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Original Research

Private pharmacy staff in Hanoi dispensing steroids - theory and practice

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ABSTRACT[*]

Objective: To investigate self reported practice and actual practice of private pharmacy staff in relation to drug regulations and provision of prednisolone (a prescription-only corticosteroid) on request to treat lower back pain.

Method: Sixty private pharmacies in Hanoi were randomly selected. Self reported practice was assessed through interviews with pharmacy staff using a questionnaire; actual practice was assessed with the Simulated Client Method with 5 encounters in each pharmacy (a total of 295 encounters).

Results: Sixty percent of the pharmacy staff interviewed said that they would not dispense corticosteroids without prescription and 60% could mention some adverse effects. In practice all but one pharmacy dispensed corticosteroids without prescription in 76 % of all the encounters. Questions and advice given to the clients were associated with significantly lower dispensing of corticosteroids.

Conclusion: The low compliance with prescription regulations and the discrepancy between stated practice and actual practice raises concerns. This study indicates that commercial pressures exceed the deterrent effect of current drug regulations and their implementation and hence enforcement of regulations needs to be improved.

Keywords: Corticosteroid. Simulated Client. Good Pharmacy practice. Pharmacy Staff. Knowledge. Vietnam.

RESUMEN

Objetivo: Investigar la práctica auto-comunicada y la práctica real del personal de las farmacias privadas en relación a la regulación sobre medicamentos y provisión de prednisolona (un corticoide de prescripción) solicitado para tratar un dolor lumbar.

Método: Se seleccionaron aleatoriamente sesenta farmacias privadas en Hanoi. Se evaluó la práctica auto-comunicada a través de entrevistas con el personal de la farmacia mediante un cuestionario; la práctica real fue evaluada con el método del Cliente Simulado con 5 visitas a cada farmacia (un total de 295 visitas).

Resultados: El sesenta por ciento del personal de farmacia entrevistado dijo que no dispensaría corticoides sin receta, y el 60% pudo mencionar algunos de los efectos adversos. En la práctica, todas menos una farmacia dispensaron corticoides sin receta en el 76% de las visitas. Las preguntas y los consejos dados a los clientes se asociaron con significativamente menor dispensación de corticoides.

Conclusión: El bajo cumplimiento con las regulaciones y la discrepancia entre práctica declarada y práctica real produce preocupación. Este estudio indica que las presiones comerciales exceden al efecto preventivo de las regulaciones sobre medicamentos y su implantación y por tanto es necesario mejorar la vigilancia de las regulaciones.

Palabras clave: Corticoides. Cliente simulado. Buenas prácticas de farmacia. Personal de farmacia. Conocimiento. Vietnam.

(English)

INTRODUCTION

In many low-income countries, health care reforms and privatization have increased the availability of drugs for lay people through private pharmacies. The private provision of drugs has, however, frequently been associated with inequitable affordability, impaired rational use and substandard drug quality. Effective regulatory framework is therefore a major opportunity and challenge.[1,2] Although regulations commonly exist, the regulatory authorities often lack resources for effective implementation and enforcement, limiting their ability to influence private sector activity.[1,3] Little work has been done to assess the compliance of regulations as well as exploring how, and to what extent, regulations fail.

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Vietnam has been progressive in dealing with basic health problems, and has achieved a comparably low infant mortality rate and high life expectancy.[4,5] In the late 1980s, there were shortages of drugs after a period of isolation from the international community and a costly post-war reconstruction.[6] In 1986, an economic reform, the "Doi Moi" renovation towards market economy, was initiated. The pharmaceutical industry and drug retail business were liberalized. Pharmacists were allowed to open retail pharmacies, and the pharmaceutical market shifted from publicly financed to private enterprise. Between 1986 and 1994, there was a six-fold increase in per capita drug consumption.[7] The number of private pharmacies increased from none in 1986 to more than 6000 in 1996[8] and currently acts as the first line medical care providers, a situation also found in other low-income countries.[9-11] Hence the quality of pharmacy service is of great public health importance. The formulation of both the Tokyo declaration of Good Pharmacy Practice (GPP) in 1993[12] and the GPP Guidelines issued by WHO in 1994[13] attest to their importance.

In Vietnam, a prescription and drug dispensing regulation has been in place since 1995 and includes detailed information regarding prescription-only drugs, which includes all corticosteroids and all but 8 antibiotics.[14] A drug policy was adopted 1996 and includes paragraphs regarding rational use of drugs.[15] The private pharmacies are obliged to continuously stay updated and comply with the current regulations. However, several studies in Vietnam and other low-income countries have found that pharmacy customers commonly request specific drugs and that the pharmacies dispense prescription-only drugs such as corticosteroids and antibiotics, often without any questions.[9-11,16-19] Hence the ability of the pharmacy staff to deal with drug requests is important.

Corticosteroids are an important group of drugs used mainly for two purposes: (i) replacement therapy in patients with adrenal gland deficiency; (ii) immunosuppressive and anti-inflammatory therapy. When indicated, they may be lifesaving, such as for patients with anaphylactic shock or life expanding as for patients with autoimmune diseases. However, there are serious adverse effects of steroid use such as peptic ulcers, immuno-suppression and metabolic effects on water and electrolyte balance, muscle wasting, osteoporosis, hyper-glycaemia, hypertension-increased fatty tissue (moon face and buffalo hump), all part of Cushing's syndrome.[20,21] For most infectious diseases, steroid use is contraindicated, as steroids tend to disguise inflammatory symptoms, giving a subjective feeling of improvement, while in fact the immunosuppressive effect decreases the ability of the infected person to fight the invasive organism.[20] It has been found that corticosteroids are commonly irrationally used for health problems like diarrhoea, fever, jaundice and lower back pain in low and middle-income countries.[19,22] Due to the severe adverse effects, most countries, including Vietnam, have chosen to restrict the availability of steroids through prescription-only regulations.

In this study we have assessed private pharmacy self reported practice and actual practice in relation to dispensing of prednisolone on request for treatment of lower back pain. This tracer condition was used to assess compliance with prescription regulations as well as determining the current level of rational dispensing of corticosteroids in private pharmacies in Hanoi. Most episodes of lower back pain are mechanical in origin, associated with muscle strain and resolve naturally within 1 to 2 weeks. The pain can in most cases successfully be relieved with paracetamol, NSAIDs including diclofenac and ibuprofen[23] as well as with acupuncture[24], whereas corticosteroids are not indicated. This study was part of the European Union supported "Towards Good Pharmacy Practice in Thailand and Vietnam", a randomised controlled trial aiming to improve dispensing of prescription only steroids and antibiotics as well as case management of Acute Respiratory Infections and Sexually Transmitted Diseases.

METHODS

Study population: The study was conducted in the urban area of Hanoi with 789 private pharmacies, pharmacies located in hospitals and wholesalers were excluded. From the list of the remaining 641 pharmacies, 60 pharmacies were randomly selected by computerized randomization using the Excel program. This paper reports baseline data from a randomized-controlled trial where the pharmacies are the unit of analysis. Analysis is also done at the level of individual simulated client encounters (SCM) client encounters in the pharmacies.

Questionnaire: Interviews of pharmacy staff at the selected pharmacies were conducted with a semi-structured questionnaire containing mainly multiple choice and a few open-ended questions regarding dispensing of prescription-only drugs including prednisolone. The interviews aimed to get the respondent to state how they would manage a client requesting prednisolone to treat lower back pain. Questions included: "My back is aching. Could I have 2, 3, 4 or 5 tablets of prednisolone please?" If they did not offer to ask questions or give advice, the interviewer would prompt with "would you ask any questions?" or "would you give any advice?". The interviewees were aware that they were answering a survey. Four interviewers, two pharmacists, one medical doctor and one sociologist, were trained through role-play on how to conduct the interviews. All sixty pharmacies were visited by one of the interviewers and all the staff working (mostly one) at the pharmacy at the time of the visit where interviewed. The answers were coded and entered into the computer by using the program Epi Info 6 (a computer program for processing and analyzing epidemiological data). The interviews took place after all the simulated clients' visits had been completed.

The Simulated Client method (SCM) was used to measure provider behaviour and was used before the questionnaire survey to avoid contaminating the SCM results. Research assistants with fictitious case scenarios visited the selected pharmacies and

requested their assistance. SCM has frequently been used to assess practice in both low and high-income countries.[9,10,24-26] In this methodology, the simulated clients present complaints to pharmacy staff and purchase the drugs recommended. To avoid attention and recognition by pharmacy staff, five different clients visited all the pharmacies simultaneously according to a prearranged rotating schedule. All clients were trained to act in a reproducible way. A specific recording sheet for the clients containing information regarding the drugs, questions and advice was developed. Five female assistant pharmacists from Hanoi College of Pharmacy were selected as simulated clients and trained to act according to the client scenario. Each simulated client encountered all 60 pharmacies, presented the scenario complaining about lower back pain, asking for a few capsules of prednisolone without providing a prescription (Table 1), bought the recommended drugs and within 15 minutes recorded the events in the record sheet. A total of 295 encounters were conducted. Data on 5 encounters were not collected since the pharmacies were closed at the time of the visit. The simulated clients submitted the drugs purchased and the record sheets to the research staff at the College of Pharmacy in Hanoi. Drugs were classified according to the Anatomical Therapeutic Chemical (ATC) classification, an instrument for classification of drugs adopted by the World Health Organisation and whether they were prescription-only drugs or over the counter (OTC) drugs, according to Vietnamese regulations.

Table 1: Simulated Client method scenario.

The simulated client knows what his/her problem is and they know how to treat it. This is because he/she has tried the drugs before or because someone has recommended them to him/her.

Presentation of the problem at the pharmacy: "My back is aching. Could I have 2, 3, 4 or 5 tablets of Prednisolone please"

In response to questioning by the pharmacy staff, the client will provide the following information selectively:

- Your moderate lower back pain has lasted for one week. You have done some repetitive movements at work, in the household or wherever. For example, you work a lot by the typewriter/computer and have an ache in your back from all the typing you have to do. This has now gone on for 1 week now, and you're getting a bit fed up. One of your friends at work recommended you to go to the pharmacy and get some Prednisolone. "That works wonders" according to your friend, who uses it sometimes.
- Your back has been aching before, a year ago. At that time you used Paracetamol, but it didn't help much. You still felt the pain, which bothered you at work. You have no other medical problem.

The results were coded and entered into a computer using "Microsoft Access" 1998 and the Statistical Package for Social Sciences for Window Software (SPSS) version 9.0 (a software for data processing and statistical analysis). The pharmacies are the unit of analysis for SCM and questionnaire data as well as for comparisons between SCM and questionnaire data. Analysis of SCM data is also done at the level of individual SCM client encounters at the pharmacies. Statistical analysis was performed with chi square, Wilcoxon and a 2-tail t-test to determine group differences.

The study was planned and conducted in collaboration with the Ministry of Health (MoH), the Hanoi Health Bureau and the Hanoi Pharmacy Association, who were formally responsible for the study. Informed consent from the individual pharmacy staff was not obtained in advance, as this could have seriously impaired the results by introducing observation and selection bias.[25] There were no punishments for those private pharmacy staff members who acted against the regulations. The pharmacies were coded and the results are provided as group averages. One important reason for using SCM was that the potential harm of the low quality of pharmacy practice, including the frequent irrational provision of drugs, was considered by the national health authorities to be an increasing problem.

RESULTS

Self reported practice assessed with questionnaire interviews

Seventy interviews were performed in the 60 pharmacies, in ten pharmacies there were 2 staff members present who both were interviewed (table 2).

Table 2: Private Pharmacy profile (n=60)

	N	%
Number of pharmacy staff interviewed	70	100
Background of pharmacy staff		
• Pharmacist	35	50
• Assistant pharmacist	25	36
• Medical doctor	4	6
• Assistant Medical doctor	1	1
• Not health related training	5	8
Number of pharmacies with one working staff	26	43
Number of pharmacies with two working staff	34	57
Opening hours/week average (SD)	74 (20)	
Stated average number of clients per day (SD)	31 (20)	
Stated percentage of customers with prescription		17

In response to the question "Have you ever had a customer who asked for some tablets of corticosteroids" 86% of the interviewees stated yes. The majority, 60% of the pharmacy staff interviewed, said that they would not dispense corticosteroids on request without prescription. The reasons mentioned are shown in Figure 1. Of the

40% who stated that they would dispense, 90% justified this by saying that they wanted to comply with the client's request, and 3% that "otherwise other pharmacies would sell the drugs". In 2 of the 10 pharmacies with two staff interviewed, one of the staff stated that they would dispense and the other that they would not.

Regarding knowledge of adverse effects, 43% mentioned osteoporosis, 41% peptic ulcers, 16% edema, 9% immune defence inhibition and 9 % muscle wasting. Moon face (4%), high blood pressure (3%) and mental disturbance (3%) were also mentioned.

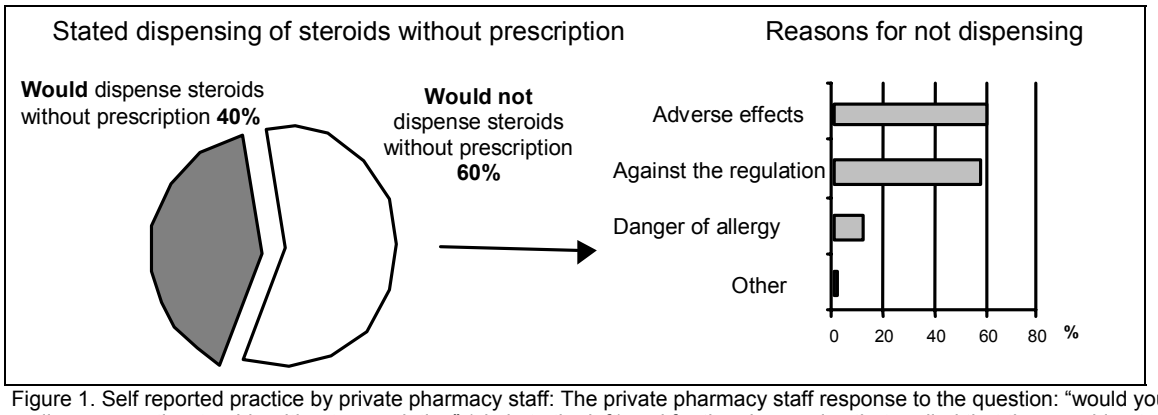

Figure 1. Self reported practice by private pharmacy staff: The private pharmacy staff response to the question: "would you dispense corticosteroids without prescription" (circle to the left) and for the pharmacies that replied that they would not dispense, the reasons for not dispensing (graph to the right). Several reasons for not dispensing could be mentioned, thus the graph adds up to more than 100%.

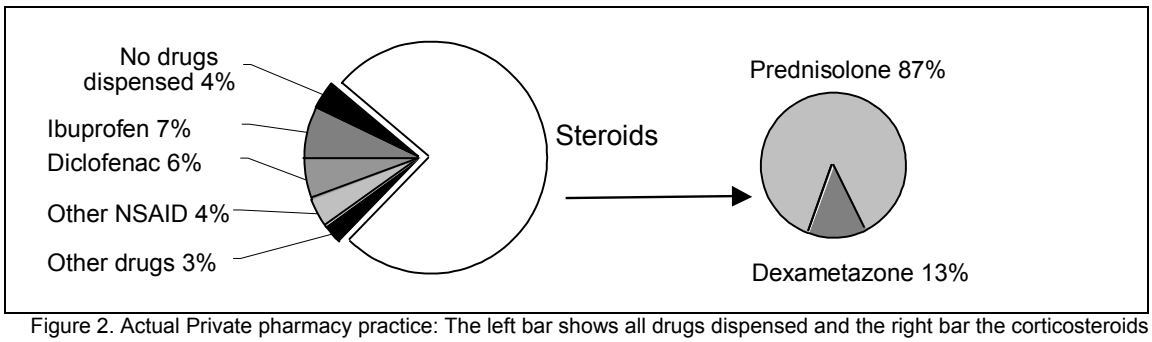

Figure 2. Actual Private pharmacy practice: The left bar shows all drugs dispensed and the right bar the corticosteroids dispensed. In total 295 SCM encounters were conducted, five in each pharmacy (5 encounters could not be performed as the pharmacy was closed). NSAID: Non steroid anti-inflammatory drugs.

Pharmacy staff practice assessed with SCM

All but one pharmacy (98%) dispensed corticosteroids. 16 pharmacies (27%) dispensed in all 5 encounters, 26 pharmacies (43%) dispensed in 4 encounters, 9 (15%), 3 (5%) and 5 (8%) pharmacies dispensed in 3, 2 and 1 of the encounters, respectively. In total, corticosteroids were dispensed in 76 % of all the encounters. In only three encounters (1%) did the pharmacy staff ask for a prescription. Drugs dispensed are shown in figure 2.

In the encounters, where questions were asked and advice given there were significantly less steroids dispensed, 66 % and 64% respectively (table 3 and 4), compared to the encounters where no questions were asked (82%) and no advice given (91%).

Questions were asked in 41% of the encounters with an average of 1.15 questions per encounter (table 3). Questions related to significantly less dispensing ($p<0.01$) were: questions related to back-pain; previous use; alternative treatment with other analgesic drugs; who had advised you to buy and; why do you want to take prednisolone (table 3). Questions related to significantly more dispensing ($p<0.05$) were: stomach problems and if they just wanted the requested amount of tablets.

Advice was given in 57% of all the encounters with an average of 1.47 advices per encounter (table 4). Advice related to significantly less dispensing ($p<0.01$) were: not to use corticosteroids; use other drugs; visit a doctor; take before meals; and to use massage. Advice related to significantly more dispensing ($p<0.05$) were: information about adverse effects (4% of the encounters) and recommended to take the drug at least 5-7 days.

Comparison between self reported practice and actual practice

There was a significant difference ($p<0.001$) between stated (questionnaire) dispensing (40%) and actual dispensing (98% of the pharmacies in 76% of all the encounters). Pharmacies stating they would not sell dispensed significantly ($p<0.001$) less corticosteroids, in 70% of the encounters, compared to the pharmacies stating that they would sell which dispensed in 84% of the encounters. All pharmacies that justified not dispensing by saying, that it is against the regulation, nevertheless did so in practice in at least one encounter.

Table 3. Encounters where questions were asked and the frequency of corticosteroids dispensed in those encounters.

Questions	Nr. of questions asked	% of total encounters with questions	% of all encounters	Nr. of encounters steroids dispensed	% of encounters steroids dispensed	Significantly more (↑) less (↓) steroids dispensed*
Regarding stomach pain	38	31%	13%	33	87%	↑
Why do you want to buy such a small dose?	23	19%	8%	23	100%	↑
Have you used corticosteroids before?	15	12%	5%	5	33%	↓
Questions regarding back pain?	12	10%	4%	3	25%	↓
Who advised you to buy corticosteroids?	10	8%	3%	2	20%	↓
Do you want to buy another analgesic drug?	8	7%	3%	1	13%	↓
Why do you take prednisolone?	5	4%	2%	1	20%	↓
Do you have a prescription?	3	2%	1%	0	0%	↓
Other questions?	25	21%	8%	14	56%	↓
Total number of encounters	121**	100%	41%	81**	66%	↓

*Significantly ($p<0.05$) more (↑) or less (↓) encounters where corticosteroids were dispensed compared to all other encounters. **The total number of encounters does not add up to the number of questions asked as there were in average 1.15 questions per encounter where questions were asked.

Table 4. Encounters where advice was given and the frequency of corticosteroids dispensed in those encounters.

Advice	Nr. of advice given	% of the total encounters with advice	% of all encounters	Nr. of encounters steroids dispensed	% of encounters steroids dispensed	Significantly more (↑) less (↓) steroids dispensed*
Take after meals	130	78%	44%	101	78%	**ns**
Don't use corticosteroids	37	22%	13%	0	0%	↓
Recommended other drugs	20	12%	7%	7	35%	↓
Visit a doctor	12	7%	4%	2	17%	↓
Harmful, adverse effects	9	5%	3%	8	89%	↑
Take before meals	7	4%	2%	3	43%	↓
Use massage, gymnastics or special movements	7	4%	2%	3	43%	↓
Take at least 5-7 days	5	3%	2%	5	100%	↑
No corticosteroids left	4	2%	1%	0	0%	↓
Other advice	14	8%	5%	12	86%	↑
Total number of encounters	167**	100%	57%	107**	64%	↓

*Significantly ($p<0.05$) more (↑) or less (↓) encounters where corticosteroids were dispensed compared to all other encounters. **Total number of encounters does not add up to the number of advice given as there were in average 1.4 items of advice per encounter where advice was given. (ns = non significant)

DISCUSSION

Corticosteroids were dispensed by all but one pharmacy on average in 76 % of the encounters and prescription requests were only recorded in 1% of the encounters. This was done despite that 60% stated during interviews that they would not dispense steroids on request without prescription. A decree regulating prescribing, stating that all corticosteroids are prescription-only drugs, has been in place since 1995.[28] Clearly this shows that the regulations regarding prescriptions are generally not respected. Several studies have shown that prescription-only drugs are commonly dispensed without prescription in Vietnam and other Asian countries.[10,11,17,18] In a Brazilian study clients asked

for corticosteroids; the pharmacies complied with the request in 65% of the encounters.[19]

The effectiveness of regulation is strongly influenced by the socioeconomic context.[1,2] Determinants such as customers' expectations, social acceptance, commercial pressures and profit needs may have more impact on actual practice compared to regulations and clinical indications.[29,30] As the number of pharmacies has grown dramatically in Vietnam competition has increased and profit margins decreased.[4] Pharmacy staff may feel compelled to focus more on profit than on their professional role.[29-31] The potential risk of not complying with the regulation might not be enough of a deterrent, especially if economic margins are small. In Vietnam, the control needed to implement regulations has been lacking, due to weak and not clearly defined sanctions for violations as well as few incentives for officials and inspectors to focus on the issue.[32-34] This has also been described in other low-income countries.[3,29] In Lao PDR, the regulatory system was not able to deal with the existence of dangerous, fake or substandard drugs.[1] In Vietnam, an enforcement system including sanctions is being developed.[33]

The difference between stated behaviour and actual practice is often attributed to observation bias.[25] This has previously been shown with oral rehydration solution treatment for diarrhoea in Kenya[35] as well as in other studies in low-income countries[25,27,29,36] showed that even though 74% of private pharmacies in Hanoi stated that they would not treat STD symptoms, 84% still dispensed prescription-only antibiotics and none gave the syndromically correct treatment. This underlines the importance to assess not only self reported practice or knowledge but also actual practice; using a questionnaire by itself would have grossly underestimated the incidence of irrational steroid dispensing.

Asking diagnostic questions such as "what kind of back pain do you have" and "duration of back pain" were associated with significantly less dispensing of corticosteroids. Hence strategies to initiate communication in combination with case management training might be important. Much of the pharmacy staff advice was poor and the most common advice, to take after meals, has no relevance. Lack of knowledge about standard treatments and regulations, commercial pressures and a failure to implement the existing regulations has been identified as major factors behind poor pharmacy advise.[37] In Vietnam, continuous education among practitioners is often non-existent or depends heavily on information from the representatives of the pharmaceutical companies which tends to be biased.[38]

Information about adverse effects was only given in 4% of the encounters, although it was mentioned by 60% in the questionnaire. It has been shown that some physicians deny hazardous drug effects, even though they have acknowledged adverse effects during interview.[30] The importance of awareness regarding adverse drug reactions is emphasized by the fact that adverse drug reactions now may account for up to 10% of the admissions of patients to internal medicine wards at a cost of hundreds of millions of US dollars annually.[39] The extent of disease due to adverse drugs reactions in Vietnam is not known, but might - considering the ubiquitousness of self-medication - be extensive.

Corticosteroids are potent drugs that are useful for many diseases; this is also perceived by the patients.[11] The serious adverse effects however justify restrictive use only on correct indications.[40] Being relatively cheap, in Vietnam one tablet costs less than 1000 Dong (about 7 cents), corticosteroids could without loss of profit be substituted by less harmful non-steroid anti-inflammatory drugs. Studies in Kenya and Indonesia have shown that it is possible to improve private pharmacy practice through a combination of focused small group training and supporting their self-image as health professionals.[35] Multi-faceted interventions including regulatory enforcement and education have been proven effective in public sector[29] as well as to improve private pharmacy case management of common diseases and regulatory compliance.[33] In addition, empowering consumers to make informed choices must also be taken into account.[3] In addition to monitoring of the effects of the enforcement system reform in Vietnam, more research is needed to understand, in more detail, aspects relevant for counter staffs motives for their practices including profit motives, customer's demand and commercial pressures.

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