

Recommendations of apex health bodies remain localized: not in conformity with international implementation policy for urological disorders



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Summary

In developing/underdeveloped countries there is still a great burden of adverse drug reaction (ADR), morbidity and mortality because of poor regulations and implementation of preventive measures. These countries try to copy/follow guidelines from international bodies like American Urology Association (AUA), European Association of Urology (EAU), AGS, UMC and WHO irrespective of their country of origin and success in implementation. Although recommendations of these organizations are obligatory, yet these are taken as the gold standard for good clinical practices. This manuscript highlights difference in view point of various apex health organizations in formulating health policies for prevention, diagnosis, treatment and ADR monitoring for urological disorders. Lacking role of regulatory bodies in implementation of existing policies may lead to potentially inappropriate medication and produce a great economic burden. This analysis has prompted us to recommend that these apex bodies should have better coordination in producing a single value document, make it mandatory part of curricula in medical schools for better awareness, awareness campaigns and separate reporting column in ADR form.

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Geriatric population is increasing day by day. As per 2019 data there were 46.8 million persons aged 65 or above in ASEAN countries and 703 million (UN 2019)¹ all over the world. According to “World Population Prospects: the 2019 Revision”, 1/6th of world population will be over age 65 by 2050.² To promote the quality of life (QoL) and well-being of older populations, the Association of South East Asian Nations such as Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam endorsed a “statement on active aging” in 2016.³ Southeastern Asia is overgrowing with a rate of aging population increasing from 9.8%, 13.7%, to 20.3% in 2017, 2030, to 2050, respectively.⁴ The incidence of potentially inappropriate medication (PIM) increases with age due to comorbidities and polypharmacy. In the United States, about 46.2% of patients attending urology visits were >65 years age and more than 62% of this population had already undergone urologic procedures. This rapid expansion in geriatric population will pose a challenge for healthcare system.⁵

World Health Organization (WHO), Uppsala Monitoring Center (UMC) and American Geriatric Society (AGS) are apex healthcare bodies to formulate health policies and co-ordinate for the prevention, diagnosis, treatment and adverse drug reaction (ADR) monitoring for all diseases including urological disorders in geriatric population. In addition, American Urology Association (AUA) and European Association of Urology (EAU) are the top recommendatory bodies specialized for recommending appropriate medication/dosage/contraindications etc for the population with urological disorders. Although recommendations of these organizations are only obligatory not mandatory, yet these are taken as the gold standard for good clinical practices all over the world. It has been observed that some lacunas have crept in the criteria either by ignorance or due to different requirements of local regulatory authorities of the countries worldwide. This might exert a devastating effect on the data generated on same disease in different countries and further affect treatment strategies.

Authors selected search criteria like “geriatric population” along with PIM in urological disorders, polypharmacy, benign prostatic hyperplasia (BPH), erectile dysfunction (ED), urinary tract infections (UTI), BEER criteria, STOPP/START criteria, AUA guidelines/EAU

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recommendations etc and reviewed literature database on pubmed, google, googlescholar and research gate by applying The Boolean rule. Authors have analyzed STOPP/START criteria, Beer criteria 2019 and recommendations of AUA and EAU for treatment of patients with urological disorders. It is astonishing and perplexing that recommendations and policies of all these apex bodies are not in chorus with each other (Fig. 1) and put the geriatric health care at risk. This leads to increased incidence of PIM as reported in our previous studies,⁶⁻⁸ increased morbidity in older adults and increased burden on the health system worldwide especially in developing/underdeveloped ASEAN countries and India. This compilation focuses on very important facts being ignored worldwide by not following a unison pattern for geriatric health care.

Fact sheet of lacunas

Incoordination in use of antimicrobial drugs

A 2019 Chinese survey on more than 74,648 antibiotic prescriptions in 16 rural primary care centers have shown that more than 84% prescriptions were unnecessary.⁹ Nitrofurantoin use in older adults has been controversial. As per WHO, AUA and EAU guidelines, Nitrofurantoin is the first line drug for acute UTI in women with concern of potential serious risk of pulmonary, hepatic toxicity and peripheral neuropathy especially with its long-term use if other safe alternatives are available for use,¹⁰ whereas STOPP/START criteria are silent and it is listed as a PIM for older adults by Beers Criteria. Trimethoprim-sulfamethoxazole (TMP-SMX) is the first line drug for the treatment of symptomatic UTIs in women as per AUA, whereas according to Beers Criteria,[®] it should be used with caution in older adults using angiotensin-converting enzyme inhibitors or angiotensin receptor blockers. The dosage of the TMP-SMX is to be reduced in older adults having creatinine clearance of 30 ml/min and is to be avoided in patient having creatinine clearance of <15 ml/min whereas STOPP criteria are silent on this issue. EAU guidelines recommend Co-trimoxazole/trimethoprim to be considered as drugs of first choice only in areas with known resistance rates of <20% for *E. coli* and restrains the use of trimethoprim in the first trimester and sulfamethoxazole in the last trimester of the pregnancy.¹⁰ (Table 1).

Lack of serious considerations on use of oral phosphodiesterase inhibitors (PDE5i)

ED is a highly prevalent age-related phenomenon in geriatric population. According to a recent study conducted by the University of Wisconsin, about 50% of the men between 40 and 70 years of age suffer with ED.¹¹ Food and Drug Administration (FDA) approved use of oral PDE5i for management of ED despite common adverse effects like flushing, headache, dyspepsia, altered blood pressure, palpitation and tachycardia. PDE5i can cause a precipitous drop in blood pressure in men taking nitrates regularly.¹² Drugs used for HIV/AIDS, anti-depressants, anti-fungal, anti-hypertensives can also influence the metabolism of PDE5i. PDE5i are the first line treatment in urological practice guidelines whereas Beer criteria are silent on its use in older people. STOPP/START and EAU guidelines suggest to avoid its use¹³ and AUA guidelines absolutely contradict its use in patients concomitantly taking nitrates.¹⁴ AUA guidelines recommend its use with caution in combination with anti-hypertensive drugs. Despite potential adverse effects and serious drug interactions, there is no consensus among various international guidelines. It is more interesting to mention that these products are being sold as OTC drugs despite being prescription drugs and accessible to everyone especially in developing and underdeveloped countries. In addition, other herbal based OTC products like dehydroepiandrosterone (DHEA), L-arginine, ginseng, yohimbe, propionyl-L-carnitine are also available.¹⁵

Use of loop diuretics

Loop diuretics are commonly prescribed to patients with acute/chronic heart failure with signs of fluid overload, acute/chronic renal failure, hepatic failure, hypertension and peripheral edema. The use of loop diuretics in patients with suspected coronary artery disease without systolic heart failure or renal impairment is associated with increased risk of all-cause mortality.¹⁶ The incidence of diuretic use increases with age and approximately 40% of those aged over 80 years are prescribed diuretics. STOPP/START criteria recommend avoiding loop diuretics for the treatment of hypertension with concurrent urinary incontinence in older adults. Beer criteria are against its use in combination with peripheral alpha-1-blockers, whereas there are no clear guidelines by AUA and EAU.



Fig. 1: Gap between apex bodies for geriatric health. UMC: Uppsala Monitoring Centre; WHO: World Health Organization; AGS: American Geriatrics Society; AUA: American Urological Association; EAU: European Association of Urology.

S. No	Drugs/drug classes/combinations	STOPP/START criteria	Beers criteria 2019	AUA guideline	EAU guidelines
1.	Antimicrobial drugs (Nitrofurantoin, Trimethoprim-Sulfamethoxazole)	Silent	Avoid in individuals with Creatinine clearance <30 ml/min	a) First line treatment for uncomplicated UTIs b) Avoid in patients with chronic lung disease and for long term use	a) First line antibiotic for Acute UTIs, but potential serious risk of pulmonary and hepatic toxicity b) Avoid if GFR <30 ml/min
2.	Drugs for ED Phosphodiesterase type-5 inhibitors (Sildenafil, Tadalafil, Vardenafil, Avanafil)	Avoid in severe heart failure characterized by hypotension i.e. systolic BP <90 mmHg, or concurrent daily nitrate therapy for angina (risk of cardiovascular collapse)	Silent	Avoid Phosphodiesterase type-5 inhibitors in combination with nitrate containing medication	a) Absolute contraindication with organic nitrates or NO donors b) Use with caution in combination with anti-hypertensive drugs like calcium channel blockers, beta blockers and diuretics etc.
3.	Loop diuretic (Frusemide, Torsemide)	Avoid loop diuretics for the treatment of hypertension with concurrent urinary incontinence (may exacerbate incontinence)	Avoid combination of Peripheral alpha 1 blockers with loop diuretics	Silent	Silent
4.	Selective alpha 1 blockers (Alfuzosin, Doxazosin, Prazosin, Tamsulosin, Terazosin, Silodosin)	Avoid in persons with symptomatic orthostatic hypotension/micturition syncope	Avoid in combination with loop diuretics in older women (Increased risk of urinary incontinence)	Silent	First line treatment in men with LUTD
5.	Drugs with anticholinergic properties I. Anti-muscarinic drugs (Oxybutynin, Tolterodine, Propiverine, Solifenacin, Darifenacin, Trospium, Fesoterodine II. Tricyclic antidepressants with anticholinergic properties (Amitriptyline, Amoxapine, Clomipramine, Desipramine, Doxepin, Imipramine, Nortriptyline, Paroxetine, Protriptyline, Trimipramine III. Neuroleptics with moderate-marked antimuscarinic/anticholinergic effects (Chlorpromazine, Clozapine, Lupenthixol, Fluphenzine, Pipothiazine, Promazine, Zuclopenthixol IV. Anti-muscarinic bronchodilators (Ipratropium, Tiotropium) V. First generation antihistamines (constituent of OTC cough syrup preparations) in older people who are suffering from BPH (potential of precipitating acute retention of urine) (Brompheniramine, Carbinoxamine, Chlorpheniramine, Clemastine, Cyproheptadine, Dexbrompheniramin, Dexchlorpheniramin, Dimenhydrinate, Diphenhydramine (oral), Doxylamine, Hydroxyzine, Meclizine, Promethazine, Pyrilamine, Triprolidine)	a) Avoid concomitant use of two or more drugs with such properties b) Avoid in persons with chronic constipation c) Avoid in overactive patients with dementia, narrow angle glaucoma, chronic prostatism Avoid TCAs with dementia, narrow angle glaucoma, cardiac conduction abnormalities, prostatism, or prior history of urinary retention (risk of worsening these conditions) STOPP STOPP in patients with a history of narrow angle glaucoma (may exacerbate glaucoma) or bladder outflow obstruction (may cause urinary retention) Silent	Avoid except anti-muscarinics for urinary incontinence Avoid (Because of anticholinergic side effects and orthostatic hypotension) Avoid in patients with a history of prostatism or previous urinary retention (high risk of urinary retention) Silent Silent	a) Use with caution in patients using other medications with anticholinergic properties b) Use with caution in frail OAB patients Silent Silent Silent	a) Avoid if post void urine >150 ml b) Prescribe with caution in older adults Silent Silent Silent

(Table 1 continues on next page)

S. No	Drugs/drug classes/combinations	STOPPP/START criteria	Beers criteria 2019	AUA guideline	EAU guidelines
(Continued from previous page)					
6.	Desmopressin/DDAVP	Silent	Avoid for the treatment of nocturia and nocturnal polyuria (High risk of hyponatremia)	Silent	<p>a) <65 year older adults: start with low dose (0.1 mg/day) and gradually increased upto 0.4 mg/day</p> <p>b) >65 year patients: low dose may be prescribed, avoid if serum sodium levels below normal</p> <p>c) >75 year patients: should be used with caution as increased risk of hyponatremia</p>
7.	Androgens Methyltestosterone Testosterone	Avoid in absence of primary or secondary hypogonadism (Risk of androgen toxicity)	Avoid unless indicated for confirmed hypogonadism with clinical symptoms	Avoid unless there is confirmed hypogonadism (<300 ng/ml)	<p>a) Avoid in absence of symptomatic hypogonadism</p> <p>b) Absolutely contraindicated in untreated breast and prostate cancer</p> <p>c) Relative contraindication in poorly controlled CHF, acute CVS events, Severe LUTS</p>
8.	Complementary and Alternative Medicine	Silent	Silent	Silent	<p>Recommends Hexane extracted Serenoa repens to men with LUTS who want to avoid potential adverse effects related to sexual function</p>

Table 1: Fact sheet of lacunas/points of incoordination between WHO/JUMC/AUA/EAU/AGS.

Disputed use of selective alpha-1-blockers

The prevalence of BPH has been reported to increase with age, from 14.8% (in younger males aged 40) to 36.8% (in males aged 80 and above).¹⁷ Selective alpha-1-blockers are used to treat BPH and essential hypertension in older adults. Tachycardia and tremulousness are less common with the selective alpha-1-blockers; however it can cause first-dose hypotension, syncope, dizziness, and headache in the older people and increase the risk of falls.¹⁸ AUA being silent, EAU recommends it as the first line medical treatment of BPH whereas STOPP/START criteria recommends to avoid it in patients with symptomatic orthostatic hypotension/micturition syncope.

Drugs with anti-muscarinic and anti-cholinergic properties

Anti-muscarinic drugs

The incidence of anti-muscarinic drugs use has been reported to increase with age.¹⁹ Various muscarinic receptor antagonists like darifenacin/fesoterodine/oxbutynin/propiverine/solifenacin/tolterodine etc. are licensed for treatment of overactive bladder (OAB) symptoms. Some drugs like antipsychotics, antidepressants, anti-histaminics etc. have anticholinergic properties and have non-life-threatening side effects such as dry mouth, constipation, dry/itchy eyes, blurred vision, dyspepsia, UTI, urinary retention and impaired cognitive function. Rarely, life-threatening side effects such as arrhythmias have been reported.²⁰

The concurrent use of other anti-cholinergic medications may potentiate the side effects of the anti-muscarinic OAB medications. These drugs should therefore be prescribed with caution, and regular evaluation of IPSS and PVR urine is advised. Men should be advised to discontinue medication if worsening voiding LUTS or urinary stream is noted after initiation of therapy. In patients of dementia, anti-muscarinics should be used with extreme caution or may be contraindicated entirely depending on the level of cognitive impairment. As per Beer criteria, these medications should be avoided in older adults except a few selective drugs for the treatment of urinary incontinence. AUA recommends their use with caution in frail older adult patients with OAB and those using anticholinergic drugs concomitantly. However, EAU recommends to avoid their use in older adults or use with caution if volume of post void residual urine >150 ml. STOPP/START guidelines recommends avoiding its use in older adults with dementia, narrow angle glaucoma and chronic prostatism and avoid concomitant use of two or more such drugs.

Tricyclic antidepressants (TCAs) with anti cholinergic properties

TCAs can cause symptoms such as constipation, blurred vision, dry mouth, and urinary retention.²¹ According to

STOPP/START criteria, these drugs should be avoided in older adults with prostatism and/or prior history of urinary retention. Beer criteria also recommends against their use in geriatric patients because of anticholinergic properties and chances of causing orthostatic hypotension whereas AUA and EAU guidelines are silent over their use in older adults.

Antihistaminic drugs with anticholinergic properties

Antihistaminic (Brompheniramine/chlorpheniramine/cyproheptadine/diphenhydramine/hydroxyzine) and sympathomimetics (alpha-adrenergic-agents Ephedrine/phenylephrine/phenylpropanolamine/pseudoephedrine) are constituent of OTC cough syrup preparations. These drugs have the potential of precipitating acute retention of urine in older people suffering with BPH.²² According to a recent study conducted on 166,288 South Korean geriatrics, at least half were exposed to medications against recommendations of Beers Criteria.²³ None of these guidelines recommend the use of these drugs in older adults.

Anti-muscarinic bronchodilators with anti cholinergic properties

Older adult are at higher risk for developing drug-induced urinary retention because of existing comorbidities such as BPH and the use of other concomitant medication that could reinforce the impairing effect on micturition.²⁴ The use of anti-muscarinic bronchodilators (ipratropium, tiotropium) in older adults with bladder outflow obstruction may precipitate urinary retention.²⁵ Only STOPP/START guidelines recommend against use of these drugs in older adults. Other guidelines are silent on their use in geriatric patients.

Desmopressin/DDAVP (deamino-D-arginine-vasopressin)

Nocturia is one of the common and early symptoms of BPH that impairs sleep at night, reduces the QoL, leads to daytime sleepiness and increased risk of falls in older adults. Desmopressin (synthetic replacement for vasopressin) is currently approved for the treatment of nocturia along with nocturnal polyuria or multiple sclerosis.²⁶ This is being used voraciously even though it leads to hyponatremia induced morbidity in older adult patients. Most surprising fact is that STOPP/START and AUA guidelines are silent whereas Beer criteria advocate avoiding its use in said population. As per EAU guidelines cautioned use in people >75 years of age is recommended as decisive factor not the outcome (hyponatremia). In patients <75 years of age, low dose is recommended with monitoring of serum sodium levels.

Androgens

Adult male hypogonadism also called (late-onset-hypogonadism (LOH)) usually presents with persistent

sexual, physical and psychological symptoms and may adversely affect multiple organ functions and QoL in older adult. The prevalence of hypogonadism increases with age. EAU considers serum testosterone <3.5 ng/ml as cut off value while AUA recommends serum testosterone levels below 300 ng/ml in support of the diagnosis of low testosterone. All these apex bodies recommended androgens in LOH, however there is lack of harmony with regard to their contraindications. AUA guidelines (2018) state that PSA should be measured prior to commencement of testosterone therapy to exclude prostate cancer diagnosis and patient should be informed of inadequate evidence available regarding effect of testosterone therapy on the risk of cardiovascular events.²⁷ EAU absolutely contraindicated its use in patients with untreated prostate and breast cancer.

Traditional medicines

As per WHO data, 80% of the world population still relies on traditional medicines for health care. Although medicinal plants are widely used and assumed to be safe, they can potentially be toxic. Adults who use herbal supplements in conjunction with prescription drugs are potentially at risk for a variety of serious drug interactions. Herbal supplements are regulated by the USFDA, but not as strictly as prescription or OTC drugs. Dietary supplement market doesn't need FDA approval. In Austria, France and Germany, phytotherapeutic agents are first line treatment for moderate LUTS and comprise roughly 90% of all prescriptions for BPH management. In US about 40% of men opting for non-surgical therapy for BPH use herbal supplements alone or in combination with other medical preparations.²⁸ EAU guidelines recommend Hexane extracted *Serenoa repens* to men with LUTS who want to avoid potential adverse effects related to sexual function however Beer criteria, STOPP/START and AUA guidelines keep silent about the use of these traditional medicines in geriatric population.

More specific population guidelines and steps to be taken

1. There is a need for concerted coordination between WHO, UMC, AUA, EAU and AGS for formulation of unified guidelines and to implement it worldwide specifically wherever there is population explosion of geriatric component in relation to urological ailments.
2. The curriculum of medical schools in many countries has been screened. The Beer criteria and STOPP/START criteria have not been included in curriculum of undergraduate/postgraduate medical programs like Medicine/Nursing/Pharmacy in majority of medical schools. Only postgraduates working on a specific problem related to inappropriate medication go through these topics. Hence

the human resources being produced in routine are not aware of prevailing guidelines.

3. There is a need to create awareness among medical professionals through refresher courses so that treating physician and dispensing staff is aware of the guidelines. In addition, information in form of videos/pamphlets/audios should be shared on social platforms to make the geriatric population aware of these effects of medication. This can be done with help of clinical pharmacists. A 2021 study in China proved 50% reduction in PIM due to intervention by clinical pharmacists.²⁹
4. Uppsala Monitoring Center is monitoring ADR through different ADR monitoring centers at hospitals/districts/states/countries and compiling the data, whereas no column in the ADR reporting form exists about any ADR due to PIM. Hence an additional column for ADR arising out of the PIM in the ADR performa will serve the purpose and give us authentic data about the geriatric population.
5. AUA and EAU are two apex organizations from high income countries looking into the PIM for urological patients, however both express different opinion with respect to guidelines... There is a need to fill the gaps in the important points of poly-pharmacy and tools to minimize inappropriate prescribing directions in deprescribing protocols with respect to clinically important differences between women and men. In Argentina, educational workshops, deprescribing algorithms and automated email-alerts were found to successfully reduce inappropriate medications.³⁰
6. Stringent actions to be initiated by regulatory bodies in low income countries for sale of prescription drugs being sold as OTC drugs.
7. Ethical clearance for clinical trials on medicinal products is being issued by central regulatory agencies in various countries. No clinical trial for development of drugs useful in urological disorders involving geriatric population should be given ethical clearance which uses medications against recommendations of AGS, WHO, UMC, AUA, EAU and other regulatory bodies of respective countries.
8. There is a need to keep a check on individual level drivers as well as system level drivers. Pharmaceutical companies launching any product in the market that comes under any such regulation should bear a label which clearly depicts "Not for geriatric use" and product insert should clearly indicate the consequences in case of misuse/overuse. A special mention may be included in product insert for urological disorder patients.
9. Computerized decision support systems might help in controlling PIM. In Thailand, a large study of 11,915 patients across four community hospitals

found that computerized decision support systems that detect PIM was associated with 13.3% decrease in PIM. Hence such software support systems may be installed to minimize PIMs.³¹

Possible harms of continuing with present guidelines

WHO is an apex body for giving directions to the member states all over the world regarding any new policy in favor of better health. Hence lacking role of regulatory bodies countrywide in implementation of existing policies may produce a great economic burden in shape of geriatric population with PIM, increase morbidity rates and will continue to adversely impact QoL in older adults. Absence of Beer criteria, STOPP/START, EAU, AUA etc guidelines in curriculum for medical graduates will continuously result in production of human resources that are inadequately trained and ill-equipped for taking care of geriatric health. Continuing with the contraindicated guidelines may further complicate the existing medical problems rather than curing it. Import/export and Indiscriminate use of unregulated botanicals under banner of complimentary alternative medicine/food supplements is an important risk factor. Stringent import/export policies framed in close conjunction with Ministry of AYUSH, Govt. of India and other such apex health bodies in traditional medicine worldwide may be a potential solution to come out of this situation. So keeping the regulatory aspect of such issues under one umbrella like WHO or any other suitable body might benefit mankind.

Conclusion

There is still a great burden of ADR, morbidity and mortality in developing as well as underdeveloped countries just because of poor regulations and implementation of preventive measures. These countries try to follow guidelines from international bodies irrespective of its country of origin and success in implementation by respective regulatory bodies. The analysis presented by us regarding the implementation of AUA, EAU, AGS, UMC and WHO guidelines reflects a very casual approach of regulatory bodies. Everyone in this world has to be a part of geriatric population at one time. Hence it is imperative for all of us to think and work in a purposeful way. Geriatric population being light house and think tank is a very important part of the society and needs to be judicially protected. There is a need to create an umbrella with all these components as supporting pillars for better geriatric health care.

Contributors

SKG: Conceptualization, Writing-Original Draft, Visualization. RB: Conceptualization, Writing-Review and Editing. VG: Writing-Review and Editing. CB: Writing-Review and Editing. PB: Conceptualization, Supervision, Writing-Review and Editing.

Declaration of interests

We declare no competing interests.

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