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Creators	Sinopoulou, Vassiliki, Gordon, Morris and Rutter, Paul

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## Manuscript Details

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<b>Title</b>	A systematic review of community pharmacies' staff diagnostic assessment and performance in patient consultations
<b>Article type</b>	Review Article

### Abstract

Background: Increases in patients seeking advice at pharmacies has led to pharmacy staff engaging in diagnostic behaviours. Approaches to diagnosis include using mnemonics and clinical reasoning. Objectives: The primary aim of this review was to assess the degree to which the criteria authors use to evaluate diagnostic performance in pharmacy consultations, in studies that use simulated patients or vignettes, conform with a clinical reasoning and a mnemonic framework. A secondary aim of the review was to characterise staff performance in the studies, based on the authors' comments of their results. Methods: MEDLINE, EMBASE and Web of Science were searched between October 2016 and April 2017. Only peer-reviewed studies assessing pharmacy staff's diagnostic performance by using simulated patients or vignettes were eligible for inclusion. Data were extracted about how each study's criteria conformed with clinical reasoning and mnemonic frameworks. A scoring system between 0 and 4 was devised to determine the degree to which studies aligned to these two approaches. Risk of bias was assessed using the NHI Study Quality Assessment Tools. The review was registered in PROSPERO with identification number CRD42017054827. Results: Sixty-eight studies (55 cross-sectional, 11 educational interventions and 2 RCTs) with sample sizes between 10 and 2700 were included in the review. Most studies were of poor or fair quality. Performance of pharmacy staff was overwhelmingly reported as poor by study authors. This was the case regardless of geography, scenario used or whichever assessment framework was utilised. Scrutiny on how authors arrived at these conclusions revealed that mnemonic criteria were employed to assess pharmacy staff's diagnostic performance rather than a clinical reasoning approach. Conclusions: Potentially important aspects of the decision-making process, that clinical reasoning accounts for, were left unexplored. The scope of the number and locations of the included studies is a strength of this review, however, the system employed does not represent a validated tool.

<b>Keywords</b>	community pharmacy; diagnosis; clinical reasoning; mnemonics;
<b>Manuscript category</b>	Research Paper
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## Submission Files Included in this PDF

### File Name [File Type]

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Response to reviewers.docx [Response to Reviewers (without Author Details)]

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### Data set

<https://data.mendeley.com/datasets/n2h8t6vg54/draft?a=b2ab23c1-73bd-411a-aea5-83a4598a2331>

Data for: A systematic review of community pharmacies' staff diagnostic assessment and performance in patient consultations

The dataset includes reference list of the included studies, the extracted data for both extraction rounds and the analysis of the results presented in the paper.

COVER LETTER FOR SUBMISSION OF MANUSCRIPT

Subject: SUBMISSION OF A MANUSCRIPT FOR EVALUATION

Dear Editor,

I submit herewith a manuscript entitled "**A systematic review of community pharmacies' staff diagnostic assessment and performance in patient consultations**" for publication in "Research in Social and Administrative Pharmacy" for possible evaluation.

With the submission of this manuscript all authors give consent for its publication and would like to undertake that the above mentioned manuscript has not been published elsewhere or is being considered for publication elsewhere.

Thank you.

Sincerely,

Vassiliki Sinopoulou

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University of Central Lancashire

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## **Response to reviewers:**

Once more, we would like to thank all reviewers for their comments and we greatly appreciate the time they put in reviewing our paper. We were very happy to read that our paper would be accepted for publication, pending these minor changes. As previously, we have tried to respond to each comment as it was presented to us. The original comments appear in italics and our responses are in plain text below each comment. Hopefully any changes can be easily traced based, as line count was not greatly affected.

### **Reviewer 1**

*Thank you for the opportunity to review this revised manuscript. I am happy to confirm that overall the authors have addressed the issues raised in my review. In a number of instances the responses illustrate some limitations of the methodology - e.g. it would have been preferable for the additional databases explored to have been formally included in the PRISMA flowchart showing the larger number of replicates arising from these additional searches which were then excluded, rather than only addressed informally; similarly it would have been preferable to have retained a manual record of inter-rater agreement statistics as this is not captured by the Covidence software. However, as these data are unavailable, the manner in which the authors have addressed the issues in the manuscript is acceptable. A small number of typographical/grammatical errors and inconsistencies remain (including some in new sections such as the conclusion and the amended tables, which it should be possible to remove in final proofreading. However, overall the manuscript describes a worthwhile study which is likely to be of interest to a broad readership, and I recommend its publication.*

We are very happy to hear this reviewer is satisfied with our responses and in any future work we will make sure that the database issue and inter-rater agreement are addressed better. We have tried to correct any remaining typographical/grammatical errors and inconsistencies but as these were not explicitly identified we might have missed some, especially since after reading the manuscript so many times we might have become blind to them. We apologise for this and we hope that they might be picked up by an editor's "fresh pair of eyes" before publication.

### **Reviewer 4**

*Noted the addressed comments to previous reviewers.*

*Minor comments which can be considered but do not change the content of the article. No changes would preclude me from accepting the article.*

1. *Line 93, why is nursing in parentheses? this seems to entail a judgement that I am unsure you wanted to make.*

We have removed the parentheses.

2. *Line 165, knowing what they scenario... you mean the scenario*

We have made the correction.

3. *Lines 182 - 189, this lacked clarity. I think this is in response to previous reviewer to explain why you didn't use additional databases so may need to keep it but could be clearer if written in shorter, active tense*

We have rephrased this in an effort to be more clear.

- 4 *Lack a reference for line 366, UN country classification*

We have provided a link to the UN document.

4. *Line 396, as this studies... you mean these studies*

We made the correction.

5. *Line 464, you lack a reference for WWHAM. You should spell this out for international audiences prior to using*

We have spelled it out.

7. *Line 502, A better transition between the scoring and the mnemonic would help your reader. It is an abrupt transition*

We were not entirely sure what the “transition between the scoring and the mnemonic” refers to but we have rephrased line 502 to hopefully make it more clear.

8. *Line 519 - 520, The use of the words "few" and "some" lead your reader to judgement. Implicitly few seems like less articles than some to me, as a reader. Consider using specific numerical values instead of putting those in parentheses*

We have removed the use of “few” and “some” and replaced them with the actual numbers.

9. *Under section "study authors' outlook on performance" - you could provide examples of what a positive and negative outlook were to help the audience*

*understand what you classified each way. Consider reviewing examples of "quotes for qualitative interviews"*

We have provided one positive and one negative example. However, we are unsure about what was meant by "Consider reviewing examples of 'quotes for qualitative interviews'".

*10. Line 553, you discuss that overwhelmingly reported as poor, but if the framework ratings are poor (e.g. "0") can you use them to provide you a valid response.*

The "overwhelmingly reported as poor" quote refers to the authors' outlook on performance in their studies, not our own. The framework ratings we used were to scrutinise what methods authors used to arrive to their conclusions. We would need further clarification of this comment to understand it better, if our response is not enough.

*11. Line 604, should only new tools be validated or should previous tools be validated? Your framework did not show positive*

We have removed the word "new" to indicate that any tools should be validated, whether entirely new or validated versions of older ones. The last sentence of the comment appears to be unfinished and we are not unsure about what the reviewer meant to say.

*12. Line 669, relies on mnemonic than a clinical, should be mnemonic rather than a clinical*

We have corrected this.

## Abstract

Background: Increases in patients seeking advice at pharmacies has led to pharmacy staff engaging in diagnostic behaviours. Approaches to diagnosis include using mnemonics and clinical reasoning.

Objectives: The primary aim of this review was to assess the degree to which the criteria authors use to evaluate diagnostic performance in pharmacy consultations, in studies that use simulated patients or vignettes, conform with a clinical reasoning and a mnemonic framework. A secondary aim of the review was to characterise staff performance in the studies, based on the authors' comments of their results.

Methods: MEDLINE, EMBASE and Web of Science were searched between October 2016 and April 2017. Only peer-reviewed studies assessing pharmacy staff's diagnostic performance by using simulated patients or vignettes were eligible for inclusion. Data were extracted about how each study's criteria conformed with clinical reasoning and mnemonic frameworks. A scoring system between 0 and 4 was devised to determine the degree to which studies aligned to these two approaches. Risk of bias was assessed using the NHI Study Quality Assessment Tools. The review was registered in PROSPERO with identification number CRD42017054827.

Results: Sixty-eight studies (55 cross-sectional, 11 educational interventions and 2 RCTs) with sample sizes between 10 and 2700 were included in the review. Most studies were of poor or fair quality. Performance of pharmacy staff was overwhelmingly reported as poor by study authors. This was the case regardless of geography, scenario used or whichever assessment framework was utilised. Scrutiny on how authors arrived at these conclusions revealed that mnemonic criteria were employed to assess pharmacy staff's diagnostic performance rather than a clinical reasoning approach.

Conclusions: Potentially important aspects of the decision-making process, that clinical reasoning accounts for, were left unexplored. The scope of the number and locations of the included studies is a strength of this review, however, the system employed does not represent a validated tool.



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3 **A systematic review of community pharmacies' staff diagnostic assessment and**  
4 **performance in patient consultations**  
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24 using simulated patients or vignettes were eligible for inclusion. Data were extracted about  
25 how each study's criteria conformed with clinical reasoning and mnemonic frameworks. A  
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39 framework was utilised. Scrutiny on how authors arrived at these conclusions revealed that  
40 mnemonic criteria were employed to assess pharmacy staff's diagnostic performance rather  
41 than a clinical reasoning approach.  
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48 reasoning accounts for, were left unexplored. The scope of the number and locations of the  
49 included studies is a strength of this review, however, the system employed does not  
50 represent a validated tool.  
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## Introduction

In recent decades self-care has been heavily promoted worldwide due to rising health-care costs<sup>1,2</sup>. This move toward patient empowerment has been supported by an increase in medicines being available to the public without the need for a prescription<sup>3</sup>. Community pharmacy staff are ideally placed to facilitate patient self-care and self-medication<sup>4-6</sup> and indeed, community pharmacies have seen a rise in patients who visit in order to ask for help on minor ailments and advice on appropriate medication<sup>7</sup>. However, community pharmacists tend to find accommodating this task particularly challenging<sup>7</sup> due to time constraints and therefore most consultations are often first conducted by counter staff who do not possess the knowledge and experience of pharmacists<sup>8,9</sup>.

To support pharmacy staff in this role, various protocols and guidelines, often using mnemonics, have been widely advocated and adopted, as they are easy to remember and quick to implement<sup>10</sup>. This, in theory, allows standardised questions to be asked, which are the same in every consultation and will help gather all the necessary information for a diagnosis and an appropriate action to be taken. However, data suggests that these standardised methods do not necessarily improve consultation performance<sup>11-13</sup>, possibly because staff may ask questions with no direct relation to the examined conditions and the gathered information is not useful for the decision-making process.

In medicine and nursing clinical reasoning processes are extensively used<sup>14</sup>. Clinical reasoning is an evidence-based, dynamic process in which the health professional combines scientific knowledge, clinical experience and critical thinking, with existing and newly gathered information about the patient. By the end of the process, all available information and logical inferences lead to the formation of a diagnosis<sup>15-17</sup>. This method has the disadvantage of being difficult to describe and hard to learn but it has the major advantage of improving clinical ability and being an effective method in establishing a diagnosis, possibly because all consultation information, either gathered through questioning or examining the patient, plays a part in the decision-making. In a community pharmacy context reaching decisions is equally pertinent but appears to be poorly described in the literature.

A previous review<sup>18</sup>, examined the rate and type of information gathered during community pharmacy consultations (only in developing economies) based on “common themes of the types of information that should be included in the information gathering process according to the literature”. Besides examining the rate and type of gathered information, however, it

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121 is also important to examine their relevance and purpose and how they contribute to the  
122 decision-making process. It is not known if and to what degree these aspects of a consultation,  
123 which are related to clinical-reasoning, are performed in pharmacy settings. .  
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126 The primary aim of this review was to assess the degree to which the criteria authors use to  
127 evaluate diagnostic performance in pharmacy consultations, in studies that use simulated  
128 patients or vignettes, conform with a clinical reasoning and a mnemonic framework. A  
129 secondary aim of the review was to characterise staff performance in the studies, based on  
130 the authors' comments of their results.  
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### 135 **Methods**

136 A protocol for the review was submitted to PROSPERO with identification number  
137 CRD42017054827 and can be accessed at:  
138 [http://www.crd.york.ac.uk/PROSPERO/display\\_record.php?ID=CRD42017054827](http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017054827).  
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141 The inclusion criteria were that the study assessed pharmacy staff diagnostic performance  
142 and the assessment was described in some form; the pharmacist/pharmacy staff should have  
143 been presented with and required to have responded to a diagnostic scenario; the scenario  
144 was presented in the form of simulated patients (SPs) or vignettes. Any study design was  
145 considered, including cross-sectional studies, interventions and randomised controlled trials.  
146 Studies needed to be peer-reviewed and published in English; no limit was set on publication  
147 date.  
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150 Studies were excluded when they did not provide an assessment of performance or a  
151 description of the assessment; the pharmacist/staff had to deal with an already diagnosed  
152 condition; they only looked at pharmacists'/staff's opinions on performance; they asked  
153 pharmacists/staff to follow specific screening methods or pre-set guidance that would  
154 prevent the potential use of any critical thinking.  
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162 The rationale behind the eligibility criteria was to include any study that had pharmacists and  
163 pharmacy staff presented with a diagnostic scenario to which they had to respond without  
164 knowing what the scenario would be and in a setting as close to a real life consultation as  
165 possible. A more exhaustive list of inclusion/exclusion criteria was included in the PROSPERO  
166 protocol, however, only the criteria that were encountered during the selection process are  
167 mentioned above.  
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171 Databases used to identify eligible studies were MEDLINE, EMBASE and Web of Science. Two  
172 of the authors (VS and PR) performed an initial scoping of the literature using the search  
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180 algorithm ("community pharmac\*") AND ("simulated patients" OR "mystery shopp\*" OR  
181 "secret shopp\*" OR "pseudo\*" OR vignette\*). Originally, we planned to adapt the algorithm  
182 further, however, more detailed iterations of the algorithm did not improve the search results  
183 and we eventually decided not to change it. Use of other bibliographic databases, as  
184 mentioned in the PROSPERO protocol, only provided us with duplicate results to the three  
185 databases previously mentioned and thus we decided not to use more databases.

189 Two rounds of searches were carried out. The first one took place on 03-11-2016 and the last  
190 one on 10-4-2017, immediately before the extraction process. During the second round of  
191 searches, the reference lists of related literature were searched for additional titles. VS and  
192 PR independently screened the retrieved results titles and abstracts with the third reviewer  
193 (MG) acting as arbitrator whenever conflicts arose and the same process was followed for full  
194 text screening. The website platform Covidence was used to facilitate this process.

199 Risk of bias analysis was conducted at study level for each included study using the National  
200 Blood, Heart and Lung Institute's (NIH) of the U.S. Department of Health and Human Services  
201 Study Assessment Quality Tools, which rate studies as "good", "fair" or "poor". The Quality  
202 Assessment Tool for Observational Cohort and Cross-Sectional Studies was used for the  
203 included cross-sectional studies and the Quality Assessment of Controlled Intervention  
204 Studies tool was used for the included educational interventions and randomised controlled  
205 trials (RCTs). The analysis was conducted by VS, PR reviewed it and disagreements were  
206 resolved through discussion.

207 Data were manually extracted and inserted in to Microsoft Excel by VS and checked for  
208 accuracy by PR. The extracted data were; *study characteristics*: publication year, country, type  
209 of study, participant characteristics, type of results (quantitative or qualitative); *quality*  
210 *characteristics*: reporting of study piloting, SP training, data collection method ; *methodology*  
211 *characteristics*: type of methodology (SPs or vignettes), number of SPs, number of scenarios,  
212 type of scenarios (symptom presentation or product request), SP role (presenting for  
213 themselves or someone else); *assessment characteristics*: how assessment criteria were  
214 derived, whether studies assessed diagnostic performance in general or focused on the  
215 diagnosis of a specific condition, which medical conditions were used for the scenarios,  
216 whether staff knowledge was assessed and whether studies compared community  
217 pharmacists' performance with other pharmacy staff performance. A sub-analysis was  
218 conducted to establish whether there were differences in the types of conditions that studies  
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239 of developed and developing economies focused on as this might have been a reason for  
240 subsequent differences in results between countries of different economic profiles.  
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242 Descriptive statistics (total numbers and percentages) were used to report the results.  
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244 Data were also extracted about how each study's criteria conformed with clinical reasoning  
245 and mnemonic frameworks. To achieve this, both were broken down into 4 characteristics  
246 (see below) and study texts were qualitatively analysed and coded for passages that  
247 corresponded to each characteristic. A value of one was assigned for each characteristic  
248 exhibited, meaning each study could score between 0 and 4. Mode and modal values were  
249 used to report the results.  
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254 These characteristics were developed by VS, after an initial familiarisation with the included  
255 studies, as summaries of key aspects of clinical reasoning and mnemonic questioning that the  
256 authors could have reflected on in their studies. The characteristics were reviewed by PR and,  
257 after discussion, adjustments were made until an agreement was reached. All included  
258 studies were then searched by VS for passages that indicated whether the authors have  
259 considered each respective characteristic in the methodology they used, when reporting their  
260 results or when discussing their results. If that had occurred the study would be awarded one  
261 point per characteristic, if not it would be awarded no points. The scoring was reviewed by  
262 PR and disagreements were resolved through discussion.  
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270 The characteristics for each framework were the following.  
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272 For the clinical reasoning framework:

- 273 1. The authors assessed staff against questions with specific relevance to the scenario  
274 condition (this is to show a basic level of clinical reasoning, even if they don't explicitly  
275 mention how or why the questions are relevant) e.g. for an emergency contraception  
276 scenario staff were expected to ask the question "when was your last menstrual cycle"  
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- 279 2. The authors have mentioned the purpose of the questions they assessed staff against  
280 (this shows that authors have considered why the questions are asked) e.g. for a  
281 sleeplessness scenario, patients' were asked about their medication because it might  
282 be causing or contributing to the patient's sleeplessness  
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- 286 3. The authors have reflected on how staff use the gathered information during the  
287 decision-making process (this is to show that authors have considered the importance  
288 of information interpretation in some way) e.g. in a dyspepsia scenario, a response to  
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298 the question about pain location led the pharmacist to consider indigestion as a  
299 possibility  
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302 4. The authors considered whether there is a connection between the information  
303 gathered and the final decision taken by staff (to show that information gathering  
304 should be used for decision-making, even if the decision-making process is not  
305 described)  
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308 For the mnemonic framework:

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310 1. The authors have assessed staff against questions (regardless of whether they're  
311 relevant to the condition or not) e.g. in a common cold scenario staff were expected  
312 to ask the patient's age  
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314 2. The authors have assessed staff against a checklist of questions they were expected  
315 to ask e.g. • Check symptoms • Check length of symptoms • Check other medication  
316 • Check other health condition • Refer if needed • Provide information  
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318 3. The authors have explicitly mentioned they used a known mnemonic method,  
319 guidelines or recommendations to assess performance e.g. WWHAM, WHO  
320 guidelines, Australian practice? recommendations  
321  
322 4. The authors have reported the final decision staff took (irrespective of whether it was  
323 connected to the information gathering or not) e.g. "In 90% of the scenarios not  
324 appropriate for self- medication, a recommendation was made for the customer to  
325 see a physician/GP, but in only 30% of those referrals was there sufficient urgency"  
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332 Each study was also coded for passages that indicated whether the authors' outlook on the  
333 diagnostic performance of the staff assessed in their studies was positive, negative or mixed.  
334 The results and discussion sections of each study were searched by VS for language that  
335 indicated whether authors viewed the diagnostic performance of the staff in their studies in  
336 a positive or negative way or whether they had a mixed reaction, and were coded accordingly.  
337 The coding was reviewed by PR and revisions were made until consensus was reached.  
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## 344 **Results**

345 The database search yielded 732 results, 353 of which were excluded as duplicates. The titles  
346 and abstracts of the remaining 379 were screened and 264 of them were excluded. Full text  
347 screening was performed for 115 studies. From those, 47 studies were excluded based on the  
348 inclusion/exclusion criteria leaving 68 studies to be included in the review (Figure 1).  
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359 *Study characteristics*

360 The included studies were published between 1989 and 2017, with the number of studies  
361 increasing steadily with each passing decade. The majority of the studies took place in  
362 Europe, most prominently the UK, Australasia and Eastern Asia. Forty-one of the studies  
363 originated from developed countries and 27 from developing economic regions (based on UN  
364 country classification available at [www.un.org/development/desa/dpad/wp-](http://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/2015wesp_full_en.pdf)  
365 content/uploads/sites/45/publication/2015wesp\_full\_en.pdf) (Table 1).

366 Most studies (n=55) employed a cross-sectional study design, however eleven<sup>25,29-31,34,35,38-</sup>  
367 40,46,70 studies were educational interventions with a before and after design and two<sup>37,75</sup> were  
368 RCTs. Sample size varied widely between studies (10-2700 staff tested); Only  
369 thirteen<sup>27,46,53,56,59,60,64,67,68,71,72,86,87</sup> studies reported on how the sample size was calculated.  
370 (Appendix)

371 In the majority of the studies (n=43), any member of the pharmacy team were the subject of  
372 investigation. In some cases,<sup>21,25,26,33,41,42,50,52,57,72,78</sup> it was not possible to verify staff role,  
373 either because the researchers stated they were not able to do so, or because the study did  
374 not make it clear. The terminology used to describe 'other' pharmacy staff was divergent and  
375 often location-specific and it was not always clear to gauge what role they had or the level of  
376 training/qualification they held. All studies except one<sup>55</sup> (purely qualitative) used quantitative  
377 methods to report their results, although four<sup>36,48,79,87</sup> studies did use a combination of  
378 quantitative and qualitative methods. (Table 2)

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394 *Quality characteristics*

395 Risk of bias assessment analysis for the cross-sectional studies rated ten<sup>21,26,33,41,42,50,52,57,72,78</sup>  
396 to be of poor quality and the other 45 to be of fair quality. As these studies had many things  
397 in common, in terms of research questions, methodology and outcome measures, the main  
398 differentiating factor between fair and poor quality was whether they accurately defined their  
399 study population and between fair and good the fact that no studies assessed their population  
400 more than once, all studies' outcome measures were not reliable enough and only one study<sup>86</sup>  
401 mentioned that their SPs were blinded to the correct scenario responses.

402 Assessment for the educational interventions and RCTs found nine studies<sup>25,29,30,31,34,35,37, 70,75</sup>  
403 to be of poor quality and four<sup>38,39,40,46</sup> to be of fair quality with the main reasons for lowering  
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416 quality being non-adequate randomisation, not describing adherence to training protocols  
417 and not reporting the statistical power of their main outcomes as well as that, due to their  
418 nature, sufficient blinding and training allocation were not possible.  
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421 Study piloting was reported to have happened in only 29% (n=20) of studies. Only one<sup>34</sup> of the  
422 educational interventions reported piloting. Despite low levels of reported piloting, most  
423 (71%, n=44 out of 62) SP studies, did report on the training provided to SPs prior to data  
424 collection. In the vast majority of the studies (84%, n=57), data collection forms were  
425 completed after pharmacy staff interaction. In 18 studies (26%) the use of audio or video  
426 recording was employed. Twelve (18%) used both of these methods to be able to verify the  
427 content of the collection forms.(Appendix  
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#### 434 435 *Methodology characteristics*

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437 The most prominent methodology used to assess pharmacist and staff performance was  
438 through simulated patients; only 5 studies used vignettes,<sup>44,47,48,55,62</sup> whilst one<sup>80</sup> study used  
439 both. The number of SPs used in the studies ranged from one to more than 10, however most  
440 studies employed one or two SPs (n=24). Similarly, the numbers of scenarios used in the  
441 studies ranged from one to 64, however most used one or two scenarios (n=48). A mixture of  
442 symptom presentation and product request scenarios (n=38) were most commonly  
443 employed, although 20 studies solely used symptom presentation scenarios and 6 studies  
444 were product request scenarios only. In the majority of the scenarios (n=39) the SPs  
445 presented as themselves and in 19 studies the SP requested advice or product for a third  
446 person such as a child, relative or a friend. Nine studies used both types of presentation.  
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#### 457 *Assessment characteristics*

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459 Many of the studies (n=29) used published guidelines, recommendations and standards, and  
460 a further 10 based their assessment on criteria used in other published studies. Eighteen  
461 studies stated that the authors had derived their own criteria, whilst 10 studies used 'expert  
462 panels'. Eight studies explicitly mentioned basing their criteria on mnemonic acronyms, most  
463 commonly mentioned of which was WWHAM (Who is the patient, What are the symptoms,  
464 How long have the symptoms been present, Action taken, Medication being taken). Sixteen  
465 studies used some form of scoring system for their results (Table 2).  
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The majority of studies (n=46) evaluated staff's performance on specific health conditions whilst the remainder (n=22) assessed general diagnostic performance. Sub-analysis of data comparing condition with country showed that studies conducted in developed economies tended to concentrate on women's health, such as emergency contraception, and central nervous system conditions such as insomnia and headache. Those studies emanating from developing economies concentrated on conditions such as diarrhoea and sexually transmitted diseases (Appendix).

#### *Assessment framework ratings*

Based on our scoring system, studies tended to have, in total, higher mnemonic characteristics in their assessment methods of pharmacy staff's performance, with a modal value of 3 and lower clinical reasoning characteristics with a modal value of 0. Inter-rater agreement for the clinical reasoning rating was 80.5% and 82.4% for the mnemonic rating, before disagreements were resolved through discussion. There were no great differences in modal values between developed and developing economies ratings (clinical reasoning modal value of 0 for both, 2 for developing countries' mnemonic rating and 3 for developed countries' mnemonic rating) or between studies that set out to assess general diagnostic performance or a specific condition (clinical reasoning modal value of 0 in both cases, mnemonic rating modal value of 3 for general performance and 4 for specific conditions) . For each mnemonic framework characteristic individually, 69% of studies assessed performance based on questions not always relevant to scenario condition, 85% used checklists, 43% used named mnemonics or guidelines and 74% have reported the final decision staff took. For each clinical reasoning framework individually, 53% of studies assessed performance based on questions with relevance to the condition at hand, 12% reported purposes for the questions asked, 7% reflected on how the gathered information was used and 24% considered a connection between the information gathering process and the decision-making outcome.

#### *Study authors' outlook on performance*

Nine of the 68 studies' authors described pharmacy staff's performance in positive terms (example quote: "Results across all scenarios indicated the provision of a training program [...] led to a significant improvement in performance<sup>30</sup>"), whilst 8 described them in mixed terms;

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534 the vast majority of authors (n=51) used negative terms (example quote: “assessment and  
535 counselling provided to such patients were inadequate”<sup>63</sup>) to describe their results of  
536 pharmacy staff’s performance. Three of the thirteen educational interventions and RCT  
537 studies used positive language compared to 6 of the 55 cross-sectional studies. Three of the  
538 four educational interventions that were assessed to be of fair quality used negative language  
539 for their results. (Table 5)  
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#### 545 546 *Comparisons*

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548 Eleven studies included a theoretical assessment of staff’s knowledge (in the form of a  
549 questionnaire) which was then compared to actual performance through SPs or vignette  
550 methodology. Seven<sup>21-23,35,45,71,86</sup> reported actual performance was worse than the  
551 performance measured with the questionnaires, one<sup>41</sup> study found them to be similar and  
552 the other two<sup>25,39</sup> did not report that information . In the 13 studies that reported  
553 comparisons between community pharmacists and other staff, nine<sup>20,37,43,59,66,67,73,76,83</sup>  
554 reported pharmacists performing better and four<sup>21,60,85,86</sup> reported similar performances.  
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#### 561 **Discussion**

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563 Performance of pharmacy staff was overwhelmingly reported as poor by study authors, a  
564 result which has been reflected in other reviews<sup>88</sup>. This appeared to be the case regardless of  
565 geography, scenario used or whichever assessment framework was utilised. Scrutiny on how  
566 authors arrived at these conclusions revealed that they relied on mnemonic criteria to assess  
567 pharmacy staff’s diagnostic performance rather than a clinical reasoning approach. This  
568 means that potentially important aspects of the decision-making process, that clinical  
569 reasoning accounts for, were left unexplored.  
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575 The mnemonic framework provided simple quantifiable results, such as numbers of questions  
576 asked and the ability then to produce a score, however mnemonic characteristics have been  
577 called into question in establishing pharmacy staff ability to derive a diagnosis<sup>12,13,48</sup>. The  
578 various existing guidelines and well used mnemonics, such as WWHAM (commonly taught in  
579 UK pharmacy schools), appear to be viewed as appropriate instruments by authors. However,  
580 to aid a better representation of the actual level of diagnostic staff performance, new tools  
581 need to be developed, more aligned with a clinical reasoning approach, which would allow  
582 for the assessment of all parts of the decision-making process. New tools should expand  
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591 further than measuring the amount of questions being asked based on standardised  
592 mnemonic methods and examine whether questions being asked by pharmacists and staff  
593 are based on evidence-based knowledge of the scenarios presented to them, what  
594 pharmacists or staff want to achieve through their questions and observations and how  
595 everything relates to their decision-making process and their final decisions. Because these  
596 concepts are very difficult to be described and examined in quantitative terms, more  
597 qualitative methods could be employed by researchers, as they could be used in researching  
598 community pharmacists' and other staff's thought process during consultations, identify  
599 pharmacists', staff's and pharmacy students' needs and attitudes towards improving their  
600 diagnostic skills, examine the impact of educational interventions on decision-making and  
601 diagnostic abilities and other potential research topics. Qualitative methodology has been  
602 underutilised so far, with only four of all included studies in this review using it.

603 Tools that would be validated, and subsequently more reliable, would help improve the  
604 overall quality of future studies and avoid risk of bias. Future studies should also take care in  
605 defining their study populations and having their participants and assessors be blinded to the  
606 correct scenario responses. Educational interventions aimed at improving diagnosing ability  
607 in particular, could employ adequate randomisation, include in their results to what extent  
608 protocols are adhered to, report the statistical power of their results and have a longer length  
609 and more follow-ups to make sure any positive results can last over time.

610 Comparisons of pharmacy staff versus pharmacists showed that, on the whole, pharmacists  
611 performed better. This is to be expected, as pharmacists have more extensive training than  
612 other pharmacy staff, and this finding favours pharmacists being more visible and proactive  
613 in undertaking patient consultations rather than leaving this role to less well trained staff<sup>9</sup>. In  
614 studies where actual performance was compared to theoretical performance, staff  
615 performed more poorly in the real-life situation scenarios. This dissonance suggests that  
616 decision making skills of staff are poorer than they perceive, whereby they possess knowledge  
617 but do not know how to use it critically. This performance gap is somewhat substantiated  
618 through the findings of the educational intervention studies, which showed broadly positive  
619 results (Table 5), although these studies were mostly short-term and of not good quality so  
620 we cannot draw any firm conclusion about how long these effects may last. However, these  
621 comparisons were based on very limited numbers of studies and larger reviews would be  
622 needed to substantiate these findings.

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652 Limitations of this review were that it only captured studies published in English and did not  
653 include any relevant grey literature. However, it included studies from all over the world and  
654 its scope was not narrowed to the specific sets of practices and attitudes of any given location.  
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656 The characteristics we developed to code for the clinical reasoning and mnemonic  
657 frameworks and the coding of the authors' outlook on their results do not represent a  
658 validated tool and are instead the review authors' attempt at establishing a method that  
659 would allow to study the extent to which these two diagnostic frameworks are used and how  
660 results are interpreted in the current literature, something that has not thus far been  
661 attempted in community pharmacy, to the best of our knowledge. By including only studies  
662 that used simulated patients and vignettes, the benefit is that the included studies  
663 approximated real-life consultations. The studies included in this review did not allow for  
664 meta-analysis, but inclusion of diverse studies did allow for a greater variety of data sources  
665 to be included.  
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## 676 **Conclusion**

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678 The current literature assessing pharmacists' and pharmacy staff's diagnostic ability via  
679 simulated patients or vignettes overwhelmingly relies on a mnemonic rather than a clinical  
680 reasoning framework. Based on authors' comments about their results, the common  
681 perception is that pharmacists' and staff's diagnostic ability is poor, regardless of geography,  
682 diagnostic scenarios or assessment framework. A limited amount of studies found  
683 pharmacists perform better than other pharmacy staff. The quality of future studies can be  
684 improved and new tools should be developed for future assessments that go further than  
685 measuring the amount of questions asked and deeper examine the decision-making process  
686 during consultations.  
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Table 1 Publication year and country

Criterion	Studies	References
<b>Year</b>		
1989	1	20
1990-1999	6	21,22,23,24,25,26
2000-2009	21	27,28,29,30,31,32,33,34,35,36,37,38,39, 40,41,42,43,44,45,46,47
2010-2017	40	48,49,50,51,52,53,54,55,56,57,58,59,60,61,62,63,64, 65,66,67,68,69,70,71,72,73,74,75,76,77,78,79,80,81 82,83,84,85,86,87
<b>Country</b>		
UK	14	13-15,20,22,28,35,36,43,48,51,52,84
Europe	9	27,31,34, 42, 46, 50, 58, 78, 79
Eastern Asia	13	26, 41, 49, 54, 59-61,67,68,72, 80, 83, 86
Western Asia	3	21,73, 63
Northern America	4	24,47,55, 70
Southern America	4	44,56,69,74
Australasia	15	29,30,33, 57,62,64,65,66,75-77,81,82,85,87
Africa	5	32, 40, 45, 53, 71
Transnational	1	25
<i>developing countries</i>	27	21,25,26,32,40, 41,44,45,47,49,53,54,56,59- 61,63,67,68,69,71,72-74,80,83,86
<i>developed countries</i>	41	20,22-24,27-31,33-39,42,43,46,48,50-52,55,60,62,64- 66,70,75-79,81,82,84,85,87

Table 2 Other study characteristics

Sample characteristics	studies	references
CPs only	18	22-24, 28,36,44,48,54-56, 58, 62-64, 69-71, 74
Any pharmacy staff	44	20,21,26,27,29-31,33-35,37,38,40-43,46,47,50-52,57,59-61,65-68, 72,73, 75-87
Non-CP staff only	5	25,32,39,45,53
CPs and GPs	1	49
<b>Type of results</b>		
Quantitatively (descriptive or more advanced statistics)	67	all studies except 55
Quantitatively (using a scoring system)	16	24,27,30,34,38,46,58-60,64,68,69,79,81-83
Qualitatively (themes)	1	55
Both quantitatively and qualitatively	4	36,48,79,87

(CP=Community Pharmacist, GP=General Practitioner)

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Table 3 Assessment criteria basis

Assessment criteria were decided based on:		
author derived	18	22,23,31,34,35,43-48,57,72,75,79,82,85
paper	10	49,50,52,62,64-66,69,70,74
standards/guidelines/recommendations	29	25,28-30,32,34,37,39,44,47,51,54,57-61,64,68,71,75-78,83,84,86,87
WWHAM protocol	6	37,38,39,42,54,84
WHAT-STOP-GO protocol	1	81
other protocols	1	54
expert panel	10	24,33,36,38,56,62,64,69,84,86
n/a	9	20,21,27,41,45,53,63,73,80

Table 4 Mode score values per characteristic and median values for total scores

characteristic	CR1	CR2	CR3	CR4	MN1	MN2	MN3	MN4	Total CR	Total MN
mode	1	0	0	0	1	1	0	1		
median									1	3

(CR=clinical reasoning, MN=mnemonic)

Table 5 Authors outlook on staff's performance results

Authors' outlook on diagnostic performance	n	reference(*denotes educational intervention)
positive	9	28, 29*, 30*, 37*, 46*, 53, 55,65, 66
mixed	8	27, 31*, 58, 62, 70*, 79, 80, 84
negative	51	20-24, 25*, 32, 33, 34*, 35*, 36, 38*, 39*, 40*, 41-45, 47-52, 54, 56, 57, 59-61, 63, 64, 67-69, 71-74, 75*, 76-78, 81-83, 85-87



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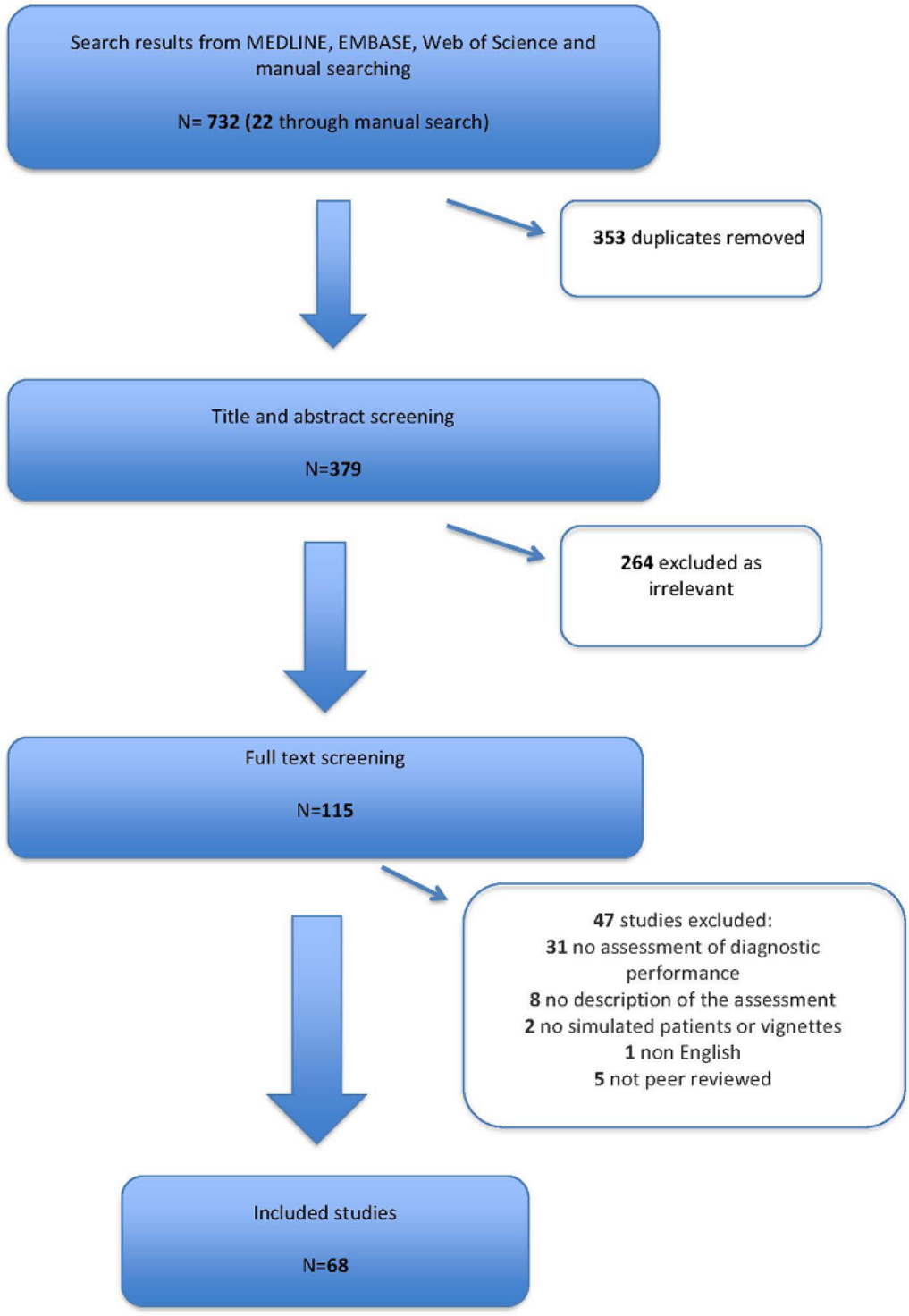


Figure 1: Inclusion and Exclusion Flow Chart

## Appendix

Table 6 Types of studies and sample sizes

Type of study	Studies	References	Sample size	Studies	References
Cross-sectional	55	20-24, 26-28, 32,33,36, 41-45, 47-49, 50-69, 71-74, 76-87	<100:	28	20,22,23,28,32,36,43-45,48,51,52,54-58,61,64,69,73,74,77,79,81,84,85,87
			101-200:	12	24,26,42,47,49,62,65,71,76,80,82,86
			201-300:	8	21,27,41,66-68,72,78
			>301:	7	33,50,53,59,60,63,83
Educational interventions	11	25, 29-31, 34,35, 38-40, 46, 70	<100:	5	31,38,39,40,70
			101-200:	2	35,46
			201-300:	1	34
			>301:	3	25, 29,30
Randomised Controlled Trials (RCTs)	2	37, 75	<100:	1	75
			>301:	1	37

Table 7 Quality characteristics

Criterion	Studies	References
<b>Was there a pilot to the study reported by the authors?</b>		
yes	21	22,26,33,34,36,42,44,48-50,54,56,58,62,63,71,76,77,80,82,87
no	47	20,21,23-25,27-32,35,37-41,43,45-47,51-53,55,57,59-61, 64-70, 72-75, 78,79,81,83-86
<b>Did SPs* receive training for the study?</b>		
yes	54	
training mentioned	44	24,25,27-30, 33-41, 45,46,49,52,53,56-60, 65,69, 70,72-87
the SPs had previous experience	5	20,42,66,67,68
One or more of the authors were SPs	6	26,22,31,43,54,61
external paid service was used	1	50
not mentioned	6	21,23,26,32,51,63
<b>How was data captured?</b>		
audio/video recorded and transcribed	18	28,30,33,34,38,39,42,46,48,55,56,58,65,66,69,74,79,84
data collection form	57	20-27, 30-45,47,51,54, 57-64, 67-87
paid service	1	50

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n/a	3	29,52,53
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(SP=Simulated Patient)

Table 8 Methodology characteristics

Methodology	Studies	References
SP*s	62	20-43, 45,46, 49-54, 56-61, 63-79, 81-87
vignettes	5	44, 47, 48, 55, 62
both	1	80
<i>Number of SPs</i>		
1	13	20,22,23,26,31,36,43,45,54,64,70,87
2	11	24,28,32,42,51,56,57,69,73,75
3	4	21,58,77,78
4	4	52,76,82,86
5	1	41
6	4	27,65,72,81
7	2	70,72
8	1	71
9	1	37
10	4	40,67,80,84
>10	4	33,49,50,63
n/a	12	25,29,30,46,53,60,61,66,68,79,83
<i>Number of Scenarios</i>		
1	32	20-23,25,27,35,41-45,48,49,51,52,59,60,64-68,70,71,74,76,77,80,83,86,87
2	16	26,28,31,32,33,36,46,55,56,57,63,69,73,75,82,85
3	7	30,38,47,50,53,58,72
4	5	24,34,39,78,84
≥5	4	37,62,79,81
n/a	4	21,29,61,40
<i>Type of scenario</i>		
Symptom presentation	20	20,21,23,25,26,28,35,36,40,42,43,45,47-49,51,52,65,71,73
Product request	6	46,64,75,77,82,87
both	38	22,24,27,30-34,37-39,41,44,50,53-58,60,62,66-70,72,74,78-80,83-86
n/a	4	29,59,61,63
<i>SP role</i>		
for themselves	32	22,27,28,31-33,36-38,40,45,46,49,56,58-61,63,64,66-68,70,74-77,80,82,85,87
for someone else (child, relative, friend)	19	20,21,23,25,35,41-43,51-54,65,71,78,81,83,84,86
both	9	24,26,34 50,57,69,72,73,79
n/a	3	29,30,39

(SP=simulated patient)

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Table 9 Conditions for general performance assessment or specific condition

Criterion	Studies	References (*denotes developing country)
<i>Studies assessing diagnostic ability of a specific condition</i>		
<b>women's health</b>		
<b>Contraceptive management</b>	4	28,57,77,78
<b>Diseases of the genitourinary system</b>		
dysmenorrhoea	1	22
<b>Diseases of the visual system</b>		
dry eye	1	51
allergic conjunctivitis	1	52
<b>Diseases of the musculoskeletal system</b>		
back pain	1	54*
<b>Diseases of the nervous system</b>		
headache	2	58,74*
insomnia	4	59*,64,70,85
serotonin syndrome	1	65
<b>Diseases of the respiratory system</b>		
Acute respiratory infection	1	60*
chronic cough	1	76
common cold	1	81
<b>Diseases of the digestive system</b>		
peptic ulcer	1	61*
lower bowel symptoms	1	62
GORD	1	66
dyspepsia	1	68*
diarrhoea	9	21*,23, 25*,42, 44*,71*,73*,83*,86*
<b>Conditions related to sexual health</b>		
gonorrhoea and genital ulcer disease	1	32*
urethral discharge	4	40*, 41*, 45*, 47*
<b>Diseases of the circulatory system</b>		
acute cardiac symptoms	1	63*
<b>Neoplasms</b>		
oral cancer	3	20,43,59
<b>Certain infectious or parasitic diseases</b>		
malaria	1	67*
tuberculosis	1	80*

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<b>Product requests</b>		
codeine analgesics	1	82
Antibiotics	1	26*
<b>Criterion</b>	<b>Studies</b>	<b>References</b>
<i>Studies assessing general diagnostic performance using scenarios of</i>		
<b>Contraceptive management</b>	1	79
<b>Certain infectious or parasitic diseases</b>		
vaginal thrush	2	33,34
<b>Diseases of the visual system</b>		
eye discomfort	1	84
<b>Diseases of the musculoskeletal system</b>		
back pain	1	84
leg cramps/fatigue	1	24
<b>Diseases of the nervous system</b>		
headache	4	27,31,36,69*
insomnia	1	55
facial pain	1	56*
<b>Diseases of the respiratory system</b>		
Acute respiratory infection	1	53*
allergic rhinitis	1	24
common cold	6	49*,50, 53*, 56*, 79,84,24
<b>Diseases of the digestive system</b>		
abdominal pain	1	36
indigestion	1	38
vomiting	1	84
dyspepsia	2	48,79
diarrhoea	4	24,69*,79,84,
Product requests	11	27,31,33,34,38,46,50,53*,72*,78,79
<b>Study evaluated:</b>		
General performance	22	24,27,29-31,33,34,36,38,39*,46,48,49*,50,53,55,56*,69*,72*,78,79,84
Specific condition	46	20,21*-23, 25*, 26*, 28, 32*, 35, 37, 40*, 41*, 42, 43, 44*, 45*, 47*, 51,52, 54*, 57,58, 59*, 60*, 61*, 62, 63*, 64-66, 67*, 68*, 70, 71*, 73*, 74*, 80*, 83, 83*, 85, 86*, 87

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Table 10 Clinical reasoning (CR) and mnemonic characteristics scoring for each study

study reference	CR1	CR2	CR3	CR4	CRTOTAL	MN1	MN2	MN3	MN4	MNTOTAL
20	0	0	0	0	0	0	0	0	1	1
21	1	0	0	0	1	0	1	0	1	2
22	1	1	0	0	2	1	1	0	1	3
23	1	0	0	0	1	1	1	0	1	3
24	1	0	0	1	2	0	1	0	0	1
25	1	0	0	0	1	0	1	0	1	2
26	1	0	0	1	2	0	1	0	0	1
27	0	0	0	0	0	1	1	0	1	3
28	1	0	0	0	1	1	1	1	1	4
29	0	0	0	0	0	1	1	1	0	3
30	0	0	0	0	0	1	1	1	0	3
31	0	0	0	0	0	1	1	0	1	3
32	1	0	0	1	2	0	1	1	0	2
33	1	1	0	1	3	0	1	0	0	1
34	0	0	0	0	0	1	1	1	0	3
35	1	0	0	0	1	1	1	0	1	3
36	1	1	1	1	4	0	0	1	0	1
37	1	0	0	0	1	1	1	1	1	4
38	0	0	0	0	0	1	1	1	1	4
39	0	0	0	0	0	1	1	1	1	4
40	1	0	0	1	2	0	1	0	0	1
41	1	0	0	0	1	1	1	0	1	3
42	1	0	0	0	1	1	1	1	1	4
43	0	0	0	0	0	0	0	0	1	1
44	1	0	0	0	1	0	1	1	1	3
45	1	0	0	0	1	0	1	0	1	2
46	0	0	0	0	0	1	1	0	1	3
47	0	0	0	0	0	0	0	0	1	1
48	1	1	1	1	4	0	0	0	0	0
49	1	0	0	1	2	1	1	0	0	2
50	0	0	0	0	0	1	1	0	1	3
51	1	0	0	1	2	1	1	1	0	3
52	1	0	0	1	2	1	1	0	0	2
53	0	0	0	0	0	1	1	0	1	3
54	0	0	0	0	0	1	1	1	1	4
55	1	1	1	1	4	0	0	0	0	0
56	1	0	1	1	3	1	1	0	0	2
57	1	0	0	0	1	1	0	1	1	3
58	0	0	0	0	0	1	1	0	1	3
59	0	0	0	0	0	1	1	1	1	4
60	0	0	0	0	0	1	1	1	1	4

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<b>61</b>	1	0	0	0	1	1	1	1	1	4
<b>62</b>	1	1	1	1	4	0	0	0	0	0
<b>63</b>	0	0	0	0	0	1	1	1	1	4
<b>64</b>	1	0	0	0	1	1	1	0	1	3
<b>65</b>	1	1	0	1	3	0	1	0	0	1
<b>66</b>	0	0	0	0	0	1	1	0	1	3
<b>67</b>	0	0	0	0	0	1	1	1	1	4
<b>68</b>	0	0	0	0	0	1	1	1	1	4
<b>69</b>	0	0	0	0	0	1	0	0	1	2
<b>70</b>	1	1	0	0	2	1	1	0	1	3
<b>71</b>	1	0	0	1	2	0	1	1	0	2
<b>72</b>	0	0	0	0	0	1	1	0	1	3
<b>73</b>	1	0	0	0	1	1	1	0	1	3
<b>74</b>	0	0	0	0	0	1	1	0	1	3
<b>75</b>	0	0	0	0	0	1	1	0	1	3
<b>76</b>	0	0	0	0	0	1	1	1	1	4
<b>77</b>	1	0	0	0	1	1	1	1	1	4
<b>78</b>	0	0	0	0	0	1	1	1	1	4
<b>79</b>	0	0	0	0	0	1	1	0	1	3
<b>80</b>	0	0	0	0	0	0	0	0	1	1
<b>81</b>	0	0	0	0	0	1	1	1	1	4
<b>82</b>	0	0	0	0	0	1	1	1	1	4
<b>83</b>	0	0	0	0	0	1	1	1	1	4
<b>84</b>	1	0	0	0	1	1	1	1	1	4
<b>85</b>	1	0	0	0	1	1	1	1	1	4
<b>86</b>	1	0	0	1	2	0	1	0	1	2
<b>87</b>	1	0	0	0	1	0	1	0	1	2
<b>MODE</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>		<b>1</b>	<b>1</b>	<b>0</b>	<b>1</b>	
<b>MEDIAN</b>					<b>1</b>					<b>3</b>