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RESEARCH ARTICLE

# Comprehensive assessment of reliability and validity for the clinical cases in simulated community pharmacy

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## Abstract

**Background:** The objective structured clinical examination (OSCE) is used to measure the clinical competence of pharmacy students in a community pharmacy setup. However, the OSCE needs to be standardised to assess the clinical competence of the student accurately. **Objectives**: The present study was aimed to assess the reliability and validity of two clinical cases used in the simulated community pharmacy. **Methods**: OSCE simulation was performed by the students with two clinical cases in a simulated community pharmacy. The reliability was measured using Cronbach's α and Mc Donald's ω. Exploratory factor analysis (EFA) and Confirmatory factor analysis (CFA) were used to measure the validity of the cases. **Results**: Among the two cases, the first case scenario was found to have a good model fit. However, the second case scenario has a poor model fit which was determined by the CFA. The inadequate sample size and factor loading in EFA were the main reasons for poor model fit in the second case scenario. **Conclusion**: The internal consistency, sample adequacy, factor loading, test for an exact fit, and fit measurements should be ensured for the clinical cases included in OSCE. This will help the academician to ensure the accurate assessment of the clinical competence of the student in a simulated community pharmacy.

## Introduction

Doctor of Pharmacy (Pharm. D.) curriculum is intended to produce the competent pharmacist through the good pharmacy practice (GPP) for the safe use of medications in a community pharmacy (Achary *et al*., 2020; Badro *et al*., 2020). Pharmacy practice courses were implemented to undergraduate pharmacy curriculum to train the students regarding skills needed for GPP (Al-Jedai *et al*., 2016; Rasheed *et al*., 2020). GPP is "*a mission of pharmacy practice to contribute to health improvement and to help patients with health problems to make the best use of their medicines*"(WHO, 2020) which can be achieved by following the guidelines in preparation, dispensing, labelling and patient education in community pharmacy (Badro *et al*., 2020). In vision 2030, Saudi Arabia has a clear plan to implement GPP in all undergraduate pharmacy curriculum (Almaghaslah *et al*., 2021). Objective structured clinical examinations (OSCE) were established already in various pharmacy schools across the world (Peeters *et al*., 2021) for assessing the professional competence of clinical pharmacists in a structured manner (Al-Haqan *et al*., 2021) and for undergraduate pharmacy students (Abdi *et al*., 2019; Lim *et al*., 2020).

The quality of clinical cases used in simulated community pharmacies could directly affect the assessment of the OSCE. Therefore, it's the responsibility of the academicians to ensure the suitability of the clinical cases for OSCE in a systematic manner. In this context, validation in OSCE may help to construct a quality enough clinical case scenario that is suitable for measuring the clinical competence of the student (Majumder *et al*., 2019). A cohort study was found that the students recognise themselves as pharmaceutical care providers through OSCE (Savage *et al*., 2021). Even though OSCE is a gold standard for assessing medical students (Furmedge *et al*., 2016; Said

*et al*., 2021), there is no such designation for pharmacy students. The OSCE used in medical school has been validated and found to demonstrate the ability to assess learning. (Brennan *et al*., 2015; Paul *et al*., 2017; Htay *et al*., 2019). No such validation or standardisation has yet been established in pharmacy education. To the best of the author's knowledge in the present study, there is no well-established study in the past regarding the validation procedure for OSCE simulation in pharmacy. Further, previous researchers insist on the determination of the reliability and validation of clinical cases used in OSCE in pharmacy simulation (Shirwaikar *et al*., 2015; Susi *et al*., 2019). Thus, the present study aimed to share the experience of validating the OSCE in the Pharm. D. curriculum, which may provide insight to the pharmacy academicians who want to validate the clinical case scenarios used in their OSCE simulation.

## Methods

### *Conceptualisation*

In the Faculty of Pharmacy, the Pharm. D. curriculum has an Introductory pharmacy practice experience course which has a learning outcome that offers knowledge and skills required for the pharmacist to deal with the minor ailments in community pharmacy. In this study, the cognitive and interpersonal skills were planned to measure among the students enrolled for OSCE in the author's simulated community pharmacy. Usually, traditional simulation takes place to assess the clinical competence of the student by using the cases which are not validated in a simulated community pharmacy. Recently, we planned to introduce the OSCE in the curriculum and also to validate clinical cases to ensure its suitability in OSCE. The protocol for validating the case scenarios in OSCE was made by the course instructor (Figure 1). It includes the various steps such as preparation of case scenarios, preparation of blueprint, preparing the details of the workstations, data collection, implementing the OSCE, data collection, reliability, and factor analysis.

### *Subjects*

A total of 75 third-year students in the second term were given an activity to solve the clinical cases based on the chief complaint of patient or patient representative in OSCE at a simulated community pharmacy at the end of the term. The students were given the necessary orientation to handle the OSCE before the beginning of the simulation. The course instructors were standardised to mimic patients in the corresponding workstations in simulated community pharmacies (Table I). All the data from 75 students have been included for the validation as they completed the first case scenario within thirty minutes. However, five students failed to complete the task within the time frame of 30 minutes in the second case scenario, and they were excluded from the study. Therefore, the second case scenario included only seventy students who completed the case within the given time frame.

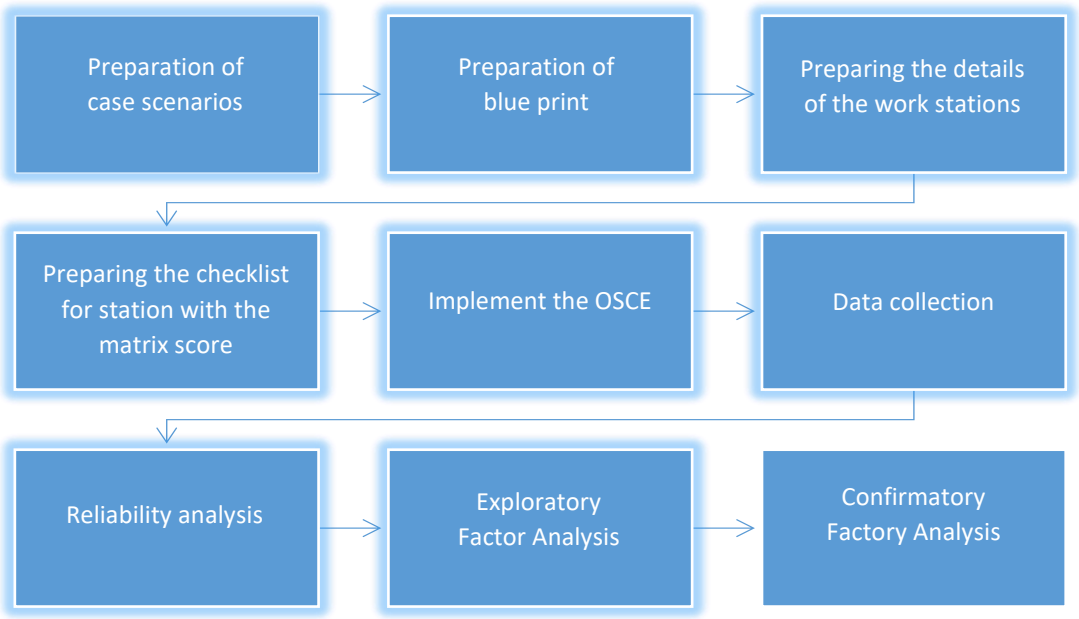


**Figure 1: Protocol for validating the cases**

**Table I: Details of Objective Structured Clinical Examination (OSCE)**

| Work station number | Title of the workstation | Interactive/ Non-interactive approach | Clinical competence | Time given | Score range |
|---|---|---|---|---|---|
| 1 | Staging | Interactive | Not applicable | 5 minutes | Not applicable |
| 2 | Patient interview | Interactive | Medication reconciliation skills | 10 minutes | 5-25 |
| 3 | Dispensing | Non-interactive | Treatment decision skills | 5 minutes | 5-25 |
| 4 | Labelling | Non-interactive | Data entry skills | 5 minutes | 5-25 |
| 5 | Patient counselling | Interactive | Patient education skills | 10 minutes | 5-25 |

***Preparation of case scenarios***

The case scenarios were prepared by the course instructor, and the same were peer-reviewed by the other two colleagues in the department. The case scenario was about "*the patient seeking medication for his/her minor ailments in simulated community pharmacy*". The student was a community pharmacist in OSCE simulation who should deal with the patient in terms of dispensing the medication with a suitable label based on the patient interview. Then, the appropriate patient education should be provided by the student.

***Items included in the assessment***

Four items are included in the OSCE, which includes: 1) Patient interview, 2) Dispensing, 3) Labelling and 4) Patient counselling (Table I). Every 25 marks were distributed to every item, and the total sum of the OSCE was 100 marks.

***Patient interview***

This was considered an interactive approach, and the medication reconciliation skills were assessed. Every five marks were distributed for asking the following in each sub-items to the patient: a) Patient demographics, b) Chief complaint and history of present illness, c) Past medical and medication history, d) Known allergies to any drugs, e) Social history.

***Dispensing***

Dispensing included the following five sub-items for evaluation: a) Prescription monitoring, b) Drug selection, c) Dosage form selection, d) Dose selection, and e) Quantity selection. In this non-interactive approach, each sub-item carries five marks.

***Labelling***

Labelling, which is also a non-interactive approach, has five sub-items, and each carrying five marks is a) writing the date and patient details, b) quantity of medication, c) direction for use, d) refill instructions, and e) pharmacist name with signature.

***Patient counselling***

Patient counselling was considered as an interactive approach and included five sub-items, each carrying five marks: a) chief complaint, b) purpose of medication, c) direction for use, d) storage of medication, and e) non-drug therapy.

***Implementing the OSCE***

Both the simulations included five workstations: 1) Staging, 2) Patient interview, 3) Dispensing, 4) Labelling, and 5) Counselling. In the first workstation (staging), the student was given the case details briefly to perform the activity, and the student was allowed to ask the questions to the instructor. Once the staging was completed, the student was asked to complete the tasks in the next four stations. Each station was allowed a definite period of time to complete the task. A maximum of thirty minutes was given for the students to complete the exercise (Table I).

***Data collection***

The students were evaluated by the evaluator, and the marks given to the students according to their performance for each sub-item score starting from one to five represents from needs improvement to excellent respectively. The recorded score was transferred to the excel sheet for further evaluation.

***Reliability and validation methods***

The reliability was assessed with the help of Cronbach's α and Mc Donald's ω. The interpretation of the Cronbach's α included 0.91 to 1.00 is excellent; 0.81 to 0.90 is good; 0.71 to 0.80 is acceptable; 0.61 to 0.7 is questionable; 0.1 to 0.6 is unacceptable (Deng *et al*., 2017; Viladrich *et al*., 2017). The construct validity of the case scenario was tested by using exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) (Paul *et al*., 2017). The EFA was included in various measurements factor analysis (where factors loading the value close to -1 or 1 indicate the factor strongly

influencing the variable; the value close to zero indicate the factor influencing the variable poorly), Eigenvalue, and percentage of variance. Kaiser-Meyer-Olkin (KMO; ≥ 0.90 - marvellous, 0.80 to 0.89 - meritorious, 0.70 to 0.79 - average, 0.60 to 0.69 - medicore, less than 0.5 - unacceptable) and Bartlett's test of sphericity (<0.001) were included for the measurement of sampling adequacy (Andrew *et al*., 2020).

In CFA, a chi-square test was used to assess how well the case scenario fit for the evaluation. Root mean square error of approximation (RMSEA) was used to assess the sampling adequacy in validation < 0.05 indicates the model fit to the sample size and comparative fit index (CFI), tucker-lewis index (TLI) > 0.95, and standardised root mean square (SRMR) value between 0 to 0.8 indicates the case scenario is fitting for the evaluation (Andrew *et al*., 2020). The latest versions of SPSS and Jamovi databases were included to analyse the above parameters corresponding to the reliability and validation procedure.

## Results

### *Reliability analysis for internal consistency*

All the items included in OSCE have more than 0.7 of Cronbach's α and more than 0.8 Mc Donald's ω (Table II). This item reliability statistics indicated that the case scenario was reliable and also helped to move towards the validation procedure. Further, the excellent reliability was noted with the patient interview (Cronbach's α 0.921; Mc Donald's ω 0.943) and patient counselling (Cronbach's α 0.963; Mc Donald's ω 0.970) respectively. The remaining items in both the case scenarios had more than 0.7 in Cronbach's α, and Mc Donald's ω indicates acceptable reliability (Table II).

**Table II: Reliability testing**

| Variable | Cronbach's α | Mc Donald's ω |
|---|---|---|
| **Case scenario 1 (n=75)** | | |
| Patient interview | 0.921 | 0.943 |
| Dispensing | 0.843 | 0.867 |
| Labelling | 0.822 | 0.868 |
| Counselling | 0.822 | 0.868 |
| **Total score** | **0.790** | **0.815** |
| **Case scenario 2 (n=70)** | | |
| Patient interview | 0.831 | 0.889 |
| Dispensing | 0.802 | 0.861 |
| Labelling | 0.796 | 0.872 |
| Counselling | 0.963 | 0.970 |
| **Total score** | **0.788** | **0.846** |

### *Exploratory factor analysis (EFA)*

The factor loadings of all items in both cases were close to 1, which indicates the factor strongly influences the variable. KMO was found to be 0.841 in case scenario 1, which indicates sample adequacy to proceed further; on the contrary, case scenario 2 has a 0.609 KMO value which indicates inadequate sample size to analyse the factor. However, Bartlett's test of sphericity (<0.001) indicates that the correlation matrix in both cases is suitable for factor analysis (Table III). Percentage of the analytical value measured as:

$$\frac{Eigenvalue}{Number\ of\ items} * 100$$

it was noted that 51.1% ($^{2.5546 * 100}/_{5}$) and 71.3 % ($^{3.5724 * 100}/_{5}$) for the case scenario 1 and 2, respectively (Table III).

**Table III: Exploratory factor analysis**

| Variable | Factor analysis | | | Test for sample adequacy | | | |
|---|---|---|---|---|---|---|---|
| | | | | Kaiser-Meyer-Olkin measure of sampling adequacy | Bartlett's test of sphericity | | |
| | Factor loadings | Eigenvalue | % of variance | | χ2 value | df | *p*-value |
| **Case scenario 1 (n=75)** | | | | | | | |
| Patient interview | 0.750 | 2.5546 | | | | | |
| Dispensing | 0.790 | 0.0978 | | | | | |
| Labelling | 0.746 | 0.0162 | 51.1 | 0.841 | 132 | 10 | <0.001 |
| Counselling | 0.706 | -0.0271 | | | | | |
| **Total score** | **0.791** | **-0.0870** | | | | | |
| **Case scenario 2 (n=70)** | | | | | | | |
| Patient interview | 0.723 | 3.5724 | | | | | |
| Dispensing | 0.767 | 0.2626 | | | | | |
| Labelling | 0.764 | 0.0131 | 71.3 | 0.327 | 935 | 10 | <0.001 |
| Counselling | 0.690 | -0.0669 | | | | | |
| **Total score** | **0.782** | **-0.2142** | | | | | |

Factor loadings in both the case scenarios have more than 0.7, which indicates the OSCE score was moderately influenced by the items included, i.e. patient interview, dispensing, labelling, and counselling in case scenario 1. On the other hand, factor loading 0.690 in counselling for case scenario 2 indicates that the item is not suitable for factor analysis. Eigenvalue more than 1 was noted in both clinical case scenarios (Figures 2 and 3).

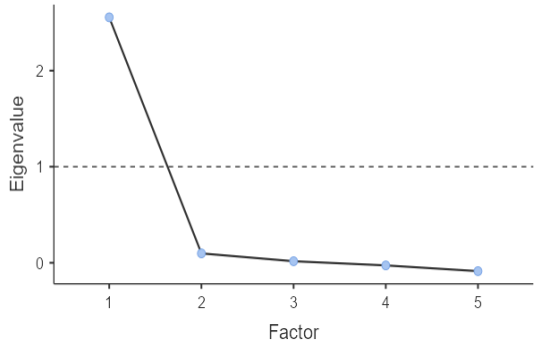


**Figure 2: Exploratory factor analysis plot for case scenario 1**

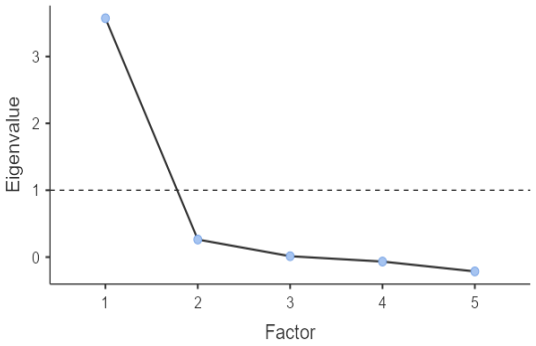


**Figure 3: Exploratory factor analysis screen plot for scenario 2**

***Confirmatory factor analysis (CFA)***

Case scenario 1 was found to have good model fit for the OSCE which passes the test for exact fit ($\chi2 = 2.37$ (df=5), $p = 0.795$) and fit measures (90% Confidence interval from 0.001 to 0.103; RMSEA = 0.001; CFI = 1.00; TLI = 1.04; SRMR = 0.0218). Meanwhile, case scenario 1 test for exact fit ($\chi2 = 150$ (df=5), $p$=<0.001) and fit measures (90% Confidence interval from 0.558 to 0.735; RMSEA = 0.644; CFI = 0.851; TLI = 0.702; SRMR = 0.235) (Table IV).

**Table IV: Confirmatory factor analysis**

| Variable | Test for exact fit | | | Fit measures | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | χ2 | df | *p* value | 90 % Confidence interval | | RMSEA | CFI | TLI | SRMR |
| | | | | Lower | Upper | | | | |
| **Case scenario 1 (n=75)** | | | | | | | | | |
| Patient interview | | | | | | | | | |
| Dispensing | | | | | | | | | |
| Labelling | 2.37 | 5 | 0.795 | 0.001 | 0.103 | 0.001 | 1.00 | 1.04 | 0.0218 |
| Counselling | | | | | | | | | |
| **Total score** | | | | | | | | | |
| **Case scenario 2 (n=70)** | | | | | | | | | |
| Patient interview | | | | | | | | | |
| Dispensing | | | | | | | | | |
| Labelling | 150 | 5 | <0.001 | 0.558 | 0.735 | 0.644 | 0.851 | 0.702 | 0.235 |
| Counselling | | | | | | | | | |
| **Total score** | | | | | | | | | |

*RMSEA: Root mean square error of approximation; CFI: comparative fit index; TLI: tucker-lewis index; SRMR: standardised root mean square*

## Discussion

This study pioneered to check the reliability and validity of clinical case scenarios of OSCE in the pharmacy curriculum. Case scenario 1 was determined to be suitable for OSCE because it demonstrated success in reliability, EFA and CFA. Meanwhile, case scenario 2 managed to succeed in reliability analysis and EFA; however, it has failed to succeed in CFA. Though the recent recommendations established that the Mc Donald's ω is superior to measure the reliability over Cronbach's α (Flora *et al*., 2020; Ravinder *et al*., 2020), this study used both the parameters to investigate the internal consistency of two clinical case scenarios. In this context, the results of the observed score from the student performance in each item (out of 100 marks) are consistent with the true score (out of 100 marks). Therefore, both the case scenarios succeeded with the reliability assessment. It can be considered as a primary finding to go forward for further factor analysis (Bartlett, 1954; Kaiser, 1974).

Previously, content evidence, such as cut scores, was used to measure the construct validity (Yazbeck *et al*., 2018; Dizon *et al*., 2021) in a medical school. In the present study, the construct validity with EFA and CFA was used to ensure whether the case scenarios were suitable to measure the clinical competence of each item included in the OSCE (Paul *et al*., 2017). Case scenario 1 is found to have construct validity to proceed in OSCE since it has acceptable competence from both factor analysis.

In EFA, case scenario 1 has sample adequacy to test the relationship between the items and student performance. The minimum sample size required to perform factor analysis is based on the ratio of the number of items included to the number of students (Kyriazos, 2018). Sample size determination is yet to be resolved since the traditional one is 5:1(Kyriazos, 2018); however, the other researchers recommended 10:1 to 20:1 (Jackson *et al*., 2003; Schumacker *et al*., 2015), and this can be modifiable according to the strength and uniformity of items included in the factor analysis (Guadagnoli *et al*., 1988; Lee *et al*., 2012; Hancock *et al*., 2013). In this context, a strong sample size is vital for the reliability and validity analysis (Costello *et al*., 2005; Wang *et al*., 2013). In this study, the ratio is 15:1 in the first case and 14:1 in the second case. Henceforth, the present study recommends a sample size of more than 15 for each item for validating the clinical cases in OSCE for community pharmacy exercises. The sample size adequacy is a strongly influencing parameter in CFA (Schumacker *et al*., 2015). Therefore, careful consideration is required in sample size selection.

In EFA, the factor loadings in both the case scenarios have more than 0.7, which is consistent with a rule of thumb that indicates that the case scenarios extract sufficient variance from the items (Liou *et al*., 2008) except counselling item in case scenario 2. Eigenvalue more than 1, and the case scenarios are considered for OSCE, and also it helps to estimate the percentage of variance in factor analysis (Watkins, 2018). In percentage of variance, both the case scenarios are higher than the threshold value of 50.2 % determined by the recent meta-analysis of EFA (Peterson, 2000). Interestingly, case scenario 2 has inappropriate sample adequacy since KMO measurement is 0.327 but still managed to succeed in EFA. Overall, the EFA results show that the items included in both cases have a close relationship with their corresponding case scenarios.

The present study has hypothesised that the given case scenarios are suitable for measuring the cognitive and interpersonal skills of OSCE in simulated community pharmacies. This null hypothesis was measured by using the CFA. This null hypothesis has been accepted with the case scenario 1 since it has succeeded in test for exact fit (Kline, 2005) (low $\chi 2$ value; $p$= 0.795) and various fit measures (RMSEA = 0.00; CFI = 1.00; TLI = 1.04; SRMR = 0.0218) (Alavi *et al*., 2020). Nevertheless, case scenario 2 is failed to succeed in both the test for exact fit (Dagnall *et al*., 2018) and various fit measures (Alavi *et al*., 2020). Factor analysis is already a known standard tool to determine the OSCE in a medical school (Chesser *et al*., 2004; Paul *et al*., 2017; Peeters, 2021). In the present study, the measurement of both verbal and non-verbal communication skills has been ruled out due to the difficulty in measuring it across the various stations, and this decision is consistent with the recent research (Piumatti *et al*., 2021). Meanwhile, the students' ability to deliver the contents (i.e. chief complaint, the purpose of the medication, direction for use, storage of medication) to the patient was used to measure the patient counselling skills. The simulation for both the cases has similarities in students, evaluators in each unit, and time allowed to complete the task.

However, the reduction in the sample size from 75 to 70 in case scenario 2 could be the main reason for the poor fit of case scenario 2 for the OSCE simulation. Planning the sample size is a challenging criterion in validating clinical cases for OSCE due to the difference of opinion in sample size determination by the previous researchers (Abdi *et al*., 2019; Majumder *et al*., 2019; Lim *et al*., 2020; Almaghaslah *et al*., 2021; Al-Haqan *et al*., 2021; Peeters *et al*., 2021). In this regard, the study once again emphasizes that the sample size should be more than 15 for each item to ensure the fitness of the clinical cases for the OSCE simulation. Further, the EFA helps to detect the other reason for poor fitness of case scenario 2, which is an inadequate factor loading in counselling item (i.e. < 0.7) mentioned in Table III since factor loading at least 0.7 is desirable for validation (Knekta *et al*., 2019). This provides an insight to revise all its sub-items included, such as; a). chief complaint, b). purpose of medication, c). direction for use, d). storage of medication e). non-drug therapy. Hopefully, the revised sub-items will be helpful to improve the quality of core counselling items; thus, case scenario 2 could be standardised in the near future by repeating the OSCE simulation in simulated community pharmacy.

## Conclusion

The study concludes that the measurement of reliability for internal consistency and factor analysis with appropriate sample size will help to standardise the clinical cases used in OSCE in the pharmacy curriculum. Also, these measurements also help to rule

out the bias in all the aspects in selecting case scenarios, subjects, work stations, matrix for evaluation, and time given for OSCE. The internal consistency, sample adequacy, factor loading, test for exact fit and fit measurements should be ensured for the clinical cases included in OSCE. This will help the academician to achieve the expected learning outcome and be able to provide competent training in simulated community pharmacy.

## Conflict of interest

The author declares that there is no conflict of interest in the present study.

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