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Review Article

USING THE SIMULATED PATIENT METHODOLOGY TO ASSESS THE QUALITY OF COUNSELLING IN GERMAN COMMUNITY PHARMACIES: A SYSTEMATIC REVIEW FROM 2005 TO 2018

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ABSTRACT

The simulated patient methodology (SPM) is a form of participatory observation and can be used to assess the quality of counselling. The aim is to review those papers reporting the use of the SPM in German community pharmacies (CPs) from the beginning of 2005 to the end of 2018. The reporting items in the study were derived from the PRISMA Statement. We conducted a systematic search in the GVK-Plus, Embase, Web of Science, PubMed and Google Scholar databases. Additional sources included the personal literature collection of 1 of the reviewers and the reference lists from international systematic reviews and potentially relevant papers. The quality of the papers included was evaluated using the AXIS tool. A total of 5 papers were included. The SPM that was used varied greatly in the papers. The quality of counselling was assessed in the papers as being rather poor. The quality of the papers differed for specific assessment criteria. Only an extremely small number of papers could be included, in contrast to other countries. The papers for Germany demonstrate that there is a considerable need for improvement in the quality of counselling in CPs. Also, the deficits identified here for the application of the SPM should be avoided in future papers. It must also be recommended that the SPM be reported in future papers using uniform reporting standards, which are yet to be developed, to ensure better comparability.

Keywords: Systematic review, Counselling, Simulated patient methodology, Community pharmacies, Germany

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INTRODUCTION

Depending on the laws in a country, defined establishments are authorised to dispense 2 fundamentally different groups of medications, prescription-only medicines (POM) and over-the-counter medicines (OTC) for which no prescription is required. Compared to countries in which OTC medicines and even POMs can be dispensed outside community pharmacies (CPs), such as by doctors or in supermarkets or petrol stations [1], in Germany, it is almost exclusively CPs and the mail-order pharmacies operated by them that are authorised to dispense such medicines [2]. Only specific OTC medicines (e. g., curative waters, medicinal clays) are not pharmacy-only medicines and can, for example, be sold in drugstores as well [2, 3]. Because this market segment plays a minor role, CPs are the most significant location for the dispensing of POMs and OTC medicines in the German medicinal product market [4].

The importance of CPs in Germany (31.12.2018: approx. 83 million residents; 19,423 CPs; a density of approx. 23 CP per 100,000 residents, making it below-average in the EU comparison [5, 6]) is also derived from the fact that they must satisfy certain requirements. These requirements include providing counselling for medicines that must be conducted by pharmacists but can also be carried out by pharmacy technicians and pharmaceutical technical assistants if this has been previously specified by the pharmacy manager [7]. The legally envisaged objective is that the CPs provide an 'adequate' quality of counselling [7]. This objective is intended to be achieved using the internal quality management system operated by the CPs, whereas external quality assessments remain only a recommendation at this stage [7]. In this context, the Federal Chamber of Pharmacies provides guidelines and, for several indications, corresponding tools [8]. For external quality assurance, each regional chamber of pharmacists carries out regular inspections of the quality of counselling provided by CPs [9]. As a matter of principle, first and foremost, independent scientific studies–also to achieve the least distorted results possible–are of great importance for clarifying the extent to which CPs provide an 'adequate' quality of counselling.

Regarding the methodology to be used, there are several options available for investigating the quality of counselling in CPs. These include surveys, interviews of the persons involved (customers, pharmacy staff), clinical vignettes and non-participatory observations [10, 11]. The validity of surveys, interviews and clinical vignettes as a means of assessing quality is limited due to social desirability bias because in particular, pharmacy staff who are surveyed or interviewed tend to describe their counselling performance as better than what was provided [12]. For non-participatory observations, there is the drawback that the pharmacy staff generally modify their behaviour when they become aware that they are being observed. This behavioural adaptation is known as the Hawthorne effect [13] and can lead to an overly good quality of counselling compared to the everyday situation. Therefore, to avoid the problems described above, the simulated patient methodology (SPM) [14-16], which has often been used in the past in the CP setting to assess the quality of counselling, is recommended [17, 18]. The SPM is, as defined in the international literature [14-16], a covert participatory observation by a person, who in an ideal case, cannot be differentiated from a real customer (simulated patient, SP), who visits a CP to simulate a real-life counselling situation based on a previously defined scenario. The data are then collected according to previously defined criteria using an assessment form and the CP is provided with performance feedback, if applicable. The SPM is considered the gold standard in the international literature [11], even if its relatively high administrative and financial costs and the comparatively smaller sample sizes [11], as well as any intra-and inter-observer variabilities, are taken into account [19].

This study aims to review papers reporting on the use of the SPM for assessing the quality of counselling in German CPs. To ensure that the object of the current investigation is as current as possible, only papers from the beginning of 2005 onwards will be reviewed. Due to the country-specific differences present, for example, regarding the subject contents of the pharmacy degree [20], the pharmacy density [21] or the guidelines used as a benchmark for a quality assessment [18], an international systematic review could lead to distortions in the results. For this reason, this study was limited to Germany.

MATERIALS AND METHODS

The current study was reported using the reporting items defined in the 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement' [22].

Literature search

The search is derived from the recommendations of an umbrella review for implementing a regional limitation when searching for papers from Germany [23]. In July 2019 a search was conducted for papers that had been published between the beginning of 2005 and the end of 2018. The systematic search (table 1) was conducted in the following online databases by 1 of the reviewers: GVK-Plus, Embase, Web of Science, PubMed and Google Scholar. The choice of search terms regarding the term 'simulated patient' was based on the synonyms used in international systematic reviews [14-16]. The synonyms were combined with other search terms. If the preferred search option 'Title/Abstract' was not available in the online databases, 'Abstract' or 'Title' was selected. Additionally, the other reviewer searched manually in his literature collection and the reference lists of international systematic reviews [14-16].

Table 1: Search strategy for the systematic search in online databases

Search terms algorithm with German search terms (21 different search combinations per database)				
'simulierter Patient' **or** 'simulierter Besucher' **or** 'simulierter Käufer' **or** 'simulierter Verbraucher' **or** 'simulierter Klient' **or** 'simulierter Kunde' **or** 'Testkäufer' **AND** 'öffentliche Apotheken' **or** 'Vor-Ort-Apotheken' **or** 'Präsenzapotheken'				
Search terms algorithm with English search terms (264 different search combinations per database)				
'simulated patient' **or** 'simulated customer' **or** 'simulated client' **or** 'simulated shopper' **or** 'simulated patron' **or** 'simulated participant' **or** 'standardised patient' **or** 'standardised customer' **or** 'standardised client' **or** 'standardised shopper' **or** 'standardised patron' **or** 'standardised participant' **or** 'standardized patient' **or** 'standardized customer' **or** 'standardized client' **or** 'standardized shopper' **or** 'standardized patron' **or** 'standardized participant' **or** 'undercover patient' **or** 'undercover customer' **or** 'undercover client' **or** 'undercover shopper' **or** 'undercover patron' **or** 'undercover participant' **or** 'mystery patient' **or** 'mystery customer' **or** 'mystery client' **or** 'mystery shopper' **or** 'mystery patron' **or** 'mystery participant' **or** 'secret patient' **or** 'secret customer' **or** 'secret client' **or** 'secret shopper' **or** 'secret patron' **or** 'secret participant' **or** 'pseudo patient' **or** 'pseudo customer' **or** 'pseudo client' **or** 'pseudo shopper' **or** 'pseudo patron' **or** 'pseudo participant' **or** 'covert patient' **or** 'covert customer' **or** 'covert client' **or** 'covert shopper' **or** 'covert patron' **or** 'covert participant' **or** 'surrogate patient' **or** 'surrogate customer' **or** 'surrogate client' **or** 'surrogate shopper' **or** 'surrogate patron' **or** 'surrogate participant' **or** 'disguised patient' **or** 'disguised customer' **or** 'disguised client' **or** 'disguised shopper' **or** 'disguised patron' **or** 'disguised participant' **or** 'fictitious patient' **or** 'fictitious customer' **or** 'fictitious client' **or** 'fictitious shopper' **or** 'fictitious patron' **or** 'fictitious participant' **AND** 'community pharmacies' **or** 'community pharmacists' **AND** 'German' **or** 'Germany'				
Online database	**Provider**	**Date of searching**	**Search option**	**Records**
With German search terms				
GVK-Plus	VZG	26.07.2019	'Title'	0
With English search terms				
Embase	Ovid	31.07.2019	'Abstract'	6
Web of Science	Clarivate Analytics	30.07.2019	'Title'	1
PubMed	NCBI	28.07.2019	'Title/Abstract'	6
Google Scholar	Google	28.07.2019	'Title'	1
Total				14

Selection process

Inclusion and exclusion criteria

A selection process was then carried out by the 2 reviewers independently of each other (fig. 1). According to the current object of investigation, it was aimed to include papers that assessed the quality of counselling in German CPs using the SPM. The CPs must have been physically visited in the papers. Papers were also included regardless of the mode of publication, the type of medicines investigated and the study design. The papers also had to be publicly accessible original research with transparent details about the methodology used and had to be written in German or English. Papers were excluded that did not describe original research (e. g. all types of reviews), that were carried out in pharmacies outside Germany or published in a language other than German or English, that were conducted in a non-community pharmacy setting (e. g. hospital pharmacies) or using soft quality factors for the counselling (e. g. non-verbal skills) and other SPMs that did not require a physical visit to the CPs (e. g. mystery calls).

Eligibility

After excluding duplicates, the titles and, if available, the abstracts of the records were screened. The full text of the remaining potentially relevant papers was then screened. This was then followed by a manual review of the reference lists (backward snowballing) of the remaining potentially relevant papers for possible inclusion in the list of potentially relevant papers found up to that point [24]. Because the aim of this systematic review was to investigate papers and not studies, in the end, all papers were included regardless of whether they reported about the same study.

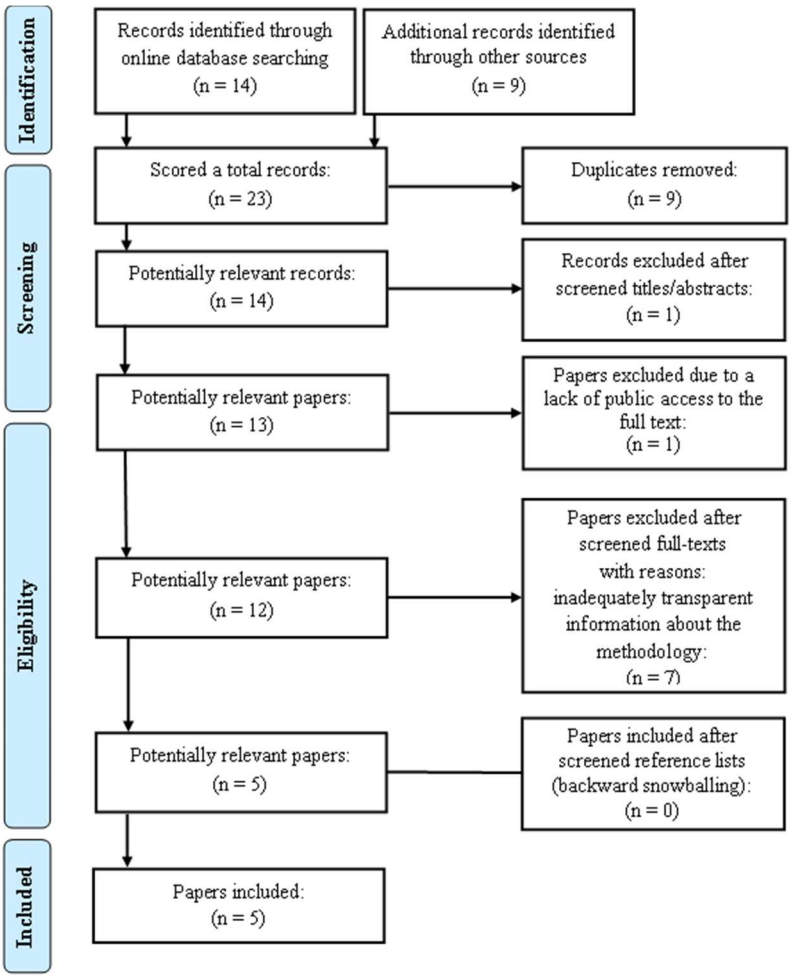

Fig. 1: Flow diagram; derived from the PRISMA statement [22]

Data extraction

The data extraction subsequently carried out by both reviewers independently of each other was performed using the 2 major criteria 'use of the simulated patient methodology' (5 minor criteria: scenarios, community pharmacies, simulated patients, visits, data collection and performance feedback) and 'assessment of the quality of counselling'. The minor criteria were derived primarily from the criteria in PICOS [25] and from those criteria that were used in international systematic reviews [14-16]. The criteria prepared in this way were then summarised in a corresponding form that was used as the basis of the qualitative synthesis of the data extracted from the papers. Due to the heterogeneity of the papers included, we refrained from generating a meta-analytical summary.

Quality assessment

The quality of the papers included was also assessed using the AXIS tool. This tool addresses the quality of reporting and the quality of design as well as the risk of bias [26]. The assessment was carried out by both reviewers independently of each other with neither reviewer having previously used the tool. The inter-rater reliability was measured using Cohen's kappa (κ) [27].

Ethical approval

Not applicable as no human subjects were involved.

RESULTS

Included papers

Initially, 23 records were identified. After duplicates were removed and the titles and, if applicable, the abstracts were screened, 13 papers remained; after excluding 1 [28] there were then 12 potentially relevant papers available. Of these, 7 potentially relevant papers [29-35] were excluded after screening the full text. Using a manual review of the reference lists of the now 5 potentially relevant papers, no further papers were identified. In the end, 5 papers [36-40] were included. Of these 5, 2 papers [38, 39] reported about the same study. In addition, 1 paper [40] was a follow-up to a previously conducted baseline study [38, 39]. Further general information about the included papers is shown in table 2.

Use of the simulated patient methodology

All information about the SPM used in the included papers can be seen in table 3 and table 4.

Scenarios

The 5 included papers applied relevant scenarios to simulate a real-life counselling situation: 2 papers used 2 scenarios [36, 37] and the other 3 papers used 4 scenarios [38-40]. In 1 scenario [36, 37] and 2 scenarios [38-40] respectively, the SPs started the consultation either by providing symptom-based information or making a medication-based request. The person for whom the medication was requested or whose symptoms were described was the SP themselves in 2 papers [36, 37] and in the other 3 papers [38-40] it was a third person. The particular person concerned was revealed in 11 of 12 scenarios upon enquiry by the pharmacy staff. In 1 scenario in 1 paper [37], the information about the person concerned was provided at the start of the consultation. In 3 papers [38-40], the practical functionality of the scenarios was tested. These pre-tests were carried out in CPs outside the planned study region. The other 2 papers [36, 37] did not provide any information about possible pre-tests.

Table 2: General information

	Berger *et al.* 2005 [36]	**Alte *et al.* 2007 [37]**	**Langer *et al.* 2016 *et al.* 2018 [38, 39]**	**Langer *et al.* 2018 [40]**
Year of execution	n/s	2005	2014	2017
Design	CS	CS	CS	CS
Aim	To evaluate counselling performance of staff in CPs and to assess the quality of patient counselling	To estimate aspects of consultation quality in CPs, study factors related to consultation quality	To assess the quality of counselling in CPs and to evaluate the role of the patient's approach and different user groups in determining the outcome of counselling	To analyse whether the quality of advice provided by CPs in the period between 2014 [38, 39] and 2017 [40] could be increased and to analyse whether the quality of advice differed depending on the professional group providing the advice
Medicinal product market	OTC	OTC	OTC	OTC
Ethical approval	n/s	n/s	n/s [38]; Yes [39]	Not explicit but implicit because analogous follow-up study to the baseline study [38, 39]
Funding	n/s	Regional Chamber of Pharmacists of Mecklenburg-Pomerania, GERMANY	n/s [38]; No specific grant from any funding agency [39]	No specific grant from any funding agency
Institution of authors	Federal Union of German Associations of Pharmacists (ABDA), GERMANY	Ernst-Moritz-Arndt-University Greifswald, GERMANY	University of Applied Sciences Neubrandenburg, GERMANY	University of Applied Sciences Neubrandenburg, GERMANY
Conflict of interest	n/s	n/s	No	No

n/s = not specified; CS = cross-sectional; OTC = over-the-counter drugs

Table 3: Scenarios

	Scenario	**Key contents**
Berger *et al.* 2005 [36]	1	*Start of consultation*: The SP asks for preparation for headache. *Type of scenario*: symptom-based *Person concerned*: SP (revealed upon enquiry)
	2	*Start of consultation*: The SP asks for a pack of 120 tablets of Rennie. *Type of scenario*: medication-based *Person concerned*: SP (revealed upon enquiry)
Alte *et al.* 2007 [37]	1	*Start of consultation*: The SP asks for a recommendation for headache. *Type of scenario*: symptom-based *Person concerned*: SP (revealed at the start of consultation)
	2	*Start of consultation*: The SP asks for a pack of Fenistil, and after receiving that the SP asks for a pack of Hoggar. *Type of scenario*: medication-based *Person concerned*: SP (revealed upon enquiry)
Langer *et al.* 2016 *et al.* 2018 [38, 39]	1	*Start of consultation*: The SP asks for a pack of loperamide. *Type of scenario*: medication-based *Person concerned*: SP's 74-year-old grandmother (revealed upon enquiry)
	2	*Start of consultation*: The SP asks for a preparation to treat acute diarrhoea. *Type of scenario*: symptom-based *Person concerned*: SP's 74-year-old grandmother (revealed upon enquiry)
Langer *et al.* 2018 [40]	3	*Start of consultation*: The SP asks for a pack of loperamide. *Type of scenario*: medication-based *Person concerned*: SP's 30-year-old partner (revealed upon enquiry)
	4	*Start of consultation*: The SP asks for a preparation to treat acute diarrhoea. *Type of scenario*: symptom-based *Person concerned*: SP's 30-year-old partner (revealed upon enquiry)

Community pharmacies

In 1 paper [36], participation was initially offered to all 872 CPs in the city of Berlin, with no information provided about how the CPs were found. As part of a convenient sampling, in the end, 49 CPs were willing to participate, all of which could be visited. For the study region, this corresponded to a participation rate of about 6%. In the other paper [37], 150 CPs were selected from all 398 CPs in the state of Mecklenburg-Pomerania using random sampling from a list from the state's Regional Chamber of Pharmacists. Due to an erroneous listing, 1 CP was deleted, leaving 149 CPs included. In the end, 146 CPs were visited, with about 37% of the CPs participating.

All CPs received a notification letter with no CP declining to participate. In the other 3 papers [38-40], all 21 CPs in the northern German city of Neubrandenburg in the state of Mecklenburg-Pomerania were selected using total sampling, whereby 2 papers [38, 39] did not provide any details about how the CPs were found while the other paper [40] cited in a footnote the link to an online pharmacy finder used to form the basic population. Because each CP could be visited, for these 3 papers [38-40] the participation rate was 100%. The CPs were not informed beforehand and thus did not have an opportunity to decline participation (no opt-out). The 2 papers with advance notification [36, 37] did not report about the time between the advance information and the visits to the CPs.

Table 4: Use of the simulated patient methodology based on the 5 minor criteria: scenarios, community pharmacies, simulated patients, visits, data collection and performance feedback

	Berger *et al.* 2005 [36]	Alte *et al.* 2007 [37]	Langer *et al.* 2016 *et al.* 2018 [38, 39]	Langer *et al.* 2018 [40]
Scenarios				
Number of scenarios	2	2	4	4
Pre-tests of scenarios	n/s	n/s	Yes	Yes
Community pharmacies (CPs)				
Region of CPs	Berlin (city)	Mecklenburg-pomerania (state)	Neubrandenburg (city)	Neubrandenburg (city)
Number of planned CPs	49	149	21	21
Number of CPs that could not be visited	0	3	0	0
Number of planned CPs that have been replaced	n/a	0	n/a	n/a
Sample size of CPs	49 out of 872	146 out of 398	21 out of 21	21 out of 21
Sampling type of CPs	Convenient	Random	Total	Total
Kind of finding of CPs	n/s	List of Regional Chamber	n/s	Online pharmacy finder
Advance information of CPs	Yes	Yes	No	No
Opt-out for CPs	Yes	Yes	No	No
Time between advance information and visits to CPs	n/s	n/s	n/a	n/a
Simulated patients (SPs)				
Number of SPs	2	6	5	5
Age of SPs	n/s	About 25 y	n/s	n/s
Gender of SPs	n/s	5 women, 1 man	5 women	3 women, 2 men
Social background of SPs	i. a. pharmacy technician	Students in pharmacy	Students in health sciences	Students in health sciences
Training of SPs (SPM)	'Trained'	Yes	Yes	Yes
Training of SPs (nonverbal skills)		Yes	n/s	n/s
Visits				
Number of planned/done visits	49/50	298/292	84/84	84/84
Number of incomplete visits	0	6	0	0
Number of planned visits that have been replaced	n/a	0	n/a	n/a
Visit completion rate	102%	98%	100%	100%
Each of the SPs visited the same CP max. 1 time	Yes	Yes	Yes	Yes
Several different SPs visited the same CP	No	Yes	Yes	Yes
Data collection and performance feedback				
Type of data collection	Written	Written	Written	Written
Time of data collection	Right after visits	Right after visits	Right after visits	Right after visits
Audio for data collection	n/s	n/s	No	No
Second observer for data collection	n/s	n/s	n/s	No
Individual performance feedback immediately after the visit	Yes	No	n/s	n/s
Individual performance feedback after the last visit	Yes	Yes	Yes	Yes
General performance feedback after the last visit	Yes	n/s	Yes	Yes

n/s = not specified; n/a = not applicable

Simulated patients

In 1 paper [36] 2 persons described as 'trained', 1 of which was a pharmacy technician, carried out the role of the SPs. In the other paper [37] 6 pharmacy students (5 women and 1 man) in their final year of study and who were aged about 25 y were used as the SPs. The SPs were briefed and trained to carry out the visits, to complete the assessment forms and in interpersonal skills with licensed pharmacists acting as mock pharmacists. In 2 other papers [38, 39], 5 female Master's students were used as the SPs, who were described in 1 paper [38] as 'untrained', whereas this term was no longer used in the other paper [39]. In these 2 papers [38, 39], the use of the SPs was based on their participation in a student research project in their first year of graduate studies in Health Sciences. The follow-up study [40] used the same selection, whereby 5 students in Health Sciences (3 women and 2 men) were also used as SPs. In 3 papers [38-40], the SPs received practical training by performing pre-tests, although these tests were not described as such.

Visits

In 1 paper [36], starting from 49 planned visits, ultimately 50 visits were successfully performed because 1 CP was visited a second time by a different SP due to the unblinding of the SP. The visit completion rate was accordingly, more than 100%. In the other paper [37] 292 visits were carried out, whereby the number of planned visits of 298 was greater due to CPs that were closed or could not be located. Thus, about 98% of the planned visits were successfully carried out. In the other 3 papers [38-40], 84 visits were planned in each and later successfully carried out, which corresponded to a visit completion rate of 100%. In the end, each of the SPs in all 5 papers visited the same CP a maximum of 1 time. In 4 papers [37-40], however, the same CP was visited by several (different) SPs, while this only applied to 1 of the 49 visited CPs in the other paper [36].

Data collection and performance feedback

Immediately after completing the visit, the data collection in all 5 papers was documented in writing by the SP outside the CPs on an assessment form. 3 papers [38-40] omitted audio recordings and the other 2 papers [36, 37] did not provide any information about this. 1 paper [40] did not use any second observers, while the other 4 papers [36-39] did not provide any information in this regard. In 1 paper [36] the SP entered the CP again immediately after the visit and provided the counsellor with personal, individual performance feedback. Another paper [37] reported that personal, individual performance

feedback immediately after the visit was omitted because the student SPs would probably not have been accepted by the pharmacy staff. In all 5 papers, the CPs received written individual performance feedback after the last visit in the study. In 4 papers [36, 38-40], the CPs also received written general performance feedback for all the participating CPs, whereby 3 papers [38-40] also reported on benchmarking for the CPs with anonymised competitors.

Assessment of the quality of counselling

The 5 included papers each used assessment forms. For this purpose, 3 papers [38-40] based the forms on the tools provided by the Federal Chamber of Pharmacies. The other 2 papers [36, 37] did not provide any information about this. The assessment form used included for scenario 19 and 14 criteria [36], 16 and 6 criteria [37] and 9 [38-40] criteria, respectively. The overall score measured across scenarios for the quality assessment was a mean of 13.8 (SD 9.6) out of 40 points (35%) [37], a mean of 3.3 out of 9 points (37%) [39], a mean of 2.7 out of 9 points (30%) [40] and 277 out of 756 points (37%) [38] In the other paper [36], rather than an overall assessment, a question was asked about the general impression of the professional knowledge and skills using German school grades (1 = very good to 6 = insufficient) and assessed as 2.95 (SD 1.41).

Paper quality

The assessment using the AXIS tool indicated that in some cases, the quality of the papers included differed considerably regarding the individual criteria (table 5). Thus, only 9 out of 20 criteria had a consistently positive assessment. For 11 criteria, at least 1 paper was negatively evaluated. 1 criterion (criterion 12: 'Were the basic data adequately described?') received a negative assessment for 4 out of 5 papers (table 5). For 4 criteria, there were a total of 8 deviations in the evaluation, which could be solved by a consensus of the two reviewers. A "substantial" [41] interrater reliability of κ=0.749 ($p<0.001$) could be measured.

Table 5: Assessment using the criteria in the AXIS tool [26]

		Berger *et al.* 2005 [36]	Alte *et al.* 2007 [37]	Langer *et al.* 2016 *et al.* 2017 [38, 39]	Langer *et al.* 2018 [40]
Introduction					
1	Were the aims/objectives of the study clear?	Yes	Yes	No [38]; Yes [39]	Yes
Methods					
2	Was the study design appropriate for the stated aim(s)?	Yes	Yes	Yes	Yes
3	Was the sample size justified?	No	Yes	Yes	Yes
4	Was the target/reference population clearly defined? (Is it clear who the research was about?)	Yes	Yes	Yes	Yes
5	Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Yes	Yes	Yes	Yes
6	Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	No	No[1]	Yes	Yes
7	Were measures undertaken to address and categorise non-responders?	No	Yes[1]	Yes[1]	Yes[1]
8	Were the risk factor and outcome variables measured appropriate to the aims of the study?	Yes	Yes	Yes	Yes
9	Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialed, piloted or published previously?	No	No	Yes	Yes
10	Is it clear what was used to determining statistical significance and/or precision estimates? (e. g. p-values, confidence intervals)	No	Yes	Yes	Yes
11	Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	No	Yes	Yes	Yes
Results					
12	Were the basic data adequately described?	No[1]	Yes	No[1]	No[1]
13	Does the response rate raise concerns about non-response bias?	Yes	No	No	No
14	If appropriate, was information about non-responders described?	No	Yes[1]	Don't know	Don't know
15	Were the results internally consistent?	Yes	Yes	Yes	Yes
16	Were the results presented for all the analyses described in the methods?	Yes	Yes	Yes	Yes
Discussion					
17	Were the authors' discussions and conclusions justified by the results?	Yes	Yes	Yes	Yes
18	Were the limitations of the study discussed?	No	Yes	Yes	Yes
Other					
19	Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	Yes	Yes	No	No
20	Was ethical approval or consent of participants attained?	Yes	Yes	Don't know [38]; Yes [39]	Yes

No[1]: different evaluations of the two reviewers, solved by consensus, Yes[1]: different evaluations of the two reviewers, solved by consensus

DISCUSSION

Applying the simulated patient methodology

Scenarios

The basis of each SP study is the use of at least 1 previously defined scenario with specific responses to be made by the SPs for the corresponding enquiries by the pharmacy staff. The 5 included papers used between 2 and 4 scenarios. Using scenarios for different indications–as was the case in 2 included papers [36, 37]–better represents routine counselling than scenarios for only 1 indication. The same also applies for a relevant mix of symptom-based and medication-based scenarios [42], as used in all the 5 papers included. The quality of counselling also depends greatly on the use of symptom-based or medication-based scenarios because as a rule, the quality is better for symptom-based scenarios, both in 2 included papers [38, 39] and in the international literature [43, 44]. On the other hand, the question of whether the quality of counselling differs between a scenario with an enquiry made for the SP themselves and a scenario with an enquiry on behalf of a third person indicates a need for future research. This issue should be investigated because to date this was only discussed in 1 included paper [38] and in few

international papers [45, 46] as a possible influencing factor for the quality of counselling.

Regarding the start of the consultation to be defined for a scenario, if the SP discloses less information this means that the quality assessment is more comprehensive and thus more meaningful because the pharmacy staff had to extract more information by making enquiries. Thus, the person concerned was only revealed in 1 scenario in an included paper [37] at the start of the consultation in addition to the stated symptoms. Otherwise, only a request for the medication was made or the symptoms were described in the other 4 papers included [36, 38-40]. However, before the scenarios defined for an SP study are used, they should be tested for their practical functionality to be able to identify any possible weak points in their design and to then eliminate them. It must be recommended here that corresponding pre-tests be conducted outside the planned study region so that, particularly for a covert study design, the covert nature of the study is not jeopardised. Carrying out such pre-tests was reported by 3 included papers [38-40] analogous to international papers [47, 48].

Community pharmacies

Which CPs participated in an SP study depended on the possibility of locating the CPs. The basis for this was ideally a list maintained by the particular regional chamber of pharmacists that is made freely available to the public. However, such lists are not publicly available for all German states. But they can now be generated across Germany using databases available online. Because only 2 included papers [37, 40] reported using a list, more comprehensive reporting would be desirable for future SP studies. To test how up to date the CPs identified using such a search are, an online search (e. g. using Google) and a final covert call to the CPs is recommended, although not a single included paper reported about this. Such a procedure enables identification of whether the CPs are currently in operation and when they are open. This thus reduces the risk that CPs–as in 1 included paper [37] and in international papers [49-51] are closed or cannot be located.

Whether the CPs should be informed in advance is viewed differently internationally. For example, it is cited in favour of informing the CPs in advance that the quality of counselling increases if they are aware of the pending visits and a higher quality of counselling then becomes routine [42]. In addition, it is only by means of advance information with an additional opt-out–as was the case in 2 included papers [36, 37]–that informed consent can be obtained [14]. However, the opt-out generally leads to a selection bias that becomes greater the more CPs refuse to participate [52]. Advance information is also associated with a Hawthorne effect [13] and thus a distorted assessment of the quality of counselling [52]. This effect, which suggests that the quality of counselling of the CPs being visited increases because of the advance information, possibly resulting in a counselling situation that does not reflect real life, is generally larger the shorter the time between the advance information and the visits. Both 3 included papers [38-40] and 1 international paper [53] attempted to resolve this dilemma by carrying out the visits–as suggested internationally [54]–without informing the CPs beforehand but informing the CPs after the visits that they had been carried out. Other international papers planned a longer interval of several months to up to 1 y between the advance information and the visits [47, 48, 55]. These 2 variations appear to be a good compromise between the need to inform the CPs on the one hand and the requirements for the least possible distortion to the quality assessment on the other.

Simulated patients

In order to visit the selected CPs using a scenario, at least one SP is required. It must be ensured that not too few (generalisability) and not too many SPs (standard disability) are used [16], with between 2 and 6 SPs used in the 5 included papers and considerably more SPs used in the international papers [14]. The age–which was only reported by 1 included paper [37]–and gender of the SPs depends on the scenario. For example, when describing their symptoms during menopause the SPs should be female and of an age typical for such an indication. A 'typical' selection of SPs corresponding to the scenario ensures a counselling situation that reflects real life as far as possible. In contrast, an atypical selection of SPs for a scenario (e. g. an enquiry for the morning after pill for the partner by male SPs) enables an investigation of the quality of counselling for specific counselling situations [56].

It must also be recommended that particularly those SPs who are unfamiliar with the SPM complete training before starting the visits to familiarise themselves with the theoretical and practical requirements of the SPM. Carrying out pre-tests serves as practical training of the SPs as well as verifying the functionality of the collection form and the scenarios. Whether training of non-verbal skills is also necessary should be decided based on each scenario. This could be useful to non-verbalize as authentically as possible when, for example, the SP indicates that they are in pain. Only 1 included paper [37] provided concrete information about the different forms of training of the SPs. The extent and content of such training can vary considerably [14] and can range, for example, from paper manual training, interactive web-based training to mock mystery shopping training with feedback.

Further research is needed on whether experts or non-experts should be used as SPs. In a recent SP systematic review, it was shown–analogous to 4 of the included papers [37-40]–that internationally, non-experts are predominantly used as SPs [14]. According to Haller the use of professional SPs or specialist pharmaceutical personnel–as reported by 1 included paper [36] or in the internal pharmacy SP studies by the German chambers of pharmacists [33-35]–is discouraged because these persons may have different benchmarks than the average customer would [57]. Ultimately, the SPs should have reasonable intelligence and emotional maturity as well as being trustworthy [16] to not have to exclude the data due to concerns about their correctness, which was not the case in any of the included papers but was so in 1 international paper [58].

Visits

A consultation lacking in authenticity–possibly also reinforced by informing the CPs too recently in advance–could be the reason why visits are detected by the pharmacy staff, as was the case in 1 included paper [36] and 1 international paper [58]. The risk of detection would then also be greater if the same SP repeatedly visits the same CP either with several scenarios or the same scenario in an attempt to increase the validity of the quality assessment. Therefore, it must be recommended that a CP is only visited once at most by the same SP, as was the case in all 5 included papers and in the international literature [42, 58]. It must also be ensured, particularly for several visits using the same scenario, that the (different) SPs carry out the visits with a certain interval between to avoid detection.

If visits that are detected by the pharmacy staff are excluded from the data analysis and are also not repeated or replaced, this leads to a difference between the planned and successfully carried out visits as do other causes such as concerns about the correctness of the data that is usually documented by the SPs [58] or CPs that are closed or cannot be located [59]. This difference is defined as the visit completion rate and was below 100% in only 1 included paper with a value of 98% [37]; in some international papers, the rate was as low as 91% [58] and 82% [59]. Because the visit completion rate can also affect the quality assessment of the study, it should, therefore, always be reported analogously to the response rate in self-reported questionnaires [14]. While this was implemented by all the included papers, this information was missing in some international papers [14].

Data collection and performance feedback

The data for the completed visits must then be appropriately collected. In this regard, it must be recommended that the SPs themselves document the data immediately after completing the visits, as was the case in all 5 included papers, to reduce distortions in the quality assessment due to potentially missing or erroneously recalled information [15]. Instead of documenting the data in writing in the first place, as was the case in all 5 included papers, the data could immediately be entered digitally for the analysis to save resources and avoid error-prone transfer from the written

documentation and the subsequent digitalisation. For quality assurance, the data could be supplemented with audio recordings [60] or by a second observer accompanying the SP [61] and thus recall bias could be avoided or at least reduced, although this was either not considered or not reported in the 5 included papers. Because audio recordings, at least in Germany, always require the consent of the person being recorded and therefore the person must always be informed [62], they do not suit a covert study design, at least with a short notification interval, and usually create a selection bias due to a possible opt-out. The use of 1 or more second observers requires additional human resources. It must also be ensured that this person, who may be distracting for the pharmacy staff, does not lead to the detection of the visit.

With a view to the effectiveness, we recommend providing any individual performance feedback immediately after the visit because the pharmacy staff's memory of the counselling they provided is best then [15]. However, this procedure, which was carried out by 1 included paper [36], is not useful with repeated visits to the same CP and the aim of making the most objective assessment possible of the quality of counselling. The reason is that short-term sensitisation of the pharmacy staff cannot be ruled out as a result of providing repeated immediate individual performance feedback, which in turn could lead to distortions in the quality assessment for subsequent visits. Therefore, in such cases, the individual performance feedback should only be provided after the final visit in an SP study. This procedure, which was implemented by all 5 included papers, would not be necessary if the objective was to sensitise the pharmacy staff to a high quality of counselling by making repeated visits to the same CPs [42] with subsequent feedback loops–taking into account any possible familiarisation effect [63]. The individual performance feedback after the final visit is even more effective if it is supplemented by general performance feedback, as was the case in 4 included papers [36, 38-40]. Ideally, this should then be supplemented by benchmarking, as was the case in 3 included papers [38-40] whereby the CPs were informed about their competitors' position.

In order to ensure the effectiveness of personal individual performance feedback, it should be given by a person accepted by the pharmacy staff (e. g. a pharmacist) due to the possible problem of acceptance of, for example, students [37]. Whether individual performance feedback leads to an improvement in the quality of counselling should be reviewed in a follow-up study, as had already been carried out in 1 included paper [40] as well as in international papers [42, 64, 65]. However, feedback as a form of intervention proved to be ineffective, not only in 1 included paper [40] but also for certain indications (e. g. acute diarrhoea) in an international follow-up study [42]. Because SP studies conducted internally by pharmacies in Germany also use feedback as an instrument for quality improvement [33-35], these study results raise the question of whether such measures are effective. Presumably, considerably more powerful interventions (e. g. training) are required to improve the quality of counselling [64, 65]. Regarding successful interventions, future SP studies should pose the question of how sustainable the improvements achieved in this way are, that is, how does the quality of counselling change once the intervention measures are discontinued.

Assessment of the quality of counselling

For the assessment of the quality of counselling, an appropriate assessment form is required. However, a suitable assessment form must first be developed using the tools provided by the Federal Chamber of Pharmacies, as was done in 3 included papers [38-40]. As a supplement to the tools, standardised assessment forms, which have not been available in Germany to date, could be developed which would enable better comparisons of the quality assessment. Regarding the design of the assessment form, the number of criteria should not be greater than necessary, with 1 included paper [36] using up to 19 criteria. Because of the large number of criteria, there is a risk of recall bias for the data being documented if the data collection is based solely on the memory protocol of the SP and is not supported by additional audio recordings or the use of a second observer.

The quality of counselling was assessed in all 5 included papers as being rather poor. These results are congruent with those from the covert SP studies conducted by Stiftung Warentest (excluded from this systematic review because of inadequately transparent information about the methodology) [29-32], an independent German consumer organisation. In stark contrast to this, predominantly good to very good results were reported in SP studies that were conducted by the regional chambers of pharmacists (also excluded from this systematic review because of inadequately transparent information about the methodology) [33-35]. This leads to the general question of whether the SP studies organised by the various chambers, as maintained by the professional associations, actually ensure the greatest possible degree of objectivity and neutrality [33-35] or whether there is rather a conflict of interest if there are institutional links between the object of the study and the client that commissioned the study. Positive results were also reported in an older questionnaire-based study, but this study is prone to a social desirability bias and a Hawthorne effect [66].

The rather poor assessment of the quality of counselling in the included papers should make both the Federal Union of German Associations of Pharmacists (ABDA) and legislators aware that they must greatly intensify their previous quality management efforts. In this context, as part of the pharmacy degree (pharmacist) or professional training (pharmaceutical technical assistant), patient consultations should therefore be more intensively trained. Mandatory continuing education would also be a possible option for improvement. Another option would be to expand the use of checklists [67], which in Germany are only currently used for counselling on the morning after pill. Finally, regular, independent reviews with an appropriate sanction mechanism could also be considered to provide the necessary stimulus to sustainably increase the quality of counselling [45].

Strengths and limitations of the review

As far as the authors are aware this is the first review that has systematically investigated the use of the SPM for assessing the quality of counselling in German CPs. Another strength is that the literature search was conducted using a high number of English terms. Because many synonyms for the term 'simulated patient' are used in the literature, however, it is possible that potential search terms were not considered. In addition, the aim of presenting the current status of the object of investigation is not compatible with the possibility of also finding papers that were published before 2005. Forward snowballing was not carried out, which also may have led to additional relevant papers being identified [24]. For the reasons indicated, it is possible that there is a publication bias in the search results. The search results may also have a language bias because we only searched for papers that were published in German or English.

Distortions in the study results for this systematic review also cannot be ruled out. Thus, for the procedure for the data extraction, only the reporting of the papers was significant. In addition, only 2 reviewers were involved in the study. Furthermore, only 23 records could be identified and only 5 papers could be included. On the other hand, few identified records [68, 69] and very few [70-74] or no [75, 76] included studies are not unusual in systematic reviews. Also, the included papers have a relatively low level of evidence (CS design) and moreover 1 paper [36] used only a small convenient sample of a major city and 3 papers [38-40] are only representatives of a medium-sized city. For these reasons, the present study results should be interpreted with caution.

CONCLUSION

Only an extremely small number of papers, unlike other countries, could be included for Germany and all of them were conducted in north-eastern Germany. More SP studies that are conducted in other regions in Germany are therefore urgently required. The included papers demonstrate that the quality of counselling in the CPs that were investigated with an SPM approach showed a considerable need for improvement. In addition, the deficits identified here for the use of the SPM should be avoided in future papers. It is also recommended that the SPM be reported in future papers using uniform reporting standards that must be developed to ensure greater ease of comparison.

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AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICTS OF INTERESTS

The authors declare no conflict of interest.

REFERENCES

1. Martins SF, Van Mil JF, da Costa FA. The organizational framework of community pharmacies in Europe. Int J Clin Pharm 2015;37:896-905.
2. AMG–Medicinal products act in the version of the notification of 12 December 2005 (Federal Law Gazette I, p. 3394), last amended by Article 0 of the Act dated 22 March 2020 (Federal Law Gazette I, p. 604); 2020. Available from: https://www.gesetze-im-internet.de/amg_1976/AMG.pdf. [Last accessed on 14 Apr 2020]
3. AMVerkRV–Regulation about pharmacy-only and over-the-counter medicinal products dated 24 November 1988 (Federal Law Gazette I, p. 2150), last amended by Article 2 of the Regulation dated 26 September 2018 (Federal Law Gazette I, p. 1386); 2020. Available from: https://www.gesetze-im-internet.de/amverkrv/AMVerkRV.pdf. [Last accessed on 14 Apr 2020]
4. BAH–German Association of Medicinal Product Manufacturers. The medicinal product market in Germany; 2019. Available from: https://www.bah-bonn.de/bah/?type=565andfile=redakteur_filesystem%2Fpublic%2FBah_Zahlenbroschuer_042019_WEB.pdf. [Last accessed on 14 Apr 2020]
5. German Federal Statistical Office. GENESIS online database; 2020. Available from: https://www-genesis.destatis.de/genesis/online/data?operation=previousandlevelindex=2andstep=2andtitel=Ergebnisandlevelid=1582578734872andacceptscookies=false. [Last accessed on 31 Jan 2020]
6. ABDA–Federal Union of German Associations of Pharmacists. The pharmacy–fig.–Data–Facts 2019; 2019. Available from: https://www.abda.de/fileadmin/user_upload/assets/ZDF/ZDF_2019/ABDA_ZDF_2019_Brosch.pdf. [Last accessed on 14 Apr 2020]
7. ApBetrO–Ordinance on the Operation of Pharmacies in Germany dated 26 September 1995 (Federal Law Gazette I, p. 1195), last amended by Article 2 of the Act dated 13 January 2020 (Federal Law Gazette I, p. 66); 2020. Available from: https://www.gesetze-im-internet.de/apobetro_1987/ApBetrO.pdf. [Last accessed on 14 Apr 2020]
8. BAK–Federal Chamber of Pharmacies. Guidelines and tools; 2020. Available from: https://www.abda.de/fuer-apotheker/qualitaetssicherung/leitlinien/leitlinien-und-arbeitshilfen/. [Last accessed on 14 Apr 2020]
9. Anon. Test purchases: Advise well, dispense very well; 2015. Available from: http://www.apotheke-adhoc.de/nachrichten/apothekenpraxis/nachricht-detail-apothekenpraxis/nrw-kammern-werten-15000-testkaeufe-aus/. [Last accessed on 14 Apr 2020]
10. Driscoll DL. Introduction to primary research. In: Lowe C, Zemliansky P, editors. Writing spaces: Readings on writing. Vol. 2. Anderson, South Carolina: Parlor Press; 2011. p. 153-74.
11. Converse L, Barrett K, Rich E, Reschovsky J. Methods of observing variations in physicians' decisions: the opportunities of clinical vignettes. J Gen Intern Med 2015;30 Suppl 3:586-94.
12. Callegaro M. Social desirability. In: Lavrakas PJ. editor. Encyclopedia of survey research methods. Vol 1-0. Thousand Oaks, CA: Sage Publications, Inc.; 2008. p. 825-6.
13. McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects. J Clin Epidemiol 2014;67:267-77.
14. Björnsdottir I, Granas AG, Bradley A, Norris P. A systematic review of the use of simulated patient methodology in pharmacy practice research from 2006 to 2016. Int J Pharm Pract 2020;28:13-25.
15. Xu T, de Almeida Neto AC, Moles RJ. A systematic review of simulated-patient methods used in community pharmacy to assess the provision of non-prescription medicines. Int J Pharm Pract 2012;20:307-19.
16. Watson MC, Norris P, Granas AG. A systematic review of the use of simulated patients and pharmacy practice research. Int J Pharm Pract 2006;14:83-93.
17. Caamaño F, Ruano A, Figueiras A, Gestal Otero JJ. Data collection methods for analyzing the quality of the dispensing in pharmacies. Pharm World Sci 2002;24:217-23.
18. Puspitasari HP, Aslani P, Krass I. A review of counseling practices on prescription medicines in community pharmacies. Res Soc Adm Pharm 2009;5:197-210.
19. Bardage C, Westerlund T, Barzi S, Bernsten C. Non-prescription medicines for pain and fever--A comparison of recommendations and counseling from staff in pharmacy and general sales stores. Health Policy 2013;110:76-83.
20. Atkinson J. Heterogeneity of pharmacy education in Europe. Pharmacy 2014;2:231-43.
21. OECD. Health at a glance 2019: OECD indicators. Paris: OECD Publishing; 2020.
22. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009;6:e1000097.
23. Pieper D, Mathes T, Palm R, Hoffmann F. How do authors of systematic reviews restrict their literature searches, when only studies from germany should be included? Z Evid Fortbild Qual Gesundhwes 2016;117:1-8.
24. Wohlin C. Guidelines for snowballing in systematic literature studies and a replication in software engineering. In: Association for computing machinery. editor. Proceedings of the 18th International Conference on Evaluation and Assessment in Software Engineering (EASE '14). New York, NY, USA; 2014. p. 1-10.
25. CRD–Centre for reviews and dissemination. Systematic Reviews. CRD's guidance for undertaking reviews in health care, CRD, University of York, Layerthorpe; 2009. Available from: https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf. [Last accessed on 14 Apr 2020]
26. Downes MJ, Brennan ML, Williams HC, Dean RS. Development of a critical appraisal tool to assess the quality of cross-sectional studies (AXIS). Br Med J Open 2016;6:e011458.
27. Cohen J. A coefficient of agreement for nominal scales. Educ Psychol Meas 1960;20:37-46.
28. DtGV–Deutsche Gesellschaft für Verbraucherstudien mbH. [German association for consumer studies] Pharmacy Study 2012: Audit of the quality of service 09/2012, Berlin, DtGV; 2012. Available from: https://www.dtgv.de/wp-content/uploads/sites/4/2012/10/120910_DtGV-Test-Apothekenkooperationen_2012_kurz.pdf. [Last accessed on 14 Apr 2020]
29. Stiftung Warentest. Mehr schlecht als recht. [More bad than good.] test; 2004. p. 91-100.
30. Stiftung Warentest. Falsch beraten. [Bad advice.] test; 2008. p. 84-9.
31. Stiftung Warentest. Bittere Pillen. [Bitter pills.] test; 2010. p. 80-91.
32. Stiftung Warentest. Mit Risiken und Nebenwirkungen. [With risks and side effects.] test; 2014. p. 88-97.
33. Berger K, Sauerwein C, Schulz M. Venöse Insuffizienz. Evidenzbasierte Beratung in Apotheken. [Venous insufficiency. Evidence-based advice in pharmacies.] Pharm Ztg 2005;150:4580-1.
34. Berger K, Sauerwein C, Schulz M. Pseudo-Customer-Konzept. Verbesserung der Beratung in Sachsen. [Pseudo-customer concept. Improvement of consulting in Saxony.] Pharm Ztg 2007;152:3972-4.
35. Eickhoff C, Berger K, Wind S, Schulz M. Beratungschecks. Unangekündigter Besuch. [Consulting checks. Unannounced visit.] Pharm Ztg 2005;150:3294-5.
36. Berger K, Eickhoff C, Schulz M. Counselling quality in community pharmacies: implementation of the pseudo customer methodology in germany. J Clin Pharm Ther 2005;30:45-57.
37. Alte D, Weitschies W, Ritter CA. Evaluation of consultation in community pharmacies with mystery shoppers. Ann Pharmacother 2007;41:1023-30.

38. Langer B, Bull E, Burgsthaler T, Glawe J, Schwobeda M, Simon K. Using the simulated patient methodology to assess counselling for acute diarrhoea-evidence from Germany. Z Evid Fortbild Qual Gesundhwes 2016;112:19-26.
39. Langer B, Bull E, Burgsthaler T, Glawe J, Schwobeda M, Simon K. Assessment of counselling for acute diarrhoea in german pharmacies: a simulated patient study. Int J Pharm Pract 2018;26:310-7.
40. Langer B, Kieper M, Laube S, Schramm J, Weber S, Werwath A. Assessment of counselling for acute diarrhoea in North-Eastern german pharmacies–a follow-up study using the simulated patient methodology. Pharmacol Pharm 2018;9:257-69.
41. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics 1977;33:159-74.
42. Collins JC, Schneider CR, Naughtin CL, Wilson F, de Almeida Neto AC, Moles RJ. Mystery shopping and coaching as a form of audit and feedback to improve community pharmacy management of non-prescription medicine requests: an intervention study. Br Med J Open 2017;7:e019462.
43. Horvath N, Koder M, Kos M. Using the simulated patient methodology to assess paracetamol-related counselling for headache. PLoS One 2013;7:e52510.
44. Watson MC, Bond CM, Grimshaw J, Johnston M. Factors predicting the guideline compliant supply (or non-supply) of non-prescription medicines in the community pharmacy setting. Qual Saf Health Care 2006;15:53-7.
45. Chowdhury F, Sturm Ramirez K, Mamun AA, Al Mamun A, Iuliano AD, Chisti MJ, *et al.* Effectiveness of an educational intervention to improve antibiotic dispensing practices for acute respiratory illness among drug sellers in pharmacies, a pilot study in Bangladesh. BMC Health Serv Res 2018;18:676.
46. Morris CJ, Cantrill JA, Weiss MC. 'One simple question should be enough': consumers' perceptions of pharmacy protocols. Int J Pharm Pract 1997;5:64-71.
47. Mobark DM, Al-Tabakha MM, Hasan S. Assessing hormonal contraceptive dispensing and counseling provided by community pharmacists in the United Arab Emirates: a simulated patient study. Pharm Pract (Granada) 2019;17:1465.
48. da Rocha CE, Bispo ML, dos Santos AC, Mesquita AR, Brito GC, de Lyra Jr DP. Assessment of community pharmacists' counseling practices with simulated patients who have minor illness: a pilot study. Simul Healthc 2015;10:227-38.
49. Brata C, Marjadi B, Schneider CR, Murray K, Clifford RM. Information-gathering for self-medication via Eastern Indonesian community pharmacies: a cross-sectional study. BMC Health Serv Res 2015;15:8.
50. Zawahir S, Lekamwasam S, Aslani P. Community pharmacy staff's response to symptoms of common infections: a pseudo-patient study. Antimicrob Resist Infect Control 2019;8:60.
51. Khojah HMJ, Abdalla AME. Do community pharmacies in Saudi Arabia provide medication-related information to nonbuyers? A Mysterious Shopper Survey Pharmacol Pharm 2019;10:169-76.
52. Rhodes KV, Miller FG. Simulated patient studies: an ethical analysis. Milbank Q 2012;90:706-24.
53. Ibrahim MIM, Awaisu A, Palaian S, Radoui A, Atwa H. Do community pharmacists in qatar manage acute respiratory conditions rationally? A simulated client study. J Pharm Health Serv Res 2018;9:33-9.
54. Fitzpatrick A, Tumlinson K. Strategies for optimal implementation of simulated clients for measuring quality of care in low-and middle-income countries. Glob Health Sci Pract 2017;5:108-14.
55. Kayshap KC, Nissen LM, Smith SS, Kyle G. Management of over-the-counter insomnia complaints in Australian community pharmacies: a standardized patient study. Int J Pharm Pract 2014;22:125-34.
56. Bell DL, Camacho EJ, Velasquez AB. Male access to emergency contraception in pharmacies: a mystery shopper survey. Contraception 2014;90:413-5.
57. Haller S. Beurteilung von Dienstleistungsqualität. Dynamische Betrachtung des Qualitätsurteils im Weiterbildungsbereich [Evaluation of service quality. Dynamic approach to quality evaluation in the continuing education sector.]. 2nd ed. Wiesbaden: Deutscher Universitäts-Verlag; 1998.
58. Watson MC, Skelton JR, Bond CM, Croft P, Wiskin CM, Grimshaw JM, *et al.* Simulated patients in the community pharmacy setting–Using simulated patients to measure practice in the community pharmacy setting. Pharm World Sci 2004;26:32-7.
59. Diwan V, Sabde YD, Byström E, de Costa A. Treatment of pediatric diarrhea: a simulated client study at private pharmacies of Ujjain, Madhya Pradesh, India. J Infect Dev Ctries 2015;9:505-11.
60. Werner JB, Benrimoj SI. Audio taping simulated patient encounters in community pharmacy to enhance the reliability of assessments. Am J Pharm Educ 2008;72:136.
61. Yaacoub SG, Lahoud NA, Francis NJ, Rahme DW, Murr TH, Maison PF, et al. Antibiotic prescribing rate in lebanese community pharmacies: a nationwide patient-simulated study of acute bacterial rhinosinusitis. J Epidemiol Glob Health 2019;9:44-9.
62. StGB–German criminal code in the version of the notification of 13 November 1998 (Federal Law Gazette I, p. 3322), last amended by Article 1 of the Act dated 3 March 2020 (Federal Law Gazette I, p. 431); 2020. Available from: https://www.gesetze-im-internet.de/stgb/StGB.pdf. [Last accessed on 14 Apr 2020]
63. Mesquita AR, Lyra Jr DP, Brito GC, Balisa Rocha BJ, Aguiar PM, de Almeida Neto AC. Developing communication skills in pharmacy: a systematic review of the use of simulated patient methods. Patient Educ Couns 2010;78:143-8.
64. Watson MC, Cleland J, Inch J, Bond CM, Francis J. Theory-based communication skills training for medicine counter assistants to improve consultations for non-prescription medicines. Med Educ 2007;41:450-9.
65. Gastelurrutia MA, Larranaga B, Garay A, de Asis Echeveste F, Fernandez-Llimos F. Impact of a program to reduce the dispensing of antibiotics without a prescription in spain. Pharm Pract (Granada) 2013;11:185-90.
66. Krishnan HS, Schaefer M. Evaluation of the impact of pharmacist's advice giving on the outcomes of self-medication in patients suffering from dyspepsia. Pharm World Sci 2000;22:102-8.
67. Chong WW, Aslani P, Chen TF. Adherence to antidepressant medications: an evaluation of community pharmacists' counseling practices. Patient Prefer Adherence 2013;7:813-25.
68. Pan B, Lazarus HM, Gale RP. Microtransplantation for acute myeloid leukemia: a systematic review. JAMA Oncol 2020;6:1614-20.
69. Maida M, Camilleri S, Manganaro M, Garufi S, Scarpulla G. Radiofrequency ablation for treatment of refractory gastric antral vascular ectasia: a systematic review of the literature. Gastroenterol Res Pract 2017;2017:5609647.
70. Osman MT. Nigella sativa has beneficial effect on osteoporosis and bone healing: Is it a fact or fiction? A systematic review. Asian J Pharm Clin Res 2017;10:41-6.
71. Mappangara S, Basir I, Oktawati S, Adam M, Achmad H. Periodontal disease associated with corticosteroid in asthma patients-A systematic review. Int J Appl Pharm 2019;11:68-70.
72. Prabakar J, John J, Arumugham M, Kumar P. Go natural, say no to chemicals-a systematic review on effectiveness of green tea extract containing formulations on dental caries. Asian J Pharm Clin Res 2019;12:63-9.
73. Fahira A, Soraya A, Achmadsyah A, Hakim RW. Efficacy and safety of curcuma longa extract in the treatment of osteoarthritis: a systematic review. Int J Appl Pharm 2019;11:140-5.
74. Permaisuari N, Rahmawati NA, Nusanti S, Thamrin H. Efficacy of high-dose intravenous steroid treatment in methanol-induced optic neuropathy: a systematic review. Int J Appl Pharm 2019;11:97-100.
75. Campillo ISL, Meaney S, McNamara K, O'Donoghue K. Psychological and support interventions to reduce levels of stress, anxiety or depression on women's subsequent pregnancy with a history of miscarriage: an empty systematic review. Br Med J Open 2017;7:e017802.
76. Alajaji WA, Akl EA, Farha A, Jaber WA, AlJaroudi WA. Surgical versus medical management of patients with acute ischemic mitral regurgitation: a systematic review. BMC Res Notes 2015;8:712