Practice Plus Webinar

27th September 2023

Steve Williams

Lead Clinical Pharmacist
PrescQIPP Practice Plus

Agenda

Time	Title	Presenter
12.45	Welcome, introduction and reflections Should I worry about the medico-legal aspects of prescribing & deprescribing ?	Steve Williams Lead Clinical Pharmacist PrescQIPP Practice Plus
12.50	Breach of Duty and Tort Law	Stephen Webber Medical Litigation Lawyer & Partner at Hugh James Solicitors
13.10	Case examples (GP prescriber) then questions	Dr Julian Treadwell Research Fellow and GP Nuffield Department of Primary Care Health Sciences
13.25	Case examples (Pharmacist prescriber) then questions	Steve Williams
13.40	Future PrescQIPP Webinars	Steve Williams

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General Practice medication errors: NHS Resolution April 22 https://resolution.nhs.uk/resources/general-practice-medication-errors

Did you know?

- Medication errors are any Patient Safety Incidents (PSI) where there has been an error in the process of prescribing, transcribing, dispensing, administration and monitoring medicines.
- PSI can be divided into errors of commission or omission[1].
- NHS Resolution operates a state indemnity scheme called the Clinical Negligence Scheme for General Practice (CNSGP), covering clinical negligence liabilities in England arising in general practice in relation to incidents that occurred on or after 1 April 2019.
- Additionally, on 6 April 2020, a new state indemnity scheme for general practice in England, the Existing Liabilities Scheme for General Practice (ELSGP), was established to cover the historical liabilities of general practice staff.
- ELSGP currently covers historical liabilities for those who were members of the Medical and Dental Defence Union of Scotland (MDDUS) or the Medical Protection Society (MPS) at the time of the incident in respect of which a claim is made, and any practice staff working for a MDDUS or MPS member at the time of that incident.

Due to the recent creation of the general practice indemnity schemes, this leaflet is intended to provide a baseline for the volume and initial themes of general practice medication error claims only.

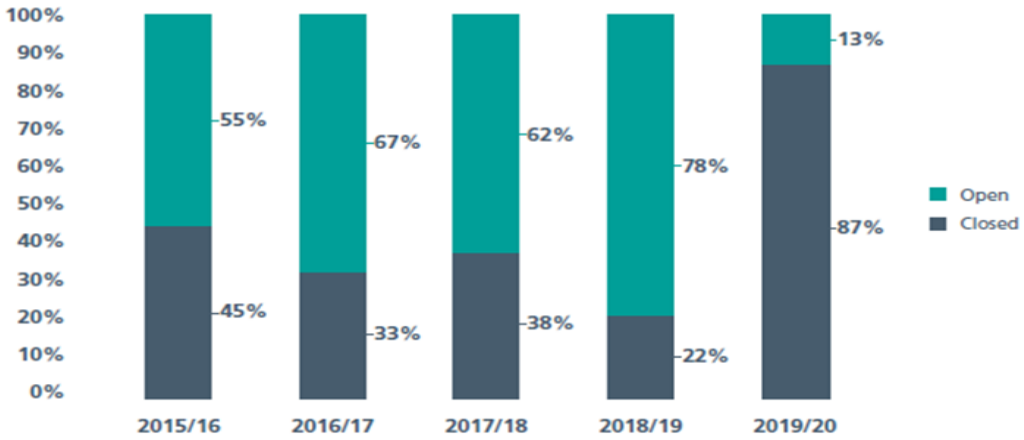
[1] psa-sup-info-med-error.pdf (england.nhs.uk)

Did you know?

The initial NHS Resolution data for general practice indicates that anticoagulants, antimicrobials, anticonvulsants and opioids are the most common medications to be implicated in incidents.

We recognise that these are currently small numbers of claims. The purpose of the data set is to provide a baseline for any future general practice medication errors.

Figure 2 Percentage of ELSGP & CNSGP medication claims by status - NHS Resolution 2021.



Insights into medication errors : NHS Resolution March 22 https://resolution.nhs.uk/resources/did-you-know-insights-into-medication-errors

Did you know?

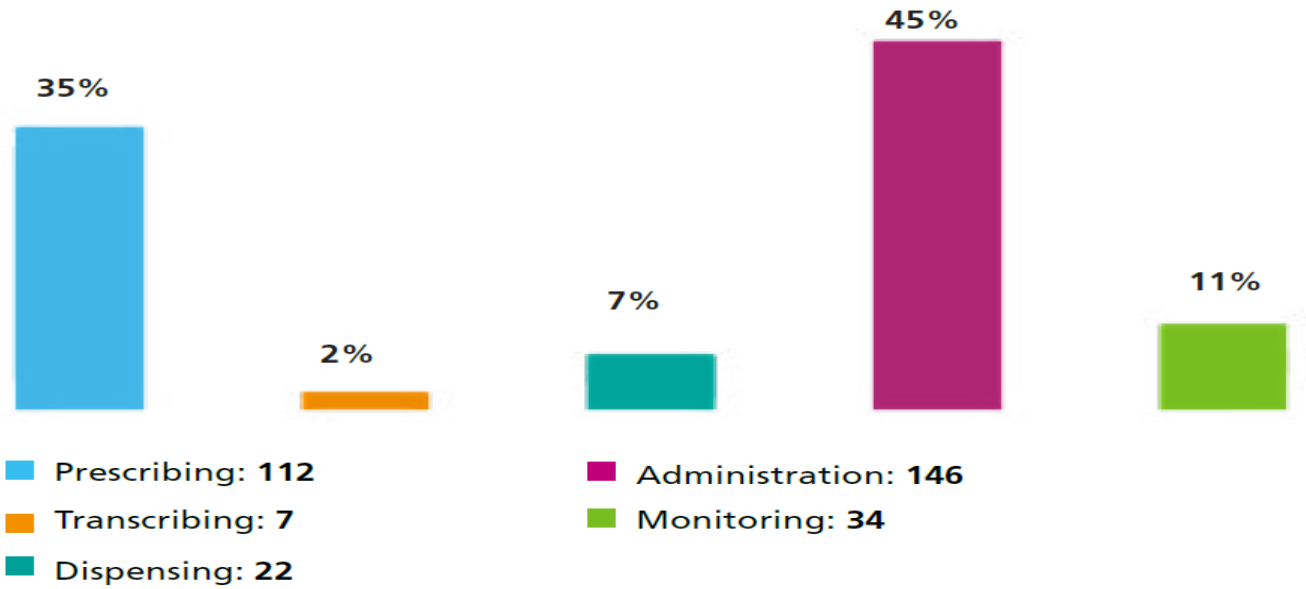
From 1 April 2015 until 31 March 2020 NHS Resolution received 1420 claims relating to medication errors. Of those claims:

- **487** claims were settled with damages paid
- **438** claims were without merit
- **495** remain open

Total cost of closed claims = £19,324,495
Total damages paid in closed claims = £10,419,356

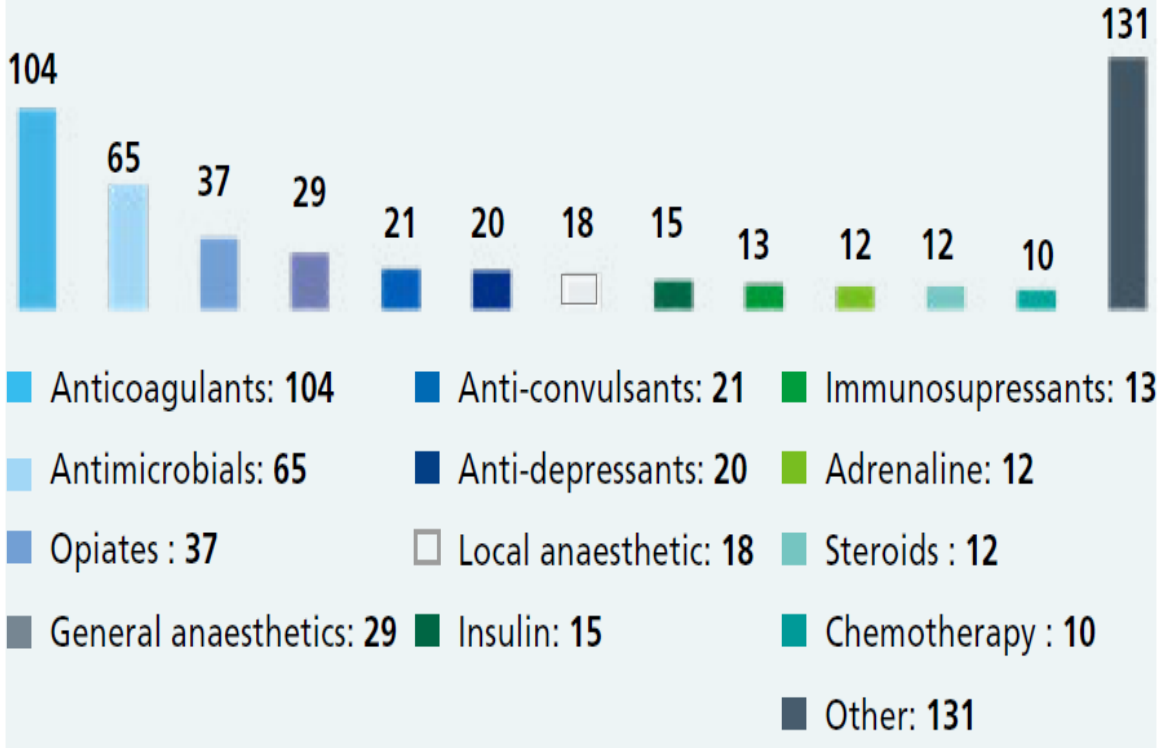
The analysis held within this leaflet only focuses on closed claims that have been settled with damages paid and concern an element of the medication process: prescribing, transcribing, dispensing, administering and monitoring

Did you know? Of the 321 claims that concerned one element of the prescribing process, an error in administration occurred most frequently.



Did you know? From the NHS Resolution initial data for medication errors, the most common medications to be implicated in claims are:

- anticoagulants
- antimicrobials
- anti-convulsants
- opioids
- antidepressants



What are your medico-legal concerns re prescribing / deprescribing ?

6 responses

Being asked to prescribe meds recommended by hospital consultants that are out of my area of practice

Deprescribing for example a DOAC when no longer indicated and then pt going on to have a PE

Not backed up by GPsIs insurance enough

Negligence- not able to access or having time to review records thoroughly

DOAC monitoring - prescribing DOAC Rx when bloods are overdue?

Prescribing 'by proxy' - being asked to prescribe a drug where you've not been involved in the initial consult/diagnosis

Breach of Duty and Tort Law

Stephen Webber – Partner Hugh James

HUGH | JAMES

Understanding law, understanding you

The Law of Tort

What are the elements?

Duty of Care

⇩

Breach of Duty of Care

⇩

Causation

⇩

Quantum

Breach of Duty of Care

- Bolam Test (1957)
  - Acceptable standard of care
  - Any reasonable body of opinion

    “A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men, skilled in the particular art …. Putting it the other way around, a doctor is not negligent if he is acting in accordance with such a practice merely because there was a body of opinion which takes a contrary view”

- Bolitho Test (1997)
  - Any responsible body of doctors
  - Commenting on the decision in Bolam the Court confirmed as follows in Bolitho

"…….the use of these adjectives – responsible, reasonable and respectable all show that the Court has to be satisfied that the exponents of the body of opinion relied on can demonstrate that such opinion has a logical basis. In particular in cases involving, as they often do, the weighing of risks against benefits the Judge before accepting a body of opinion as being responsible, reasonable or respectable will need to be satisfied that, in forming their views, the experts have directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter".

Expert Evidence

- Same speciality
- Burden on claimant to prove case – balance of probabilities
- Judge to decide which expert is preferred

Causation

“But for” Test

- Burden on Claimant (Wilsher)

- Material contribution (Bailey)

Informed Consent
Montgomery v Lanarkshire HB

- In a move away from the ‘reasonable doctor’ to the ‘reasonable patient’.

- The Supreme Court’s ruling outlined the new test:

- “The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.”

- The assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors in addition to its magnitude: the nature of the risk, its effect on the patient's life , the importance to the patient of the benefits sought by the treatment, the alternatives available, and the risks involved in the alternatives. It is bespoke like a Saville Row suit; and

- The doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands all the matters involved. The information provided is to be comprehensible and is not fulfilled by bombarding with technical information and/or copious brochures/literature

Quantum

- Pain, suffering and loss of amenity (general damages)
- Special Damages (out of pocket expenses)
- Provision of Care
- Loss of Earnings
- Expenses, e.g. travelling, medical equipment, motor vehicles

Causes of Litigation

- Medical Records – make detailed notes particularly if concerns
- Oral evidence v contemporaneous notes
- Consider the notes
- Take a detailed history and listen to the patient
- I know this is a perfect world!

Case examples (GP prescriber)

Dr Julian Treadwell Research Fellow / GP
Nuffield Department of Primary Care
Health Sciences

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Statin for primary prevention

- Middle age patient with
  - hypertension (treated)
  - Moderately high cholesterol
  - ex-smoker

- QRISK score: 20%

- NICE guideline: Offer statin if QRISK ≥ 10%

- “I’d rather not take a statin…”

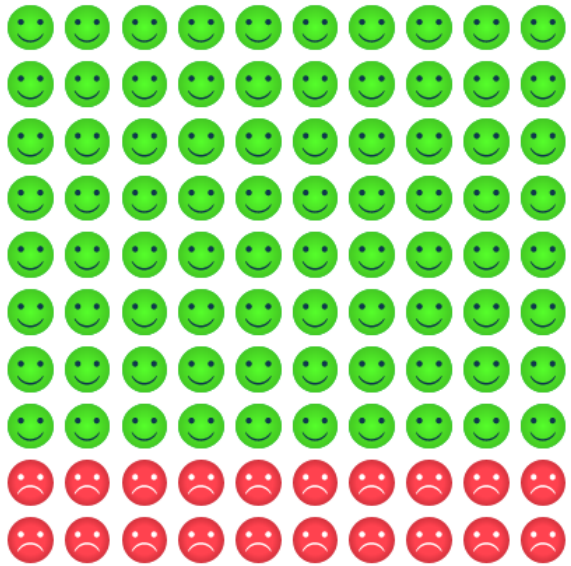
QRISK score

20%

Reduce risk of:

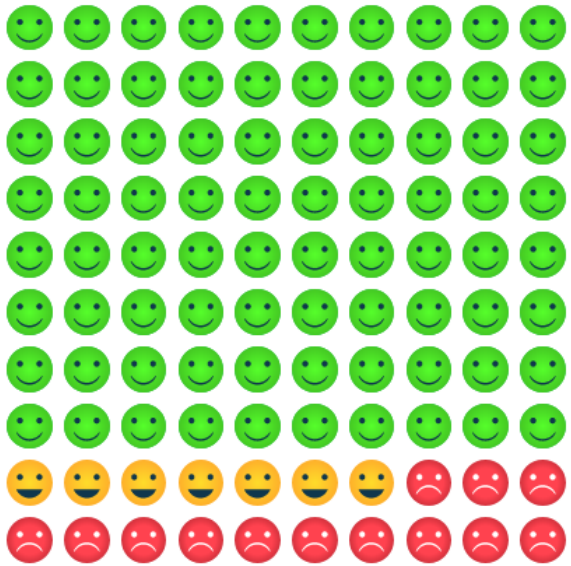
Combined cardiovascular events

No treatment



20 people have a cardiovascular event over 10 years

With treatment



13 people have a cardiovascular event over 10 years

key

ARR 7%
Absolute Risk Reduction

NNT 14
Number Needed to Treat

RRR 37%
Relative Risk Reduction

EXPLAIN STATS

If 100 people with a baseline 10-year risk of cardiovascular disease of 20% take a statin for 10 years, 7 will avoid a cardiovascular event compared with if they hadn't taken a statin

Screengrab from: gpevidence.org

LAMA inhaler in COPD

- Older housebound person with multiple LTCs and polypharmacy
- COPD – 2 exacerbations at home and 1 hospital admission for COPD in the last year
- Would like not to bother with daily LAMA inhaler
- …but COPD guidelines say this can prevent exacerbations and hospital admissions…right?

Treatment comparison

Placebo v LAMA

Outcome

Exacerbations of COPD (moderate/severe)

Control group

30.8 people will have an exacerbation of COPD over 6 months

Treatment group

23.2 people will have an exacerbation of COPD over 6 months

key

ARR 7.6%
Absolute Risk Reduction

NNT 13
Number Needed to Treat

RRR 24.6%
Relative Risk Reduction

EXPLAIN STATS

If 100 people with COPD take a LAMA (tiotropium), 7.5 fewer will have an exacerbation over 6 months compared to those who took a placebo inhaler

Screengrab from: gpevidence.org

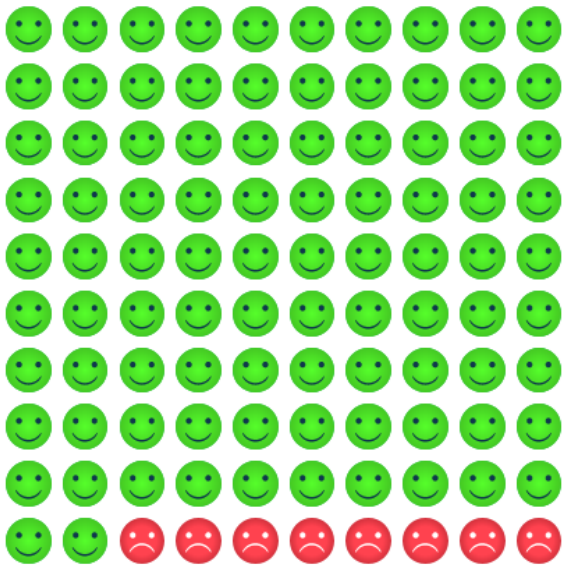
Treatment comparison

Placebo v LAMA

Outcome

Hospitalisation for COPD

Control group



8.4 people have a hospital admission for COPD over 6 months

Treatment group

5.6 people have a hospital admission for COPD over 6 months

key

ARR 2.7%
Absolute Risk Reduction

NNT 36
Number Needed to Treat

RRR 32.6%
Relative Risk Reduction

EXPLAIN STATS

If 100 people with COPD take a LAMA (tiotropium), 7.5 fewer will have a hospitalisation for COPD over 6 months compared to those who took a placebo inhaler

Screengrab from: gpevidence.org

Case examples (Pharmacist prescriber)

Steve Williams

Lead Clinical Pharmacist PrescQIPP
Practice Plus

Case 1

- The GP saw the patient about two weeks after they had started taking 60 mg daily of fluoxetine and they documented that they would increase the fluoxetine to the maximum dose. There was no findings / clinical thoughts recorded or checking of their self-harm status
- The GP prescribed 80mg daily , more than the max BNF dose of 60mg daily, which caused Serotonin syndrome and then a subsequent withdrawal

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Case 2

- Patient referred to the practice pharmacist on a Friday with worsening testicular swelling and pain after an ED admission for suspected epididymo-orchitis and varicocele, two days before and Ciprofloxacin not helping
- Spoke to patient within an hour & established 1) Antibiotics given by ED were not improving Sx 2) Discussed case with GP, who confirmed patient needed urgent urology opinion to exclude testicular torsion. (*Referral made but admin dealt with as routine not urgent)* Follow up call made in PM by Pharmacist & advised if they thought testicular swelling / pain getting worse, they must go immediately to ED
- Patient did not attend ED until Tuesday and ended up with Orchidectomy , despite the advice of the pharmacist and the GP but notes suggested said “would not wait for 3 hours in ED Fri night”

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Case 3

- Pharmacist added SSRI for anxiety in a 67 yr old but Hx of low Na (130) in past, was on a thiazide (which the pharmacist had stopped themselves due to low Na in recent past) and other medication also associated with low Sodium (Omperazole and Losartan)
  - Advised re signs of hyponatraemia to watch for confusion, disorientation, movement changes
- Patient reviewed by pharmacist 6 weeks later but failed to consider that the patient may be suffering from hyponatraemia,(exhaustion and sleeping 11 hours a day) and did not consider checking their plasma Sodium level, and increased the Sertraline

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Case 4

- Multiple issues of acute course of Prednisolone (7-day course of 30mg OD) by GPs and Pharmacist without any documented review of urticarial medicines/**expected follow-up** with the dermatologists, nor the number of issues already made, of this high-risk medication, since it was first prescribed on Jan 2014 (19 issues in total)

- All prescribers well aware of the risks to bone and endocrine (weight gain and diabetes) health and to a lesser extent skin and mental health from multiple courses of Prednisolone. On the balance of probabilities Osteopenia was caused / worsened by the intermittent long-term use of moderately high doses of Prednisolone

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Case 5

- Patient on Azathioprine as part of anti-rejection treatment following a liver transplant (not recorded on GP system). Nurse prescriber spoke to the patient on phone about gout diagnosed by podiatrist. Aware had a liver transplant but documented was only on Tacrolimus for anti-rejection treatment

- Consulted pharmacist, seemingly also unaware patient was on Azathioprine, and nurse prescribed 100mg Allopurinol daily + plan to check Renal , Liver, FBC but the clinical information only stated, “monitoring on Allopurinol, known CKD”

- Results checked 3 weeks later by the nurse, and discussed with GP, and found to be abnormal (Haemoglobin and Platelets below normal range, and lower than when last checked) but only action was to forward the results to “Nephrology” *sic*

- Patient admitted 3 months later with pancytopenia necessitating a blood transfusion

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My Medico-legal takeaway messages for Pharmacy Professionals

- Assume nothing , question everything ….
- Good documentation of
  - Clinical thinking (after reviewing Hx) and Tx option discussions
  - Management plan agreed with patient and follow up including worsening advice guidance
- Discuss case with other clinicians if not comfortable or perceive as tricky OR refer to another clinician if outside your clinical competence / scope of practice <u>especially if unconfirmed diagnosis</u>

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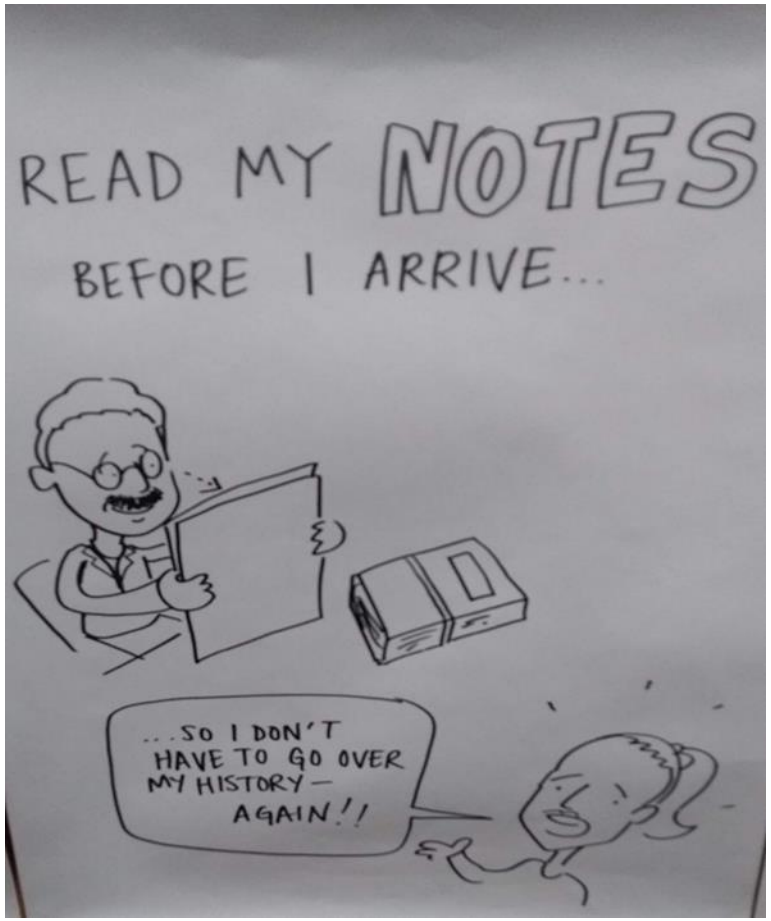
Get a **PLAN !**

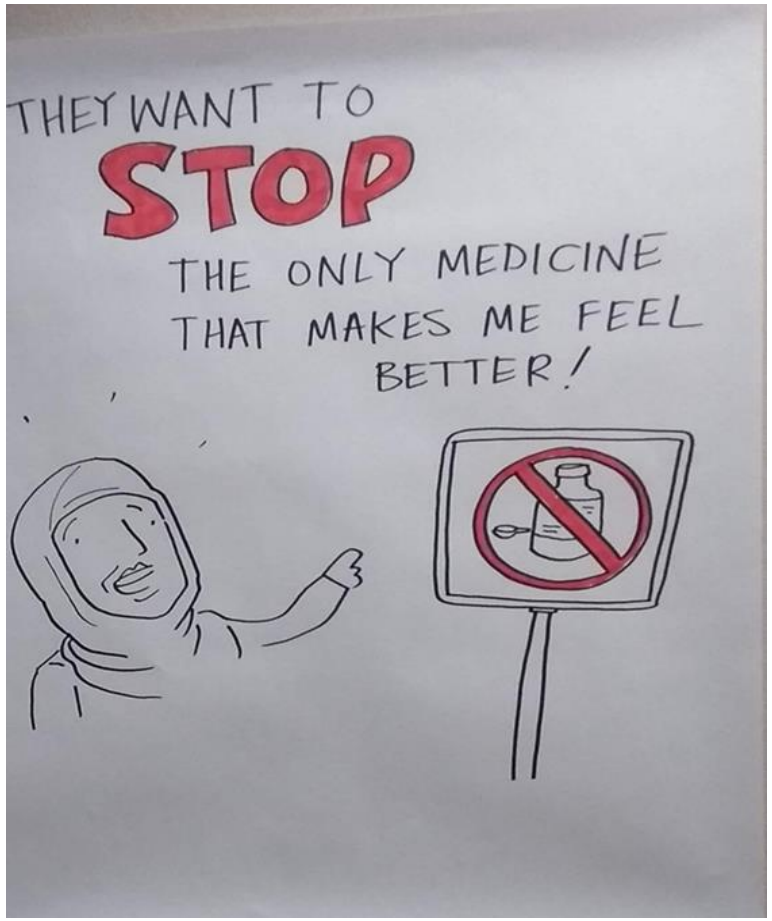
Prepare

Listen

Agree

Notes





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Future Practice Plus Webinars

Date	Key themes	Guest Presenters
18th Oct 2023	Medication Safety Research into Primary Care Practice -Clinical decision support -Mental health-related prescribing	Dr Richard Keers Director, BSc Clinical Pharmacy Senior Clinical Lecturer in Pharmacy Manchester Pharmacy School
29th Nov 2023	PrescQIPP Awards / PrescQIPP Practice Plus members showcase	TBC
13th Dec 2023	Antimicrobial Stewardship	Elizabeth Beech MBE Regional Antimicrobial Stewardship Lead NHS South West Naomi Fleming Regional Antimicrobial Stewardship Lead NHS East of England
17th Jan 2024	Palliative Deprescribing	Dr Jo Hayes Consultant in palliative medicine, Medical Director of the Marie Curie Hospice, Penarth

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