Schneider CR, Gudka S, Fleischer L, Clifford RM. The use of a written assessment checklist for the provision of emergency contraception via community pharmacies: a simulated patient study. Pharmacy Practice 2013 Jul-Sep;11(3):127-131.

Original Research

The use of a written assessment checklist for the provision of emergency contraception via community pharmacies: a simulated patient study

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Received (first version): 26-Mar-2013 Accepted: 23-Jul-2013

ABSTRACT[*]

Background: The Pharmaceutical Society of Australia recommends use of a written assessment checklist prior to supply of emergency contraception by pharmacists.

Objective: The aim of this research was to determine the prevalence of use of a written assessment checklist by community pharmacists and secondly, to ascertain the effect of the checklist on appropriate assessment and supply.

Methods: Three female simulated patients visited 100 randomly selected pharmacies requesting supply of 'the morning after pill'. Information provided when assessed by the pharmacist was that she had missed one inactive pill of her regular hormonal contraception. The amount of assessment provided and the appropriateness of supply were used as comparative outcome measures.

Results: Eighty-three pharmacies used a written assessment checklist. Twenty-four of the pharmacies visited provided the appropriate outcome of non-supply. Pharmacies that used a written assessment checklist provided a greater quantity and consistency of assessment (11.3 ±2.5 v. 6.5 ±3.8 questions, p<0.0001) but this did not result in an improved frequency of an appropriate outcome (20%, n=16 v. 23%, n=3).

Conclusions: While a written patient assessment checklist improved the quantity and consistency of patient assessment, it did not improve the advice provided by community pharmacies when handling requests for emergency contraception.

Keywords: Patient Simulation; Contraception, Postcoital; Community Pharmacy Services; Professional Practice; Health Knowledge, Attitudes, Practice; Pharmacists; Australia

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USO DE UN *CHECKLIST* ESCRITO DE EVALUACIÓN PARA LA PROVISIÓN DE CONTRACEPCIÓN DE EMERGENCIA EN FARMACIAS COMUNITARIAS: UN ESTUDIO DE PACIENTE SIMULADO

RESUMEN

Antecedentes: La Sociedad Farmacéutica de Australia recomienda el uso de un *checklist* escrito antes de que los farmacéuticos proporcionen contracepción de emergencia.

Objetivo: El objetivo de esta investigación fue determinar la prevalencia de uso del *checklist* escrito de evaluación por los farmacéuticos comunitarios y, secundariamente, determinar el efecto del *checklist* en la evaluación y entrega apropiadas.

Métodos: Tres pacientes simulados femeninos visitaron 100 farmacias aleatoriamente seleccionadas solicitando la provisión de 'la píldora del día después'. La información proporcionada, cuando era evaluada por el farmacéutico, era que se había olvidado de una píldora activa de su contraceptivo hormonal normar. La cantidad de evaluación realizada y la adecuación de la provisión fueron utilizadas como medidas comparativas de resultados.

Resultados: 83 farmacéuticos utilizaron un *checklist* escrito de evaluación. 24 de los farmacéuticos visitados proporcionaron el resultado adecuado no proporcionando. Los farmacéuticos que utilizaron el *checklist* escrito de evaluación evaluaron en mayor frecuencia y con más consistencia (11.3 ±2.5 v. 6.5 ±3.8 preguntas, p<0.0001), pero esto no produjo una mayor frecuencia de resultado adecuado (20%, n=16 v. 23%, n=3).

Conclusiones: Mientras que un *checklist* escrito de evaluación del paciente mejoró la cantidad y la consistencia de la evaluación, no mejoró el asesoramiento proporcionado por los farmacéuticos comunitarios cuando abordan solicitudes de contracepción de emergencia.

Palabras clave: Simulación de Paciente; Anticoncepción Postcoital; Servicios de Farmacia Comunitaria; Ejercicio profesional; Conocimientos, Actitudes y Práctica en Salud; Farmacéuticos; Australia

INTRODUCTION

In 2004, emergency contraception (EC) was rescheduled in Australia to allow pharmacists to supply EC without a prescription ('Pharmacist Only': product must be sold under the direct supervision of a pharmacist).[1] The Pharmaceutical Society of Australia (PSA) has provided guidance on the professional obligations when providing EC. The PSA protocol for EC is designed as a flowchart outlining the processes involved to ensure that EC is provided appropriately.[2] The protocol provides information on areas such as patient assessment, medication efficacy, contra-indications and interactions, advice regarding regular contraception methods, screening for sexually transmitted infections (STIs) and any follow up that might be required should treatment failure occur.

In conjunction with the protocol, the PSA has recommended the use of a written patient assessment checklist, for completion prior to supply.[3] The checklist is a document consisting of assessment questions that either the patient can fill in themselves or the pharmacist can refer to when assessing the patient. The checklist assesses the following areas; usual means of contraception, reason for EC, time since last episode of unprotected intercourse, patient age, details of menstrual cycle, medical history, medication history, and whether the patient recently had an episode of vomiting, diarrhoea, a pregnancy test or is currently breastfeeding. There are several variations of the PSA checklist in use in Australia.

In Australia information gathered during patient assessment is not routinely documented, with the checklist for provision of EC being the only written patient assessment form recommended by professional pharmacy organisations. Some pharmacies in Canada and Switzerland are also reported to be using a written patient assessment checklist for provision of non-prescription EC.[4,5] A written patient assessment checklist has also been used in the United Kingdom where EC was only available without prescription via a group prescribing protocol.[1] Despite its use in various countries, the effect of a written patient assessment form for non-prescription medication requests on pharmacy practice behaviour has yet to be evaluated.

The objective of this research was to determine the use of a written assessment checklist for provision of non-prescription EC by community pharmacies and to measure the effect of the checklist on appropriate assessment and supply of EC.

METHODS

The University of Western Australia Human Research Ethics Committee granted approval for the study.

Setting

All community pharmacies in a metropolitan region were initially identified as eligible for inclusion (n=411); of these, 6 pharmacies were chosen for inclusion in a pilot study and excluded from the main study. Pharmacies which employed staff known to the simulated patients, that had knowledge of the study and those that did not supply non-prescription medication to the public were also excluded (n=8). From the remaining 397 eligible pharmacies, 100 were randomly selected for inclusion using a random number generator and then randomly allocated to 1 of 3 simulated patients.

Visits were undertaken using the same simulated patient methodology outlined in a previous study.[6] One of 3 female simulated patients presented to

Table.1. Scenario description
Simulated patient enters the pharmacy and asks: "Can I please have the 'morning after pill'?" The pharmacy staff member is provided with the following information on assessment:
Information obtained from the PSA[a] and PCWA[b] written assessment checklist on completion -Combined Oral Contraception is the usual means of contraception -Missed a pill -Last period 3 weeks ago, of 5 days duration -28 day menstrual cycle -Last period was normal -1 case of unprotected sex: 15 hours ago -No vomiting/diarrhoea -No recent pregnancy test -No medical conditions -No previous ectopic pregnancy -Not currently breastfeeding -No other medications taken
Additional information: - The request is for herself. - Missed one pill in the "red" section. - Taken no action. - Using Triphasil 28® for over a year, takes one at night. - Has not used EHC before. - Last seen a medical practitioner a year ago. - In a stable relationship. - Doesn't smoke. - No allergies.
Outcome: Identify that the patient is currently at the end of her menstrual cycle and that she has missed a single pill of her regular contraceptive, containing lactose. Advise patient that the missed pill is inactive, has no impact on the efficacy of her regular contraceptive, and emergency hormonal contraception is not indicated.
[a]Pharmaceutical Society of Australia, [b]Pharmaceutical Council of Western Australia

pharmacies with a request for the 'morning after pill', the request being made to the first available pharmacy staff member. Simulated patients were instructed to provide answers to questions asked but without providing information not specifically requested. The information provided was that the patient had missed a single dose of their combined oral contraceptive pill in the lactose (inactive) section (Table 1). If the pharmacy staff member advised the simulated patient that EC was not therapeutically required and provided a choice to purchase or not, the simulated patient was to decline supply. Training of the simulated patients was conducted via role-play and a pilot study (n=16). Completion of a written data collection form by the simulated patients was undertaken immediately post-visit. The data collection form was designed to record all relevant demographic information, and assessment and counseling elements provided during the interaction.

Outcome

The appropriate outcome for the scenario was non-supply of EC, as the simulated patient had missed a single lactose (inactive) pill of their regular combined oral contraception. The efficacy of their regular contraception was not altered.

Data analysis

Descriptive statistics were performed for all data. A Fisher Exact Test was used to compare categorical data as small counts (under 5) were obtained. A Student t-test was used to compare continuous data (amount of assessment). The amount of assessment was defined as the number of questions asked by either verbal or written assessment (multiple questions eliciting the same information were only counted once). The consistency of assessment was defined as the level of variance (standard deviation).

RESULTS

Demographic data of the 100 pharmacies visited is presented in Table 2. Overall, 76% of visits (n=76) resulted in EC being supplied to the simulated patient. In 14% of these visits (n=11), the pharmacy staff member informed the simulated patient that EC was not therapeutically required but was nevertheless recommended. In visits where EC was not supplied, the reasons provided were: EC was not therapeutically indicated (n=19), EC was currently out of stock (n=3), personal reasons of the pharmacist (n=1) and in one visit the simulated patient was referred to the medical surgery next door.

Of all pharmacies visited, 83% (n=83) provided the patient with a checklist for completion by the patient and 80 (96%) of these used the PSA or PCWA checklist. Of the 17 (17%) pharmacies that did not provide a checklist, three pharmacies (3%) supplied EC without any written or verbal assessment. Where non-supply was due to a non-therapeutic reason (n=5, 1 from the checklist group, 4 from the no checklist group), data were removed from the comparative analysis. Table 3 shows that the proportion of visits resulting in appropriate non-supply when a checklist was provided to the simulated patient were not significantly different to visits without (20%, n=16 v. 23%, n=3, p value not significant). An increase in the amount and consistency of assessment performed was found in the pharmacies using a written assessment checklist when compared with pharmacies that did not (11.3 ±2.5 v. 6.5 ±3.8 questions, p<0.0001).

The type of assessment questions most frequently covered by pharmacy staff are shown in Table 4. A significant increase in assessment was found for all assessment elements covered by the checklist when a checklist was used. A significant difference (p=0.009) was also found for the additional assessment of whether the simulated patient had a regular menstrual cycle in the visits when a checklist was used.

Table 2. Pharmacy and staff characteristics (n=100)

Characteristics	Percentage
Pharmacies	
Pharmacy Type	
Chain	51
Independent	49
Pharmacy Location	
Shopping Centre	49
Street	40
Medical Centre	9
Other	2
Pharmacy Busyness	
Staff > Customers	59
Staff ≤ Customers	41
Wait for consultation	
No	53
Yes	47
Staff	
Gender	
Female	65
Male	35
Type	
Pharmacist	47
Pharmacy Assistant	4
Pharmacist referral (by assistant)	40
Pharmacist consulted (by assistant)	2
Other/Unsure	7
Estimated Age (years)	
< 20	0
20 – 29	44
30 – 39	31
40 – 49	8
> 50	17
Visit Time (minutes)	
< 1	1
1 – 3	12
> 3	87

Table 3. Outcome measures

	Checklist (n) (n=82)	No checklist (n) (n=13)	p value
Inappropriate outcome - supply of EC	80% (66)	77% (10)	n.s
Appropriate outcome - non-supply of EC	20% (16)	23% (3)	n.s
Amount of assessment	11.3 ±2.5[a]	6.5 ±3.8[a]	p<0.0001

[a] mean ± standard deviation

Table 4. Frequency of Patient Assessment Questions asked by Pharmacy Staff

	Checklist (n) (n=82)	No checklist (n) (n=13)	p value
Checklist Questions			
Reason for request	96% (80)	62% (8)	0.0004
Medication history	95% (79)	46% (6)	<0.0001
Medical history	95% (79)	38% (5)	<0.0001
Time since unprotected sex	95% (79)	69% (9)	0.006
Time since last menstruation	95% (79)	46% (6)	<0.0001
Regular contraception	94% (78)	62% (8)	0.002
Pregnancy/Breastfeeding	94% (78)	8% (1)	<0.0001
Non-checklist questions			
Prior use of EHC	87% (72)	92% (12)	n.s.
Menstrual cycle regular	70% (58)	31% (4)	0.009
Patient identity	46% (38)	69% (9)	n.s.
When pill missed	46% (38)	38% (5)	n.s.
Number of pills missed	40% (33)	38% (5)	n.s.
Type of pill missed	33% (27)	23% (3)	n.s.

DISCUSSION

The vast majority of pharmacy staff used a written patient assessment checklist during the simulated patient visit. These results suggest that the use and acceptability of checklists by pharmacy staff is high. The vast majority of pharmacy staff that used a checklist (96%, n=80) used either the PSA or the PSWA checklist These checklists differed in format but covered the same information listed in Table 1. Queddeng and colleagues recently published a study investigating the supply of EHC in Australia using similar methodology.[7] Interestingly, they found that a written assessment checklist was used for 10% of visits in their research.[7] The rate of use is markedly different to that found in our research. The difference may be due to their research being conducted in a different state of Australia. Separate bodies in other states carry out the dual responsibility the PCWA has of performing the statutory role of administering pharmacy legislation and also representing pharmacists as a professional society. As the checklist is only recommended by the professional society (PSA) in other states, this might lead to a lower compliance rate. A more regulated environment in the United States has previously been shown to increase the amount of counseling provided by pharmacists.[8]

In the scenario presented, missing an inactive (lactose) pill did not have any effect on the efficacy of the simulated patients' regular combined oral contraceptive. Therefore the correct outcome in this scenario was "non-supply" as EC was not required. However, 76% of all simulated patient visits resulted in inappropriate supply of EC. This figure is consistent with previous studies in this population looking at appropriate supply of non-prescription medication, where a written checklist was not used in practice.[6,9] The finding of variable practice is also similar to other research assessing EC supply in Australia using similar methodology.[7,10]

Using a checklist increased both the quantity and consistency of patient assessment exhibited by pharmacy staff as the number of different questions asked either verbally or orally was significantly higher and the variance lower. Questions contained by the written checklists used were all increased with only menstrual cycle regularity of the non-checklist elements increased. This suggests that the use of a checklist does increase further verbal assessment but not to any great extent for this particular scenario. However, despite the increased amount of information gathered, the use of a checklist only resulted in an appropriate outcome in less than a quarter of visits with no significant difference found than when no checklist was used to aid patient assessment. Research in Australia and the UK has shown that increased patient questioning has resulted in improved outcomes.[6,11] The results of this research suggest that increasing the amount of information gathered alone is insufficient. The pharmacy staff member must also accurately appraise the information gleaned during patient assessment.

Interestingly, pharmacy staff provided advice to the simulated patient in 14% of visits that in their situation they were unlikely to therapeutically require EC, but still went on to recommend use. No staff advised purchase of EC for future use ('advanced provision'). This compares to the 19% of visits where the staff advised that EC was not required. Staff in these visits have gathered sufficient information, correctly appraised the patient's situation, yet have come to a different decision on the need for EC. The results demonstrate that decision-making is a separate process to both information gathering and appraisal. Thus, use of a written assessment checklist without addressing information appraisal and decision-making by pharmacy staff cannot be recommended. Strategies to enhance both information appraisal and decision making are required in order to take advantage of the increased quantity of information gained by use of a written assessment checklist research is required to determine which strategies are effective.

The strength of this research is that it is the first to describe the impact of the use of a written assessment checklist on the provision of non-prescription medication by community pharmacies. Further, this research examines the use of the written checklist as part of established practice as opposed to a new intervention. Finally, the research demonstrates that patient assessment by pharmacy staff relies on more than information gathering alone as pharmacy staff may not use the gathered information effectively in order to make appropriate clinical decisions. However, there are limitations to

this study. Some variables, including the age and position held by pharmacy staff members, were assessed by simulated patient observation and thus might potentially be subject to estimation error. To minimise potential error, estimated age was grouped by decade and an 'unsure' category was used for visits where the staff characteristic was difficult to determine. The results were recorded immediately post-visit and relied on recollection by the simulated patient. Prior research suggests that this might introduce an error rate of up to 10%.[12] Ethics approval was sought for audio-taping of the interaction but was refused due to lack of consent of the individual pharmacy staff member prior to or at the point of recording.

CONCLUSIONS

Less than a quarter of visits resulted in appropriate non-supply of EC, despite the majority of pharmacy staff using a written patient assessment checklist. The checklist increased quantity and consistency of patient assessment exhibited by pharmacy staff however the information gathered may not have been used effectively. For supply of EC without prescription, use of a written patient assessment checklist increases the amount of assessment provided by pharmacy staff but does not improve appropriate medication supply.

ACKNOWLEDGEMENTS

The authors wish to thank the Pharmaceutical Council of Western Australia for facilitating the research and Asma Yassin for assisting in data collection. The University of Western Australia funded the costs of this research. The Asthma Foundation of Western Australia also funded a PhD scholarship for the first author.

CONFLICT OF INTEREST

Nil.

This study was completed under a grant from the Pharmaceutical Council of Western Australia.

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