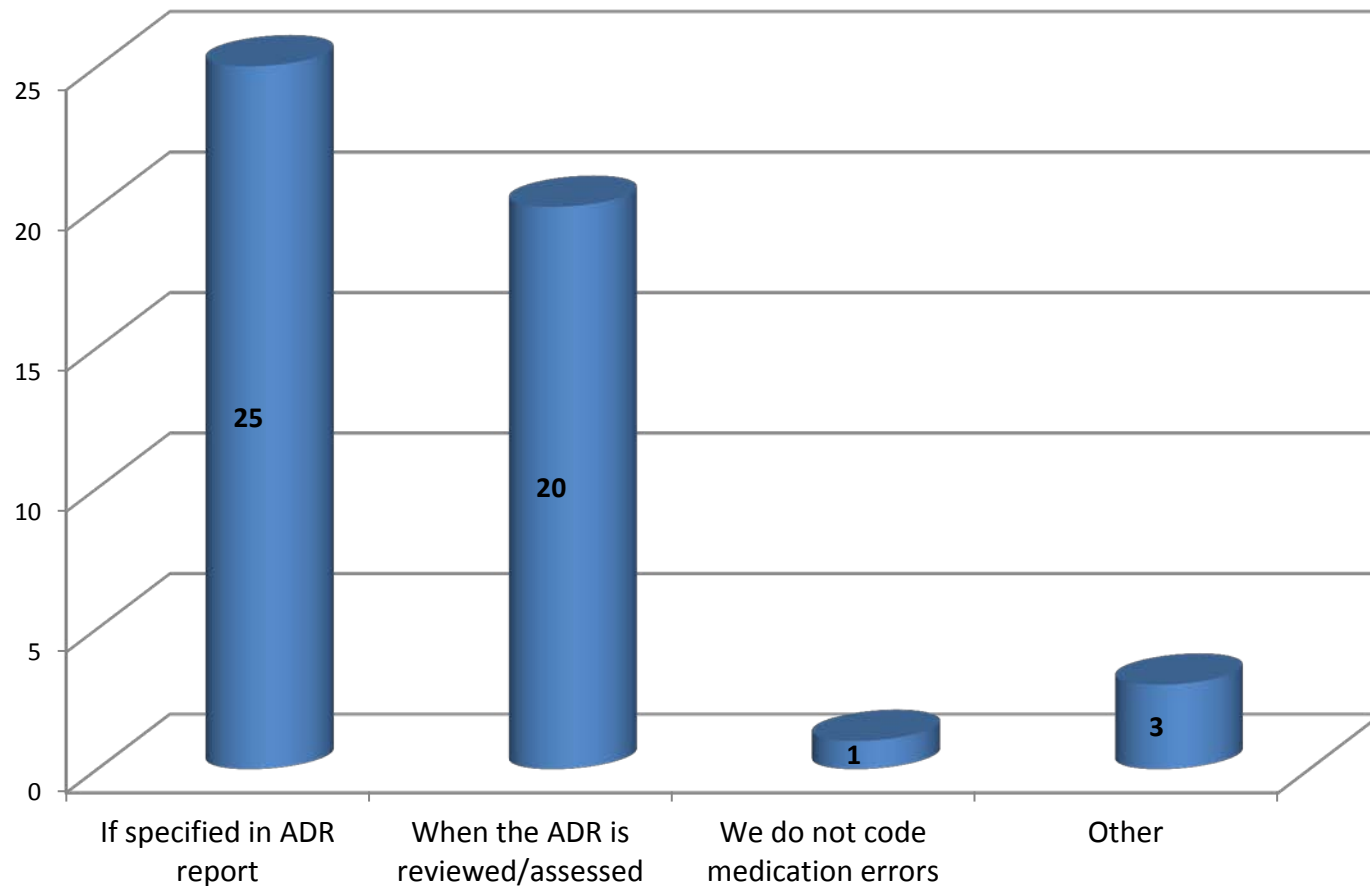
WP4.1a: Key survey findings



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When do you code medication errors?



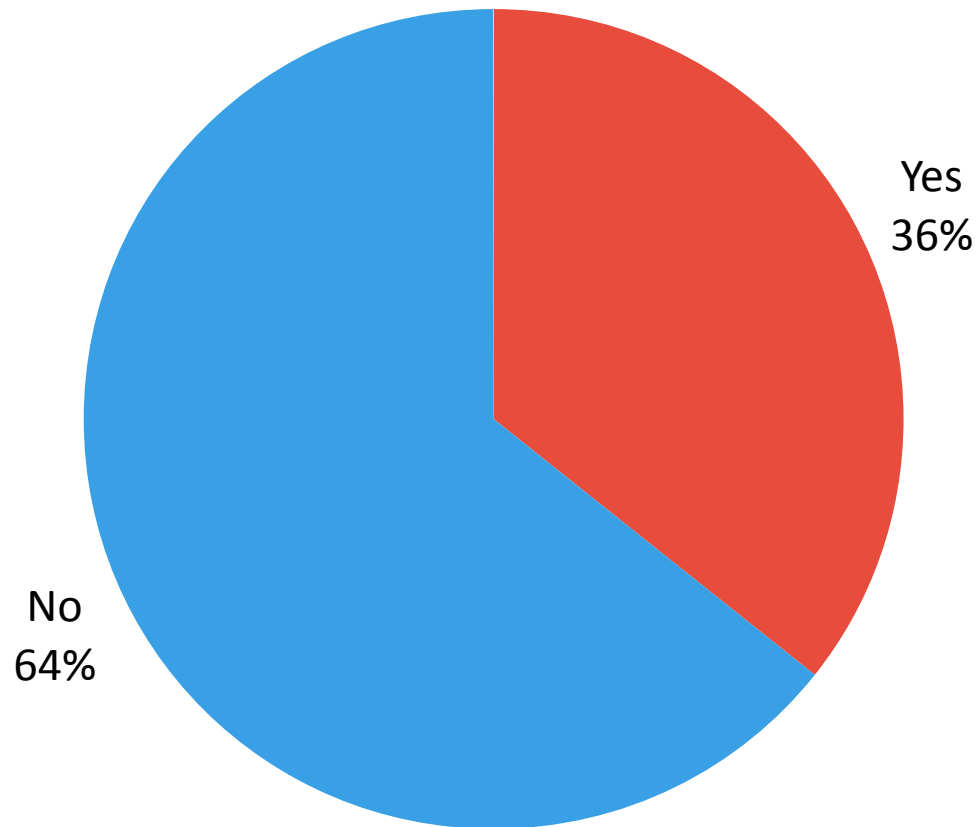
WP4.2: Key survey findings



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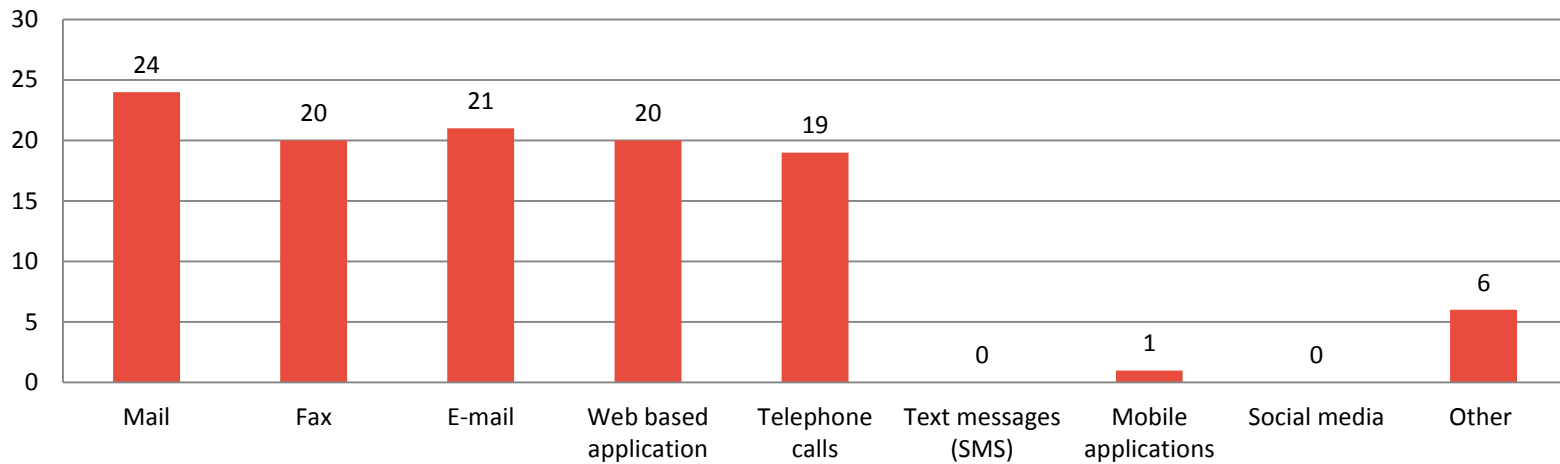
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Were any aspects of patient reporting piloted?

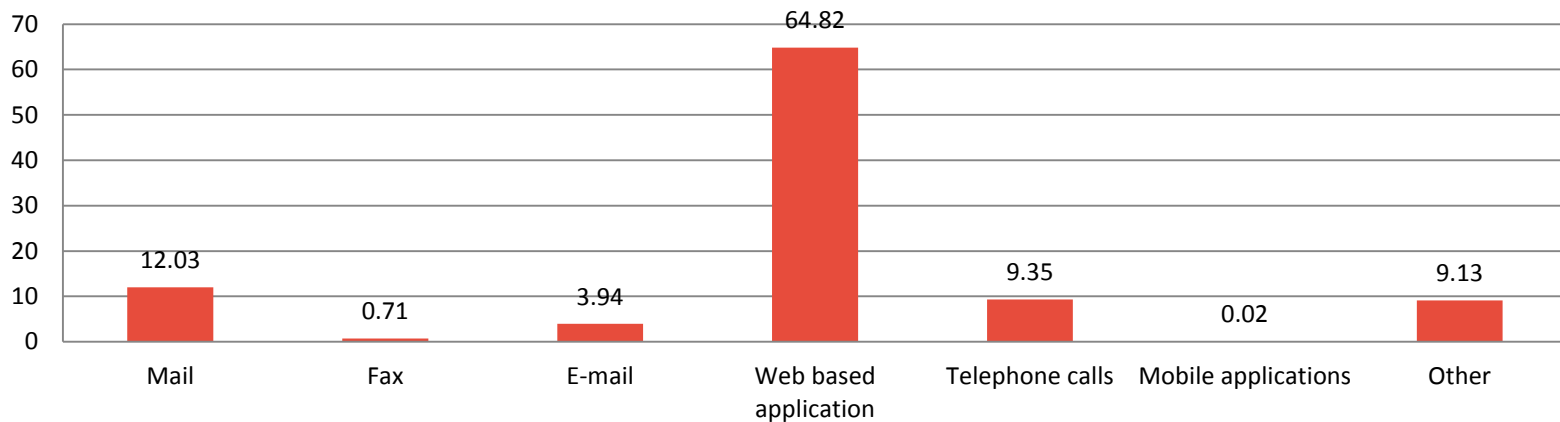


WP4.2: Key survey findings

Available channels for patient ADR reporting

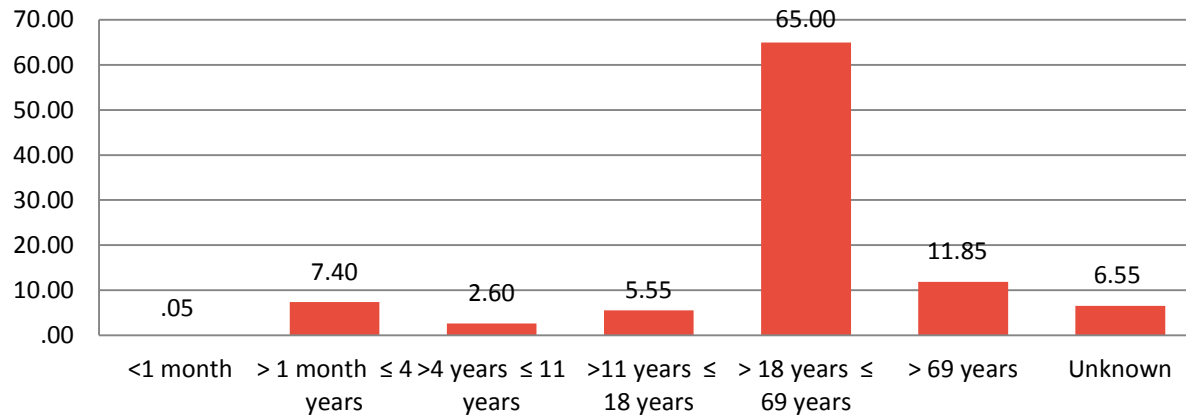


% of patient ADRs received in 2013

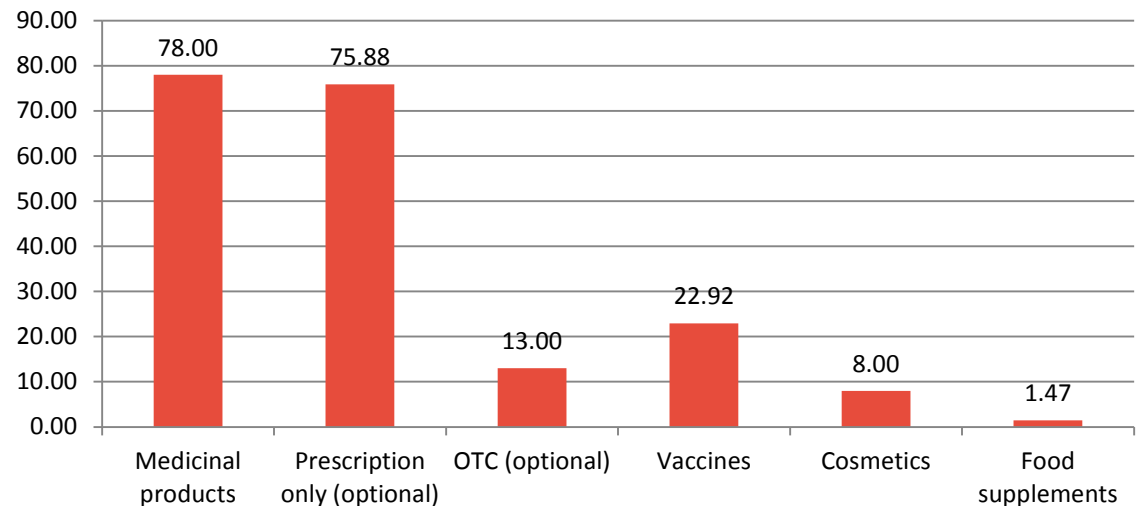


WP4.2: Key survey findings

**% of patient reports in ADR database by age group in 2013
(MEDIAN)**



% of the patients ADR reports in 2013



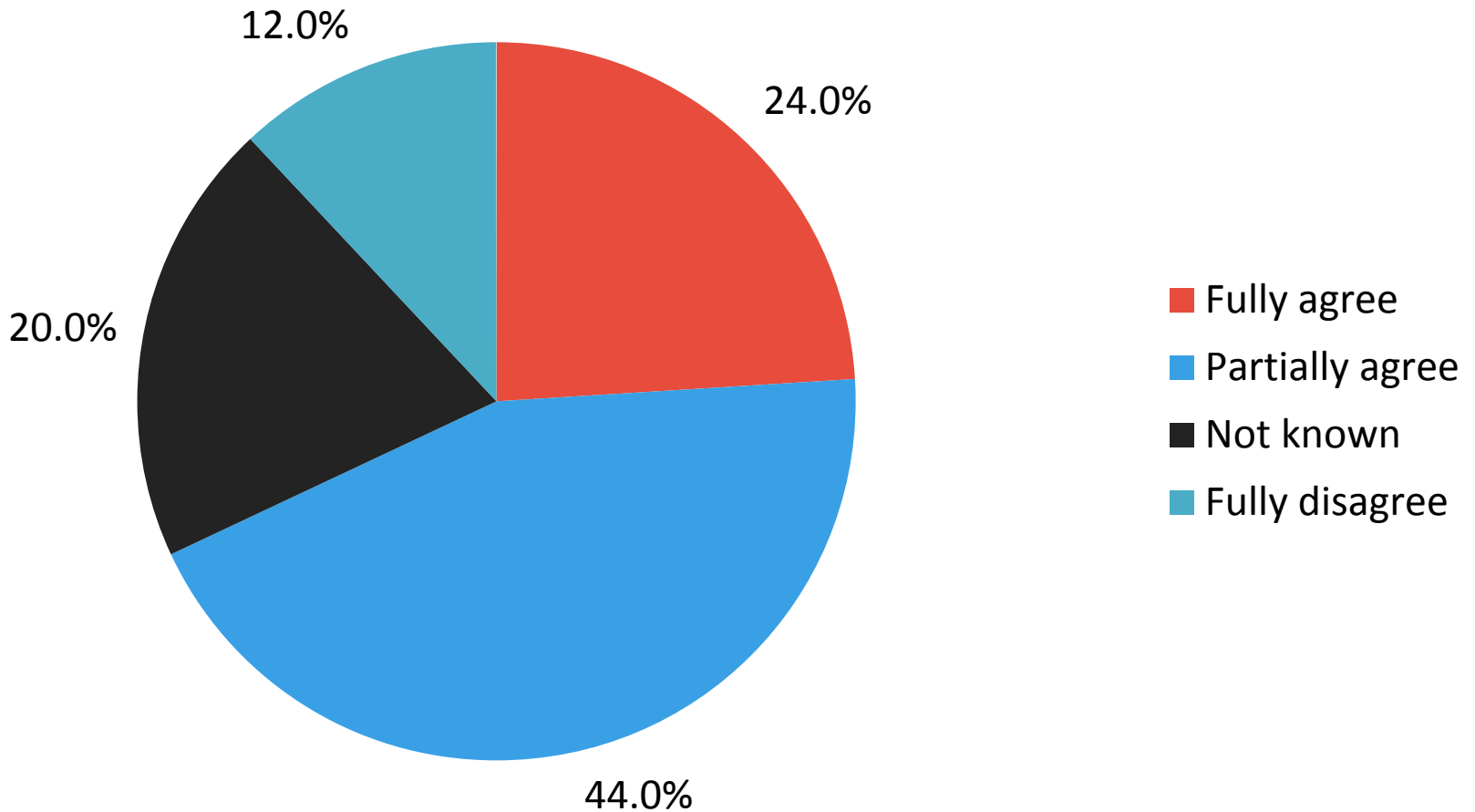
WP4.2: Key survey findings

If patient ADR reports are processed manually in your Institution, what is the most time-consuming part of the process?

	MEAN	MEDIAN
Manual data entry (minutes)	50	33
Manual validation (minutes)	22	25
Assessment (minutes)	72	53

WP4.2: Key survey findings

Patient reporting has made a positive contribution to PHV and patient safety

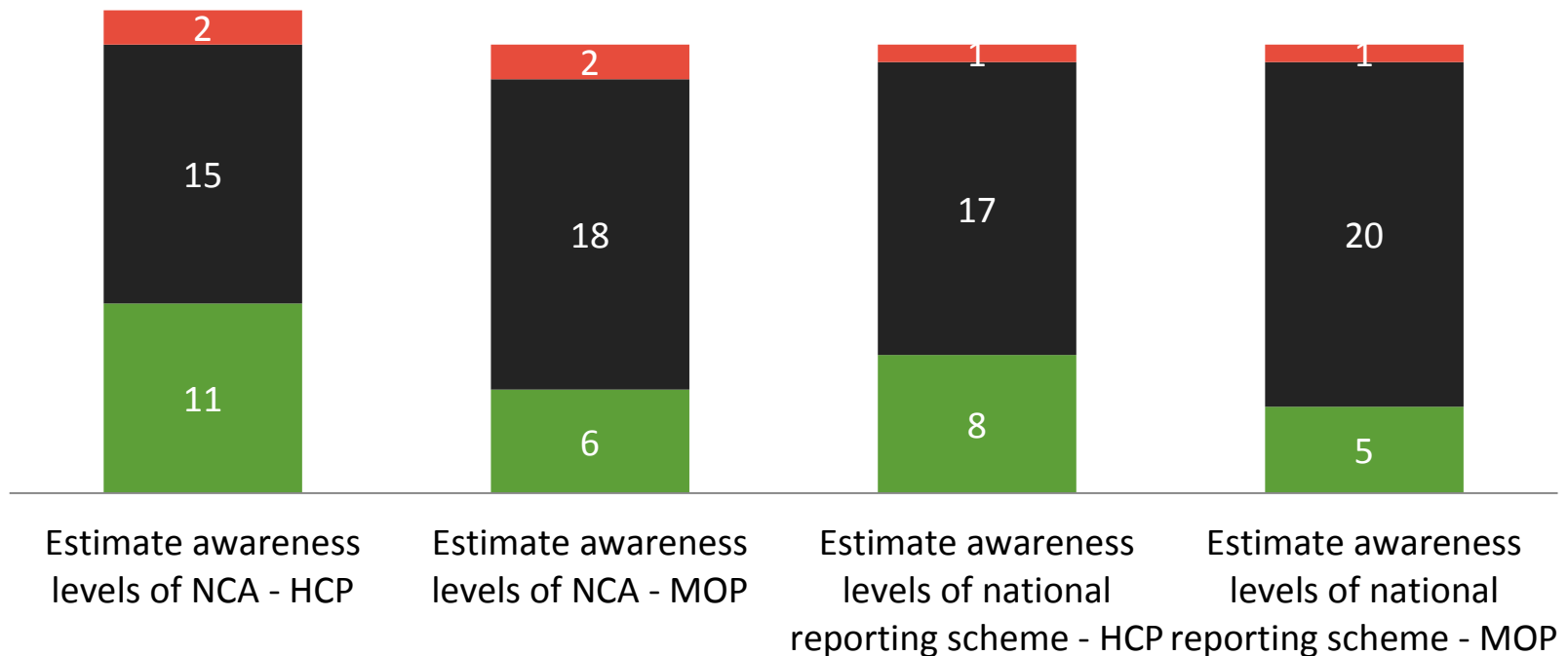


WP4.3: Key survey findings

Baseline awareness results

Responses to whether any formal assessment of awareness levels has been conducted of the NCA and national reporting schemes; with HCP or MOP, via polls or surveys

■ Yes ■ No ■ Our institution is not responsible for this activity



WP4.3: Key survey findings

Strategy

- defined as a plan or systematic approach for raising awareness levels, typically over a long period of time



Summary points

- The largest proportion of MSs (64% , 18) state that they have a strategy in place to raise awareness levels but (32% ,9) do not and 1 is not responsible for this activity

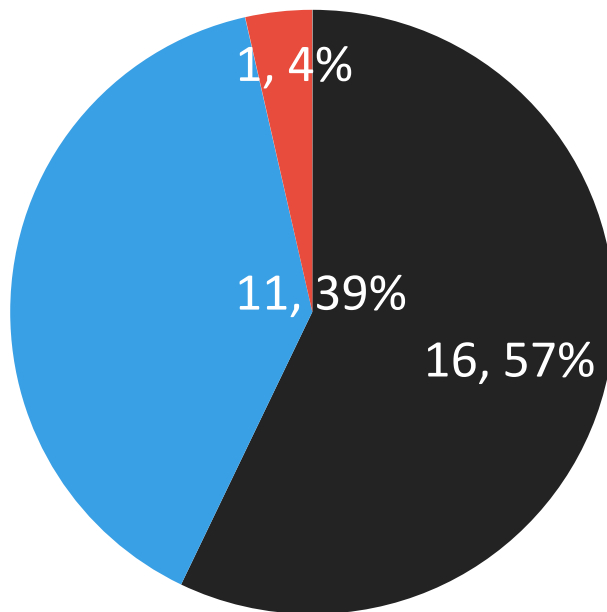
Qualitative analysis:

- From the qualitative analysis of free text comments, 12 MSs might be considered to have elements of a formal strategy, with 5 having a documented strategy;
- The large majority of respondents have only a limited strategy of one which is not mature or long term and are usually not document or publicised
- Education through publication and lectures are common themes

Education of HCPs

- Case studies showing example outcomes of regulatory action and communicated signals are used equally to show the importance of ADR reporting
- 57% of MS (16) have developed or contributed to learning packages about ADR reporting

Have you developed or contributed to any learning packages?



■ Yes

■ No

■ Our institution is not responsible for this activity

Regional Centres

Summary

- Seven MSs have regional centres, of which 6 collect ADR reports
- All regional centres have the role of raising awareness levels
- Only the regional centres of one MS engage with MOP stakeholders
- The most common ways of measuring the effectiveness are through the monitoring of predefined objectives, contracts, Key Performance Indicators (KPIs), annual reports, and trends in ADR reporting

WP4.4: Key findings (1)

- **Availability/Accessibility of forms**
 - Paper forms – 27
 - Electronic forms – 23
 - Most respondents have general paper and electronic forms and fewer have reporter specific form
- **Form layout/format/accessibility**- very various answers
- **Guidance**
 - 23/26 for paper forms
 - 21/23 for electronic forms
 - Guidance provided as explanatory text, via NCA website and as additional booklets
- **Background/Supplementary information**
 - 15/26 with paper forms
 - 22/23 for electronic forms
 - Need for information in national and multiple languages

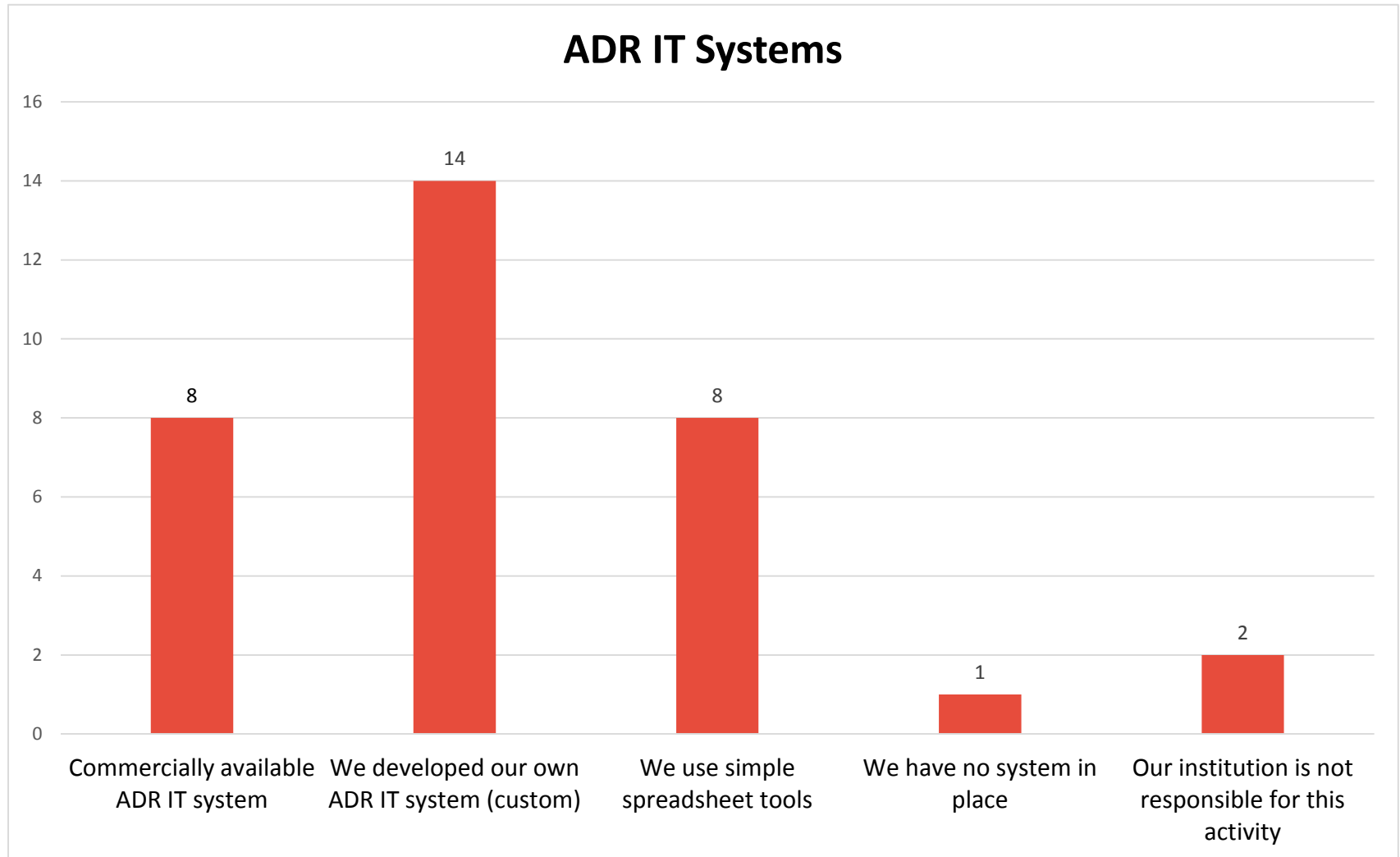
WP4.4: Key findings (2)

- Studies, user testing, pilots
 - <50% have carried out studies prior to development of paper and electronic forms
 - More detail on development of forms for specific reporter groups
 - No consistency in target reporters
 - Varied results for periods of times for which testing and pilots are carried out

WP4.4: Key findings (3)

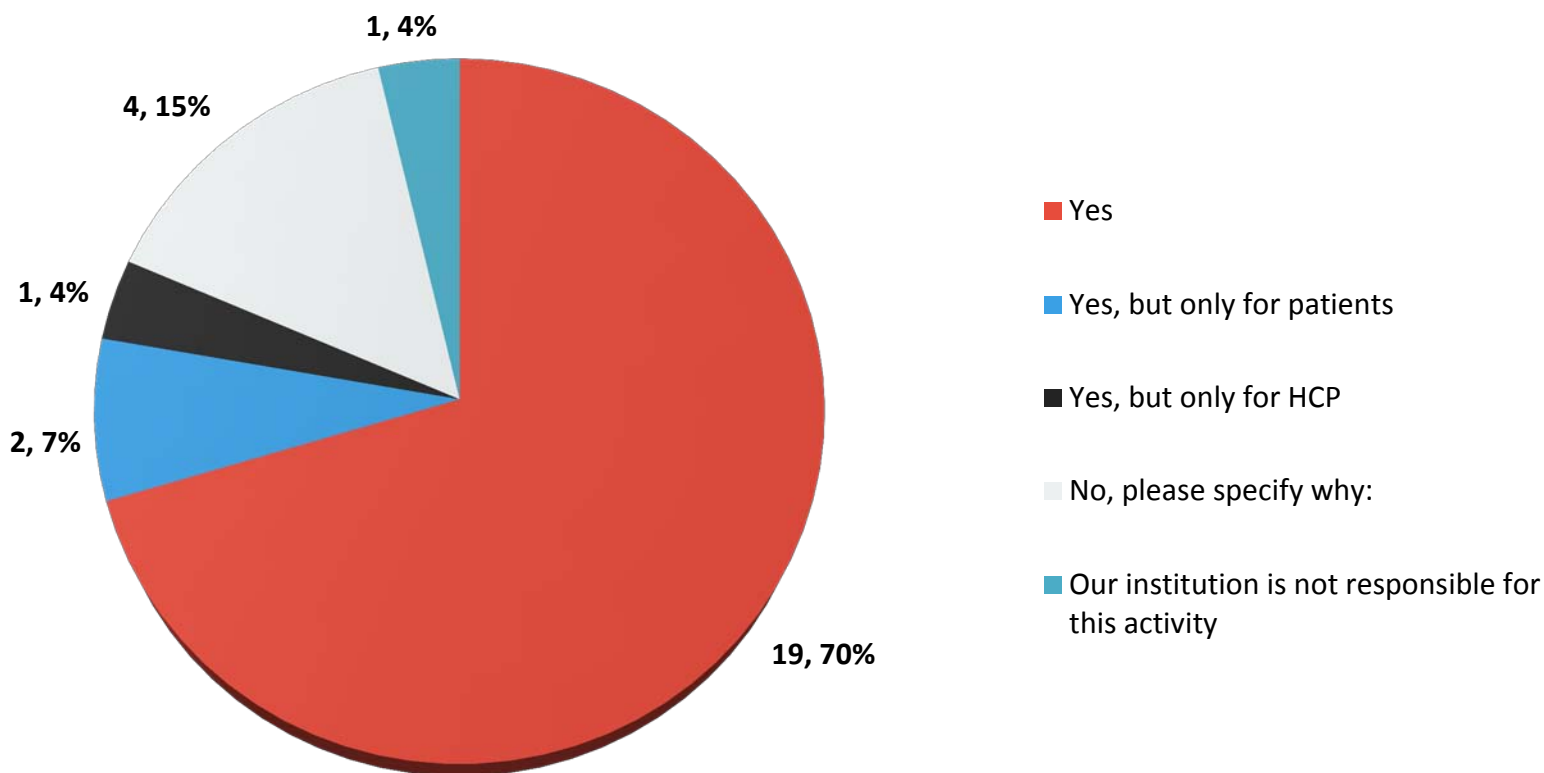
- Only 12% and 23% of respondents stated that they seek permission to contact the reporter for further information for electronic HCP and patient **electronic** forms respectively whilst only 4% and 12% seek permission for electronic HCP and patient **paper** forms
- Almost all respondents stated that their paper forms (23/25) and electronic forms (20/22) are updated as necessary
- 22/25 (88%) MSs are planning to maintain their paper forms indefinitely

WP4.5: Key survey findings



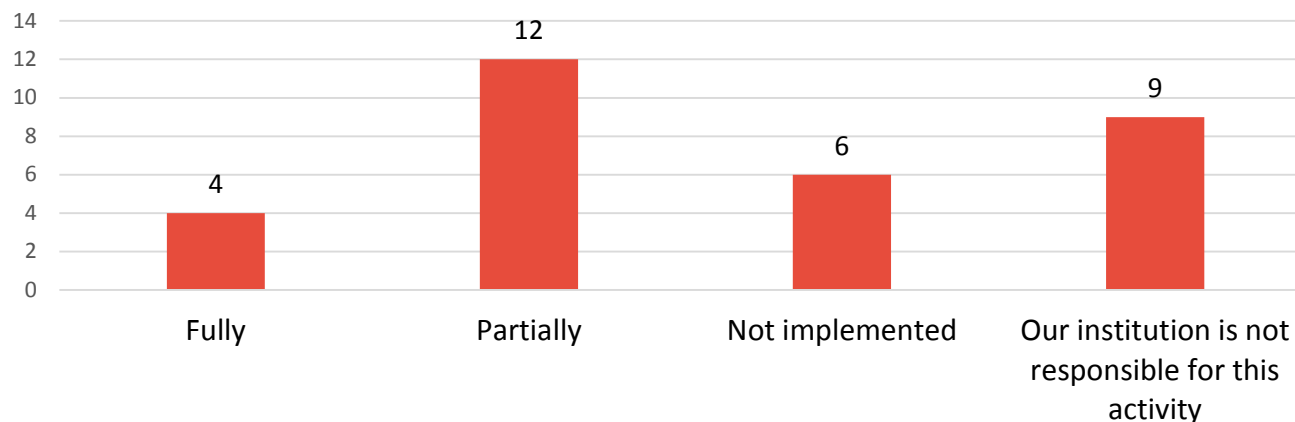
WP4.5: Key survey findings

Is ADR e-reporting implemented in your MS?

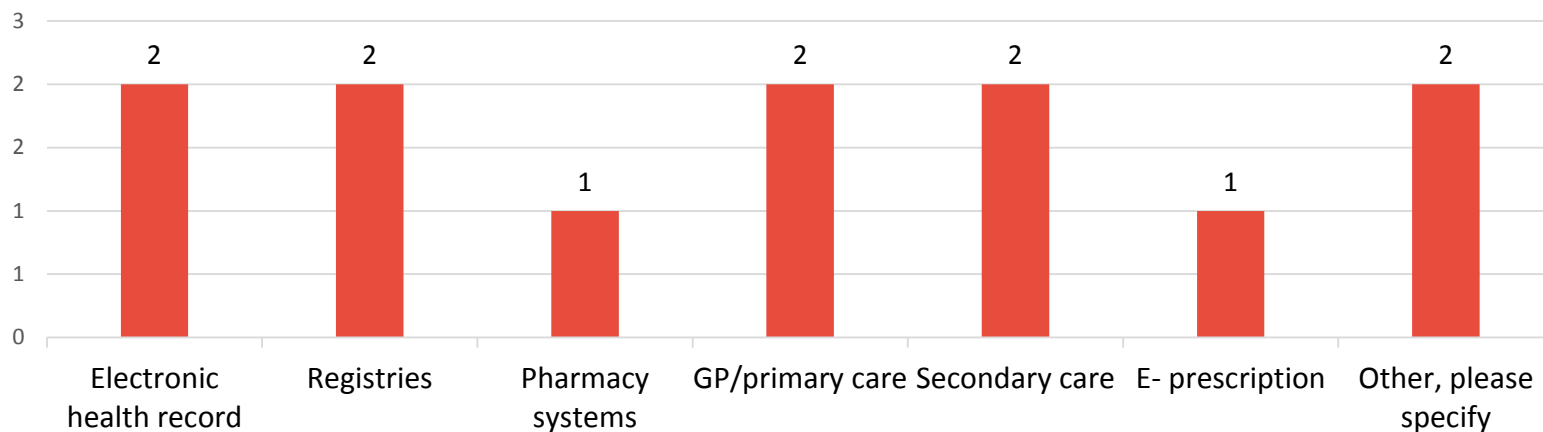


WP4.5: Key survey findings

Electronic health record systems implementation stage



Receiving ADR reports from any system containing patient records or medical data



WP4.1: Recommendations

- **Transition to E2B-R3**
- **Providing ADR data to the public**
- **Duplicate detection**
- **Additional monitoring**
- **Traceability of biologics**
- **Benchmarking tools**

WP4.1a: Recommendations



- **Exemption from liability for HCPs when reporting cases of ME**
- **Coding of medication errors**
- **Collaboration with other institutions**

WP4.2: Recommendations

- **Collaboration with patient organizations to promote and support patient ADR reporting**
- **Feedback to patients**
- **Active approach to comparison of ADR reports from different reporter groups**

WP4.3: Recommendations

- **Baseline awareness**
- **Strategy**
- **Education of HCPs**
- **“Digital” strategy/plans**
- **Development of media materials for raising awareness**
- **Regional Centres**
- **Training and WG**

WP4.4: Recommendations

- **Design a paper reporting form that can be used by NCAs**
- **Design an electronic reporting form that can be used by NCAs**
- **Standard set of guidance to be supplied with reporting forms**
- **Background/supplementary information and user testing/studies**
- **Design of a phone reporting toolkit**

WP4.5: Recommendations



WP4: Deliverables



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- National Reporting systems – T1
- Medication errors – T1a
- Patient reporting - T2,3,4
- Awareness levels – T3
- Reporting Forms – T4
- IT systems T5

Deliverable 1
Overarching
guidance
document on
ADR reporting
systems

- All WP4 topics except WP4.5

Deliverable 2
Publication
articles i.e. in
scientific
journals

- Workshops for best practice – all topics
- Strategies – overall and digital plans – T3
- Materials for raising awareness e.g. video and campaign collateral for national adaptation - T3
- Educational materials including e-learning package - 3
- Reporting forms - T4
- Telephone handling – T4
- E-Reporting transmission & comms – T5

Deliverable 4
Training and
awareness
raising
materials

Deliverable 3
Specification to
EMA re MS
requirements
for transition to
E2B-R3

- Position paper – T1

WP4: Planned work

- Publishing WP4 reports in January 2016
- Drafting guidance documents and articles for publication in scientific journals
- Development of training materials
- Drafting position paper for EMA