

Qualitative laboratory analysis for the detection of conventional drugs in herbal preparations supplied by healers in major towns of Ethiopia

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Abstract

Background: There has always been an air of uncertainty whether or not traditional healers, especially those in the urban areas, supplied herbal remedies adulterated with modern drugs.

Objectives: This study aims to analyze herbal preparations prescribed by healers against malaria, gonorrhea, tuberculosis, etc. for the presence of conventional drugs, with emphasis on anti-microbial pharmaceutical ingredients.

Methods: Patient simulated convenience based survey method was employed to collect samples of remedies supplied by healers along with other pertinent information on quality of services provided in 60 traditional health care establishments. Presence or absence of conventional drug ingredients in the collected samples of herbal preparations was tested using a validated analytical laboratory method.

Result: Active pharmaceutical ingredients were detected in 39 or 51% of the 76 samples of traditional remedies tested. The average price that healers charge for herbal preparations adulterated with modern drugs was higher than the full dose of conventional drugs sold in retail pharmacies. Even the unadulterated preparations were found to be more expensive than the latter. Documentation of patient history, diagnostic techniques, dispensing practices of the remedies, etc. as observed in the traditional health service delivery outlets/clinics were generally less satisfactory.

Conclusion: Supplying herbal preparations adulterated with modern drugs, particularly with anti-microbial agents entails a number of untoward effects including increased emergence of resistant pathogenic strains. Sustained effort in creating awareness among the communities by health workers and authorities is, therefore, crucial to curb the looming danger to public health. While existing legal frameworks may be sufficient to consider punitive measures against perpetrators of such inappropriate and unauthorized use of anti-microbial agents, new ones that particularly govern the activities of traditional healers need to be put in place. [*Ethiop.J.Health Dev.* 2008;22(1):55-62]

Introduction

It is often acknowledged that the majority of the population in Ethiopia as elsewhere in most developing countries has, for centuries, relied heavily on traditional or indigenous health care delivery system which consists of empirico-rational and/or magico-religious elements (1, 2). The National Rural Health survey of 1982-83, for example, reported that more than half of all health seekers used the service of traditional healers or self-treatment with herbs (3). Even in major urban areas such as in Addis Ababa where modern health care service is relatively easily accessible, a significant percentage of the population was shown to have used herbal medicines (4, 5).

The fact that it is an integral component of the local culture as well as its presumed low cost and ease of accessibility are said to account for the continued popularity of traditional medicine. Furthermore, the popularity of this system of care, it is argued, stems not only from its bio-medically beneficial elements but also the remedies prescribed are often less bio-stable and bio-cumulative to build up in the body in harmful amounts and, therefore, presumed to be more preferred as safer drugs than potent synthetics (6, 7). For such many reasons, the widespread use of traditional medicine is widely assumed to persist into much of the 21st century.

This is even more so considering the shortfall between the demand for and supply of modern health care system which is further compounded by chronic economic difficulties and the unprecedented contemporary population growth (8).

Thus, regardless of incremental expansion of modern health services, it is feared that there will remain an enormous volume of unmet needs and the cost of meeting them could prove staggering. Therefore, devising affordable care system such as the integration of the ubiquitous indigenous medicine with the conventional care system is believed by many to offer a solution to much of the problems of providing modern primary health care for the under-served population (9).

Opinions about the benefit of integration of traditional medicine with the conventional care are, however, often divided. Opponents to any external move to integrate or streamline one system with another reject such attempt on the ground that in nearly every cultural setting health care systems are pluralistic. Given equal access to multiple treatment resources, they allege, consumers resort to one or another depending on their perception of the nature of the illness, the time needed to obtain care, and the anticipated costs (10).

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Different sets of outright skeptics about the value of integration believe that traditional medical system lumps together scientifically different diseases, especially when the ills in question share similar syndromes and epidemiological profiles and, therefore, unreliable or even dangerous. They also assert that an array of diseases are claimed to be treated by those who practice traditional medicine, the diagnosis in most of which should have ideally been supported by modern techniques and instruments which are either not available or unfamiliar to the healers. Many refute the idea that traditional medical system represents a viable complementary/alternative option worthy of promotion or integration into the main stream of health care services because of its alleged lack of rigorous methods of determining optimum therapeutic dose, the use of perplexing intangible means and ends of particular forms of therapy, inappropriate storage condition of bulk remedies, etc. (11, 12).

The fact that traditional remedies are crude drugs with uncertain quality parameters (lack of knowledge of active principles and/or the variation of their quantities) has been a strong source of resistance to opponents of the indigenous medical system who dismiss the notion of its utilization at any level, not to mention at the level of the official health care delivery system. Such resistance and misgiving against official utilization of traditional medicine has further been compounded by the increasing commercialization of herbal preparations with its attendant profit motive that is feared to open the floodgate of fraudulent practice. Many health professionals, therefore, assert that such situation has already prompted the healers to resort to, *inter alia*, adulteration of their products with synthetic active pharmaceutical ingredients in the hope of inducing at least transitory therapeutic effect and hence attracting more clients.

Indeed, adulteration of herbal preparations with active pharmaceutical ingredients (APIs) is posing a worldwide problem, particularly in a number of developing countries where herbal products are smuggled or imported. For example, adulteration of certain Chinese medicines with drugs like phenytoin, carbamazepine and valproate has led to severe poisoning incident (13). Deaths have been reported from Japan and the USA due to consumption of Chinese sliming aid admixed with N-nitroso-fenfluramine, a toxic chemical substance (14). A study conducted on the quality of herbal drugs also indicated the presence of non-steroidal anti-inflammatory drugs (phenylbutazone, indomethacine) and benzodiazepines in the Chinese patented traditional medicine referred to as Miracle herb (15). Even in remote parts of rural Ethiopia it was reported that some healers admitted dispensing herbal remedies mixed with conventional drugs (16).

So far there is, however, no systematic epidemiological and laboratory study to determine extent, if any, of adulteration of herbal remedies with modern drugs in Ethiopia. In this study attempt was, therefore, made to analyze herbal preparations supplied by healers with a particular emphasis on those prescribed for malaria, Sexually Transmitted Infections (STI) (specifically gonorrhoea), and tuberculosis. These infections do not only contribute to most of the morbidity and mortality globally, but are also those in which emerging antimicrobial resistance is most evident.

In view of the widespread perception that traditional remedies are more affordable than modern drugs, a comparative cost analysis, albeit limited, was also made during this study along with assessment of the kind of quality of service observed in the outlets or clinics run by the healers.

Method

Study site: The study was conducted in 20 major towns of Ethiopia with estimated population size of 50,000-3,000,000 from January, 2005 to December, 2006.

Study design and sampling technique: In view of the fact that there is no official registration or licensing for the practice of traditional health care delivery services by the Ministry of Health or Regional Health Bureaus, a convenience based sampling method was used by relying mostly on sign posts or billboards and on individual local informants to identify and select the traditional health care facilities in each town.

Because of the general tendency among most of the healers to keep their art and remedies shrouded in secrecy, official enquiry based on prior informed consent into their practice is bound to raise suspicion and hence withholding of crucial information as well as outright resistance to any request of samples of their remedies for laboratory investigation. Therefore, patient simulated approach was employed to record the quality of service provided in each facility visited and to purchase adequate quantities of herbal preparations dispensed by the healers for treatment of mainly malaria, gonorrhoea, tuberculosis and for diabetes or hypertension. A total of 60 traditional health care facilities (premises) in 20 towns were considered during this survey. Students from health science teaching colleges were used to collect relevant information and to purchase samples of the remedies for the aforementioned diseases after being given proper orientation by the investigating team members. The observations that the data collectors required to note during their visitation of the facilities/outlets mainly include:

1. Documentation of patient history (yes/no),
2. Patient examination or diagnosis is based on information solely supplied by the patient (yes/no),

3. Are storage facilities such as shelf or chest of drawers available for bulk preparations (yes/no),
4. Are special tools (spoons, spatulas, etc.) used for measuring out dose of the remedies (yes/no),
5. Presence of bulk modern drugs or medical equipment/supplies (yes/no),
6. Presence of rubber stamped document displayed on the wall as permit or license to deliver traditional health care service (yes/no),
7. The overall sanitary situation of the premises and the room(s) where patients are received is fair to good compared to modern health posts or clinics (yes/no).

Methods of Data analysis

Observational data: Information pertaining to quality of service and patient handling practices in each facility were pulled together and tabulated as 'yes' or 'no' responses both in terms of absolute figures and as percentage expression.

Laboratory analysis of the remedies for the presence of API: The samples of the remedies purchased from the healers were subjected to laboratory test to check whether or not they were adulterated with conventional drugs. Thus, the samples were processed and extracted with appropriate solvents and analyzed for the presence of ampicillin, benzyl penicillin, tetracycline, erythromycin, co-trimoxazole (Sulphamethoxazole-trimethoprim), rifampycin, INH, chloroquine, fansidar (Sulfadoxine-trimethoprim), glibenclamide and methyl dopa. The negative control used in all cases is the vehicle (80% ethanol or distilled water). Laboratory analysis of the samples were carried out using a validated (for specificity, accuracy, sensitivity, limit of detection and interferences with the matrix) analytical method (17), that was adopted from German pharma health fund ev, various pharmacopeias, and reported methods on analysis of API, etc.

Results

A total of 76 samples of herbal remedies prescribed or supplied by traditional healers for the treatment of malaria, gonorrhoea, tuberculosis, tropical ulcer and diabetes and/or hypertension were tested for the presence of APIs of conventional drugs. Fifty one percent of these samples were found to be adulterated with one or more modern drugs (Table 1). Fifty six percent of the samples of the herbal preparations supplied as anti-malarial contained mostly fansidar or a combination of fansidar and chloroquine. Almost the same rate of adulteration was detected in the samples of the remedies supplied for the treatment of gonorrhoea where five antibiotics, viz., ampicillin, benzyl penicillin, tetracycline, erythromycin and co-trimoxazole were identified, the latter being the most common adulterant followed by tetracycline. Co-trimoxazole was also detected in 40% of the herbal samples prescribed for tropical ulcer. Rifampycin and INH were detected in over 55% of the herbal samples

delivered as remedies for tuberculosis. Glibenclamide and methyl dopa were detected in about 29% of the samples of traditional preparations supplied for patients who claimed to suffer either from diabetes/hypertension or both.

Average price of adulterated herbal preparations with APIs were up to twice more expensive than unadulterated preparations (Table 2). Average price of both adulterated and unadulterated remedies were invariably more expensive than full dose of conventional drugs. For example, adulterated herbal preparations prescribed as anti-malarial or for gonorrhoea were nearly 24 and 18 times more expensive than full dose of conventional drugs, respectively. Anti-tuberculosis conventional drugs are supplied free of charge in all public health institutions while the healers consulted during this study charge birr 277 and 106 for their adulterated and unadulterated herbal preparations, respectively. A single dose of adulterated and unadulterated traditional remedies against diabetes or hypertension cost more than twice of the full monthly dose of conventional drugs sold in the retail pharmacies.

The overall sanitary condition of the 60 surveyed establishments where healers provide their services was rated fair to good (57%) in comparison with matching health institutions such as health posts and clinics (Table 3). The same table demonstrates that 68% of the healers who own the visited centers claim to have been licensed either by the Ministry of Health or by the so-called healers association to deliver health care service which was apparent from the rubber stamped document hanging on the wall of the patient reception room. However, the existing proclamation on health practice pertaining to traditional medicine does not have any provision for licensing of the healers. Therefore, it is the opinion of the investigators that the Ministry of Health or any other health authority could not have issued such a license. It is also difficult to believe that the 'healers association' could issue such a document given the fact that any professional association is neither legally entitled nor authorized to license any practice, not to mention health care service which is exclusively the domain of the Ministry. Therefore, it is likely that the licenses the healers are so keen to exhibit on their walls are forged documents intended to mislead their client.

Ninety five percent of the healers do not record any background information such as sex, age, address, health complaints, etc. of their patients, a practice which undoubtedly hampers follow up measures and referral systems. Fifty seven percent of the practitioners also do not label containers of the remedies before or after dispensing even though they all provide oral instructions to the patients on methods of administering or applying the remedies. Though they don't have the necessary qualification, some 8% of the healers were in

possession of blood pressure (BP) apparatus and stethoscope. In 25% of the establishments substantial amounts of discarded capsule shell as well as medical supplies such as syringes and needles were observed

which also proves, albeit indirectly, the use of modern drugs and injections under the guise of traditional medicine.

Table 1: Qualitative analysis for a possible adulteration with active modern pharmaceutical ingredients (APIs) of herbal preparations prescribed/sold by traditional healers; January 2005 - December 2006, major towns in Ethiopia

Prescribed for	Code of herbal samples purchased	Town where samples purchased	APIs detected in the samples										
			1	2	3	4	5	6	7	8	9	10	11
Malaria	NZ-MA-8	Adama										+	+
	NZ-MA-12	"										+	
	NZ-MA-13	"											+
	NZ-MA-14	"											
	AA-MA-6	Addis Ababa										+	+
	AA-MA-16	"											+
	AA-MA-24	"											+
	AD-MA-9	Adwa											+
	AG-MA-2	Agaro										+	+
	AM-MA-3	Ambo											
	AM-MA-4	"											
	AM-MA-5	"											
	AM-MA-23	"											
	AW-MA-19	Awassa										+	+
	AX-MA-20	Axum											+
	BA-MA-7	Bahir Dar											+
	GN-MA-17	Gondar											+
	GN-MA-18	"											
	JM-MA-15	Jimma											+
	JM-MA-21	"											
	KC-MA-25	Kombolcha											
MK-MA-22	Mekele												
NK-MA-1	Nekempt												
SR-MA-10	Shire										+	+	
WO-MA-11	Wolayita Sodo												
Gonorrhoea	NZ-GC-16	Adama											
	AA-GC-13	Addis Ababa											
	AA-GC-14	Addis Ababa				+							
	AA-GC-15	Addis Ababa				+		+					
	AG-GC-17	Agaro						+					
	AM-GC-19	Ambo					+	+					
	AW-GC-10	Awassa											
	AX-GC-1	Axum											
	BA-GC-3	Bahir Dar											
	DR-GC-22	Dire Dawa	+	+					+				
	DR-GC-23	"											
	GM-GC-20	Gimbi				+			+				
	JM-GC-5	Jimma				+	+						
	JM-GC-6	"							+				
	JM-GC-7	"											
	JM-GC-12	"							+				
	KC-GC-18	Kombolcha											
	MK-GC-4	Mekele				+	+						
	NK-GC-21	Nekempt					+	+					
	SH-GC-8	Shashamane											

Table 1. Contd.

Prescribed for	Code of herbal samples purchased	Town where samples purchased	APIs detected in the samples													
			1	2	3	4	5	6	7	8	9	10	11			
Tuberculosis	SH-GC-9	Shashamane														
	SR-GC-2	Shire														
	WO-GC-11	Wolayita Sodo	+	+		+										
	AG-TB-8	Agaro														
	AM-TB-2	Ambo												+		
	AM-TB-6	"												+		
	AW-TB-9	Awassa														
	BA-TB-4	Bahir Dar													+	
	DS-TB-1	Dessie														
	DR-TB-5	Dire Dawa														
GN-TB-3	Gondar													+		
NK-TB-7	Nekempt													+		
Tropical ulcer	GM-TU-5	Gimbi												+		
	HA-TU-1	Hayik														
	HA-TU-2	"														
	MK-TU-4	Mekele														
	SH-TU-3	Shire												+	+	
Diabetes and/or hypertension	NZ-DB/HY-12	Adama														
	NZ-HY-14	"														
	AD-DB-11	Adwa														
	AW-DB/HY-1	Awassa														
	AW-DB/HY-6	"														
	BA-HY-10	Bahir Dar														
	GM-HY-3	Gimbi														
	GM-DB/HY-9	"													+	+
	JM-HY-13	Jimma														
	NK-DB/HY-8	Nekempt													+	
	SH-DB/HY-2	Shashamane													+	
	SR-HY-4	Shire														
	WO-DB-5	Wolayita Sodo														
WO-DB/HY-7	Wolayita Sodo													+	+	

Drugs used as a positive control during testing: 1= Ampicillin, 2=Benzyl penicillin, 3=Tetracycline, 4=Erythromycin, 5=Co-trimoxazole (sulphamethoxazole-trimethoprim), 6=Rifampycin, 7=INH, 8=Chloroquine, 9=Fansidar (sulfadoxine-trimethoprim), 10=Glibenclamide, 11=Methyldopa
+depicts presence of API

Though separate consultation or examination room was present in 63% of the centers visited, privacy is not strictly enforced by the attending traditional healer who in most instances tolerates on-lookers of his family members or friends. In fact, at times up to 20 patients are made to lineup in the same room and to tell their individual complaints after which the healer scoops out the remedies, usually from one or two sources, and pours them into used bottles or plastic carrier bags dismissing all in just under 10 minutes and to receive the next batch of patients.

Most healers (92%) do not make diagnosis of their own but prescribed remedies based exclusively on self-

diagnosis of the patient. If and when they try to diagnose, some of them come up with impertinent claims of diagnosis. For example, one of the data collectors for this study who simulated malaria patient had his side tapped by the healer and was then told that his condition from the infection had progressed to splenomegaly. Similarly another data collector simulating gonorrhea patient had his urethral opening examined with the aid of small flash light and was informed that the infection had gravely complicated his condition and cure will only be possible if he takes the remedy for which he charges the maximum amount, about birr 200. Our simulated-patients also met healers who insisted in administering a certain drug that induces vomiting and diarrhea so that they

Table 2: Comparison of average price within adulterated and unadulterated herbal prescriptions and between full doses of conventional drugs, January 2005 - December 2006, major towns in Ethiopia

Prescribed for	Quality of herbal samples	Individual price in \$ birr of samples purchased for laboratory screening										Total price	Average price	Average retail price of full dose of conventional drugs			
		250	30	50	150	150	20	100	55	200	80				50	150	50
Malaria	Adulterated	250	30	50	150	150	20	100	55	200	80	50	150	50	1485	106	4.50
	Unadulterated	70	15	15	150	150	108	20	50	140	110	40			733	67	
Gonorrhea	Adulterated	1000	45	35	75	120	120	200	50	130	130	700	200	80	2885	222	12.00
	Unadulterated	600	50	50	80	140	120	15	120	100	100	75			1450	132	
Tuberculosis	Adulterated	700	35	40	520	90									1385	277	*Free
	Unadulterated	50	200	25	150										425	106	
Tropical ulcer	Adulterated	45	30												75	37	12.00
	Unadulterated	12	12	50											74	25	
Diabetes and/or hypertension	Adulterated	60	60	200	50	60									430	86	**35.00
	Unadulterated	65	50	200	50	20	150	60	100	70					765	85	

* In public health institution

** Monthly dose

\$ 9 Birr = USD1

Table 3: General observations of the traditional health care centers, drugs and patient handling methods by the healers in sixty establishments of surveyed, January 2005 - December 2006, major towns in Ethiopia.

No	Variables	Yes (%)	No (%)
1	Presence of private consultation/examination room	38 (63)	22 (37)
2	Use of modern diagnostic aids such as BP apparatus, stethoscope, etc. by the healers	5 (8)	55 (92)
3	Documentation of patient background history (e.g. age, sex, type of health complaint, etc.)	3 (5)	57 (95)
4	Are shelves or cupboards available for proper storage of bulk remedies	33 (55)	27 (45)
5	Habit of labeling containers of remedies before or after dispensing	26 (43)	34 (57)
6	Use of special equipment (other than the hand) to measure out dose of prescribed remedies	18 (30)	42 (70)
7	Presence of evidence claiming to have been licensed to provide health care service	41 (68)	19 (32)
8	Provision of simultaneous out-patient and in-patient care	9 (15)	51 (85)
9	Overall sanitation condition of the establishments is fair to good	34 (57)	26 (43)
10	Presence of promotional billboards and/or advertisements in the premise or in the vicinity	58 (97)	2 (3)
11	Apparent presence of modern drugs (e.g. discarded capsule shell) and modern medical supplies (e.g. syringes and needles) in the clinics	15 (25)	45 (75)

could confirm the self-diagnosis of the patient, achievable, according to them, by looking at what is eliminated. Still others who were queuing from around 2:00 in the morning were instructed to return next day because the healer had to summon evil spirit (*diabolus*) to aid him in the diagnosis of the disease and in the drug to be prescribed.

Discussion

Although there are many potent traditional remedies for certain conditions, many are shown to be ineffective and/or toxic both of which may be associated with increased human suffering, lost productivity and often death (12). The possible adverse effects from the use of some traditional remedies could even get more compounded when such remedies are used adulterated with certain modern drugs. Such use might lead to unpredictable interaction between medicinal herbs and modern drugs which could increase or decrease undesirable pharmacological effect of either or both components. Bleeding, development of serotonin syndrome, decreased bio-availability of drugs, induction of mania, exacerbation of extrapyramidal effects, increased risk of hypertension, potentiation of corticosteroids, hypoglycemia and reduction in absorption of drugs are some of the reported cases of herb-drug interaction (15).

Malaria, tuberculosis and STIs such as gonorrhea are among the major diseases in developing countries like Ethiopia and these diseases' emerging anti-microbial resistance is most evident for which inappropriate drug usage is one of the key drivers (18). Few professionals could have imagined that traditional healers would adulterate herbal remedies with antibiotics, as observed during the present investigation, and aggravate this frustrating situation any further. The trend is worrisome in view of the obvious limitations the healers have ascertaining as to whether the patient has an illness that will benefit from traditional remedies adulterated with antimicrobials, not to mention the uncertainty they also have regarding dosage and/or dosage interval, duration of therapy and route of administration.

Delivering inadequate amounts of active drug or single drug such as rifampycin or INH in the adulterated herbal prescriptions, as observed in this study, not only fails to achieve the desired therapeutic outcomes but it is also associated with emergence of resistance by increasing the selective pressure in favor of drug resistant microorganisms although these risks occur even when antimicrobials are used appropriately (18).

Older antimicrobials such as chloroquine and tetracycline which were employed as adulterants of herbal preparations are no longer effective even when used in their pure form and their use only increases toxicity and incurs unnecessary health expenditure.

In the absence of quantitative laboratory analysis it is not easy to guess whether the healers over use antimicrobials in their adulterated preparations, though overuse or under use of these drugs have similar effect as far as emergence of resistance is concerned. However, the fact that antimicrobials are among the most frequently counterfeited drugs and, therefore, generally cheap makes the healers to venture forth to over use them in the remedies they supply while at the same time withholding information as to the components of the remedies (19). Also given the fear they may have that the patients could suffer poor outcomes, the healers could be motivated to overuse antimicrobials just to be on the safe side.

It may be true that the healers, like most other people, do not understand the issues of resistance uniquely related to inappropriate use of antimicrobials. However, the audacity of supplying herbal preparations admixed with antimicrobials by many of the urban-based healers stems purely from profit motive and/or lack of confidence in their ethno-medicine and not merely from ignorance. Their action bears grave consequences to public health both nationally and globally. Though hard data is not yet available, adulteration of herbal preparations with antimicrobial agents could be a widespread practice already inflicting a considerable damage. The question now is what to do about it?

The survey undertaken in this study noted that patients flock to traditional healers in spite of the fact that modern health care facilities are available within a radius of two kilometers and treatments for which they consult the healers are, on the average, far less expensive. It, therefore, seems that what motivates patients to visit traditional health care outlets is not a mere preference for indigenous remedies but mostly either lack of information about the conventional health care services or perceived poor quality of the services. Hence, a lot more needs to be done by health workers, the Ministry of Health and other concerned authorities not only in expanding quality health care services but also in creating awareness among the communities to promote utilization of such services.

Furthermore, existing legal frameworks intended to govern the activities of the healers should be reviewed or new ones be formulated with emphasis in controlling and restricting dangerous practices under the guise of traditional medicine. As much as they are important we must ensure that such legal instruments do not further embolden the healers in pursuing the unauthorized dispensing of modern drugs that perpetuate havoc to public health.

Our observation concerning patient privacy, record keeping, storage of bulk remedies, product labeling, etc., in the traditional health service outlets generally demonstrated a substandard level of practice compared to

comparable modern health care facilities like health posts or clinics. Such shortcomings stem mostly from lack of awareness, thus they are not unexpected nor are they uncorrectable. Indeed, most can be remedied provided that appropriate information is imparted to the healers on a regular basis.

What is, however, not necessarily linked to lack of awareness and therefore cannot be easily rectified is the dispensing of adulterated remedies with modern drugs, especially with antibiotics, whose negative effect on health and life is not limited only to the individual client but the community at large. In the interest of safe guarding public health, sustained punitive measures, therefore, need to be considered to curb such dangerous practices.

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