Original Research Article

A prospective observational pilot study on medication reconciliation in a tertiary care hospital in West Bengal

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Abstract

Background: Challenges faced in today´s health care system around the medication of a patient, is the lack of accurate and complete information about his pharmacotherapy; this makes the patient vulnerable in a situation of risk of medication errors which can be resulted in an ineffective therapy, or adverse effects and avoidable hospital admissions. Medication reconciliation is an unmet need to avoid medication error and patient safety. However, it can be difficult to see the true value of medication reconciliation and to commit to it professionally in an already busy and challenging work environment. Clinical Pharmacologists can help in health care by bridging this gap. The need of a Therapeutics Clinic becomes more valuable especially in a Government setup of developing country like India in the face of growing patient load where the doctor- patient ratio is heavily at odds and doctor patient interaction is also limited. **Methodology:** Collection of relevant data was done at the out-patients department of Therapeutics clinic or Clinical pharmacology in R. G. Kar Medical College and Hospital, Kolkata from 05.10. 2020 to 01.02.21.In the Therapeutics clinic or Clinical pharmacology out-patient department (OPD), only referred patients for medication related issues from different clinical department from this institute will be treated initially. We had given an accurate list of all medications that a patient was given from different clinical departments, even mentioned over the counter medicine and other kind of medicines in that medicine list. We had checked the medicines through drug-drug interaction checker. We had reconciled the medicine in polypharmacy and reduce unnecessary medications. Adverse drug reactions were also reported. **Results:** A total of 40 patients were referred to Therapeutics Clinic for medication reconciliation from 5.10. 2020 to 01.02.21.There were 80% referral from medicine department, 15% from psychiatry and 5% from other clinical (pediatrics, physical medicine and rehabilitation, orthopedics) departments. Approximately 50% referral was due to poly-pharmacy and 40% because of drug-drug interaction checking. Modifications were required for 78% patient and outcome in term of recovery was 76% and patient came back for follow up visit was 87%. **Conclusion:** Maximal referral is due to drug-drug interaction checking & poly-pharmacy. Outcome for this new venture in term of recovery and patient came back for next follow up visit was good. An adequately trained and informed pharmacologist, with his/her professional wisdom can add enormous value as a member in health care provider team and contribute in fulfilling the benefits of medication reconciliation. It is high time we health professionals of all categories along with clinical pharmacologist should join hands to help our patients. They may also contribute in ensuring patient compliance by reducing unnecessary pill burden and certainly provide an opportunity to educate patient about the disease and drug.

Keywords: medication reconciliation, poly-pharmacy, adverse drug reaction.

Introduction

Medicines remain one of the most important tools in healthcare delivery. But use of medicines is a complex matter that involves informed engagement of multiple stakeholders – patients, physician (practitioners), pharmacist, nursing personnel and others. The optimum success in any therapeutic endeavor relies mostly, if not always, in use of medicinal products – their prescribing, dispensing, administration and consumption.

According to the Institute for Healthcare Improvement (IHI): "Medication reconciliation is defined as a formal process of obtaining a complete and accurate list of each patient's current home medications—including name, dosage, duration, frequency, and route and comparing the physician's admission, transfer, and/or discharge orders to that list. Discrepancies are brought to the attention of the

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prescriber and, if appropriate, changes are made to the orders. Any resulting changes in orders are documented'[1].The goal is to provide correct medications to the patient at all transition points within the hospital. Medication reconciliation can be considered complete when each drug the patient is taking has been actively continued, discontinued, held, or modified at each transition point.Medication reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions[2]. A structured medication reconciliation process comprises five steps: (1) develop a list of current medications; (2) develop a list of medications to be prescribed; (3) compare the medications on the two lists; (4) make clinical decisions based on the comparison and also considering other factors like drug-drug and drug-disease interactions, adjusting doses for renal and hepatic impairment interaction, cost effectiveness etc; and (5) communicate the new list to appropriate caregivers and to the patient.Customized selection of the right medicine in a given patient, optimizing its dose in view of the context and background of the individual patient, eliminating redundancy by promoting legitimate de-prescribing, minimizing medication errors – all can be achieved through the willing and proactive participation of a trained pharmacologist in the 'therapeutics provider team'.A medication error can be defined as 'a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient[3].Medication error, constitute a security problem and have been signaled by organisms as the OMS, NICE, Institute for Healthcare Improvement (IHI) or Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as a priority issue within the patient safety strategy, which requires a systematic approach within organizations [4]. In a move to maximize the benefit of pharmacotherapy, policy makers often advocate 'prescription audit' in hospitals, which has proved very useful in providing important inputs to health administration towards optimizing patient care.The pharmacists should assume a pivotal role in collaborating as a team with other health care professionals on medication reconciliation processes, as a training and assuring the continuing competency of those involved in medication reconciliation (residents, physicians and nurse), providing therapeutic expertise in the development of information systems that support medication reconciliations, also offer medication reconciliations programs in the community and patient education medication adherence[5,6].In the following study we discuss a few cases we encountered in our Therapeutics clinic (TC) or clinical pharmacology OPD and highlight the need of medication reconciliation to achieve optimal therapeutic benefit and patient safety.

Objectives:

General Objective:

To study the therapeutic reconciliation for better patient care

Specific Objective:

- To avoid drug-drug interactions
- To identify drug-disease interaction and titrate the dose accordingly
- To identify poly-pharmacy and reduce unnecessary medications
- To avoid prescribing cascade, better replacing with suitable alternative
- To identify and report adverse drug reactions

Methodology

We from Department of Pharmacology, R G Kar Medical College and Hospital, Kolkata, West Bengal, India proposed to establish a weekly Therapeutics Clinic initially. It was started from 5.10.2020. Collection of relevant data was done at the out-patients department of Clinical pharmacology in R. G. Kar Medical College and Hospital, Kolkata. The study was implemented over a period of 4 months, commencing from 05.10.2020 to 01.02.2021.Enrolment of patients commenced after obtaining the approval from the Institutional Ethics Committee and taking written informed consent of the patient. A separate specific operative procedure (SOP) document on proposed functioning of the OPD was developed. In the Therapeutics clinic or Clinical pharmacology out-patient department (OPD), only referred patients for medication related issues from different clinical department from this institute will be treated initially. Patients were referred to the therapeutics clinic OPD as per proposed SOP when-

- Receiving multiple medicines > 5 medicines.
- Visiting multiple specialties (>3)-need to reconcile.
- Having concomitant conditions which modify medicines' response in the body,like diseased kidney and liver, aging, pregnancy.
- Medicine information is needed.
- Any adverse drug reaction is suspected.

We had given an accurate list of all medications that a patient was given from different clinical department, even mentioned over the counter medicine and other kind of herbal, homeopathic or ayurvedic medicines in that medicine list. That list included the drug name (generic and brand), dose, frequency, route, and indication and if any suggestion advised was mentioned in that list. Patients made aware of potential drug confusions: sound-alike names, look-alike pills, and combination medications. We had checked the medicines through drug-drug interaction checker. If there were any interaction found, we mentioned that gave our suggestions regarding any alternative medicines (if available).After therapeutic reconciliation the suggested reconcile prescription would be referred back to respective referring clinical department.

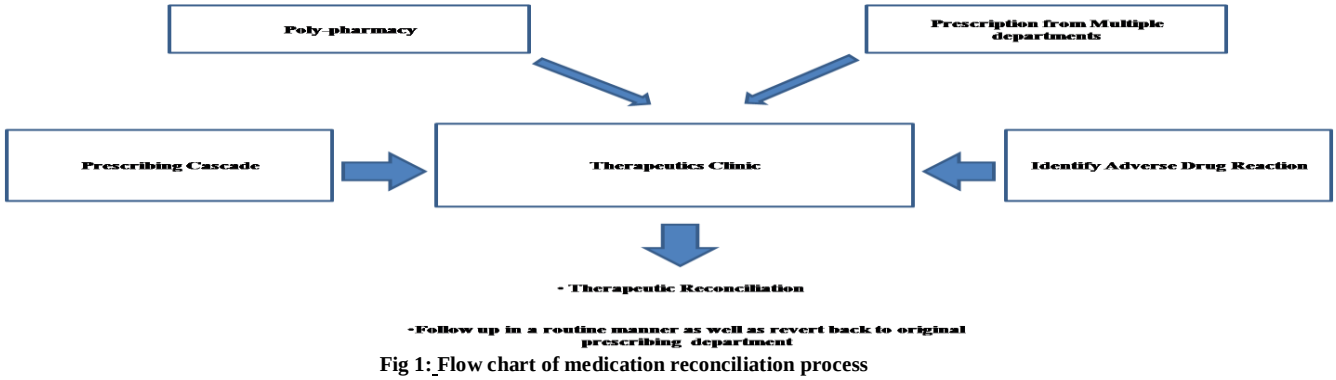

Fig 1: Flow chart of medication reconciliation process

The clinical data on the patients are reported as percentage owing to the small sample size.

Results

A total of 40 patients were referred to Therapeutics Clinic for medication reconciliation from 5.10. 2020 to 01.02.21.There were 80% referral from medicine department, 15% from psychiatry and 5% from other clinical (pediatrics, physical medicine and rehabilitation, orthopedics) departments. Approximately 50% referral was due to poly-pharmacy and 40% because of drug-drug interaction checking (Table 1). Modifications were required for 78% patient and outcome in term of recovery was 76% and patient came back for next follow up visit was 87% (Table2). Here, we are discussing a few interesting cases we had encountered in our Therapeutics clinic or Clinical Pharmacology OPD.

Case 1 (drug –drug interaction & ADR)

A 59-year-old lady was admitted with h/o low grade fever, nonproductive cough for 3 to 4 days and one episode of syncope. There was past h/o hypertension, IHD and type 2 DM for last 6 to 8 yrs. Initial impression was lower respiratory tract infection and left ventricular dysfunction. Patient was stabilized with moist oxygen, furosemide, systemic antibiotics with amoxicillin-clavulanic acid and clarithromycin. Lab investigation revealed total WBC count, blood C/S, dengue NS1 antigen titre, Malaria dual antigen titres, urine routine examination, microbiological examination and culture sensitivity, serum Na+, K+, Urea &creatinine- all within normal limit. Chest X-ray showed Infective changes in right lung. CT brain, Bilateral venous Doppler study, Echo, Holter monitoring were performed for evaluating syncope but were noncontributory. Patient improved symptomatically and discharged.

Following medicines given at discharge

- Tab Pantoprazole (40mg)once daily in the early morning for 10days
- Tab Telmisartan (80 mg) once daily at evening
- Tab Metoprolol XL (50mg) once daily after meal
- Tab Atorvastatin / Clopidogrel (75/10mg) once daily after breakfast
- Tab Co-amoxiclav (625mg)1tab thrice daily after food for 3days
- Tab Clarithromycin (500 mg) 1tab twice daily after food for 4days
- Tab Cetirizine (10mg) 1tab once daily at bed time for 4 days
- Tab Calcium (500mg)1 tab once daily after lunch
- Tab Metformin (500) 1tab twice daily after breakfast and after dinner
- Tab GTN (Sorbitrate) (2.6mg) 1 tab twice daily
- Tab Ranolazine (500 mg) 1tab twice daily after meal

Following suggestions& rationale were given from our OPD

- Ranolazine concentration will increase by clarithromycin - more chance of arrhythmia and QTc prolongation
- Atorvastatin concentration increases by clarithromycin, ranolazine - chance of myopathy more
- Clopidogrel concentration decreases by ranolazine and clarithromycin - may predispose thrombotic episode
- Metoprolol concentration increases by ranolazine - better to avoid and select more cardio selective beta blockers like bisoprolol or nebivolol
- Needs de prescribing some drugs like ranolazine, need to assess rationale for prescribing specific antibiotics

Case 2: (Prescribing cascade)

A 66-year-old woman fell at her residence followed by left sided fracture neck femur. She had H/o Parkinson's disease (PD), hypertension, hypothyroidism for last 6 to 8 yrs. H/o recent hospitalization (6 wks ago) with acute urinary tract infection (UTI) with urinary incontinence. Lab finding revealed LFT, complete blood count, ACR, creatinine (0.8), Na+, K+ all within normal limit.

Medication history (8wks ago)

- Tab Pantoprazole (40mg)once daily in the early morning
- Tab Levothyroxine (100µg) once daily
- Tab Telmisartan (40mg) once daily
- Tab Metoprolol XL (12.5mg) once daily at 6 p.m
- Tab Levodopa/Carbidopa (Syndopa 110) 1-1/2-1
- Tab Calcium(500mg) once daily

To control tremor (6 weeks back)

- Tab Trihexyphenidyl (Pacitane 2 mg) twice daily

After 2 weeks of adding trihexyphenidyl she reports urinary incontinence and UTI and had received following medicines after hospitalized

- Inj. Piperacillin-Tazobactam (4.5 mg) BD for 7days
- Tab Oxybutynin (Oxyspas 2.5) twice daily

After 4 weeks of discharge on follow up visit, she had complained of anxiety and insomnia

- Tab Lorazepam (Ativan 1) at night
- Tab Quetiapine (50) at night

Then, she became dizzy, fell and broke her hip. It was a typical case of prescribing cascade. A prescribing cascade develops when an adverse event is misinterpreted as a new medical condition and additional drug is then prescribed to treat this medical condition. Like that case:

To control PD tremor

- **Trihexyphenidyl**

Urinary incontinence

- **Oxybutynin**

Anxiety and insomnia

- **Lorazepam, Quetiapine**

Dizzy, Fall and broke a hip

Suggestion given:When drug- drug Interaction was checked (Medscape Drug Interaction checker) we had found there was serious interaction between levodopa & quetiapine and suggested to administer other antipsychotic if possible.

Case 3 (Medication error and therapeutic reconciliation)

An elderly male, 75 years of age with ischaemia heart disease, benign prostatic hyperplasia, hypertensive,and type 2diabetes, admitted to the hospital. He was already on cilnidipine, telmisartan, tamsulosin, metformin. While on discharge amlodipine, and valproate and nitroglycerin were added. Patient was already on two BP lowering drug so adding one more will specially with same class may low his BP more. Suggestion given: Omission of amlodipine as patient was already receiving drug from same group.Close monitoring of BP should be done and doses should be moderated accordingly.

Case 4 (drug –drug interaction)

A 20 years male factory worker came with extensive tinea corporis or fungal infestation1 month back. He was non diabetic, non-hypertensive and nonsmoker asthmatic. He was onInhalational steroid and also pantoprazole 40mg (as OTC).He was given antifungal drug such as itraconazole 200 mg OD for 4weeksprescribed but problem solved a little. Systemic examination was within normal limit (WNL), complete blood count, ESR, LFT, urea, Cr was within normal limit, and HIV test was negative.

Suggestion given

- PPI stopped. (Pantoprazole causes significant increase in gastric pH that inhibits the absorption of antifungal drug.)
- Itraconazole was continued for another 15 days as previous dose.
- Inhalational steroid was continued as before. Patient came after 3 weeks with complete recovery.

Case 5(drug –drug interaction and dose titration)

It was a follow up patient of resistant schizophrenia planning for ECT referred from psychiatry department to check poly-pharmacy aspect and drug-drug interaction. He had a history of hypertension for last 6months and was on antihypertensive (amlodipine)

He was on following medicines

- Tab Primidone (25 mg) oral 0-1-1 x cont
- Tab Chlorpromazine (50 mg) oral 0-1-1 x cont
- Tab Aripiprazole (30 mg) oral 0-0-1 x cont
- Tab Amisulpride (Sulpitac) (400 mg) oral 0-1/2-1 x cont

- Tab Clonazepam (Zapiz)(0.5 mg) oral0-1/2-0 x cont
- Tab Clozapine (Alkepin ODT) (300 mg) oral0-1-1 x cont
- Tab Amlodipine (5 mg) oral 1tab OD x cont

Suggestion given

- Evaluate if primidone would be required at all
- As it is a resistant schizophrenia case, better not to reduce the clozapine concentration, that primidone dose by virtue of enzyme induction. Further valporate is good option, as it is enzyme inhibitor and also mood stabilizer
- Otherwise the DDI are minor (apart from enzyme induction by primidone and summation of sedative effect of all drugs)
- Sub-clinical hypothyroidism needs correction
- If pulse and anxiety is more (possible in agitated patient) then beta-blocker may be considered

Case 6 (medication reconciliation and dose titration)

It was a referred patient of 40 yrs old from psychiatry medicine with chronic alcohol abuse with hypertension and dyslipidemia admitted for deaddiction to check drug –drug interaction and polypharmacy. He was taken Cap Probiotic 1 cap daily (self-medication) over the counter on and off for last 1 yr. He had addiction h/o smoking bidi (20/d), and alcohol (whisky) - for 20yrs (2-3 peg per week)

He was on following medicines:

- Tab Chlordiazepoxide

10 mg, oral1-1-3 x 2d

⬇

1-1-2 x 2d

⬇

0-1-1 x cont

- Inj Thiamine (100 mg) iv 1amp OD x 3d
- Inj Lorazepam (4 mg) iv 1amp SOS
- Tab Pantoprazole (40 mg) oral 1tab ODAC x cont
- Tab Losartan(50 mg) oral1tab OD x cont
- Tab Amlodipine (5 mg) oral1tab BD x cont
- Tab Atorvastatin + Fenofibrate (10/ 160 mg) oral1tab HS x cont

Suggestion given

- No potential drug-drug adverse interactions in this prescription,
- Losartan - twice daily regimen is better for 24 hours BP Control,
- Do one Ambulatory BP monitoring (ABPM)
- OTC medication should be stopped as there is no indication

Case 7 (Polypharmacy and Deprescribing)

A 62 yrs obese male patient with hypothyroidism, type2 DM, hypertension for last 5 yrs came with non-resolving joint pain and high blood pressure to medicine OPD. He was referred to the Therapeutics Clinic OPD for medication reconciliation. He was prescribed total 17 medicines from different clinical department and so it was typical case of noncompliance due to poly-pharmacy. He was given – tab prednisolone, Iron capsule, tab methotrexate, tab HCQ, VitB12 capsule, tab levothyroxine, tab teneligliptin, tab metformin, tab aspirin, tab clopidgrel, tab folcovit, tab cilnidipine and tab telmisartan, tab calcium vitD3, tab pantoprazole and tab paracetamol (total 17medicines). We had reduced the medicines to 7 from 17 (some combination medicines were prescribed as he was able to purchase outside pharmacy shop if not available in hospital store).

Suggestion given

- Tab Cilnidine and Telmisartan (10/40mg) once daily at evening
- Tab Aspirin / Clopidogrel (75/10mg) once daily after breakfast
- Tab levothyroxine(75mg)1tab in early morning and empty stomach daily
- Tab Teneligyptin/ Metformin (20/500 mg) 1tab once daily after food
- Tab Methotrexate (15mg) 1tab once weekly
- Tab Folvite (5mg) 1tab twice weekly
- Tab Paracetamol (650mg) 1tab SOS

Patient came after 4 weeks with little joints pain and better compliance. He had normal thyroid function, controlled blood sugar and controlled blood pressure (BP-120/80).In the above mentioned cases we want to highlight the need of medication reconciliation to achieve optimal therapeutic benefit and patient safety.All the adverse events identified in this study reported to theADR monitoring centre in R.G.Kar Medical College under the pharmacovigilance programme of India (PvPI). There was considerable evidence regarding the high incidence of medication errors[3]and of the role of interface and communication problems in the etiology of medication errors[7-9].In a prospective observational study conducted in patients with diabetes disease where they are patients who present a polymedication, the medication reconciliation reveals that one third of the treated patients have medication errors[10].There was also considerable evidence concerning the potential benefits of medication reconciliation in reducing such errors. For example, Whittington and Cohen[11]at OSF Healthcare found that medication reconciliation and other interventions combined to yield a 70% decrease in the medication error rate and a 15% decrease in the adverse drug event (ADE) rate.These functions of a therapeutic clinic become more valuable especially in a Government setup of developing country like India in face of growing patient load where the doctor- patient ratio is heavily at odds and doctor patient interaction is also limited[12].

Table 1:Distribution of referral according to different indications

Indications for Referral to Therapeutics Clinic	No. of Patients (%)
Polypharmacy(Receiving multiple medicines > 5 medicines)	20(50)
Visiting multiple specialties (>3)-need to reconcile	3(7.5)
Having concomitant conditions which modify medicines' response in the body- like diseased kidney	1(2.5)
Having concomitant conditions which modify medicines' response in the body- like diseased liver	0
Having concomitant conditions which modify medicines' response in the body- like pregnancy	1(2.5)
Drug-drug interaction	10(40)
Adverse drug reaction suspected	5(12.5)

Table 2: Types of major medication reconciliation

Types of medication reconciliation	No. of Patients (%)
Drug-drug interaction checking	36(90%)
Adverse drug reaction reporting	32(80%)
Suggesting reducing medicines in poly-pharmacy	10(40%)

Table 3: Outcome of medication reconciliation

Outcome variables	No. of Patients (%)
Recovery	30(75%)
Subsequent follow up	32(80%)
Increase referral on the last month compared to first month	20(50%)
Suggestion implemented	36(90%)

Conclusion

In this study we have found maximum patients referred from medicine department. Maximal referral isdue todrug-drug interaction checking & poly-pharmacy. Outcome for this new venture in term of recovery and patient came back for next follow up visit was good. The main limitation is very short period of time and little sample size. But it is too early to comment on outcome and for this we have to do long term study. More awareness is required by delivering sensitizing programme in the clinical departments about the scope and utility of Therapeutics Clinic in patient care. The process is complex, time consuming and need expertise. Therapeutic clinics run by clinical pharmacologists have enormous potential to avoid medication error, enhance therapeutic benefit of medication therapy at the same time ensure patient safety by avoiding adverse effects, drug interaction. They may also contribute in ensuring patient compliance by reducing unnecessary pill burden and certainly provide with an opportunity in patient education about the drug. It is high time we health professionals of all categories along with clinical pharmacologist should join hands to help our patient.

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