Do north-eastern German pharmacies recommend a necessary medical consultation for acute diarrhoea? Magnitude and determinants using a simulated patient approach [version 1; peer review: 1 approved, 2 approved with reservations]

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Abstract

Background: To determine if pharmacy staff in Germany referred patients to a medical consultation for a scenario in which consulting a doctor was mandatory ('appropriate outcome') and what the quality of questioning and – if a medication was dispensed – the quality of information provided were in this context. Moreover, to determine which factors predicted a necessary referral to a doctor.

Methods: A cross-sectional covert simulated patient study was conducted in a random sample of community pharmacies stratified by location in the German state of Mecklenburg-Vorpommern. Each pharmacy was visited once by one of four trained investigators. They simulated a symptom-based request involving a grandmother with acute diarrhoea. A multivariate binary logistic regression analysis using potential variables from bivariate analysis was carried out to determine the predictors for a referral to a doctor.

Results: All 199 planned visits were conducted. A necessary referral to a doctor was recommended in 59.8% (n=119) of all test purchases. Multivariate analysis revealed that a non-pharmacist as opposed to a pharmacist and two or more questions as opposed to no questions were significantly associated with a referral to a doctor.

Conclusions: Regarding the necessary referral to a doctor, an enormous potential for improvement was revealed for community pharmacies in the German state of Mecklenburg-Vorpommern. The results should make both the Mecklenburg-Vorpommern pharmacy association and legislators aware of the need to significantly escalate their quality management efforts.

Keywords
Non-prescription drugs, Community pharmacies, Consultation, Patient simulation, Diarrhoea, Germany
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Author roles: Langer B: Conceptualization, Data Curation, Formal Analysis, Methodology, Project Administration, Validation, Visualization, Writing – Original Draft Preparation; Kunow C: Writing – Review & Editing

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Introduction

Acute diarrhoea is one of the most common diseases worldwide\textsuperscript{1}, including in Germany\textsuperscript{2}. While worldwide about 1 billion people develop acute diarrhoea each year\textsuperscript{1}, causing about 2 billion cases of acute diarrhoea\textsuperscript{1}, about 30\% of the German population suffer from acute diarrhoea episodes each year\textsuperscript{1}. Because those affected report becoming ill on average 1.7 times per year\textsuperscript{1}, this means that about 42 million cases of acute diarrhoea can therefore be expected in Germany.

According to the guidelines of the German Society of General Medicine and Family Medicine, acute diarrhoea is an imbalance between secretion and absorption in the bowels, whereby the symptoms last fewer than 14 days and are associated with an increased frequency (≥ three loose stools in a day) or an increased water content (≥ 75\%) or an increased stool weight (≥ 250 g)\textsuperscript{1}.

Acute diarrhoea may be a result of infections with viruses (for example, noroviruses or rotaviruses), bacteria (for example, non-typhoidal Salmonella or diarrheagenic Escherichia coli) or parasites (for example, Cryptosporidium parvum)\textsuperscript{3}. More than 90\% of cases result from infections, with viral infections being the most common cause\textsuperscript{4}. Bacterial infections on the other hand are more often associated with travel, food poisoning and comorbidities. Medications (e.g. antibiotics, cytostatics, diuretics), gastroenterologic disorders (e.g. ulcerative colitis, Crohn's disease), endocrine disorders (e.g. hyperthyroidism, adrenocortical insufficiency) or other medical conditions (e.g. amyloidosis) can also trigger acute diarrhoea\textsuperscript{1}.

In Germany there is no medical consultation in about two-thirds of cases of acute diarrhoea\textsuperscript{1}. Therefore, advice should be provided by the pharmacy, not least because of the wide range of possible causes, when the diarrhoea is self-mediated with over-the-counter (OTC) medications only available from pharmacies in Germany. As part of a high quality consultation, pharmacy staff should also identify when it is necessary to refer a patient to a medical consultation based on the symptoms\textsuperscript{5}. In Germany, in addition to pharmacists, pharmacy technicians and pharmaceutical technical assistants are also permitted to advise on and sell medications but only under the supervision of pharmacists.

Although studies available from Germany regarding the quality of advice provided in pharmacies reveal significant deficits, analogous to the international literature\textsuperscript{6-12}, indications other than acute diarrhoea in adults are usually investigated in scientific\textsuperscript{13,14} and non-scientific studies\textsuperscript{15-19}. The quality of advice provided for acute diarrhoea in adults was analysed for Germany for the first time in 2014 and also identified clear deficiencies\textsuperscript{20}. Despite performance feedback used in the process, a follow-up study identical to that conducted in 2014 was carried out for the first time in Germany in 2017 and also showed poor quality of advice\textsuperscript{21,22}. All the above mentioned studies have in common that they are based on the simulated patient (SP) method to determine the quality of advice provided. In this method test persons simulate participation in an apparently real service provision process to subsequently evaluate the process and reveal any deficiencies as a result\textsuperscript{23}.

In the baseline study in 2014 (as well as the follow-up study in 2017) the four scenarios investigated were designed as ‘moderate’ in that none of the scenarios predicted referral to a medical consultation by the pharmacy staff as an ‘appropriate outcome’. Both studies also investigated only the quality of advice in 21 pharmacies in a medium-sized northern German city (a total of 84 test purchases for each study).

The aim of this study was, therefore, to determine on the basis of a considerably larger number of pharmacies whether the pharmacy staff referred patients to a medical consultation for a scenario in which consulting a doctor was mandatory (‘appropriate outcome’) and what the quality of questioning and – if a medication was dispensed – the quality of information provided were in this context. Factors influencing the ‘appropriate outcome’ were also determined analogous to other national and international studies\textsuperscript{24-27}.

Methods

Design

A cross-sectional study design was chosen in accordance with the ‘STROBE Statement – Checklist of items that should be included in reports of cross-sectional studies’\textsuperscript{28} and, to determine the quality of advice provided in the pharmacies investigated, based on the highly recommended\textsuperscript{29} SP method that is often used internationally\textsuperscript{23,30-35} as a form of participatory observation\textsuperscript{34}.

Setting and participation

Because of time constraints of the SPs, the test purchases took place over winter between 1 November and 15 December 2018 in the German state of Mecklenburg-Vorpommern (31 December 2017: approx. 1.61 million residents, 23,214 km\textsuperscript{2} area, low population density of 69.4 residents/km\textsuperscript{2})\textsuperscript{36}. Upon request by telephone, the Pharmacy Association of Mecklenburg-Vorpommern did not want to provide a list of all registered community pharmacies in the state. Consequently, these pharmacies were identified using the pharmacy finder of the website Apotheken-Umschau.de\textsuperscript{37}. All community pharmacies that had a postcode in the state of Mecklenburg-Vorpommern on the reference date of 1 October 2018 using the postcode search of the pharmacy finder were included in the study. These hits were validated with a corresponding Google search. As a result, a basic population of N=396 pharmacies was determined. A comparison with the last available information from the German Federal Chamber of Pharmacists (ABDA) for the end of 2018 regarding the total number of pharmacies in Mecklenburg-Vorpommern\textsuperscript{37} showed a 99\% agreement. The minimum necessary sample size (n) was determined for a population size (N) of 396 and an error margin (e) of 0.05 using the following formula, which is based on a degree of variability of P=0.5 and a 95\% confidence interval\textsuperscript{38}:

\[
n = \frac{N \cdot \sqrt{1+N(e^2)}}{1+396(0.05)^2} = 396 \cdot 1.99 = 198.99
\]

In Germany there are no studies yet on a necessary referral to a doctor for acute diarrhoea by community pharmacies. Therefore, the degree of variability is unknown. The assumed degree
of variability of P=0.5 maximises the required sample size. The 396 pharmacies were stratified by location of the pharmacy as an indicator for urban/rural and assigned a random number using the MS Excel random number generator and then a simple random sampling was performed in each stratum to select the 199 participating pharmacies.

Scenarios and assessments

The Ordinance on the Operation of Pharmacies in Germany includes an obligation for pharmacies to introduce a quality management system. The aim is to ensure a preferably adequate advice outcome”. To ensure that this can be achieved, the Federal Chamber of Pharmacists has drafted various guidelines and tools, including the tool ‘Information and advice as part of self-medication using the example of self-diagnosis of diarrhoea”16. This forms the basis of the symptom-based test scenario developed (Table 1) and the evaluation form used (see the assessment items in Table 4). The recommendation to consult a doctor by pharmacy staff is defined as the appropriate outcome and the test scenario was also designed according to this. Diarrhoea being present for five days as well as a high fever (40°C) are both considered to exceed the limits of self-medication according to the tool. The evaluation form includes a total of eleven items with the first six items evaluating whether appropriate questions were asked. On this basis the pharmacy staff should then decide whether to recommend that the patient consult a doctor (item seven). Because the tool also considers ‘dispensing a medication in an appropriate quantity up to referring to a doctor’ within the discretionary powers of the pharmacy staff, also in the case of the limits of self-medication being exceeded and the necessary referral to consult a doctor, items eight to eleven evaluate whether a medication was dispensed and whether in the process information on the dosage, duration and side effects was provided.

Only objective items were used in order to avoid a subjective assessment and thus latitude in the evaluation by the SPs (for example, on the friendliness of the pharmacy staff). Therefore, to complete the individual items only dichotomous scales were used (closed yes/no questions). To avoid the Hawthorne effect22 and to ensure a realistic consultation situation, the test purchases took place without first informing the pharmacies included in the random sample in accordance with other national20,21 and international22-24 studies.

Data collection

As part of their three-semester research project at the Neubrandenburg University of Applied Sciences, two female and two male Masters students in the Health Sciences faculty, that is, four SPs, were available for the test purchases. Each pharmacy was visited once (a total of 199 test purchases), whereby the pharmacies were distributed randomly across the four SPs (three SPs 50 test purchases, one SP 49 test purchases). Before the start of the data collection, each of the SPs familiarised themselves with the theoretical principles of the methodology and the contents of the evaluation form.

A pilot study with four test purchases was then carried out by each of the SPs to train the SPs in the use of the methodology and to verify the functionality of the collection form and the four test scenarios. The total 16 test purchases were carried out in pharmacies that were not part of the stratified random sample. No changes to the test scenarios and the collection form were required after testing the scenarios.

The test purchases were carried out on different days of the week and at different times of the day. The SPs made their request to the pharmacy staff who first approached them. The SPs only provided additional information if they were then asked by the pharmacy staff to ensure that the information provided is invariable.

Along with the items on the evaluation form, the SPs planned, analogous to the international literature (Table 2), to also collect a number of variables before, during and after the test purchases that may possibly affect the appropriate outcome.

The particular evaluation form was completed immediately after the test purchases by the SPs to minimise any recall bias of the study results due to faulty memories.

Data analysis

Data were entered in duplicate into and analysed with SPSS software (IBM, Armonk, NY, USA), version 25 for Windows. As part of the descriptive statistics, frequencies and percentages were determined. Furthermore, 95% confidence intervals (CI) for categorical data using bootstrapping methods were also...
reported. Because the rule of thumb for sample size assumptions (minimum of 10 events per predictor variable) is given for a logistical regression; a binary logistic regression model was developed to identify the influence of various independent variables (Table 2) on the appropriate outcome. All independent variables were checked for outliers and multicollinearity. According to Hosmer et al., variables with a $p$ value less than 0.25 in the bivariate analysis were included in the multivariate analysis. Crude odds ratios (COR) and adjusted odds ratios (AOR), 95% confidence intervals (CI) and $p$ values were reported. A $p$ value less than 0.05 was deemed significant in multivariate analysis.

**Ethical approval**

The study protocol was approved by the institutional ethics committee of the Neubrandenburg University of Applied Sciences (registration number: HSNB/GPM/139/18). According to the ‘Guideline for the use of mystery research in market and social research’; the data collected were anonymised and recorded in such a way that the pharmacies involved could not be identified. Because of the nature of this study, pharmacies were not asked for consent to participate. Recruited students provided their written informed consent to act as SPs.

**Results**

All 199 planned test purchases were actually carried out, with a total of €784.70 used from the primary author’s own resources. Table 3 shows the socio-demographic data for the 199 pharmacies and the advising pharmacy staff.

This reveals that the pharmacies are mostly in locations with competing pharmacies nearby. In addition, only a minority of the pharmacies had a quality certificate. In most of the test purchases, the advising pharmacy staff were female, between 30 and 49 years of age and did not have a pharmacy degree (non-pharmacist).

The appropriate outcome was achieved in 59.8% (n=119) of all test purchases (Table 4). Most commonly the question ‘for whom is the medication?’ was asked (75.4%, n=150), while ‘clarification by a doctor’ was asked the least (17.6%, n=35). In 87.9% (n=175) of all test purchases a medication was dispensed. Regarding the test purchases in which a medication was dispensed, in 88.6% (n=155) information was provided about the dosage of the medication whereas information about possible side effects was only provided by the pharmacy staff in 8.0% (n=14) of test purchases.

The binary logistic regression model is shown in Table 5. Bivariate analysis demonstrated that only three (quality certificate, professional group of the pharmacy staff, number of questions asked) of eight predictor variables having a $p$ value < 0.25 were included in a multivariate logistic regression model.

In this multivariate analysis, being a non-pharmacist (AOR = 2.446; 95% CI = 1.025–5.835; $p = 0.044$) or pharmacy staff with an undetermined professional group (AOR = 3.269; 95% CI = 1.208–8.843; $p = 0.020$) was associated with referral to a doctor and two (AOR = 15.291; 95% CI = 4.876–47.955; $p < 0.001$) or three or more (AOR = 23.406; 95% CI = 8.204–66.773; $p < 0.001$) questions as opposed to no questioning were significantly associated with referral to a doctor. The location of the pharmacy, the presence of a quality certificate and a queue, the age and the gender of the pharmacy staff, as well as the time of day of the test purchases did not have any significant effect on the appropriate outcome. The model returned a Nagelkerke $R^2$ value of 0.45.

**Discussion**

Although the appropriate outcome, that is, the recommendation to consult a doctor, was achieved in approximately 60% of all test purchases, approximately 40% of all pharmacies did not

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Table 2. Possible influencing factors and time and type of data collection.

<table>
<thead>
<tr>
<th>Possible influencing factors</th>
<th>Time of data collection</th>
<th>Type of data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of the pharmacy as indicator for urban/rural</td>
<td>Before the test purchase necessary, using a telephone query by the SP after completing the test purchase</td>
<td></td>
</tr>
<tr>
<td>Pharmacy quality certificate</td>
<td>After the test purchase</td>
<td>Precise measurement using a telephone query by the SP after completing the test purchase</td>
</tr>
<tr>
<td>Age of the pharmacy staff</td>
<td>During the test purchase</td>
<td>Estimate using visual impression of the SP</td>
</tr>
<tr>
<td>Gender of the pharmacy staff</td>
<td>During the test purchase</td>
<td>Exact measurement using visual impression of the SP</td>
</tr>
<tr>
<td>Professional group of the pharmacy staff</td>
<td>During and after the test purchase</td>
<td>Exact measurement based on the name tag, the receipt and, if necessary, using a telephone query by the SP after completing the test purchase</td>
</tr>
<tr>
<td>Queue – patients waiting after the SP</td>
<td>During the test purchase</td>
<td>Exact measurement using visual impression of the SP</td>
</tr>
<tr>
<td>Time of the test purchase</td>
<td>During the test purchase</td>
<td>Exact measurement using the SP's watch</td>
</tr>
<tr>
<td>Number of questions asked</td>
<td>After the test purchase</td>
<td>Exact measurement by adding up the individual questions asked</td>
</tr>
</tbody>
</table>

Note: The possible influencing factors are taken from the particular literature sources.
**Table 3. Socio-demographic data for the pharmacies or the advising pharmacy staff.**

<table>
<thead>
<tr>
<th></th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All pharmacies</td>
<td>199</td>
<td>100</td>
</tr>
<tr>
<td><strong>Location of the pharmacy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 1 pharmacy in the location</td>
<td>37</td>
<td>18.6</td>
</tr>
<tr>
<td>• 2–4 pharmacies in the location</td>
<td>58</td>
<td>29.1</td>
</tr>
<tr>
<td>• 5–19 pharmacies in the location</td>
<td>45</td>
<td>22.6</td>
</tr>
<tr>
<td>• ≥ 20 pharmacies in the location</td>
<td>59</td>
<td>29.7</td>
</tr>
<tr>
<td><strong>Pharmacy quality certificate</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No</td>
<td>125</td>
<td>62.8</td>
</tr>
<tr>
<td>• Yes</td>
<td>52</td>
<td>26.1</td>
</tr>
<tr>
<td>• Not able to be determined</td>
<td>22</td>
<td>11.1</td>
</tr>
<tr>
<td><strong>Age of the pharmacy staff</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• &lt; 30</td>
<td>39</td>
<td>19.6</td>
</tr>
<tr>
<td>• 30–49</td>
<td>110</td>
<td>55.3</td>
</tr>
<tr>
<td>• ≥ 50</td>
<td>50</td>
<td>25.1</td>
</tr>
<tr>
<td><strong>Gender of the pharmacy staff</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Male</td>
<td>20</td>
<td>10.1</td>
</tr>
<tr>
<td>• Female</td>
<td>179</td>
<td>89.9</td>
</tr>
<tr>
<td><strong>Professional group of the pharmacy staff</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pharmacist</td>
<td>54</td>
<td>27.1</td>
</tr>
<tr>
<td>• Non-pharmacist</td>
<td>90</td>
<td>45.2</td>
</tr>
<tr>
<td>• Not able to be determined</td>
<td>55</td>
<td>27.6</td>
</tr>
</tbody>
</table>

**Table 4. Assessment items (n = 199).**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. For whom is the medication?</td>
<td></td>
<td>150</td>
<td>75.4</td>
<td>69.3–81.4</td>
</tr>
<tr>
<td>2. How long have the symptoms been present?</td>
<td></td>
<td>97</td>
<td>48.7</td>
<td>42.2–55.8</td>
</tr>
<tr>
<td>3. How often do the symptoms occur?</td>
<td></td>
<td>46</td>
<td>23.1</td>
<td>17.6–29.1</td>
</tr>
<tr>
<td>4. Have other symptoms occurred?</td>
<td></td>
<td>56</td>
<td>28.1</td>
<td>22.1–34.7</td>
</tr>
<tr>
<td>5. Have the symptoms already been clarified by a doctor?</td>
<td></td>
<td>35</td>
<td>17.6</td>
<td>12.6–23.1</td>
</tr>
<tr>
<td>6. Are there other medical conditions or which medications are taken regularly?</td>
<td></td>
<td>65</td>
<td>32.7</td>
<td>26.1–39.2</td>
</tr>
<tr>
<td>7. Is a medical consultation recommended (appropriate outcome)?</td>
<td></td>
<td>119</td>
<td>59.8</td>
<td>53.3–66.3</td>
</tr>
<tr>
<td>8. Dispensing of a medication</td>
<td></td>
<td>175</td>
<td>87.9</td>
<td>83.4–92.5</td>
</tr>
<tr>
<td>9. Information about dosage</td>
<td></td>
<td>155</td>
<td>88.6</td>
<td>83.4–93.1</td>
</tr>
<tr>
<td>10. Information about duration</td>
<td></td>
<td>82</td>
<td>46.9</td>
<td>39.4–54.3</td>
</tr>
<tr>
<td>11. Information about side effects</td>
<td></td>
<td>14</td>
<td>8.0</td>
<td>4.0–12.6</td>
</tr>
</tbody>
</table>

recommend that the patient consult a doctor even though this would have been necessary. Due to the design of the scenario as a symptom-based query, the study results obtained would probably be worse in everyday consultations with its mix of symptom- and product-based queries because in the international and national literature (otherwise identical) scenarios showed a better quality of advice for a symptom-based query than for a medication-based query\(^{20,48}\). In another study a recommendation rate for a necessary medical consultation of 57% was determined for a medication-based query, likewise for acute diarrhoea in adults, in Australian community pharmacies\(^{27}\). Considerably worse results for the recommendation of a necessary
Table 5. Possible factors influencing the recommendation of a necessary medical consultation.

<table>
<thead>
<tr>
<th>Possible influencing factors and categories</th>
<th>Total n = 199 n (%)</th>
<th>Referral n = 119 n (%)</th>
<th>No referral n = 80 n (%)</th>
<th>COR (95% CI)</th>
<th>P value</th>
<th>AOR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of the pharmacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 1 pharmacy in the location</td>
<td>37 (18.6)</td>
<td>24 (20.2)</td>
<td>13 (16.3)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 2–4 pharmacies in the location</td>
<td>58 (29.1)</td>
<td>33 (27.7)</td>
<td>25 (31.3)</td>
<td>0.715 (0.305–1.676)</td>
<td>0.440</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 5–19 pharmacies in the location</td>
<td>45 (22.6)</td>
<td>27 (22.7)</td>
<td>18 (22.5)</td>
<td>0.813 (0.330–2.000)</td>
<td>0.651</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ≥ 20 pharmacies in the location</td>
<td>59 (29.7)</td>
<td>35 (29.4)</td>
<td>24 (30.0)</td>
<td>0.790 (0.337–1.851)</td>
<td>0.587</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy quality certificate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No</td>
<td>125 (62.8)</td>
<td>70 (58.8)</td>
<td>55 (68.8)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Yes</td>
<td>52 (26.1)</td>
<td>35 (29.4)</td>
<td>17 (21.3)</td>
<td>1.618 (0.821–3.188)</td>
<td>0.165</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Not able to be determined</td>
<td>22 (11.1)</td>
<td>14 (11.8)</td>
<td>8 (10.0)</td>
<td>1.375 (0.538–3.512)</td>
<td>0.506</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age of the pharmacy staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• &lt; 30</td>
<td>39 (19.6)</td>
<td>21 (17.6)</td>
<td>18 (22.5)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 30–49</td>
<td>110 (55.3)</td>
<td>66 (55.5)</td>
<td>44 (55.0)</td>
<td>1.286 (0.616–2.684)</td>
<td>0.503</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ≥ 50</td>
<td>50 (25.1)</td>
<td>32 (26.9)</td>
<td>18 (22.5)</td>
<td>1.524 (0.649–3.580)</td>
<td>0.334</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender of the pharmacy staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Male</td>
<td>20 (10.0)</td>
<td>10 (8.4)</td>
<td>10 (12.5)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Female</td>
<td>179 (89.9)</td>
<td>109 (91.6)</td>
<td>70 (87.5)</td>
<td>1.557 (0.617–3.933)</td>
<td>0.349</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional group of the pharmacy staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pharmacist</td>
<td>54 (27.1)</td>
<td>25 (21.0)</td>
<td>29 (36.3)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Non-pharmacist</td>
<td>90 (45.2)</td>
<td>54 (45.4)</td>
<td>36 (45.0)</td>
<td>1.740 (0.880–3.439)</td>
<td>0.111</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Not able to be determined</td>
<td>55 (27.6)</td>
<td>40 (33.6)</td>
<td>15 (18.8)</td>
<td>3.093 (1.391–6.877)</td>
<td>0.006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time of the test purchase</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 8:00 am – 12:00 pm</td>
<td>77 (38.7)</td>
<td>48 (40.3)</td>
<td>29 (36.3)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 12:01 pm – 4:00 pm</td>
<td>89 (44.7)</td>
<td>49 (41.2)</td>
<td>40 (50.0)</td>
<td>0.740 (0.397–1.379)</td>
<td>0.343</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 4:01 pm – 8:00 pm</td>
<td>33 (16.6)</td>
<td>22 (18.5)</td>
<td>11 (13.8)</td>
<td>1.208 (0.512–2.850)</td>
<td>0.666</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Queue</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No</td>
<td>146 (73.4)</td>
<td>86 (72.3)</td>
<td>60 (75.0)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Yes</td>
<td>53 (26.6)</td>
<td>33 (27.7)</td>
<td>20 (25.0)</td>
<td>1.151 (0.603–2.196)</td>
<td>0.669</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of questions asked</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• None</td>
<td>36 (18.1)</td>
<td>7 (5.9)</td>
<td>29 (36.3)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• one</td>
<td>39 (19.6)</td>
<td>10 (8.4)</td>
<td>29 (36.3)</td>
<td>1.429 (0.478–4.268)</td>
<td>0.523</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• two</td>
<td>41 (20.6)</td>
<td>12 (10.4)</td>
<td>9 (11.3)</td>
<td>14.730 (4.863–44.616) &lt; 0.001</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ≥ three</td>
<td>83 (41.7)</td>
<td>70 (58.8)</td>
<td>13 (16.3)</td>
<td>22.308 (8.079–61.597) &lt;0.001 &lt;0.001</td>
<td>&lt;0.001*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: COR = Crude Odds Ratio; AOR = Adjusted Odds Ratio.

* significant at P < 0.05.
medical consultation are seen in the international literature for other indications such as pain (recommendation rate: approx. 27%1), vaginal thrush (recommendation rates: 10% and 22%49) and asthma (recommendation rates: 40% and 19%49) which were all medication-based queries. In contrast, the only study that has investigated the recommendation for a necessary medical consultation to date in Germany showed a very high recommendation rate of 90% once again for a medication-based query for an antacid53.

Possible reasons discussed in the international literature for the poor quality of advice provided include lack of time, manpower, interest and knowledge on behalf of the pharmacy staff50,51,52. In regards to the lack of knowledge, as part of the pharmacy degree (pharmacist) or professional training (pharmaceutical technical assistant) patient consultations should be more intensively trained using examples44. In addition, the systematic use of checklists could also help to ensure a better quality of advice in daily patient contact51.

On the other hand, the international literature reveals that pharmacy staff most definitely have the knowledge to provide good advice, but it is only inadequately applied in actual patient contact53,54,55,56.

In a German study, pharmacy staff suggested that this is due to the worry that the client may feel patronised52. In contrast to this, another German study determined that most patients would like to have a consultation in the pharmacy; however, due to the study design this involved rather health-conscious and therefore not representative study participants54. In a very recent German study it was stated by pharmacy staff that patients frequently did not want any advice in terms of drug handling, sometimes due to a lack of time55. In a somewhat older English study, 62.5% of the patients interviewed did not expect to be asked any questions by the pharmacy staff during their last purchase of a non-prescription medication54. Similar results were obtained in a more recent study in Qatar in which the pharmacist cited ‘no interest by the patients’ as the central reason for providing insufficient advice56. Another very recent qualitative study from Australia was also able to determine in this context that from the perspective of both the consumers and the pharmacy staff, the frequent lack of privacy is also an important reason for the poor exchange of information57. It would, therefore, be necessary to require pharmacy owners in future to provide appropriate spaces that ensure privacy.

Analogous to other international studies50,51,52, the number of questions asked had a significant effect on the appropriate outcome. This is based on the rationale that the right decision – in our case to recommend consulting a doctor – can only be made if appropriate questions are asked and thus information is obtained about the patient. In contrast to this, a Saudi Arabian study revealed that there was no relationship between the number of questions asked and the appropriate outcome – in this case the dispensing of prescription medications without a medical prescription52. However, the outcome ‘dispensing prescription medications without a medical prescription’ is not comparable to the outcome ‘recommendation to consult a doctor’. While for the first a sensible decision can be made even without asking appropriate questions (that is, refusing to dispense a prescription medication without a corresponding medical prescription), for the latter a sensible decision is only possible on the basis of appropriately asked questions.

In regards to individual questions, the question about the duration of the acute diarrhoea was asked more frequently compared to comparable national studies50,51. In a recent SP study, also for acute diarrhoea in adults, that was conducted in Iraq, this question was asked in almost 80% of all test purchases63. Considerably worse, on the other hand, are the results of a comparable Turkish SP study, which also investigated the quality of advice provided for acute diarrhoea in adults, in which this question was only asked in 26% of all test purchases64. Because certain medications can cause diarrhoea, the question about any pre-existing medical conditions or the patient’s medical history is particularly important65. This question was asked in this study in approximately one-third of the test purchases and is thus more frequent than in the comparable national studies50,51. In the similar Turkish SP study, this question was not asked in a single test purchase64.

Depending on the particular criteria being investigated, there are also clear differences in the information that is given to the patients when medication is dispensed. Analogous to the national50,51 and international literature54,66, information is often provided about the dosage of the medication but rarely about possible side effects. An active query by patients could help to greatly improve the frequency of advice provided for the criterion ‘side effects’, as was shown in a recent SP study from Tanzania66.

Along with the number of questions asked, the professional group of the pharmacy staff providing the advice also had a significant influence on the appropriate outcome. Non-pharmacists (pharmaceutical technical assistants and pharmacy technicians) have a significantly higher likelihood of achieving the appropriate outcome than pharmacists. On the other hand, two comparable SP studies from Germany and Australia – also for acute diarrhoea in adults – did not show any significant difference in the quality of advice provided by the two professional groups51 or a significantly higher likelihood for pharmacists71 of achieving the appropriate outcome. In the Turkish SP study pharmacists made significantly more recommendations to their patients than pharmaceutical technical assistants64. For indications other than acute diarrhoea in adults there was an analogous picture – either a significantly better quality of advice provided by pharmacists compared to non-pharmacists13,62 or no significant differences between the two professional groups66,68. Due to inconsistent national and international studies and in light of the surprising results obtained in this study, future studies should investigate in greater depth this influencing factor for the advice provided.

Strengths and limitations
This is the first German study that investigated to what degree community pharmacies recommend a necessary medical consultation for acute diarrhoea in adults. The sample size used
The restrictions on time and resources and the very high number of pharmacies visited mean that it was also not possible to provide the pharmacies with individual written performance feedback after the test purchases.

Conclusions
In terms of achieving the appropriate outcome, an enormous potential for improvement was identified for community pharmacies in the German state of Mecklenburg-Vorpommern. Furthermore, more questioning and involvement by non-pharmacists was identified as relevant factors influencing the appropriate outcome. There is a further need for research to identify why the advice provided is so often poor and particularly why the quality of advice provided by pharmacists is so inadequate. The results should make both the Mecklenburg-Vorpommern pharmacy association and legislators aware of the need to significantly escalate their quality management efforts. In this context appropriate mandatory continuing education courses as well as regular independent reviews with an adequate sanction mechanism could provide a stimulus to sustainably improve the quality of advice.

Data availability
Underlying data
Harvard Dataverse: Replication Data for: Do north-eastern German pharmacies recommend a necessary medical consultation for acute diarrhoea? Magnitude and determinants using a simulated patient approach, https://doi.org/10.7910/DVN/5KVLW.

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

Acknowledgements
The authors thank the four master students for acting as simulated patients.

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Current Peer Review Status: ? ✔️ ?

Version 1

Reviewer Report 11 February 2020

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Subish Palaian
Department of Clinical Sciences, College of Pharmacy and Health Sciences, Ajman University, Ajman, United Arab Emirates

I enjoyed reading the manuscript. It is a well conducted study with robust methodology and focusing on 'community pharmacist referral' which is an important aspect of community pharmacy practice. I thank the F1000Research for providing me the opportunity in reviewing this manuscript. The 'simulated client method' used in this research is suitable in evaluating the real-life practice happening at the community pharmacies.

I have few concerns associated with the manuscript and are as below:

Abstract:

- The result section of the abstract mentions about ‘non-pharmacist’. It would be nice to elaborate more on those non-pharmacists somewhere in the Introduction section. Though it is mentioned in the Results, para 2, one would like to know whether non-pharmacists are allowed to dispense medications. This may be useful for international readers. Similarly, in the result part the statement 'two or more questions as opposed to no questions were significantly associated with a referral to a doctor' doesn’t appear to be novel. It is understood that someone who had not asked any question will be unable to refer. Authors might consider other observations to be mentioned at this section of the abstract.

Introduction:

- The paragraph 6, authors need to clearly mention which ‘baseline’ and ‘follow-up’ study are they mentioning. What is the relation between the current study and those previous studies. Are they the same sample?

- I also found some similarity with few of the previous publications by the author using the same 'acute diarrhea' scenario. Authors need to verify the contents and avoid any similarities.
May be the Introduction section should elaborate more on the justification of this research. Why did all these studies used only ‘acute diarrhea’ as the scenario? This needs further elaboration.

Methodology

Under scenario and assessment, it is not clear how authors categorized ‘Diarrhoea being present for five days as well as a high fever (40°C) are both considered to exceed the limits of self-medication’. I suppose even if there is presence of mucus and/or blood in the stool may be considered referral. I suggest more explanation on development of the scenario and content validation and why ‘Dysentery’ was excluded from the scenario.

Results:

In this research, 45.2% of the dispensers were ‘non-pharmacists’. If that is the case then how can we correlate the research findings to evaluate the Community Pharmacy practice? The term ‘non-pharmacist’ needs more elaboration. Probably in the Introduction section, as I mentioned elsewhere.

Table 4, response 8. Dispensing of a medication 175 (87.9%). What were these medications. Were there any antibiotics? What happened to the rest 22.1%? Why they did not dispense medications? These are some missing information and needs to be incorporated in the Results section.

Discussion:

The discussion can focus on reason for non-referral by the pharmacists. Are there skills related issues? Do the pharmacists possess adequate skills in assessing patients with diarrhea? These aspects may further enrich the discussion.

Limitations:

Authors could explore any seasonal impact on the finding.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
I cannot comment. A qualified statistician is required.

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

**Competing Interests:** No competing interests were disclosed.
Reviewer Expertise: Pharmacy Practice, Pharmacovigilance, Pharmacoepidemiology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

1. Ethical approval: I appreciate that in this study obtaining a written consent from the staff of the pharmacies would have greatly and negatively impacted the results and any “appropriate outcome” obtained would have been a biased one.

2. Pre-piloting the scenario with other than the researchers may have improved the approach.

3. The SPs made their request to the pharmacy staff who first approached them. Were the SPs certain whether “the pharmacy staff who first approached them” a pharmacist or pharmacy technician? In table 3, about 72% were not pharmacist and not able to determine. Moreover, the authors stated in the results that “In most of the test purchases, the advising pharmacy staff were females, between 30 and 49 years of age and did not have a pharmacy degree (non-pharmacist)”. Since those they should practice under the supervision of a pharmacist, the authors need to elaborate on this in relation to their discussion where they state” Non-pharmacists (pharmaceutical technical assistants and pharmacy technicians) have a significantly higher likelihood of achieving the appropriate outcome than pharmacists”.

4. Point 2 must be also discussed in relation to their conclusion where they state” Furthermore, more questioning and involvement by non-pharmacists was identified as relevant factors influencing the appropriate outcome. There is a further need for research to identify why the advice provided is so often poor and particularly why the quality of advice provided by pharmacists is so inadequate”.

5. In table 5, under Queue and Number of questions asked the percentages do not total to 100%. Therefore, the authors need to check their original data, or declare “Missing data” in the table to total the percentage to 100%.
Is the work clearly and accurately presented and does it cite the current literature?  
Yes

Is the study design appropriate and is the work technically sound?  
Yes

Are sufficient details of methods and analysis provided to allow replication by others?  
Yes

If applicable, is the statistical analysis and its interpretation appropriate?  
Yes

Are all the source data underlying the results available to ensure full reproducibility?  
No source data required

Are the conclusions drawn adequately supported by the results?  
Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Drug Utilization Studies, Pharmacy education, Pharmacy Practice, Neuropharmacology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 15 November 2019

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Mohamed Izham Mohamed Ibrahim
Department of Clinical Pharmacy and Practice, College of Pharmacy, Qatar University, Doha, Qatar

Thank you for allowing me to review this article. It is an interesting study using an interesting approach i.e. SP. I have a few comments:

1. The conclusion in the abstract section must be consistent with the objective of the study and main findings.

2. Percentages reported in tables must equal to 100% - kindly check all figures.

3. Tables cited in the main text should in proper order.

4. Even though due to the nature of the study, subjects selected were not asked for consent, did the authors contact them after the study informing that a study was conducted with reasons? This is
one way that the researchers could resolve the issue of informed consent prior to the study.

5. Create a paragraph on Study recommendations at the end of the Discussion section. Consider to move some parts of the conclusion. Rewrite the conclusion section.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
No

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Social-behavioral and Administrative aspects of health and pharmacy

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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