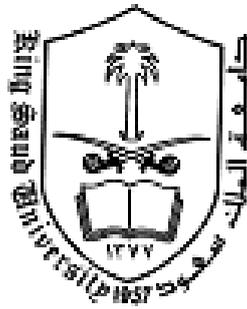


# Potentially Inappropriate Medications Prescribing among Elderly Population in Outpatient Pharmacy: Trend and Cost



## Research Project Proposal

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## **Introduction:**

Elderly represent a large segment of population in the world; the word geriatric referred to people who are 65 years old and greater. According to one study published in year 2000 the Percentage of geriatrics in some countries in year 2000 is as follow : Australia 12.1, Canada 12.8, France 15.9, Germany 16.4, Japan 17.1, UK 16.0, US 12.5 and the projected Percentage of the geriatrics in year 2020 is found to increase to be 16.8,18.2, 20.1, 21.6, 26.2, 19.8, 16.6 respectively.(1)

In Saudi Arabia the estimated number of geriatric population according to Saudi Arabia profile published in year 2004 by WHO Regional Office for the Eastern Mediterranean is about 700,000 (3.1% of the total population) individual this population is expected to reach 7,000,000 by year 2020. (2)

As this population increases, an ever-greater need exists to improve the health and quality of life of geriatrics. Discovering new treatment and prevention strategies and improving health behaviors and medication use will be required to accomplish this improvement in the health service.

The term potentially inappropriate medications refer to medications in which risks outweigh benefits. According to many published studies inappropriate medications have been estimated to affect 4.8%-45.6% of elderly population and the use of such medications can be consider as a challenge for all health caregivers at any institute due to varied and incomplete clinical information about the safety of medications use in elderly. For these reasons, vigilant monitoring in vulnerable populations such as the elderly is essential to wide the margin of patient safety and relieving unnecessary economic burden on healthcare resources.(3)

Inappropriate medication use or/and medication related problems in the elderly has been associated with a substantial number of adverse drug reactions, worsening physical function, and excessive healthcare utilization. Nearly 5% of all hospital admissions are believed to be related to adverse drug reactions (4), and some studies reported a rate as high as 17% for elderly persons.<sup>2</sup> and up to 140,000 deaths per year may be due to adverse drug reactions.<sup>(5)</sup>

Geriatric patients are more at risk for adverse medication outcomes because they often have complex drug regimens, age related physiological changes, and alteration in drug pharmacokinetics and pharmacodynamics. Inappropriate medication can be categorized into the following: (1) potentially inappropriate medication; (2) Potentially inappropriate duration; (3) Potentially inappropriate dosage; and (4) Potentially inappropriate drug-drug interaction. <sup>(6)</sup> These medications they are either lacking the efficacy or pose an unnecessarily high risk to geriatrics and other safer alternatives are available, these medications have been assessed based on a mixed of explicit criteria published in the literatures.

The first explicit criteria is known as **Beers criteria (Table-1)** that was proposed by Mark Beers and his group which first published in 1991, 1997, and finally updated and revised in year 2002 and published in year 2003. Beers group consist of 13 nationally recognized experts in geriatric pharmacology came to a consensus and provided explicit criteria for defining inappropriate use of medications. The experts identified medications they believed should not be prescribed to elderly persons and other drugs for which doses, frequencies, or durations of use should not be exceeded.

They also described medications that should be avoided in patients known to have various medical conditions. Beers categorized the criteria into two lists of medications, one is independent on diagnosis or condition while the second depend on diagnosis and condition and since the diagnosis is difficult to be obtain; in this project the list of medications independent on diagnosis or condition which published in year 2003 will be used.(7)

The second explicit criteria that will be included in this project is the Canadian criteria which is known as McLeod criteria (**Table-2**) that was developed by a panel of experts in 1997 were they initially categorized inappropriate practices in prescription of drugs for elderly people into 3 types: (1) prescription of drugs generally contraindicated for elderly people because of an unacceptable risk–benefit ratio, (2) prescription of drugs that can cause drug–drug interactions and (3) prescription of drugs that can cause drug–disease interactions. After developing the preliminary list, it was sent to the national consensus panel to assess it, suggest any additions of medications and to recommend relevant lower-risk alternative therapies before approving it to be published. Only criteria from the Canadian list that is independent on diagnosis will be used in this project. (8)

Inappropriate prescribing in the elderly is often attributed to the lack of training in geriatrics in medical and pharmacy education. An effective way to overcome this problem may be through a concurrent drug utilization review (DUR). DUR is designed to send warning to pharmacists when potentially inappropriate drugs are prescribed. The warning provides an opportunity to educate the both pharmacist and

physician through a discussion about the safety and effectiveness of a targeted medication before it is dispensed. (9)

In one study conducted in US to determine the extent of potentially inappropriate outpatient prescribing for elderly patients as defined by the Beers criteria. The study included a total of 162370 geriatrics and there was 21% filled a prescription for 1 or more medications of concern. More than 15% of subjects filled prescriptions for 2 medications of concern, and 4% filled prescriptions for 3 or more of the medications within the same year. (10)

In Taiwan a study conducted to determine the prevalence of drug prescribing among elderly outpatients that included 882 elderly and the results is 97 inappropriate medications were identified in 10.5%, 20.6% of these medications had a high severity potential according to Beers criteria, patients prescribed potentially inappropriate medications were more likely to be prescribed several drugs versus those who were not prescribed potentially inappropriate medications ( $4.0 \pm 1.9$  vs  $2.8 \pm 1.4$ ,  $p < 0.001$ ). (11)

From economical perspective; Most drugs labeled as inappropriate tend to be older, less costly the alternative products that accomplish the same effect with a greater margin of safety tend to cost substantially more; however, it could be argued that spending more initially for a safer drug would save money if serious adverse effects or hospitalization could be avoided. The expenditures on prescribed medications are significantly higher among those aged 65 years and over than among younger people. It is difficult to obtain reliable estimates of expenditure levels for most countries. However, in the US in 1989 mean expenditure among the elderly on prescribed

medications was 324 US dollar compared with 102 US dollar among non-elderly adults (12). In the US average expenditure on prescribed drugs among the elderly was estimated at between 500-700 US dollar in 1991 (13-15), 827 US dollar in 1997 and 1378 US dollar in 2000 which represents a growth of around 130%. In Japan in 1991 where elderly consumed disproportionately more medications than non-elderly, spending was estimated at 130 US dollar per elderly (16). In one Canadian study, expenditures on prescribed medications among elderly were found to have increased by 317% between year 1981 to year 1988. (17)

Bodenheimer has raised three main explanations for the increase in pharmaceutical expenditures observed among US elderly. These factors include: (1) increased utilization of prescription medicines; (2) increased prices for existing prescription medicines and (3) substitution of newer, higher priced medicines for older, less expensive medicines. (18)

In general; the cost of health care associated with the older population can be expected to increase annually. While pharmaceutical care represents only one component of healthcare, its costs are increasing rapidly because of advances in technology and increasing use. However, such costs should be considered within a context of decreasing disability in the elderly population, improving economic conditions among elderly and the relationship of these costs with those in other aspects of healthcare. Where medications have been demonstrated to be cost-effective, attempts to curtail expenditure growth may prove a false economy resulting in significantly higher growth elsewhere such as in the hospital and long-term care

sectors. Use of evidence-based principles of practice and strategies to ensure that this population obtains maximum benefit from medications. (19)

## **Study Objectives:**

The purpose of this project is to identify the following:

1. Identify the prevalence of inappropriate use of medications in elderly patients.
2. Identify the trend and the pattern of prescribing of inappropriate medications in elderly patients.
3. Calculate the cost of inappropriate use of these medications in elderly patients.

## **Methodology:**

This study will be a cross-sectional retrospective study utilizing the outpatient pharmacy prescription records at tertiary care hospital in Riyadh, Saudi Arabia. Obtained data will be analyzed by using Statistical Product and Service Solutions (SPSS) version 13.0.

Data obtain from hospital through a software retrieving system designed in cooperation with computer department The period that will be studied will be from 2002 to 2004. The term elderly in our project will be for those any patient 65 years old or older. Both Beers explicit criteria and Canadian criteria will be used to identify inappropriate medications that are independent on diagnosis. After establishing the explicit criteria based on the literature, we will include only prescriptions from

outpatient pharmacy by retrieving the prescriptions information for years 2002, 2003, and 2004.

Information required for this project include patient name, file number, age, gender, diagnosis, medication name, medication code, dose, duration, frequency, physician name, physician specialty, physician country of higher education study, and cost of each drug in the criteria list.

Statistical Analysis of data will include descriptive statistics and logistic regression to identify the different factors attributed to the inappropriate prescription pattern.

After identifying the pattern and prevalence, cost will be calculated by counting the misused medications and multiply each medication based on its strength, number of tablets per day and duration of administration than adding all the output from calculation of the cost and tries to compare it for the 3 years.

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**Table 1: Criteria for Potentially Inappropriate Medication Use in Older Adults: Independent of Diagnoses or Conditions (Beers)**

<b>Drug</b>	<b>Concern</b>	<b>Rate</b>
<b>Propoxyphene (Darvon) and combination products (Darvon with ASA, Darvon-N, and Darvocet-N)</b>	<b>Offers few analgesic advantages over acetaminophen, yet has the adverse effects of other narcotic drugs.</b>	<b>Low</b>
<b>Indomethacin (Indocin and Indocin SR)</b>	<b>Of all available nonsteroidal anti-inflammatory drugs, this drug produces the most CNS adverse effects.</b>	<b>High</b>
<b>Pentazocine (Talwin)</b>	<b>Narcotic analgesic that causes more CNS adverse effects, including confusion and hallucinations, more commonly than other narcotic drugs. Additionally, it is a mixed agonist and antagonist.</b>	<b>High</b>
<b>Trimethobenzamide (Tigan)</b>	<b>One of the least effective antiemetic drugs, yet it can cause extrapyramidal adverse effects.</b>	<b>High</b>
<b>Muscle relaxants and antispasmodics: methocarbamol (Robaxin), carisoprodol (Soma), chlorzoxazone (Paraflex), metaxalone (Skelaxin), cyclobenzaprine (Flexeril), and oxybutynin (Ditropan). Do not consider the extended-release Ditropan XL.</b>	<b>Most muscle relaxants and antispasmodic drugs are poorly tolerated by elderly patients, since these cause anticholinergic adverse effects, sedation, and weakness. Additionally, their effectiveness at doses tolerated by elderly patients is questionable.</b>	<b>High</b>
<b>Flurazepam (Dalmane)</b>	<b>This benzodiazepine hypnotic has an extremely long half-life in elderly patients (often days), producing prolonged sedation and increasing the incidence of falls and fracture. Medium-or short-acting benzodiazepines are preferable.</b>	<b>High</b>
<b>Amitriptyline (Elavil), chlordiazepoxide-amitriptyline (Limbital), and perphenazine-amitriptyline (Triavil)</b>	<b>Because of its strong anticholinergic and sedation properties, amitriptyline is rarely the antidepressant of choice for elderly patients.</b>	<b>High</b>
<b>Doxepin (Sinequan)</b>	<b>Because of its strong anticholinergic and sedating properties, doxepin is rarely the antidepressant of choice for elderly patients.</b>	<b>High</b>
<b>Meprobamate (Miltown and Equanil)</b>	<b>This is a highly addictive and sedating anxiolytic. Those using meprobamate for prolonged periods may become addicted and may need to be withdrawn slowly.</b>	<b>High</b>

<b>Drug</b>	<b>Concern</b>	<b>Rate</b>
Doses of short-acting benzodiazepines: doses greater than lorazepam (Ativan), 3 mg; oxazepam (Serax), 60 mg; alprazolam (Xanax), 2 mg; temazepam (Restoril), 15 mg; and triazolam (Halcion), 0.25 mg	Because of increased sensitivity to benzodiazepines in elderly patients, smaller doses may be effective as well as safer. Total daily doses should rarely exceed the suggested maximums.	High
Long-acting benzodiazepines: chlordiazepoxide (Librium), chlordiazepoxide-amitriptyline (Limbitrol) clidinium-chlordiazepoxide (Librax), diazepam (Valium), quazepam (Doral), halazepam (Paxipam), and chlorazepate (Tranxene)	These drugs have a long half-life in elderly patients (often several days), producing prolonged sedation and increasing the risk of falls and fractures. Short- and intermediate-acting benzodiazepines are preferred if a benzodiazepine is required.	High
Disopyramide (Norpace and Norpace CR)	Of all antiarrhythmic drugs, this is the most potent negative inotrope and therefore may induce heart failure in elderly patients. It is also strongly anticholinergic. Other antiarrhythmic drugs should be used.	High
Digoxin (Lanoxin) (should not exceed &#1;0.125 mg/d except when treating atrial arrhythmias)	Decreased renal clearance may lead to increased risk of toxic effects.	Low
Short-acting dipyridamole (Persantine). Do not consider the long-acting dipyridamole (which has better properties than the short-acting in older adults) except with patients with artificial heart valves	May cause orthostatic hypotension.	Low
Methyldopa (Aldomet) and methyldopa-hydrochlorothiazide (Aldoril)	May cause bradycardia and exacerbate depression in elderly patients.	High
Reserpine at doses &#1;0.25 mg	May induce depression, impotence, sedation, and orthostatic hypotension.	Low
Chlorpropamide (Diabinese)	It has a prolonged half-life in elderly patients and could cause prolonged hypoglycemia. Additionally, it is the only oral hypoglycemic agent that causes SIADH.	High
Gastrointestinal antispasmodic drugs: dicyclomine (Bentyl), hyoscyamine (Levsin and Levsinex), propantheline (Pro-Banthine), belladonna alkaloids (Donnatal and others), and clidinium-chlordiazepoxide (Librax)	GI antispasmodic drugs are highly anticholinergic and have uncertain effectiveness. These drugs should be avoided (especially for long-term use).	High

<b>Drug</b>	<b>Concern</b>	<b>Rate</b>
<b>Anticholinergics and antihistamines: chlorpheniramine (Chlor-Trimeton), diphenhydramine (Benadryl), hydroxyzine (Vistaril and Atarax), cyproheptadine (Periactin), promethazine (Phenergan), tripeleennamine, dexchlorpheniramine(Polaramine)</b>	All nonprescription and many prescription antihistamines may have potent anticholinergic properties. Nonanticholinergic antihistamines are preferred in elderly patients when treating allergic reactions.	High
<b>Diphenhydramine (Benadryl)</b>	May cause confusion and sedation. Should not be used as a hypnotic, and when used to treat emergency allergic reactions, it should be used in the smallest possible dose.	High
<b>Ergot mesyloids (Hydergine) and cyclandelate (Cyclospasmol)</b>	Have not been shown to be effective in the doses studied.	Low
<b>Ferrous sulfate &amp;#1;325 mg/d</b>	Doses &#1;325 mg/d do not dramatically increase the amount absorbed but greatly increase the incidence of constipation.	Low
<b>All barbiturates (except phenobarbital) except when used to control seizures</b>	Are highly addictive and cause more adverse effects than most sedative or hypnotic drugs in elderly patients.	High
<b>Meperidine (Demerol)</b>	Not an effective oral analgesic in doses commonly used. May cause confusion and has many disadvantages to other narcotic drugs.	High
<b>Ticlopidine (Ticlid)</b>	Has been shown to be no better than aspirin in preventing clotting and may be considerably more toxic. Safer, more effective alternatives exist.	High
<b>Ketorolac (Toradol)</b>	Immediate and long-term use should be avoided in older persons, since a significant number have asymptomatic GI pathologic conditions.	High
<b>Amphetamines and anorexic agents</b>	These drugs have potential for causing dependence, hypertension, angina, and myocardial infarction.	High
<b>Long-term use of full-dosage, longer half-life, non-COX-selective NSAIDs: naproxen (Naprosyn, Avaprox, and Aleve), oxaprozin (Daypro), and piroxicam (Feldene)</b>	Have the potential to produce GI bleeding, renal failure, high blood pressure, and heart failure.	High
<b>Daily fluoxetine (Prozac)</b>	Long half-life of drug and risk of producing excessive CNS stimulation, sleep disturbances, and increasing agitation. Safer alternatives exist.	High

<b>Drug</b>	<b>Concern</b>	<b>Rate</b>
<b>Long-term use of stimulant laxatives: bisacodyl (Dulcolax), cascara sagrada, and Neoloid except in the presence of opiate analgesic use</b>	<b>May exacerbate bowel dysfunction.</b>	<b>High</b>
<b>Amiodarone (Cordarone)</b>	<b>Associated with QT interval problems and risk of provoking torsades de pointes. Lack of efficacy in older adults.</b>	<b>High</b>
<b>Orphenadrine (Norflex)</b>	<b>Causes more sedation and anticholinergic adverse effects than safer alternatives.</b>	<b>High</b>
<b>Guanethidine (Ismelin)</b>	<b>May cause orthostatic hypotension. Safer alternatives exist.</b>	<b>High</b>
<b>Guanadrel (Hylorel)</b>	<b>May cause orthostatic hypotension.</b>	<b>High</b>
<b>Cyclandelate (Cyclospasmol)</b>	<b>Lack of efficacy.</b>	<b>Low</b>
<b>Isoxsurpine (Vasodilan)</b>	<b>Lack of efficacy.</b>	<b>Low</b>
<b>Nitrofurantoin (Macrochantin)</b>	<b>Potential for renal impairment. Safer alternatives available.</b>	<b>High</b>
<b>Doxazosin (Cardura)</b>	<b>Potential for hypotension, dry mouth, and urinary problems.</b>	<b>Low</b>
<b>Methyltestosterone (Android, Virilon, and Testrad)</b>	<b>Potential for prostatic hypertrophy and cardiac problems.</b>	<b>High</b>
<b>Thioridazine (Mellaril)</b>	<b>Greater potential for CNS and extrapyramidal adverse effects.</b>	<b>High</b>
<b>Mesoridazine (Serentil)</b>	<b>CNS and extrapyramidal adverse effects.</b>	<b>High</b>
<b>Short acting nifedipine (Procardia and Adalat)</b>	<b>Potential for hypotension and constipation.</b>	<b>High</b>
<b>Clonidine (Catapres)</b>	<b>Potential for orthostatic hypotension and CNS adverse effects.</b>	<b>Low</b>
<b>Mineral oil</b>	<b>Potential for aspiration and adverse effects. Safer alternatives available.</b>	<b>High</b>
<b>Cimetidine (Tagamet)</b>	<b>CNS adverse effects including confusion.</b>	<b>Low</b>
<b>Ethacrynic acid (Edecrin)</b>	<b>Potential for hypertension and fluid imbalances.</b>	<b>Low</b>
<b>Desiccated thyroid</b>	<b>Concerns about cardiac effects. Safer alternatives available.</b>	<b>High</b>
<b>Amphetamines (excluding methylphenidate hydrochloride and anorexics)</b>	<b>CNS stimulant adverse effects.</b>	<b>High</b>
<b>Estrogens only (oral)</b>	<b>Evidence of the carcinogenic (breast and endometrial cancer) potential of these agents and lack of cardioprotective effect in older women.</b>	<b>Low</b>

Abbreviations: CNS, Central Nervous System; COX, Cyclooxygenase; GI, GastroIntestinal; NSAIDs, Nonsteroidal Anti-Inflammatory Drugs; SIADH, Syndrome of Inappropriate Antidiuretic Hormone Secretion.

**Table 2: McLeod Criteria for Inappropriate Medications Use**

<b>Practice</b>	<b>MCSR*</b>	<b>Risk to Patient</b>	<b>Alternative Therapy</b>	<b>Accepted Alternative (%)</b>
Prescription of reserpine to treat hypertension	3.14	May cause depression and extrapyramidal effects in high dosages	Another antihypertensive drug	76
Prescription of disopyramide to treat atrial fibrillation	3.09	May cause anticholinergic side effects and sudden cardiac death	Digoxin Quinidine Procainamide	59 31 25
Long-term prescription of long-half-life benzodiazepine to treat insomnia Chlordiazepoxide Diazepam, Flurazepam	3.72	May cause falls, fractures, confusion, dependence and withdrawal	Nondrug therapy or short-half-life benzodiazepine	97
Long-term prescription of barbiturate except phenobarbital to treat insomnia	3.59	May cause falls, fractures, confusion, dependence and withdrawal	Nondrug therapy or low dosage of short-half-life benzodiazepine	94
Long-term prescription of long-half-life benzodiazepine to treat anxiety	3.55	May cause falls, fractures, confusion, dependence and withdrawal	Nondrug therapy or short-half-life benzodiazepine	88
Long-term prescription of long-half-life benzodiazepine to treat agitation in dementia	3.52	May cause falls, fractures, confusion, dependence and withdrawal	Loxapine or haloperidol Short-half-life benzodiazepine	88 56
Long-term prescription of triazolam to treat insomnia	3.23	May cause cognitive and behavioural abnormalities	Nondrug therapy or low dosage of short-half-life benzodiazepine	91
Prescription of nylidrin, niacin or pentoxifylline to treat dementia	3.16	Ineffective treatment for dementia and moderate risk of side effects	Discontinue	81
Long-term prescription of diphenoxylate to treat diarrhea	3.13	Drowsiness, cognitive impairment and dependence	Nondrug and diet therapy or loperamide	84

<b>Practice</b>	<b>MCSR*</b>	<b>Risk to Patient</b>	<b>Alternative Therapy</b>	<b>Accepted Alternative (%)</b>
Prescription of tricyclic antidepressant with active metabolites (e.g., imipramine or amitriptyline) to treat depression	3.12	May cause anticholinergic side effects	Tricyclic antidepressant without active metabolites or SSRI	91
Prescription of methylphenidate to treat depression	3.11	May cause agitation, stimulation of central nervous system and seizures	SSRI or short-half-life tricyclic antidepressant without active metabolites	81
Prescription of phenylbutazone to treat chronic osteoarthritis	3.69	May cause bone-marrow depression	Acetaminophen or intermittent dosage of an NSAID of another class	100
Long-term prescription of meperidine or pentazocine for pain	3.58	May cause falls, fractures, confusion, dependency and withdrawal	Stepped approach involving non-drug therapy, then acetaminophen, then codeine, morphine or hydromorphone if needed	91
Long-term prescription of piroxicam, oxaprozin, ketorolac or mefenamic acid to treat pain	3.35	Greater risk of upper gastrointestinal-tract bleeding than that associated with other NSAIDs	acetaminophen; switch to a different NSAID or to codeine	81
Long-term prescription of indomethacin to treat gout	3.32	May cause gastropathy, neurologic side effects and salt and water retention	Allopurinol or intermittent dosage of NSAID as needed	50
Long-term prescription of NSAIDs to treat osteoarthritis	3.22	May cause gastropathy, bleeding and salt and water retention	Acetaminophen	100
Prescription of dipyridamole to prevent stroke	3.3	Ineffective	ASA Ticlopidine	94 69
Prescription of cyclobenzaprine or methocarbamol to treat muscle spasms	3.06	Drowsiness, agitation and disorientation	Non-drug therapy (physiotherapy, application of heat and cold or TENS)	94

\* Mean clinical significance Rating scale from 1 (not significant) to 4 (highly significant).