Table 3 **Comments received from respondents in the pilot evaluation and action taken during the pilot phase of developing the new national adverse drug reaction (ADR)/medication error reporting form for Malta**

Respondent #	Respondent's comment	Action taken to address comment	Time (min)*
1	Include an introduction to clarify which sections need to be filled in	Introduced statement to bring to the attention of reporter which sections must be filled in. "Before you start reporting please check which sections should be filled in". Introduced a decision tree under this statement on the right-hand side of the form, before section 1 so that reporters can quickly identify which sections need to be filled in. On the left-hand side, the decision tree is explained in text	12
	For section 1.7 include option to be filled in for more than 1 drug	Section 1.7 was modified to include the option of answering yes or no for more than one medication in relation to the questions on whether the medicine was discontinued and on whether the patient was rechallenged with the medicine	
2	Section 3 was going to be left out because it was not clear that it had to be filled in	Addressed by actions from comment of respondent 1 above	5
	At the end of section 1 there should be a statement saying to proceed to section 3 if section 2 is not relevant	This issue was addressed by putting in a tick box yes/no question (question 1.9) which asks whether the side-effect was caused by a medication error or not. Depending on the answer the reporter is then directed to section 2 or 3	
3	Include fatal/deceased in section 1.6 as a possible outcome for each ADR	This was adopted in section 1.6	10
4	Do not use technical terms in the form	This was addressed by simplifying terms as much as possible, e.g. ADR (side-effect); ethnicity (race); medicinal product (medicine); INN (active ingredient); congenital anomaly (birth defect); dechallenge (was medicine stopped?); rechallenge (was medicine restarted?)	10
5	It should be clearer which sections need to be filled in	Already addressed elsewhere	20
	The form should look less complicated. The layout should be more pleasing to the eye and easier to follow	Sections 1.5, 1.6 and 1.7 were changed into tick-box format.	
	The name of the form should be more understandable	Substituted adverse drug reaction with side-effect in the title	
6	It would be useful to elaborate on the definition of adverse drug reaction in the instruction form and to give examples	Made two definitions for ADRs and for medication error; one addressed to patients, and one for health-care professionals. Then in section 1.3 of instructions examples of ADRs were added to the instruction sheet	45
	Explain in more detail how to complete the form	Already addressed elsewhere	
7	Instructions are too long to read	Instructions were shortened	10
8	Instructions should be at the front not at the back	This comment will be considered during the design phases of both electronic and paper forms	10
9	No comment	n/a	12
10	Suggested that there should be a section specifically for over-the-counter products	Layout restrictions mean that it is not possible to add a section specifically for over-the-counter medicines	8
11	Section 1.4 contains too little space to fill in day month and year	The row height was adjusted to address this	20

Table 3 **Comments received from respondents in the pilot evaluation and action taken during the pilot phase of developing the new national adverse drug reaction (ADR)/medication error reporting form for Malta (*concluded*)**

Respondent #	Respondent's comment	Action taken to address comment	Time (min)*
12	Format of sections 1.5 to 1.7 is somewhat confusing	Addressed by changing format from table to check-boxes and arranging the sequence to be more logical	20
	The instructions should not be at the back	This will be considered at a later stage	
	It will be difficult for patients to answer section 1.5 on severity	This was addressed by simplifying terms in this section	
	Instructions should be divided into two parts, one part for ADR form and one part for medication error form, and placed in front of each section respectively	This is difficult considering the cost implications, but may be considered at the design stage	
13	No comment	n/a	15
14	No comment	n/a	10
15	Boxes should be included for areas/ sections which are not applicable	Addressed by rearranging structure	15
16	No comment	n/a	20
17	Layout numbering is confusing, especially sections 1.5 to 1.7	Already addressed	15
	Terms should be simplified	Already addressed	
	Instructions should be above the boxes being filled in	Already addressed	
	Using letters, a,b,c would be better than numbers since there is a question that is numbered as 1.10 which is confusing when there is a question numbered 1.0	Problem no longer exists since some questions were grouped together and section 1.10 was removed	
	Lay people will not report if they do not know why they are reporting	This text was introduced to address this: "The reporting of side effects is an important process whereby Regulatory Authorities can learn more about the medicine and its uses and take appropriate action in order to protect and enhance public health." A phrase thanking reporters was also introduced "The Medicines Authority thanks you for the time taken to fill in this form."	

**Time needed to complete the form.*