Cyflwynwyd yr ymateb i ymgynghoriad y Pwyllgor Iechyd a Gofal Cymdeithasol ar dyfodol ymarfer cyffredinol yng Nghymru

This response was submitted to the Health and Social Care Committee consultation on the future of general practice in Wales

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Inquiry into the future of general practice in Wales

Patient-centred monitoring to avoid medicines-related harm

Senedd Cymru, Health and Social Care Committee

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Patient-centred monitoring to avoid medicines-related harm

Opportunities to improve general practice to make it fit for the future and take a more preventative approach to care. Consultation display

1. Summary

The Minister has indicated that the balance of care and support in primary care might be amended. To augment the current NHS focus on illness prevention and early intervention, we suggest greater attention to the structured monitoring of people prescribed 5 or more medicines or high-risk mental health medicines. The Adverse Drug Reaction Profile (ADRe) developed in Swansea University is an electronic instrument to identify potential adverse drug reactions (ADRs) and adverse drug events (ADEs) before patients deteriorate, suffer pain, dyspnoea, confusion, sedation, bleeding or falls or other events that might lead to hospitalisation. ADRe is an information-sharing and problem-solving system, which, when incorporated into medicines' reviews, helps service users inform healthcare professionals of real-time problems that might be caused by their prescribed medicines. It has benefited patients using it in 3 clinical trials and 5 observational studies. Although ADRe is acknowledged as best practice (WG 2018), and is an available resource (ADRe for AWTTC), it is yet to be incorporated into the digital systems of NHS Wales, where it would be easily accessed in routine practice, and used in medicines reviews.

One impetus for the proposed change is the long-standing problem of overlooked ADRs – a symptom iceberg whereby significant problems remain unseen beneath surface appearances. For two decades, ~11% of unplanned hospital admissions have been due to largely preventable, adverse effects of prescribed medicines, and the problem is worsening. Most of these ADRs and ADEs could be pre-empted by more careful monitoring. Therefore, whilst much of this work would be undertaken in primary care, the greatest savings would accrue to secondary care.

2. Introduction

Medicines are prescribed for their therapeutic, preventative or diagnostic actions; however, some of their effects may be undesirable. ADRs may be defined as 'appreciably harmful or unpleasant reactions, resulting from an intervention related to the use of a medicinal product; adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, or alteration of the dosage regimen, or withdrawal of the product' (Aronson & Ferner, 2005, p. 855). ADEs include ADRs, sub-therapeutic effects of therapy, drug dependence, intoxication and untreated symptoms (Gyllensten et al, 2013)

The problems in the Welsh NHS are well documented. As the Minister reported to Senedd on 3rd December 2024, https://record.senedd.wales/Plenary/14207#A92569, much remains to be done: para 216 There are many people who are being admitted to hospital who could have been better supported either at home or in the community, if

the right services were available; para 213-4 Our challenge is to provide the right balance of care and support at or as close to home as possible (…). But, at the moment, we haven't got this balance right.

Meanwhile ~11% of unplanned hospital admissions are due to adverse effects of prescribed medicines (AWMSG 2023), taking ~2% of the NHS budget (Osanlou et al 2022). Most ADRs and ADEs represent predictable and avoidable harm (Woo et al 2020), which the WHO (2019, 2023, 2024) attribute to suboptimal prescribing and inadequate monitoring (Hodkinson et al 2020). The avoidable and increasing harm due to incomplete monitoring of repeated prescriptions has been documented for over 20 years (Gurwitz et al., 2000, 2003; Beijer et al 2002; Gandhi et al., 2003; Vincent et al., 2001; Howard et al 2003; Pirmohamed et al 2004; NICE 2015, Zaidi et al 2022), but has proved intractable (Oscanoa et al 2017; Poudel et al 2017; Verren & Weiss, 2017; Zhang et al., 2019; Jordan et al., 2021, Koyama et al 2024), despite the WHO global challenge (WHO, 2017, 2023). Appendix 1 has a summary of relevant pharmaco-epidemiology.

The efficacy of different models for managing general practice

3. Monitoring patients for ADRs/ ADEs

Both the Royal Pharmaceutical Society's (RPS's) medicines optimisation framework (RPS 2013), and the WHO's approach depend upon monitoring and evaluating the effects of medicines on patients' outcomes and experiences. Methods currently employed for ADR identification and mitigation include voluntary reporting of suspected ADRs and reviews of prescription charts, often relying on pre-emptive lists of potentially inappropriate medicines (Department of Health, 2021). Despite these long-standing initiatives, the 'ADR problem' continues to increase, cost lives, engender preventable suffering, and strain health services' resources (WHO 2023, Koyama et al 2024, Veeren & Weiss 2017). Medicine-related problems have proved resistant to existing strategies, such as medication reviews, which, in the main, improve prescribing, but not clinical outcomes (Cooper et al., 2015; Tecklenborq et al., 2020; Jordan et al 2021, Atmaja et al., 2022; Braithwaite et al., 2023; Cole et al., 2023). Reactive, voluntary reporting of serious ADRs (such as the Yellow Card scheme), whilst essential for post-marketing pharmacovigilance, overlooks 94% of ADRs (Hazel & Shakir 2006), and ~98% of drug-induced GI haemorrhages (Shuttleworth et al 2023). The role of pharmaceutical manufacturers in analysing (Schroll et al 2012) and disseminating ADR information may be suboptimal (Light and Lexchin 2021).

Despite convenience, standardised approaches may not be universally applicable or effective, particularly for frail individuals with multiple comorbidities, prescribed multiple medicines (WHO 2023). Systematic review identified 6 symptom checklists identifying such patients' real-time, actual health problems. When these lists informed medicine reviews, patients benefitted, particularly if the list was comprehensive (Logan et al., 2025). The ADRe profile developed this model of comprehensive patient-reported

outcome questionnaires, with decision support, to complement and facilitate scheduled medicine reviews undertaken by prescribers and / or pharmacists.

4. The ADRe Profile

The Adverse Drug Reaction Profile (ADRe) (http://www.swansea.ac.uk/adre/) developed by the Swansea team provides a systematic approach for identifying potential ADRs / ADEs, preventing clinical deterioration, and pre-empting adverse events necessitating hospitalisation. ADRe is an instant-access information-sharing and problem-solving system, which helps service users inform healthcare professionals of any real-time problems that might be caused by their prescription medicines. Whilst current digital prescribing systems identify errors and drug interactions, ADRe brings the patient's actual problems into focus, so that symptoms can be linked to prescriptions. ADRe has benefited most patients using it in 3 clinical trials and 5 observational studies.

The ADRe Profile is detailed elsewhere (Jordan et al 2018, 2021a,b). It addresses the problem of unmonitored avoidable medicines-related harm by structuring communication between patients and prescribers. Patients, carers or nurses record the signs and symptoms that may be caused by prescription medicines, before sharing the document with pharmacists and prescribers; the ADRe instrument incorporates supporting information to link signs and symptoms to known effects of medicines and diseases. If patients' vital signs are not currently documented, nursing assistants complete this section of ADRe, including checks for postural hypotension.

5. Benefits of ADRe

Studies from community mental health settings (Jordan, 2002; Jordan et al 2022; Jones et al., 2016) and care homes (Jordan et al., 2014, 2015, 2019, 2021b) demonstrate the effectiveness of the ADRe Profile in identifying and resolving health problems that may be attributed to ADRs, such as abnormal movements, postural hypotension, balance problems, falls, cognitive decline or irritability. The scale of problems addressed ranged from bothersome (e.g. pain or sedation) to serious (seizures or dyspnoea) to potentially life threatening, such as cardiac arrhythmia with chest pain and breathlessness or valproate-induced pancreatitis (Jordan et al 2002, Jones et al., 2016). A recent trial in primary care with patients >64 prescribed >4 long-term medicines similarly addressed the full range of problems, from dry skin to tremors (with gabapentinoids), abnormal gait, bleeding (with anticoagulants), falls, unrecognised cancer and B12 deficiency (with metformin) (Logan 2024).

Completed ADRe profiles help pharmacists and doctors review medicines by ensuring they have a ready-made list of patients' current problems in a single document, which can be juxtaposed with the medicines chart. ADRe is used easily by patients (Logan et al in 2nd review) or, in nursing homes, their carers (Jordan et al 2019, 2021). Further examples are in Appendix 2.

The ADRe Profile is accompanied by guidance, a change package, FAQs and a glossary of terms.

6. Costs of ADRe in primary care

There may be no regular scheduled medicines reviews for patients of general practitioners (GPs). Pharmacists then need to review completed ADRe Profiles (~15 minutes @£14), and they may then request additional GP review (£32 per consultation). Patient self-completion of ADRe reduces nursing input to recording of vital signs by a nursing assistant (~£4 for 5-10 minutes' work). Unlike care homes, primary care services are not obliged to record vital signs. Even where patients were prescribed multiple medicines, including antihypertensives, we found incomplete records. Total costs per patient for 1 ADRe Profile were £18 or £50, depending on GP involvement, rising to £73 if 20-30 minutes of nursing time were needed. Economists indicate these costs would be offset by the reduction in direct costs of experiencing ADEs, estimated at ~$200 (£157) per 30 days per patient (Gyllensten et al 2013). Many issues can be resolved by pharmacists (Jordan et al 2021, Logan 2024). (Staff costs taken from Jones et al 2022.)

7. Potential Savings

Administration of ADRe reduces ADEs in most participants, by prompting appropriate actions, for example, to relieve pain or falls (Jordan et al 2015, 2019, 2021, Logan 2024). Adverse drug events (ADEs) are responsible for 8% of healthcare spend in the USA (Aitken et al 2013) and 9.5% of direct healthcare costs in Sweden. In Sweden, ADEs increase annual healthcare costs (direct + indirect) by ~£3k per person. Much of this additional cost emanates from additional demands on professionals' time and hospitalisation (Gyllensten et al 2014; Robinson et al 2022). In Wales, quarterly administration of ADRe costs £100-300 a year, far less than the estimated direct costs of living with ADE (~£2447 per year) (Gyllensten et al 2014). In the ADRe studies, some 10% participants had a serious ADR, that would have led to an admission had not problems been identified by ADRe (Jordan et al 2002, 2015, 2019, 2021b, Jones et al 2016, Logan 2024) [5, 11, 12]. Each preventable admission due to ADRs or ADEs costs ~£5k (Leendertse etl al 2011; Senst et al 2001). Since administering 10 ADRe Profiles costs £250-730, this represents a cost-effective use of resources.

8. Policy context

ADRe meets the WHO criteria for management of polypharmacy (WHO 2023 p.10) in that it implements medication reviews in collaboration with the patient (WHO 2019 p. 10). ADRe addresses the lack of formal systems and structure for patient-level medicines optimisation and checking repeat prescriptions (DH 2021, p.35, p.41). The UK's nurses' and midwives' regulatory body, the Nursing and Midwifery Council (NMC), expects nurses to ensure patient safety and demonstrate competence in "recognising and responding to adverse or abnormal reactions to medications" (NMC 2018 p.37 2024, section 11.10). This expectation is echoed in policy documents from NHS England (2019), Care Quality Commission (2019), Department of Health (2021), and the GMC (2021/ 2024). (Further details in Appendix 3.)

9. Patient experience of general practice, including equitable access to care, effective management of patient demand, quality of care, and public trust in services provided

The relationship between primary care service provision and socio-economic status is well established (Hart 1971, 1988, King's Fund 2024). Prescription of antipsychotics (Marston et al 2014), SSRIs in pregnancy (Jordan et al 2015) and polypharmacy (>9 medicines) are concentrated in more deprived socio-economic groups (Guthrie et al 2015), leading to concerns that adverse drug reactions are contributing to health inequalities (WG 2016). Practices servicing more deprived areas employ fewer doctors and more non-medical prescribers (Pedersen et al 2014), increasing the prevalence of nurse prescribing (Drennan et al 2014). The ADRe profile democratises knowledge and makes the relevant information available to all professionals and service users, despite shortages of doctors. It therefore has potential to address health inequalities (WG 2016).

Service users' views

These *verbatim* quotations are taken from our process evaluations.

"If you are not monitoring these kind of things, *in extremis* you are going to end up with disasters - you can easily have disasters, you can easily have people made ill or conditions deteriorate or mistakes made or lots of valuable information about somebody's condition not being properly picked up on, so it's very important." (SU2 spouse of care home resident) (Jordan et al 2019)

"You don't know that that person is suffering (...) I think that's [ADRe is] a very good thing. I agree with that, that's a very good thing." (Residents of care home, 5.1, 5.2) (Jordan et al 2019)

"... this is a better system than seeing the GP, I find that GPs are reluctant to make any changes, they follow what the hospital prescribed and are reluctant to stop any medicines. Also talking to GPs is very rigid and formal, you got more out of me than a GP would" (participant 407 from general practice, Logan 2014).

"'People, especially elderly, do not want to bother the doctor. With this kind of set-up, (it is) much friendlier, you get more out of people. It is a 3-cornered arrangement which works, it is the worst feeling that the surgery don't *[SIC]* care." (participant 606 from general practice, Logan 2024).

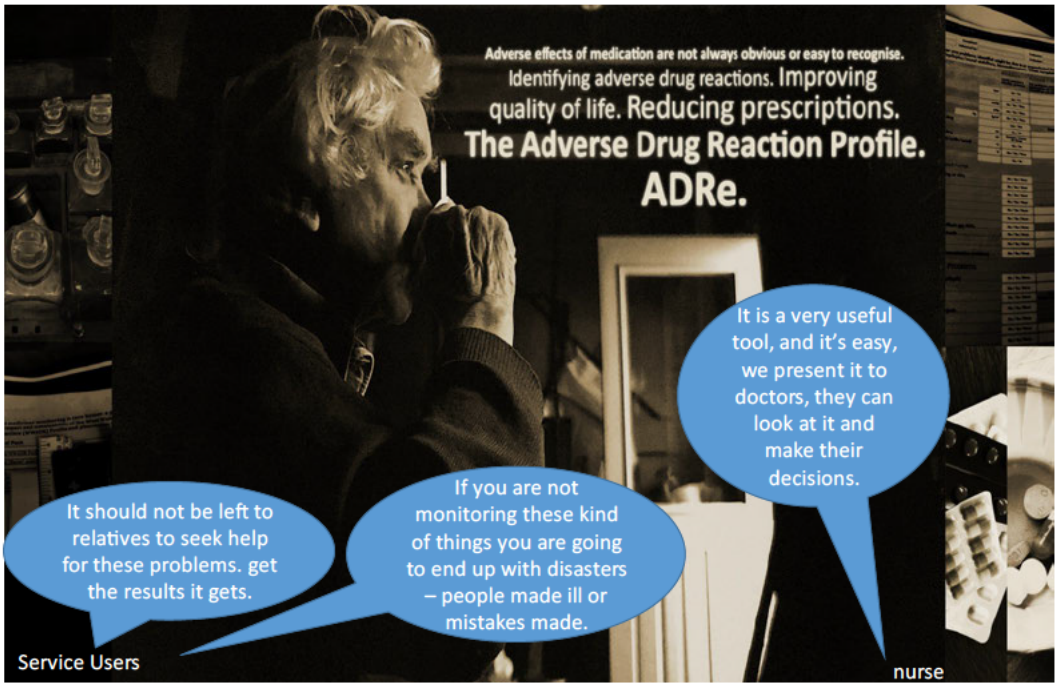
Views of healthcare professionals are quoted in Appendix 4.

10. Conclusion

ADRe could and should be a component of the 'medicines without harm' action plan (WHO 2023). It removes the barrier of health literacy in pharmacology by ensuring that information on the patient's health reaches the professional reviewing medicines, even when the patient is non-verbal and the reviewer is unable to take a full history from the

patient, whether due to time or role constraints (NAfW 2018). ADRe helps most patients who use it, and could reduce NHS costs.

We hope that electronic ADRe ADRe for AWTTC will be incorporated into the Wales digital medicines management systems, and our work will contribute to the successors to the 50-day challenge, laying the groundwork for longer-term transformation.



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Appendix 1. Pharmaco-epidemiology of the ADR problem

- Medication-related harm accounts for ~50% of preventable harm during healthcare delivery & costs ~$42 billion p.a. (WHO 2022).
- Globally, mortality due to adverse drug events (ADEs) rose from 2.05 (0.92–3.18) per 100,000 population in 2001 to 6.86 (5.76–7.95) in 2019, attributed to primary care prescribing (Koyama et al 2024).
- Adverse Drug Reactions (ADRs) / ADEs, 64% predictable and avoidable (Woo et al 2020), cause:
  - 11% unplanned UK hospital admissions in older people (AWMSG 2023)
  - 16% medical admissions (Osanlou et al 2022).
- 20.4% (16.9-23.9) primary care patients experience ADRs [12 studies, low risk of bias] (Insani et al 2021).
- Community pharmacists report drug-related problems in >80% patients, in Germany (Sell & Schaefer 2020).
- Not all serious ADRs are reversible (Faurbye et al 1964, Wang et al 2024), including those affecting the unborn child (Peters et al 2015).
- “Definitely avoidable” ADRs cause 712 deaths directly, and contribute to another 1,708, costing NHS ~£98.5 million p.a. (Elliott et al 2018).
- Potentially inappropriate prescribing doubles costs in primary care (Robinson et al 2022): 1 preventable ADR costs €2,851-9,015 (Formica et al 2018).
- Hospital admissions to manage ADRs cost £490.716 / month in 1 UK hospital ~£2.2bn pa to NHS England (Osanlou et al 2022). (The total NHS budget for England 2023 was £163bn (Health Foundation 2024).
- Non-indicated, unnecessary prescribing of dependency-forming medicines costs NHS England ~£500,000 p.a. (Davies et al 2022).
- Voluntary reporting of serious ADRs omits 94% (Hazel & Shakir 2006), <1% of GI haemorrhages are reported in UK (Shuttleworth et al 2023).

References are in the main list

Appendix 2: Supporting Evidence - Table of Studies using ADRe

	Design	Clinical Area	Findings	Case Reports, Examples of ADRs Addressed without Hospitalisation
			Studies Using the ADRe Profiles	
Logan 2024	RCT	6 GP practices, patients >64 prescribed >4 long-term medicines	Patients self-completed ADRe profiles were reviewed by the practice pharmacist. Medical records were reviewed before and after ADRe implementation. ADRe increased the number of problems noted. ADRe arm participants were significantly more likely to have two or more problems addressed than control arm participants (OR 6.33, 95% CI 1.97-20.38). Twenty of 27 intervention arm participants experienced at least one substantive clinical gain, for example, resolved pain, fatigue or sleep problems. It was expected that all participants in the intervention arm would benefit when the scheduled prescriber reviews were completed.	At follow up, intervention arm patients had fewer clinical problems. Some 50% of problems were addressed by the pharmacist by discontinuing medicines, including flecainide or gabapentin, advice or prescribing for symptom management e.g. emollients. Gains included: B12 deficiency recognised and treated for a patient prescribed metformin. Prostate cancer diagnosed in early stages for a patient with urine hesitancy Posture and movement problems identified in 4 patients prescribed gabapentinoids. Insomia resolved when duloxetine was deprescribed.
Jordan et al. 2019	Interview and observation follow up of the RCT	Care Home residents prescribed mental health medicines	Implementation of the Profile took 10-50 minutes and led to clinical gains. Interviews with nurses, service users and stakeholders indicated that the Profile is effective and can be integrated into existing care and documentation to support medicines reviews before repeat prescribing. Where reviews were not scheduled, it helped care home staff liaise with prescribers to discontinue antipsychotic medication or adjust doses.	Nurses using ADRe picked up issues which resulted in nursing care being changed for 27 of 30 residents and medication for 17 patients being reviewed. Nurses using ADRe with 30 residents found: • Antipsychotic medicines were reduced. • Eight were identified as being in pain, and ADRe helped to resolve this e.g. by recommending review of painkillers. • Six were short of breath and were referred for medication review. • Care plans were changed for five of nine residents who had suffered falls. • Residents were 'brighter' or less agitated or less aggressive when care changed to reduce antipsychotic medicines.
Jordan et al 2021	ADRe used at baseline, and again after nurse and pharmacist review. Participants were interviewed.	Care Home residents prescribed >4 medicines long-term	At baseline, most of the problems listed on ADRe were not documented or not accessible in the residents' notes. Accessing the notes to find information took ~1hour, whereas ADRe completion took 5-15 minutes. Pharmacists took 10-15 minutes to review ADRe. Nurses, pharmacists and doctors appreciated the clear list of problems presented on ADRe. 2-4 problems were addressed per resident.	The outcomes for the 19 patients involved meant that:- • 6 residents were no longer in pain • 3 no longer experienced convulsions • 3 no longer experienced aggression • 2 had swallowing difficulties treated • 4 no longer reported insomnia

	Design	Clinical Area	Findings	Case Reports, Examples of ADRs Addressed without Hospitalisation
				• 1 had breathing difficulties treated • 2 had their laxative prescriptions adjusted to reduce diarrhoea • falls ceased for 2 residents (of 4 noted as falling and of 5 able to stand)" The research team also found that few new problems arose, there was no clinical deterioration, and no harms were associated with the intervention.
Jones et al. 2016	'Before-and-after' study of 20 patients	Community mental health, crisis resolution home treatment	The Profile identified previously unreported physical health problems for all participants, including two previously unreported potentially life-threatening problems (cardiac arrhythmia, and valproate-induced pancreatitis). In all, 4 participants had medicines discontinued, 3 were referred to consultant psychiatrists, 3 to general practitioners, 1 to ECG technicians, and 1 to dentists. Previously neglected health promotion issues were also recognised.	A middle-aged man, diagnosed with schizophrenia, had previously unrecorded but potentially serious cardiovascular problems (cardiac arrhythmia, intermittent acute chest pain) that worsened with exertion and radiated. He was referred immediately to his GP. The consultant determined that this case, and one other, fulfilled the criteria for a serious ADR, as it would have resulted in hospitalisation if unattended.
Jordan et al. 2015	Stepped wedge randomised controlled trial (RCT) over 7 months, 5 homes, 41 participants, 125 record reviews before Profile implementation and 124 after	Care home residents with permanent cognitive impairment	Profile administration increased the number of problems addressed from a mean of 6.02 [SD 2.92] to 9.86 [4.48], effect size 3.84, 95% CI 2.57–4.11, $p < 0.001$. For example, pain was more likely to be treated (adjusted Odds Ratio (aOR) 3.84, 1.78–8.30), and more patients attended dentists and opticians (aOR 52.76 (11.80–235.90) and 5.12 (1.45–18.03), respectively). Profile use was associated with reduction in mental health medicines (aOR 4.45, 1.15–17.22).	A lady in her late 80s, diagnosed with dementia at first administration of the Profile, was noted to be aggressive, restless, confused, sedated, and agitated. The ADRe Profile helped staff identify that hyoscine might be the cause. Hyoscine was discontinued. By the end of the study, 5 months later, aggression, restlessness, and sedation were no longer problems.
Jordan et al. 2014	Feasibility study, 11 patients' records reviewed 3 times (before Profile implementation, after, and 3 months later), 3 homes. Feedback from clinicians	Care home residents with permanent cognitive impairment	The Profile took 20–25 min to implement, caused no harm, and supplemented usual care. On first use, the Profile identified previously undocumented problems for all service users: mean 12.7 [SD 4.7]. One month later, a mean of 4.9 [3.6] problems had been ameliorated. Clinical gains documented included: new prescriptions to manage pain (2 participants), psoriasis (1), Parkinsonian symptoms (1), rash (1); dose reduction of benzodiazepines for one service user; new care plans for oral hygiene, skin problems, and constipation.	A lady in her mid-60s, diagnosed with 'Korsakoff's syndrome' and psoriasis, was noted to be oversedated. Benzodiazepine and antipsychotic prescribing were reduced, and sedation was no longer a problem at follow up. Itching rashes were also identified, more creams were administered, including an 'as needed' prescription for hydrocortisone, and symptoms were ameliorated.
Gabe et al. 2014	Parallel group RCT Researcher observed clinical visits before and after implementation of the Profile in the intervention arm.	Respiratory medicine, outpatient department, 54 patients recruited and followed up	The increase in numbers of problems per participant identified at follow up was significantly higher in the intervention arm where the median change was +20.5 (inter-quartile range (IQR) 13–26) while that in the control arm was −1 (−3 to +2) (Mann–Whitney U test: z = 6.28, $p < 0.001$). The increase in numbers of actions per participant taken at follow up was significantly higher in the intervention arm,	Without the Profile, no actions were taken by nurses for a lady in her 50s, with respiratory problems sufficiently severe as to warrant oral prednisolone. Using the Profile, nurses advised her to contact her GP to seek advice regarding mood swings, depression, headaches, and immunisations. The

	Design	Clinical Area	Findings	Case Reports, Examples of ADRs Addressed without Hospitalisation
	Feedback from patients and clinicians		where the median increase was +2.5 (1–4), while that in the control arm was 0 (−1.75 to +1) (Mann–Whitney U test: z = 4.40, $p < 0.001$).	nurse commented: "I would not have picked up on x's depression without the Profile".
Gabe & Jordan 2014	Inter-rater reliability Profiles completed in the presence of an observer	Respiratory medicine, outpatient department, 48 patients prescribed respiratory medicines	Cohen's κ for inter-rater reliability for each item ranged 0.73–1 (good to complete agreement). The Profile identified previously unsuspected problems in all participants, including muscular weakness, skin, and mouth problems.	A lady in her 70s prescribed corticosteroids, bronchodilators, and other respiratory medicines, reported multiple oral problems, plus losing two stone in weight over the last six months, because her mouth was too sore to eat comfortably. She was advised to rinse her mouth shortly after each inhaler use, seek advice from the nurse for information on inhaler technique, and maintain routine dental check-ups.
Jordan et al. 2004	Comparison of instruments available to monitor antipsychotic medicines. Inter-rater reliability, 20 Profiles completed in the presence of an observer	Community mental health teams, 20 service users prescribed long-term medicines	The ADRe Profile assessed a broader range of physiological parameters and potential problems than other instruments. It is the only instrument with supporting information to prompt action in routine care. Items on the Profile had moderate-to-complete inter-rater reliability (ranging 0.44–1.00)	NA
Jordan et al. 2002	'Before-and-after' study with 1 intervention and 1 comparator group	3 community mental health teams in post-industrial South Wales, 40 service users prescribed long-term mental health medicines	Amongst the 20 clients in the intervention group, the Profile highlighted several problems, two of which were urgent. In the intervention group, the mean number of problems actioned per client increased from 0.35 (range = 0–4) without the Profile to 3 (range = 0–6) with (z = −3.747, 2 tailed $p < 0.001$). Nurses offered appropriate advice or encouraged clients to contact the relevant agencies to resolve the physical health problems identified. In the comparator group, the number of problems actioned declined from 0.85 (0–3) to 0.5 (0–2), a statistically insignificant difference (z −1.47, p 0.14).	Of 20 clients in the intervention group: • One had coupled beats, and was urgently referred to the prescriber, who immediately reduced the dose of the antipsychotic depot. • One had severe hypertension, 200/120 mmHg, and was immediately referred to his general practitioner (GP), and subsequently to renal physicians. • Two had postural hypotension. They were encouraged to maintain adequate fluid intake. Notes were attached to the medical notes to alert the psychiatrist. • Six had a degree of hypertension, above 140/90 mmHg. Measurements were repeated at three subsequent clinic visits. Five clients were advised to contact their GPs, one refused. The 6th client was being investigated for a cerebral tumour. • Inflation of the cuff revealed marks of intravenous injections on the forearm of one client. There were no previous records of substance misuse.
Jordan 2002	'Before-and-after' study with intervention and	Community mental health teams in post-industrial South Wales	Profiles apportioned aspects of medication management between nurses and medical prescribers. Most actions taken by nurses to alleviate adverse effects concerned clients' physical health and	One client was referred to his GP with chest pain; since he was receiving 100mg fluphenazine decanoate per week, the

	Design	Clinical Area	Findings	Case Reports, Examples of ADRs Addressed without Hospitalisation
	comparator groups, 40 patients. Interviews with professionals and service users		advice on health-promotion. Nurses' interventions would have been more effective had they been able to supply clients with certain medicines, for example for sunblock or oral care. For some clients, ameliorating the adverse effects of medication would have involved changes to prescribed antipsychotic medication; here, decisions were more equivocal.	absence of an ECG recording contravened current guidelines. Nurse: You can attach this to the notes. Show the psychiatrist a copy. If you took the time to take it to the psychiatrist—it could work. (...) By using this we'll have more evidence to show that there are side effects and we're concerned, to get medication reviewed. Outpatient appointments are very 'in and out' and things get missed.
			Studies undertaken before the Profile was introduced	
Jordan et al. 2000	Stakeholder interviews and 3 service user focus groups	Mental health nursing: 7 service user representatives, 3 service user focus groups	Service users described serious shortfalls in professionals' abilities to inform them of common adverse effects of medication; these problems were attributable to inadequate educational preparation.	User group representative: CPNs (Community Psychiatric Nurses) focus on the psychiatric illness, they don't see the medical side, or want to become involved. It's to do with their training. They wouldn't help with the constipation or the sunburn for my daughter. This should be in their training.
Jordan et al. 1999	Interviews, observations, and questionnaires with 14 community mental health nurses.	Community mental health teams	Service users were experiencing ADRs, but nurses did not have a structure to record and report problems. Doctors were seeking information from nurses, rather than directly from service users.	Nurse: There should be a form of structure for it (client education). It's down to individuals whether or not they see the importance of educating people regarding their medication, and I think that should be part and parcel of the assessment. I think it should be there, and I know that it's not, from my own experience. To me, whoever is on medication, I will ask them if they understand their medication. People say "Oh well, that's the GP's role, that's the doctor's role", but it isn't. It isn't done and I always ask them that question, "Do you understand what your medication's doing?", and I suppose my knowledge maybe isn't enough either, and I think that maybe I need more training to carry that further. (...) We've got to be prepared to answer questions—informed answers have got to be given, then people will ask, 'What's this for, what's this supposed to do to me?' (...)

ADRe was formerly known as the West Wales ADR Profile.

Appendix 3 Policy Details

Department of Health (2021)
Challenges identified include: using information (p.31), a prescribing culture where information is scarce (p.33), lack of formal systems and structure for patient-level meds optimisation (p.35).
ADRE would address:
R7 for checking repeat prescriptions (p.41),
R8 to help with reviews,
R9 to increase awareness,
R10 in giving information and feedback,
R11 in simplifying medicines reviews,
R16 in enhancing nurse education.

Medicines' Optimisation G5 2015 (NICE 2015)

Recommendation 9
Consider using a screening tool to identify potential medicines-related safety incidents.
Recommendation 27
During a structured medication review, take into account …

- How safe the medicines are, how well they work for the person, how appropriate they are
- Any monitoring that is needed

GMC 2024

Item 100: At each review, you should confirm that the patient is taking their medicines as directed and check that the medicines are still needed, effective and tolerated.

Item 101: When you issue repeat prescriptions or prescribe with repeats, you should make sure that procedures are in place to monitor whether the medicine is still safe and necessary for the patient.

Appendix 4 Views of healthcare professionals.

The nurses said:

"Without using the (ADRe) profile, we tend to find GPs would prescribe mental health medications that weren't really appropriate. ADRe identified you didn't really need these on a regular basis: PRN or not at all. So for all of us at H10, it did identify that we needed to be more in contact with the GPs & say, look you know, this isn't working. This person doesn't need to be on risperidone etc. You can distract residents: they're much more settled without risperidone. That's what we found." N10 (Jordan et al 2019)

"You've got to produce the evidence to the GP and this is ideal to produce the evidence." N2 (Jordan et al 2019)

The pharmacists said:

"The GPs are busy, the nurses are busy sometimes. The GPs head over [to care homes] when they can, at the end of their clinics. The nurses might've been stressed all morning, they are trying to explain themselves to the GP, the GP is trying to obtain a really good thorough history and it's difficult. Whereas, if you've got one of these [ADRe], you could just cross-reference, and

be like this is what I was concerned about see, you know. So yeah we were saying it is a really useful tool." P1 (care homes Jordan et al 2021)

"Patient care will improve because these are being picked up and it's going to benefit the patients' health and wellbeing." P2 (care homes Jordan et al 2021)

"… the more the nurses fill out these things, the more in their mind it's going to be, they'll know what the side effects are (…) they'll see something and automatically associate." P2 (care homes, Jordan et al 2021)

"…empower them [nurses] to say 'this has changed, and look I've got proof'". (…) "Like me, the GP might go in and see the patient for a snapshot of time, but the nurses are there with the patients a lot more than we are." P1 (care homes, Jordan et al 2021)

Who monitors patients for ADRs & ADEs?
An orphan task

Unoccupied professional territory

The bit that's missing is the recording and feeding back, so that any changes can be made. (Nurse, Logan et al 2021)

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